Advances in 3D Electro anatomical Mapping Systems

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Sheffield Teaching Hospitals

Heart Rhythm Congress

www.heartrhythmcongress.org

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:

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

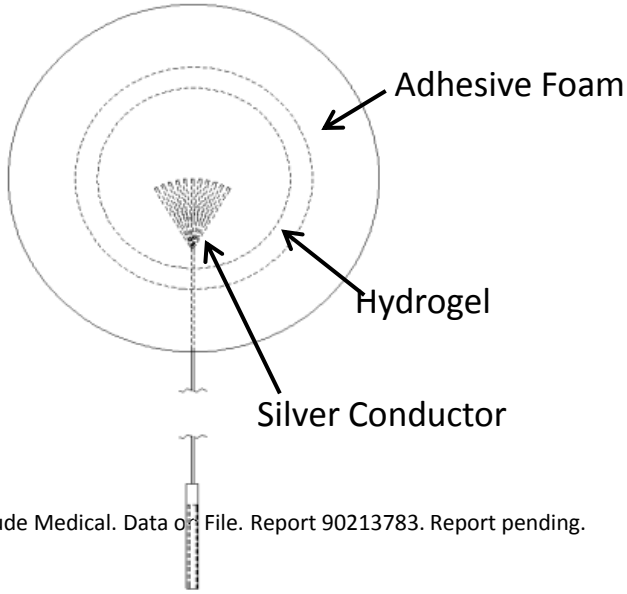
CARTO 3 SYSTEM

CARTO® 3 System

Biosense Webster
a Johnson & Johnson company

Improve Stability with Redesigned Patches[1]

- Electrode positioned in centre of patch. More consistent current density
- Improved adhesive hydrogel patches[1]
- Smaller design. More options for ECG, cardioversion patches…
- Accommodate patients of all sizes
- Further aides stability of the system

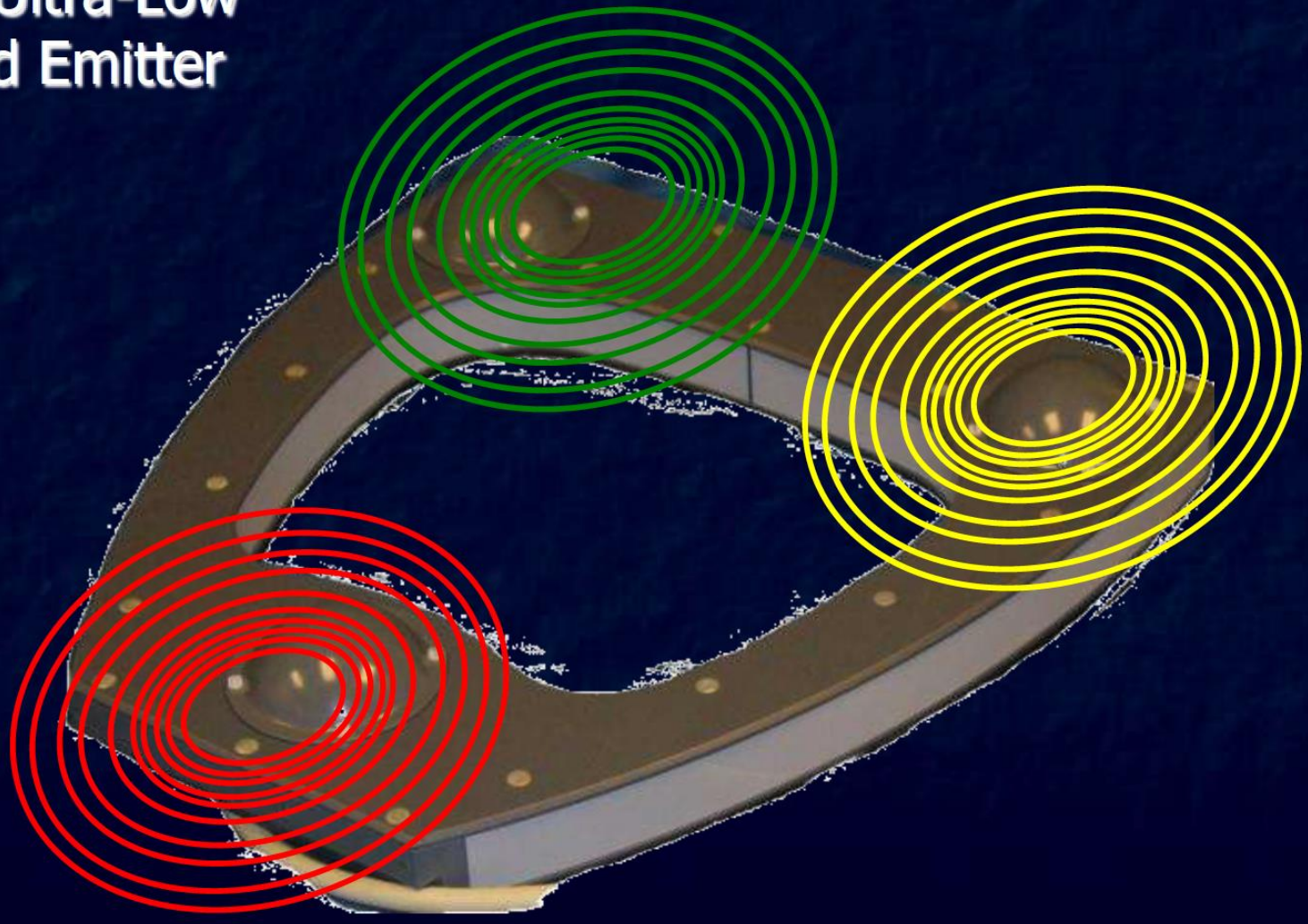


1. St. Jude Medical. Data on File. Report 90213783. Report pending.

The Location Pad

CARTO 3 SYSTEM

- An External Ultra-Low Magnetic Field Emitter



Effectively Manage Patients through Greater Precision

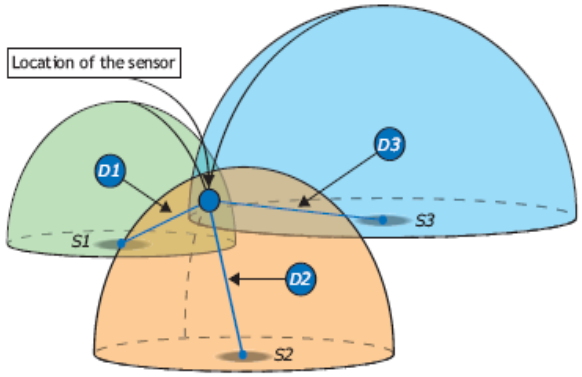
Impedance field flexibility + magnetic field stability

- Enhanced navigation and model creation with dual technology[1]

1. St. Jude Medical. Data on File. Report 90212729.

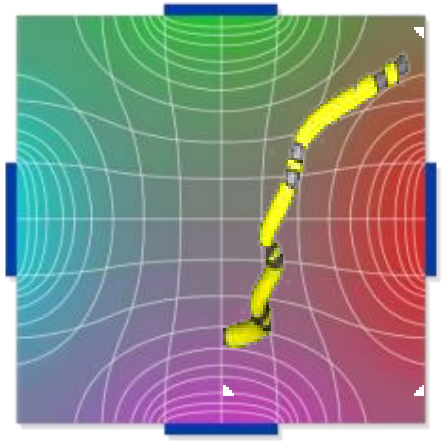
ST. JUDE MEDICAL

Magnetic Technology



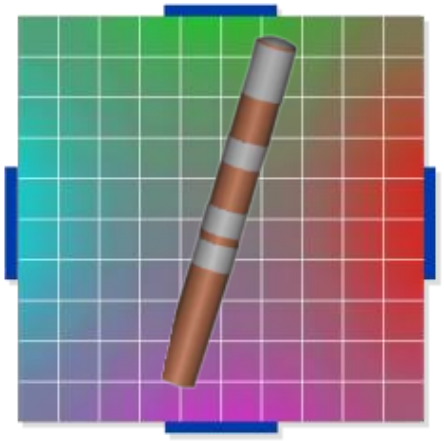
- **Sensor-based navigation**
- **Outstanding accuracy (±1mm)**
- **Not affected by biological changes**

Current-Based Technology



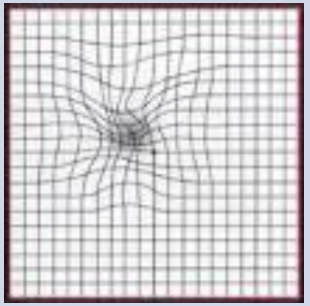
- **Visualize nearly any catheter**

Hybrid Technology



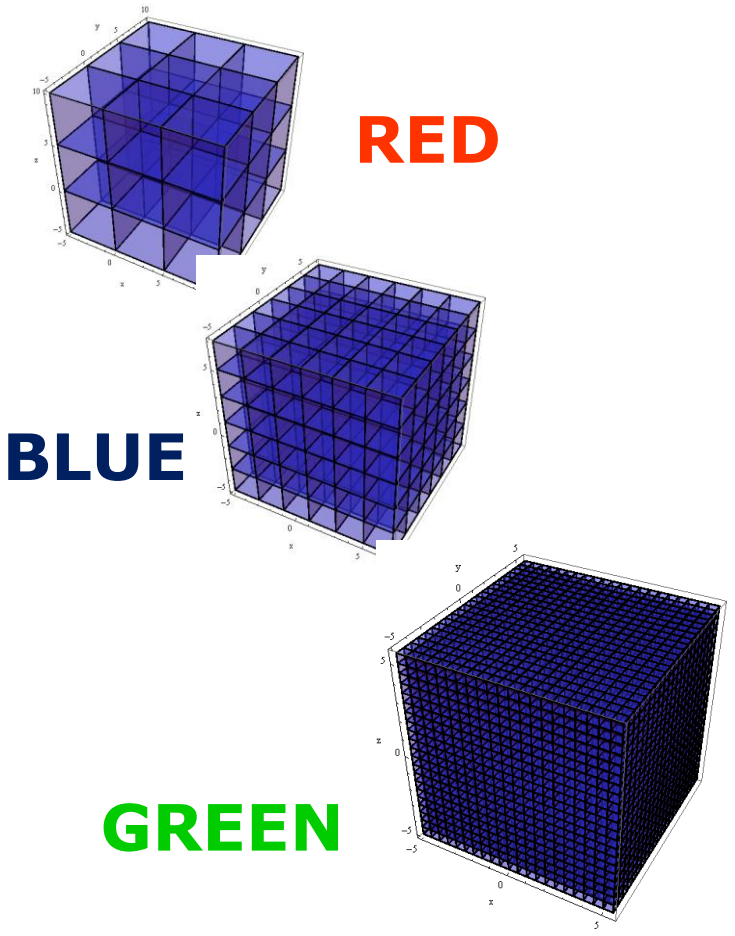
Accurate Visualization

Coordinate System Options

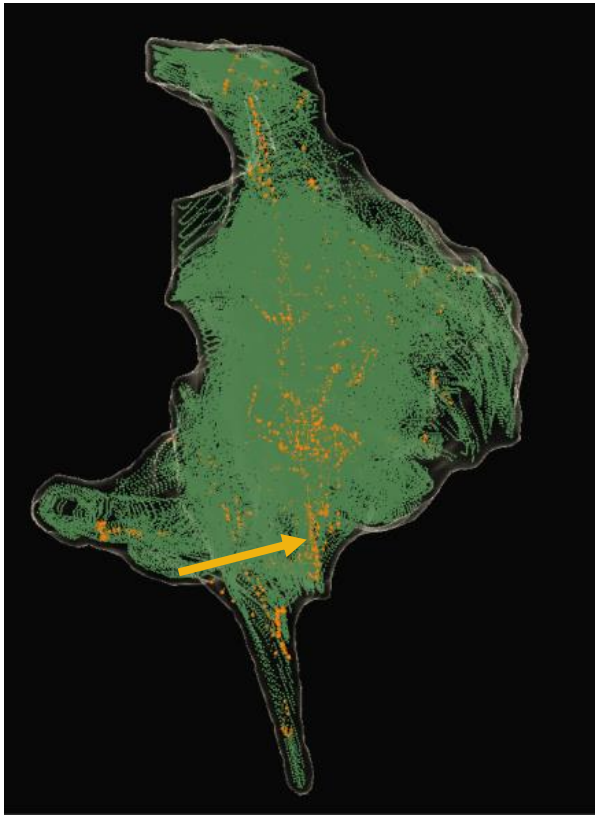
Coordinate System	Benefits	Drawbacks	
Impedance	▪ Utilizes EP electrodes as sensors (cost effective, coincident with ECG sensors) ▪ Coordinate system linked to patient; immune to movement.	▪ Non-linear ▪ Impedance field is effected by changes in tissue properties. ▪ Coordinate system (patches) can move	
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.)	

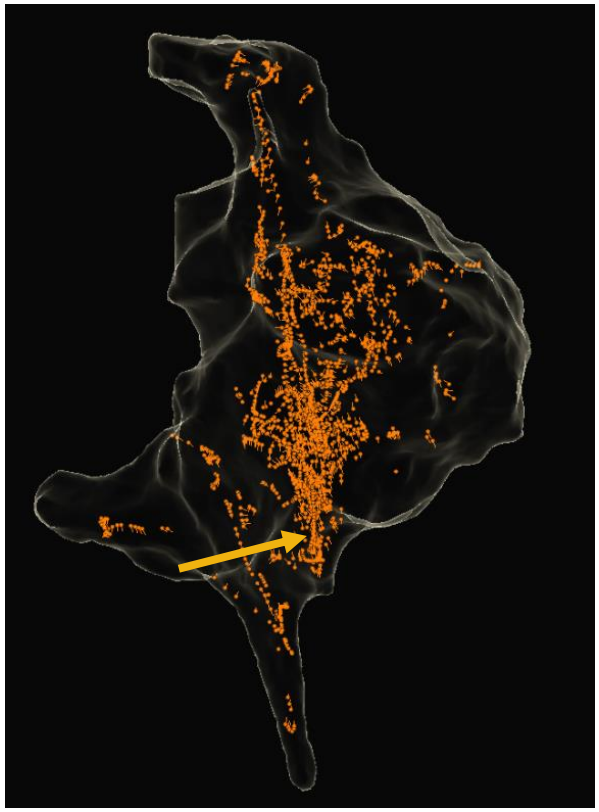
Catheter Location Matrix Formation

- 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

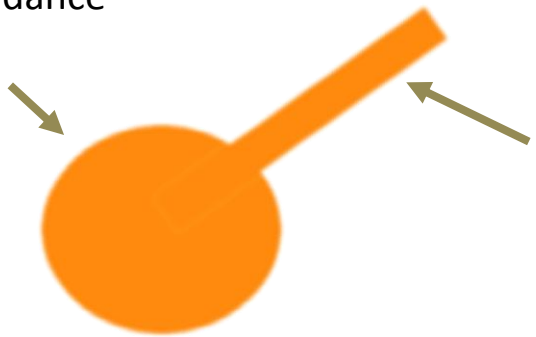


NavX SE points





Location of electrode within impedance field

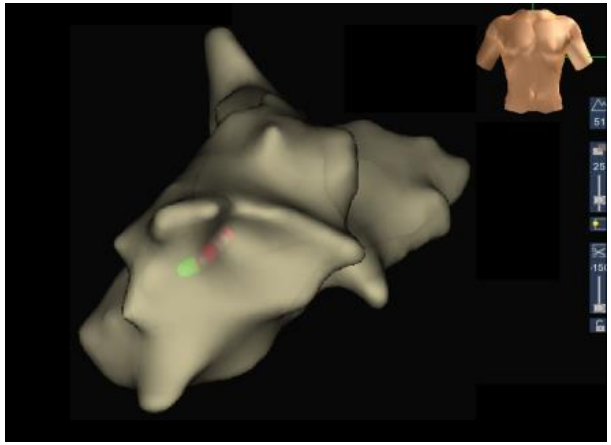


Points towards corresponding sensor location

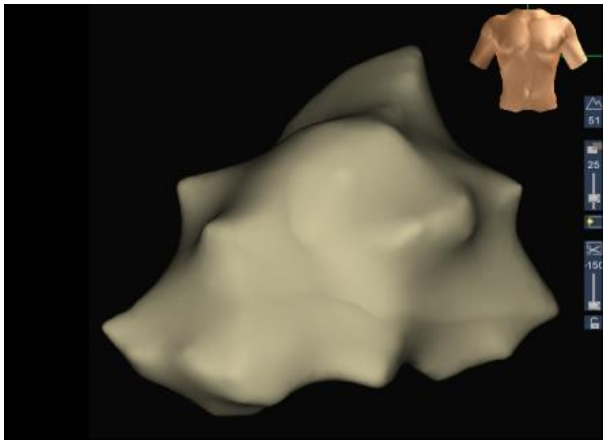
How are we using Magnetic information?

