

MediGuide New Technology Assessment (NTA)

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ST. JUDE MEDICAL[®]

MORE CONTROL. LESS RISK.

Status NTA (1) October 2012

- n=87 procedures using MediGuide
- 30 procedures including ablation catheter (Safire Duo MG, Cool Path Duo MB)
 - 19 Atrial Fibrillation
 - 5 VTs
 - 4 Atrial Flutter
 - 2 WPW



First AF Procedure

Safire Duo MediGuide enabled

July 2012

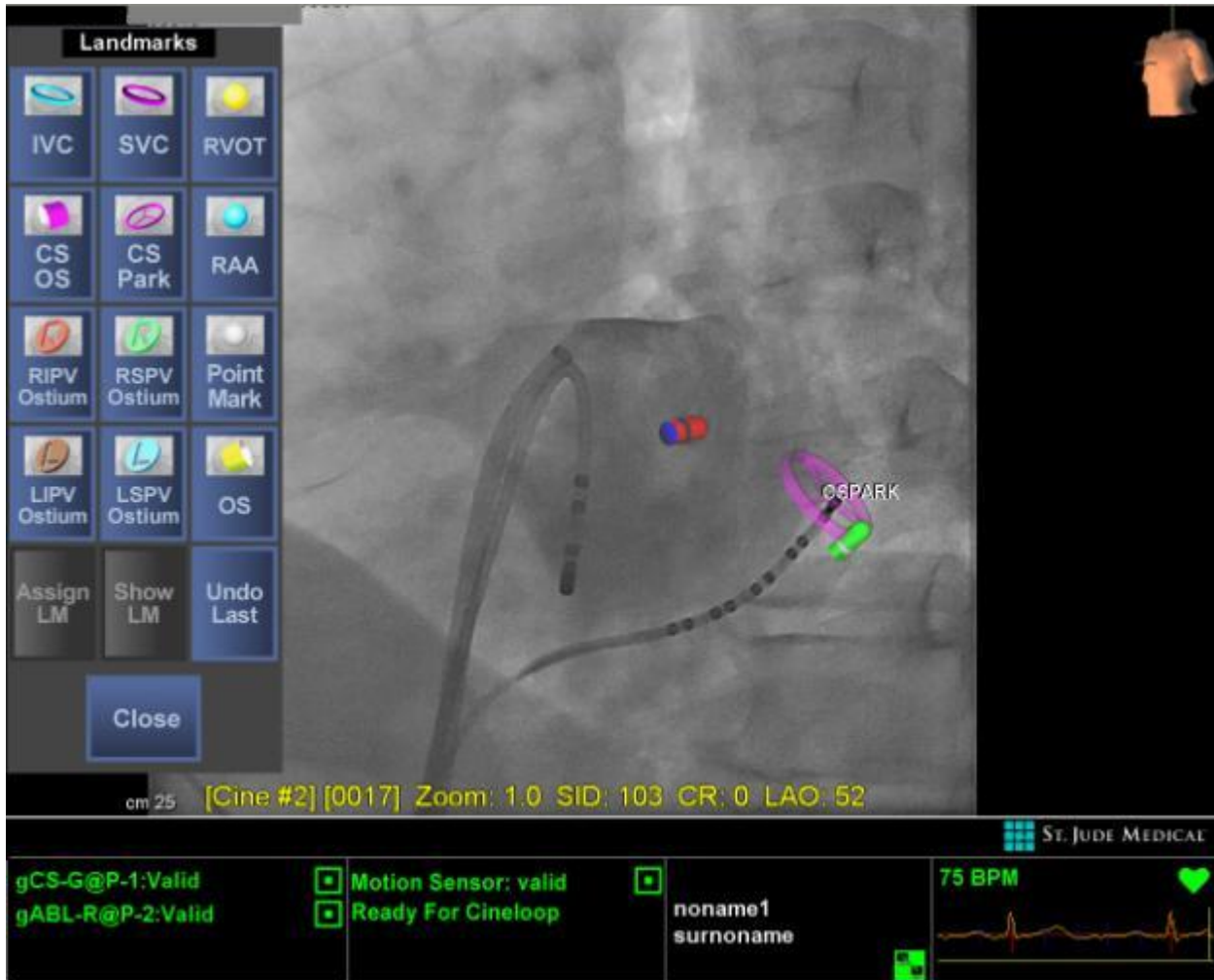


AF Procedure (1)



Atriography of left atrium in AP Projection – Contrast Agent applied through transseptal sheath

AF Procedure (2)



Atriography of
left atrium in
LAO projection

AF Procedure – Marker (1)



AF Procedure – Marker (2)

The screenshot displays a cardiac mapping system interface. On the left is a 'Landmarks' menu with the following options:

- IVC, SVC, RVOT
- CS OS, CS Park, RAA
- RIPV Ostium, RSPV Ostium, Point Mark
- LIPV Ostium, LSPV Ostium, OS
- Assign LM, Show LM, Undo Last
- Close

The central 3D map shows the heart with several catheters and landmarks: RSPV (green circle), LSPV (blue circle), LIPV (red circle), and CSPARK (pink circle). A patient thumbnail is visible in the top right corner.

