



The CARTO[®] Solution

For Your Lab and Your Hospital.

Important information: Prior to use, refer to the instructions for use supplied with this device for indications, contraindications, side effects, warnings and precautions.

Caution: US law restricts this device to sale by or on the order of a physician.

This product can only be used by healthcare professionals in US and EMEA

027680-180712

© Biosense Webster, Inc. 2020 | CARTO[®] Solution Overview



Executive Summary

Many Arrhythmias, One Solution™

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Integration. Scalability. Insights.

The CARTO® 3 System uses current and magnetic based technology to deliver outstanding catheter visualization and location accuracy, without distortion. The CARTO® 3 System enables EPs to be efficient while empowering them to diagnose and treat more arrhythmias.

Unparalleled integration

- ✓ Combine diagnostic data, mapping, imaging, and treatment into one resource
- ✓ Seamlessly integrate a complete suite of technologies in the lab

True Scalability

- ✓ Build a unique approach for any case
 - Physicians can choose from the largest number of modules and catheters on market
- ✓ Enhance and upgrade without replacing
 - Stay up-to-date and acquire the latest technology to meet increasing demands in fast growing areas, such as AF and VT, without having to reinvest in a new system

Actionable insights

- ✓ The CARTO® 3 System allows physicians to make the most informed treatment decisions
- ✓ Get real-time feedback and unique insights about when and how to proceed with treatment

THERMOCOOL® Navigation Catheters are approved for drug refractory recurrent symptomatic paroxysmal atrial fibrillation, when used with CARTO® 3 Systems (excluding NAVISTAR® RMT THERMOCOOL® Catheter).
THERMOCOOL® Navigation Catheters are indicated for the treatment of recurrent drug/device refractory sustained monomorphic ventricular tachycardia (VT) due to prior myocardial infarction (MI) in adults.

Ready for growth

Biosense Webster, Inc., the maker of the CARTO® 3 System, knows your lab needs a proven system that can help you meet increasing AF and VT patient demand.

A legacy of first-to-market innovations

- ✓ Biosense Webster, Inc. has provided ground breaking technological advancements to support physicians, such as:
 - Image integration
 - Irrigated ablation technology
 - 3D integrated contact force therapy

Setting the standards of today

- ✓ For over 20 years, Biosense Webster, Inc. has been a leader in cardiac electrophysiology; with numerous first-to-market products that have advanced the field and gone on to become today's benchmarks central to how physicians treat

Focused on advancements for tomorrow

- ✓ With over 2000 patents in the electrophysiology space, we continue to partner with customers with the goal of improving lab efficiencies, safety during procedures, and, ultimately, finding a cure for all arrhythmias

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THERMOCOOL® Navigation Catheters are indicated for the treatment of recurrent drug/device refractory sustained monomorphic ventricular tachycardia (VT) due to prior myocardial infarction (MI) in adults.

An investment in innovation for today and tomorrow

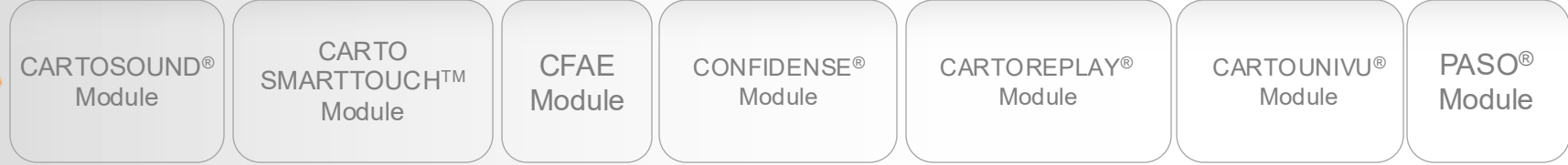


Clinical Features and Benefits

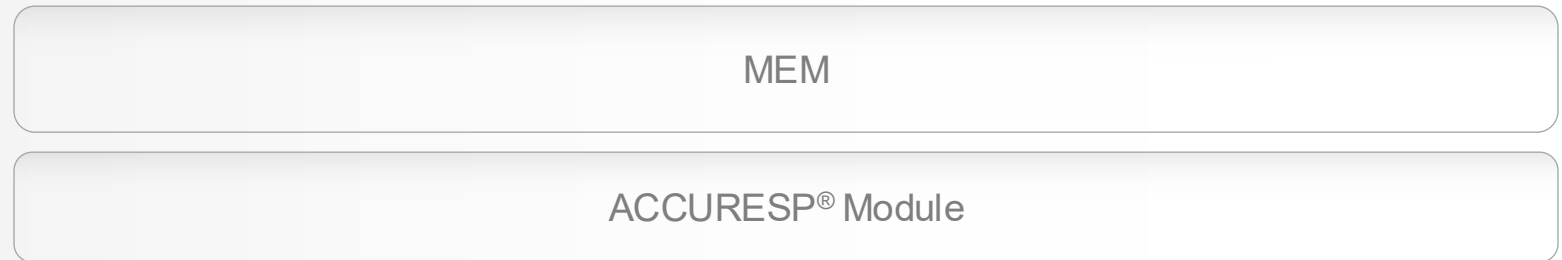
How does the CARTO[®] 3 System work?



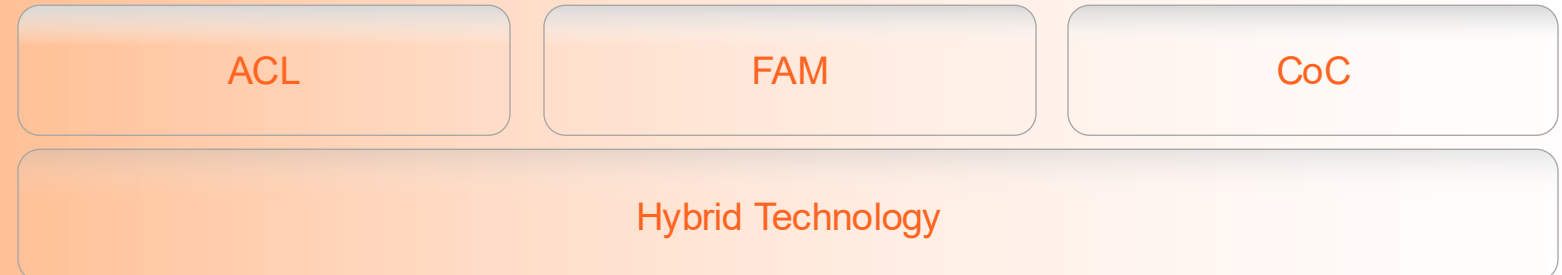
Software Modules



Base Software Enhancements



Core Technology and Features— Base Hardware



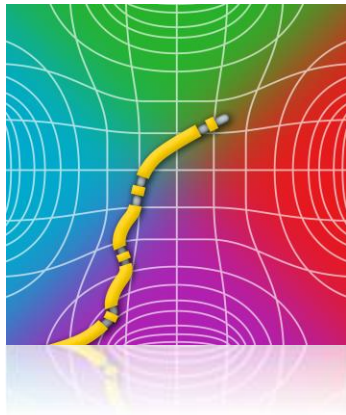
Integration is at our core



The CARTO[®] 3 System: Core Technology

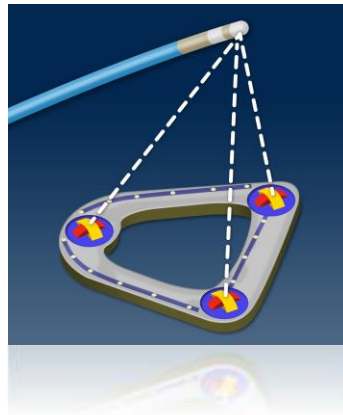
Impedance

- ✓ Visualization of any catheter
- ✓ Non-linear field (low accuracy)
- ✓ Sensitive to biological changes



Magnetic

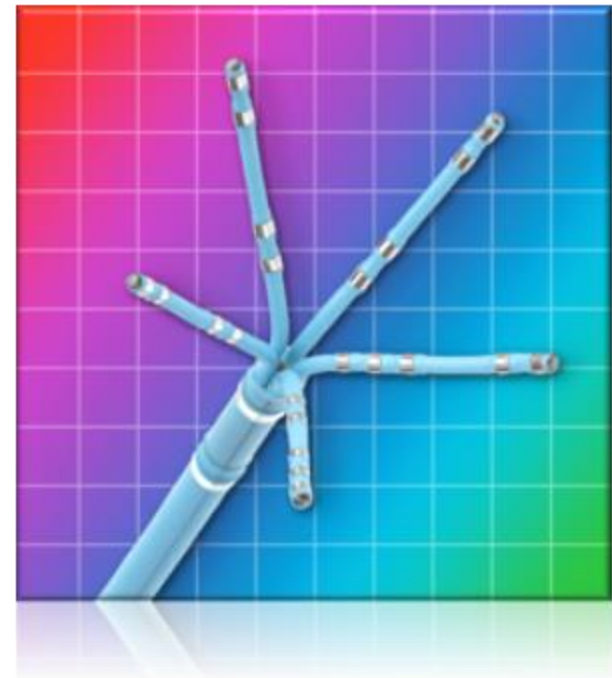
- ✓ Sensor-based technology (good accuracy, +/- 1mm)
- ✓ Not affected by biological changes



Hybrid

- ✓ Linear field
- ✓ Not affected by biological changes
- ✓ Current-based + Magnetic Navigation =

Outstanding Accuracy

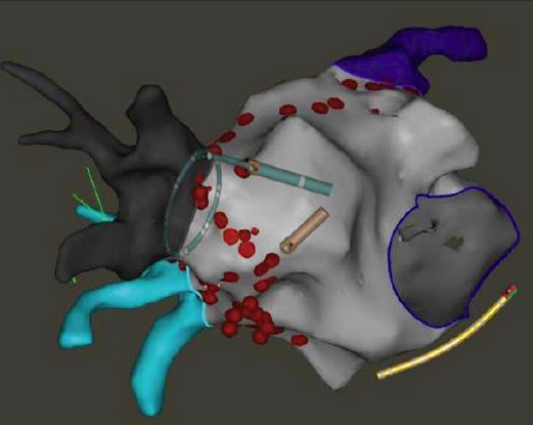


Built to take on the complexities of arrhythmias



Key System Features

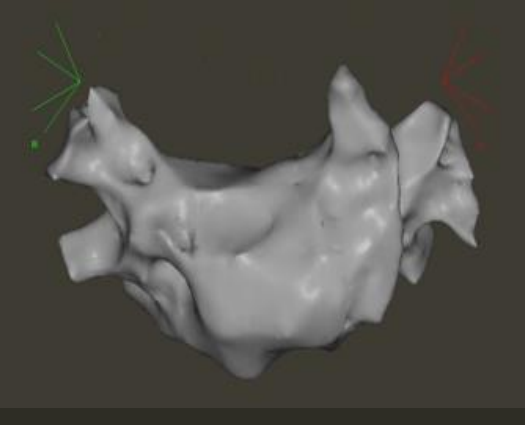
ACL
Advanced Catheter Location



ACCURACY

The image shows a 3D anatomical model of a heart. A catheter is positioned within the heart's chambers. Various regions are highlighted in different colors: red for the endocardium, blue for the atria, and purple for the ventricle. A yellow line indicates the catheter's path. The model is set against a dark background.

