Advances in 3D Electro anatomical Mapping Systems

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Disclosures

- Consulting: St Jude Medical, Inspira Health.

- Travel grants: Medtronic; Boston Scientific; Bayer; SJM.

- Educational support: Biosense Webster; Cooke Medical; Spectranectics.
Conflicts of Interest

- Heavy NavX user!
- Slides from:

St. Jude Medical

Boston Scientific

Medtronic

cardiInsight

Biosense Webster®

Acutus Medical
Requirements of the perfect mapping system

• To provide an accurate anatomical representation of the specified cardiac chamber

• Onto this shell, EP data should be displayed accurately including
  – signal amplitude;
  – signal complexity;
  – local activation timing,
  – .....all ideally on a beat to beat basis
  – Ablation localisation and quantification
Current mapping systems

CONTACT MAPPING

• **NavX Ensite Precision**
• CARTO 3
• Rhythmia

NON CONTACT MAPPING

• Ensite Array
• CardioInsight
• Acutus
Current mapping systems

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Contact Mapping - Catheter location
Improve Stability with Redesigned Patches

- Electrode positioned in centre of patch. More consistent current density
- Improved adhesive hydrogel patches
- Smaller design. More options for ECG, cardioversion patches...
- Accommodate patients of all sizes
- Further aides stability of the system

The Location Pad

- An External Ultra-Low Magnetic Field Emitter
Effectively Manage Patients through Greater Precision

Impedance field flexibility + magnetic field stability

• Enhanced navigation and model creation with dual technology

Advanced Catheter Location (ACL)

• Visualize nearly any catheter
• Sensor-based navigation
• Outstanding accuracy (±1mm)
• Not affected by biological changes

Accurate Visualization

Magnetic Technology

Current-Based Technology

Hybrid Technology

• Visualize nearly any catheter
# Coordinate System Options

<table>
<thead>
<tr>
<th>Coordinate System</th>
<th>Benefits</th>
<th>Drawbacks</th>
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| Impedance         | - Utilizes EP electrodes as sensors (cost effective, coincident with ECG sensors)  
                   - Coordinate system linked to patient; immune to movement. | - Non-linear  
                   - Impedance field is effected by changes in tissue properties.  
                   - Coordinate system (patches) can move |
| Magnetic          | - Not affected by biological material  
                   - Inherently linear  
                   - Stable over time | - Magnetic sensors needed to locate electrodes  
                   - Limited to only sensor enabled tools  
                   - Coordinate system linked to bed / fluoro, not patient  
                   - Distorted by metal (bed, flat detector, ICDs, etc.) |
Catheter Location Matrix Formation

• As you visit the chamber with a sensor based catheter, clusters are built. These are where the location information from the catheter is registered with it’s electrode current pattern.

• The more thorough you are the smaller the cluster regions become

• Catheter visualization accuracy is directly proportional to the amount of clusters.

• If the impedance (and therefore current) changes due to ablation it won’t affect the system, as the matrix is continually updated by the sensor based catheter, so always remains accurate
NavX SE points

Location of electrode within impedance field

Points towards corresponding sensor location
How are we using Magnetic information?

MODEL CREATION = USES BOTH IMPEDANCE and MAGNETIC DATA

LV Model – EnSite™ NavX™

LV Model- EnSite™ NavX™ SE
CONTACT MAPPING – Improved features
CONFIDENSE™
Module
Continuous Mapping: Filters

**Cycle Length** - Only acquiring points with a consistent cycle length

**Force** - Ensuring the catheter is in contact at the time of point collection

**Catheter stability** - Acquiring points when the catheter location is stable
- LAT stability
- Position stability

**Density** - Minimises acquisition of points when the catheter is not being moved

**Tissue proximity indicator (TPI)**

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Click here for more details on Continuous Mapping filters
Enhanced Mapping

• Automated point inclusion/exclusion criteria$^{1-3}$
• Automated morphology matching for both atrial & ventricular cases$^{1,2}$
  – Only include mapping points with the surface lead morphology of interest. Full 12 or any combination.
  – Automatically reject points outside of the clinical morphology, including catheter-induced ectopy

EnSite™ AutoMap Module – TurboMap Feature
Facilitate Diagnosis of Complex Arrhythmias with the SparkleMap Feature

- Live activation map overlaid on voltage map
Facilitate Diagnosis of Complex Arrhythmias with the SparkleMap Feature

- Live activation map
THERMOCOOL® SMARTTOUCH™ Catheter Design

TRANSMITTER coil in the tip sends location reference signal.

