Remote Navigation for VT Ablation

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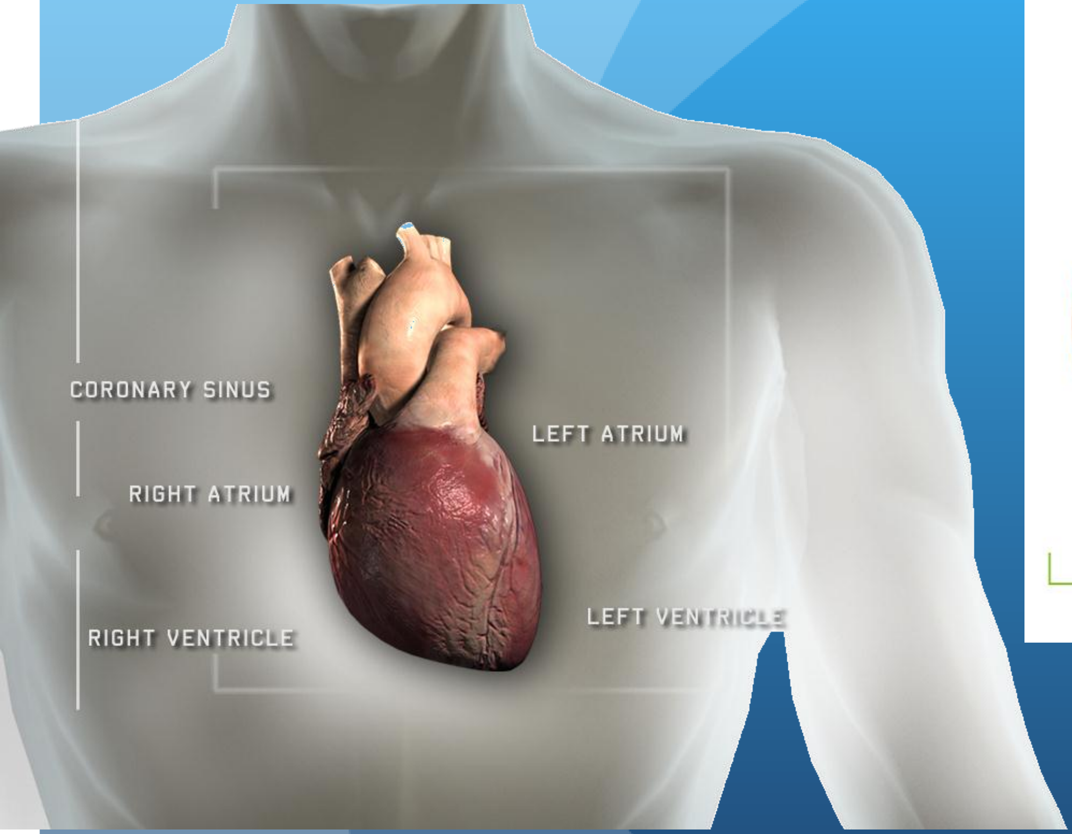
FACULTY/PRESENTER DISCLOSURE

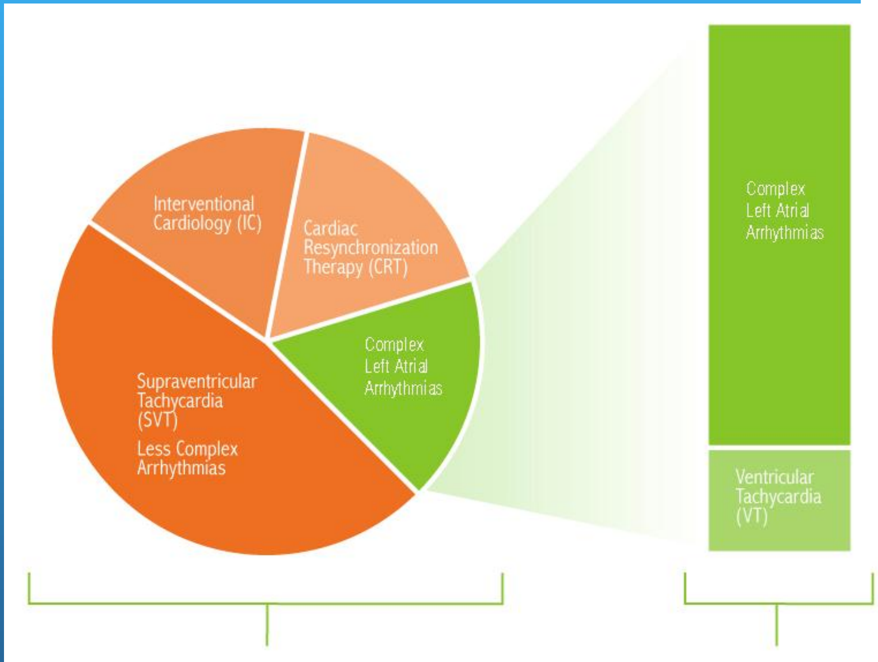
- Faculty: J. David Burkhardt
- Relationships with commercial interests:
  - Speakers Bureau/Honoraria: Biosense-Webster, St. Jude, Stereotaxis, Boeringer-Ingelheim

Needs in Electrophysiology

- Navigation for complex procedures
- Automation and standardization of procedures
- Platforms for new ablation technologies

A Platform Technology for Daily Clinical Use





Over 100 Peer Review Articles on Multiple Applications

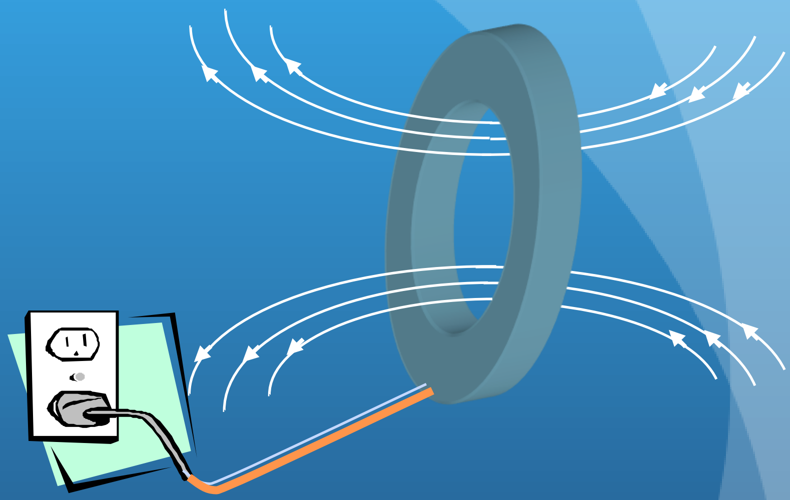
Technology Overview

What is the Magnetic Field Strength of Stereotaxis?

- 1 .001 T
- 2. .08-.1 T
- 3. 1T-3T
- 4. 10T

Magnetic Field Basics

- Magnetic fields are caused by moving electrical charges

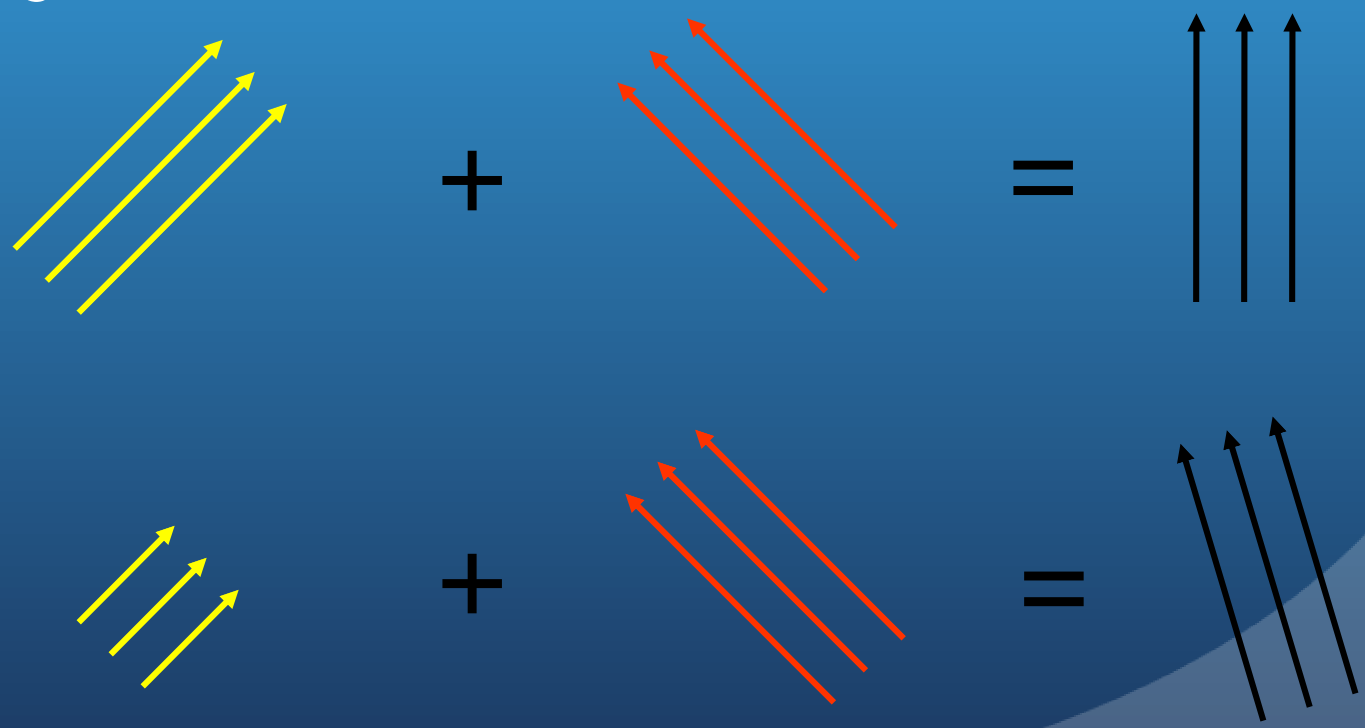


- **Can be created by:**
  - Passing current through a superconducting coil (i.e., superconducting magnets)

  - Atomic or molecular currents within a material (i.e., permanent magnets)

Magnetic Navigation Systems

- Multiple magnets
- Navigational field direction is a combination of all magnetic fields



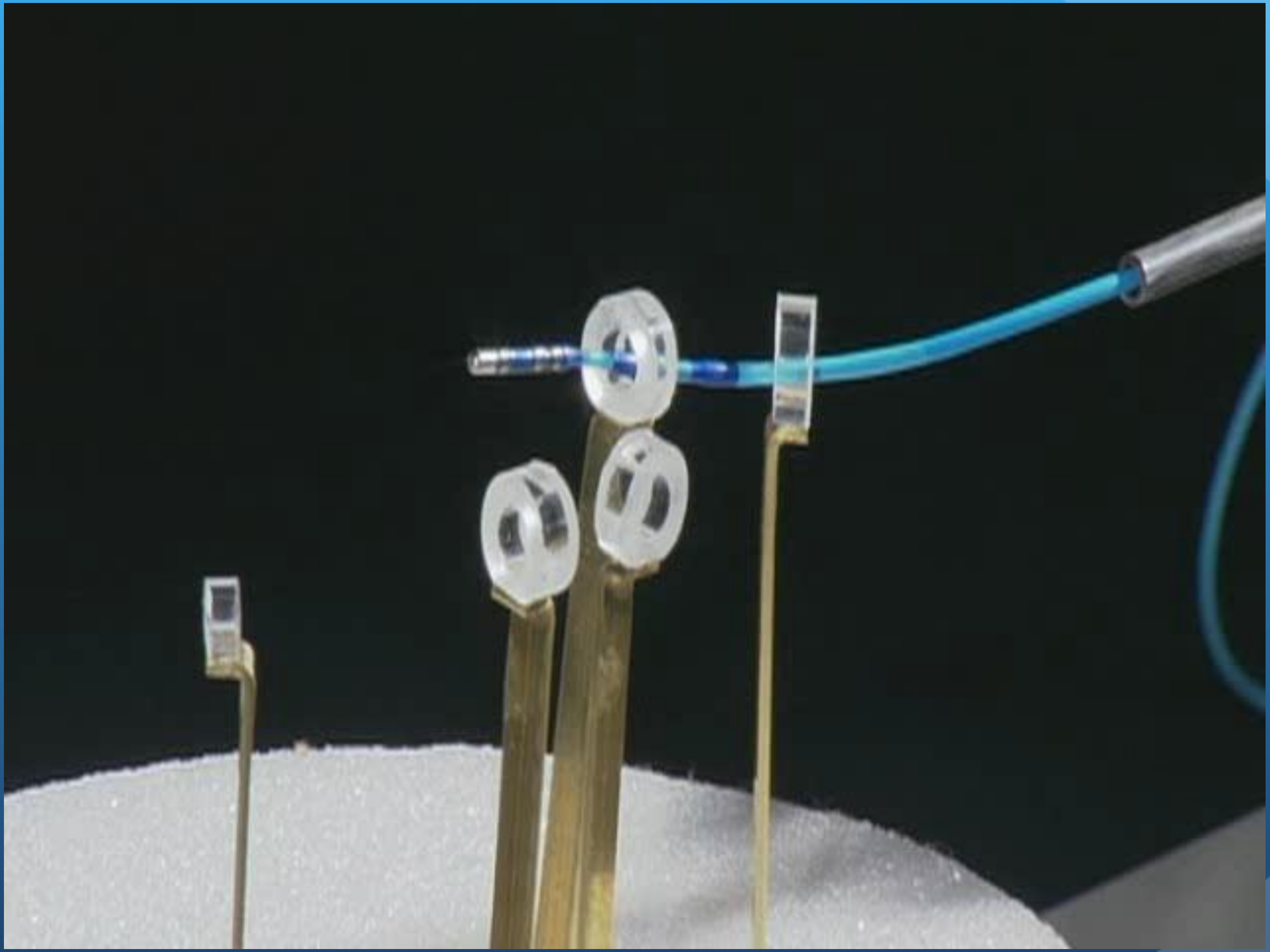
How Stereotaxis System Works…

2 computer controlled magnets (0.08 Tesla) surround patient and move to control a relatively uniform magnetic field (15cm in dia); Vector is steerable in any direction

Primary Differences

Magnetic Navigation vs Manual Navigation

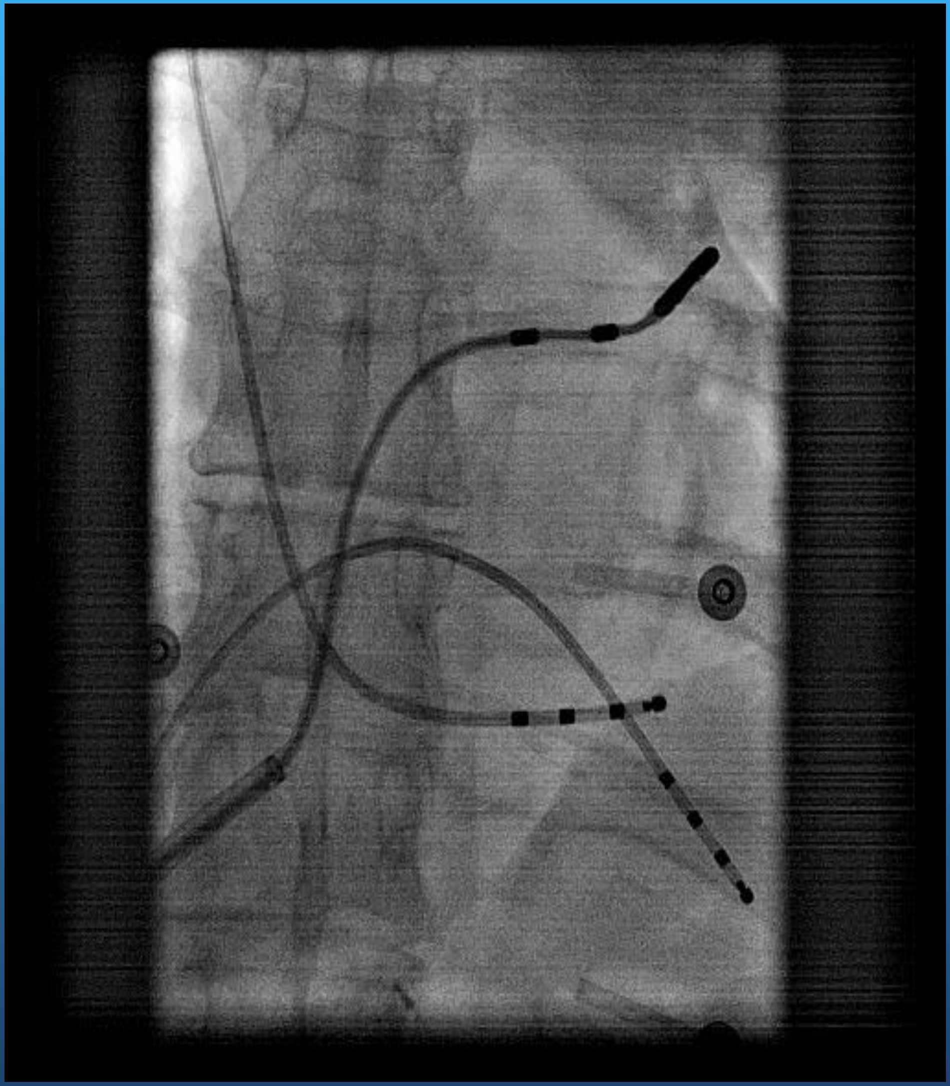
- Device controlled directly at distal tip
- Highly flexible devices
- Remote navigation
  - No Lead Vest
  - No Radiation to physician
- Computerized control and integration