FAM
Fast Anatomical Mapping



SPEED

The image shows a 3D anatomical model of a heart. Green and red lines are overlaid on the model, representing the fast anatomical mapping process. The model is set against a dark background.

CONNECTION OF CHOICE®



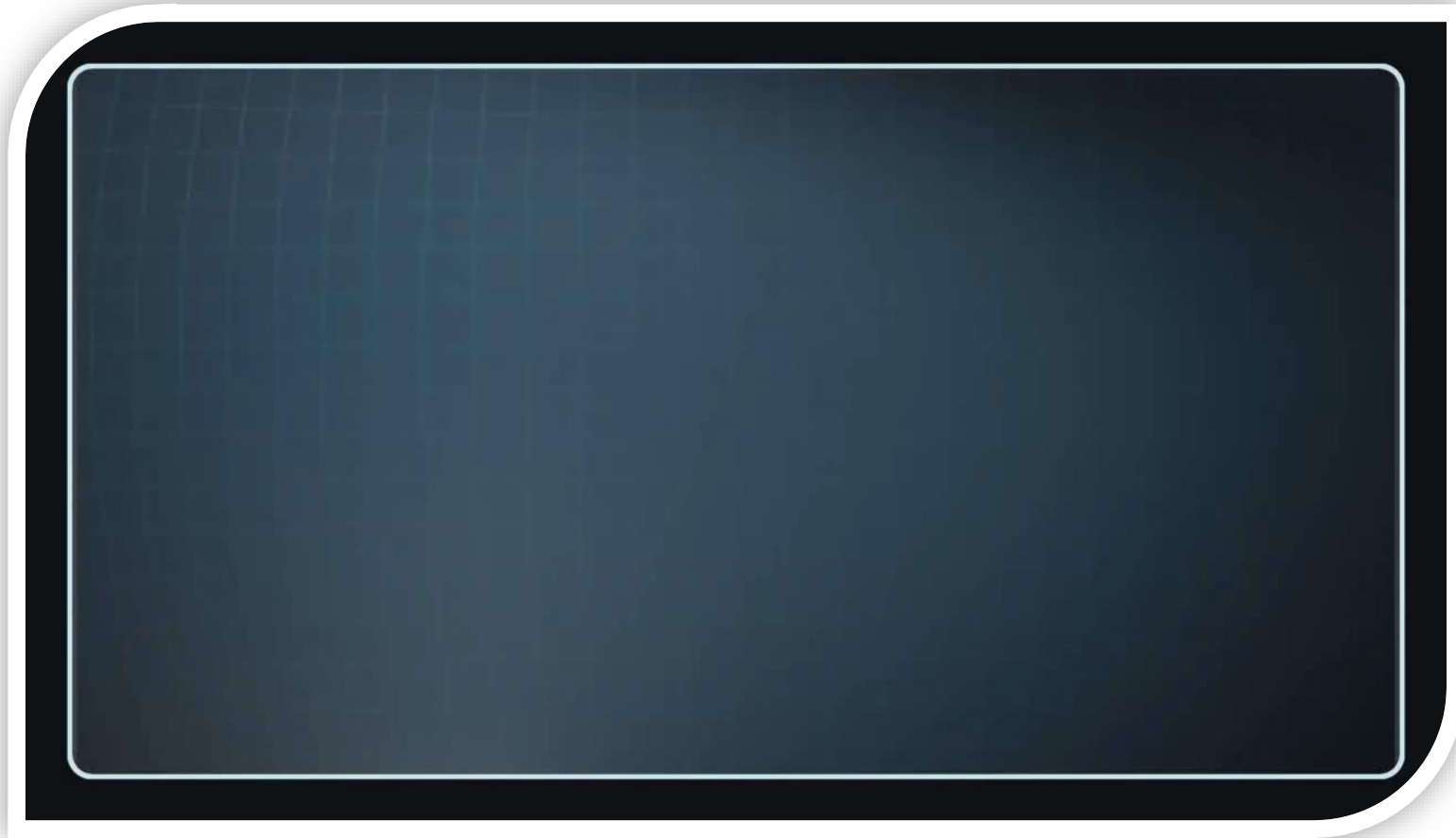
EFFICIENCY

The image shows a surgeon in a blue scrub suit and cap, standing in a catheterization lab. The room is filled with multiple monitors displaying various data and images. The surgeon is looking at the screens, which are part of the CARTO system. The room is dimly lit, with the primary light coming from the monitors.

Calibration

**If you can see it,
you can trust it.**

If you can see your catheters, the field is calibrated and the image is accurate—the system will not display a catheter with ‘semi’ accuracy



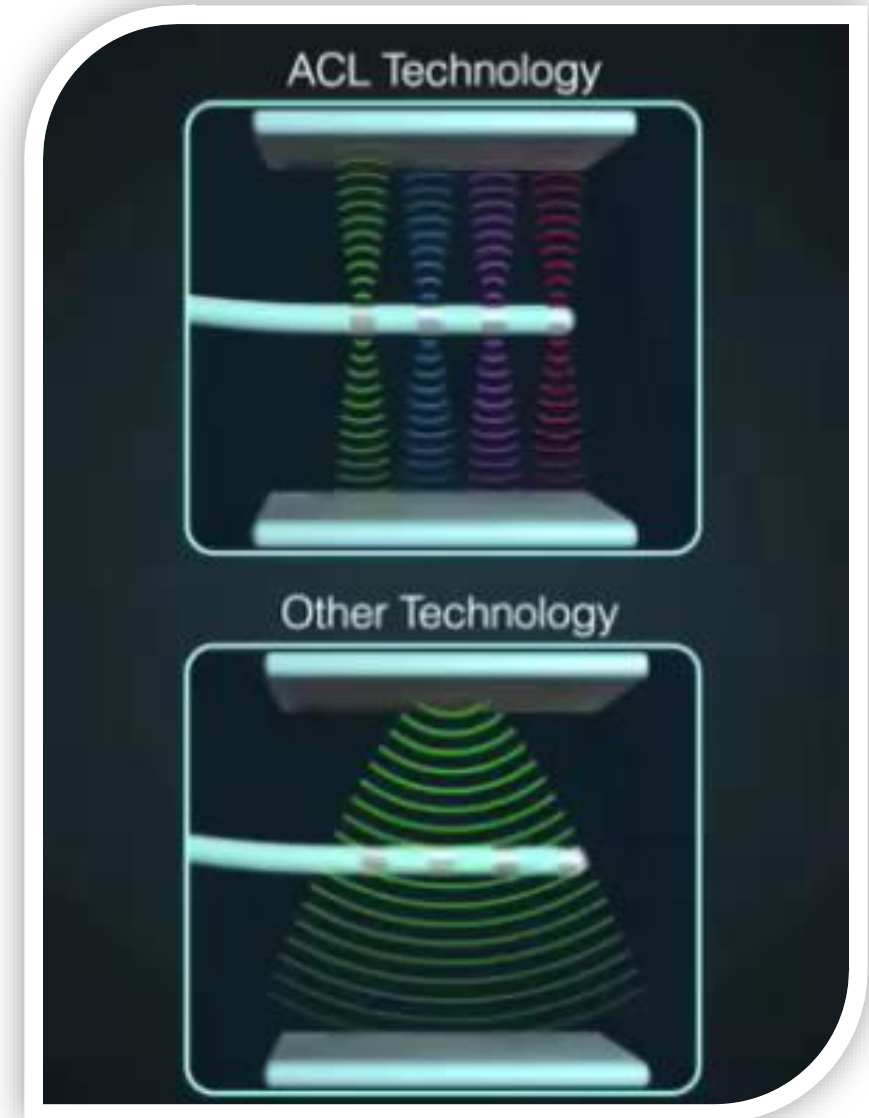
Visualization

The system generates a low current high frequency signal, which is sent through the electrodes of all catheter

