

High resolution mapping in treating arrhythmias

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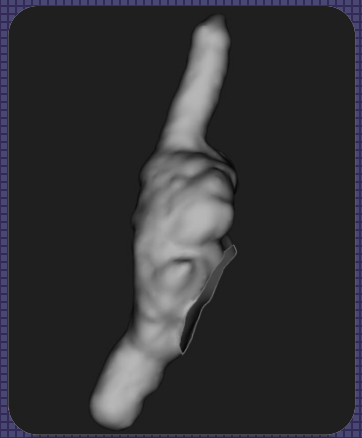
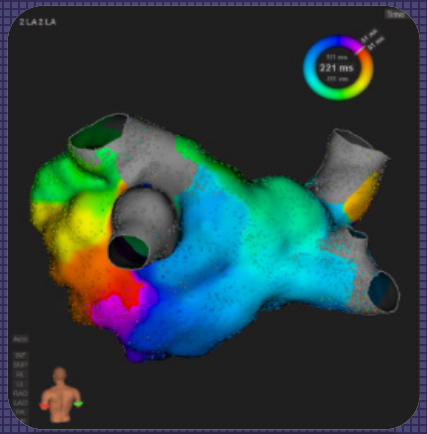
Rhythmia™ Mapping System

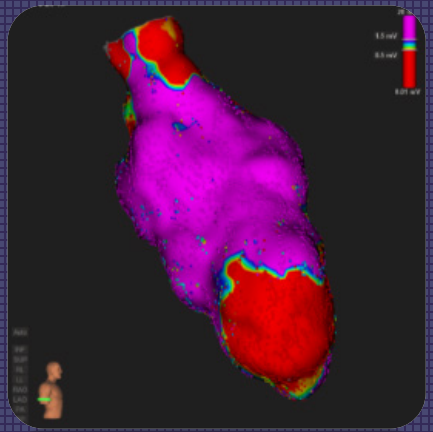
- Rhythmia Mapping System is a new NFNS able to perform fast and precise high-density electroanatomic maps by combining a 64-pole mini-basket catheter with a software capable of automatic acquisition of the location, orientation and the local electrogram information.
- Catheter tracking is both magnetic, based on a built-in magnetic sensor for the Orion and for the Intella Nav OI ablation catheter, and also by impedance-based, for any other non-proprietary catheters without magnetic sensor.
- The location of the OC is calculated magnetically and impedance is measured through its electrodes in order to establish an association between its magnetic position and impedance at those specific points. This information enables the Rhythmia system to determine the position and track non-magnetic catheters after the OC has generated an impedance field map during chamber mapping.



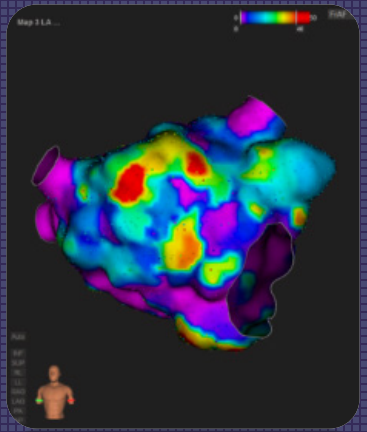
Anatomical



Activation



Voltage



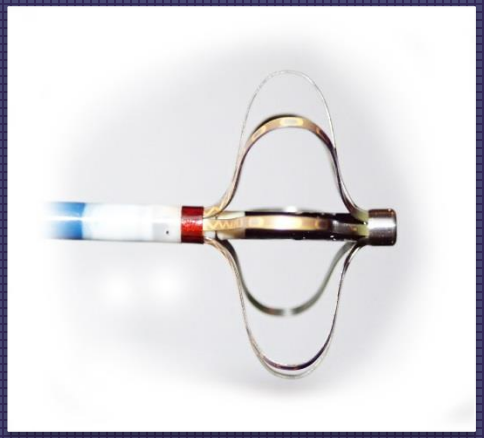
Fractionation

IntellaMap Orion™ Catheter

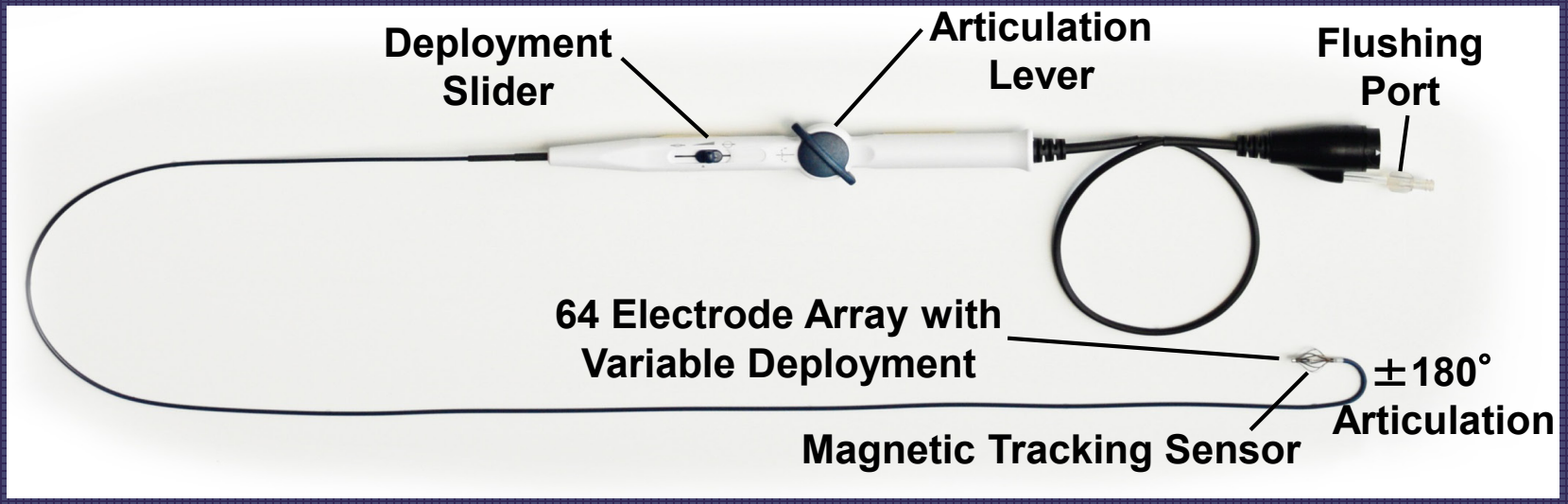
Flexible printed circuit bonded to nitinol

64-electrodes array. 2.5 mm inter-electrode spacing (center to center). 8.5F, 3-22mm)

0.4mm^2 electrode area (0.9 × 0.45 mm)

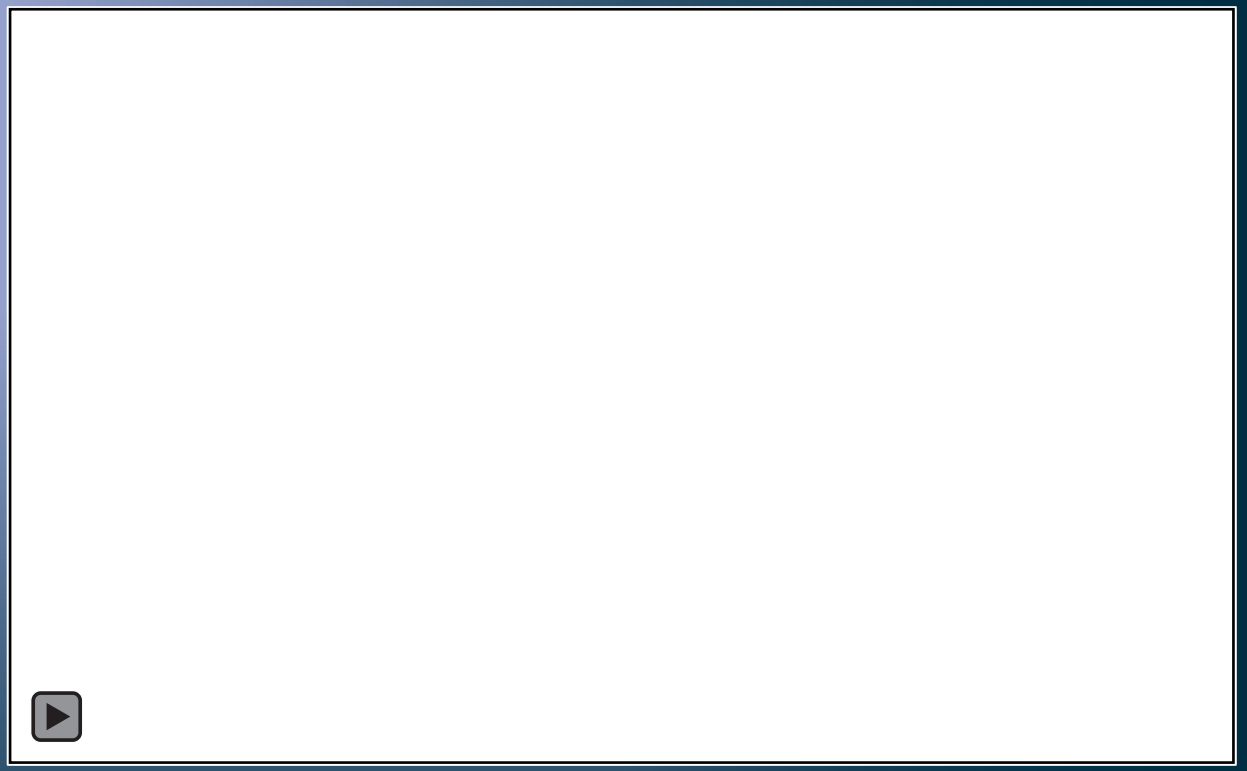


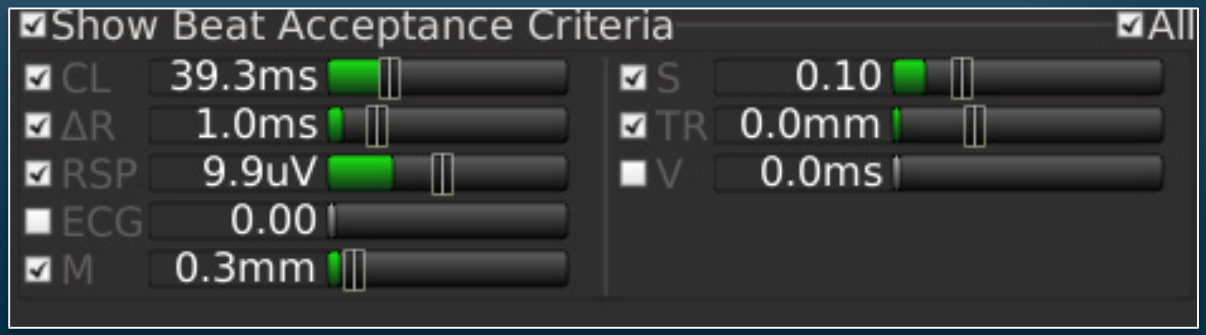




Beat Acceptance Criteria. *Continuous mapping mode*

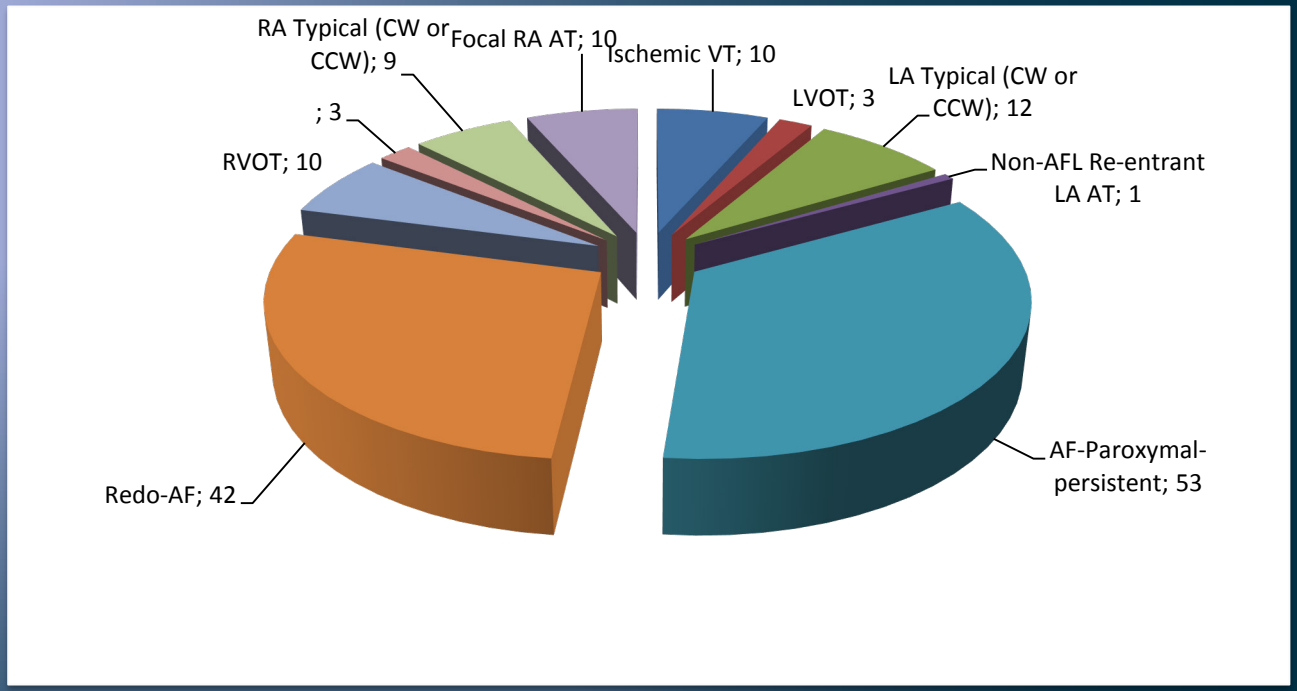
- *Cycle length*
- *Propagation reference*
- *Respiration*
- *ECG morphology reference*
- *Catheter motion*
- *Catheter electrogram stability*
- *Tracking quality*

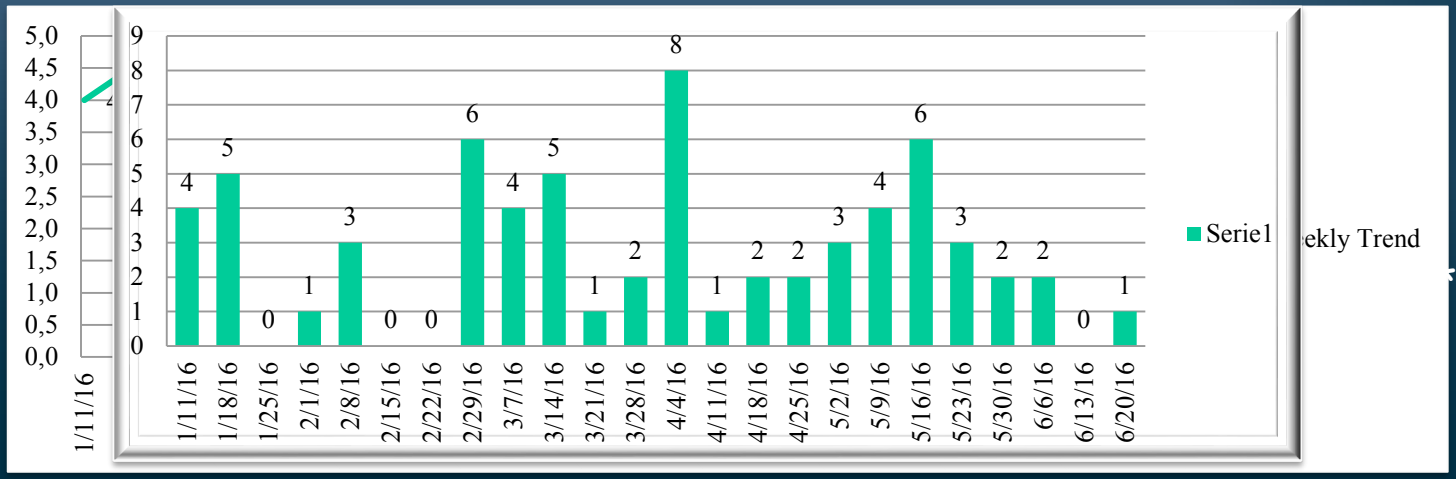




CUN (7/2015-9/2016)

	Total
Focal RA AT	10
RA Typical (CW or CCW)	9
LA Typical (CW or CCW)	12
Non-AFL Re-entrant LA AT	1
AF-Paroxymal	53
Redo-AF	42
RVOT	10
LVOT	3
Non-Ischemic VT	9
Ischemic VT	10
Non-AFL Re-entrant RA AT	1
Focal LA AT	0
Fascicular VT	2
Right Sided WPW	0
Left Sided WPW	0
Right Sided Concealed AP	0
Left Sided Concealed AP	2
TOTAL	164