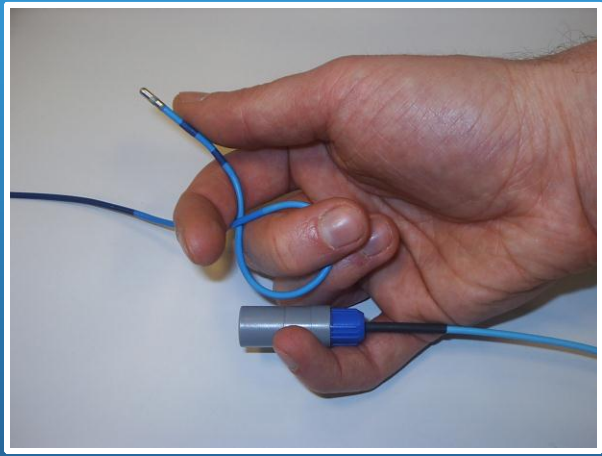


Stereotaxis Remote Magnetic Control

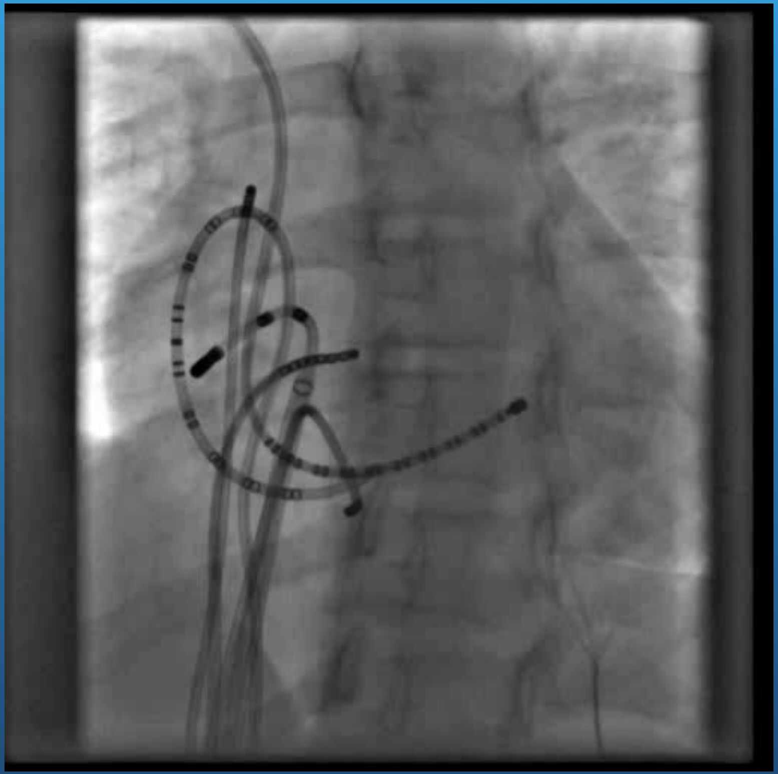
Remote AFib Ablation Procedure

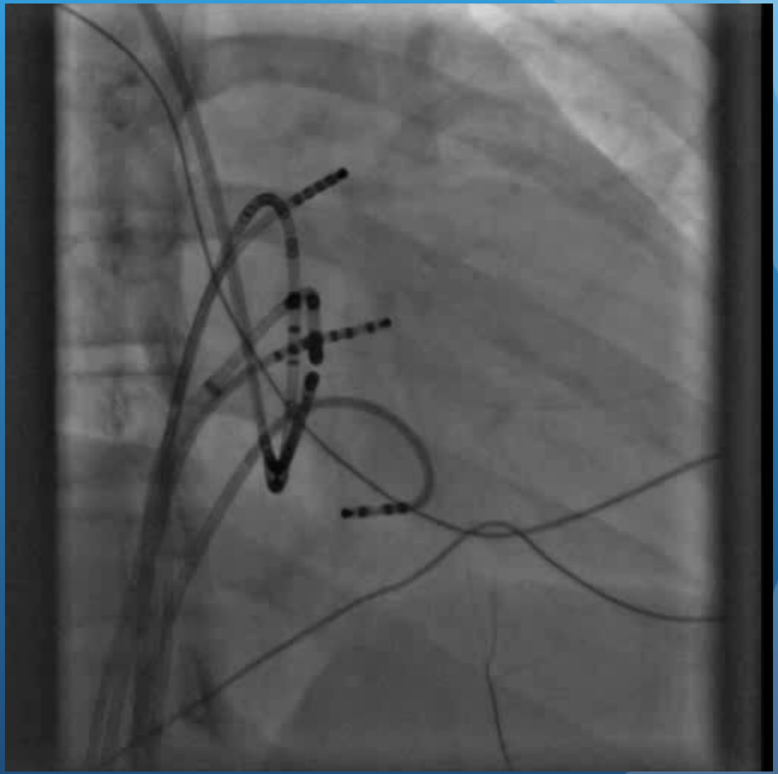
Flexibility and Softness of Catheters





Stable Catheter Contact





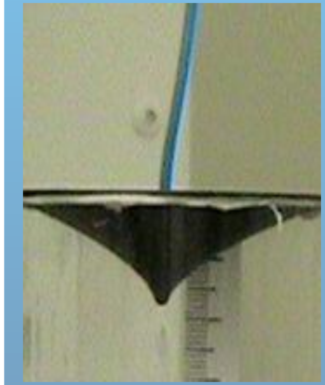
Courtesy of University Hospital of Oklahoma

The Lesion for a Specific Contact Force is Equivalent for All Catheters?

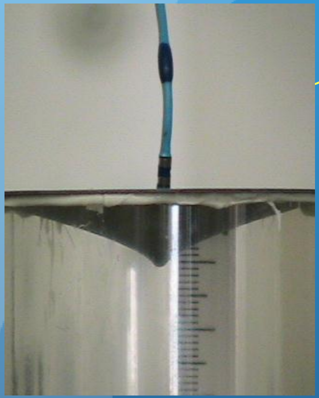
- 1. Yes
- 2. No

Stereotaxis Safety - Electrophysiology

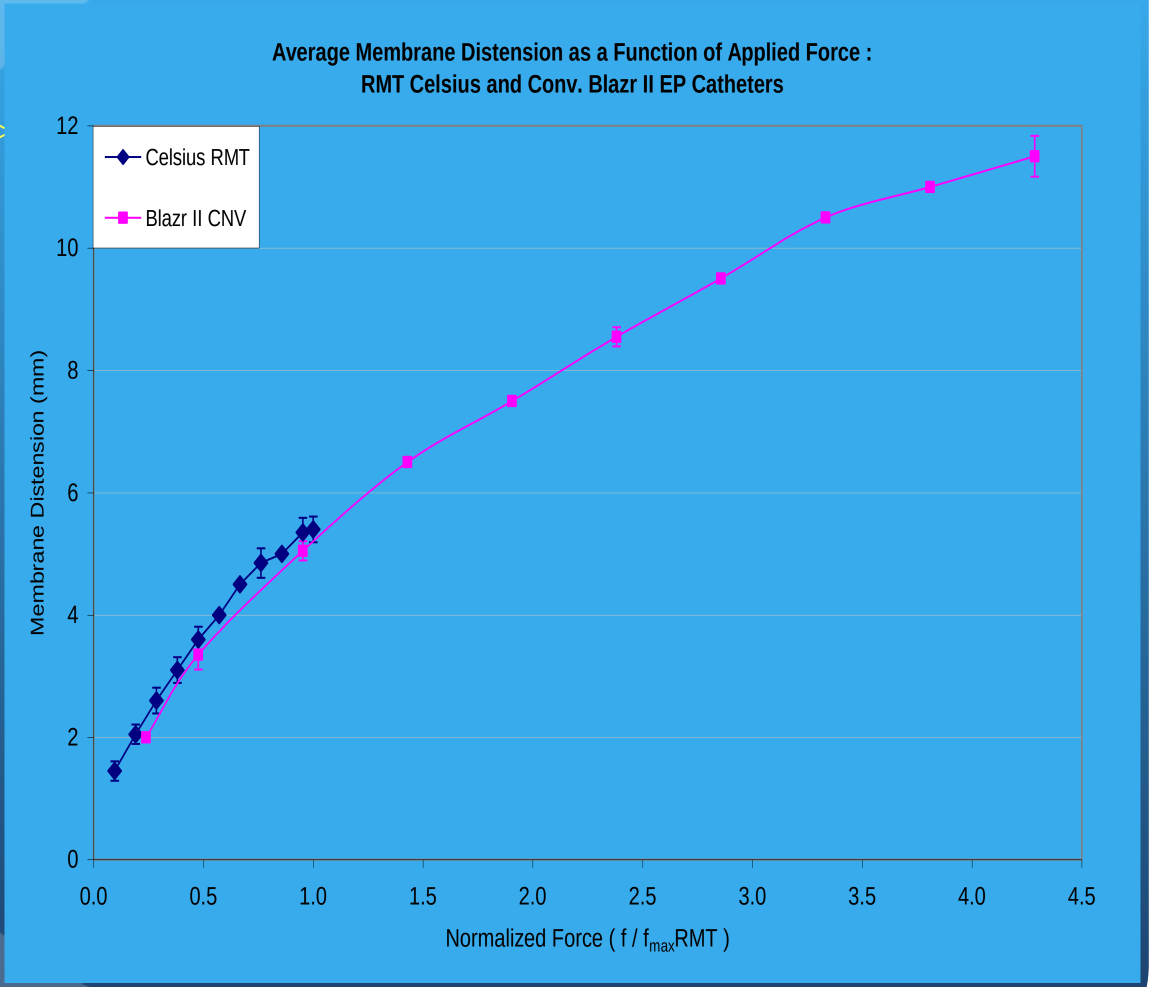
Soft-Touch catheters reduce tissue distension and force on cardiac tissue



Conventional



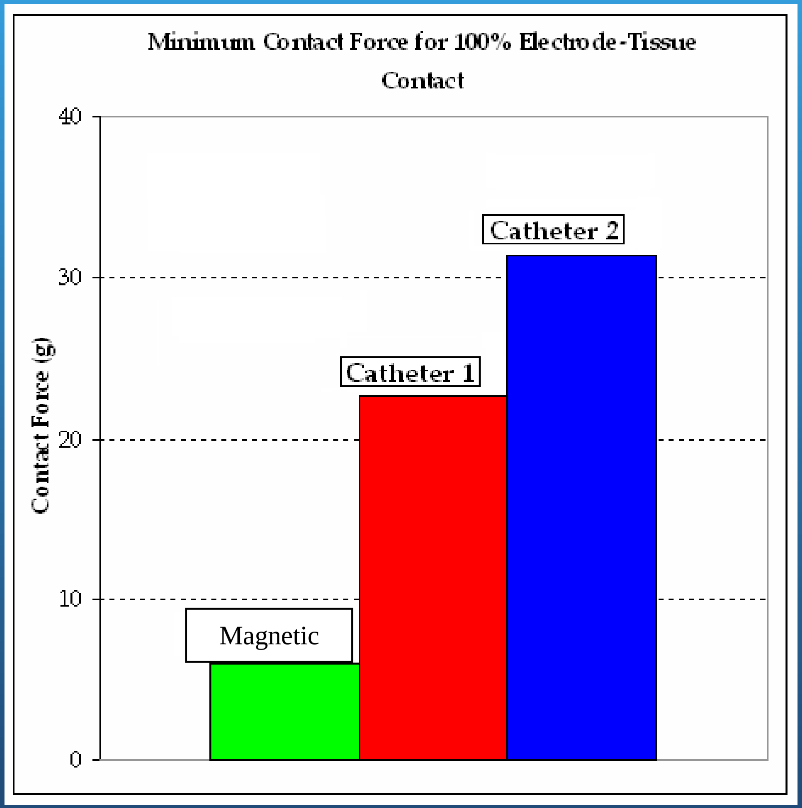
Soft Touch Magnetic



Conventional catheter applied 4 times as much force compared with a magnetic catheter

Force Required for Stable Tissue Contact

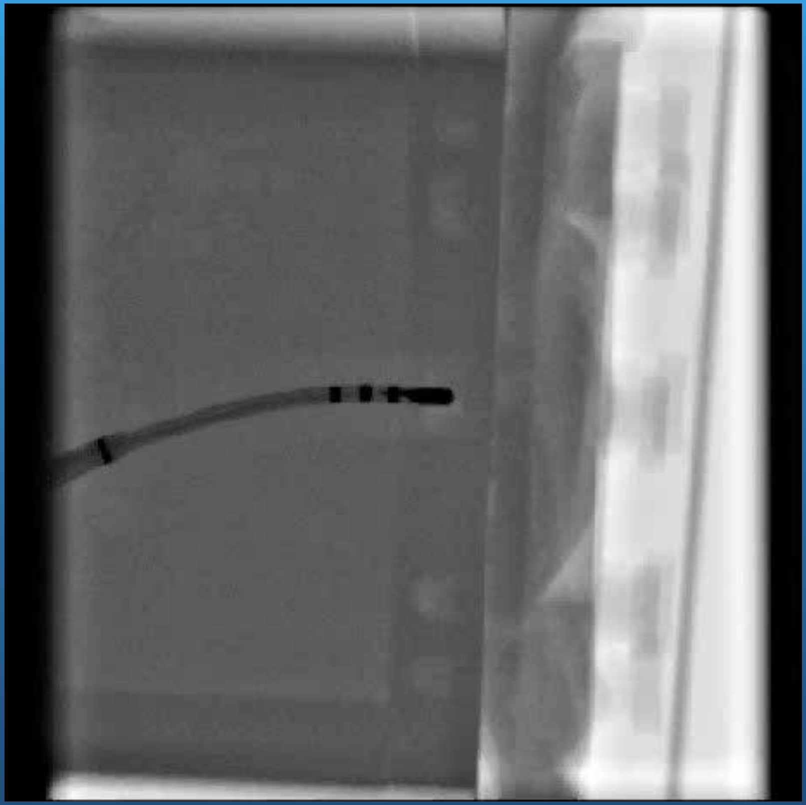
- Stiffer catheter shafts require more force to maintain stability
- Magnetic catheters remain stable at lower contact forces



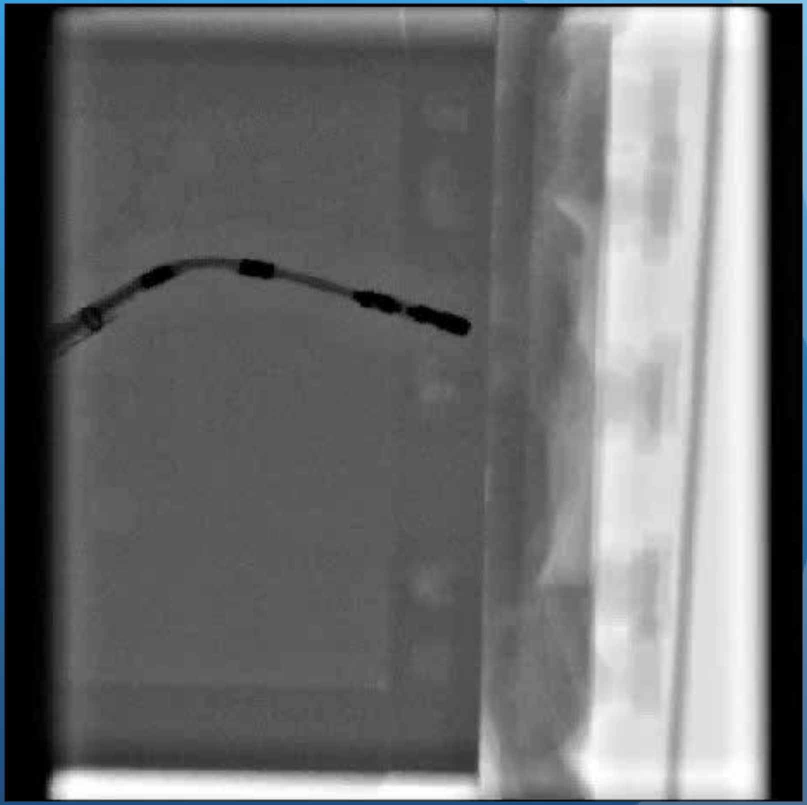
Model-estimated forces

Courtesy: Prof. K.H. Kuck

Dynamic Phantom: Both Catheters in Contact?



