Clinical Grade Guidewire Designs for Interventional Cardiovascular MRI

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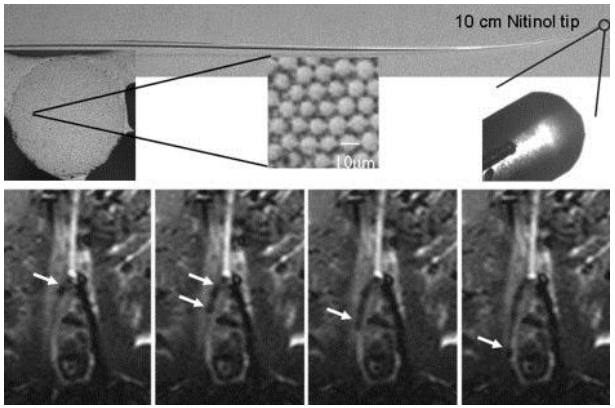
Interventional Cardiovascular MRI

Missing Component:

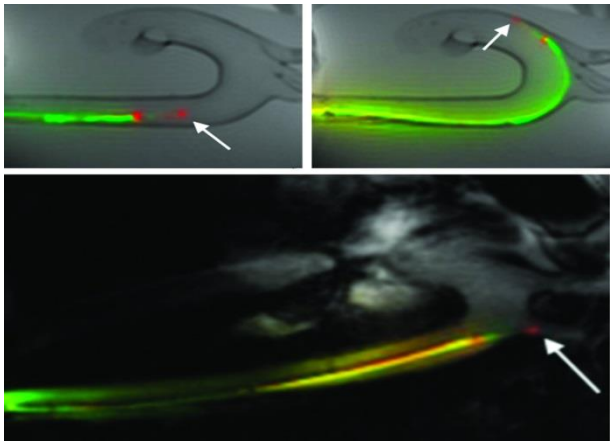
Clinical Grade Interventional Devices!!!!

Passive Visualization

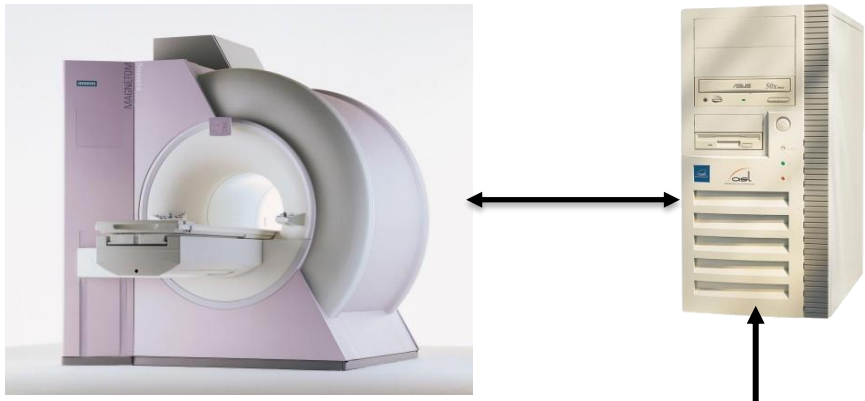


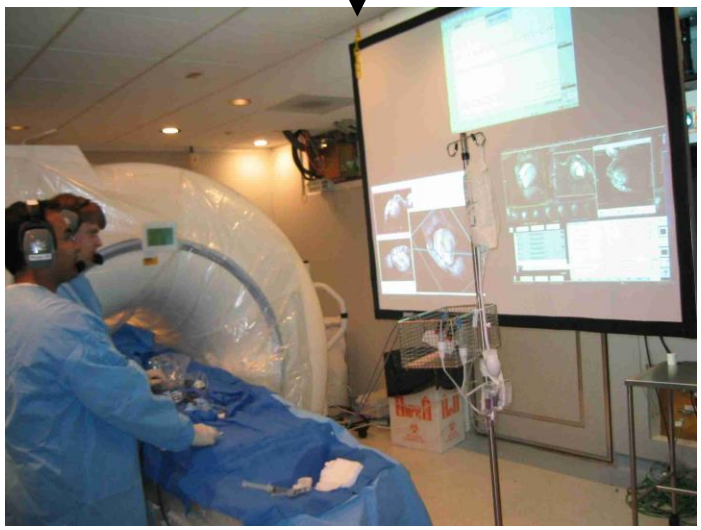
Weiss et al. *Magn Reson Med*. 60 2008:1190-1196

Active Visualization



Kocaturk et al. J Magn Reson Imaging. 2009 Aug; 30(2): 461–465



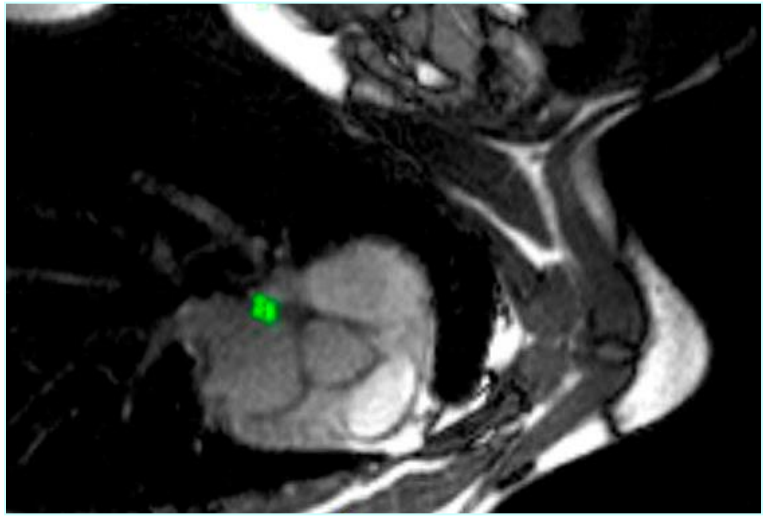


Active Device Visualization under MRI

Incorporating small RF antennas connected to the MR scanner for device profiling or visualization

