

Development of the Electroanatomical Mapping System

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Technion - Israel Institute of Technology

Stages in the Development and Clinical Use of the Carto System

- Conception of the idea, technology development, preclinical studies
- Initial human studies
- Development of mapping and ablation strategies for complex arrhythmias
- Ablation for atrial fibrillation
- Related technological developments (imaging, ablation technologies)

Shlomo Ben-Haim



Founds Biosense in Haifa, Israel in 1993

First clinical cases – November 1995

Johnson & Johnson buys Biosense, Inc. in 1997

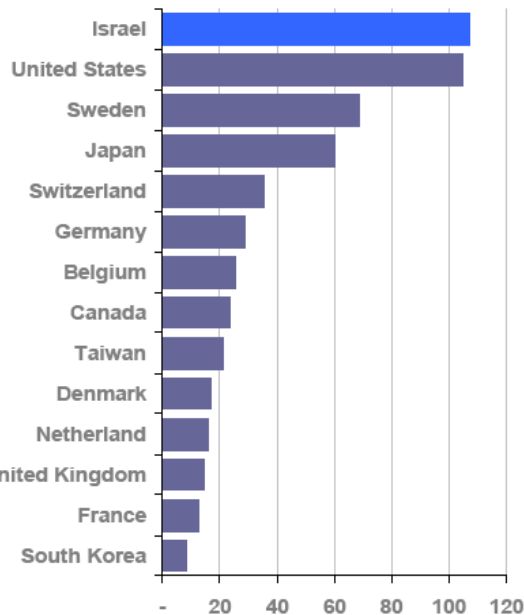
Johnson & Johnson merges Biosense, Inc. and Cordis Webster in 1998

Innovation Requirements

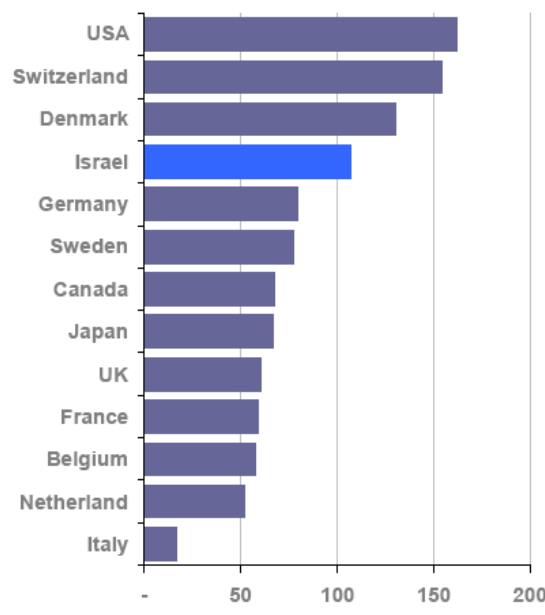
- Clinical problem/need
- Market
- Innovative idea/technology
- Innovative environment
- Funding/ business plan

Innovations in Israel

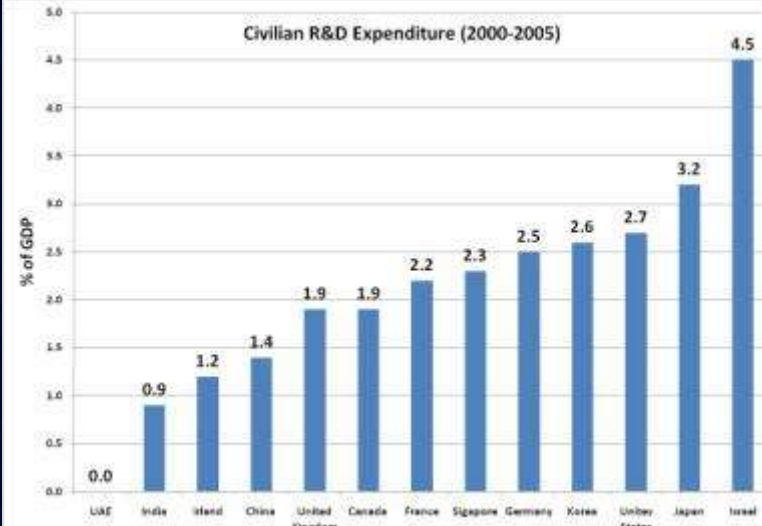
Medical patents/capita



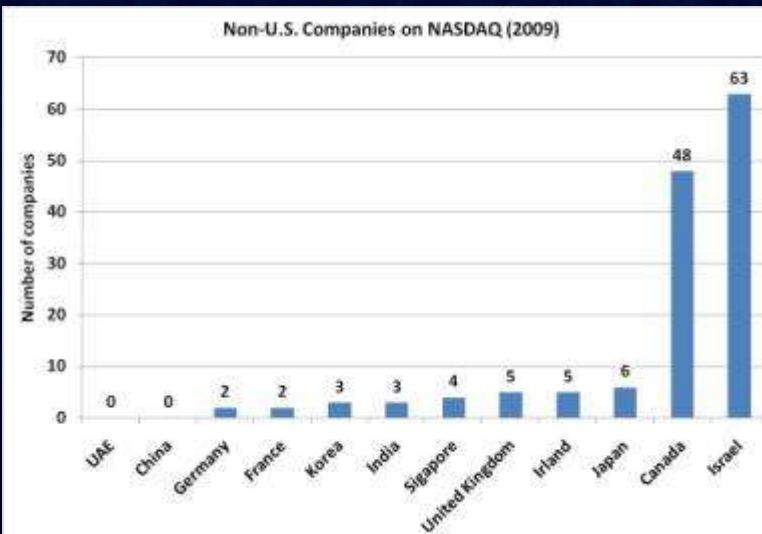
BioPharma patents/capita



Civilian R&D Expenditure (2000-2005)

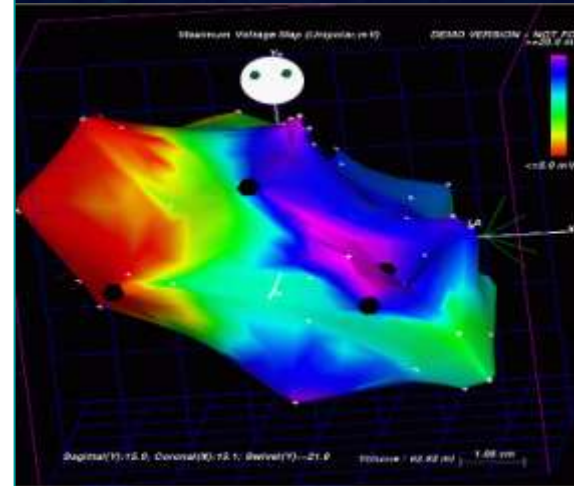


Non-U.S. Companies on NASDAQ (2009)



Innovations in Israel

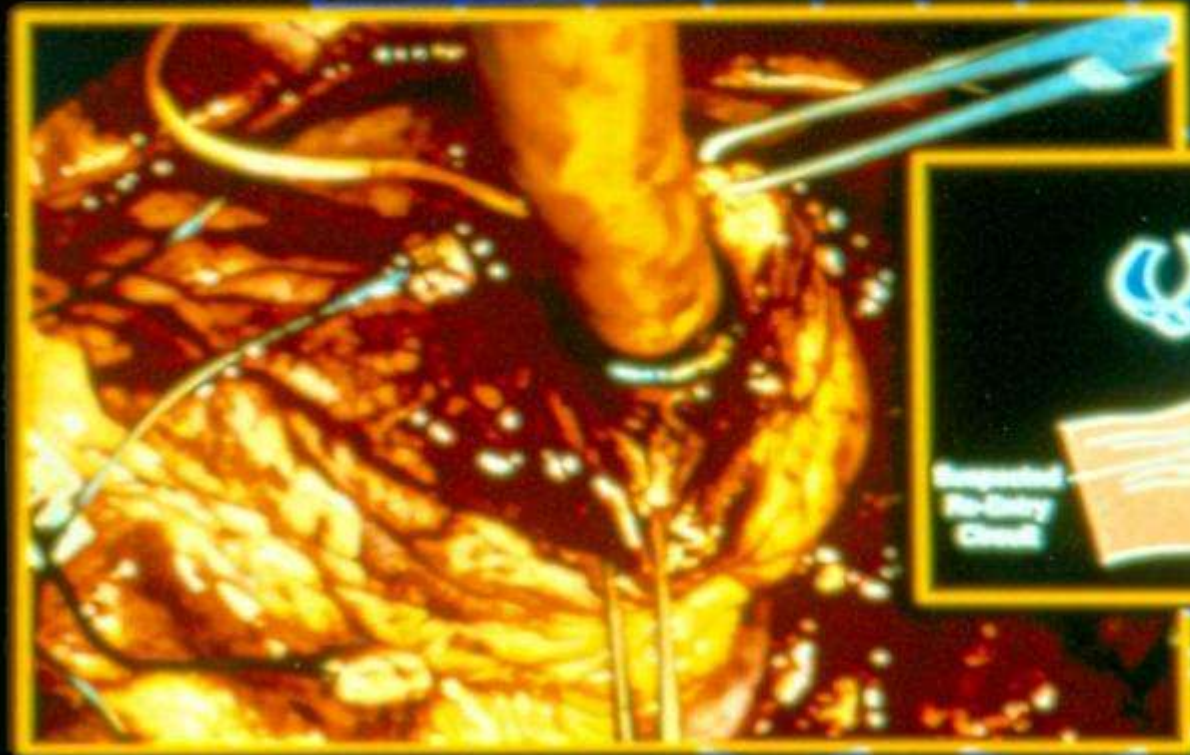
- **Teva Industry**
 - Copaxon, Azilect
- **Stents**
 - InStent, Nir, Many more
- **Biosense**
 - Revolutionized EP
- **Given Imaging**
 - Revolutionized GI diagnosis
- **Ventor**
 - Novel Transapical Valve



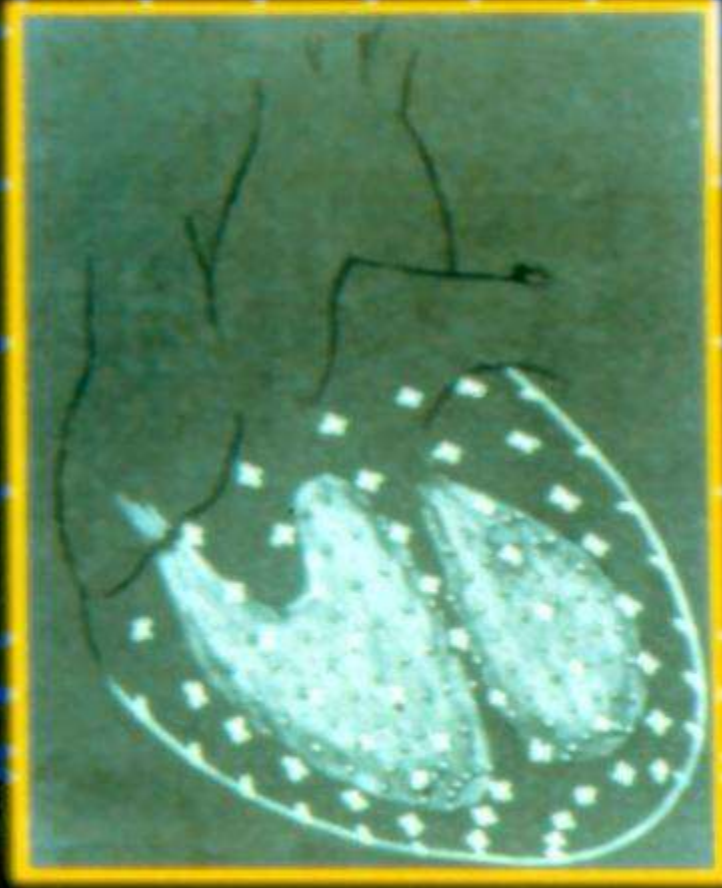
Cardiac Mapping

- Mapping is a general term that relates to the assignment and display of encoded-information according to its spatial coordinates.
- Cardiac Mapping:
 - Spatial coordinates of the recording sites
 - Electrophysiological information
- Beat-by-beat single site vs. multi-site recording

Finger electrode

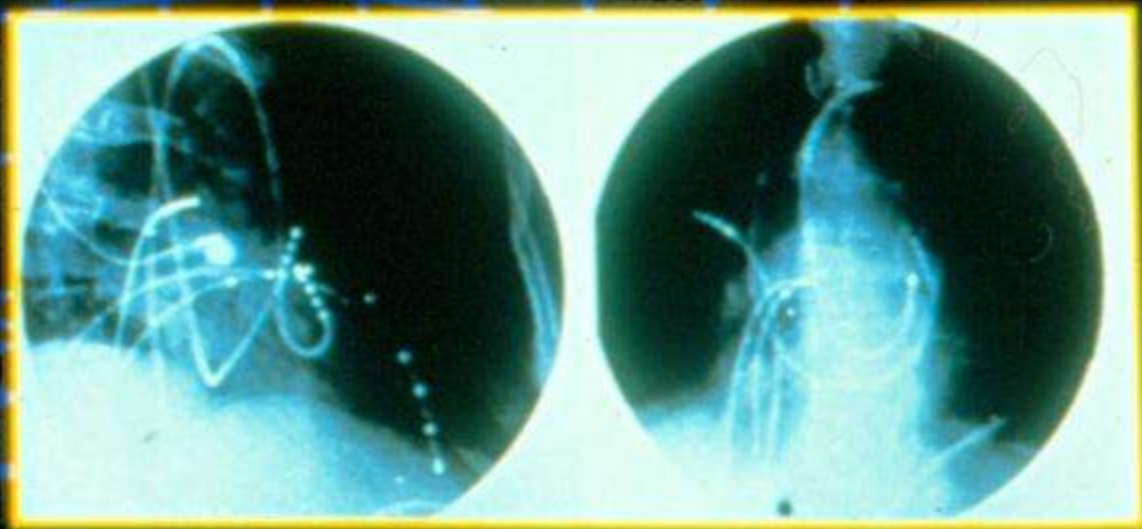


Epicardial sock

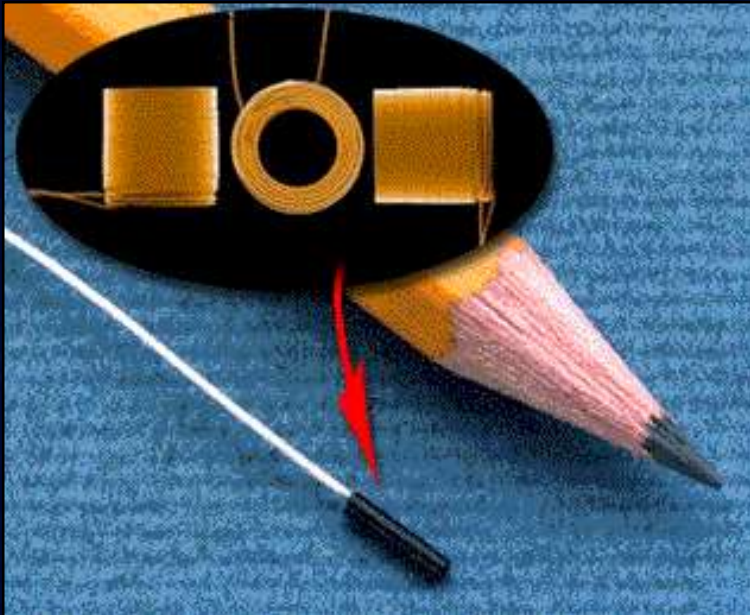


Cardiac mapping history-3

- Catheter mapping
 - fluoroscopic location
 - basket
 - non-contact



The Navistar Catheter

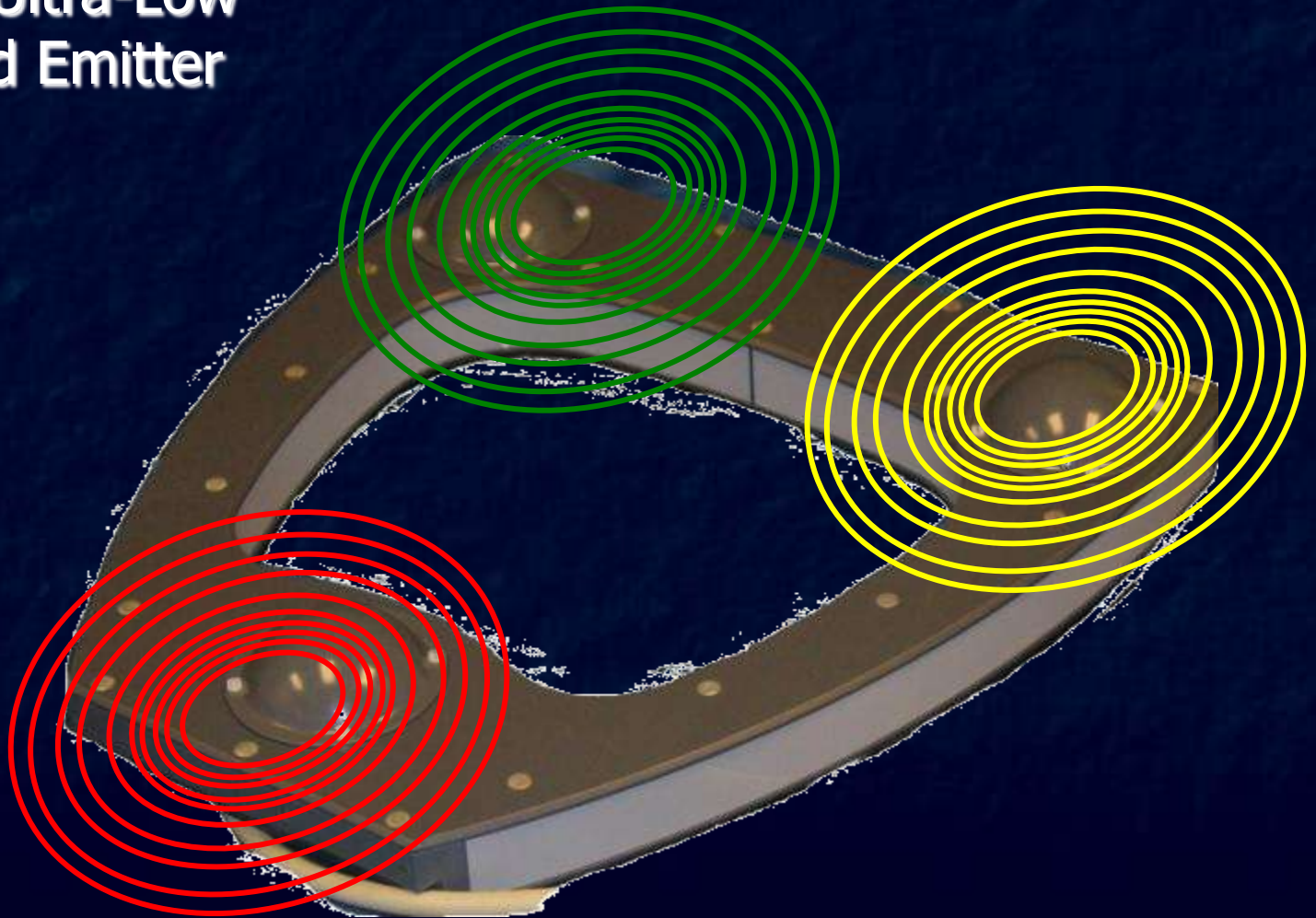


Locatable tip:

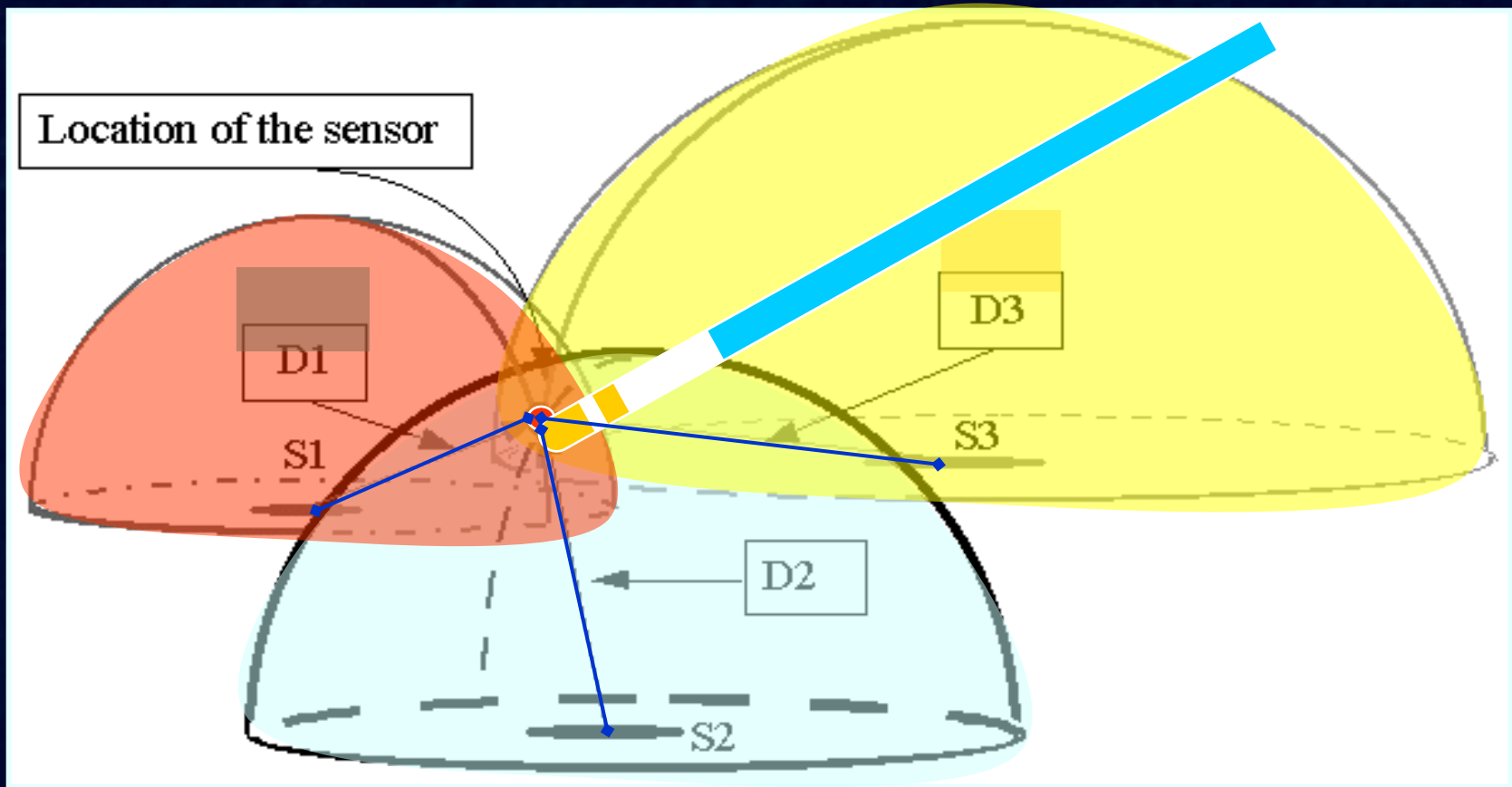
- Real-time
- Six degrees of freedom

The Location Pad

- An External Ultra-Low Magnetic Field Emitter

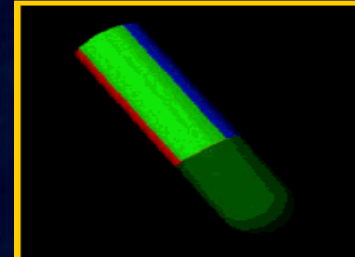
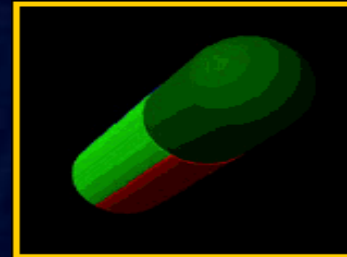
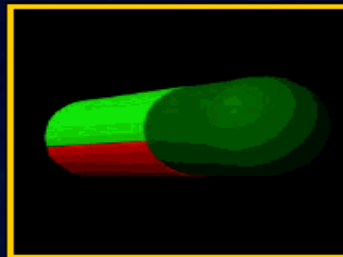


Catheter Tip Location

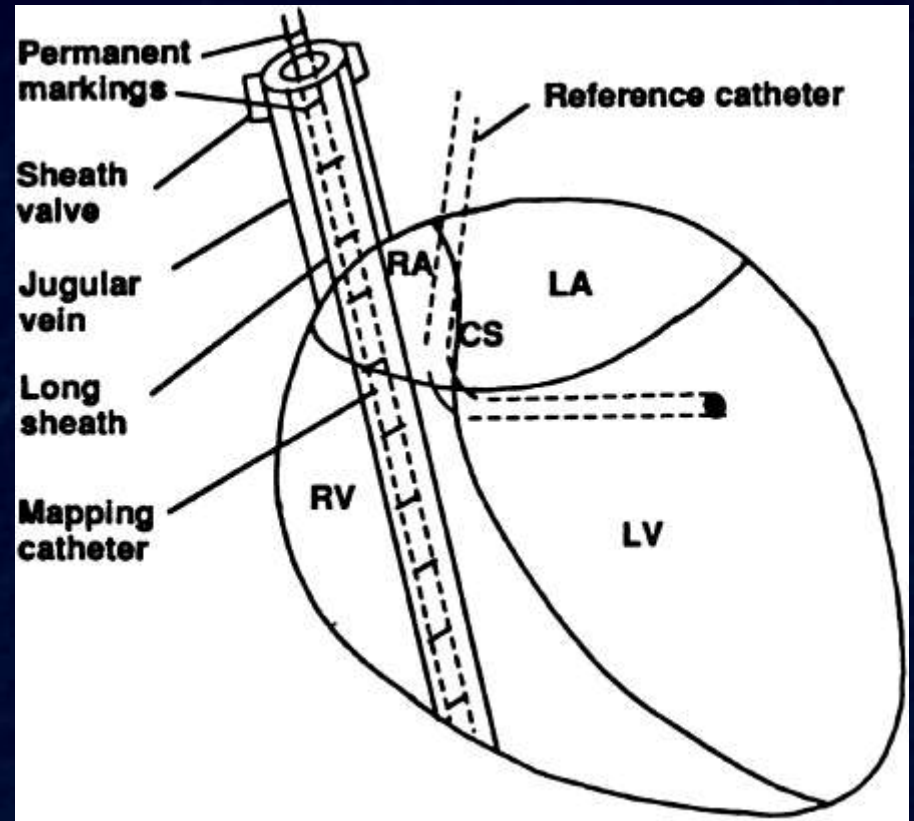
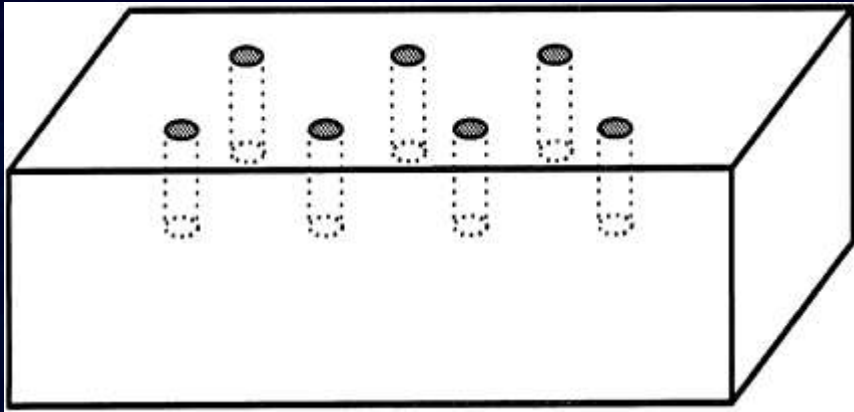


Gepstein et al. Circulation 1997

Carto Locatable Catheter



- ⇒ Magnetic Sensor, Real time
- ⇒ 6 degrees of freedom; location and orientation



- ⇒ *Statistic in vitro* accuracy: 0.2 mm
- ⇒ *Statistic in vivo* accuracy: 0.7 mm

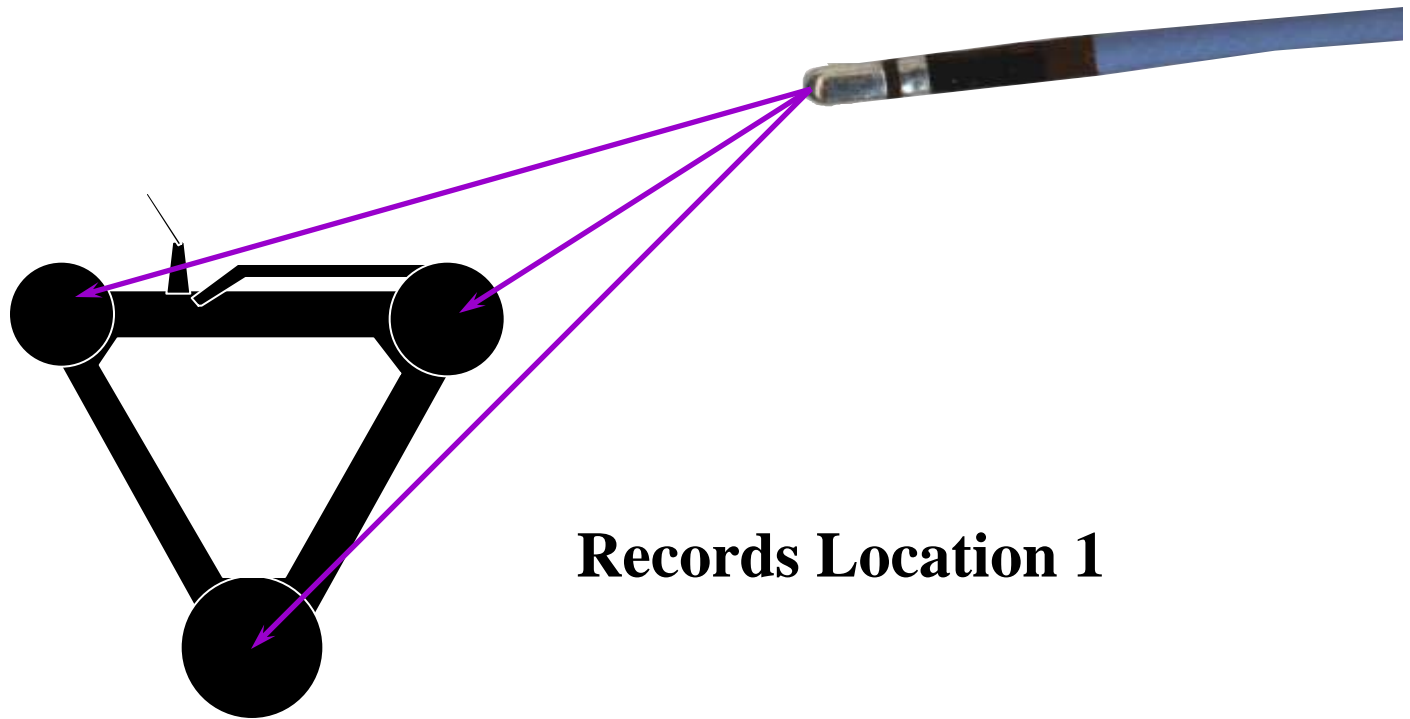
Ben-Haim SA, et al. Nature Medicine 1996

Gepstein L, et al. Circulation 1997

Surface Reconstruction

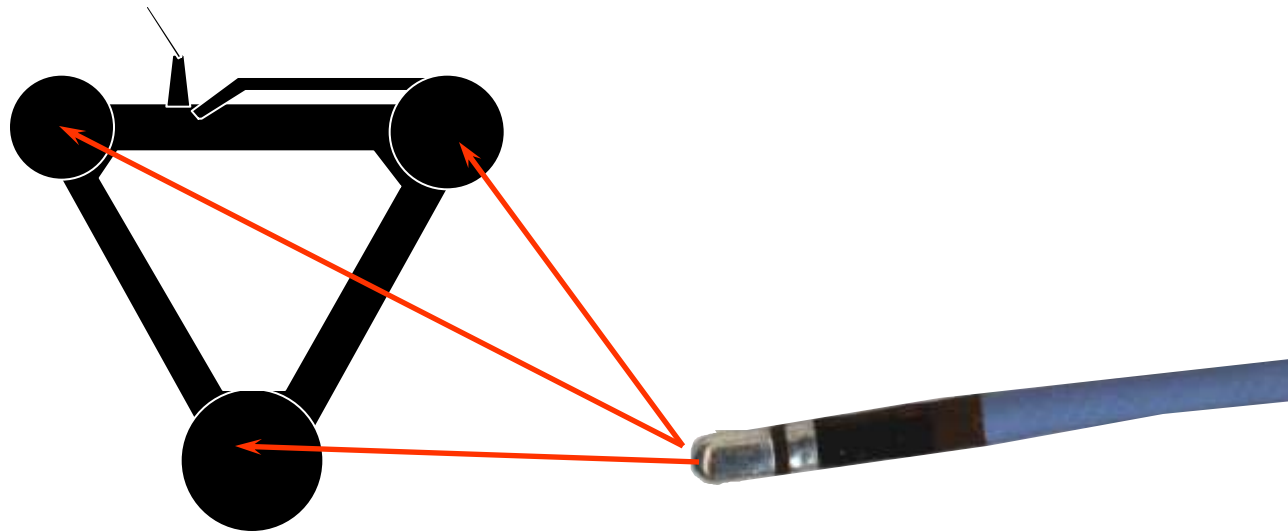


Surface Reconstruction



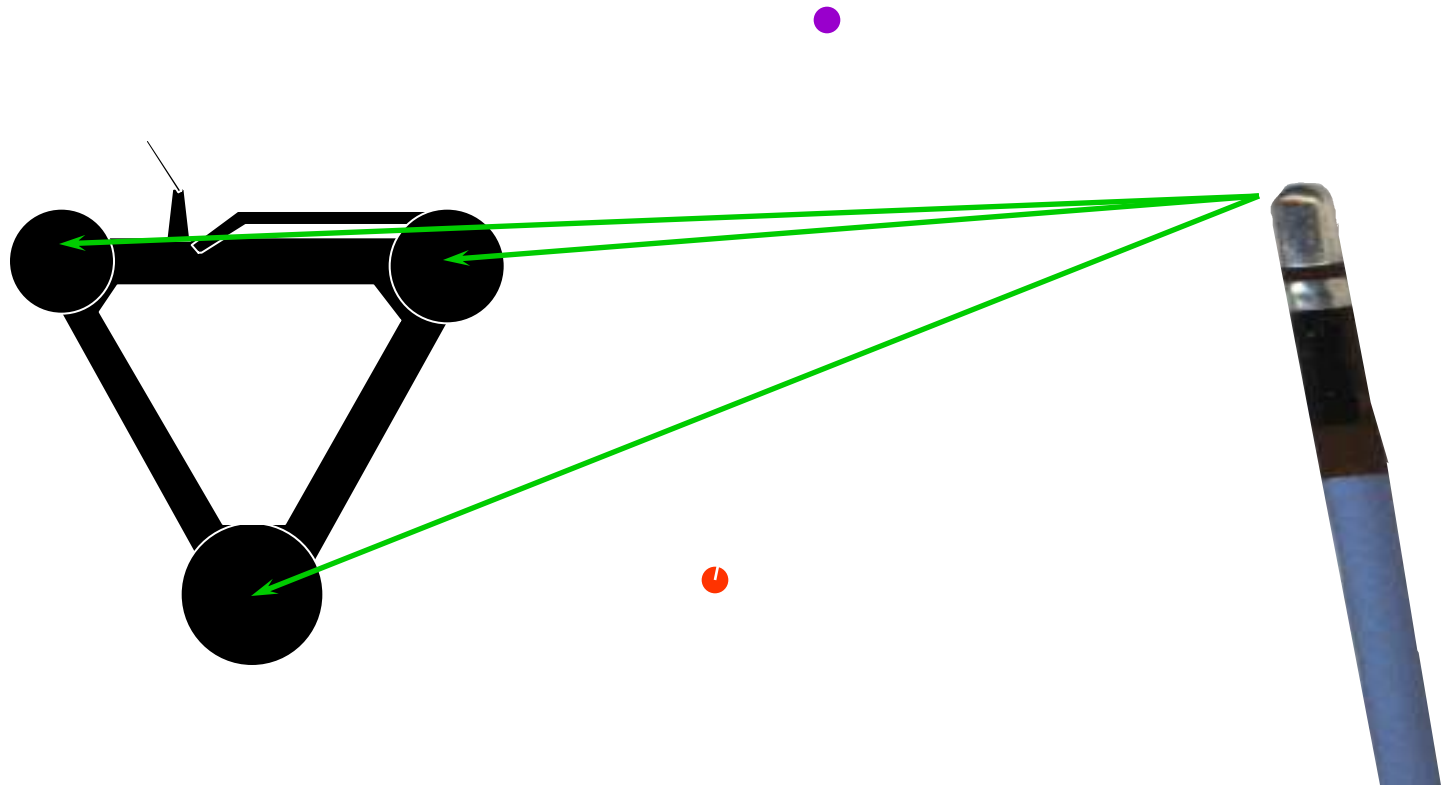
System records location through constant interrogation of the magnetic field generated from the location pad