Manual Catheter @ 6g



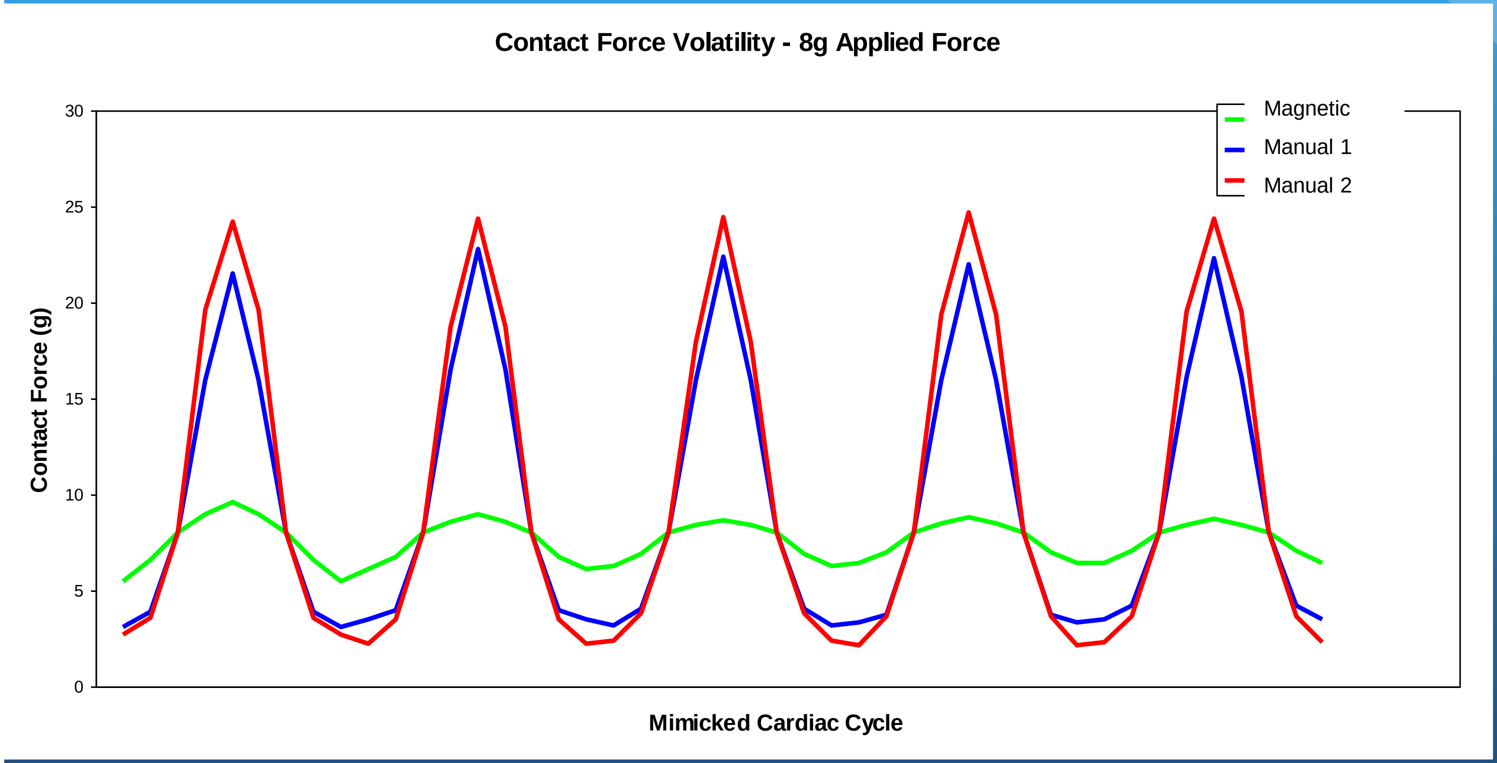
Magnetic Catheter @ 6g

Dynamic Phantom

Manual Catheter

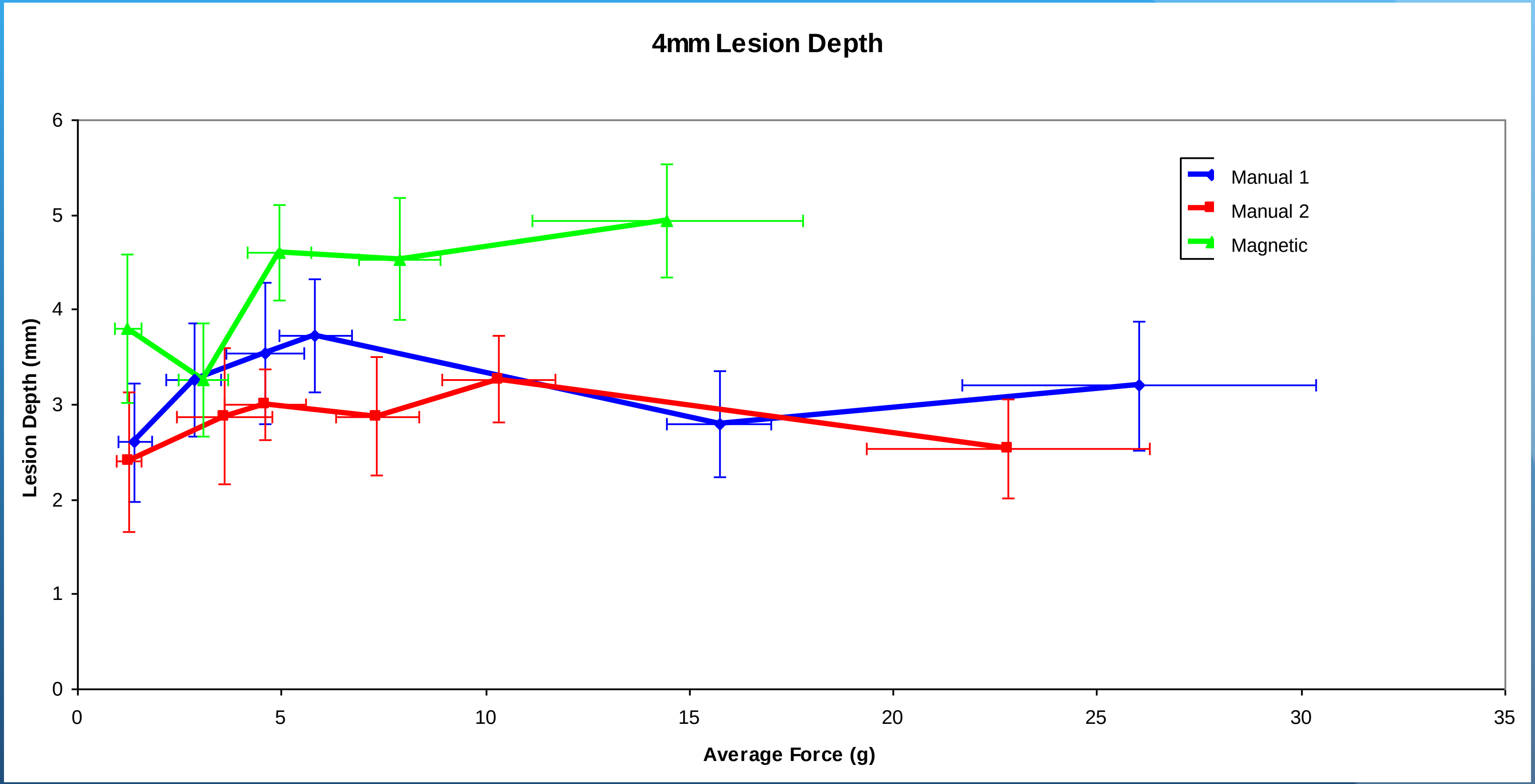
Magnetic Catheter

Magnetic Catheter Maintains More Consistent Contact During Simulated Heart Cycle



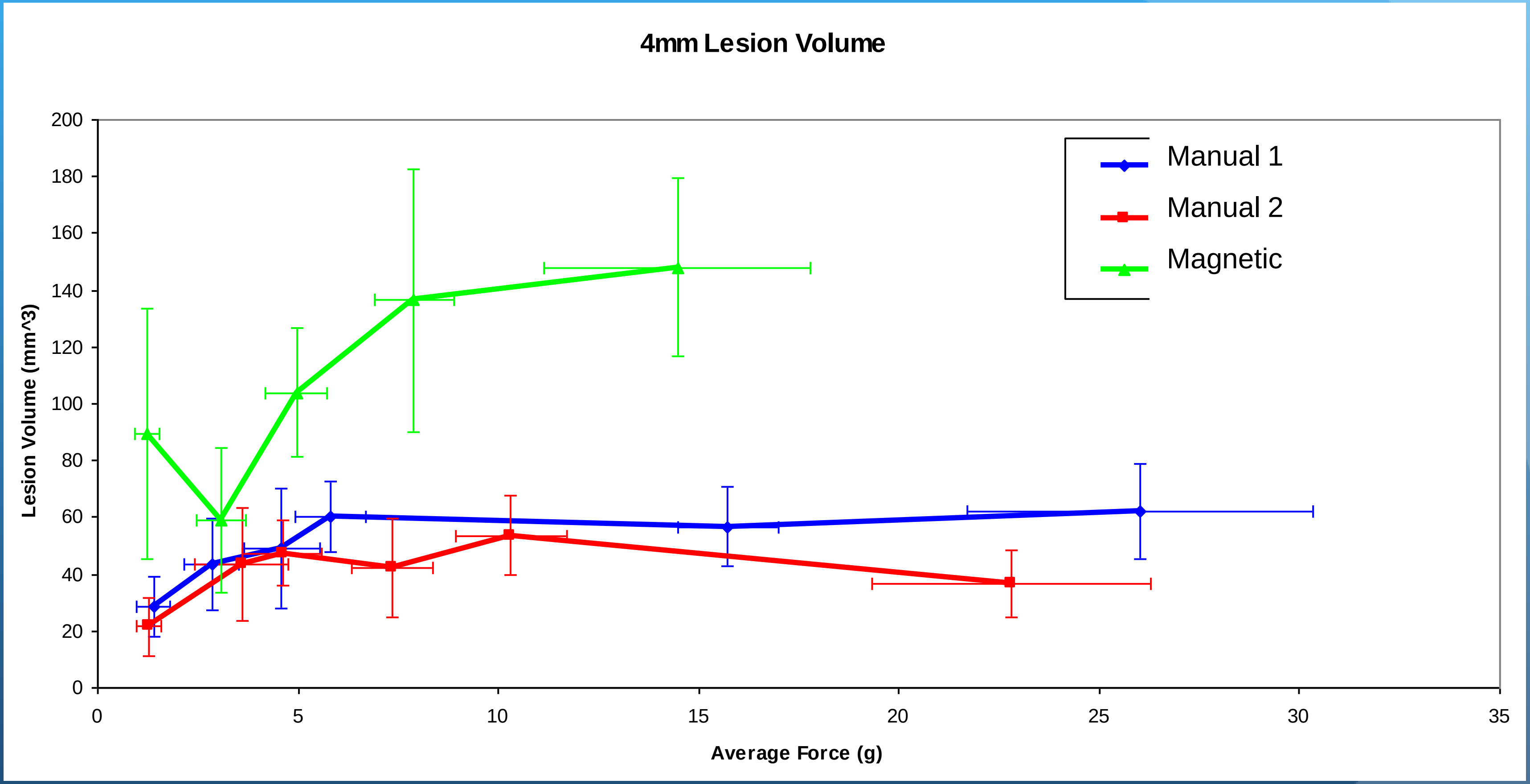
- Force averaged over attack angles
- Trend maintained at higher force

Dynamic Phantom
Lesion Depth in Chicken



* n = 15 for all points

Dynamic Phantom
Lesion Volume in Chicken



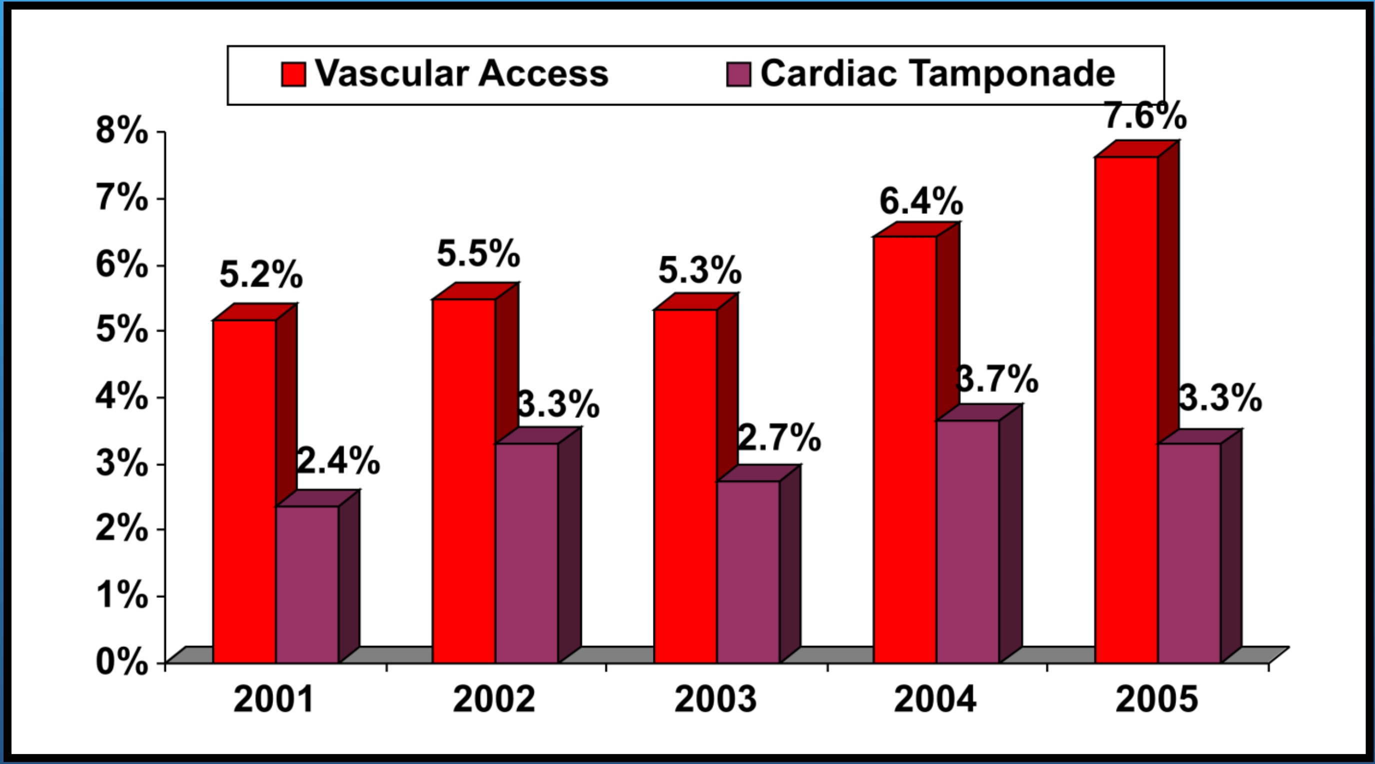
* n = 15 for all points

Safety

- Perforation
- Radiation
- Automation and Replication

Excellent Safety, especially in Complex Cases

Complication Rate without Magnetic Navigation*



With Magnetic Navigation, reported complication rate is less than 0.1%**

* Source: Reynolds et al. Heart Rhythm. May Suppl. 2007

** Data on file

Perforation

- Perforation is a combination of pressure and ablation power

AF Ablation - Perforation risk

Outcomes After Cardiac Perforation During Radiofrequency Ablation of the Atrium

T. JARED BUNCH, M.D., SAMUEL J. ASIRVATHAM, M.D., PAUL A. FRIEDMAN, M.D., KRISTI H. MONAHAN, R.N., THOMAS M. MUNGER, M.D., ROBERT F. REA, M.D., LAWRENCE J. SINAK, M.D., and DOUGLAS L. PACKER, M.D.

From the Division of Cardiovascular Disease, Department of Internal Medicine, Mayo Clinic, Rochester, Minnesota, USA

Cardiac Perforation During Radiofrequency Ablation. ***Background:*** Perforation during catheter procedures in either the atrium or ventricle is relatively uncommon, but potentially fatal if tamponade ensues. This study analyzes the occurrence and outcomes of cardiac perforation during catheter-based radiofrequency ablation procedures in the left atrium.

Methods: All patients with a periprocedure perforation who have undergone radiofrequency ablation for

Results: Of 632 procedures performed from January 1999 to October 2004, 15 (2.4%) were complicated by perforation requiring pericardiocentesis.

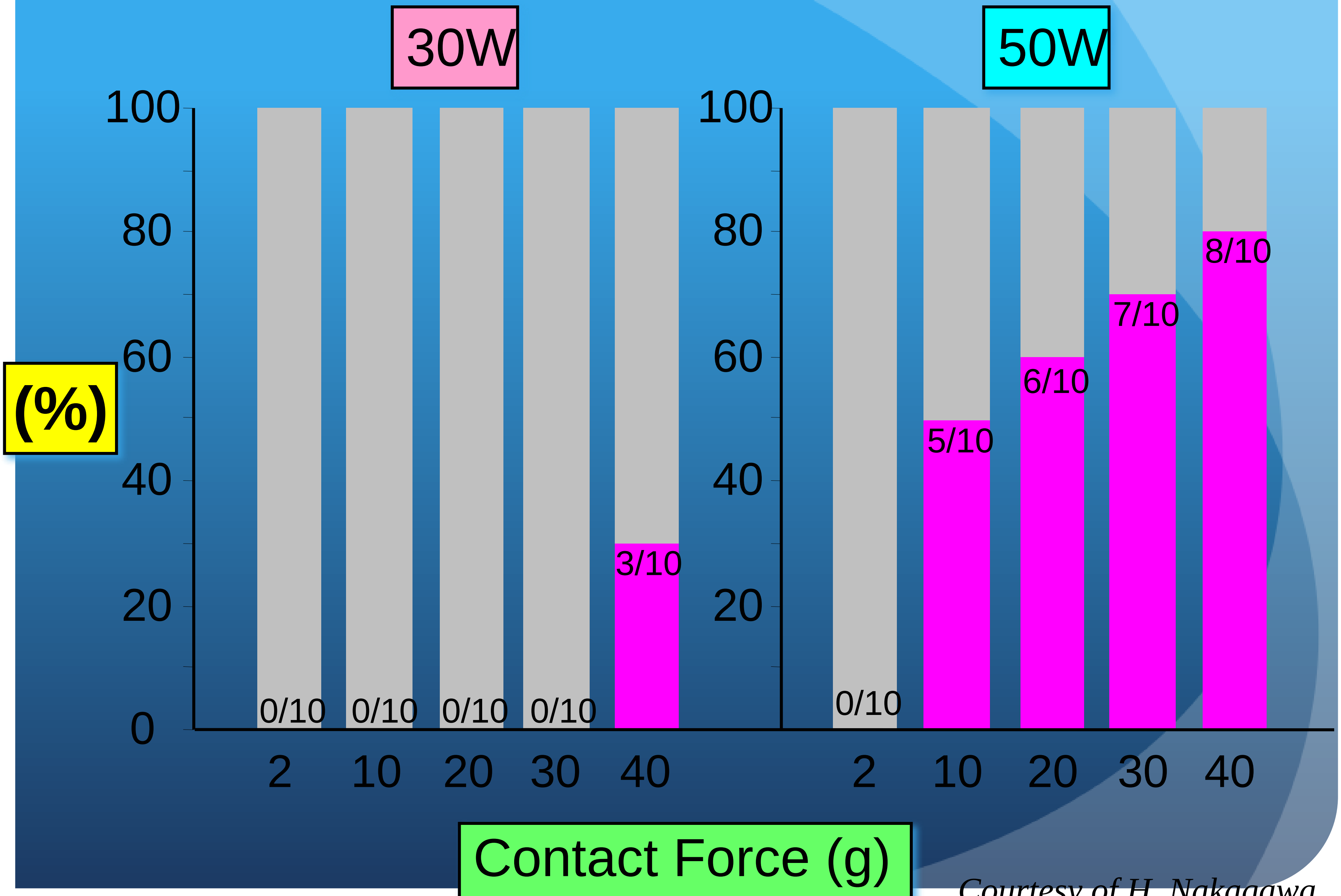
an effusion before overt instability in 11 (73.3%). Thirteen (86.7%) patients developed a blood pressure <60 mmHg. The pressure stabilized in all patients after pericardiocentesis (hypotension to intervention: 10.1 ± 5.1 minutes). The total blood volume removed was 848 ± 880 mL (left atrium/right atrium: 1,074 ± 1,002 vs right ventricle: 396 ± 266, P = 0.168). Two patients required surgery to close left atrium dome perforations. The ablation was completed in 7 (46.7%) patients. Ten (66.7%) later developed early reoccurrence of AF.

