



PLATFORM OF LABORATORIES FOR ADVANCES IN CARDIAC EXPERIENCE

ROMA

Centro Congressi
di Confindustria

**Auditorium
della Tecnica**

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1 Ottobre

2022

**QUALE LAMA PER SCONFIGGERE LA FIBRILLAZIONE ATRIALE
OTTIMIZZAZIONE DELLA STRATEGIA ABLATIVA NELLA
FIBRILLAZIONE ATRIALE ATTRAVERSO LA MISURAZIONE
(**REAL-TIME**) DELLO SPESSORE MIOCARDICO ATTRAVERSO
ANALISI DIELETTRICA**

Ermenegildo de Ruvo, Pol Casilino, Roma





Dielectric Sensing for Electrophysiology

Shlomo Ben-Haim, MD



- Inventor of Biosense Carto mapping system

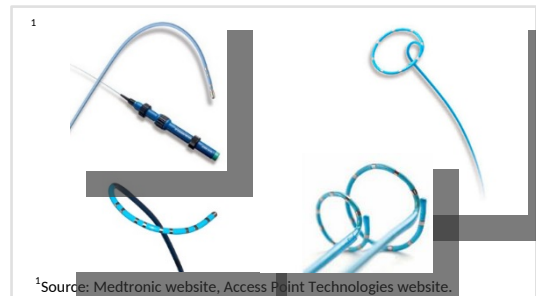
KODEX-EPD™ System



- EPD Solutions was founded in 2014 to develop a system dedicated to dielectric measurements for electrophysiology
- The KODEX-EPD system is designed to be used with validated commercially available diagnostic and therapeutic catheters and operates within existing workflows
- Acquired by Philips in June 2018



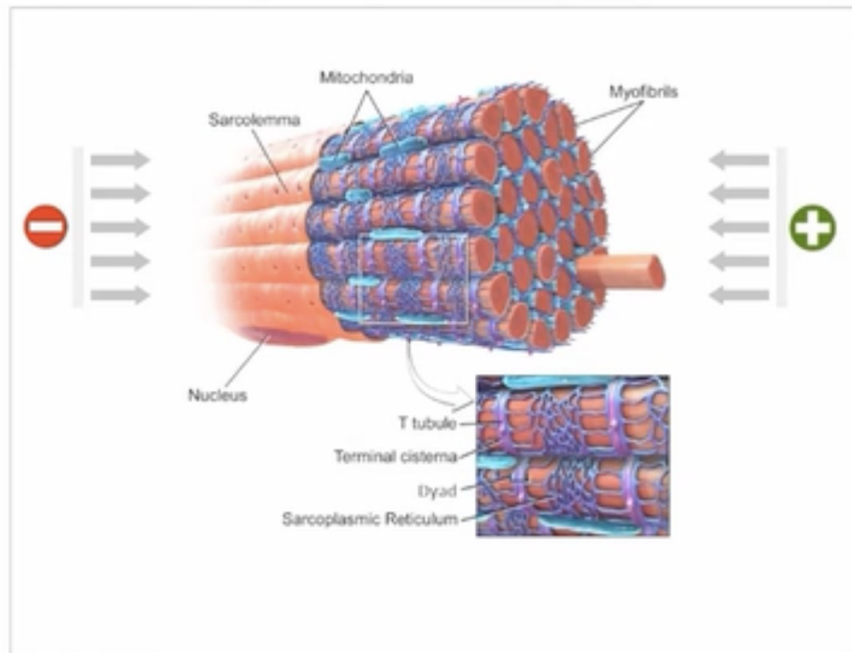
Existing 3rd Party EP Catheters



¹Source: Medtronic website, Access Point Technologies website.



Principles of Dielectric Sensing



- **Dielectric sensing** method of differentiating material characteristics by their dielectric coefficients¹ over a range of electrical current frequencies
- When a **dielectric material**² like myocardium is placed in an electrical field, electrical charges will be conducted directly through the tissue
- Part of the charges will be **temporarily stored and released** after a short delay
- This **dielectric response** can be used for many different purposes



Today we are often working in the shadow

What we can see today



Image source: www.fimmakersmagazine.com

- Contact-based “flat” shell by 3D mapping
- Electrical activation patterns by HD mapping
- RF: catheter-tissue alignment at the expense of contact force sensors
- Energy delivery to tissue as power-force-time
- Cryo: PV occlusion in 2D, x-ray/contrast/ICE

What we would like to see



- Anatomical structures with **wall thickness**
- **Tissue characteristics** - healthy/scar/edema
- RF **catheter-tissue alignment** without the need for sensor driven catheters
- **Tissue response** to energy delivery
- Cryo: PV occlusion in 3D, no x-ray/contrast/ICE

➤ Dielectric imaging offers fundamental understanding of tissue properties



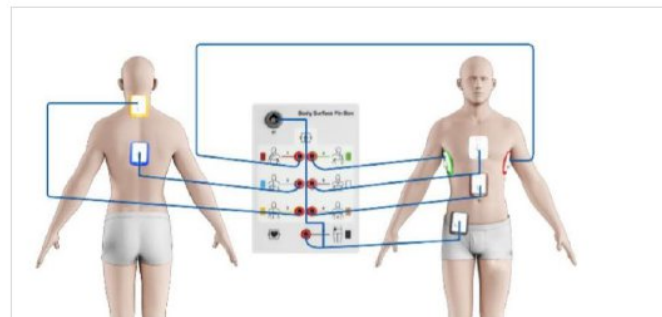
KODEX-EPD: system and procedural disposables