Surface Reconstruction



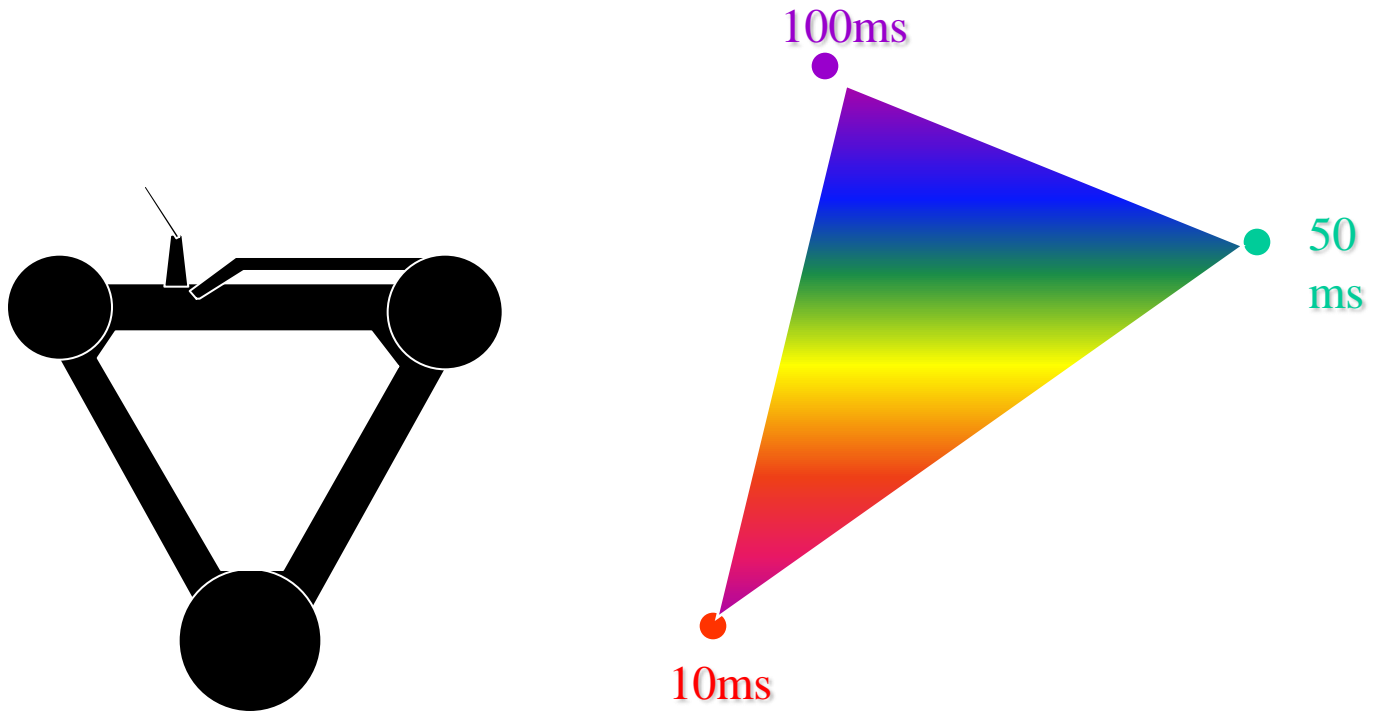
Records location 2

Surface Reconstruction



Records location 3

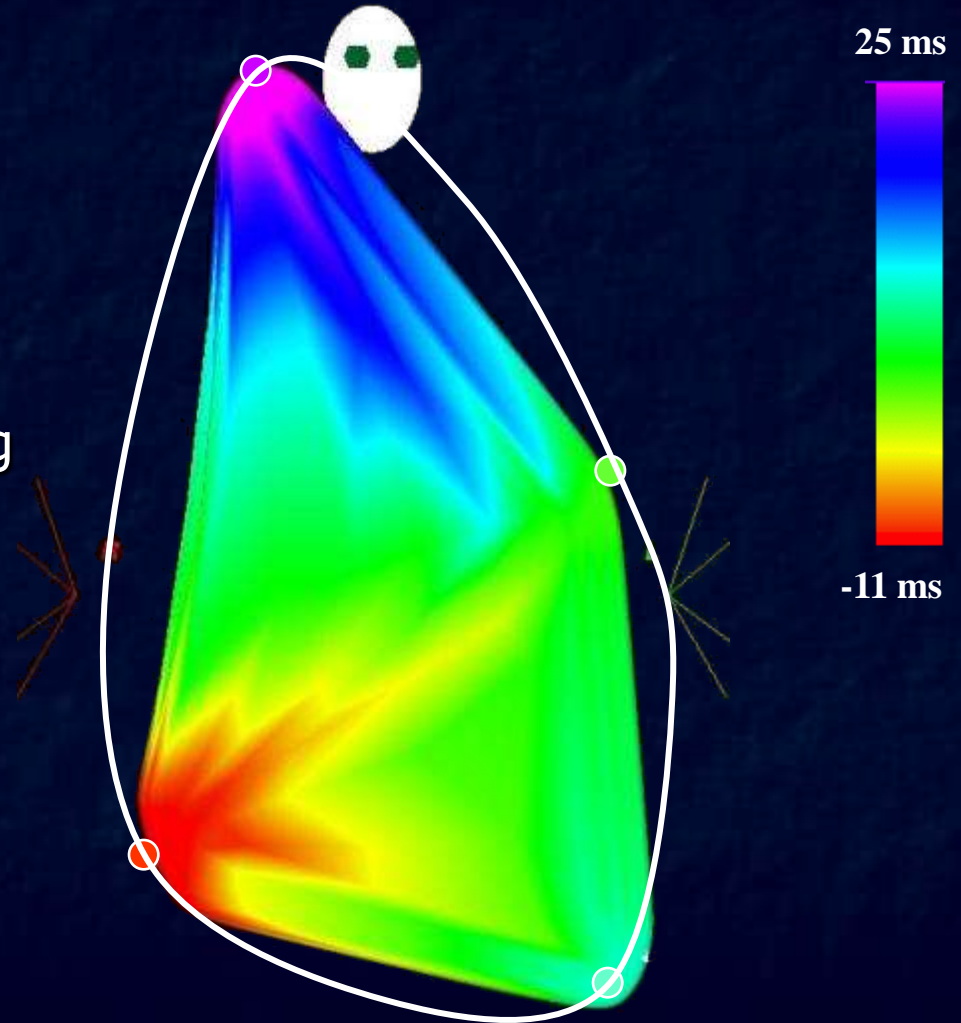
Surface Reconstruction



- Superimposes point location and local activation times

Smooth Reconstruction

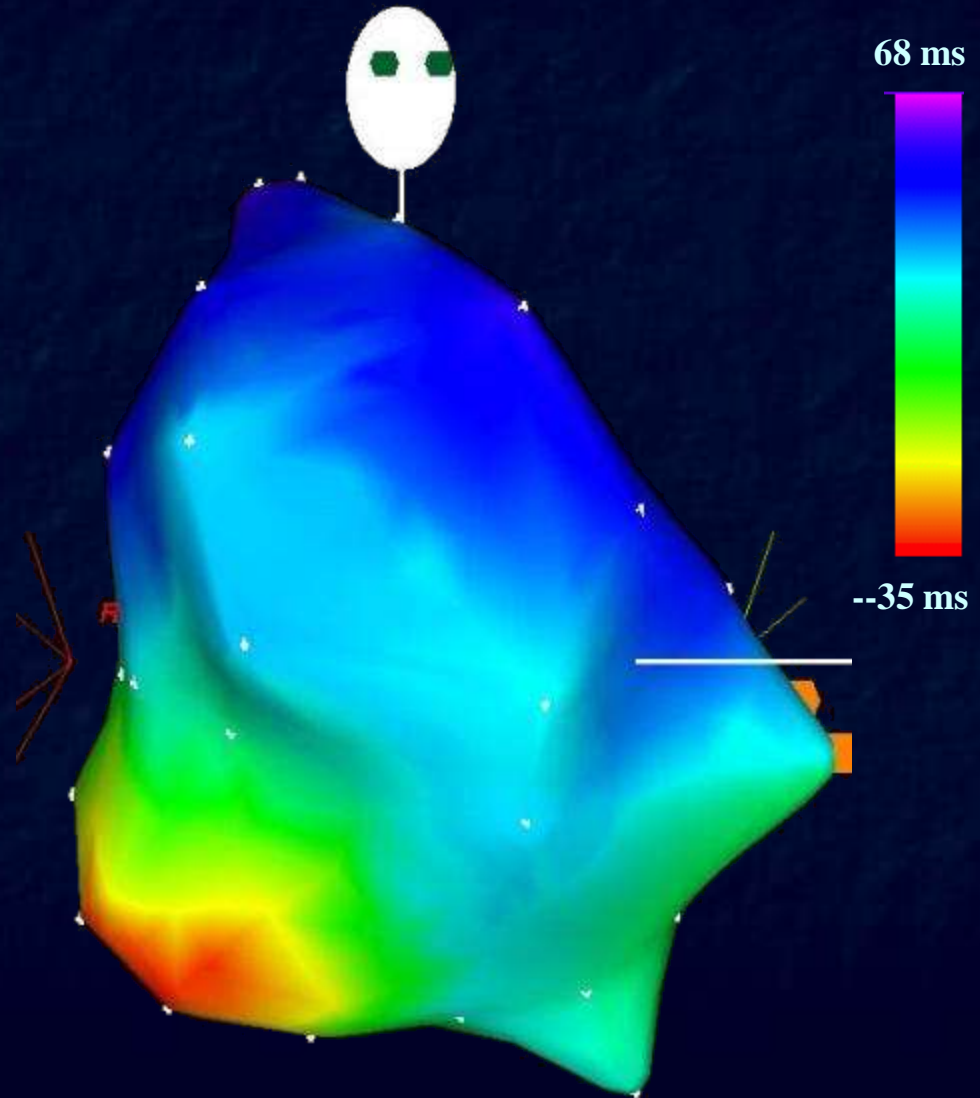
- **The initial phase :**
matching an ellipsoid to the acquired points.
Bounding all the points with an egg shell shape.
- **The second phase:** Stretching and bending the shell to fit the points.



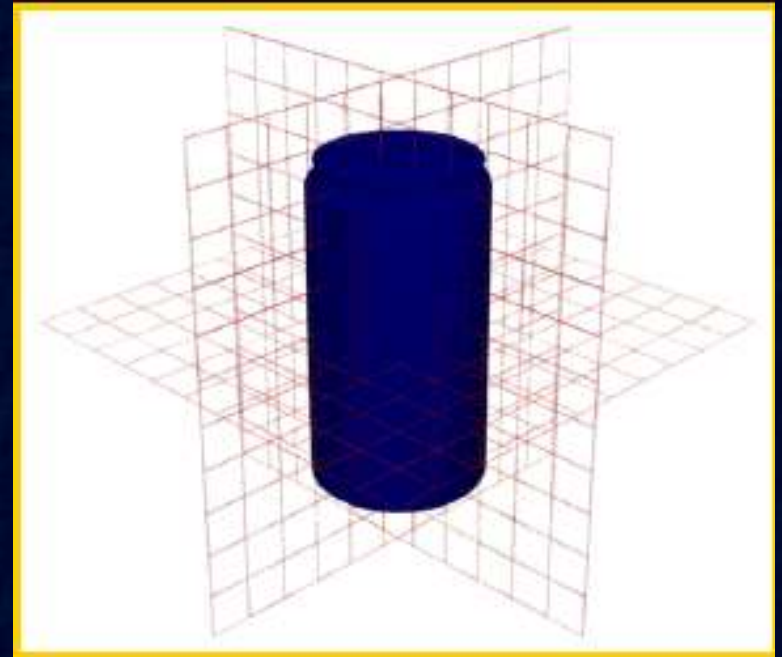
Smooth Reconstruction

When each point is added,
the shape of the
reconstruction is updated.

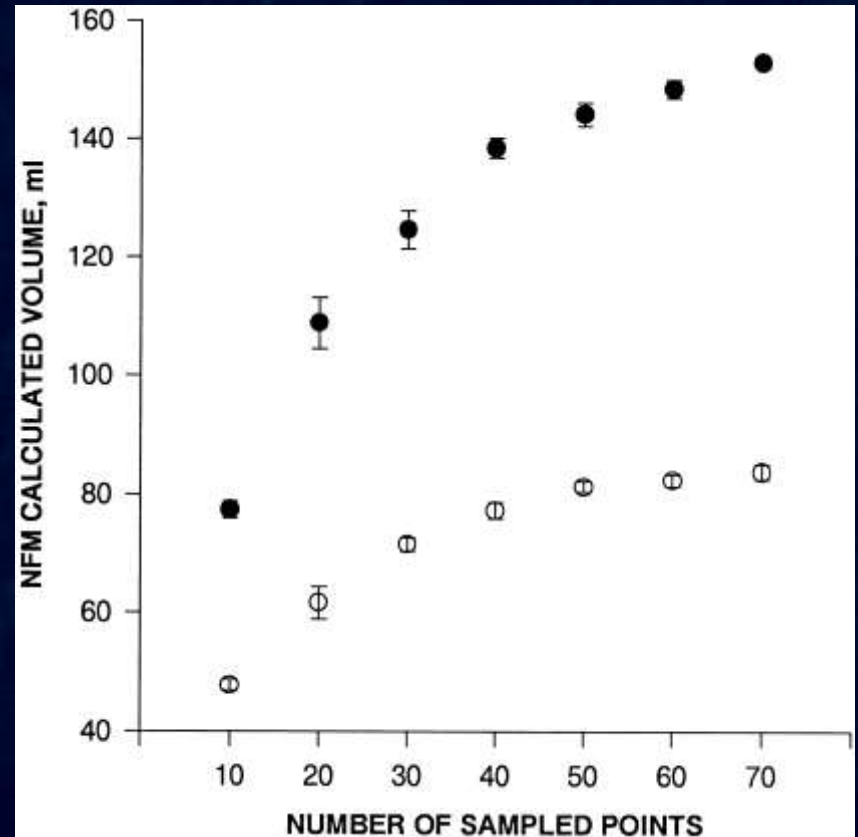
The shape of the chamber is
stretched and bent to
intersect through the real
points locations.



Surface Reconstruction

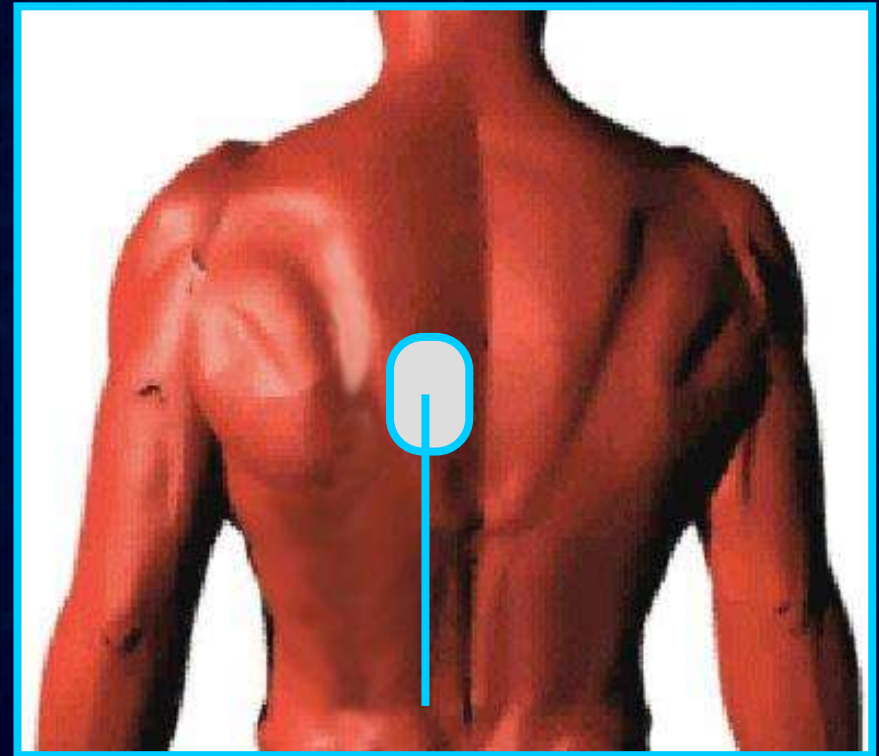
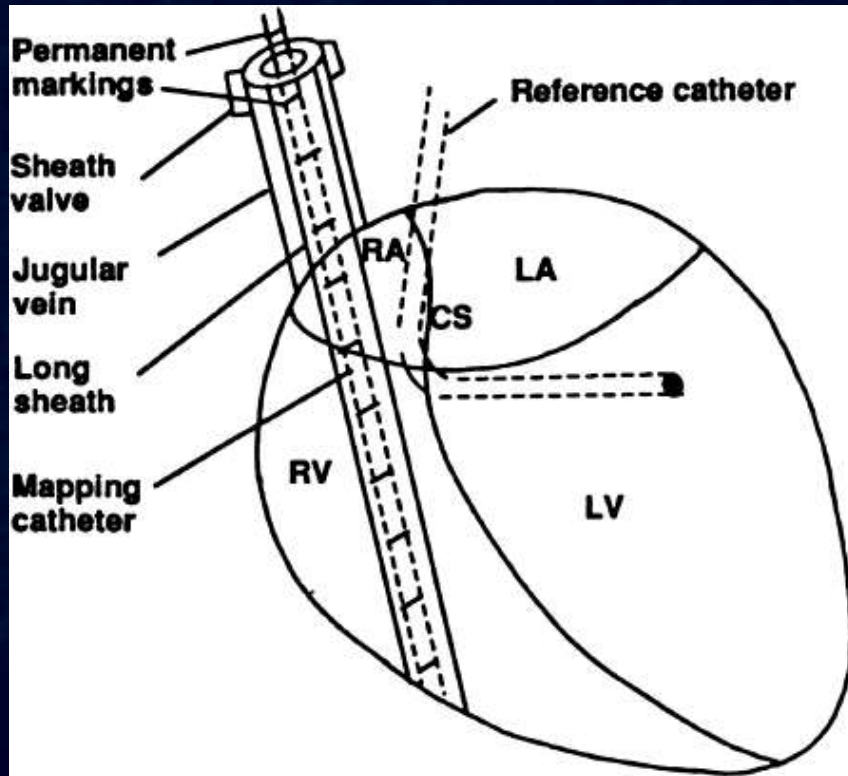


Surface Reconstruction



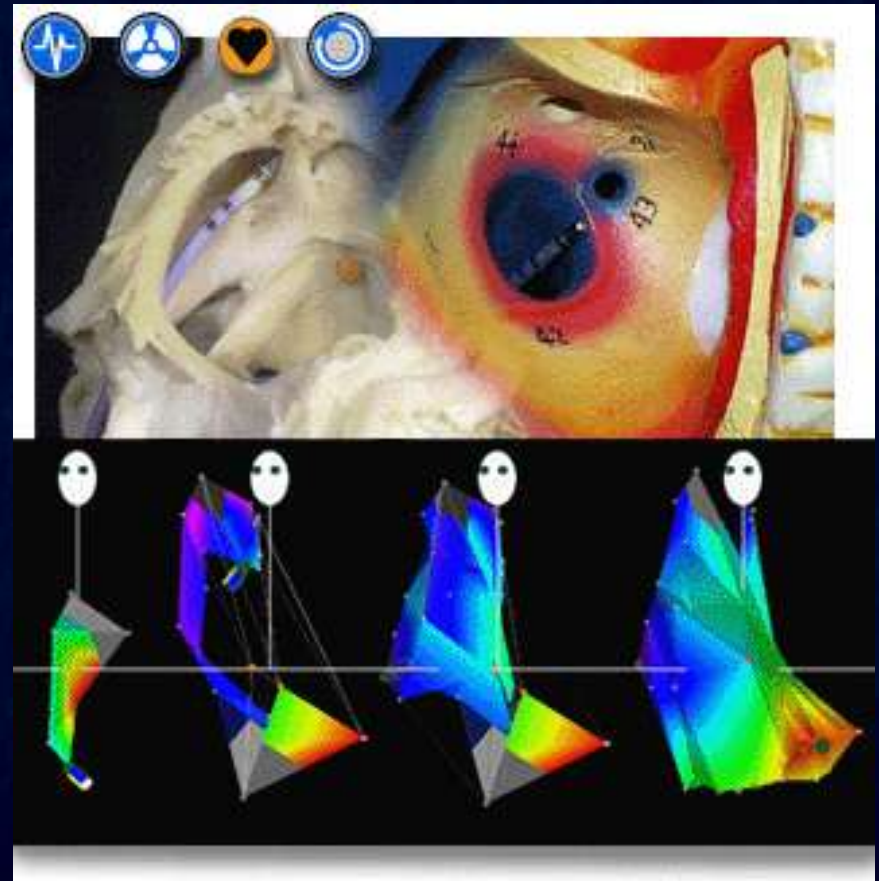
Location Reference

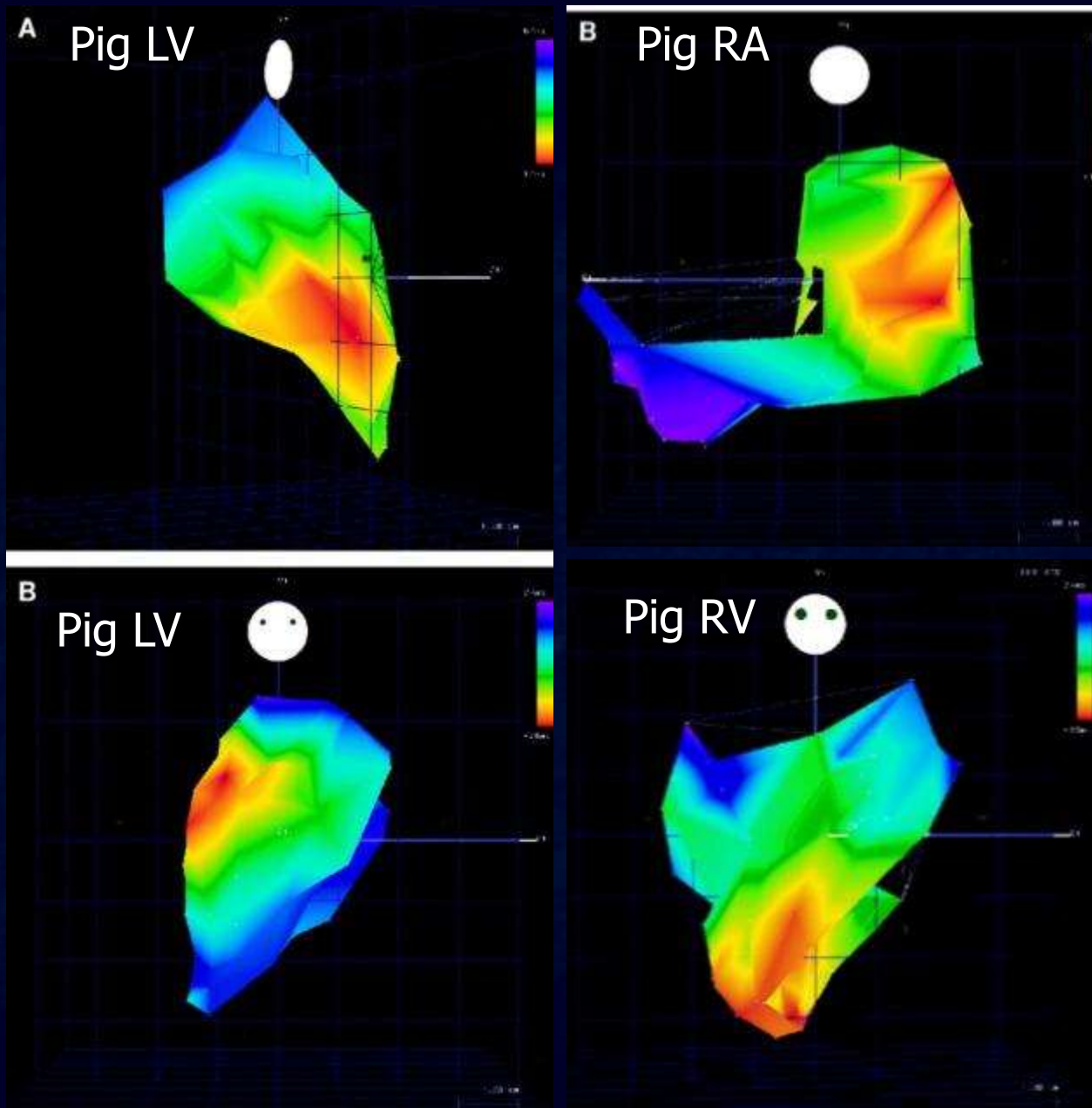
- To compensate for patient X, Y, Z movements and respiration



