Active Implantable Medical Device (AIMD) Interactions with MRI: Modeling To Demonstrate Safety

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Contributor/Member of:
- *ISO/TS 10974*
- *AAMI PC76*
- *IEC60601-2-33*
- *ASTM F2182 & F2503*

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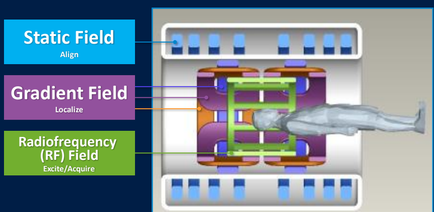
Further, Together

THE MRI ENVIRONMENT
THREE POWERFUL MAGNETIC FIELDS



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MRI HAZARDS FOR AIMDS
DEFINED BY MRI JOINT WORKING GROUP DEVELOPING ISO/TS 10974

Hazard	Static (B0)	Gradient	RF (B1)
Force and torque Patient discomfort, dislodgement	♦		
Vibration Patient discomfort, device damage	♦	♦	
Device interactions/malfunction Therapy delivery, device reset/damage	♦	♦	♦
Case heating Patient discomfort, necrosis		♦	♦
Unintended stimulation Nerve stimulation, cardiac arrhythmia induction, asystole		♦	♦
Lead electrode heating Patient discomfort, necrosis, therapy delivery, sensing			♦

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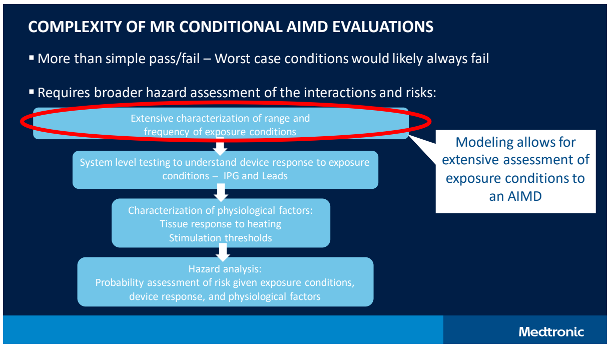
COMPLEXITY OF MR CONDITIONAL AIMD EVALUATIONS
More than simple pass/fail – Worst case conditions would likely always fail
Requires broader hazard assessment of the interactions and risks:
Extensive characterization of range and frequency of exposure conditions
System level testing to understand device response to exposure conditions – IPG and Leads
Characterization of physiological factors: Tissue response to heating Stimulation thresholds
Hazard analysis: Probability assessment of risk given exposure conditions, device response, and physiological factors
Modeling allows for extensive assessment of exposure conditions to an AIMD
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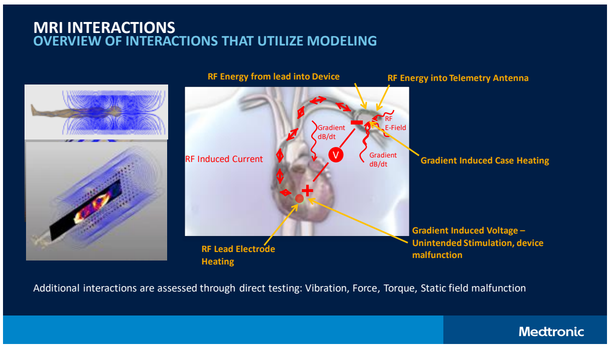
MRI INTERACTIONS
OVERVIEW OF INTERACTIONS THAT UTILIZE MODELING
RF Energy from lead into Device
RF Energy into Telemetry Antenna
RF Induced Current
Gradient dB/dt
RF E-Field
Gradient dB/dt
Gradient Induced Case Heating
Gradient Induced Voltage – Unintended Stimulation, device malfunction
RF Lead Electrode Heating
Additional interactions are assessed through direct testing: Vibration, Force, Torque, Static field malfunction
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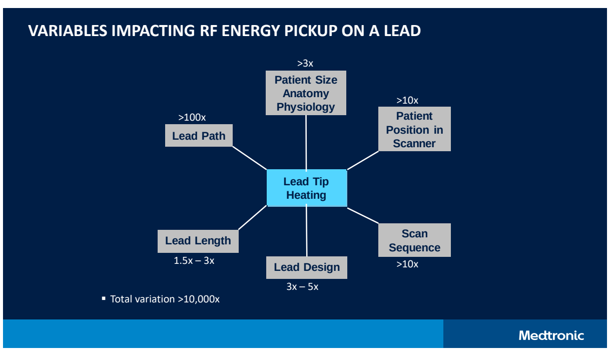
VARIABLES IMPACTING RF ENERGY PICKUP ON A LEAD
>3x
Patient Size Anatomy Physiology
>10x
Patient Position in Scanner
>100x
Lead Path
Lead Tip Heating
Lead Length
1.5x – 3x
Lead Design
3x – 5x
Scan Sequence
>10x
Total variation >10,000x
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VARIABLES IMPACTING RF ENERGY PICKUP ON A LEAD

>3x
Patient Size Anatomy

>10x

Robust, Validated Modeling Framework is Required to Assess Patient Safety

- "Computer-aided modeling is a practical and efficient method for exploring **millions of variable combinations** in a holistic manner. Computer modeling also **allows for analysis of parameter extremes**, outside the bounds of normal clinical practice, which allows further assessment of safety margin and the sensitivity of influencing variables" [1]

Lead Length
1.5x – 3x

Lead Design
3x – 5x

Sequence
>10x

- Total variation >10,000x

[1] Wilkoff, Bruce L., et al. "Safe magnetic resonance imaging scanning of patients with cardiac rhythm devices: a role for computer modeling." *Heart Rhythm* 10.12 (2013): 1815-1821.

