ACUTUS™
MEDICAL

900100 AcQMap®

High Resolution Imaging and Mapping System

Operator Manual

Contents

EXPLANATION OF SYMBOLS


CE Mark


Defibrillation-Proof Type BF applied part


Manufacturer


Date of manufacture


Alternating current


Equipotentiality


Ultrasound Emission


Temperature limit


Auxiliary Input

Batch Code


Console


Caution, see Instructions for Use


Defibrillation-Proof Type CF applied part

Catalogue number

Serial number


Caution: Use only fuse rated at the indicated voltage, current, operating speed, and breaking capacity.

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


Non-ionizing electromagnetic radiation

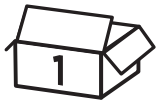

Humidity limitation


Auxiliary Output


Do not dispose of this product in the unsorted municipal waste stream. Dispose of this product according to local regulations

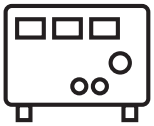

Workstation

Elevation Rating



Quantity of devices

Ablation Catheter



Ablation Generator

Keep dry

Ingress Protection: Drip Proof

Surface Electrode

Patient Return

ECG In

ECG Out

Authorized representative in the European Community

No patient contact

No sitting

Do not lean

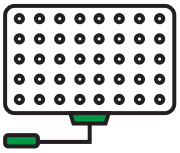
MR Unsafe

No access for forklift trucks and other industrial vehicles

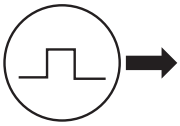
Access for forklift trucks and other industrial vehicles

System meets the applicable Canadian and U.S. electrical safety standards

System Status



Auxiliary Interface Box



Ablation Catheter Pacing Input

Importer

EXPLANATION OF ICONS


Redo


Revert


Show All

Zoom


Show/Hide Mesh


Show/Hide Chamber Surface


Show
Cut-away


Close Holes


AcQMap Catheter

Show Aux 1

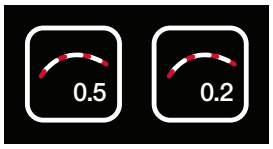
Show Aux 2

Show Aux 3

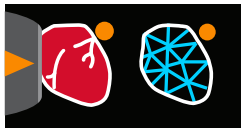

Undo


Green Undo
Arrow


Hide All

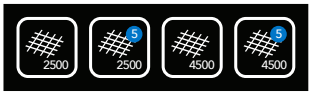


Smooth Mesh

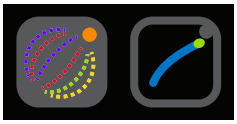

Show/Hide
Mesh


Hide
Cut-away

Re-mesh
Surface 2500
Icon



Re-mesh


AcQMap
Silhouette

Aux Shortcut

Aux Cath
Silhouette

Live
Signals


Ultrasound Off

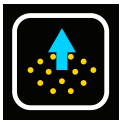

Save


Exit Session


Delete


Add Map


Clear Selection


Build Vein Structure


Grid


Cancel


Confirm Change


Record Button


Pause/Resume


Refresh


Ultrasound On


Copy Map

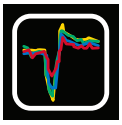

Close Map


Pin


OK


Clear


Erase Points


Overlay


Close


Editor


Reset Camera


Clear Waveforms


Contact Configuration Setup


Merged Anatomy

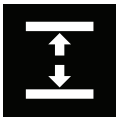

Collect Point Cloud

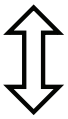

Delete


Directional Lighting


Start button


Advance button


Distribute Channels


Independent


Trim EGM

SuperMap


Segmented Anatomy

Auto Select Triangles


Cut-Plane


Patient Records


Reverse button


Align Channels


Arrows


Unit


Link — Synchronized Displays


Link — Independent Displays

CHAPTER 1 – INTRODUCTION

1.1. – AcQMap System Description

The AcQMap High Resolution Imaging and Mapping System is an advanced imaging, navigation and mapping System capable of displaying:

- 3-D cardiac chamber reconstructions – contact and non-contact (ultrasound)
- Cardiac electrical activity as waveform traces
- Contact LAT and voltage amplitude maps
- Dynamic, three-dimensional, Charge 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 and conventional electrophysiology catheters

The AcQMap® System includes the following components:

- AcQMap Console, Model 800500
- AcQMap Workstation, Model 800520
- AcQMap Workstation Cable, Model 800255
- AcQMap Auxiliary Interface Box, Model 800604
- AcQMap ECG Input Cable, Model 800532
- AcQMap → Ampere™ Ablation Catheter Adapter Cable, Model 800430
- AcQMap → Ampere RF Generator Adapter Cable, Model 800431/800623
- AcQMap ECG Output Cable 800424
- AcQMap Ablation Reference Cable 800505
- AcQMap Ablation Electrogram Interface Cable, Model 800508
- AcQMap ECG Out w/Snaps Cable, Model 800525
- AcQMap ECG POST Cable, Model 800526
- AcQMap 2mm Pin Jumper Set, Model 800523
- MAESTRO™ Adapter Cable, AcQMap → Ablation Catheter, Model 800510
- MAESTRO Adapter Cable, AcQMap → MAESTRO, Model 800511

The AcQMap System also requires the following components:

- AcQMap 3D Imaging and Mapping Catheter, Model 900003

- AcQGuide Steerable Sheath - Model 900002
- AcQRef Introducer Sheath, Model 900005 or Electrical Reference Catheter (see specifications below)
- AcQMap Patient Electrode Kit, Model 800365, or the following equivalent list of patient electrodes:
  - Repositionable Monitoring Electrodes – 3M Red Dot™ Model 2670-5.
  - Patient Return Electrode – Covidien™ Valleylab™ Model E7507.
  - Localization Dispersive Electrodes – ConMed® 425-2200 Dispersive Electrodes (four) and ConMed® 440-2400 Dispersive Electrodes (two).
- The AcQMap System also requires interface cables for connection to ablation systems. For details, please refer to Appendix A.

Optional placement of an anatomic reference catheter is only required when the Surface Leads are inadequate. See specifications below.

CHAPTER 2 — WARNINGS AND PRECAUTIONS

AcQMap Console and AcQMap Workstation Placement — Place on a level surface. Do not place other equipment on top of the AcQMap Console or AcQMap Workstation. Do not place AcQMap Console or AcQMap Workstation on top of other equipment.

AcQMap System Compatibility — Use only the following compatible disposable components with the AcQMap System:

- AcQMap 3D Imaging and Mapping Catheter Model 900003
- AcQGuide Steerable Sheath, Model 900002
- Anatomic Reference Catheter – any non-proprietary decapolar Electrophysiology Mapping Catheter with ≥ 5-5-5 electrode spacing or any non-proprietary duodecapolar Electrophysiology Mapping Catheter with 2-8-2 or 2-10-2 electrode spacing. (Chapter 5, *Figure 5-3*). An anatomic reference catheter is only required if the Surface Leads are unable to adequately compensate for respiration.
- AcQRef Introducer Sheath, Model 900005 or alternative Electrical Reference requiring a minimum of one electrode that can be placed in the inferior vena cava inferior to the diaphragm from a femoral approach. (Chapter 5, *Figure 5-2*)
- AcQMap Patient Electrode Kit, Model 800365 or equivalent.

AcQMap System use with Other Navigation and Ultrasound Systems — The AcQMap System may not function properly if used simultaneously with other navigation and ultrasound systems.

AcQMap Workstation

- The AcQMap Workstation is intended to be installed outside the patient area
- Keep all fluids, including IV solutions, away from the AcQMap Workstation
- If the AcQMap Workstation is powered off by the user, rather than shutdown by the operating system, data on the hard drive may become corrupted and the AcQMap System may not operate properly.
- The AcQMap Workstation will always have its wheels locked when in use.
- Do not push or lean on the Workstation when in use.
- The AcQMap Workstation shall only be moved if the monitor and keyboard are in the lowest position.
- To prevent accidental tipping, the handle shall always be used to move the AcQMap Workstation.
- The AcQMap Workstation may overbalance at slopes greater than five degrees in the normal operating condition.

- Do not connect the AcQMap Console or any other unauthorized electrical equipment into the AcQMap Workstation Power Strip. Connecting unauthorized equipment to the AcQMap Workstation Power Strip may overload the circuit and interrupt power from the AcQMap Workstation and Display.

Acutus Medical installs locking covers on unused outlets of the Workstation power strip to prevent utilization of unauthorized electrical equipment.

Cardioversion/Defibrillation

- Overlap of cardioversion electrodes and Localization Reference Electrodes may result in patient skin burns
- All patient signals must only be connected to the defibrillation-proof connectors of approved medical equipment.

Cleaning — Do not attempt to clean any of the electrical connectors. Do not allow moisture or fluids to enter any of the electrical connectors or vents. Isopropyl alcohol (70%) is the only approved cleaner for the outer surfaces. The use of unapproved cleaners, and failure to follow the product cleaning procedures and recommended dilution may result in instrument malfunction or product damage.

Cybersecurity — The AcQMap System is designed to operate securely in the Windows 10 environment. AcQMap security includes:

- Password protection - Microsoft Windows 10 password protection. Auditing enabled by default.
- Firewall protection - Microsoft Windows 10 firewall application. Enabled by default.
- Antivirus/Malware protection - Microsoft Security Essentials. Enabled by default.

Security procedures that are recommended:

- Store the AcQMap workstation and console in a locked room to prevent unauthorized insertion of USB devices or other types of unauthorized equipment.
- Never plug a USB device of unknown provenance into the workstation.
- Change the password regularly and use strong passwords.
- Never store the written password in a public place, particularly near the workstation.
- Update the anti-virus definitions regularly.
- Install the security updates from Microsoft when available.

Disposable Catheters and Patient Electrodes — Refer to each product's Instructions for Use when utilizing disposable catheters and Patient Electrodes.

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

Electromagnetic Compatibility — Connection of any device or cable other than those specified may result in increased emissions or decreased AcQMap System immunity. Do not place AcQMap Console within 1 meter of any device displaying the **Non-ionizing electromagnetic radiation** symbol.

Non-ionizing electromagnetic radiation

Emergency Pacing — Do not connect life-sustaining pacing through the AcQMap System. The System is not intended to provide life-sustaining therapy and should not be used as such. In case of need for emergency pacing, or any failure of the stimulator routing, directly connect the desired paced channel to the stimulator.

Emergency Power Disconnect — To remove power from the Console in the event of an emergency, unplug the line cord from the wall outlet.

Equipment Modification — Do not modify any component of the AcQMap System. Modifications may impact safety and reduce System effectiveness.

External Stimulation — Ensure external stimulus (pacing) is not delivered through multiple paths when using multiple EP Systems.

Fluid Incursion — Some components of the AcQMap System may not function correctly if the electronic circuitry or the connectors become wet. Do not:

- allow any fluid or moisture into any non-patient contacting component of the AcQMap System or into associated connectors of patient contacting components.
- hang fluids above the AcQMap Console or AcQMap Workstation.
- immerse any reusable or non-patient contacting component into fluids.

Fuse Replacement (Console) — Disconnect the power before replacing an AcQMap Console fuse. Failure to disconnect power may result in serious injury or death.

Handling — All components of the AcQMap System should be handled with care.

Installation — Leave shipping containers sealed until trained personnel from Acutus Medical, Inc., arrive to perform AcQMap System installation.

Inspection — All AcQMap System components should be inspected for damage prior to use. Regularly inspect reusable cables and accessories for visual evidence of damage. Replace damaged components.

IT Connections — Connection to IT networks including other equipment could result in previously unidentified risks to patients, operators or third parties.

- Responsible organizations should identify, analyze, evaluate and control these risks.
- Changes to the IT Network could introduce new risks that require additional analysis.

Navigation — Make all connections between Systems prior to use of the AcQMap System. Adding or removing connections during use, may affect navigation quality.

Overheating the AcQMap Console and AcQMap Workstation — Do not place the AcQMap Console or AcQMap Workstation near heat-generating equipment. Do not block cooling inlets or outlets.

Patient Electrodes — To avoid patient injury, use care in applying and removing Patient Electrodes (Repositionable Monitoring, Localization Dispersive and Patient Return).

- To avoid patient injury, the Patient Return Electrode must be the first Patient Electrode connected to the AcQMap System at the beginning of the study and the last Patient Electrode to be disconnected at the end of the study.
- Ensure that all Patient Electrodes and connections are not in contact with each other or any other surface electrodes from other equipment (e.g., ablation return electrodes, defibrillation electrodes), electrical ground or metallic objects.
- Do not warm the Repositionable Monitoring Electrodes, Localization Dispersive Electrodes or Patient Return Electrode prior to application to the patient.
- Do not use any Patient Electrodes if the packaging seal is not intact, the conductive adhesive is dry, or the "Use By" date has passed.
- Before applying Patient Electrodes, ensure the application site is hair-free, clean and dry.
- Re-use of disposable electrodes may result in degradation of performance of the AcQMap High Resolution Imaging and Mapping System.
- Do not place electrodes on skin folds, dry or damaged skin.
- Do not modify electrodes prior to use.
- MRI compatibility for the electrodes contained in the AcQMap Patient Electrode Kit has not been tested by Acutus Medical.

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

Related Product Literature — Do not attempt to operate the AcQMap System prior to completely reading and understanding the **AcQMap High Resolution, Imaging and Mapping System Operator Manual** and relevant **AcQMap Catheter, AcQRef Introducer Sheath and AcQGuide Steerable Sheath Instructions for Use**.

Required Use Environment — Cardiac mapping procedures should be performed only in a fully equipped electrophysiology laboratory.

Service — Only trained and certified personnel should perform Service. Contact your AcQMap System representative or distributor for service and technical support. Do not service the AcQMap Console or AcQMap Workstation while System is in use on a patient.

Shipping Containers — Leave shipping containers sealed until trained personnel from Acutus Medical, Inc. arrive to perform System installation.

Software Warning Messages — Respond to warning messages as soon as possible. Failure to do so may result in an inability to record data or to communicate properly with the AcQMap Console.

Storage Conditions — All components of the AcQMap System should be stored within the conditions specified. Refer to Chapter 16 Technical Description, Section 19.1 System Specifications for details.

Wireless Compatibility — Portable and mobile wireless communications equipment (e.g. cell phones, laptop computers, etc.) may affect the performance of the AcQMap System and should not be used near the equipment.

CHAPTER 3 — SAFETY ESSENTIALS

3.1. — Indication for Use

The AcQMap System is intended for use in patients for whom electrophysiology procedures have been prescribed.

When used with the AcQMap Catheters, the AcQMap System is intended to be used in the right and/or left atria to visualize the selected chamber and display electrical impulses.

— AND —

When used with the specified Patient Electrodes, the AcQMap System is intended to display the position of AcQMap Catheters and conventional electrophysiology (EP) catheters in the heart.

— OR —

When used with conventional electrophysiology catheters, the AcQMap System provides information about the electrical activity of the heart and about catheter location during the procedure.

3.2. — Contraindications

Use of the AcQMap System is contraindicated in patients with:

- implanted prosthetic, artificial, or repaired cardiac valves in the chamber being mapped.
- 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.

3.3. — Potential Adverse Events

Refer to the **AcQMap Catheter Instructions for Use**.

CHAPTER 4 — ACQMAP SYSTEM COMPONENT DESCRIPTIONS

The AcQMap System has been tested and found to comply with the limits for medical devices to EN 60601-1.

The AcQMap System includes the following hardware components:

- **AcQMap Console**

  The AcQMap Console connects to the AcQMap Workstation, AcQMap Catheter, AcQMap Auxiliary Interface Box, compatible ablation generators and Patient Electrodes. The AcQMap Console formats and transmits signals to the AcQMap Workstation for display and analysis. The AcQMap Console and AcQMap Auxiliary Interface Box contain all electronics for interfacing with patient-contacting devices required by the AcQMap System. The AcQMap Console also provides patient isolation, signal filtering, signal digitization, and transmission of ultrasound and localization signals. The Console includes an internal auxiliary power supply to provide clinical grade ECG output signals in the event of a power outage or other disruption of service. (See Appendix I for more detail.) The AcQMap Console is attached to the AcQMap Workstation through an AcQMap Workstation Cable.

- **AcQMap Workstation**

  The AcQMap Workstation is the primary location for data storage, algorithm execution and user interface. The AcQMap Workstation contains the AcQMap System Software, which is used for interpreting and displaying the data from the AcQMap Console. The AcQMap Workstation consists of a portable cart containing a mounted desktop computer; color display, USB keyboard and a USB mouse for user input. The AcQMap Workstation provides multiple color display outputs for use within the EP lab.

- **AcQMap → Ablation Catheter Adapter Cable**

  Connects the AcQMap Console to an Abbott/St. Jude Medical ablation catheter cable.

- **AcQMap → Ampere™ RF Generator Adapter Cable**

  Connects the AcQMap Console to an Abbott/St. Jude Medical Ampere RF Ablation Generator Cable.

- **MAESTRO Adapter Cable, AcQMap → Ablation Catheter**

  Connects the AcQMap Console to the Boston Scientific Intellatip MiFi XP ablation catheter cable.

- **MAESTRO Adapter Cable, AcQMap → MAESTRO**

  Connects the AcQMap Console to the Boston Scientific MAESTRO 4000 RF Generator Adapter Cable.

- **AcQMap Ablation Reference Cable**

  The AcQMap Ablation Reference Cable connects to the patient ablation reference electrode and the AcQMap Console front panel and selected ablation generator. This cable provides an ablation reference signal to the Console for localization accuracy.

- **Ablation Electrogram Interface Cable**

  Connects the AcQMap Console to the Recording/Pacing System to perform pacing through the ablation catheter.

WARNING: Do not connect life-sustaining pacing through the AcQMap System. The system is not intended to provide life-sustaining therapy and should not be used as such. In case of need for emergency pacing, or any failure of the stimulator routing, directly connect the desired paced channel to the stimulator.

- **AcQMap ECG Input Cable**

  Connects Repositionable Monitoring Electrodes to the AcQMap Console. This cable is a Defibrillator Protected Type BF applied part. This defibrillation-proof feature is implemented in the ECG trunk cable. Use only Acutus Medical supplied patient cables. Failure to do so may seriously damage the AcQMap System hardware.

- **AcQMap ECG Output Cable**

  Connects the AcQMap Console to the Recording System for display of ECG signals using 2mm shrouded pins.

- **AcQMap Auxiliary Interface Box**

  The AcQMap Auxiliary Interface Box provides connection to the auxiliary catheters (optional) used during the procedure. The AcQMap Auxiliary Interface Box also provides amplification of signals collected from auxiliary catheters and transfers these signals to the AcQMap Console for display. A universal bed rail clamp is provided for mounting.

- **AcQMap Workstation Cable**

  Connects the AcQMap Workstation to the AcQMap Console.

- **AcQMap ECG Out/Snaps Cable**

  Connects the AcQMap Console to the Recording System for display of ECG signals using snaps.

- **AcQMap ECG POST cable**

  Provides the ability for the end user to test ECG functionality upon demand.

- **AcQMap 2mm Pin Jumper Set**

  Provides the ability to connect the Auxiliary Interface Box outputs (40 total) to the EP Lab pin box or monitoring system.

The AcQMap System also requires the following disposable components:

- **AcQMap Patient Electrode Kit**

  Contains Localization Dispersive Electrodes, Patient Return Electrode and Repositionable Monitoring Electrodes. These different electrodes are used to provide catheter-positioning information, a common reference between the patient and AcQMap Console and provide Surface ECG information respectively. The Electrodes are all BF applied parts. See Chapter 5 AcQMap System Installation and Set Up and Chapter 6 AcQMap System Patient Preparation for additional information.

NOTE: Please refer to each product's Instructions for Use when utilizing these disposable electrodes.

- **AcQMap 3D Imaging and Mapping Catheter, Model 900003**

  The AcQMap Catheters collect cardiac electrical activity and send / receive ultrasound acoustic waves. This catheter is a Defibrillator Protected CF applied part.

- **AcQGuide Steerable Sheath, Model 900002**

  The AcQGuide Steerable Sheath is used to introduce the AcQMap Catheter into the heart chamber of interest.

- **Anatomic Reference Catheter**

  The Anatomic Reference Catheter provides a stationary anatomic reference, when generating cardiac chamber reconstructions. The Anatomic Reference Catheter is only required when the Surface Leads are unable to satisfactorily remove the cardiac respiration component. See Chapter 5 AcQMap System Installation and Setup for requirements. This catheter is a Defibrillator Protected CF applied part.

- **Electrical Reference**

  The Electrical Reference is a sheath (AcQRef Introducer Sheath, Model 900005) or catheter that provides a floating unipolar system ground to reduce AcQMap System electrical noise through common mode rejection. See Chapter 5 AcQMap System Installation and Setup for requirements. This catheter or sheath is a Defibrillator Protected CF applied part.

CHAPTER 5 — ACQMAP SYSTEM INSTALLATION & SETUP

5.1. — AcQMap System Installation

WARNING: Leave shipping containers sealed until trained personnel from Acutus Medical arrive to perform AcQMap System installation.

1. Acutus Medical personnel will unpack and install the AcQMap System.
2. Acutus Medical personnel will inspect the AcQMap System for damage and test the AcQMap System prior to clinical use.

5.1.1. — AcQMap System connections

Refer to *Figure 5-1* through *Figure 5-3* when performing the following steps.

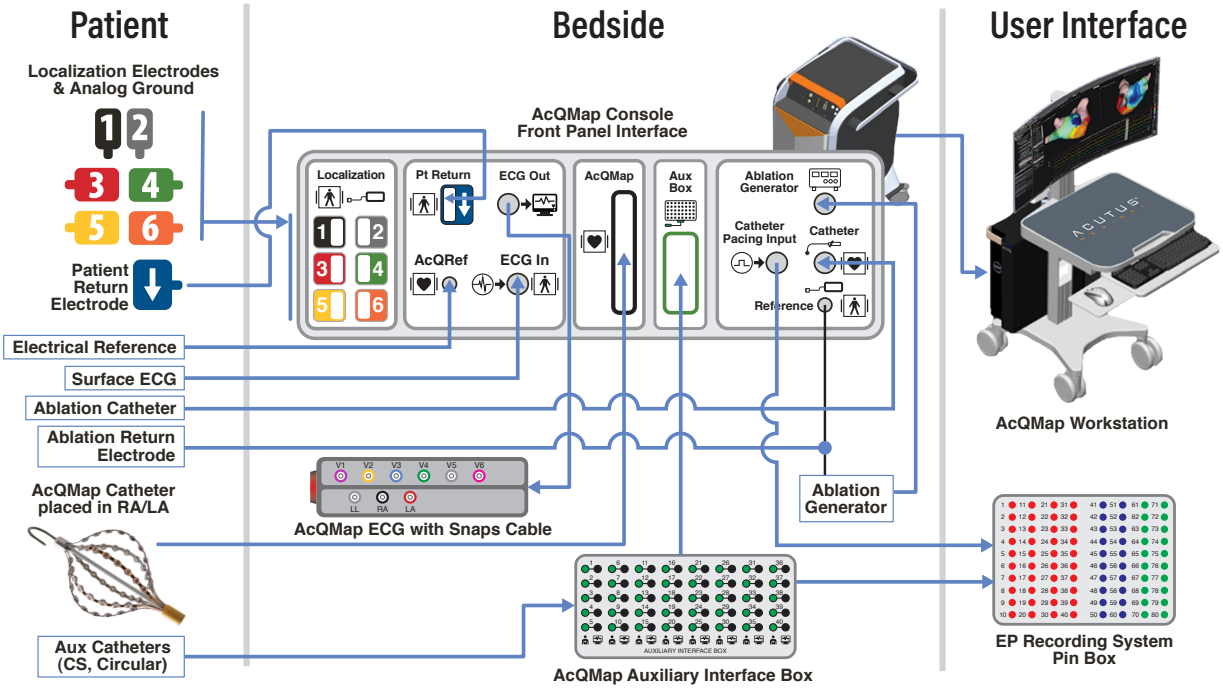


Figure 5-1. AcQMap System connections.

The AcQMap System requires a Daily System Test to be run before it can be used. The Daily System Test is a two part test that consists of (1) a Console power-on-self-test (POST) to check hardware functionality and (2) a software initiated Functional Test that tests the full system functionality. The software initiated functional test only needs to be run once per day. The Daily System test may require up to 40 minutes to complete.

1. Plug the AcQMap Console into a 3-wire receptacle.
2. Connect the potential equalization terminal on the rear of the console to the potential equalization terminal in the laboratory.
3. Clamp the AcQMap Auxiliary Interface Box to the fluoroscopy table rail in a position where fluids will not be present and that will be acceptable to the physician.
4. Connect the AcQMap Auxiliary Interface Box to the front panel of the AcQMap Console.

NOTE: No electrodes should be connected to any pin on the Auxiliary Interface Box

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NOTE: No other connections should be made to the Console.

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5. Power on the AcQMap Console using the Mains ON/OFF switch, located on the rear panel. A green power indicator will illuminate next to the power cord entry when power is on.
6. Turning on the console initiates a Console Power On Self-Test (POST). Observe the Status Indicators on the console front panel. At the completion of the Console POST, if the test has passed only the center status indicator will be green.

7. Connect the AcQMap Console to the AcQMap Workstation using the AcQMap Workstation Cable.
8. Power up the AcQMap Workstation computer and display. Launch the Functional Test software application. Wait for Functional Test software to be executed. When you see "Waiting on Clinical", press

9. Observe the data collection and passage of the functional tests on the Workstation monitor. At the completion of the Functional Test, if the System has passed, all status indicators on the console front panel will be green. If one or more of the status indicators is not green, refer to Appendix G – POST and Functional Test Status Indicators.

Following successful completion of the Functional Test, make the following connections before using the System:

10. Connect the ECG Input Cable to the front panel of the AcQMap Console.
11. Connect the ECG Output Cable to the front panel of the AcQMap Console.
12. Connect the Ablation Reference cable from the Ablation Patient Return Electrode to the front panel of the AcQMap Console.
13. Connect the Ablation Electrogram Interface cable to the front panel of the AcQMap Console.
14. Launch the AcQMap System Software.

NOTE: When power cycling with a patient attached: It is recommended to turn the Console OFF, wait 20 seconds, and then turn the Console ON. Following the restart, observe that the Status Indicators on the Console front panel return to green before proceeding. There is no need to disconnect the patient or close the AcQMap application on the workstation prior to power cycling the Console.

AcQMap Electrical Reference Connection

A minimum of one electrode that can be placed in the inferior vena cava inferior to the diaphragm from the femoral approach

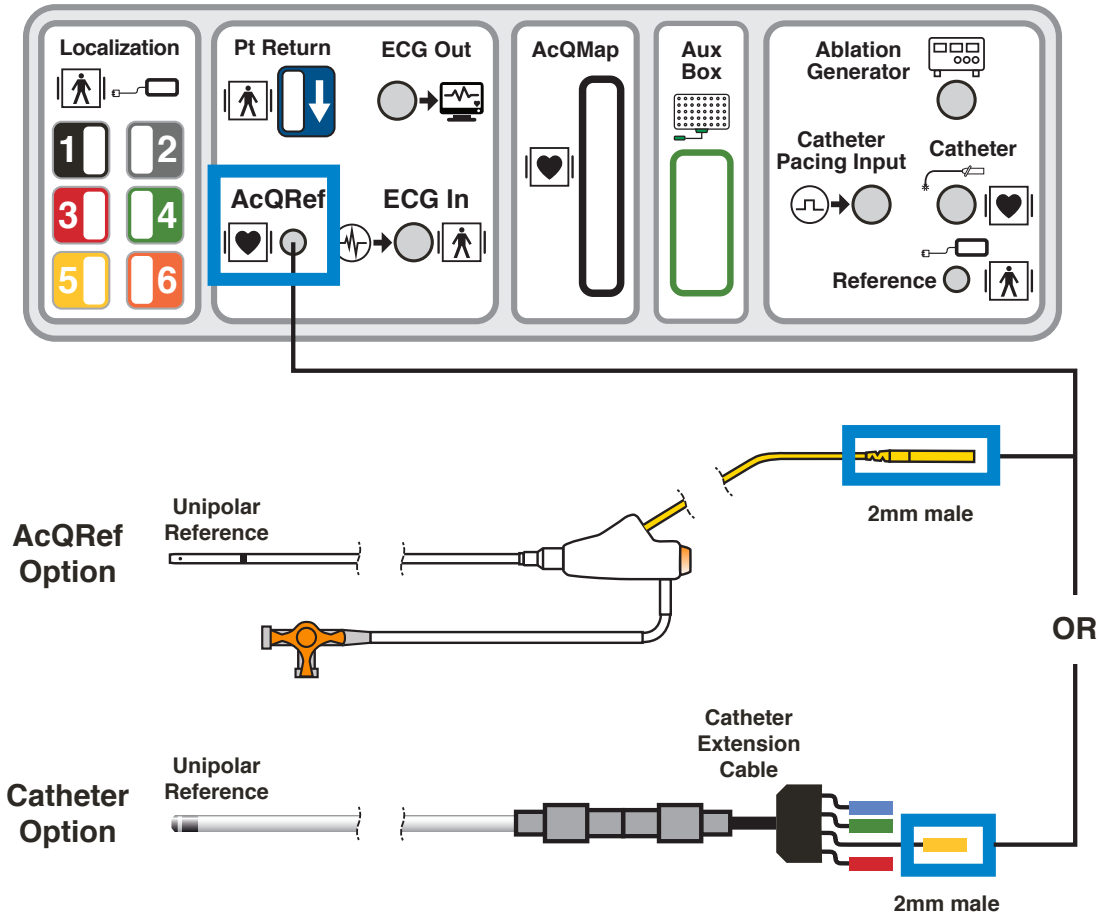

Figure 5-2. Electrical Reference Catheter specifications and connections.

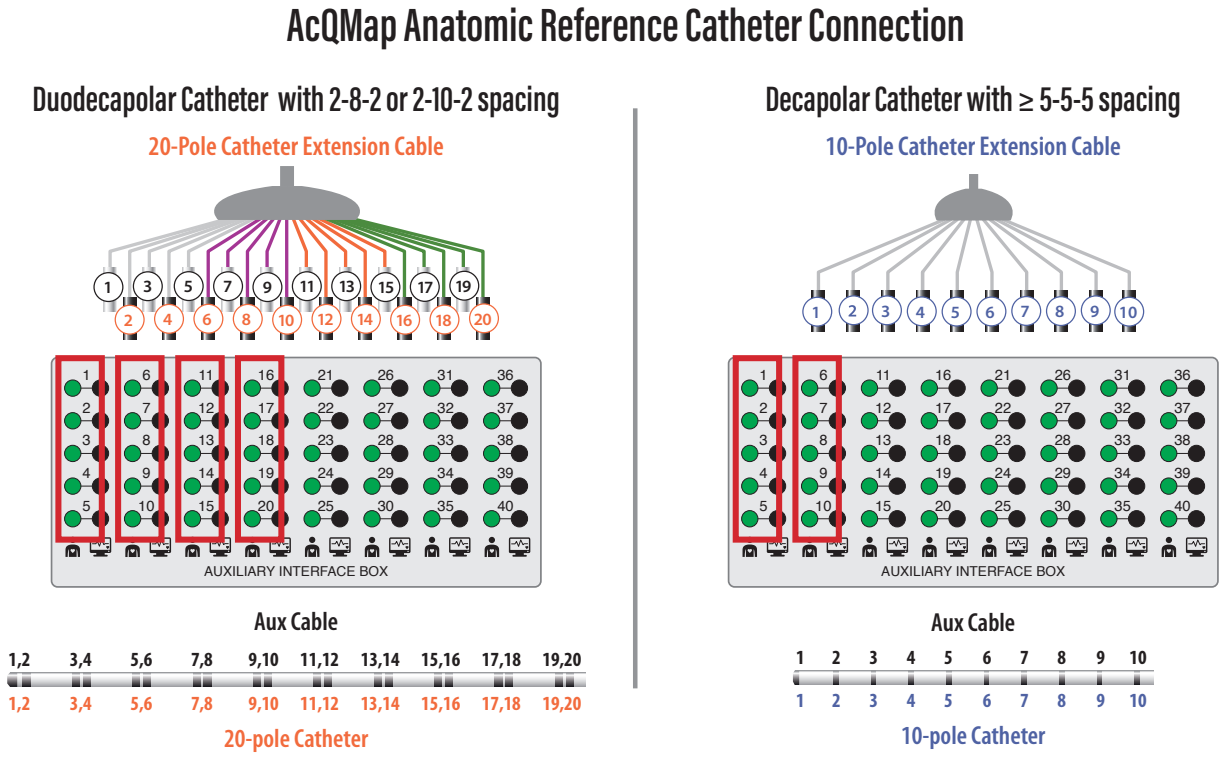

Figure 5-3. Anatomic Reference Catheter specifications and connections.

NOTE: Use of an auxiliary catheter as an Anatomical Reference is only required when use of the Surface Leads is inadequate.

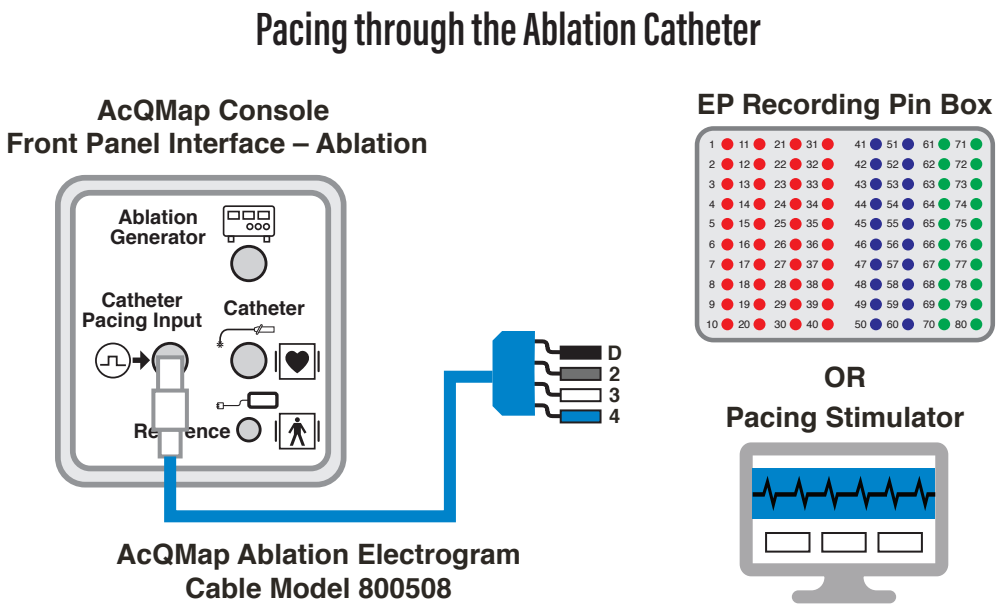

Figure 5-4. AcQMap Console connections to pace through the ablation catheter.

CHAPTER 6 — ACQMAP SYSTEM PATIENT PREPARATION

The following sets of instructions are for identifying the patient electrodes and placing the electrodes on the patient prior to use of the AcQMap System.

