



CUSTOMER PRESENTATION

# EnSite™ X EP System

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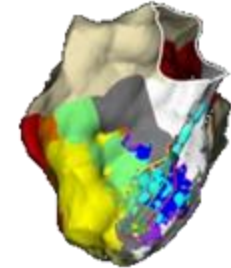
## THE FUTURE OF MAPPING

Designed by physicians, the EnSite™ X EP Mapping System is the **ONLY SYSTEM** giving you the advantage to choose between either magnetic stability or impedance flexibility, **OPTIMIZING PATIENT-SPECIFIC CARE** with confidence. Our vision for the EnSite X EP Mapping System is to provide an **EFFICIENT, CONSISTENT AND POWERFUL** user experience in every procedure. The system will integrate our proprietary software and Sensor Enabled™ technology.



### STABILITY

Earning trust in the system regardless of clinical situation



### MAPPING/WORKFLOW

Providing users flexibility to use tools and maps



### USABILITY

Efficient, reliable & reproducible user experience



### SERVICE/SUPPORT

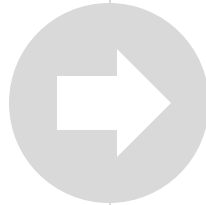
Minimizing downtime related to system issues, upgrades and PMs

# System Overview: EnSite™ X EP System

## ENSITE PRECISION™ CARDIAC MAPPING SYSTEM



- 10+ year old technology platform



## ENSITE™ X EP SYSTEM



TECHNOLOGY PLATFORM TO  
SUPPORT FUTURE ENSITE X  
PHASES

- New Amplifier
- New Graphical User Interface
- New Computer Workstation
- New Cart Designs
- New Direct Connect Abbott Catheter Cables

The EnSite X EP System will represent an **ENTIRELY NEW, NEXT GENERATION ADVANCED MAPPING SYSTEM.**



**Abbott**

# Noise Reduction

## IMPEDANCE LOCALIZATION

### New Amplifier

- Up to 50% less patient facing connections\*

### Continuous frequency vs. switching frequency

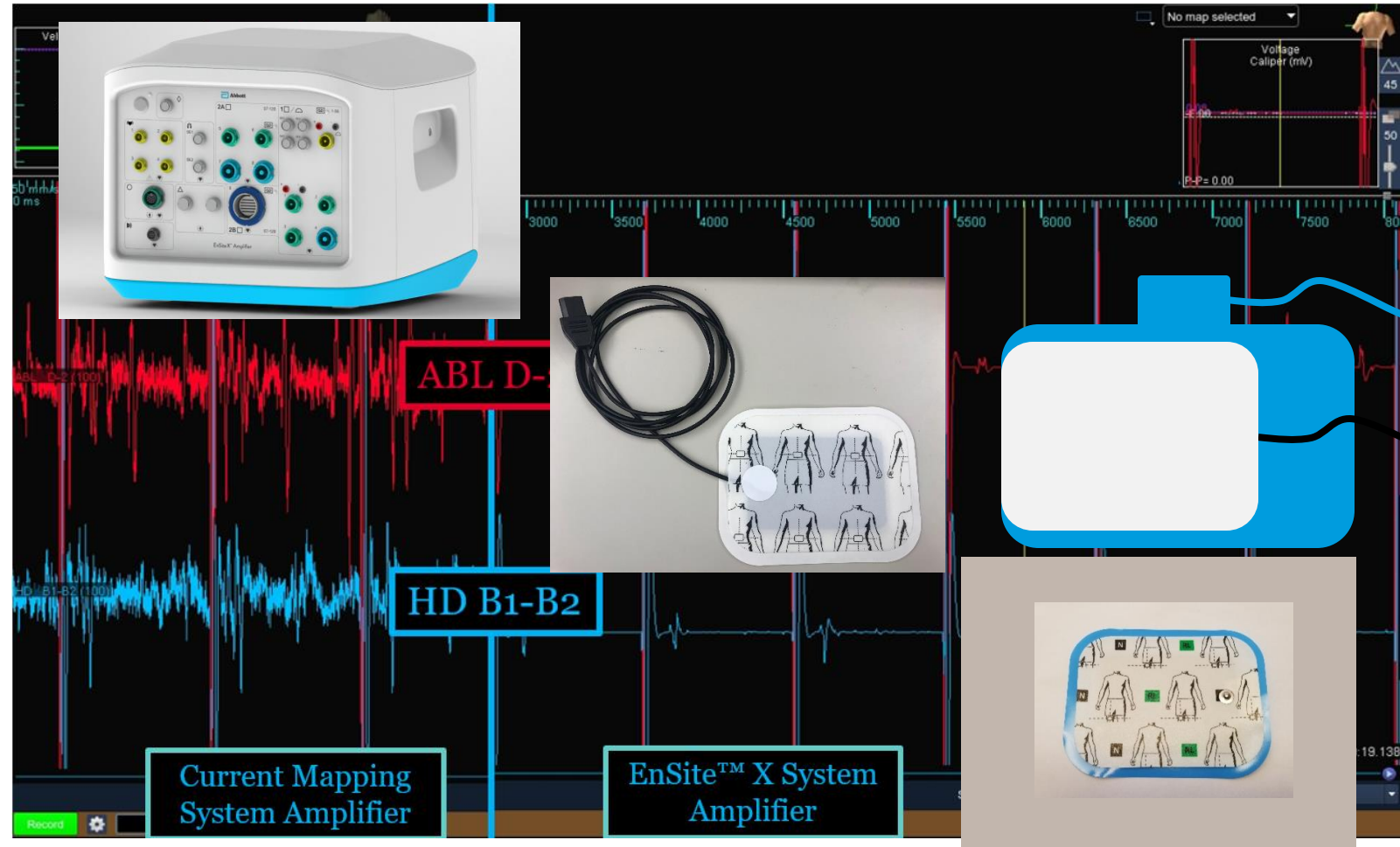
- Assess Latency
- Visualization of cardiac motion