System overview



- Processing unit
- Workstation
- Body surface pin box
- Diagnostic catheter pin box
- Recording system pin box
- Foot pedal

Procedural disposables

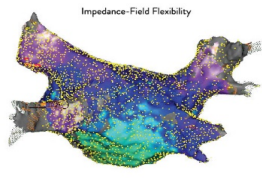


- Dielectric sensors
- Catheter activation keys

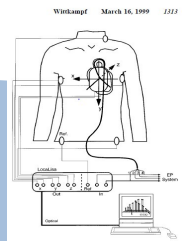
KODEX-EPD is 510(k) cleared and is CE Marked
Note: KODEX-EPD does not support 12-lead ECG in this release

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EPD
Solutions
A Philips company

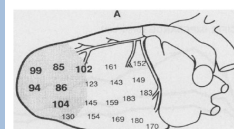


Tissue Properties

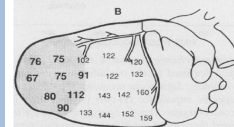


RF Ablation

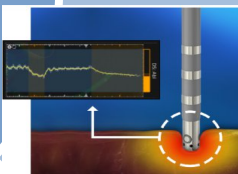
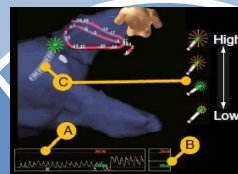
Circulation Vol 87, No 1 January 1993



Specific-impedance (ohm-cm), 1 week, 1 kHz



Specific-impedance (ohm-cm), 6 week, 1 kHz



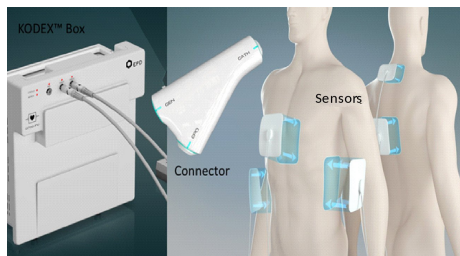
Dielectrics
(resistive and capacitive properties)
have been critical to our
understanding of cardiac anatomy,
RF ablation, and tissue properties.



EPD Solutions: establishing disruptive dielectric imaging modality

With uniquely differentiated value propositions for EP and CRM

KODEX: disruptive Imaging Modality

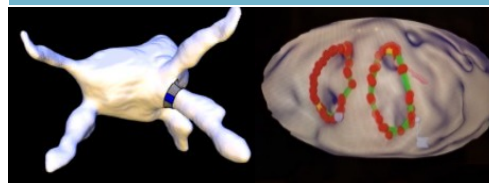


Dielectric imaging: breakthrough technology with unique potential for:

- **Real-time therapy assessment**
 - ⌚ reduced re-do rates
- **Simplified navigation**
 - ⌚ shorter procedure time
- **Fluoroless imaging**
 - ⌚ lower/no x-ray exposure
- **Open system**
 - ⌚ works with all device vendors

Building unique value propositions

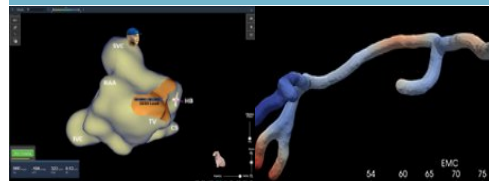
Electrophysiology (EP)



Cryoablation

RF ablation

Cardiac Rhythm Management (CRM)



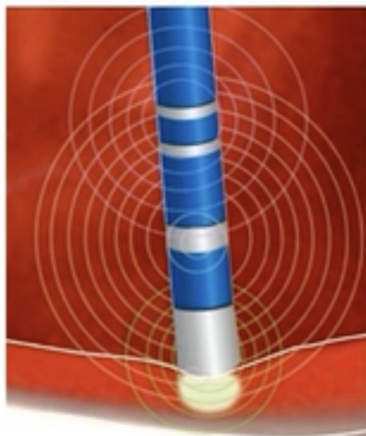
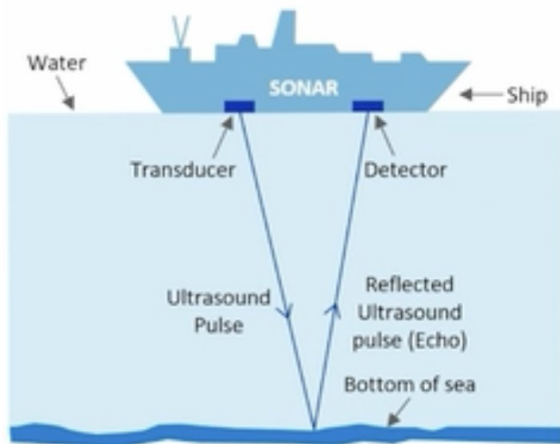
HIS bundle pacing

CRT implants



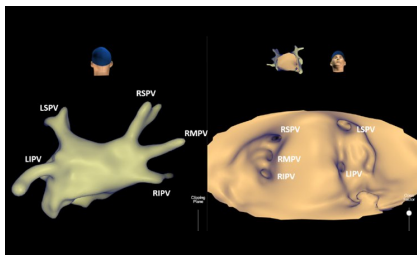
How does KODEX Tissue Thickness & Lesion Assessment work?