6.1. — Patient Electrode Identification

To connect all six (6) Localization Dispersive Electrodes and the Patient Return Electrode to the AcQMap Console front panel, a set of colored, numbered stickers are provided to apply to the electrodes just prior to application on the patient. Apply the stickers as follows:

1. Open a Localization Dispersive Electrode 1&2 and place the black colored sticker, with a "1", in the center on the non-patient contacting side of the electrode. Wrap the black sticker, with two "1"s, around the electrode cable, near the connector so the "1" is visible from either direction.
2. Open the 2nd Localization Dispersive Electrode 1&2 and place the gray colored sticker, with a "2", in the center on the non-patient contacting side of the electrode. Wrap the other gray sticker around the electrode cable, near the connector so the "2" is visible from either direction.
3. Open a Localization Dispersive Electrodes 3-6 and place the red colored sticker, with a "3", in the center on the non-patient contacting side of the electrode. Wrap the red sticker, with two "3"s, around the electrode cable, near the connector so the "3" is visible from either direction.
4. Repeat Step 3 for all remaining Localization Dispersive Electrode 4-6 (Numbers 4 – 6).
5. Open the Patient Return Electrode and place the one blue colored sticker, with ↓, in the center on the non-patient contacting side of the electrode. Wrap the other blue sticker, with ↓, around the electrode cable.

WARNING: Re-use of disposable electrodes may result in degradation of performance of the AcQMap High Resolution Imaging and Mapping System.

WARNING: Ensure that all patient surface electrodes and connections do not contact each other or any other surface electrodes from other equipment (e.g., ablation return electrodes), electrical ground or metallic objects.

6.2. – Patient Electrode Placement

Refer to *Figure 6-1* for the correct placement of the Patient Electrodes. When placing the electrodes, ensure that the cables are directed to the side of the table where the AcQMap Console is located. Start with the patient sitting upright on the fluoroscopy table.

1. Place the Patient Return Electrode ↓ (blue) on the lower right back. (*Figure 6-1*) Connect the Patient Return Electrode to the AcQMap Console front panel.

WARNING: The Patient Return Electrode must be the first Patient Electrode connected to the AcQMap System at the beginning of the study, and the last electrode disconnected from the AcQMap System at the end of the study.

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2. Place Localization Dispersive Electrode 5 (yellow) on the patient's back in a horizontal position with the superior border of the electrode at the level of T3. (*Figure 6-1*)
3. Place Localization Dispersive Electrode 3 (red) in a horizontal position across the lower back. (*Figure 6-1*) This electrode will be parallel to #6. (see Step f)
4. Ensure that both Localization Dispersive Electrodes are flat and have adequate adhesion to the patient's skin. Help the patient lay down and route the connector cables to the same side as the AcQMap Console.
5. Place Localization Dispersive Electrode 4 (green) in a horizontal position with the superior edge at the level of the sternal notch. (*Figure 6-1*)
6. Place Localization Dispersive Electrode 6 (orange) in a horizontal position across the abdomen midway between the xyphoid process and umbilicus. (*Figure 6-1*)
7. Place Localization Dispersive Electrode 2 (gray) in a vertical position across the right ribs. (*Figure 6-1*) This electrode should be centered on the heart. Connect this electrode to the gray (#2) receptacle on the AcQMap Console front panel.
8. Place Localization Dispersive Electrode 1 (black) in a vertical position across the left ribs. (*Figure 6-1*) This electrode should be centered on the heart. Connect this electrode to the black (#1) receptacle on the AcQMap Console front panel.
9. Connect all remaining cables to the AcQMap Console front panel color-coded/numbered receptacles.
10. Place the ten Repositionable Monitoring Electrodes as shown in *Figure 6-1*.

NOTE: If at any time during the study, the AcQMap Catheter appears flat (i.e., 2 dimensional), the most likely cause is a poorly attached or poorly located Localization Dispersive Electrodes. The Localization Dispersive Electrodes and associated connections should be inspected as soon as possible and replaced if necessary. After replacing any Localization Dispersive Electrode, a new anatomy should be acquired.

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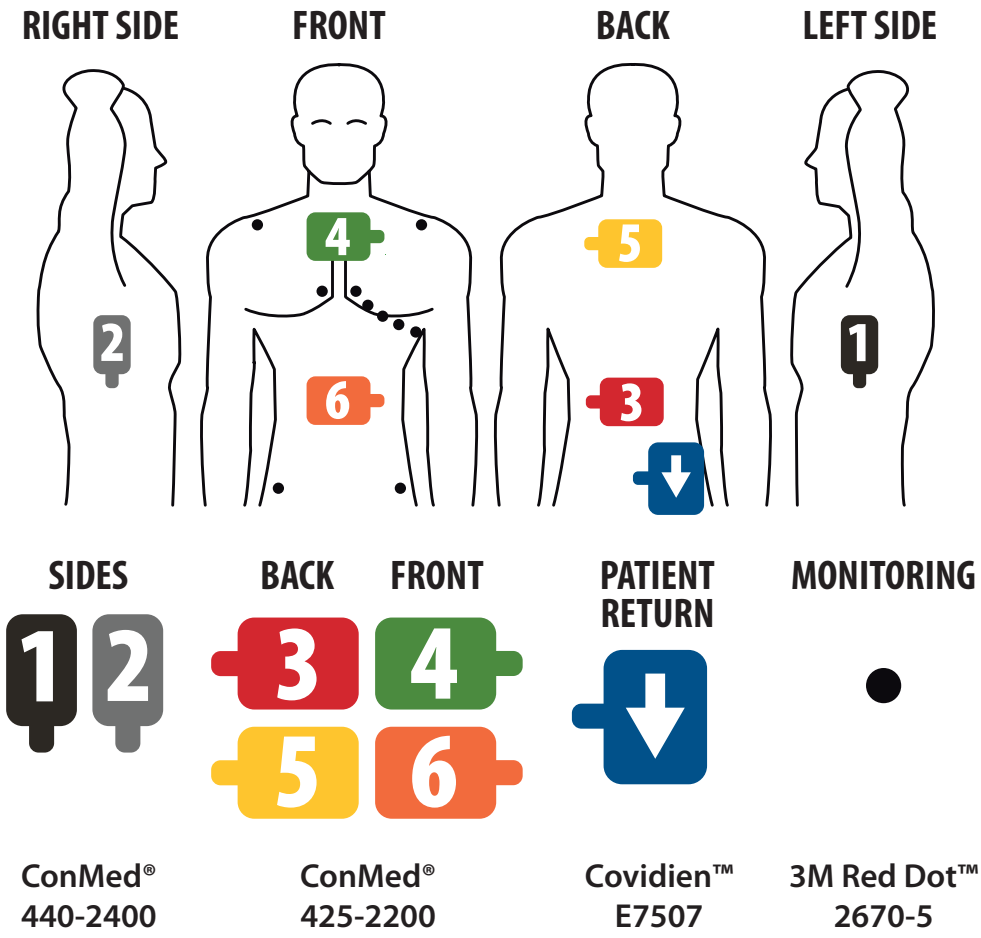
11. Connect the Repositionable Monitoring Electrodes to the AcQMap Console front panel using the AcQMap ECG Input Cable.
12. Connect the ECG Output Cable to the EP Lab ECG Monitoring System.



1	BLACK	Upper left side torso mid-axillary line at level of 4th intercostal space
2	GRAY	Upper ride side torso mid-axillary line at level of 4th intercostal space
3	RED	Lower back, opposite 6 – (Orange) on abdomen
4	GREEN	Upper chest, top edge at level of sternal notch, opposite 5 (Yellow) on upper back
5	YELLOW	Upper back, top edge at level of T4, opposite 4 (Green) on upper chest
6	ORANGE	Abdomen, midway between xyphoid process and umbilicus, opposite 3 (Red) on lower back
↓	BLUE	Lower back, rightward between spine and 2 – (Gray) and below level of 3 – (Red)

Figure 6-1. Placement of Localization Dispersive, Repositionable Monitoring and Patient Return Electrode.

6.3. — Electrical Reference Sheath or Catheter Placement

1. Insert an Electrical Reference Sheath (AcQRef Introducer Sheath) or Catheter into the right or left femoral vein per standard laboratory procedure. Refer to Chapter 5, *Figure 5-2* for recommended sheath/catheter/electrode requirements.
2. Position the electrical reference into the femoral vein, with the distal electrode(s) in the inferior vena cava (IVC) inferior to the diaphragm.
3. Connect the Electrical Reference Catheter/Cable to the AcQMap Console front panel per Chapter 5, Figures 5-1 and 5-2.

6.4. — Anatomic Reference Catheter Placement

NOTE: An anatomic reference is only required if the Surface Leads are unable to adequately compensate for respiration.

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1. Insert an Anatomic Reference Catheter into the right or left femoral vein per standard laboratory procedure. (Refer to *Figure 5-3* for recommended catheter/electrode spacing requirements).
2. Position the catheter into the best location (Azygous vein, subclavian vein, superior vena cava or coronary sinus) to provide a stationary anatomic reference.
3. Connect the Anatomic Reference Catheter/Cable to the AcQMap Auxiliary Interface Box using the appropriate manufacturer's catheter extension cable per Figures 5-1 and 5-3.

6.5. — AcQMap Catheter – Non-contact Procedures

1. Insert an AcQMap Catheter into the appropriate heart chamber according to the Catheter's Instructions for Use.
2. Connect the AcQMap Catheter to the AcQMap Console front panel.

CHAPTER 7 — NAVIGATING THE USER INTERFACE

7.1. — Operating Modes

The AcQMap High Resolution Imaging and Mapping System can be operated in two modes: Study View and Study Review. The operating mode determines which features and functions are available.

- Study View collects, records and displays data during each patient procedure. Live Signals, Patient Record Window, Acquisition, Waveforms and Mapping functions are all available in Study View mode.
- Study Review is used to review and process data from previous procedures. Only Waveforms and Maps windows are available in Study Review mode.

When the AcQMap Console is not detected by the Workstation via the AcQMap Workstation Cable, the AcQMap Software will default to the Study Review mode. A limited set of functionality is available in the Acquisition Window. Live Signals functions are not available in Study Review mode.

7.2. — Main Window Components – Non-contact Mapping

Main Window Components can be accessed from any of the three main windows – Acquisition, Waveforms and Maps. Main Window Components provide access to task windows, system-level controls and information, tools and configuration settings.

Title	Function
Menu Bar	The Menu Bar provides access to system-level controls, tools, and configuration settings
Acquisition Tab	The Acquisition Tab provides access to the Acquisition Window.
Waveforms Tab	The Waveforms Tab provides access to the Waveform Window.
Maps Tab	The Maps Tab provides access to the Maps Window.
Patient Records Button	The Patient Records Button accesses the window that displays the available sessions, recordings, and maps for each patient data set stored on the System hard drive.
Search Window	The Search Window is used to locate patient sessions, anatomies and maps stored in the System database. Searches can be performed using patient number or descriptive text.
Live Signals Icon	The Live Signals Icon provides access to the Live Signals Window.
Notes Window	The Notes Window allows note entries and then displays all entered notes for the session. All notes entered are labeled with a timestamp. Notes cannot be edited once entered. Notes are displayed when the Patient Records Window is open.
Disk Space	Disk Space provides a graphical display of remaining disk space on the Workstation storage drive. The remaining recording time is also displayed.
System Status	The System Status Display provides AcQMap System status information.
Start/Stop Recording Button	The Start/Stop Recording Button is used to initiate and stop recordings that are saved to disk storage. Once a recording has begun, the button flashes red. After clicking the button the newly completed recording will appear in the Patient Record Window associated with the current Patient Session with a sequential recording number.
Recording Duration	The Recording Duration Display shows the duration of the current recording.
Workstation Local Time	The Workstation Local Time Display shows the local time of the Workstation operating system.

7.3. – Patient Records and Notes Window


Patient Records


Pin


X

The Patients Records and Notes Window can be pinned or unpinned to the Acquisition, Waveforms or Maps Windows as access is required. The Patients Records section provides access to the current patient session, recordings, and maps as well as past patient sessions stored on the System hard drive. Patient Records are configured as a hierarchical database that can be searched using the Search Window or by scrolling through the data files. The Notes portion of the window allows the user to record notes during the procedure.

If the Patient Records and Notes Window is not visible, it can be accessed through the **Patient Records** button. Once the window is visible, clicking on the **Pin** button in the upper right- hand corner will fix the window on the screen. Clicking on the **X** button will unpin and close the window.

Title	Function
Patient Records Button	The Patient Records Button accesses the window that displays the available sessions, recordings, and maps for each patient data set stored on the System hard drive.
Search Window	The Search Window is used to locate patient sessions, anatomies and maps stored in the System database. Searches can be performed using patient number or descriptive text.
Workstation	More than one Workstation can be listed if data has been imported from another AcQMap System. The active Workstation is indicated by the blue console. Clicking on the arrow next to the active Workstation will display the patient records list associated with the console. Right-clicking on the active Workstation allows the user to create a new patient or find out important details related to the System.
Patient ID	The Patient ID is the top level in the hierarchy. All patient sessions, recordings and maps associated with the unique identifier will be stored together. Click the arrow to see the available Sessions associated with the Patient Identifier. Right-clicking on the patient identifier allows the user to create new patient sessions and edit patient information.
Notes Window	The Notes Window allows note entries and then displays all entered notes for the session. All notes entered are labeled with a timestamp. Notes cannot be edited once entered. Notes are displayed when the Patient Records Window is open.

Title	Function
Patient ID	The Patient ID is the top level in the hierarchy. All patient sessions, recordings and maps associated with the unique identifier will be stored together. Click the arrow to see the available Sessions associated with the Patient Identifier. Right-clicking on the patient identifier allows the user to create new patient sessions and edit patient information.
Sessions	Identifies each unique session for the patient by the date/time of the session. Clicking the arrow will display the data available for each unique session. Right-clicking on a session allows the user to export, copy or delete the session. It also provides access to the Anatomy Browser which locates the raw data and final anatomy(ies) associated with the patient session.
Anatomy Recordings	Anatomy Recordings hold the raw data that was collected during the patient session. Double-clicking on an Anatomy Recording will bring the dataset into the appropriate window for review and processing.
Map Recordings	Map Recordings hold the raw data that was collected during the patient session. Double-clicking on a Map Recording will bring the dataset into the Waveform Window for review and processing. Right-clicking on a Map Recording allows the user to assign a different anatomy to the dataset.
Maps	Maps are Charge Density-based and Voltage-based maps that were created from the associated dataset. Double-clicking on a map will bring the map into the Maps window for review. Right-clicking on a map allows the user to copy the map or assign a new anatomy on which to display the map.
Note Entry Box	Allows the user to enter procedure-related notes during the patient session.
Notes Log	The Notes Log displays all user-contributed notes for the session. All notes entered are labeled with a timestamp. Notes cannot be edited once entered. Notes are displayed when the Patient Session is open.
Session Label and Exit Session	The Session Label displays the current patient ID and session number. The door icon will exit and close the current session.

Session Label and Exit Session

7.3.1. — Adding Text Descriptions to Sessions, Recordings and Maps

Text descriptions can be added to any Session, Recording or Map located in the Patient Record list. Right click on any Session, Recording or Map. In the menu, select Details to access the Details window. Enter text description in the Note section of the Details window. Click **[Update]** to save the note with the Session, Recording or Map.

NOTE: All Notes can be exported to a .txt file on the Workstation desktop. After creating the note and updating the Details, click **[Export]** to save the details to the .txt file.

Adding a quick note to an existing text description:

1. To add to a previously entered text description, select the appropriate session, recording or mapping and press Ctrl+N.
2. A text box popup will appear in which a single line text description can be written.
3. Press the Enter key or move away from the text box popup to add the additional text description. Press the Escape key to clear the text description.

7.4. – Common Controls

7.4.1. – Menu Bar

The menu bar provides access to system-level controls, tools, and configuration settings. Menu bar options are shown on the upper left corner of the Main Workspace.

Selecting a menu item will reveal a set of sub-menu options. The menu bar contents and functions are described below.

Menu	Sub-Menu	Function
File	Create New Patient	Allows a new patient to be created in the System
	Create New Site	Allows the user to name the location where the AcQMap System is being used
	Import Session	Import a full session file into the AcQMap System Software.
	Exit	Exit the AcQMap System Software
Configure	Acquisition Channels	Select channels to be displayed in the Trace Display of the Acquisition Window
	Waveform Channels	Select channels to be displayed in the Trace Display of the Waveforms Window
	Maps Channels	Select channels to be displayed in the Trace Display of the Maps Window
	Group Gain	Modify the display gain of trace groups
	Expert Mode	Enables additional features and parameters for Expert users.
	Calculate Voltage Maps	Enables the ability to simultaneously calculate both charge density- and voltage-based maps. When disabled only the charge density-based maps will be calculated. Default is enabled.
Window	Debug Window	Provides access to the ACM Data Recorder Log. The log reflects the communication between the AcQMap Console and Workstation.
	Background Color	Allow changes to be made to the background color of the windows. The color change is applied to the background of all 2D and 3D windows including the Acquisition, Waveforms and Maps windows.
	Background Tasks	Shows a list and progress of tasks being performed in the background while the AcQMap System is in use. Background tasks when completed are automatically removed from the list. Tasks can also be selected and manually removed from the list.
Tools	Disk Cleaner	Function clears redundant temporary C:/ files & clears all calculated mapping data for all sessions (NB, this data can be recalculated).
Help	About	Display hardware and AcQMap System Software version information.

7.5. — Using the Mouse

7.5.1. — Basic Mouse Actions

The following terms are used to describe ways to use the mouse.

- **Click** — Move the mouse pointer over the desired element and press the left mouse button once and release.
- **Right-click** — Move the mouse pointer over a desired element and press the right mouse button once and release.
- **Double-click** — Move the mouse pointer over a desired element and press and release the left mouse button twice.
- **Drag** — Press and hold the appropriate mouse button, move the mouse, and release the mouse button.
- **Scroll wheel** — Advance the scroll wheel forward or backward to "Scroll up" or "Scroll down," respectively.
- **Select** — "Select" is a generic term for choosing a desired element by using the mouse. "Select" could refer to a single-click on a desired element, such as button on the screen, choosing from desired text on a list of items, or choosing an item in the menu, highlighting that item, and clicking again.

7.5.2. — Rotating, Zooming and Panning

The mouse is used to rotate, pan, and zoom the view in 3D displays.

- **Rotate** — To rotate the view, click and drag in any direction within the 3D view display using the left mouse button. When the left mouse button is depressed, the cursor will transition to a crossed pair of arrows indicating that the view is ready to be rotated. See table below.
- **Zoom** — To zoom the view, scroll up or scroll down on the middle mouse scroll wheel to zoom the view in or out, respectively.
- **Pan** — To pan the view, click and drag in any direction within the 3D view display using the middle mouse scroll wheel. When the middle mouse scroll wheel button is depressed, the cursor will transition to a pointed finger indicating that the view is ready to be panned. Panning translates all visual elements in the 3D space, including the axes, horizontally or vertically, in the plane of the screen view. To pan in other planes, rotate the view first and then proceed to pan. 3D panning is available in the Acquisition, Waveforms and Maps windows. Shortcut keys have also been designated for this function. (See table below)

Task	Keyboard Shortcut	Results
Rotating	↑	Rotate the image upward
	↓	Rotate the image downward
	←	Rotate the image to the left
	→	Rotate the image to the right
Panning	Q or Shift + ↑	Move the image up on the screen
	Z or Shift + ↓	Move the image down on the screen
	A or Shift + ←	Move the image to the left on the screen
	D or Shift + →	Move the image to the right on the screen

7.5.3. — Selecting and Adjusting Waveforms

The mouse is used to select and adjust waveforms.

- To select a waveform, move the mouse cursor on top of the desired waveform and single-click. When the cursor is positioned on top of a waveform, the cursor will transition to a vertical double-headed arrow.
- To increase the displayed amplitude of a waveform, move the mouse cursor on top of the desired waveform, then left-click and drag vertically. When the cursor is positioned on top of a waveform, the cursor will transition to a vertical double-headed arrow.
- To move a waveform vertically, left-click and drag the waveform label (on the left of the Trace Display) vertically.
- All remaining adjustments to waveforms, including color and group, may be accomplished via the Trace Display Control Panel.

7.5.4. — Time Point

The mouse is used to change the Time point in all displays.

- Move the mouse cursor to an area of the Trace Display where the cursor does not overlay any waveforms. Click and drag with the left mouse button to change the Time point. The vertical yellow Time Cursor will follow the mouse position as it is dragged.

7.5.5. – Common Interface Elements

The mouse and keyboard are used to interact with the graphical elements on the display. Controls that are common throughout the interface are described below.

Title	Function
Drop-down menu	Click on the arrow to display a list of choices.
Slide-out menu	Click on the arrow to show/hide a panel or a list of choices.
Tab	Click the tab to display a panel.
Slider	Click and drag the marker to change the value. In some cases, the value is shown adjacent to the slider.
Option button	Click on one of the round markers to select the option described by the adjacent label. Option buttons (or “radio” buttons) designate the selection of one out of a set of choices. Only one selection is possible at a time. The option is selected when the button is orange.
Button	Click on the face of the button to initiate the action described by the button’s label.
Checkbox	Click on the box adjacent to the text label to enable/disable the action described. Check-boxes are active when a white check appears in the box.
Text field	Click on the white area of a text field to enable editing of the text within. Once editing is enabled, use the keyboard to enter information. Text fields often appear with an adjacent **[Update]** button. Click **[Update]** to accept any changes to the text field. If a button does not appear adjacent to the text field, changes are applied once the **[Enter]** key is pressed on the keyboard.
Lists	Lists display information that can be selected using the mouse.
Shortcut icons	Provides easy access to commonly used 3-D settings.

7.6. — Live Signals Window – Non-contact and Contact Mapping

Live Signals

The Live Signals Window is accessed via the **Live Signals** button in the upper left corner of the screen. The Live Signals Window allows the user to view the Surface ECG, AcQMap and Auxiliary Catheter electrograms, AcQMap and Auxiliary Localization signals and Ultrasound.

Title	Function
Signal View Title Bar	The Signal View Title Bar provides access to the six (6) signal views: Surface Lead Biopotentials (Sur ECG), AcQMap Catheter Biopotentials (QMap EGM) Auxiliary Biopotentials (Aux EGM), AcQMap Catheter Localization (QMap Loc), Surface and Auxiliary Localization (Aux Loc), and Ultrasound (US). When a signal view button is selected, the signal view window will display the selected set of signals.
Signal View Title	The Signal View Title shows the current set of selected signals.
Signal View Window	The Signal View Window displays the selected set of signals. Each set of signals is displayed as a table of plots.
Signal Plot	Signal plots are identified by a signal name or designator displayed above the plot. Each plot includes both X (bottom) and Y (left) axes. **NOTE:** Plots in the table view are decimated to meet the screen display resolution and aliasing may occur. Double-clicking on any individual plot will bring up a larger view display window of the selected plot that is non-decimated. **Arrows** are provided to scroll through the larger view display window. Clicking on the **X** button will return to the full plot table view.  X  Arrows
Exclusion Checkbox	Each plot in the QMap and US signal view window includes a small checkbox that is used to exclude the signal. Excluded signals can also be edited in the Acquisition Window.
Gain Control	Gain Control is used to increase or decrease the vertical gain on all plots. When the gain control is moved away from a value of 1.0, the y-axis labels on each plot are not fully accurate to the measured signal amplitudes.
Refresh	The Refresh Button is used to refresh the real-time display of plot traces
Signal View Filters	The Signal View Filters may be used to apply pre-configured low-pass or high-pass filtering to the displayed signals.

7.7. — Acquisition Window

The Acquisition Window appears when the Acquisition Tab is selected. The Acquisition Window is available in both Non-contact and Contact mapping modes.

7.7.1. — Acquisition Window in Non-contact Mapping Mode

Title	Function
3D Displays	The 3D Displays will show localized catheters, cardiac surface reconstructions, markers, and labels in 3-dimensional space
Trace Display	The Trace Display shows the real-time waveforms of measured surface ECG leads and internal EGMs.
3D Settings	The 3D Settings contains display settings for all displayed elements in the 3D Display.
Shortcut Icons	Provides easy access to commonly used 3D Settings in the Acquisition Window.
Reference View	The Reference View provides quick access to pre-configured anatomic reference views: RAO, AP, LAO, LLat, LPO, PA, RPO, and RL.
Surface in Use	Surface in Use contains configuration settings for building a new cardiac surface reconstruction or displaying the Existing Surface.
Reference View Indicator	The Reference View Indicator shows the orientation of the current camera view relative to the displayed elements.
▲Localization Configuration	Clicking the up arrow will hide the Localization Configuration area from view.
Open Full Localization Setup	The Open Full Localization Setup button provides access to localization configuration settings.
Coordinate Reference Box	The Coordinate Reference Box provides display and user-editable comma-separated entry of auxiliary channels used for position reference. This list is also accessible through the Open Full Localization Setup button.
Auxiliary Catheter Channel Mapping: Aux 1 Box	The Auxiliary Catheter Channel Mapping: Aux 1 Box provides display and user-editable entry of auxiliary channels used for the display of Auxiliary Catheter 1. This list is also accessible through the Localization Settings Control Panel. Input should be a series of comma-separated auxiliary channel numbers (1-40).
AcQMap Excluded Electrodes Box	The Excluded AcQMap Electrodes Box allows the user-editable comma-separated entry of AcQMap Catheter channels known to provide errant localization.
AcQMap View Selection	The AcQMap View Selection allows the AcQMap Catheter to be displayed with the fitted model or with raw measured electrode locations.
Aux 2 Input Box	The Aux 2 Input Box provides display and user-editable entry of auxiliary channels used for the display of Auxiliary Catheter 2. This list is also accessible through the Localization Settings control panel. Input should be a series of comma-separated auxiliary channel numbers (1-40).
Auxiliary 3 (Abl) Input Box	The Aux 3 - Abl Input Box provides display and user-editable entry of auxiliary channels used for the display of Auxiliary Catheter 3. This list is also accessible through the Localization Settings control panel. This auxiliary catheter input is pre-configured to display an ablation catheter. Input should be a series of four (4) comma-separated auxiliary ablation channel numbers (1-4).
Trace Display Control Pane	The Trace Display Control Pane allows access to the display settings of the displayed traces.

Title	Function
Signal Filtering	The Signal Filtering panel may be used to apply pre-configured low-pass or high-pass filtering to the displayed signals.
Pause Live 3D Display	Allows the Live 3D Display to be paused to evaluate the on-screen view.
Aux 4 Input Box	The Aux 4 Input Box provides display and user-editable entry of auxiliary channels used for the display of Auxiliary Catheter 4. This list is also accessible through the Localization Settings control panel. Input should be a series of comma-separated auxiliary channel numbers based on the selected channels on the Auxiliary Interface box. (1-40).
Aux 5 Input Box	The Aux 5 Input Box provides display and user-editable entry of auxiliary channels used for the display of Auxiliary Catheter 5. This list is also accessible through the Localization Settings control panel. Input should be a series of comma-separated auxiliary channel numbers based on the selected channels on the Auxiliary Interface Box. (1-40).
SuperMap Toggle Switch	In non-contact mode toggle the icon to N for standard single position data acquisition or S for SuperMap multi-position data acquisition.

7.7.2. – Acquisition Window in Contact Mapping Mode

Title	Function
Menu Bar	The Menu Bar provides access to system-level controls, tools, and configuration settings
Acquisition Tab	The Acquisition Tab provides access to the Acquisition Window.
Patient Records Icon	The Patient Records Icon accesses the window that displays the available sessions, recordings, and maps for each patient data set stored on the System hard drive.
Live Signals Icon	The Live Signals Icon provides access to the Live Signals Window.
Contact Configuration Setup Icon	The Contact Configuration Setup Icon provides access to the contact mapping setup parameters including catheter definition and assignment, filter settings and activation detection parameters.
Anatomy Build and Edit	Anatomy Build and Edit contains configuration settings and editing tools for building a new surface reconstruction or displaying and editing an existing surface reconstruction.
3D Displays	The 3D Displays show localized catheters, cardiac surface reconstructions, markers and labels in 3-dimensional space.
Live/Review Annotation Window	The Live/Review Annotation Window is used to acquire mapping points, assess data quality and adjust detection parameters.
Collect Localization Field	Sets up the localization field for contact mapping.
Auxiliary Catheters	Auxiliary catheters provide the display and user-editable entry of auxiliary channels used to display Aux 1, Aux2 and Aux3-Abl catheters. Input should be a series of comma-separated auxiliary channel numbers.
Coordinate Reference	The Coordinate Reference configuration box provides display and user-editable comma-separated entry of auxiliary channels used for position reference. This list is also accessible through the Open Full Localization Setup button.
Trace Display Control Panel	The Trace Display Control Pane allows access to the display settings of the displayed traces.
Points List/Recycle Bin	All acquired points included or excluded from the map are located in the points list or recycle bin, respectively.
Map List	This provides a list of available data sets and allows the user to select the active map for display or point collection. A new entry is created when the + (new map) is clicked and the first point is acquired.
Map Type	Select the type of map information to display from the Active Map data set.

Waveforms Window

The Waveforms Window appears when the Waveforms tab is selected. The Waveforms Window is only available in non-contact mapping mode.

Title	Function
3D Display	The 3D Display shows three-dimensional anatomy and localization information at the time marked by the Time Cursor. The displayed view is selected in the 3D Display Selection Panel. Localization view shows the position of the AcQMap Catheter and auxiliary catheters as well as the reconstructed cardiac surface.
3D Settings	The 3D Settings contains display settings for all displayed elements in the 3D Display.
Shortcut Icons	Provides easy access to commonly used 3D Settings in the Waveforms Window.
Create Mapping	The Create Mapping button is used to export selected data for mapping. Data is selected using time-calipers in the Trace Display.
Multi-Channel Visualization Selection	The Multi-Channel Visualization Selection is used to switch to a full-screen Trace View. The Trace View shows all AcQMap Catheter or auxiliary channels in a grid of individual plots or as a single plot with all signals on the same axes (see Multi-Channel Visualization Window).
Filtering Control	Filtering Control provides access to selection and configuration settings for the set of filters that may be applied to signals shown in the Trace Display: Respiration, High-Pass, Notch, Low-Pass, Smoothing and VWave removal filters.
Trace Layout Selection Buttons	The Trace Layout Selection Buttons are used to expand or collapse the vertical positioning of traces displayed in the Trace Display.
Trace Display	The Trace Display shows the biopotential signals of interest. The displayed trace(s) is/are chosen from the Trace Display Selection panels.
Trace Display Control Panel	The Trace Display Control Panel allows access to the settings of the displayed traces.
Pin	The Pin Checkbox vertically offsets all AcQMap Catheter traces such that the voltage at the time point marked by the Time Cursor is equal to 0.
Time Window Slider	The Time Window Slider is used to navigate the Trace Display in time.
Time Cursor	The Time Cursor is used to change the selected time point used in the Grid Map and 3D Displays.
Add/Delete Calipers	The Caliper button allows you to add or delete calipers to the map.
Caliper	The map caliper measures the cycle length between the ends of the calipers and displays the measurement.
Bookmarks	Bookmarks allows the user to save configuration settings for all the available display and signal processing parameters in the Waveforms window.

7.8. – Maps Window

The Maps Window appears when the Maps tab is selected. The Maps Window is only available in Non-contact mapping mode.

Title	Function
3D Display 1	The 3D Display 1 shows the three-dimensional surface map at the time marked by the Time Cursor.
3D Display 2	The 3D Display 2 shows the three-dimensional surface map at the time marked by the Time Cursor in a second reference view.
Trace Display	The Trace Display shows the biopotential signals of interest. Displayed channels are selected by navigating to Configure – Maps Channels.
3D Settings	The 3D Settings is used to display or hide various visual elements in the 3D Displays. Lighting Options are used to change the lighting method and model transparency. Curve Fitting is used to adjust the fitting and display parameters for auxiliary catheters. View is used to adjust the display settings for all catheters and the anatomic surface in the 3D display. Camera is used to change the rotation mode, change the camera perspective or the location of the visual center point
Shortcut Icons	Provides easy access to commonly used 3D Settings in the Maps Window.
Anatomic Labels	The Anatomic Labels panel is used to organize and define labels used in the 3D Displays. Labels may be dragged into the 3D Displays and placed on the chamber surface. Shortcut keys are also available – see Appendix F AcQMap System Keyboard Shortcuts.
Markers	The Markers panel is used to organize the markers shown in the 3D Displays. Markers may be dragged into the 3D Displays and placed on the chamber surface. Shortcut keys are also available – see Appendix F AcQMap System Keyboard Shortcuts.
Bookmarks	Bookmarks allows the user to save configuration settings for all the available display and signal processing parameters in the Waveforms window.
Mapping Control Panel	The Mapping Control panel is used to configure the mapping method and parameters displayed in the 3D Displays.
Color Bar Control	The Color Bar Control is used to vary the color scaling of the surface map displayed in the 3D Displays.
Color Bar Tuner	The Color Bar Tuner is used for manual input of the Color Bar maximum and minimum settings.
AcQTrack	Calculates the type and location of 3 discrete patterns often found in the maps.
Trace Display Clearing Controls	The Trace Display Clearing Controls are used to clear calculated traces from the Trace Display or revert to the default zoom level.
Playback and Timer Control Panel	The Playback and Timer Control Panel provide controls to start, stop, and change the speed of time-progression playback in the 3D and Trace Displays. The Timer Control allows the time window shown in the Trace Display to be changed through the use of the mouse.
Time Cursor	The Time Cursor is used to change the selected time point used in the Trace and 3D Displays.
Map Designator	The Map Designator identifies the map type that is being displayed.

7.9. — Configure 3-D Display

3-D Display Controls are configured via the 3D Settings. The 3D Settings contains settings for the 3-D Display. The settings are accessed by clicking on the different titles.

7.9.1. — 3D Settings - View

The following controls are used when building the anatomy or to adjust the appearance of the surface in the 3-D Display after it has been reconstructed.

Chamber Settings

Show/Hide Chamber Surface

- **Show Chamber Surface**
  - Enable or disable display of the reconstructed surface polygons.
  - Clicking on the **Show/Hide Chamber Surface** icon will enable or disable the display.

Show/Hide Mesh

- **Show Mesh**
  - Shows the surface mesh of the reconstructed chamber.
  - Appears to the right of the **Show/Hide Chamber Surface** icon above when the cursor is hovered over icon. Enables or disables display of the surface mesh.

Show/Hide Mesh

AcQMap Catheter

The following controls are used to adjust the appearance of the AcQMap Catheter in the 3-D display. The AcQMap Catheter icon is only available in Non-contact mapping mode.

- **Show AcQMap Splines**
  - Enable or disable rendering of the AcQMap splines and electrodes in the 3D display.
  - Clicking on the **AcQMap Catheter** shortcut icon will enable or disable the display.

AcQMap Catheter

Auxiliary Catheter

The following functions are used to adjust the appearance of the Auxiliary Catheters in the 3D display.

- **Show Aux 1**
  - Enables or disables the display of the fitted Auxiliary Catheter 1 as configured in the auxiliary catheter connections. (Chapter 9, Aux Catheter Channel Mapping).
  - Clicking on the **Show Aux 1** shortcut icon will enable or disable the display.