### System Reference Electrode Design

- Smaller size
- Stronger Adhesive<sup>1</sup>
- Shielded cable

### Right Leg ECG

- Larger surface area
- Designed to work in conjunction with System Reference to minimize electrical noise

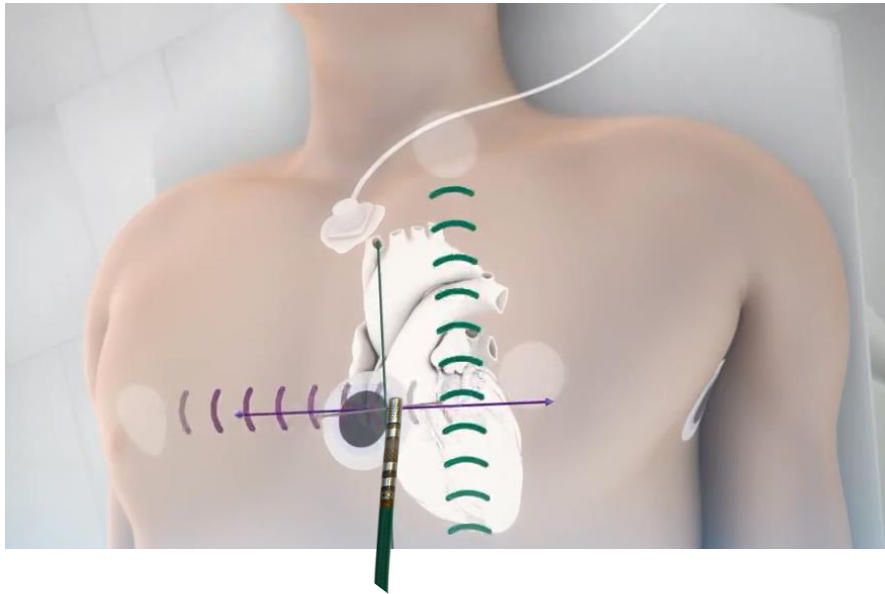


\* Reduction of connections from the patient connecting to the amplifier from 55 (EnSite™ Precision System) to 25 (EnSite™ X System) for an AF case (CS, Advisor™ HD Grid, TactiCath™ SE Ablation catheter)

# Navigation Mode Introduction

## ENSITE NAVX™ MODE

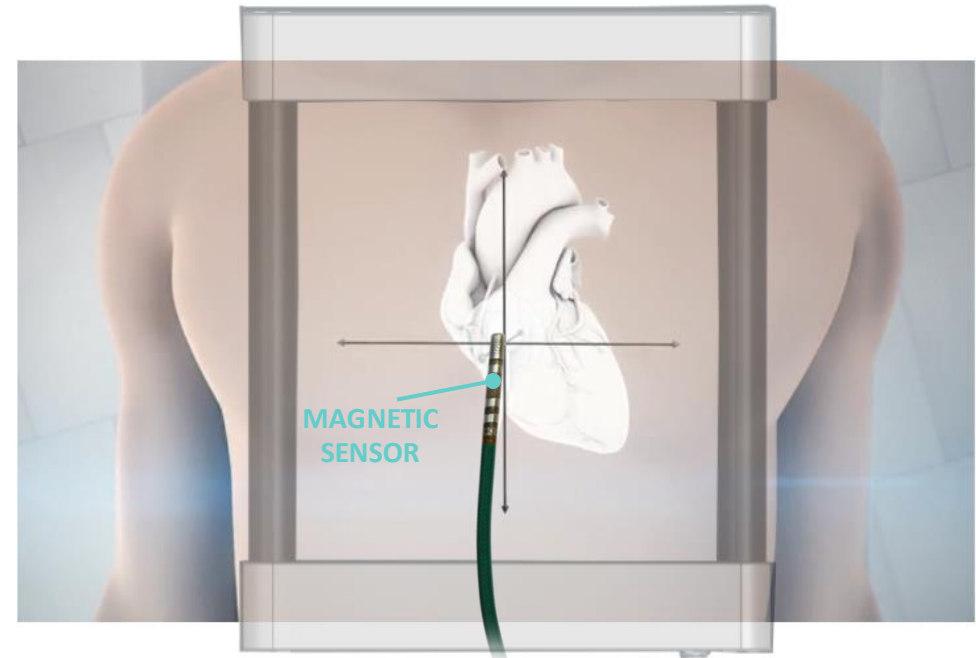
- Create a voltage field via the surface electrodes
- Measure the strength of the voltage field with an electrode on the catheter to determine 3D location



ELECTROPHYSIOLOGY

## ENSITE™ VOXEL MODE

- Create a magnetic field via a magnetic field generator placed under the patient table
- Measure the strength of the magnetic field with a coil sensor in the catheter



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# Navigation Mode Introduction

## ENSITE NAVX™ MODE

- Enhanced version of current EnSite Precision™ Cardiac Mapping System
- Catheter location is **PURELY** based on impedance data
- Magnetic data is (optional and) used to make the impedance data more **LINEAR** (Nav SE Field scaling)\*
- Presentation responds to local changes in thoracic impedance (lungs, sheath, etc.)