MODEL CREATION = USES BOTH IMPEDANCE and MAGNETIC DATA

LV Model – EnSite™ NavX™



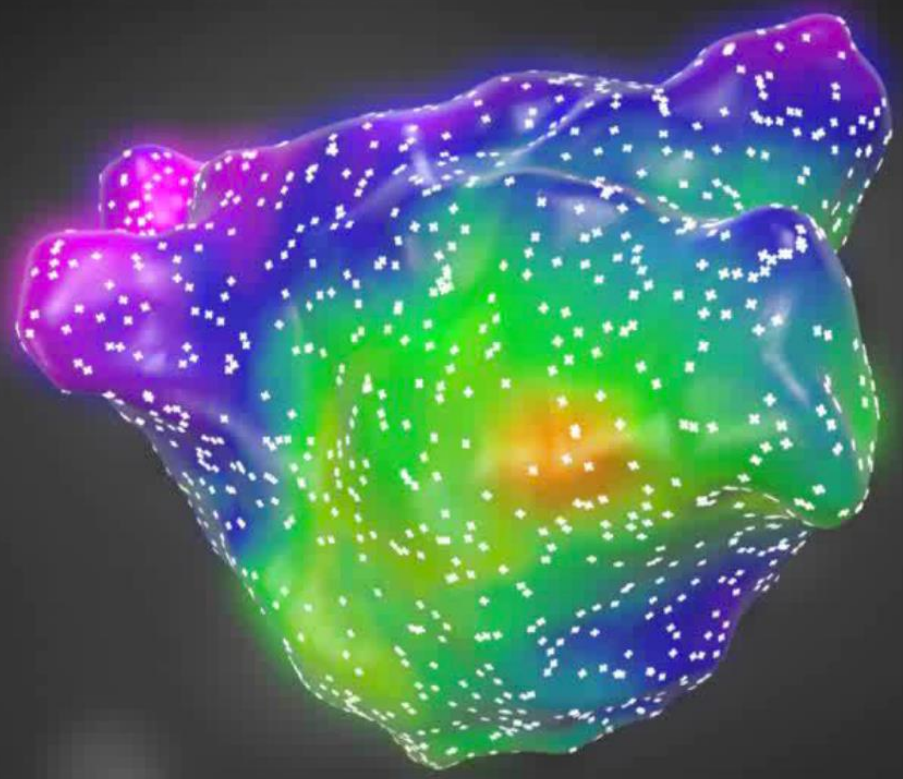
LV Model- EnSite™ NavX™ SE



CONTACT MAPPING – Improved features

CONFIDENSE™

Module



Biosense Webster
PART OF THE Johnson & Johnson FAMILY OF COMPANIES

Continuous Mapping: Filters

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

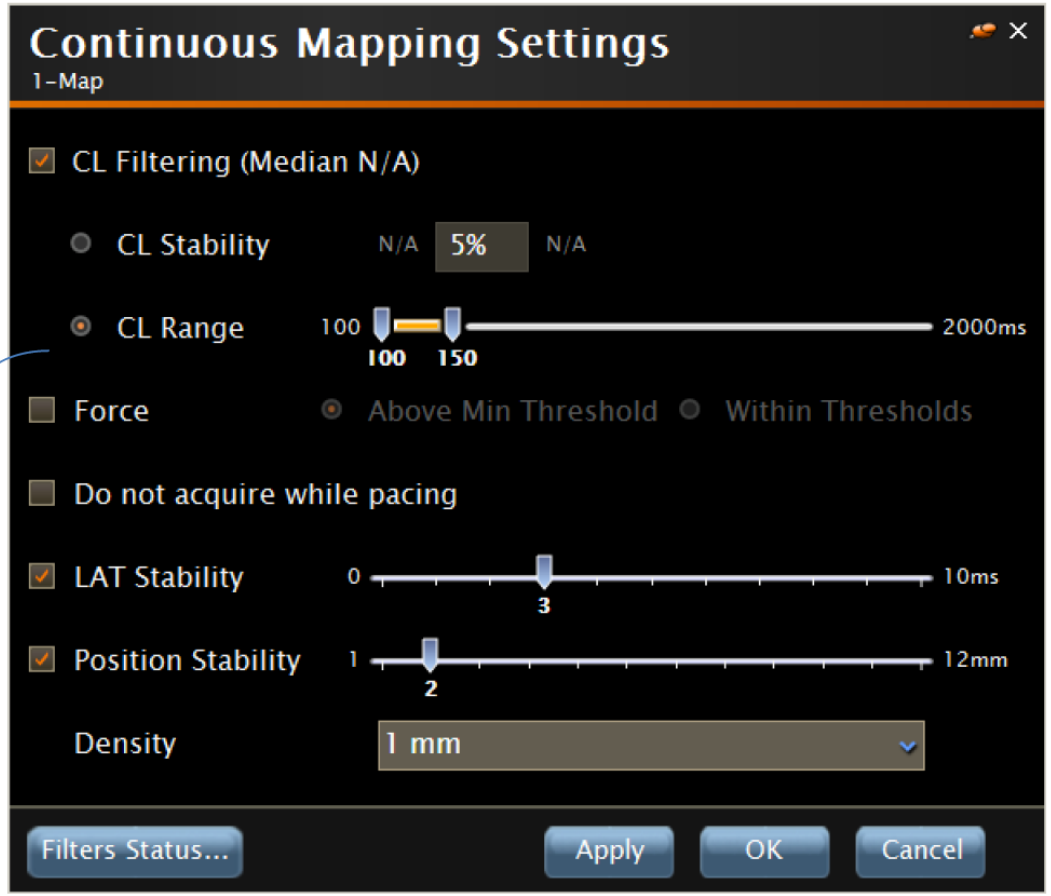
Force -> Ensuring the catheter is in contact at the time of point collection

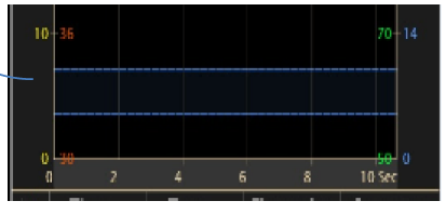
Catheter stability -> Acquiring points when the catheter location is stable

- LAT stability
- Position stability

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

Tissue proximity indicator (TPI)

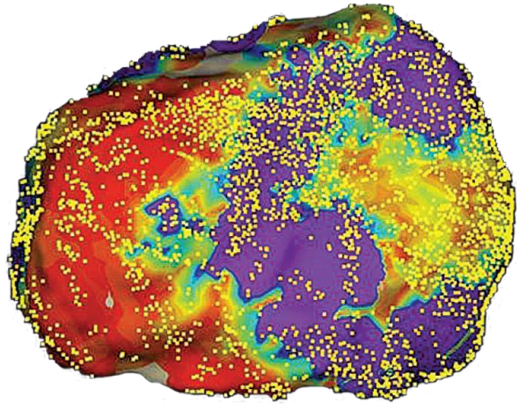




Click here for more details on Continuous Mapping filters

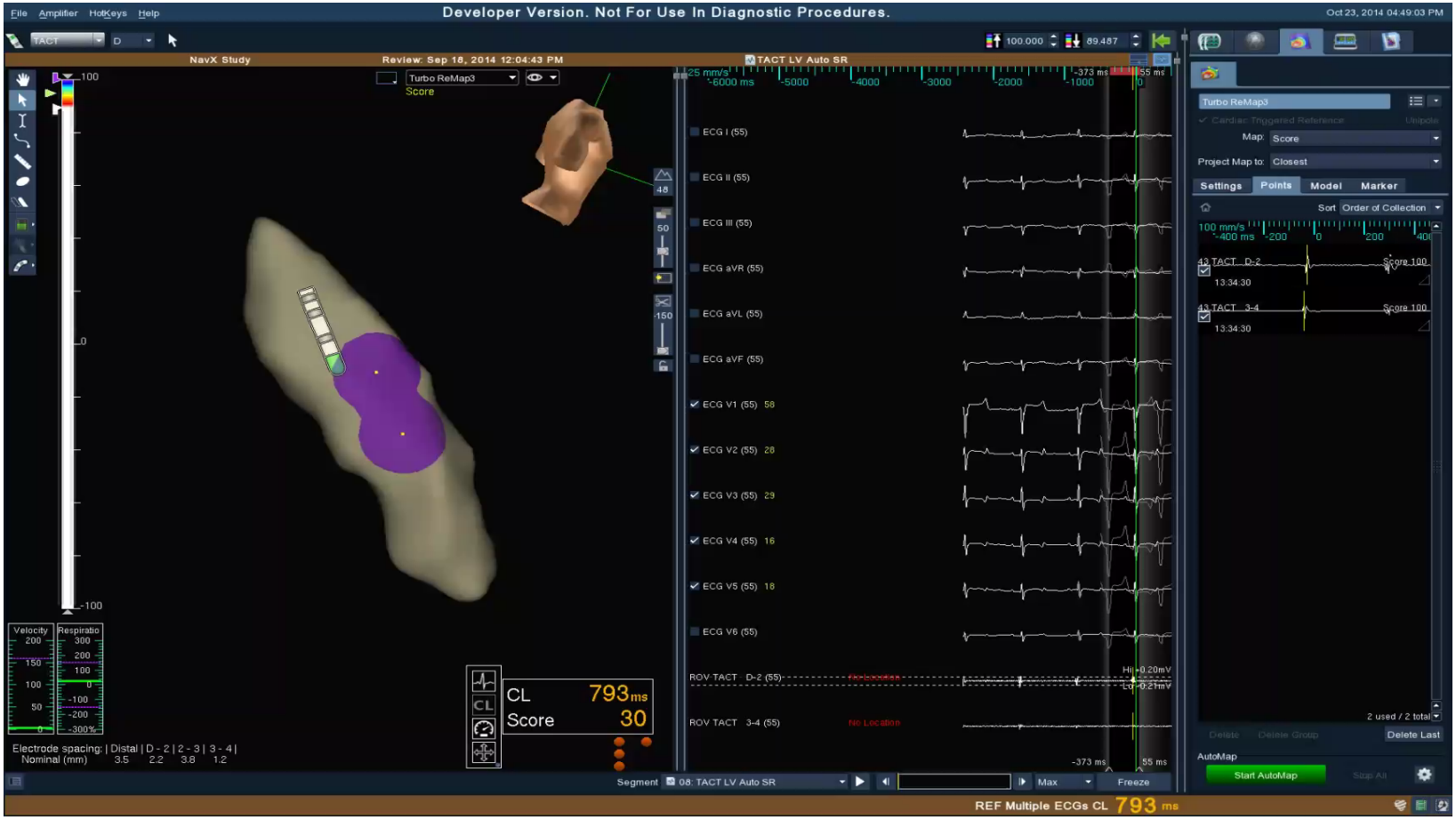
Enhanced Mapping

- 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



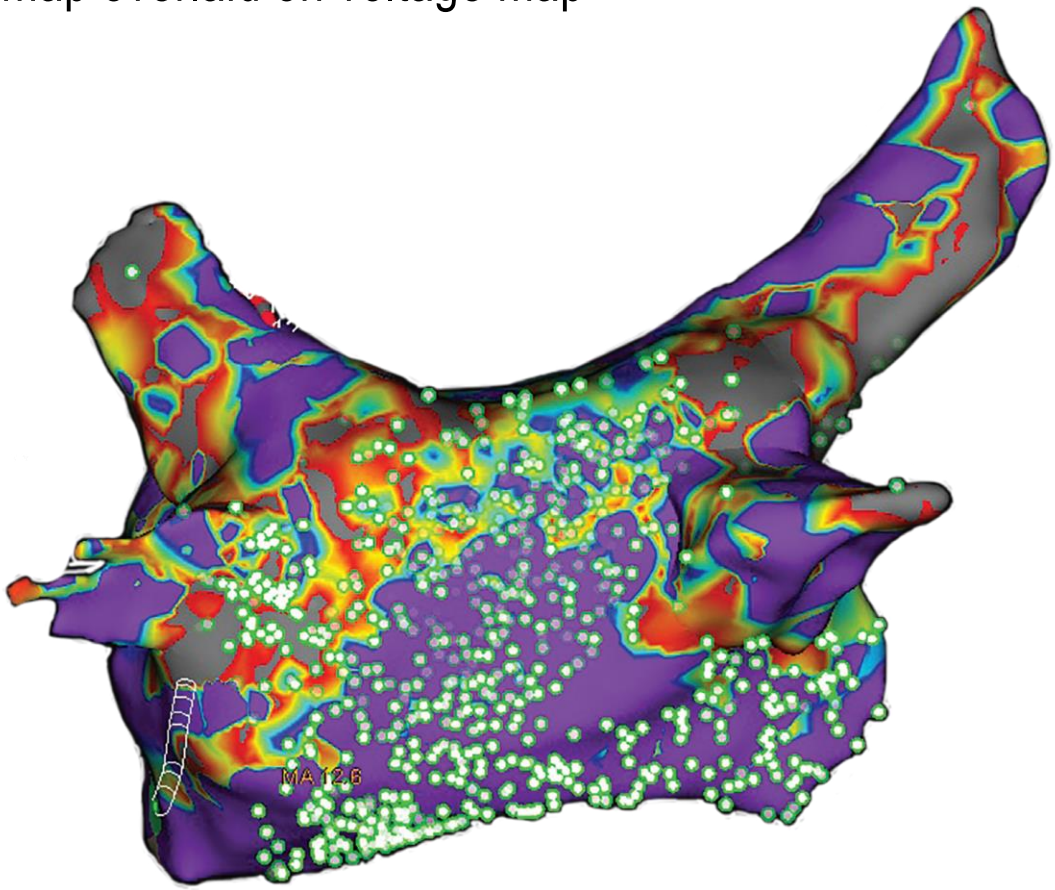
1. Ptaszek, L., Moon, B., Sacher, F., Jais, P., Mahapatra, S., & Mansour, M. (2015). *A novel tool for mapping multiple rhythms from a single mapping procedure.* Poster abstract P849. *Europace, 17*(Suppl 3), iii115.
2. Ptaszek, L., Moon, B., Mahapatra, S., & Mansour, M. (2015, Nov). *Rapid high density automated electroanatomical mapping using multiple chambers and catheter types.* Pending poster abstract. APHRS 2015, Melbourne.
3. St. Jude Medical. Data on File. Report 90214738.