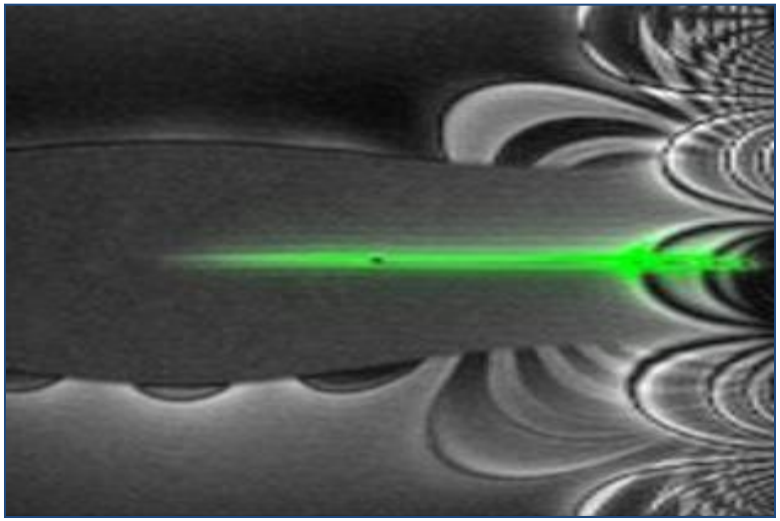
Provides unique device signatures in real-time imaging

Loop Antenna



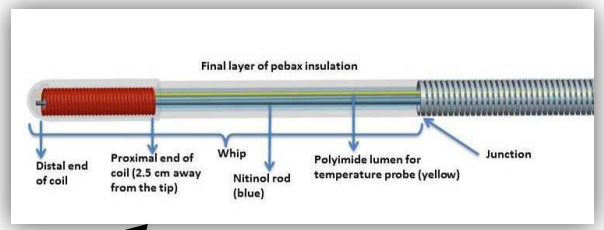
Signal sensitivity falls off very rapidly ($1/r^3$, where r is the radial distance from the loop)

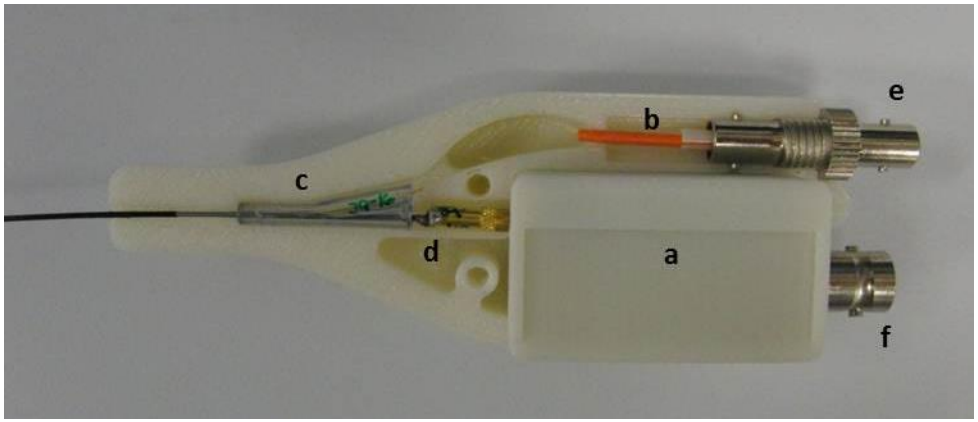
Monopole Antenna

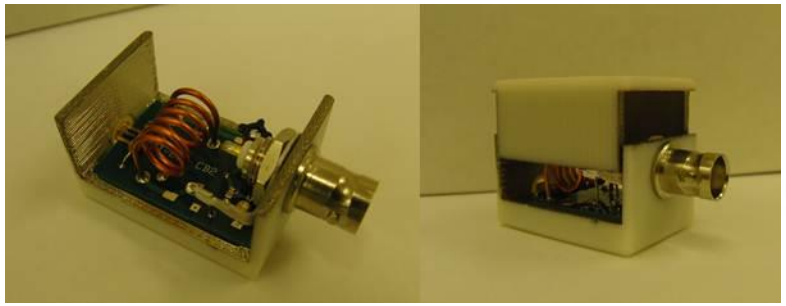


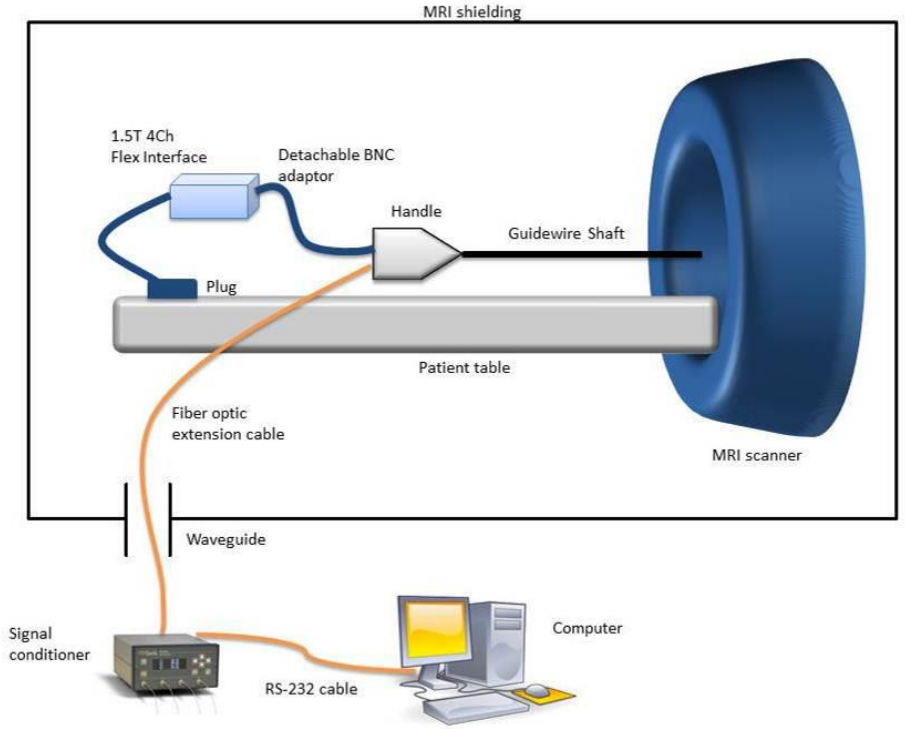
Signal sensitivity is almost same along the longitudinal length and falls off radially (1/r)