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**FLEXIBLE WORKFLOW**  
**LOW FLUORO TECHNIQUES**

## ENSITE™ VOXEL MODE

- Rigid portion of SE catheter location is based on **MAGNETIC DATA**
- Collects **VoXels (Impedance Fiducials)** which allow Impedance-based electrodes to be shown
- Introduce SE tool first
- Non-Rigid portion of SE catheter location is based on impedance & magnetic data
- Catheter shape consistent despite local impedance changes

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**NATIVE LINEARITY**  
**ENHANCED STABILITY**

\*compared to impedance data alone

# Sensor Enabled™ Tools

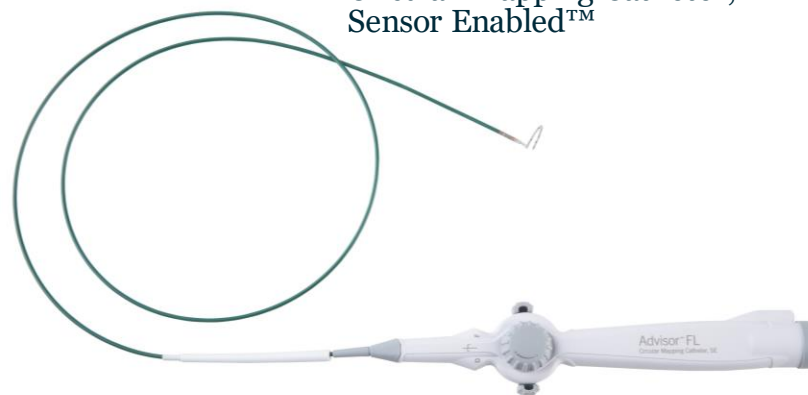
**FlexAbility™**  
Ablation Catheter, Sensor  
Enabled™



**TactiCath™**  
Ablation Catheter,  
Sensor Enabled™



**Advisor™ FL**  
Circular Mapping Catheter,  
Sensor Enabled™



**Advisor™ VL**  
Circular Mapping Catheter,  
Sensor Enabled™



**Advisor™ HD Grid**  
Mapping Catheter,  
Sensor Enabled™



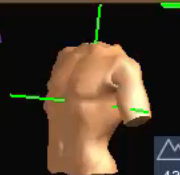
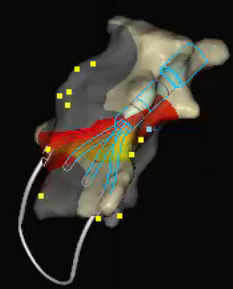
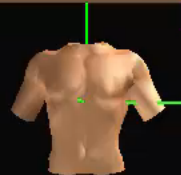
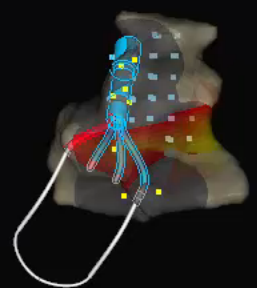
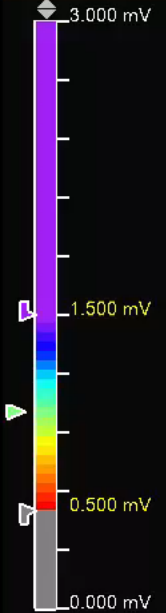
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Review: Apr 03, 2020 02:28:08 PM

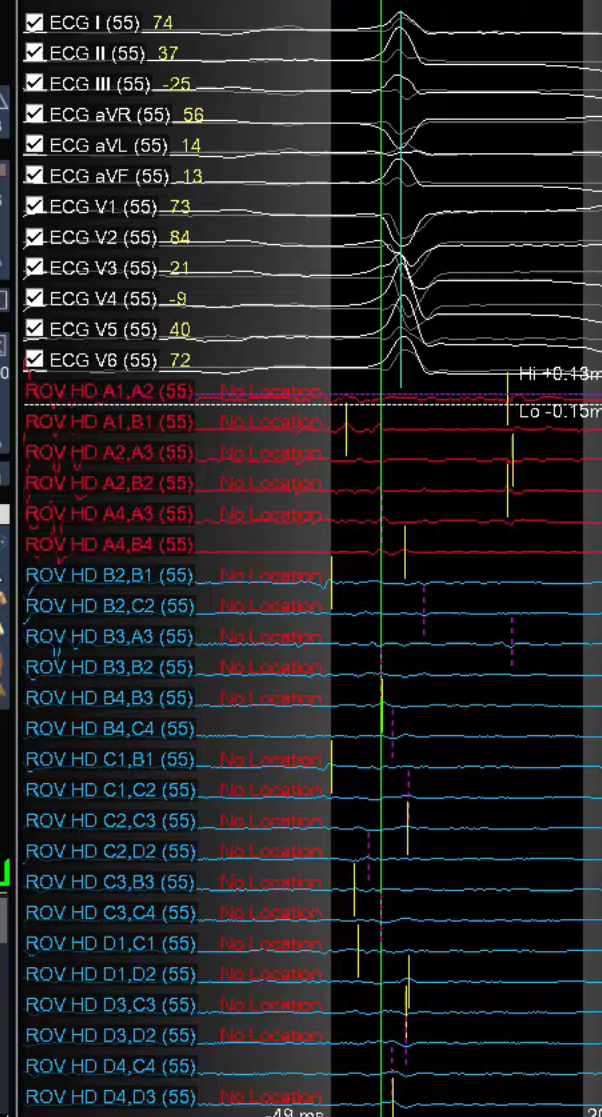
Auto Model Collection

Points: 20 used / 33 total

LV HRS P-P Voltage

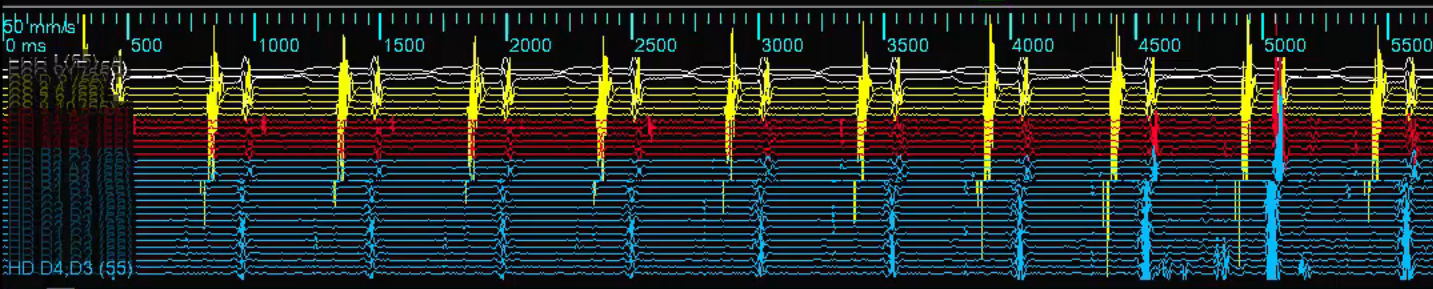
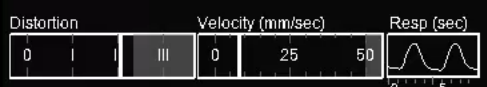