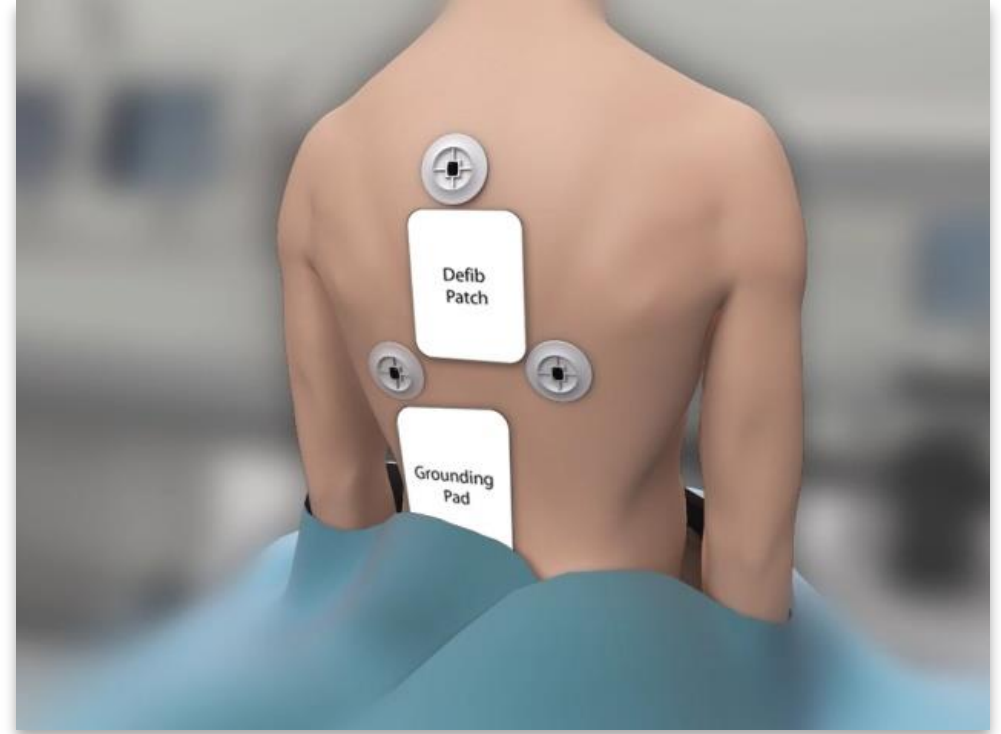
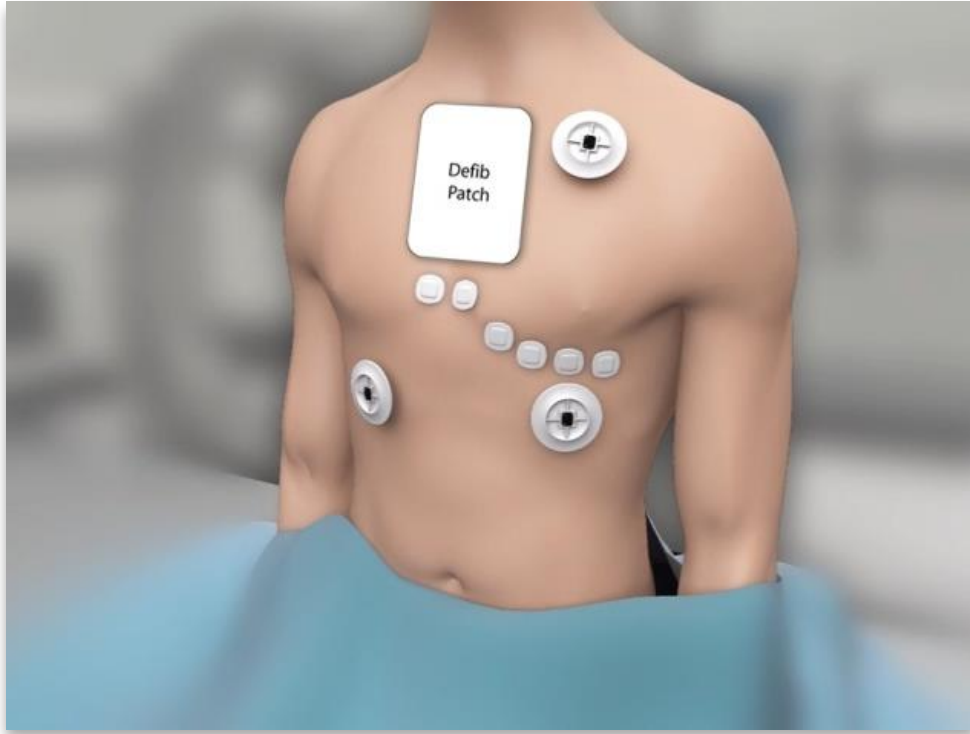
- ✓ Each catheter electrode emits a current at a unique frequency

The six adhesive patches on the patient's body are designed to collect the small current transmitted from the catheter electrodes and calculates a current ratio

For proper patch placement, refer to the Instructions for Use and the CARTO® 3 System's User Manual when using the CARTO® 3 System External Reference Patches in conjunction with the CARTO® 3 System



Example of Patch Placement



For proper patch placement, refer to the Instructions for Use and the CARTO® 3 System's User Manual when using the CARTO® 3 System External Reference Patches in conjunction with the CARTO® 3 System

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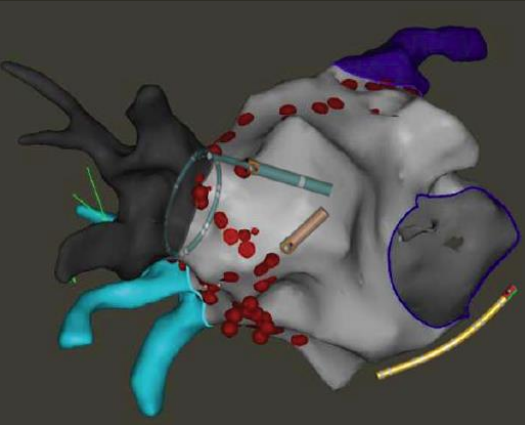
Accuracy

- ✔ Near perfect matches when compared to fluoroscopy imaging
- ✔ Click & See allows user to target chosen electrodes non-fluoroscopically

Shpun S, Gepstein L, Hayam G, et al. Guidance of radiofrequency endocardial ablation with real-time three-dimensional magnetic navigation system. *Circulation*. 1997; 96:2016-2021.

Key System Features

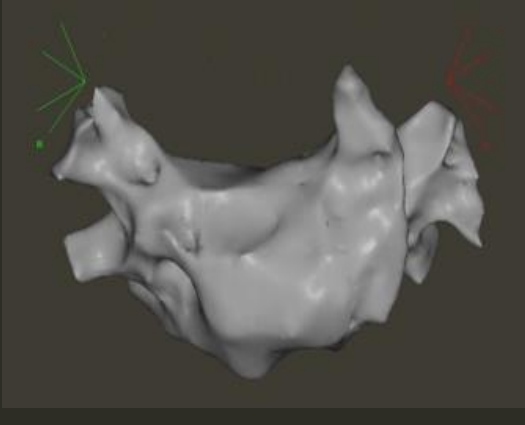
ACL
Advanced Catheter Location



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FAM
Fast Anatomical Mapping



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CONNECTION OF CHOICE®



EFFICIENCY

The image shows a person in a clinical setting, likely a catheterization lab, looking at multiple monitors displaying medical data. The person is wearing a blue scrub suit and a white cap. The monitors show various medical data, including anatomical maps and waveforms.

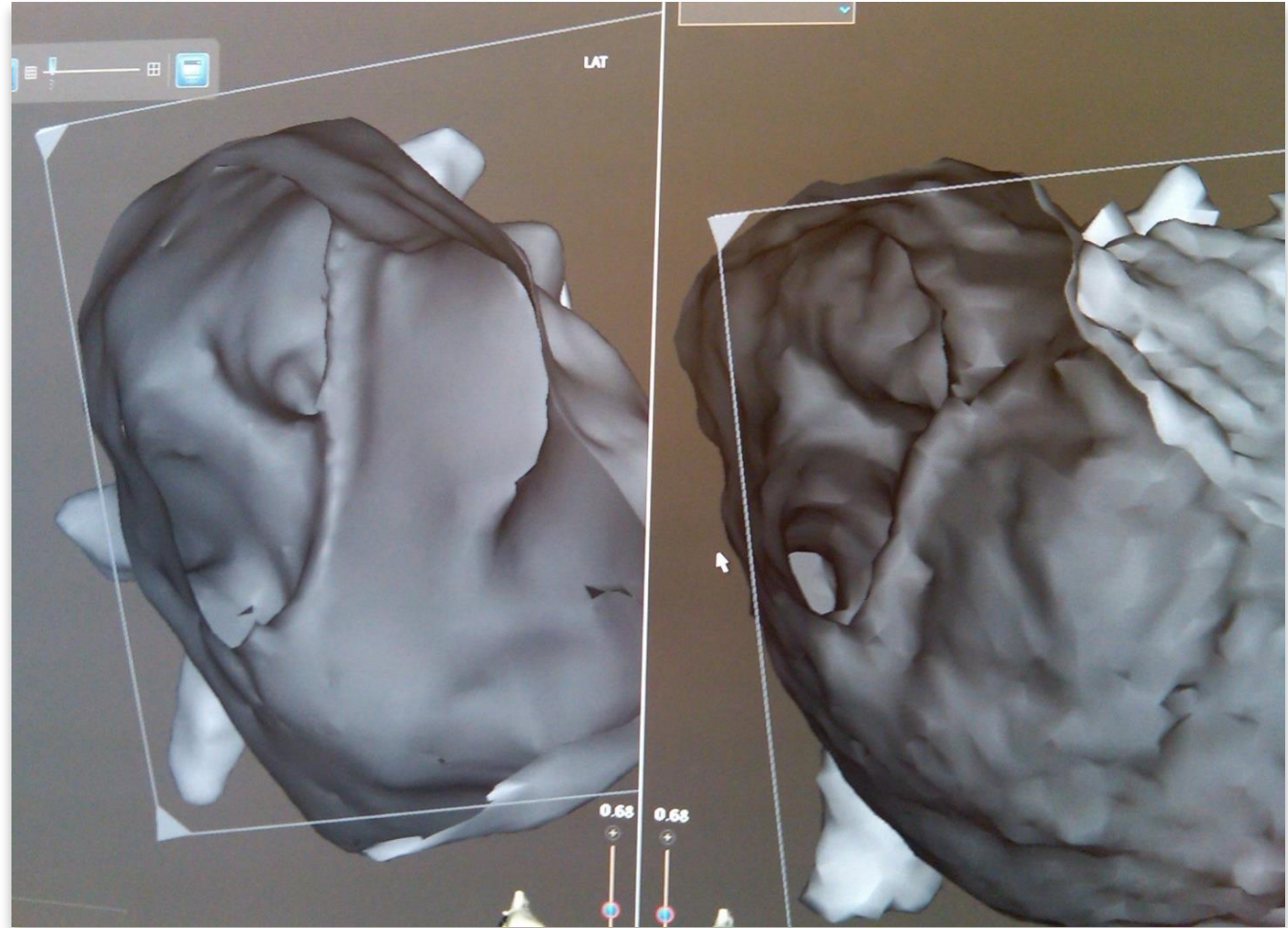
Fast Anatomical Mapping (FAM)

- ✓ A new and unique way of mapping based on an entirely new algorithm for the CARTO® 3 System
- ✓ FAM provides highly detailed maps with speed
- ✓ As you move the sensor catheter in the chamber, a volume is quickly created
- ✓ The entire chamber including veins can be created in one workflow
- ✓ Advanced resolution tools
- ✓ Simultaneously acquire electrical and anatomical point data

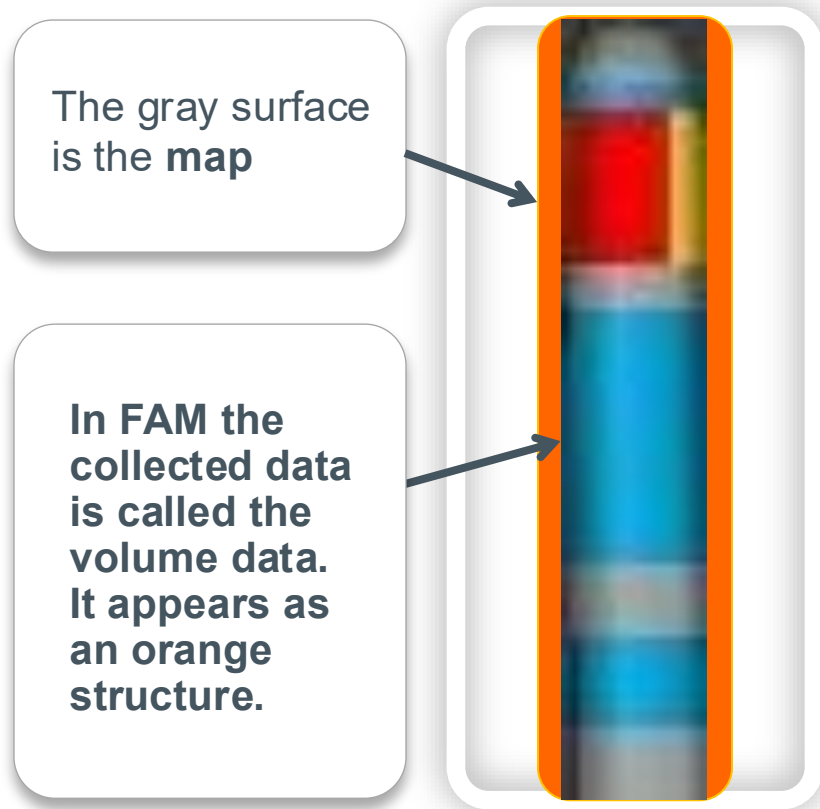
Highly Detailed Maps

Sensor-based catheters are used to create the volume, maintaining our location accuracy