Show Aux 1

– Initial Position
When the Aux 1 Catheter is registered, the System stores the initial location. If the Aux Catheter moves during the procedure, select the initial position checkbox in the View mode to show the original catheter position. A fixed ghosted image will show the initial catheter position that can then be used to reposition the displaced catheter. An alternative method is described in Appendix E - Manual Catheter Registration. If repositioning is unsuccessful, a new anatomy must be created. (*Figure 7-1*)

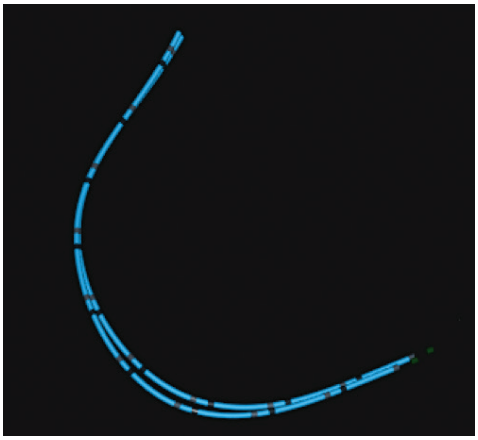


Figure 7-1. Initial catheter position.

- **Show Aux 2**
  - Enables or disables the display of the fitted Auxiliary Catheter 2 as configured in the auxiliary catheter connections. (Chapter 9, Aux Catheter Channel Mapping).
  - Clicking on the **Show Aux 2** shortcut icon will enable or disable the display.

Show Aux 2

  - Initial Position
When the Aux 2 Catheter is registered, the System stores the initial location. If the Aux 2 Catheter moves during the procedure, select the initial position checkbox in the View mode to show the original catheter position. A fixed ghosted image will show the initial catheter position that can then be used to reposition the displaced catheter.
- **Show Aux 3 (ABL)**
  - Enables or disables the display of the fitted Auxiliary Catheter 3 as configured in the auxiliary catheter connections. (Chapter 9, Aux Catheter Channel Mapping).
  - Clicking on the **Show Aux 3** icon will enable or disable the display.

Show Aux 3

- **Show Aux 4**
  - Enables or disables the display of the fitted Auxiliary Catheter 1 as configured in the auxiliary catheter connections. (Chapter 9, Aux Catheter Channel Mapping).
  - Clicking on the **Show Aux 4** shortcut icon will enable or disable the display.

Show Aux 4

- Initial Position
  When the Aux 4 Catheter is registered, the System stores the initial location. If the Aux Catheter moves during the procedure, select the initial position checkbox in the View mode to show the original catheter position. A fixed ghosted image will show the initial catheter position that can then be used to reposition the displaced catheter.

- **Show Aux 5**
  - Enables or disables the display of the fitted Auxiliary Catheter 5 as configured in the auxiliary catheter connections. (Chapter 9, Aux Catheter Channel Mapping).
  - Clicking on the **Show Aux 5** shortcut icon will enable or disable the display.

Show Aux 5

  - Initial Position
    When the Aux 5 Catheter is registered, the System stores the initial location. If the Aux 5 Catheter moves during the procedure, select the initial position checkbox in the View mode to show the original catheter position. A fixed ghosted image will show the initial catheter position that can then be used to reposition the displaced catheter.

- **Ultrasound**

  The following function adjusts the display appearance. Ultrasound is only available in non-contact mapping mode.

  - Show Vectors
    Enables or disables the display of the ultrasound ranging vectors. Default is ON.

7.9.2. — 3D Settings - Curve Fitting

Auxiliary Catheter Control

The following controls are used to vary the parameters of the auxiliary catheter curve-fitting algorithm.

- **Show Aux 1 Labels, Aux 2 Labels, Aux 4 Labels, Aux 5 Labels**
  Select the Aux 1, Aux 2, Aux 4 or Aux 5 catheter. This will enable the display of the electrode labels. The font size can be adjusted by changing the value: larger values = larger font size and smaller values = smaller font size.

  Shortcut icon: Select the appropriate Aux Catheter, once clicked a separate icon appears that allows the font size to be changed. Click on the new icon and hover over it and scroll the middle mouse wheel.

Aux Shortcut

- **Show Aux 1 Raw Electrodes, Show Aux 2 Raw Electrodes, Show Aux 3 Raw Electrodes, Show Aux 4 Raw Electrodes, Show Aux 5 Raw Electrodes**

  Enables or disables the display of the raw measured auxiliary electrode positions. This setting is not recommended for general use.

- **Show Initial Aux 1 Raw Electrodes, Show Initial Aux 2 Raw Electrodes, Show Initial Aux 4 Raw Electrodes, Show Initial Aux 5 Raw Electrodes**

  Enables or disables the display of the initial position of the raw measured auxiliary electrode positions. This setting is not recommended for general use.

- **Alignment Factor**
  Varies the overall alignment of electrodes – from distal-matched to proximal-matched.

7.9.3. — 3D Settings - Camera

The following controls are used to adjust the Camera settings in the 3-D display.

- **Center Point**
  Select the rotational center for the camera.
- **Center of AcQMap Catheter**
  Uses the centroid of the AcQMap Catheter as the rotational center for the Camera.
- **Center of Chamber**
  Uses the centroid of the surface as the rotational center for the Camera.
- **Center at Origin**
  Uses the origin of the coordinate axes as the rotational center for the Camera. This is the default setting.
- **Reset button**
  Resets the camera view. Shortcut icon: Click on the **Reset Camera** icon to reset the camera view.

Reset Camera

7.9.4. — 3D Settings - Lighting

The following controls are used to adjust the Lighting in the 3-D display.

- **Surface Transparency**
  Adjust the level of transparency of the Surface Anatomy. Shortcut icon: Hover over the **Show/Hide Chamber Surface** icon and use the mouse scroll wheel to change the level of transparency.

Show/Hide Chamber Surface

- **Directional Lighting**
  This mode shows shadowing and relief on the surfaces. Click use the mouse scroll wheel to change shadowing and relief.

Directional Lighting

7.10. – Electrode Highlighting

The Electrode Highlighting Tool is located as part of the Shortcut Icon list on the Acquisition Screen. This tool is used to visually identify electrode locations on any auxiliary catheter.

Electrode Highlighting Tool

With the Electrode Highlighting Tool open, select the AUX catheter you want to highlight electrodes on. Only one AUX catheter can be selected at a time. Use the mouse to select the electrode to highlight and de-select any other highlighted electrodes. Shift + mouse clicks allow consecutive electrodes to be selected. Ctrl + mouse clicks allow non-consecutive electrodes to be selected. All selections can be cleared by clicking the **Clear Selection** icon. Use the **Close** icon to close the tool.


Clear Selection


Cancel

7.11. – Cut-Plane Tool

The Cut-Plane tool removes a portion of the surface anatomy to allow viewing of the interior chamber surface. The Cut-Plane tool is only available in the Acquisition Window.

1. In either the left or right 3D Display select the view in which to cut the plane of the surface anatomy. Different views can be cut in each viewport.
2. Click on the Cut-Plane Shortcut Icon. An initial transverse planar surface cut will be performed.
3. To rotate the view to see the interior aspects, left click on the blue frame and hold the mouse button. A white four direction arrow set indicates that the view can be rotated.
4. To adjust the plane of the surface cut, right click on the blue frame. The frame will turn green allowing the plane of the surface cut to be adjusted in the selected view.
5. To adjust the degree of the planar surface cut, right click and hold on one of the gold corners. The corner will turn green allowing the plane to be moved to increase or decrease the degree of the planar surface cut. Releasing the right mouse button, will retain the degree of the planar surface cut.
6. To show the portion of the anatomy that was cut-away, toggle the show/hide cut-away surface icon. The anatomy and markers will be shown on the side of the cut plane denoted by the arrow point at the gold corners.

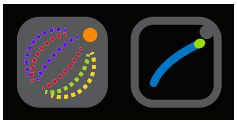

Cut-Plane


Hide Cut-away


Show Cut-away

7.12. — 3D Settings – View Catheter Silhouette

When localized catheters are inside or behind the surface anatomy, a silhouette of the catheter can be enabled to visualize the location of the catheter. The Catheter Silhouette is available in the Acquisition, Waveforms and Maps Windows. All localized Aux Catheters and the AcQMap Catheter can be silhouetted.



AcQMap Silhouette

To access the Catheter Silhouette tool, hover over either the AcQMap Catheter shortcut icon or one of the Aux Catheter icons (Aux1, Aux2, Aux3-Abl). Click on the catheter that appears to the right to enable the silhouette for the selected catheter. A silhouette of the selected catheter will be visible within the surface anatomy.

Aux Cath Silhouette

CHAPTER 8 — STARTING A STUDY

Refer to Chapters 5 and 6 for AcQMap System set up and connections

8.1. — Starting the AcQMap System Software

1. Wait for the AcQMap Console start-up as indicated by the presence of the AcQMap logo screen. (*Figure 8-1*).

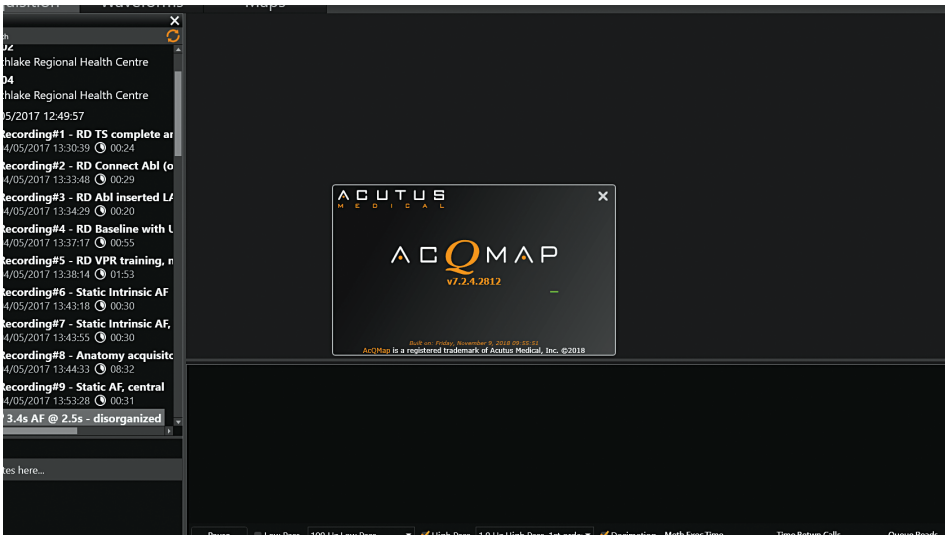


Figure 8-1. AcQMap Console start-up screen.

2. Click **[Next]** at the bottom of the screen after startup process is complete.

8.2. — Starting a New Study

In the Patient Records Window select the active Console as denoted by the blue console. Use the search window to locate previous studies for a returning patient or right click on the AcQMap Console name to access the window that will allow you to create a new patient.

8.2.1. – Creating a New Patient

1. A new patient record can be created by either selecting File à Create New Patient from the menu bar or Right-click on the active Console and select Create New Patient.
2. The Patient Info Window will appear.
3. Complete all required fields. Required fields are shown in red.
4. Click the Permission to Export box if the patient data will be exported.
5. Click **[OK]**.
6. Select mapping mode. Contact or AcQMap
7. The patient will be listed under the active console.
8. Session 1, with the associated time and date, is automatically created when a new patient is entered. Subsequent patient Sessions can be created by navigating to Patient Identifier, right-clicking and selecting Create New Session.

NOTE: Contact mapping sessions are denoted by a blue line adjacent to the session record. Non-contact mapping sessions are denoted by an orange line adjacent to the session record.

Contact mapping session

Non-contact mapping session

8.2.2. – Starting a New Session for an Existing Patient

9. Use the Search window to locate the patient or expand the data list for the active console and scroll through the data to locate the patient's files.
10. Right-click on the patient and select Create New Session.
11. A confirmation box will appear asking to "Confirm New Session". Click **[Yes]**.
12. A new Session will be created with an automatically generated number based on the number of Sessions that already exist for the patient. The new Session is identified by the current date and time.
13. Navigate to and double-click on the newly created Patient Session.
14. The screen will now show the Acquisition Window with the selected Patient ID and Session number in the Session Label at the top of the screen.

8.2.3. – Resuming a Study

15. Navigate to and double-click on the existing session for the patient to resume the session.
16. The screen will now show the Acquisition Window with the selected Patient ID and Session number in the Session Label at the top of the screen.

CHAPTER 9 — SETUP FOR NON-CONTACT MAPPING

This chapter describes the steps for setting up the AcQMap System for non-contact data acquisition, biopotentials display, anatomy reconstruction, and map creation. Refer to Chapter 16 for the steps to set up the AcQMap System for contact mapping.

Before starting data acquisition, ensure that the following steps have already been completed:

- ☑ System set up – see Chapter 5
- ☑ Perform Console Power On Self Test and Functional Test – Chapter 5
- ☑ Create patient record – Chapter 8
- ☑ Attach Localization Dispersive Electrodes, Patient Return Electrode and Repositionable Monitoring Electrodes – Chapter 6
- ☑ Connect Patient Electrodes to Console – Chapter 6
- ☑ Verify ECG quality – Chapter 9
- ☑ Insert, place and connect Electrical Reference Sheath – Chapter 6
- ☑ Insert and position AcQMap Catheter – Chapter 6
- ☑ Insert and position Auxiliary Catheters
- ☑ Insert and position Ablation Catheter. Connect Ablation Catheter and Generator as recommended in Appendix A.

The following remaining **mandatory steps** will be described in the sections below:

- ☐ Calibrate Localization Phase – Chapter 9, Section 9.1.5
- ☐ Map Excluded Channels – Chapter 9, AcQMap Catheter Channel Exclusion
- ☐ Set up Anatomical Reference Channels to be used – Chapter 9, Setting up an Anatomical Reference Channel using Surface Electrodes
- ☐ Rescale – Chapter 9, Rescaling of the Localization Sub-system

9.1. — Checking Signals

The Live Signals window is used to verify input connectivity and signal quality of the AcQMap System.

Navigate to the Live Signals Window by clicking the **Live Signals** button.

Live Signals

The Live Signals Window consists of six (6) signal views:

- Surface ECG (Sur ECG)
- AcQMap Catheter biopotentials (QMap EGM)
- Auxiliary Catheter biopotentials (Aux EGM)
- AcQMap Catheter localization (QMap Loc) — Magnitude and phase for each of the three localization axes
- Surface and Auxiliary Catheter localization (Aux Loc) — Magnitude and phase for each of the three localization axes
- Ultrasound ranges (US)

Section 9.1 describes the use of each Signal View screen. Signals may be verified on all applicable (connected) channels.

NOTE: Located on the bottom of each screen except Ultrasound (US) is a set of pre-defined filters that may be applied to the displayed signals by selecting the LP (low pass) or HP (high pass) filter.

NOTE: The Surface and AcQMap Catheter localization (QMap Loc), and Auxiliary Catheter localization (Aux Loc) screens contain a Localization View Sub-Menu which will enable the display of localization magnitude or phase for each of the three localization frequencies. (X-axis = IQ1, Y-axis = IQ2, Z-axis = IQ3).

For better viewing, double clicking on any signal grid will bring up an expanded view of the selected signal. The Forward and Back arrows can be used to scroll through the trace and the “X” will close the expanded viewing window.

9.1.1. — Surface ECG

Biopotentials – Surface ECG

The Surface ECG Screen displays surface ECG leads I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6. Signal gain can be adjusted using the Gain slider on the left side of the screen. Signals can be refreshed using the Refresh button.

9.1.2. — AcQMap Catheter Setup

Biopotentials – QMap EGM

The QMap EGM screen displays the 48 measured electrograms from the AcQMap Catheter. Click **[QMap EGM]** to access the AcQMap EGM screen.

Localization – QMap Loc

The AcQMap Loc Screen displays the localization signal selected in the Localization View Sub-Menu for all 48 electrodes of the AcQMap Catheter. The phase of localization signal should be near constant for *in vivo* connections. The magnitude of the localization signal should be stable for *in vivo* connections with slight modulation from cardiac or respiratory cycles. Click **[QMap Loc]** to access the AcQMap Loc screen.

9.1.3. — EP Auxiliary Catheter Setup

Biopotentials – Aux EGM

The Aux EGM Screen displays the measured electrograms from the Auxiliary Catheter channels as well as the surface electrode signals. Click **[Aux EGM]** to access to the Aux EGM screen.

Localization – Surface and Aux Loc

The Surface and Aux Loc screen displays the localization signal selected in the Localization View Sub-Menu for the Surface electrode channels (e.g. ECG) and for all auxiliary catheter channels. Click **[Aux Loc]** to access the Aux Loc screen.

The Surface channels are located in the top two rows on the screen. The phase of the localization signal should be near constant. The magnitude of the localization signal should be stable with slight modulation with cardiac or respiratory cycles.

The Auxiliary Catheter channels are located starting at the end of row 2 through row 6. The phase of the localization signal should be near constant for *in vivo* connections. The magnitude of the localization signal should be stable for *in vivo* connections with slight modulation with cardiac or respiratory cycles.

When Phase View is selected an IQ Phase Correction Panel appears next to the Sub-Menu. This panel is used to select auxiliary channel numbers to be used for calibration of the localization sub-system. Refer to “Calibrate localization phase” section for additional detail.

9.1.4. – Ultrasound

The Ultrasound view shows histograms of range data from each of the 48 AcQMap Catheter transducers. Click **[US]** to access the Ultrasound screen.

9.1.5. – Calibrate Localization Phase

The localization phase can be calibrated using either *in vivo* auxiliary catheter connections or in vivo AcQMap connections.

Calibrating the Localization Phase using Auxiliary catheter connections

1. Ensure that localization electrodes have been properly applied and auxiliary catheter connections have been made.
2. Go to the Aux Loc tab in the Live Signals menu.
3. Click Phase. The IQ Phase Correction panel will appear.
4. Click through IQ1, IQ2 and IQ3 to identify several channels that are connected and display a stable phase in all three axes. Stable signals should be flat and consistent in phase with one another.
5. Enter the stable Aux channels in the Channels box in the IQ Phase Correction panel using commas to separate the channel numbers.
6. If the correction value is not 0, click **[Clear Phase Correction]** to clear the value.
7. Click **[Calculate IQ Phase]** to calculate the corrective value.
8. Click **[Send]** to complete the phase correction.

Calibrating the Localization Phase using AcQMap catheter connections

1. Ensure that localization electrodes have been properly applied and the AcQMap Catheter is connected and in the chamber of interest outside the sheath.
2. Go to the QMap Loc tab in the Live Signals menu.
3. Click **[Phase]**. The IQ Phase Correction panel will appear.
4. If the correction value is not 0, click **[Clear Phase Correction]** to clear the value.
5. Click the **[Detect]** button. Ten (10) to 11 channels from the AcQMap Catheter will be detected and the IQ phase correction will be automatically calculated.
6. Click **[Send]** to complete the phase correction.

NOTE: This step MUST be performed prior to use of AcQMap Catheter localization.

NOTE: A manual mode may be configured according to Appendix B - Manual Configuration of Orientation Reference.

9.1.6. — Exit the Live Signals Window

Click on the **[Acquisition]** tab at the top of the screen to proceed to the Acquisition mode.

9.2. — Acquisition Setup

Localization, 3D Display, and Trace Display settings must be configured prior to acquiring data. Navigate to the Acquisition window by clicking on the **[Acquisition]** tab.

9.2.1. — Localization Configuration

Localization with the AcQMap System can be configured in three ways, (1) using surface electrodes, (2) using an auxiliary catheter or (3) without an anatomic reference. Localization settings are configured via the Localization Configuration panel.

Initial configuration
Initial configuration of localization settings is completed via the Localization Configuration panel. Click the [**Open Full Localization Setup]** button in the Localization Configuration panel to access the Localization Configuration Window.

NOTE: Two configuration modes are possible for the AcQMap localization sub-system.

Localization Setup
Localization settings are entered manually, including assignment of excluded electrodes, Anatomic Reference Electrodes, and auxiliary catheter connections.

Load Registration
Localization settings and registration data that have been previously saved for the current Patient Session are loaded from file. Localization settings are automatically saved when a surface reconstruction is saved. Use of localization settings saved concurrently with a surface reconstruction ensures the reliability of spatial registration. The registration presumes a static position of all Anatomic Reference Electrodes through all registered records.

NOTE: Refer to Chapter 9, **Loading Registration Files,** when registering to a previously reconstructed surface.

For initial setup, the Manual Configuration option must be used. Select ⊙Localization Setup and then click **[Next]**.

Mapping Catheter Model
The Mapping Catheter Model should match the AcQMap Catheter being used.

Excluded AcQMap Electrodes

AcQMap Catheter channels may be excluded from the localization sub-system calculation by entering a comma-separated list.

NOTE: AcQMap Catheter channels excluded from localization are independent of electrograms marked as excluded for mapping.

Electrodes to exclude will typically appear as a single or subset of node(s) displaced from the set of well-ordered, well-structured AcQMap Catheter electrodes. Viewing the set of raw electrode positions in voltage and position modes will help to identify the electrodes to exclude. Examples of nodes to be excluded are shown in *Figure 9-1*.

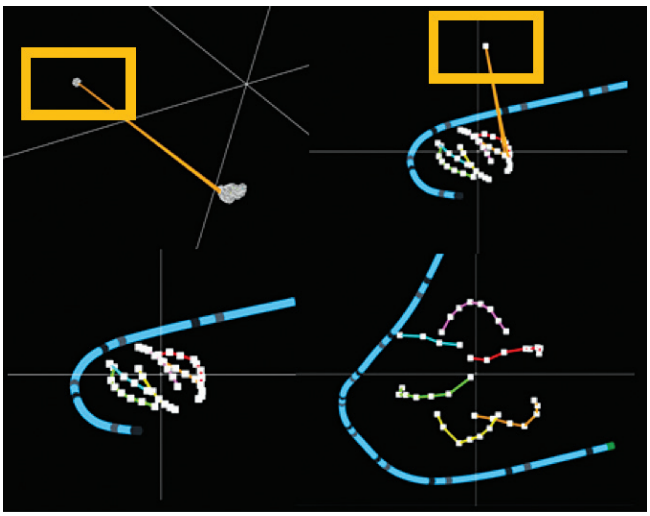


Figure 9 – 1. Identifying nodes to exclude.

Figure 9-1 Quadrants:

- Top left: The yellow box indicates the single node to exclude in voltage mode.
- Top right: The yellow box indicates the same node to exclude in position mode.
- Bottom left: The remaining AcQMap electrodes in position mode after exclusion.
- Bottom right: The remaining AcQMap electrodes in position mode after rescaling.

Click **[Next]** to proceed to the next screen.

Setting up Anatomical Reference Channels

Anatomical Reference Channels can be setup in one of two ways (1) using the Surface Leads or (2) using an auxiliary catheter.

Setting up an Anatomical Reference Channel using Surface Leads

The use of surface leads as an anatomical reference should be suitable for use in most patients. If setup cannot be completed, then use of an auxiliary catheter will be required. The System will prompt the user to setup the anatomical reference. See Chapters 5 and 6 for specifications, placement and connections. See Chapter 9 for setup instructions.

1. Under the heading Anatomical Reference Channels select Surface Leads. Anatomical Reference Channels are displayed as a comma-separated list in the allotted box. The box will be automatically populated with V1, V2, V3, V4, V5, V6, LL, LA, and RA. This can be edited if needed.
2. Center the AcQMap Catheter in the cardiac chamber. It is recommended to leave the AcQMap Catheter stationary throughout the setup period.
3. Click the **[Finish]** button to start the setup process. A progress bar will be shown on screen to indicate level of completion. Once the setup is complete, the settings will be saved.

NOTE: If the AcQMap Catheter is moved it may extend the time required to complete the setup.

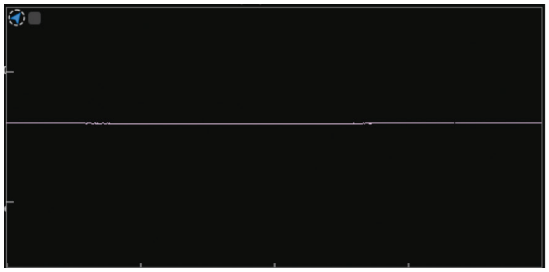
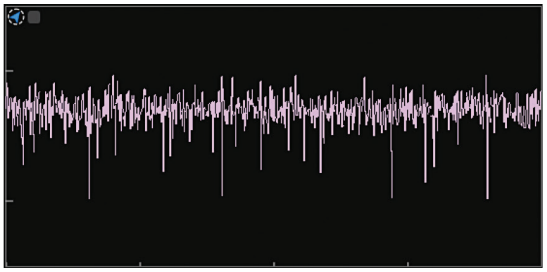
NOTE: Setup may be canceled at any time, doing so will cause the System to revert to previously saved values. If setup has not been previously performed, no correction will be applied and motion due to respiration will be unchanged.

NOTE: If excessive residual respiration motion (catheters appears to move >5 mm due to respiration) is observed, setup can be repeated except during a recording.

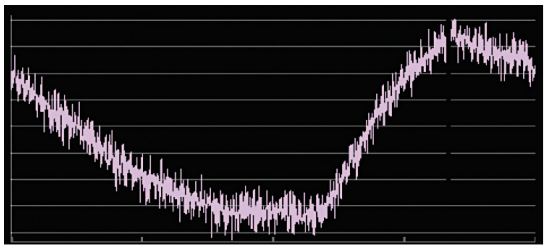
If setup does not complete successfully, check the following:

- The surface leads are all properly positioned and well-adhered to the body surface.
- In the Live Signals Window, navigate to the Aux Loc tab, ensure that the following criteria are met:
  - For the LA, RA, and one or more of the V leads,

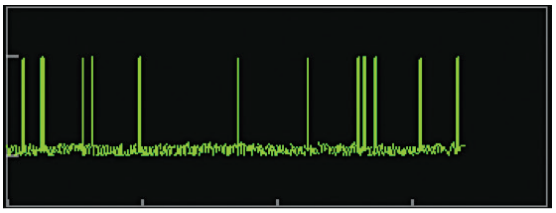
    The localization magnitude is stable (as shown below, left). An example of an unstable channel is shown below right.

    The localization magnitude, when magnified (double-click on each channel) has a characteristic respiration pattern – a periodic signal with 4-5 sec period.



    The localization phase is stable, as shown below left. An example of an unstable phase is shown below right.

Setting up an Anatomical Reference Channel using an Auxiliary Catheter

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NOTE: Use of an auxiliary catheter as an Anatomical Reference Channel is only required when use of the surface leads is inadequate. Refer to Chapters 5 and 6 for specifications and placement of an auxiliary catheter as an Anatomical Reference Channel.

Under the heading **Anatomical Reference Channels** select Auxiliary Catheter. Anatomical Reference Channels are selected by entering a comma-separated list of auxiliary channel numbers (1-20) into the allotted box.

NOTE: Refer to Appendix C: Choosing Anatomic Reference Electrodes for a guide on how to assign the Anatomic Reference Electrodes.

Auxiliary Catheter Connections – Non-contact Mapping

Up to five Auxiliary Catheters may be localized and displayed in the 3D Display. Auxiliary Catheter connections are configured by selecting the desired catheter from the "Catheter Type" drop-down list under each Auxiliary Catheter configuration box. Once a catheter type is selected, a set of text boxes will appear, one for each available electrode connection on the catheters. Enter auxiliary channel numbers (1-40) into the text entry fields.

Auxiliary Catheters 1, 2, 4 and 5 may be configured with any combination or order of channel numbers, but must reflect the connectivity at the Auxiliary Interface Box to be displayed accurately.

Auxiliary Catheter 3 is pre-configured for the ablation input channel numbers 1-4 which are separate from channels 1-40 used to define Auxiliary Catheters 1, 2, 4 and 5.

Rescaling of the Localization Sub-system – Non-contact Mapping

Rescale the localization sub-system by clicking on the Open Full Localization Settings button in the Localization Configuration panel. Click on the **[Rescale]** button in the Localization Configuration Window. This will re-calculate the scaling transform applied to the voltage data to calculate electrode positions in position-space. As errant electrodes are excluded, rescaling of the localization sub-system will produce a more accurately localized AcQMap Catheter electrode spacing.

NOTE: Clicking Rescale will not initiate a setup process

Advanced Settings

- **Manual Orientation – Non-contact mapping**

  To access the Manual Orientation parameters, check the Manual Orientation checkbox ☑ under the Advanced title in the Localization Configuration Window. This setting enables the user to bypass the automatic orientation of the localization sub-system and define the orientation of the localized axes manually. Click **[Next]** to proceed.

NOTE: Refer to Appendix B – Manual Configuration of Orientation Reference for additional information.

Click **[Finish]** to apply all settings and close the Localization Configuration window.

Loading Registration Files

1. If registration to a previously reconstructed surface is needed, the registration and localization configuration files saved with the surface reconstruction may be loaded by selecting ⊙Load Registration Files in Localization Configuration Window and click **[Next]**.
2. Once the file has completed loading, a notification window will appear stating "Registration Info was loaded."
3. Click **[Next]** to proceed to the Acquisition Window.

Live Adjustments to the Localization Configuration

A number of localization settings may be changed from the Acquisition Window without returning to the Localization Settings Dialogue Window. These settings include channel assignment AcQMap Excluded Electrodes, Auxiliary Catheter Channel Mapping, Coordinate Reference and AcQMap Catheter viewing modes.

Coordinate Reference – Using Surface Leads

1. Click on the Configure button under the heading Coordinate Reference in the Localization Configuration panel.
2. Select Surface Leads. Enter Anatomical Reference Channels into the text field. The field should be pre-populated with V1, V2, V3, V4, V5, V6, LL, LA, and RA.
3. Calibration Reference Channel: Three options are available, AcQMap Catheter, Ablation Catheter or Auxiliary Catheter. Default is AcQMap Catheter. If the AcQMap Catheter is not in the chamber, select one of the other catheters that is in the chamber and repeat the setup process, making sure the catheter is centered in the chamber and stationary.
4. Click **[Apply]** to complete the setup.

Anatomical Reference Selection – Using an Auxiliary Catheter

NOTE: Only required when an auxiliary catheter is in place

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1. Select Auxiliary Catheter.
2. Enter Anatomic Reference Electrode channel numbers into the text field.
3. Click **[Apply]** to make the changes.

Operating without an Anatomic Reference

To bypass the use of either the Surface Leads or Auxiliary Catheter uncheck the box next to ON under the Coordinate Reference heading.

NOTE: It is recommended to leave this ON at all times.

AcQMap Excluded Channels

AcQMap Excluded Channels can be entered into the text fields. Click **[Apply]** to apply changes.

Auxiliary Catheter Channel Mapping

Auxiliary Catheter Channel Mapping is displayed in the boxes entitled Aux 1 - Aux 5 in the Localization Configuration panel. Auxiliary Channels can be configured by clicking the **[Configure]** button located under the Auxiliary Catheters heading.

AcQMap Catheter

Identifies the AcQMap Catheter currently in use. Changing the view from Fitted to Raw will bypass the fitting applied to the AcQMap Catheter. The Raw setting is not recommended for general use.

9.3. — Configure Trace Channels and Trace Display

9.3.1. — Configure Trace Channels

1. Trace channels settings are configured via the Configure Menu → Select Acquisition Channels, Waveforms Channels or Maps Channels. Once values have been set they are transferred to the Trace Display Control Panel on the respective screen.
2. Select up to 63 channels between all input channels across the tabs: AcQMap Catheter, Surface ECG and Auxiliary Catheters by selecting the ☑ checkbox in the column labeled Visible. The Maps Channels includes an extra tab – Chamber Prefixes – that allows the user to select the Trace color for Virtual electrograms (Charge or Voltage) selected when reviewing maps. In the lower left-hand corner, a count of the Number of Visible Sensors is shown. Select Save Configuration to transfer the data to the Trace Window within the Trace Display Control Panel on the respective screen.
3. User-configurable options
   a. Designator – User-editable field for the displayed name of the channel in the Trace Display. Double-click to access the field. Only available in the AcQMap Catheter and Auxiliary Catheters tabs.
   b. Color – Change the color of the signal on the Trace Display.
   c. Visible – The visible check box can be toggled on or off.

9.3.2. — Trace Display Control Panel

The Trace Display Control Panel provides access to trace display and gain settings.

- **Trace Menu**
  The Trace tab allows adjustment to trace visibility, trace color, trace groups and trace gain. Click on the **undo arrow** to revert to default settings for the selected trace. Click on the **green undo arrow** to revert to default settings for the entire set of traces.
- **Group Menu**
  Quickly adjust the gain for an entire Group designation.

CHAPTER 10 — BUILDING A SURFACE ANATOMY USING ULTRASOUND

This chapter describes the process by which a Surface Anatomy is created for non-contact mapping.

NOTE: If initial setup has not yet been completed, refer to Chapter 9 – Setup to complete the AcQMap System setup.

10.1. — Step 1: Verify Settings

Verify that localization scaling, orientation, and center position are configured correctly.

10.1.1. — Scaled

Check the raw localization data for the AcQMap Catheter. All excluded nodes should be identified and added to the excluded nodes list. All remaining electrodes should be localized to appear as a reasonably scaled AcQMap Catheter for which none of the X-, Y-, or Z-axis dimensions appear "flattened". As nodes are excluded, click the **[Open Full Localization Setup]** button in the Localization Configuration Panel. Click **[Rescale]** in the Field Estimation box.

10.1.2. — Oriented

The relative orientation of the AcQMap Catheter and Auxiliary Catheters should be correct and the standard Left-Posterior-Superior (LPS) orientation should match the fluoroscopy. Clicking **[AP]**, **[LAO]**, **[RAO]**, etc. should display the AcQMap Catheter and Auxiliary Catheters with the same orientation as the fluoroscopy display. If the orientation does not match the fluoroscopy display, enable the manual orientation mode and configure as shown in Chapter 9, Section 9.2.1 Advanced Settings > Manual Orientation.

10.1.3. — Centered

The AcQMap Catheter should appear near the origin of the coordinate axes when placed near the center of the chamber of interest. Click **[Rescale]** in the Localization Configuration window as shown above to re-center the AcQMap Catheter.

10.2. — Step 2: Configure and Enable Ultrasound

NOTE: Ultrasound default settings are loaded during AcQMap System startup.

10.2.1. — Toggle Ultrasound On/Off


Ultrasound Off


Ultrasound On

Ultrasound can be toggled ON or OFF by either 1) using the shortcut key Ctrl+U or 2) clicking the icon located next to the record button at the bottom of the screen.

1. When Ultrasound is enabled, the biopotential traces in the Trace Display may exhibit a continuous pulsatile pattern on top of the biopotential signals. The amplitude of the pulses may vary between channels.
2. If the system detects acoustic reflections, green ultrasound vectors will be displayed on the 3D Display. The length of the vectors should change as the AcQMap Catheter is moved closer and further from detected targets.

10.2.2. — Verify that Ultrasound settings are configured appropriately

Live Signals

1. Click the **Live Signals** button to enter the Live Signals window.
2. Click the **[Ultrasound]** (**[US]**) view button. A grid of plots will appear, which display distance histograms.

NOTE: Refer to Appendix F – Troubleshooting Ultrasound as a guide to confirm that all channels are detecting the target surface with minimal noise. Transducers that exhibit noise may be excluded by clicking the white check box in the corner of each histogram plot.

NOTE: Disable any non-functioning ultrasound transducers on the AcQMap Catheter prior to creating a reconstruction.

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3. Click either the **Live Signals** button again or the Acquisition tab to return to the Acquisition window.

10.3. — Step 3: Surface Build Menu

From the Acquisition Menu, click on the **[Build]** selection button under the Surface in Use heading on the upper right corner of the 3-D Display to open the Surface Build menu. The Surface Build menu provides controls and options for setup and acquisition of a Surface Anatomy.

10.4. — Step 4: Build a Surface Anatomy

This section describes the setup and acquisition of a Surface Anatomy.

