

Advanced Robotic Technology for Ablation of AF: V Drive and Ablation History

Winter Arrhythmia, 2015

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- New Emerging Technology for CLA Ablation

Aside from the Ablation catheter,
which other catheter or sheath is most
important to have robotic control?

- A. Lasso
- B. Ultrasound
- C. Fixed Sheath
- D. Steerable Sheath
- E. Pentaray

Vdrive™ Duo System Overview



Vdrive Controller in conjunction with Epoch™ user interface enable remote catheter manipulation from the control room

Support platforms provide catheter shaft support and transmits commands to the drive unit

Disposable drive units translates system commands to catheter handle movements

Patient table controller enables catheter manipulation from the bedside



Epoch™ and Vdrive™ are trademarks of Stereotaxis, Inc.

STEREOTAXIS

Vdrive™ Disposables



V-Sono™

V-Sono ICE

Catheter Manipulator

Provides control of the Biosense Webster SoundStar™ or Siemens AcuNav™ ICE Catheters



***+V-CAS™**

***+V-CAS**

Catheter Advancement System

Controls both the magnetic catheter body and a standard fixed-curve sheath



V-Loop™

V-Loop Circular Catheter Manipulator

Provides control of the Biosense Webster LASSO® 2515 Circular Mapping Catheter and LASSO® 2515 NAV Catheter



***V-CAS™ Deflect**

***V-CAS Deflect**

Catheter Advancement System

Controls both the magnetic catheter body and a robotic deflectable sheath

+ pending FDA review

***Not available for sale in the United States**

*Vdrive™, V-Sono™, V-Loop™ and V-CAS™ are trademarks of Stereotaxis, Inc.
All other trademarks are the property of their respective owners.*

V-Drive with V-Sono



Most important feature of V-Sono is

- A. Stable imaging during Transeptal Access
- B. Real time monitoring for complications
- C. Esophageal imaging for Safety
- D. Carto Sound Mapping
- E. Real time Catheter-Tissue Contact

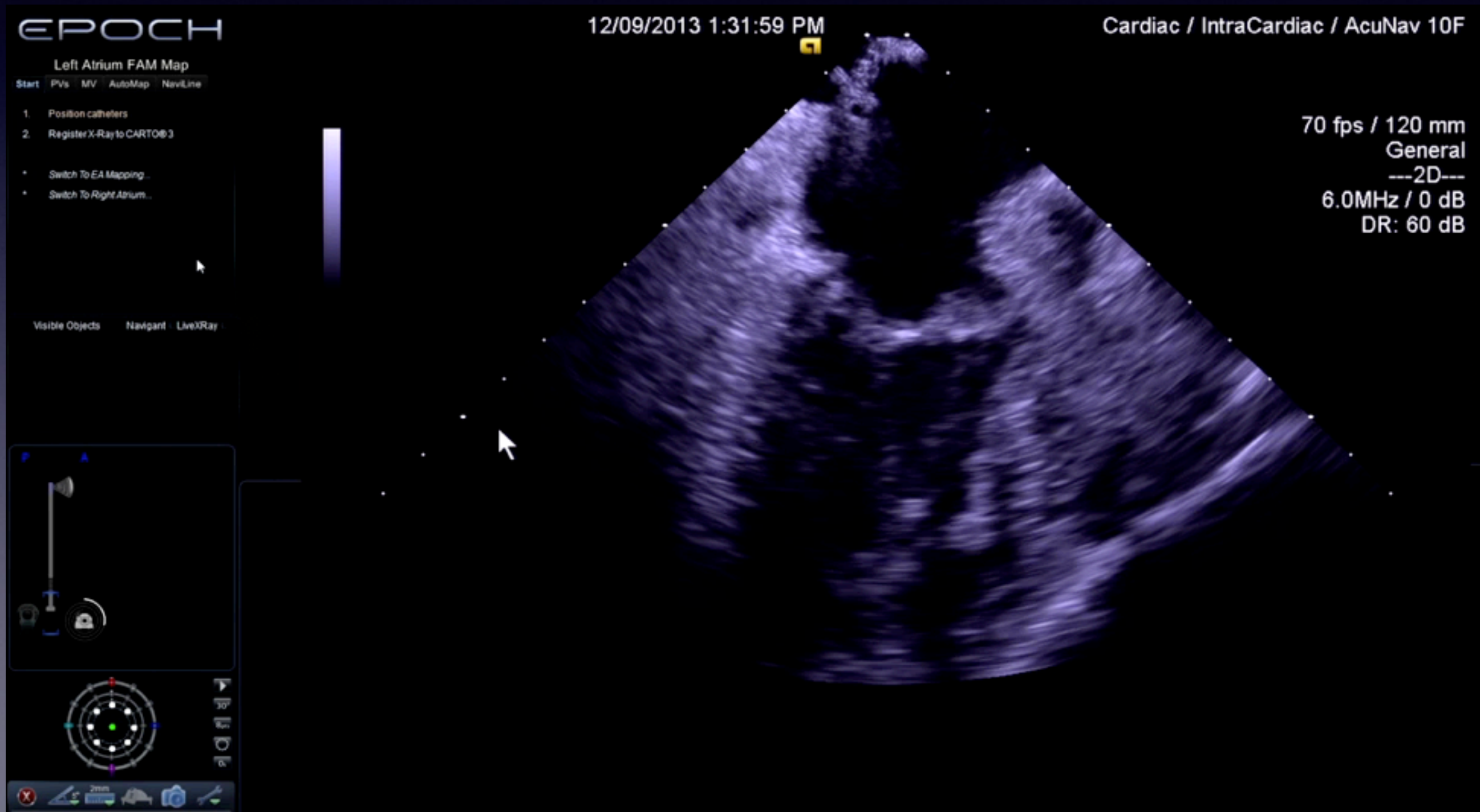
Carto Sound Map can be created with magnets in position?

- A. True
- B. False

V-Sono with 8F Sound-Star

- First to utilize the 8FR soundstar in the US with magnetic navigation
- Allows use of SoundStar Catheter with magnets engaged
- Allows realtime tip visualization, visualization of tags and points on US
- Contour creation with magnets in
- Brings the full utility of V-Sono with magnetic navigation to life

Transeptal with V-Sono



Transeptal with V-Sono

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Cardiac / IntraCardiac / AcuNav 10F