Point Acquisition

- Each point has location and electrical information associated with it
- While adding points, each point is connected to neighboring points
- Electrical activation is interpolated between points
- A 3D color-coded map is created





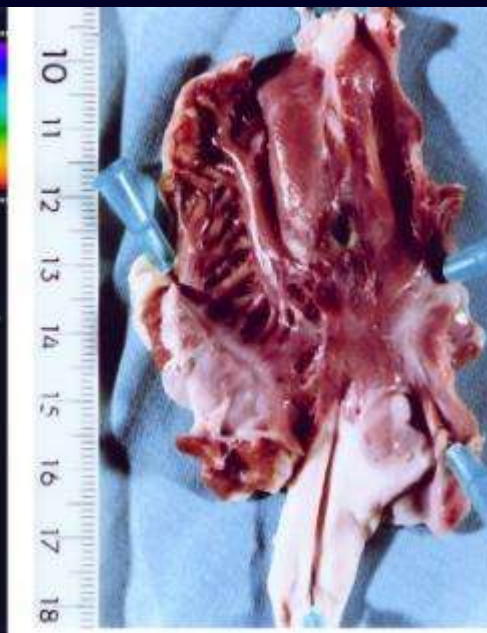
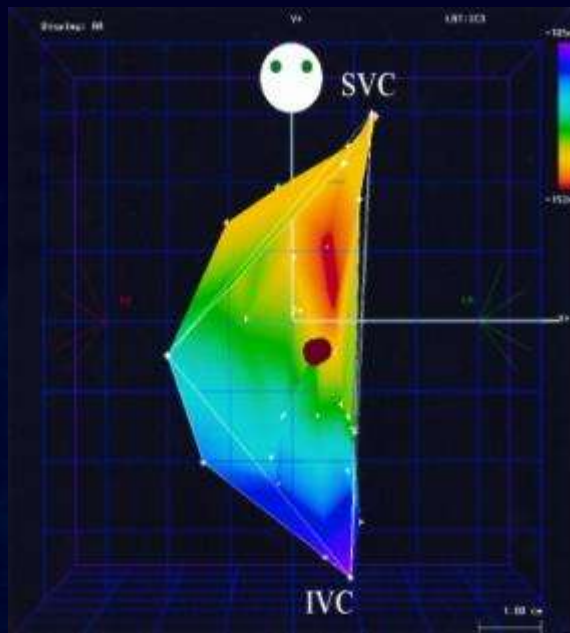


Table 1. Point Ablations in Swine RA

Experiment No.	Area Shape	Dimensions, mm	Area, mm ²	Ablation Point Distances, mm		
				AB	AC	BC
1	Ellipse	8x5	31.4	0	3	3
2	Ellipse	9x5	35.3	0	0	0
3	Circle	10	78.5	5	5	3
4	Ellipse	12x3	28.2	0	0	0
5	Ellipse	9x4	28.3	5	2	4
6	Ellipse	15x10	117.8	4	8	6
7	Ellipse	11x8	69.1	3	4	7
8	Circle	5	19.6	0	0	0
9	Circle	4	12.6	0	0	0
Mean			46.8	2.3		
SEM			11.5	0.5		
Minimum			12.6	0		
Maximum			117.8	8		

Each point ablation was repeated three times (A, B, and C) in an attempt to navigate to the same

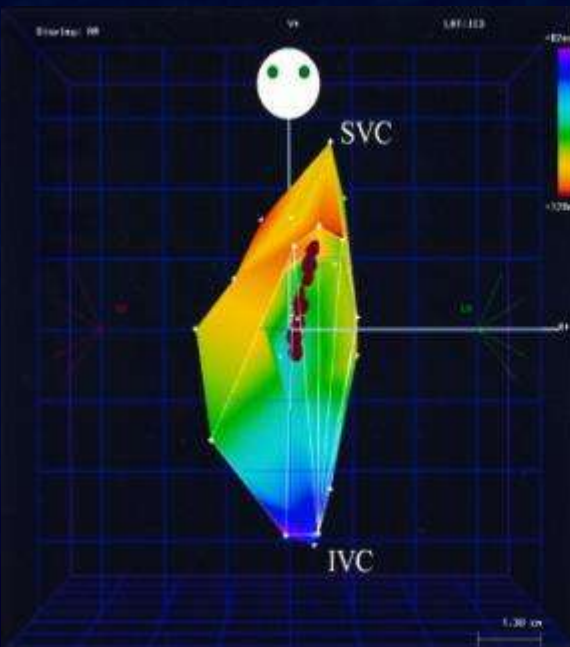


Table 2. Linear Ablations in Swine RA

Experiment No.	RA Line Ablation Dimensions, mm		NFM RA M
	Line Length	Line Width, Minimum-Maximum	
1	26.0	3.0-5.5	24.9
2	20.0	4.5-6.5	17.6
3	28.0	4.0-6.5	27.3
4	29.0	4.5-7.0	25.6
5	24.0	3.5-8.0	18.5
6	37.0	3.0-4.0	39.4
Mean±SEM	27.3±2.3	3.9-6.7	25.6±3.2

Each line of ablation was obtained from 6 to 12 individual point ablations.

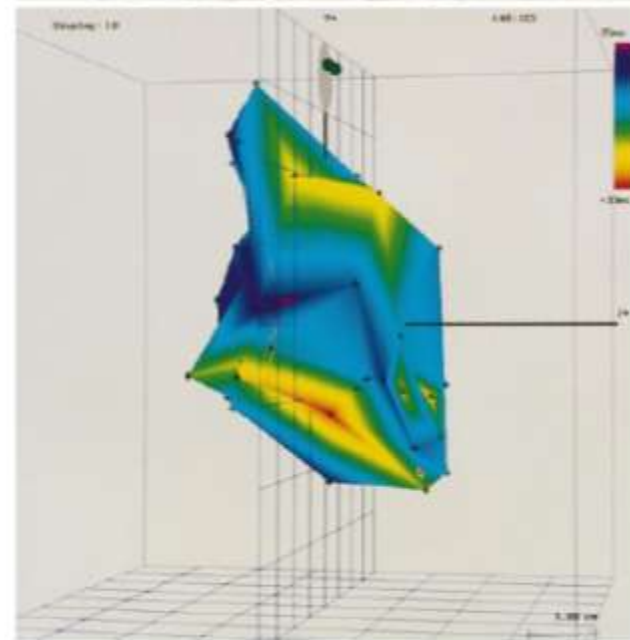
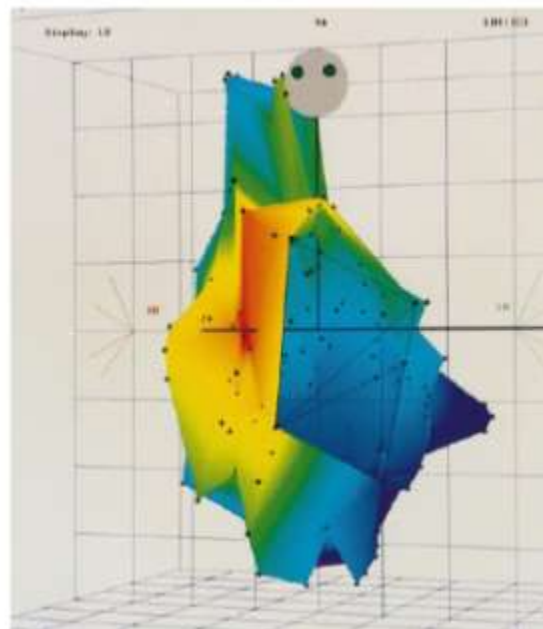
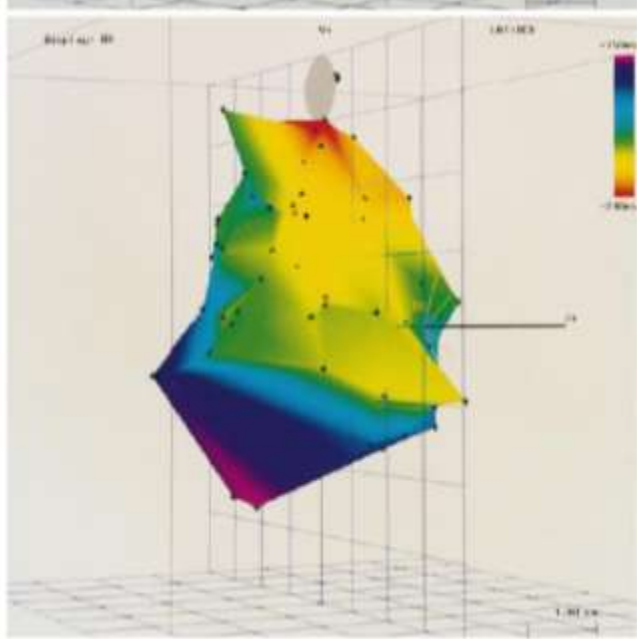
Stages in the Development and Clinical Use of the Carto System

- Background, conception of the idea, technological development, preclinical studies
- **Initial human studies**
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- Ablation for atrial fibrillation
- Additional technological developments
- The future

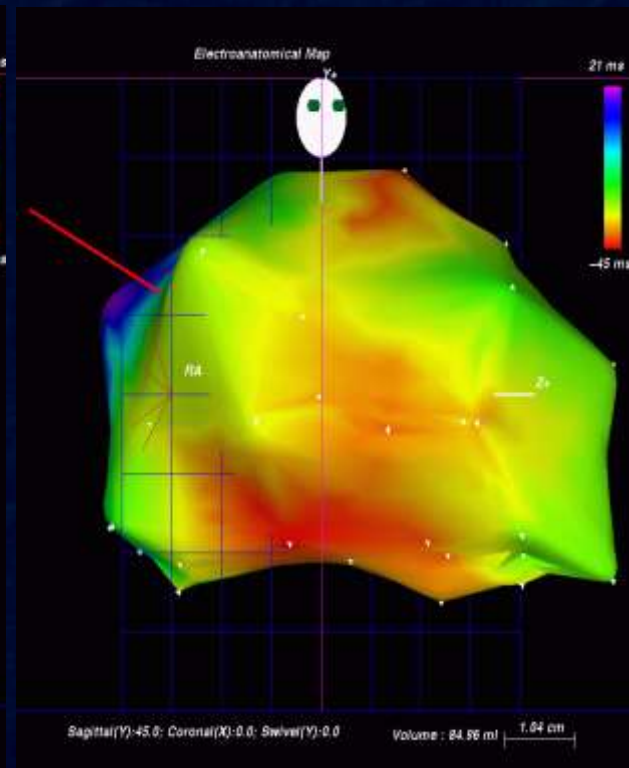
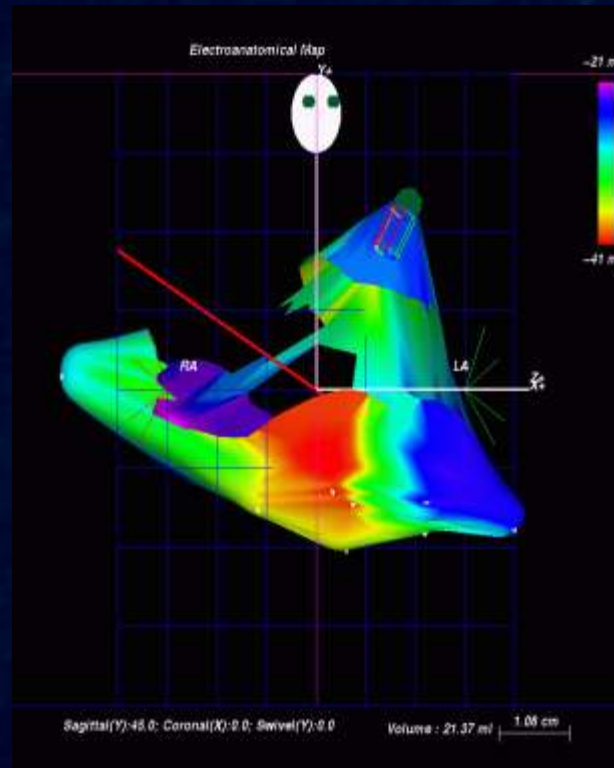
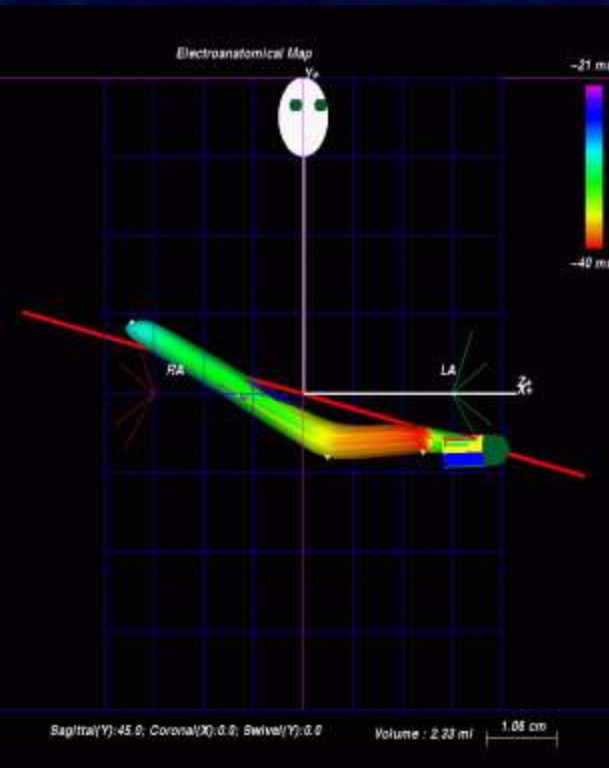
New Method for Nonfluoroscopic Endocardial Mapping in Humans

Accuracy Assessment and First Clinical Results

Joep L.R.M. Smeets, MD; Shlomo A. Ben-Haim, MD; Luz-Maria Rodriguez, MD;
Carl Timmermans, MD; Hein J.J. Wellens, MD



Mapping in Humans



Stages in the Development and Clinical Use of the Carto System

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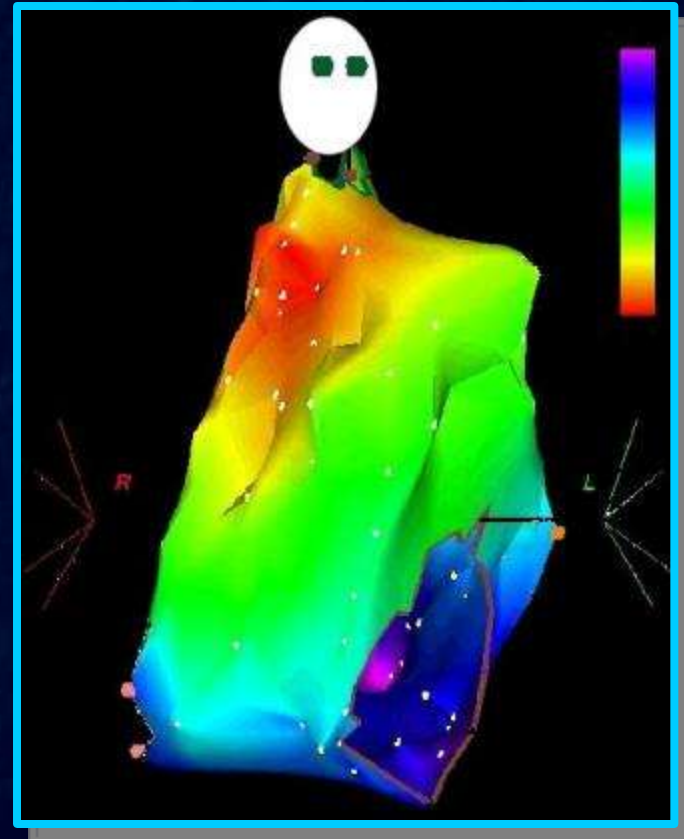
Three-Dimensional Mapping Systems

- Understanding the mechanism of the arrhythmia and the underlying substrate
- Defining the anatomy
- Designing an ablation strategy
- Delivering the therapy (ablation)
- Assessment of the lesion

Mapping Methods: Electrophysiological information

- Activation mapping
- Propagation maps - videos
- Voltage mapping
- Pace mapping
- Entrainment
- Fibrillation indices: FFT, Fragmentation index