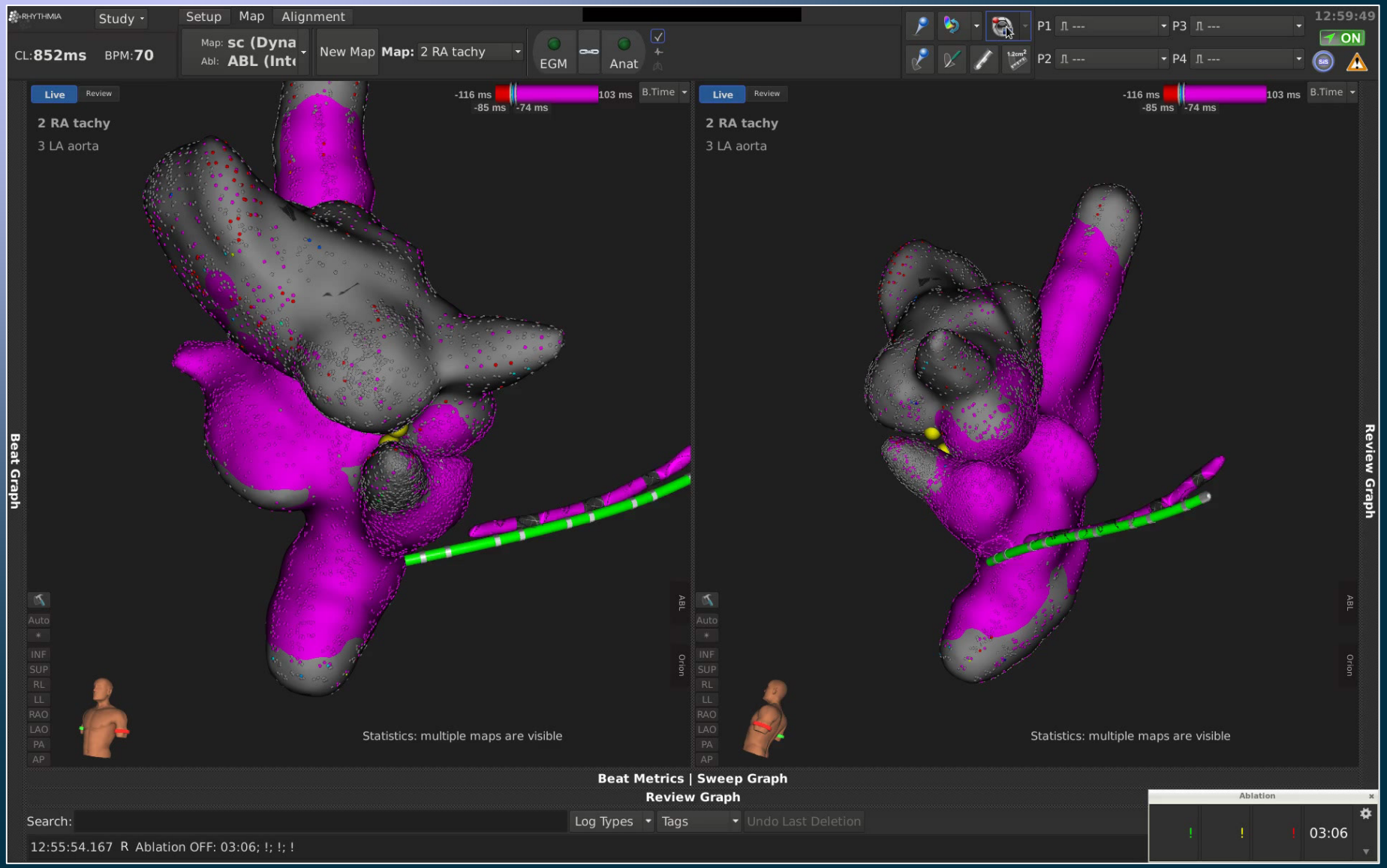


* Updated on Sep 20th, 2016

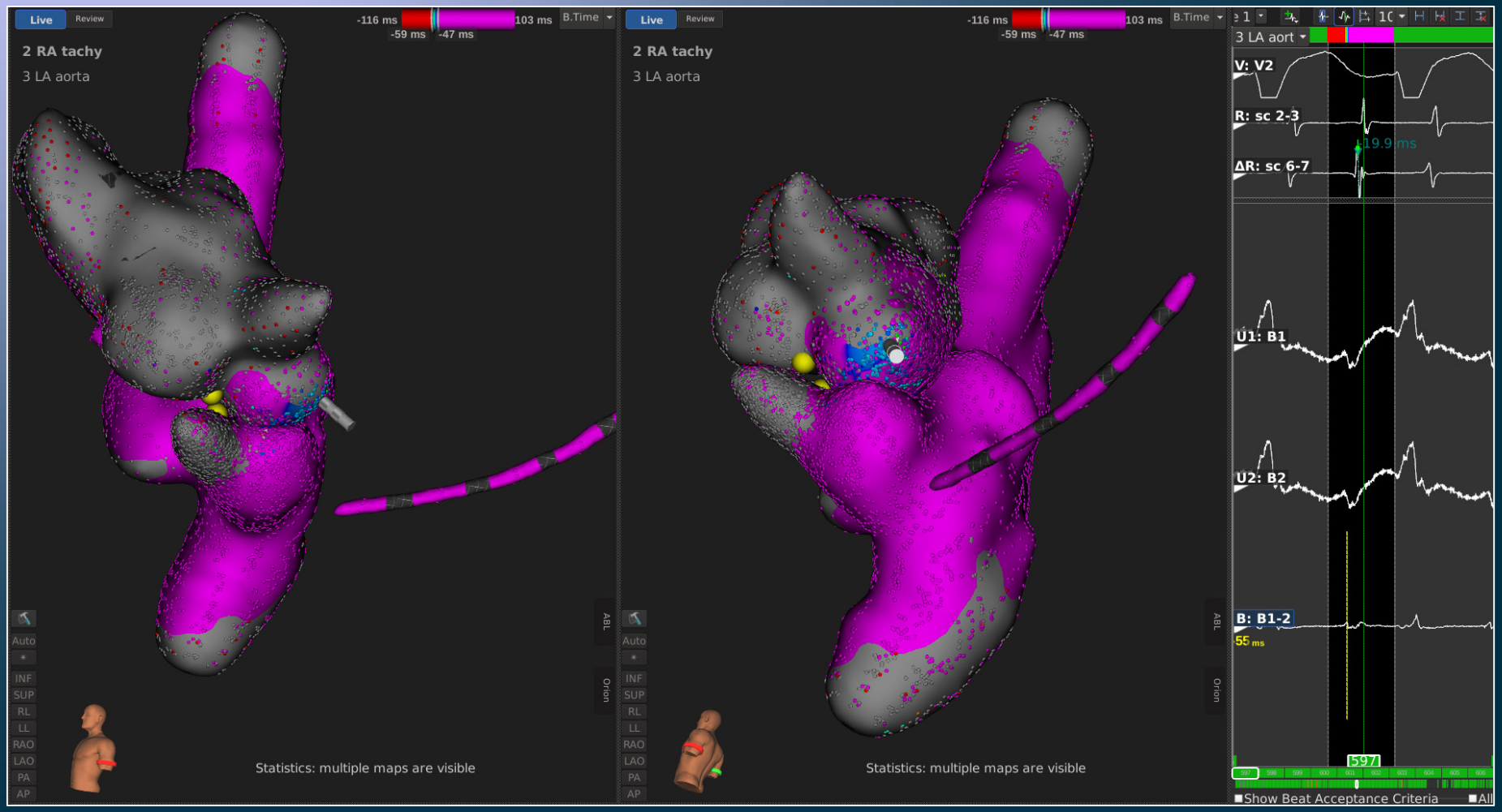
1. Focal arrhythmias substrates

- Fast maps
- High anatomic precision
- Low rate of inconsistent points and easy identification of outliers
- ECG morphology reference