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Volume Data and Map

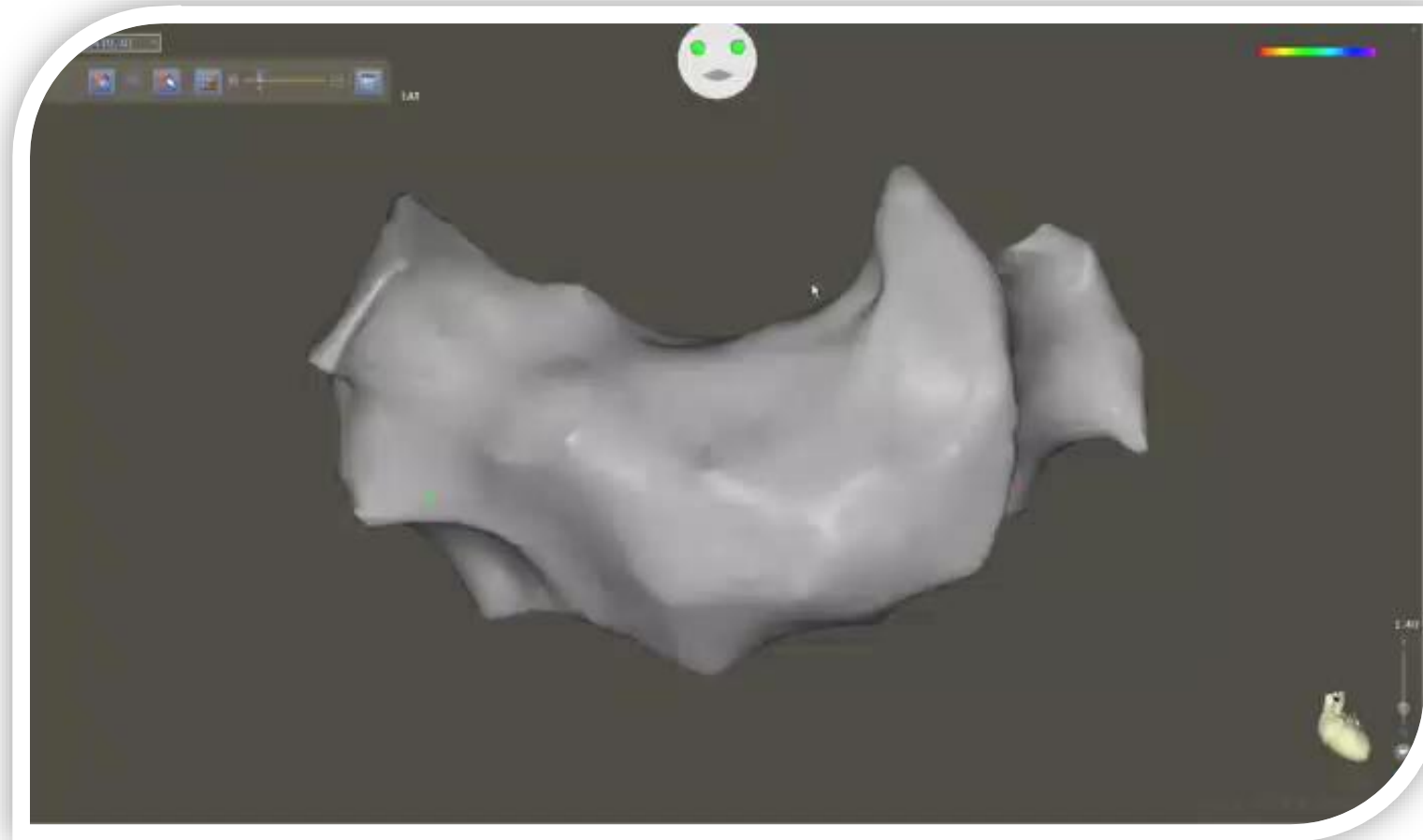


FAM Demo

During FAM mapping, the volume created corresponds to the width of the catheter tip and 10mm in length. It is collecting data at 60 times per second.

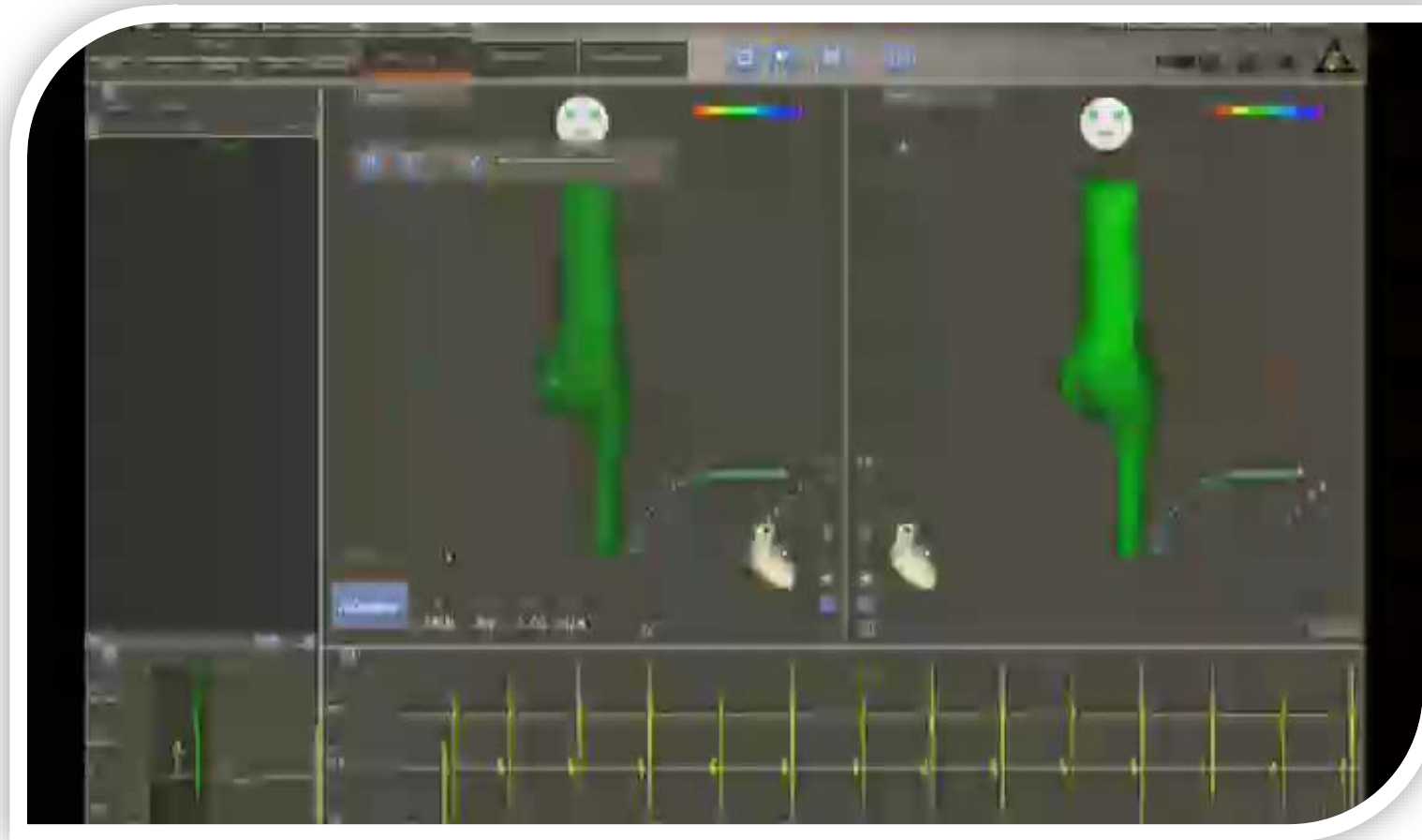
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Advanced Resolution Tools



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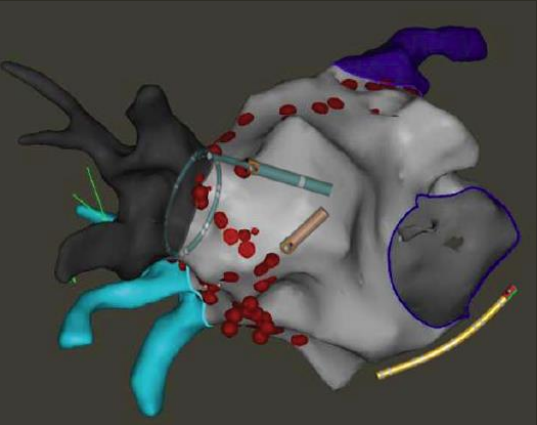
Electro-Anatomical Data



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Key System Features

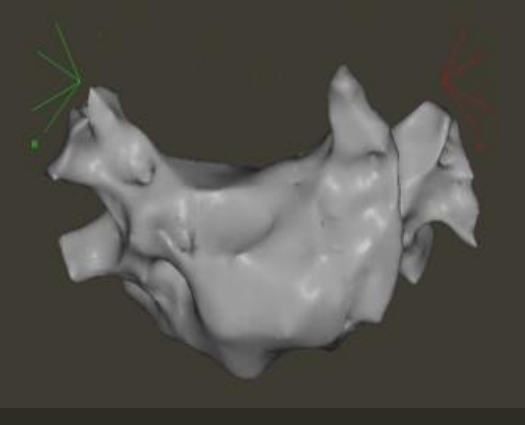
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Fast Anatomical Mapping



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The image shows a 3D anatomical model of a heart. Green and red lines are overlaid on the model, representing the fast anatomical mapping process. The model is set against a dark background.

CONNECTION OF CHOICE®



EFFICIENCY

The image shows a person in a clinical setting, wearing a blue scrub suit and a white cap, looking at multiple monitors displaying medical data. The person is standing in front of a desk with several monitors. The monitors show various medical data, including what appears to be a 3D anatomical model of a heart. The person is looking at the monitors from the left side of the frame.