# LV VOLTAGE MAP VOXEL MODE

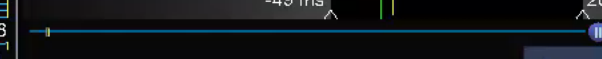


Score **38**  
CL **407 ms**  
P-P **0.28 mV**

ABL@SE1 PRS-A  
SPI@7 PRS-P  
HD@8 Resp



Stop Model Stop AutoMap Stop All  
HD A A1  
Pointer (P)  
Use to Edit Points or to deselect other Tools.



# Inherent Magnetic Challenges in the EP lab

## IMPACTS TO MAGNETIC FIELD

- **Size of Image Intensifier**
- **Location of the Image Intensifier**
  - Proximity
  - Direction
- **Additional metal in the room**
  - Table
  - Anesthesia equipment
  - Bair hugger
  - Stool/chair
  - Monitor Boom

## MITIGATIONS TO ENSURE ACCURATE DATA COLLECTION

- **Installation Lab Characterization**
- **Patient Prep**
- **Intra-procedure Detection**



# Patient Movement

VoXel Mode May 01, 2020 01:29:36 AM

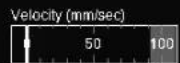
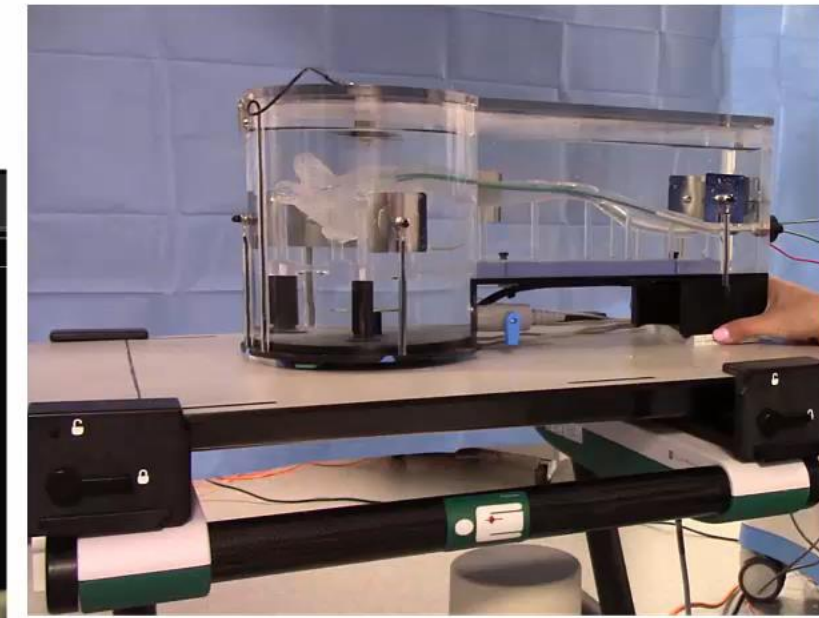
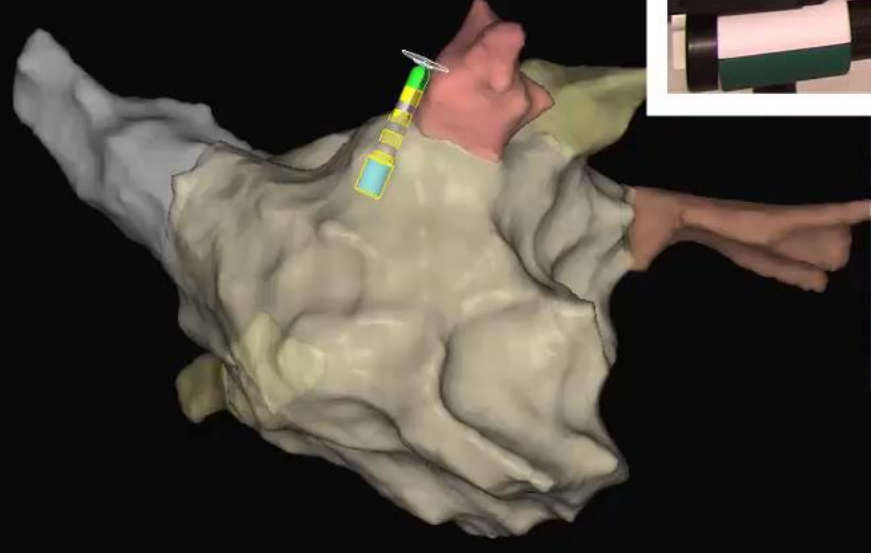
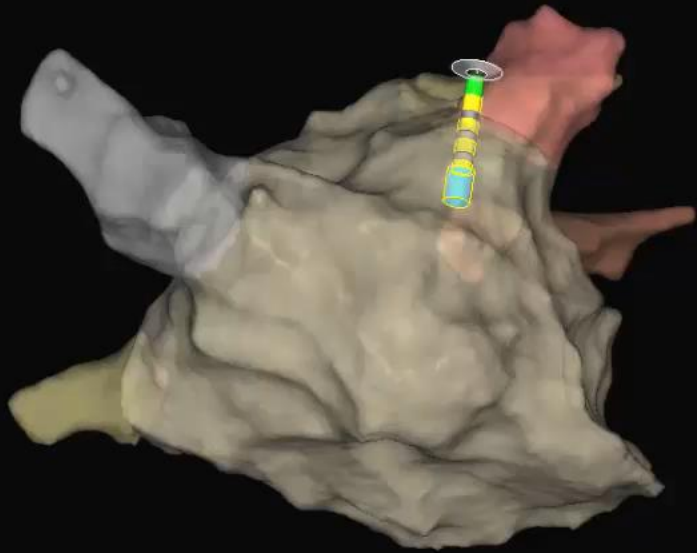
Search, View, and other icons