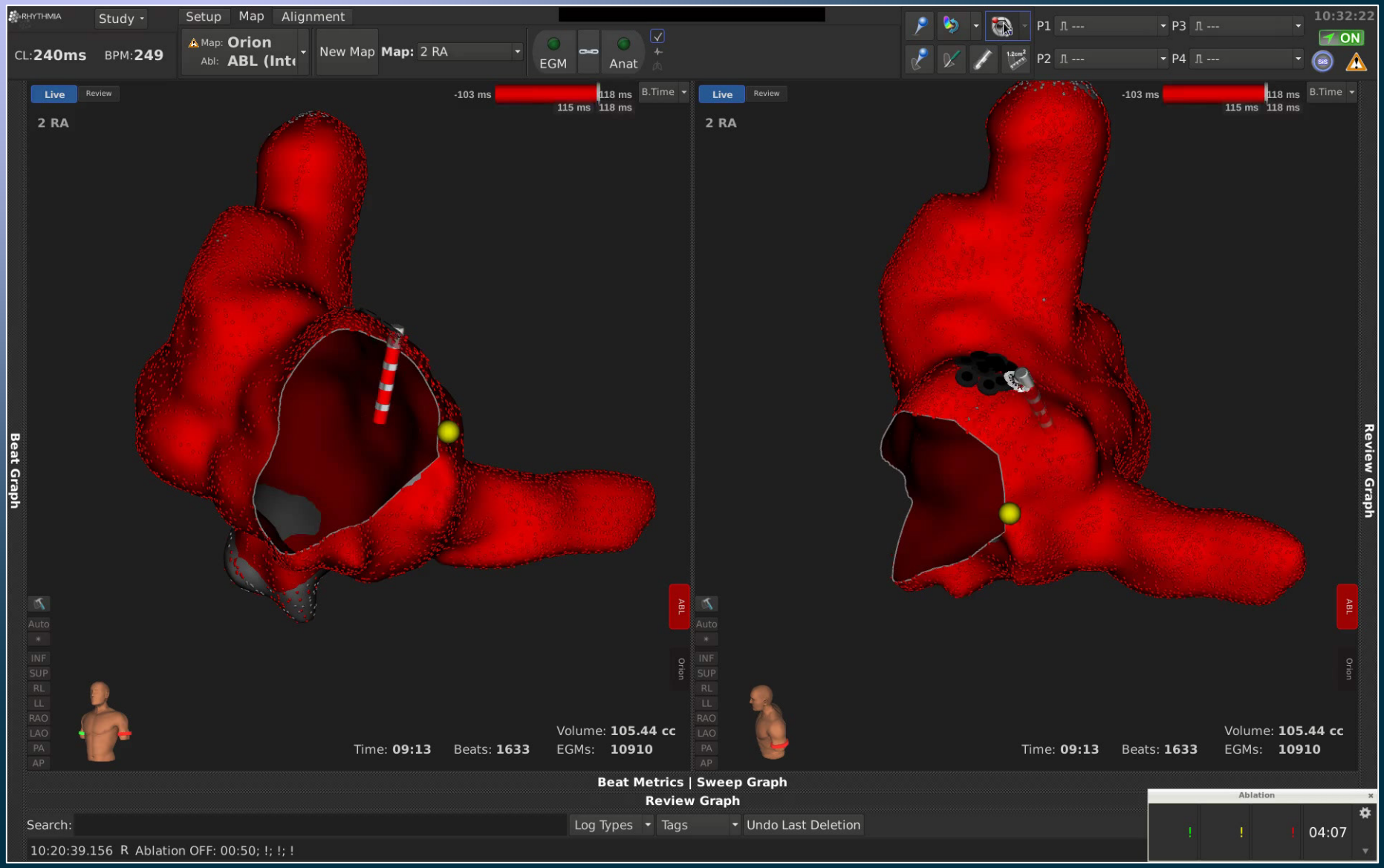
Non-coronary aortic cusp focal AT



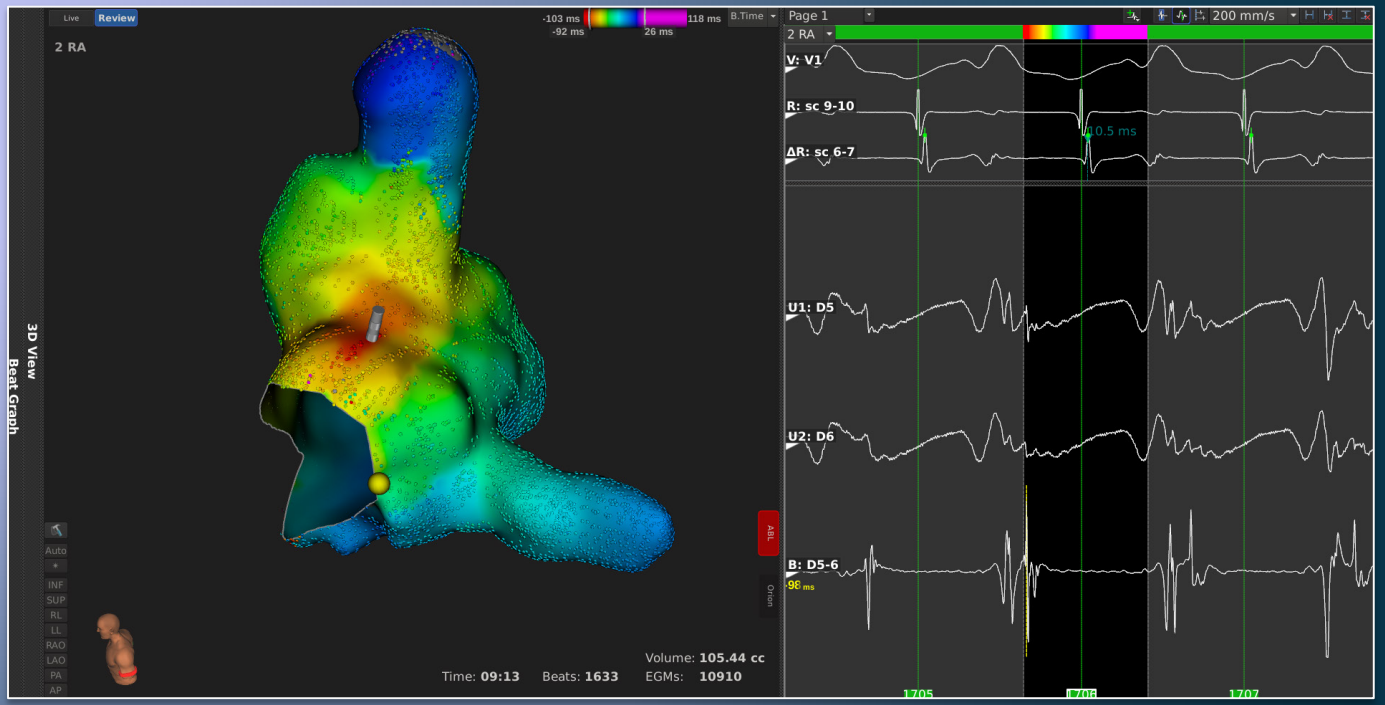
Non-coronary aortic cusp focal AT

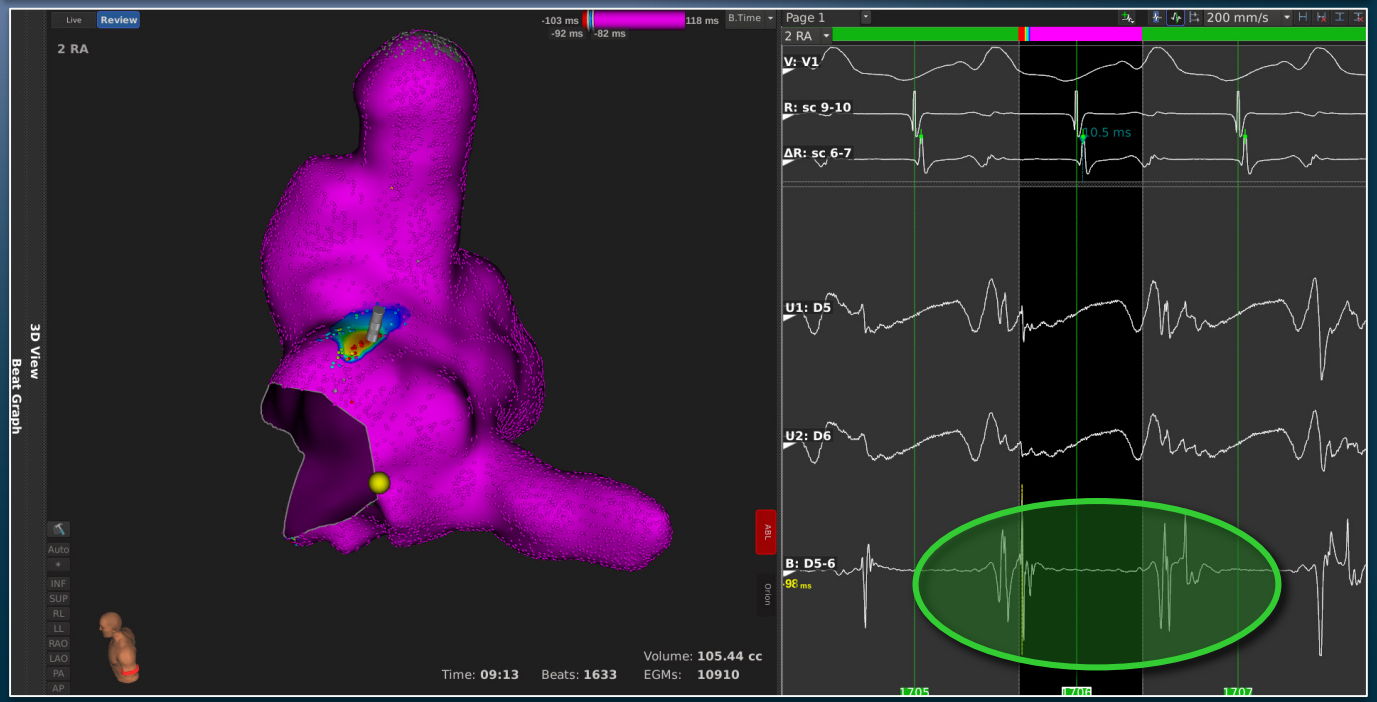


Anterior tricuspid ring focal AT



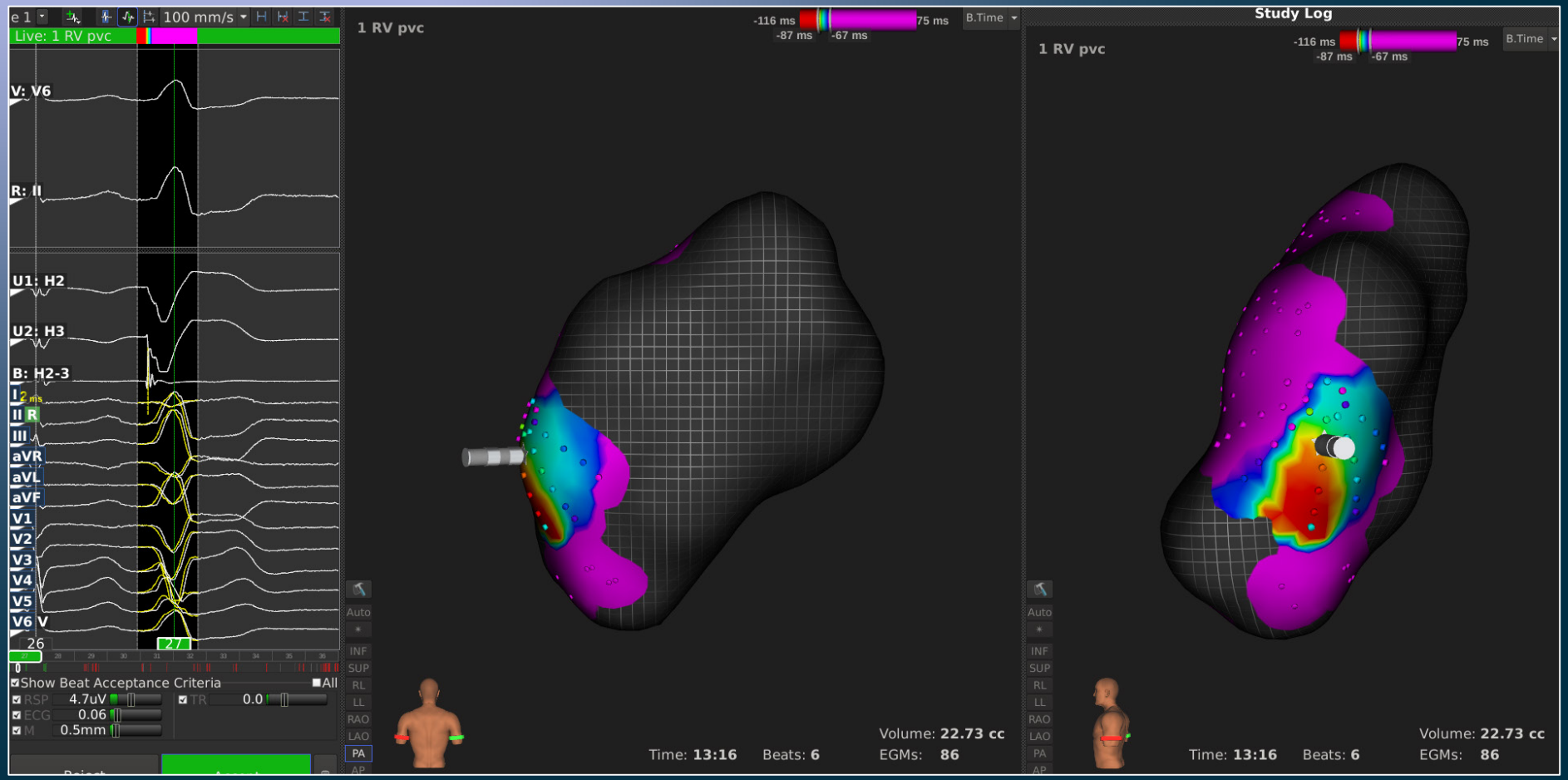
Anterior tricuspid ring focal AT



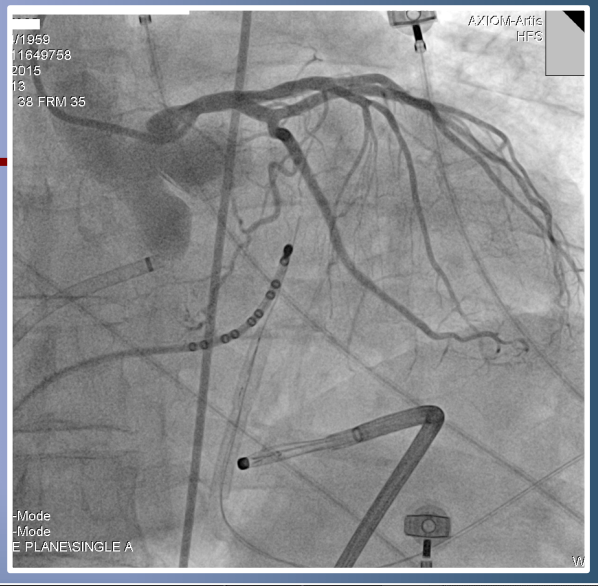


RVOT

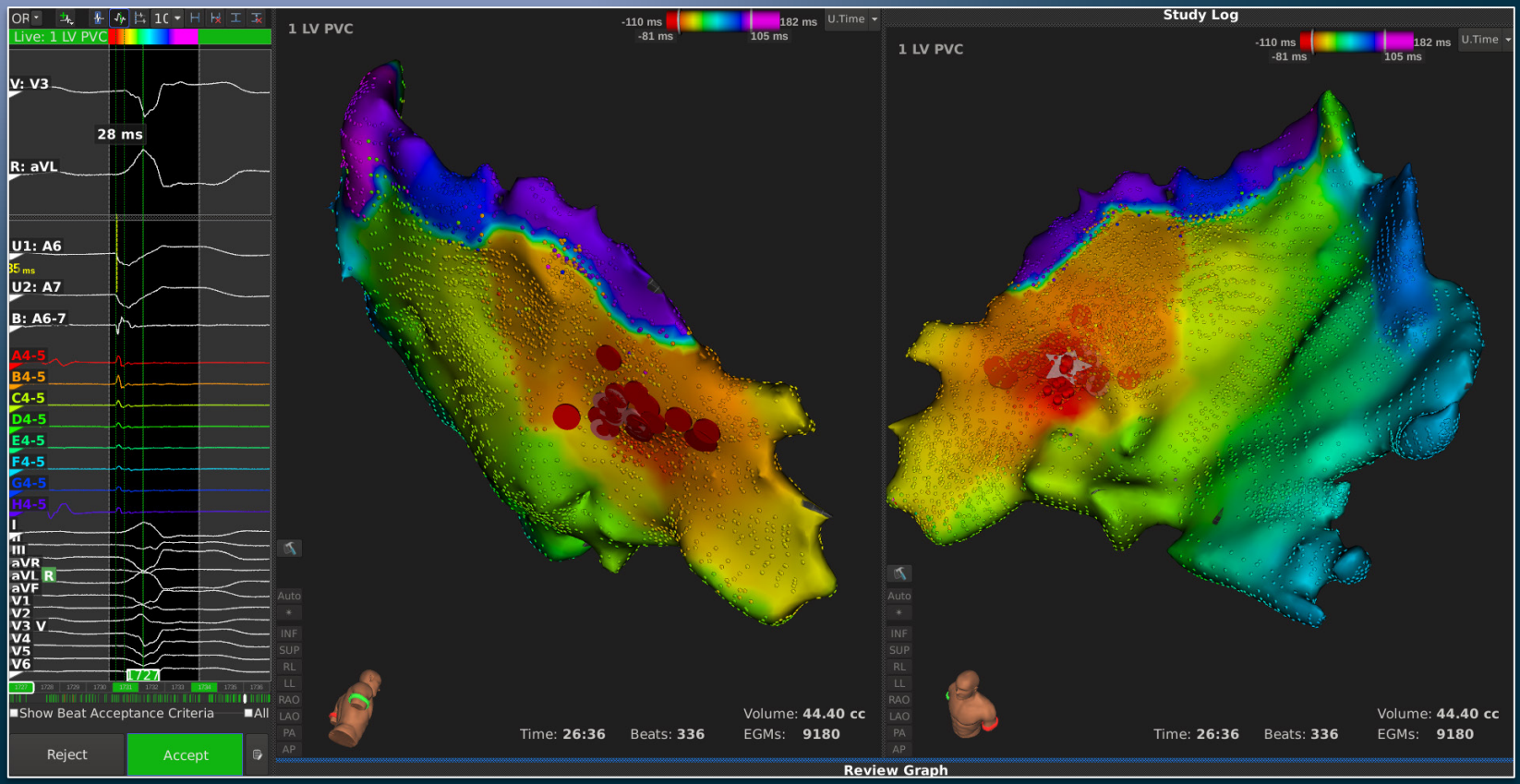
Beat Acceptance Criteria. ECG



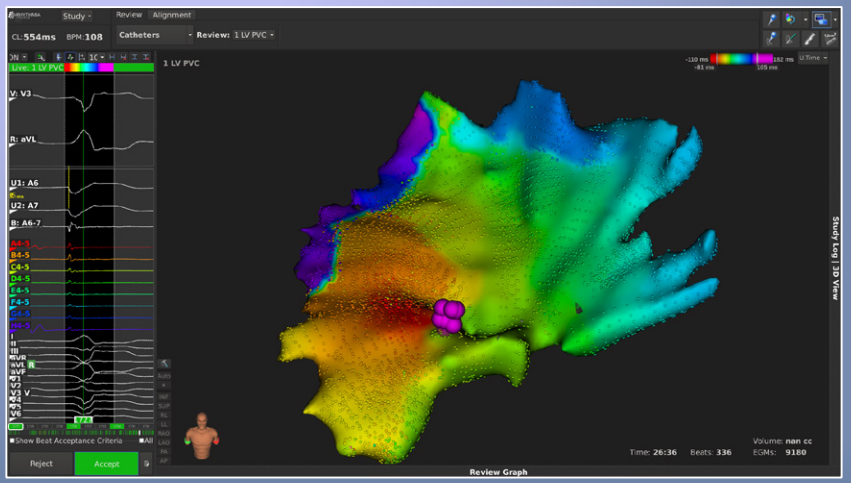
Endo-epi VT

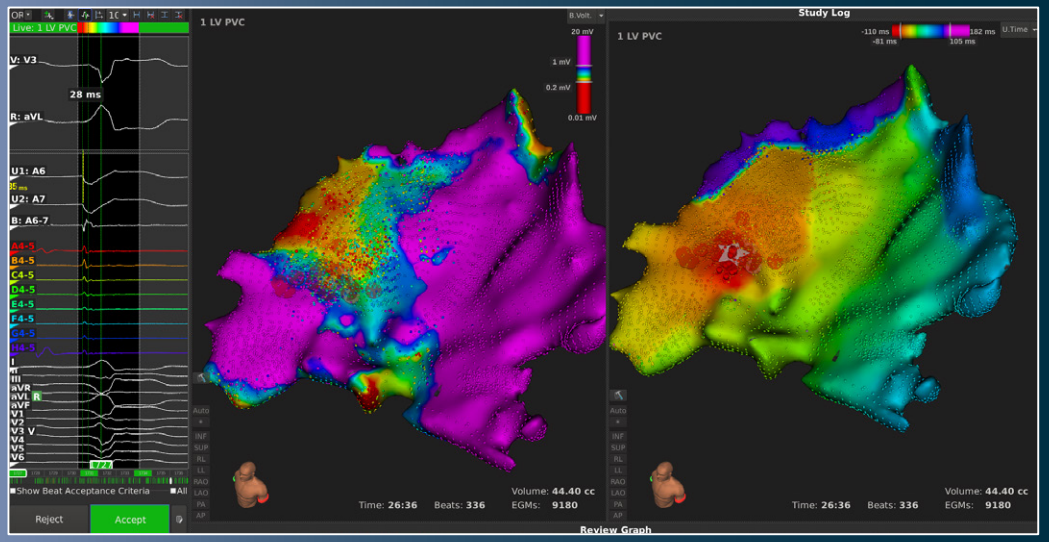

AXIOM-Artis
HFS
-Mode
-Mode
E PLANE\SINGLE A




Live: 1 LV PVC
V: V3
28 ms
R: aVL
U1: A6
U2: A7
B: A6-7
A4-5
B4-5
C4-5
D4-5
E4-5
F4-5
G4-5
H4-5
I
II
III
aVR
aVL
aVF
V1
V2
V3
V4
V5
V6
Show Beat Acceptance Criteria
All
Reject
Accept
1 LV PVC
-110 ms
-81 ms
182 ms
105 ms
U.Time
Time: 26:36
Beats: 336
Volume: 44.40 cc
EGMs: 9180
Study Log
Review Graph

Endo-epi VT


Study
Review
Alignment
CL: 554ms
BPM: 108
Catheters
Review: 1 LV PVC
1 LV PVC
Live: 1 LV PVC
V: V3
R: aVL
U1: A6
U2: A7
B: A6-7
Show Beat Acceptance Criteria
Reject
Accept
Volume: nan cc
Time: 26:36
Beats: 336
EGMs: 9180
Review Graph


Live: 1 LV PVC
V: V3
28 ms
R: aVL
U1: A6
U2: A7
B: A6-7
Show Beat Acceptance Criteria
Reject
Accept
1 LV PVC
Volume: 44.40 cc
Time: 26:36
Beats: 336
EGMs: 9180
Study Log
Review Graph