Example: Tissue Response Viewer

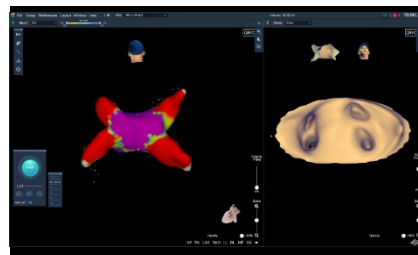


- Current sent out from the catheter electrode (transducer)
- Current detected back on the catheter electrodes (detector)
- Different tissue types/thicknesses have a different signature or 'sound and delay'
- The system detects these small differences and interprets this information to assess tissue characteristics (e.g. thickness, touch)
- Tissue Response Viewer also takes in other variables (e.g., catheter position/stability) to increase sensitivity to lesion creation, like sonar may compensate for rough seas, marine lift

Potential application areas of Dielectric Sensing for EP



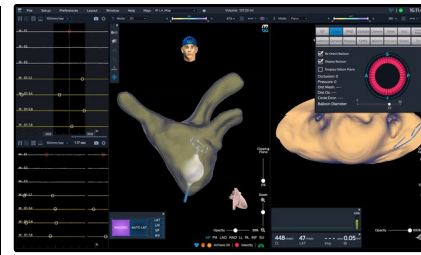
Anatomical Imaging
(Commercial)



Mapping - Voltage and Activation
(Commercial)



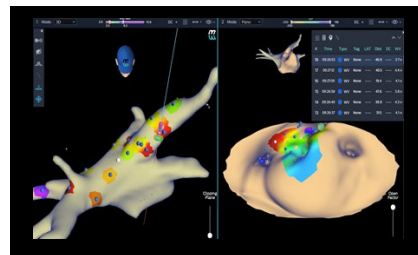
Cryoballoon Occlusion
(Commercial)



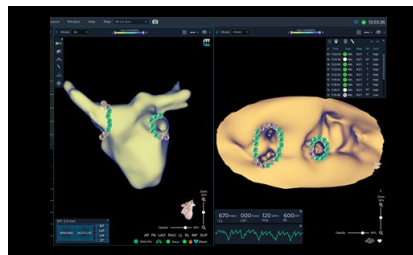
Cryoballoon Visualization
(Research)*



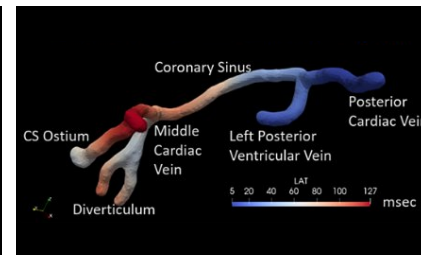
Tissue Contact
(Commercial)*



Wall Thickness
(Commercial)*



Lesion Classification
(Commercial)*



CRM Lead Guidance
(Research)*

*Disclaimer: Features labeled "Research" are explored as possible future functionalities, not CE marked / FDA cleared, and not available for sale. Their future availability cannot be guaranteed.



KODEX-EPD Electric fields

Global Fields

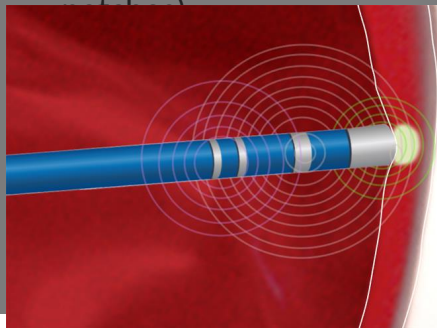
- Used for anatomy imaging
- Generated between body patches
- Sensed by catheter (and patches)



Source: Internal modeling data

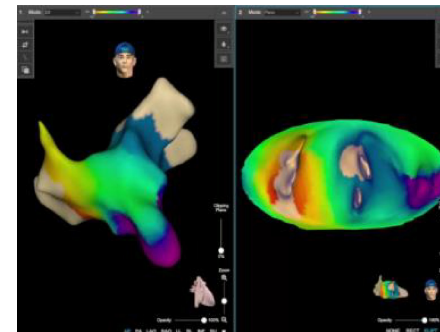
Local Fields

- Used for local tissue properties
- Generated between catheter electrodes (and patch)
- Sensed by catheter (and patches)



Cardiac Fields

- Used for EGM mapping
- Sensed by catheter and patches



Source: Dielectric Imaging explanation



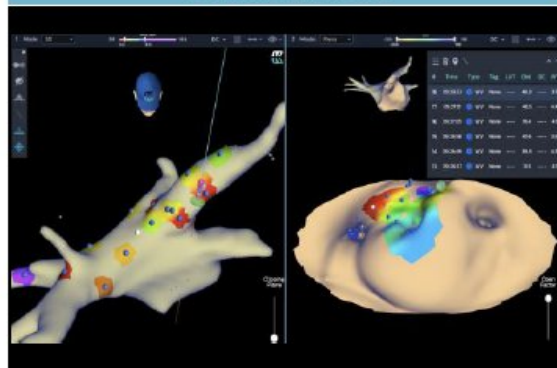
Tissue Engagement Viewer



- Tissue-Electrode Interface Interrogation, Touch/No-Touch Tissue-Pressure Level
- Standard irrigated ablation catheters, without contact force sensing apparatus