Conclusion: The incidence of perforation during ablation of the left atrium is low. Most perforations occur in the left atrium; however, few require surgical closure. Although less than with uncomplicated procedures, the majority of patients with complete ablations achieve long-term elimination of AF.

Electrophysiol, Vol. 16, pp. 1172-1179, November 2005)

!!!!!!!

Incidence of Steam Pop



Courtesy of H. Nakagawa

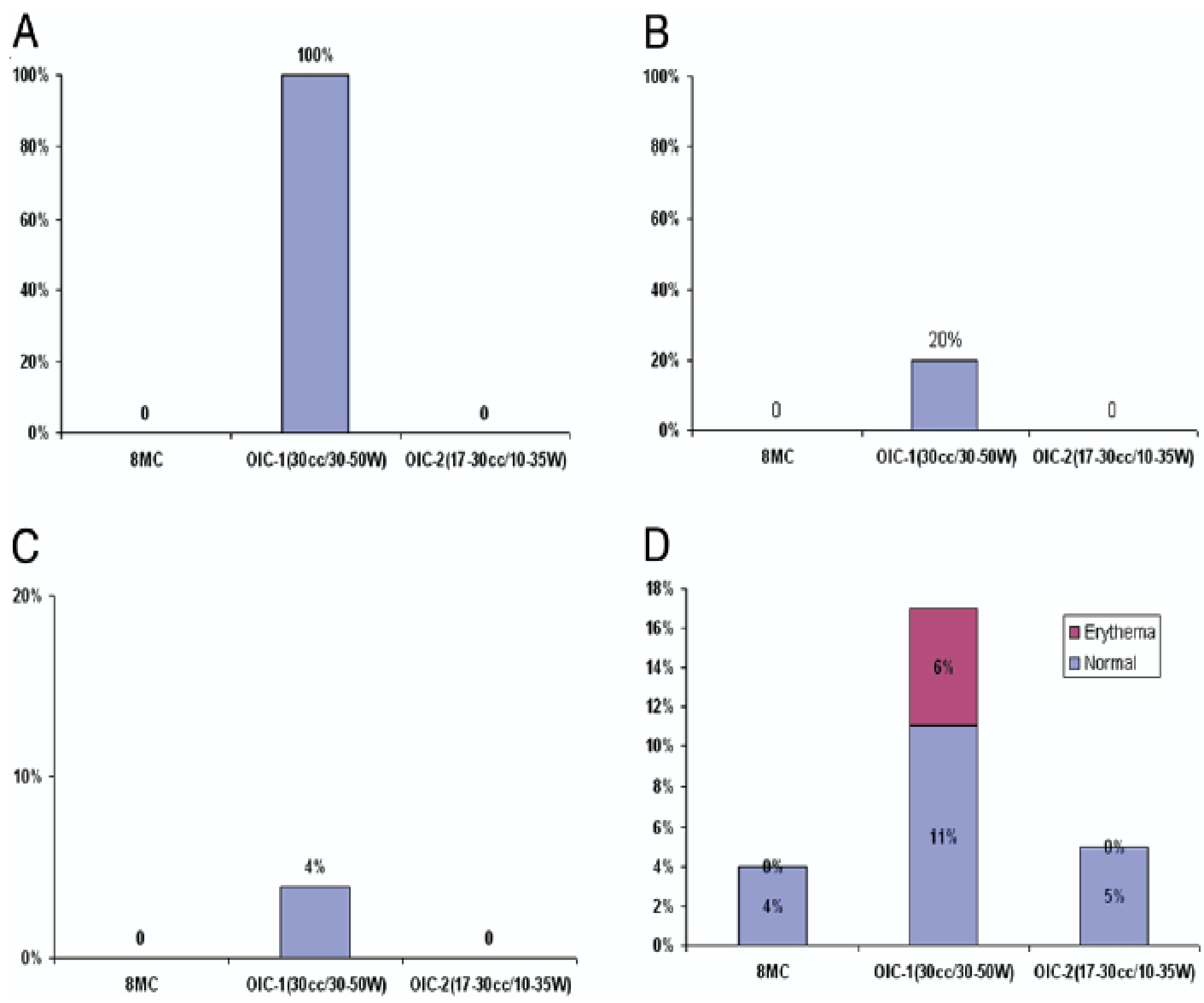
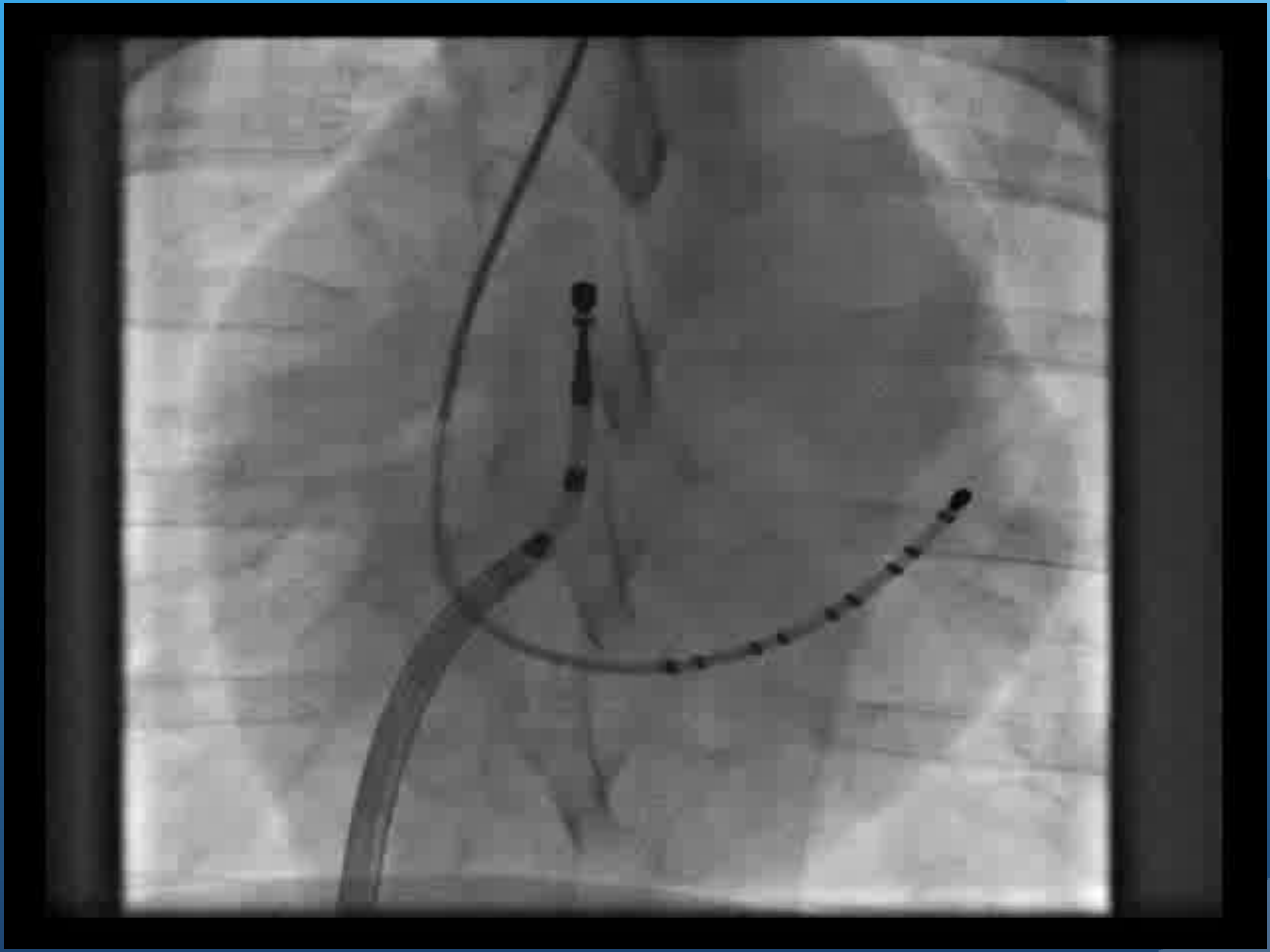
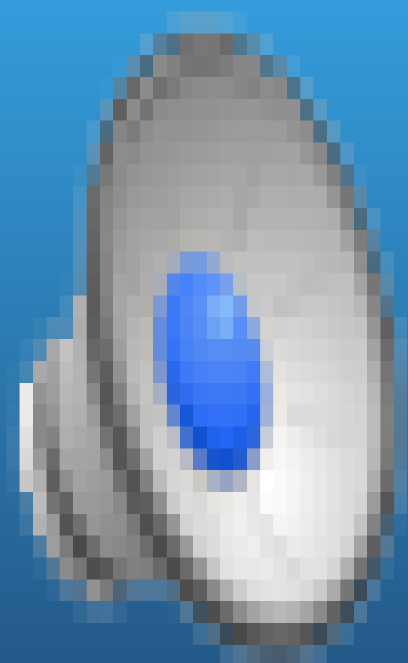


Figure 4 Periprocedural Complications



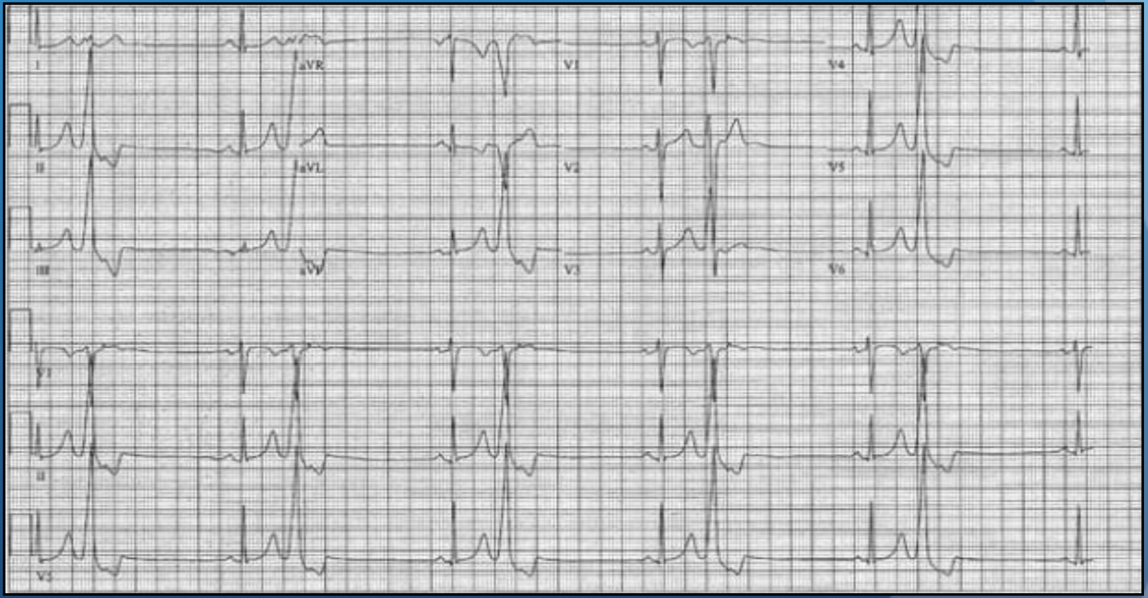


Coronary Cusp VT

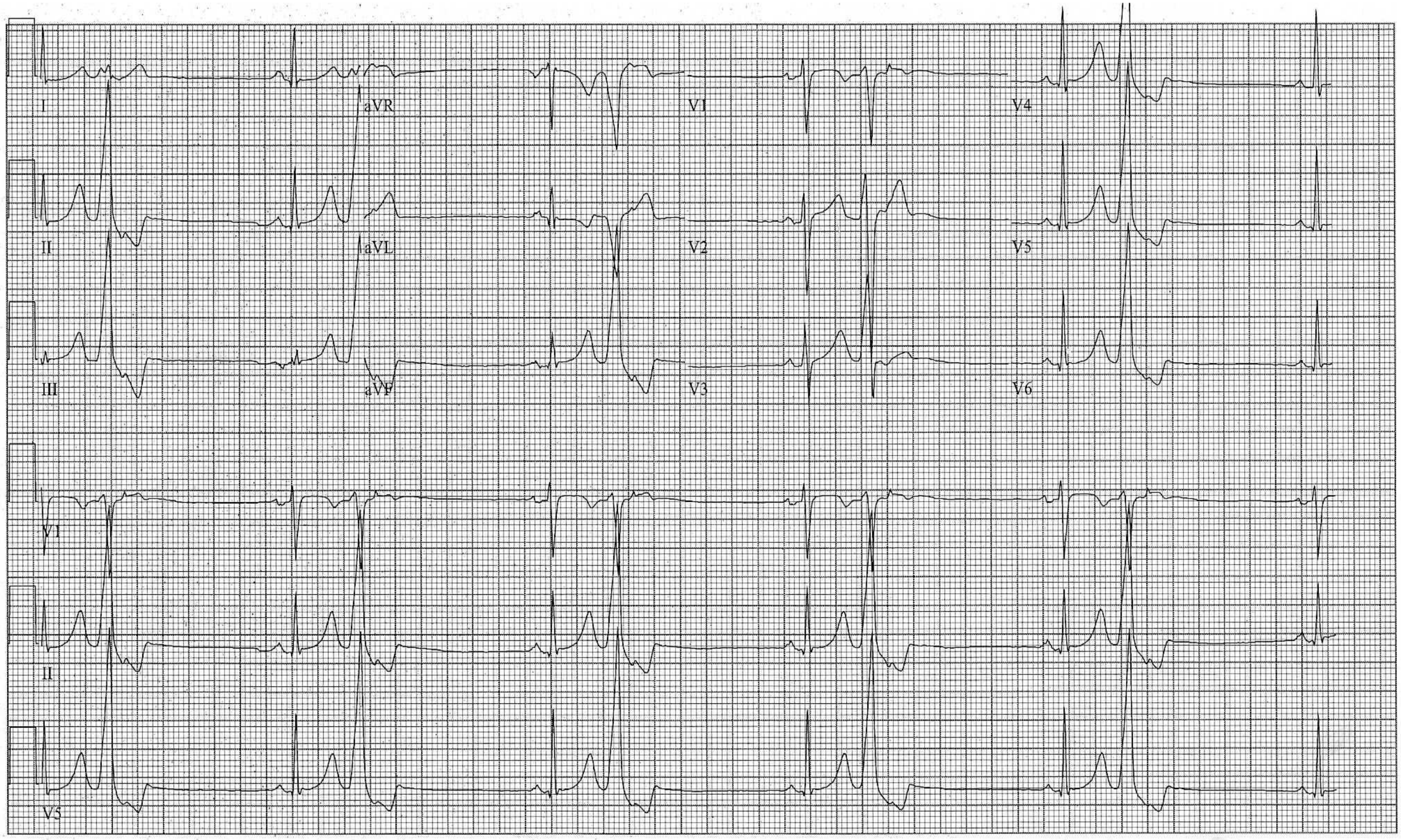
Remote Magnetic Navigation to Map and Ablate Left Coronary Cusp Ventricular Tachycardia

J. DAVID BURKHARDT, M.D., WALID I. SALIBA, M.D., ROBERT A. SCHWEIKERT, M.D., JENNIFER CUMMINGS, M.D., and ANDREA NATALE, M.D.

28-year-old male patient with symptomatic paroxysmal monomorphic NSVT/PVCs



J Cardiovasc Electrophysiol 2006;17: pp. 1-3.