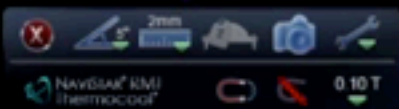
Left Atrium FAM Map

Start PVs MV AutoMap NavLine

1. Position catheters
 2. Register X-Ray to CARTO® 3
- * Switch To EA Mapping...
 - * Switch To Right Atrium...

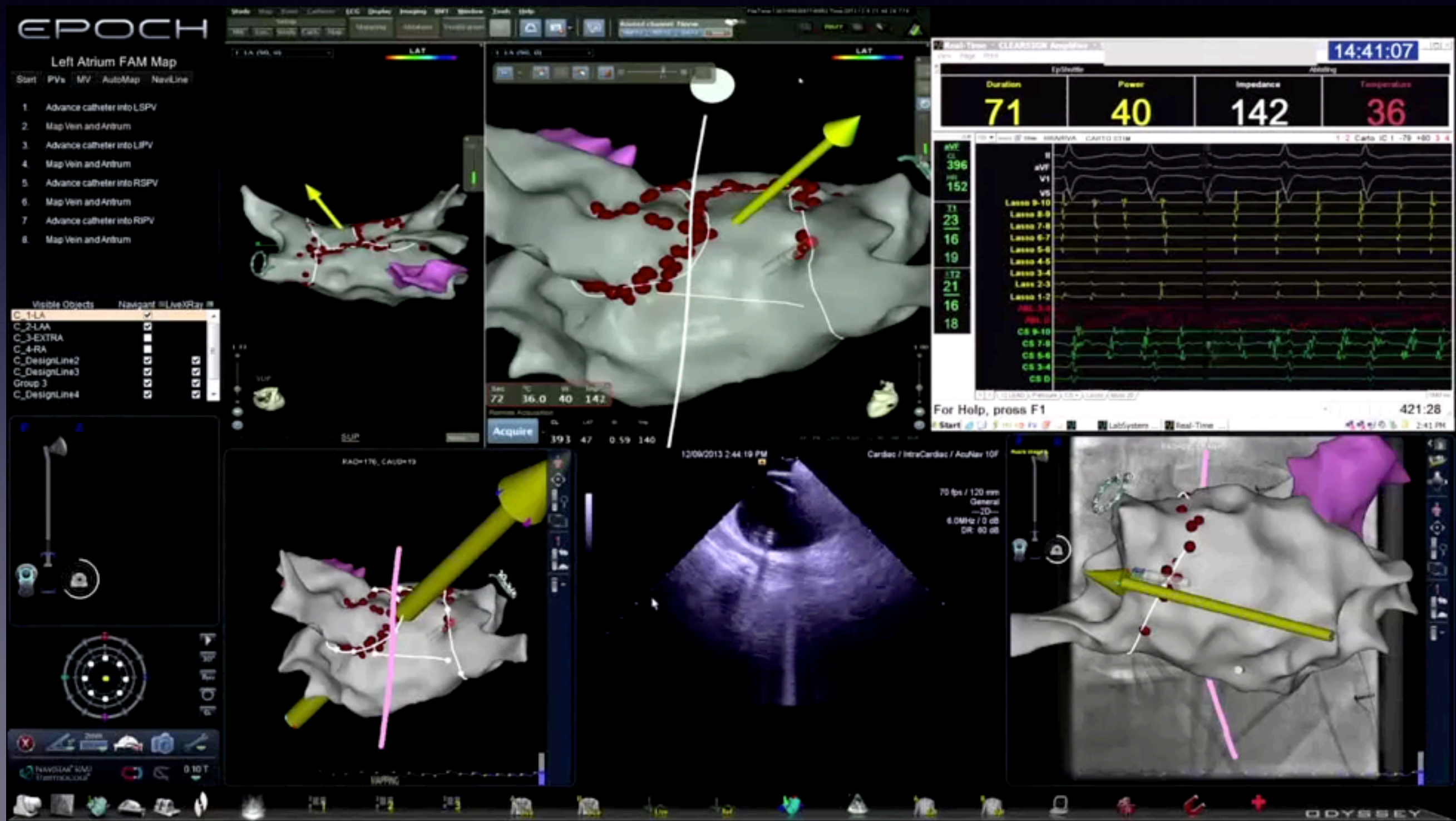
Visible Objects Navigant LiveXRay

70 fps / 120 mm
General
---2D---
6.0MHz / 0 dB
DR: 60 dB



ODYSSEY

Catheter-Tissue Contact: Visualized

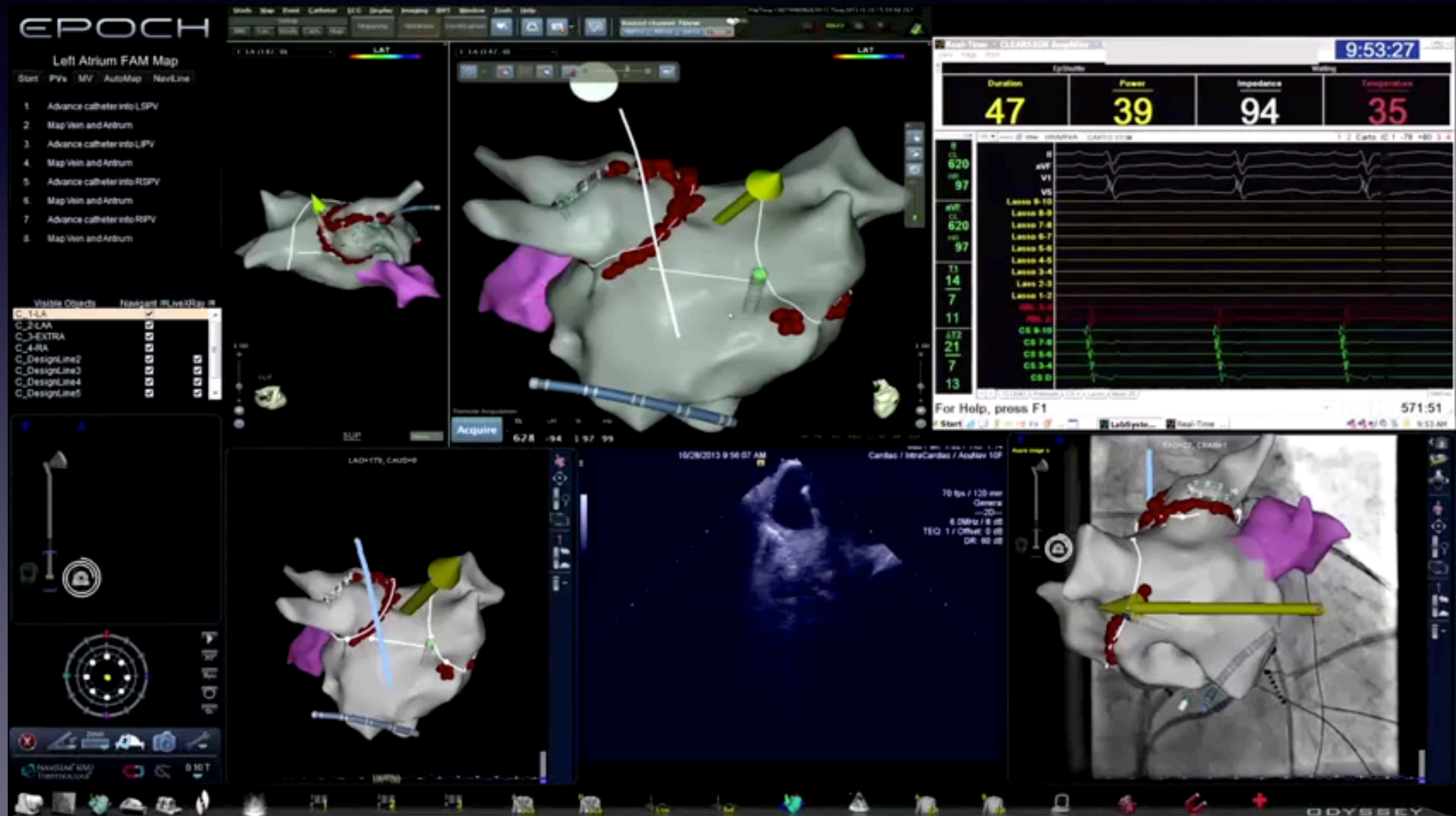


Does the catheter have good contact?

- A. Yes
- B. No

Do I have Contact?

The answer



Does the catheter have good contact?

- A. Yes
- B. No

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Left Atrium FAM Map

Start PVs MV AutoMap NavLine

1. Advance catheter into LSPV
2. Map Vein and Antrum
3. Advance catheter into LIPV
4. Map Vein and Antrum
5. Advance catheter into RSPV
6. Map Vein and Antrum
7. Advance catheter into RIPV
8. Map Vein and Antrum

12 Channel Temperature Monitor

Warning	Max	Min
35.4	35.4	35.4
35.4	35.3	35.3
35.2	35.2	35.2
37.4	37.3	37.3
35.2	35.2	35.2
35.8	35.8	35.8
37.4	35.4	35.4

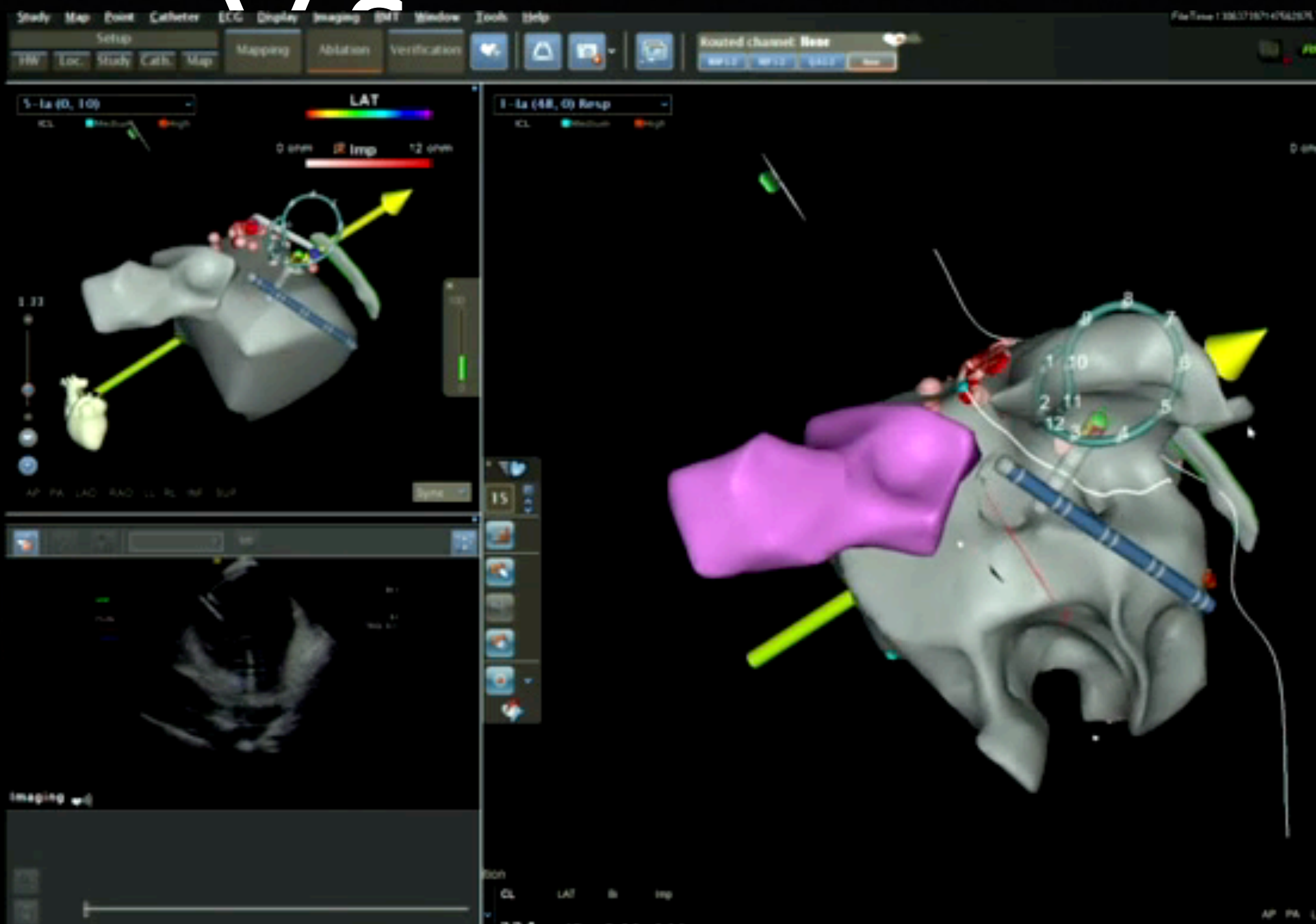
Temperature (°C)

Audio Off

Max Min Temperature Channel Graphs Set Up

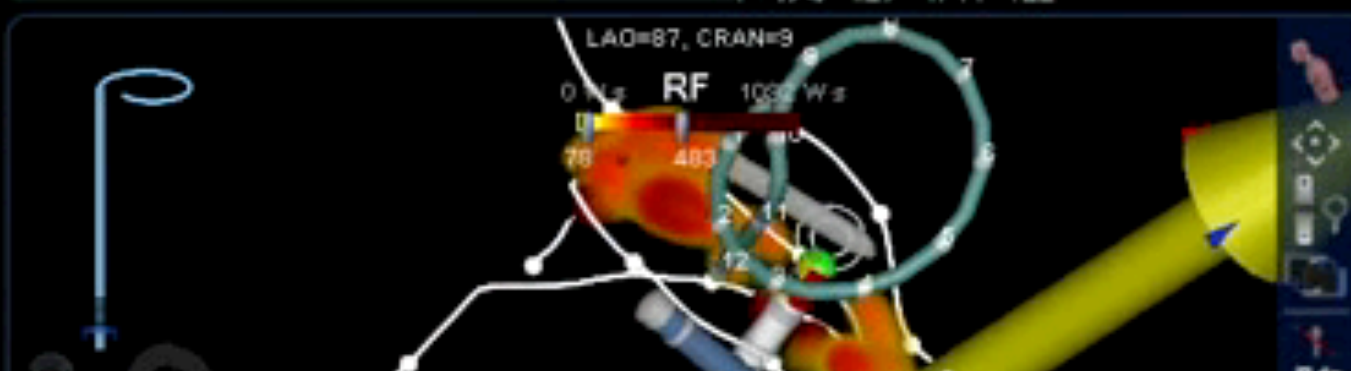
Temperature (°C)	Audio
Alarm High	Low Volume
Warning High	Warning
Warning Low	Alarm
Alarm Low	
Graph Maximum	42.0
Graph Minimum	16.0

Shut Down



Visible Objects

Visible Objects	Navigator	LiveXRay
Carto Tags	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
C_1-la	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
C_2-laa	<input type="checkbox"/>	<input type="checkbox"/>
C_3-ra fam	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
C_4-RA	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
C_5-la	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
C_6-lipv	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>



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Benefits of V-Sono

- Stability of US imaging can guide therapy
- Tip Visualization, Contour Creation
- Catheter Tip-Tissue interface
- A future where the tip is automatically tracked to provide constant feedback of catheter position