10.4.1. — Configuration Setup

Before building a Surface Anatomy, the Ultrasound must be configured and initialized.

1. **Enter channel numbers** for excluded ultrasound nodes in the Filters box to disable the acoustic range data generated by these channels. Surface points collected by these channels are not included in Surface Anatomy reconstruction. Click Apply.
2. **Clear Current Surface**
   This button is used to clear the current anatomy. When clicked, the ultrasound data structure is re-initialized, so all previously collected surface points are deleted and the coordinate system is re-centered at the current AcQMap Catheter position.

10.4.2. — Initial Position of the AcQMap Catheter

For best results in building a Surface Anatomy, the AcQMap Catheter should be positioned at or near the center of the chamber of interest. Once the AcQMap Catheter is initially positioned in this location, click the **[Clear Current Surface]** button to center the Catheter on the screen.

1. Begin a Surface Anatomy Reconstruction
   Start the Surface Anatomy reconstruction by clicking on the Start Recording button. Ensure the Start Recording checkbox is checked prior to clicking on the Build Surface button.

NOTE: Recordings must be stopped manually regardless of the state of this checkbox by clicking the Stop Recording button at the bottom of the screen. The button will flash red during the recording.

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2. Maneuver the AcQMap Catheter around the chamber to acquire surface points. The raw reconstructed surface will build in the 3D Display window.

NOTE: If the Anatomic Reference Catheter is repositioned or is unintentionally moved during chamber reconstruction, a new reconstruction must be created.

— TIPS AND TRICKS —

Tips for Successful Surface Anatomy Reconstruction

Rotation of the AcQMap Catheter is the primary motion recommended for scanning large regions of the anatomy.

Rotations of the AcQMap Catheter need only be through a quarter- or half-turn to cover the circumferential area of the chamber. This will also reduce AcQMap Catheter shaft and cable strain.

Rotations of the AcQMap Catheter should be at a moderate rate. If the AcQMap Catheter is rotated too quickly, surface points may be missed. A rotational rate of approximately 2-3 seconds per half-turn is recommended.

Initial maneuvers of the AcQMap Catheter should be performed to capture the gross structure of the chamber. Capturing the general anatomic structure early will aid in establishing the limits of maneuverability as the AcQMap Catheter is moved to capture more anatomic detail.

To capture ostia, veins, and other anatomic structures extending from the chamber of interest, the AcQMap Catheter can be placed near the structure and rotated.

It is not recommended for the AcQMap Catheter to remain in one position and orientation for an extended period of time (>10 seconds). A large number of surface points acquired in one position and orientation may be over-emphasized in the reconstructed surface.

3. Rotate the 3D Display to identify areas of limited acquisition. Holes and "spikes" in the raw surface reconstruction will give visual indication of limited acquisition.

— TIPS AND TRICKS —

Tips to Identify and Remedy Areas of Limited Acquisition

Holes or "spikes" may appear in the rendered Surface Anatomy when only a small number of surface points, or no surface points, have been acquired in a region of the chamber. This may be reduced or eliminated by positioning the AcQMap Catheter near the desired region with the ultrasound transducers facing the region of interest and then maneuvering the AcQMap Catheter slowly through a few degrees (< 90°) of rotation. This will increase the number of acquired surface points in the region of interest.

The raw surface reconstruction need not be visually perfect. "Spikes" will be removed and holes filled in the post-process editing mode.

NOTE: Effort should be taken to fill in holes to the point where a flat "patch" will span the omitted parts of the surface and smoothly align with the surrounding surface. This "patch" will contain larger triangles than the rest of the constructed anatomy.

NOTE: Effort should be taken to minimize the number of neighboring spikes within a region of the reconstructed surface. The spikes can be trimmed in post-processing, but will leave holes in their place. Therefore, reducing the number of neighboring spikes by acquiring more surface points when possible is preferred.

10.4.3. — Assess the Quality of the Raw Reconstructed Surface

Surface assessment may be done during or after acquisition. Performing the assessment during acquisition will provide continuous data quality feedback, which can be addressed immediately by maneuvering the catheter to improve the surface reconstruction in specific regions. Live assessment of data quality is recommended.

Applying a color overlay on the displayed surface allows assessment of the quality of the surface reconstruction. Settings and controls for the data quality color overlay are accessed via the Data Quality panel.

10.4.4. — Filters

Four data filtering settings may be applied for data quality assessment. The surface data filters allow visualization and assessment of the distribution of surface points in each pyramidal bin of the PointCloud data structure in terms of the following statistics:

- **None** – no filter and no color overlay are applied.
- **Number of Points** - The number of points in each bin.
- **Number of Points in one Standard Deviation** - The number of points whose radial distances from the origin fall within one standard deviation of the arithmetic mean of the set-of-radii within each bin.
- **Standard Deviation** - The standard deviation of all radial distances from the origin to each point within each bin, called the "set-of-radii".

Click on the desired data filter selection button in the Data Quality panel. (*Figure 10-4, A*)

Filter Threshold Slider Controls

- **# of Points ≥** - Adjusting the slider changes the threshold value used to determine the color applied to each bin for the color overlay on the displayed surface. Bins with the surface data quality statistic below the threshold value will be one color while bins with a quality statistic above the threshold will be a second color. For the # of Points in 1 Std, it is recommended to use a value > 3 – this value may be increased as the surface acquisition time increases to allow identification of critical areas to apply the Weighted Average.
- **Enable Weighted Average** - This setting applies a weighting function to the surface points in each bin with an emphasis on the most recent points – the weighting function is applied only in bins with a surface data quality statistic below the configured threshold. Enable this setting when the number of surface points is large and the responsiveness of the Surface Anatomy to newly acquired points is reduced. This setting may be enabled and disabled sequentially during the surface anatomy acquisition, as needed. Default is disabled.
- **Remove Vertices that are Under Threshold** - Bins with a surface data quality statistic below the configured threshold will be rejected from the raw Surface Anatomy by checking the box labeled "Remove vertices that are under threshold".

— TIPS AND TRICKS —

The effects of this setting are particularly helpful in rendering the SVC, IVC, and pulmonary veins when the AcQMap Catheter is oriented to image these structures.

- **Colors**
  Color definitions for above-threshold and below-threshold regions are set in the Color Control panel. Click on the color sample bar to open a color selection palette. (*Figure 10-4, B*)

  The colorized surface should appear above threshold across the displayed surface when the Number of Points and Number of Points in one (1) Standard Deviation are chosen. The colorized surface should appear below threshold when the Standard Deviation filter is chosen.

NOTE: Exceptions from the above conditions are acceptable in regions of the anatomy where surface data is expected to be more widely varying. Examples include the mitral and tricuspid valves, superior and inferior vena cava, pulmonary veins and the right and left atrial appendages. If only these areas of the anatomy differ in color, the surface reconstruction may be considered to be sufficiently sampled.

10.5. — Pausing or Resuming an Anatomy Acquisition

Click the **Pause/Resume** button to pause or resume the anatomy acquisition. If a recording is in process, the recording may be stopped by clicking the **Record** button at the bottom of the screen.


Pause/Resume


Record

When using an Anatomic Reference Catheter, a surface reconstruction should only be resumed if the Anatomic Reference Catheter has not been displaced.

10.5.1. — Saving a Surface Reconstruction

Click the **[Save Raw Surface]** button to save the raw Surface Anatomy reconstruction. The generated polygon and vertices files will be saved to the current patient session.

NOTE: Right-clicking on the current Session provides access to the Anatomy Browser, which locates the raw and final anatomies associated with the patient session.

10.5.2. — Pre-processing a Surface Reconstruction

After saving the raw surface reconstruction the surface can be preprocessed. Pre-process is used after the anatomy data has been collected to adjust bulk properties of the raw surface reconstruction, including repositioning of the reconstruction centroid. This function is applied when the catheter starting position appears to be away from the chamber's center. Pre-processing allows the user to align the reconstruction centroid closer to the center of the chamber and reprocess the data to the new reference point. This may help to reveal details of the acquired surface not shown in the initial raw anatomy.

10.5.3. — Editing a Surface Reconstruction

Click on the **[Edit Surface]** button to open the Anatomy Editor Window.

Verify that the displayed surface is the surface reconstruction to be edited. If it is not, load the desired surface files by right-clicking on the current Session and selecting the Anatomy Browser to locate the correct raw surface. The Surface Edit Controls contains two editing tool tabs: Edit (Manual and Auto Selection), and Enhance plus three (3) edit correction icons: Revert to Original, Undo and Redo.

Edit Correction Icons


Revert


Undo


Redo

- **Revert To Original**
  Clicking on the **Revert** icon will undo all editing steps and revert to the raw Surface Anatomy reconstruction.
- **Undo**
  Clicking on the **Undo** icon will undo the most recent editing step.
- **Redo**
  Clicking on the **Redo** icon will redo the most recent editing step that was undone using the undo icon.

Edit Tool tab

- **Selection tools**
  Selection tools are used to select faces or regions of the anatomy for editing.
- **Individual selection**
  Individual faces of the surface mesh may be selected by right-clicking on faces, one at a time. To de-select a face, repeat the right-click.
- **Auto Select**
  Based on a user defined set of parameters, the Auto Select tool will automatically select areas of the surface to be deleted. The Auto Select process can be repeated multiple times until the "No more triangles identified" message appears.
- **Floating Triangles**
  By checking the Floating Triangles box, the AcQMap System will automatically identify single triangles that are not connected to any other triangles of the bulk raw surface.
- **Isolated Triangles**
  Checking the Isolated Triangles box, the AcQMap System will identify groups of triangles that are separated from the raw surface.
- **Inward Triangles**
  Checking the Inward Triangles box will automatically select triangles that point inward toward the center of the raw surface.
- **Sharp Triangles**
  Checking the Sharp Triangles box will automatically select triangles forming a sharp outward "spike".
- **Angle Limit**
  Angle Limit defines the angular threshold of the raw surface triangle normal that will be automatically selected by the inward and sharp triangle detection tools.

Figure 10-1 shows examples of each type of triangle as it is selected for removal.

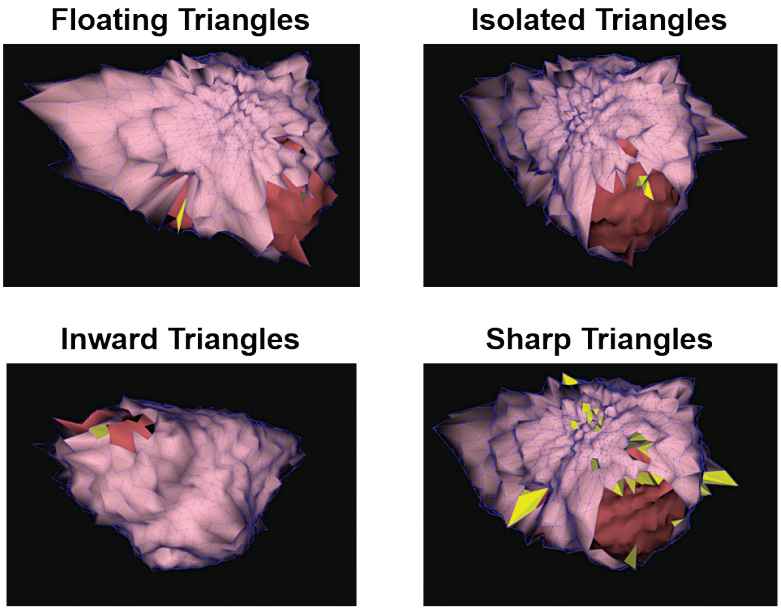


Figure 10-1. Examples of each type of triangle auto-selected for removal.


Auto Select Triangles

Click the **[Execute]** button to identify the triangles to be removed. An **Auto Select Triangles** shortcut icon is available that highlights triangles based on the selections made in the Auto Select menu. When one or more faces are selected buttons to remove or clear the selected triangles are made available.


Delete

Clicking the **Delete** icon or pressing the Delete key on the keyboard will delete the selected points and faces from the display. Clicking the **Clear Selection** button or pressing the Esc key will deselect all the selected triangles.


Clear Selection

- **Manual Select**
  Provides two regional options for editing – Rectangle and Ellipse.
- **Ellipse**
  Under Manual Select, select the **Ellipse** tool. Click on the **[Select Region]** button to activate the Ellipse selection tool. (Keyboard shortcut **Alt + E**). The Select Region button will change to "OK" when the Ellipse selection tool is activated. Faces and vertices of the surface can now be selected in bulk using an ellipsoid shape. Click the right-mouse button and drag to select an elliptical region. When the right-mouse button is released, all faces and vertices that lie within the elliptical boundary will be selected.
- **Rectangle**
  Under Manual Select, select the **Rectangle** tool. Click on the **[Select Region]** button to activate. (Keyboard shortcut **Alt + R).** Faces and vertices of the surface can now be selected in bulk. Click the right-mouse button and drag to select a rectangular region. When the right-mouse button is released, all faces and vertices that lie within the rectangular boundary and volume projected on the screen will be selected. The 3D model can still be rotated, zoomed, and panned with the same mouse actions as described previously. Additional mouse functionality will be active while the 3D Display is dimmed.

- **Front Surface Only**
  If the **Front Surface Only** box is checked only the faces and vertices on the front side of the anatomy will be selected. Unchecking the Front Surface Only box selects the faces and vertices within the selection on both the front and the back of the surface. (Keyboard shortcuts **Shift+Alt+R** and **Shift+Alt+E** are equivalent to temporarily disabling the Front Surface Only checkbox and will select both the front and back surface)
- **Move and Resize**
  Move and Resize allows the user to move or change the size of the rectangle or ellipse that has been placed on the surface. A hand will appear when the cursor is placed inside the shape which allows it to be moved. An arrow will be shown when the cursor is placed on the shape outline to allow the size to be changed.

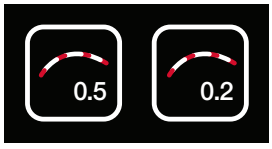
10.5.4. – Enhance Controls tab

The Enhance Controls tab contains tools to prepare a Surface Anatomy reconstruction for mapping and analysis.

To execute any or all of these processes, enable the desired tools by checking the check box next to the tool label. Click the **[Execute]** button to run all checked processes. Some processes may require additional input to be entered via the text fields shown above. (e.g., Smooth Mesh, Remesh Surface, etc.)

- **Adaptive Subdivide Mesh**
  This function increases the number of triangles by dividing triangles into multiple separate triangles. Only triangles with all edge lengths greater than the user-defined edge length limit will be subdivided.
- **Smooth Mesh**
  The smooth mesh function reduces the surface variation and adjusts positions of surface vertices to reduce the variation in surface normals between neighboring nodes.

  Smoothing Factor – normalized (0 to 1) control of the degree to which surface vertices may be displaced to achieve smoothing. A higher value allows more vertex displacement. Values of 0.1 - 0.5 are recommended. Shortcut icon: **Smooth Mesh** icon offers two present values of 0.5 and 0.2.



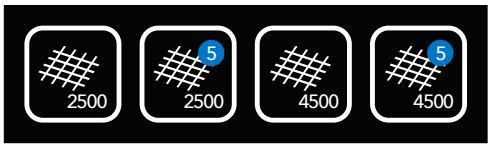
Smooth Mesh

- **Close Holes**
  Identifies and automatically closes holes in the surface.


Close Holes

- **Re-mesh Surface**
  Re-distributes the mesh triangulation to make the surface triangles more uniform in size. The # Samples indicates the minimum number of vertices of the re-meshed surface.

- **Use Size Limit**
  Re-mesh will occur only on triangles that have all edges smaller than the selected value. The **Re-mesh** icon offers 2 preset # of Samples available at 2500 or 4500 which can be executed with or without a Use Size Limit of 5.



Re-mesh

- **Save the New Surface**
  Use the Save Anatomy button located at the bottom of the Anatomy Editor Window to save the Final Surface. Saving the Anatomy will save the file with the current Session in the Anatomy Browser as Final. The file name can be changed within the Anatomy Browser by clicking on the name and changing it.

10.6. — Exit the Anatomy Editor

Exit the Anatomy Editor by clicking the white "X" in the upper right-hand corner of the window. If the anatomy has not been saved, a pop-up window will appear stating "Anatomy has been changed. Do you want to save the change?"

10.7. — Adding Definition to the Pulmonary Vein Structures

Two separate methods are available to add definition to the pulmonary vein structures: Catheter Guided and Visually Guided.

10.7.1. — Catheter Guided

In Catheter Guided mode, the localization data from an auxiliary catheter (Circular or ablation) is used to create a point-cloud from which the software builds a vein anatomy.

In the Surface in Use window select Catheter Guided.

Select the Aux Catheter (Aux 2 or Aux 3) to be used. Aux 1 should only be selected if using a virtual position reference.

Click the **Collect Points** button to start data collection.


Collect Points

Move the catheter within the vein structure to collect points. If Preview Vein is selected, the vein structure will be visible as it is built.

NOTE: Once a point-cloud has been created, it can be cleared by clicking on the **Clear** button

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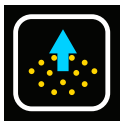
Clear


Build Vein Structure

Click the **Collect Points** button to stop the data collection. An erasure tool is available to trim points off the point-cloud.

Click **Build Vein Structure** button to build the final vein structure (meshed and smoothed).

NOTE: Any new structure can be deleted by clicking the **Delete** button.

Delete

NOTE: Any step can be undone or redone by clicking on the **Undo** or **Redo** buttons, respectively.

Undo

Redo

Click the **Save** button to save the vein structure. Repeat the process until all vein structures have been added.

Save

Select Existing Surface to complete the process.

10.7.2. – Visually Guided

The Visually Guided method is a manual method that adds a vein-like structure onto the current anatomy. To help guide the placement of the vein structure, ultrasound points previously collected during the anatomy acquisition can be displayed.

In the Surface in Use window, select Visually Guided.

Select Show Ultrasound Points to display the previously collected ultrasound points.

It is recommended to rotate the anatomy so that the vein ostium is directly facing the user. (*Figure 10-2, Panel A*)

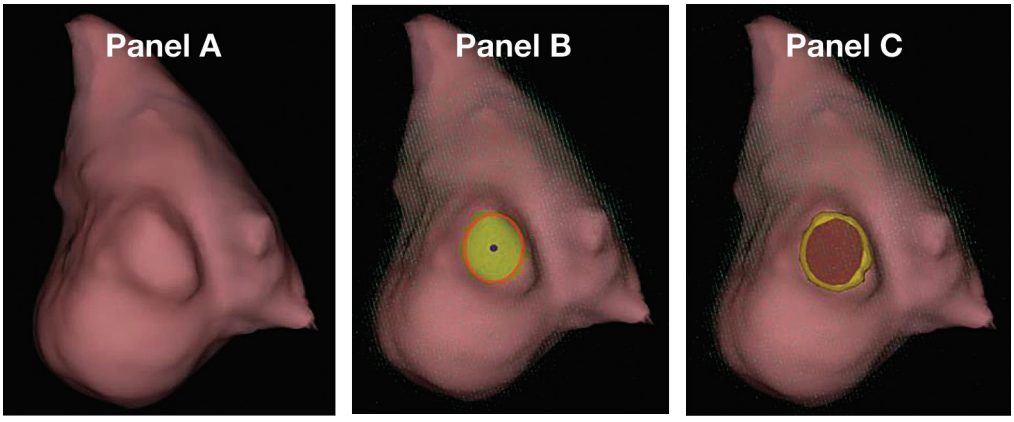


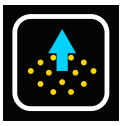
Figure 10-2. Panel A: Vein ostium facing user. Panel B and C: Ellipse placed on the vein ostium.

Click the right mouse button and drag to define an ellipse on the vein ostium. The dimensions or position of the ellipse can be adjusted by clicking and dragging with the right mouse button. The orientation of the structure can be changed by adjusting the orientation of the anatomy. (*Figure 1, Panels B and C*). Change the location or dimensions of the ellipsoid selection or click the right mouse button within the ellipse to update its selection if the location or dimension do not require modification.

NOTE: Once a section of the anatomy has been selected, it can be cleared by clicking on the clear button.


Clear

In the Surface in Use Window, click on **Build Vein Structure** to build the vein. (*Figure 10-3*)


Build Vein Structure

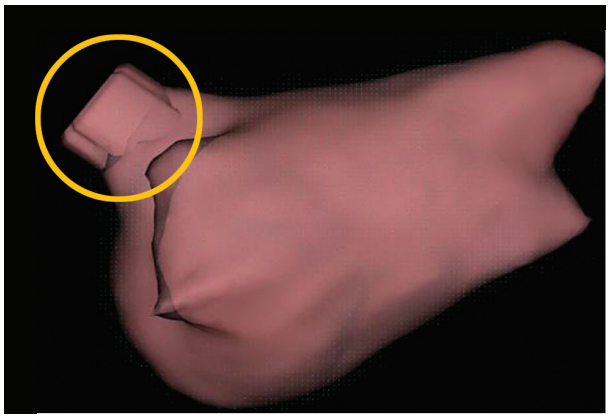


Figure 10-3. New vein structure added.

If the vein structure appears disproportionate, the length can be adjusted from 5mm – 10mm.

NOTE: Any new structure can be deleted by clicking the **Delete** button.


Delete

NOTE: Any step can be undone or redone by clicking on the **Undo** or **Redo** buttons, respectively.


Undo


Redo

Click the **Save** button to save the vein structure. Repeat the process until all vein structures have been added.


Save

Select Existing Surface to complete the process.

10.8. — Surface Processing of the Modified Anatomy


Segmented Anatomy

10.8.1. — Merging the anatomy into a single mesh

1. Open the Anatomy Browser from the Sessions window
2. Find the modified anatomy to process. Modified anatomies will be denoted in the Anatomy Browser with the Segmented Anatomy designator.
3. Right-click on the anatomy to process and click on "Create Merged" with the left mouse button to unify the anatomy into a single mesh.
4. Upon completion, a new anatomy will appear in the Anatomy Browser with the Merged Anatomy designator.


Merged Anatomy

10.8.2. — Edit the Merged Anatomy

1. Right-click on newly created Merged Anatomy and select **[Edit]** to open the Anatomy Editor.
2. Follow 10.5.3 – 10.5.4 to process the surface of the anatomy. Re-meshing and smoothing operations are recommended to process the Merged Anatomy.
3. Save the anatomy and exit the Anatomy Editor

10.9. — Automatic Identification of Added Structures


Merged Anatomy

The added vein structures can be automatically identified and re-indexed for mapping.

1. In the Anatomy Browser, find the Merged Anatomy that was processed.
2. Right-click on the anatomy and click on **[Create Segmented]** using the left mouse button.


Segmented Anatomy

A new Segmented Anatomy will be created in the Anatomy Browser with the Segmented Anatomy designator.

10.10. — Use a Surface Reconstruction in Acquisition Mode

1. Navigate to the Acquisition window and ensure that the current patient Session is selected in the Patient Records window.
2. Existing Surface selection box
   From the Acquisition Window, click the "Existing Surface" selection button on the upper right of the 3D display. This action will load the most recent Final Anatomy into the Acquisition Mode display.
3. The edited Final Anatomy will appear in the 3D display with the same registration parameters as the raw Surface Anatomy. The AcQMap catheter and all auxiliary catheters will appear and be well-registered to the edited final anatomy. Proper registration can be further verified by turning on ultrasound and evaluating the relationship of the ultrasound reflection vectors (green) to the surface.

4. If the registration appears to be improperly registered, re-load the saved registration information.
   a. Access the Localization Configuration window by clicking the **[Open Full Localization Setup]** button in the Localization Configuration Panel.
   b. Choose Load Registration Files and click **[Next]**.
   c. Click the **[Load Registration]** button.
   d. Click the **[Next]** button to load the registration files.

10.11. – Resume an Existing Surface Reconstruction

Load the existing surface reconstruction, if necessary, by selecting the correct Patient Session and double-clicking on any of the recordings in the Patient Records Window.

NOTE: When using an Anatomic Reference Catheter, a surface reconstruction should only be resumed if the Anatomic Reference Catheter has not been displaced.

---

1. Press the **Pause/Resume** button to resume the surface reconstruction.
2. Press the **Pause/Resume** button to pause the surface reconstruction.
3. All other tools and functions described in Chapter 10, Section 10.4 “Build a Surface Anatomy” are available.

Pause/Resume

CHAPTER 11 — ACQUIRING RECORDINGS

Recordings are periods of data that are saved to the hard drive and may be used for analysis or mapping. These recordings are recorded in the Acquisition Window and are made available in the Waveforms and Maps Windows for analysis and mapping.

Recordings must be a part of a Session. New recordings are acquired in the Acquisition Window and will become part of the active Session.

Recordings contain all AcQMap System data available at the time of acquisition. Electrograms and localization data will be included in the recorded files. Ultrasound range data is available if Ultrasound was enabled at the time of the recording.

Recordings may be acquired at any time the catheter is located within the chamber of interest. A Surface Anatomy reconstruction is not a requirement for acquiring recordings.

NOTE: Recordings will be properly spatially registered to a Surface Anatomy reconstruction (a requirement for 3D mapping) only if:

The same Anatomic Reference is used for both the recording and the surface reconstruction AND the Anatomic Reference has not been disturbed or displaced between the reconstruction and the recording.

— OR —

No Anatomic Reference is required or enabled for both the recording and the surface reconstruction

---

Data is recorded by using the recording controls on the bottom of the screen in either the Acquisition Window.

Prior to starting the recording and under fluoroscopic guidance, place the AcQMap Catheter in the approximate center of the chamber of interest. The AcQMap Catheter should remain in a relatively stable position throughout the recording period without rotation or movement of the Catheter within the chamber. Ultrasound may also be used to verify a central location. With Ultrasound activated check to see that the vectors displayed on the screen are similar in length across the catheter splines.

To start the recording toggle the SuperMap icon to the N position, and click on the green **[Record]** button to create a new record. The Recording button is green when a recording is not in progress.

Once a recording has started, the **[Record]** button will flash red. The recording timer will begin counting the recording time (mm:ss format).

Click on the **[Record]** button to end the data acquisition.

Once the recording has been finalized, a new recording will appear in the Patient Record Window. It will be assigned the next incremental recording number. The recording name may be edited by double-clicking on the recording name to edit the text.

NOTE: The AcQMap System has a continuous 9-second recording buffer. When a recording is started, the content of the 9-second recording buffer is added at the beginning of the recording.

CHAPTER 12 — REVIEWING RECORDINGS

Current and past records may be reviewed in the Waveforms window. The Waveforms window is accessed by clicking on the Waveforms Tab.

The Waveforms Window contains the following displays and controls: 3D Display, Trace Layout, Filtering options, Create Mapping Panel, 3D Settings Control Panel Shortcut Icons, and Signal Display options.

Navigate to the desired Patient Session via the Patient Record Window. Double-click on a recording to review.

Once the data is loaded, the Trace Display and 3D Display will be shown with the Time Cursor at the beginning of the segment. If a surface reconstruction was made for the Patient Session, it will appear in the 3D Display with all connected catheters localized throughout the segment.

Note: Previously configured filter settings for the segment will be applied to the displayed electrograms in the Trace Display.

There are two primary views in which to review signals: Single-Channel and Full-Screen Multi-Channel Visualization. Single-Channel View is primarily used to determine filter settings, while All-Channel View is used to select segments for mapping.

12.1. — Signal View and Filter Settings

12.1.1. — Single-Channel View

In the Single-Channel view, one channel is selected for review. The channel may be selected in the Channel Selection panel.

Multiple calculated waveforms may be displayed concurrently in the Trace Display. These calculated waveforms may include any of the following signals, with appearance selected in the Displayed Signals area.

- **Filtered**
  The filtered signal from the selected channel. The filtering is configured in the Filtering area. (See Section 12.1.2 Signal Filters).
- **ECG Lead II**
  ECG lead II is offered as an on-screen reference electrogram for comparison purposes.
- **BCT**
  The AcQMap Catheter Central Terminal (BCT). The arithmetic mean of all filtered channels on the AcQMap Catheter.
- **CH – BCT**
  The mathematical subtraction of the selected filtered channel and BCT.

NOTE: Trace colors may be changed in the Trace Display Control Panel.

12.1.2. – Signal Filters

Filtering of the electrograms in the Waveforms window is an important precursor to mapping. Filters are applied via the Filtering area.

- **Respiration Removal Filter**
  The Respiration Removal Filter removes the low frequency respiration signal from the electrograms while minimizing signal processing artifacts that a standard high pass filter would impose. The filter can be set to Wide, Medium or Narrow, based on the rate of respiration. The default setting is Wide.
- **High-Pass Filter**
  The High-Pass Filter is an N-order Butterworth HPF with variable -3dB cutoff. The filter is applied in the forward direction. (Bi-directional is available in Expert Mode. See Chapter 14) The cutoff frequency is entered below in the text field to the right of the "High Pass" label. Recommended initial setting for the High-Pass Filter is Off.
- **Notch Filter**
  The Notch Filter rejects a specific frequency and its harmonics. Any frequency between 30Hz and 200Hz may be selected.
- **Low-Pass Filter**
  The Low-Pass Filter is an N-order Butterworth LPF with variable -3dB cutoff. The filter is applied in the forward direction. (Bi-directional is available to reduce phase shift in Expert Mode. See Chapter 14) The cutoff frequency is entered below in the text field to the right of the "Low Pass" label. Recommended initial setting for the Low-Pass Filter is100 Hz cutoff.
- **Smoothing**
  - The Smoothing Filter is an adaptive Low-Pass Filter that is used to reduce baseline noise on the electrograms.
  - Click on **[Apply Filters]** when all settings have been entered.
- **Segment Zeroing**
  - Please refer to section 12.5, below, for additional information related to removal of the V-wave.

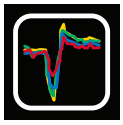
– TIPS AND TRICKS –

Use the Single-Channel view mode to set initial filter settings. Use the Multi-Channel and Full-Screen Multi-Channel views to verify the filter settings across all channels.

12.2. — Full-Screen Multi-Channel Visualization

The Full-Screen Multi-Channel view allows a full-screen immersive display of AcQMap or Auxiliary Catheter signals.


Grid

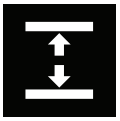

Overlay

The Full-Screen Multi-Channel view is accessed by clicking on either the **Grid** button or the **Overlay** button for the All AcQMap Channels or All Auxiliary Channels.

- **Grid**
  - In Grid view, each channel is plotted on a separate graph with all graphs arranged in a rectangular grid and displayed simultaneously. The grid for AcQMap is organized with the AcQMap Catheter splines arranged across the columns, from spline 1 to 6, with AcQMap electrodes arranged down the rows, from distal to proximal.
  - Channels deemed to be performing poorly will be excluded by selecting the small checkbox in the upper right corner of each individual plot. Once marked, a yellow border will be displayed around the plot and the check-mark will remain.
  - Cursor and Gain sliders are located at the bottom of the screen. The Cursor slider can be used to simultaneously scroll through the displayed channels. The Gain slider is used to change the gain on all channels.
  - Clicking the "X" will close the Grid View Window and return to the Waveform Window.
- **Overlay**
  - The Overlay displays all channels on the same axes. The Overlay view is accessed by clicking the Overlay icon for either the AcQMap or Auxiliary All-Channel view in the Signal Display panel on the Waveforms screen.


Align Channels

  - All channels may be aligned by clicking on the **Align Channels** button located on the bottom left of the display.


Distribute Channels

  - Channels may also be evenly distributed on the vertical axis by clicking on the **Distribute Channel** button located on the bottom left of the display.
  - Cursor and Gain sliders are located at the bottom of the screen. The Cursor slider can be used to simultaneously scroll through the displayed channels. The Gain slider is used to change the gain on all channels.
  - Channels that have been excluded can viewed or hidden with the Excluded Channels icon.
  - All Channels can be viewed or hidden using the All Channels icon.

12.3. — Select a Time Window for Mapping

From the Signal Overlay view locate a segment that represents the arrhythmia to be mapped and has the most consistent baseline. Use the calipers to select the segment.

- Calipers are added by clicking on the "+" symbol in the bottom right corner of the Overlay Window. Multiple calipers may be added by clicking the "+" again. Calipers may be removed by clicking the "x" symbol.

With the left mouse button:

- click and drag each Caliper marker to move its position in time.
- click and drag the Caliper label to move the Caliper as a unit (maintaining caliper duration).
- select Calipers into focus on the Caliper label. A yellow dashed box will appear around the label to designate that it is selected.

Zooming in on the time scale may also be beneficial in selecting the time window for mapping. To zoom the time scale to the selected window, right-click anywhere on the Trace Display and drag to another point in time.

Return to the default time scale by clicking the Zoom arrow icon in the lower right corner of the Overlay Display.

Zoom arrow icon

Calipers may also be set from the Single-Channel view mode. The Caliper Add/Delete controls are located in the lower right hand corner of the Trace Window.

12.4. — Exclusion of Signal Traces for Mapping

There are certain types of signal traces that should be considered for exclusion for purposes of mapping. It is recommended to exclude any of the following types of traces:

- Traces that show a large "outlier" deviation from the baseline "pack" of the rest of the trace-baselines.
- Traces that have much larger peak-values than the "pack" of the rest of the trace-peak-values.
- Traces that have significantly more noise than the "pack" of the rest of the traces.

NOTE: Identification and exclusion of channels with poorly performing electrode or outlier-signals is important for mapping accuracy.

Traces can be excluded by right clicking on the Trace to be excluded. A pop-up box will appear that identifies the Trace and options to Exclude Sensor, Make Invisible or Cancel.

Continue excluding signals until the remaining pack of traces have a balanced level of peak-values. The list of excluded channels will be propagated to the mapping algorithm upon export from the Waveforms Window.

NOTE: Electrograms excluded from mapping are independent of AcQMap Catheter channels marked as excluded during Localization Configuration.

When all appropriate Traces have been excluded from the selected segment, click on the cursor label to record the data segment in the Create Mapping fields in the Waveform Window. Click on the **[X]** to return to the Waveform Window.

12.5. — VWave Removal and Zeroing in Atrial Fibrillation

VWave Removal and VWave Zeroing tools are filters that remove or zero the V-wave from the biopotential recordings. For best results, identify the most consistent V-wave morphology in the data segment using the filtered electrogram.

- **Select VWave Removal in the Filtering Area**
  Selecting VWave removal will automatically place a time cursor in the Trace Display Panel. Use the time cursor to identify the start and finish of the ventricular QRS morphology on the "Filtered" trace. A reference surface ECG lead can also be used to facilitate identification of the QRS complex. Once identified, the appropriate values will be automatically entered in the Start and Finish boxes below VWave Removal and a reference electrogram will appear.

  The period between the time calipers will be used as a template to identify all VWaves in the recording. The VWave segments identified across the channels will be used to form a subtraction template for each individual channel. The subtraction template for a given channel is time-aligned and subtracted at each identified VWave location for that channel.
- **Optionally adding VWave Zeroing**
  Clicking on the Zero VWave checkbox will use the same time calipers placed above to identify VWave segments across the recording. Rather than calculating a per-channel subtraction template, by selecting Zero VWave the waveform at each identified VWave segment will be interpolated across the identified segment between the first and last samples of the segment, applied on the raw waveform data prior to all other filters.
- **Click on Apply Filters**
  Applying the filter results in a new electrogram appearing in the Trace Window called CH-EstV. This represents the filtered electrogram with the V-Wave removed.