25mm/s 10mm/mV 150Hz 005E 12SL 250 CID: 19

EID:23 EDT: 13:20 06-FEB-2006 ORDER: 256788740 ACCOUNT: 0999

Page 1 of 1


9:28:44 am
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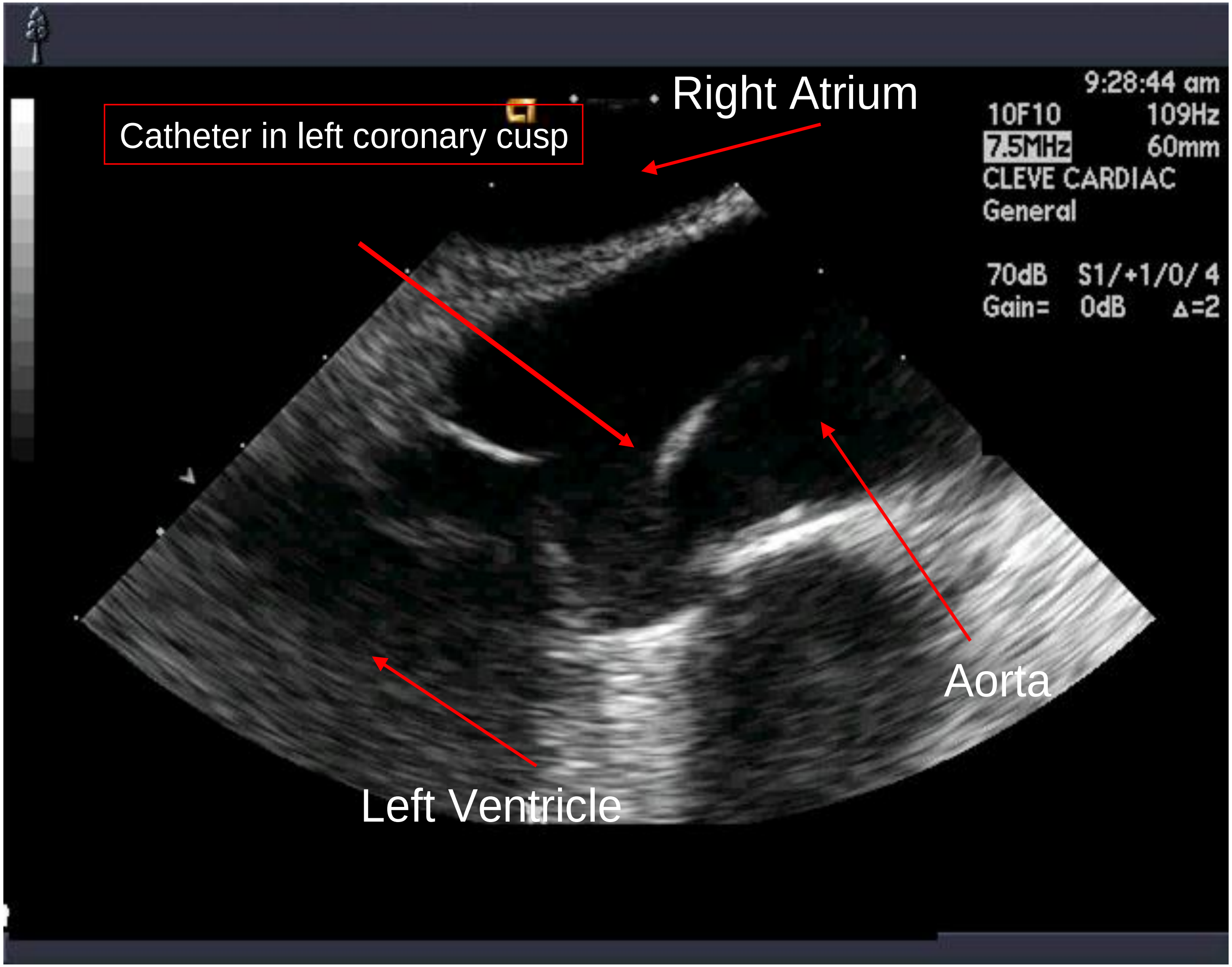
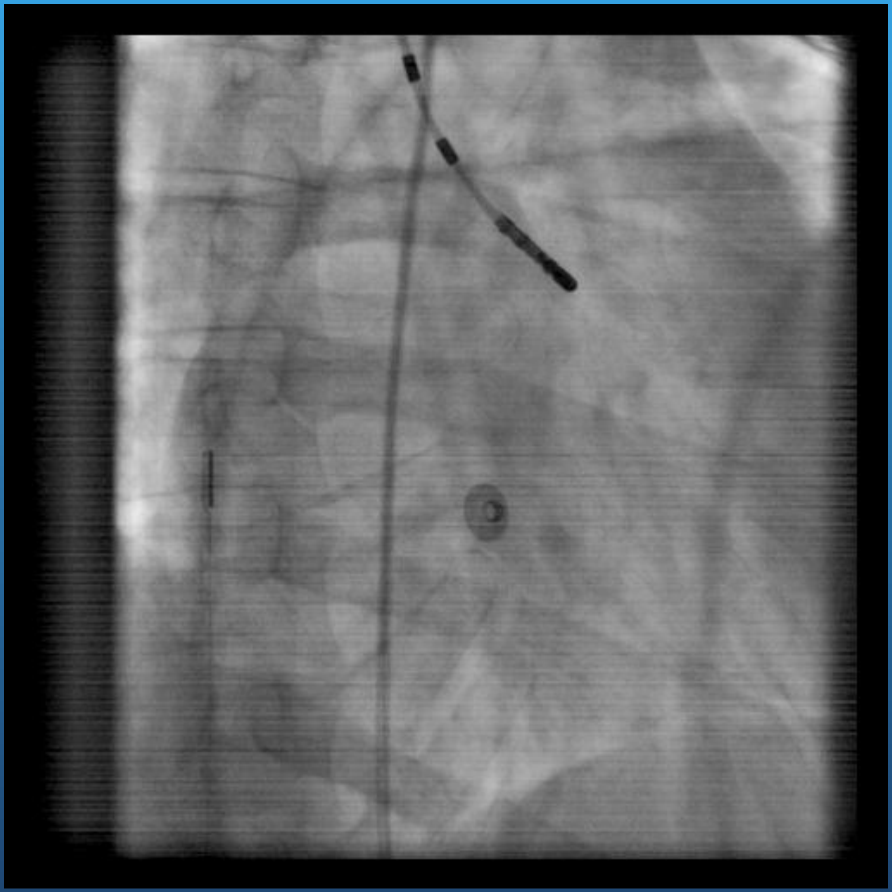
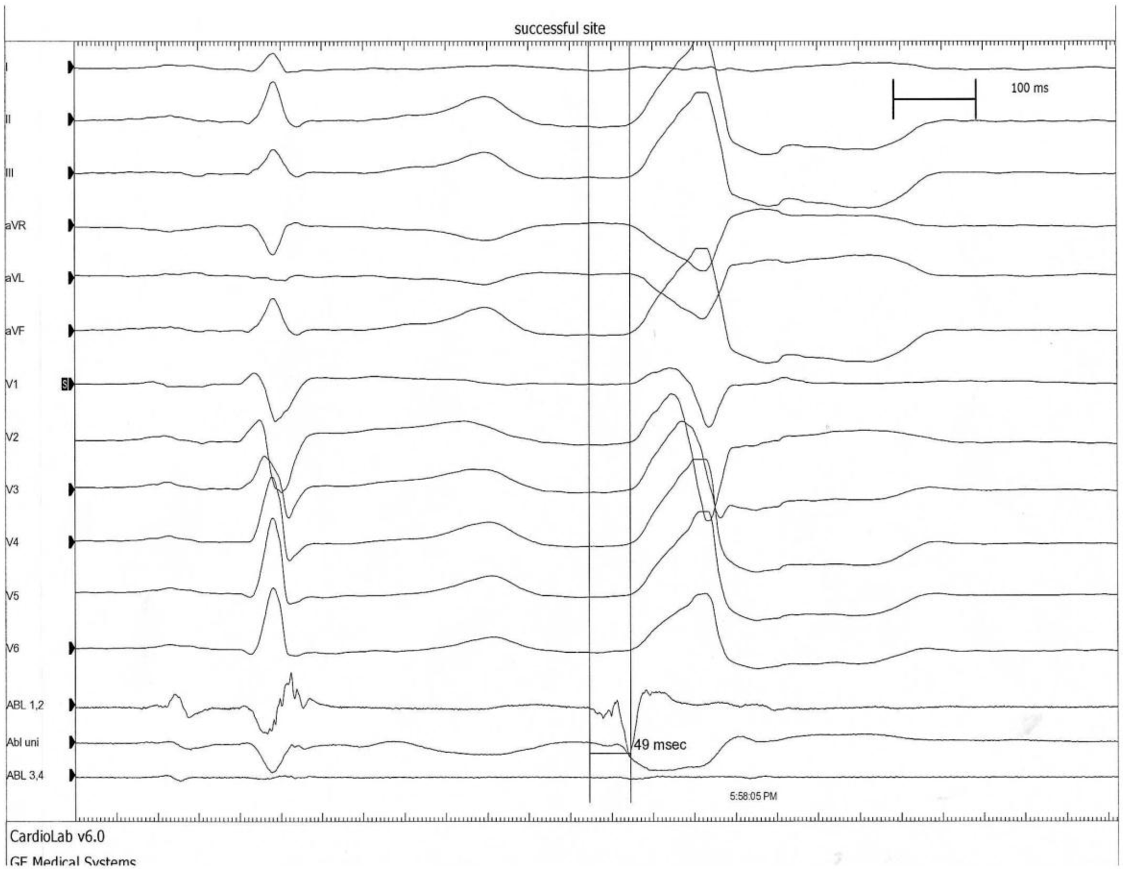
7.5MHz 60mm
CLEVE CARDIAC
General
70dB S1/+1/0/ 4
Gain= 0dB ▵=2


Catheter in left coronary cusp
Right Atrium
Aorta
Left Ventricle
9:28:44 am
10F10 109Hz
7.5MHz 60mm
CLEVE CARDIAC
General
70dB S1/+1/0/4
Gain= 0dB Δ=2




successful site
100 ms
I
II
III
aVR
aVL
aVF
V1
V2
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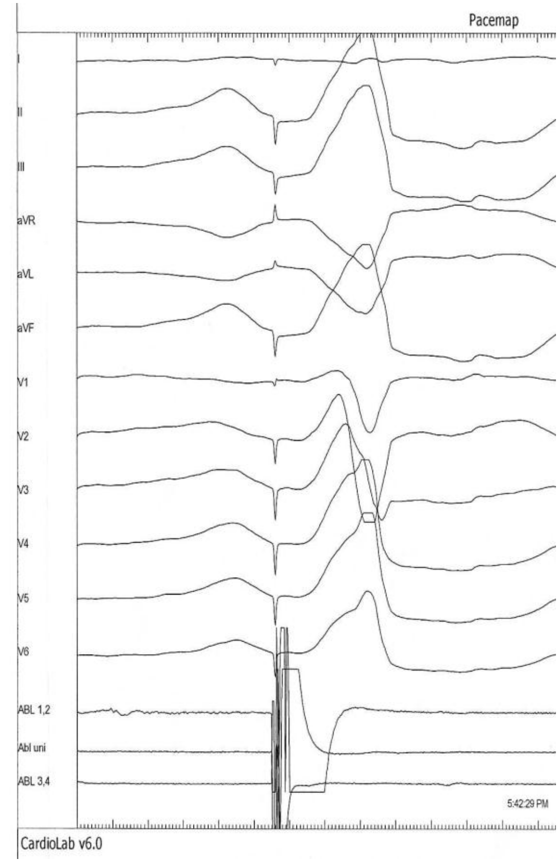
V5
V6
ABL 1,2
Abl uni
ABL 3,4
49 msec
5:58:05 PM
CardioLab v6.0
GE Medical Systems


Pacemap
I
II
III
aVR
aVL
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V1
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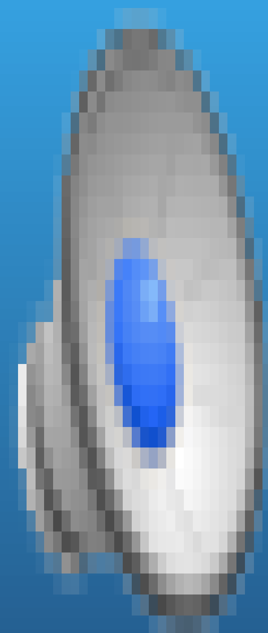
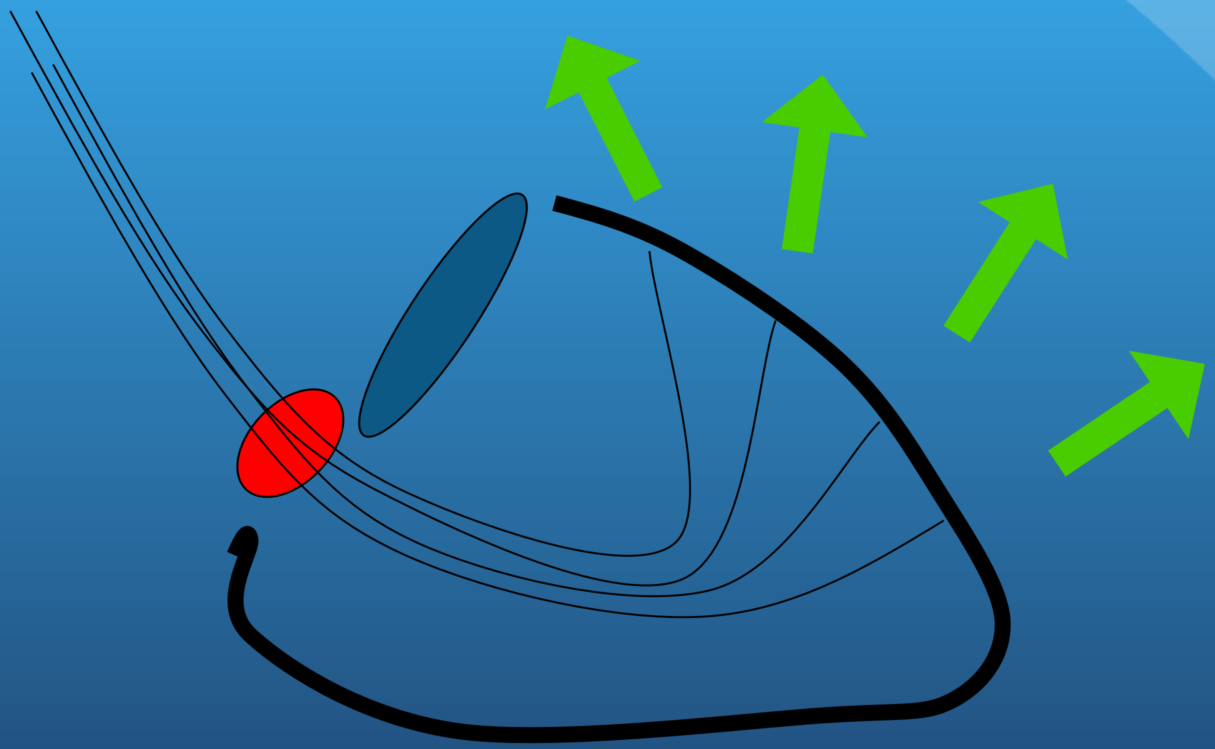
V3
V4
V5
V6
ABL 1,2
Abl uni
ABL 3,4
5:42:29 PM
CardioLab v6.0