Single Channel Active 0.035” Guidewire



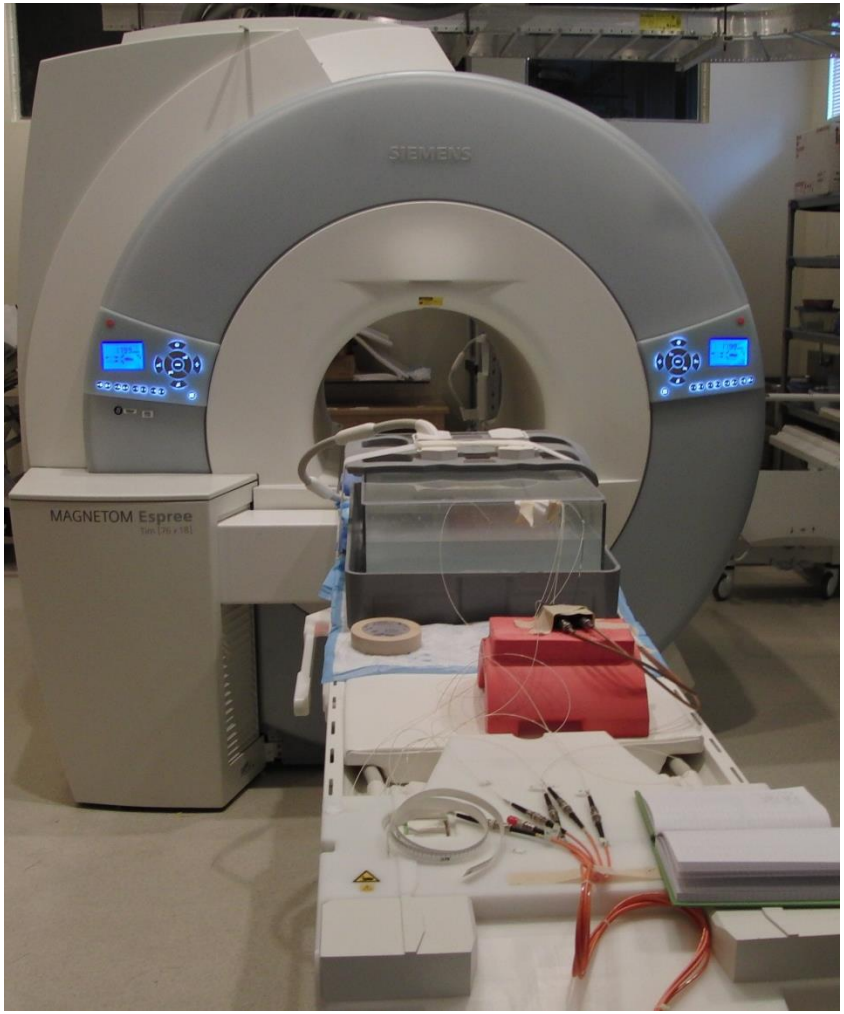




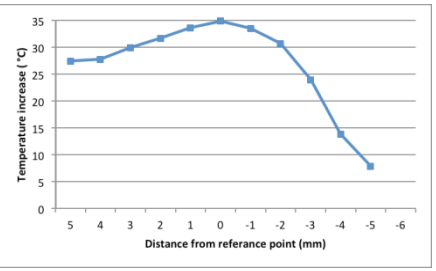


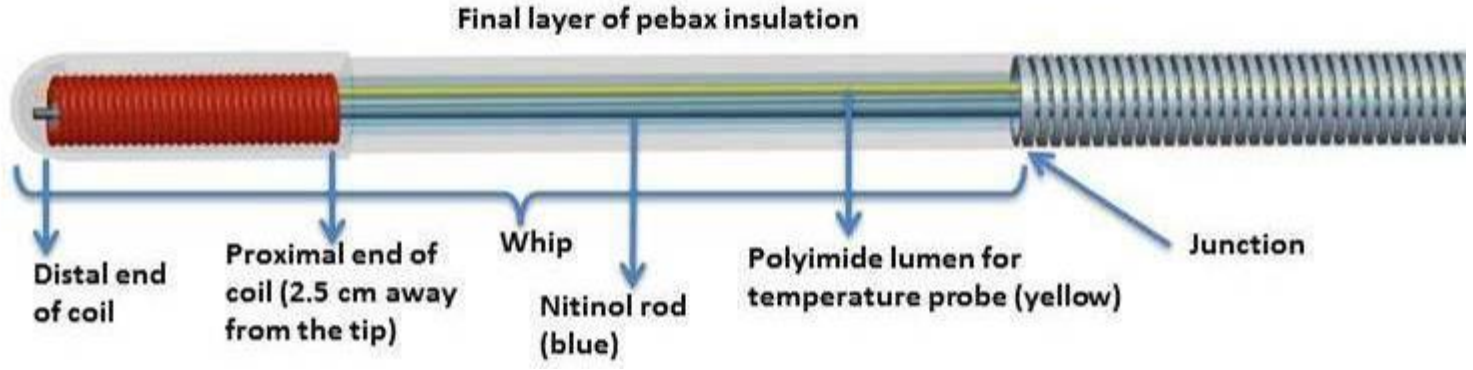
RF Induced Heating Measurement

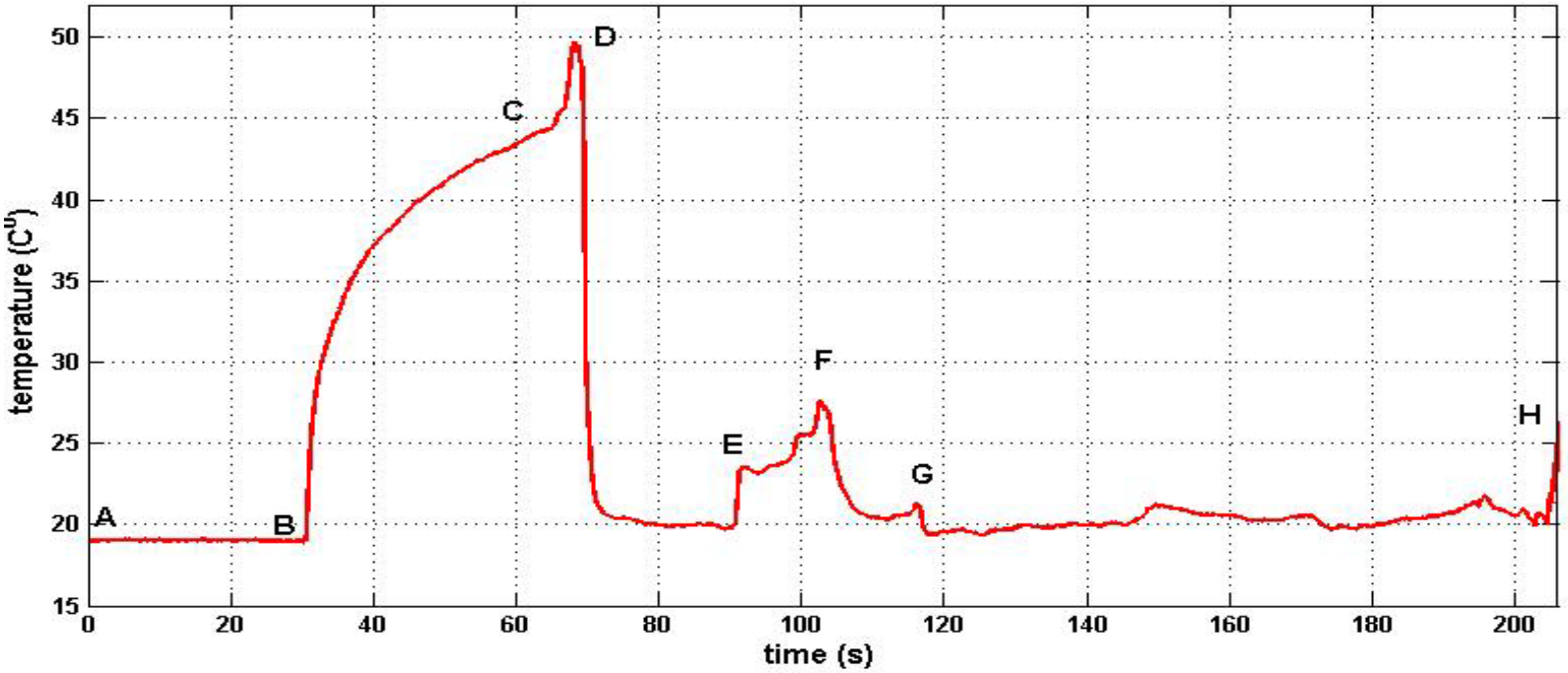
- Siemens Aera 1.5T Scanner
- ASTM F2182 Gel Phantom
- Real-time sequence (exact sequence used in clinical studies)