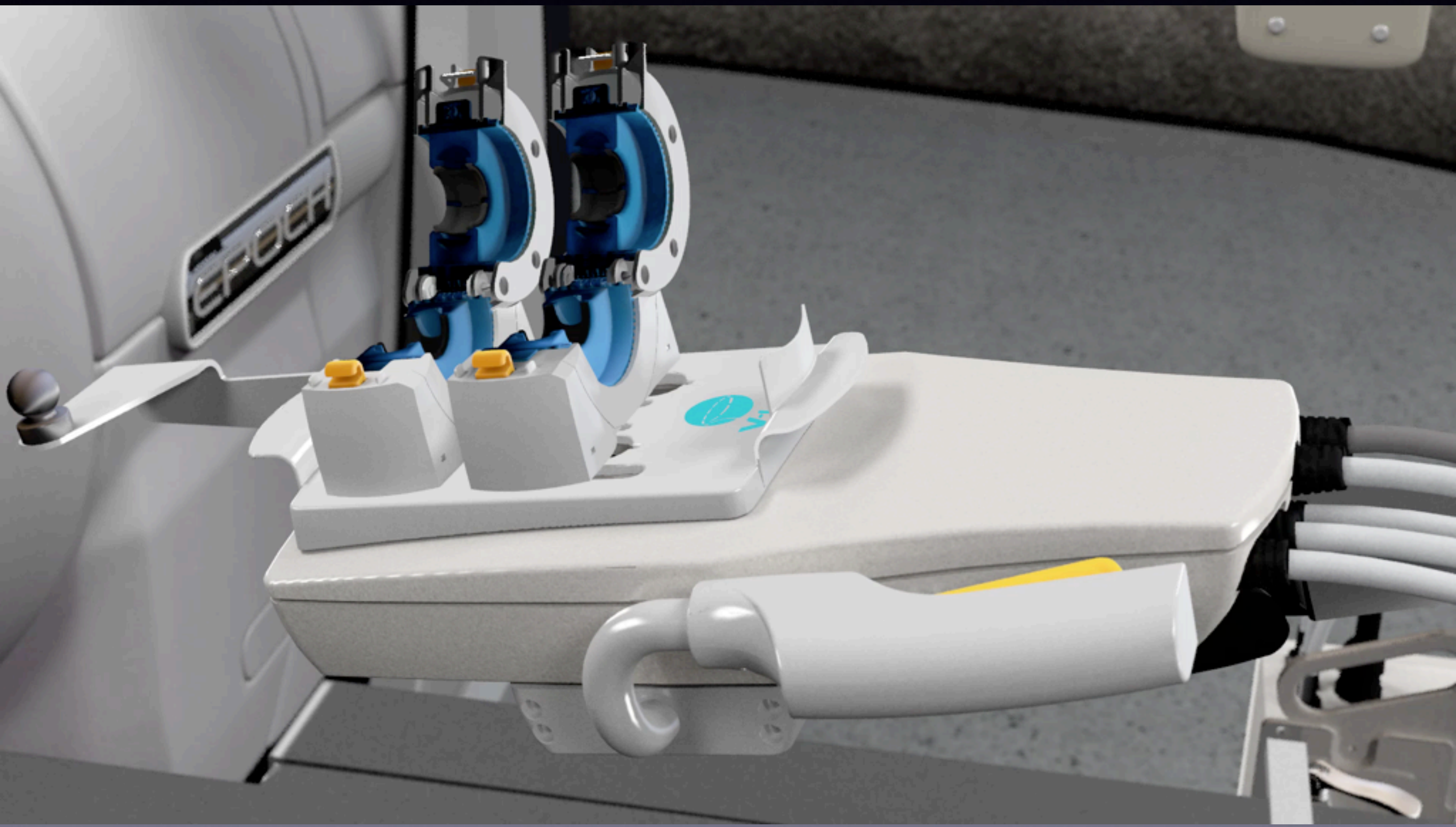
V-Loop

- Robotic Control of the Lasso Catheter
- Reduced need to approach table to adjust and reposition the Lasso
- Recently FDA approved in the US
- Limited Experience

Do you use a lasso catheter for AF ablation?

- A. Yes, Only for confirmation of Pulmonary Vein isolation.
- B. Yes, for confirmation of vein isolation, mapping and ablation outside the veins.
- C. No, I do not use lasso at all.

V-Loop



Will V-Loop be more important for PAF or Pe AF cases?

- A. PAF
- B. Persistent AF

V-Loop-Initial Experience

- Paroxysmal
 - Verification of vein isolation during ablation
 - Less downtime repositioning lasso
- Persistent
 - Huge difference
 - stable positioning on posterior wall
 - allows for isolation of PV utilizing lasso guided technique
 - minimize extra ablation on posterior wall

EPOCH

Left Atrium FAM Map

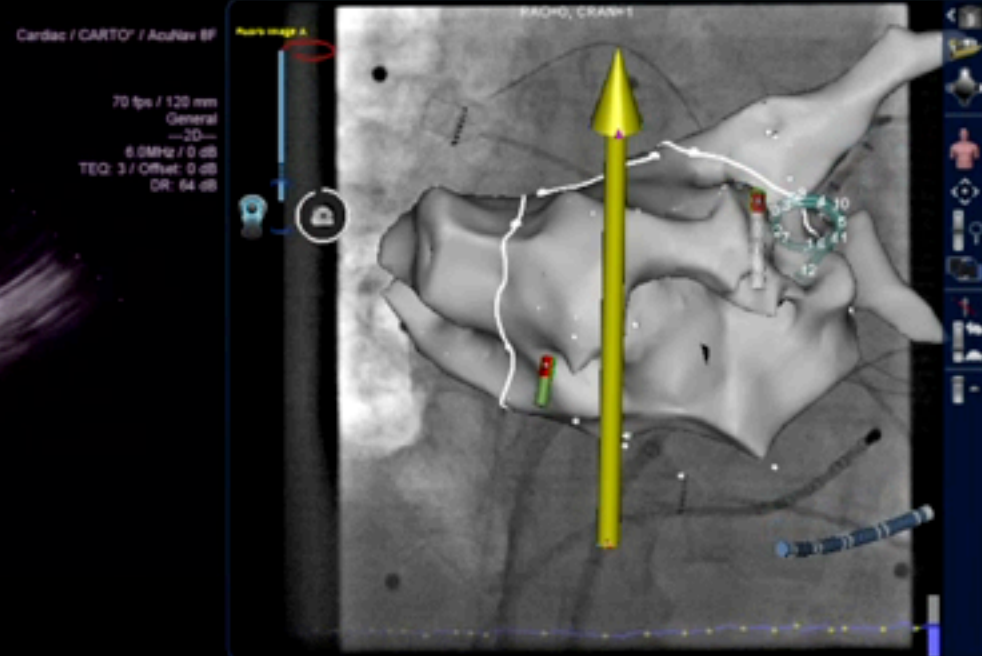
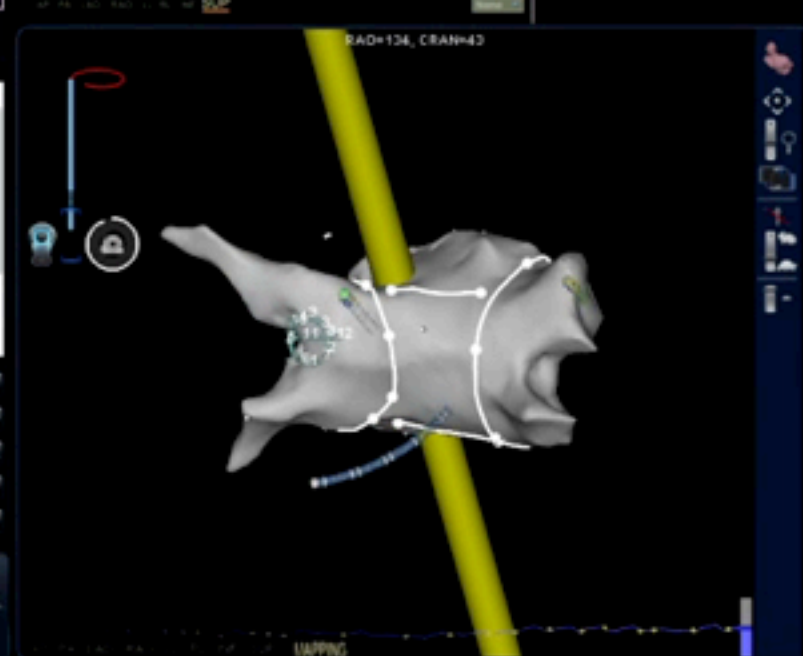
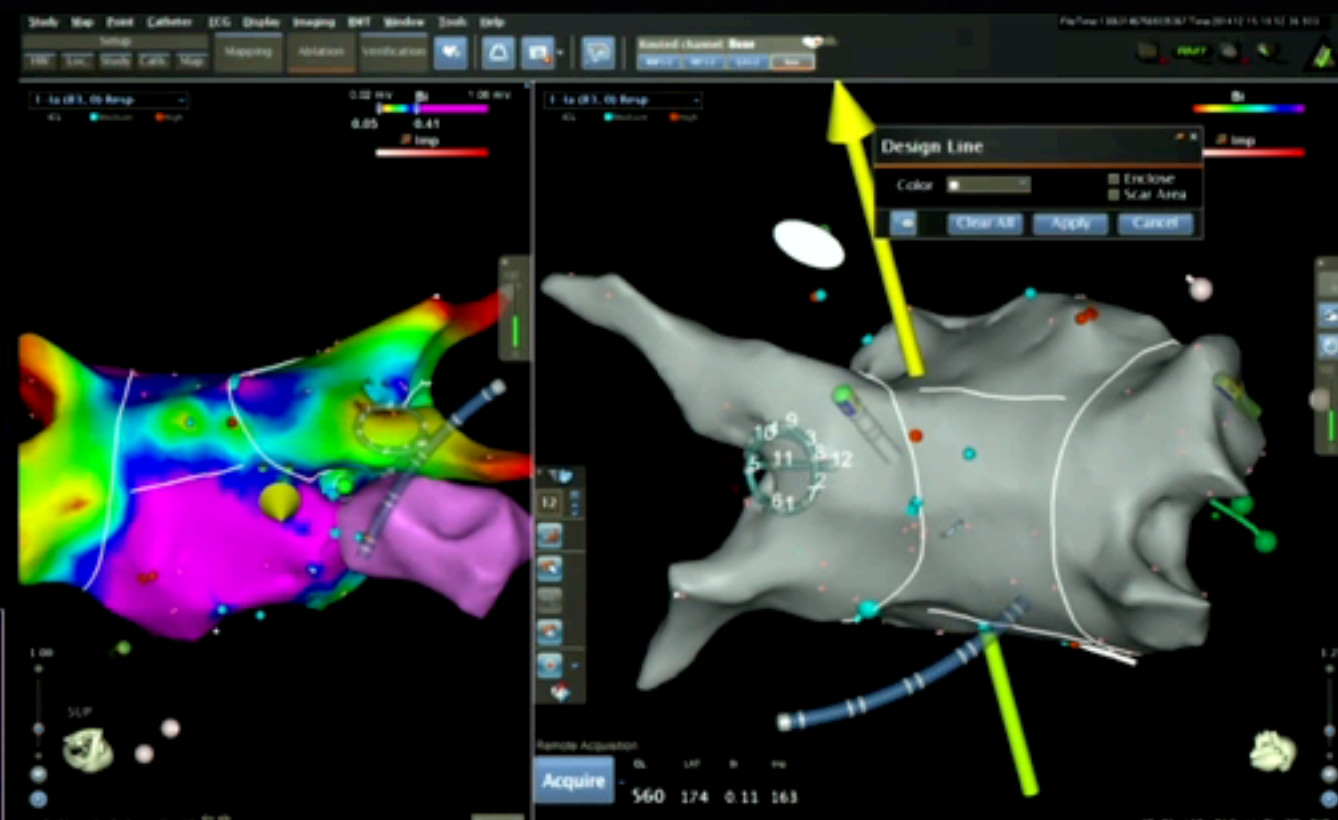
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4. Map Vein and Antrum
5. Advance catheter into RSPV
6. Map Vein and Antrum
7. Advance catheter into RIPV
8. Map Vein and Antrum

12 Channel Temperature Monitor	Temperature (°C)	Alert
1	37.8	OK
2	37.8	OK
3	37.8	OK
4	37.8	OK
5	37.8	OK
6	37.8	OK
7	37.8	OK
8	37.8	OK
9	37.8	OK
10	37.8	OK
11	37.8	OK
12	37.8	OK

Visible Objects
Carto Tags

- C_1-1a
- C_2-1a
- C_3-extra
- C_4-ra
- C_5-1a
- C_6-1a
- C_7-lpv
- C_8-lspv
- C_9-esoph
- C_10-ripv
- C_11-rspv
- C_DesignLine2



Ablation History

1. Records the path followed by the ablation catheter during RF delivery.
2. Integrates the two most important factors in lesion creation, power and time. Given the consistent contact the Niobe® system provides, force is treated as a constant.
3. Helps guide contiguous energy delivery during the creation of linear lesion sets.
4. Scale can be adjusted depending on anatomic location. e.g. posterior wall vs anterior ridge.