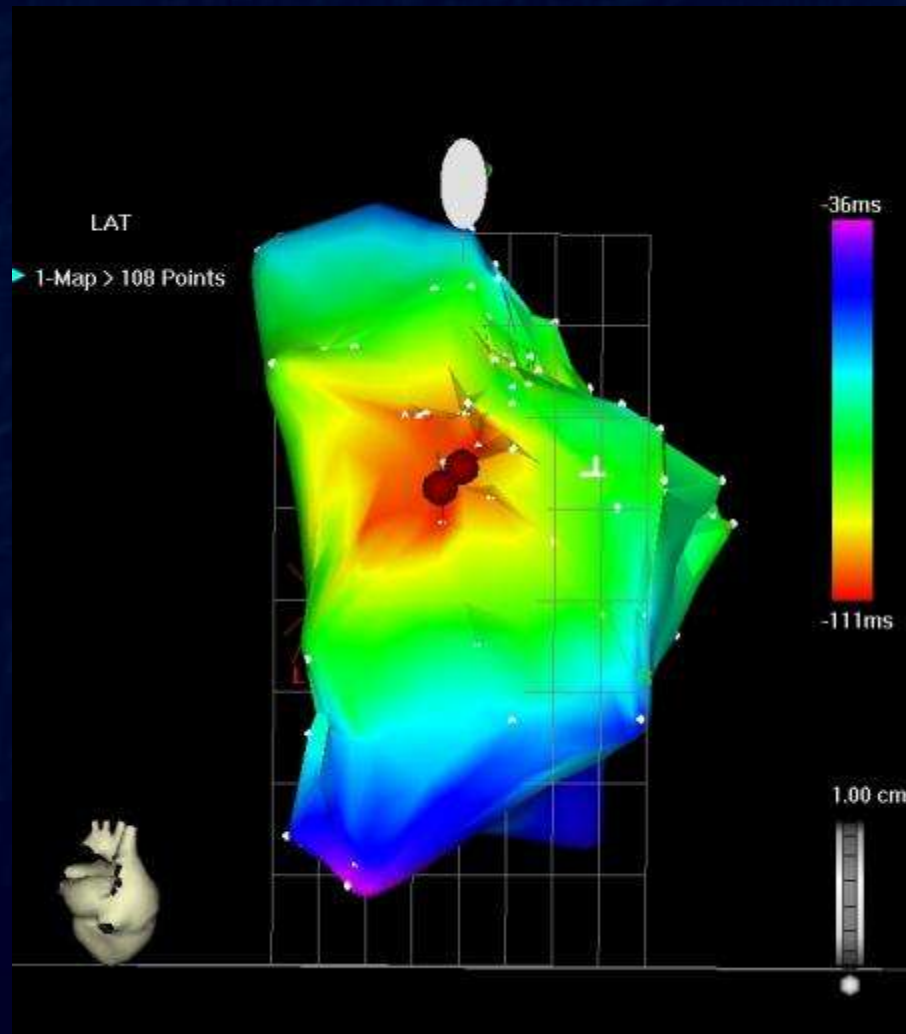
Activation Mapping



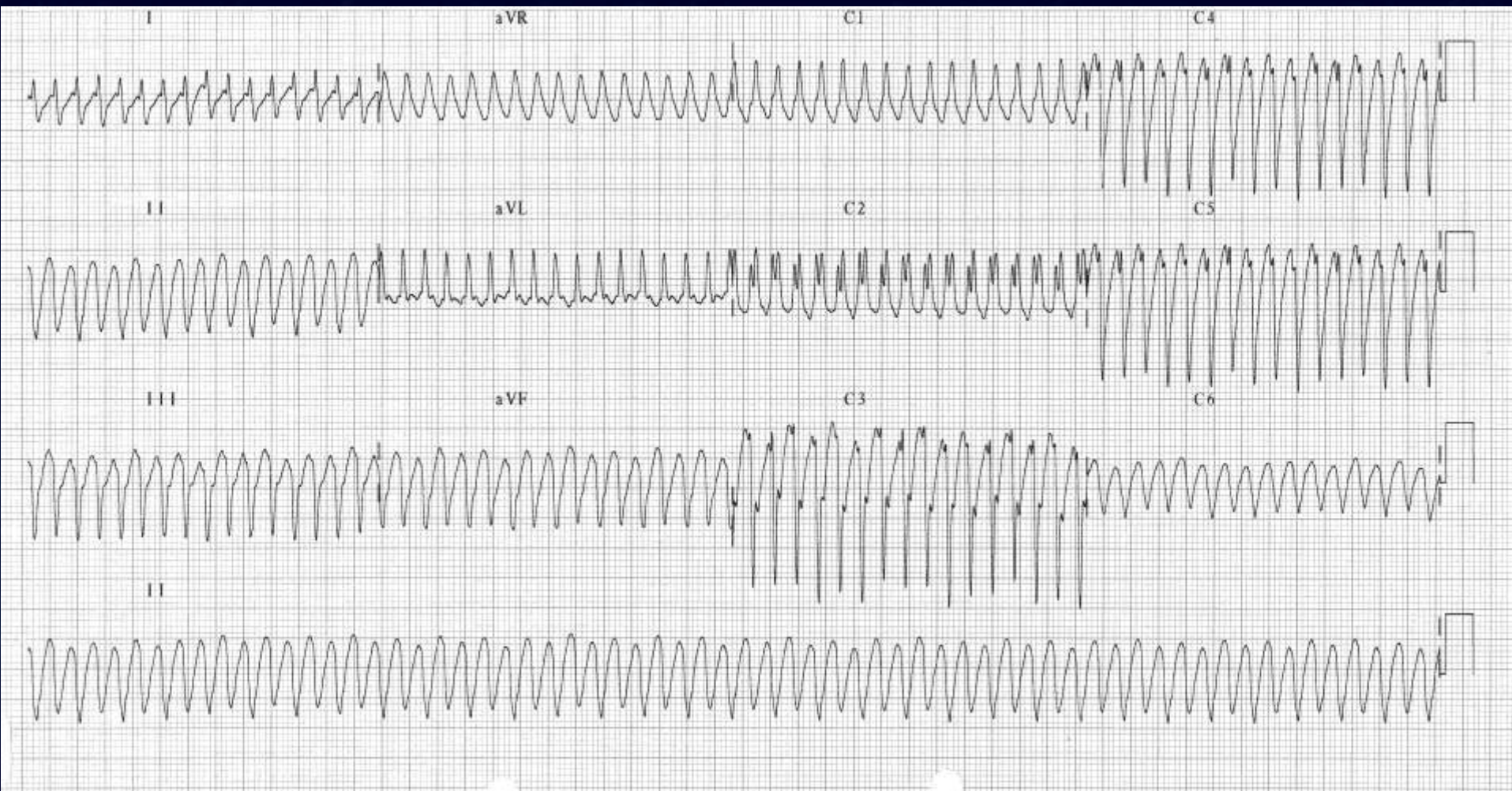
Activation Mapping

- Macro reentrant arrhythmias
 - Mapping of the full cycle-length of the arrhythmias
 - Head-meets-tail
- Focal Arrhythmias
 - Total activation time $<$ CL
 - Early (red) surrounded by later sites

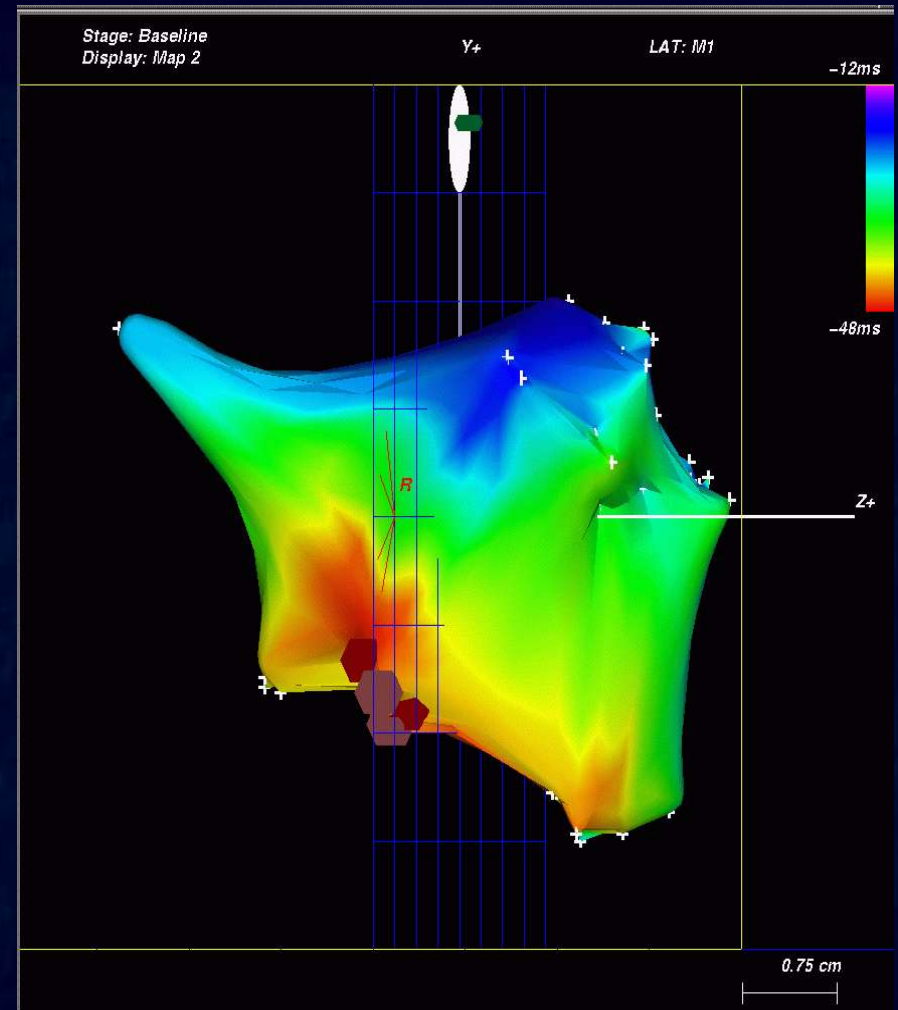
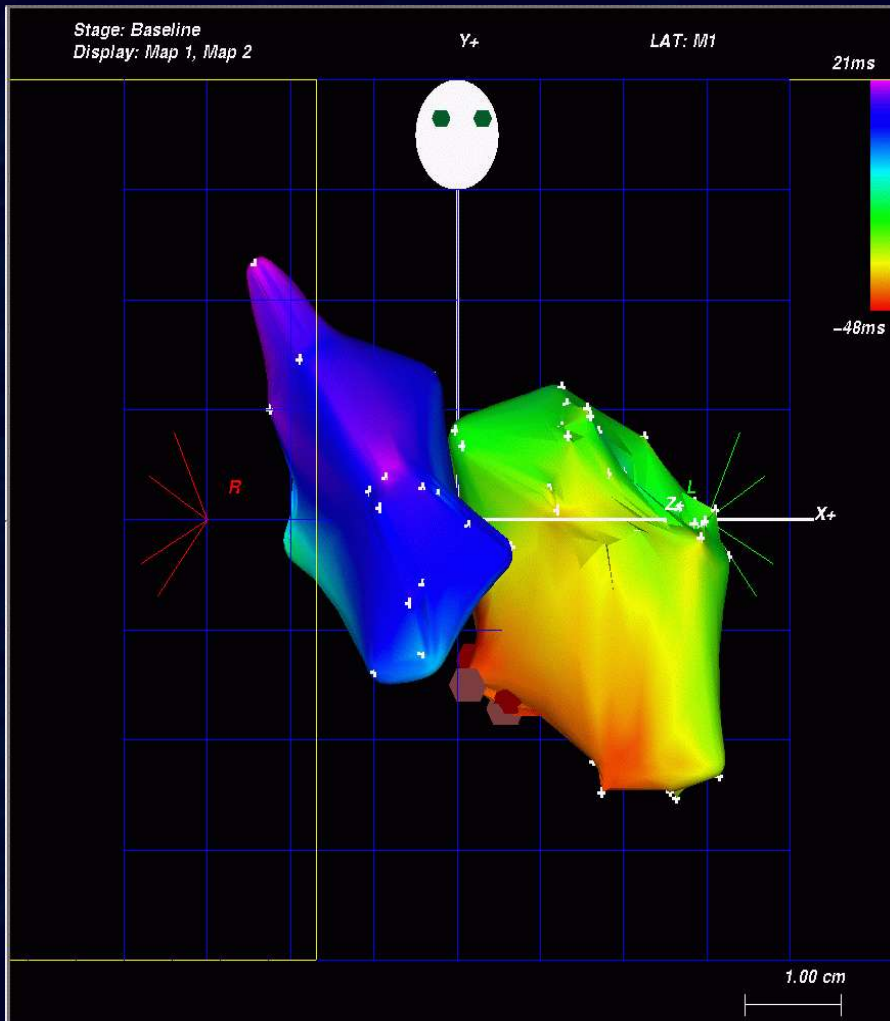
Focal Arrhythmias



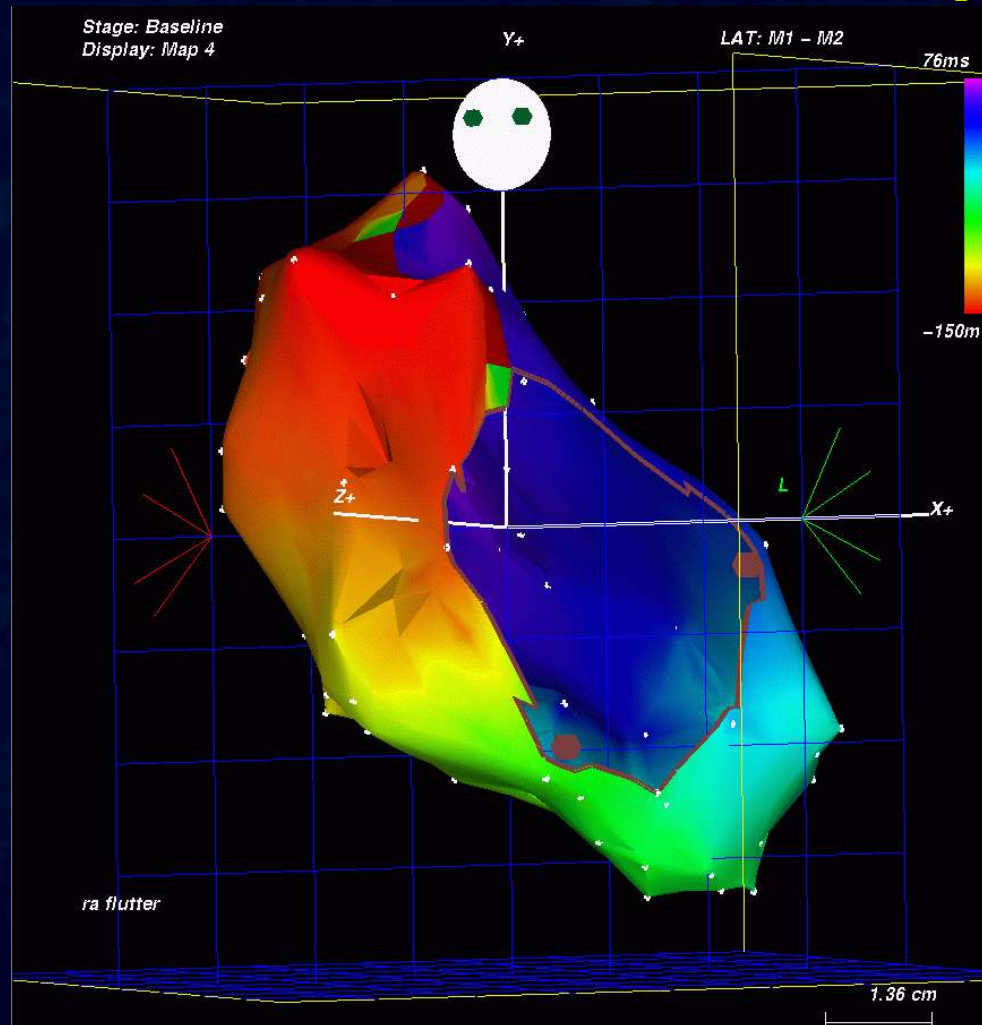
VT in Infant



VT in Infant

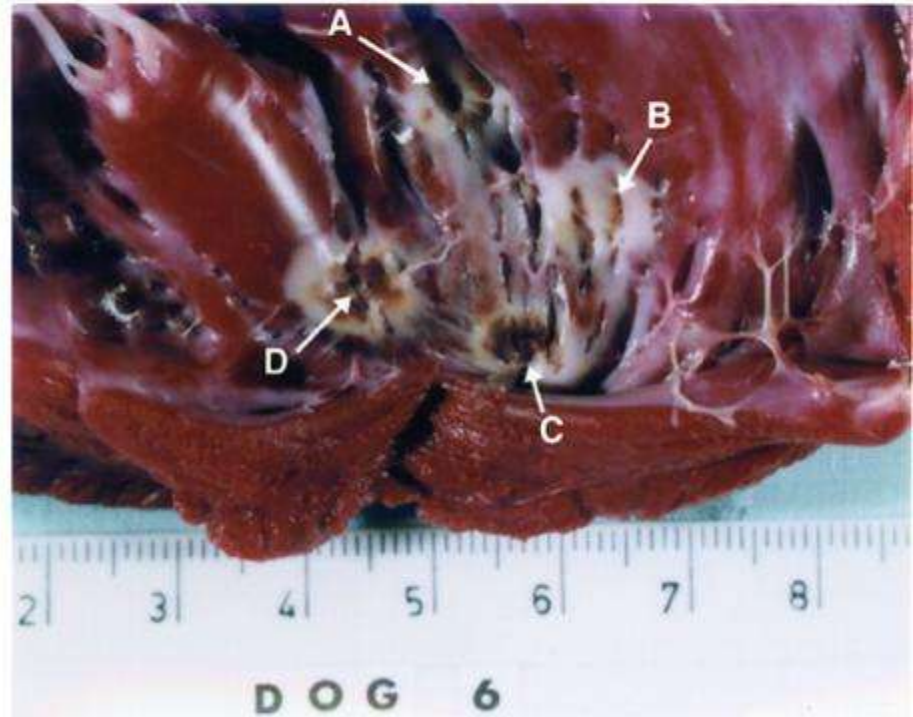
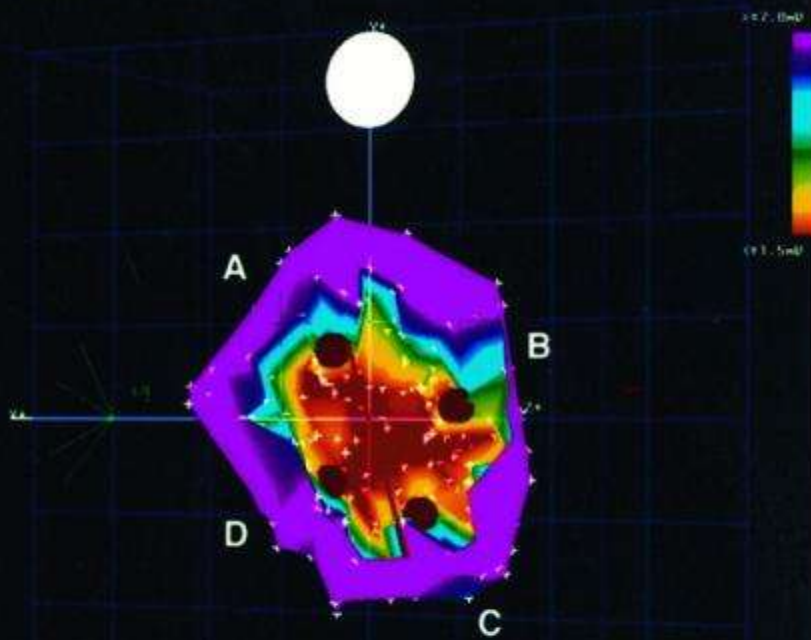


Macro Reentrant Arrhythmias



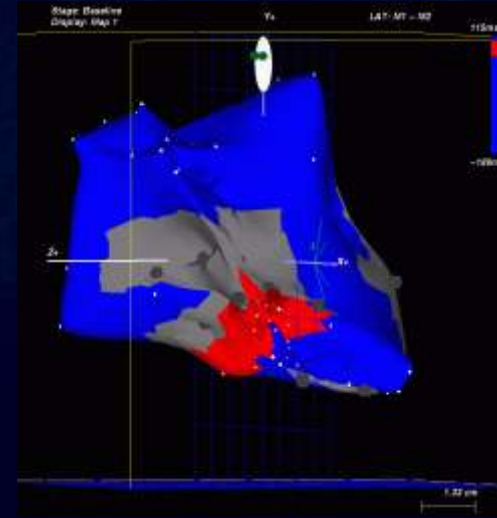
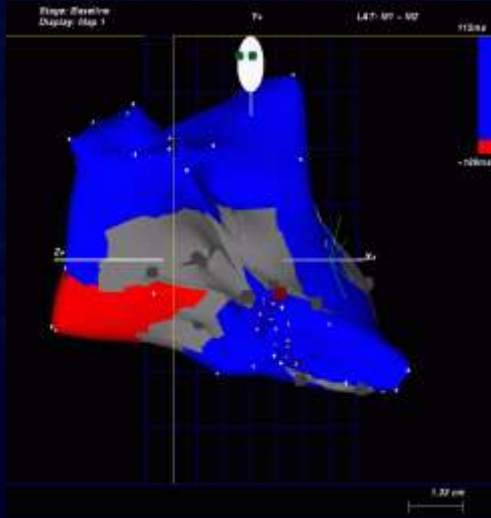
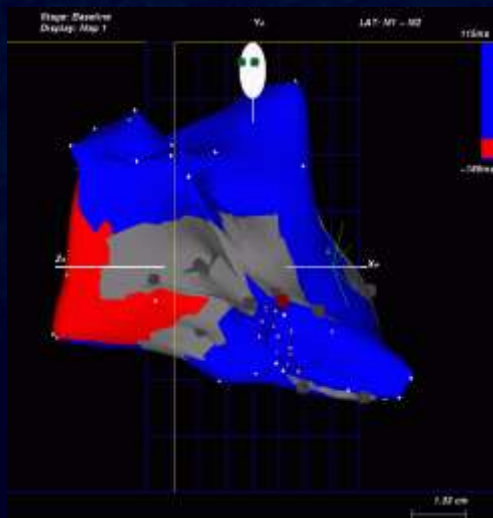
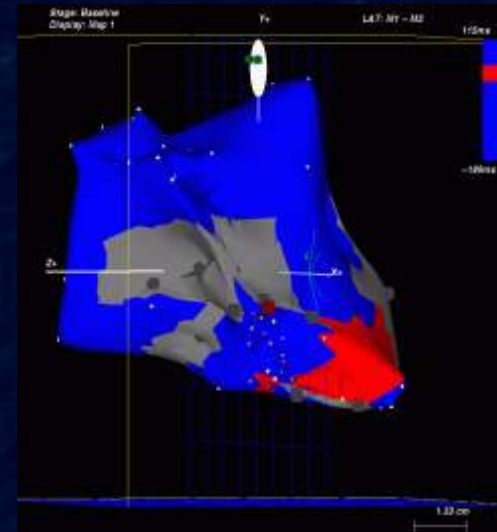
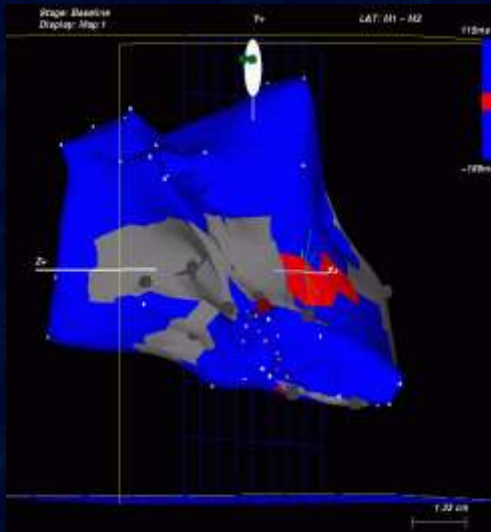
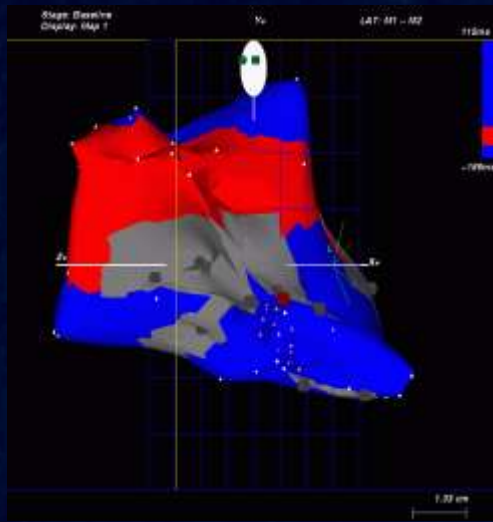
Mapping Methods: Electrophysiological information