PRECISION SPRING allows small amount of electrode deflection.

SENSORS receive transmitter coils location signal and micro-movements of the spring.
The VISTAG™ Module provides access to data collected during the application of RF energy. The data does not indicate the effectiveness of RF energy application.

*Where THERMOCOOL® SMARTTOUCH™ Catheter is approved*
Both CARTO and Precision allow import of CT/MRI

Optimized system controls

• Easily visualize scar tissue – integration of delayed enhancement MRI imaging\(^1,2\)
  – File types; VTK, VTP, DIF, extended DIF
• Review and analyze data faster via USB export\(^3\)

3. Precision 2.0 Instructions For Use.
Epicardial voltage map
Rhythmia™ Mapping System

- IntellaMap Orion™ Mapping Catheter
- Signal Station
- Localization System
- Rhythmia™ Algorithm Suite
The Rhythmia™ Mapping System uses a hybrid location technology that combines impedance location with magnetic location technology. This combination enables the Rhythmia Mapping System to accurately track catheters that are connected to the system.

**Magnetic location technology** uses magnetic fields generated by the localization generator positioned under the patient table to track catheters with magnetic sensors.

**Impedance location technology** is used to track catheters that are not equipped with a magnetic location sensor.
Localization System

Open architecture gives you the freedom to choose and visualize any ablation or diagnostic tool.

Highly accurate hybrid tracking provides the optimal blend of magnetic and impedance technologies.

- Magnetic localization: Accurate to $\leq 1\text{mm}^1$
- Impedance localization: Accurate to $\leq 2\text{mm}^1$

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IntellaMap Orion™ Catheter Electrode Array

Flexible printed circuit bonded to nitinol

2.5 mm inter-electrode spacing (center to center)

0.4mm² electrode area (0.9 × 0.45 mm)
Speed

Ideal blend of speed and ease-of-use allows you to collect thousands of relevant data points within minutes.

**Continuous Mapping**
- Continuous acquisition of points based on user-defined criteria creates maps in 1/3 of the time
- Repeatable maps generated in minutes offer more predictability and less variability
- 99.8% accuracy in automated annotation algorithm eliminates the need for manual beat acceptance

27,000+ EGM High-Resolution, 3D Electroanatomical Map Captured in 15 Minutes
Dynamic Review
- Virtually review and edit high-density maps
- Manually accept/reject beats or change annotations with full control

Tissue Targeting
- Rapidly identify target ablation sites away from the patient table

Case Example – Macoreentrant Atrial Tachycardia

From the workstation PC, Virtual Roving Probe sweeps the left atrium to aid in the identification and tagging of the target ablation site.
NON-CONTACT MAPPING
SJM Ensite Array
SJM Ensite Array

- Array of 64 electrodes over a saline filled balloon used to calculate unipolar signals in 3000 locations

- Uses inverse Laplace law to determine electrograms on surface up to 4.5cm away

- Geometry defined with ablation catheter – moving within impedance field created by Array

- Most negative waveform is tracked - the tracking virtual – allow you to identify areas of EA and BO – help ablation strategy
• Ideally position equator of Array balloon over area of interest
Problems with Ensite Array

• Acts as it own reference – if balloon moves, the whole map moves

• Often induces ventricular ectopy – which ectopics are spontaneous and which are due to the balloon?

• In a large ventricle Array can be more than 4.5cm from endocardial surface

• Risk of thrombus formation on Array
Body Surface Mapping
Body Surface Mapping to Guide Atrial Fibrillation Ablation

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AcQMap System

- Non-contact, instantaneous mapping
- Ultrasound anatomy reconstruction
- Dipole density or Voltage mapping
- Unique map display mode tracks leading edge of wave front conduction
- Efficient remapping to assess substrate modification post ablation

AcQMap is not for sale in the United States
AcQMap 3D Mapping Catheter

- 48 Engineered Electrodes
- 48 Ultrasound Transducers
- 25mm diameter
- Up to 115,000 ultrasound points/minute
- 150,000 intra-cardiac unipolar voltage samples/second

AcQMap is not for sale in the United States

Brief Summary: Please review the Instructions for Use prior to using these devices for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.
Electrode X,Y,Z localization and ultrasound distances are combined to acquire anatomy