EPOCH

Left Atrium FAM Map

Start PVs MV AutoMap NavLine

1. Advance catheter into LSPV
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5. Advance catheter into RSPV
6. Map Vein and Antrum
7. Advance catheter into RIPV
8. Map Vein and Antrum

Channel	Temperature	Channel	Temp	Temp	Temp
1	35.7	2	35.7	3	35.7
4	35.7	5	35.7	6	35.7
7	35.7	8	35.7	9	35.7
10	35.7	11	35.7	12	35.7
13	35.7	14	35.7	15	35.7
16	35.7	17	35.7	18	35.7
19	35.7	20	35.7	21	35.7
22	35.7	23	35.7	24	35.7
25	35.7	26	35.7	27	35.7
28	35.7	29	35.7	30	35.7
31	35.7	32	35.7	33	35.7
34	35.7	35	35.7	36	35.7
37	35.7	38	35.7	39	35.7
40	35.7	41	35.7	42	35.7
43	35.7	44	35.7	45	35.7
46	35.7	47	35.7	48	35.7
49	35.7	50	35.7	51	35.7
52	35.7	53	35.7	54	35.7
55	35.7	56	35.7	57	35.7
58	35.7	59	35.7	60	35.7
61	35.7	62	35.7	63	35.7
64	35.7	65	35.7	66	35.7
67	35.7	68	35.7	69	35.7
70	35.7	71	35.7	72	35.7
73	35.7	74	35.7	75	35.7
76	35.7	77	35.7	78	35.7
79	35.7	80	35.7	81	35.7
82	35.7	83	35.7	84	35.7
85	35.7	86	35.7	87	35.7
88	35.7	89	35.7	90	35.7
91	35.7	92	35.7	93	35.7
94	35.7	95	35.7	96	35.7
97	35.7	98	35.7	99	35.7
100	35.7	101	35.7	102	35.7
103	35.7	104	35.7	105	35.7
106	35.7	107	35.7	108	35.7
109	35.7	110	35.7	111	35.7
112	35.7	113	35.7	114	35.7
115	35.7	116	35.7	117	35.7
118	35.7	119	35.7	120	35.7
121	35.7	122	35.7	123	35.7
124	35.7	125	35.7	126	35.7
127	35.7	128	35.7	129	35.7
130	35.7	131	35.7	132	35.7
133	35.7	134	35.7	135	35.7
136	35.7	137	35.7	138	35.7
139	35.7	140	35.7	141	35.7
142	35.7	143	35.7	144	35.7
145	35.7	146	35.7	147	35.7
148	35.7	149	35.7	150	35.7
151	35.7	152	35.7	153	35.7
154	35.7	155	35.7	156	35.7
157	35.7	158	35.7	159	35.7
160	35.7	161	35.7	162	35.7
163	35.7	164	35.7	165	35.7
166	35.7	167	35.7	168	35.7
169	35.7	170	35.7	171	35.7
172	35.7	173	35.7	174	35.7
175	35.7	176	35.7	177	35.7
178	35.7	179	35.7	180	35.7
181	35.7	182	35.7	183	35.7
184	35.7	185	35.7	186	35.7
187	35.7	188	35.7	189	35.7
190	35.7	191	35.7	192	35.7
193	35.7	194	35.7	195	35.7
196	35.7	197	35.7	198	35.7
199	35.7	200	35.7	201	35.7
202	35.7	203	35.7	204	35.7
205	35.7	206	35.7	207	35.7
208	35.7	209	35.7	210	35.7
211	35.7	212	35.7	213	35.7
214	35.7	215	35.7	216	35.7
217	35.7	218	35.7	219	35.7
220	35.7	221	35.7	222	35.7
223	35.7	224	35.7	225	35.7
226	35.7	227	35.7	228	35.7
229	35.7	230	35.7	231	35.7
232	35.7	233	35.7	234	35.7
235	35.7	236	35.7	237	35.7
238	35.7	239	35.7	240	35.7
241	35.7	242	35.7	243	35.7
244	35.7	245	35.7	246	35.7
247	35.7	248	35.7	249	35.7
250	35.7	251	35.7	252	35.7
253	35.7	254	35.7	255	35.7
256	35.7	257	35.7	258	35.7
259	35.7	260	35.7	261	35.7
262	35.7	263	35.7	264	35.7
265	35.7	266	35.7	267	35.7
268	35.7	269	35.7	270	35.7
271	35.7	272	35.7	273	35.7
274	35.7	275	35.7	276	35.7
277	35.7	278	35.7	279	35.7
280	35.7	281	35.7	282	35.7
283	35.7	284	35.7	285	35.7
286	35.7	287	35.7	288	35.7
289	35.7	290	35.7	291	35.7
292	35.7	293	35.7	294	35.7
295	35.7	296	35.7	297	35.7
298	35.7	299	35.7	300	35.7
301	35.7	302	35.7	303	35.7
304	35.7	305	35.7	306	35.7
307	35.7	308	35.7	309	35.7
310	35.7	311	35.7	312	35.7
313	35.7	314	35.7	315	35.7
316	35.7	317	35.7	318	35.7
319	35.7	320	35.7	321	35.7
322	35.7	323	35.7	324	35.7
325	35.7	326	35.7	327	35.7
328	35.7	329	35.7	330	35.7
331	35.7	332	35.7	333	35.7
334	35.7	335	35.7	336	35.7
337	35.7	338	35.7	339	35.7
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343	35.7	344	35.7	345	35.7
346	35.7	347	35.7	348	35.7
349	35.7	350	35.7	351	35.7
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358	35.7	359	35.7	360	35.7
361	35.7	362	35.7	363	35.7
364	35.7	365	35.7	366	35.7
367	35.7	368	35.7	369	35.7
370	35.7	371	35.7	372	35.7
373	35.7	374	35.7	375	35.7
376	35.7	377	35.7	378	35.7
379	35.7	380	35.7	381	35.7
382	35.7	383	35.7	384	35.7
385	35.7	386	35.7	387	35.7
388	35.7	389	35.7	390	35.7
391	35.7	392	35.7	393	35.7
394	35.7	395	35.7	396	35.7
397	35.7	398	35.7	399	35.7
400	35.7	401	35.7	402	35.7
403	35.7	404	35.7	405	35.7
406	35.7	407	35.7	408	35.7
409	35.7	410	35.7	411	35.7
412	35.7	413	35.7	414	35.7
415	35.7	416	35.7	417	35.7
418	35.7	419	35.7	420	35.7
421	35.7	422	35.7	423	35.7
424	35.7	425	35.7	426	35.7
427	35.7	428	35.7	429	35.7
430	35.7	431	35.7	432	35.7
433	35.7	434	35.7	435	35.7
436	35.7	437	35.7	438	35.7
439	35.7	440	35.7	441	35.7
442	35.7	443	35.7	444	35.7
445	35.7	446	35.7	447	35.7
448	35.7	449	35.7	450	35.7
451	35.7	452	35.7	453	35.7
454	35.7	455	35.7	456	35.7
457	35.7	458	35.7	459	35.7
460	35.7	461	35.7	462	35.7
463	35.7	464	35.7	465	35.7
466	35.7	467	35.7	468	35.7
469	35.7	470	35.7	471	35.7
472	35.7	473	35.7	474	35.7
475	35.7	476	35.7	477	35.7
478	35.7	479	35.7	480	35.7
481	35.7	482	35.7	483	35.7
484	35.7	485	35.7	486	35.7
487	35.7	488	35.7	489	35.7
490	35.7	491	35.7	492	35.7
493	35.7	494	35.7	495	35.7
496	35.7	497	35.7	498	35.7
499	35.7	500	35.7	501	35.7
502	35.7	503	35.7	504	35.7
505	35.7	506	35.7	507	35.7
508	35.7	509	35.7	510	35.7
511	35.7	512	35.7	513	35.7
514	35.7	515	35.7	516	35.7
517	35.7	518	35.7	519	35.7
520	35.7	521	35.7	522	35.7
523	35.7	524	35.7	525	35.7
526	35.7	527	35.7	528	35.7
529	35.7	530	35.7	531	35.7
532	35.7	533	35.7	534	35.7
535	35.7	536	35.7	537	35.7
538	35.7	539	35.7	540	35.7
541	35.7	542	35.7	543	35.7
544	35.7	545	35.7	546	35.7
547	35.7	548	35.7	549	35.7
550	35.7	551	35.7	552	35.7
553	35.7	554	35.7	555	35.7
556	35.7	557	35.7	558	35.7
559	35.7	560	35.7	561	35.7
562	35.7	563	35.7	564	35.7
565	35.7	566	35.7	567	35.7
568	35.7	569	35.7	570	35.7
571	35.7	572	35.7	573	35.7
574	35.7	575	35.7	576	35.7
577	35.7	578	35.7	579	35.7
580	35.7	581	35.7	582	35.7
583	35.7	584	35.7	585	35.7
586	35.7	587	35.7	588	35.7
589	35.7	590	35.7	591	35.7
592	35.7	593	35.7	594	35.7
595	35.7	596	35.7	597	35.7
598	35.7	599	35.7	600	35.7
601	35.7	602	35.7	603	35.7
604	35.7	605	35.7	606	35.7
607	35.7	608	35.7	609	35.7
610	35.7	611	35.7	612	35.7
613	35.7	614	35.7	615	35.7
616	35.7	617	35.7	618	35.7
619	35.7	620	35.7	621	35.7
622	35.7	623	35.7	624	35.7
625	35.7	626	35.7	627	35.7
628	35.7	629	35.7	630	35.7
631	35.7	632	35.7	633	35.7
634	35.7	635	35.7	636	35.7
637	35.7	638	35.7	639	35.7
640	35.7	641	35.7	642	35.7
643	35.7	644	35.7	645	35.7
646	35.7	647	35.7	648	35.7
649	35.7	650	35.7	651	35.7
652	35.7	653	35.7	654	35.7
655	35.7	656	35.7	657	35.7
658	35.7	659	35.7	660	35.7
661	35.7	662	35.7	663	35.7
664	35.7</				

Gap Finding



Ablation History

- First Pass isolation
- Clearer understanding of how many $W \times S$ are necessary and sufficient for durable isolation