CONNECTION OF CHOICE®

- ✓ Quick Connects for plug and play simplicity
- ✓ PIU as the central point of connection
- ✓ Excellent signal quality
- ✓ Enlarged mapping zone*
- ✓ Improved patient movement compensation*
- ✓ New Graphical User Interface (GUI) with step-by-step guides and easy setup

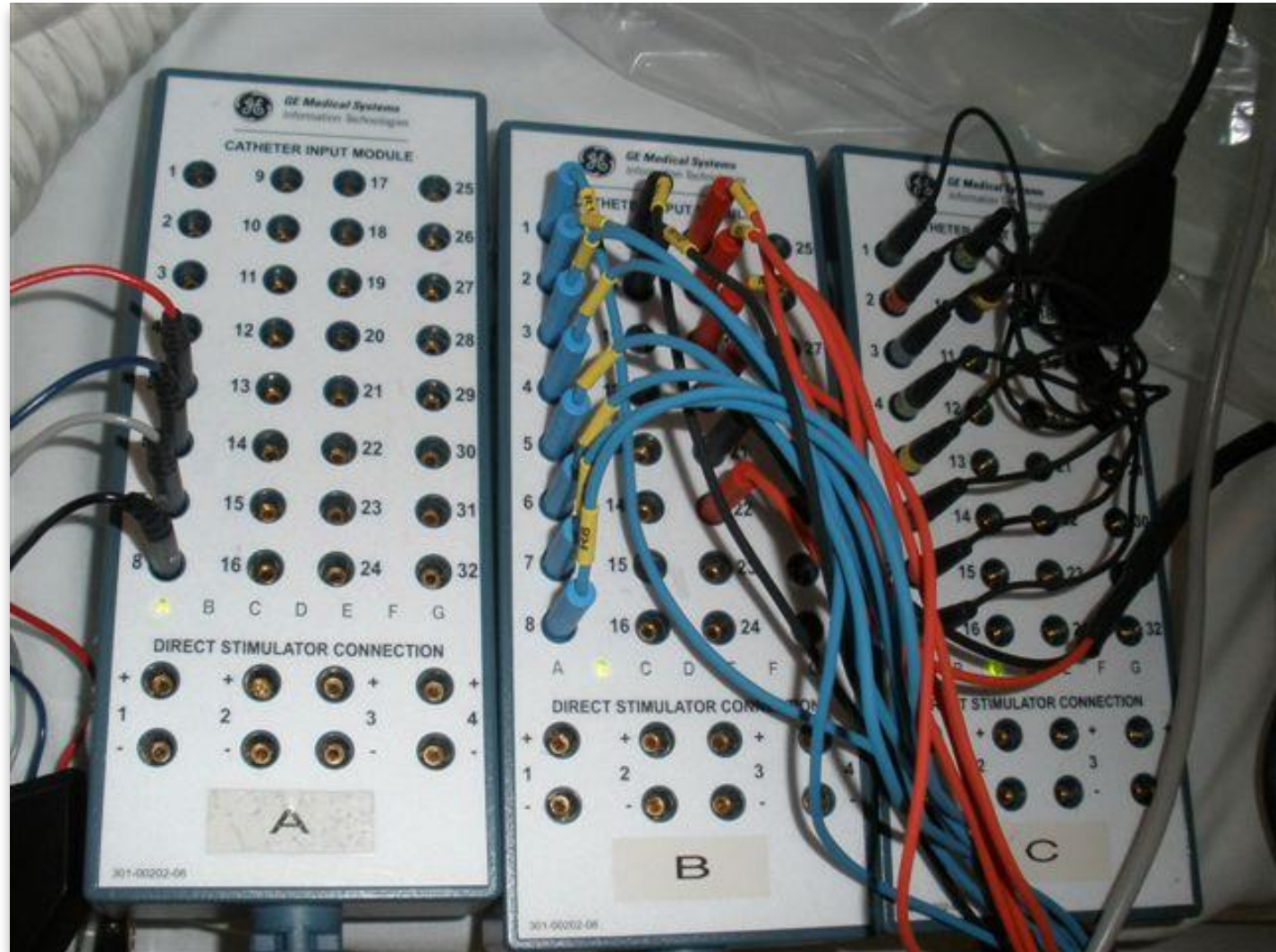


*Compared to CARTO® XP System

Plug and Play

Multiple tip pin connections invite configuration errors

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Plug and Play

The quick connect, “Plug and Play” features of our new catheters will:

- ✓ Eliminate time-consuming tip pin connections
- ✓ Reduce connection errors
- ✓ Reduce the time associated with the troubleshooting of catheter pin connection errors

Color coded cables simplify connections even further

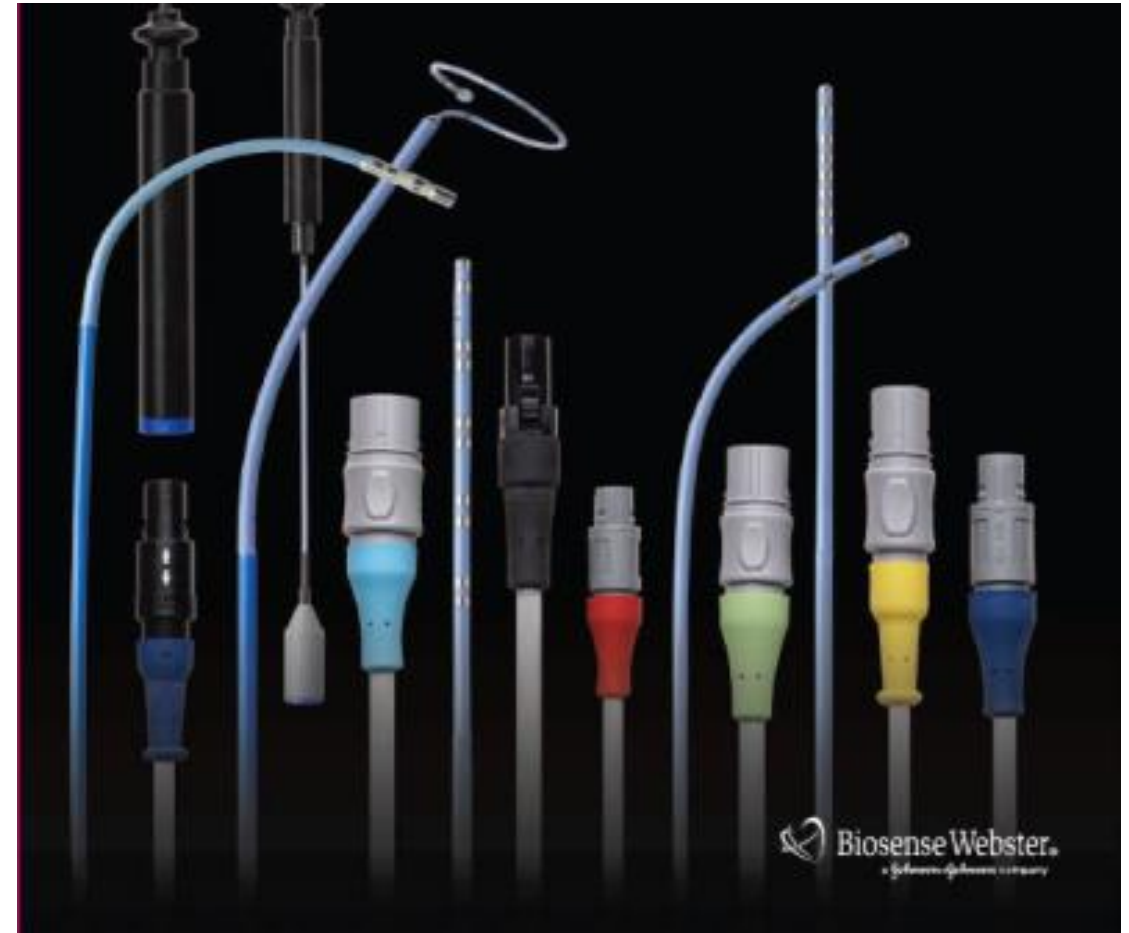
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Central Point of Connection

- ✔ Interface for all catheters
- ✔ HUB for Navigational and Conventional cases
- ✔ Interface for Pacer, Generator, and ECG
- ✔ Directly connects to most EP recording systems via a quick-connect cable

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Graphical User Interface (GUI)

- ✔ Organized step-by-step set up phases
- ✔ Explicit visualization of procedure workflow

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The screenshot displays the 'Study Setup' phase of the CARTO GUI. The interface is organized into several panels:

- Patient Details:** Includes fields for Last Name, First Name, ID, Date of Birth, and Gender (Male/Female).
- Additional Details:** Includes a Comments field, Study Name, and Physician dropdown.
- Template:** A list of arrhythmia types is shown, with 'Complex Lt Atrial Arrhythmia' selected. Below it, catheters (ThermoCool, LassoNav, CS, SoundStar, BS) and an Annotation Type (Maximum Value) are listed.
- Connected Machines:** Includes an Ultrasound dropdown (set to '<No Ultrasound>') and an RMT checkbox.
- Help:** Provides instructions for each section, including a warning: 'WARNING! To prevent inaccurate mapping, review the default parameters used by the selected template before starting the procedure.'

At the bottom of the screen, there is a waveform display showing ECG traces for II, I-M, and REF 1-2, with a scale of 200.0 mm/sec.