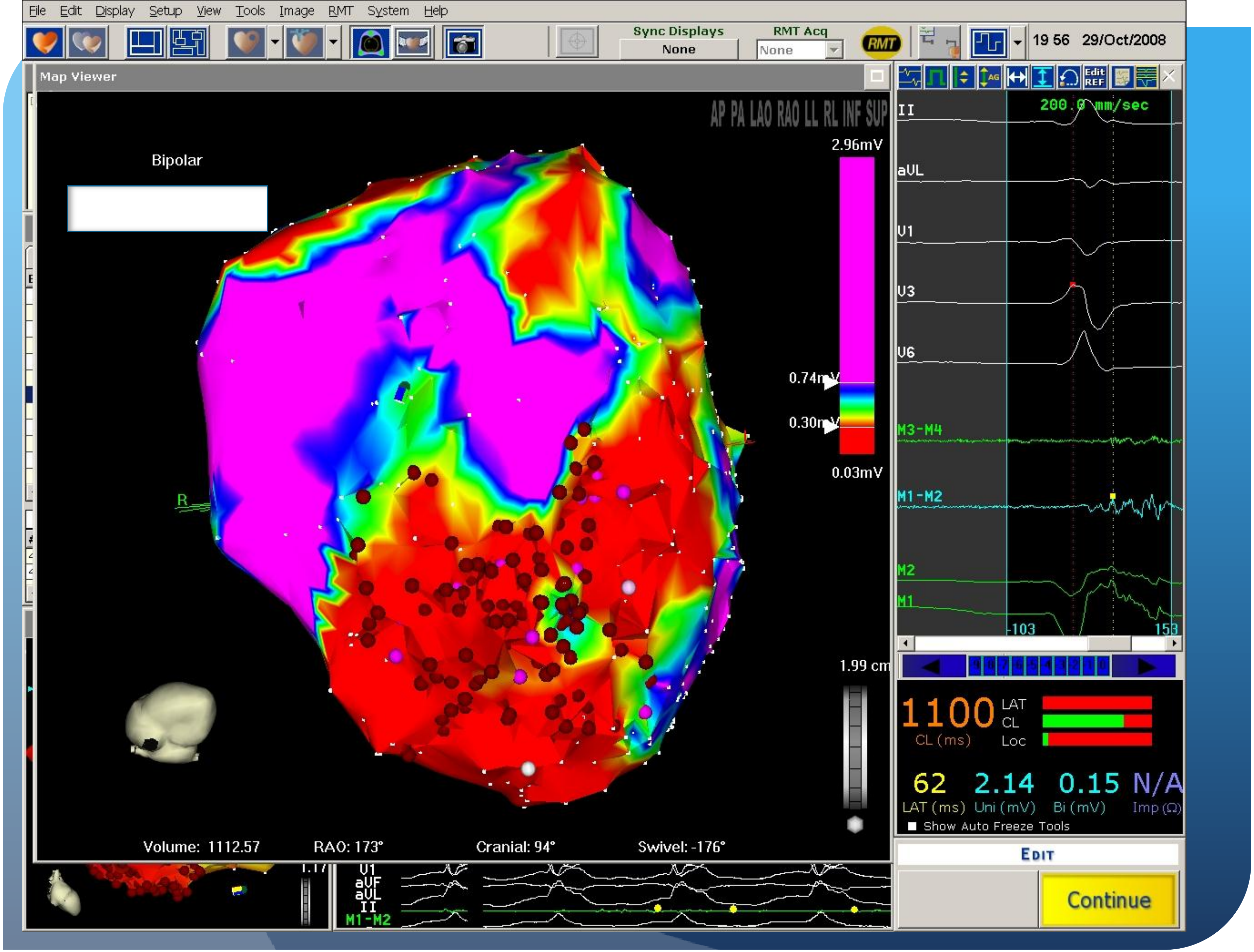


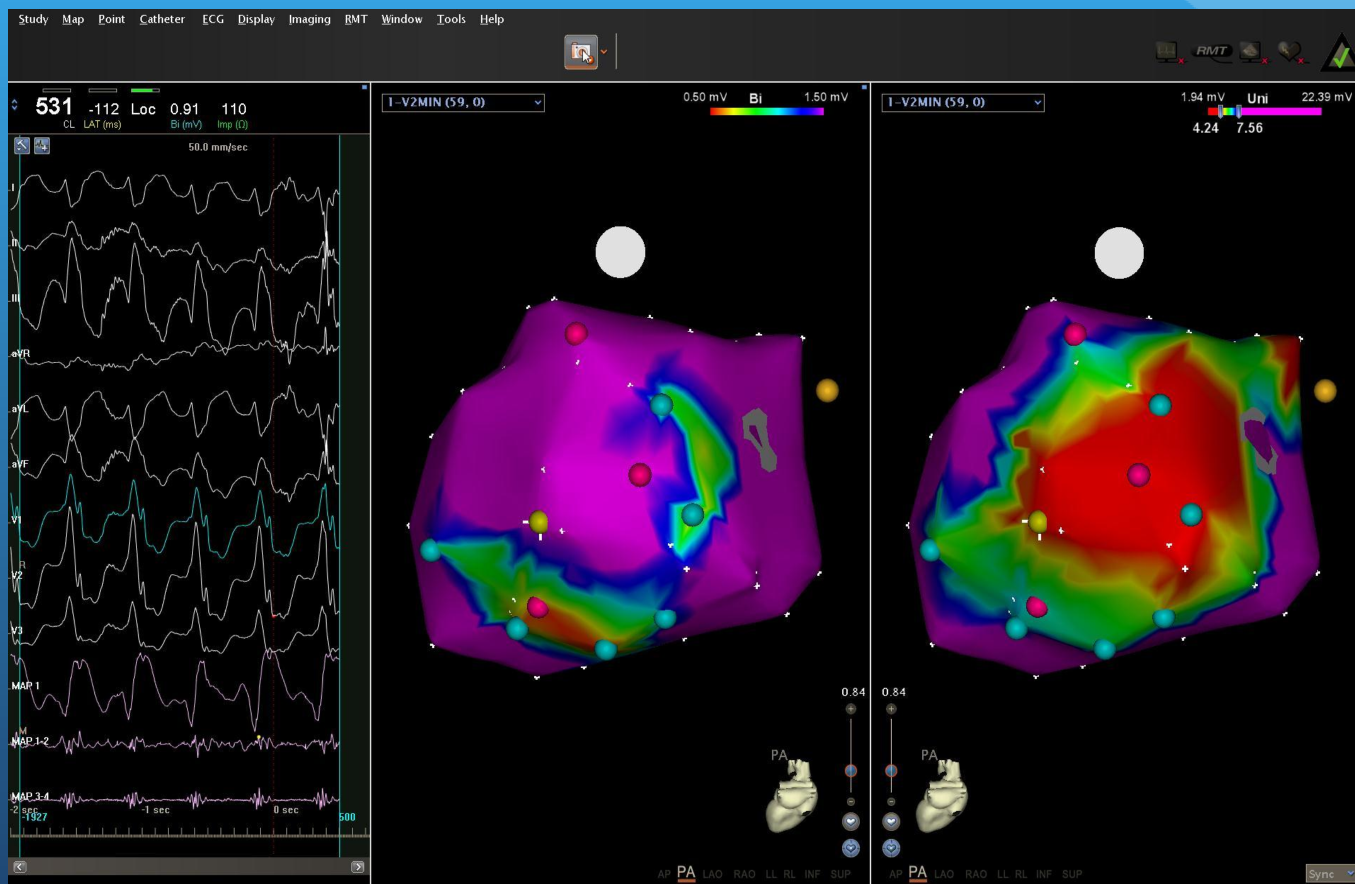
LV Navigation: TS Inferior Base

LV Navigation: TS Inferior Wall

LV Navigation: Anterior Wall




File Edit Display Setup View Tools Image RMT System Help
Sync Displays
None
RMT Acq
None
RMT
19 56 29/Oct/2008
Map Viewer
AP PA LAO RAO LL RL INF SUP
Bipolar
2.96mV
0.74mV
0.30mV
0.03mV
R
1.99 cm
Volume: 1112.57
RAO: 173°
Cranial: 94°
Swivel: -176°
II
200.0 mm/sec
aVL
V1
V3
V6
M3-M4
M1-M2
M2
M1
-103
153
1100
CL (ms)
LAT
CL
Loc
62
LAT (ms)
2.14
Uni (mV)
0.15
Bi (mV)
N/A
Imp (Ω)
Show Auto Freeze Tools
Edit
Continue
V1
aVF
aVL
II
M1-M2


Study Map Point Catheter ECG Display Imaging RMT Window Tools Help
531 CL
-112 LAT (ms)
Loc
0.91 Bi (mV)
110 Imp (Ω)
50.0 mm/sec
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II
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aVL
aVF
V1
V2
V3
MAP 1
MAP 1-2
MAP 3-4
-2 sec
-1 sec
0 sec
-1927
500
1-V2MIN (59, 0)
0.50 mV Bi 1.50 mV
1-V2MIN (59, 0)
1.94 mV Uni 22.39 mV
4.24 7.56
0.84
0.84
PA
PA
AP PA LAO RAO LL RL INF SUP
AP PA LAO RAO LL RL INF SUP
Sync

Data Suggest That Magnetic Ablation is Inferior in VT Due to Lower Contact Forces

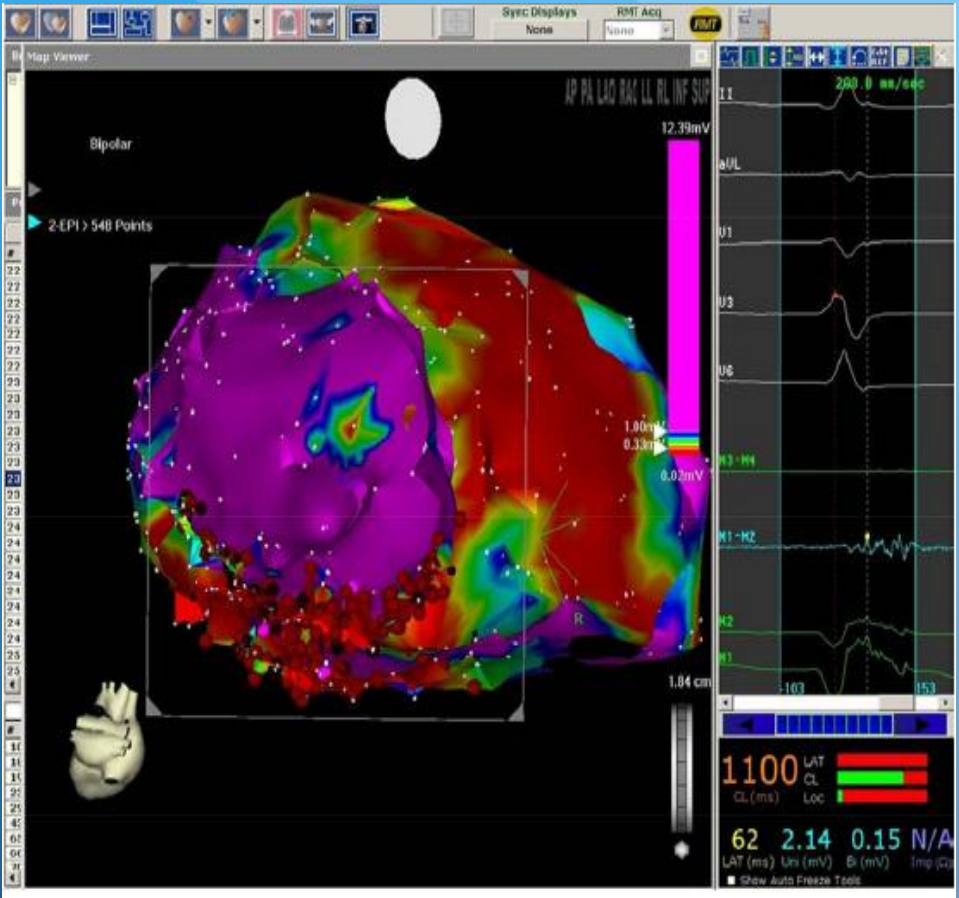
- 1. True
- 2. False

Endo-epicardial ablation of ventricular arrhythmias in the left ventricle with the Remote Magnetic Navigation System and the 3.5-mm open irrigated magnetic catheter: Results from a large single-center case–control series

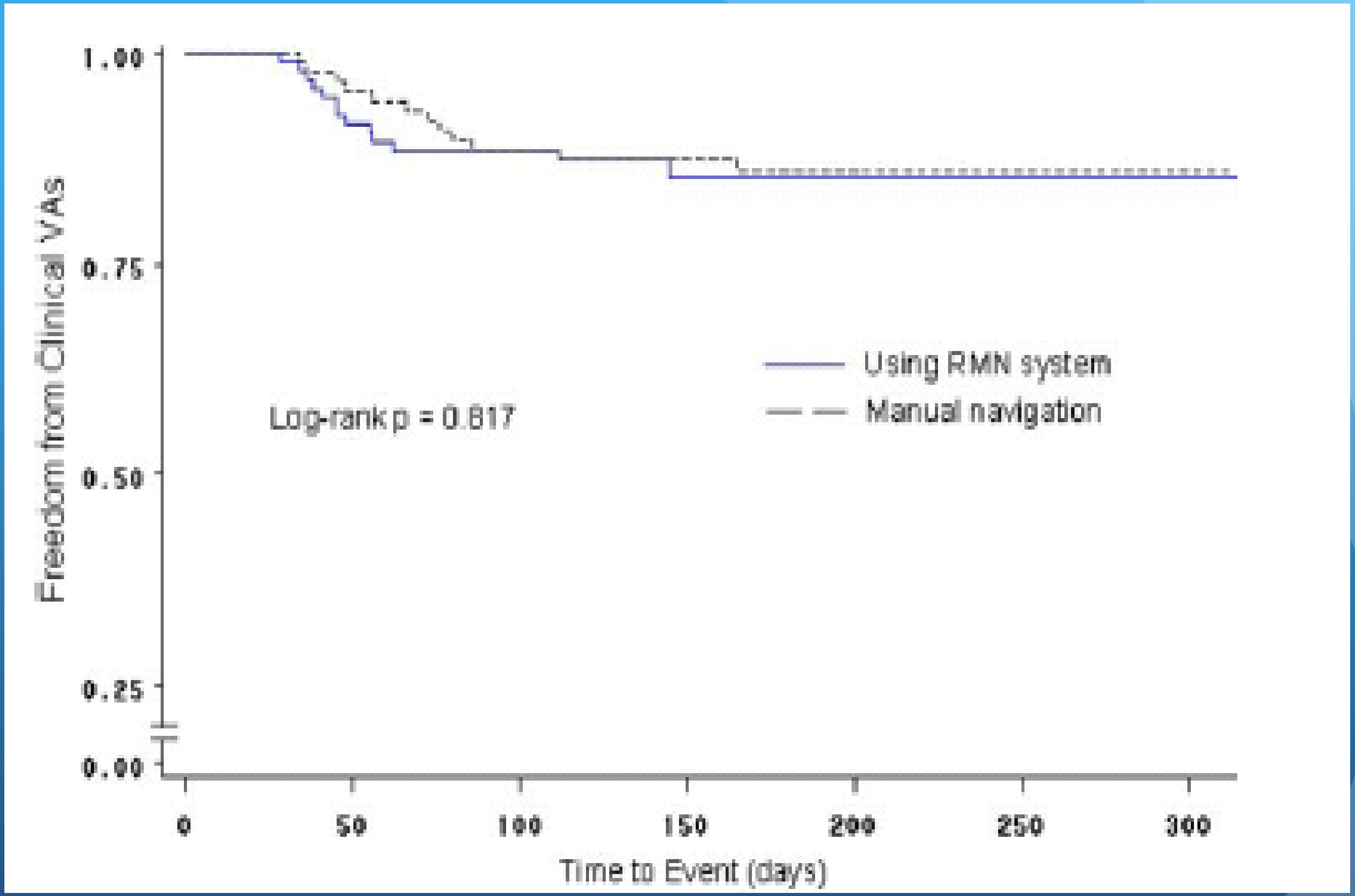
Luigi Di Biase, MD,*†‡ Pasquale Santangeli, MD,*§ Vladimir Astudillo, MD,* Sergio Conti, MD,* Prasant Mohanty, MD,* Sanghamitra Mohanty, MD,* Javier E. Sanchez, MD,* Rodney Horton, MD,*† Barbara Thomas, RN,* J. David Burkhardt, MD, FHRS,* Andrea Natale, MD, FACC, FHRS*†

Table 1 Baseline characteristics

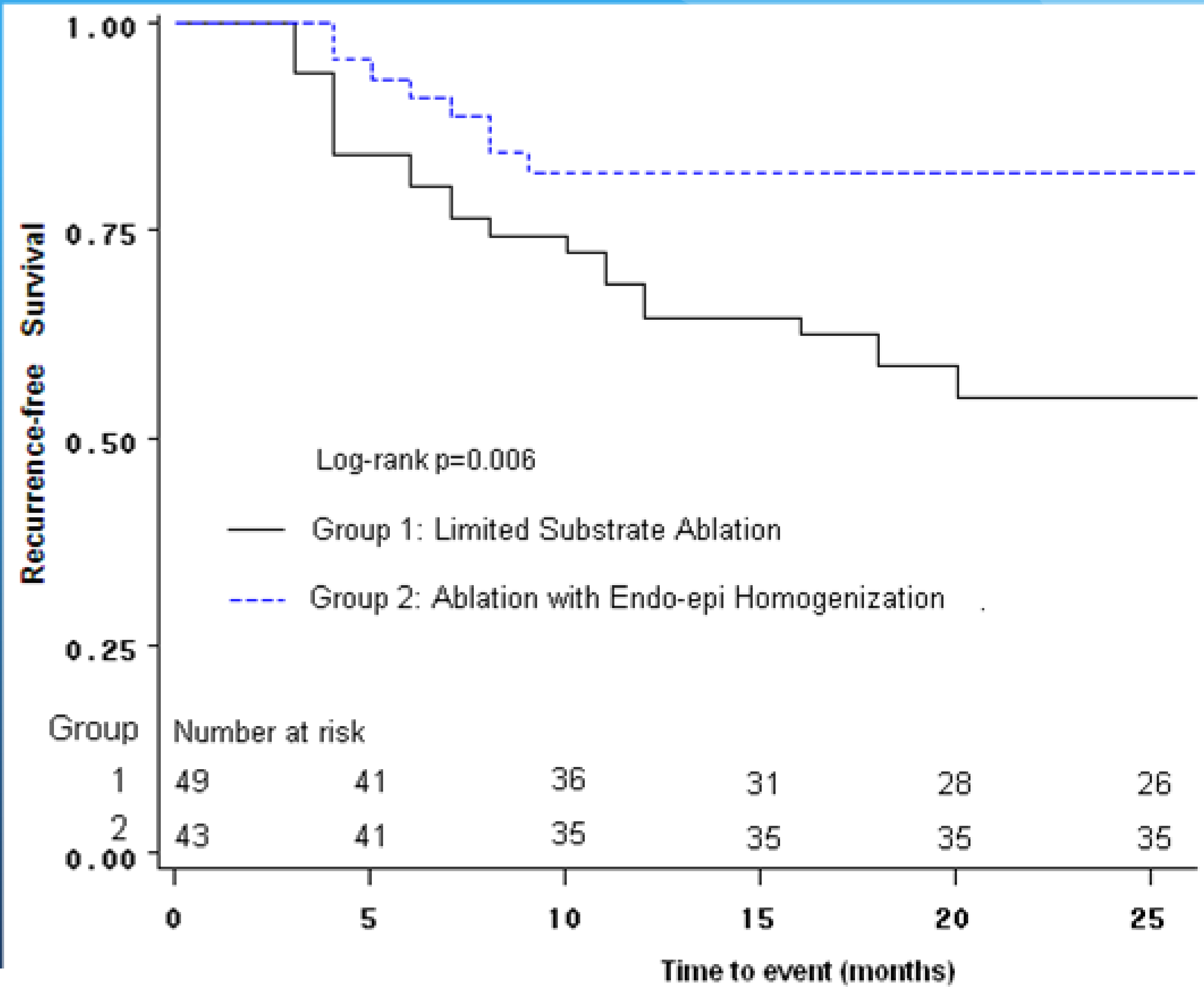
Baseline characteristics	Stereotaxis (n = 110)	Manual (n = 92)	*P* value
Age	56 ± 15	58 ± 15	0.467
Male	75 (68%)	52 (57%)	0.088
Hypertension	64 (58%)	54 (59%)	0.941
Diabetes	17 (16)	13 (14%)	0.792
Hyperlipidemia	44 (40%)	29 (32%)	0.212
BMI	28 ± 4	27 ± 3	0.924
LVEF	40 ± 14	44 ± 15	0.330
COPD	9 (8%)	8 (9%)	1.000
Previous PCI or CABG	19 (17%)	13 (14%)	0.542
ICD implanted	45 (41%)	38 (41%)	0.094
Structural heart disease			
Ischemic cardiomyopathy	33 (30%)	35 (38%)	0.228
Nonischemic cardiomyopathy	14 (13%)	14 (15%)	0.610
No structural heart disease	63 (57%)	43 (47%)	0.135
Baseline BBB			
LBBB	10 (9%)	8 (9%)	1.000
RBBB	9 (8%)	9 (10%)	0.806
None	91 (83%)	75 (82%)	0.824
Medication			
Amiodarone	20 (18%)	19 (21%)	0.423
Beta-blocker	47 (43%)	33 (36%)	0.321
Ca+ channel blocker	10 (9%)	7 (8%)	0.802
Mexiletine	13 (12%)	12 (13%)	0.489
Dofetilide	22 (20%)	14 (15%)	0.376
Flecainide	7 (6%)	9 (10%)	0.438
Sotalol	5 (5%)	7 (8%)	0.387
Other AADs	8 (7%)	5 (5%)	0.775
Electrophysiological study			
Procedure time, hr	3.3 ± 1.1	2.9 ± 1.2	0.040
Fluoroscopy time, min	26 ± 14	35 ± 22	0.033
RF time, min	33 ± 18	24 ± 12	0.005
Clinical morphology of VT			
PVC	84 (76%)	73 (79%)	0.612
Sustained VT	26 (24%)	19 (21%)	0.612
VT induced	79 (72%)	63 (68%)	0.605
VT cycle length	373 ± 106	369 ± 83	0.618
Site of ablation			
LCC	15 (14%)	12 (13%)	0.902
AMC	8 (7%)	7 (8%)	1.000
Septum	26 (24%)	26 (28%)	0.454
Lateral wall	18 (16%)	14 (15%)	0.824
Anterior wall	12 (11%)	9 (10%)	0.822
Coronary sinus	13 (12%)	9 (10%)	0.821
LV apex	7 (6%)	5 (5%)	0.387
Inferior wall	3 (3%)	5 (5%)	0.473
Mitral valve annulus	8 (7%)	6 (6%)	1.000
Type of LV access			
Antegrade approach	70 (64%)	56 (61%)	0.686
Retrograde approach	34 (31%)	31 (34%)	0.673
Both	6 (5%)	5 (5%)	1.000