- Activation mapping
- Propagation maps - videos
- **Voltage mapping**
- Pace mapping
- Entrainment
- Fibrillation indices: FFT, Fragmentation index



Gepstein et al. Circulation 1998

Scar-related Atrial Tachycardias



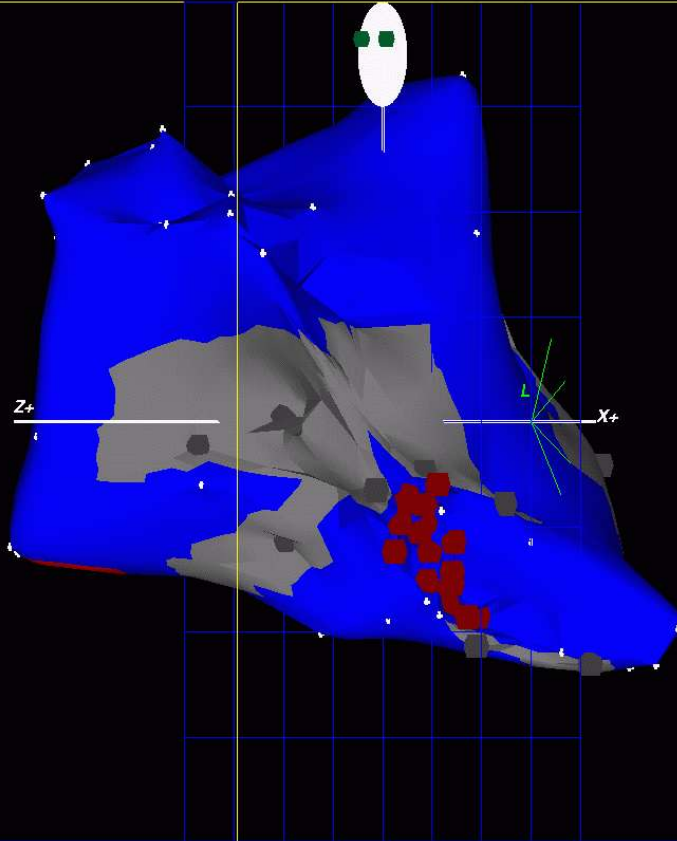
Stage: Baseline
Display: Map 1

Y+

LAT: M1 - M2

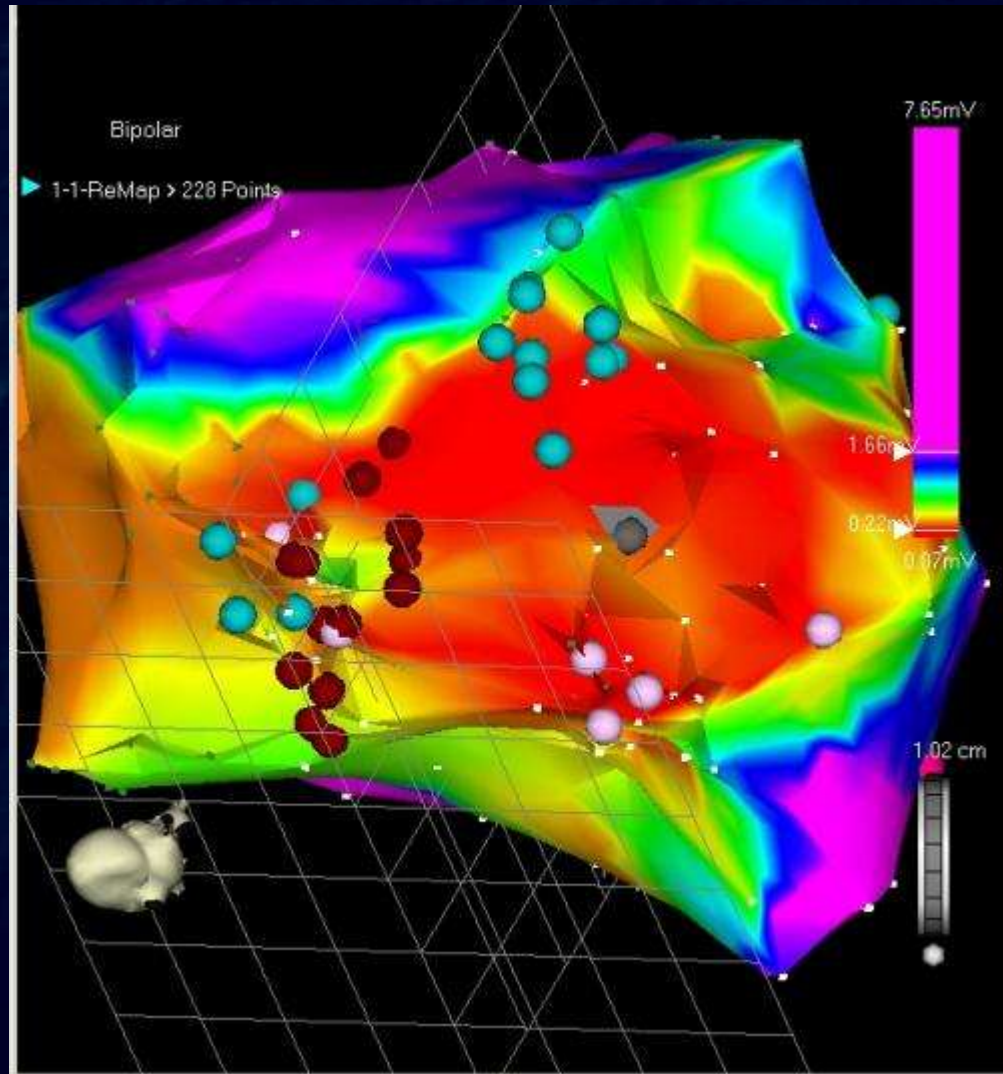
115ms

-189ms

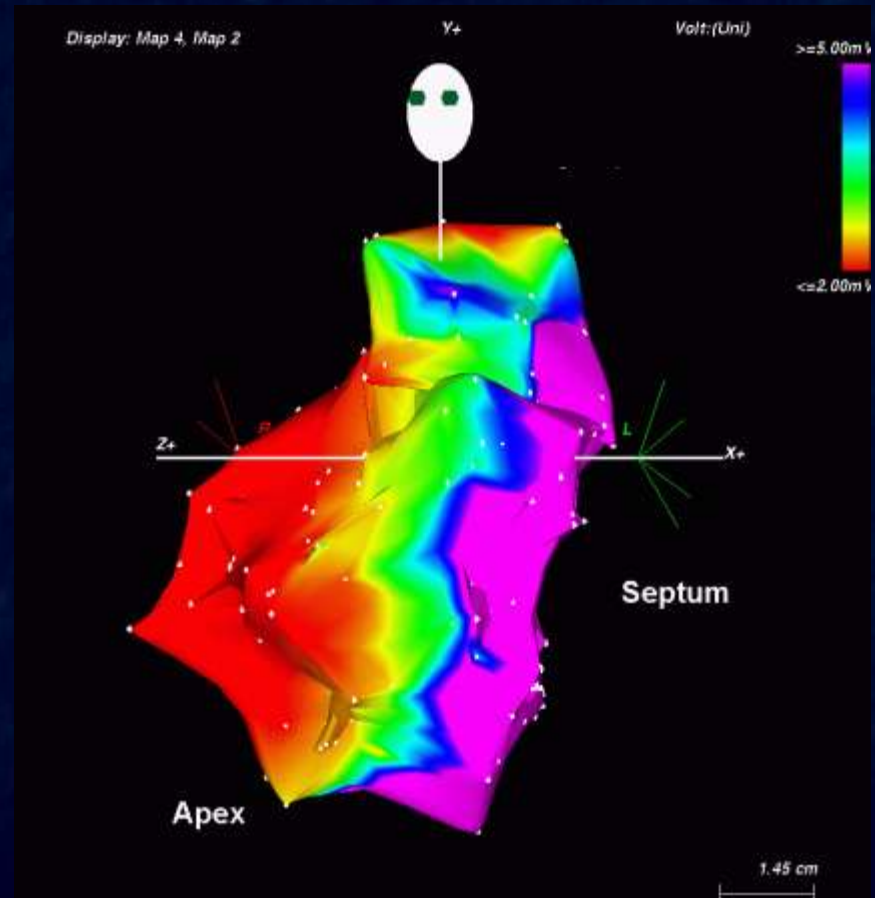
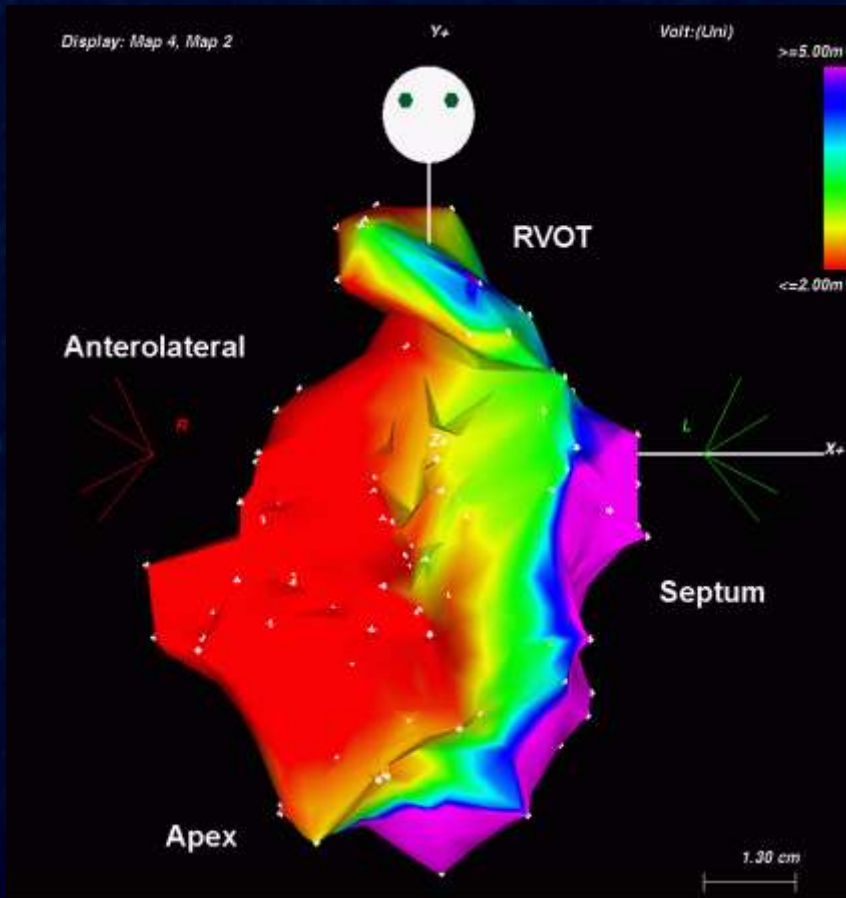


1.33 cm

Scar – Inferior Myocardial Infarction

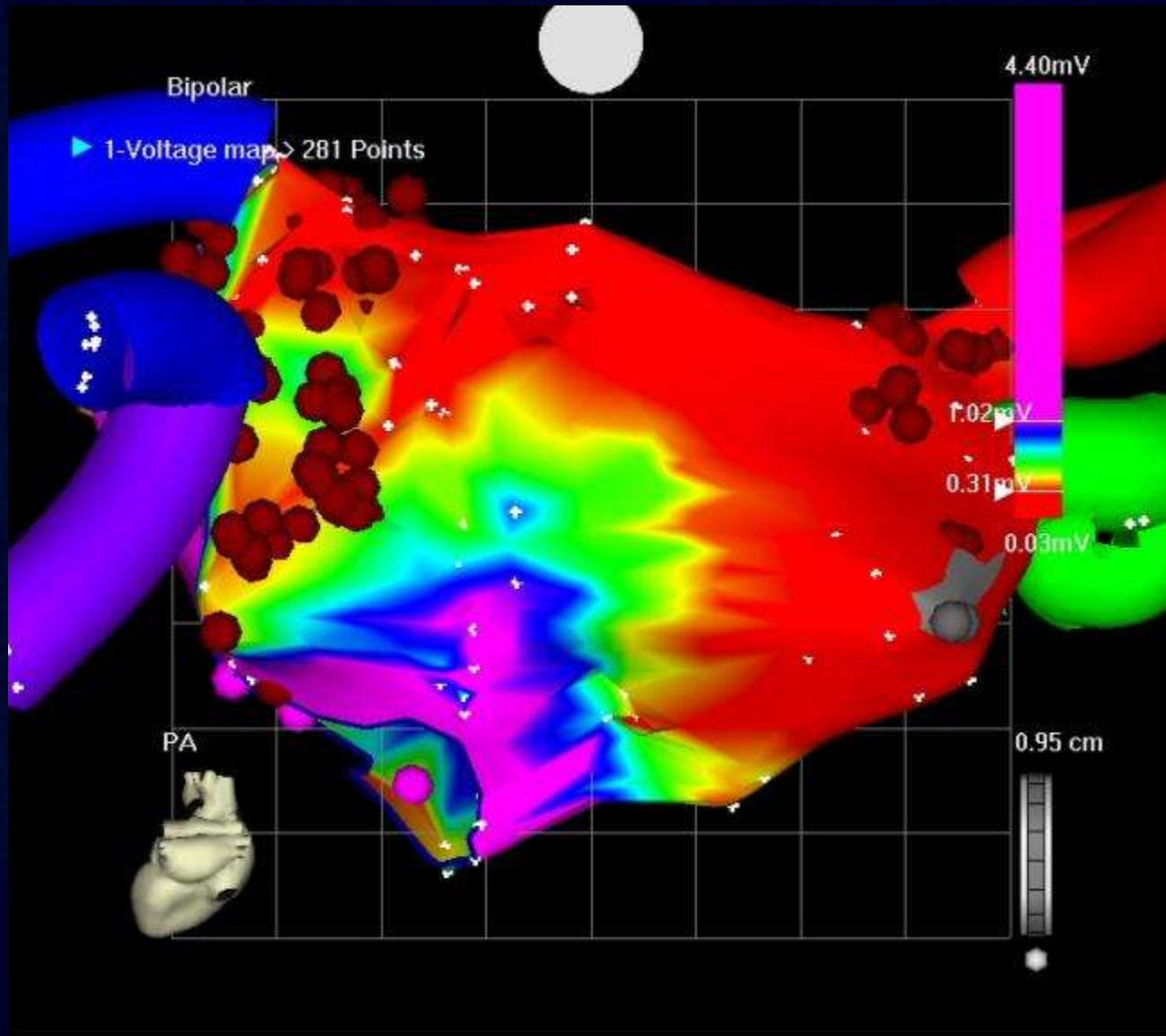


ARVD- Voltage Mapping



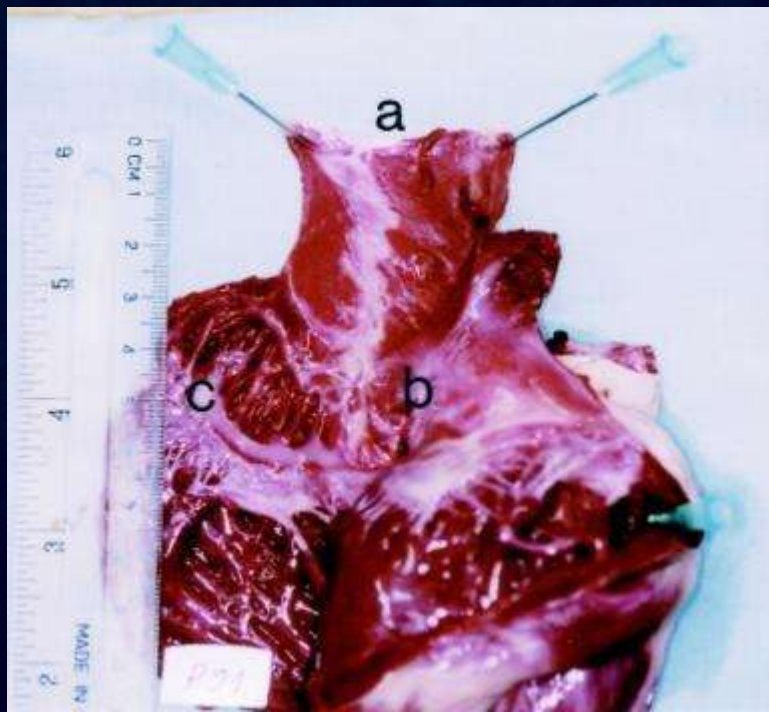
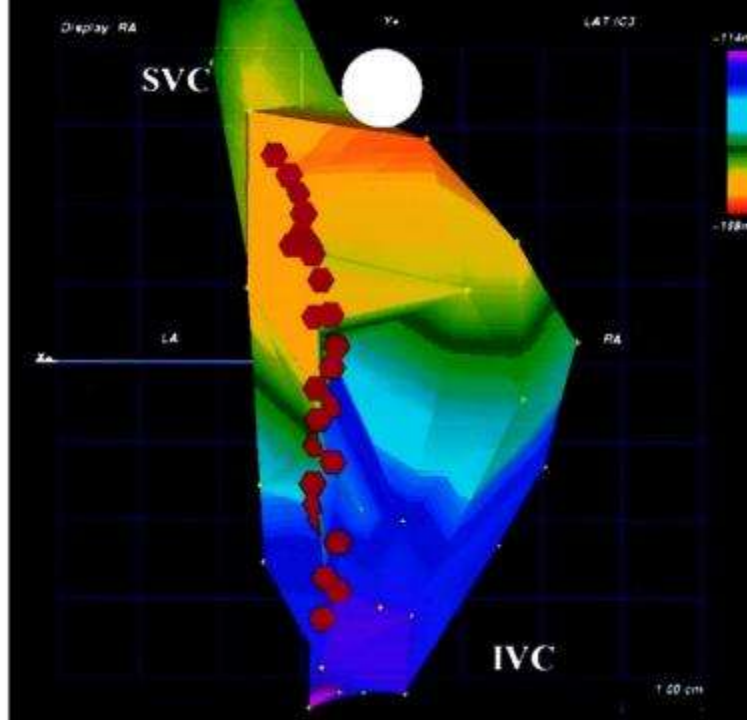
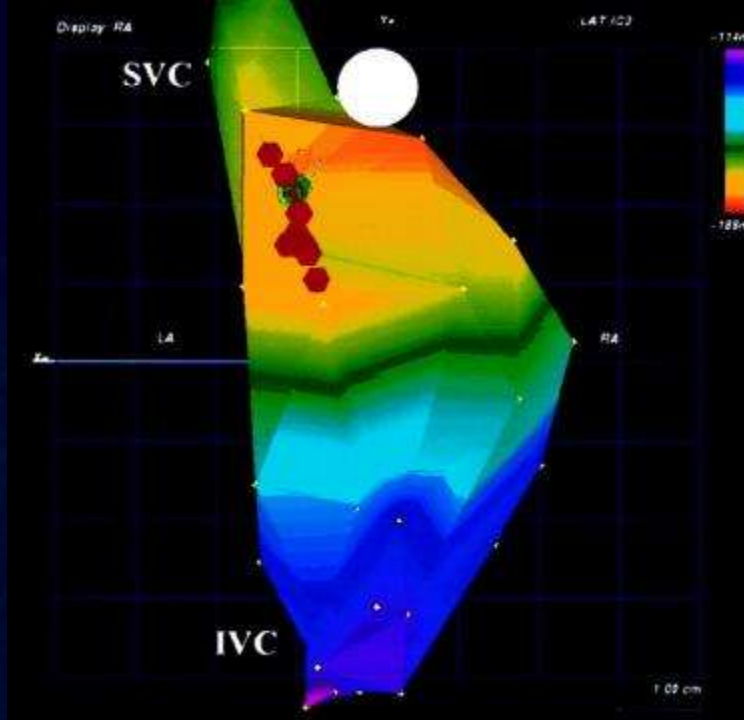
Boulos, Gepstein. J Am Coll Cardiol 2001