Future Wish List

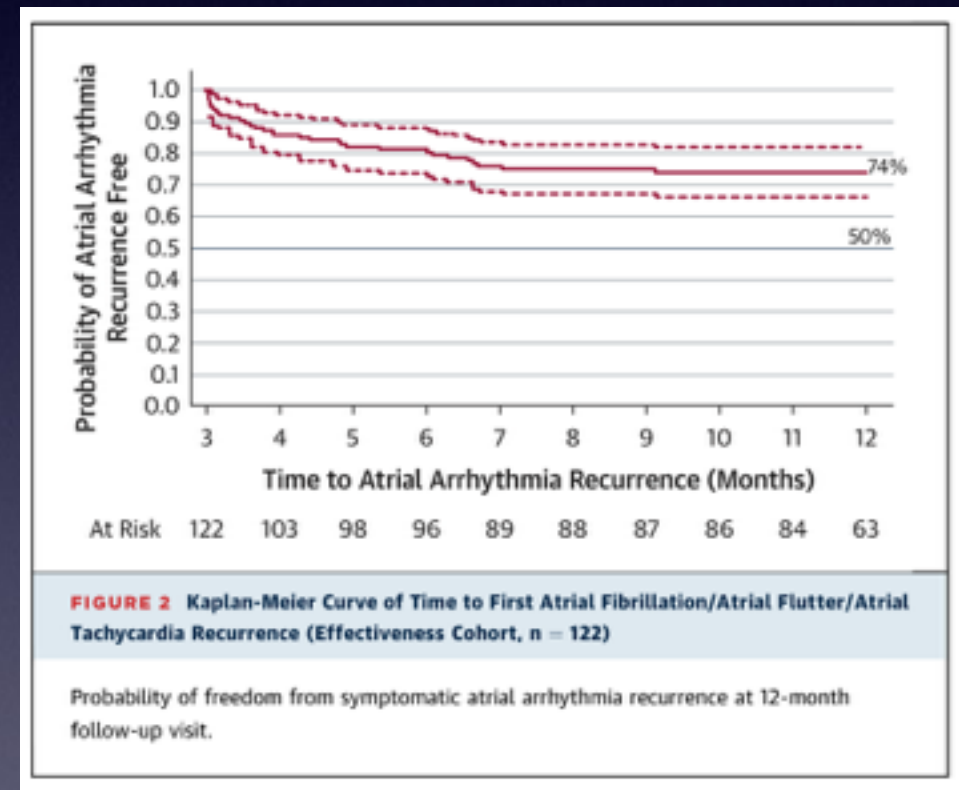
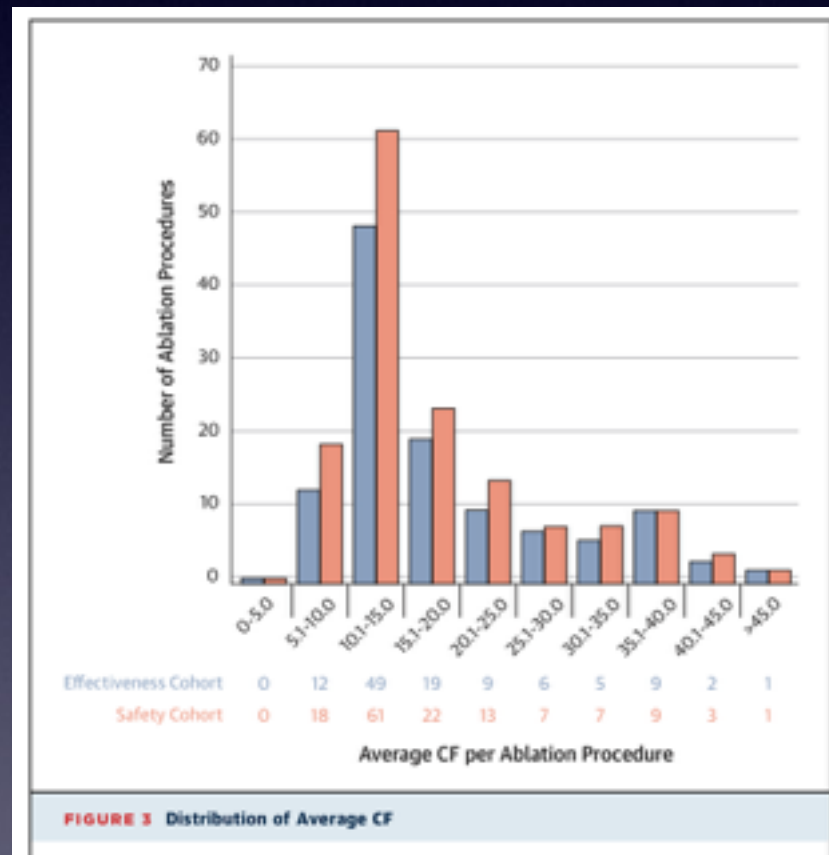
- Contact Sensor for current catheter
- Catheter with surround flow technology
- Guide therapy with ablation history
 - determine minimum power and time which is necessary and sufficient to produce durable lesions
- Tip tracking with automation
- Versatility for V-loop to steer other catheters such as penta ray and dual loop lasso.
- Further development to allow Multi electrode Mapping with magnets engaged

Thank you!

Lesion Formation: Force, Time and Power

- Lessons learned from the Smart-AF Contact Force Catheter Trial
 - Contact and Force are important
 - Maintaining a minimum amount of force during lesion formation is critical for success

Smart-AF Trial



Contact Force

Dataset	No. of Pts	12-Month Success (AF/AT-free)
SMART-AF ($\geq 80\%$ time within preselected contact force range)	51	81%
SMART-AF ($< 80\%$ time within preselected contact force range)	57	66%
Non Force-Sensing Open-Irrigated Catheter*	106	66%

CENTRAL ILLUSTRATION Outcomes Comparison With Various Types and Forces of Ablation Catheters

Twelve-month success rates, defined as freedom from atrial fibrillation (AF) and/or atrial tachycardia (AT) events, with various types and forces of ablation catheters. *Data for this row from Wilber (12).

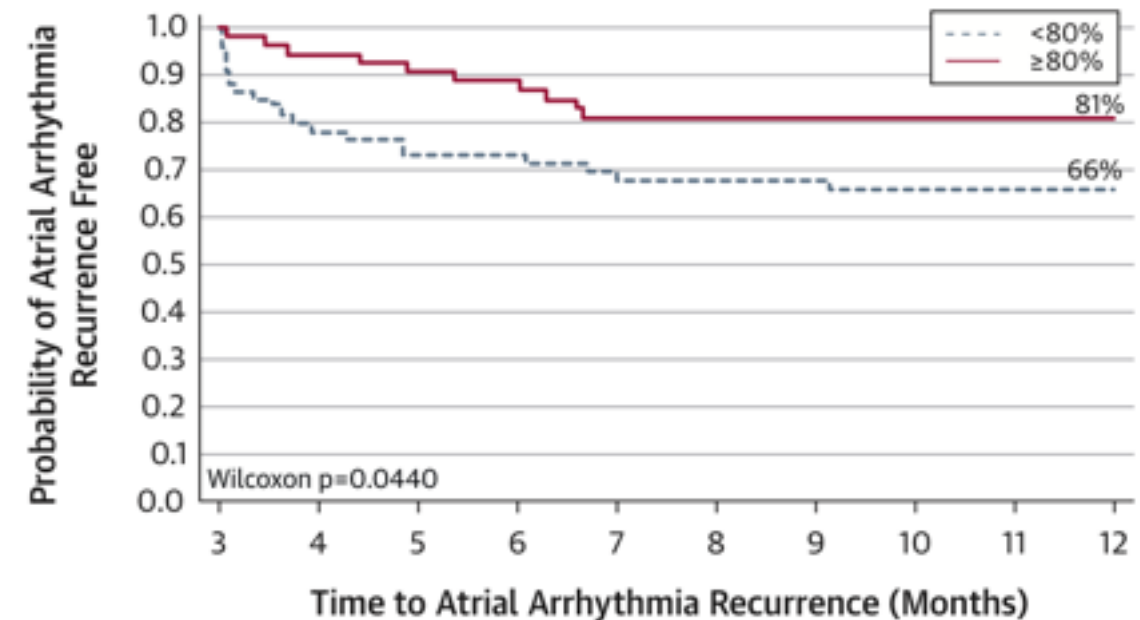
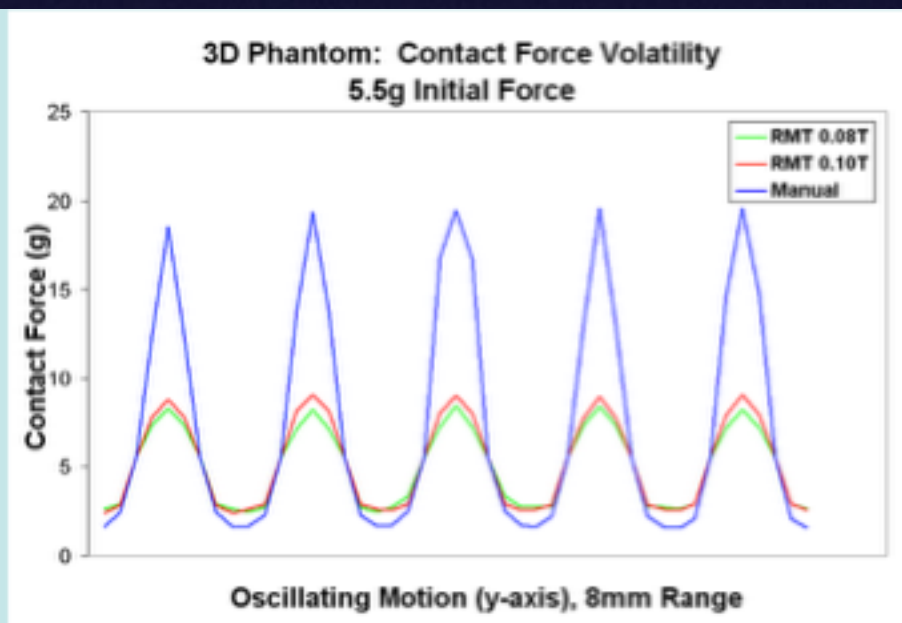


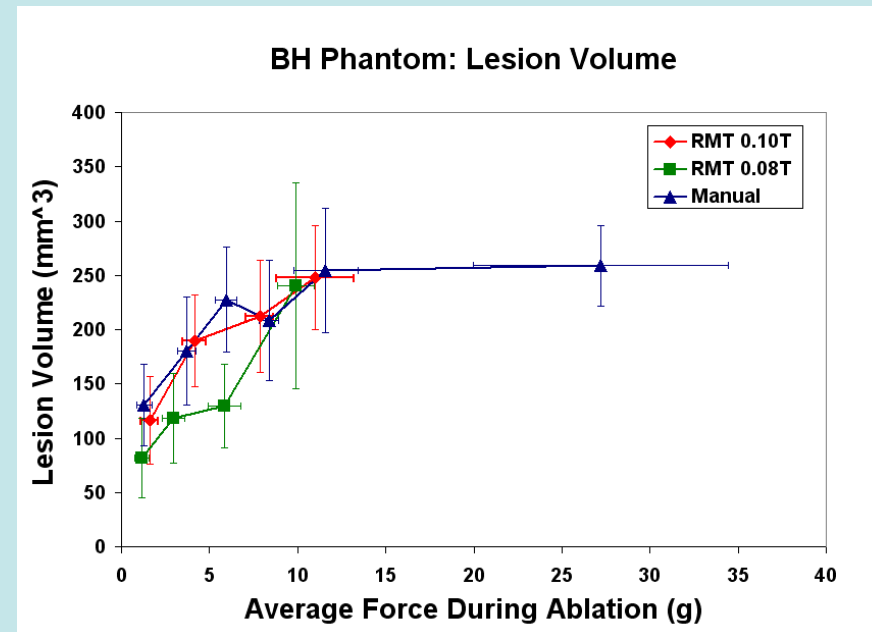
FIGURE 5 Kaplan-Meier Curve of Time to First Atrial Fibrillation/Atrial Flutter/Atrial Tachycardia Recurrence Through 12 Months

Investigators working in their selected ranges $\geq 80\%$ of the time during radiofrequency application demonstrated a significant increase of 15% in the effectiveness success at 12 months compared to those working in their selected ranges $< 80\%$ of the time (effectiveness cohort, $n = 122$).