No map selected

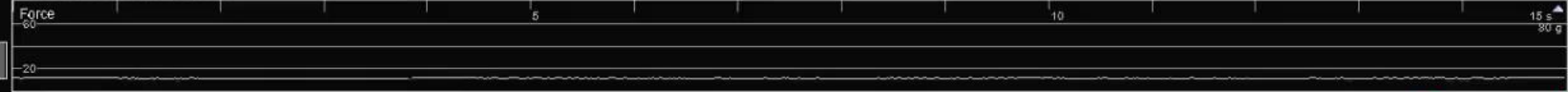
TF	11 g
LS	11 g
FT	3 g
FTI	--
FTV	-- gs
Reset FT/LSI	
Reset Force	

11 g

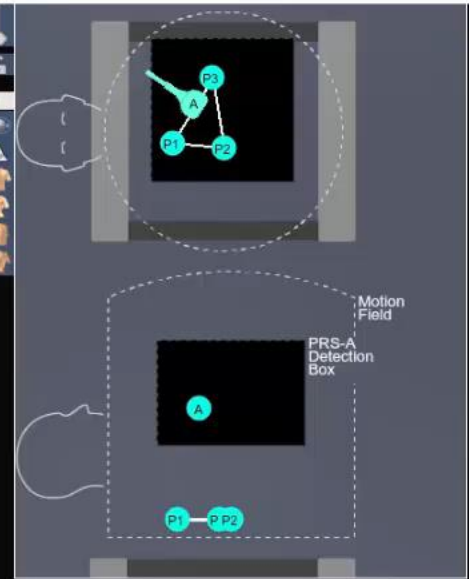
11 g



Check Contact Force baseline.



- HDG@7
- TCSE@SE1
- PR-S-A
- PR-S-P
- Resp



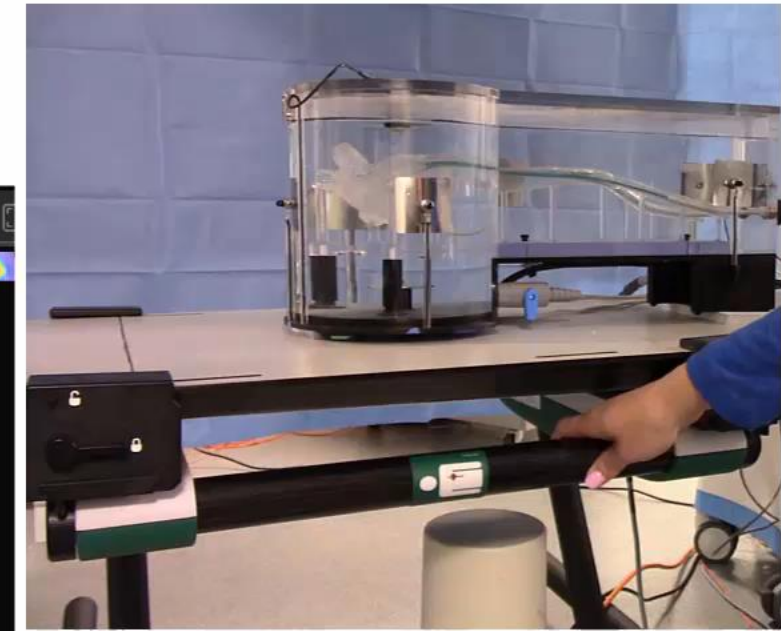
Start Model Start AutoMap Stop All

TCSE 0

Pointer (P)

Use to Edit Points or to deselect other Tools.

# Field Frame Movement



VoXel Mode May 01, 2020 01:25:58 AM

TF 11 g  
11 g  
3 g  
--  
-- gs

Reset FTI/LSI  
Reset Force

11 g 11 g

Velocity (mm/sec)  
50 100

Distortion  
0 I II III

Force  
-20 5 10 15 20 30 g

Check Contact Force baseline.

HDG@7  
TCSE@SE1

● PRS-A  
● PRS-P  
● Resp

00:32:07

Motion Field

PRS-A Detection Box

Start Model Start AutoMap Stop All

TCSE D

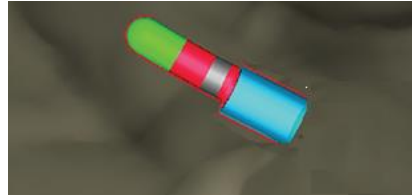
Pointer (P)

Use to Edit Points or to deselect other Tools.