Clinica Universidad de Navarra / Unidad de Arritmias / Servicio de Cardiologia y Cirugia Cardiaca
Version WINDOWS XP : EPTRACER V1.05
28115
I
II
III
AVR
AVL
AVF
V1
V2
V3
V4
V5
V6
10 mm/mV 10 mm/s
Patient :
Comment : JJLL Pre ablacion
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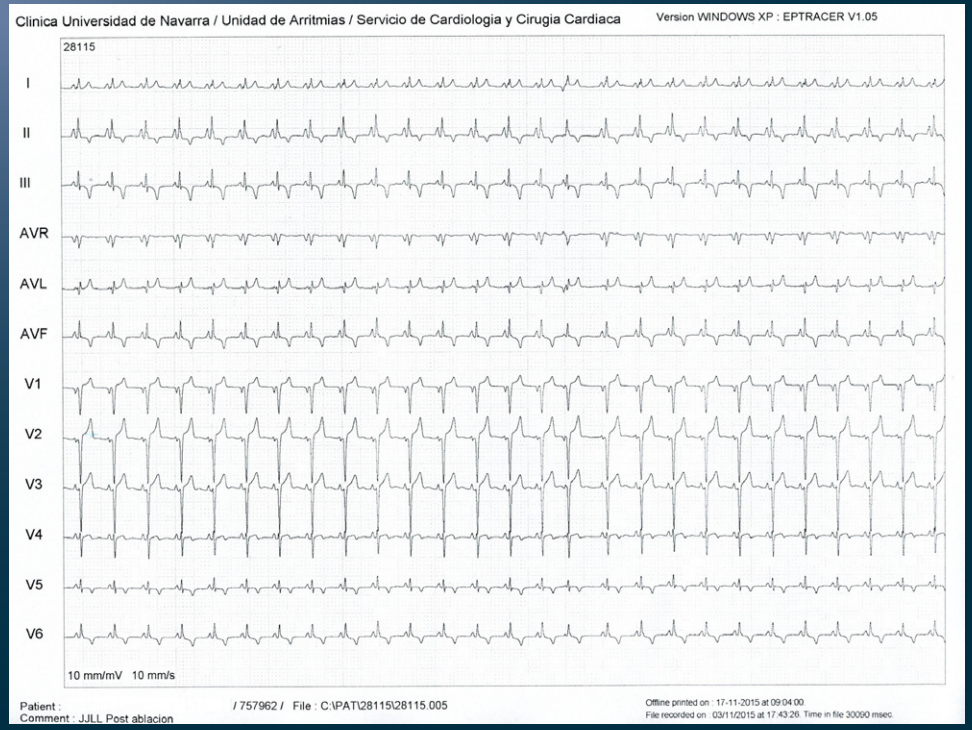
Clinica Universidad de Navarra / Unidad de Arritmias / Servicio de Cardiologia y Cirugia Cardiaca
Version WINDOWS XP : EPTRACER V1.05
28115
I
II
III
AVR
AVL
AVF
V1
V2
V3
V4
V5
V6
10 mm/mV 10 mm/s
Patient :
Comment : JJLL Post ablacion
/ 757962 / File : C:\PAT\28115\28115.005
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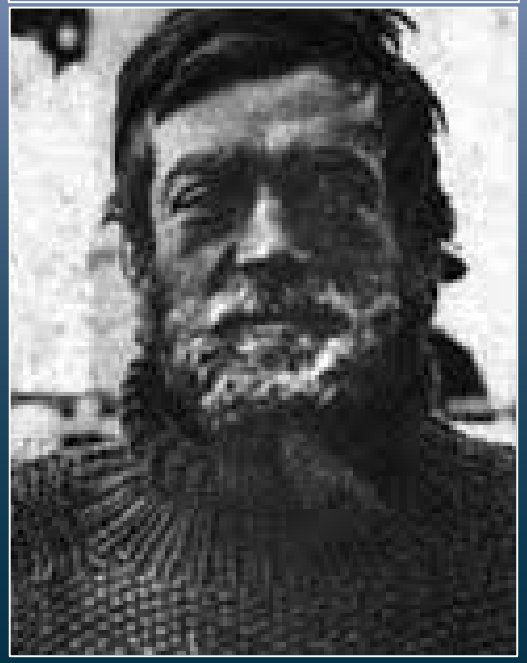
2. Macro-reentrant complex tachycardias

- Fast maps/remaps
- Precise voltage maps & high correlation with activation maps
- Ablation line assessment and detection of gaps
- Low rate of inconsistent points and easy identification of outliers





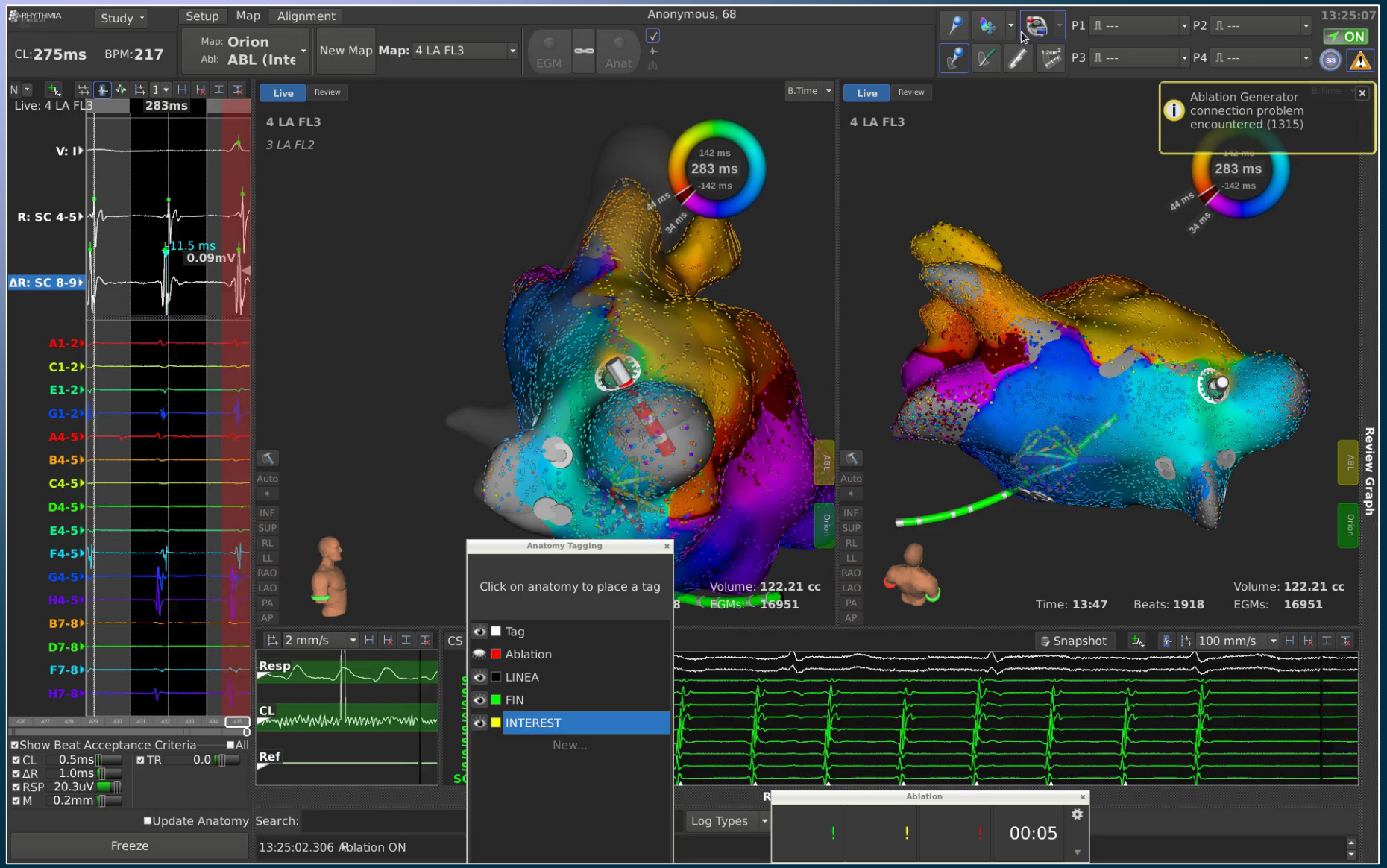


Ernest Shackleton's Ad

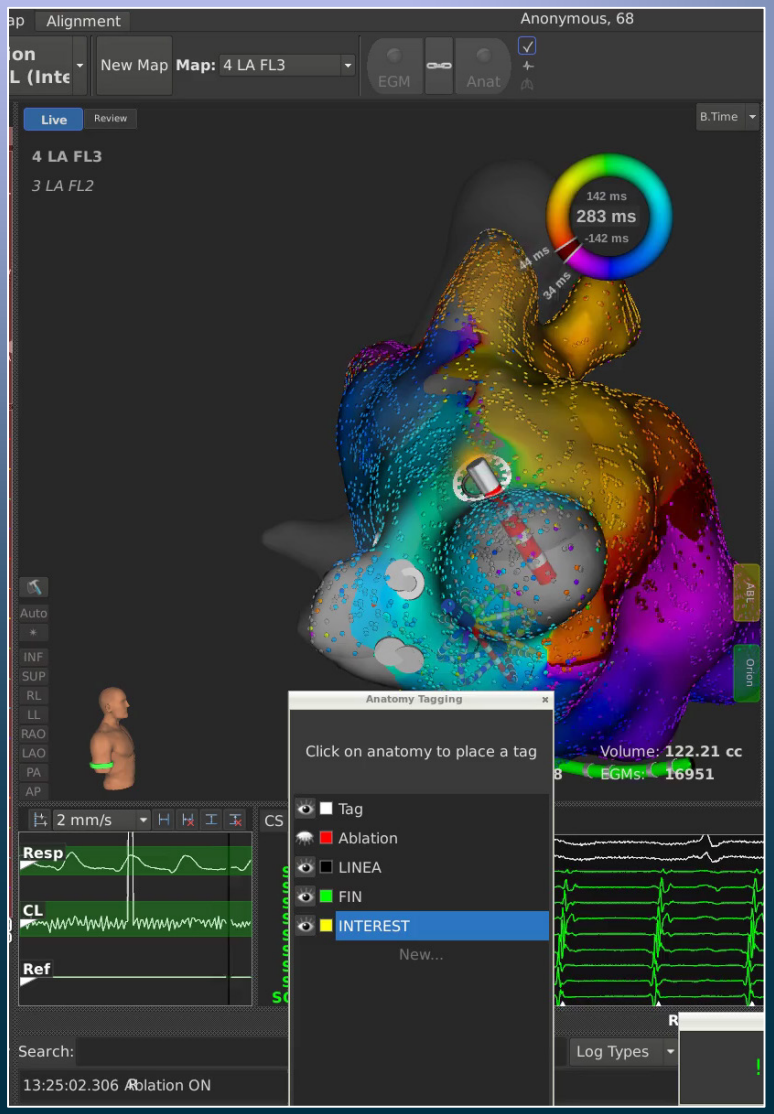
MEN WANTED for hazardous journey. Low wages, bitter cold, long hours of complete darkness. Safe return doubtful. Honor and recognition in event of success