- Ultrasound pulses (m-mode) continuously reach and reflect off the chamber wall
- Individual points are accumulated to form a surface with mesh-density equivalent to segmented CT
- Post-processing of the surface data completes the reconstruction
Dipole density measures the local charge generated by the action of the ion channels.

\[
\text{Voltage EGM (mV)} = \text{Local charge source} + \text{sum of surrounding sources}
\]

Resolution \(\sim 4\) times ‘sharper’ \(^1\)

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Propagation history tracks leading edge of wavefront conduction

Color bands show earlier location of wavefront conduction

Propagation History = 100 ms

Courtesy of Papworth Hospital, United Kingdom
SUMMARY-Contact Mapping

NavX Ensite Precision
• PROS - New version now allows for both impedance and magnetic location - maximise mapping accuracy; Open platform – can impedance map with any catheter – allows greater flexibility; New mapping and automark software eases workflow substantially
• CONS - TACTICATH CF catheter is rather stiff and currently only unidirectional

CARTO 3
• PROS - Market leader for contact mapping due to well established magnet/impedance mapping; PentaRay mapping catheter allows for high density mapping; Allows use of SMART TOUCH CF catheter
• CONS- Mapping only possible when NAV enabled ablation catheter in/ near heart; can only map from NAV catheters

Rhythmia
• PROS -High numbers of points collected quickly; mapping software gives accurate activation
• CONS- Less well established; Does not allow for import of CT/MRI; Can be used with TACTICATH CF catheter
SUMMARY - Non Contact Mapping

Ensite Array
- PROS - Allows mapping of a single beats of an arrhythmia
- CONS - Ectopy; difficult to get a stable position

CardioInsight Body surface mapping
- PROs - non invasive mapping; allows mapping of single beat outside EP lab when patient ambulant;
- CONS – can be difficult to define more ‘internal’ structures eg septum of LA; reconstructed epicardial electrograms may be affected by structures between epicardium and body surface; requires Contact map to perform ablation

AcQMap Acutus
- PROS - Uses USS to gain CT quality geometry
- CONS - New, expensive
Acknowledgements
ENSITE PRECISION™
CARDIAC MAPPING SYSTEM
NavX SE Field Scaling

Require valid impedance and magnetic data to form fiducial pair used in scaling algorithm

Sheath Filter:
- Impedance affected when within sheath
- Sheath filter automatically enabled when collecting model points with a Sensor Enabled™ tool
- Avoid fiducial pairing of distorted impedance data with valid magnetic data

Metal Distortion:
- Magnetic field distorted when in presence of metal
- Metal distortion monitored and disables fiducial collection when metal distortion out of range from reference state
- Avoid fiducial pairing of distorted magnetic data with valid impedance data

Respiration Gating of Fiducials:
- Changes in respiration pattern impact impedance and magnetic fields differently
- Impedance field compensated by respiration compensation algorithm
- NavX SE point collection gated to end expiration or empty lung state to ensure consistent relationship of impedance and magnetic data
- Gating not applied to impedance model points
- Background algorithm with gating waveform visible in waves display
**AcQMap System**

- Ultrasound chamber reconstruction
- Non-contact, global dipole density mapping
- Stable or unstable arrhythmias
- Remap in seconds after ablation therapy
- Break down complex arrhythmias during the procedure

**AcQMap Catheter**

- 48 Engineered Electrodes
- 48 Ultrasound Transducers
- 25 mm diameter
- Up to 115,000 ultrasound points/minute
- 150,000 intra-cardiac unipolar voltage samples/second

**Activation Map**

**Functional EP**
What 3D anatomical mapping systems are

History of them

Why they are useful

Recent advances with NavX and CARTO

(Could mention the ENSITE ARRAY)
  - Magnetic and impedance combined
  - More points
  - Mapping more important - finer and more detailed maps showing channels not previously seen
  - More automation – more points - but still need to be mindful of basic EP
  - Various helpful features – turbomap; visitag - tagging of points incorporating force/contact info;
  - Integration with mediguide
  - NavX is open platform


Ability to combine data with imaging – for scar/ anatomy that you cannot see with mapping system – cannot do with rhythmia

ACUTUS – combining USS and EAM in one – system

Present some cases to illustrate these features – eg clifford powell; AP; compare LAs created using velocity and those using NavX; AT near septum (DW8161)

Could go through each new aspect of mapping system – illustrating it with slides from each company

Could use slides from Precision to talk about fusion of magnetic and impedance field