At the bottom of the map area, the text reads: cm 25 [Cine #2] [0007] Zoom: 1.0 SID: 103 CR: 0 LAO: 52

The bottom status bar includes the following information:

- gCS-G@P-1:Valid
- gABL-R@P-2:Valid
- Motion Sensor: valid
- Ready For Cineloop
- noname1 surname
- 73 BPM
- ECG waveform

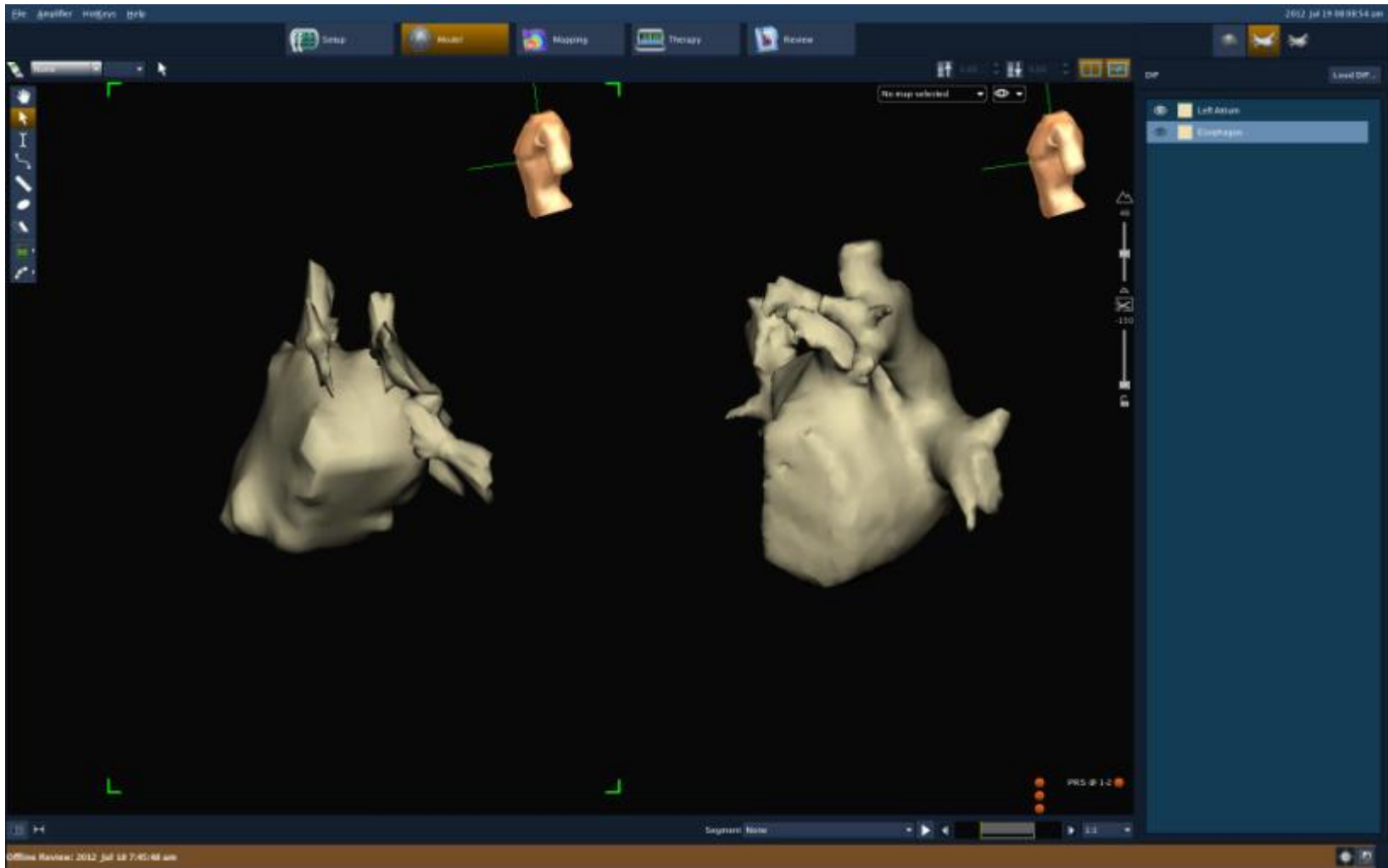
The St. Jude Medical logo is located in the bottom right corner of the interface.