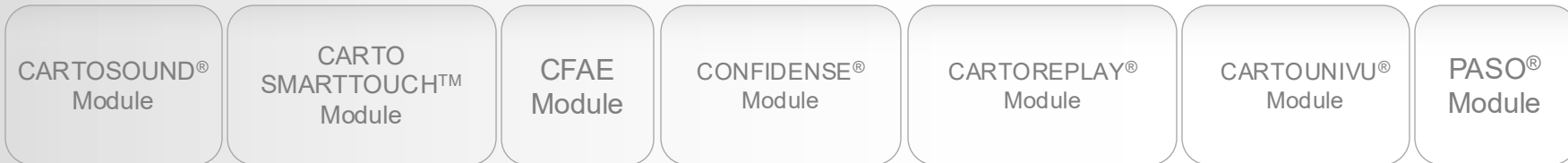
Graphical User Interface (GUI)

- ✓ Pre-set and user defined templates for easy set up
- ✓ Decreased complexity decreases learning curve

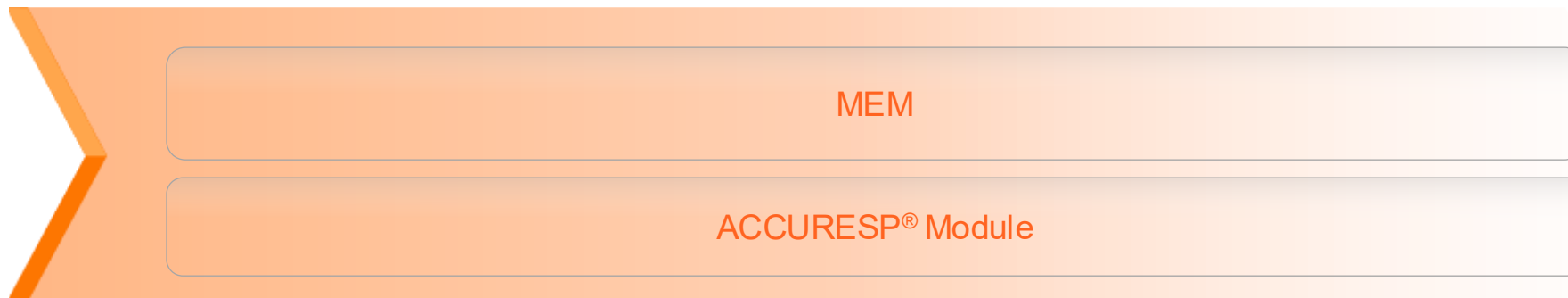
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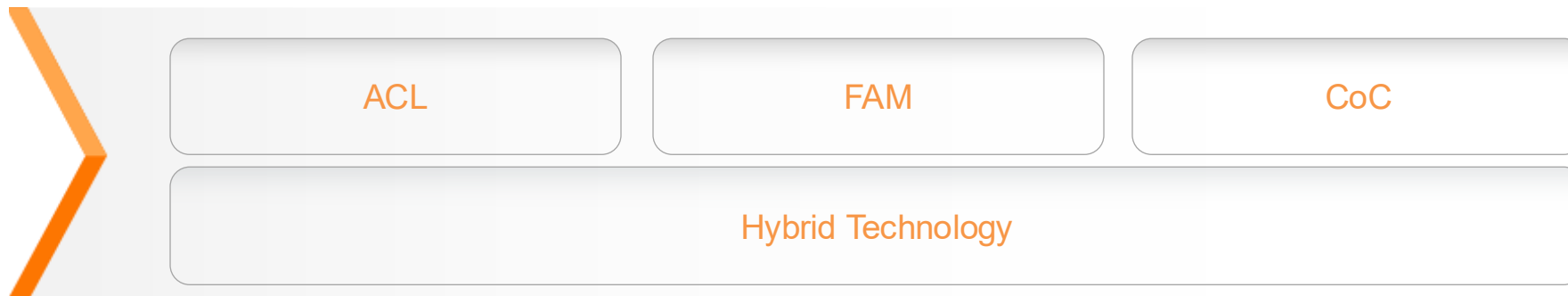
Software Modules



Base Software Enhancements



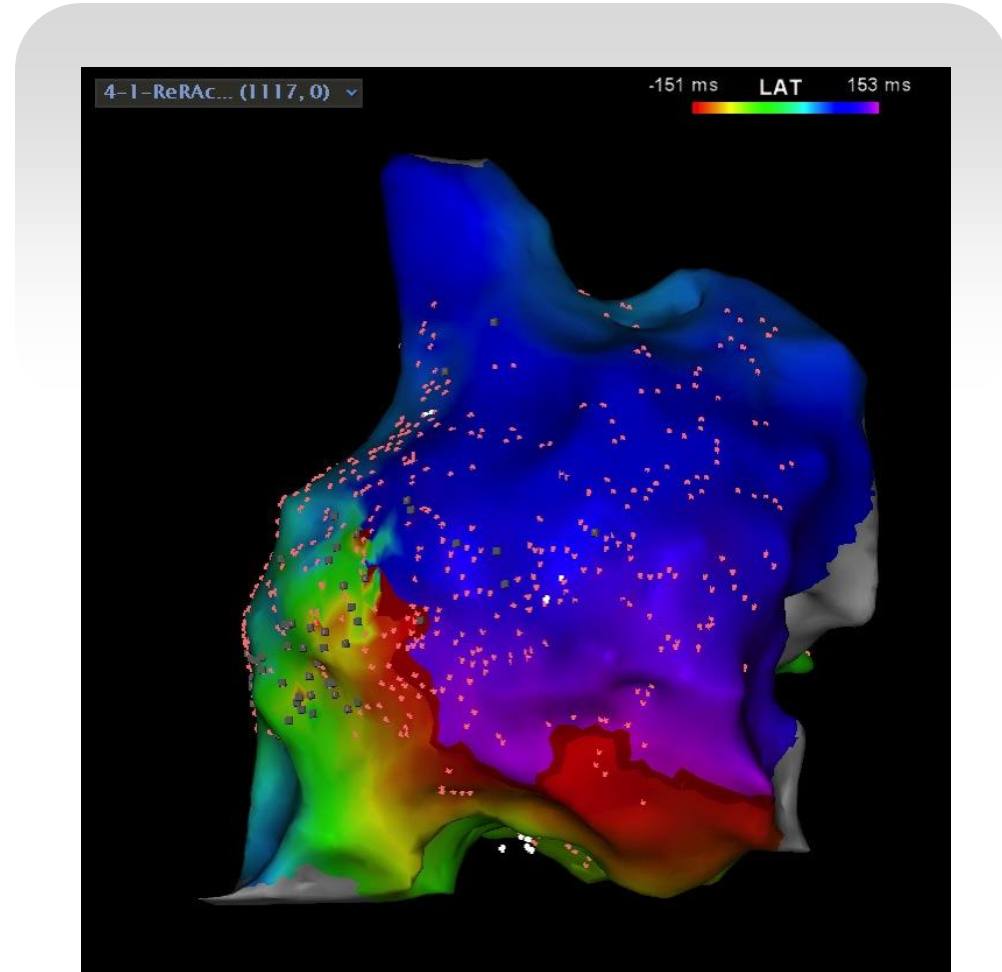
Core Technology and Features— Base Hardware



Base software enhancements are designed to simplify, streamline and improve the user experience

Multi-Electrode Mapping (MEM)

- ✔ Streamlined multi-point, high-density mapping software
- ✔ Broad portfolio of sensor-based, MEM-enabled catheters ensuring flexibility for each type of procedure
- ✔ Simultaneous acquisition of both highly accurate anatomy and high-resolution electrical information provides procedural efficiency



ACCURESP® Module

- ✓ Refines mapping experience with ability to gate to both cardiac and respiratory cycles
- ✓ Real-time respiration indication graph with a user defined gating threshold
- ✓ Clear visualization of respiration effect on anatomical reconstruction, including ultrasound contours, to set preferred combination of gated and non-gated data for any procedure



Software Modules

CARTOSOUND®
Module

CARTO
SMARTTOUCH™
Module

CFAE
Module

CONFIDENSE®
Module

CARTOREPLAY®
Module

CARTOUNIVU®
Module

PASO®
Module

Base Software Enhancements

MEM

ACCURESP® Module

Core Technology and Features— Base Hardware

ACL

FAM

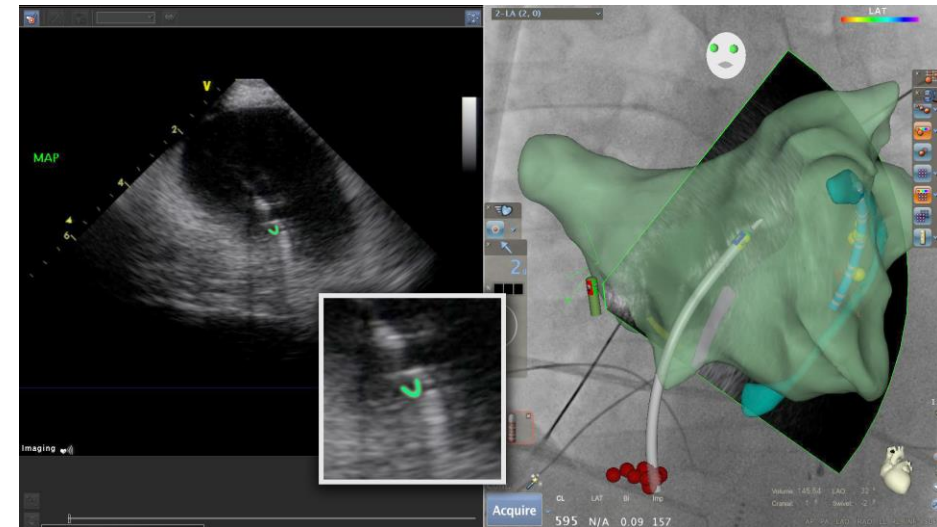
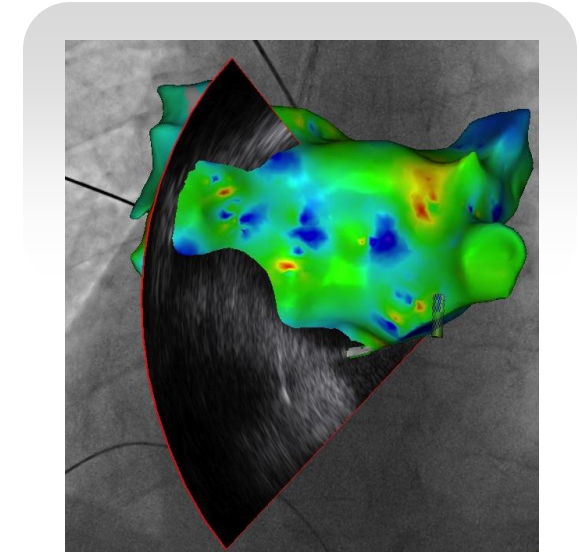
CoC

Hybrid Technology

**Software modules complement
CARTO® 3 System maps and optimize
diagnostic and treatment catheters**

CARTOSOUND® Module

- ✓ Detailed ultrasound imaging, anatomical detail and clarity, with 3D orientation
- ✓ Enhanced confidence to guide real-time complex ablations
- ✓ Integrated ultrasound technology provides exceptional anatomical image clarity
- ✓ Improve workflow efficiency



CARTO SMARTTOUCH™ Software Module

- ✓ Real-time force now integrated with 3D maps
- ✓ CARTO SMARTTOUCH™ Module allows physicians to incorporate contact force data when determining ablation progress
- ✓ Incorporates CARTO VISITAG® Module technology to catalog and display multiple radiofrequency ablation parameters, including:
 - power
 - impedance
 - stability
 - time at location



The CARTO VISITAG® Module provides access to data collected during the application of RF energy. The data does not indicate the effectiveness of RF energy application. CARTO VISITAG® Module settings are user defined based on the user's clinical experience and medical judgment. Biosense Webster, Inc. does not recommend any settings for the CARTO VISITAG® Module.

