

Human iCMR EP update 4: Active catheter atrial flutter ablation

Reza Razavi

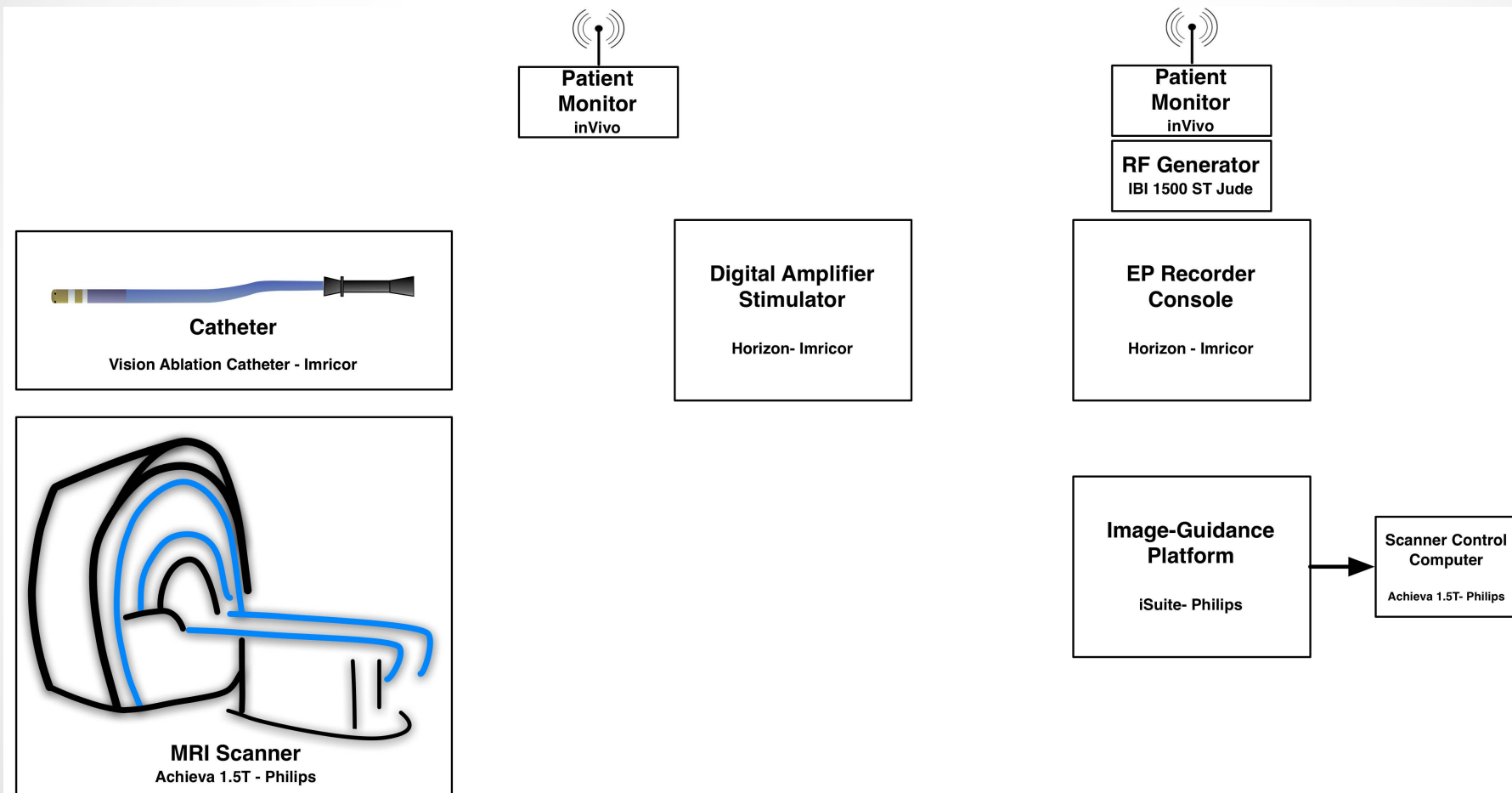
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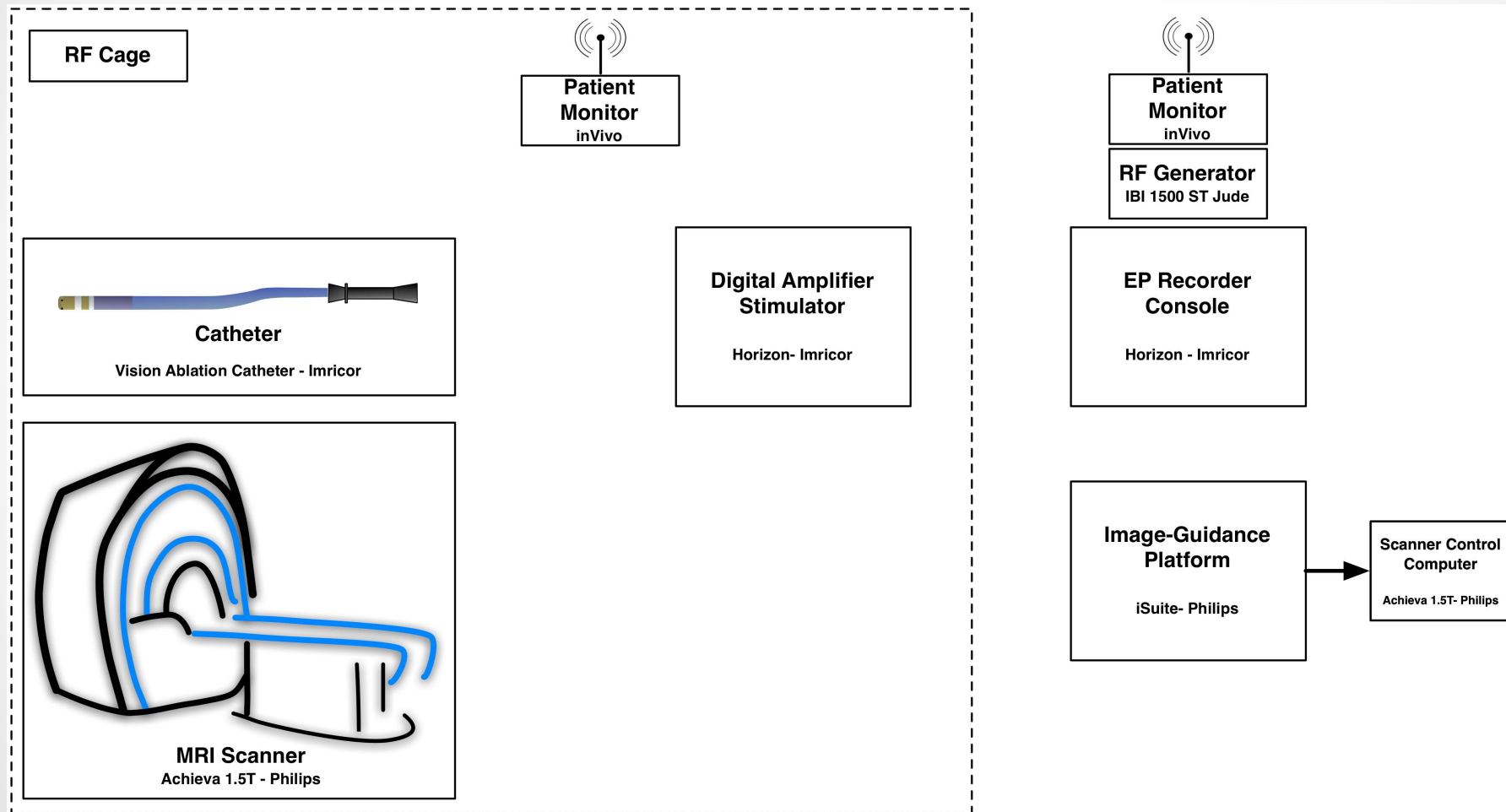
Objective