12.6. — Export Data for Mapping

When all Trace exclusions and filtering is complete, the AcQMap electrode position and electrical data may be exported for mapping. Click the **[+ Mapping]** button under Create Mapping to export all data required to map the time window selected. A "New Mapping Name" will appear under the Patient Session in the Patient Record Window.

CHAPTER 13 — MAPPING, LABELS AND MARKERS

The AcQMap System can produce different static and dynamic, three dimensional (3D) maps of electrical activation across the ultrasound acquired cardiac chamber surface. These maps can be either charge density-based or voltage-based. Charge density is the electric source that generates the voltage potential-field measured by body surface and intracardiac electrodes. Although it cannot be measured directly, charge density can be derived from potentials measured as voltage in the cardiac chamber using an inverse algorithm. The algorithm uses non-contact intracardiac potentials measured by the AcQMap Catheter to determine the dipolar distribution of positive and negative charges located across the chamber surface (*Figure 13-1*). The activation sequence of the entire chamber is derived from the dynamic change in charge density and displayed on the chamber. Voltage-based maps of activation time and amplitude can also be calculated from the derived charge density and activation sequence displayed on the chamber can be alternatively derived from the dynamic change in calculated voltage.

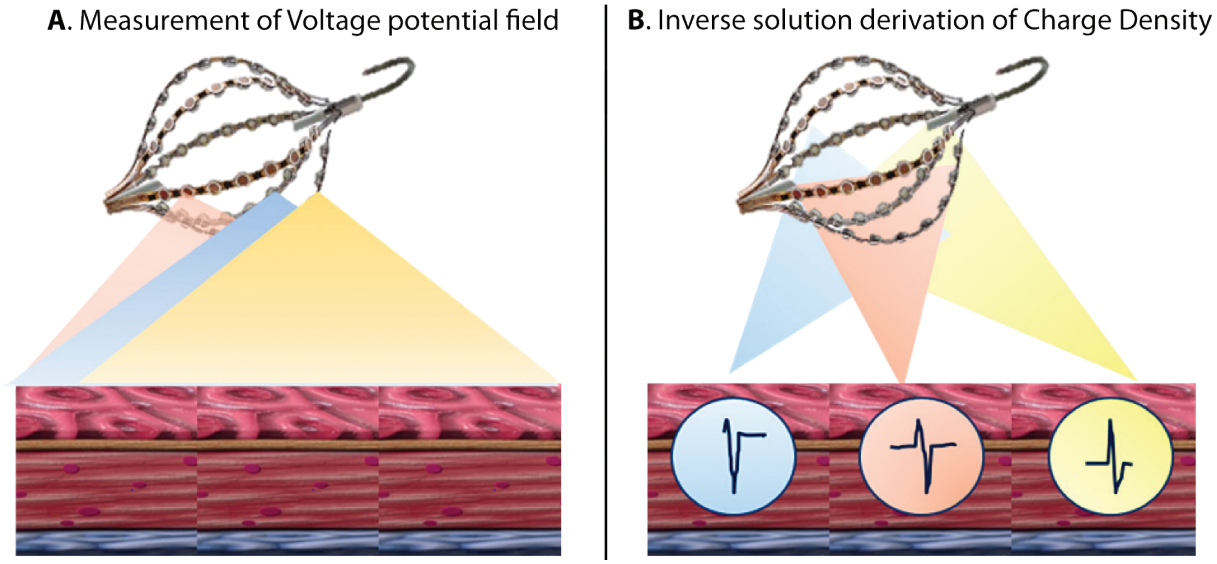


Figure 13-1. Panel A: Non-contact intracardiac potentials are measured (as voltage) by the AcQMap Catheter. Panel B: The inverse algorithm derives the dipolar distribution of positive and negative charges located across the chamber surface.

Arising from the natural, biophysical relationship between charge and the surrounding potential-field it generates (voltage), there exists an intrinsic, characteristic difference between charge-based maps and voltage-based maps. Thus, charge density-based activation maps are inherently more accurate than the corresponding voltage-based activation map. Under some testing conditions, the accuracy of voltage-based activation maps may exceed 5 mm, for which the corresponding charge density-based activation maps are intrinsically more accurate. Moreover, accuracy variability is more likely to occur in regions of higher curvature.

Maps of either the data selected and exported from the Waveforms Tab or previously generated data from a selected recording in the Patient Record Window are generated in the Maps Tab. The Maps Screen consists of 5 key areas: Dual 3D Displays, Trace Display, Playback Controls, Map Settings and Labels/Markers.

13.1. — The Maps Screen

The 3D Maps Mode is used to generate 3D Maps of the data selected and exported from the Waveforms window. 3D Maps Mode is accessed by clicking on the **Maps** tab.

13.1.1. — Dual 3D Displays

The Dual 3D Displays allow simultaneous visualization of the generated 3D Maps. The displays can work together displaying the same type of map from two viewing angles or independently displaying two different types of calculated maps. Clicking the middle link in the icon will synchronize the displays. Clicking on either the right or left link in the icon will highlight that display with an orange border. This indicates the active display which can now be changed between map types based on voltage or dipole density.

13.1.2. — Trace Display

The Trace Display shows the exported data used to generate the 3D Maps. Signals displayed are selected by navigating to Configure Maps Channels from the Menu Bar. The position of the Time Cursor in this display controls the time point displayed on the 3D Map.

13.1.3. — Playback Controls

The Playback Controls start, stop, and change the speed of time-progression playback in the Dual 3D and Trace Displays. The time control allows the time window shown in the Trace Display to be changed using the mouse.

Set the Playback step size via the Step Size list. The Step Size defines how many samples the Time Cursor moves forward and backward. Click the Start button to automatically advance the Time Cursor and the displayed 3D Map at a playback speed proportional to the selected step size. The Time Cursor may also be manually advanced or reversed, one sample at a time. Click the Reverse button or the Advance button to reverse or advance, respectively. The left and right arrow keys on the keyboard serve as hot keys for the same functions as the step-buttons. Enter the sample number in the "Current Sample" text box to move the Time Cursor to a specified sample number.

13.1.4. — Map Settings and Post Processing Tools

Map Settings and Post Processing Tools contain the configuration of parameters used to generate the displayed 3D Map. Adjustment of the mapped variable, post-processing, and ColorScale will determine the appearance of the displayed map.

13.1.5. — Labels/Markers

The Label control panel is used to organize and define Labels used in the 3D Displays.

The Markers control panel is used to organize the ablation markers shown in the 3D Displays.

13.2. — Creating Maps

13.2.1. — Loading Data

In the Maps Window, select the patient Session of interest in the Patient Record Window. Select the recorded segment from which a 3D Map is to be created. Double-click the "heart" map-icon to generate a new map, to load a previously generated map, or to re-generate a previously generated map.

If a new 3D Map will be generated from exported data, the Charge Calculation Configuration Window will open. Sources are derived as continuous charge density, distributed on the endocardial surface.

Sensor Removal Threshold is used to define one of the parameters for calculating the inverse solution. (Additional parameters are available in Expert Mode. See Chapter 15.)

When settings are verified, the CDA may be executed by clicking the **[Execute CDA]** button. Click **[Execute CDA]** to proceed.

NOTE: If a 3D Map has been previously generated with data from the selected record, the CDA Files Are Present window will appear. Click **[Yes]** to use the most recently exported data to regenerate a new 3D Map. Click **[No]** to load the previous 3D Mapping results without re-calculation. Click **[Cancel]** to cancel the operation.

13.2.2. — Execute the CDA Inverse Solution

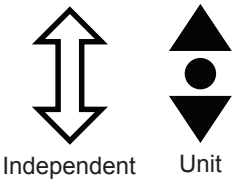
Both Surface Charge and Surface Voltage are computed from the output of the Charge Density Algorithm. After the calculations are complete, the Surface Charge map will be displayed.

- **Surface Charge**
  The Surface Charge Density is derived by an inverse solution applied on the voltages measured from the AcQMap Catheter electrodes. The source model and inverse solution parameters selected when configuring the Charge Density Algorithm govern the method by which the charge density is calculated. Click the **[Surface Charge]** button to use Surface Charge Density as the mapped variable.
- **Surface Voltage**
  The Surface Voltage is the forward calculation of voltage upon the surface from the inverse-calculated surface Charge Density above. Click the **[Surface Voltage]** button to use surface voltage as the mapped variable.

13.2.3. – Adjustment of the Surface Charge or Surface Voltage Display

- **Color Bar**
  The Color Bar is used to adjust the limits of the Map color-gradient used to color-code the magnitude of the displayed electrical data upon the surface anatomy. The colors are shown as Coulombs/cm if Surface Charge is displayed and Volts when Surface Voltage is displayed.

  The limit slider can be moved to adjust either the upper or lower limit independently or the range can be maintained with the slider moving as a unit along the scale.



- **Color Bar Tuner**
  An additional Color Bar Tuner is available to fine-tune the map color limits.

  Checking the View as Normalized checkbox, presents the data as ranging from a minimum of -1 and a maximum of +1. This enables one set of default parameters to be automatically set for all rhythms across all chambers and across all patients.

  Checking the View in Gray Scale changes the Color Bar into a new scale that displays the map on a scale from white to black.

  Click on the "% Max" and "% Min" controls the level of the upper and lower color limits, respectively. The numeric value may also be edited by clicking on the value and typing a desired percentage.

  Color limits can also be manually set as absolute magnitudes, instead of normalized-percentage, by clicking the "Manual Set" checkbox and adjusting the Max and Min values.

13.2.4. – Post Processing Tools

A set of post-processing tools may be used to augment or extract useful information from the Surface Charge-based or Surface Voltage-based maps. The System works in a hierarchy to produce the different Map types.

The user may toggle between available post-processed maps generated from Surface Charge or Surface Voltage by using the Charge and Voltage radio buttons.

NOTE: The available post-processed maps for Voltage or Charge may differ.

- **Propagation History**
  The Propagation History Map is an animated version of an Isochrone Map. Color is used to show where the activation wave front was located over a series of time-increments.

  The Propagation History Map requires calculation of an Activation Matrix based on the upper limit of the Color Bar for Surface Charge or Surface Voltage, respectively. Click on the Calculator icon next to Propagation History to calculate the Activation Matrix.

  Once the Activation Matrix calculation has been completed, an isochronal color map will be displayed on the 3D display. A shaded region will appear to the left of the Time Cursor in the Trace Display. The shaded region represents the time history of activation corresponding to the color bands on the 3-D surface. Conduction is displayed as a retrospective moving color-map. Red is present location of leading-edge, while trailing color-bands represent past locations in time.

  Dragging the Time Cursor will change the current reference time of the Propagation History. To display an advancing time-history of the temporal activation sequence the Time Cursor can be swept from left to right or the playback controls can be used to automatically sweep the Time Cursor position.
- **Adjusting the Propagation History Map**
  - **Window Width**
    The Window Width defines the time duration spanned by the color gradient of the propagation history.
  - **Time Threshold**
    The Time Threshold is used to reduce artifacts in the map by not allowing reactivation of a region for the set Time Threshold.
  - **Minimum Amplitude**
    Regions of the Surface with amplitudes below the selected value are by default colored grey.
  - **Color Bar**
    The Color Bar is used to adjust the time-step values used to colorize the displayed surface data.
  - **Color Bar Tuner**
    Checking the View in Gray Scale changes the Color Bar into a new scale that displays the map on a scale from white to black.

NOTE: If the upper Color Bar slide, Time Threshold or Minimum Amplitude values are changed the Activation Matrix must be recalculated.

13.3. — AcQTrack™ Post-Processing Tools

13.3.1. — Conduction Pattern Recognition

Many conduction patterns are observed in the propagation history map. The conduction pattern recognition tool uses the displayed propagation history data to assist with identifying three visually discrete activation patterns – focal, localized rotational activation (LRA), and localized irregular activation (LIA). Focal activation spreads radially from a single-point site, with wave fronts projecting outward in all directions from the center. An LRA spreads in a spiral-pattern around a small confined zone at least 270°. An LIA has a pattern of multi-directional, isthmus-like conduction through a small confined zone that may pivot within and around the zone or reenter into it. Such confined zones measure from 5 to 15 mm in diameter.

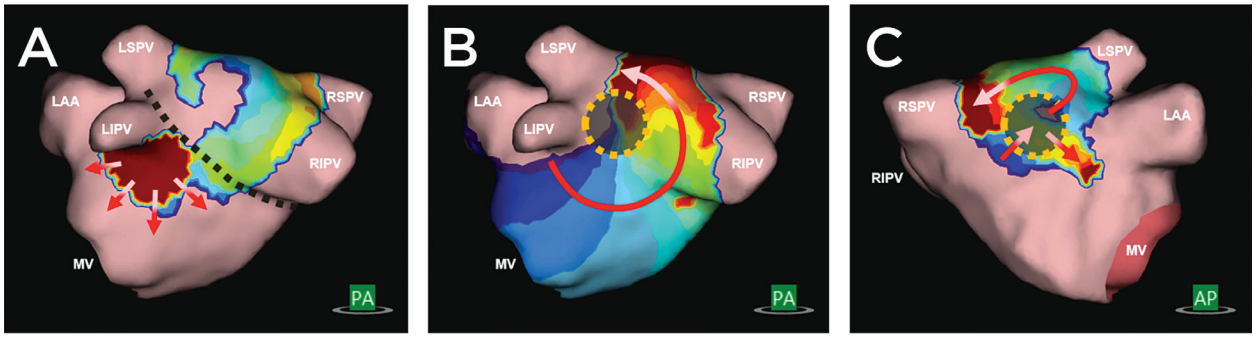


Figure 13-2. A. Focal activation spreads radially from a single-point site, with wave fronts projecting outward in all directions from the center. B. An LRA spreads in a spiral-pattern around a small confined zone at least 270°. C. An LIA has a pattern of multi-directional, isthmus-like conduction through a small, confined zone that may pivot within and around the zone or reenter into it. Such confined zones measure in the range of 5 to 15 mm in diameter.

Conduction Pattern Recognition is calculated in the background once the Propagation History map has been calculated. The Propagation History map becomes available for display and review once the Propagation History calculation is complete. Conduction Pattern Recognition overlays become available following completion of the Conduction Pattern Recognition calculations.

13.3.2. — Displaying Conduction Pattern data

Data can be displayed statically and/or dynamically by selecting the appropriate check box(es). (*Figure 13-3*)

- Static: Select static to display the aggregate count of each type of conduction pattern for the entire mapped segment. The patterns and locations identified by the algorithm are represented on the map by color. Focal is pink, LRA is shown in green and LIA is shown in yellow. The displayed aggregate counts can be configured using the slider bars.
- Dynamic: Select dynamic to display detections of each type of conduction pattern as they occur on the propagating activation wave front. Focal is pink, LRA is shown in green and LIA is shown in yellow. Detected areas will appear and disappear corresponding to the conduction patterns detected at the current time denoted by the time cursor.

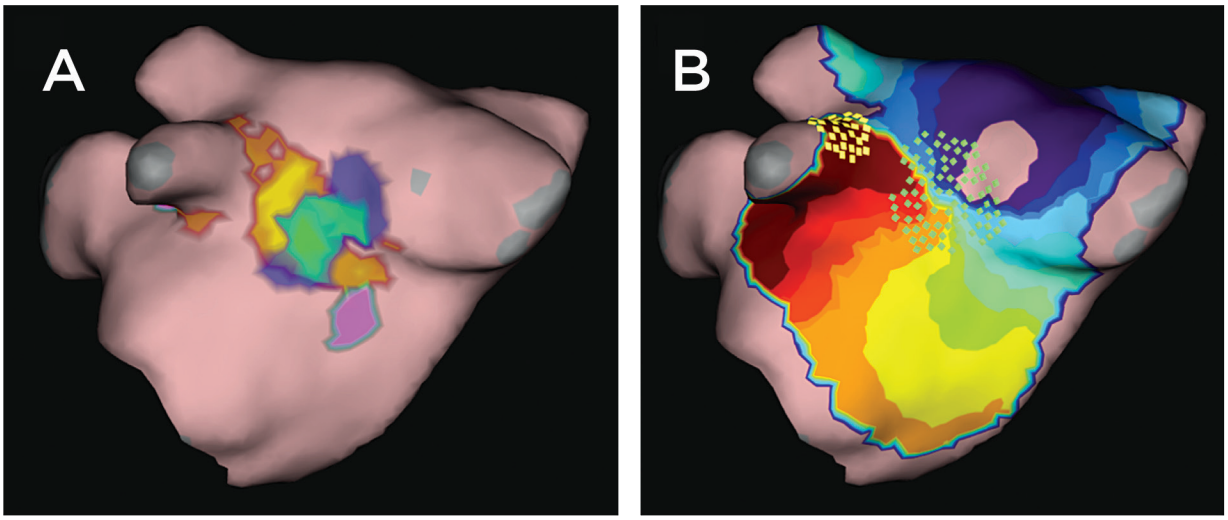


Figure 13-3. A. Shows a static representation of conduction pattern data. Pink is focal, green is LRA and yellow is LIA. B. Shows dynamic representation of conduction pattern data. The green boxes represent LRA and yellow boxes indicate LIA.

13.3.3. — Data can also be selectively hidden or displayed

- Focal: When checked, sites identified as focal, will be displayed. The slider transitions from green on the low end into pink at the high end. The low and high ends of the slider indicate the displayed range of occurrence of a focal pattern.
- Localized Rotational Activity: When checked, sites identified as LRA, will be displayed. The slider transitions from blue on the low end into green at the high end. The low and high ends of the slider indicate the displayed range of occurrence of the LRA pattern.
- Localized Irregular Activity: When checked, sites identified as LIA, will be displayed. The slider transitions from red on the low end into yellow at the high end. The low and high ends of the slider indicate the displayed range of occurrence of the LIA pattern.

13.4. — Placing Labels

The Label control panel is used to organize, define and edit Labels used in the 3D Displays.

- **Placing Labels**
  A set of Default Labels are provided. Labels in the Default Label list can be dragged and placed on the Surface Model in the display. Click on the label to display in the Default Label list and while holding the left mouse button, drag the mouse cursor into the 3D Display to the position on the Surface Model where the Label is to be placed. Release the left mouse button to place the Label. Alternatively, the selected Label can be placed at the mouse location on the surface using **[F4 + Right Click]**.

- **Label Visibility**
  Once placed in the display, the Labels can be visible or hidden. To hide the labels, click on the **Hide Labels** icon located next to the Current Labels header. The labels can be made visible by clicking the **Show Labels** icon.


Hide Labels


Show Labels

- **Creating New Labels**
  New labels can be created by clicking on the "+" next to the Default Labels header. This will open a Create Label window which is used to define the new label.
- **Deleting Labels**
  Labels can be deleted in two ways: (1) Select the Label in the Current Label list to highlight it and then click delete or (2) Right click on the Label in the Current Label list and select delete.

13.5. — Placing Markers

The Markers control panel is used to organize, edit and delete the markers shown in the 3D Displays.

13.5.1. — Marker Types

- **Active Electrode Markers**
  A marker can be placed at the location of a user-selected active electrode in two ways: (1) A marker can be placed on the reconstructed Surface Model at the location of the user-selected active electrode (e.g. ablation catheter tip) using **[F3]** or **[Space]**; (2) right clicking on the defined marker in the Default Marker list and dragging it to the desired location on the reconstructed Surface Model. A corresponding entry will be added to the Current Markers list in ascending order and denoted by Name, Time and Date Created. A default Active Electrode Marker is defined as Color-red, Marker Shape-Sphere and Marker Size-4 mm.

NOTE: When using **[F3]** or **[Space]** and the user-selected active electrode is within 4mm of the reconstructed Surface Model, the marker will be placed at the nearest location on the reconstructed Surface Model.

NOTE: Holding **[Shift + F3]** while placing the marker will optionally place the marker at the location of the user-selected active electrode.

- **User Markers**
  User Markers can be placed on the reconstructed Surface Model in two ways; (1) at the mouse location using **[F2 + Right Click]** or (2) right clicking on the defined User Marker in the Default Marker list and dragging it to the desired location on the reconstructed Surface Model. A spherical or disc shaped marker will be placed on the reconstructed Surface Model and a corresponding entry will be added to the Current Markers list. Marker IDs are enumerated in ascending order and denoted by the Name, Time and Date Created.

13.5.2. – Editing Markers

- **Default Markers**
  A list of Default Markers is provided. These can be edited and/or new Markers created. (See Section 13.4.3 Creating New Markers). Right clicking on the Default Marker will bring up a pop-up box, select Edit Selected Marker. The Description, Color, Marker Shape and Marker Size can be edited. Clicking Save will save the changes. The changes be reflected in the Default Marker List and are applied from this point forward.
- **Current Markers**
  To edit Markers in the Current Markers list, left click on the Marker ID. This brings up a Window from which the Size, Color, Type of Marker and Visibility of that Marker can be changed. The Marker Name can be changed by highlighting the Name and replacing the text. All placed Markers can be hidden by clicking on the **Hide Labels** icon located next to the Current Markers header. The Markers can be made visible by clicking the **Show Labels** icon.

13.5.3. – Creating New Markers

- New Markers can be created by clicking on the "+" next to the Default Markers header. This will open a Create Marker Window which is used to define the new Marker. Selecting Create Marker will add the new Marker to the Default Marker list.

13.5.4. – Deleting Markers

Markers can be deleted from the surface in multiple ways.

- Right click on the Marker to be deleted. This will bring up details related to the Marker. Right click on delete to remove the Marker.
- In the Current Marker List right click on the Marker to be removed. Select Delete from the pop out list to remove the marker.
- In the Current Marker List click in the box of the Marker to be removed. This will highlight the Marker in the list and cause the Marker on the surface to blink. Use the delete key to remove the Marker.

NOTE: Markers can be removed in bulk by either holding down the shift key and highlight the continuous series of Markers in the Current Marker List to be deleted or by holding down the control key while independently selecting each Marker in the Current Marker List to be deleted. When all the Markers to be deleted have been selected, use the Delete key to remove them simultaneously.

13.6. – Marker Projection Tool

The Marker Projection Tool is displayed with two concentric rings, both rings are visible when the user-selected active electrode is within 10 mm of the reconstructed Surface Model. The inner ring has the same diameter as the user-selected active electrode. The outer ring assists the user to visualize a 3-dimensional perspective (depth) when viewing a 2-dimensional display. The outer ring changes in diameter proportionally to the distance between the displayed user-selected active electrode and the reconstructed surface model. The default value is On.

Marker Projection Tool ON

Marker Projection Tool OFF

CHAPTER 14 — SUPERMAP

This chapter describes the steps for acquiring and processing data to create SuperMaps on an ultrasound anatomy reconstruction. SuperMap is an efficient way to collect data throughout the chamber of interest, which is aligned to a timing reference and processed through the charge density inverse solution to create both dynamic and static non-contact maps of simple and complex repetitive rhythms. Two types of maps are available: Propagation History and Amplitude.

14.1. — Data Acquisition

Before starting data acquisition, set-up the AcQMap System and acquire and edit the ultrasound anatomy as described in Chapters 9 and 10.

NOTE: SuperMap requires a stable timing reference (e.g. auxiliary catheter placed in the coronary sinus). At least two electrodes on the reference device must be connected to the auxiliary channels of the AcQMap console.

NOTE: The system can be switched between a standard recording (acquisition) mode and SuperMap recording mode at any time during a session. The initial system set-up is the same.

To acquire data:

1. Toggle the SuperMap icon at the bottom of the screen to enable SuperMap. The reconstructed surface anatomy will switch to a translucent surface.
2. Click the **[Record]** button to start the SuperMap recording.
3. Rove the AcQMap Catheter throughout the chamber of interest. Contact with the chamber anatomy is not required. The reconstructed anatomic surface will change color as data is collected in different regions. During acquisition, the electrodes on the AcQMap Catheter and the nearby surface mesh will illuminate when the catheter is near the displayed reconstructed surface. The mesh illumination will be white when the catheter is near the reconstructed anterior surface and gray when it is near the reconstructed posterior surface.

SuperMap

NOTE: A typical data acquisition will require 1-2 minutes to sample the entire chamber of interest.

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4. When the reconstructed surface appears well illuminated, click the **[Record]** button to stop recording. Recordings with well distributed data throughout the chamber, will produce more complete maps. It is not required to reach full illumination of the reconstructed surface anatomy.

5. Locate the recording in the Navigation Window. Double click on the recording to open it in the Waveform window.

NOTE: Right clicking on the recording will open a popup window that shows the recording is designated as a SuperMap Recording. To analyze the recording using the standard non-contact charge density algorithm, left click on SuperMap Recording. Any recording in non-contact mode can be analyzed as SuperMap or standard non-contact.

14.2. – Waveform Analysis

Waveform analysis will initially process the acquired data using default settings. The data is processed to determine unique beat groups and their cycle lengths using all available reference unipoles. Beat groups are differentiated by unipolar signal morphology and timing pattern. Cycle length values are based on the descriptive statistics (mean, median, standard deviation) of the distribution of cycle lengths in the data recording. The calculated beat groups will be displayed in the Beat Group Window. Each beat group is color-coded with cycle length and percentage of total beats displayed for each beat group. Beat groups are displayed in order from largest to smallest percentage of beats.

14.2.1. – Viewing a Beat Group

Select a beat group. In the 3D Display window, the surface illumination will correspond to the distribution of data for the selected beat group. The number of EGMs in the distribution is shown in the upper corner of the right-hand 3D Display Window. The 2D Trace Window will display the Primary Reference (unipolar) and available bipolar electrograms from the Reference catheter. Bipolar electrograms are automatically formed based on the available Reference catheter connections. Beats included in the selected beat group are color-coordinated to the beat group. The Primary Reference electrode trace is located at the top of the list and displayed in blue. Each yellow dot annotates the Local Activation Time (LAT) of both the unipolar reference and bipolar electrode pairs. The cycle length of adjacent activations is also displayed. Click the right **[Show Annotations]** button to hide the cycle length and LAT annotations. Signals to be displayed can be selected or deselected using the 2D Trace Control Panel.

14.2.2. – Adjusting SuperMap Parameters

NOTE: The user can update any of the default settings or calculated values prior to producing a SuperMap.

Filters can be selected or deselected by expanding the Signal Processing window. Filters include Respiration, Low Pass, High Pass, Notch and Smoothing. For more information on signal filtering refer to Section 12.1.2. – Signal Filters.

Once all Filtering adjustments have been made click the **[Update Settings]** button.

Beat Detection is performed based on the selected reference device, primary reference channel on that device and beat grouping method. Based on the auxiliary channels connected during acquisition, the system will evaluate cycle length stability and auxiliary signal amplitude to suggest the reference device and primary reference channel. The suggested Primary Reference will be displayed along with a dropdown list of other options. The System will default to morphology as the beat grouping method.

Detected Cycle Length Expand the Detected Cycle Length window to view basic information on cycle length(s) during acquisition. Cycle length values used by the software are based on the descriptive statistics (mean, median, standard deviation) of the distribution of time intervals on each unipolar and bipolar channel on the reference device. The Window Width value to be used for beat detection can be changed by entering a new value in the Window Width box and clicking **[Apply]**.

The plot in the Detected Cycle Length window shows the time alignment of the ECG and Intracavitary signals to the reference signals. The window can be adjusted to minimize the influence of the QRS and T-waves on the segmented signals used for beat-grouping. Default value is 50/50 of the cycle length around the primary reference channel.

Once all adjustments have been made, click the **[Update Settings]** button.

14.2.3. – Preparing Data for Mapping

Click on the **[Trim EGM]** icon to see the mapping area. To adjust the mapping signal, use the sliders to trim the signal.


Trim EGM

Click the **[Create Map]** button to prepare the data associated with the selected beat group to be mapped. After clicking the **[Create Map]** button, the button will change to **[View Map]** and a newly named map will appear in the navigation window below the selected recording.

Click **[View Map]** to load the data into the Map Window and process it through the charge density inverse solution.

14.3. — Displaying a SuperMap

Two types of SuperMaps are produced: Activation (Propagation History) and Amplitude.

- Propagation History – The propagation history map is an animated version of an isochrone map. Color is used to show where the activation wavefront was located over a series of time-increments. Conduction is displayed as a moving color-map. Red is the present location of the leading-edge, while trailing color-bands represent earlier locations in time.
- The amplitude map is a peak-to-peak amplitude map that is calculated using the Laplacian of surface charge density. Laplacian is an omnidirectional computation. Laplacian subtracts the surrounding potentials from the selected point. Amplitude in Laplacian waveform traces may vary significantly from conventional bipolar computations. Color coded display values indicate the amplitude values at each point on the reconstructed anatomic surface. Colors range from gray/red (no/low amplitude) to magenta (high amplitude).

The System will initially display the Propagation History map.

14.3.1. — Display of a Propagation History SuperMap

Propagation History isochronal maps display color-coded activation times at each point on the reconstructed anatomic surface. The activation timing is the difference in milliseconds between detected activation on the mapping catheter and the reference timing. When the propagation history map is displayed, a shaded region will appear to the left of the Time Cursor in the 2D Trace Display. The shaded region represents the time history of activation corresponding to the color bands of the 3-D surface.

14.3.2. — Adjusting the Propagation History Map

The display of the Propagation History map can be adjusted using the parameters listed below:

Window Width defines the time duration spanned by the color gradient of the propagation history.

Time Threshold is used to reduce artifacts in the map by not allowing reactivation of a region for the set Time Threshold.

Color Bar settings adjust the parameters used to display the timing data.

Color Bar Tuner Checking the View in Gray Scale changes the Color Bar into a new scale that displays the map on a scale from white to black.

Color Bar Modes For propagation history maps the Color Bar mode can be set to either reentrant or linear mode. The default setting for SuperMap is reentrant. The reentrant mode joins the beginning of the time window to the end of the time window to display the timing information as a continuum. The linear mode displays the timing information as a linear sequence of electrical activation through the mapped tissue.

NOTE: If the upper Color Bar slide or Time Threshold values are changed the Propagation History map must be recalculated.

14.3.3. — Playback settings

Timing data can be displayed as a progression played back over time. The user can adjust the playback speed, direction and mode.

Playback speed: Allows the rate at which the data is played to be adjusted.

Playback direction: Allows the data to be played either forward or backward.

Playback mode: provides different methods of dynamically visualizing the timing data.

14.3.4. — Displaying Amplitude-based Maps

Amplitude maps are used to identify areas with low amplitude (e.g. possible areas of scar). Amplitude maps display color-coded values at each point on the reconstructed anatomic surface.

14.3.5. — Adjusting the Amplitude Map

The display of the Amplitude map can be adjusted using the parameters listed below:

Color Bar settings adjust the parameters used to display the amplitude data. For amplitude maps the Color Bar operates in a single, fixed mode.

14.4. — Displaying a Propagation History Map with an Amplitude Map

The Dual 3D Displays allow simultaneous visualization of the generated SuperMaps. The 3D Displays can work together displaying the same type of map from two viewing angles or independently displaying two different types of calculated maps.

Synchronized 3D Displays

In the center, at the top of the 3D Displays in the Maps Window, there is a Link icon. When the Link icon is connected the 3D Displays will be synchronized.

Link — Synchronized Displays

Independent 3D Displays

Click on **[Link]** icon, this will highlight either the left or right 3D Display with an orange border. The orange border indicates the active 3D Display which can now be changed between map types: Propagation History or Amplitude. To switch the active 3D Display, left double-click anywhere in the black space of the non-active 3D Display.

Link — Independent Displays

CHAPTER 15 — EXPERT MODE

Enabling Expert Mode provides the user with a variety of additional user selectable parameters to enhance and refine the data and presentation by the AcQMap System. When enabled, Expert Mode activates all of the features and functions described in this chapter.

15.1. — Common Controls

15.1.1. — Configure Menu Expert Mode

Pace Blanking	Enables pace blanking for use during AcQMap procedures
Ultra Sound Blanking	Enables ultrasound blanking for use during AcQMap procedures

15.1.2. — Window Menu Expert Mode

CS Interface	Open the CS Interface for scripting interface, pace blanking control, and ultrasound controls. This function is not required to run the AcQMap System.

15.2. — AcQMap Set Up

15.2.1. — Ultrasound Live Signals Window Expert Mode

Live Signals

Navigate to the Live Signals Window by clicking the **Live Signals** button.

Click **[US]** to access the Ultrasound screen.

Additional parameters now available in the Ultrasound Live Signals Window provide access to a plotting sub-menu that allows selection of histogram parameters including the length of the time window over which the displayed histogram data encompasses as well as the vertical scaling mode for the histograms:

- Individual: Each histogram is normalized to its own maximum bin height.
- Spline: Histograms along each spline (column) are normalized to the maximum bin height across all transducers in the spline.
- Overall: All histograms are normalized to the maximum bin height across all the transducers.


Clear Waveforms

The **Clear Waveforms** icon clears the signal data and resets all the waveforms.

15.3. — Acquisition Window Expert Mode

15.3.1. — Advanced

Advanced Localization settings are found in the Advanced list in the Localization Configuration panel.

- **View voltage**
  View voltage bypasses the localization scaling from voltage to position and displays all localized electrodes in voltage space. Surface reconstructions and AcQMap System rendered Auxiliary Catheters will not be scaled correctly with this setting enabled. This setting is not recommended for general use.
- **Auxiliary Motion Damping**
  Auxiliary Motion Damping reduces high frequency movement of the ablation catheter in the AcQMap display. Available settings include Normal, Aggressive and Mild. The default setting is Normal.

15.3.2. — 3D Settings

3-D Display Controls are configured via the 3D Settings. The following controls can be used to adjust the appearance of the reconstructed surface in the 3-D display more precisely. The new settings are accessed by clicking on the different tabs.

3D Settings – View Tab

- **Inner Chamber Surface** - Select the desired color for the Inner Chamber Surface
- **Viewport Settings** - The following function is used to adjust the display appearance
  - **Show 3D Axis** - Enables or disables the display of the coordinate axes.
- **Ultrasound**
  - **Show Points** - Enable or disables the display of the endocardial surface points detected by ultrasound. This set of points is cleared by clicking the Clear Current Surface button on the Surface Build menu.

3D Settings – Curve Fitting

- **Control Point Density** - Varies the number of control points used for the fitted curve.
- **Error Falloff Offset** - Varies the range over which measured electrode locations influence the curvature of the displayed Auxiliary Catheter.
- **Error Falloff Width** - Varies the sensitivity of the curvature of the displayed Auxiliary Catheter to the measured electrode locations.

3D Settings – Camera

The following controls are used to adjust the Camera settings in the 3-D display.

- **Others**
  - **Show Camera Info** – Provides information related to the camera view.

15.3.3. — Trace Display Window

Trace Display

- **Pause Button** – The Pause Button is used to pause the real-time display of plot traces. Real-time plotting will resume when the button is clicked again.
- **Plot Monitoring Display** – The Plot Monitoring Display shows processing and read timings for the Trace Display window. These values are for information only. (*Figure 14-3*, Red box)
- **Low Pass Filter selection drop list** – provides a selection of values for the Low Pass Filter.
- **High Pass Filter selection drop list** – provides a selection of values for the High Pass Filter.
- **Decimation checkbox with corresponding** – Toggles a subset of the original Trace sample set On/Off.

Trace Display Control Panel

- **Calipers** - The Caliper tab displays information related to the user-specified calipers placed in the Trace Display. Caliper name and color may be changed within the tab. Start and end points for the calipers are adjusted by dragging the caliper markers on the Trace Display. Click the red "X" to delete a caliper. Click the red "X" in the upper left to delete all calipers.
- **Others** - The Others tab controls the Trace Sweep Speed. Available only in the Acquisition window.