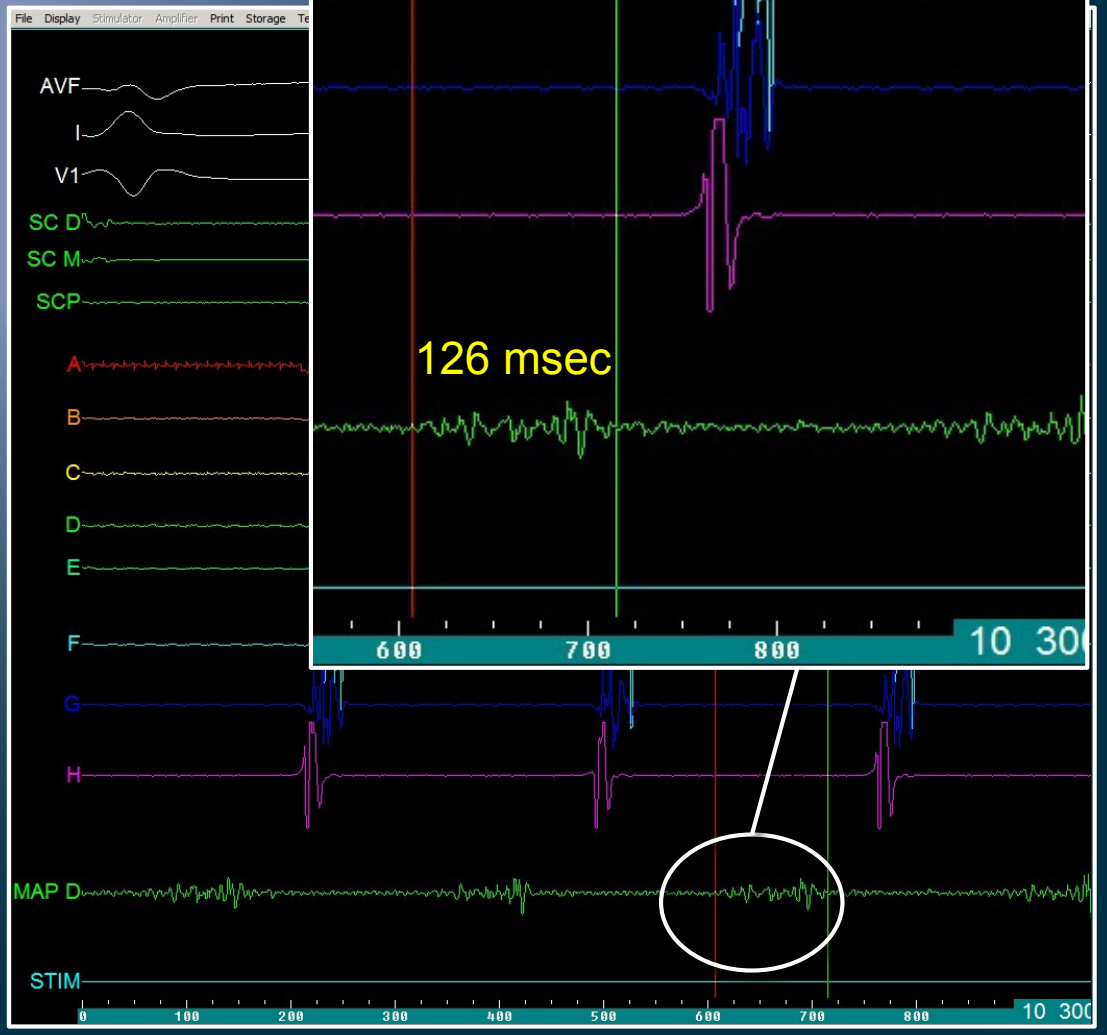
The Times, ca. 1913

Gap-in-roof reentrant LAF

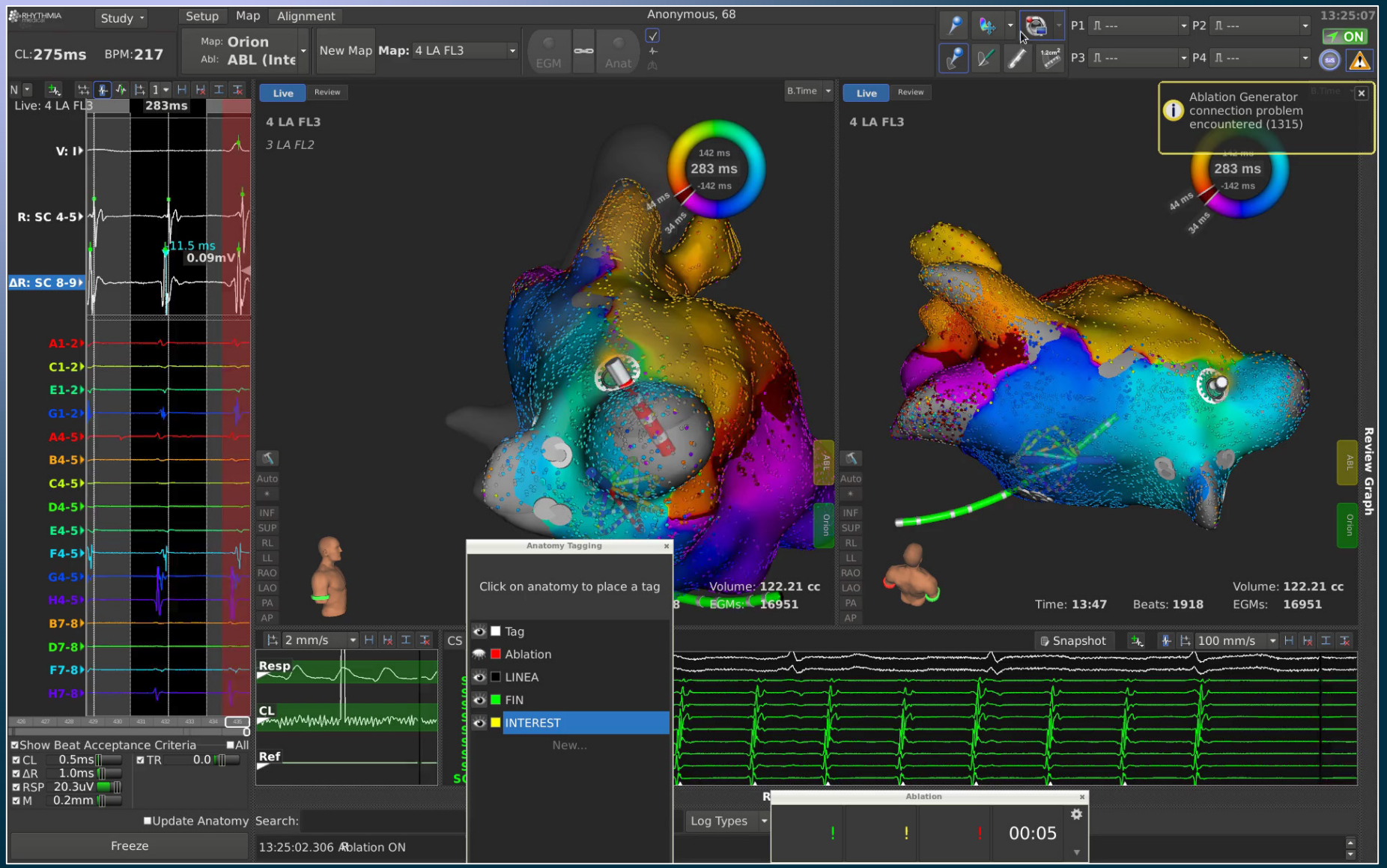


Gap-in-roof reentrant LAF



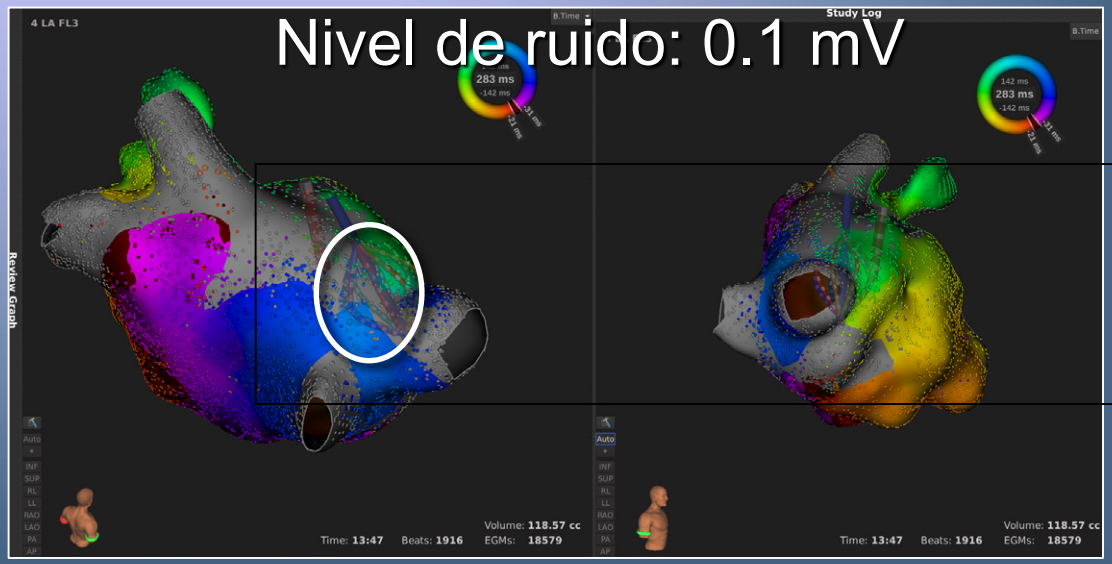


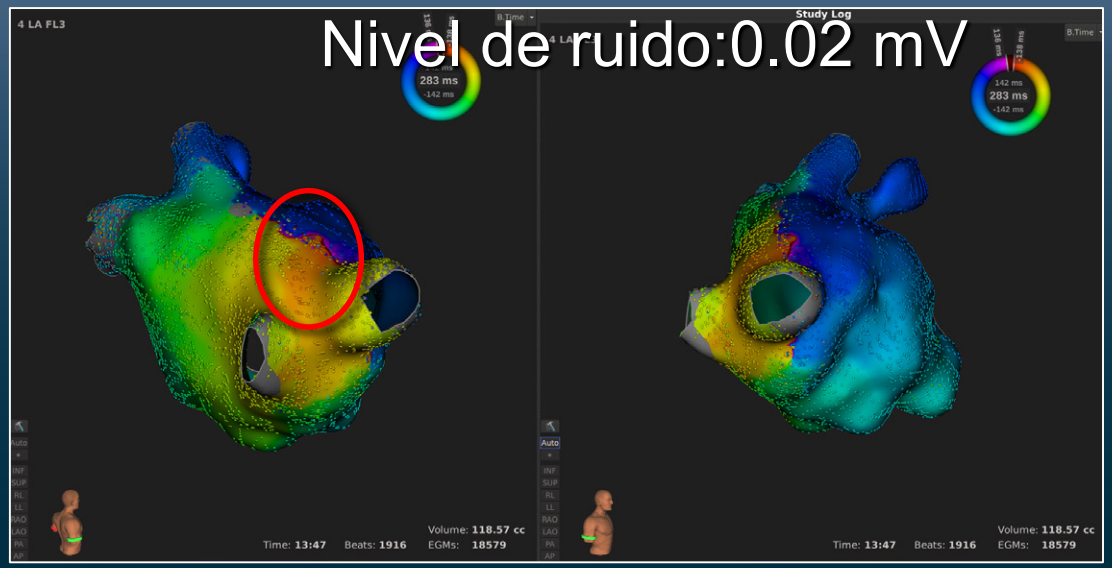
Gap-in-roof reentrant LAF

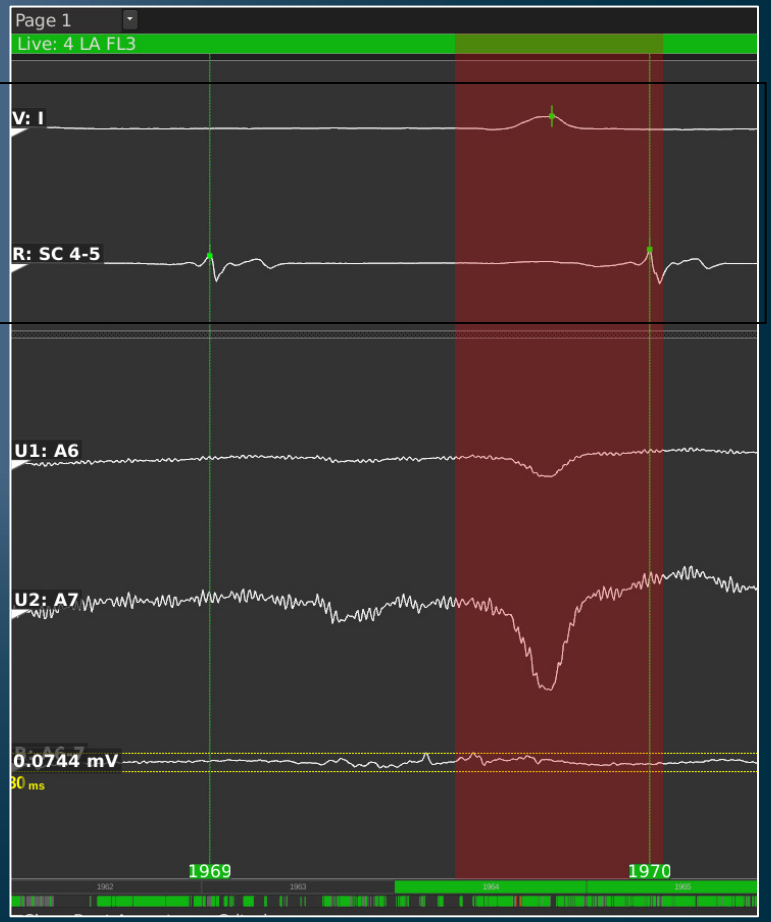


Mapas de alta definición (*densidad y ruido)*

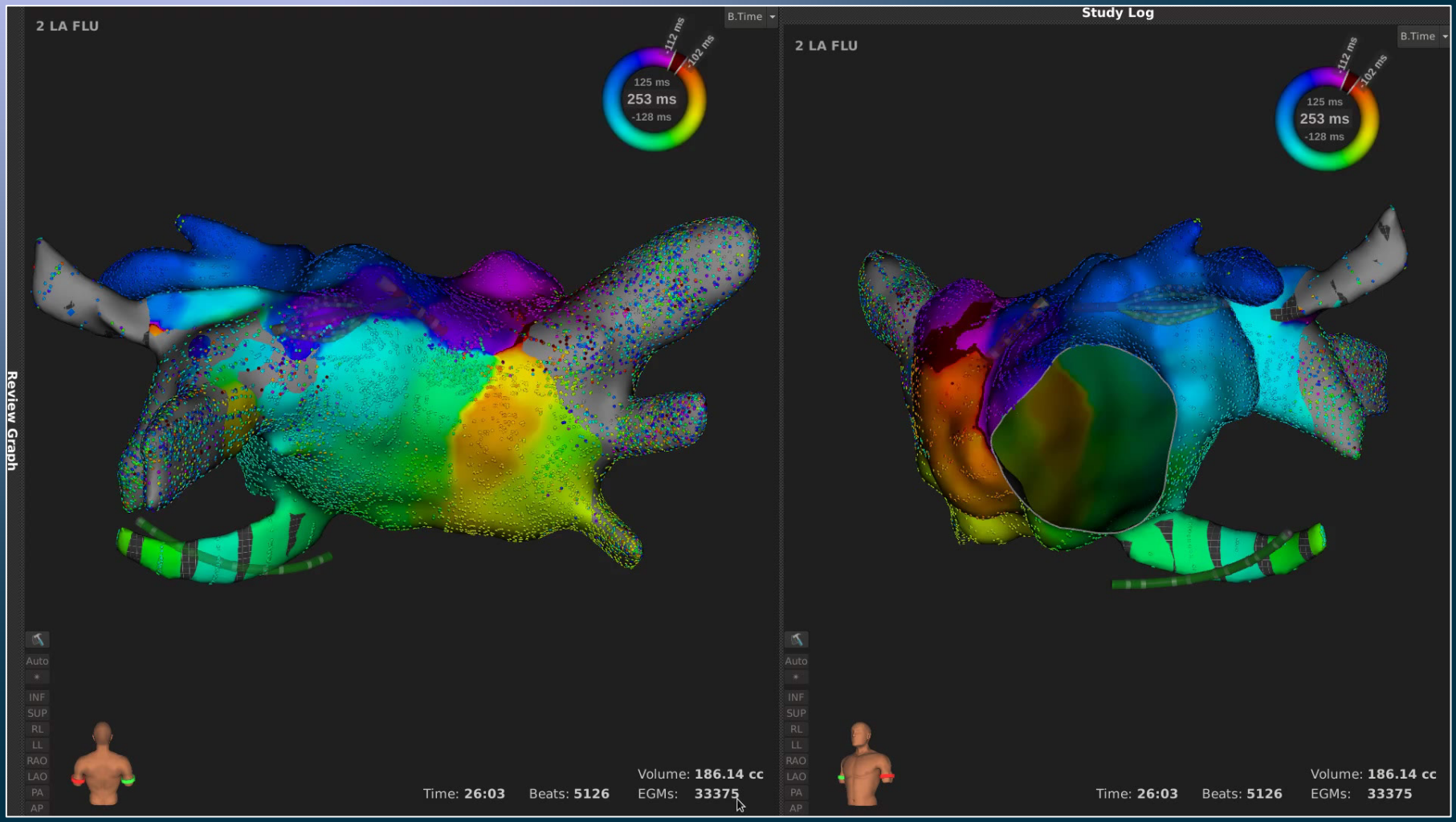
Gap-in-roof reentrant LAF



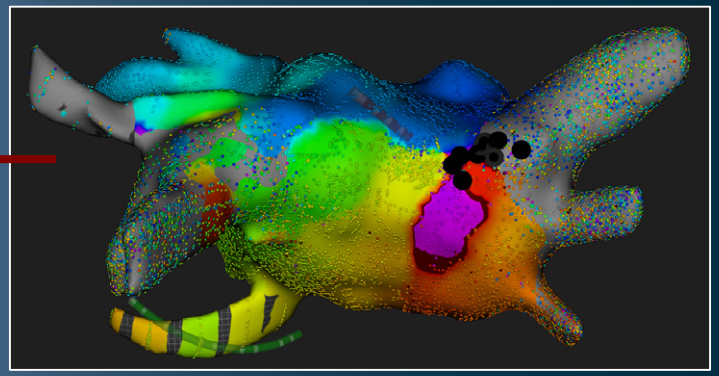




Perimitral LAF + Roof gap



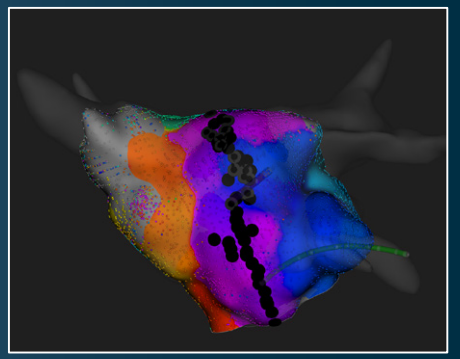
Perimitral LAF + Roof gap



1. Ablation of the roof gap & remap