Demonstrate safety and feasibility of ablation of a clinical arrhythmia (typical atrial flutter) under MR-guidance alone using active catheters and MR-EP guidance system

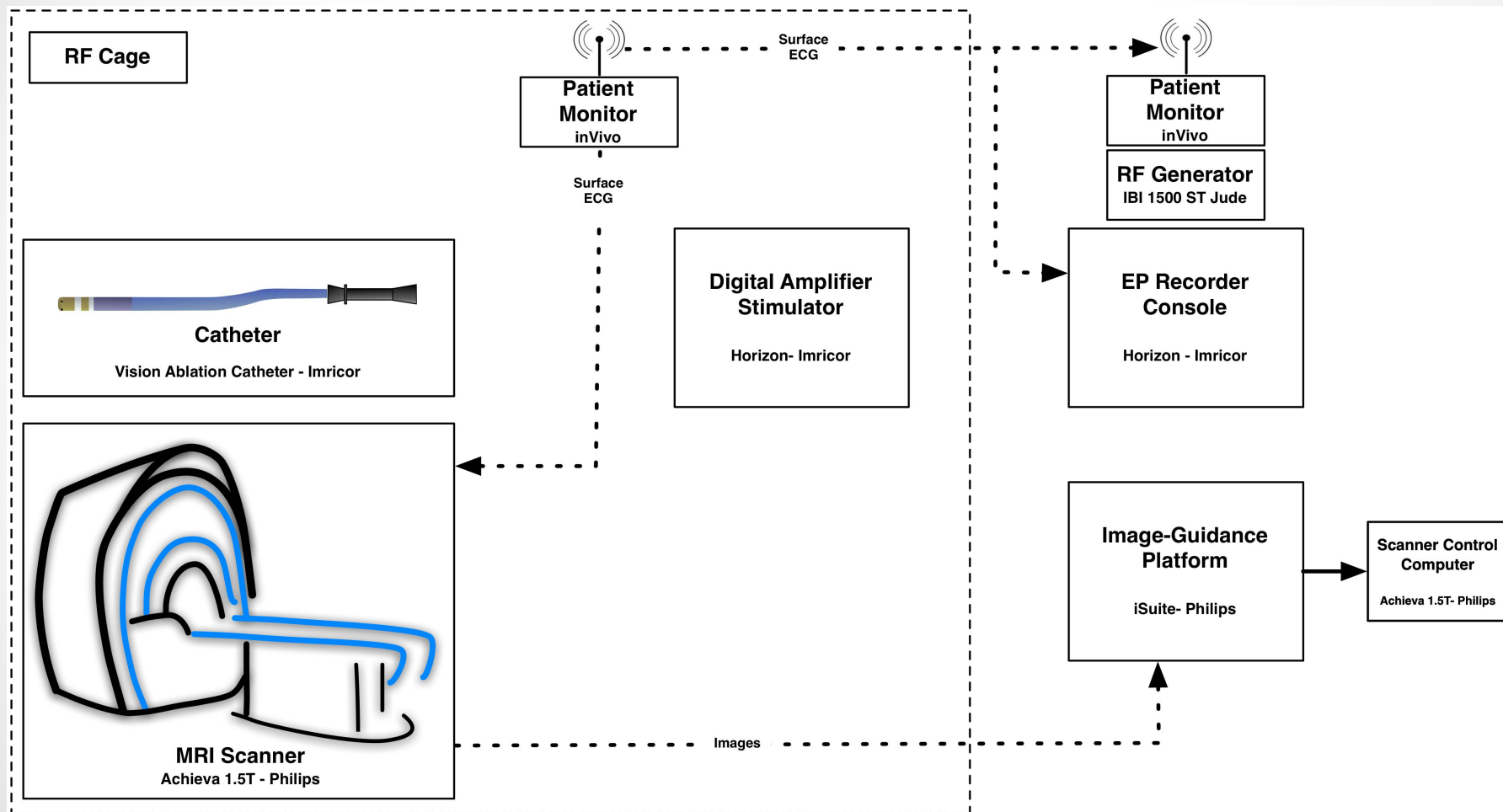
MR-EP Setup



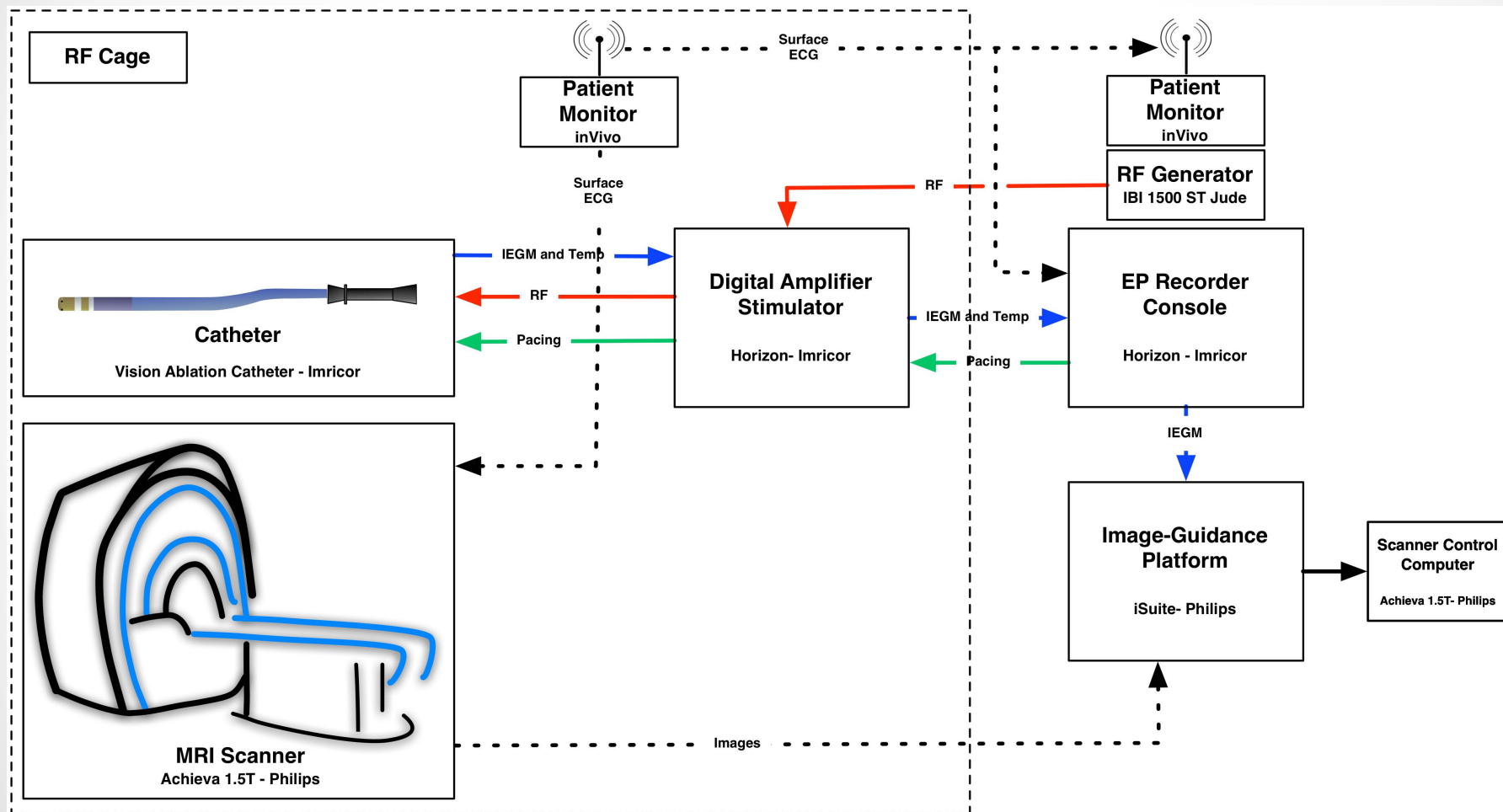