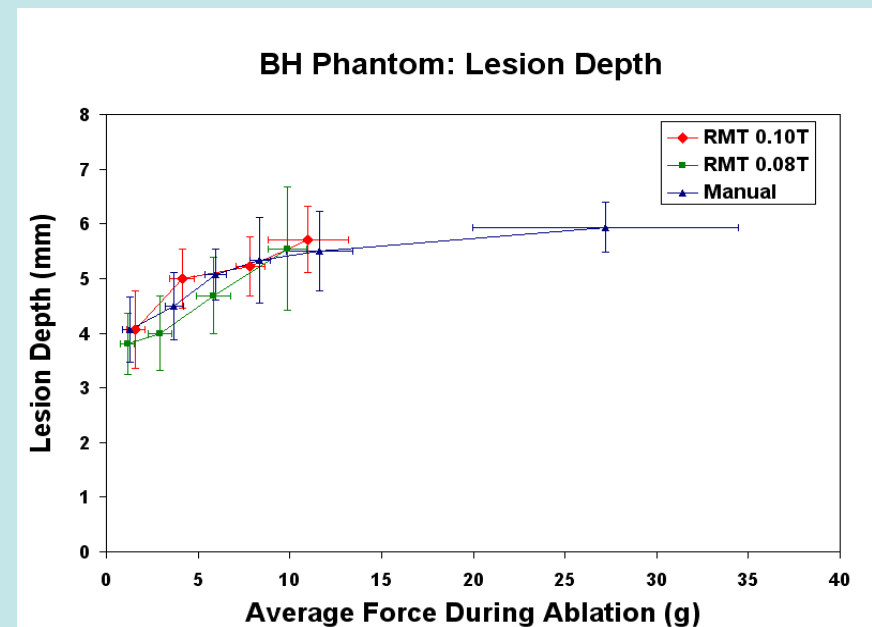
Contact Force and Lesion Size



This plot shows a lower force volatility for the RMT catheter in the mimicked cardiac cycle. Results were similar for all attack angles.



RMT lesion depth and volume near 10g are statistically equivalent ($P > .05$) to manual lesions at 40g. See statistics below.



Volume comparison:
 $P = 0.502$ for 0.1T
 $P = 0.554$ for 0.08T

Depth comparison:
 $P = 0.288$ for 0.1T
 $P = 0.303$ for 0.08T

Characterization of the Power and Lesion Volume Relationship for the Magnetic Irrigated Catheter in a Canine Beating-Heart Model

Methods (N = 5)

- Single point ablations in RV/LV
- Constant force/time
- Temp limit 43°C
- Linear lesion lines in RA/LA
- TTC for lesion visualization
- Histopathology

Hiroshi Nakagawa, MD, PhD
University of Oklahoma

KEY FINDINGS

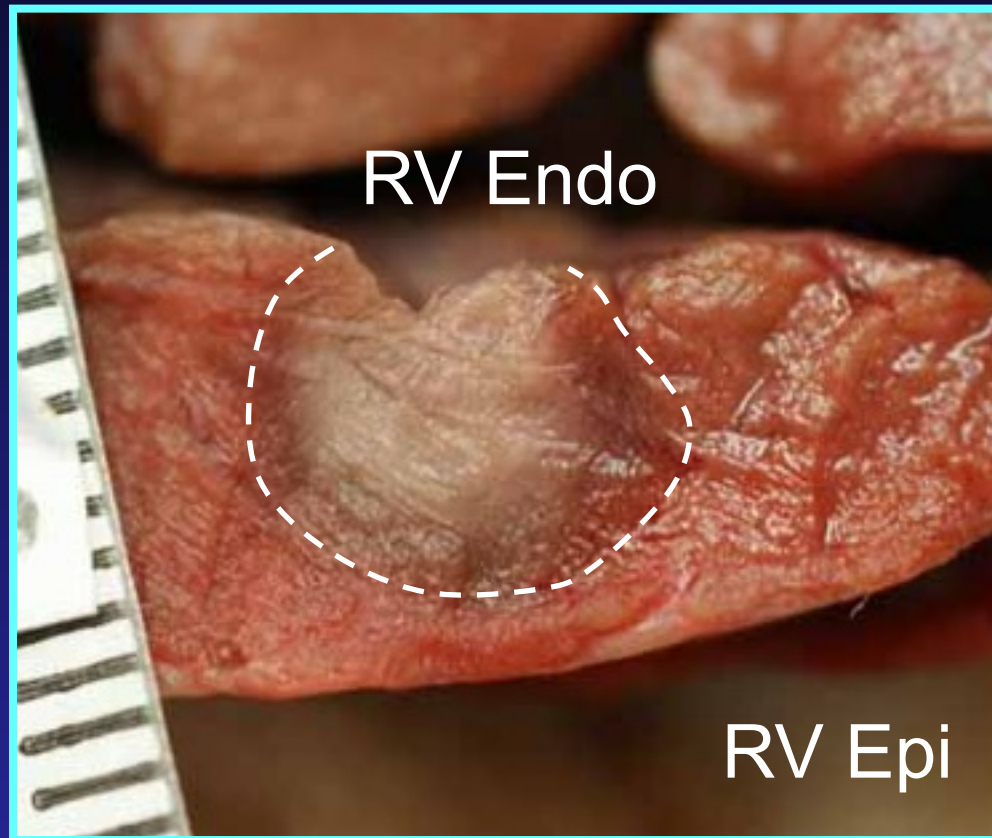
- Direct relationship between lesion volume and power titration
- Continuous lines of transmural lesions achieved with magnetic catheter
- Conduction block was achieved with no gaps in lesion lines



Ventricular Ablation

60 seconds, Irrigation 30 ml/min

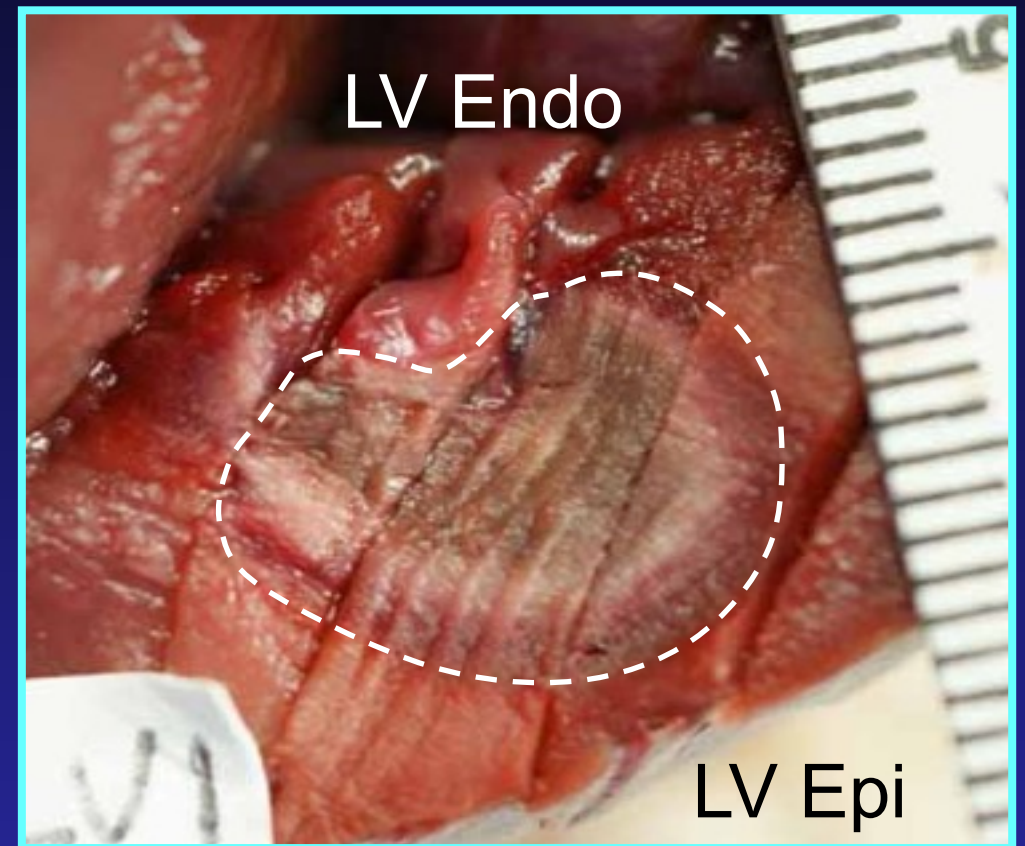
25 Watts



Irrigated
Magnetic
Ablation
Catheter

- Max Diameter: 6.8 mm
- Max Depth: 5.7 mm
- Surface Diameter: 4.5 mm

40Watts

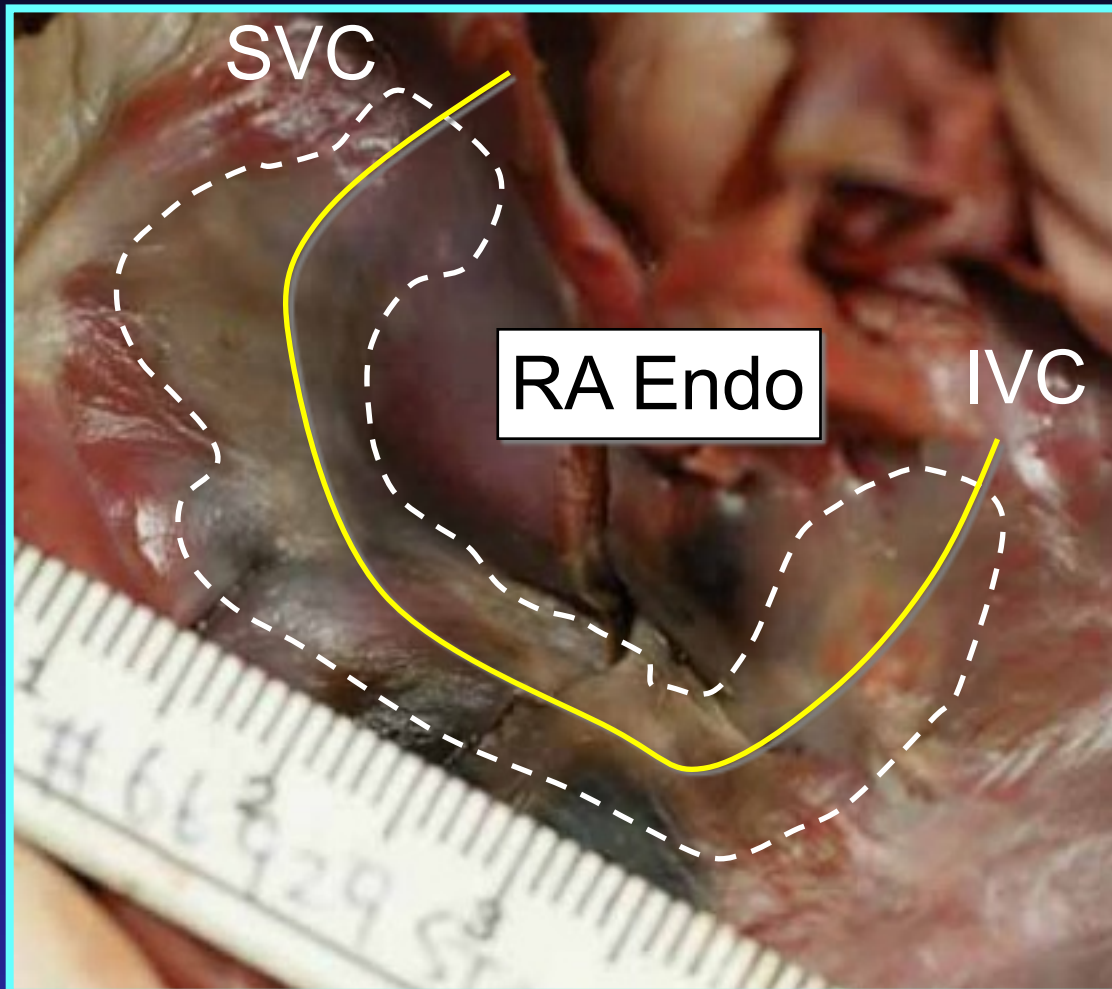


- Max Diameter: 12.2 mm
- Max Depth: 7.8 mm
- Surface Diameter: 7.9 mm

Right Atrial Linear Ablation (SVC-IVC)