# Ensure Good Data Collection

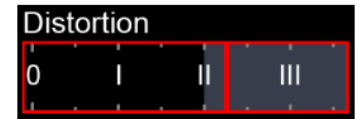
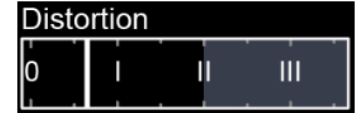
## SHEATH FILTER

- Designed to ensure good impedance data is paired to magnetics



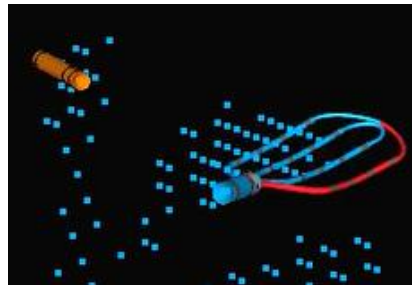
## METAL COMPENSATION & DETECTION

- Designed to ensure good magnetic data is used



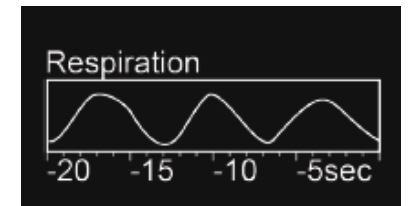
## IMPEDANCE CHANGE DETECTION

- If permanent impedance change occurs can delete VoXels without impacting map & models