For additional information related to all aspects of Set Up refer to Chapter 9 Set up.

15.4. — Ultrasound Surface Anatomy in Expert Mode

This section describes the additional tools available for setup and acquisition of a Surface Anatomy.

15.4.1. — Building a Surface Anatomy using Ultrasound

In the Acquisition Window, select the **[Build]** button on the upper right of the 3-D Display to open the Surface Build menu.

Configuration Tab

- **Surface Point Constraints**
  The maximum and minimum allowable ultrasound distances used in building the Surface Anatomy may be adjusted here. Surface points calculated using distances falling outside of the minimum-maximum limits are excluded from the Surface Anatomy reconstruction.
- **Advanced**
  - **Performance**
    Measures the calculation performance of the software while acquiring the surface data with ultrasound
  - **Debug**
    Displays reference calculations by the software for localization.

15.4.2. — Editing a Surface Anatomy

Surface Edit Controls

- **Enhance Tab**
  - Smooth Mesh - The smooth mesh function reduces the surface variation and adjusts positions of surface vertices to reduce the variation in surface normals between neighboring nodes.
  - # Iterations – the number of smoothing passes
  - Method – a default value of 0 is used in the method input field.

For more information on building an anatomy refer to Chapter 10 Building a Surface Anatomy.

15.5. — Reviewing Recordings in Expert Mode

Current and past records may be reviewed in the Waveforms window. The Waveforms window is accessed by clicking on the **[Waveforms]** Tab.

Trace Display

- Mode 1/Mode 2 Buttons – The Mode buttons are used to change between single-channel and multi-channel (Mode 2) view modes. In Mode 2 Channel Selection and Displayed Signals are not available. To configure the displayed waveforms in Mode 2, select Configure à Waveform Channels. The saved configuration of AcQMap Catheter, Surface ECG and Auxiliary Catheter Channels will automatically populate the Trace Display.

Signal Display – Mode 1

- **Channel Selection**
  Reference - A second channel used for comparison or in calculations.
- **Displayed Signals**
  - **Additional calculated waveforms** are available and can be selected under the Displayed Signals heading.
  - **Raw**
    The raw, measured signal from the selected channel, without filtering.
  - **Reference**
    A second filtered AcQMap System channel used for comparison or in calculations. The reference channel may be selected in the Channel Selection Panel.
  - **CH – Ref**
    The mathematical subtraction of the selected filtered channel and filtered reference channel.
- **Filtering is available in both Mode 1 and Mode 2**
  - **High-Pass Filter**
    In Export Mode the filter may be applied in the forward direction only or bi-directionally. The order is entered in the text field to the right of the "High Pass" label. Selecting the checkbox labeled "+Back" applies the filter bi-directionally. The filter is applied in the forward direction only when the checkbox is unchecked. Recommended initial settings for the High-Pass Filter are 1.0 Hz cutoff, first order, forward direction only.
  - **Low-Pass Filter**
    In the Expert Mode the filter may be applied in the forward direction only or bi-directionally to reduce phase shift. The order is entered in the text field to the right of the "Low Pass" label. Selecting the checkbox labeled "+Back" applies the filter bi-directionally. The filter is applied in the forward direction only when the checkbox is unchecked. Recommended initial settings for the Low-Pass Filter are 100 Hz cutoff, first order, forward direction only.

- **Smoothing Filter**
  The Smoothing Filter is an adaptive Low-Pass Filter that is used to reduce baseline noise on the electrograms. Two settings are available for adjustment of the Smoothing Filter: Nmax and Iterations. Nmax specifies an adaptive index for the filter. Iterations specifies the number of iterations of averaging that are performed by the filter. Recommended initial settings for the Smoothing Filter are Nmax = 12, Iterations = 2.

15.5.1. — Configure XYZ

Provides easy access to update the localization configuration.

15.5.2. — GridMap Display

The Grid Map Display shows the distribution of measured signals across the AcQMap Catheter, rendered as a grid organized by AcQMap Catheter spline at the time marked by the Time Cursor. This display represents signal amplitude at each electrode in both color and out-of-plane displacement (when viewed at an angle). The 3D Display Selection Panel is used to toggle between the GridMap and 3D Map displays.

Configure the GridMap

Once the electrograms have been filtered, the GridMap Display can be used to examine the distribution of voltage measured by the AcQMap Catheter. The GridMap is a good visual indicator of the location and propagation of myocardial conduction, relative to the AcQMap Catheter.

NOTE: The excluded channels will be removed from the GridMap Display, and color values in the GridMap will be interpolated.

The GridMap is an “opened-planar” representation of the AcQMap Catheter, which displays the filtered voltage amplitude at each electrode as a color-mapped color. The GridMap maintains the relative orientation of electrodes on the AcQMap Catheter. The columns of the GridMap, from left to right, represent the order of splines on the AcQMap Catheter in counter-clockwise order (viewed from a distal perspective). The rows of the GridMap, from top to bottom, represent the order of the electrodes on each spline, from distal to proximal.

Use the Time Cursor to change the time point of the signals displayed in the GridMap. The Time Cursor may be moved to any electrogram morphology of interest.

The color-mapping is adjustable via the dual-slider. Dragging either end of the slider will adjust the respective high or low voltage limits in the color mapping. Dragging the color gradient between the sliders will move the entire ColorScale, including the sliders. Voltages outside of the voltage limits will be bounded to the color limits (purple and red). Voltages between the voltage limits will be mapped to a color gradient.

The signal displayed in the GridMap Display may be changed from filtered voltage per channel (CH) to channel voltage minus reference channel (CH-REF) or channel voltage minus BCT (CH-BCT). The displayed signal is changed by selecting the desired signal from the "Signal To Plot" dropdown list.

Additional GridMap Display options are available in the GridMap/AcQMap Options control panels.

BMP button – captures a sequence of BitMap image files and places them the C:\Temp\BMPFiles\<GUID> folder. The input box is used to configure the number of samples to skip between BitMaps.

Subtract BCT checkbox removes the BCT Display Signal.

Full information on Reviewing Recordings can be found in Chapter 12 Reviewing Recordings.

15.6. — Mapping, Labels and Markers in Expert Mode

The 3D Maps Mode is used to generate 3D Maps of the data selected and exported from the Waveforms window. 3D Maps Mode is accessed by clicking on the **Maps** tab. The information below represents additional maps and functions available in Expert Mode.

15.6.1. — Loading Data

If a new 3D Map will be generated from exported data, the CDA Settings window will open. Sources are modeled as continuous charge density, distributed on the endocardial surface.

Two additional mapping parameters are available: Number of Eigenvalues and Regularization Parameter. These settings help further define the parameters for calculating the inverse solution.

Apply Distance Calibration Scaling checkbox: Applies a method to compensate for the distance of the AcQMap Catheter to the Surface into the Charge Density Algorithm (CDA).

When settings are verified, the CDA may be executed by clicking the **[Execute CDA]** button.

Click **[Execute CDA]** to proceed.

15.6.2. — Additional Mapping Tools

- **Electrode Voltage**
  The voltage at the AcQMap Catheter electrodes may be displayed as a comparative reference for the Surface Voltage-based or Surface Charge-based maps. Click the **[Electrode Voltage]** button to show the voltage measured at the AcQMap Catheter, interpolated over a continuous surface. The 3D Surface Anatomy will be hidden to show the voltages on the AcQMap Catheter within.
- **Electrode Voltage Grid Button**
  Located on the left side of the Dual 3D Display, this button will launch the "Electrode Voltage Grid Map dialog. The dialog presents a 3D figure with the following axis: Spline Number, Electrode Number and Amplitude (Scaled). The 3D figure can be rotated with the mouse.

15.6.3. – Post-Processing Tools

- **Coulombian**
  - The Coulombian (distance-weighted spatial gradient) will be applied to the Surface Voltage and Surface Charge. Application of this function will highlight areas of high rate-of-change in the Surface Voltage or Charge Density.
  - Click the calculator icon to the right of the Coulombian Map button. The "About to Execute Coulombian Processing. Continue?" window will appear. Click **[Yes]** to proceed

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NOTE: The Coulombian activation threshold is set by the upper ColorScale setting.

  - The Coulombian data will be calculated for both Charge and Voltage. Upon completion, the Charge version of the Coulombian Map will be displayed.
- **Displaying Conduction Pattern Data**
  An additional dropdown menu is available to change the display units on the Focal, LRA and LIA slider bars.
  - # of occurrences is the default mode and displays the frequency of occurrence of each conduction pattern at each location in the mapped segment.
  - # of occurrences/second displays the data using the # of occurrences (above) divided by the duration of the mapped segment.
  - Average ms/occurrence displays the data using the duration of the mapped segment (in milliseconds) divided by the # of occurrences (above).
- **Image Capture Controls**

  The Image Capture Controls panel is used to capture images from the workspace.
- **Screen Capture button** – Captures an image of the full screen.
  - **User Defined Capture button** – Captures a region of the screen defined by the user.
  - **Image Format** – Can be selected as BMP, JPG or PNG depending on the User preference and needs.
  - **Capture Method**
    User Selected: The user may use the mouse to select the screen region to capture.
    Predefined: The area specified by Capture Region Definition will be used.
  - **Capture Region Definition**
    The X,Y coordinates define the starting position of the screen capture, for example X=1 and Y=1 would start the capture in the lower left hand corner. The Width and Height define the area to be captured. All values are input in pixels.
  - **MultiCapture button** - Multiple sequential captures may be recorded by setting the number of frames and clicking the **[MultiCapture]** button.

For full information about Mapping refer to Chapter 13 Mapping, Labels and Markers.

15.7. — SuperMap in Expert Mode

The information below represents additional SuperMap functions available in Expert Mode.

15.7.1. — Data Acquisition

In Expert Mode, during Data Acquisition as the catheter is roved throughout the chamber a progress bar will be visible at the bottom of the 3D Display window. The progress bar continuously updates to indicate the percent of the reconstructed surface that has been colored.

NOTE: It is not required to reach 100% on the progress bar but a higher value will produce a more complete map.

15.7.2. — Waveform Analysis

Signal Processing when used in Expert Mode allows the user to adjust the filter settings for the ACMCatheter, 12-Lead, Raw-ECG and Auxiliary Catheters (AUX). To adjust the filter settings, left click on the text to access the filters for those signals. Check or uncheck the filters to be applied. Additional settings are available to refine the High-Pass, Low-Pass and Smoothing Filters. See Chapter 15, Section 15.5 — Reviewing Recordings in Expert Mode for additional information on the added filter settings.

QRS Width is used to blank the QRS signal in the recorded data. The default value is 100 ms. The QRS width can be adjusted by entering a new value in the QRS width box or using the arrows to increase or decrease the current value.

After all changes have been made click the **[Update Settings]** button to apply all changes.

15.7.3. — Displaying a SuperMap in Expert Mode

SuperMap, when used in Expert Mode, can display two additional types of maps: Surface Charge and Surface Voltage.

Surface Charge Surface Charge Density is derived by an inverse solution applied on the voltages measured from the AcQMap Catheter electrodes. The source model and inverse solution parameters selected when configuring the Charge Density Algorithm govern the method by which the charge density is calculated. Click the **[Surface Charge]** button to use Surface Charge Density as the mapped variable.

Surface Voltage is the forward calculation of voltage upon the surface from the inverse-calculated surface Charge Density above. Click the **[Surface Voltage]** button to use surface voltage as the mapped variable.

CHAPTER 16 — SETUP CONTACT MAPPING

This chapter describes the steps for setting up the AcQMap System for data acquisition, contact electrograms, geometry construction and contact map creation.

Before starting data acquisition, ensure that the following steps have already been completed:

- ☑ System set up – Chapter 5
- ☑ Attach Localization Dispersive Electrodes, Patient Return Electrode and Repositionable Monitoring Electrodes – Chapter 6
- ☑ Connect patient electrodes to AcQMap Console front panel – Chapter 6
- ☑ Insert and position Auxiliary Catheters. Connect Auxiliary Catheters via the Auxiliary Interface Box to the AcQMap System – Chapter 5
- ☑ Insert and position the Ablation Catheter. Connect the Ablation Catheter and Generator as recommended in Appendix A.
- ☑ Create patient record – Chapter 8
- ☑ Select session type (Contact) – Chapter 8
- ☑ Check signals (Sur ECG, Aux EGM, Aux Loc) – Chapter 9, Section 9.1 Checking Signals
- ☑ Calibrate Localization Phase – Chapter 9, Section 9.1.5 Calibrate Localization Phase

The following remaining **mandatory steps** will be described in the sections below:

- ☐ Set up contact mapping catheters and detection criteria – Chapter 16, Section 16.1
- ☐ Select catheter to establish localization and designate electrodes for field scaling – Chapter 16, Section 16.2
- ☐ Set up Anatomical Reference Channels to be used – Chapter 9, Section 9.2 Acquisition Setup
- ☐ Collect localization field and calibrate – Chapter 16, Section 16.3

16.1. — Setup Contact Mapping Catheters and Detection Criteria

Open the Contact Mapping Setup using the Contact Configuration Setup icon on the upper left side of the Acquisition window. Contact Mapping Catheters, Filters and Activation Detection Parameters. Setup includes three (3) screens: Catheters, Filters and Activation Detection Parameters.

Contact Configuration Setup

Defining Catheters

1. Select catheters to open the Catheter set-up screen.
2. Use the drop-down list under the Devices heading to select a catheter. Click **[Add]**.
3. Repeat until all catheters to be used have been added.
4. Assign a function (Ref, Map, Abl) to the appropriate catheters.
   a. The timing reference channel (Ref) is designated by the label "R" in the Trace Display and Annotation Window. The user can define the primary timing reference channel by selecting intracardiac or surface channels as needed (Icon). The selected channel should be stable and have a clear signal that is associated with the activation of the chamber being mapped.
   b. The mapping catheter is designated by the label "M" in the Trace Display and Annotation Window. The user can define the catheter and the electrodes or electrodes pairs that will be used for mapping.
5. Click on a catheter to define the Unipoles. Unipoles are defined by the catheter electrode number (CH), Pin, label and function. The Pin should match the electrode (CH) connection to the Auxiliary Catheter cable. Labels can be edited to be descriptive. Checkboxes are provided to designate the electrodes to be used for the function defined in the Devices box.
6. Bipoles can also be defined for the same catheter. Bipoles are defined by CH1, CH2, Label and Function. Click [Add] in the Bipoles box to add bipoles. Use CH1 and CH2 to define the electrodes in the bipole. Labels can be edited to be more descriptive. Checkboxes are provided to designate the electrodes to be used for the function defined in the Devices box.

NOTE: For best performance, Bipoles should be defined by electrodes that are adjacent to one another on the catheter.

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7. Repeat steps 5 and 6 for each connected catheter.

NOTE: Any catheter with a unipolar or bipolar configuration defined in the window and connected to the system is accessible to be visualized.

Set Contact Mapping Filters

The Filters screen is used to define the filter settings for the unipoles and bipoles.

Select the Filters heading to access the Filters screen. Use the checkbox to select the filter type and select the appropriate value from the drop-down list.

Set Activation Detection Parameters for Reference and Mapping Channels

The Activation Detection Parameters screen is used to setup the activation detection for the Reference and Mapping Channels.

Activation Detection for Reference Channels

The Reference Channel is used to identify a consistent time during the cardiac cycle that is used by the system to identify and align beats, set the Mapping Window for each beat, and as a zero time for activation time measurement. Beats are detected based on the selected criteria for the timing reference channel that are beyond a user-determined threshold. The user can select from 5 detection modes and set threshold levels as needed.

Detection Modes

- +Peak: Peak positive deflection
- -Peak: Peak negative deflection
- Abs Peak: Largest peak positive or negative
- +Slope: Sharpest positive slope
- -Slope: Sharpest negative slope

Threshold values

Beat detection for the reference channels use a conventional adaptive thresholding method that dynamically adjusts to the amplitude of the detected beats and exponentially decays to a minimum level

- Minimum Detection Threshold defines the minimal voltage level for peak detection
- Upper Detection Limit – defines the upper limit of the adaptive detection threshold
- Max Cycle Length Variance defines the maximum variation in cycle length

Activation Detection for Mapping Channels

The Mapping Channel is used to sample local activation time and voltages throughout the chamber(s) of interest. The mapping channel can be any intracardiac electrode, can be changed during the procedure and data can be sampled from one or multiple electrodes. Local activation times and voltages are detected based on the selected criteria for the mapping channel that are beyond a pre-determined threshold. The user can select from 5 detection modes and set threshold levels as needed.

Detection Modes

- +Peak: Peak positive deflection
- -Peak: Peak negative deflection
- Abs Peak: Largest peak positive or negative
- +Slope: Sharpest positive slope
- -Slope: Sharpest negative slope

Threshold values

- From and To define the window of interest for acquiring points. From defines the time before t=0 and To defines the time after t=0. (This can be directly changed in the Annotation window)
- Min. Amplitude defines the lowest acceptable voltage level for acquiring points.
- Distance from Geometry defines the electrode distance from the reconstructed chamber geometry for acquiring points.

16.2. — Select Catheter to Establish Localization and Field Scaling

Initial configuration of localization settings is completed via the Localization Configuration panel. Click the [Open Full Localization Setup] button in the Localization Configuration panel to access the Localization Configuration Window.

For initial setup, the Manual Configuration option must be used. Select ⊙Localization Setup and then click **[Next]**.

Use the dropdown list to select the catheter to establish localization. Designate the electrodes to be used for field scaling. Electrodes that are used for field scaling must be connected via the Auxiliary Channels. Click **[Next]**.

16.2.1. – Anatomical Reference Selection

Refer to Chapter 9, Section 9.2.1 Localization Configuration (Setting up Anatomical Reference Channels) for complete details.

1. Under the heading Anatomical Reference Channels select Surface Leads. The box will be automatically populated with V1. V2, V3, V4, V5, V6, LL, LA and RA. This can be edited as needed.

NOTE: The Calibration Reference Channel and Auxiliary Catheter configurations will be pre-populated from the prior screen and contact configuration setup, respectively.

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2. Ensure the selected catheter is centered in the middle of the chamber. It is recommended to leave the catheter stationary throughout the setup period.
3. Click the **[Finish]** button to start the setup process. A progress bar will be shown on the screen to indicate level of completion. Once setup is complete, the settings will be saved.

16.3. – Collect Localization Field

To establish the localization field, the system needs to recognize catheter movement in two planes. Ensure the catheter being used to establish the localization field matches the catheter shown under Anatomy Settings in the Aux Catheter box.

1. Click on the **[Collect Localization Field]** button and begin moving the catheter immediately.
2. Move the selected catheter back and forth in a single plane until the Direction A box turns green.
3. Move the same catheter back and forth in a second plane until the Direction B box turns green.
4. Click the **[Collect Localization Field]** button to complete the calibration. The new scaling parameters will be automatically applied.

NOTE: During the collection period, the Direction Boxes may turn orange prior to turning green. The orange color indicates that data is being collected.

CHAPTER 17 — CREATING A CONTACT ANATOMY

The AcQMap System can display three-dimensional renderings of cardiac chambers. The purpose of constructing the cardiac anatomy is to define the anatomic structures within the chamber. It is important to collect enough points within the chamber to provide enough chamber definition.

The chamber anatomy is created by gently dragging a selected catheter to locations throughout the chamber. As the catheter moves, points are collected at and between all electrodes on the catheter.

17.1. — Collecting Anatomy Points

1. Click the ⮟ next to Anatomy to access anatomy creation and editing tools.
2. Use the dropdown menu to select the catheter to be used to collect points.
3. Select the Alpha Value. The Alpha Value defines the fill threshold.
4. Click the + icon to create a new anatomy.
5. Click the Collect Point Cloud icon to begin collecting points.
6. Drag the catheter along the chamber walls to create the anatomy.
7. Click the Collect Point Cloud icon to stop collecting points.

During anatomy point collection an eraser tool is available to delete unwanted points. Select the Erase Point icon to access the eraser toolkit.


Erase Points

The anatomy point cloud will be visible, and all the points will be yellow indicating edit mode. The mouse pointer becomes a circular eraser. The size of the eraser can be adjusted using the sizing dropdown menu. Hold the right mouse button while moving the eraser over points to be deleted. Additional functions available include:

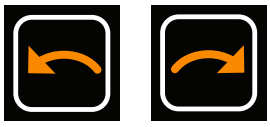
Clear icon: Clicking on the **Clear** icon will clear the entire anatomy.

OK icon: Clicking the **OK** icon will save the changes and close the eraser toolkit.

Cancel icon: Clicking the **Cancel** icon will cancel all changes and close the eraser toolkit.


Clear OK Cancel

Undo icon: Clicking the **Undo** icon will undo the most recent erasure.


Undo Redo

Redo icon: Clicking on the **Redo** icon will redo the most recent editing step that was undone using the undo icon.

NOTE: New points can be added at any time during the procedure using the selected catheter and clicking the Collect Point Cloud icon.

17.2. – Editing an Anatomy

After point collection has been stopped, the anatomy can be post-processed. Post-processing allows re-meshing, smoothing and removing areas of the surface anatomy.

Complete details for the available edit tools can be found in Chapter 10, Section 10.5.3 Editing a Surface Reconstruction and Section 10.5.4 Enhance Controls tab.

NOTE: It is recommended to re-mesh the anatomy at ≥2500 samples at least one time after point collection is complete to create uniformity among the triangles that comprise the mesh.

To re-mesh the anatomy, click on the **Re-mesh Surface 2500** icon.

Re-mesh Surface 2500

To cut out the valve plane, under Manual Select click on the **Ellipse** icon. Additionally, check the Front Surface Only and Move and Resize checkboxes. Click on the **[Select Region]** button to activate the Ellipse selection tool. The Select Region button will change to "OK" when the Ellipse selection tool is activated. Faces and vertices of the surface can now be selected in bulk using an ellipsoid shape. Click the right-mouse button and drag to select an elliptical region. When the right-mouse is released, all faces and vertices that lie within the elliptical boundary will be selected.

When all post-processing has been completed click on the **Save** icon to save the anatomy.


Save

NOTE: If the anatomy appears flatter than normal, consider repeating set up of the anatomic reference and collection of the localization field (See Chapter 16, Sections 16.2 and 16.3)

NOTE: If the anatomy is not saved prior to exiting the Edit menu, all changes will be lost.

NOTE: Adding points to a post-processed anatomy may reset some of the edits that were performed.

Once the anatomy has been saved it will appear in the Browse Anatomy window. The file can be re-named by double-clicking on the default file name. The active Anatomy is denoted by the yellow star in the blue circle adjacent to the anatomy recording.

17.3. – Add a New Structure

To add a new structure (e.g., PV, RA) to an existing anatomy, Click the **+** to create a new anatomy and repeat the steps above. When the new structure is complete, save the anatomy. Rename the new structure if desired.

To display the new structure with an existing anatomy, click on the desired saved anatomy. Deselect the hide anatomy icon to make the anatomy visible with the new structure. Multiple anatomies/structures can be displayed together.

CHAPTER 18 — CONTACT MAPPING

The AcQMap System can display conventional electrophysiology mapping data as three-dimensional maps. Data is collected from various locations within the chamber of interest in a stable rhythm using localized electrophysiology catheters. The 3D location of each point is saved along with voltage and activation data, which can be displayed on the nearest surface as color. A single set of collected data can be used to display several types of maps.

Contact maps use a surface electrogram or an intracardiac electrogram as the reference to which collected points are measured. Two types of maps are available: Local Activation Time (LAT) and Voltage amplitude.

- Local Activation Time (LAT) isochronal maps display color-coded activation times for each collected point. The LAT is the difference in milliseconds between detected activation on the mapping catheter and the reference channel. Color represents the LAT for example, red (early) and blue (late). User selected color modes are described in Section 18.3
- Voltage amplitude maps display color-coded voltage values for each collected point. Voltage amplitude measurement is user selectable (Peak-to-Peak, Peak Positive and Peak Negative). Colors range from grey/red (low amplitude) to purple (high amplitude)

18.1. — Configure Annotation Window

Use the Contact Mapping Setup window to designate the timing reference channel, mapping catheter and ablation catheter. Review Filter settings and Activation Detection Parameters to ensure suitability for the rhythm being mapped. The Live Annotation window is automatically populated based on the catheters and parameters selected. Traces will be displayed with the Timing Reference Channel at the top, followed by the sequential order of the designated mapping channels. The ablation catheter tracing will be at the bottom. See Chapter 16, Section 16.1 Contact Mapping Setup for full details.

Trace Display and Color

Adding/deleting EGM traces or changing the trace color are made in the Trace Display Control Panel located on the right side of the Live Annotation window.

To add or delete EGM traces check the checkbox next to the trace to be displayed in the Live Annotation window. Traces that have not been designated as Ref, Map or Abl will be randomly placed into the display. To move the trace, left-click on the trace and while holding the mouse button move the trace to the desired location in the window.

To change the color, locate the appropriate trace in the list and click on the color box. A color palette window will open. Select the new color – selecting a color will automatically close the window. If no change is desired, click anywhere outside the window and it will close. It is recommended to display electrodes/electrode pairs on the same catheter in the same color.

To adjust the amplitude of the traces in the Live Annotation window, left click and hold on a trace in the window, a vertical two-direction arrow will appear. Drag the mouse up or down to increase or decrease the trace amplitude respectively.

Note: All traces in the window increase or decrease together. Trace amplitude cannot be adjusted independently.

Adjust Window of Interest

The initial values for the Window of Interest are entered during setup. The Window of Interest can also be adjusted directly within the Live Annotation window by either using the mouse or entering the From and To values using the keyboard.

To use the mouse, hover over the white border of the window of interest to be adjusted. When the mouse cursor changes to a double arrow, left click and hold, then move the white border to increase or decrease the time before or after time zero. As the border is moved the positive or negative time difference from zero will be visible.

To use the keyboard, enter the desired values in the From and To boxes located at the base of the Live Annotation window.

Assess Detection Quality

Prior to starting a map, it is recommended to assess the quality of the detection on the selected reference channel. The selected channel should remain stable throughout the mapping procedure. Check that the activation detection marker is placed on the waveform signal consistent with the selected detection criterion (+Peak, -Peak, Abs Peak, +Slope or -Slope).

18.2. — Creating a Map

Points throughout the chamber are acquired to create maps. (See section 18.3 for complete information regarding map types and display options) Points can be acquired using single or multiple electrodes or electrode pairs on the designated mapping catheter. Assignment of the primary and secondary mapping channels are done in the Contact Mapping Setup window.

Acquiring points

Use the dropdown menu above the left side display window to select the map type that will be displayed as points are acquired. Move the mapping catheter to desired area in the chamber. When a stable catheter position has been achieved, click the **[Acquire Point]** button at the bottom of the Annotation Window. The point will be acquired if the detection criterion is met. The system will visually confirm point acquisition. After the first point is acquired, a new time-stamped, map entry will be added to the map list. All acquired points are added to the Points list. Points that do not meet the detection criterion are added to the Recycle Bin. Points that pass the detection criterion show up as dots at the acquired location on the chamber surface. The map will automatically be updated as points are acquired. Data between points will be interpolated and adjusted as more points are acquired. Collected points should be continually assessed to ensure the quality of the data in the map. To delete a point in the map, left click on the point and select Recycle Bin.

Note: The most recent valid beat is used to assess timing and amplitude for each point acquired.

Note: The system operates with a 5 second buffer. The preceding 5 seconds of data are stored with each point acquired.

Note: Points can always be reviewed and either moved to or restored from the Recycle Bin.

If a most recent point is not meeting the selected detection criterion it cannot be acquired. A message, that explains the reason the point was not acquired, will be displayed next to the Acquire Point button.

18.3. – Displaying Maps

Map types display the core information of the map. Other types of information can be simultaneously displayed from the same set of data. e.g. Voltage amplitude can be displayed where color indicates the amplitude and timing data can also be displayed using a secondary visual representation.

Timing-based maps

Local Activation Time (LAT) isochronal maps display color-coded activation times for each collected point. The LAT is the difference in milliseconds between detected activation on the mapping catheter and the reference channel.

Amplitude-based maps

Voltage amplitude maps are used to identify areas with low voltage. (e.g. possible areas of scar) Voltage amplitude maps display color-coded voltage values for each collected point. Voltage amplitude measurement is user selectable (Peak-to-Peak, Peak Positive and Peak Negative).

Color Bar

Color Bar settings adjust the parameters used to display the timing or voltage amplitude data.

Color Bar Modes – For timing-based maps the Color Bar can be set to either reentrant or linear mode. The reentrant mode joins the beginning of the time window to the end of the time window to display the timing information as a continuum. The linear mode displays the timing information as a linear sequence of electrical activation through the mapped tissue. For voltage amplitude maps the colorbar operates in a single, fixed mode.

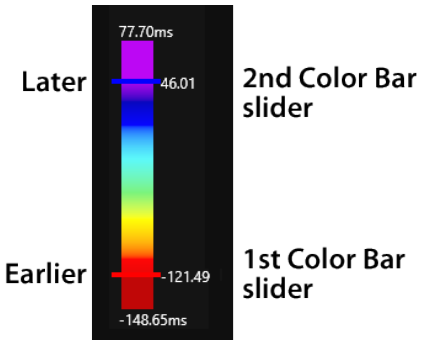
Playback settings - Timing data can be displayed as a progression played back over time. The user can adjust the playback speed, direction and mode.

- Playback speed: Allows the rate at which the data is played to be adjusted.
- Playback direction: Allows the data to be played either forward or backward.
- Playback mode: provides different methods of dynamically visualizing the timing data.
  - Color cycling: The displayed colors on the surface will dynamically change in progression. This mode is only available when the reentrant Color Bar mode is selected. Different visualizations can be achieved by configuring the color order and color depth.
  - Illumination: Regions of the surface will be illuminated in sequence based on the timing data at each location. This will appear as a moving line of illumination that progresses across the surface. Surface color information can still be adjusted manual.

Color order - Allows the user to select the order of colors represented in the Color Bar.

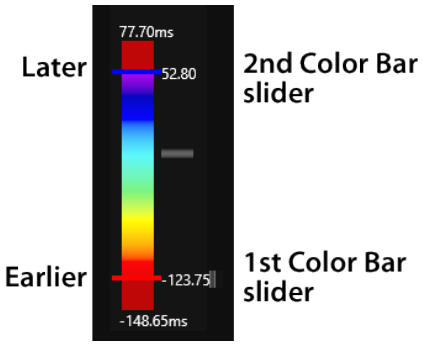
Standard isochrone: Shows a progression of color with red designating 'earlier' and purple designating 'later'. When the linear Color Bar mode is selected, times earlier than the first Color Bar slider will be designated as red, times later than the second Color Bar slider will be designated as purple.

Linear Color Bar Mode



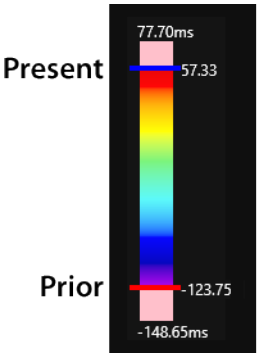
When the reentrant Color Bar mode is selected, times outside of the range between the first and second Color Bar sliders will be red.

Reentrant Color Bar Mode



Propagation history: Reverses the color order from standard isochrone. Red designates 'present' and purple designates 'prior'. Times outside the range of the first and second Color Bar sliders will be pink

Propagation History



Color depth - Allows the user to select the number of discrete colors used in the Color Bar. More colors appear smoother, fewer colors will provide more granular color bands.

User-defined thresholds - Allows the user to define thresholds for voltage amplitudes when appropriate. Voltage amplitudes below the minimum threshold will be displayed with a gray color. Voltage amplitudes above the maximum threshold will be displayed with a purple color.

18.4. – Reviewing Maps

Points in the map can be reviewed by either right clicking on the point in the map to highlight the point in the point list or selecting a point in the Points list. The selected point and associated data will be displayed in the Review Annotation window.

Points in the Recycle Bin can be reviewed by clicking on the point to be reviewed.

Note: Any point in the map (Points list) or Recycle Bin can be reviewed.

Removing points from the map

To remove a point from the map, right click on the point in the 3D display and select Recycle. Alternatively, with the point selected, hitting the **<Delete>** key will also remove the point.

Restoring points to the map

To restore a point to the map, access the Recycle Bin and right click on the point to be added. Click on **[Restore]** to add the point to the map.

Adjusting the map

- Manual adjustment to LAT time. In the Review Annotation Window, hover the mouse over the yellow line until a two-direction arrow appears. Left click to move the yellow dot to the time desired. The map will adjust accordingly.
- Adjust the global offset – In the Live Annotation window, place the mouse cursor over the blue detection indicator on the reference channel. A two directional arrow and yellow offset cursor will appear. Left click and drag the global offset cursor to the desired position in the Live Annotation window. A numeric offset value will be visible as the cursor is moved.
- Numeric values for the LAT times will adjust relative to the global offset.

Note: The color bar associated with the map will remain unchanged.

Changing the map type

The same data set can be used to display multiple map types. To move between maps, use the Type dropdown menu to select a new map type to display.

Changing detection criteria or Window of Interest

To change detection criteria, click on the **Contact Configuration Setup** icon. Make the desired changes to the Activation Detection Parameters.

Click the **Refresh** icon at the top of the 3D display window to recalculate the data.

Contact Configuration Setup

Refresh

The window of interest can be changed by updating the From/To values in the Live Annotation Window. Alternatively, values can be changed with the Contact Mapping Setup window. Click the **Refresh** icon at the top of the 3D display window to recalculate the data.

18.5. – Adding/Deleting a Map

To add a new map, select the **Add Map** icon at the top of the 3D display window. This will clear all electrical points on the anatomy. When the first point is acquired a new, time-stamped entry will be recorded in the Map List.


Add Map


Delete


Close Map

To delete the active data set, select the **Delete** icon at the top of the 3D Display window. This will remove all the acquired data from the surface reconstruction.

Selecting the **Close Map** icon will return to the anatomy window. The current anatomy can now be edited, or a new anatomy or structure can be built.

18.6. – Copying a Map

To copy the Active Map click on the **Copy Map** icon at the top of the 3D display window. A new entry will be added to the list.


Copy Map

CHAPTER 19 — ACQMAP SYSTEM POWER DOWN

19.1. — Exporting Session Files

At the end of a study, the entire session can be exported for off-line review.

1. Prior to export, plug an external drive into the USB port at the rear of the workstation computer. To export an entire session, the drive should be at least 1Terabyte. While partial exports of sessions will be smaller the average size of a recording file is 3 GB.
2. Right click on any session in the Nav Window. In the menu, there will be two options: Export Entire Session or Export Partial Session.

NOTE: The Session must be exited before any file can be exported.

Export Entire Session

- Select the appropriate data compression and data options. Click **[OK]**.
- File explorer will prompt to save the file. Choose the location to save to and name the file. Click **[Save]**.
- A message will appear stating “Exporting data in background” and a lock will appear on the session being exported.

Export Partial Session

- A popup box will appear with the list of recordings and mappings available in the session for export.
- Select the recordings or maps to Export. Click **[Export]**.
- File explorer will prompt to save the file. Choose the location to save to and name the file. While exporting, the session will be locked.
- A message will appear at the top of the screen when the file has been successfully exported.

NOTE: If a recording is de-selected, all maps underneath will also be deselected.

NOTE: If a mapping is selected, the associated recording will also be selected.

NOTE: Only anatomies linked to a recording or map will be exported.