EnSite™ AutoMap Module – TurboMap Feature



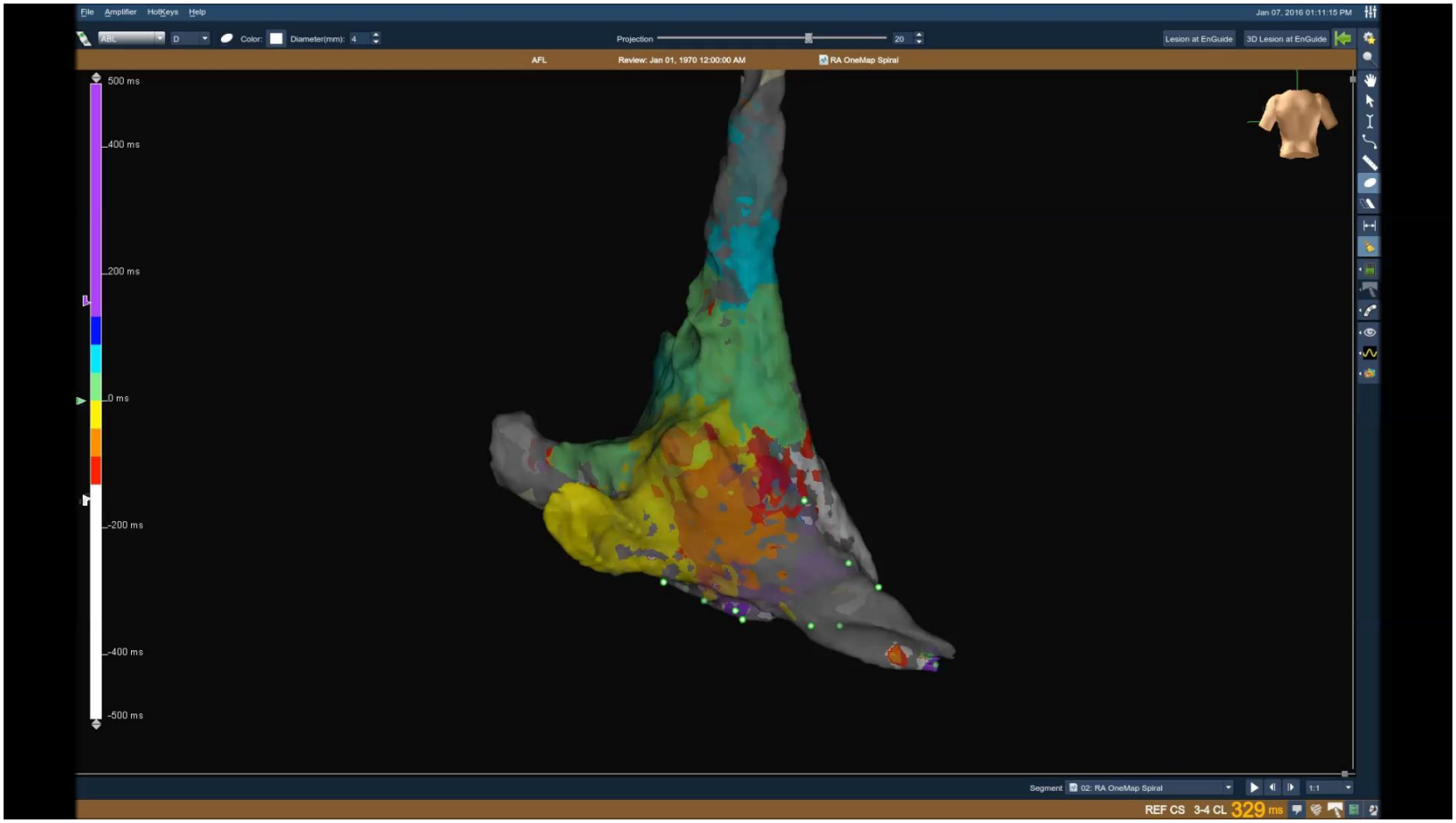
Facilitate Diagnosis of Complex Arrhythmias with the SparkleMap Feature

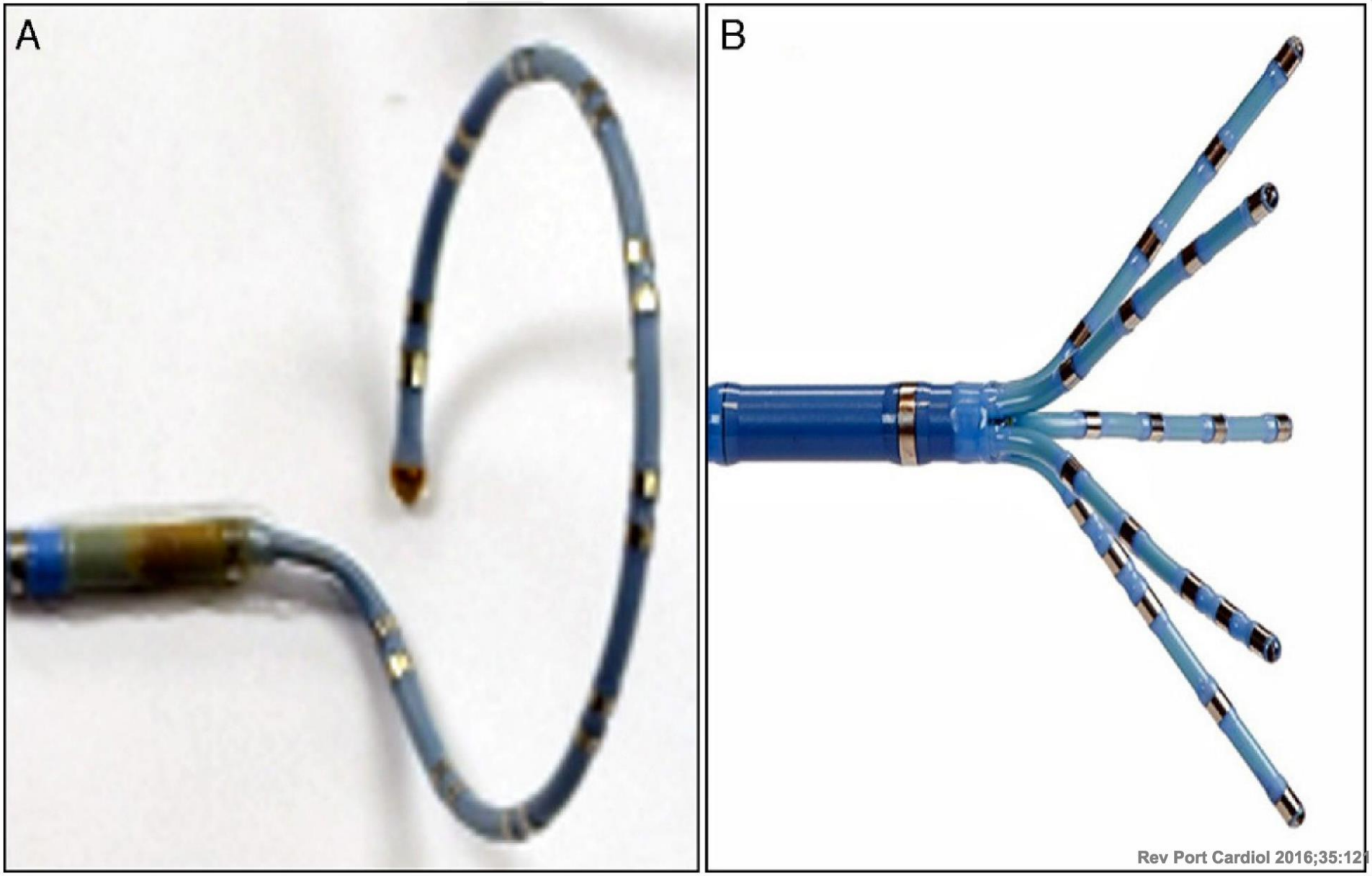
- Live activation map overlaid on voltage map



Facilitate Diagnosis of Complex Arrhythmias with the SparkleMap Feature

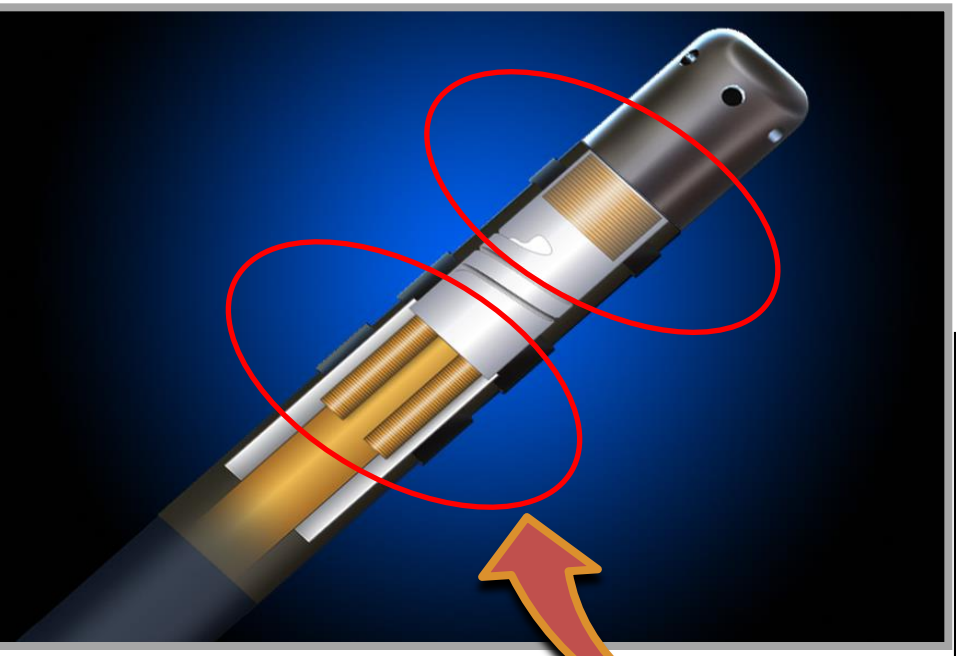
- Live activation map



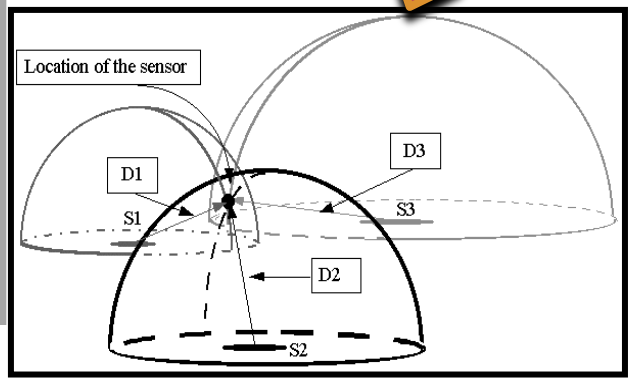

A
B

THERMOCOOL® SMARTTOUCH™ Catheter Design

TRANSMITTER coil in the tip sends location reference signal.

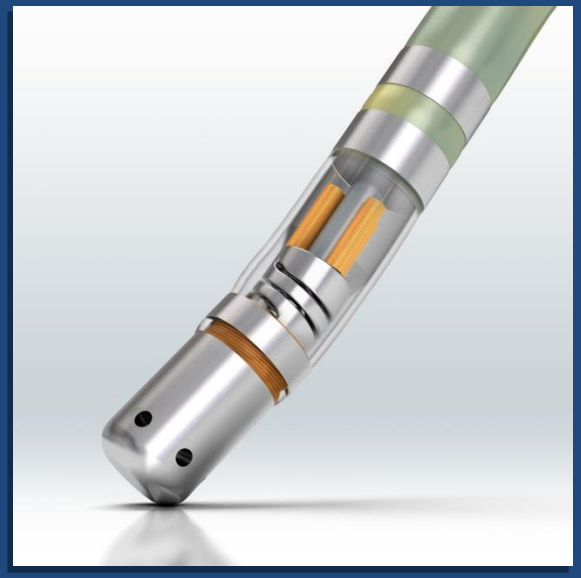


PRECISION SPRING allows small amount of electrode deflection.

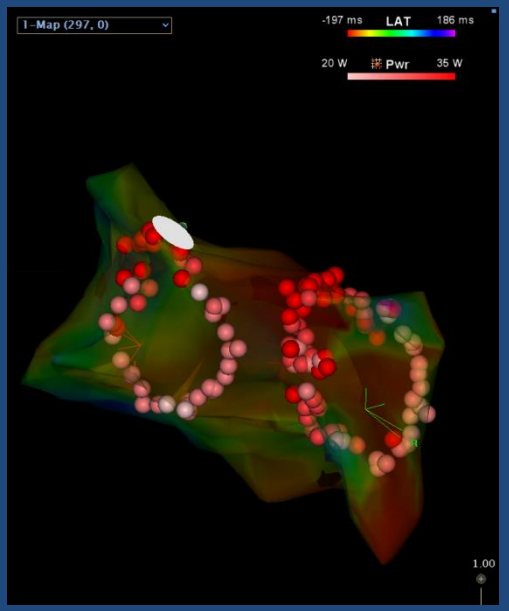


SENSORS receive transmitter coils location signal and micro-movements of the spring.

The Biosense-Webster Solution



THERMOCOOL® SMARTTOUCH ™ Catheter



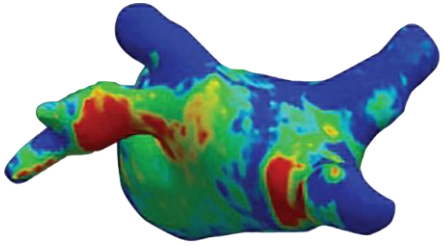
CARTO® 3 System VISITAG™ Module

Biosense Webster®
a Johnson & Johnson company

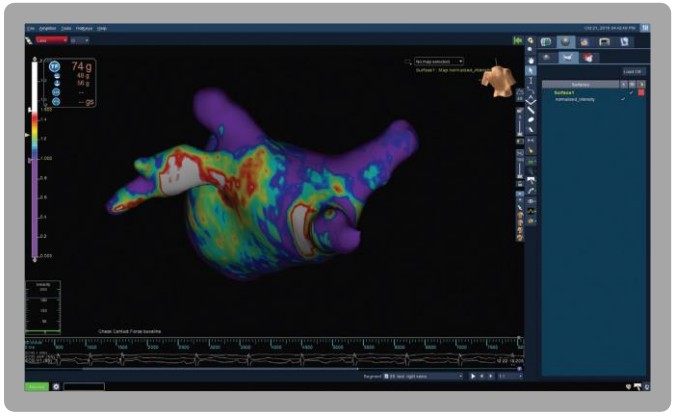
Both CARTO and Precision allow import of CT/MRI

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]



Native DE MRI Import



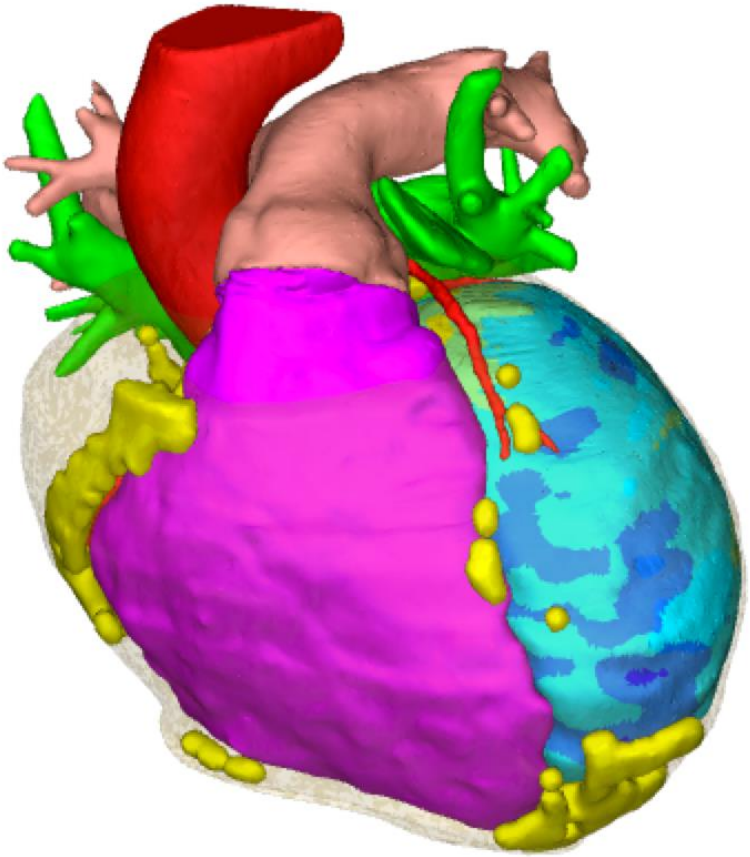
Import using EnSite Precision™ Software v2.0

1. St. Jude Medical. Data on File. Report 90214738.
2. St. Jude Medical. Data on File. Report 90202460.
3. Precision 2.0 Instructions For Use.