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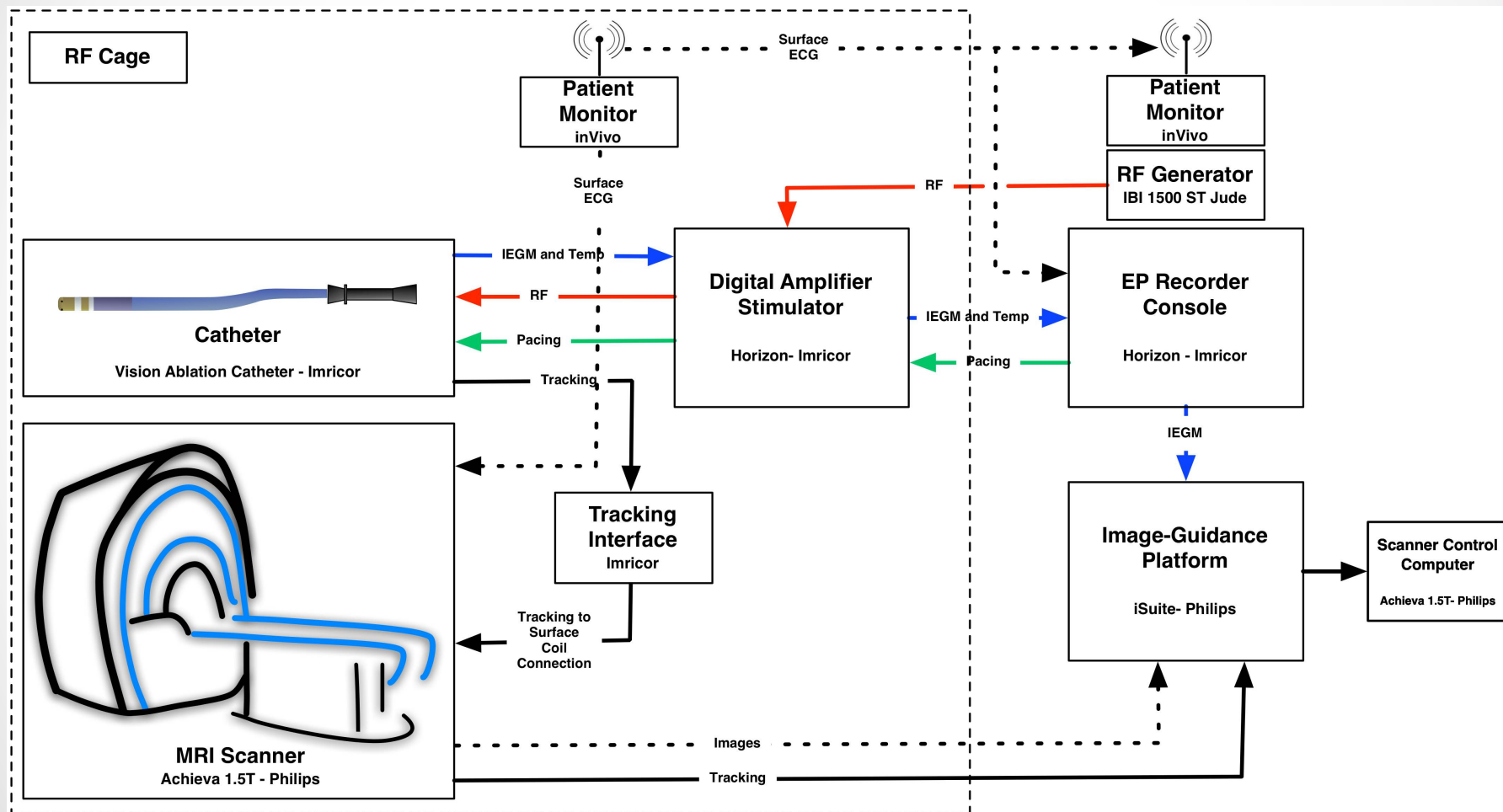
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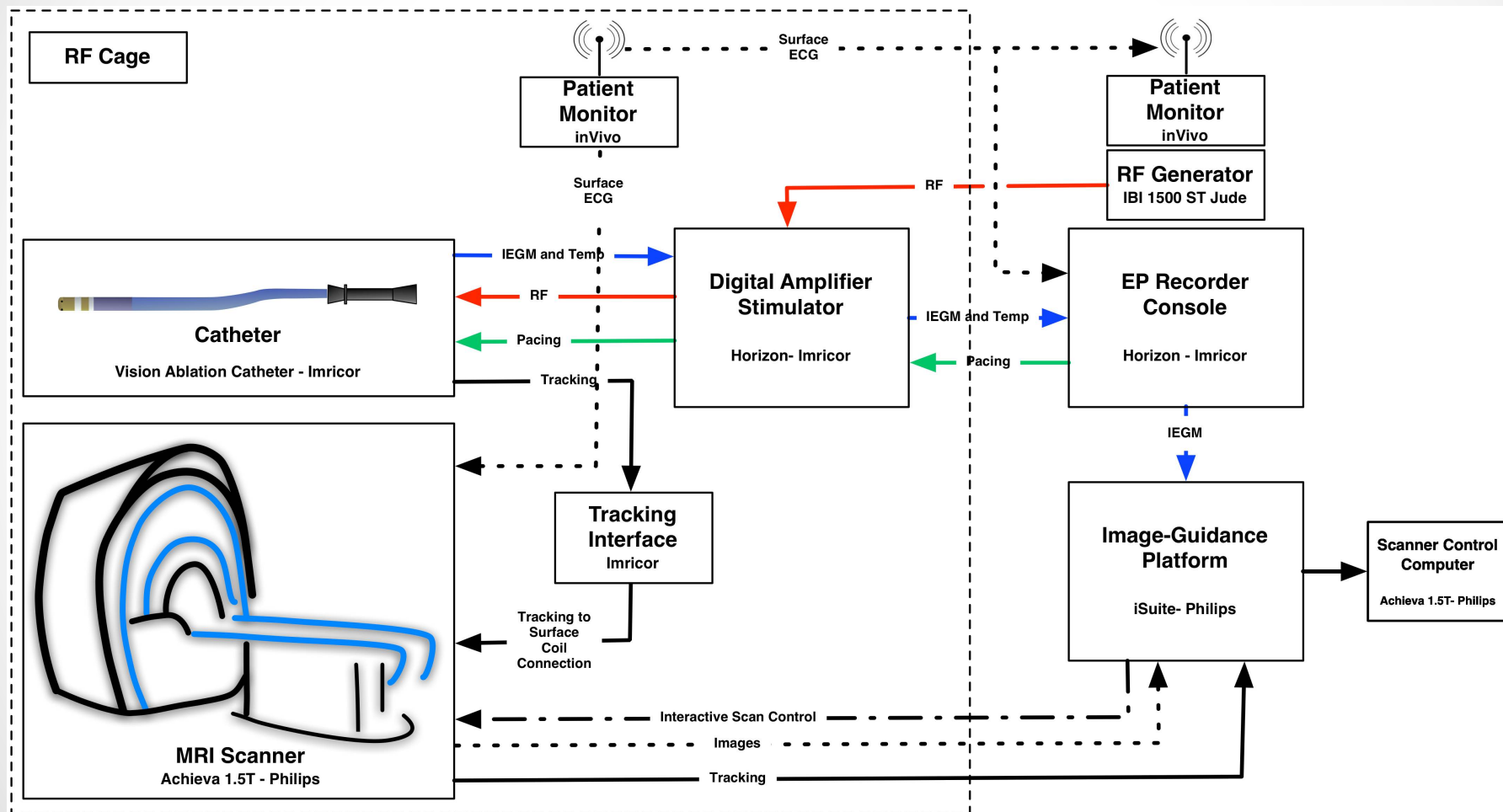
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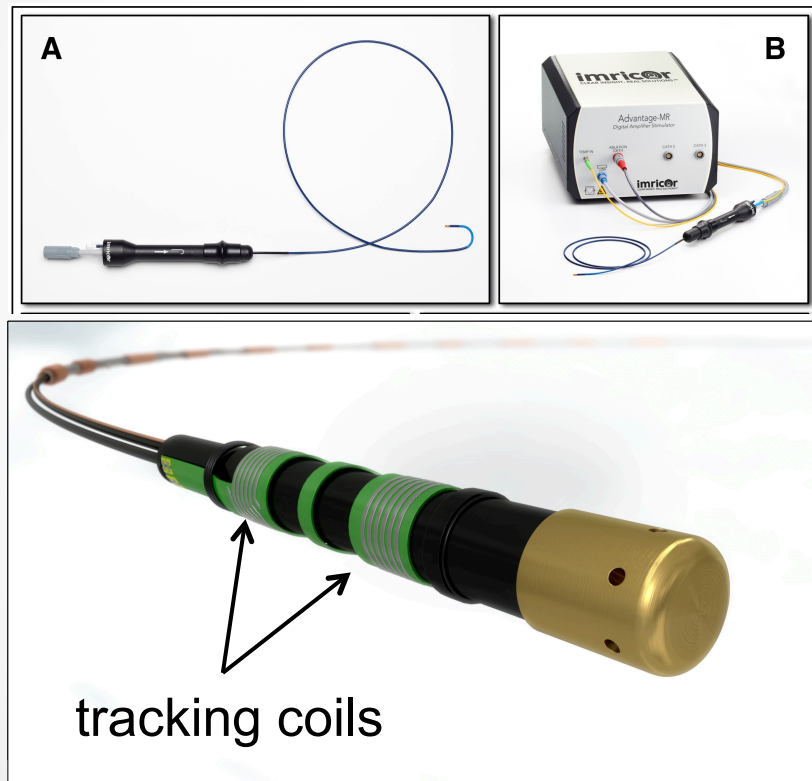
MR-EP Setup