- Fiber optic temperature measurement probes



Addressing RF Safety Concern





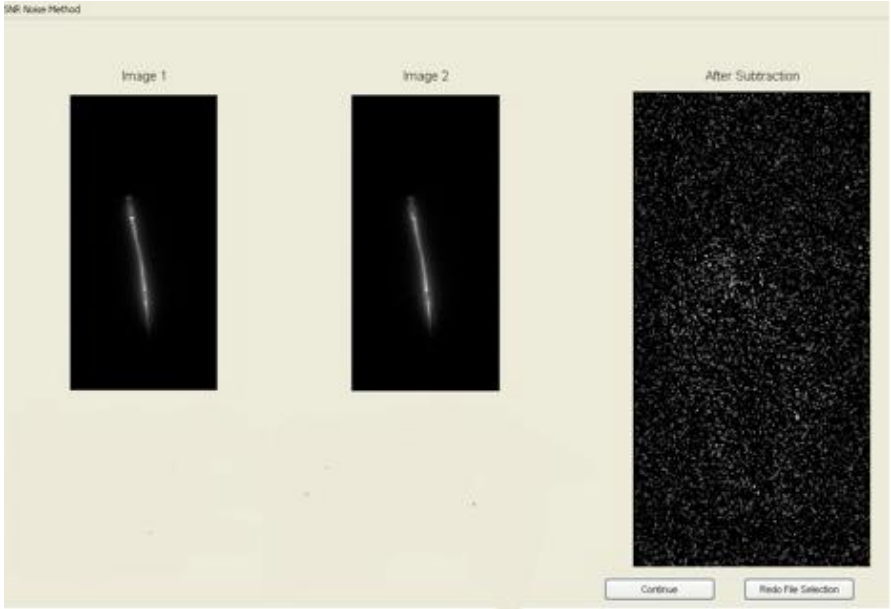


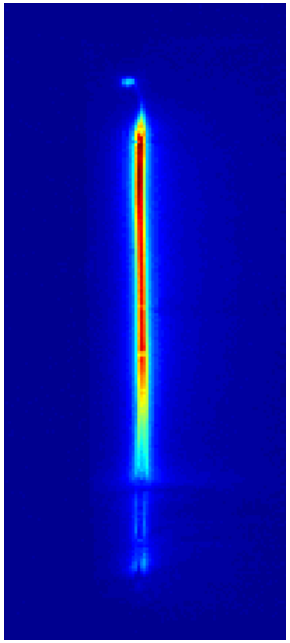
Addressing Device Visualization under MRI

- Double Acquisition Method

Two sequential MR images for each channel

- Subtracting the two images pixel-by-pixel eliminates the consistent signal, resulting in a noise-only image.