Force Vector Dashboard

Provides visibility to tip angle and contact force in a simple display

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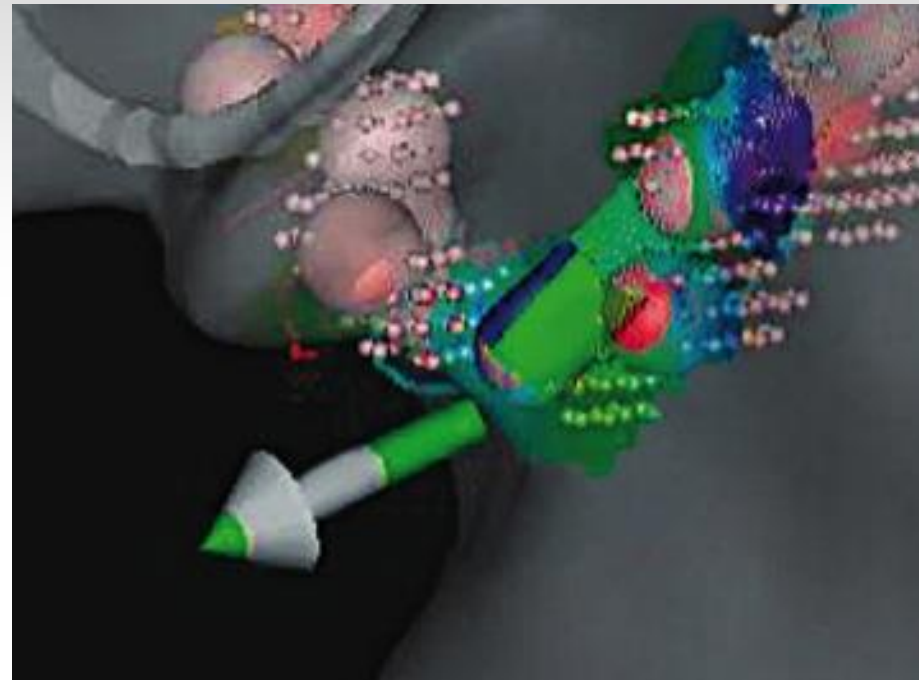


Catheter Vector

Displays force and catheter tip to tissue orientation¹

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2



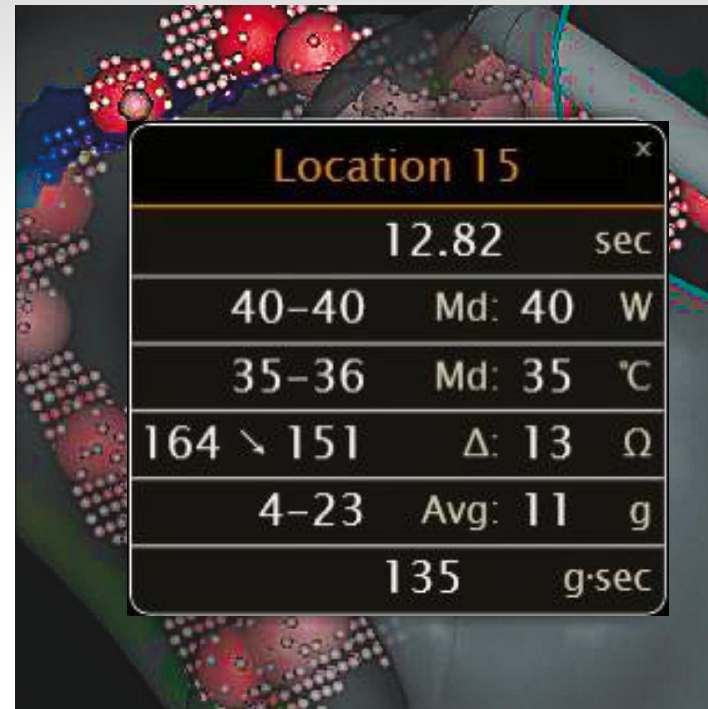
Reference: 1. Martinek M, Lemes C, Sigmund E, et al. Clinical impact of an open-irrigated radiofrequency catheter with direct force measurement on atrial fibrillation ablation. *Pacing Clin Electrophysiol.* 2012;35(11):1312-1318.

CARTO VISITAG® Module Readout

Visualizes dimensions on each RF application

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3



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Force Graph

Displays force range throughout case

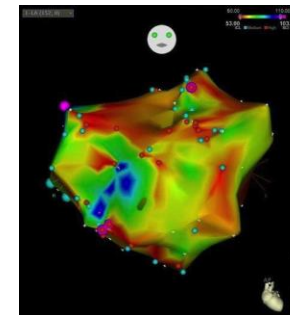
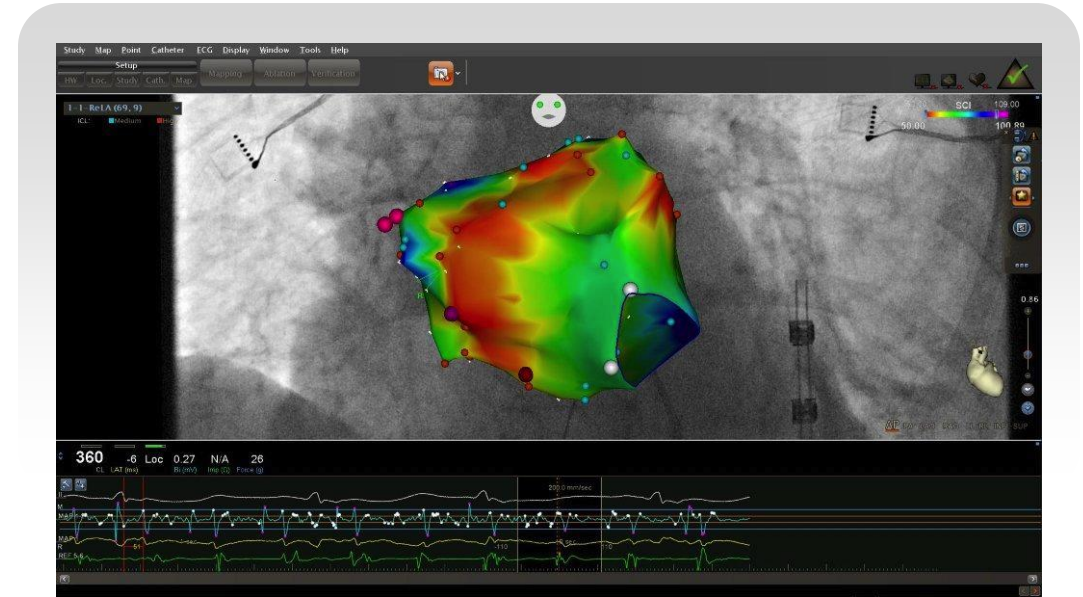
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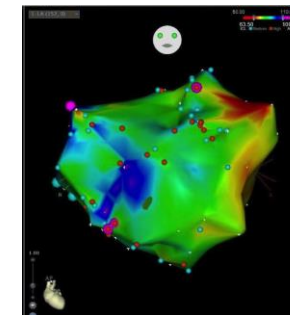


CFAE Module

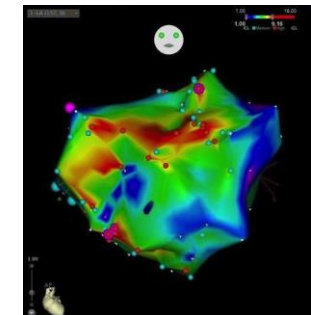
- ✓ Identify complex fractionated atrial electrograms (CFAE) with speed
- ✓ The CFAE Module uses an algorithm to find key areas of interest and automatically detects CFAE signals on a 3D map
- ✓ Flexible, user-defined parameters
- ✓ Allows the addition of interval confidence level (ICL) tags to CARTO® 3 System maps



Shortest complex interval



Average complex interval



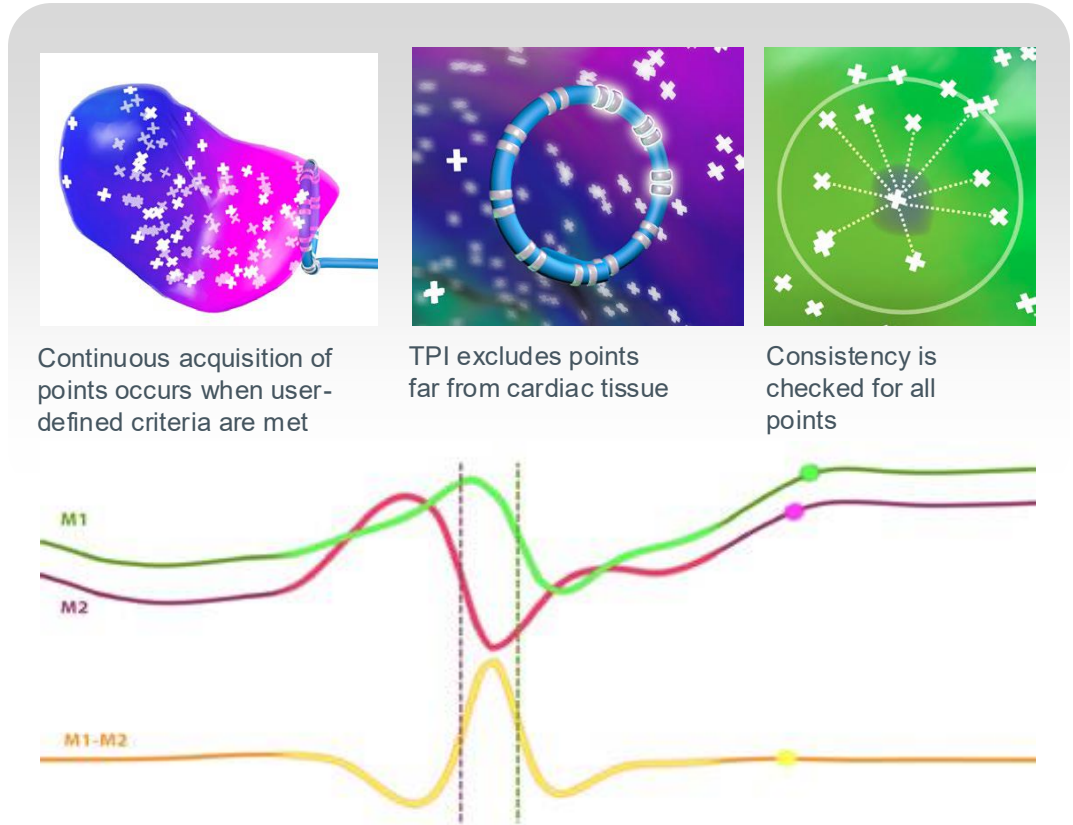
Interval confidence level

The clinical significance of utilizing the CFAE Module to help identify areas with complex fractionated atrial electrograms for catheter ablation of atrial arrhythmias, such as atrial fibrillation, has not been established by clinical investigations.