MR-EP Setup



Ablation Catheter



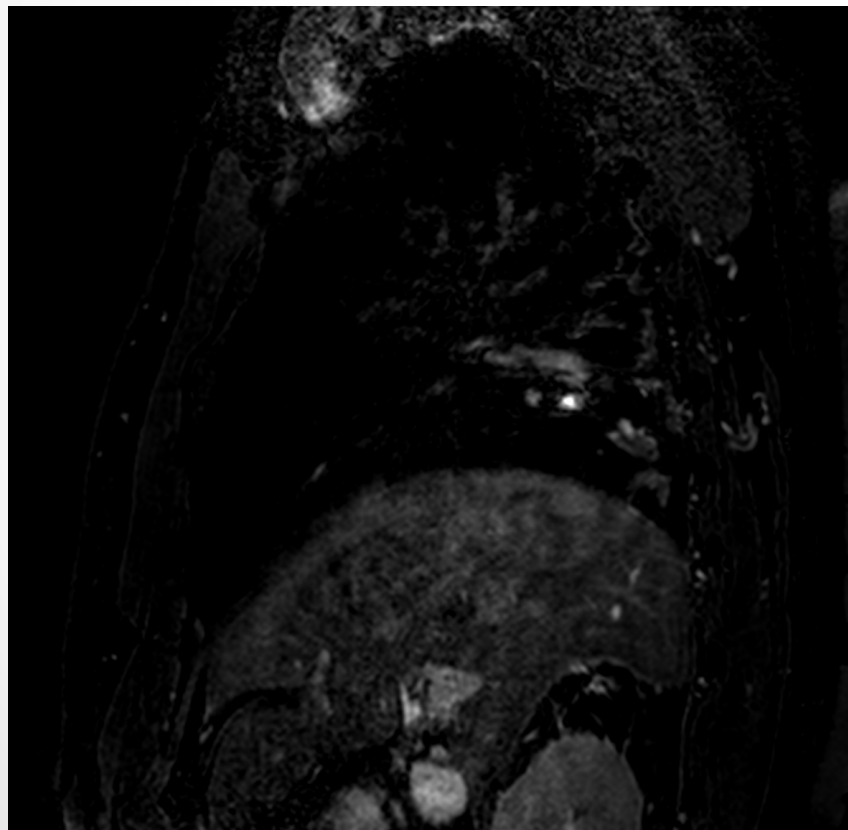
- Vision Catheter, Imricor, Burnsville, MN, USA
- MR-enabled 9Fr catheter
 - Unidirectional deflectable tip
 - Irrigated (six holes)
 - Fiber-optic tip temperature sensor
 - Gold electrodes
 - Two miniature MR receive coils
- Static Field Safety
 - Constructed of polymer and non-ferrous metals
- RF safety
 - Electrode wire assembly with novel filtering configuration¹
 - Tracking coils utilize transformer cables within catheter²
- Gradient Field Safety
 - Provided by a combination of the catheter and Advantage-MR EP Recorder/Stimulator

¹ Imricor Medical Systems, US Patent 8,588,934

² Weiss. Magn Reson Med (2011)

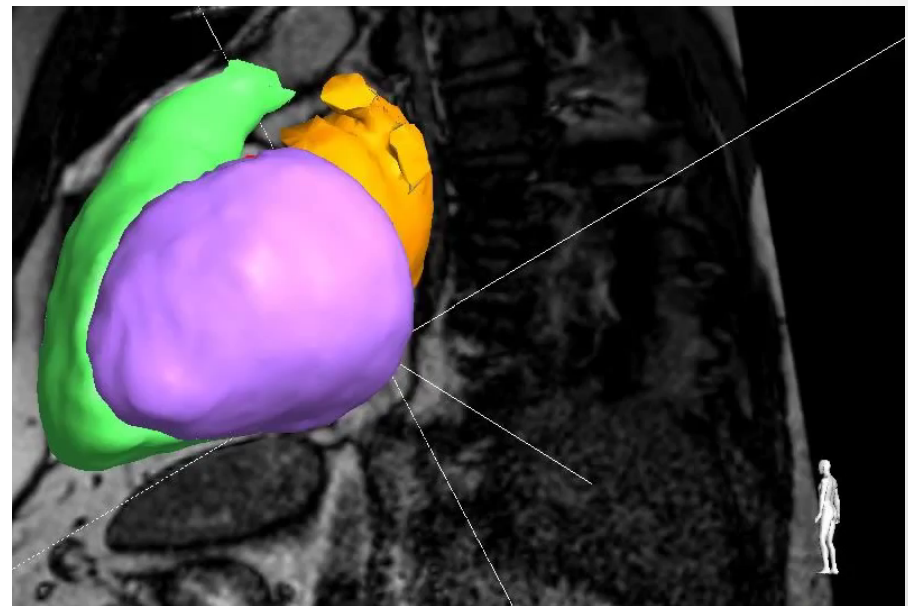
Image Guidance Platform

3D whole heart (bSSFP)