Canine
Model

40Watts, 5 min Dragging (Irrigation 30ml/min)



Continuous
Transmural
Lesion

- Total Length: 40.0 mm
- Width: 5.0 - 8.5 mm
- Maximum Depth: 4.1 mm
- Minimum Depth: 1.3 mm



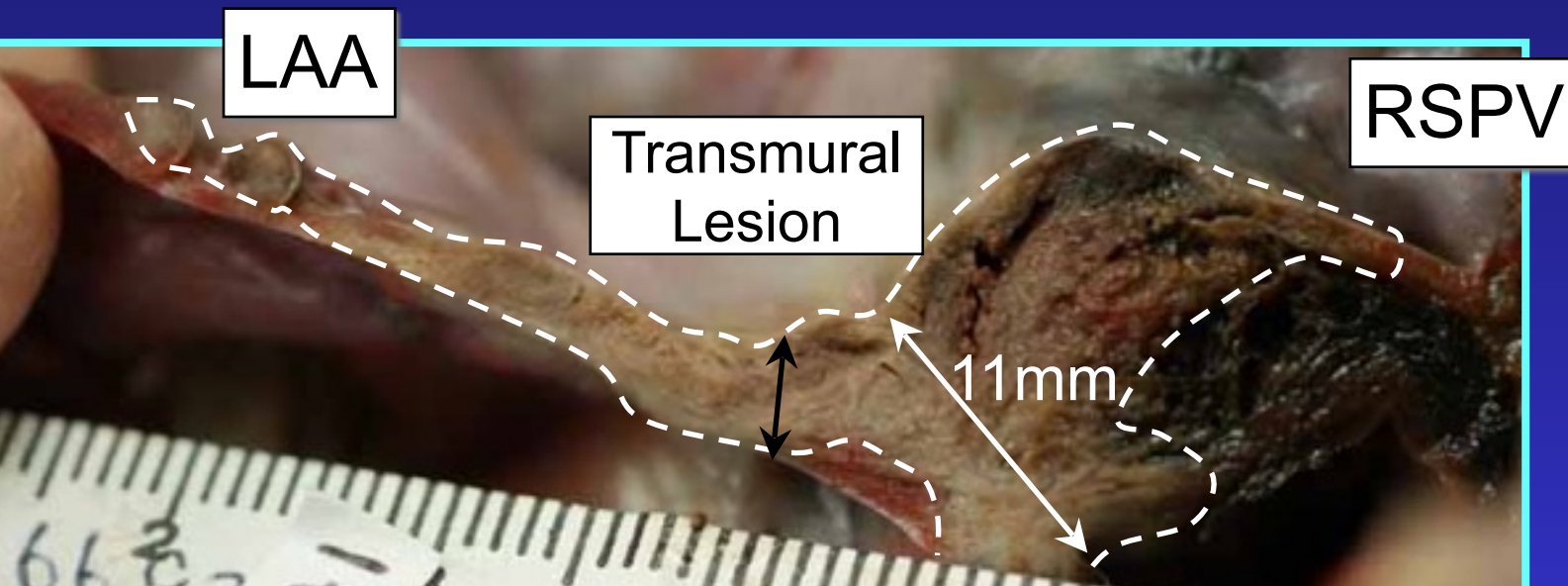
Left Atrial Linear Ablation (Roof Line: LAA - RSPV)

35Watts, 6 min Dragging (Irrigation 30ml/min)



- Total Length: 49.5 mm
- Width: 5.0 - 8.0 mm
- Maximum Depth: 6.6 mm
- Minimum Depth: 1.5 mm