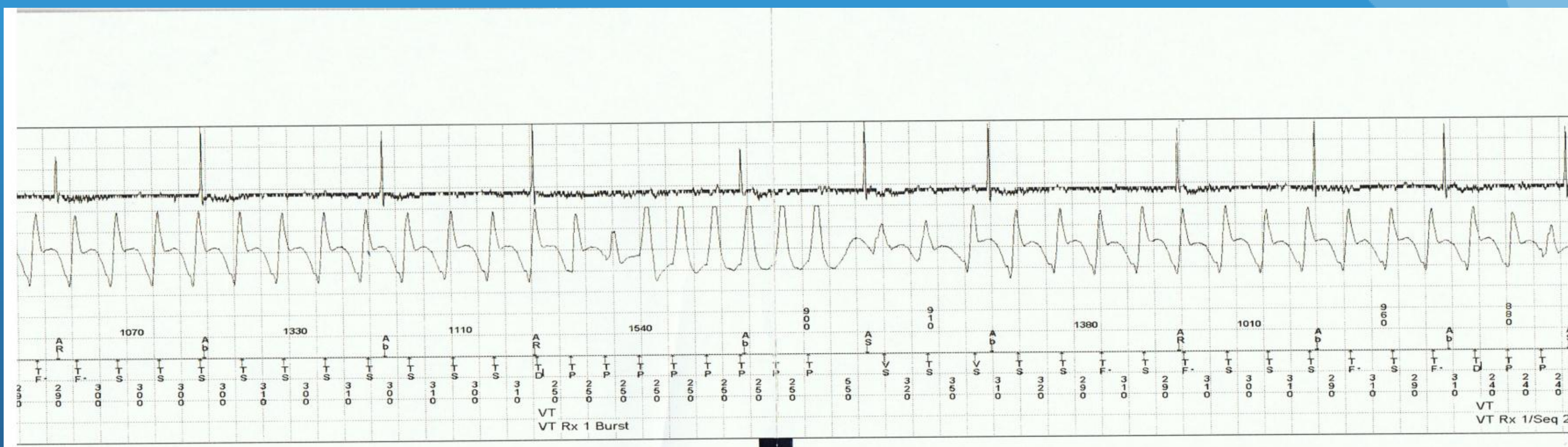
Di Biase L.,Burkhardt Natale A et al. , Heart Rhythm 2010



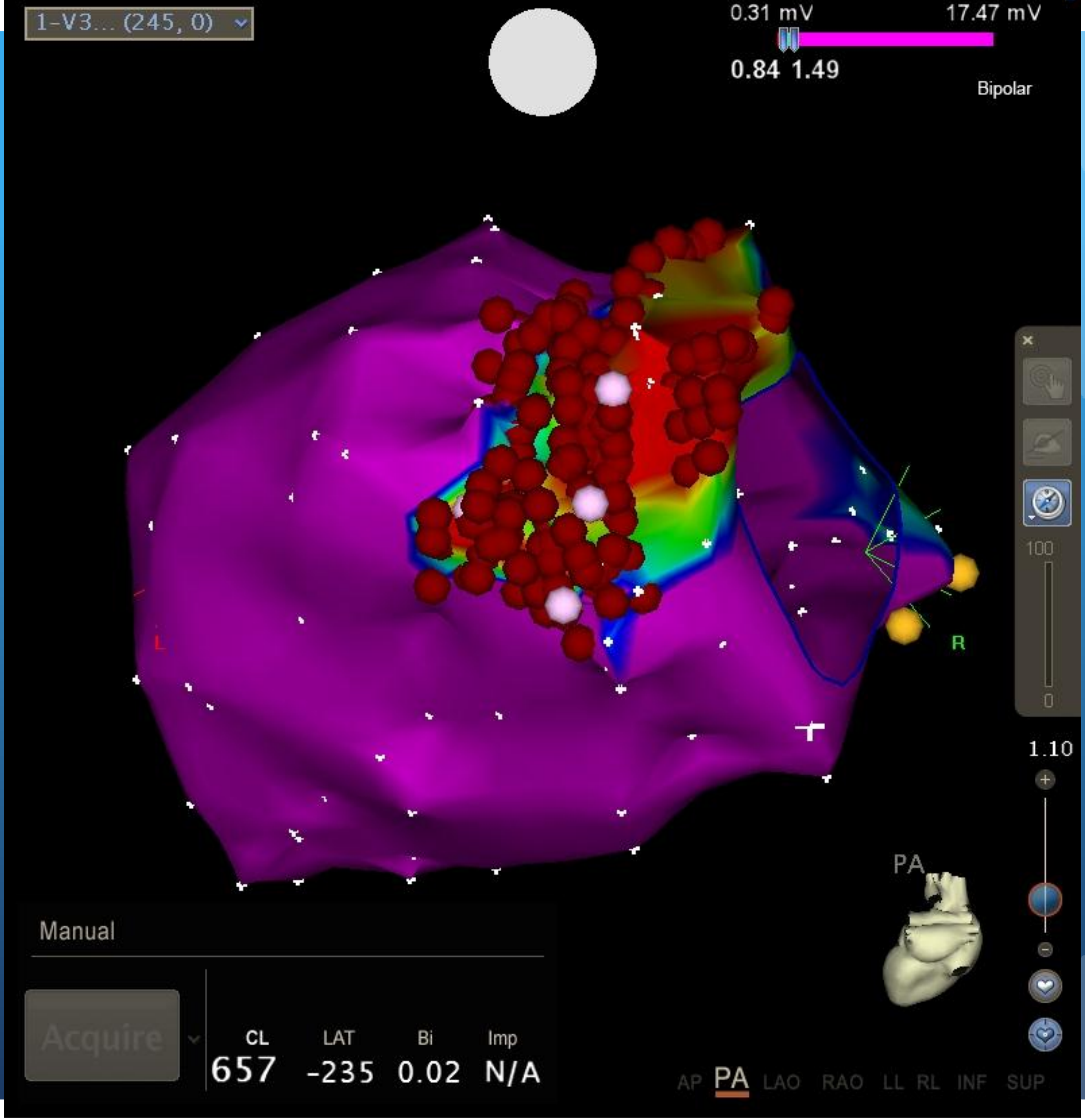
Di Biase L.,Burkhardt Natale A et al. , Heart Rhythm 2010

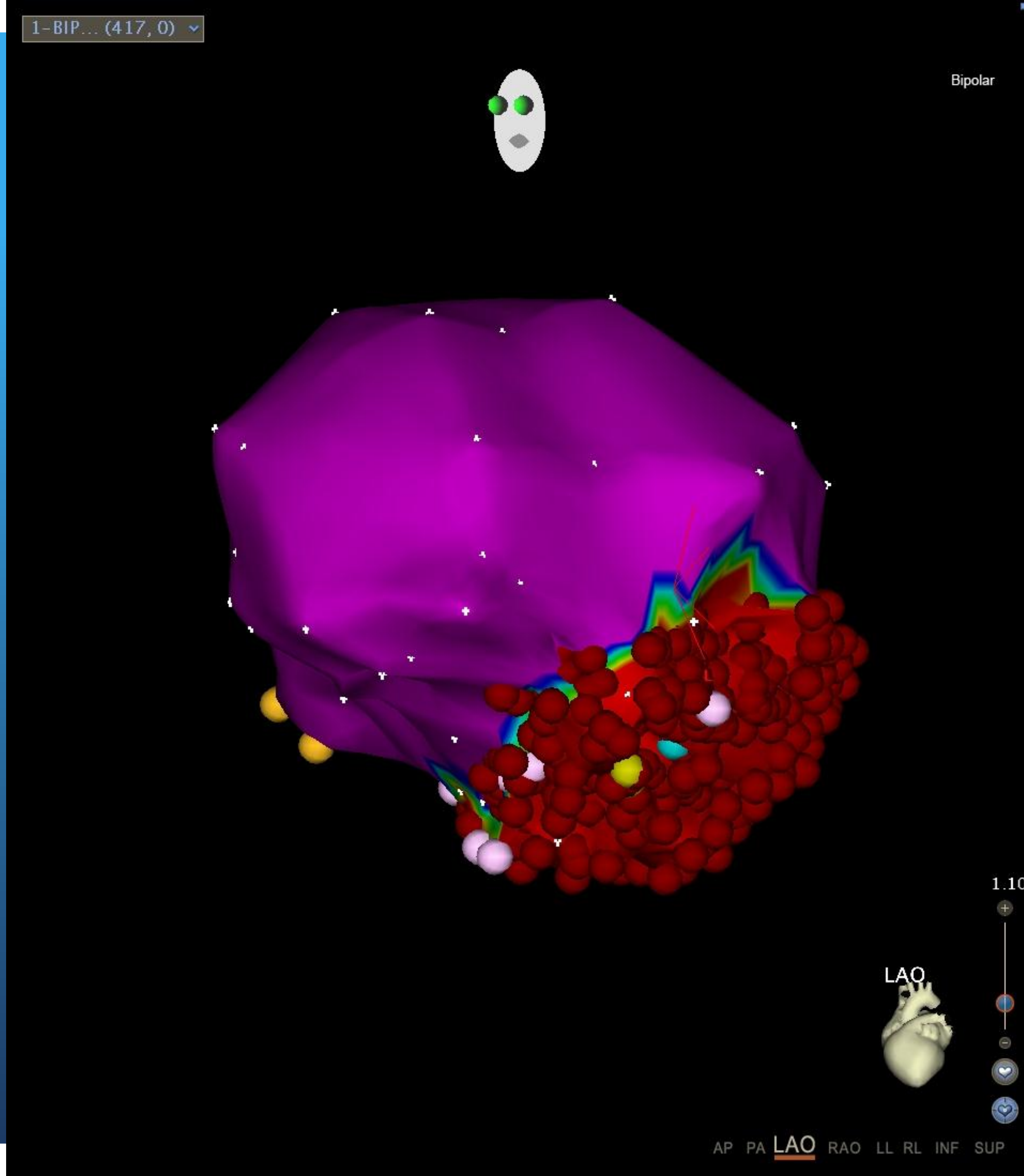


1.00
0.75
0.50
0.25
0.00
Recurrence-free Survival
Log-rank p=0.006
Group 1: Limited Substrate Ablation
Group 2: Ablation with Endo-epi Homogenization
Group
Number at risk
1 49 41 36 31 28 26
2 43 41 35 35 35 35
0 5 10 15 20 25
Time to event (months)

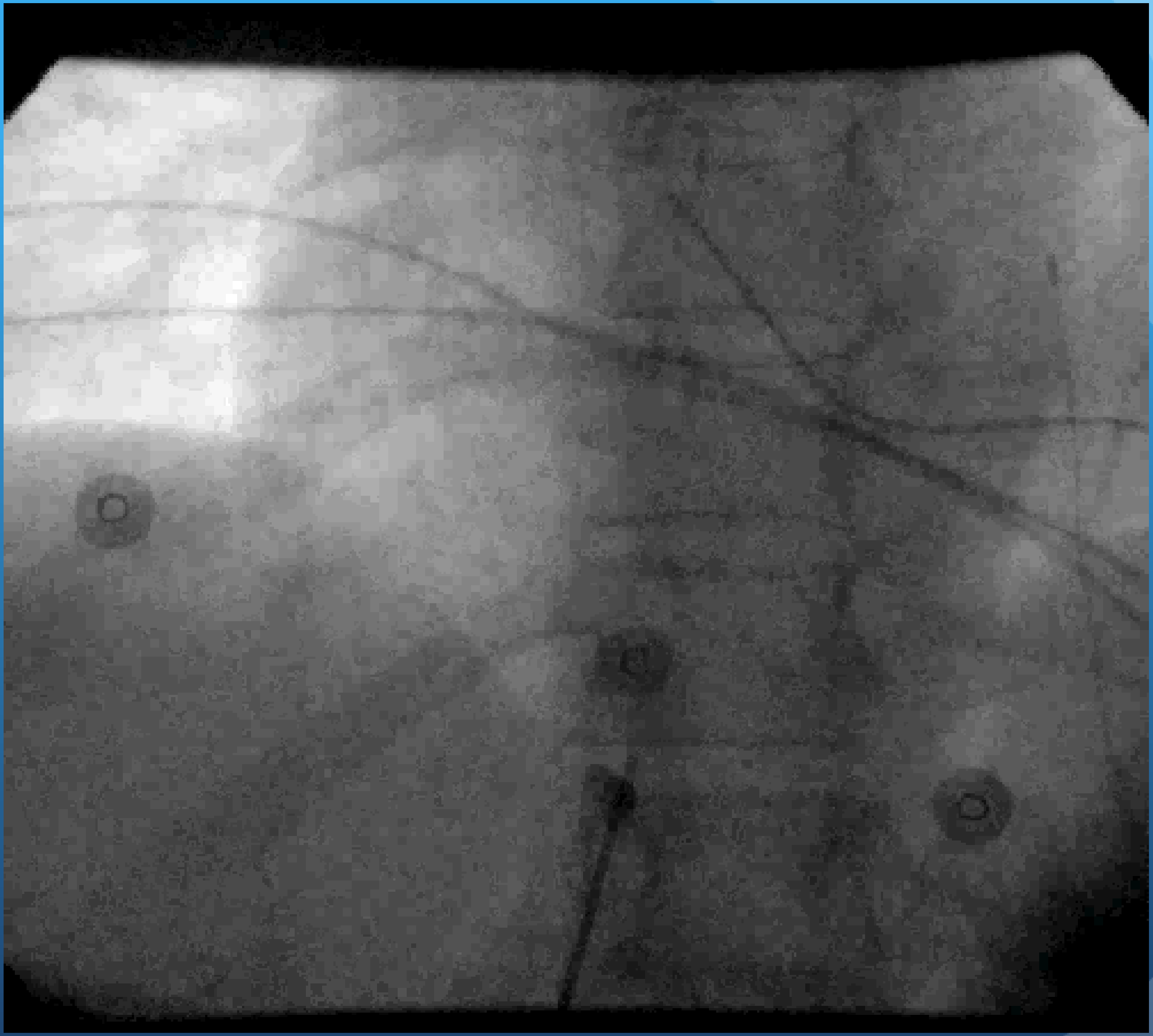

1070
1330
1110
1540
1380
1010
VT
VT Rx 1 Burst
VT
VT Rx 1/Seq 2

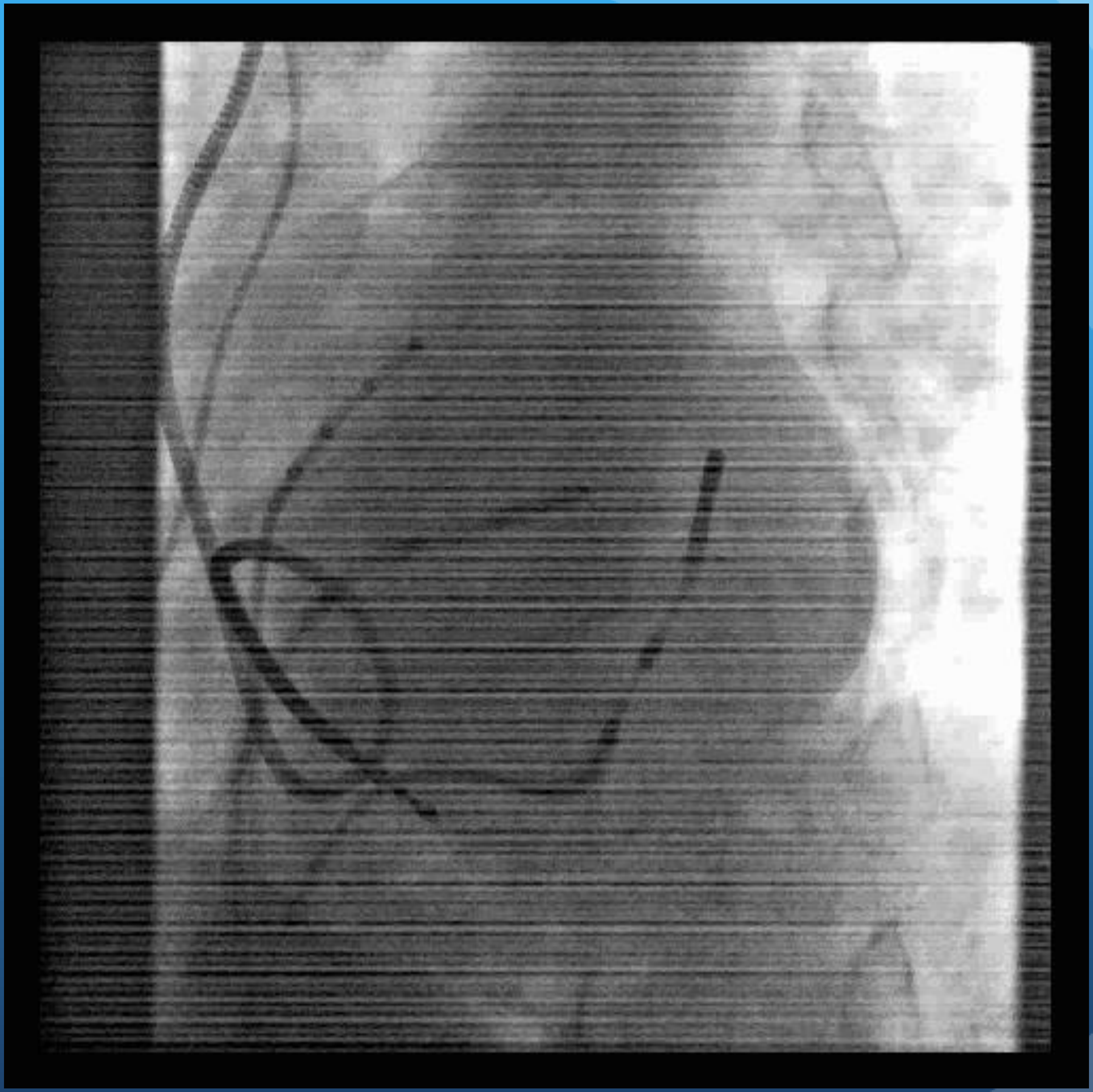

HR= 751 bpm
80 ms
BP= 27/13/17 mmHg
BL p
BL d
150 mm/sec
Freeze
Notch
Mute

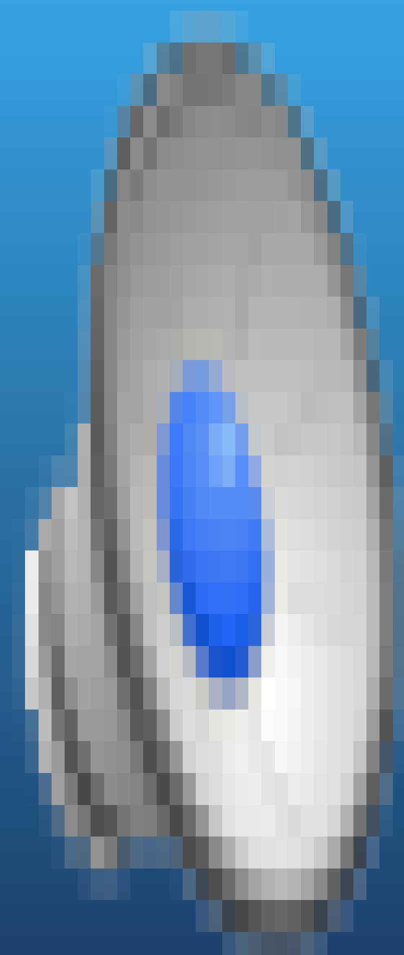

1-V3... (245, 0)
0.31 mV
17.47 mV
0.84 1.49
Bipolar
100
0
1.10
L
R
PA
Manual
Acquire
CL
657
LAT
-235
Bi
0.02
Imp
N/A
AP PA LAO RAO LL RL INF SUP