Semi-automated
segmentation

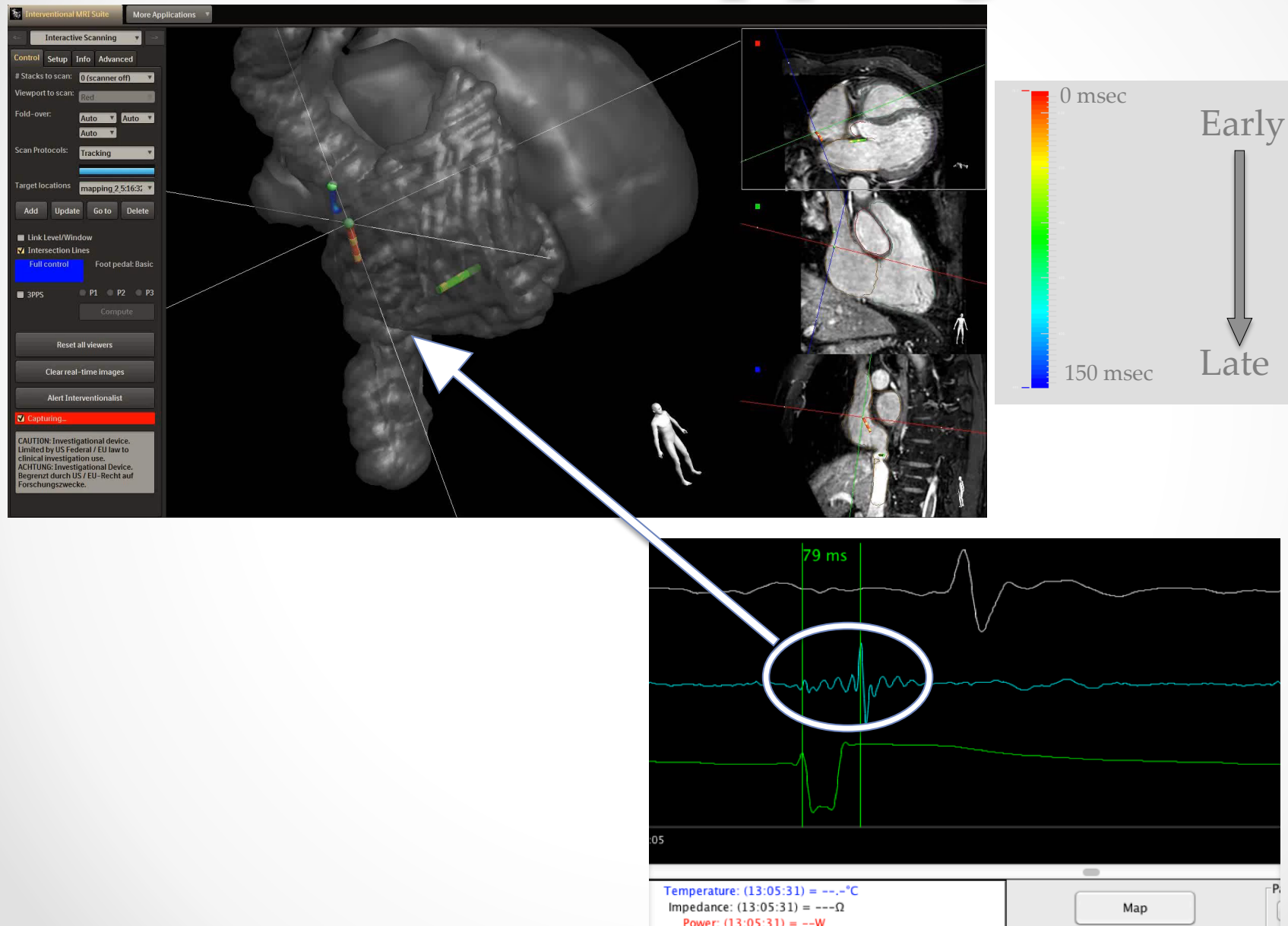
iSuite (Philips Research, Hamburg)