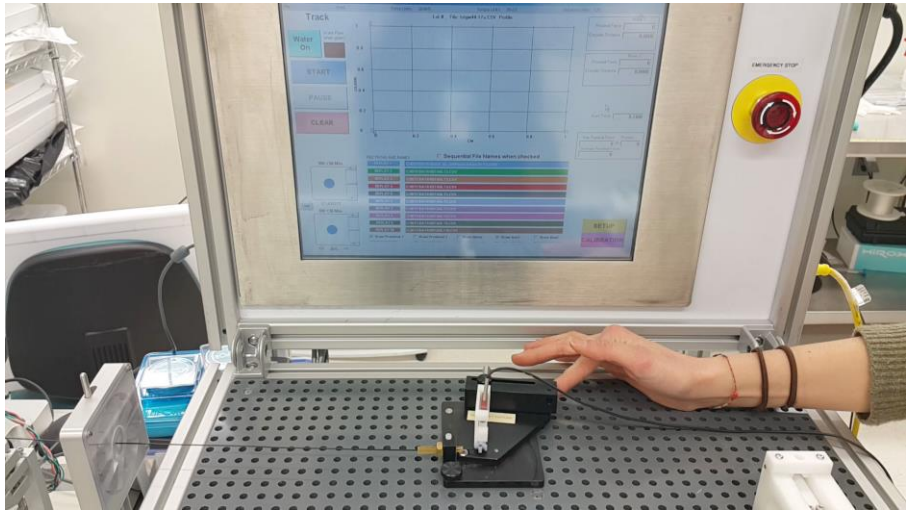


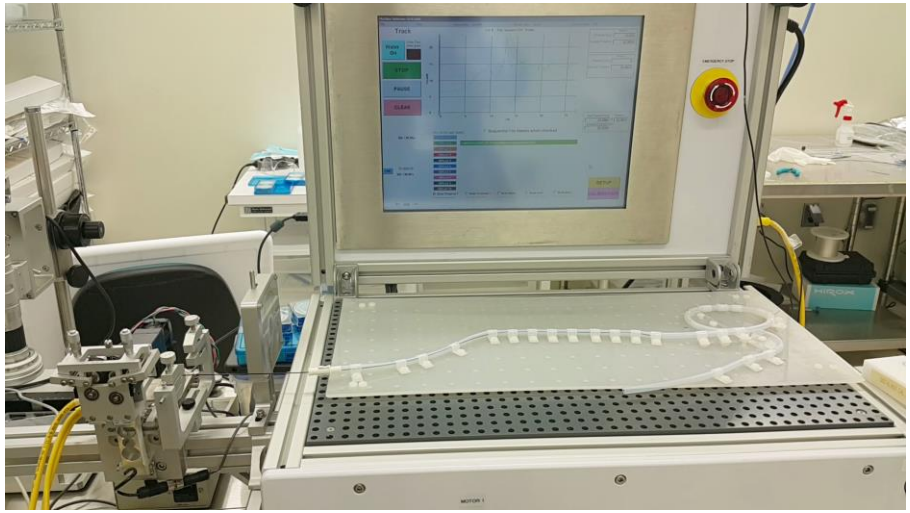


	Loopless Antenna Channel	Loop Antenna Channel
Noise ROI Size	28416	28416
Proportional SD Error	0.059	0.059
Noise Mean	4.099	6.086
Corrected Noise SD	6.8189	5.658
Correction Factor	0.6551	0.6551
Max Signal	3019	1395
Max SNR	442.74	246.55

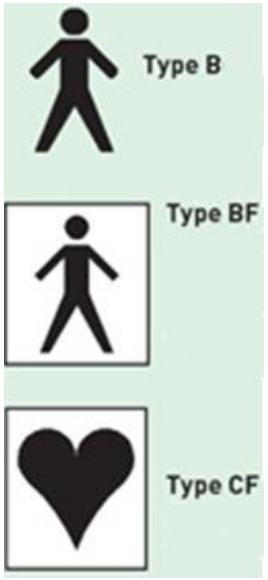
Mechanical Performance Evaluation

- Tip Flexibility
- Distal Tip Stiffness
- Distal Tip Flexibility
- Pushability
- Tensile Strength
- Torque Response
- Torque Strength