1-BIP... (417, 0)
Bipolar
1.10
LAO
AP PA LAO RAO LL RL INF SUP

- Epicardial Mapping







Sensei™ Robotic Catheter System

Clinical Advantages

✓Stable and repeatable 3D catheter control

✓Able to measure, display and vary the force exerted on the catheter tip

✓Compatible with ICE, fluoro, 3D mapping

✓Reduction in radiation exposure

✓Allows physician to remain seated

Economic Advantages

✓Fits ***existing*** EP lab suites

✓Can be configured to serve multiple procedure rooms

✓Fraction of the cost of magnetic guidance

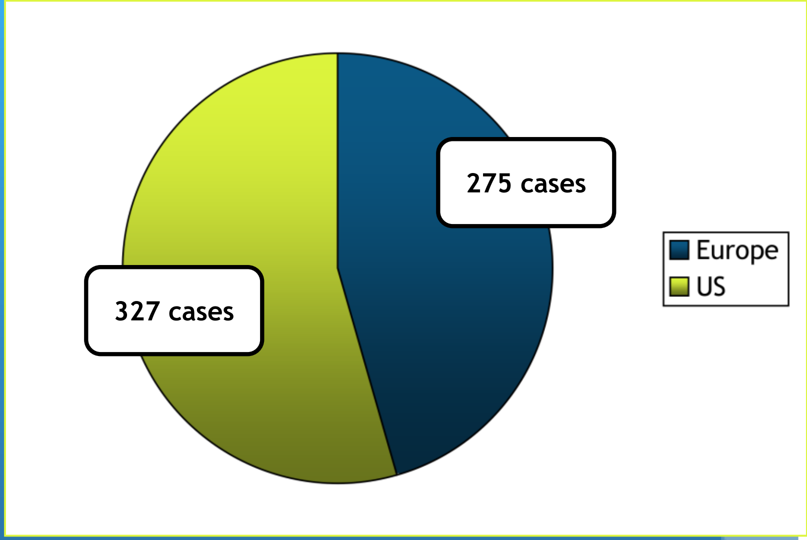
✓Uses existing catheters

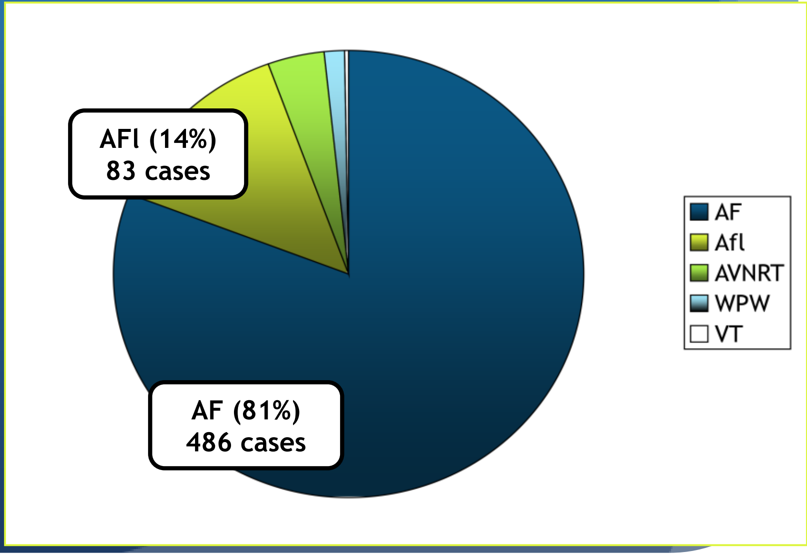
In the U.S., the safety and effectiveness of this device for use with cardiac ablation catheters, in the treatment of cardiac arrhythmias, including atrial fibrillation, have not been established.

Clinical Experience

- Average procedure time similar to manual procedure time
- Average fluoroscopy time similar to manual procedure time
  - Early data from test sites using the CoHesion integrated system with SJM show fluoroscopy times as low as 10 minutes

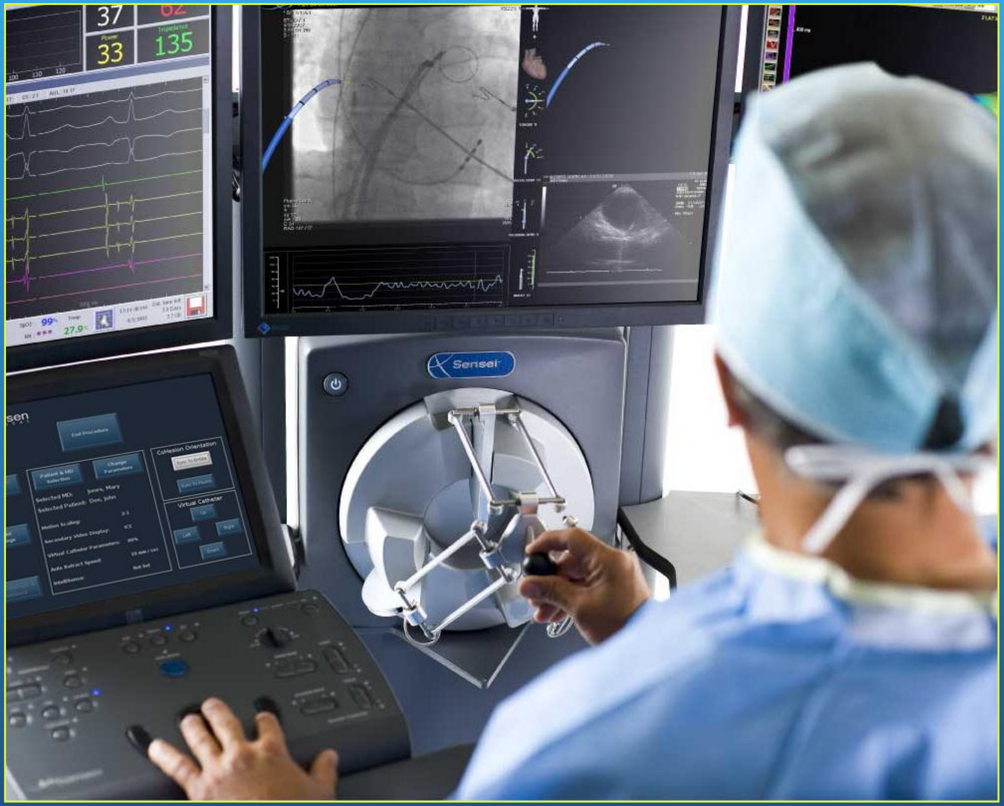
600+ clinical cases post-clearance have used Sensei technology in complex electrophysiology procedures





Data as of May 6, 2008.

Physician Workstation



- Primary interface with the Artisan™ Control Catheter
- Accurate catheter control in 3 dimensions
- Catheter response scalable up to 1:10 ratio
- Multiple monitors display EP and visualization data

Robotic Catheter Manipulator

- Houses the Artisan Control Catheter
- Catheter tip replicates the hand movements of the physician at the instinctive motion controller
- Easily attaches to the procedure table

Artisan™ Control Catheter

- Comprised of steerable inner and outer guide catheters
- Tight bend radius, 270° deflection in any direction
- Accommodates pre-approved existing catheters
  - 8.5 Fr. through lumen

In the U.S., the safety and effectiveness of this device for use with cardiac ablation catheters, in the treatment of cardiac arrhythmias, including atrial fibrillation, have not been established.

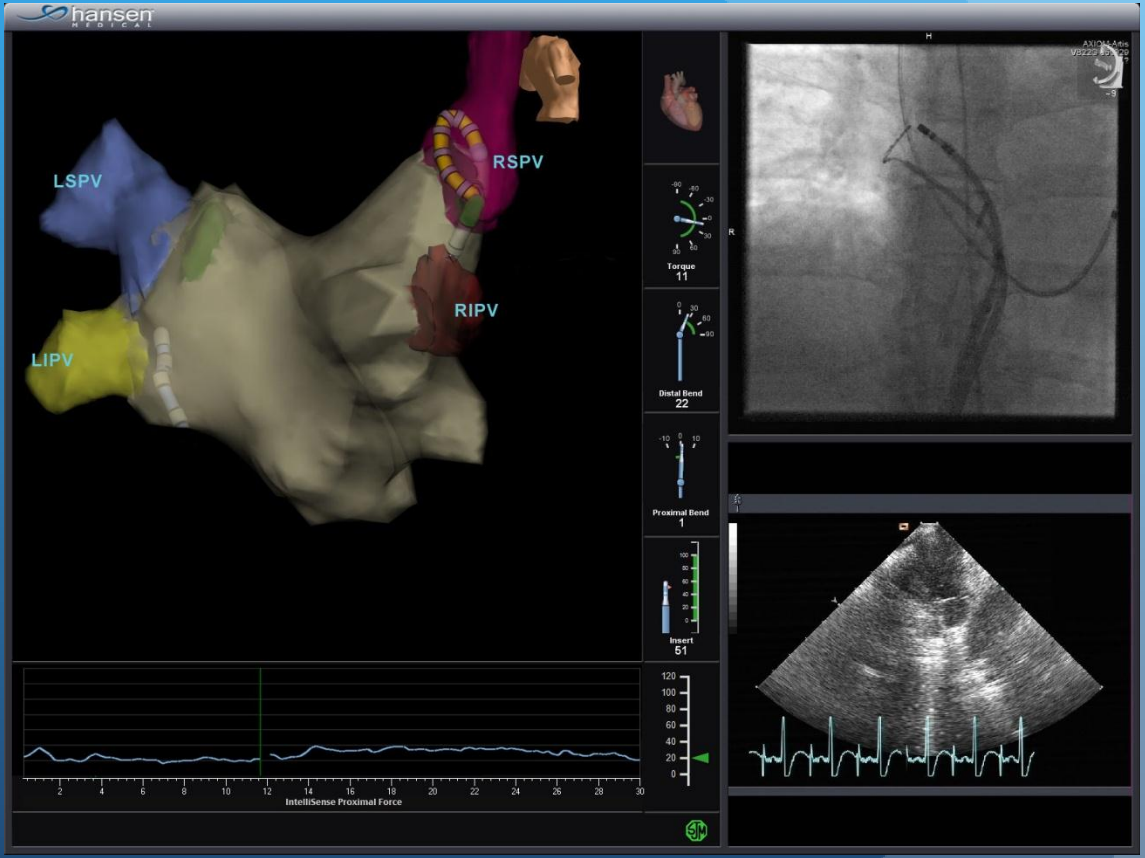
IntelliSense™ Fine Force Technology

- Provides real-time measurement and display of the proximal force along the shaft of the percutaneous catheter
- Discerns small variations in force and displays them in a clear visual format
- Allows physicians to vary the force exerted when needed.

IntelliSense™ Fine Force Technology

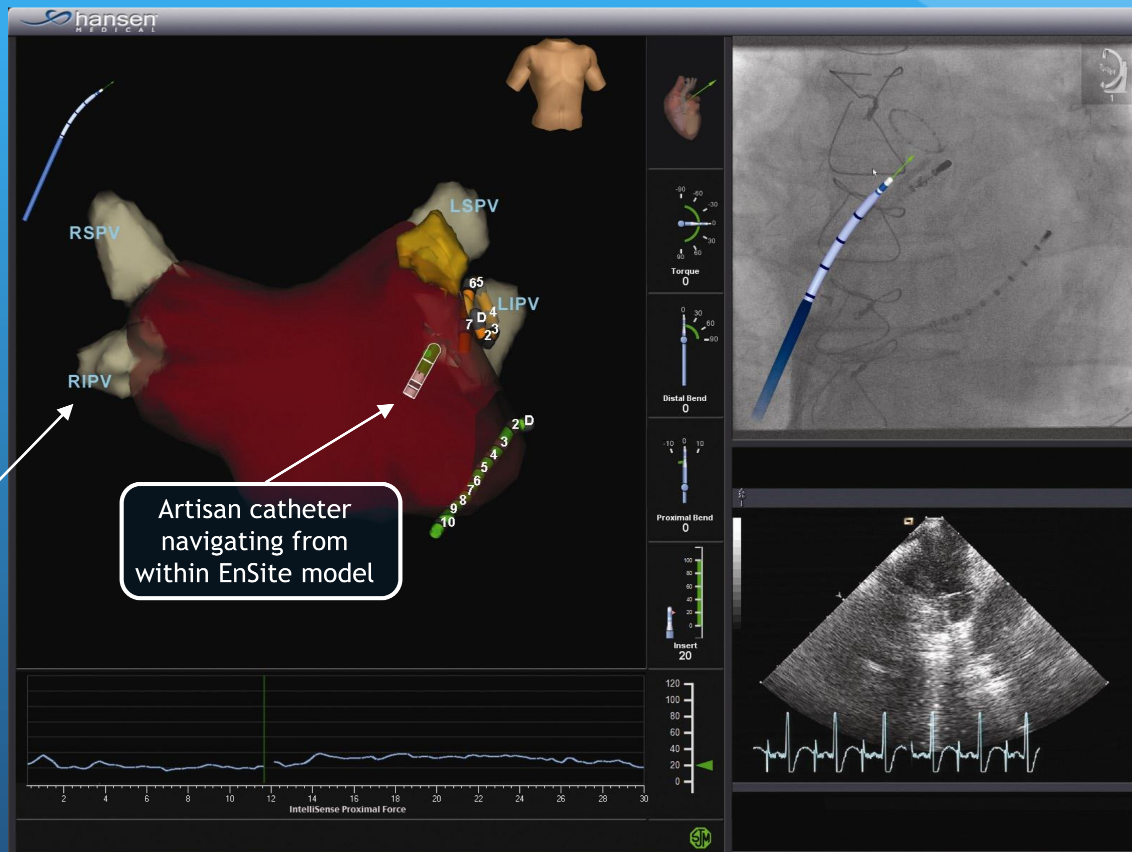
…measures & displays proximal forces on the working catheter

…early pre-clinical work suggests strong link between force and map quality[1]



[1] Okumura Y, Johnson S, Bunch J, Henz B, O'Brien C, Packer D. A Systematical Analysis of *In Vivo* Contact Forces on Virtual Catheter Tip/Tissue Surface Contact during Cardiac Mapping and Intervention. *J Cardiovasc Electrophysiol 2008. In Press*

CoHesion™ 3D Visualization Module



Labels are imported from EnSite system

Imaging Integration

EnSite data import

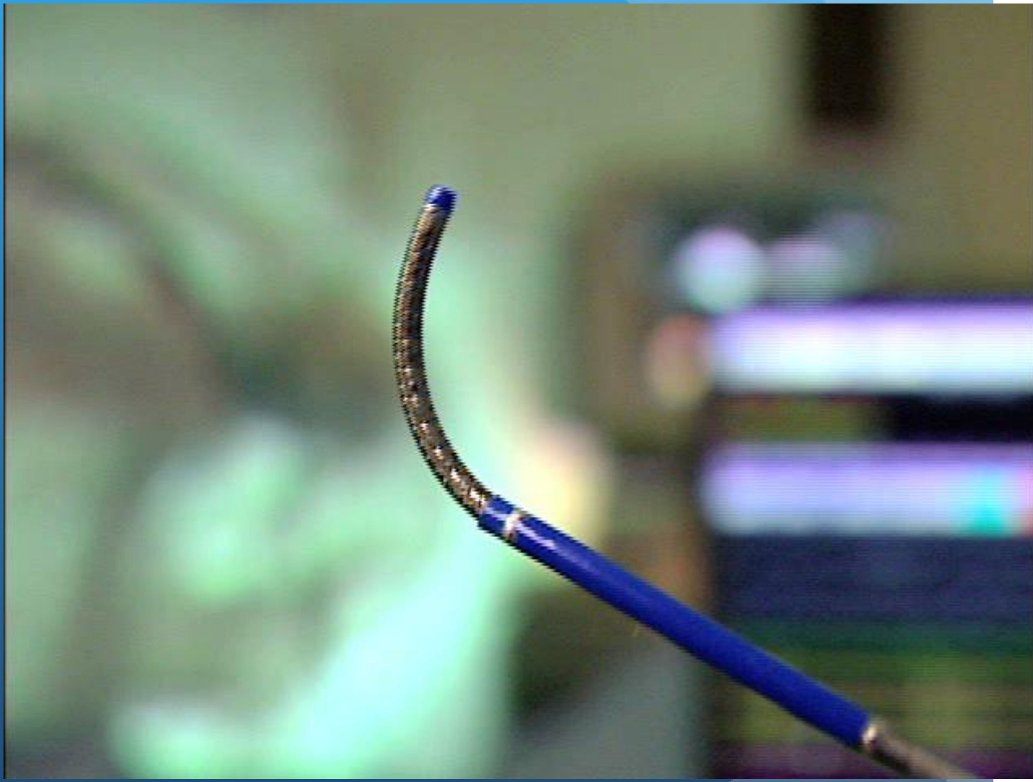
Hansen Robotic Catheter System™

Instinctive Motion Controller

Robotic Catheter Manipulator and Set-Joint

RCM and Setup Joint

Steerable Guide Catheter (SGC) and Steerable Sheath



Questions?