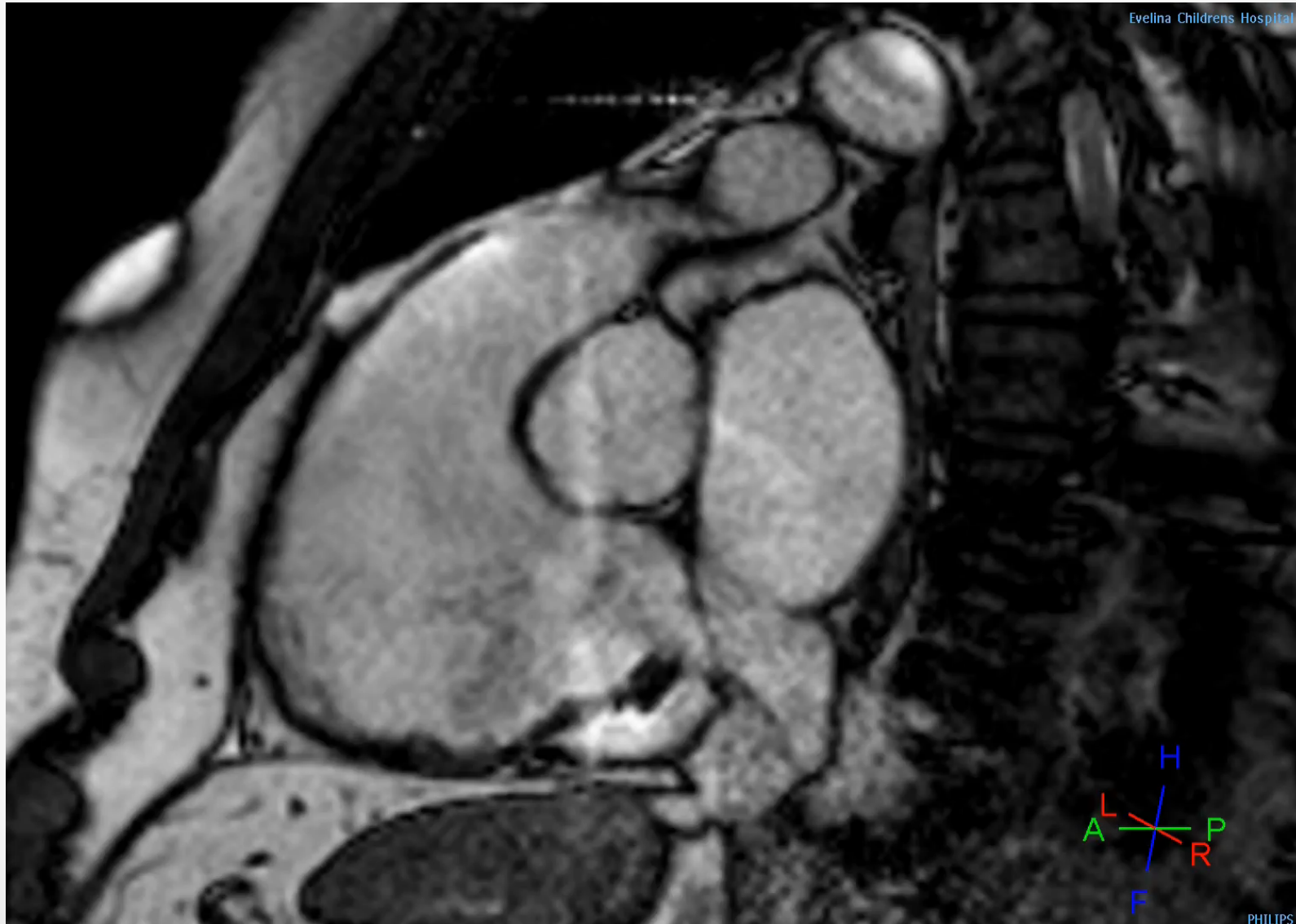
Electrograms and Pacing Capture



LAT Mapping



Switch to Real Time/ Cine Imaging



Subjects and End Points

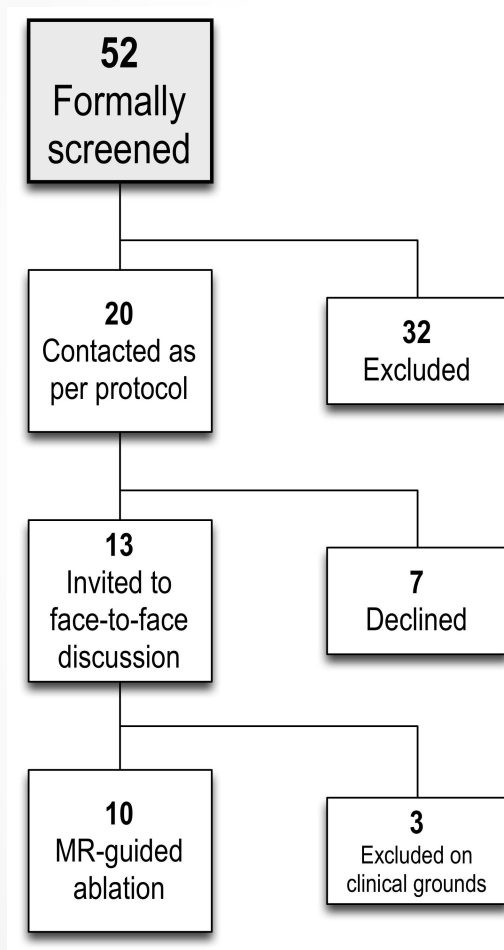
Subjects

- Inclusion criteria
 - First time clinically indicated ablation for counter-clockwise right atrial flutter
- Exclusion criteria
 - Contraindication to MRI/contrast
 - Previous ablation
 - Previous cardiac surgery
 - Pregnancy, systemic infection, thrombus

End Points

- Primary Endpoint
 - [Efficacy]: achievement of acute bidirectional block at CTI during procedure
- Secondary Endpoint
 - [Efficacy]: freedom from atrial flutter at 3 months
 - [Safety]: freedom from serious device-related adverse events

Subjects and End Points



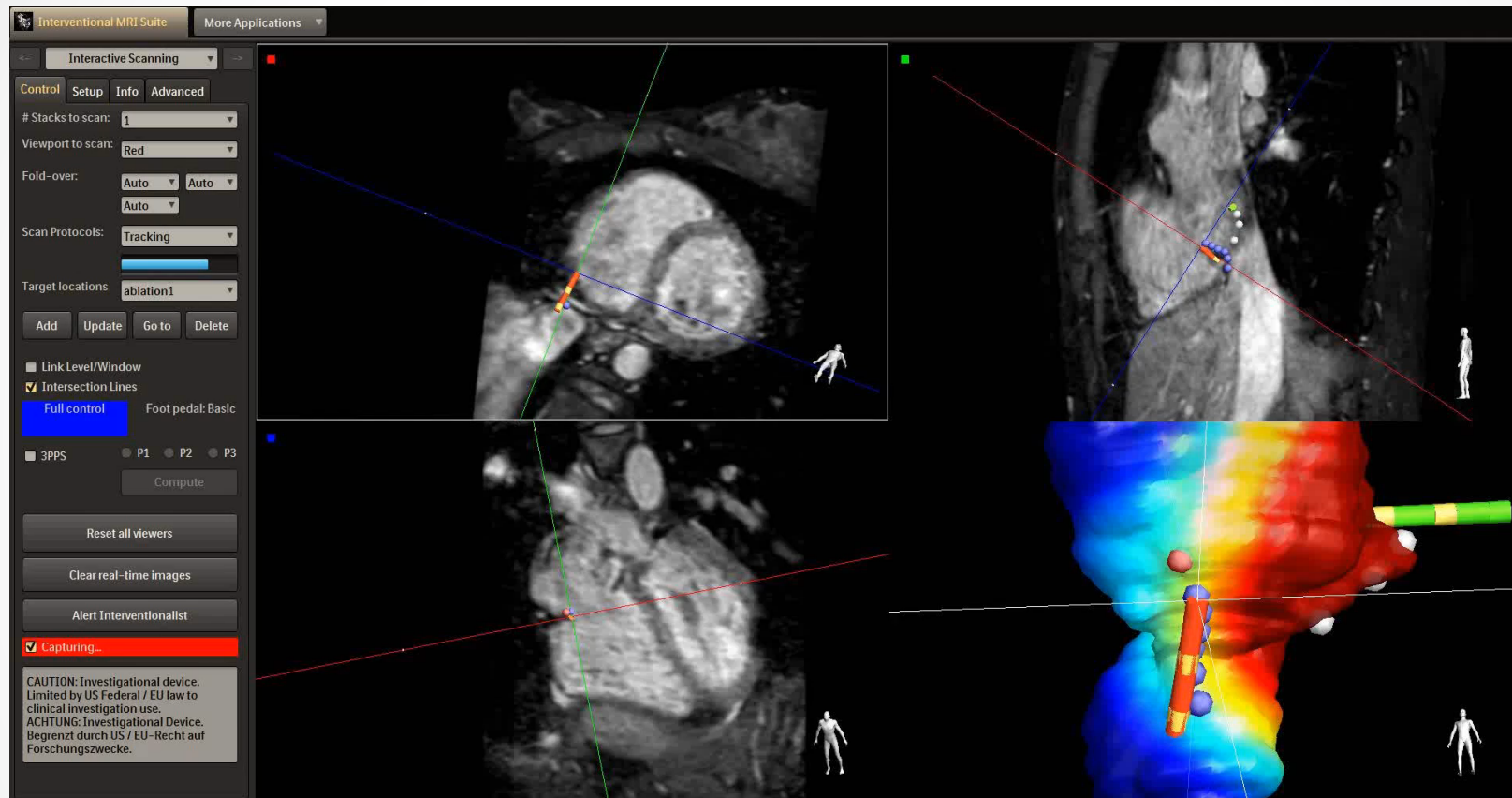
	Total n=10
Age/ years	62.1 (\pm 14.5)
Weight/ kg	82.7 (\pm 13.6)
BMI/ kg/m²	26.8 (\pm 3.9)
Male Gender	8 (80%)
Significant Comorbidities	7 (70%)
Duration of Atrial Flutter	12.9 months (\pm 22.6)
Flutter at Procedure	7 (70%)
Structural Heart Disease	0
Left atrial size/ml	121 (\pm 48)
Right atrial volume/ml	131 (\pm 72)
LV ejection fraction	64% (\pm 5.2%)

Procedure Protocol

- Recruitment and Pre-Assessment
- Phase 1: Anaesthesia and set-up
 - General anaesthesia ± Transoesophageal echocardiogram ± cardioversion
 - Moved to MRI suite
 - Vascular access then moved into MR scanner
- Phase 2: Pre-ablation MRI
 - High Resolution Anatomical MRI
 - Semiautomatic Segmentation of right atrium
 - Anatomical planning of optimal ablation sites
- Phase 3: Mapping and ablation under MR guidance
 - Pre-ablation mapping of right atrium
 - Ablation of cavotricuspid isthmus