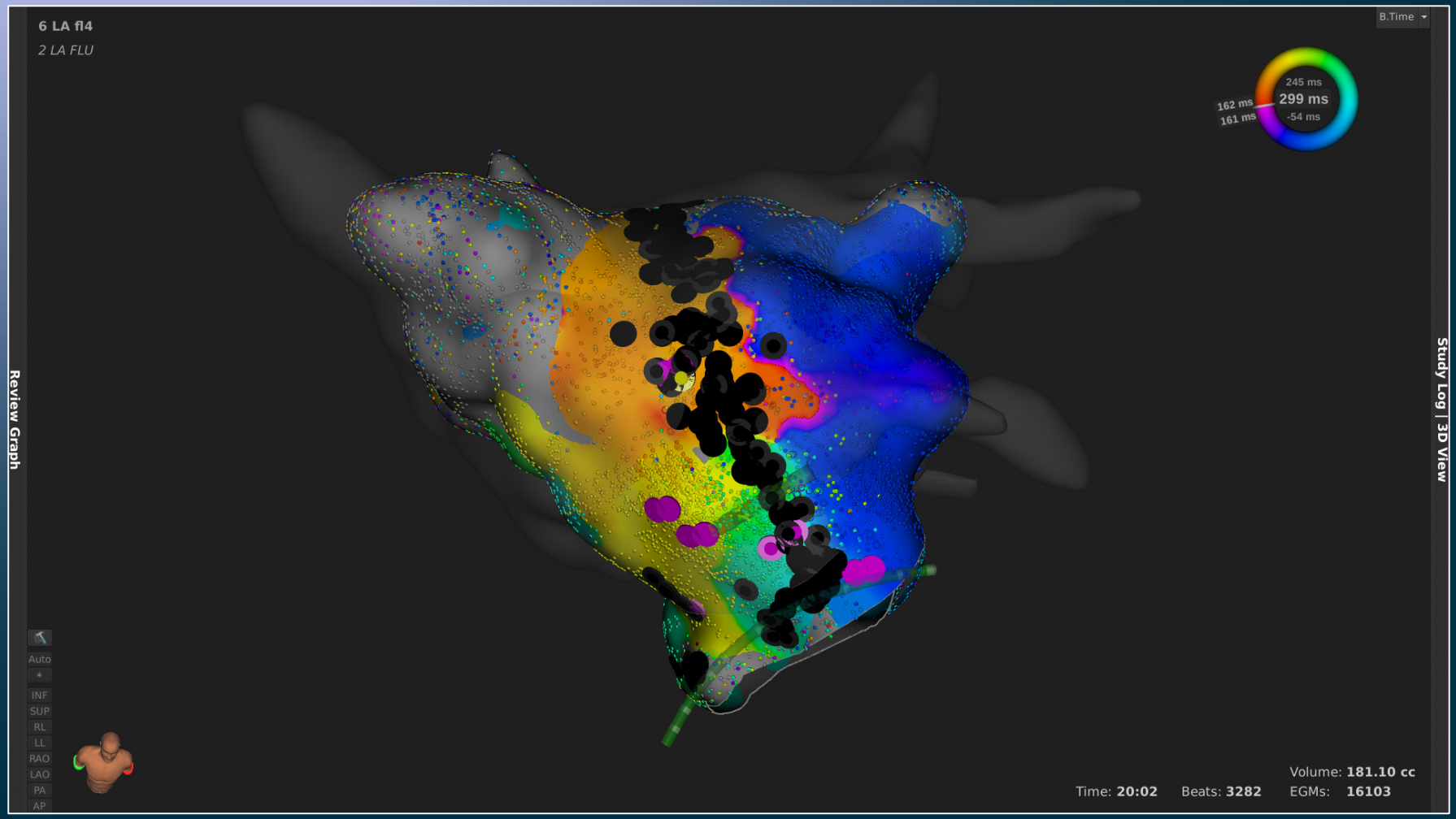
Perimitral LAF + Roof gap

2. Anterior line, change in CL by 70 msec. Remap



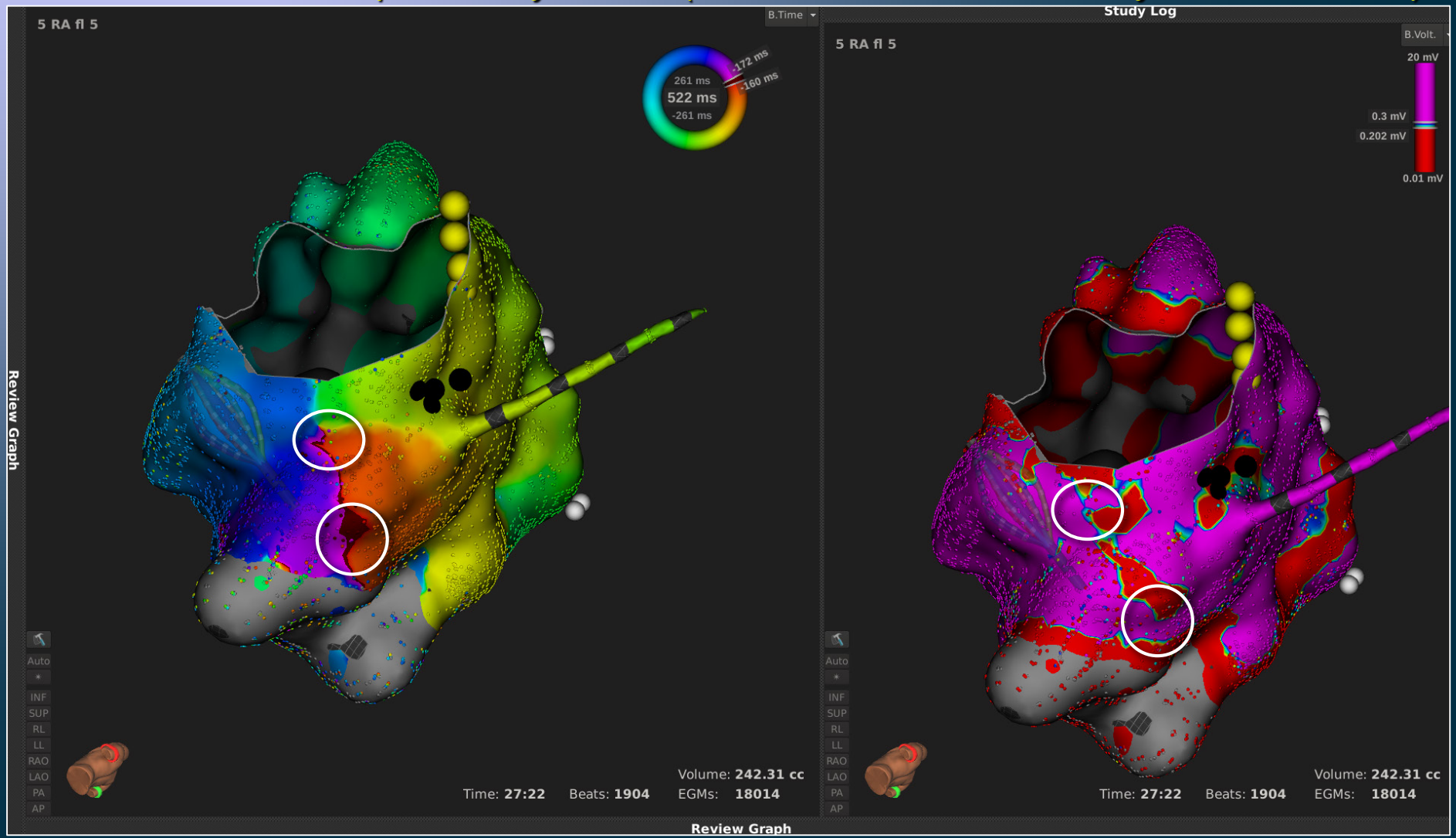
Perimitral LAF + Roof gap

3. Ablation of the gap with TactiCath

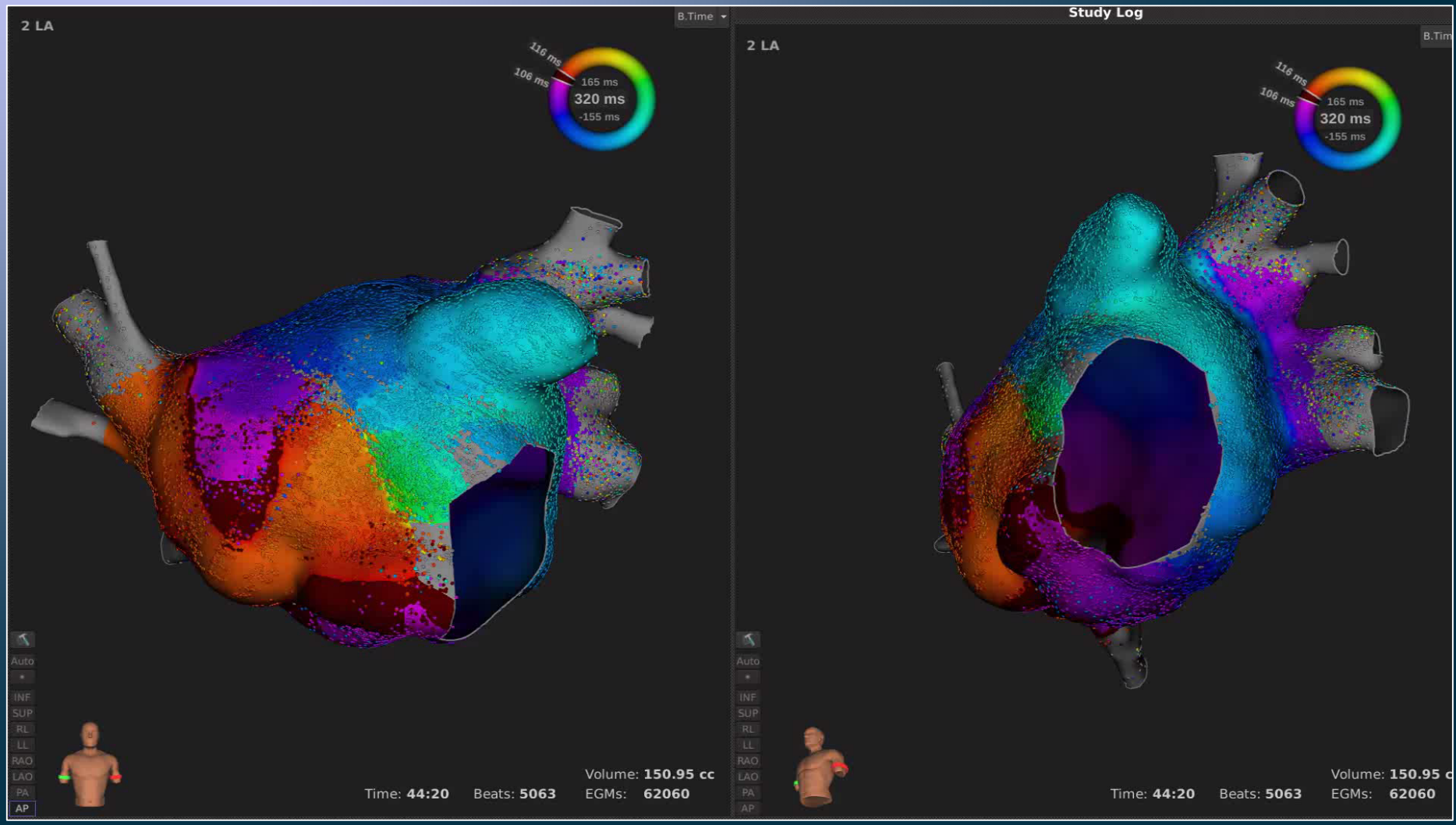


High-definition voltage & activation maps

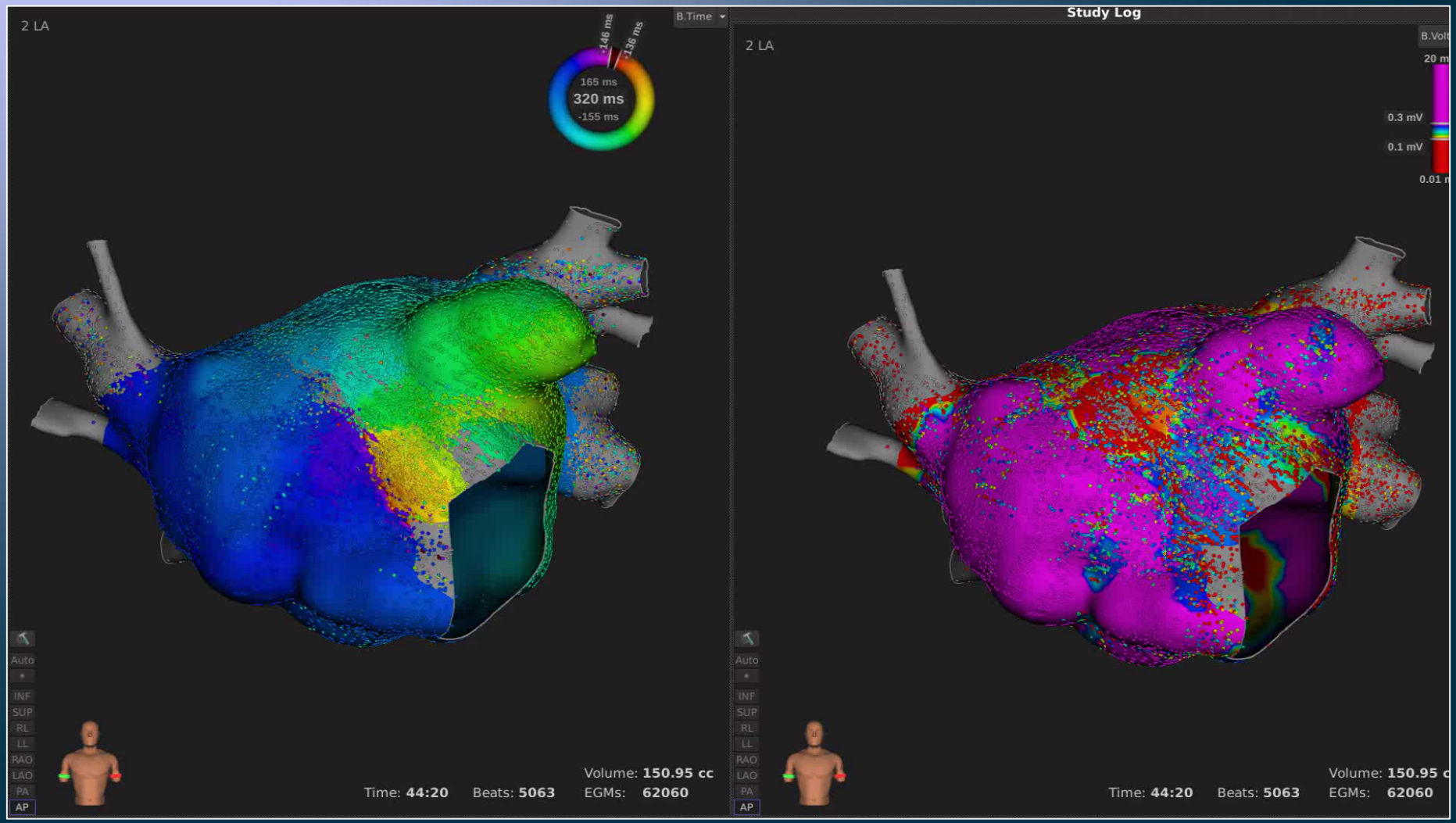
Univentricular heart + pulmonary atresia (Rashkind/Waterston-Cooley/Blalock-Hanlon)



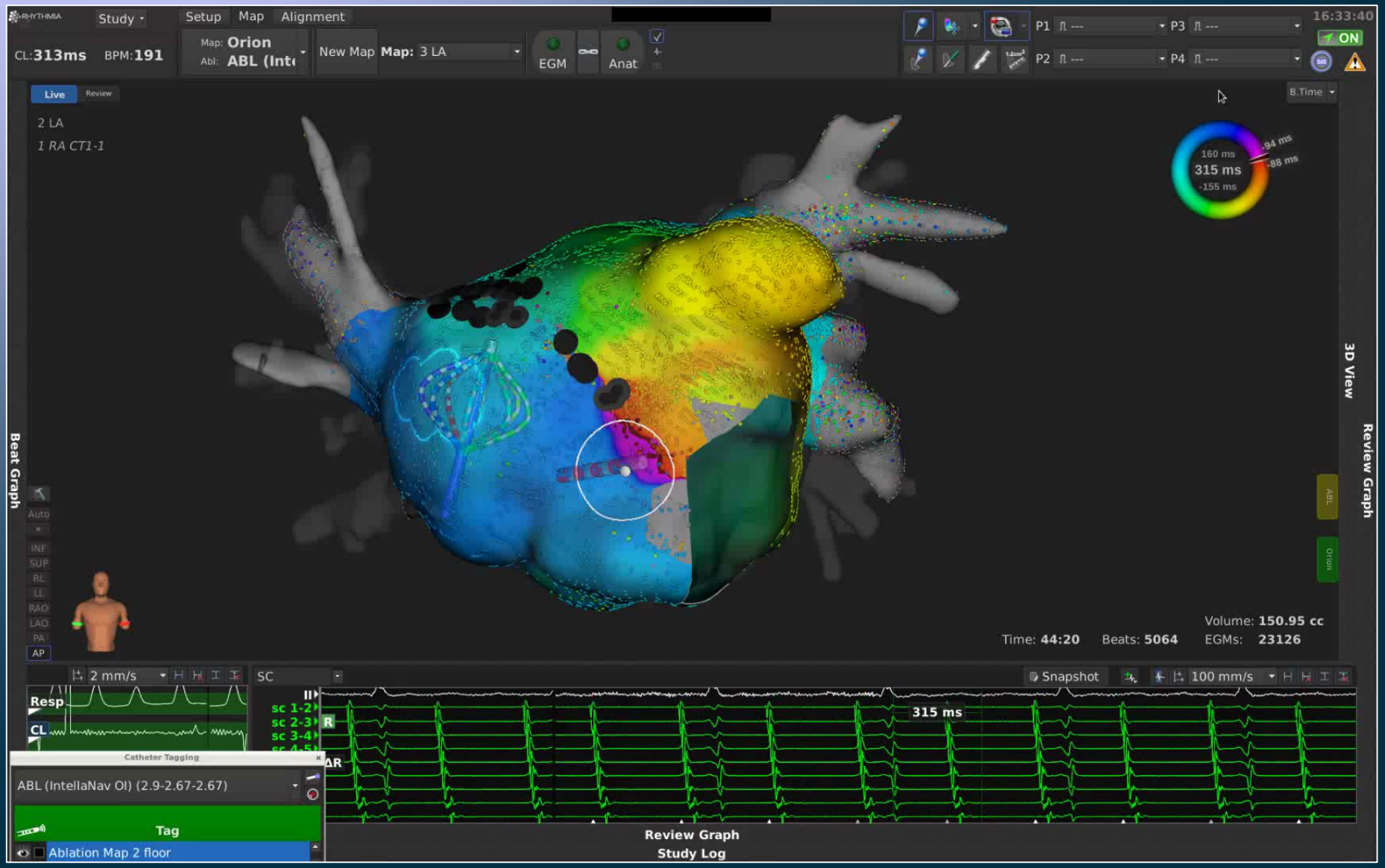
Dual-loop figure-of-eight macro-reentry LAF



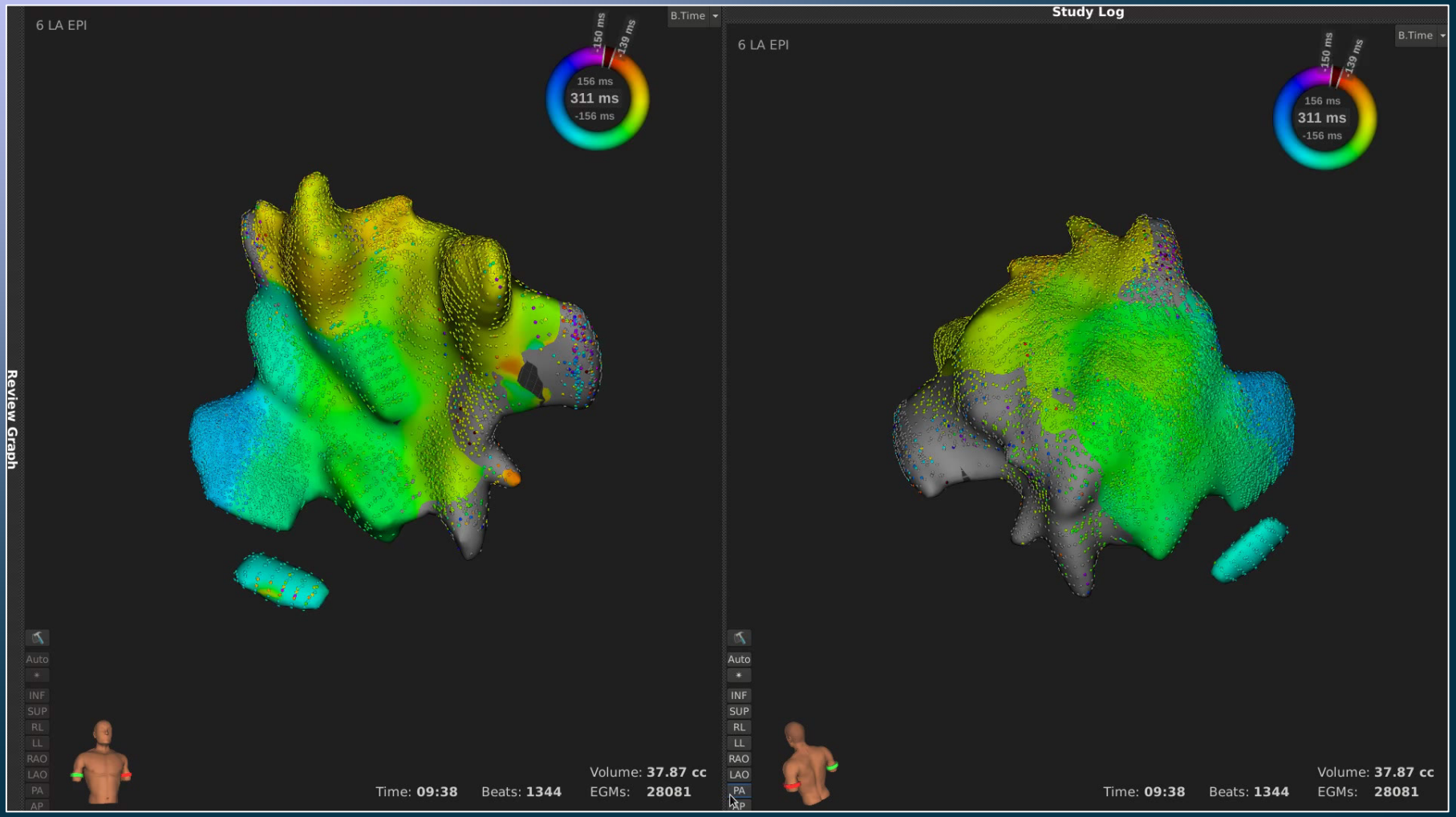
Dual-loop figure-of-eight macro-reentry LAF