Model – Safire (1)



Model Points taken with Safire only

Model – Safire (2)



Model – Safire (3)



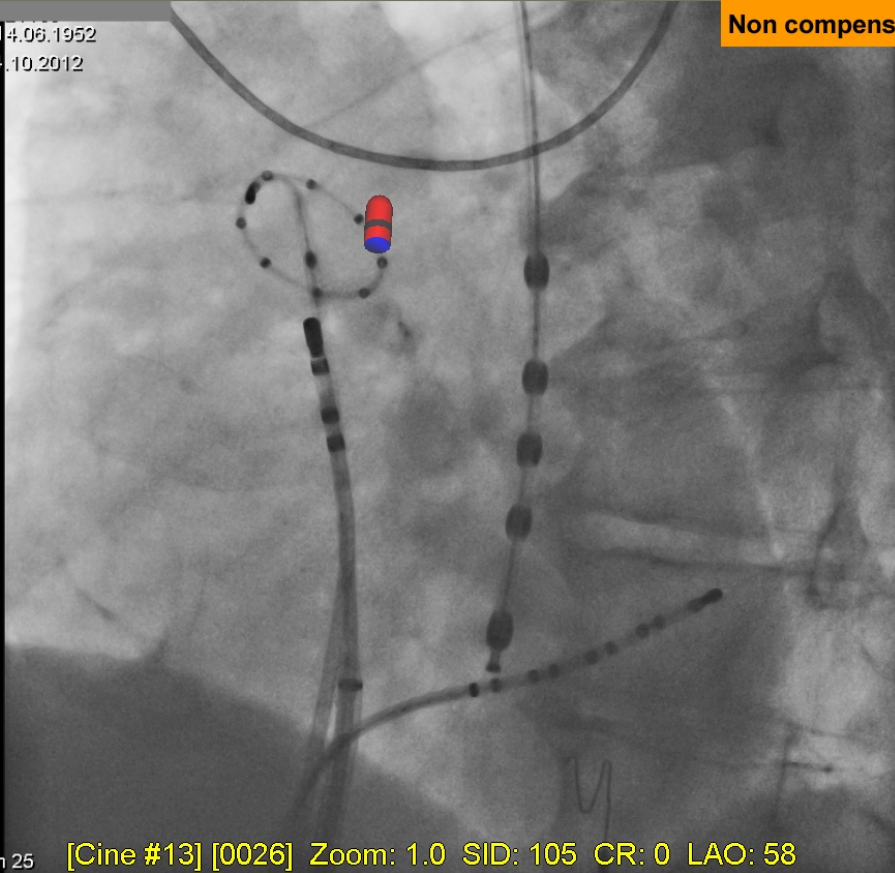
AF Procedure – Summary

- Procedure Duration: 155min
- Total Fluoro Time: 4,1min
 - Catheter Positioning: 0,6min (Biplane Mode)
 - Transseptal Puncture: 1,4min (Biplane Mode)
 - Geometry Creation: 0,7min
 - Ablation: 1,4min
- Total Dosage: 3631,1 μGym^2 (NTA Settings: 15F/s)