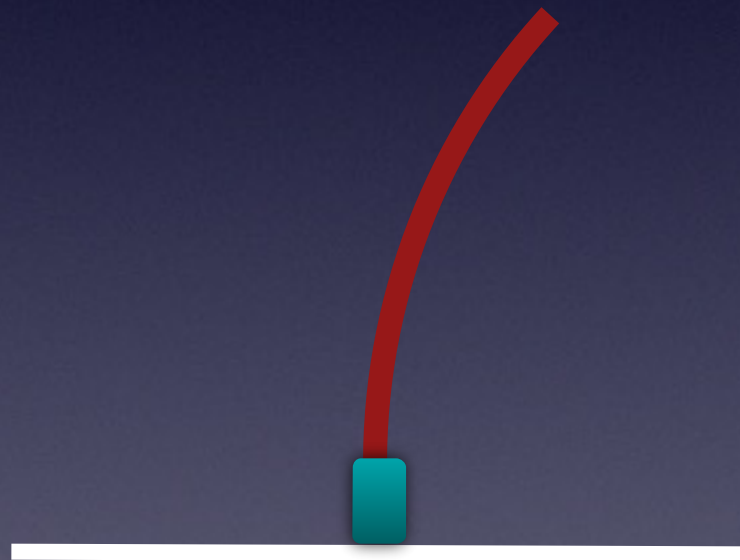
Line of Conduction Block – No Gaps



Canine Model

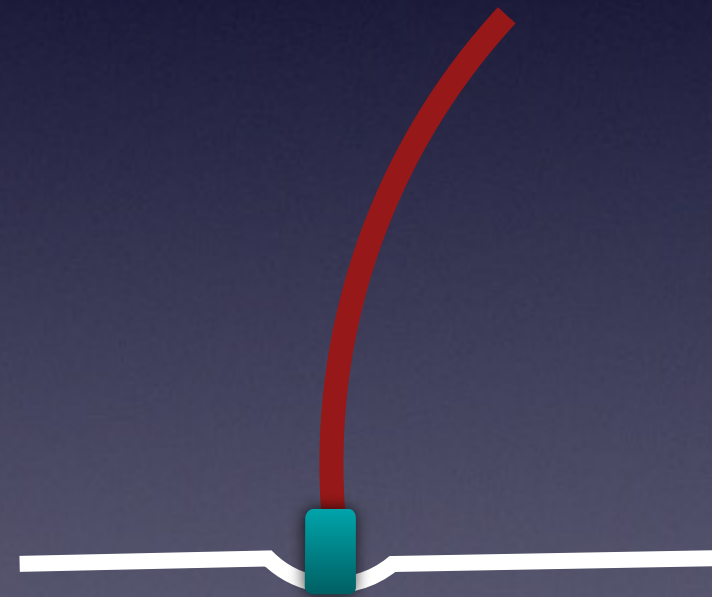
Appropriate Power

RMT



40-45W

Manual

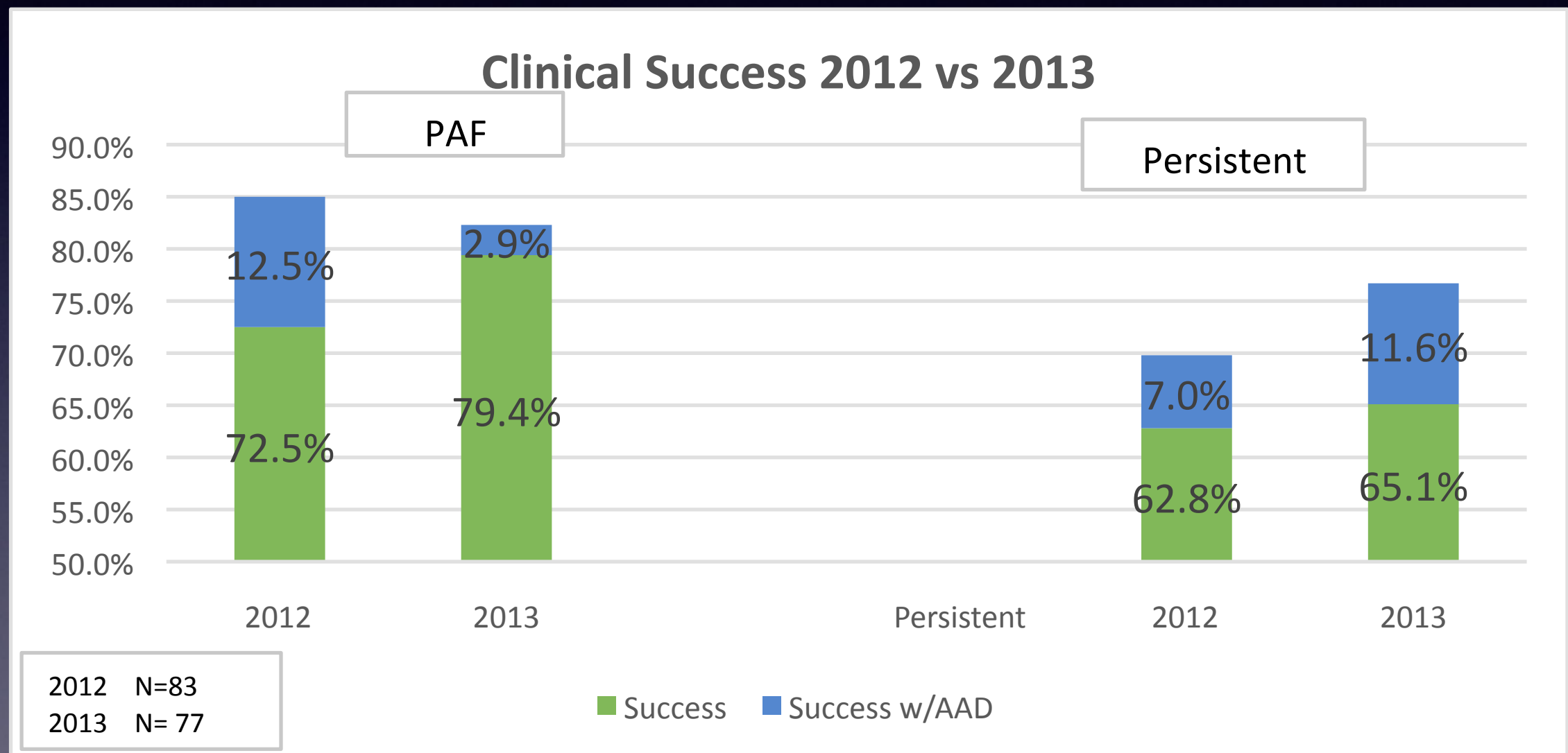


35W

1 year outcomes 2012 vs 2013

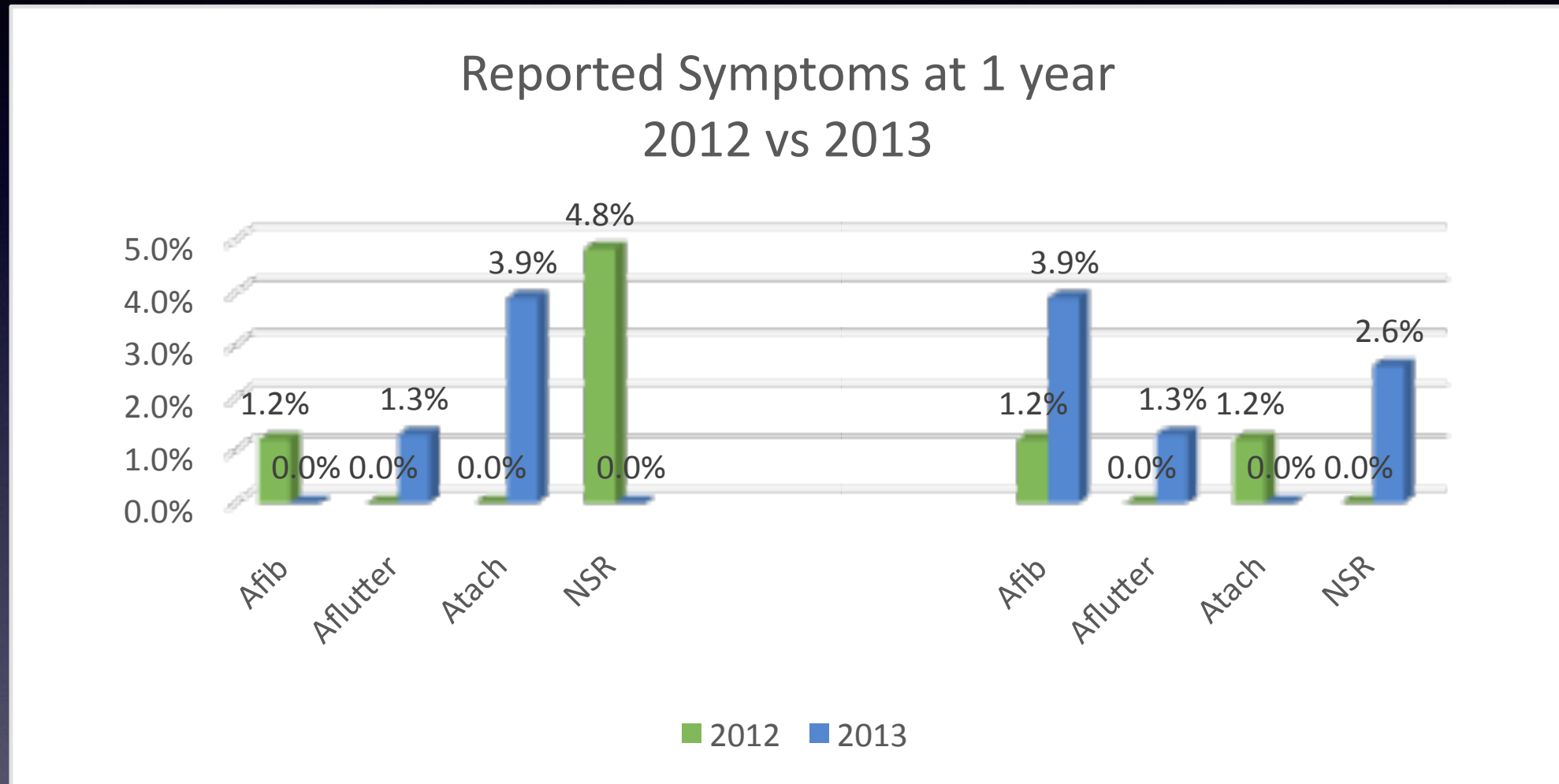
- Epoch FAM mapping technique -Single operator without V-Drive or Ablation History
- PAF-WACA +/- CTI
- Persistent AF- WACA and Box +/- CTI
- 3 month blanking period with event monitors at 3 months, 1 year and with symptoms, High CHADS Vasc patients receive ILR

Clinical Success



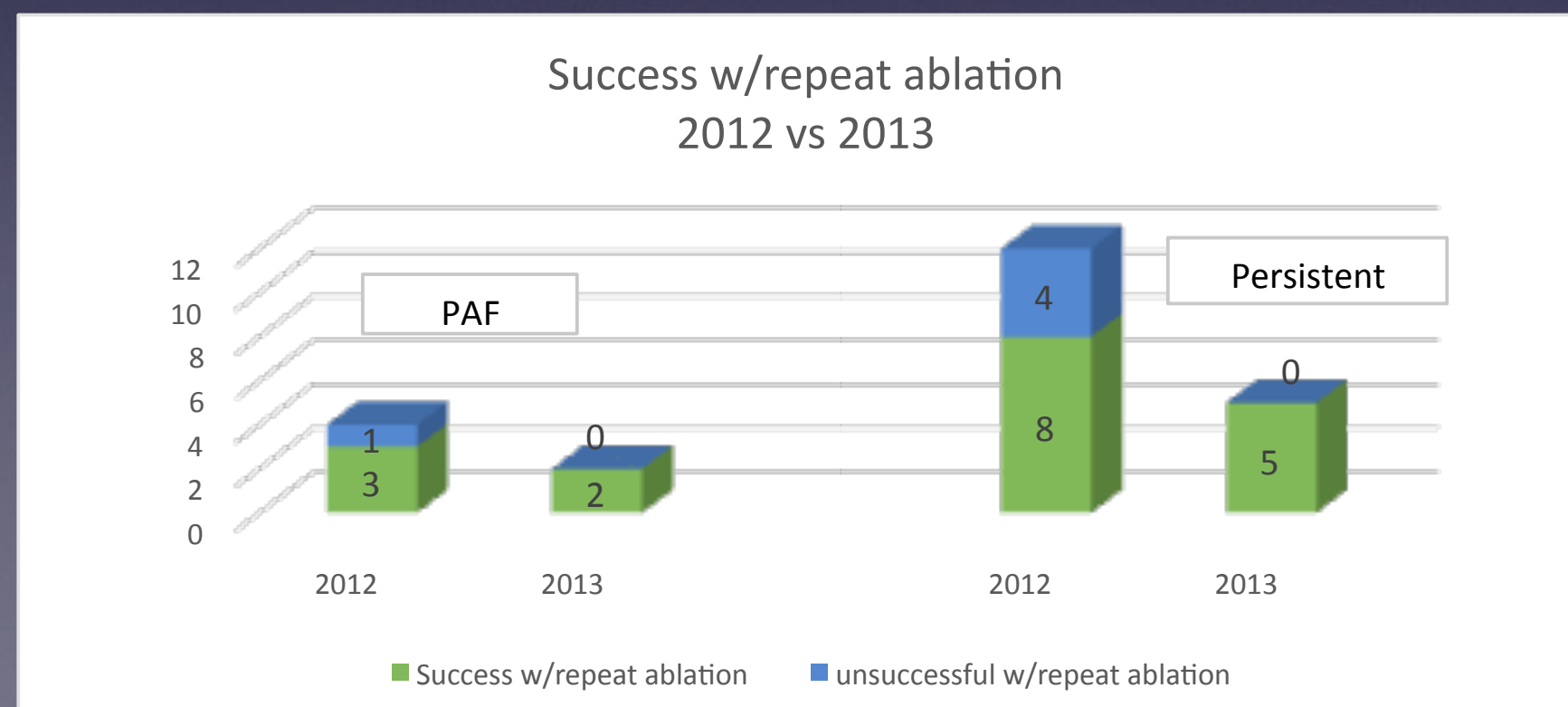
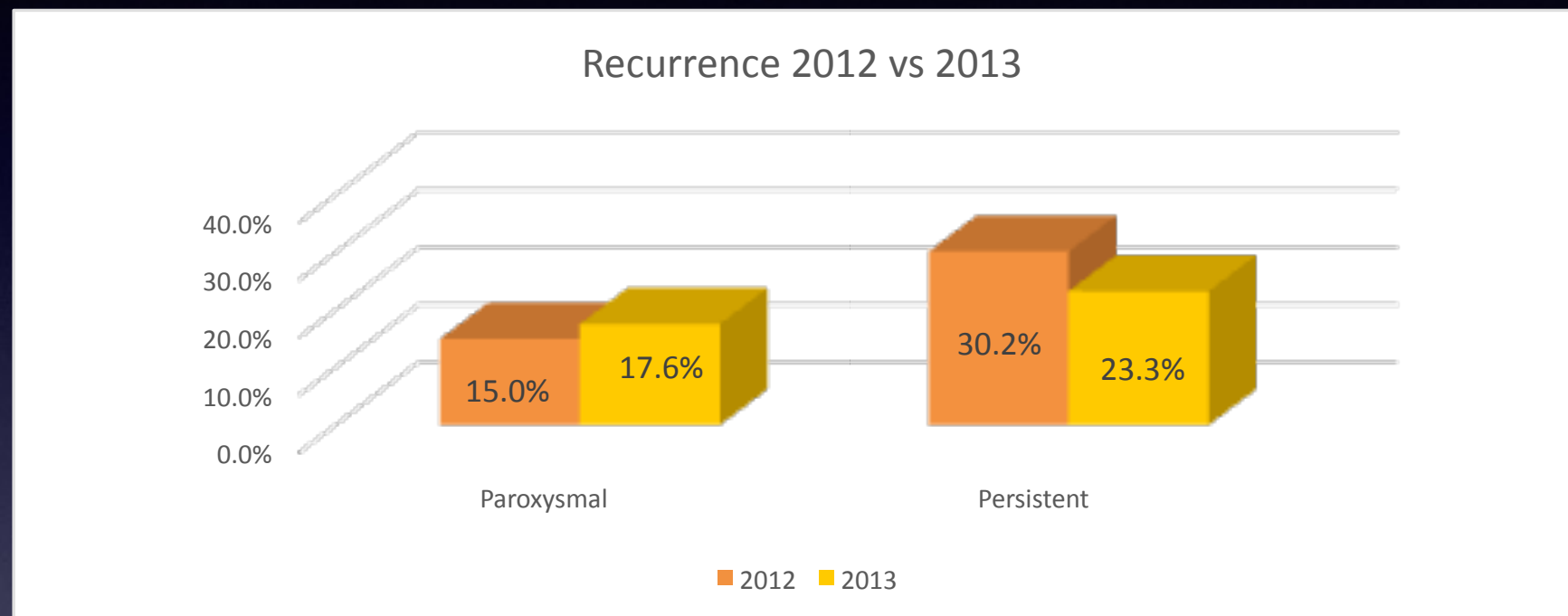
2012 Carto Sound, FAM
2013 EPOCH FAM

Clinical Success



Most Patients feel better regardless if they have recurrence.

Recurrence- Durabilty



Conclusion

- Incredible procedural efficiency gains
 - 2 hours for Paroxysmal CLA(22% less)
 - Decreased Fluoro Times(64% less)
 - Increased Patient Safety
 - Longer career, increased productivity with less back pain and time off due to debility

Conclusions:

- Robotic Ablation of CLA is equivalent to the best manual technology of AF ablation with regards to efficiency and efficacy.
- Evolving technologies such as V-Loop, V-Sono and Ablation history may further improve outcomes
- Consistent Contact Force coupled to appropriate power and time create durable ablation lesions and freedom from AF

Thank You

- Special Thanks to Michelle Nellett, APN, Atrial Fibrillation Clinical and Research Coordinator, Advocate Christ Medical Center