ST. JUDE MEDICAL

3DLAB

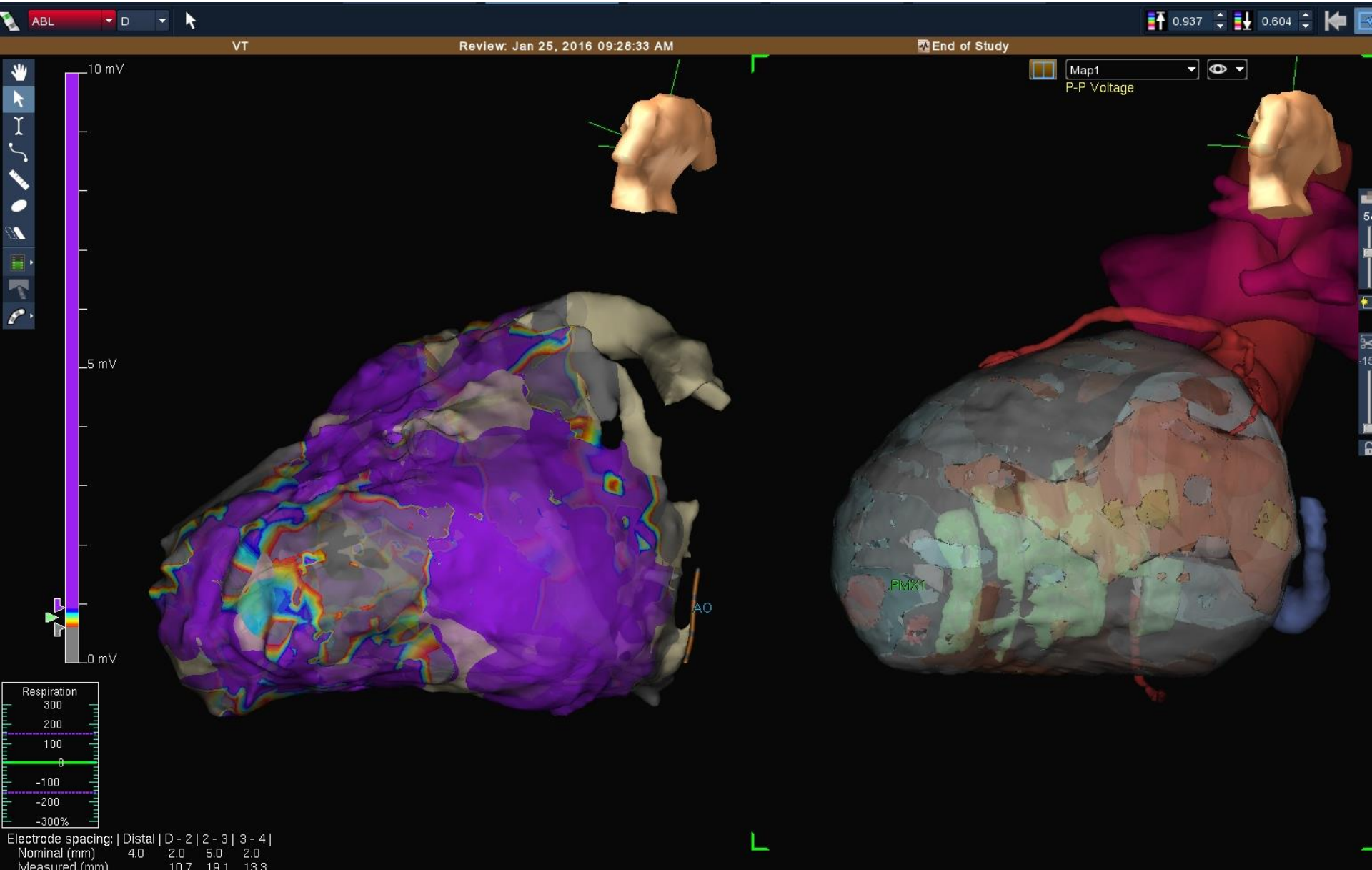
Sheffield Teaching Hospitals NHS
NHS Foundation Trust

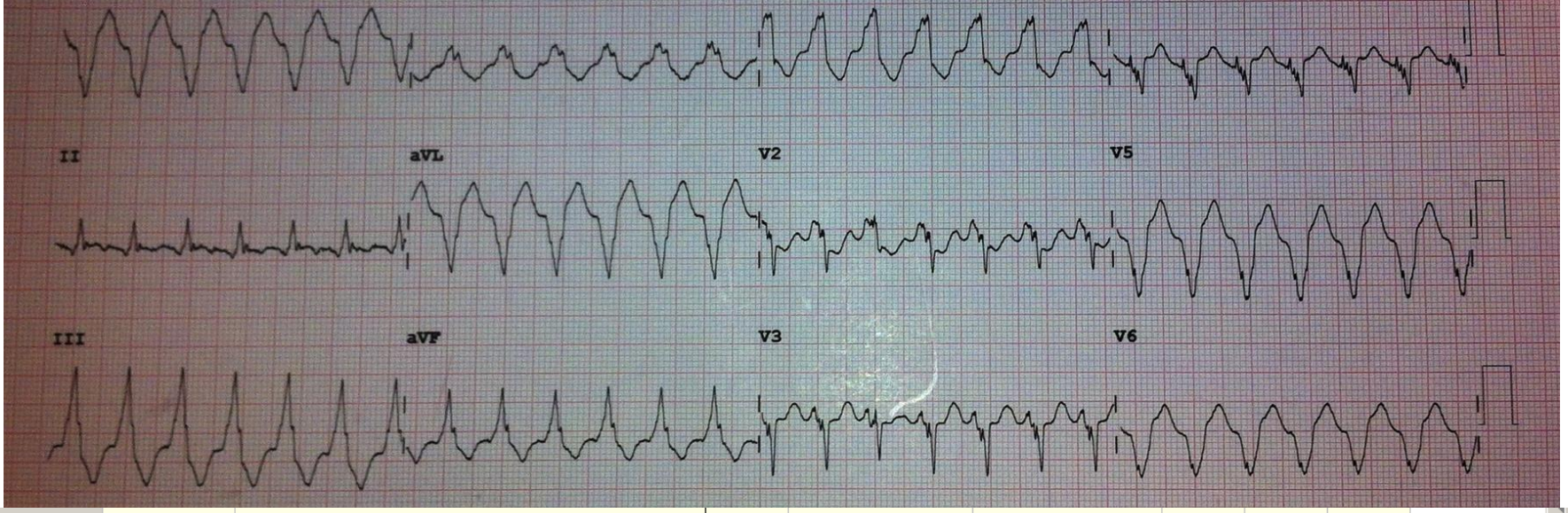


Study Details

Patient Name: [redacted]
Patient DOB:
Patient ID:
Study Date:
Accession No:

Epicardial voltage map





Pace | 12:21:29 | pm1 | 695 | ABLd E-:1 E+:2 | Off | Off | Off | ABLd

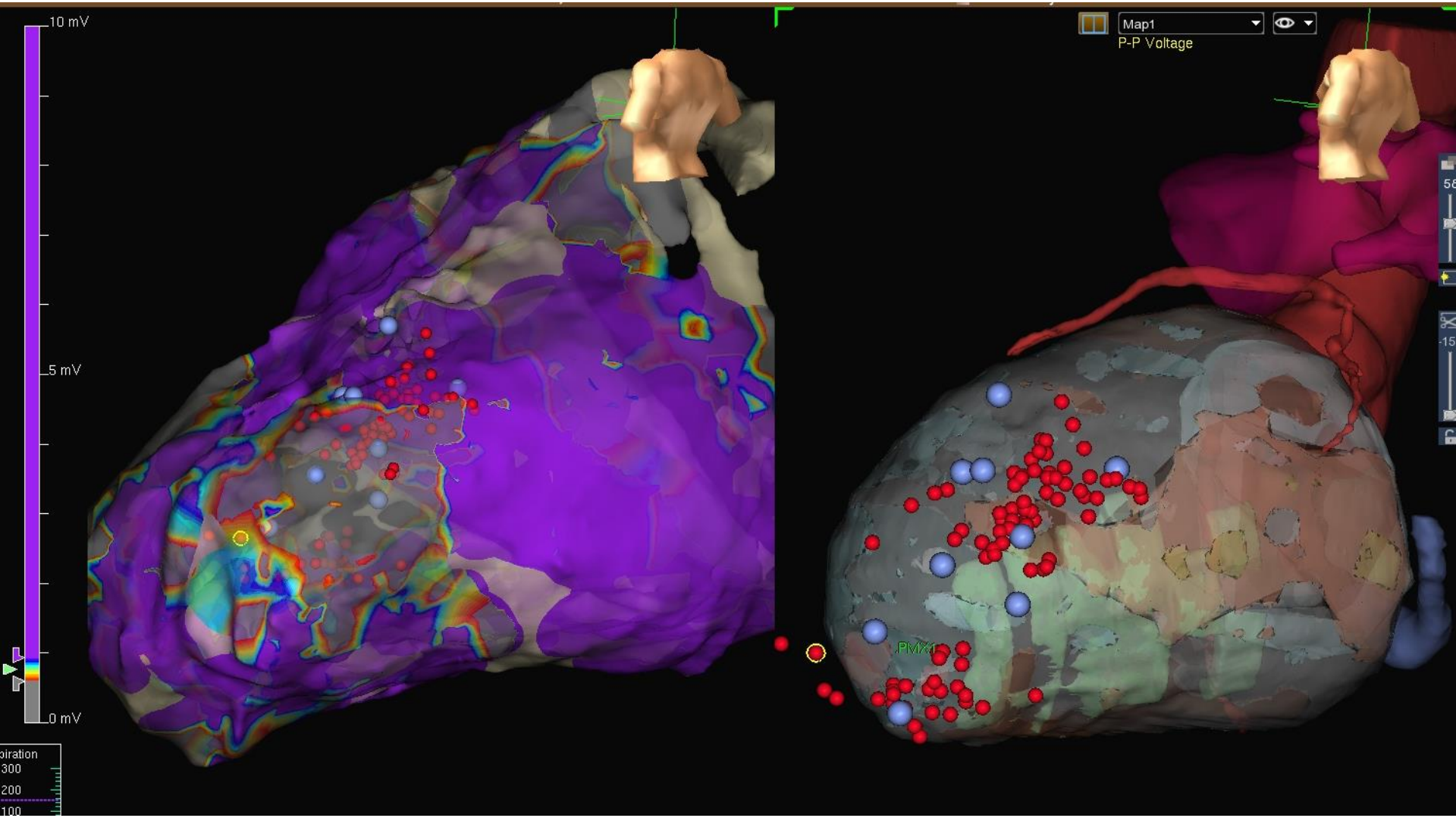
Pace

I
II
III
aVR
aVL
aVF
V1 S
V2
V3
V4
V5
V6

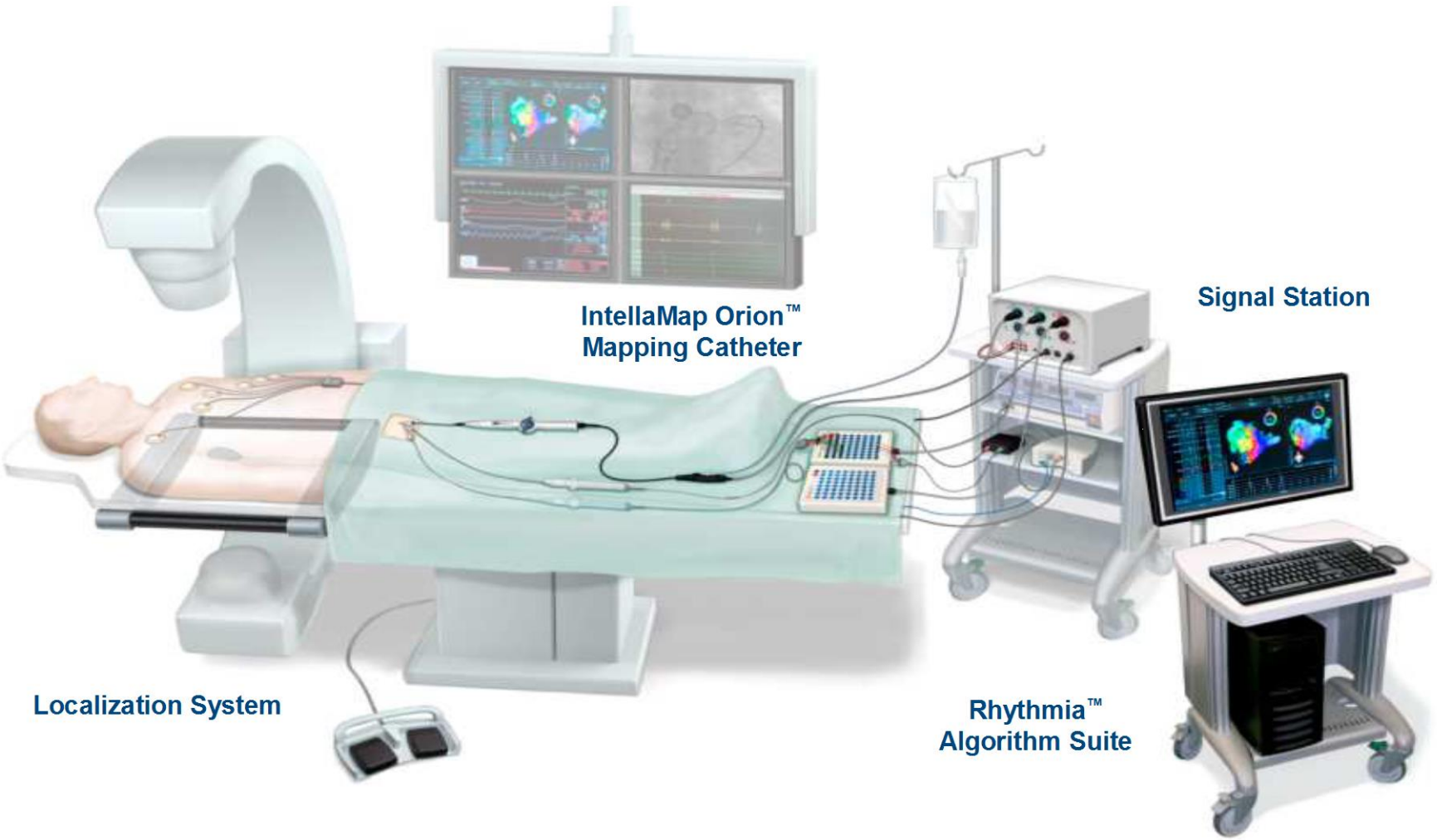
S1 695 S1 700 S1 710 S1 695 S1 695 S1 700 S1 710 S1 700 S1 695 S1

Archive:

12 lead | Study | A | 11136 ms


10 mV
5 mV
0 mV
Map1
P-P Voltage
PMV1

Rhythmia™ Mapping System



Hybrid Localization Technology

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.