Wall Viewer

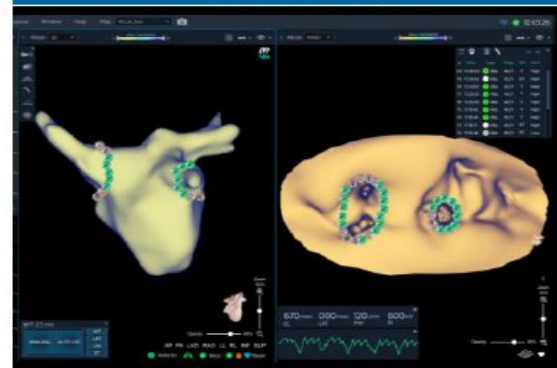
If applicable w/RF Plus Key



- Myocardial Wall Thickness through Local Dielectric Interrogation
- Standard irrigated ablation catheters, without pre-acquired imaging or real-time ultrasound

Tissue Response Viewer

If applicable w/RF Plus Key



- Immediate post-ablation lesion assessment
- Indicating High / Low Local Dielectric Tissue Response (HDR / LDR)



TEV - System Configuration

Indication shall be enabled only if the system operates with the following catheters/RF Generator combinations

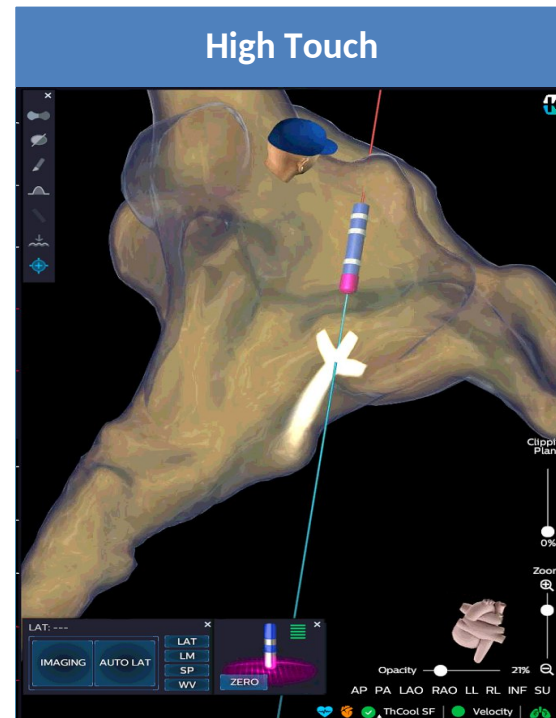
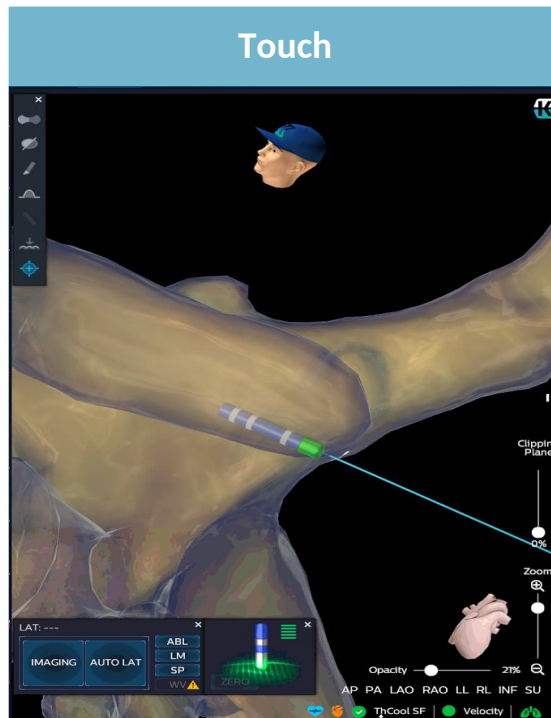
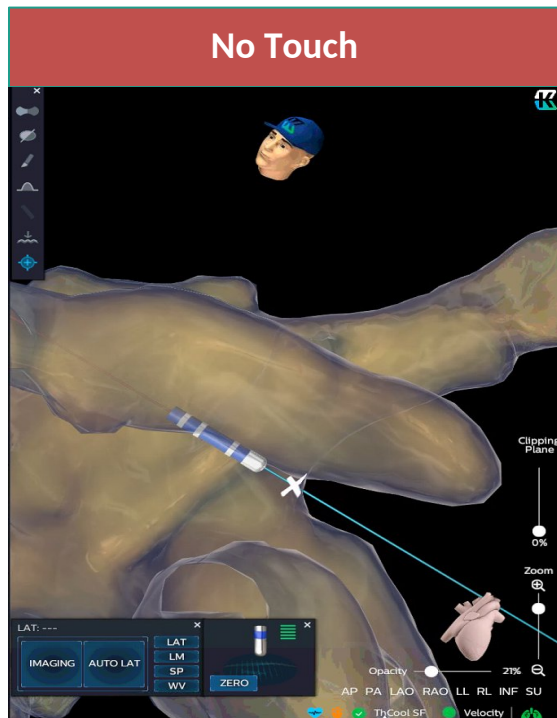
Manufacturer	Catheter name / sub type	Compatible RF Generator
Biosense Webster	THERMOCOOL® SF	SmartAblate \ KODEX RF Generator
Boston Scientific	BLAZER™ OPEN-IRRIGATED	Boston Maestro 4000
	Map-iT™ - Irrigated	SmartAblate \ KODEX RF Generator
Access Point Technologies (APT)	Triguy	SmartAblate \ KODEX RF Generator
	Triguy Cool Tip	SmartAblate \ KODEX RF Generator
Synaptic	RhithmCool W - Irrigated	SmartAblate \ KODEX RF Generator
	Micro Infusion - RhithmCool V	SmartAblate \ KODEX RF Generator

Table 1: Catheters and RF generators combinations compatible with Tissue Engagement Viewer



Three levels of Touch

The icon tip displayed in the Tissue Engagement Viewer changes the colour based on predefined thresholds measured.