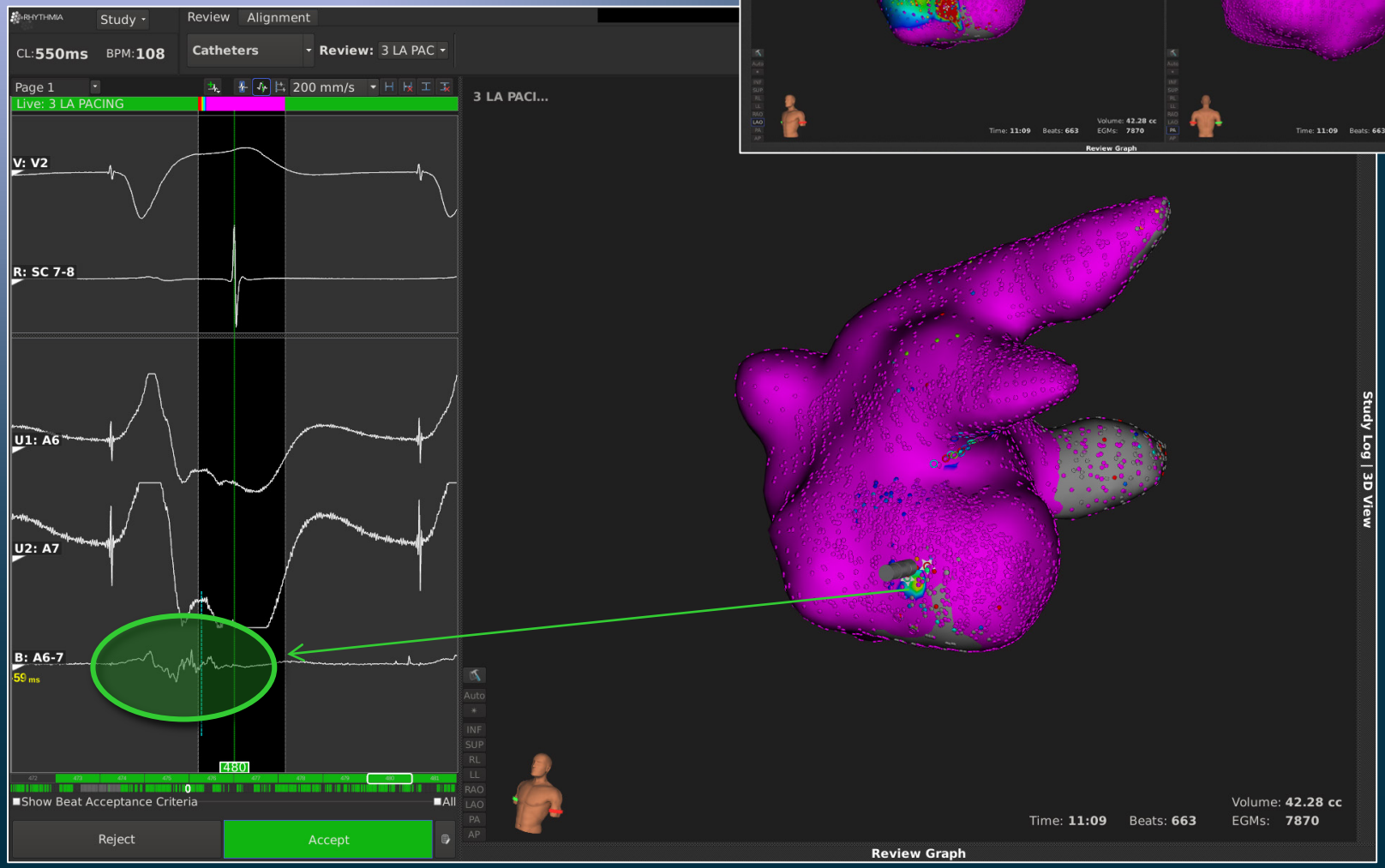
Dual-loop figure-of-eight macro-reentry LAF



Perimitral LAF. Epicardial map



Left sided AP



3. Ventricular tachycardia

- Signal quality
- Revision process
- Mapping of mild-tolerated VT´s
- Fast remaps
- ECG morphology reference

Non ischemic VT

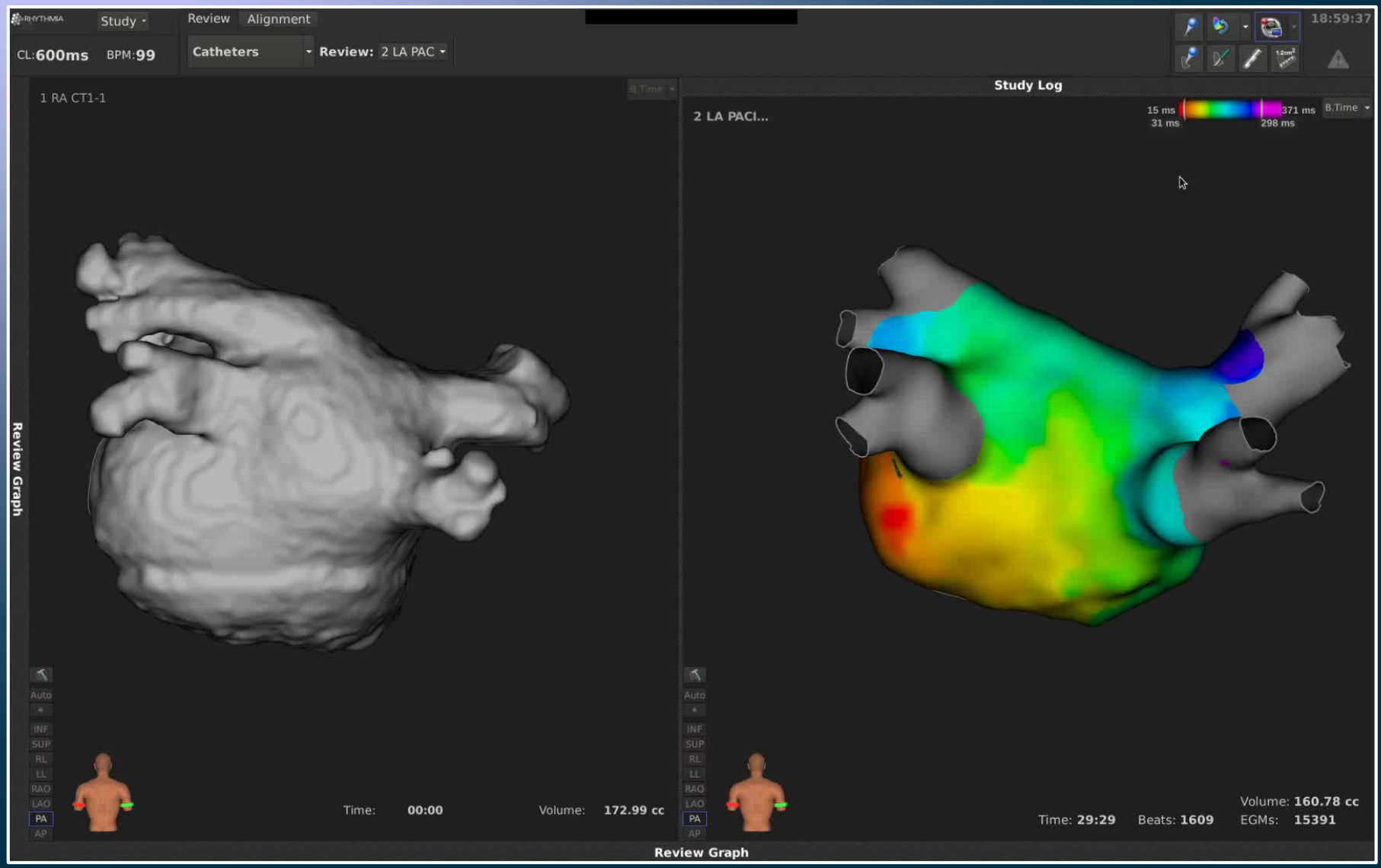
Non ischemic VT

Epicardio/pericardio

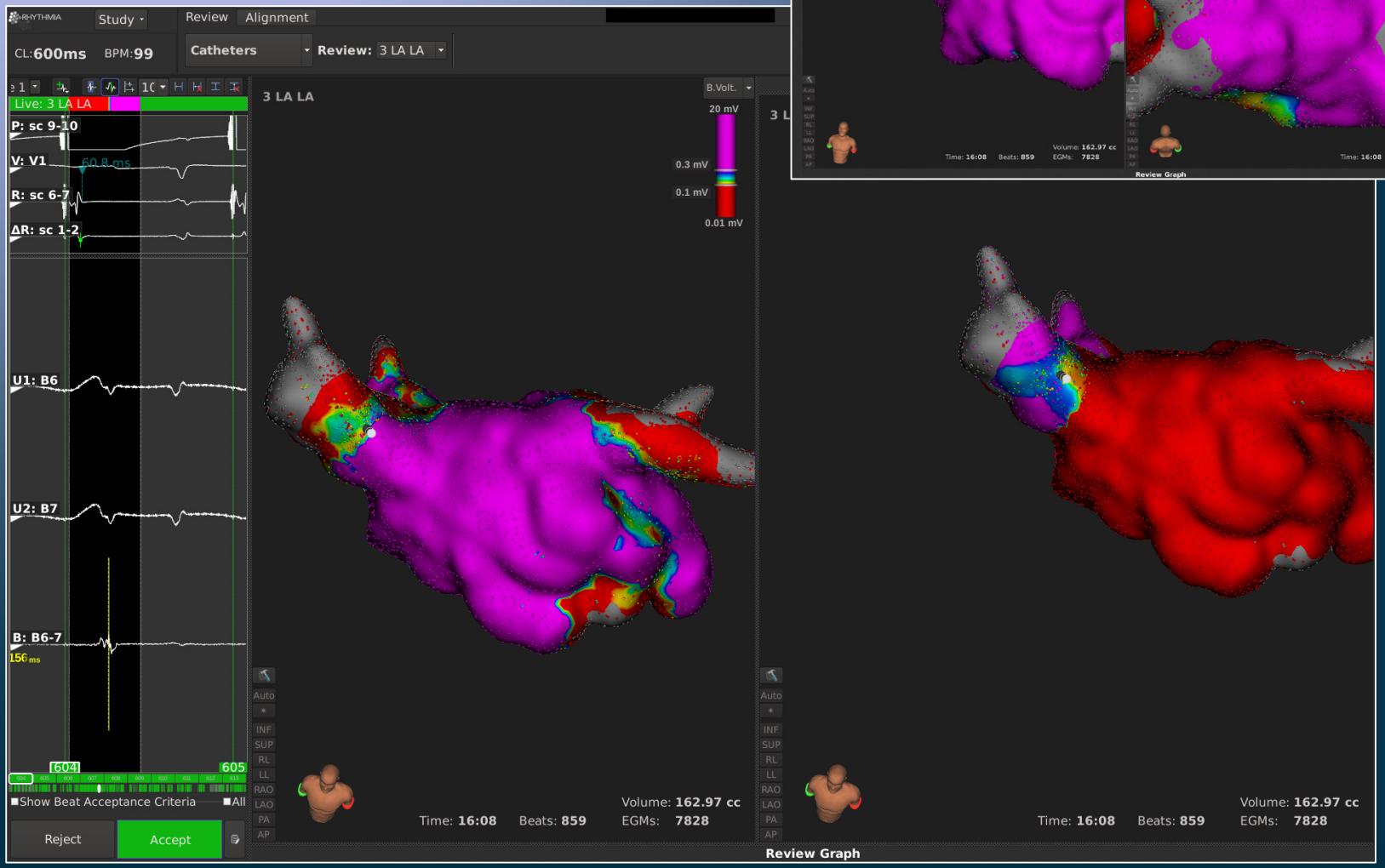
4. Atrial fibrillation

- Performance in the left atrium (Orion)
- Ability to indentify gaps
- High anatomic definition
- Entrance/exit maps
- Identification of FF signals with no further pacing manoeuvers
- Assessment of exit block