Atrial Fibrillation

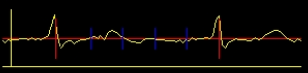

* 14.06.1952
04.10.2012

Non compensated Cineloop Selected



cm 25 [Cine #13] [0026] Zoom: 1.0 SID: 105 CR: 0 LAO: 58

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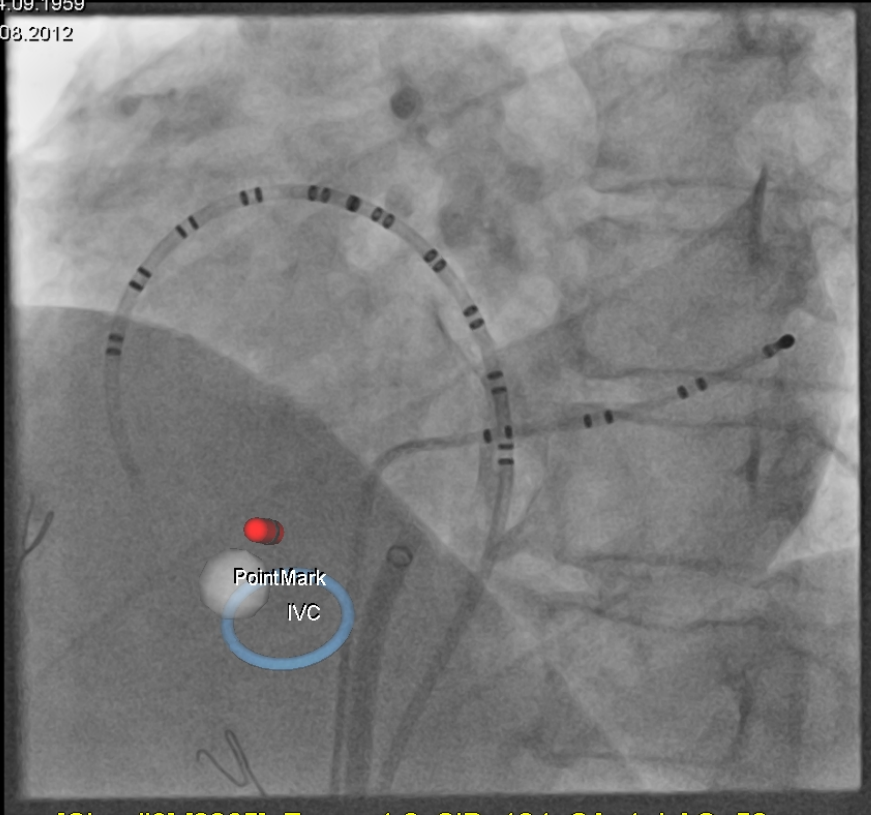
gABL-R@P-2:Valid	<input checked="" type="checkbox"/> Motion Sensor: valid Ready For Cineloop	<input checked="" type="checkbox"/> noname1 surname	79 BPM  
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Atrial Flutter

* 04.09.1959
14.03.2012



Point Mark =
TV annulus



cm 25 [Cine #2] [0065] Zoom: 1.0 SID: 104 CA: 1 LAO: 50

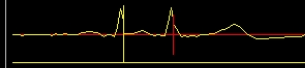
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gABL-R@P-2:Valid

Motion Sensor: valid
Not Ready For Cineloop

noname1
surname

48 BPM



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LVT - Geometry

File Amplifier HotKeys Help Sep 13, 2012 07:32:07 AM

Setup Model Mapping Therapy Review

ABL D Color Diameter(mm): 4 Projection 20 Lesion at EnGuide 3D Lesion at EnGuide -62 -69

VT Review: Sep 04, 2012 08:12:40 AM map

No map selected

No.	Time	Visible
1	09:27:12.688	<input checked="" type="checkbox"/>
2	10:44:46.658	<input checked="" type="checkbox"/>
3	10:44:47.674	<input checked="" type="checkbox"/>
4	10:44:48.397	<input checked="" type="checkbox"/>
5	10:44:49.184	<input checked="" type="checkbox"/>
6	10:44:51.171	<input checked="" type="checkbox"/>
7	10:44:53.176	<input checked="" type="checkbox"/>
8	10:44:59.045	<input checked="" type="checkbox"/>
9	10:45:02.495	<input checked="" type="checkbox"/>
10	10:45:03.203	<input checked="" type="checkbox"/>
11	10:45:04.058	<input checked="" type="checkbox"/>
12	10:45:14.129	<input checked="" type="checkbox"/>
13	10:45:15.039	<input checked="" type="checkbox"/>
14	10:45:15.914	<input checked="" type="checkbox"/>
15	10:45:18.715	<input checked="" type="checkbox"/>
16	10:45:25.734	<input checked="" type="checkbox"/>
17	10:47:35.142	<input checked="" type="checkbox"/>
18	10:47:35.782	<input checked="" type="checkbox"/>
19	10:47:37.118	<input checked="" type="checkbox"/>
20	10:47:39.447	<input checked="" type="checkbox"/>
21	10:47:41.276	<input checked="" type="checkbox"/>
22	10:47:42.828	<input checked="" type="checkbox"/>
23	10:47:44.667	<input checked="" type="checkbox"/>
24	11:08:47.422	<input checked="" type="checkbox"/>
25	11:34:18.900	<input checked="" type="checkbox"/>

Respiration: 300, 200, 100, 0, -100, -200, -300%

Electrode spacing: Distal | D - 2 | 2 - 3 | 3 - 4 |
 Nominal (mm) 4.0 2.0 5.0 2.0
 Measured (mm) 2.3 5.4 1.9

Proximity to EnSite surface: -6.9 mm

ABL @ 1-2 PRF @ 1-2

Property: Visible, Color, Diameter: 4, 3D Lesion

Therapy Display: Show Lesion Text

Segment 02: map