Ablation



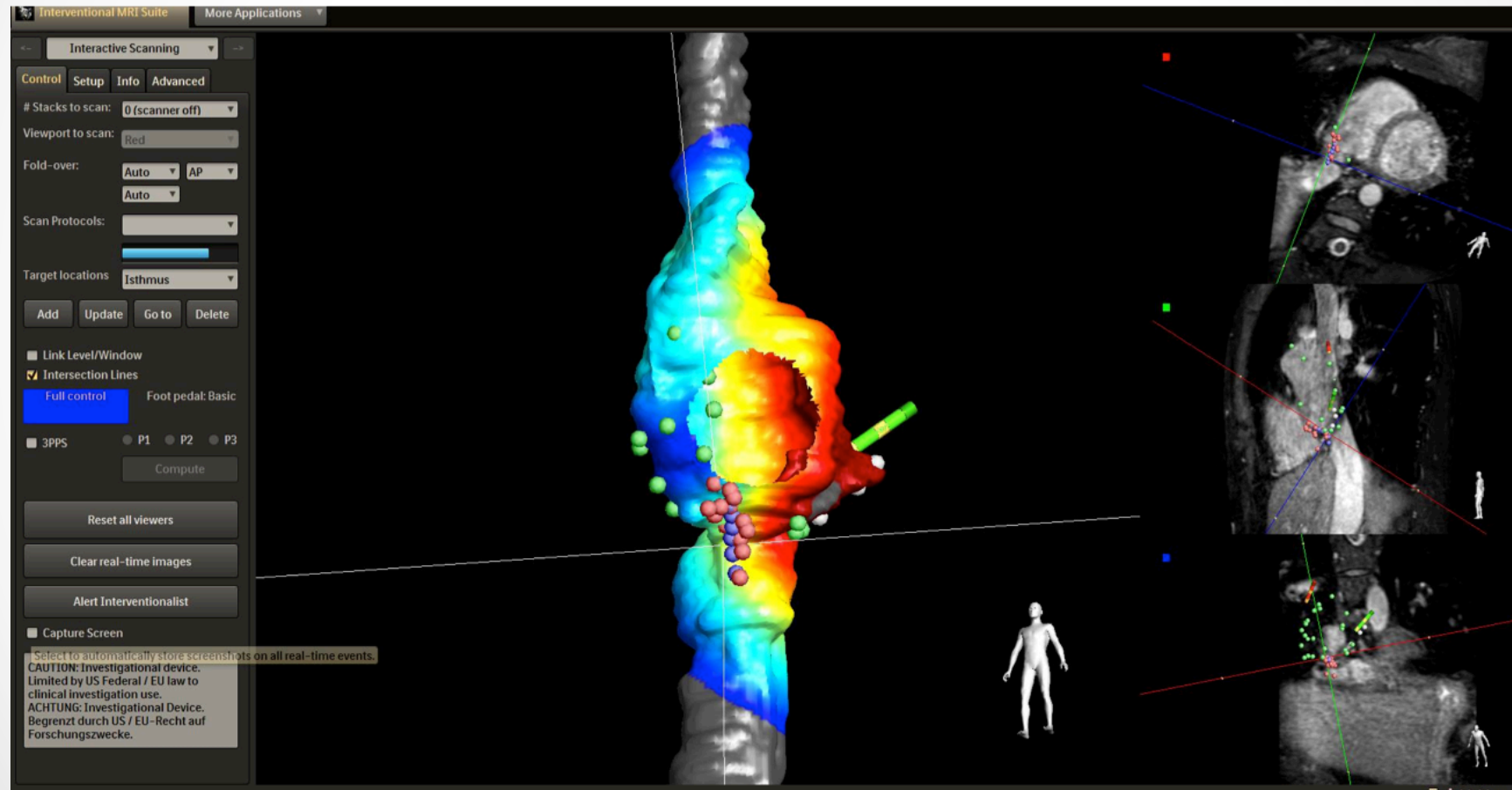
- Point-by-point ablation
 - 35-45W, 60s per lesion, 17ml/sec irrigation

Procedure Protocol

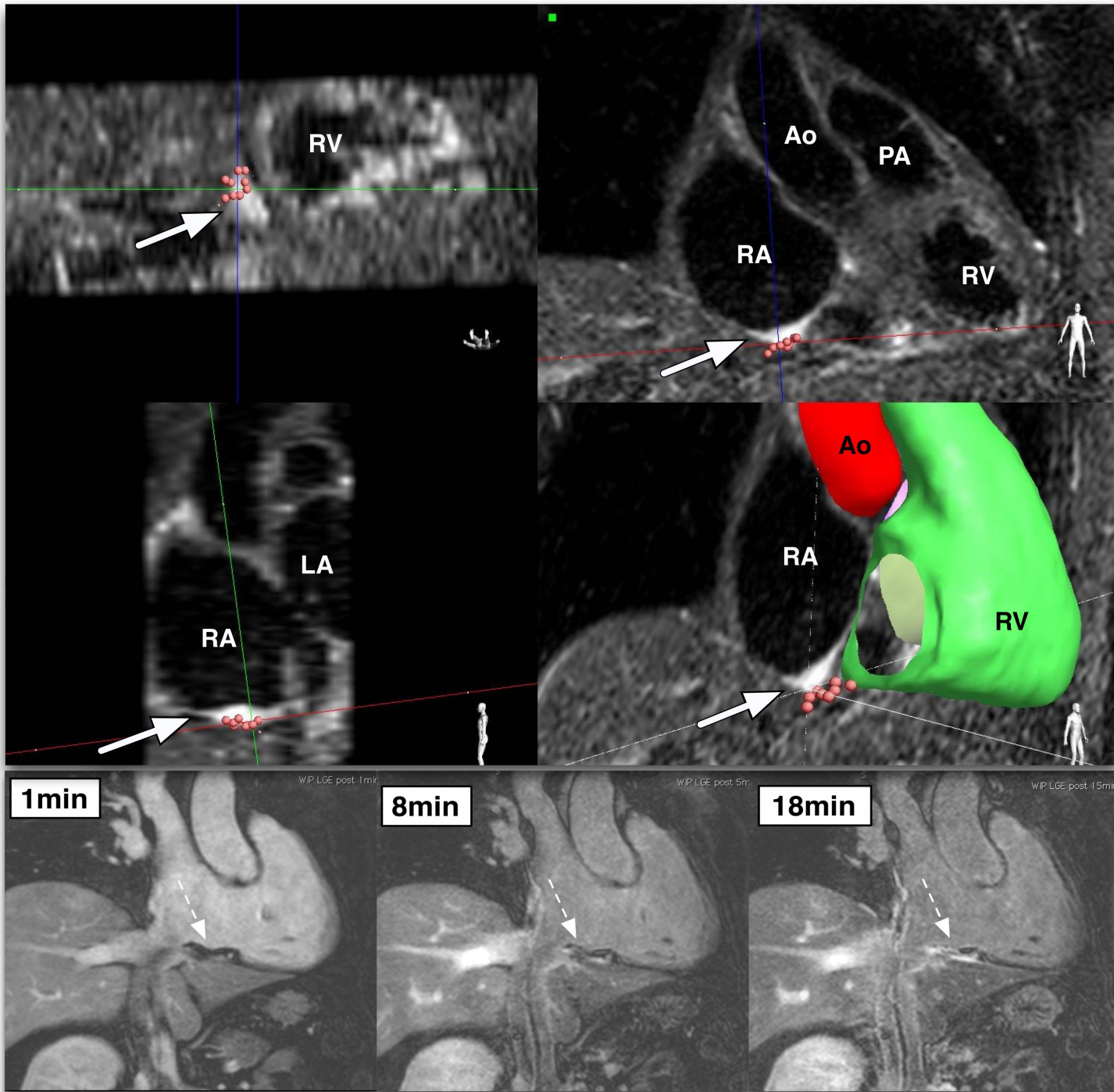
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- Phase 4: Post-ablation assessment
 - Post-ablation mapping of right atrium
 - Acute post-ablation MRI