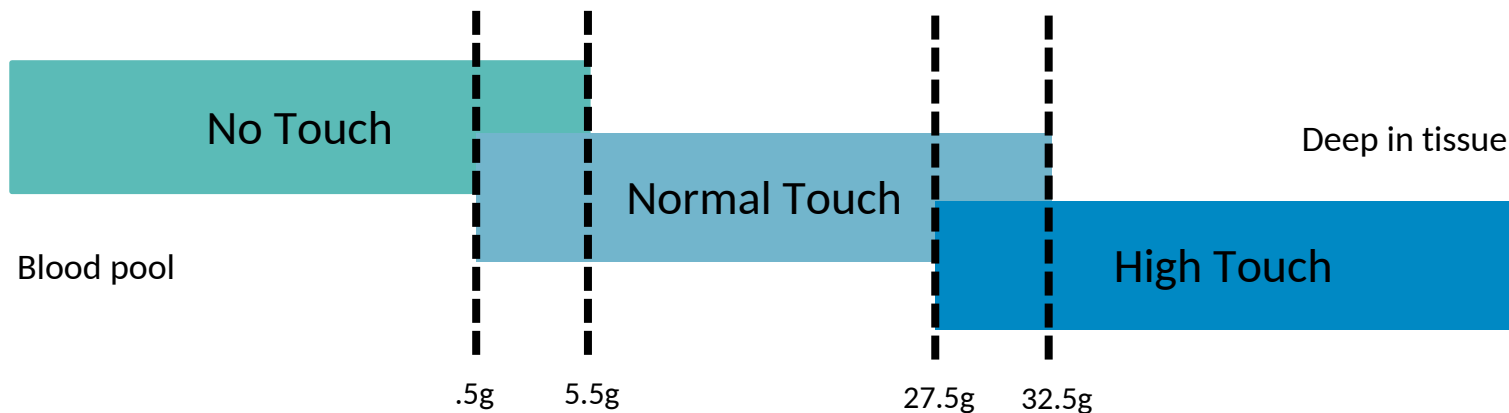




Tissue Engagement Viewer

- The Tissue Engagement Viewer displays visual feedback based on predefined set of thresholds.
- Displayed near real time

Illustration of pre-defined thresholds based on bench testing.



Optimal tissue displacement range for ablation should comply with common clinical practice and relevant guidelines applicable at the time and based on the judgment of the physician.



TEV based on tissue displacement

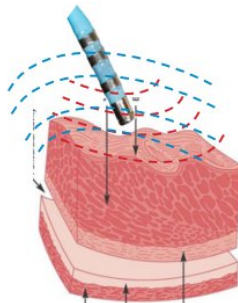
Principle of Operation

- Increased engagement generally results in more tissue displacement
- Requires 30 secs of imaging to create anatomy
- TEV measures the pressure exerted on the tissue by the catheter (Contact Force measures the pressure exerted on the catheter by the tissue)

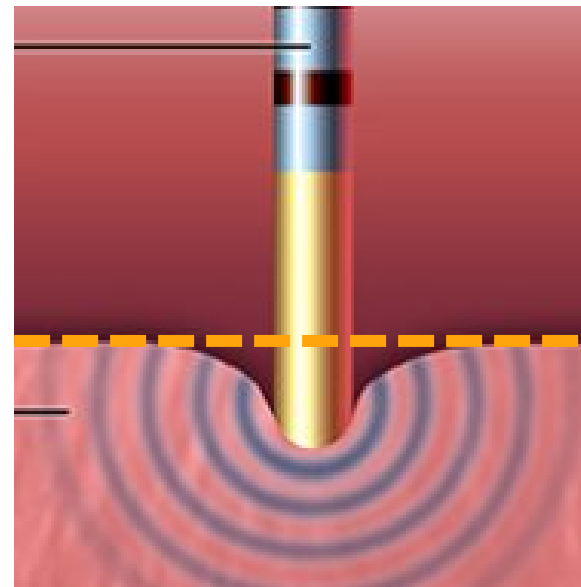
Native sensing

A small electrical field in various frequencies is being emitted by the indwelling electrodes;