## RESPIRATION COMPENSATION

- Allows data collection throughout full respiratory cycle



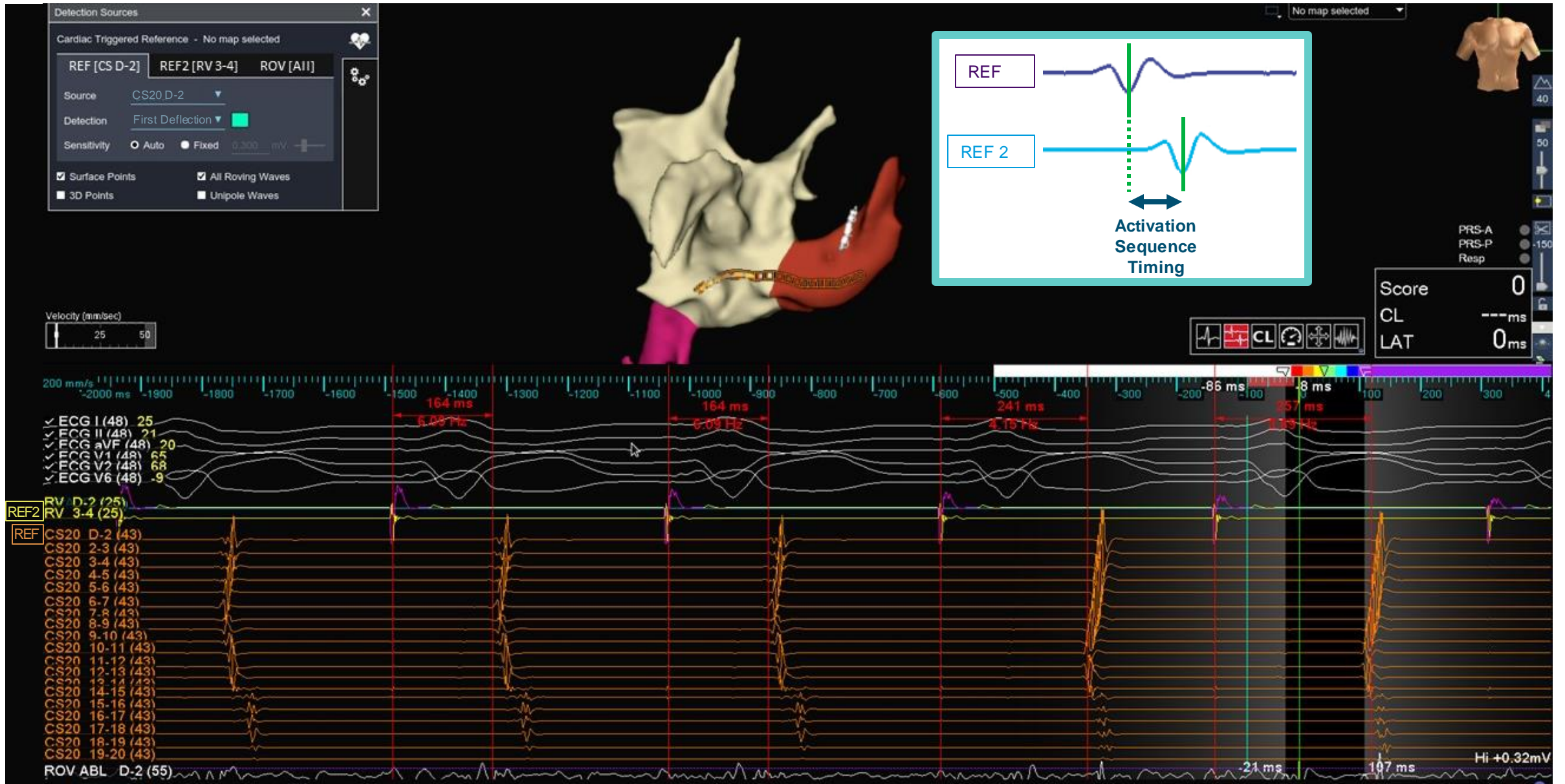
## PATIENT MOVEMENT DETECTION

- Compensations for patient movements with 3 posterior reference sensors



# Mapping

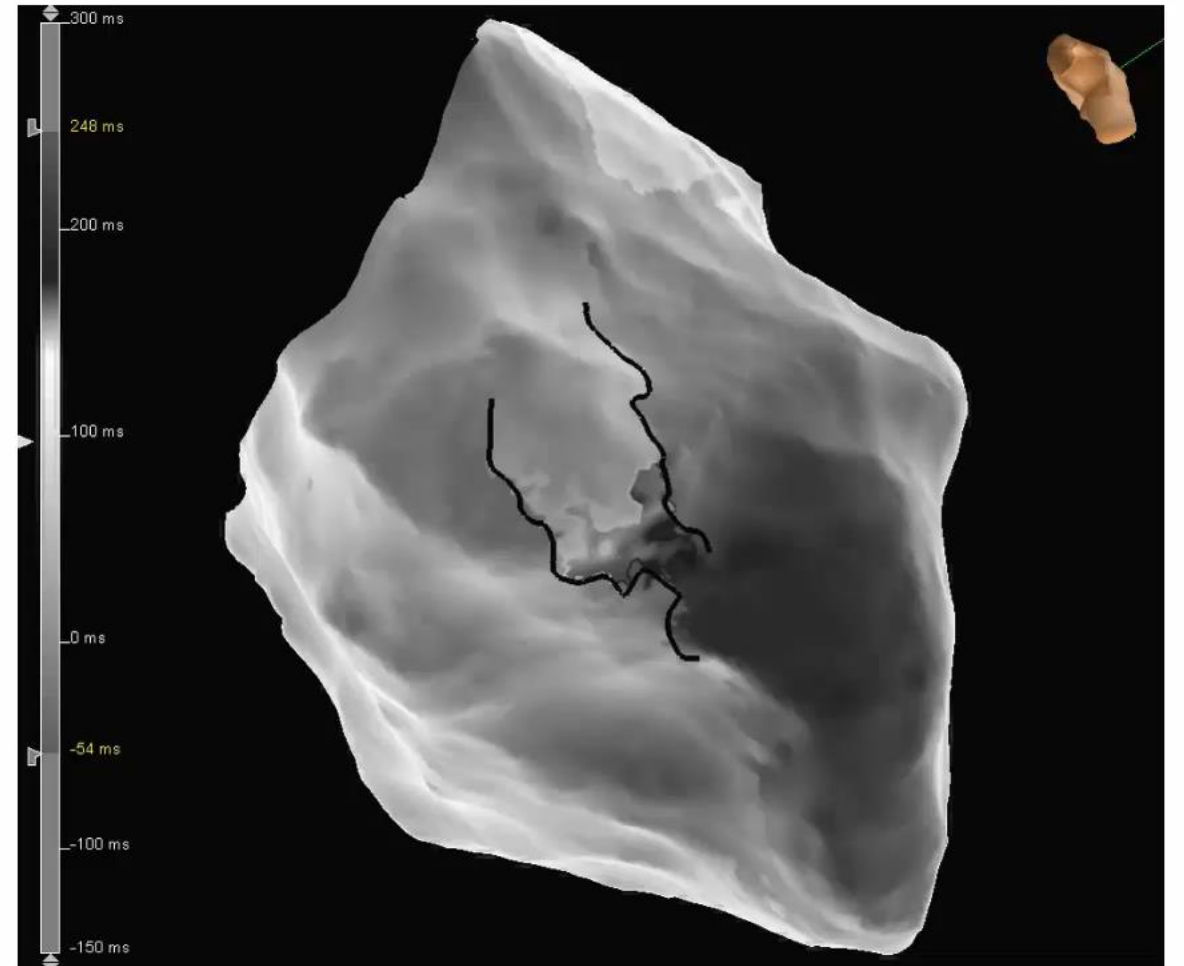
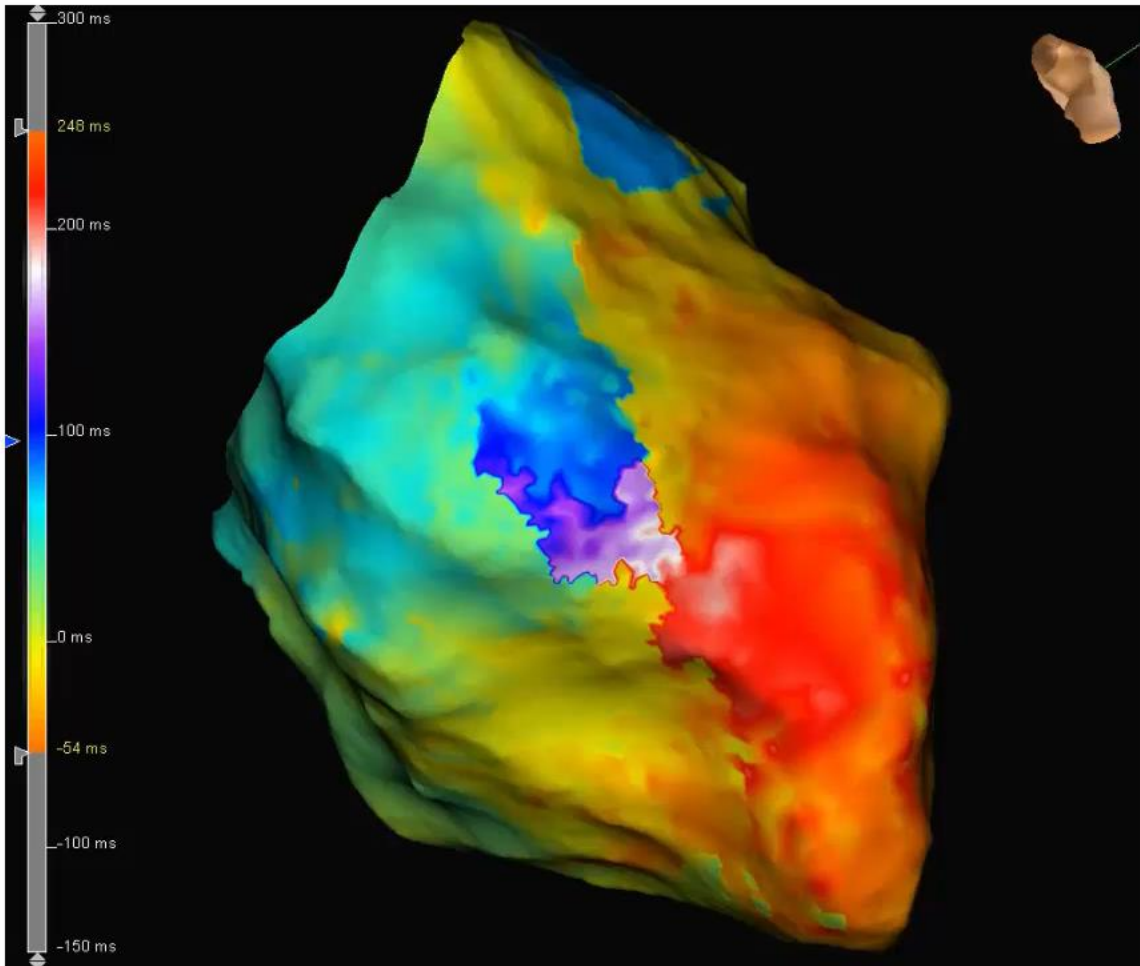
## ACTIVATION SEQUENCE