Hemochromatosis

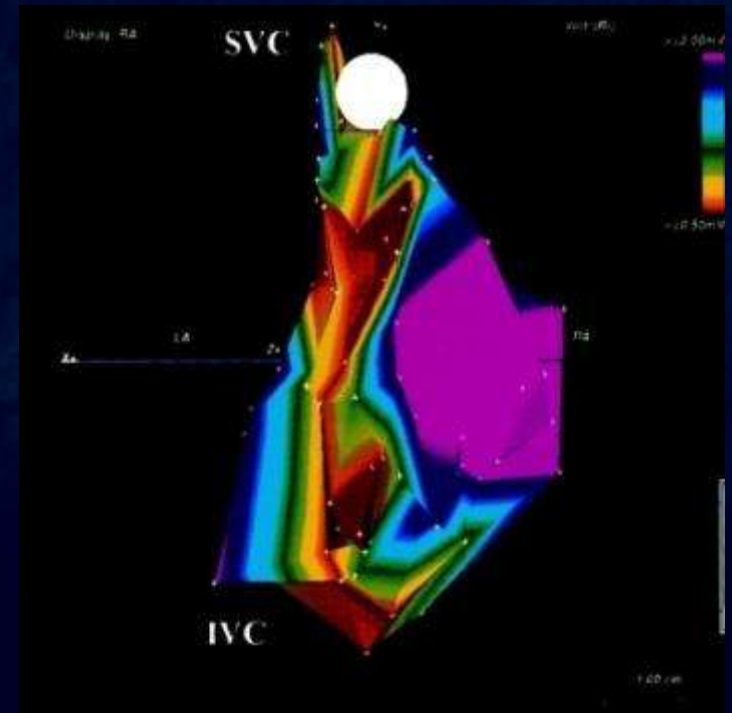
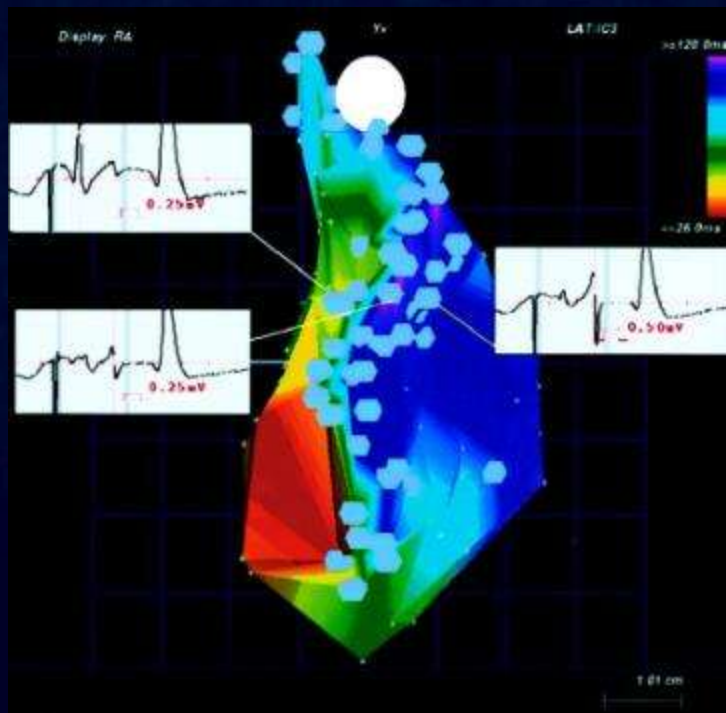
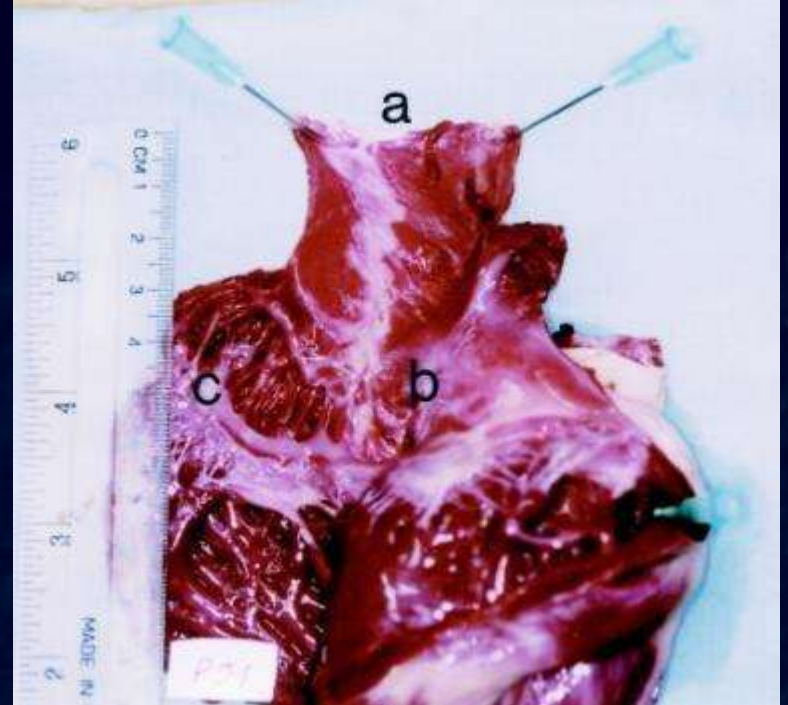
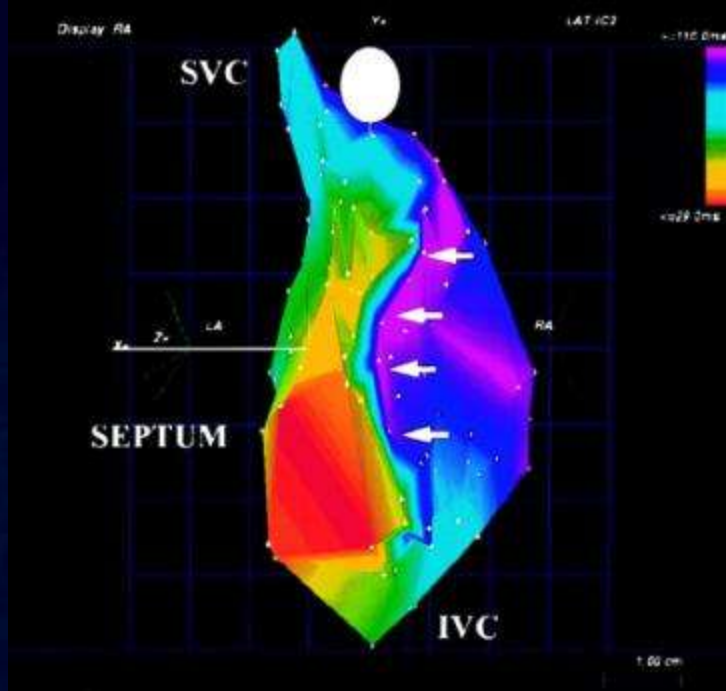


Three-Dimensional Mapping Systems

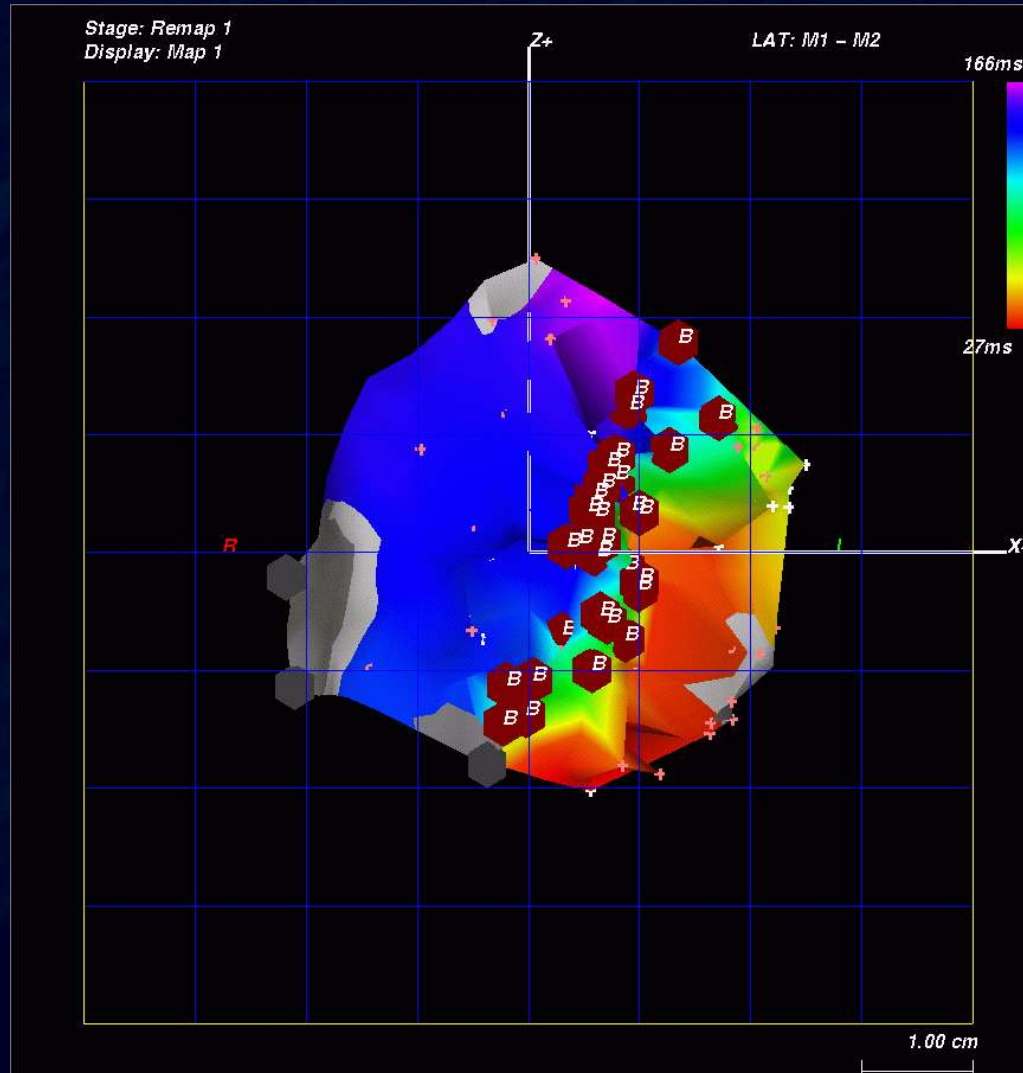
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Gepstein et al. Circulation 1999



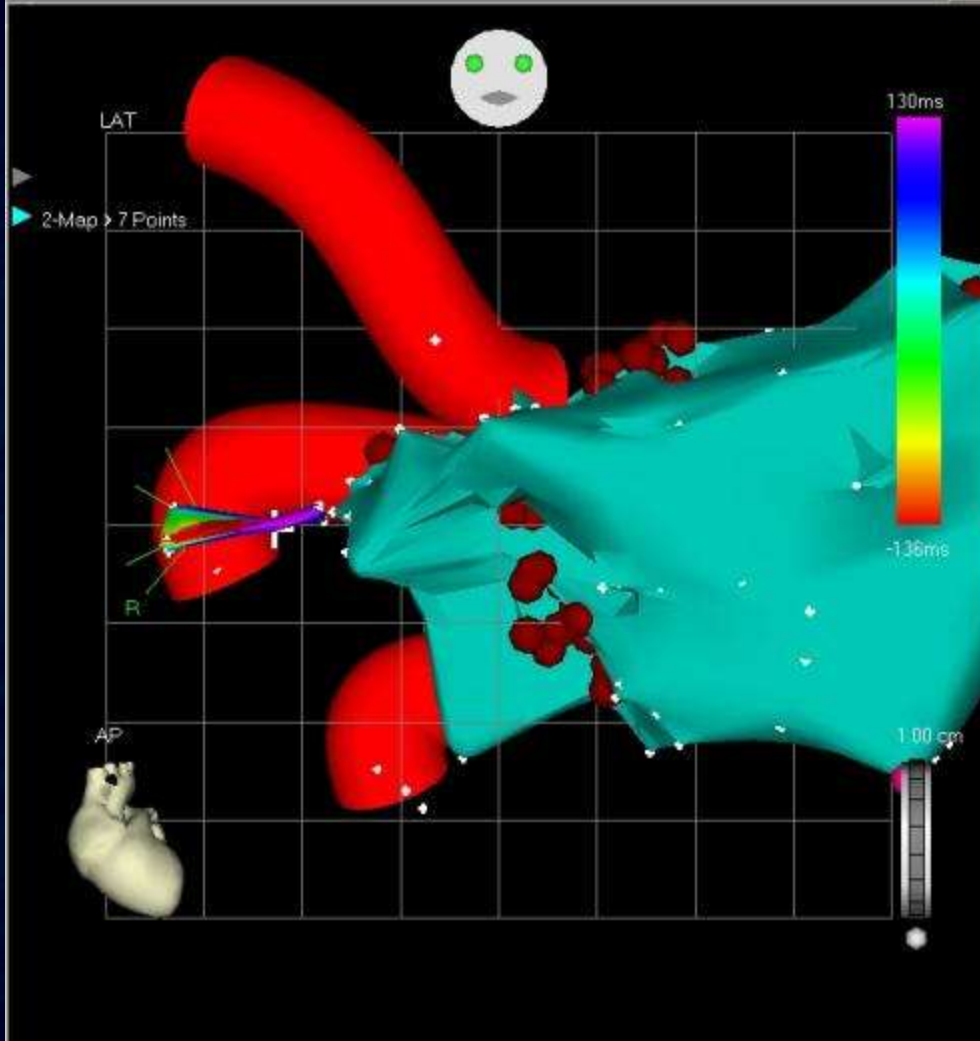
Isthmus ablation for atrial flutter

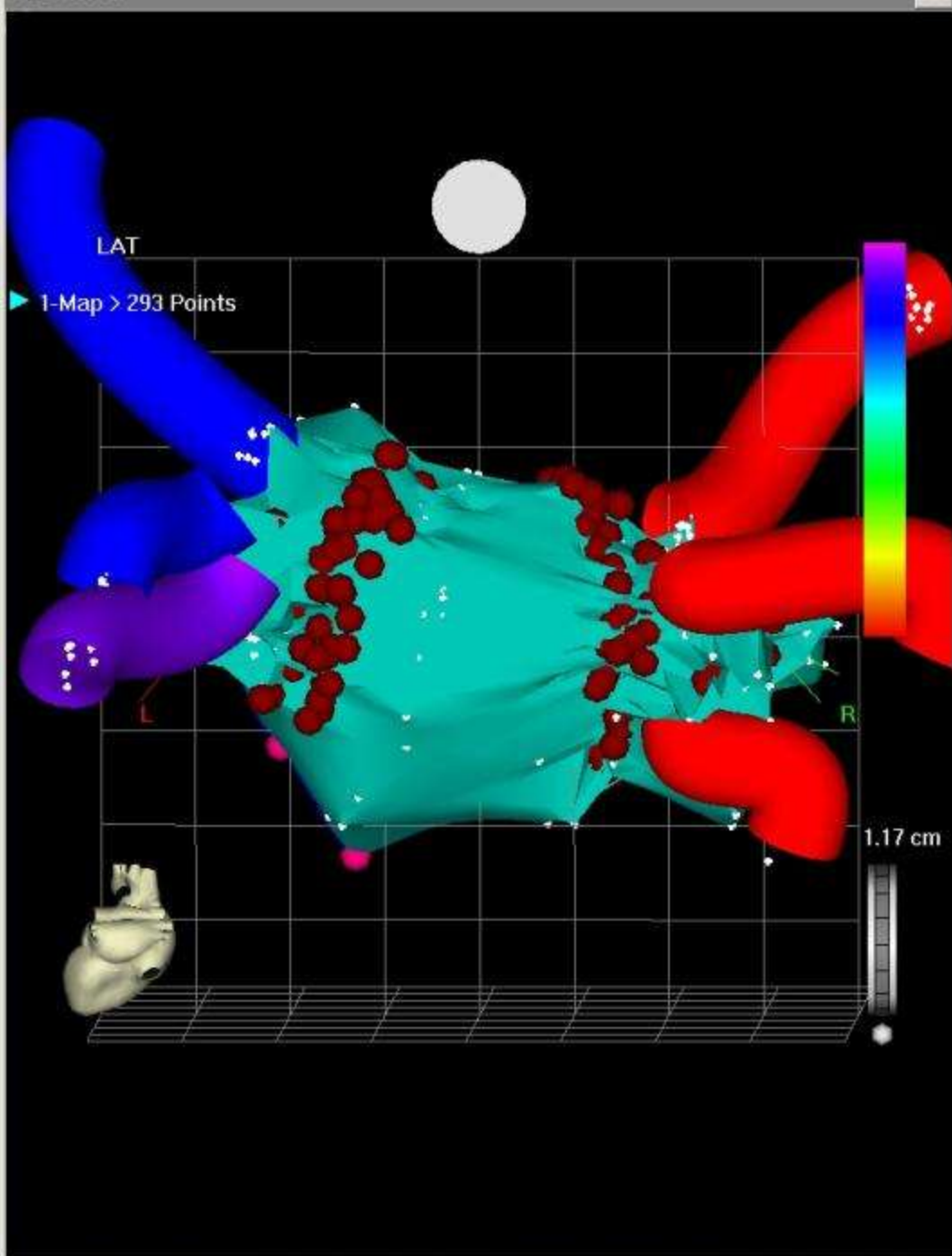


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Map Viewer



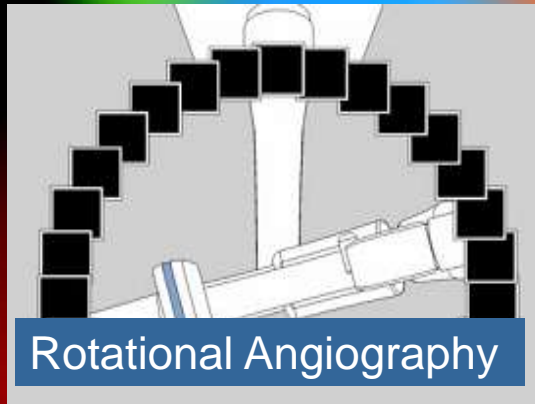


Stages in the Development and Clinical Use of the Carto System

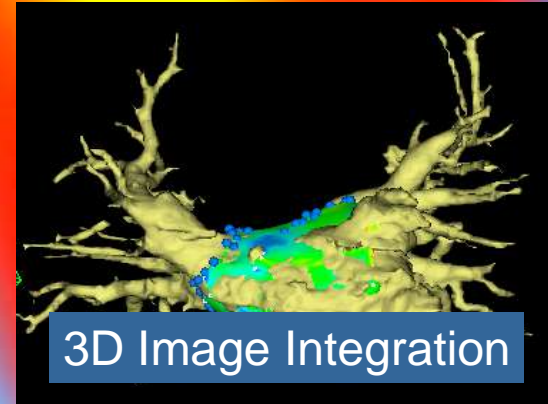
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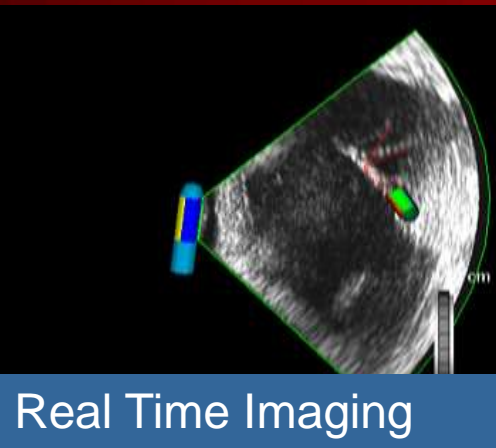
Robotic Control