All electrodes are both Transmitters and Receivers



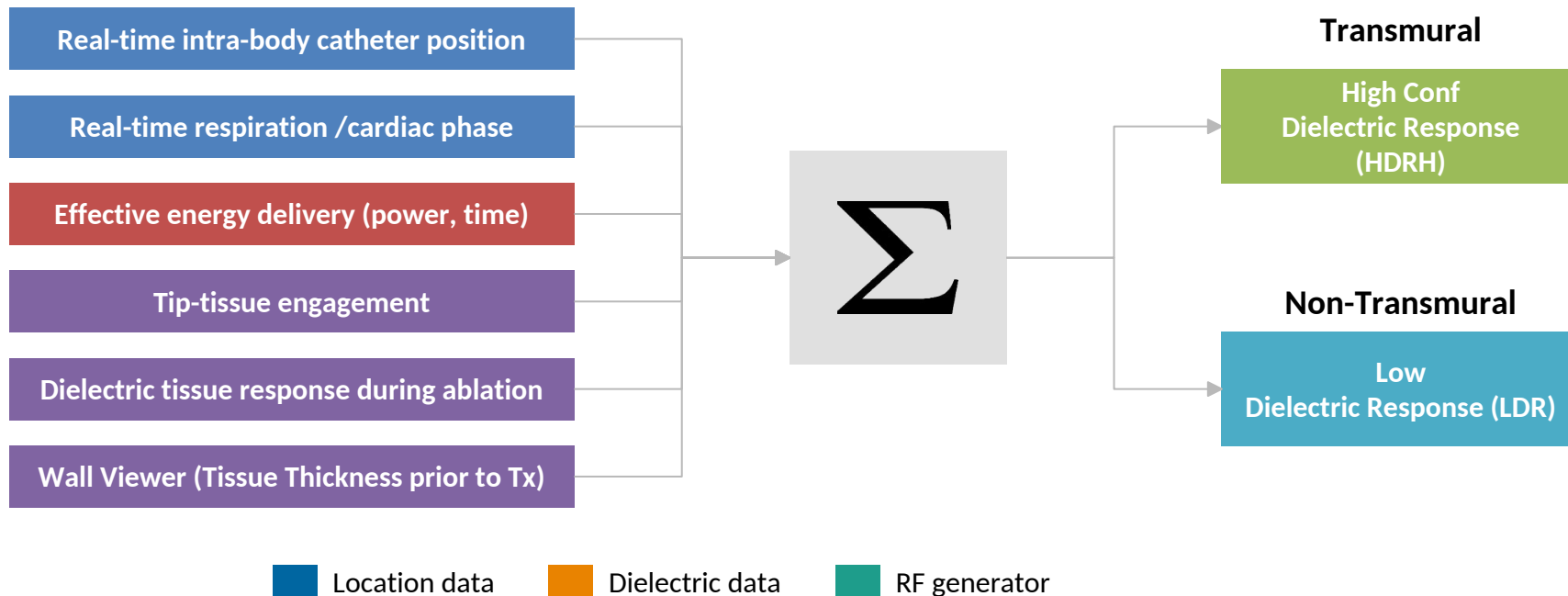
Tissue surface →



Use common clinical practices for real-time verification of catheter locations (such as inspection of intracardiac signals, available imaging modalities, navigating the catheter back to a known previously mapped anatomical landmark) throughout the procedure to avoid excessive catheter to tissue displacement.

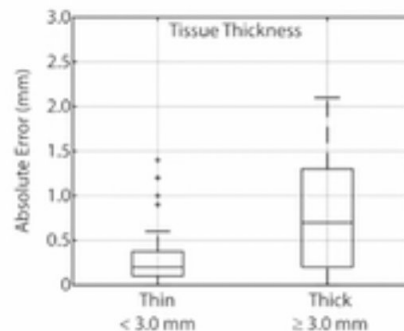
Dielectric Response – Fundamentals

Inputs for dielectric response assessment:





Wall Viewer (WV): FIH Preliminary Results /UI



Absolute error for thin (0.2 [0.1-0.4] mm, n=23)
 and thick tissue (0.7 [0.2-1.3] mm, n=33).
 HRS 2021 Abstract

WV along SVC-IVC lines is compatible with RA atlas and is highly repeatable. WV along CTI line ('design-line' prior to ablation) is well correlated with ICE; CTI morphology & anatomical variations (thick eustachian ridge, muscle bundles, pouches/recesses) are all nicely depicted by KODEX.

Dielectric Tissue Imaging in Cavotricuspid Isthmus Ablation (ERUCA);

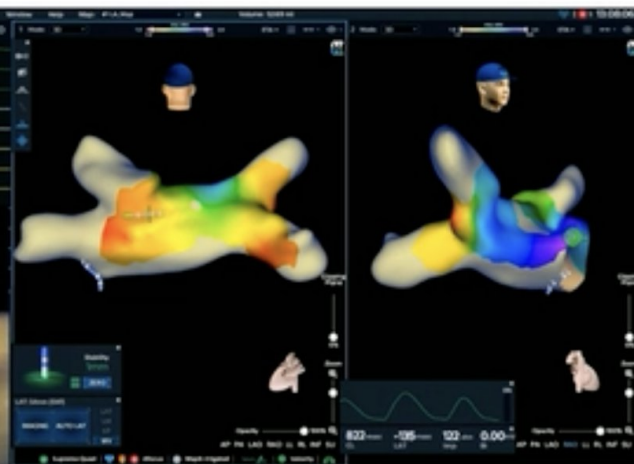
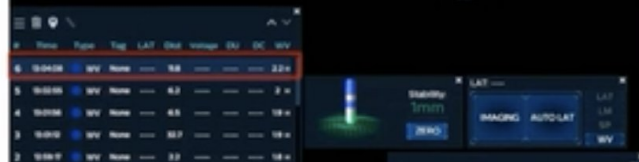
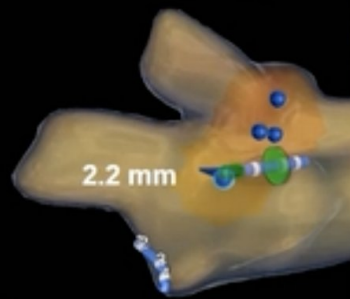
ClinicalTrials.gov Identifier: NCT04438395; PI - Dr. Larry Chinitz; Estimated enrollment N=30;