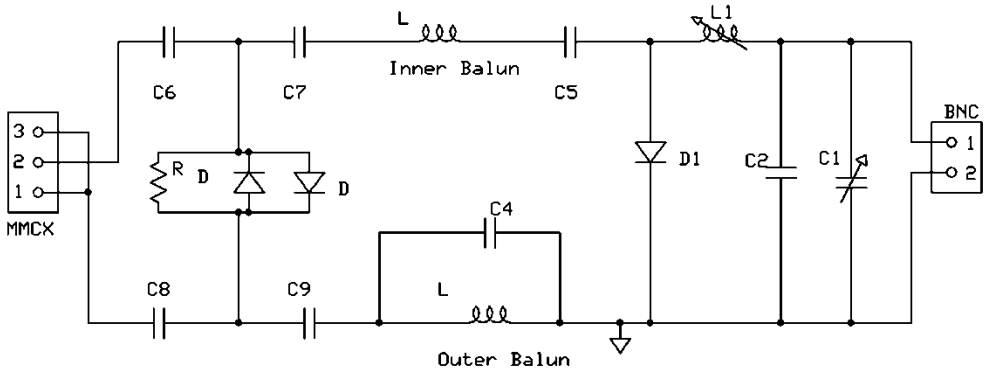




Electrical Safety of the Active Interventional Cardiovascular Devices

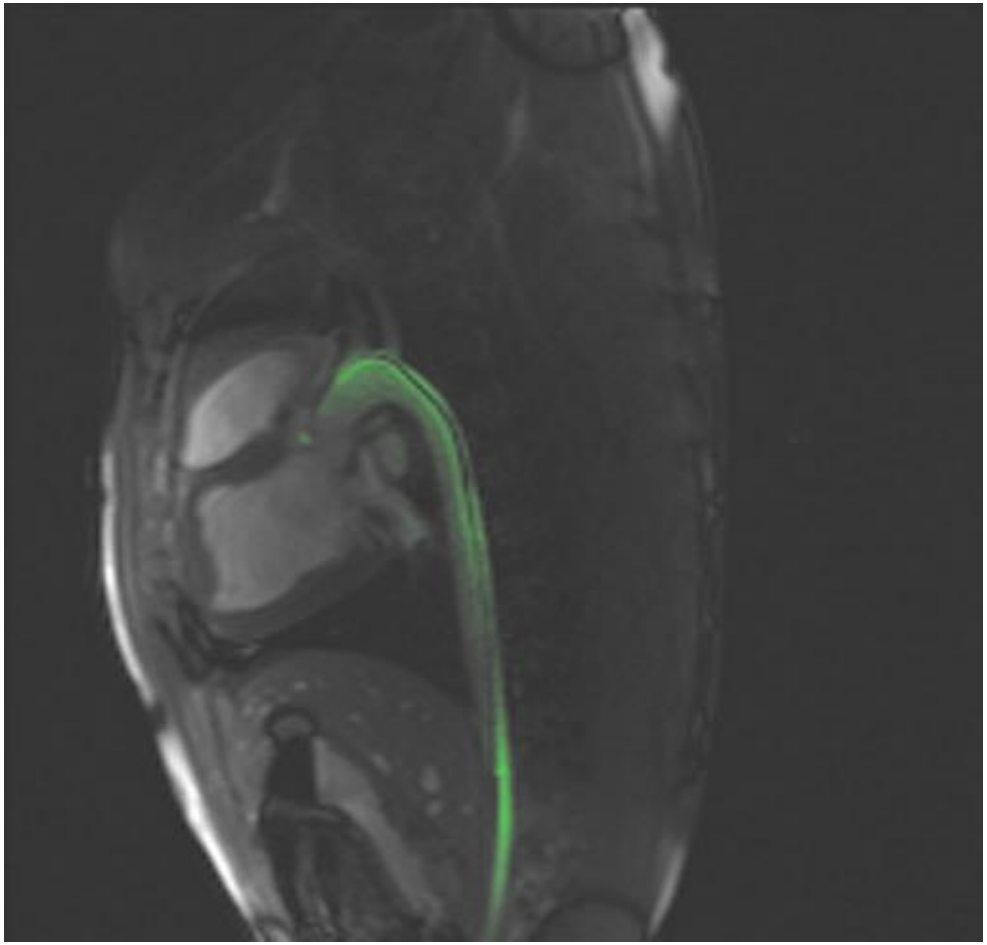


- EC 60601-1: Medical electrical equipment – Part 1:
- Applied parts are classified as Type B, Type BF or Type CF.
- For Type CF (Cardiac Floating): Leakage current limits are **10 µA** and **50 µA** in the normal and single fault conditions.
- The Siemens 1.5 T 4 Channel Flex Interface is rated as type BF, which has leakage current limits of **100 µA** and **500 µA** in the normal and single fault conditions



Active Guidewire in Vivo Performance

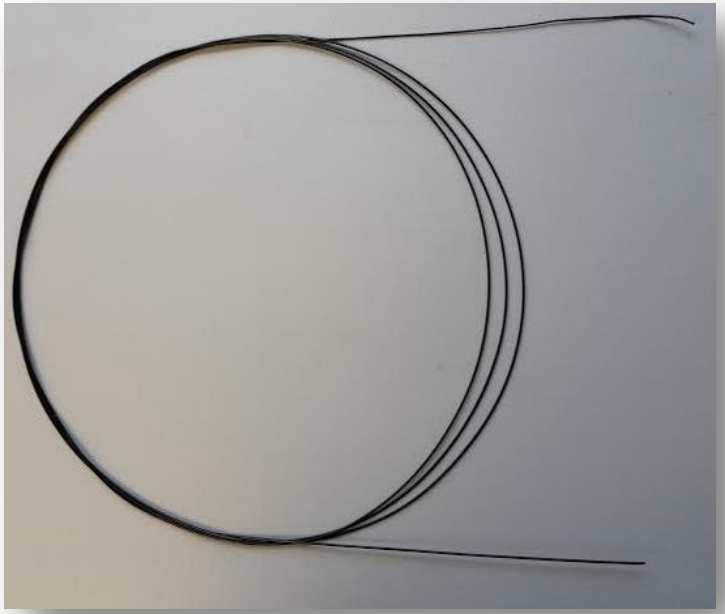
Anatomical location	In vivo hot spot
Superior vena cava	0.89 °C
Right atrium	0.22 °C
Right ventricle	0.38 °C
Main pulmonary artery	0.48 °C
Left pulmonary artery	0.71 °C
Right pulmonary artery	0.23 °C



Segmented Nitinol Based Guidewire

Challenges need to be addressed:

- Active guidewire is too short to perform most of the common interventional procedures
- The RF connectors, dedicated circuits and coax cable connections limit the guidewire maneuverability and prevent catheter exchange over the wire

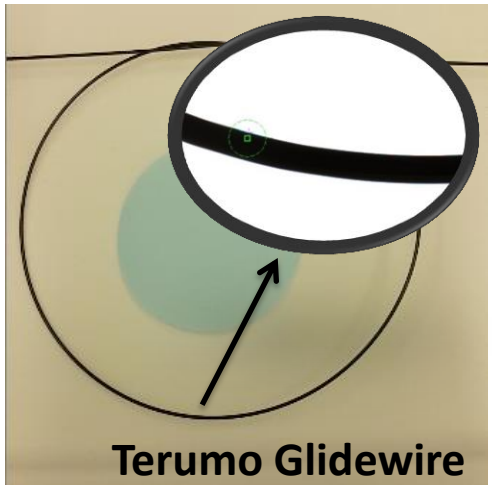


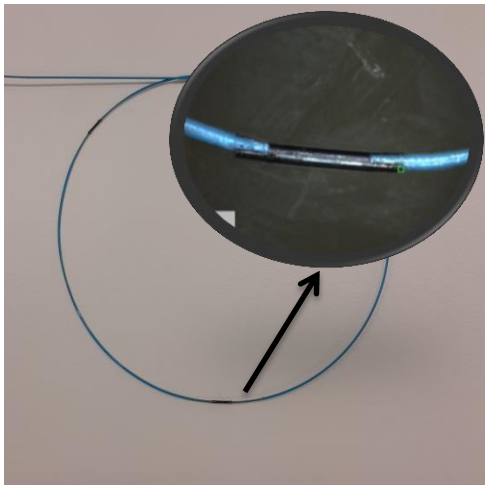
Negotiable Terms:

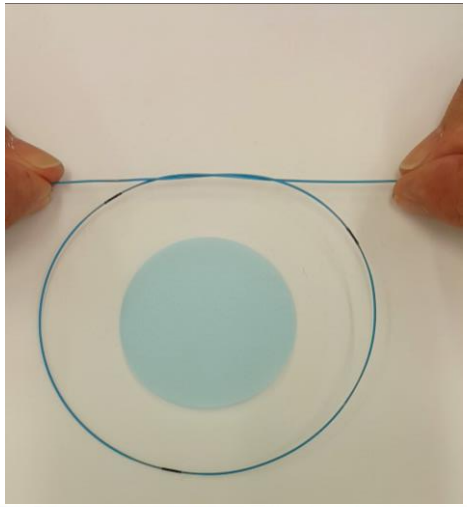
Device visualization

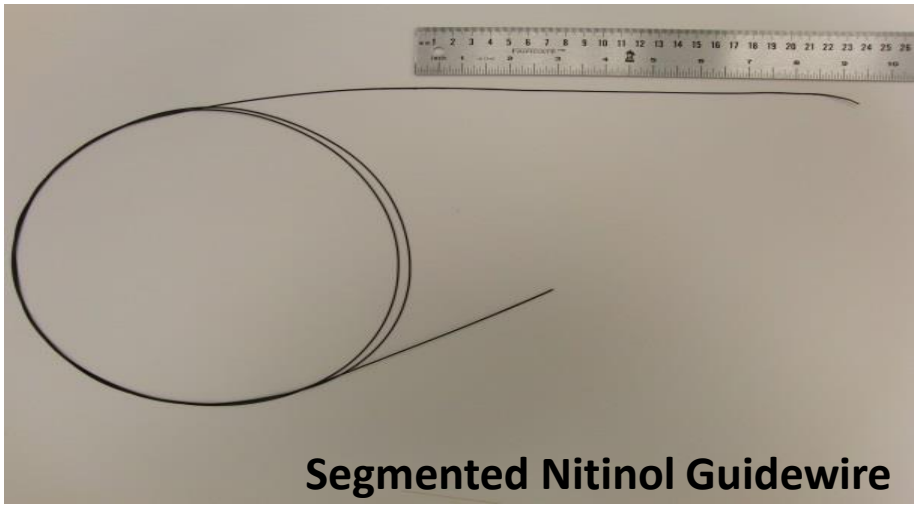
Torque Response

Stiffness Matched Connector Design



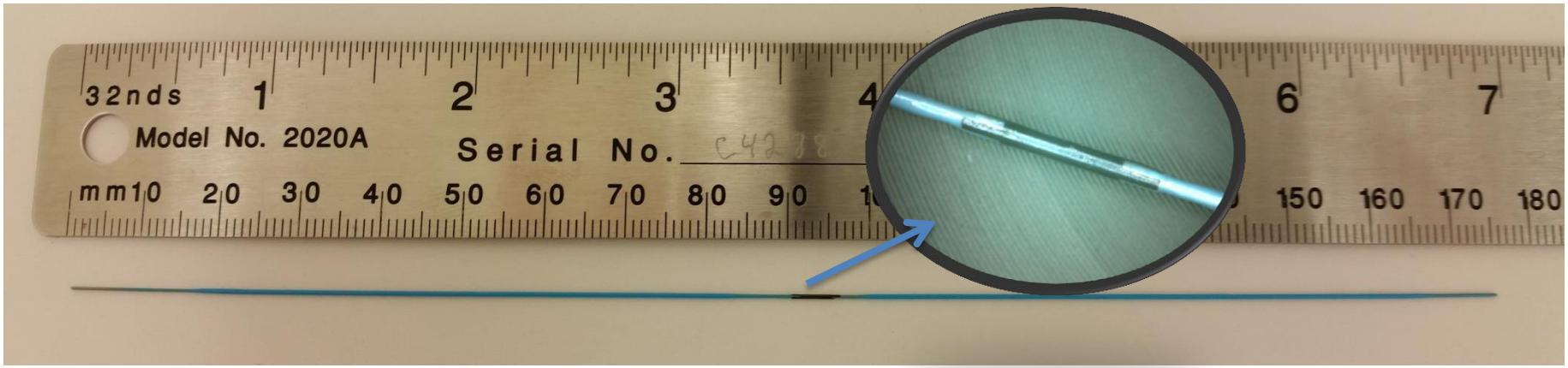




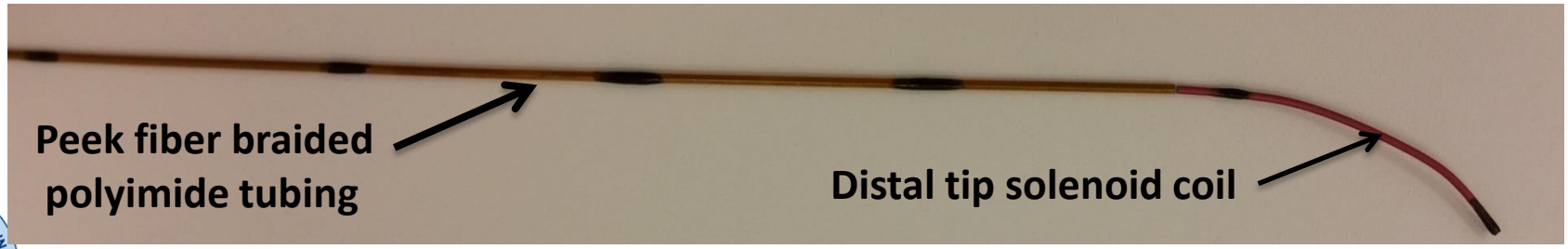


Segmented 0.035” Metallic Guidewire

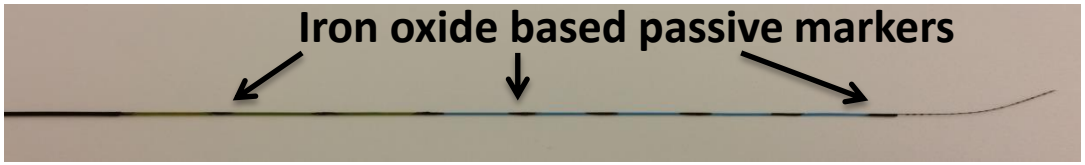
- Each segment shorter than the quarter wavelength (approximately 10 cm for 1.5 T scanner)



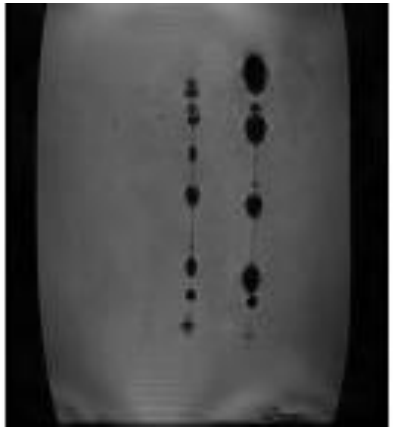
- Non metallic braided layer provides additional support to segmented core and enhanced torque response

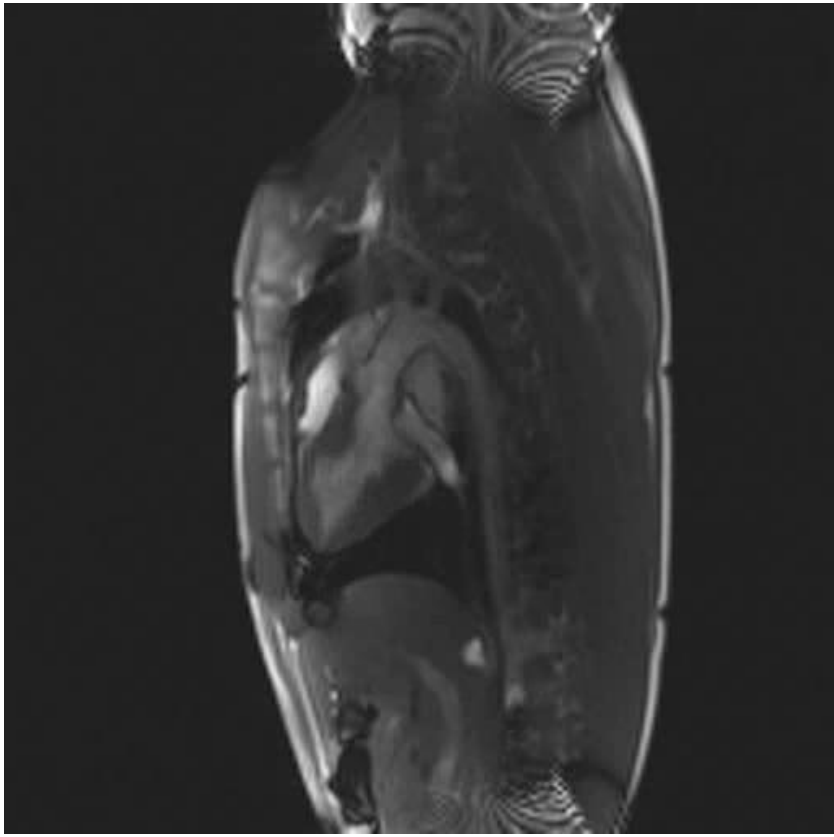


Instrument Visualization under MRI
Passive Visualization



Superparamagnetic Iron Oxide Nanoparticles (SPIONs) can be visualized based on susceptibility artifact





CONCLUSION

- Interventional MRI imposes unique safety and performance constraints on cardiovascular guidewire tools.

- Engineering solutions are approaching clinical reality for iCMR guidewires, having either complex active (antenna-based) and more simple passive (materials-based) visualization strategies

Acknowledgements

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Thank You!