Rotational Angiography



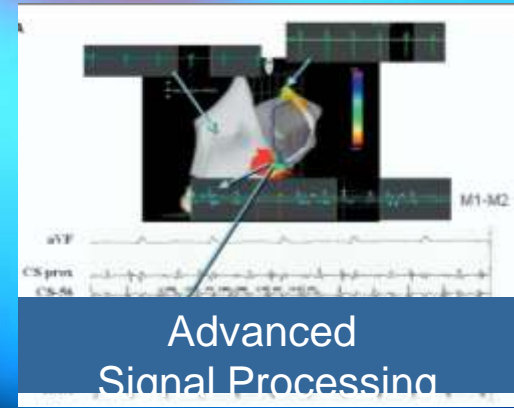
3D Image Integration



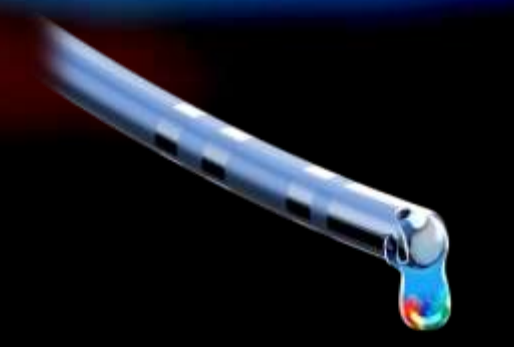
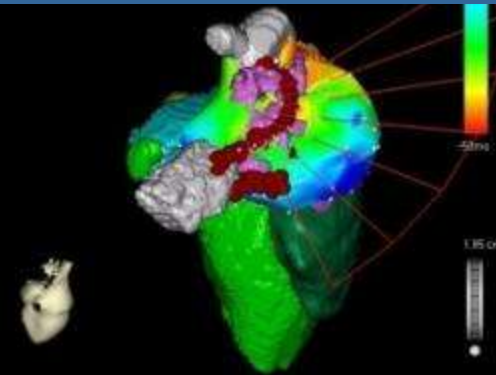
Real Time Imaging



Integrated Digital Lab

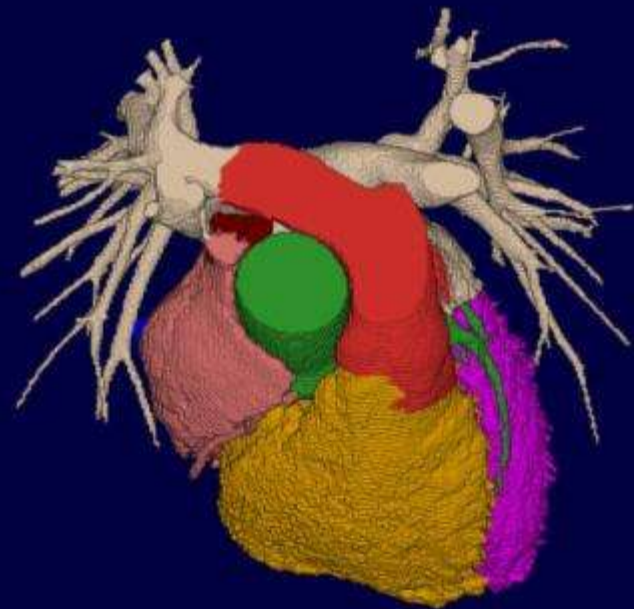


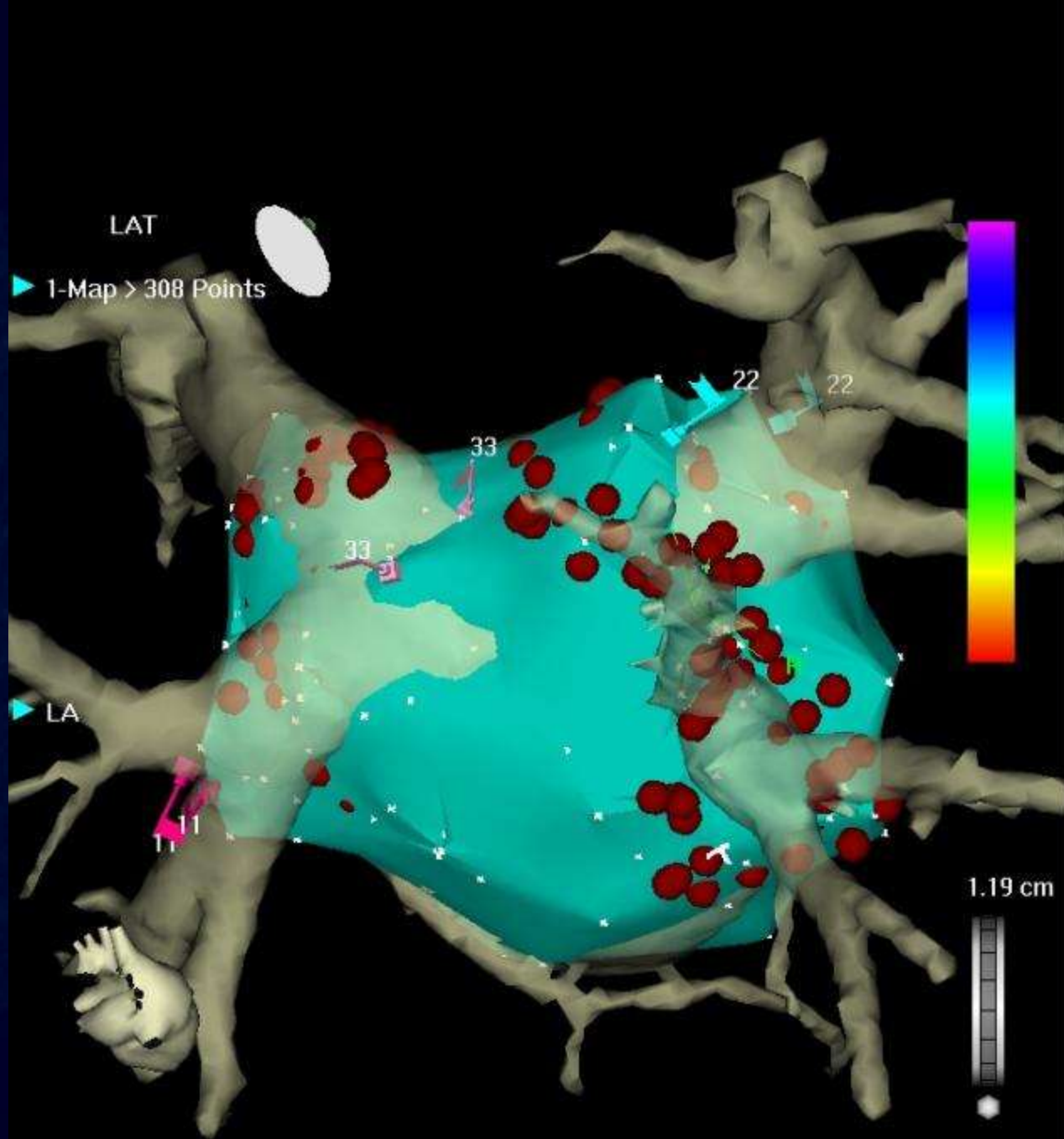
Advanced Signal Processing



CT/MR Imaging

- Three-dimensional volume/surface reconstruction of cardiac chambers and big vessels from 2D raw data CT/MR scan



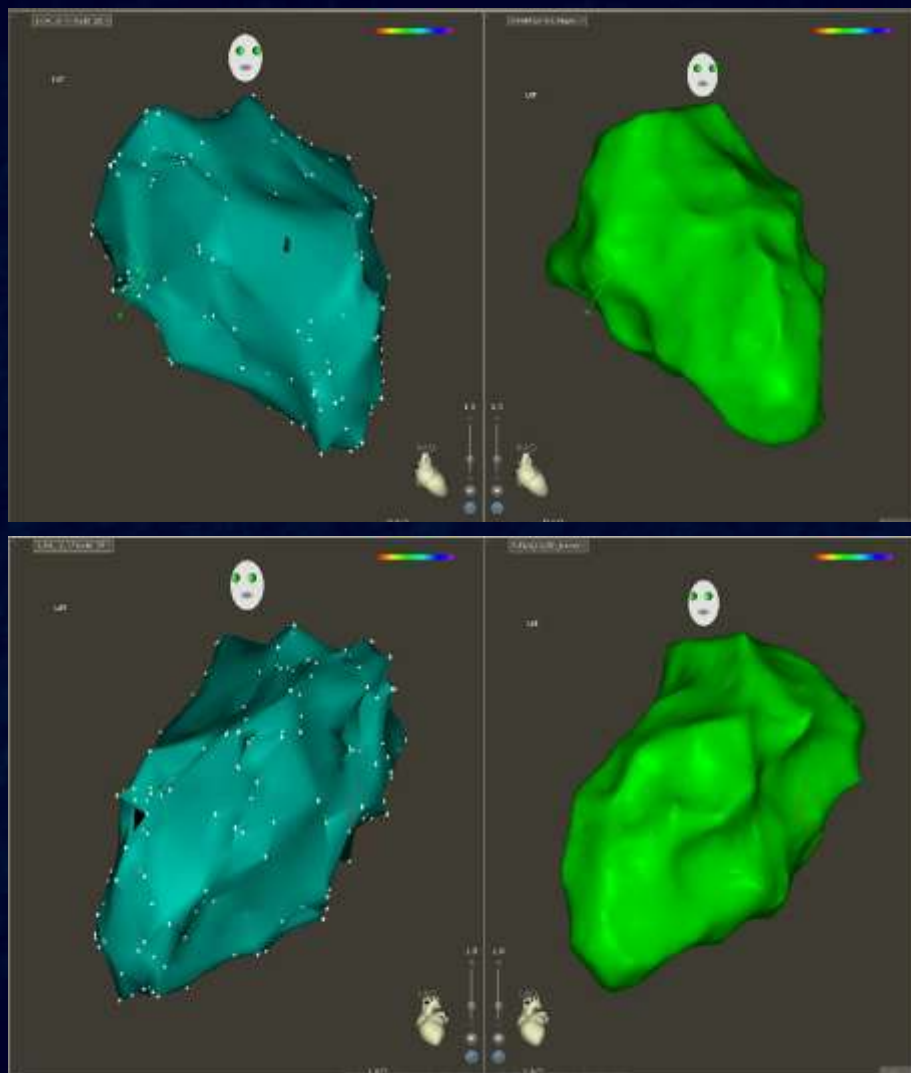


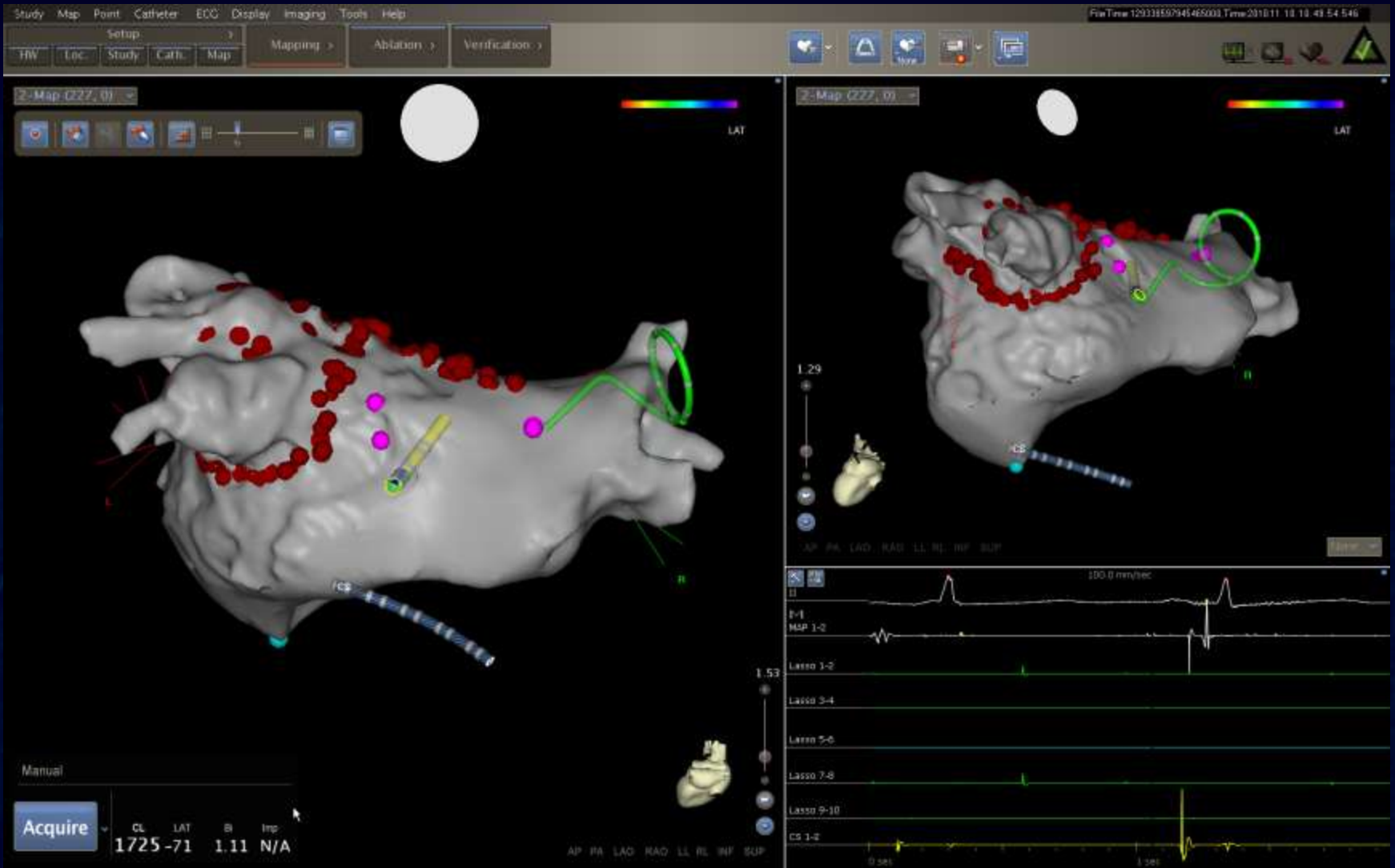
CARTOSOUND™

Module on the CARTO® XP System Software 2007



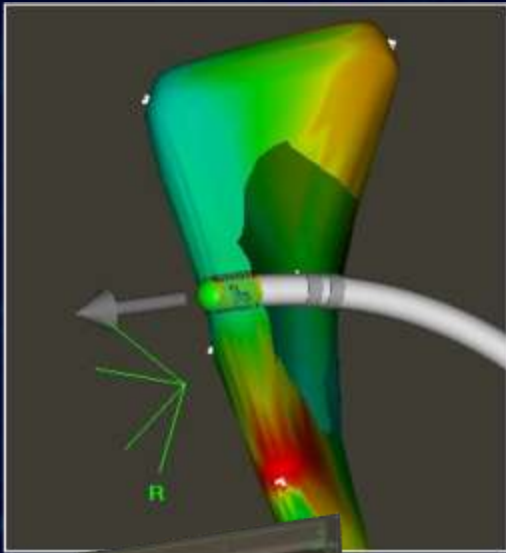
FAM vs. EA map done in Gated mode



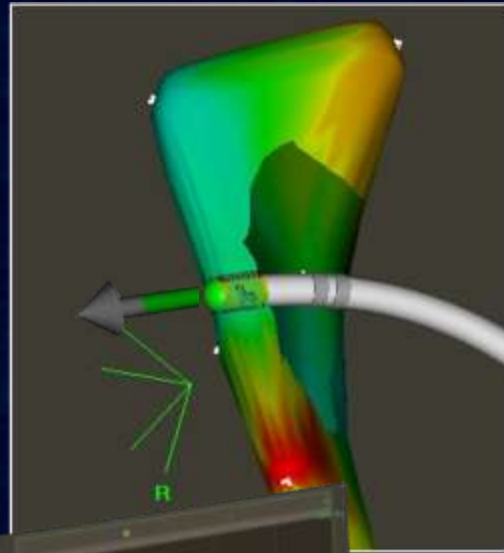


GUI: Force Value and Direction *continued...*

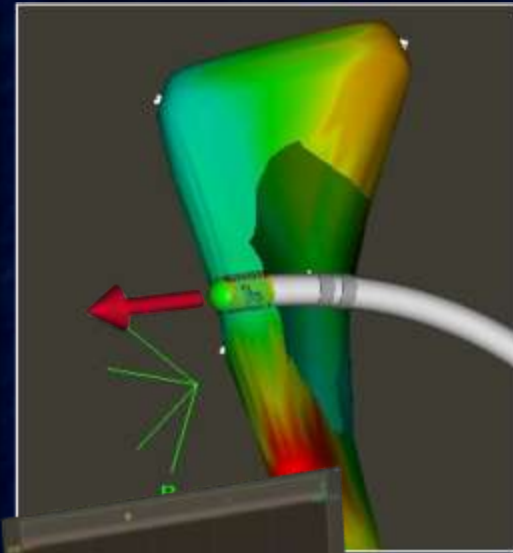
Below Threshold



Within Threshold



Above Threshold



Below the threshold

Within the threshold

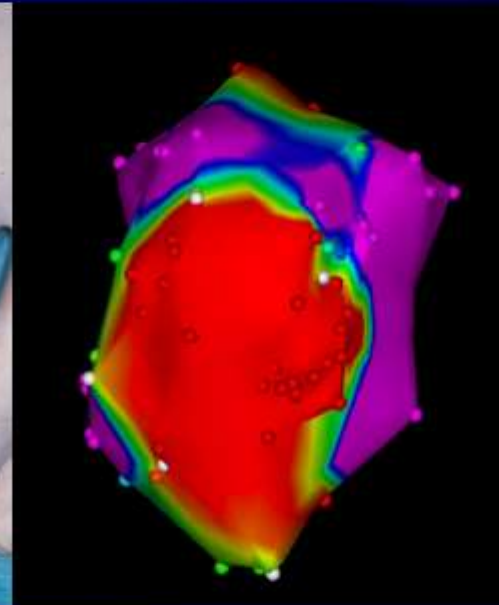
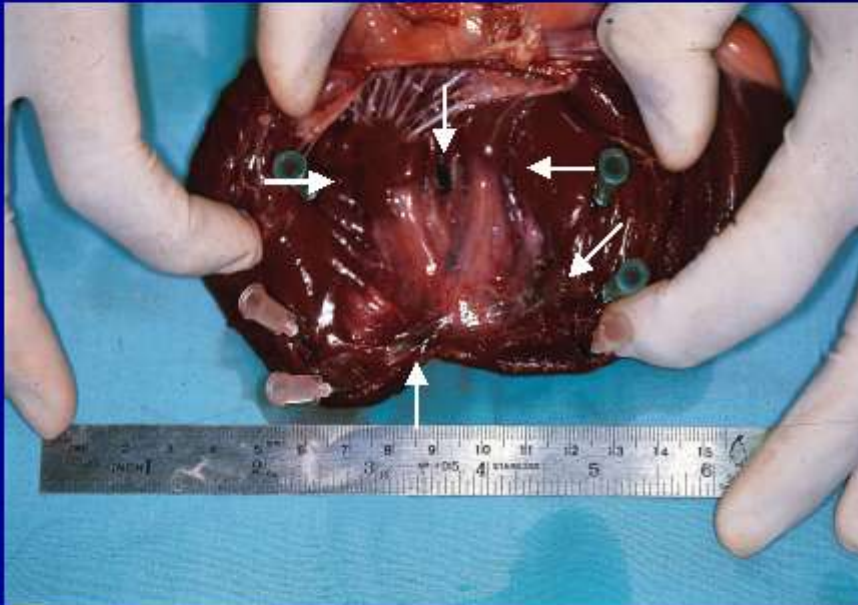
Above the threshold

Note the vector that is colored according to the force values defined by the thresholds

The Future

- Better understanding of patient-specific arrhythmia mechanism (atrial fibrillation)
- Non-destructive treatments
 - Gene therapy
 - Cell therapy
 - “Conducting cables”
 - “Molecular ablation”

Correlation with Pathology

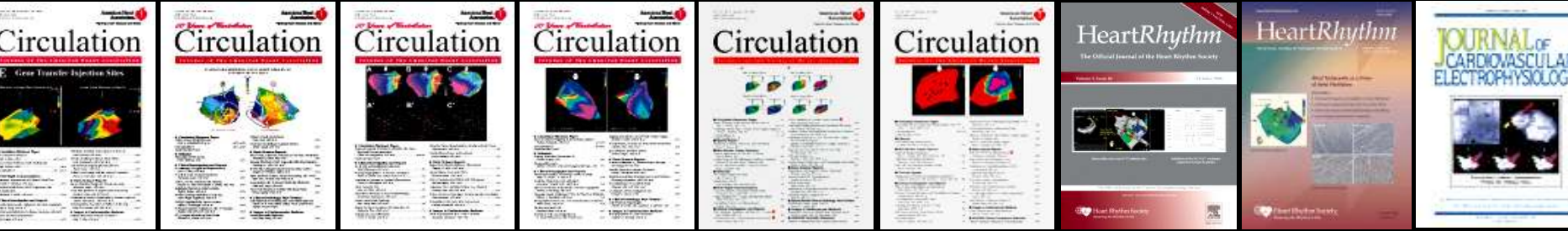


Gepstein et al.,
Circulation (1998)

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Rona Shofti, Edith Cohen





Thank You