Mapping – slides from rhythmia – lots of high density points

CARTO – ablation points eg visitag

Mention they reduce fluoro time

Mediguide
AcQMap System

- **AF Visualization** - Identify and locate mechanisms
  - Localized rotational and irregular activation
  - Focal activation

- **Image Guided Ablation** - Ablation based on evidence
  - Target the core and anchor lesions
  - Point ablation

- **Therapy Confirmation** - See the ablation effect
  - Cycle length prolongation with observable change in mapped conduction pattern
  - Elimination of activation pattern including spontaneous conversion to sinus rhythm
EnSite™ AutoMap Module

• Create higher density maps in less time using any catheter\textsuperscript{1,3}
• Use intuitive automation to increase resolution\textsuperscript{2}
• Eliminate time-consuming evaluation of each data point; Points outside of user-specified criteria are automatically excluded\textsuperscript{1,3}

Figure 5: LAO projection of the right atrium showing areas of early activation at the 12 o'clock position along the tricuspid annulus.

Figure 6: RAO projection of the right atrium showing a peri-sinus nodal area of early activation.
Rhythmia™ Mapping System and IntellaNav™: Innovation to drive share gains

Rhythmia Mapping System
- High-density cardiac maps
- Continuous and contiguous mapping
- Highly accurate annotation (software automated)
- Efficient, rapid map & re-map process
- Orion™ 64 electrode mapping catheter
- Open and closed architecture
Mechanistic mapping of cardiac arrhythmias

Use of the AcQMap High-Resolution Imaging and Mapping System (AcQMap System) is discussed by Professor Stephan Willems MD PhD

Atrial fibrillation (AF) is a debilitating disease that affects over 30 million people worldwide, including 5% of the population over 65 years of age.\(^1\)\(^2\) It doubles the risk of death and increases stroke risk five times compared with people without AF. The cost of treating AF in Europe, including hospital admissions, anti-arrhythmic medication, cardioversion, and anticoagulation is over €13.5 billion annually.\(^3\) Ablation is a relatively new treatment for AF patients but to date success rates are suboptimal, especially for patients with persistent and long-standing persistent AF despite the use of advanced-mapping modalities. Therefore, a novel mapping technology called the AcQMap High-Resolution Imaging and Mapping System from Acutus Medical has been developed to facilitate the treatment of AF.

The AcQMap System consists of a catheter with 48 ultrasound transducers and 48 electrodes connected to a console and workstation. It acquires 100,000+ ultrasound points/minute and 150,000 intracardiac unipolar voltage samples per second. The 3D anatomy reconstructed from ultrasound data is comparable with CT quality. Electrical activation is displayed as either dipole density or unipolar voltage maps on the 3D anatomy. Dipole density presents a sharper view of activation by subtracting out the redundant smoothing effect inherent in voltage signals. The AcQMap System thereby enables identification and therapeutic targeting of sources and mechanisms of complex and irregular arrhythmias, to potentially improve first-procedure ablation success and procedural efficiencies.

The first clinical assessment of the AcQMap System was performed in patients with typical atrial flutter to demonstrate that the AcQMap System could correctly map a well-characterized rhythm disorder. The team at Universitäres Herzzentrum Hamburg (UHZ), mapped three patients with atrial flutter using both the AcQMap System and a conventional 3D system. The detail seen in the 3D AcQMap System anatomies is valuable information to have during the procedure and the resolution of the dipole density maps is four times \((4 \times)\) higher than the resolution of voltage maps, all of which represents a clinically significant improvement in mapping performance. The team at UHZ is part of an international group of renowned investigators across Europe, Canada and Australia researching the AcQMap System.

Future studies starting shortly at UHZ will map more complex and irregular arrhythmias, including persistent AF. These studies will allow the basics of mechanistic mapping learned in the initial feasibility study to be applied to arrhythmias in which identifying and locating mechanisms is often very difficult, if not impossible with current technology. The ability to identify mechanisms in complex and irregular arrhythmias such as AF could lead to more predictable outcomes in these challenging procedures.

Conflict of interest: S.W. is a scientific advisor to Acutus Medical.

References

References are available as supplementary material at European Heart Journal online.
Advantage of Ensite Precision - Higher point Density

27x higher point density:
- More precise surface rendering (including PVs, PV/LAA)
- Reduced editing
- Easier to identify areas requiring editing for more consistent model creation
- Easier to identify false space from catheter tenting
- Greater anatomical detail for better catheter navigation (papillary muscles)