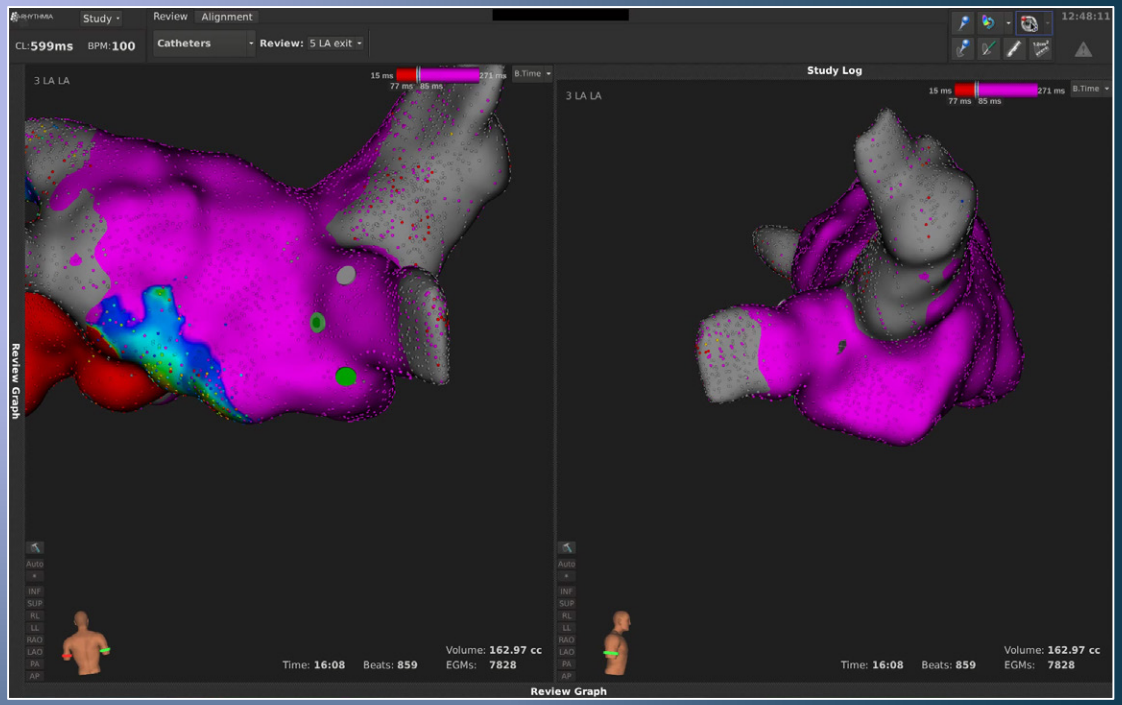
Anatomic resolution

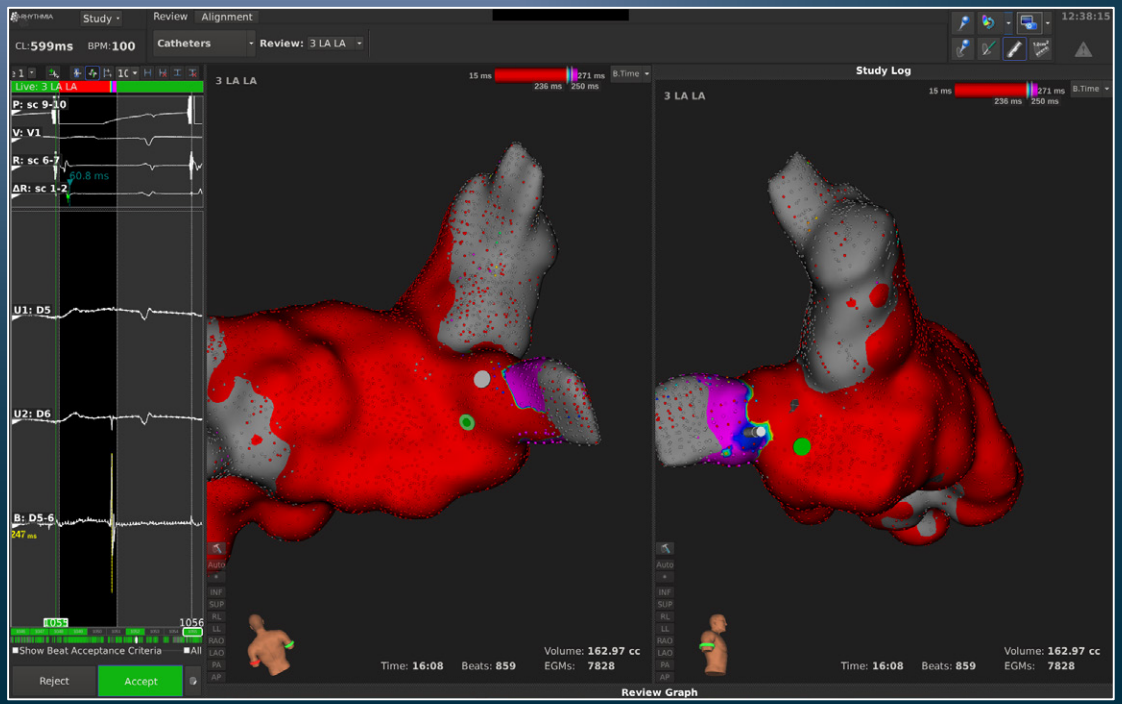


Gap RSPV. Entrance map

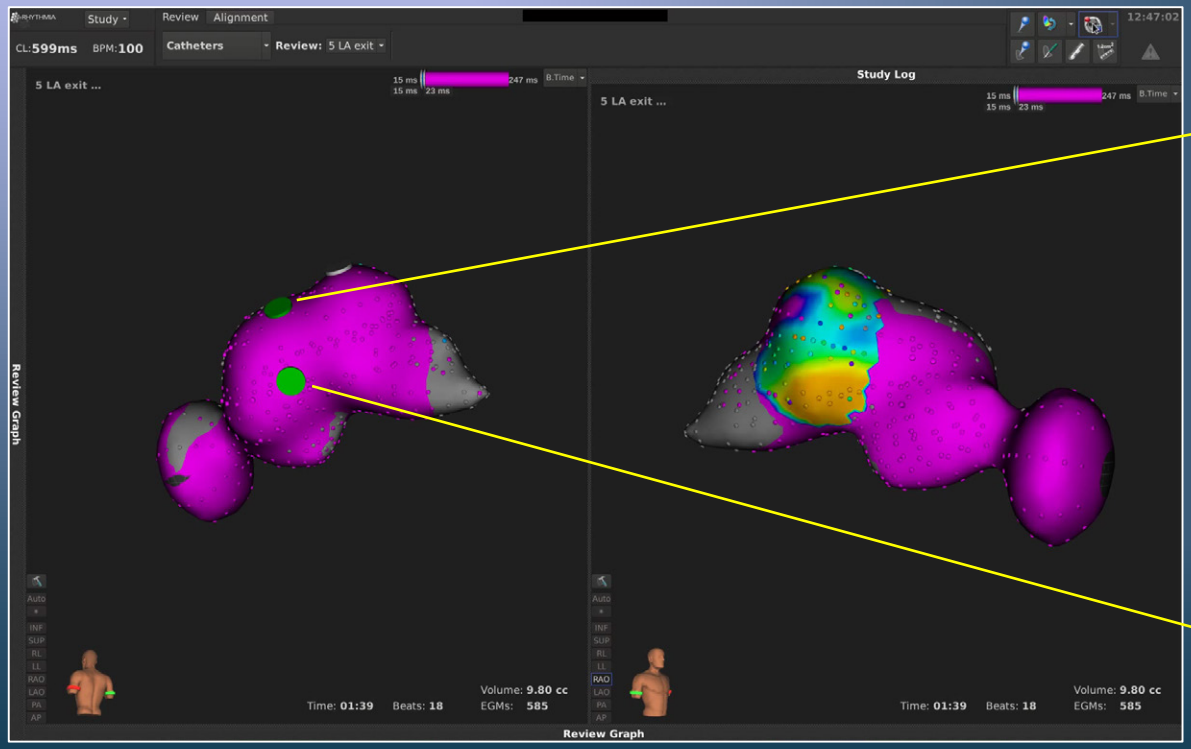


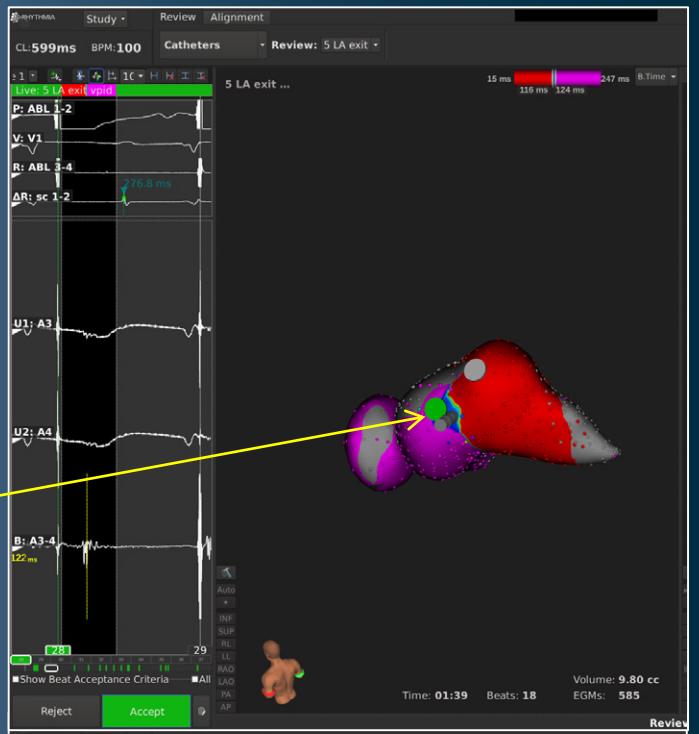
Gap RiPV. Entrance map

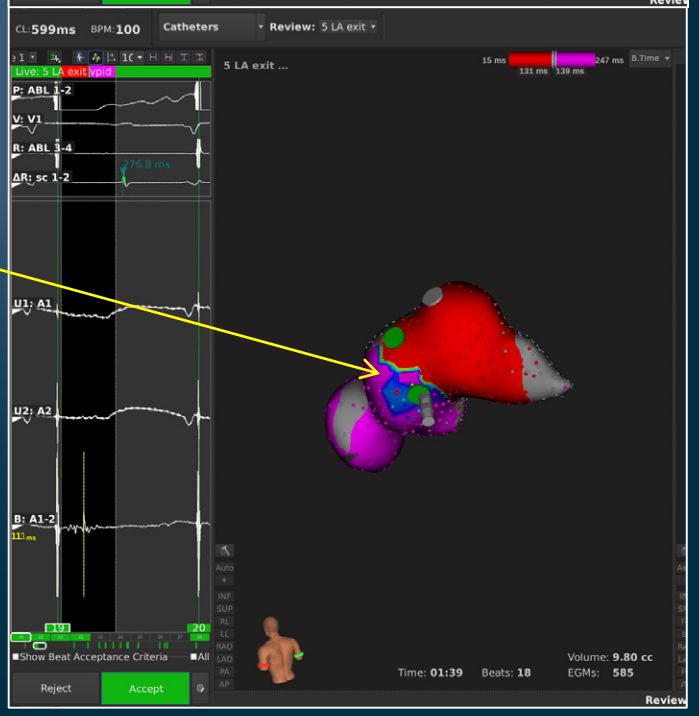




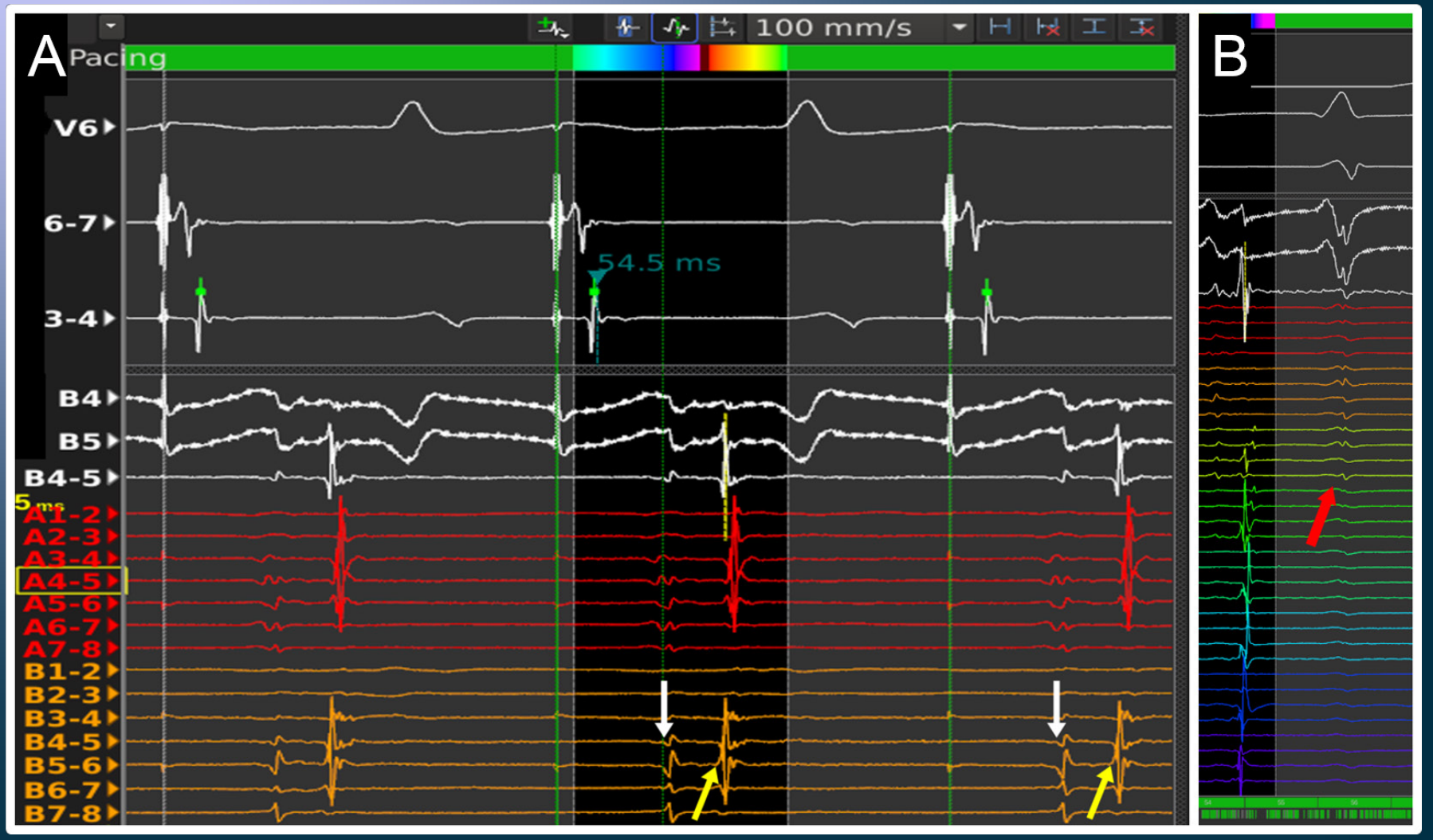
Gap RSPV. Exit map







Analysis of far-field signals



TRUE-HD

500 procedures will be included in up to 40 US, Europe & AMEA sites

- Included arrhythmias/techniques:
  - ✓ Re-do Atrial fibrillation
  - ✓ Left sided Atrial Flutter
  - ✓ Atrial tachycardia
  - ✓ Ventricular tachycardia
  - ✓ Other complex mapped cases, according to investigator's preference or decision
- Excluded arrhythmias/techniques:
  - × De Novo Atrial Fibrillation ablations

Follow up: Discharge post procedure + 1 month

TRUE-HD

1. *Primary Endpoint*

Primary analyses will include, but will not be limited to acute procedural success for all arrhythmias.
The observed rate and 95% confidence interval will be evaluated.

2. *Secondary Endpoint*

Characterize type of treated arrhythmias and ablation techniques.
Procedural success.
Procedural-related complications.
Description of mapping system features used and procedure management: number of acquired maps, type of maps, acquisition time / number of points, planned vs actual approach, numberof RF applications, total procedural time time, fluoroscopy time, number of arrhythmias mapped.

TRUE-HD

Site	Site Name	PI Name
Germany	Herzzentrum Universität Leipzig	Bollmann
Spain	Clinica Universitaria de Navarra	García Bolao
UK	Harefield Hospital	Wong
UK	The Brompton Hospital	Wong
USA	Stern Cardiovascular Foundation, Inc.	Lan
USA	Trinity Mother Frances Health System	Weiner
USA	Good Samaritan Hospital	Winner
USA	OhioHealth Riverside Methodist	Chopra
USA	Maimonides Medical Center	Yang
USA	University of Chicago Hospital	Tung
USA	University of North Carolina Hospital	Mounsey
USA	University of Alabama at Birmingham	Maddox
USA	William Beaumont	Ahmed
Hong Kong	Queen Mary Hospital	Tse

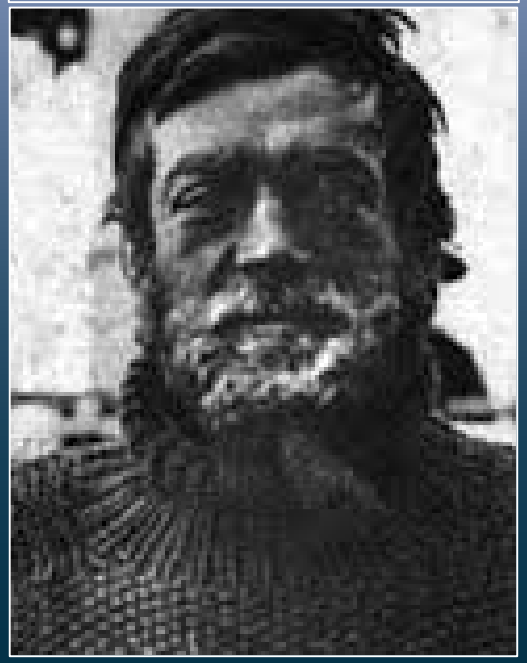
Paroxysmal AF	3
Persistent/Permanent AF	8
Atypical AFl	10
ectopic atrial tachycardia	1
Focal Atrial Tachycardia	5
Incisional (previous atriotomy)rentrance right atrial tachycardia	1
Non-AFl Reentrant Atrial Tachycardia	1
SVT	5
Typical AFl (CW or CCW)	14
Ischemic VT	2
LVOT VT	1
Non-ischemic VT	2
Atrio-Ventricular Nodal Reentrant Tachycardia (AVNRT)	9
Orthodromic Reciprocating Tachycardia (ORT)	2
Premature Ventricular Contraction (PVC)	3
WPW syndrome	1
not yet classified (recent cases)	8
total	76

* Updated on Sep 20th, 2016

Conclusions

- Rhythmia/Orion represents a new concept of high-resolution non-fluoroscopic navigation.
- The main technical features are
    1. The simultaneous acquisiton of up to 64 anatomic and EGMs per beat,
    2. High anatomic resolution,
    3. Highly precise EGM automatic annotation process
    4. The user-friendly depiction of propagation and activation maps.
- It is extremely helpful for macro-reentrant atrial tachycardias, automatic focal arrhythmias and ventricular tachycardias, and it has remarkable advantages for PVI.
- The real clinical value of these features should be assessed with RCT and observational studies.







Ernest Shackleton's Ad

MEN WANTED for hazardous journey. Low wages, bitter cold, long hours of complete darkness. Safe return doubtful. Honor and recognition in event of success

The Times, ca. 1913

Shackleton received over 5000 applications as a result of the letter