Bidirectional Block post-ablation



LGE T_2 -Weighted Imaging



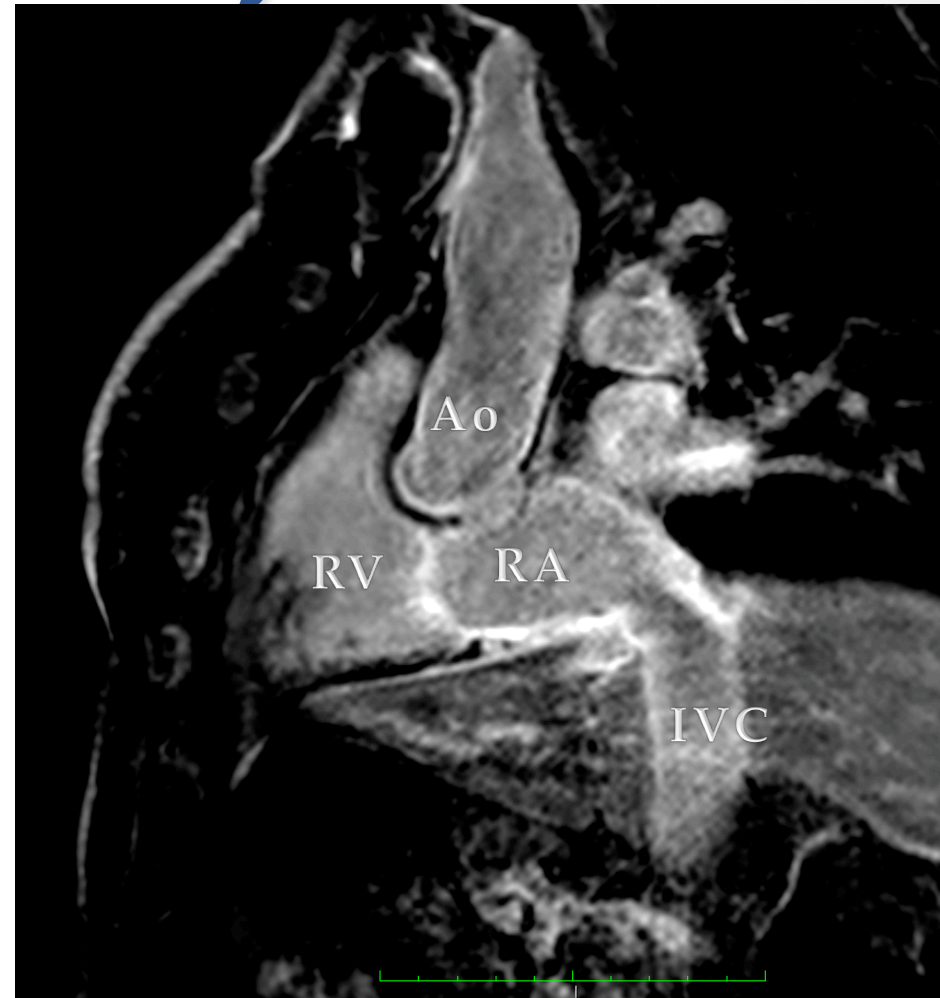
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- Phase 5: Completion and recovery
 - Removal from scanner and removal of sheaths
 - Recovery from general anaesthesia
- Discharge <24 hours post procedure
- Follow-up at 3months



Follow-up and Late Lesion Analysis

- Clinical – 3 months
 - Full examination and symptom report
 - 24 hour tape
 - ECG
- Lesion Assessment
 - MRI – 3D LGE sequence
 - ECG and Resp gated
 - 0.6x0.6x2mm reconstructed
 - Maximum intensity projection technique for scar analysis
 - Quantification – threshold 3.3SD above blood pool mean¹



¹J Harrison et al, *Eur Heart J*. 2014;**35**:1486–1495.

Why was the success rate low?

Failure of MR-guided system to form effective ablation lesions?

Failure to reach the correct location?

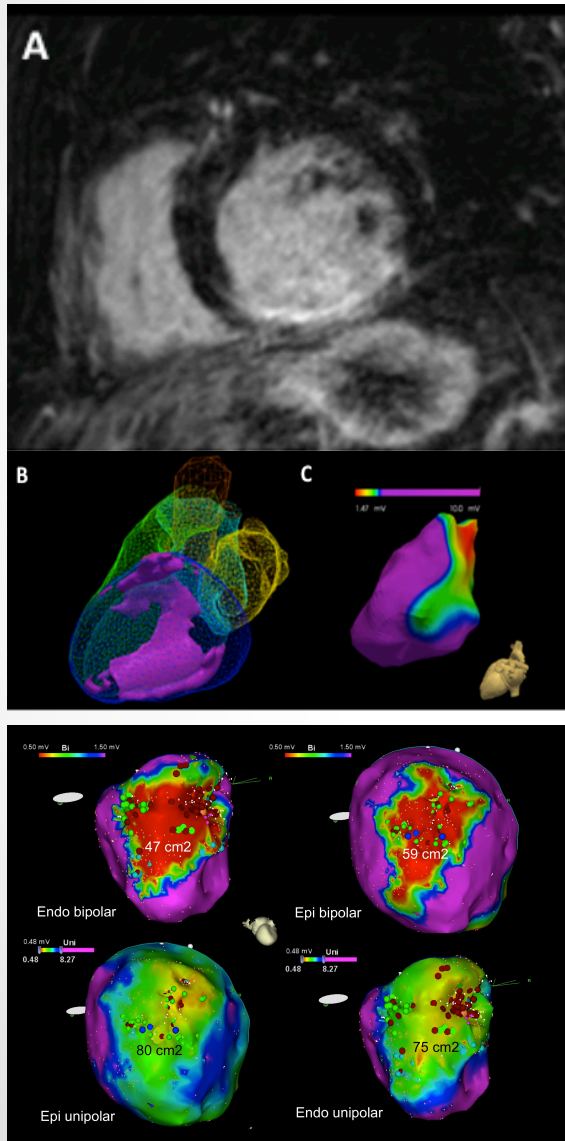
Intra-procedural cine imaging: CTI contact



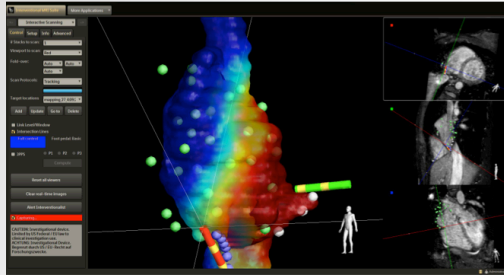
Limitations

- Small, single centre, feasibility study
- Focus on proof of feasibility
 - Not an efficacy trial
 - Acute lesion visualisation
- No mapping of tachyarrhythmia
 - b-SSFP sequence triggered poorly during arrhythmia

Future Directions



- Ventricular Tachycardia
- Scar-based substrate ablation
 - Imaging guided
 - Scar borderzone 2-4mm (heterogenous conduction)
 - EAM merge system error
- Formed the basis of a successful £1.9M Wellcome Trust/NIHR grant application



Conclusion

- Objectives
 - Primary: MR guided interventional EP is safe and feasible in humans
 - Secondary: Medium term freedom from atrial flutter is modest
- Primary determinant of failure is anatomy
 - Engineering solution
- MR-EP with active tracking represents a viable clinical tool
- Can MR-guided ablation become the gold standard for some cardiac ablations?

Acknowledgements

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Steffen Weiss

Sascha Krueger

Imricor Systems

Gregg Stenzel

Jennifer Weisz

Jason Stroup

Steven Wedan



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