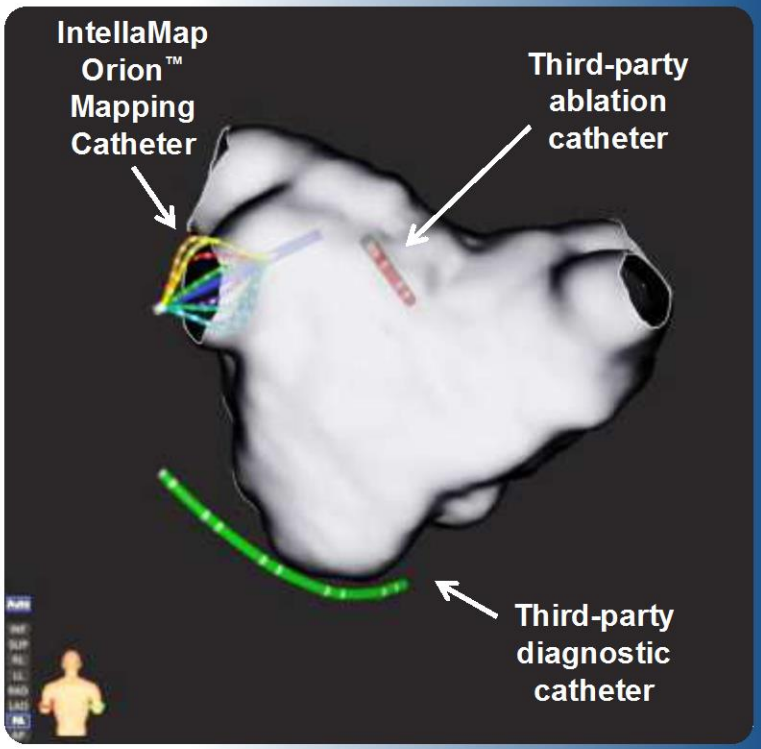
Rhythmia™ Mapping System Localization Technology

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 ≤ 1mm[1]**
- Impedance localization: **Accurate to ≤ 2mm[1]**



1. Preclinical canine study. Data on file.

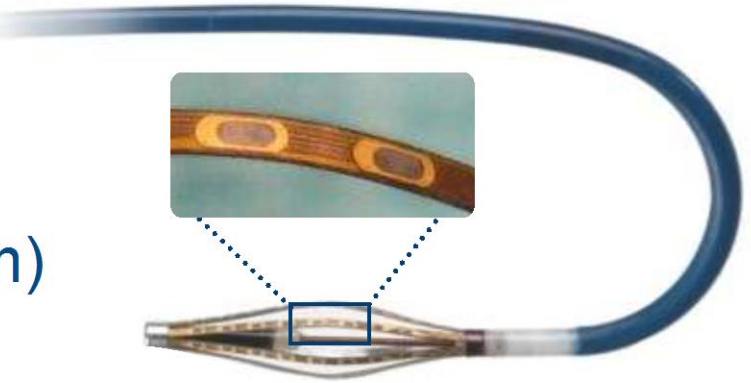
IntellaMap Orion™ Catheter Electrode Array

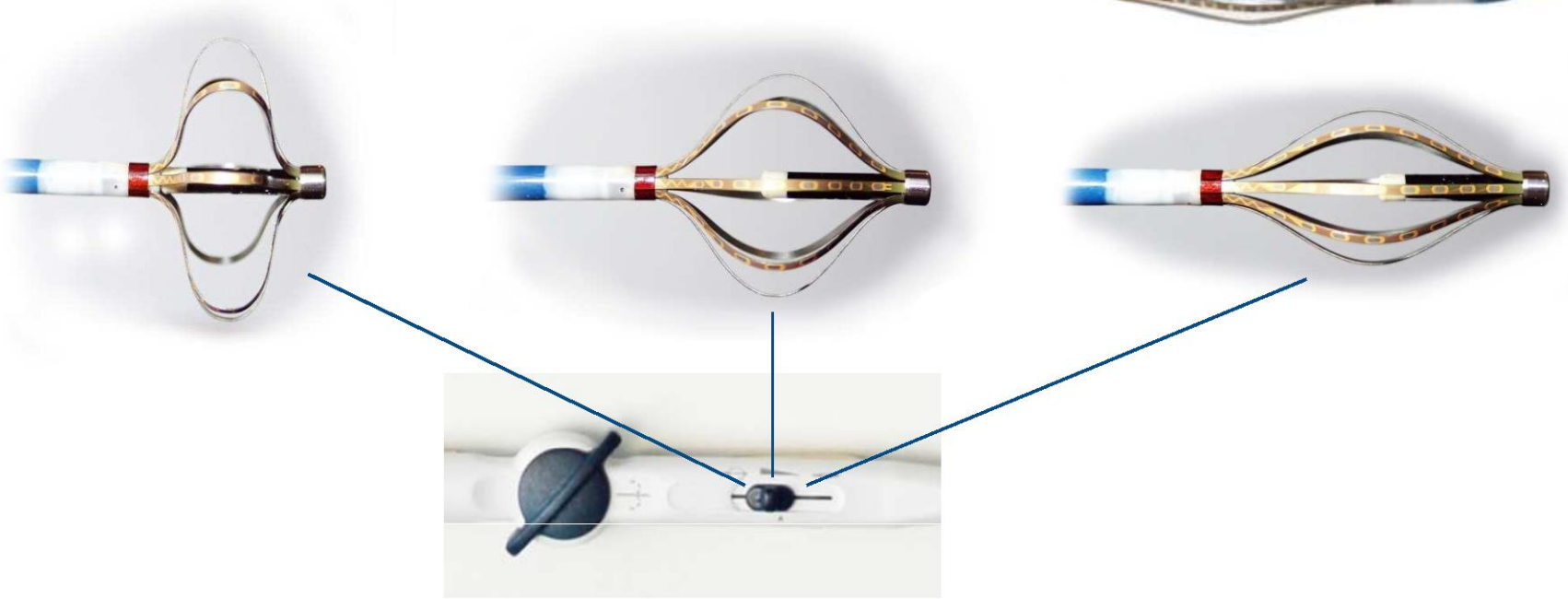
Boston Scientific

Flexible printed circuit bonded to nitinol

2.5 mm inter-electrode spacing (center to center)

0.4mm^2 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[2]

27,000+ EGM High-Resolution, 3D Electroanatomical Map Captured in 15 Minutes

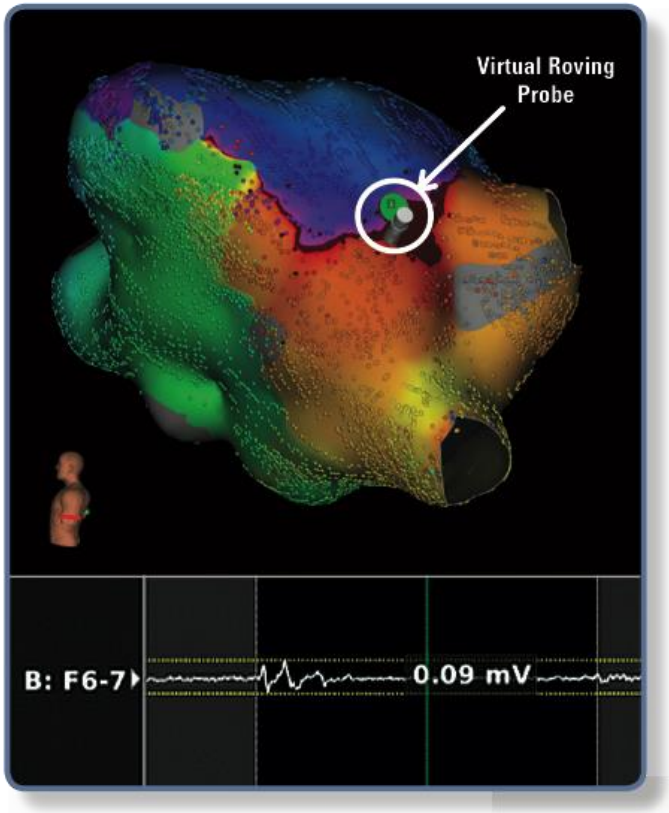
Dynamic Review

- 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

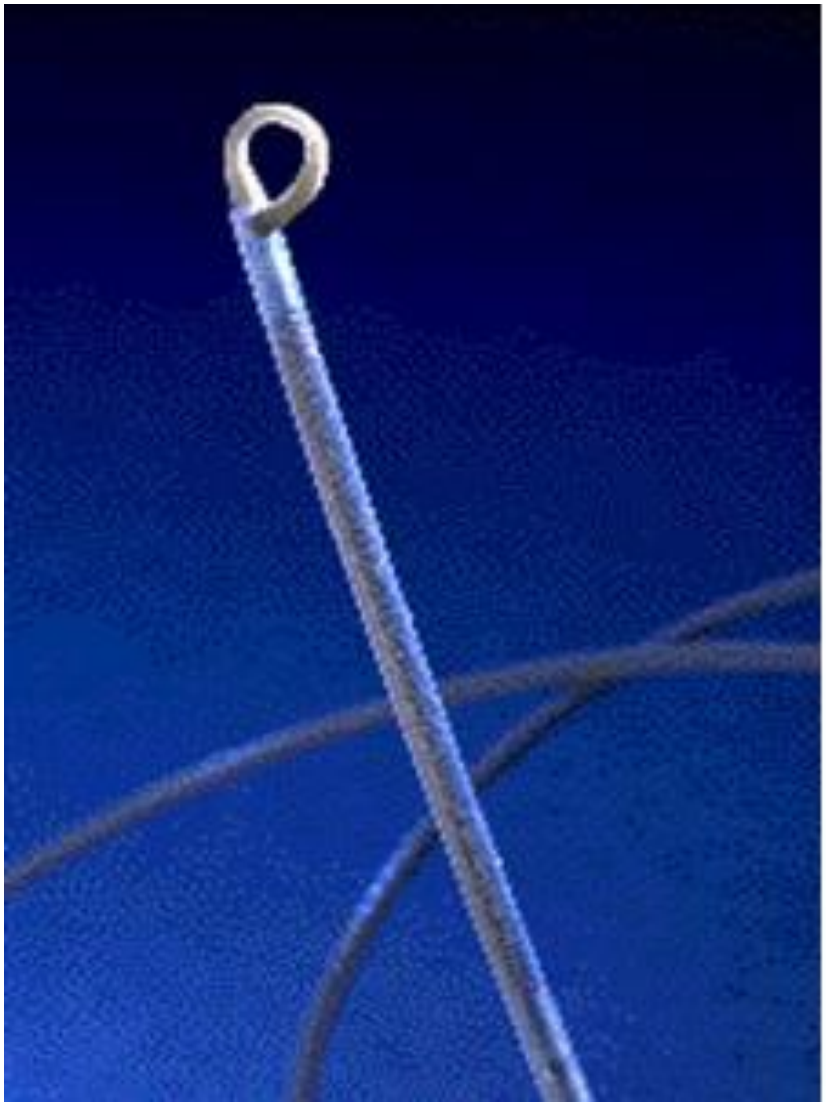
Case Example – Macroreentrant Atrial Tachycardia



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

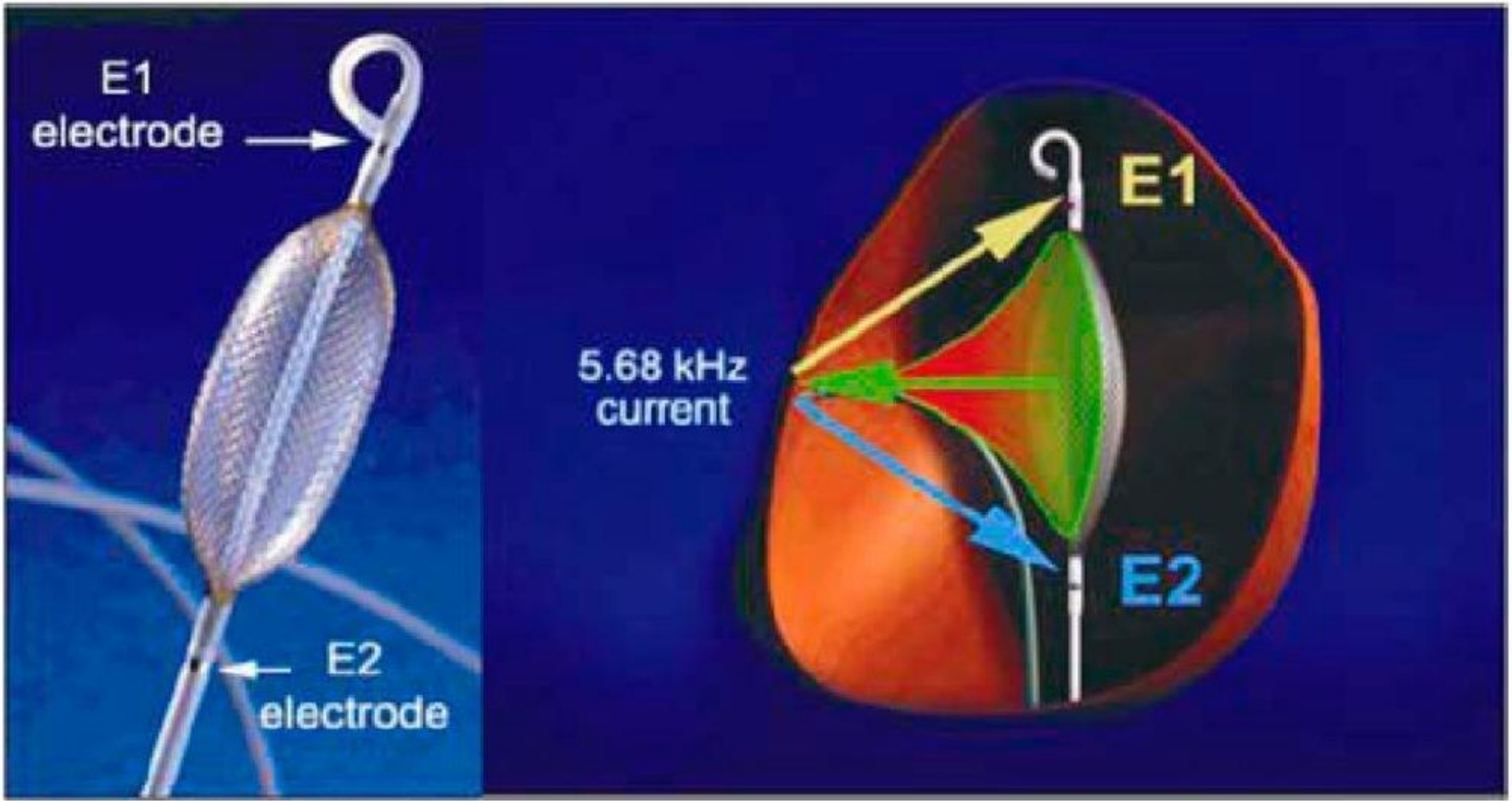
SJM Ensite Array



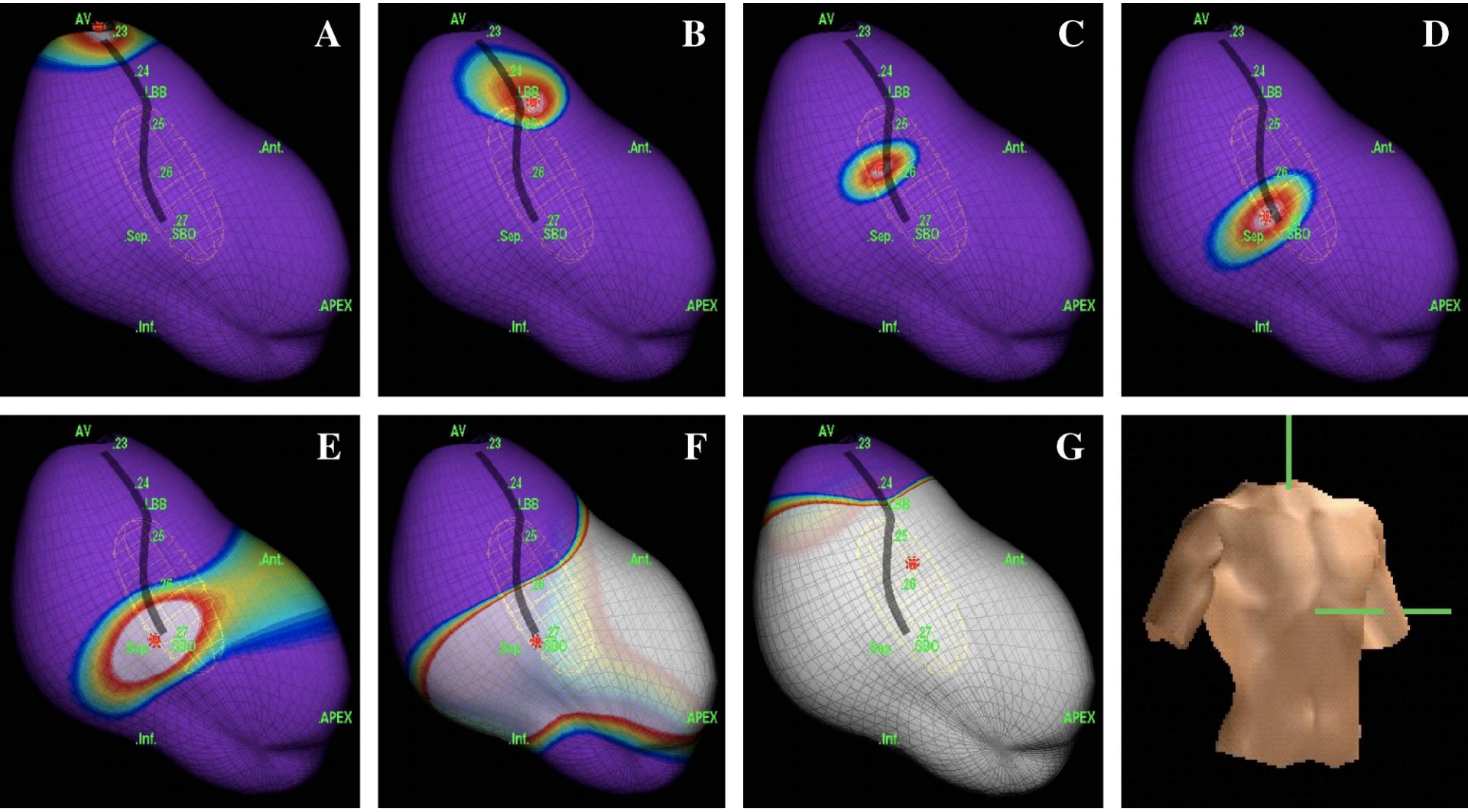
SJM Ensite Array

- 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

ST. JUDE MEDICAL



- Ideally position equator of Array balloon over area of interest


A
B
C
D
E
F
G
AV
.23
.24
LBB
.25
.26
.27
SBO
Sep.
Ant.
APEX
Inf.