# Mapping

FULL-COLOR PROPAGATION

## VIDEOS COURTESY OF DR. ROD TUNG

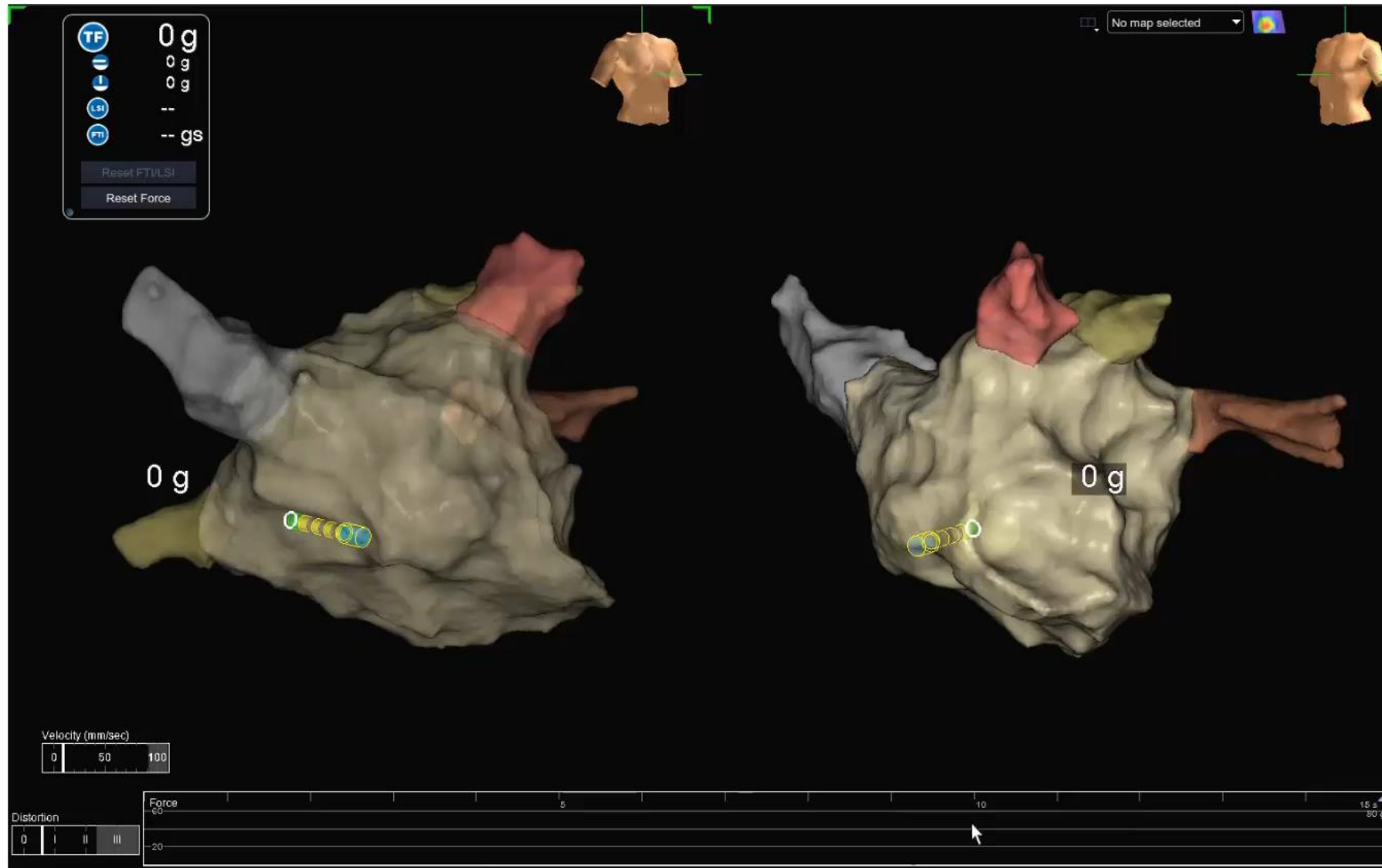


ELECTROPHYSIOLOGY

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# Mapping

## FORCE NUMBER AT CATHETER TIP



# EnSite™ X EP System

## THE FUTURE OF MAPPING

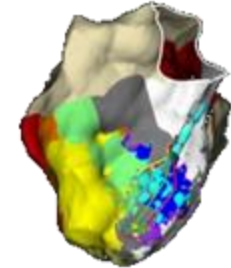
- **FLEXIBILITY TO TAILOR TO SPECIFIC PROCEDURE NEEDS**
  - VoXel Mode – Complex & Longer Cases
  - NavX Mode – Open Platform & Low Fluoro
- **VISUALIZE EVEN THE SMALLEST SIGNALS<sup>2\*</sup>**
- **EASY SYSTEM SETUP**
- **EFFICIENT, CONSISTENT, AND POWERFUL**

\*Bipolar noise floor of  $\leq 10 \mu\text{VRMs}$



### STABILITY

Earning trust in the system regardless of clinical situation



### MAPPING/WORKFLOW

Providing users flexibility to use tools and maps



### USABILITY

Efficient, reliable & reproducible user experience



### SERVICE/SUPPORT

Minimizing downtime related to system issues, upgrades and PMs

**CAUTION:** This product is intended for use by or under the direction of a physician. Prior to use, reference the Instructions for Use, inside the product carton (when available) or at manuals.sjm.com or eifu.abbottvascular.com for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events.

## **References:**

1. Abbott. Data on file. Report 90397599.
2. Abbott. Data on File. Report 90569806.

## **Abbott**

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