19.2. – Shutting Down the AcQMap System

AcQMap Workstation Shutdown

To safely shut down the AcQMap Workstation, first exit the current session. To exit the session, click on the **[Exit Session]** icon at the top of the screen.


Exit Session

This will close out the current session. Navigate to the file drop down menu and select **Exit**. This will exit the AcQMap system software and return the system to the Windows desktop. Exit Windows from the desktop.

WARNING: If the AcQMap Workstation is powered off by the user, rather than shutdown by the operating system, data on the hard drive may become corrupted and the AcQMap System may not operate properly.

AcQMap Console Shutdown

WARNING: The Patient Return Electrode must be the last Patient Electrode to be disconnected at the end of the study.

At the end of the procedure,

1. After removing:
   a. the AcQMap Catheter from the patient, disconnect it from the Console front panel.
   b. the ablation catheter from the patient and disconnect it from the Console front panel.
   c. any auxiliary catheters from the patient and disconnect them from the Auxiliary Interface Box.
2. Disconnect the ECG Input Cable and remove the Repositionable Monitoring Electrodes.
3. Remove the Localization Reference Electrodes and disconnect them from the Console front panel.
4. Remove the Patient Return Electrode from the patient's skin prior to disconnecting the electrode lead-wire from the Console front panel.
5. Power off the AcQMap Console using the Mains ON/OFF switch, located on the rear panel.

19.3. – Cleaning

- As needed, use a damp, non-abrasive cloth to clean the outer surfaces of the AcQMap Console, AcQMap Workstation, AcQMap Auxiliary Interface Box, and Cables.
- Isopropyl alcohol (70%) shall be used to clean the outer surfaces.
- Do not use abrasive cleaners.
- Do not attempt to clean any of the electrical connectors. Do not allow moisture or fluids to enter any of the electrical connectors or vents.

19.4. – Maintenance

- Only trained and certified service personnel will perform AcQMap System maintenance.
- Local standards and regulations should be followed with respect to periodic performance verification.
- Any AcQMap System component exposed to excessive shock, vibration, or any mishandling should be returned to the manufacturer for evaluation.

19.5. – Service

Only trained and certified personnel will perform Service. Contact your AcQMap System representative or distributor for service and technical support. Do not service the Console or Workstation while the System is in use with a patient.

19.6. – Replace the Console Fuse

1. The AcQMap Console includes two fuses that can be replaced in the field. Only qualified technical or hospital personnel should replace the fuses.

WARNING: Disconnect power before replacing the AcQMap Console fuses. Failure to disconnect power may result in serious injury or death.

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2. Disconnect the power cord.
3. Using a screwdriver, carefully open the door of the fuse housing.
4. Remove the cartridge.
5. Replace the fuses. See Technical Specifications for correct fuse rating.
6. Replace the cartridge
7. Close the fuse-housing door.

19.7. – Disposal of Durable Components

The durable portions of the AcQMap System shall be disposed of in accordance with local regulations. All electronics in the System are ROHS compliant. As such, they may be recycled by any electronics recycler.

CHAPTER 20 – TECHNICAL DESCRIPTION

20.1 System Specifications

Operating Environment

Operating temperature and humidity	15° to 30°C, 15% to 75% relative humidity, non-condensing
Shipping temperature and humidity	0° to 60°C, 15% to 95% relative humidity, non-condensing
Storage temperature and humidity	5° to 30°C, Maximum: 75% relative humidity, non-condensing
Elevation rating	The System is rated for operation up to 2000 meters (6500 ft) above sea level
Ingress Protection	The Console is rated IP20
Safety information	IEC 60601-1, Class I, Type Defibrillator Protected CF, continuous operation, no sterilization, equipment not suitable for use in the presence of a flammable anesthetic mixture with air, oxygen or nitrous oxide

20.2 AcQMap Console

Physical characteristics

Dimensions	99 L x 58 W x 76 D cm
Weight, maximum	80 kg
Power requirement	100-127 VAC, 50/60 Hz, 220-230 VAC, 50 Hz
Input current	4.6 A
Fuse protection	250 V, 6.3 A, two high breaking capacity fuses (user accessible)

Functional and performance characteristics

Ultrasound Output	Frequency: 10 MHz +/- 400 kHz Maximum Voltage: 50V p-p Maximum Power: 1 W peak
Ultrasound Performance	Single operating mode Thermal Index less than 1.0 Mechanical Index less than 1.0
Localization Output	Frequency: Variable 15 kHz to 50 kHz Maximum current: 1.2 mA RMS
ECG & EGM Input	Bandwidth: 0.05 Hz to 500 Hz Resolution: +/- 1uV Timing Accuracy: +/- 1.6 microsecond

NOTE: ECG limb lead outputs operate a minimum of 3 minutes without AC power.

NOTE: Operation of the AcQMap System with signals smaller than 10uV peak may result in inaccurate results.

Front panel connections

AcQMap Catheter	Custom, black, Defibrillator Protected Type CF
ECG Input	12-pin, latching, red, Defibrillator Protected Type BF
ECG Output	14-pin, latching, blue
Auxiliary Interface Box	Custom, green
AcQRef Introducer Sheath or Electrical Reference Catheter	1, 2mm female, yellow, Defibrillator Protected Type CF
Localization Reference Electrodes	6, 2-pin, square, multi-color, Defibrillator Protected Type BF
Patient Reference Electrode	1, 2-pin, square, blue, Defibrillator Protected Type BF
Ablation Generator	10-pin, latching, grey
Ablation Catheter	10-pin, latching, grey, Defibrillator Protected Type CF
Ablation Reference	1, 2mm, female, black, Defibrillator Protected Type BF
Ablation Electrogram Interface	1, 13-pin, latching, white

Rear panel connections

AcQMap Workstation	Dual LC fiber optic
System Ground	Equipotential ground post
Power inlet	IEC type 320 with power cord retention

NOTE: The Equipotential ground post is a terminal for connection of an equipotential conductor. The post is designed to prevent accidental disconnection of the equipotential conductor.

Power cord specification

Length	2.5 m
Plug type	Hospital grade
Connector type	IEC 60320 C13
Current rating	10 A
Voltage rating	250 VAC
Conductor size	3 x 1.5mm^2

20.3 AcQMap Auxiliary Interface Box

Physical characteristics

Dimensions	13 H x 36 W x 11 D (cm)
Weight	3 kg

Connections

AcQMap Console	Custom, green
Catheter Input	40, 2mm female, green, Defibrillator Protected Type CF
Catheter Output	40, 2mm female, black, Defibrillator Protected Type CF

20.4 AcQMap Workstation

Physical characteristics

Dimensions	179 (max) H x 90 W x 94 D (cm)
Weight	55 kg

Components

Portable cart	Ergotron
Desktop computer	Single processor with a minimum of 10 cores operating at 2.5GHz or higher, 32 GB of RAM or higher, 512 GB solid state hard drive or higher, Motherboard capable of accepting a Nvidia Quadro K4000 series GPU or higher
Color display	38” diagonal, 1280 x 1920 minimum resolution, capable of 60Hz or greater update rate, contrast ratio of 400 or higher
Keyboard	Wired USB
Mouse	Wired USB
Power Strip	10A @ 250VAC Resettable circuit breaker

WARNING: Only the AcQMap Desktop Computer and Display may be powered by the Workstation power strip. Do not power any other devices from the power strip. Connecting unauthorized equipment to the power strip may cause the circuit breaker to trip, resulting in loss of power to the AcQMap Workstation and Display.

AcQMap Workstation connections

AcQMap Console	Dual LC fiber optic (isolated)
Power inlet	IEC type 320
Color display output 1	VGA, connected to desktop computer (display port)
Color display Output 2 (optional)	VGA, connected to desktop computer (display port)
Keyboard	USB
Mouse	USB

AcQMap Workstation Power Consumption

Workstation Computer	6.9 Amps, maximum
Monitor	1.5 Amps, maximum
Total	8.4 Amps

20.5 AcQMap System Cables

Physical characteristics

Description	Model	Length
Workstation Cable	800255	32.81 feet (10m)
ECG Input Cable	800532	113 inches (2.87m)
ECG Output Cable	800424	113 inches (2.87m)
Ablation Reference Cable	800505	60 inches (1.52m)
Ampere Ablation Generator Adapter	800431/800623	11 inches (0.27m)
Ampere Ablation Catheter Adapter	800430	11 inches (0.27m)
MAESTRO Adapter Cable, AcQMap → Ablation Catheter	800510	11 inches (0.27m)
MAESTRO Adapter Cable, AcQMap → MAESTRO	800511	35 inches (0.89m)
Ablation Electrogram Interface Cable	800508	80 inches (2.03m)
ECG Out w/snaps Cable	800525	89 inches (2.26m)
ECG POST Cable	800526	22 inches (0.56m)
2mm Pin Jumper Set	800523	40 inches (1.01m)
AcQMap POAG Cable	800405	9.84 feet (3.0m)

20.6 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
$TIS_{non\text{-}scan}$	The Soft Tissue Thermal Index in a non-scanning mode
TI	Thermal Index

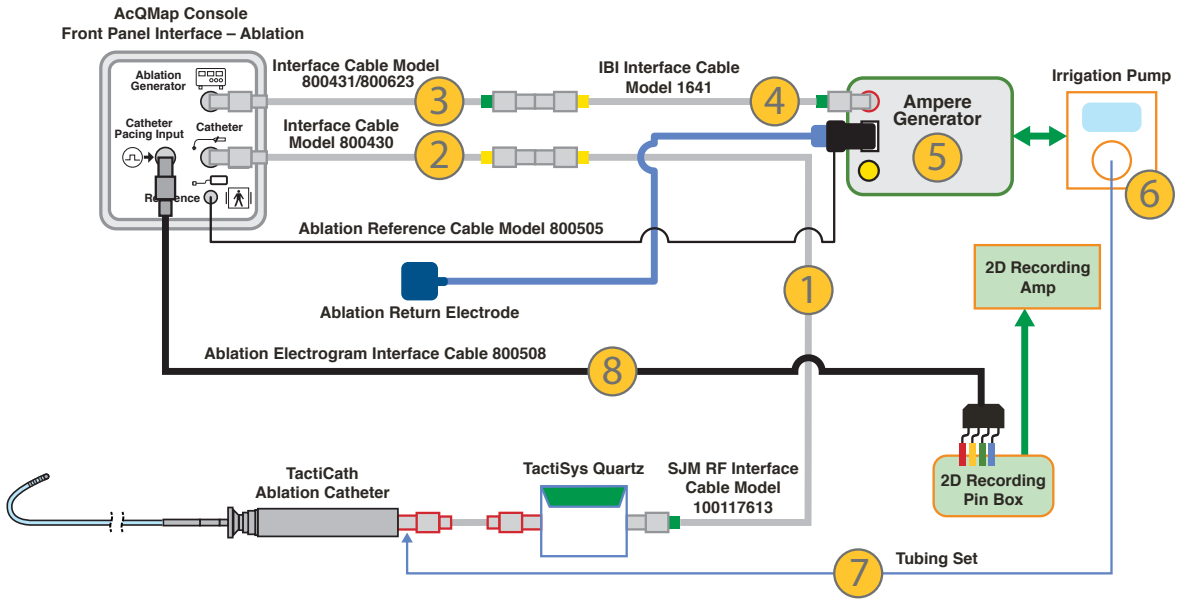
APPENDICES

APPENDIX A — CONNECTING ACQMAP WITH ADJUNCT EQUIPMENT

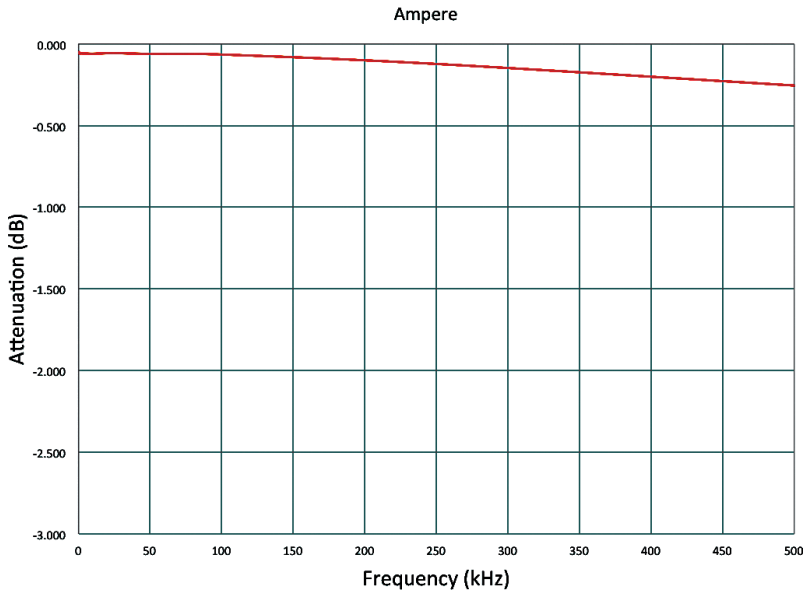
The AcQMap System has been tested with the following Ablation Generator Systems: Ampere, SmartAblate, Stockert 70 and MAESTRO 4000. The diagrams below show the connections required for ablation catheter localization and RF energy delivery.

NOTE: Connecting to the AcQMap Console may increase the observed impedance measured by the RF ablation generator by a maximum of 7Ω.

A-1. Ablation Configuration: Ampere/TactiCath

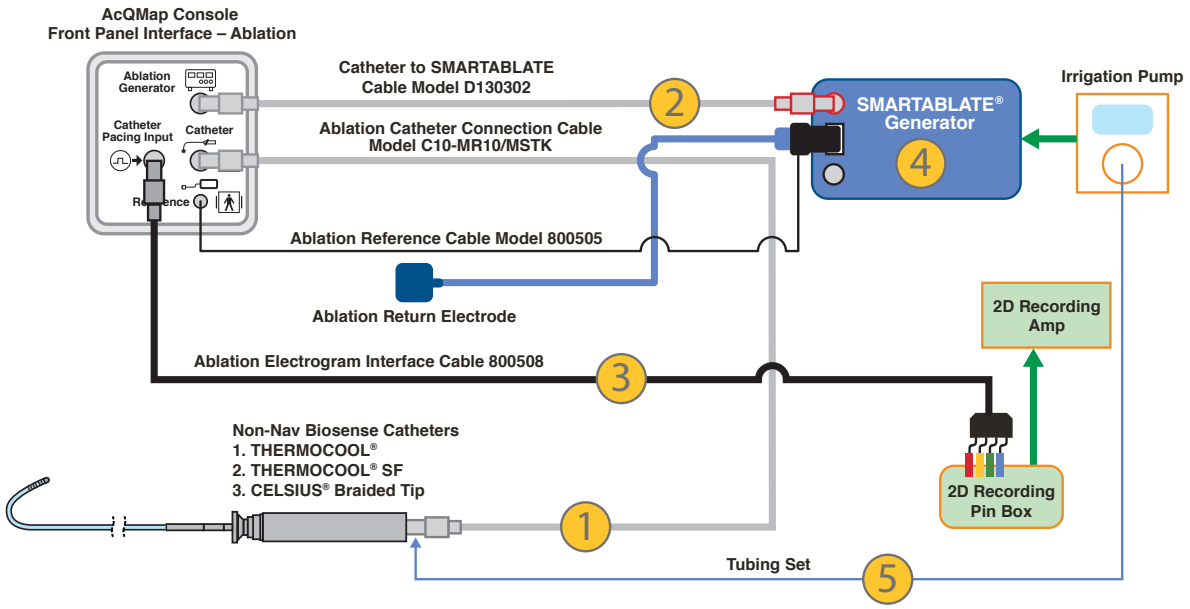


Item #	Description	PN
1	SJM RF Interface Cable	100117613
2	Ampere Adapter Cable: AcQMap to Ablation Cable	800430
3	Ampere Adapter Cable: AcQMap to Ampere	800431/800623
4	IBI RF Interface Cable	1641
5	Ampere RF Ablation Generator Kit	H700494
6	CoolPoint Irrigation Pump/Cable	IBI-89003 & IBI-85786
7	CoolPoint Irrigation Pump Tubing	85785
8	Ablation Electrogram Interface Cable	800508

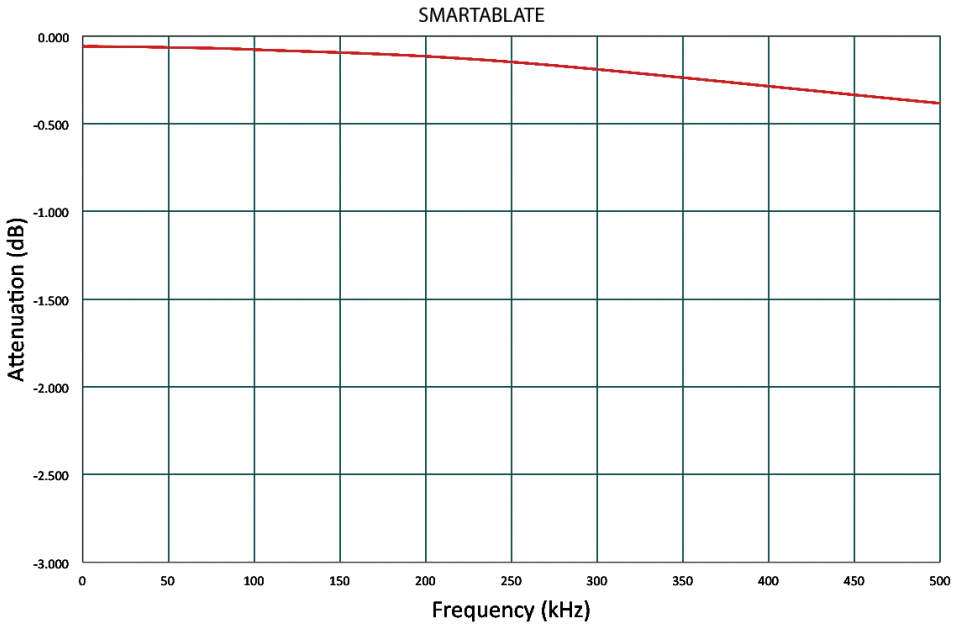


Attenuation of signals using the Ampere Generator and the AcQMap Console front panel

A-2. Ablation Configuration: SMARTABLATE

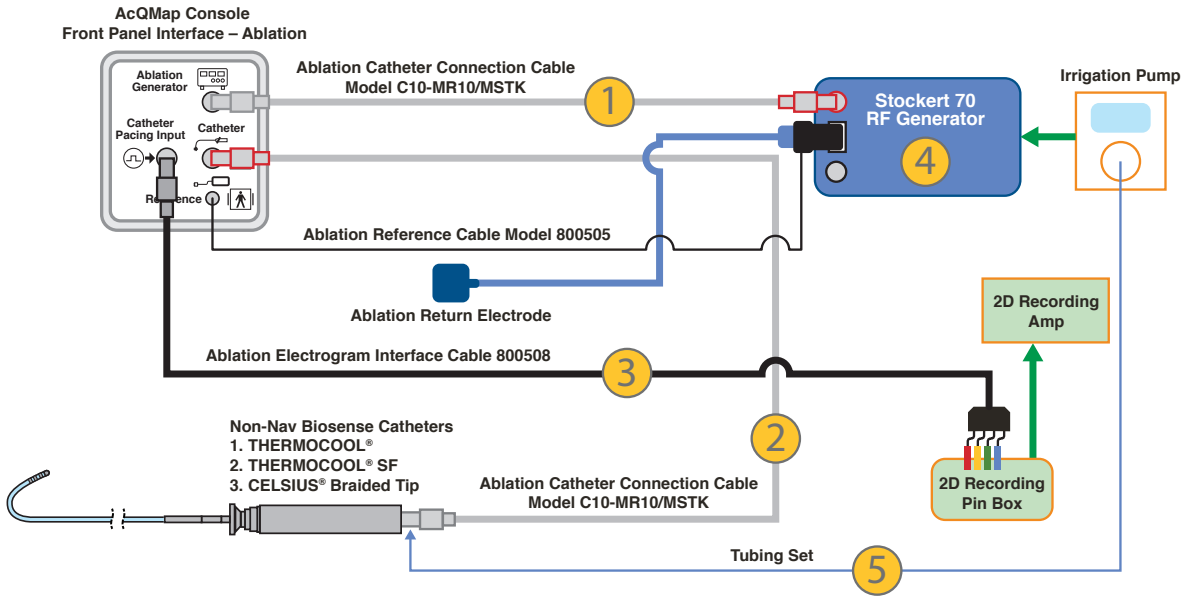


Item #	Description	PN
1	Stockert 70 RF Interface Cable	C10-MR10/MSTK
2	Catheter to Smart Ablate Interface Cable	D130302
3	Ablation Electrogram Interface Cable	800508
4	SMARTABLATE System Kit	M490006
5	SMARTABLATE Pump Tubing	SAT001

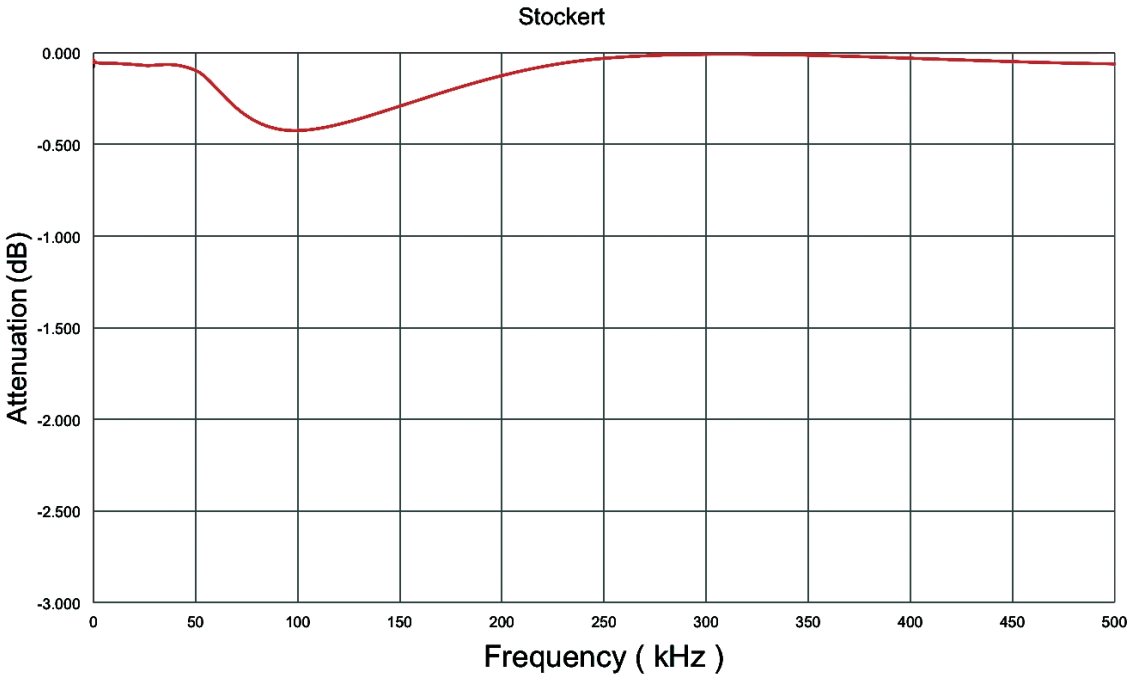


Attenuation of signals using the SMARTABLATE Generator and the AcQMap Console front panel

A-3. Ablation Configuration: Stockert 70

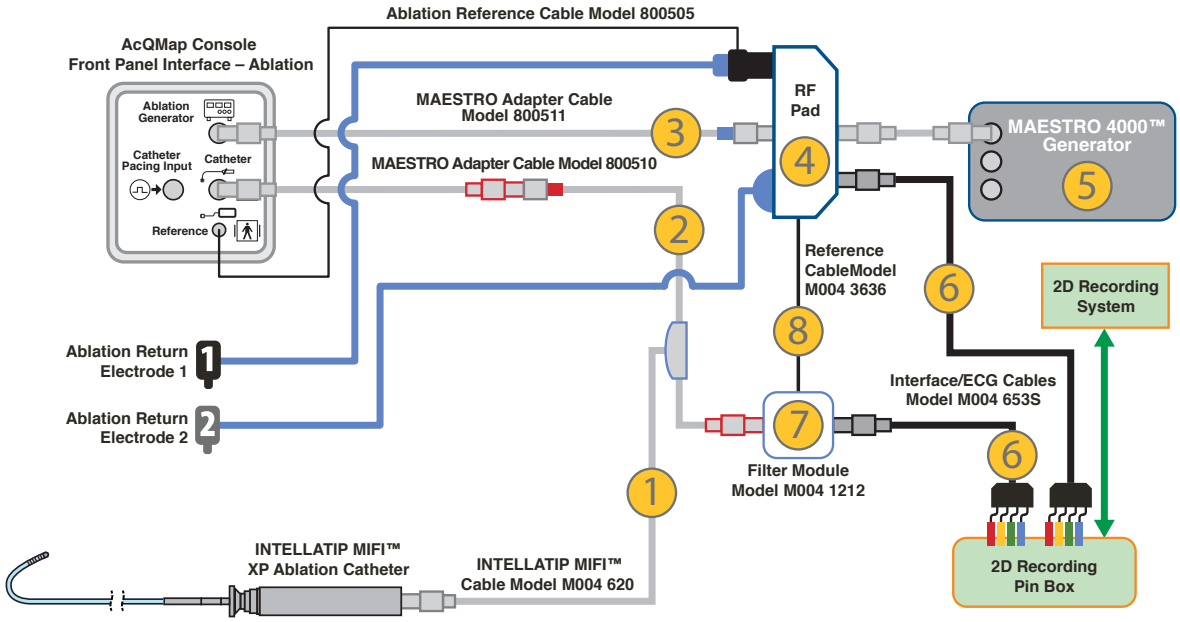


Item #	Description	PN
1	Stockert 70 RF Interface Cable	C10-MR10/MSTK
2	Stockert 70 RF Interface Cable	C10-MR10/MSTK
3	Ablation Electrogram Interface Cable	800508
4	Stockert 70 RF Generator	S-7001
5	CoolFlow Pump Tubing	CFT001

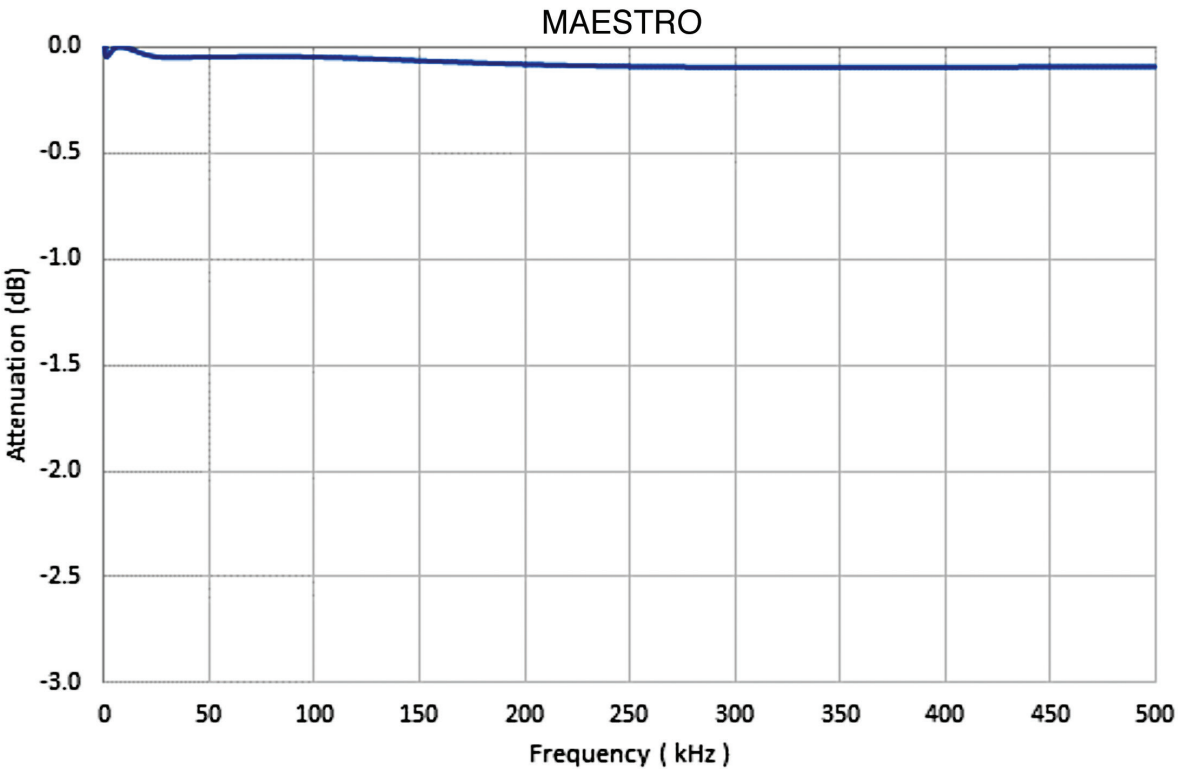


Attenuation of signals using the Stockert Generator and the AcQMap Console front panel

A-4. Ablation Configuration: MAESTRO 4000 with INTELLATIP MIFI XP



Item #	Description	PN
1	INTELLATIP MIFI XP Cable	M004 620 0
2	MAESTRO 4000 Adapter Cable: AcQMap to INTELLATIP	800510
3	MAESTRO 4000 Adapter Cable: AcQMap to MAESTRO	800511
4	RF Ablation Pad	M004 21860T 0
5	MAESTRO 4000 Controller (RF Generator)	M004 0000 0
6	ECG Cables	M004 653S 0
7	INTELLATIP MIFI XP Filter Module	M004 1212 0
8	Reference Cable: RF Pod to Filter Module	M004 3636 0



Attenuation of signals using the MAESTRO Generator and the AcQMap Console front panel

Setup Communication between AcQMap and Stereotaxis Navigant

Network configuration

1. Open Network and Sharing Center.
2. Click on [Change Adapter Settings] from the lefthand pane.
3. Right click the appropriate adapter and go to Properties.
4. Uncheck all settings except Internet Protocol Version 4 and click [OK].
5. Highlight Internet Protocol Version 4 and click the [Properties] button.
6. In the General window check use the following IP address radio button and fill in the following
    a. IP address: 192.168.168.110
    b. Subnet mask: 255.255.255.0
7. Click the [OK] button.
8. Close the Local Area Connection Properties dialog box.

Physical connection

1. Locate the corresponding network adaptor connection on the AcQMap workstation
    a. Connect a Cat-5 ethernet cable to the identified network adapter
    b. Connect the other end to the Stereotaxis switch

Verify connectivity

1. Open a command prompt or PowerShell
    a. Type in the following at the prompt: 192.168.168.3
    b. Verify the ping is successful.

When the connection between the two systems has been established, two checkboxes will be visible in the Acquisition Window on the the AcQMap Workstation.

Navigant in Procedure: indicates that the systems are connected. (Checkbox cannot be unchecked.)

Navigant View in Sync: When the Navigant View in Sync checkbox is checked, the anatomy that appears in the left viewport of the AcQMap Acquisition Window will be aligned to what is seen in the Navigant display.

APPENDIX B — MANUAL CONFIGURATION OF ORIENTATION REFERENCE

In the event that the automatic phase calibration fails to generate the correct Left/Posterior/Superior (LPS) orientation (X-axis = Left, Y-axis = Posterior, Z-axis = Superior), a manual configuration may be used to orient the axes.

Manual configuration of the orientation reference is accessed via the Localization Configuration Panel. Click the **[Settings]** button in the Localization Settings Loading panel.

Select Configure Manually and click **[Next]** to advance to the Anatomic Reference and Auxiliary Catheter setup screen.

Place a check in the Manual Orientation box under Advanced settings. Click **[Next]**.

The Anatomic Reference Matrix screen will appear. The Anatomic Reference Matrix allows the manual definition of the LPS relationship between the connected Anatomic Reference Electrodes.

Matrix entries with values of "0" are inactive. Matrix entries with non-zero integer values designate a channel number of the AcQMap System. Entries that exceed the channel count of the AcQMap in the left two columns or that exceed the number of Auxiliary channels in the right two columns are invalid.

The three rows of the matrix assign relative orientation. Only two of the three rows are required to be defined.

The columns of the matrix define channel relationships. The left two columns are for AcQMap channels and the right two columns are for Auxiliary channels. In most cases, only the right two columns will be used to manually configure the orientation reference.

Within each pair of columns, the left column designates the first relative position of the pair, and the right column designates the second relative position of the pair.

Click **[Finish]** to commit the configuration and return to the 3D Display.

APPENDIX C — ANATOMIC REFERENCE ELECTRODES – PHYSICAL POSITION REFERENCE

The Anatomic Reference Channels are used to establish a common-mode motion signal with the AcQMap Catheter for respiratory and cardiac motion rejection. Adequate common-mode motion rejection is critical to minimizing error in surface reconstruction.

The choice of channels for anatomic referencing directly affects the quality of the common-mode motion rejection. If the chosen channels do not have a predominantly common-mode motion component with the AcQMap Catheter, the use of an Auxiliary Catheter for anatomic reference may become detrimental and in some cases substantially slow. Therefore, care should be given both to the choice of Anatomic Reference Channels, as well as to the maintenance of a static position of those electrodes throughout a set of anatomically-registered recordings.

The following are the suggested steps for selecting Anatomic Reference Channels:

1. Set the Anatomic Reference mode to “None”
2. Assess the motion of the AcQMap Catheter within the 3D Display.
    a. Position the AcQMap Catheter near the center of the chamber, minimizing contact with the cardiac surface when possible.
    b. Disable the display of Auxiliary Catheters.
    c. With the AcQMap Catheter undisturbed, observe the motion of the AcQMap Catheter from several viewing angles.
    d. If the motion of the AcQMap Catheter is minimal through both respiratory and cardiac cycles, use of an Auxiliary Catheter as an Anatomic Reference may not be necessary. If the motion of the AcQMap Catheter is significant through both the respiratory and cardiac cycles, continue with the selection of Anatomic Reference Electrodes.
3. If not already enabled, enable the display of all Auxiliary Catheter connections that have been made to the AcQMap System.
4. Assess the motion of the AcQMap Catheter with respect to the Auxiliary Catheter electrodes within both 3D displays and under fluoroscopic imaging.
    a. Observe and note individual or sections of auxiliary electrodes that move in the same direction and with the same magnitude as the AcQMap Catheter.
    b. Use fluoroscopy to quickly check the observation of common-mode motion.
5. Enter the channel numbers of the selected electrodes into the Anatomic Reference Electrodes text box and click **[Apply]**.

6. Switch the Anatomic Reference mode from “None” to “Translation Only” and observe how the motion of the AcQMap Catheter changes under each mode.
   a. The AcQMap Catheter should be displaced less through the respiratory and cardiac cycles when the Anatomic Reference is used with well-selected electrodes.
7. With the Anatomic Reference mode set to “Translation Only”, repeat steps 4-6 above, editing the selected list of electrodes with each attempt.
   a. Observing the motion of both AcQMap Catheters and Auxiliary Catheters under “Translation Only” reference mode will accentuate any relative motion between them.
   b. If any electrodes among the selected reference channels are moving with an apparent angular rotation to the AcQMap Catheter, it may be advisable to remove these from the list of Anatomic Reference Electrodes.
   c. Each time that either mode is used verify, that the use of an auxiliary catheter as the Anatomic Reference REDUCES the motion of the AcQMap Catheter by comparing to the “None” setting.