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

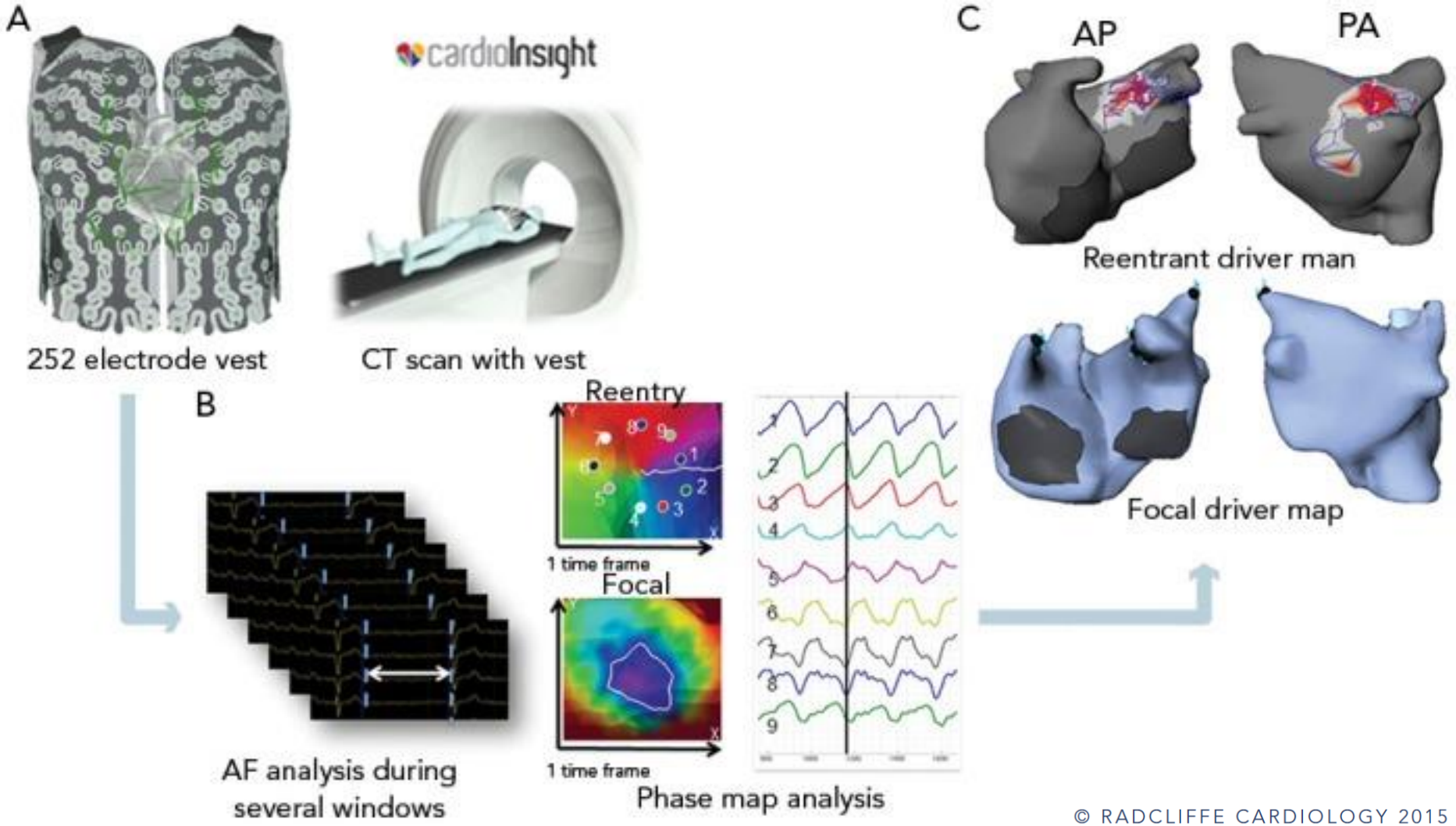
Body Surface Mapping

Medtronic cardioInsight

Body Surface Mapping to Guide Atrial Fibrillation Ablation

Seigo Yamashita,[1] Ashok J Shah,[1] Saagar Mahida,[1] Jean-Marc Sellal,[1] Benjamin Berte,[1] Darren Hooks,[1] Antonio Frontera,[1] Nora Al Jefairi,[1] Jean-Yves Wielandts,[1] Han S Lim,[1] Sana Amraoui,[1] Arnaud Denis,[1] Nicolas Derval,[1,2] Frédéric Sacher,[1,2] Hubert Cochet,[2,3] Mélèze Hocini,[1,2] Pierre Jaïs[1,2] and Michel Haïssaguerre[1,2]

1. Hôpital Cardiologique du Haut-Lévêque, CHU de Bordeaux, Pessac, France; 2. Institut Liryc/Equipex Music, Université de Bordeaux-Inserm U1045, Pessac, France; 3. Hôpital Cardiologique du Haut-Lévêque, CHU de Bordeaux, Pessac, France



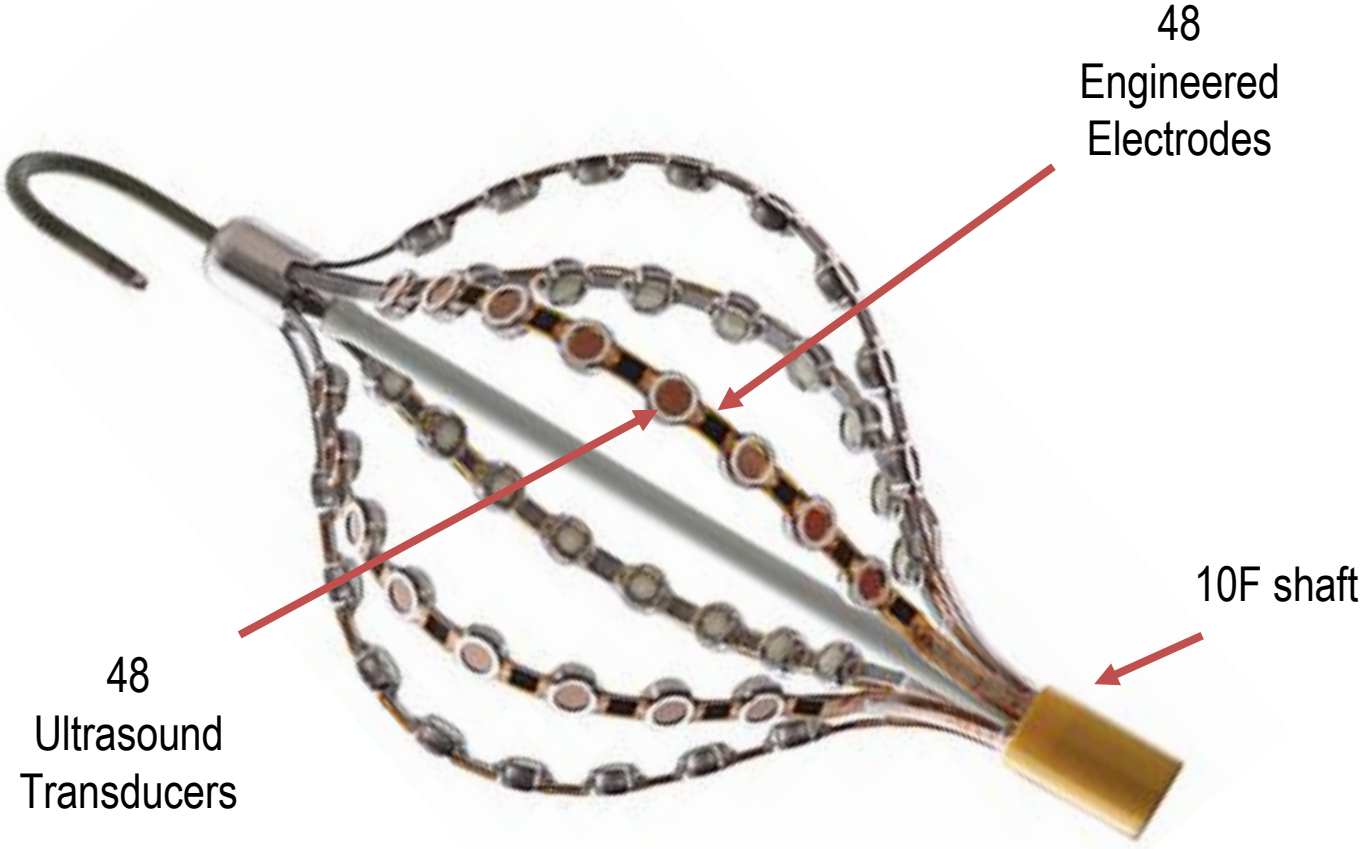
AcQMap System

- 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

ACUTUS MEDICAL

AcQMap 3D Mapping Catheter



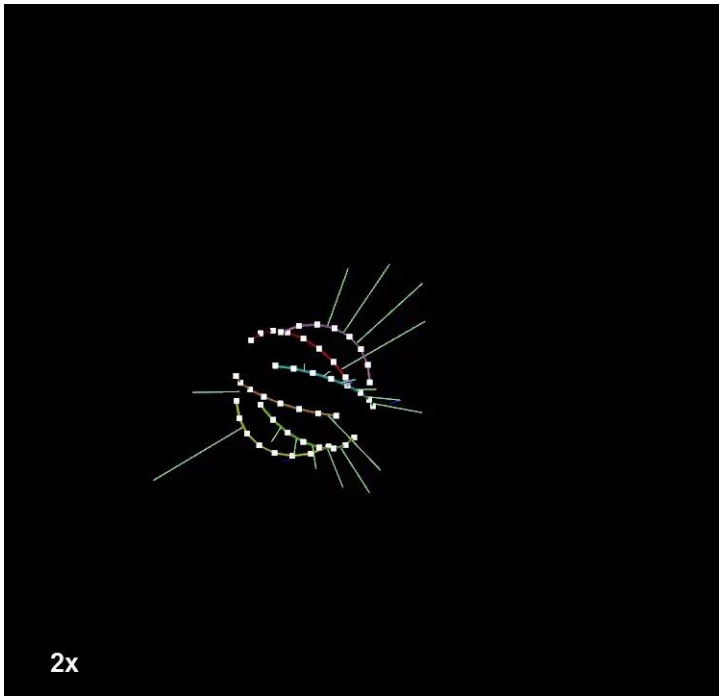
25mm diameter
Up to 115,000 ultrasound points/minute
150,000 intra-cardiac unipolar voltage samples/second

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.

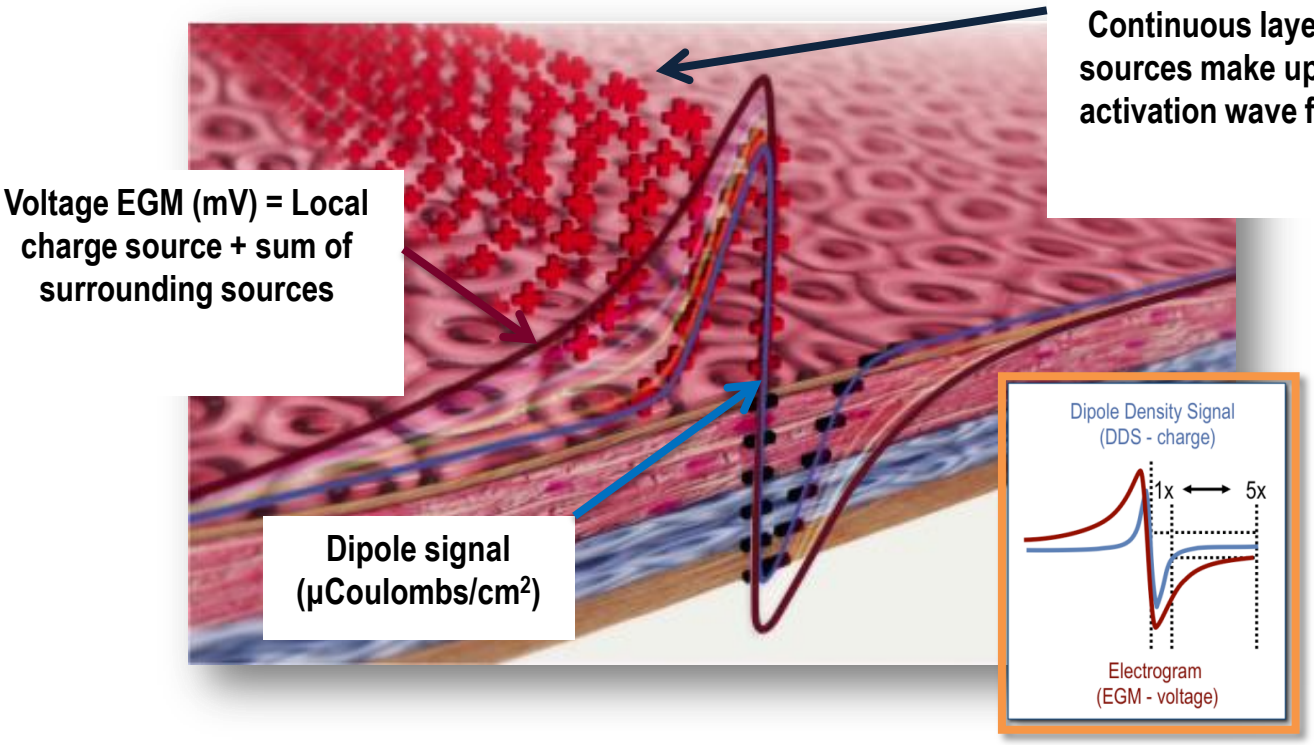
Electrode X,Y,Z localization and ultrasound distances are combined to acquire anatomy