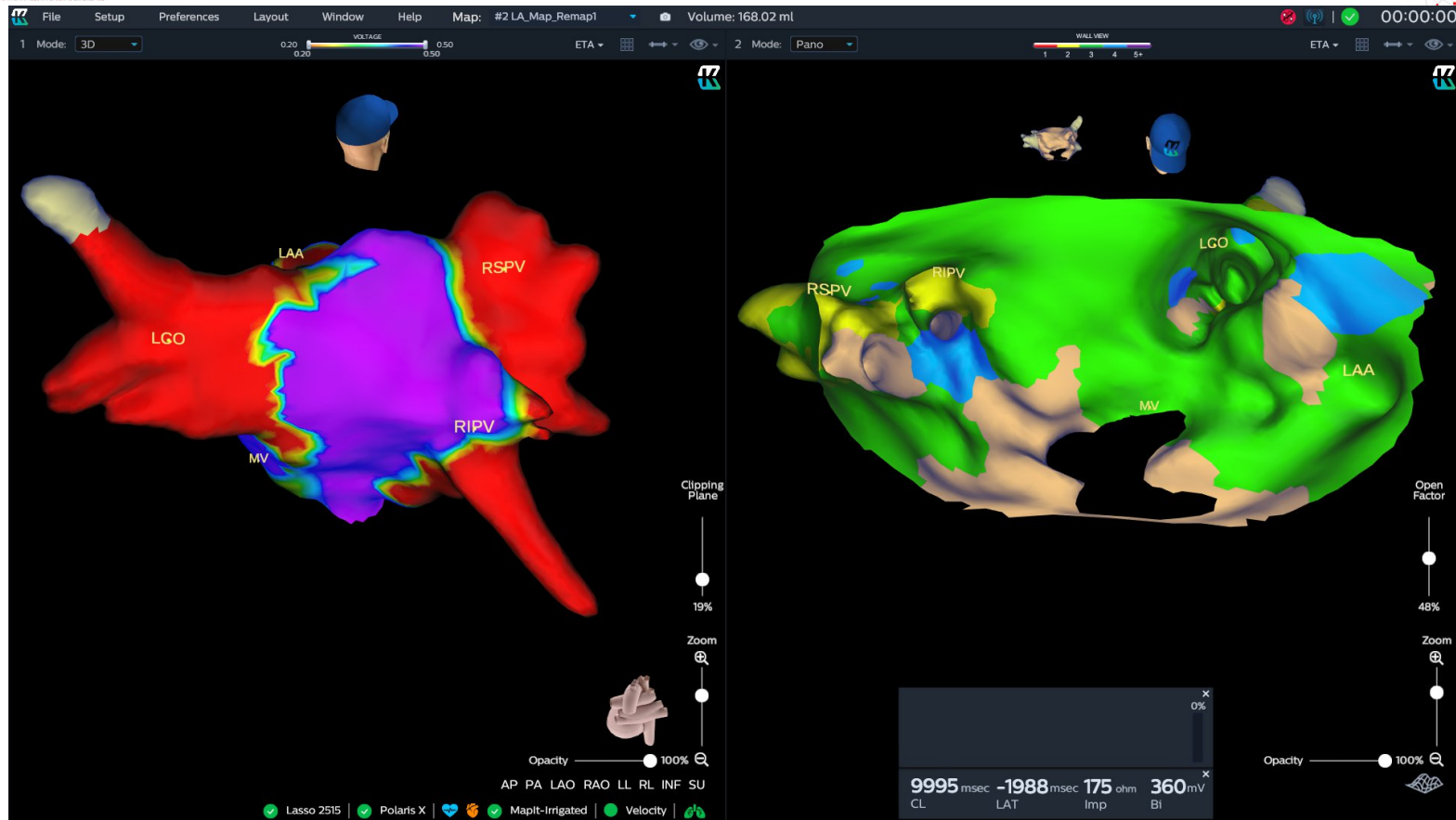


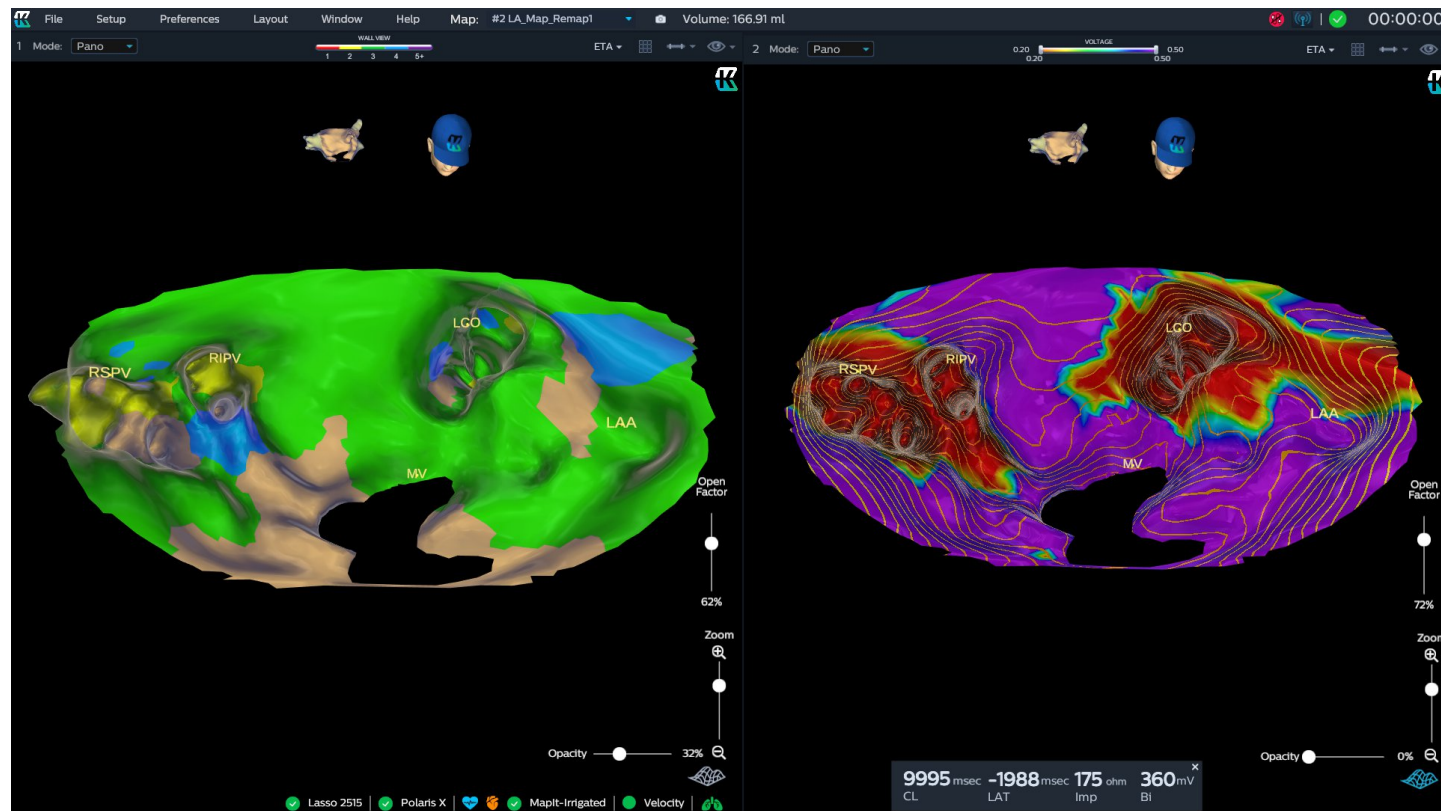
Wall Viewer map of LA on secondary KODEX system



ICE of LA wall

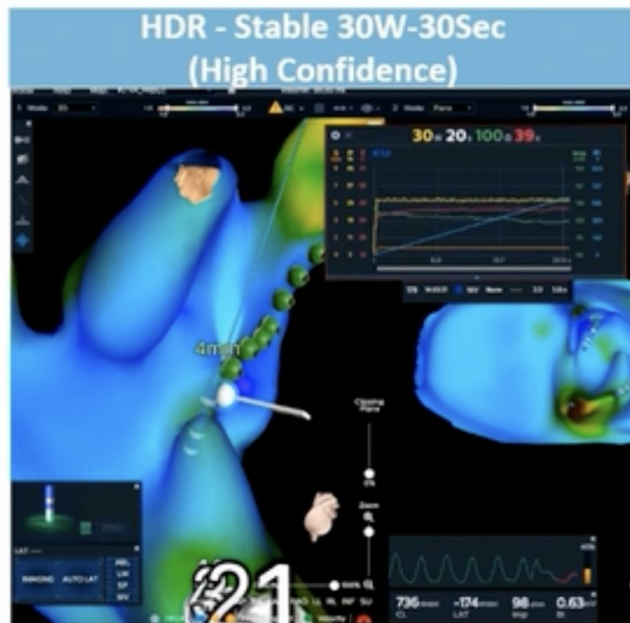






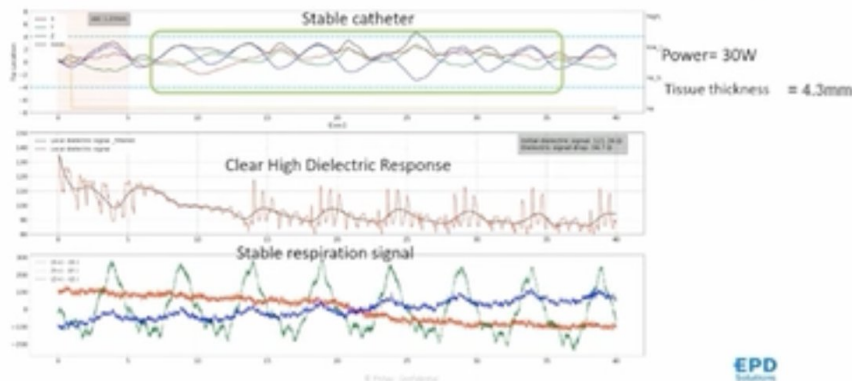


Tissue Response Viewer - Ablation Tags Indicate effective lesions



Dielectrics during RF on Caval Line

Dielectrics during RF on Caval Line



● HDRH ● HDRL ● LDR

PLACE

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