CONFIDENSE[®] Module

Automatically collect data, filter critical points and highlight important areas that require physician assessment, features include:

- ✓ Continuous acquisition
 - Ensures that only points that meet predefined criteria are collected
- ✓ Tissue Proximity Indicator (TPI)
 - Designed to filter points based on each electrode's proximity to tissue
- ✓ Wavefront annotation
 - Automatically analyzes bipolar and corresponding unipolar signals to detect the maximal negative slope
- ✓ Map consistency
 - Identifies and evaluates points whose timing is judged to be inconsistent in comparison with neighboring points



Continuous acquisition of points occurs when user-defined criteria are met

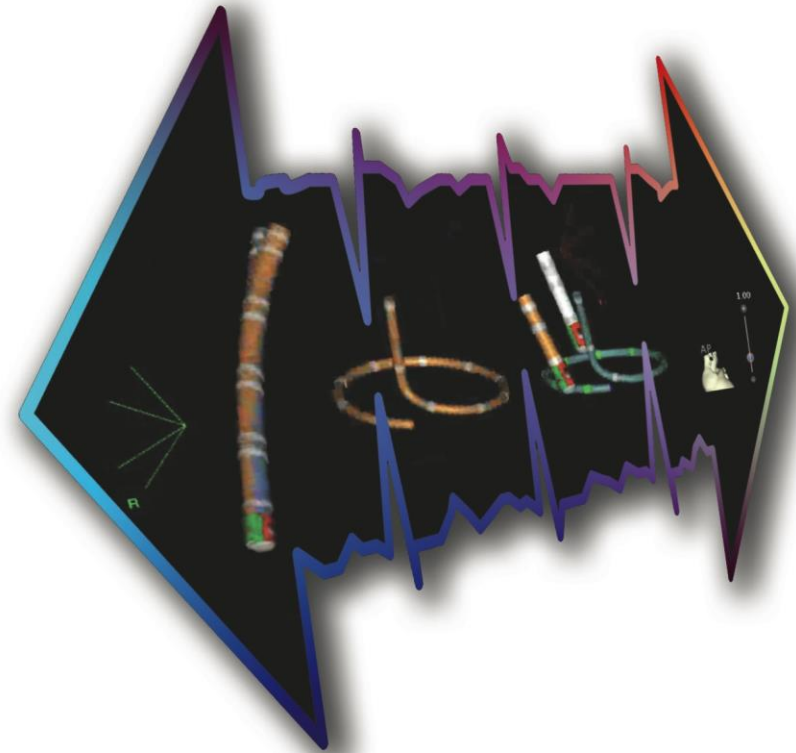
TPI excludes points far from cardiac tissue

Consistency is checked for all points

A novel algorithm provides automatic and consistent annotation.

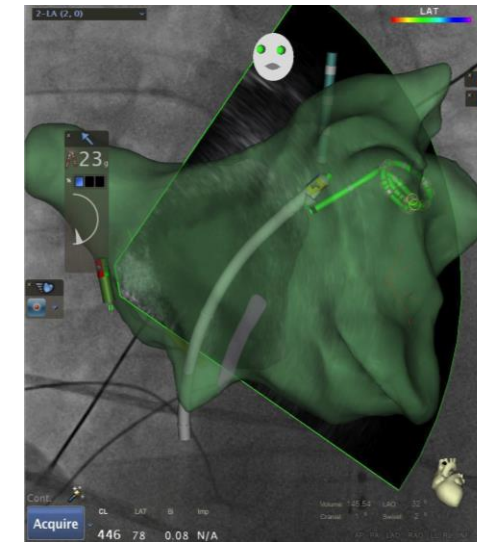
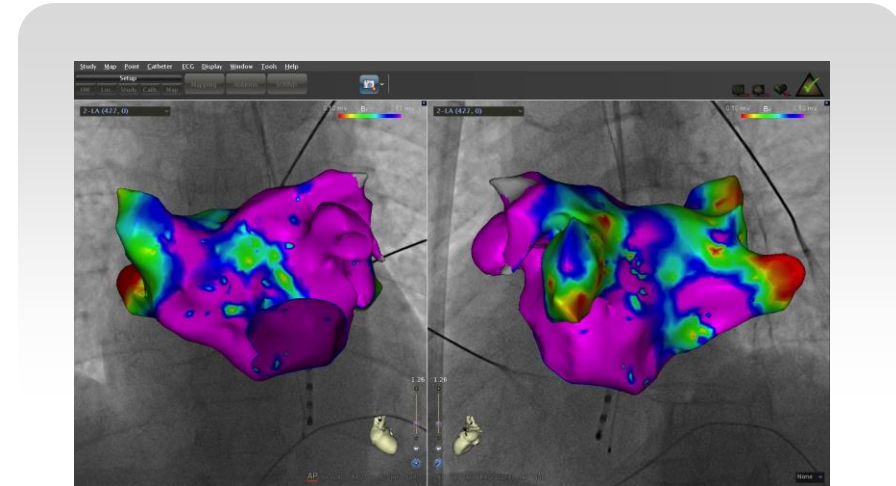
CARTOREPLAY® Module

- ✔ Evaluate signals captured at any point in time during a case
- ✔ Enables retrospective review and acquisition of data points
- ✔ Allows physicians to analyze transient but critical information of spontaneously terminated events
- ✔ Physicians can add collected data to the correct location within any map
- ✔ Organize and monitor maps, electrograms and other data across two screens for a truly streamlined workflow



CARTOUNIVU® Module

- ✔ Seamlessly integrate fluoroscopy imaging for anatomical orientation
- ✔ Navigate confidently without increasing risk of fluoroscopy exposure levels for physicians, staff and patients
- ✔ Quickly interpret catheter location, reducing the need for repetitive fluoroscopy images



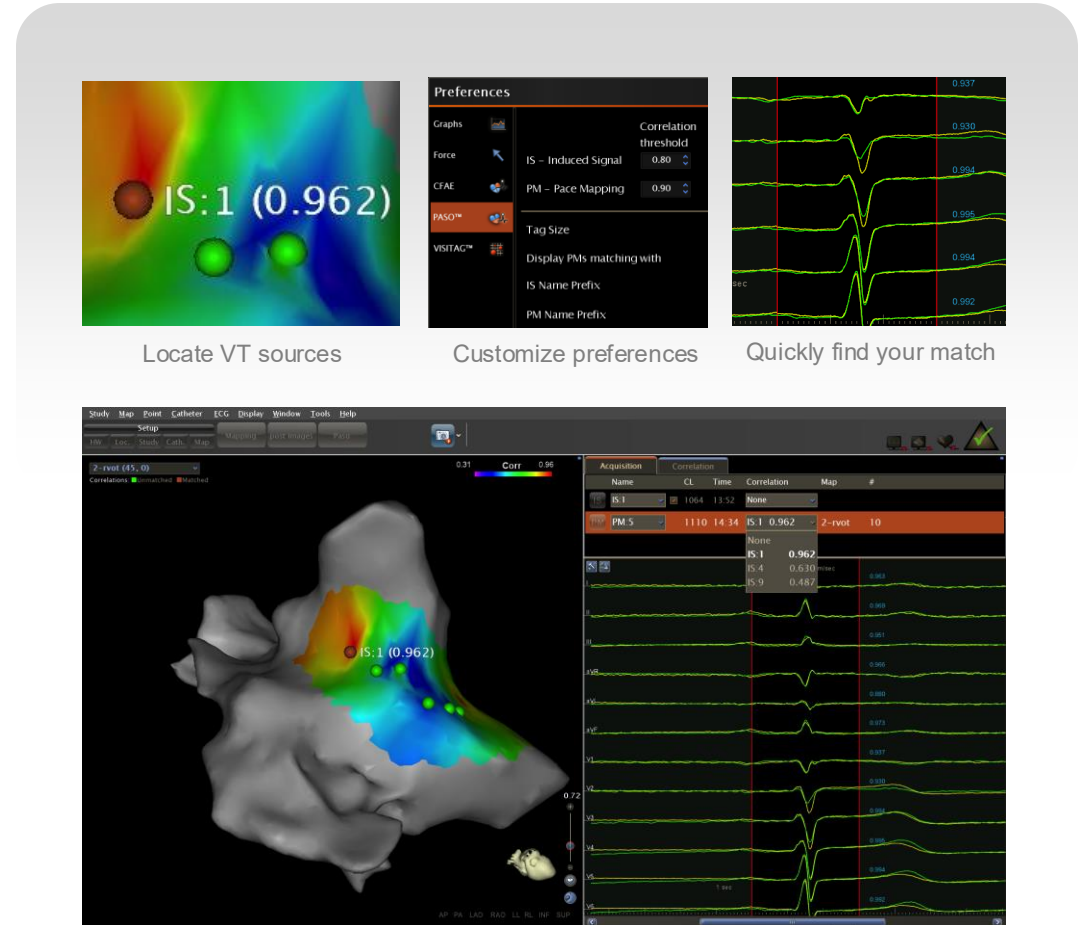
Always verify catheter tip location using fluoroscopy or IC signals and consult the CARTO® System User Guide regarding recommendations for fluoroscopy use.

Pellegrino, P.L., Brunetti, N.D., Gravina, D., Sacchetta, D., De Sanctis, V., Panigada, S., Di Biase, L., Di Biase, M., and Mantica, M. (2013). Nonfluoroscopic mapping reduces radiation exposure in ablation of atrial fibrillation. *Journal of cardiovascular medicine* 14, 528-533.

Earley, M.J., Showkathali, R., Alzetani, M., Kistler, P.M., Gupta, D., Abrams, D.J., Horrocks, J.A., Harris, S.J., Sporton, S.C., and Schilling, R.J. (2006). Radiofrequency ablation of arrhythmias guided by nonfluoroscopic catheter location: a prospective randomized trial. *Eur Heart J* 27, 1223-1229

PASO® Module

- ✓ Unparalleled insight to simplify ventricular tachycardia (VT) ablation strategy
- ✓ Interpret with precision and confidence
 - Delivers automated template matching for targeting complex VT procedures
 - Compares pace mapping and arrhythmia signals
 - Quickly locates and catalogs multiple VT sources



The clinical significance of utilizing the PASO® Module to help pace mapping for catheter ablation of ventricular arrhythmias has not been demonstrated by clinical investigations. THERMOCOOL® Navigation Catheters are indicated for the treatment of recurrent drug/device refractory sustained monomorphic ventricular tachycardia (VT) due to prior myocardial infarction (MI) in adults.

Thank you