- 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

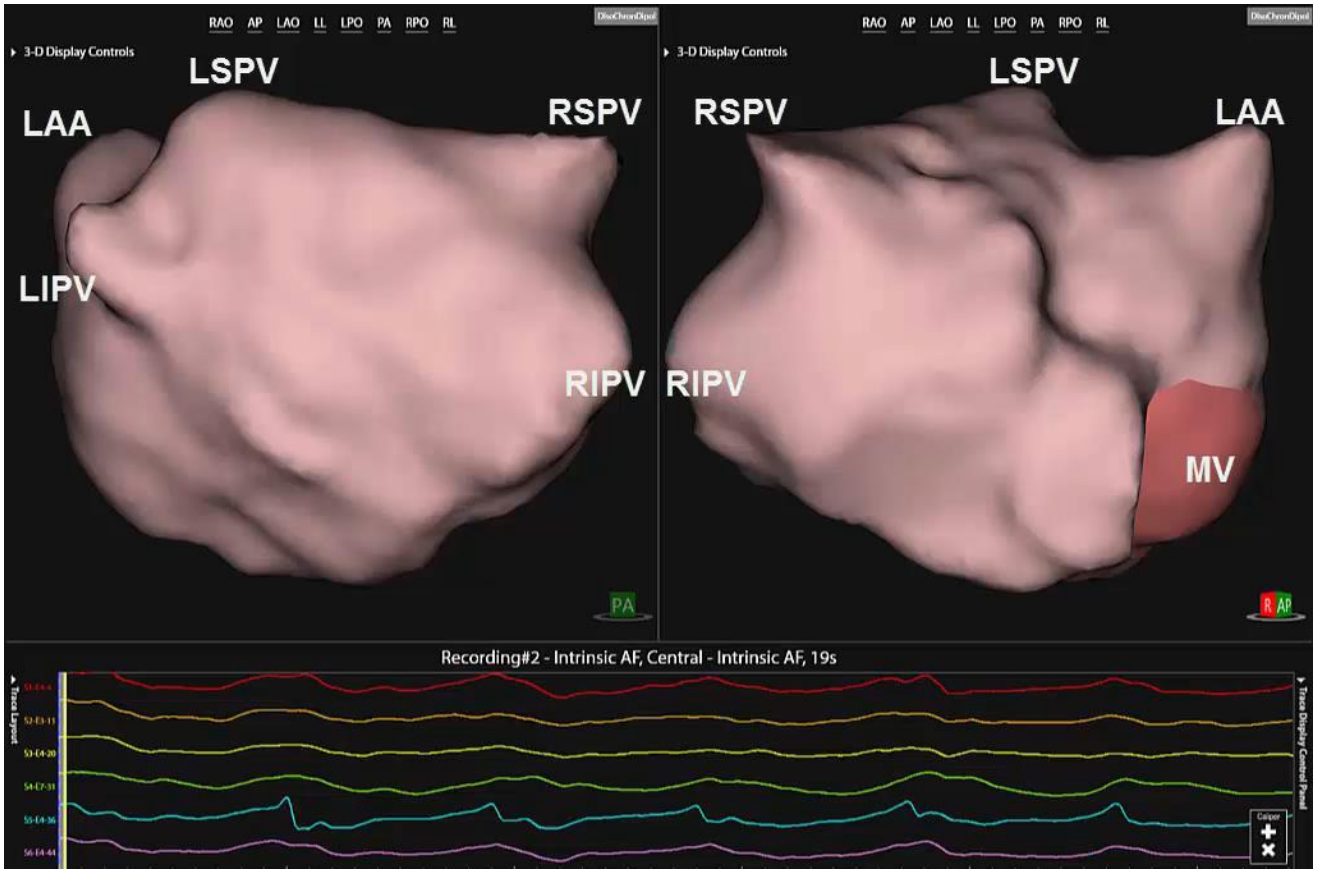
Resolution ~4 times 'sharper'[1]



1. Heck P et al. Novel global ultrasound imaging and continuous dipole density mapping: Initial findings in AF patients. Circulation. 2015:132.

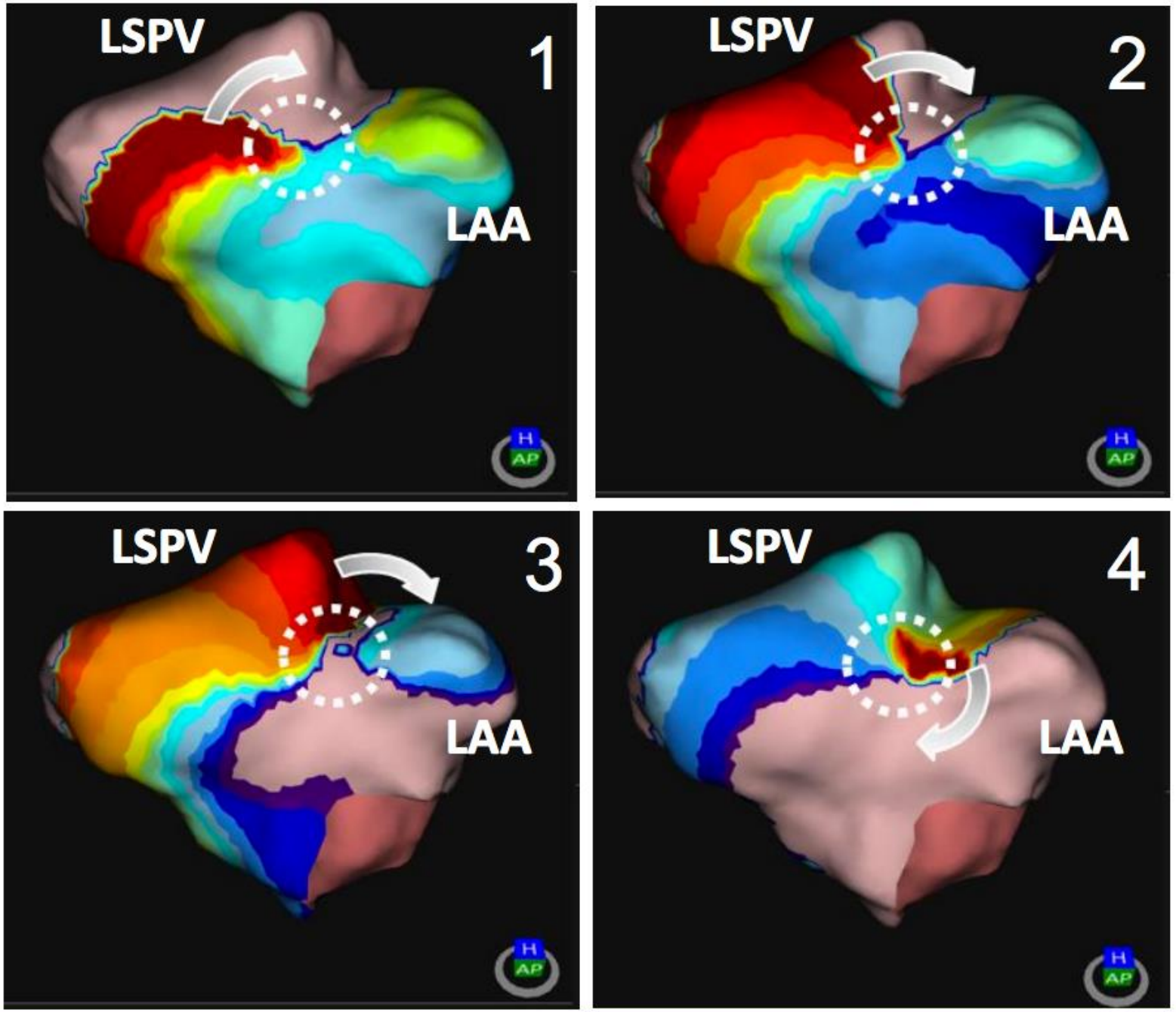
Propagation history tracks leading edge of wavefront conduction

Color bands show earlier location of wavefront conduction



Propagation History = 100 ms

Courtesy of Papworth Hospital, United Kingdom



Moser et al HRS, 2016

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

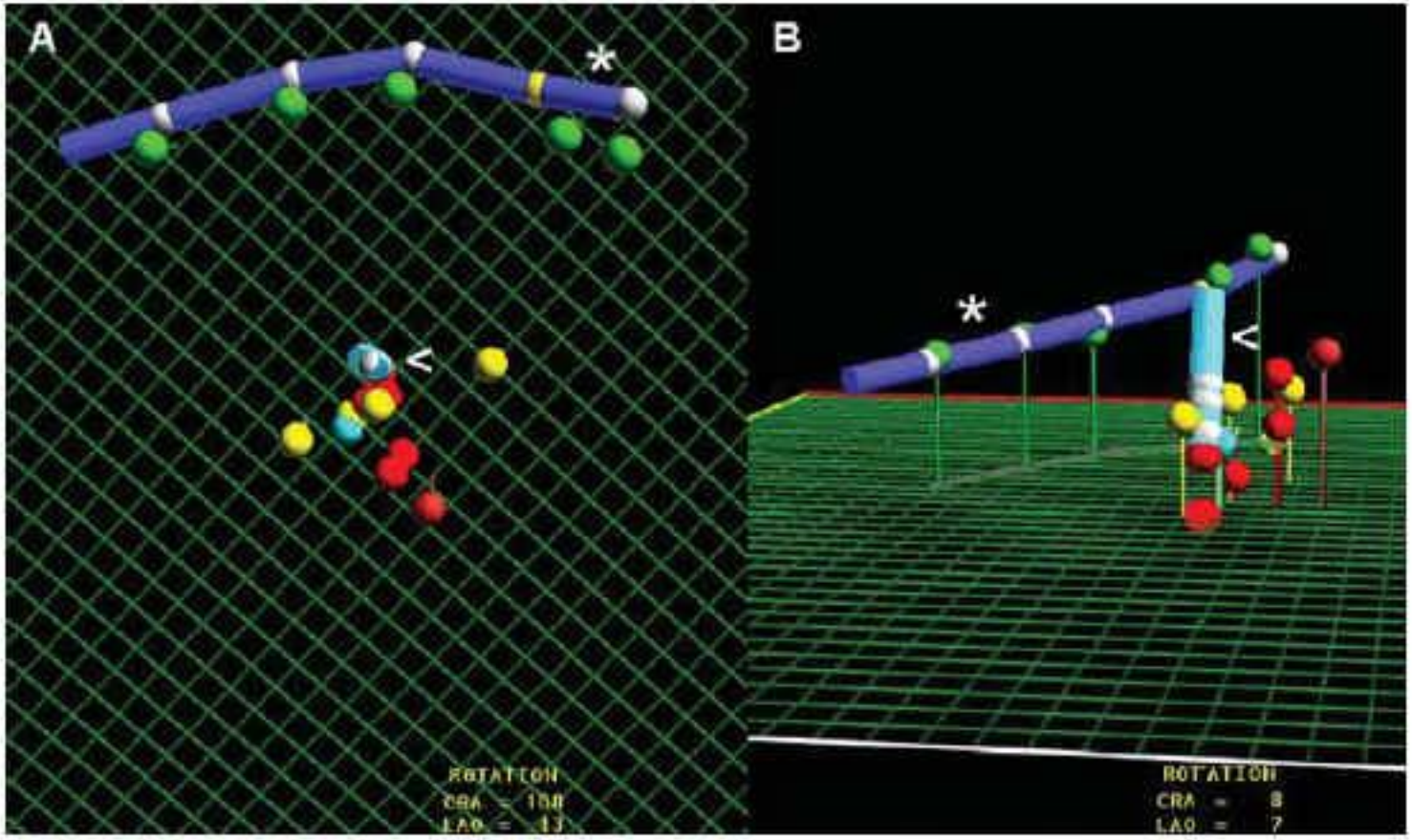
CardioInsight Body surface mapping

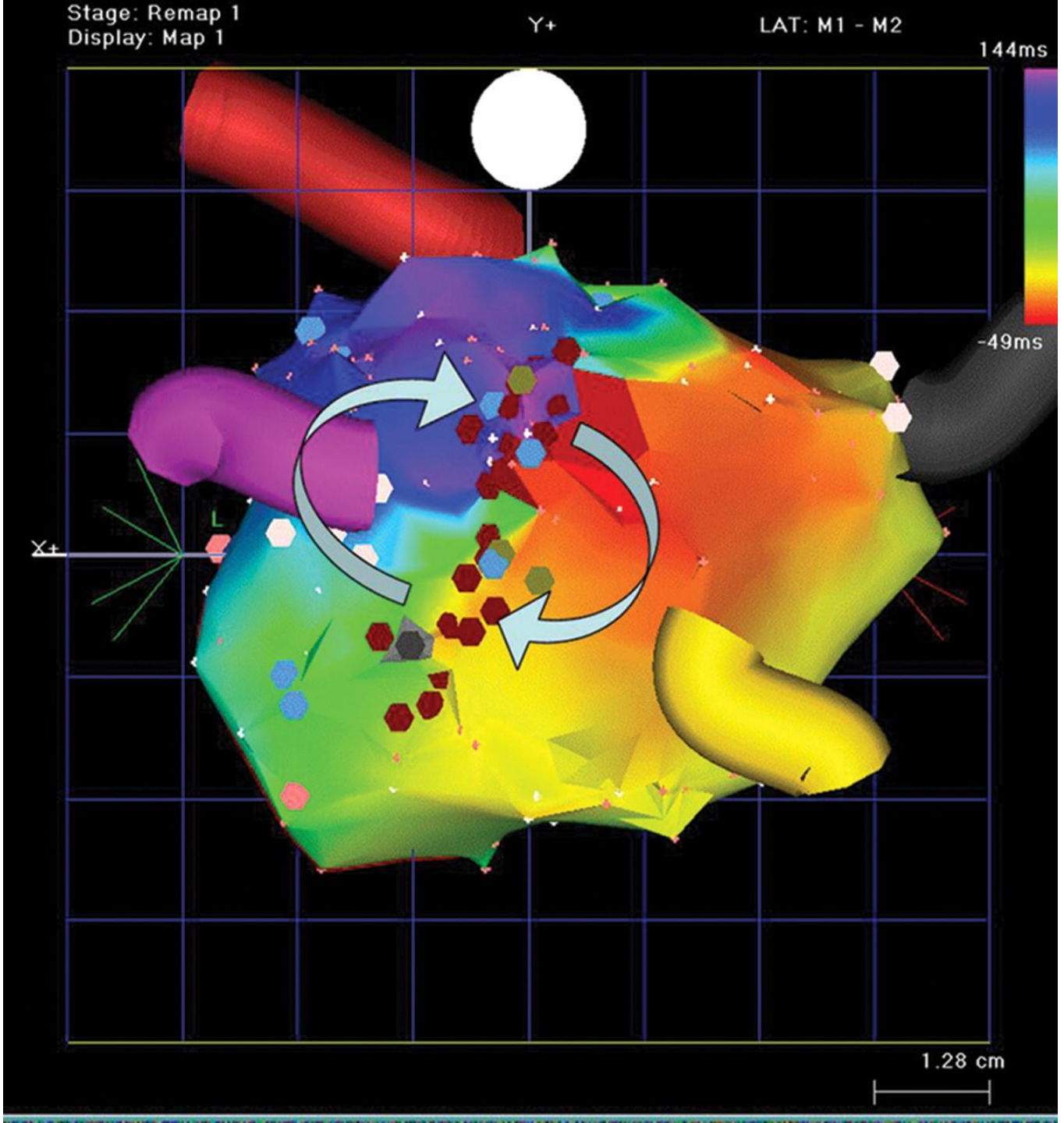
- PROs - non invasive mapping; allows mapping of single beat outside EP lab when patient ambulant;
- CONS – can be difficult to define more ‘internal’ structures eg septum of LA; reconstructed epicardia electrograms may be affected by structures between epicardium and body surface; requires Contact map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

AcQMap Acutus

- PROS - Uses USS to gain CT quality geometry
- CONS - New, expensive

Acknowledgements


A
*
<
ROTATION
CRA = 15
LAO = 13
B
*
<
ROTATION
CRA = 8
LAO = 7

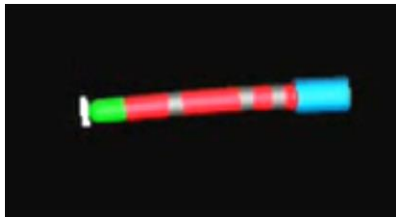

Stage: Remap 1
Display: Map 1
Y+
LAT: M1 - M2
144ms
-49ms
L
X+
1.28 cm

ENSITE PRECISION™ CARDIAC MAPPING SYSTEM

Automated. Flexible. Precise.