APPENDIX D — TROUBLESHOOTING ULTRASOUND

The AcQMap System is configured to best balance the sensitive detection of reflected acoustic signals from the chamber surface with the rejection of noise that would compromise the accuracy of the measured range to the surface. However, the behavior and interaction of the AcQMap System channels and the AcQMap Catheter transducers that is out-of-balance and produces consistent or intermittent ranging errors is an unavoidable possibility. Therefore, proper identification of these channels and disassociation of their ranging results from the surface reconstruction is paramount in producing an accurate anatomy. Below are a number of troubleshooting steps and examples of Ultrasound data that will aid in proper identification of errant Ultrasound channels.

Ultrasound channel functionality is assessed from the Ultrasound histogram view in the Live Signals window. (*Figure D-1*).

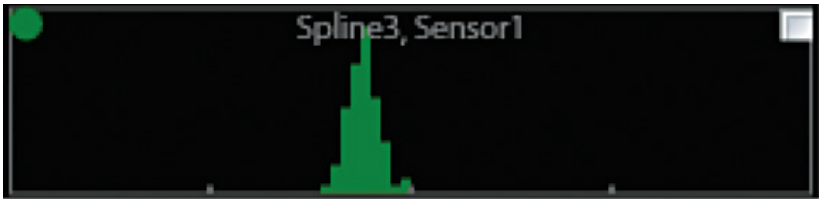


Figure D-1. Ultrasound histogram plot for Spline 3, Sensor 1.

The X-axis of the histogram is range (mm), with hash marks identifying 20mm intervals. Ranges are binned in 1mm increments. The Y-axis of the histogram is the amount of data within each range bin. The data shown in each histogram corresponds to the data within a specified time interval from a single transducer. The Sample Interval is user-configurable to be infinite or 1, 3, or 10 seconds.

The Y-axis units and markers are not shown because the Y-scaling between plots is configurable on an individual, spline, or whole catheter basis.

NOTE: The surface reconstruction interprets all measured ranges falling in between the minimum and maximum reject intervals as valid data. Therefore, an Ultrasound transducer reporting no range data is preferable to one reporting errant range data.

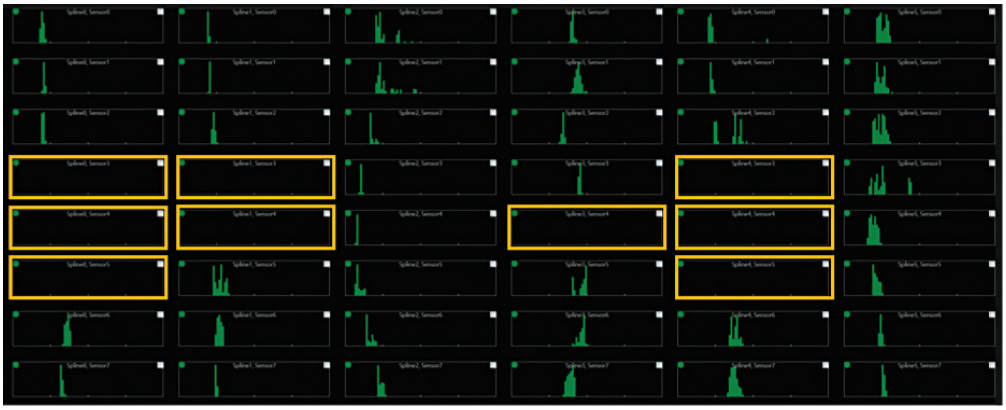


Figure D-2. Ultrasound transducers reporting no range data.

NOTE: Acoustic detection of the chamber surface is dependent on many factors, including range, angle of incidence, target reflectivity, motion, etc. In an *in vivo* state, not all areas of the chamber's surface reflect equally. Some structures will be consistently more challenging to image (e.g., pulmonary veins, appendages, etc.) while others will be intermittently detected (e.g., SVC/IVC, valves, etc.). Consideration of possible anatomic structures should be included in the assessment of Ultrasound channel functionality.

The following procedure is recommended for Ultrasound assessment:

1. Place the AcQMap Catheter near the center of the chamber of interest, minimizing the number of transducers in contact with the chamber's surface.
2. Observe the histogram plots from a static position for a few seconds. The histogram plots provide an example of a fully functional set of Ultrasound transducers for an AcQMap Catheter in an *in vivo* static position.

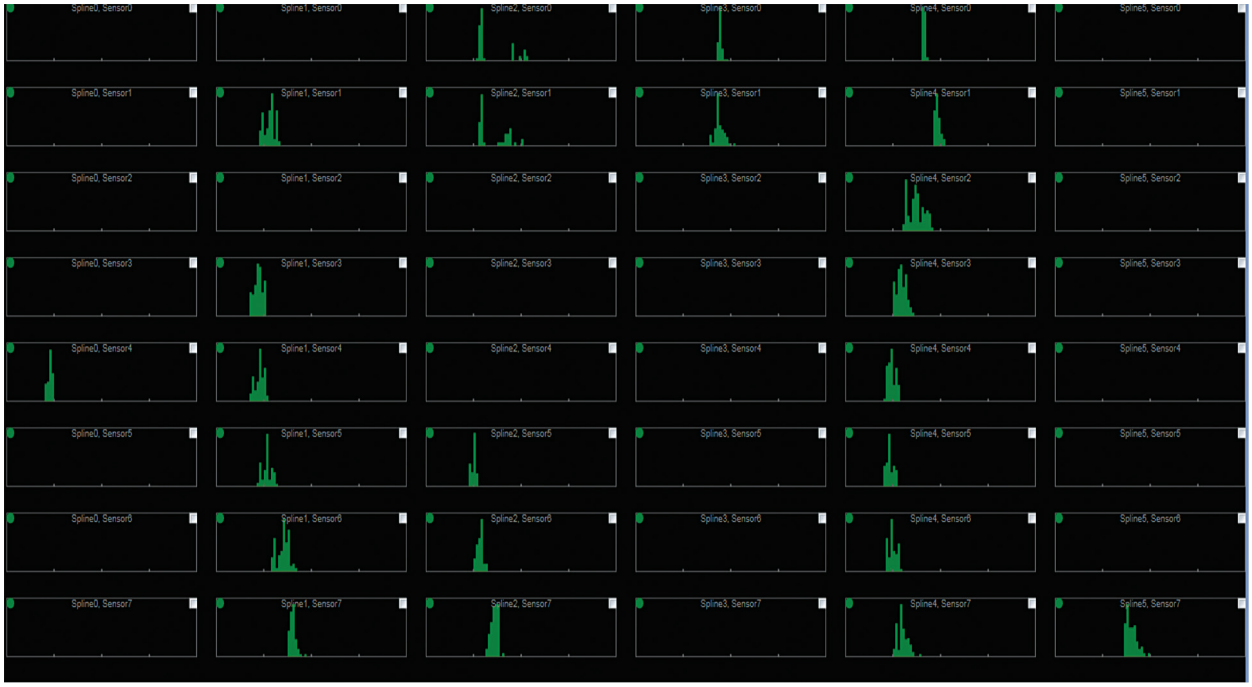


Figure D-3. Example of a fully functional set of Ultrasound transducers in an in vivo *static position.*

NOTE: The range signals in each histogram are distributed about a mean within a range consistent with cardiac wall motion or AcQMap Catheter motion during the cardiac cycle. There is also noticeable structure down the length of several splines (columns). Ranges across splines are consistent around the AcQMap Catheter. Voids in data are also generally regionalized.

3. Slowly rotate the AcQMap Catheter about its central axis. The pattern of detected surface should remain consistent, but slowly transition leftward or rightward, depending on the direction of rotation.
4. No targets should report the same range throughout a rotation of the AcQMap Catheter. (*Figure D-4*).

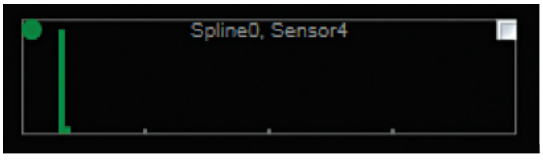


Figure D-4. Example of a static range difference throughout AcQMap Catheter rotation.

5. Similarly, detected ranges should not spread over a range that is larger than expected for wall or AcQMap Catheter motion, particularly in a static position. Excursions over a large distance will also be noticeably swept laterally within histograms. The plot in *Figure D-5* shows several nodes with detected range distributions extending beyond a reasonable excursion distance. These nodes are detecting noise and should be excluded by clicking the white checkbox in the upper, right corner of each errant histogram.

   The broad, sparse distributions shown in *Figure D-5* are consistent with a low level of noise being detected. Typically, a small reduction in detection gain or an increase in detection threshold will return the range detection behavior to normal.

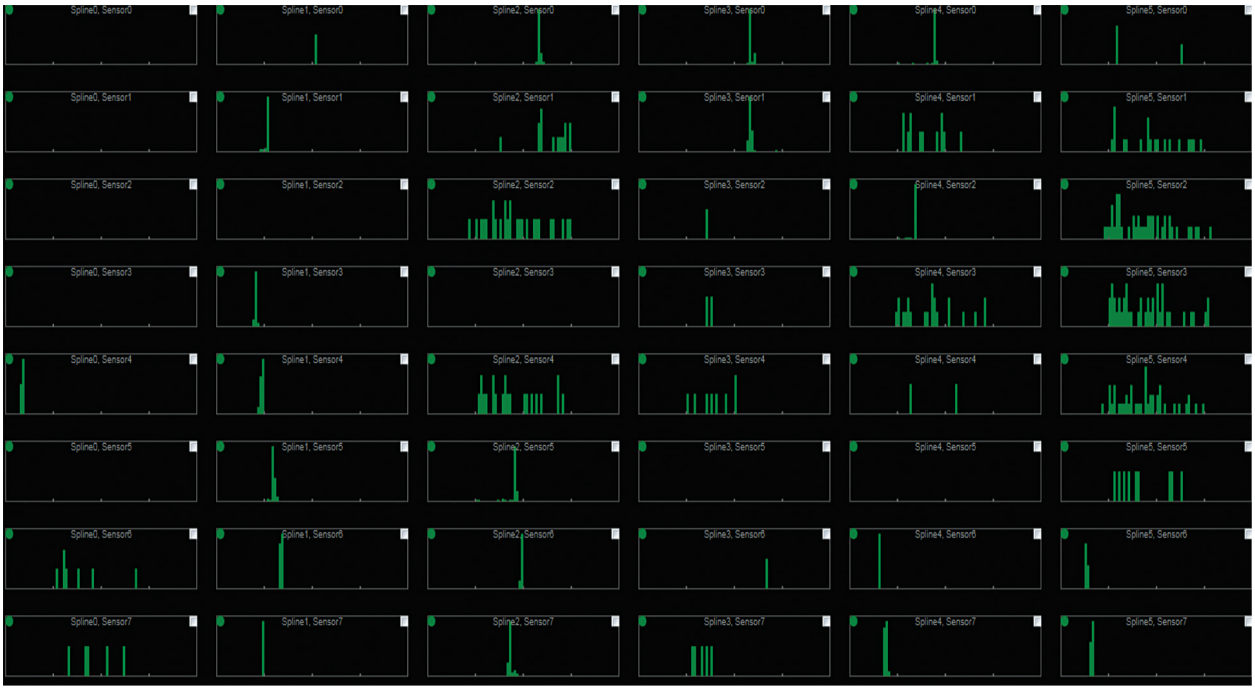


Figure D-5. Example of several nodes with detected range distributions extending beyond a reasonable excursion distance.

6. The Ultrasound detection gain and threshold are configured for typical operation. On occasion, the gain or threshold settings may be overly sensitive and noise will be detected immediately after the end of the minimum reject interval. With asynchronous noise, the errant, detected ranges will be exhibited as a skewed distribution (*Figure D-6*), with a hard limit on the left-hand side at the minimum reject interval.

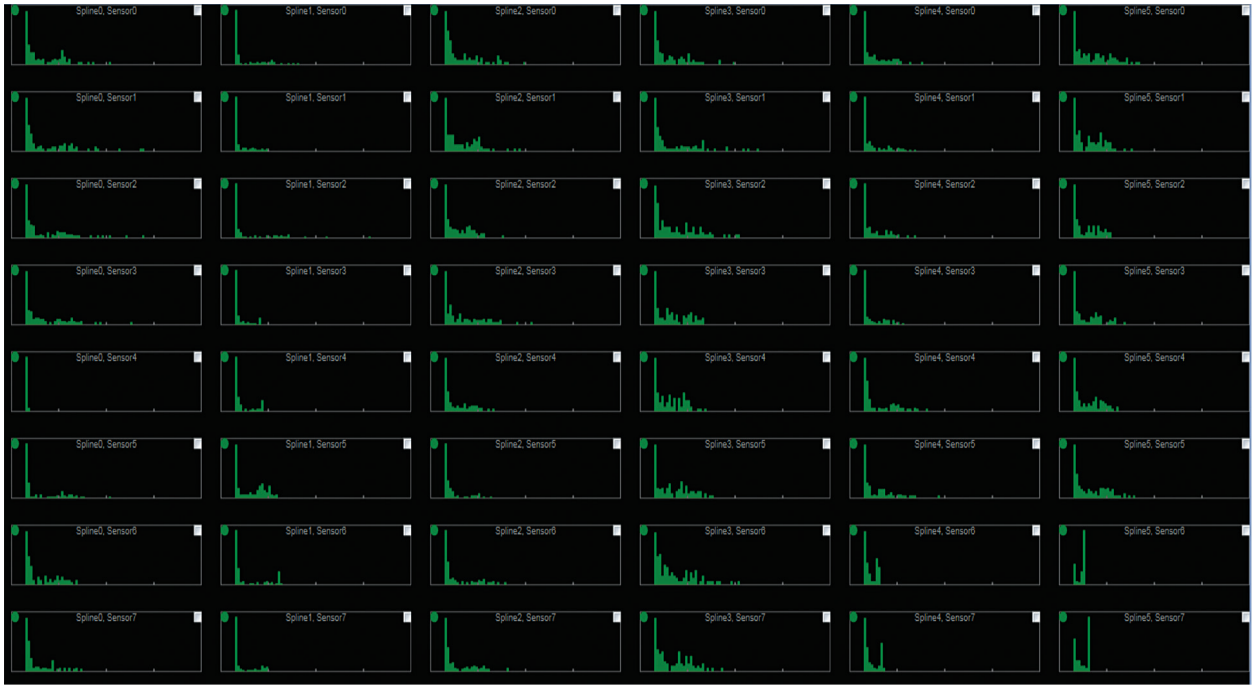


Figure D-6. Example of asynchronous noise displaying as a skewed distribution.

NOTE: The hard limit on the left is consistent from channel to channel in the plot in *Figure D-6*. This is a clear indication of a high level of noise being detected. Detection gain and threshold should be adjusted to reduce this behavior. Nodes marked as “excluded” should be entered in the “Excluded Ultrasound Channels” list under the Build menu.

APPENDIX E — MANUAL CATHETER REGISTRATION

The AcQMap System uses impedance, electric field and ultrasound measurements to establish and maintain accurate registration of the AcQMap, Auxiliary and Ablation catheters in the chamber anatomy. Over the course of a procedure, it is possible under specific circumstances that the registration of the catheters can shift from the original position. If a shift is recognized, the catheters can be manually registered within the chamber using the Manual Registration Editor.

The Manual Registration Editor is accessed through the Acquisition Window.

1. Click on the **Editor** icon located at the top, center of the 3D Display split screen.


Editor

NOTE: After accessing the Manual Registration Editor the chamber views will automatically switch to AP view in the left display and Cranial (H) in the right view.

2. Right-click on either display and drag the catheters to the desired registration location. All the catheters will move in unison.
3. Activate the Ultrasound to ensure the ultrasound vectors are approximating the chamber wall. (*Figure E-1, Panel A*) Left click to rotate the chamber views to help verify that the Chamber Surface matches the ultrasound points. (*Figure E-1, Panel B*)

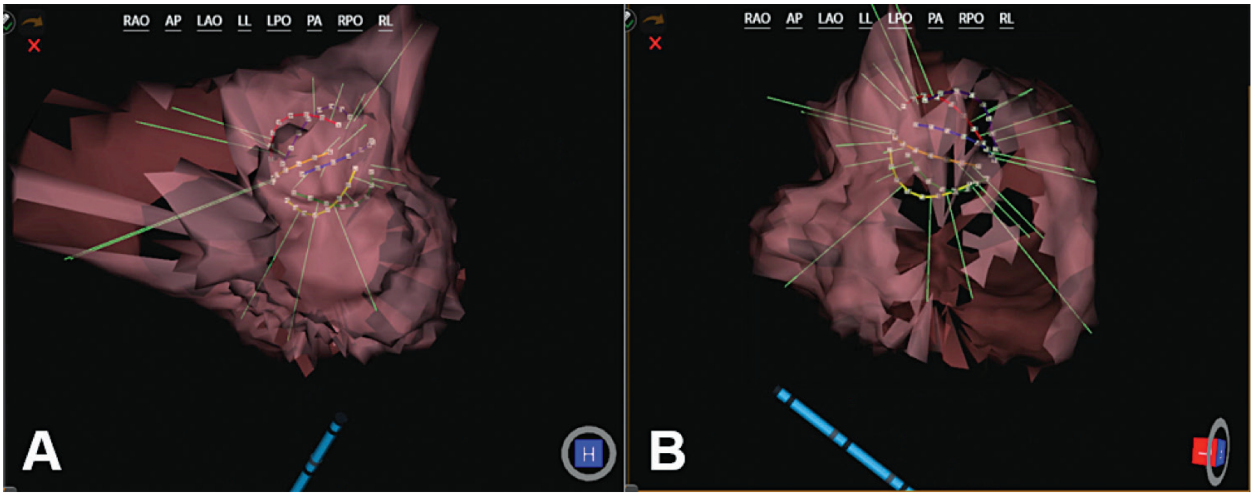


Figure E-1. Panel A. The ultrasound vectors appear to approximate the chamber surface. Panel B. Rotating the chamber, (L) verifies the ultrasound vectors are approximating the chamber surface.

4. Changes can be undone, redone or canceled prior to confirmation. The **Undo** arrow will undo any changes, the **Redo** arrow will redo the last change made, and the red **X** will cancel any changes.
5. Clicking the **Confirm Change** icon will activate the manual registration and exit the Editor mode.


Undo


Redo


Cancel


Confirm Change

NOTE: If the Start Recording button is pressed before exiting the Manual Registration Editor all changes will be canceled. Changes must be confirmed and the Manual Registration Editor exited before the changes are committed.

APPENDIX F – ACQMAP SYSTEM KEYBOARD SHORTCUTS

Task	Keyboard Shortcut	Results
Panning	Q or Shift + ↑	Move the image up on the screen
	Z or Shift + ↓	Move the image down on the screen
	A or Shift + ←	Move the image to the left on the screen
	D or Shift + →	Move the image to the right on the screen
Ultrasound Acquisition	Ctrl + U	Toggle ultrasound off and on
Surface Editor	Alt + R	Select faces and vertices of the Surface Anatomy in bulk using a rectangle
	Shift + Alt + R	Rectangle cut through – front and back
	Alt + E	Select faces and vertices of the Surface Anatomy in bulk using an ellipse
	Shift + Alt + E	Elliptical cut-through
	Delete	Delete selected points and faces from the display
	Ctrl + Z	Undo
	Ctrl + Y	Redo
	Esc	De-select all selected points and faces
Playback	→	Advance time forward
	←	Advance time backward
Placing Markers	F2 + Right Click	Place the selected marker type at the mouse location on the anatomy
	F3 or Space	Place a marker at the location of a user-selected active electrode (e.g., ablation catheter tip). If the user-selected active electrode is within 4mm of the reconstructed Surface Model, the marker will be placed at the nearest location on the reconstructed Surface Model. **NOTE**: Holding **[Shift + F3]** while placing the marker will optionally place the marker at the location of the user-selected active electrode.
Deleting Markers	Right Click on Marker	Brings up details about the Marker – Left click on delete to remove the Marker
	Right Click on Marker in Current Marker List	Brings up a pop out list to select delete to remove the Marker
	Click on selected Marker in Current Marker List	Highlights the Marker name in the Current Marker List, Marker flashes on Surface, Use delete key to remove Marker
Placing Labels	F4 + Right Click	Place the selected label type at the mouse location on the anatomy
Deleting Labels	Click on the Label in the Current Label	Highlights the Label in the list, use delete key to remove Label
	Right click on the Label in the Current Label	Select delete from the pop out list to remove the Label
Reset Data Stream	Ctrl + Alt + R	Pauses and restarts the data stream

APPENDIX G – POST AND FUNCTIONAL TEST STATUS INDICATORS

Status Indicators during Console POST

Status Indicator	Description
	Controller Board Power Up and Self Test
	Daughter Board Power Up and Self Test
	Daughter Board Verification and Super Cap Charging

Troubleshooting POST

Description	Status Indicator	Recommended Action
Functional Test does not pass	Status indicators are not all green (See below – Status indicator states)	Close Functional Test and re-open it. Re-initiate Functional Test. If after completion of Functional Test, the status indicators are not all green, disconnect workstation and shut down the console. Wait 20 seconds then restart the console. Observe the status indicator lights. Contact Acutus Medical and report the status indicator state. (See chart below of status indicator states)
ECG Cable test fails (See Appendix J for instructions to run the ECG Cable test)	All indicators are red – right and left indicators are blinking 	Check connections to the ECG Interface test box. Ensure that all connections are secure. Replace AcQMap ECG Input Cable, Model 800532. Close Functional Test and re-open it. Select ECG Cable Test, then launch Functional Test. If after completion of Functional Test, the status indicators have not changed, contact Acutus Medical and report the status indicator state.
During clinical operation, a console error is detected	All status indicators will be red and blinking 	Shutdown the Console. Wait 20 seconds before restarting the Console. If Console POST passes all indicators will turn green. Close the AcQMap software application. Re-run Functional Test. If Functional Test passes, all indicators will turn green. If after completion of Functional Test, the status indicators are not all green, contact Acutus Medical and report the status indicator state. (See chart below of status indicator states)

Status Indicator States

Status Indicator	Description
POST Console Indicators	
	Power up failure
	Daughter Board POST failure
	Daughter Board configuration failure
	Backup Power Failure
Functional Test	
	System communication failure
	Functional Test ECG Cable failure
	Functional Test Bio/Source Board failure
	Functional Test Ultrasound Board failure
Clinical Operation	
	Console Error

B = BLINKING

APPENDIX H – DECLARATION OF ELECTROMAGNETIC EMISSIONS

Guidance and Manufacturer's Declaration of Electromagnetic Emissions		
The AcQMap System is intended for use in the electromagnetic environment specified below. The customer or end user of the AcQMap System should assure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic Environment
RF emissions CISPR 11	Group 1	The AcQMap System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The AcQMap System is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration of Electromagnetic Immunity			
The AcQMap System is intended for use in the electromagnetic environment specified below. The customer or the end user of the AcQMap System should assure that it is used in such an environment.			
Immunity Test	IEC60601 Test Level	Compliance Level	Electromagnetic Environment
Electrostatic Discharge (ESD) IEC 61000-4-2	±8kV contact ±2kV, ±4kV, ±8kV, ±15kV air	±8kV contact ±2kV, ±4kV, ±8kV, ±15kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2kV 100 KHZ repetition frequency	±2kV 100 KHZ repetition frequency	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±0.5kV, ±1kV, ±2kV line to ground ±0.5kV, ±1kV line to line	±0.5kV, ±1kV, ±2kV line to ground ±0.5kV, ±1kV line to line	Mains power quality should be that of a typical commercial or hospital environment.

Voltage dips Voltage interruptions, and Voltage variations on power supply lines IEC 61000-4-11	0 % UT; 0,5 cycle, @ 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% UT; 1 cycle and 70% UT; 25/30 cycles, @ 0° 0 % UT; 250/300 cycl	0 % UT; 0,5 cycle, @ 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% UT; 1 cycle and 70% UT; 25/30 cycles, @ 0° 0 % UT; 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the AcQMap System requires continued operation during power mains interruptions, it is recommended that the AcQMap System be powered from an uninterruptible power supply or a battery.

Guidance and Manufacturer's Declaration of Electromagnetic Immunity (continued)

NOTE: UT is the AC mains voltage prior to application of the test level.

Immunity Test	IEC60601 Test Level	Compliance Level	Electromagnetic Environment
Power Frequency magnetic field (50/60 Hz) IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz or 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical commercial or hospital environment.
Proximity Field Immunity IEC 61000-4-3	1.5 V/m @ 1 m 385 MHz, 450 MHz, 710 MHz, 745 MHz, 780 MHz, 810 MHz, 870 MHz, 930 MHz, 1720 MHz, 1845 MHz, 1970 MHz, 2450 MHz, 5240 MHz, 5500 MHz, 5785 MHz Frequency range	1.5 V/m @ 1 m 385 MHz, 450 MHz, 710 MHz, 745 MHz, 780 MHz, 810 MHz, 870 MHz, 930 MHz, 1720 MHz, 1845 MHz, 1970 MHz, 2450 MHz, 5240 MHz, 5500 MHz, 5785 MHz Frequency range	Proximity fields from RF wireless communications equipment.

Guidance and Manufacturer's Declaration of Electromagnetic Immunity (continued)			
			Portable and mobile RF communications equipment should be used no closer to any part of the AcQMap System, including cables. The recommended separation distance is calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance:
Conducted RF IEC 61000-4-6	3Vrms 0, 15 - 80 MHz 6 Vrms in ISM bands, between 0.15 MHz and 80 MHz 80%AM at 1 KHz	3Vrms 0, 15 - 80 MHz 6 Vrms in ISM bands, between 0.15 MHz and 80 MHz 80%AM at 1 KHz	distance: $d=1.2*\sqrt{P}$ $d=1.2*\sqrt{P}$ 80MHz to 800MHz $d=2.3*\sqrt{P}$ 800MHz to 2.5GHz where P is the maximum output power rating of the transmitter in watts(W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).
Radiated RF IEC 61000-4-3	3 V/m 80 MHz – 2.7 GHz 80 % AM at 1 kHz	3 V/m80 MHz – 2.7 GHz 80 % AM at 1 kHz	Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the symbol: 

NOTE: At 80MHz and 800MHz, the higher frequency range applies.

NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths form fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the AcQMap System is used exceeds the applicable RF compliance level above, the AcQMap System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the AcQMap System.

[b] Over the frequency range 150kHz to 80MHz, field strengths should be less than 3V/m.

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the AcQMap System			
The AcQMap System is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The end user of the AcQMap System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the AcQMap System as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of the transmitter in watts W	**Separation distance according to frequency of transmitter calculated in meters (m)**		
	150kHz to 80MHz $d=1.2*\sqrt{P}$	80MHz to 800MHz $d=1.2*\sqrt{P}$	800MHz to 2.5GHz $d=2.3*\sqrt{P}$
0.01	0.1	0.1	0.2
0.1	0.4	0.4	0.7
1	1.2	1.2	2.3
10	3.8	3.8	7.4
100	12	12	23
NOTE: At 80MHz and 800MHz, the higher frequency range applies. **NOTE:** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
For transmitters rated at a maximum power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			

APPENDIX I — ON DEMAND ECG TEST

The Console includes an internal auxiliary power supply to provide clinical grade ECG output signals in the event of a power outage or other temporary disruption of service. In the event of a Console failure, use of the ECG POST Test Cable PN 800526 will allow patient ECG monitoring to continue. See usage details below.

NOTE: ECG limb lead outputs operate a minimum of 3 minutes without AC power.

Testing the functionality when the System is ON:

Turn off the AcQMap Console. The status indicators will remain green, but all lights will be blinking. After ~1 min, the status indicators will continue to blink but turn amber indicating the internal auxiliary power supply is low. After an additional 1 minute the status indicators will change to blinking red – the internal auxiliary power supply is now critically low. Approximately 1 minute later the status indicators will turn off indicating the internal auxiliary power supply is empty. Power should remain available for ~3 minutes, if this is not the case contact Acutus Medical.

Testing the functionality when the System is turned OFF:

1. Plug the AcQMap Console into grounded wall receptacle.
2. Connect the potential equalization terminal on the rear of the console to the potential equalization terminal in the laboratory.
3. Connect the Auxiliary Interface Box to the console front panel.
4. Power on the AcQMap Console using the Mains ON/OFF switch, located on the rear panel. A green power indicator next to the power cord entry will illuminate when power is on.
5. Turning on the console initiates a Console Power On Self-Test (POST). Observe the Status Indicators on the console front panel. At the completion of the Console POST, if the test has passed only the center status indicator will be green.

6. Connect the AcQMap Console to the AcQMap Workstation using the AcQMap Workstation Cable.
7. Power up the AcQMap Workstation computer and display. Launch the Functional Test software application.
8. Observe the status indicators on the console front panel. At the completion of the POST, if the System has passed, all status indicators will be green. If one or more of the status indicators is not green, refer to Appendix G – Troubleshooting POST and Functional Test Status Indicators.

9. Close the Functional Test application. Open the AcQMap software application.

NOTE: Once the AcQMap Workstation has established a connection with the AcQMap Console, the backup power is enabled.

10. Turn off the AcQMap Console. The status indicators will remain green, but all lights will be blinking. After ~1 min, the status indicators will continue to blink but turn amber indicating the internal auxiliary power supply is low. After an additional 1 minute the status indicators will change to blinking red – the internal auxiliary power supply is now critically low. Approximately 1 minute later the status indicators will turn off indicating the internal auxiliary power supply is empty. Power should remain available for ~3 minutes, if this is not the case contact Acutus Medical.

NOTE: The internal auxiliary power supply will be re-charged during normal AcQMap System operation.

ECG POST Cable for Continued Patient ECG monitoring

1. Retrieve the ECG POST Cable PN 800526 from the rear storage compartment of the Console.
2. Unplug the red ECG In Cable PN 800532 from the front panel of the Console and connect it to the red input on the ECG Test Cable.
3. Unplug the blue ECG POST Out Cable PN 800424 from the front panel of the Console and connect it to the blue input on the ECG Test Cable.
4. ECG monitoring should now be available on the Lab ECG monitoring system.

NOTE: For patient safety the red to blue connections within the ECG Test Cable are completely isolated from the test connections.

APPENDIX J — ECG SYSTEM TEST

The AcQMap Console includes functionality to test the ECG cable integrity. This helps to ensure that the connector, leads, yoke, and clip connections are all still functional.

Note: ECG System test should be used when it is observed that the ECG signals are noisy or not present. Routine testing should be performed per hospital standard operating procedures.

Testing the functionality when the System is turned OFF:

1. Plug the AcQMap Console into grounded wall receptacle.
2. Connect the Auxiliary Interface Box to the console front panel.
3. Power on the AcQMap Console using the Mains ON/OFF switch, located on the rear panel. A green power indicator next to the power cord entry will illuminate when power is on.
4. Turning on the console initiates a Console Power On Self-Test (POST). Observe the Status Indicators on the console front panel. At the completion of the Console POST, if the test has passed only the center status indicator will be green.
5. Connect the AcQMap Console to the AcQMap Workstation using the AcQMap Workstation Cable.
6. Power up the AcQMap Workstation computer and display. Launch the Functional Test software application.
7. Connect the ECG cable Model 800532 to the ECG input receptacle on the console front panel.
8. Connect the ECG POST Cable Model 800526 to the AcQMap Catheter receptacle on the console front panel.
9. Click the 

check on then press 

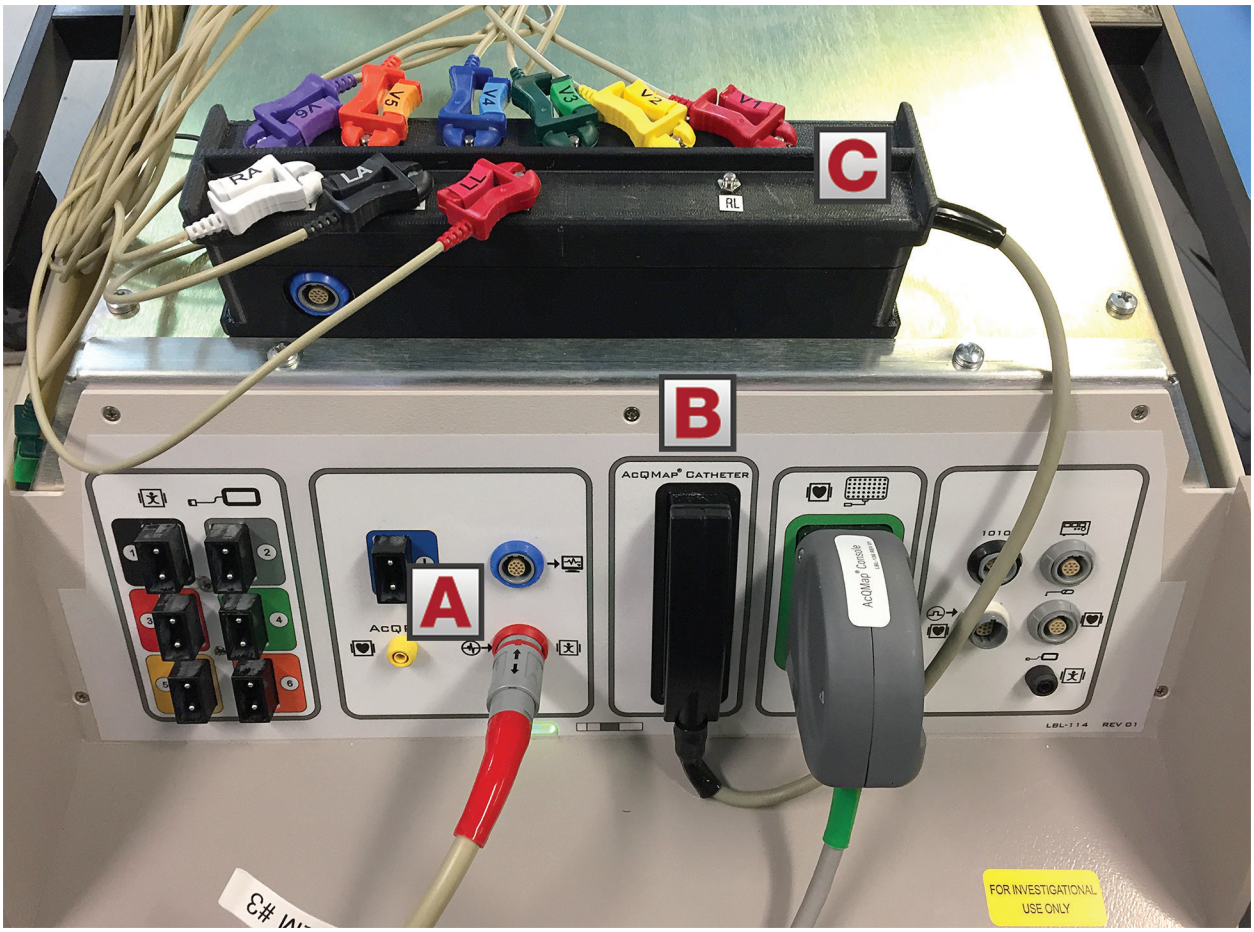


Figure J-1. ECG Cable test connections. (A) ECG Input Cable. (B) ECG POST Cable 800526 is connected to the AcQMap Catheter receptacle on the console front panel. (C) Connect each ECG connector to the corresponding name of ECG lead.

NOTE: RL Lead and Black Wire of ECG Input Cable 800532 are not connected. Leave those wires on the table or console.

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