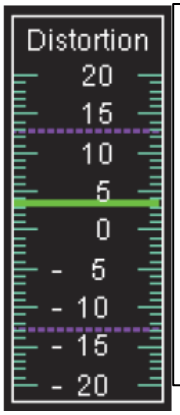
NavX SE Field Scaling

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

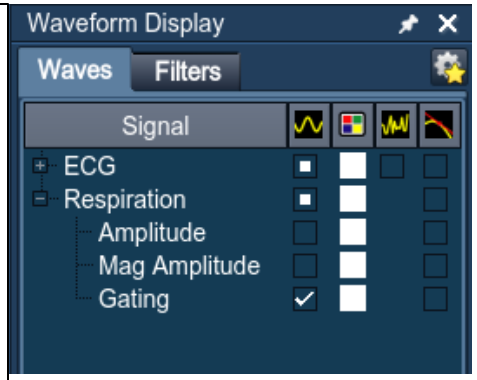


Metal Distortion:

- 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:

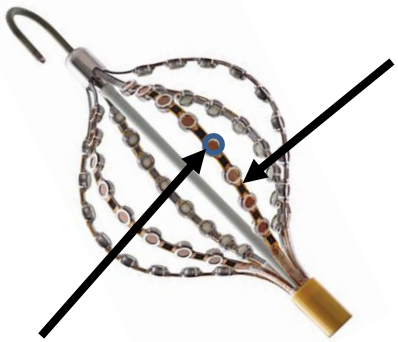
- Changes in respiration pattern impact impedance and magnetic fields differently
- Impedance field compensated by respiration compensation algorithm
- NavX SE point collection gated to end expiration or empty lung state to ensure consistent relationship of impedance and magnetic data
- Gating not applied 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

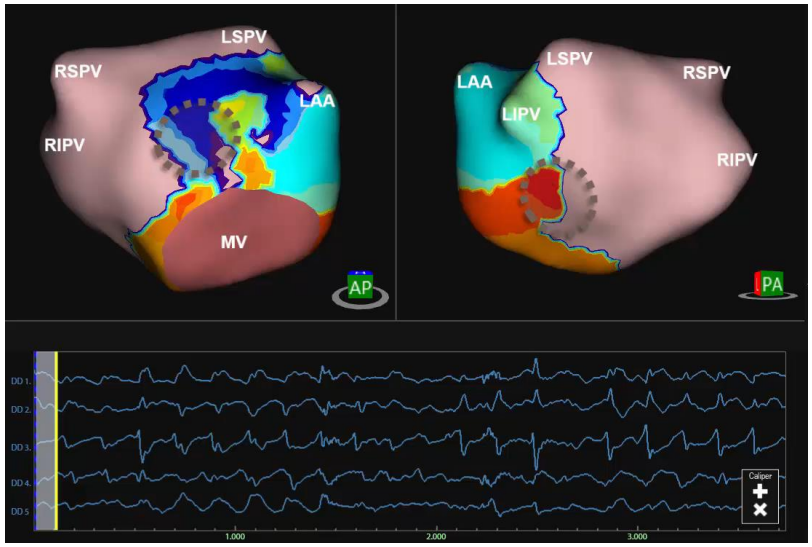
AcQMap Catheter



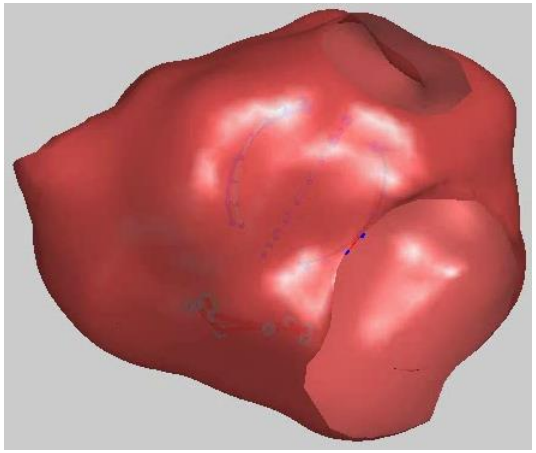
48 Engineered Electrodes

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

outline

- 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
- Rhythmia: magnetic and impedance - perhaps has the advantage of being able to collect more points more quickly. And with higher density – case reviews http://www.bostonscientific.com/en-US/products/capital-equipment--mapping-and-navigation/rhythmia-mapping-system/case-reviews.html

- 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)

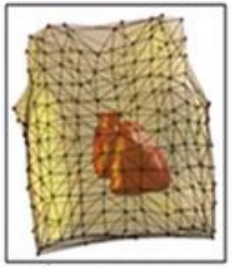
- Could go through each new aspect of mapping system – illustrating it with slides from each company

- 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

CT scan

CT images



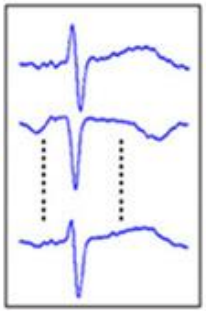
Heart-torso geometry

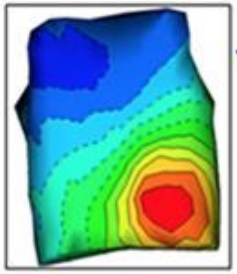
Epicardial surface

Potential (mV)

Electrodes strips

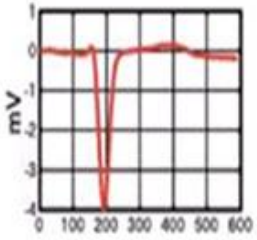
250 electrocardiograms



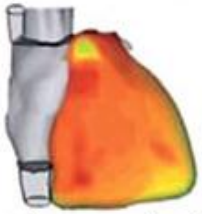


Body surface potentials

CADIS (ECGI software)



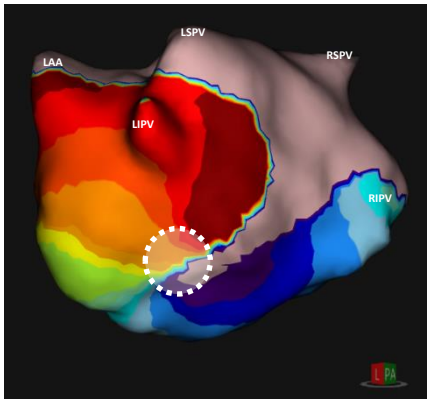
Electrograms (mV)



Isochrones (ms)

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



Identify and locate *arrhythmic mechanism – localized rotational activation*

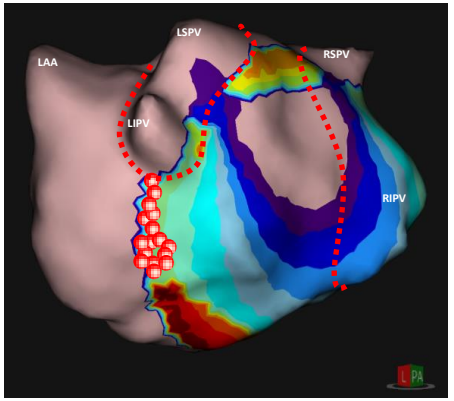
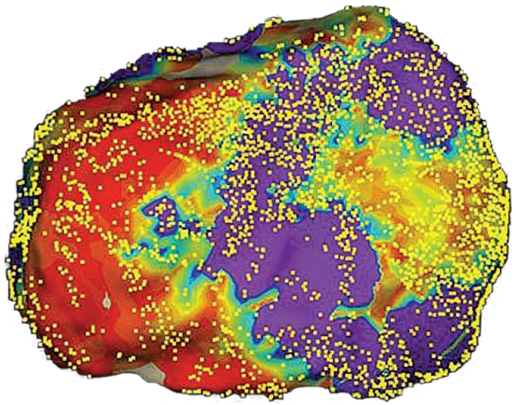


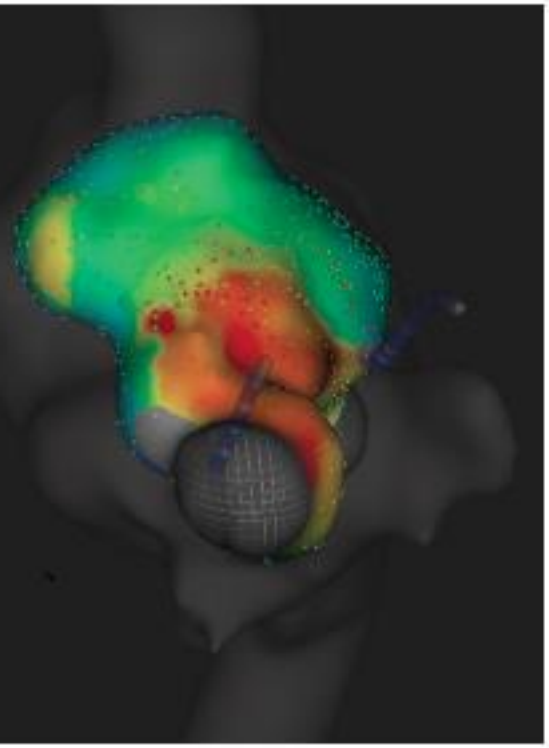
Image guided ablation *strategy with* ***therapy confirmation***

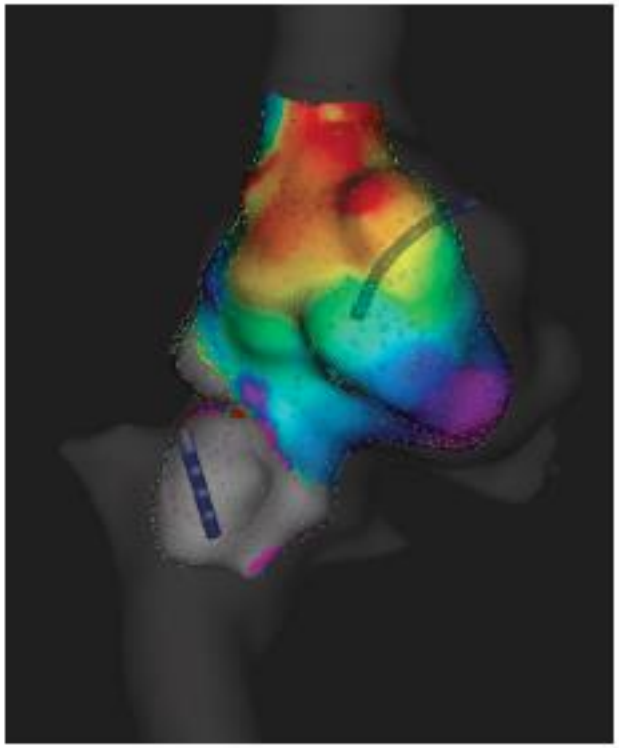
EnSite™ AutoMap Module

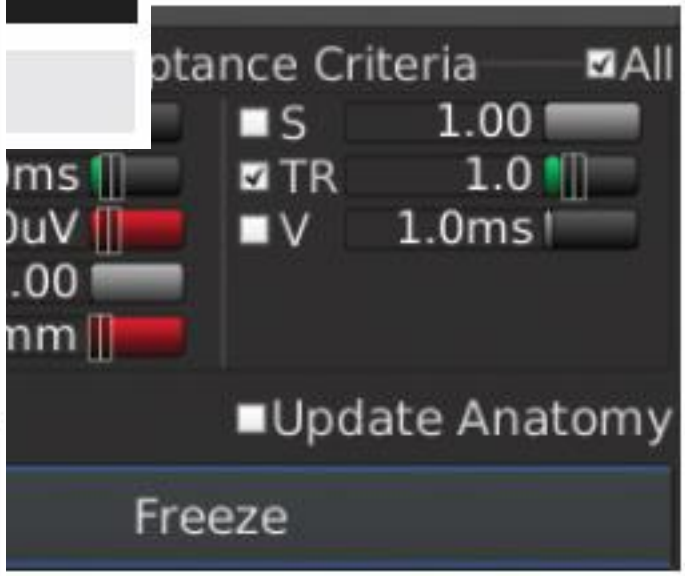
- Create higher density maps in less time using any catheter[1,3]
- Use intuitive automation to increase resolution[2]
- Eliminate time-consuming evaluation of each data point; Points outside of user-specified criteria are automatically excluded[1,3]



1. Ptaszek, L., Moon, B., Sacher, F., Jais, P., Mahapatra, S., & Mansour, M. (2015). *A novel tool for mapping multiple rhythms from a single mapping procedure.* Poster abstract P849. *Europace*, *17*(Suppl 3), iii115.
2. Ptaszek, L., Moon, B., Mahapatra, S., & Mansour, M. (2015, Nov). *Rapid high density automated electroanatomical mapping using multiple chambers and catheter types.* Pending poster abstract. APHRS 2015, Melbourne.
3. St. Jude Medical. Data on File. Report 90214738. Report pending.







ure 5: LAO projection of the
ht atrium showing areas of early
tivation at the 12 o'clock position
ng the tricuspid annulus.

Figure 6: RAO projection of the right atrium showing a peri-sinus nodal area of early activation.

mia Mapping System adjudication criteria.

Rhythmia™ Mapping System and IntellaNav™: Innovation to drive share gains

Boston Scientific

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

through the cracks'.

Mark Nicholls

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×) 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 interst: S.W. is a scientific advisor to Acutus Medical.

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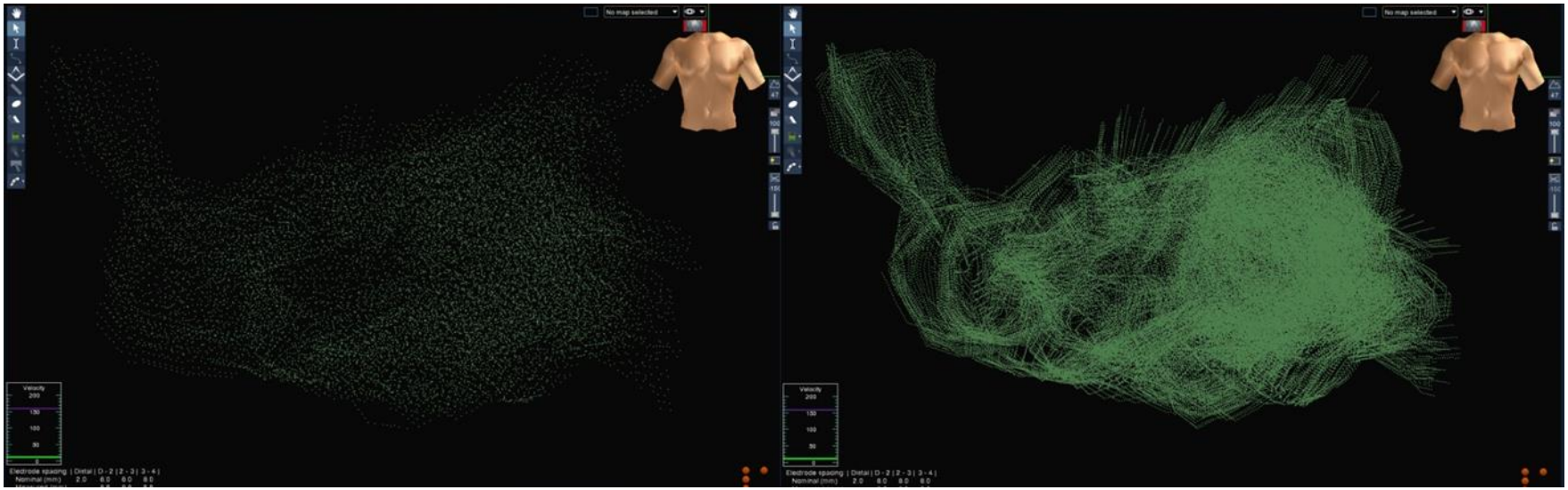
References

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)