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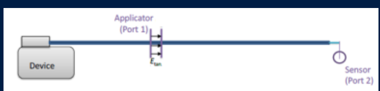
LEAD ELECTRODE HEATING - MODEL DEVELOPMENT TESTING

- Direct transfer function measurement apparatus
  - Rapid measurement of a lead's RF characteristics
  - Sensors placed at each lead electrode for heating
  - Custom electro-optical measurement device in an AIMD case used for proximal end measurements
  - Transfer functions relate heating at an electrode or voltage at the device versus E-field coupled to lead



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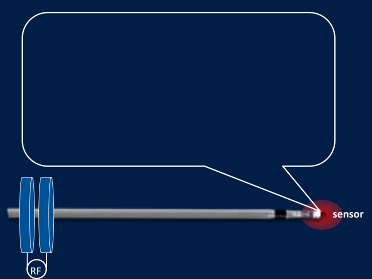
DIRECT DETERMINATION OF LEAD TRANSFER FUNCTION



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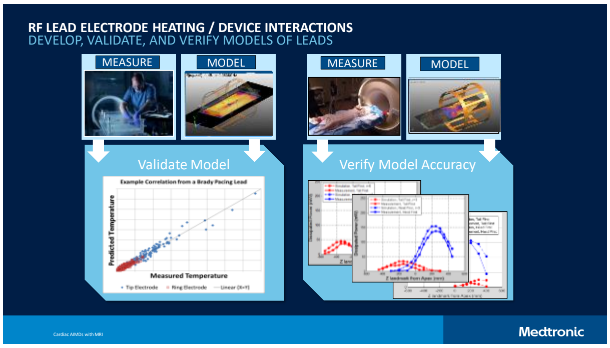
RF LEAD ELECTRODE HEATING / DEVICE INTERACTIONS
DEVELOP, VALIDATE, AND VERIFY MODELS OF LEADS
MEASURE
MODEL
MEASURE
MODEL
Validate Model
Verify Model Accuracy
Example Correlation from a Brady Pacing Lead
Predicted Temperature
Measured Temperature
Tip Electrode
Ring Electrode
Linear (X=Y)
Cardiac AIMDs with MRI
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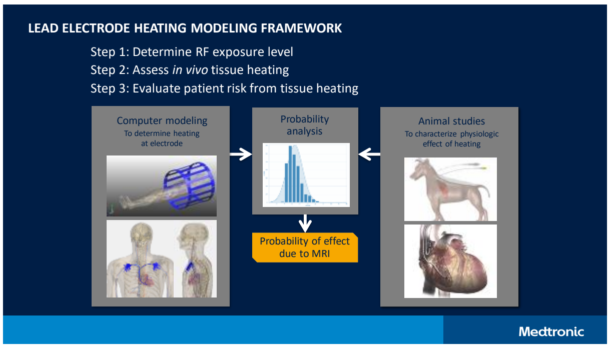
LEAD ELECTRODE HEATING MODELING FRAMEWORK
Step 1: Determine RF exposure level
Step 2: Assess *in vivo* tissue heating
Step 3: Evaluate patient risk from tissue heating
Computer modeling
To determine heating at electrode
Probability analysis
Animal studies
To characterize physiologic effect of heating
Probability of effect due to MRI
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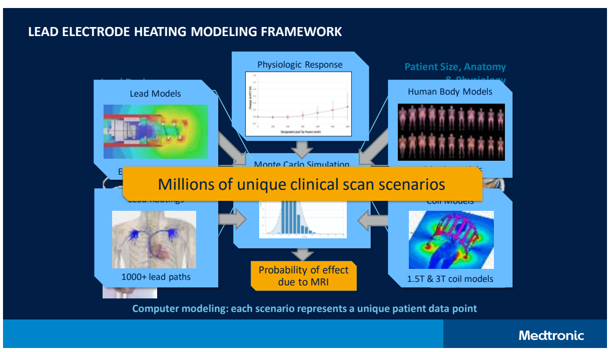
LEAD ELECTRODE HEATING MODELING FRAMEWORK
Physiologic Response
Patient Size, Anatomy
Lead Models
Human Body Models
Monte Carlo Simulation
Millions of unique clinical scan scenarios
1000+ lead paths
Probability of effect due to MRI
1.5T & 3T coil models
Computer modeling: each scenario represents a unique patient data point
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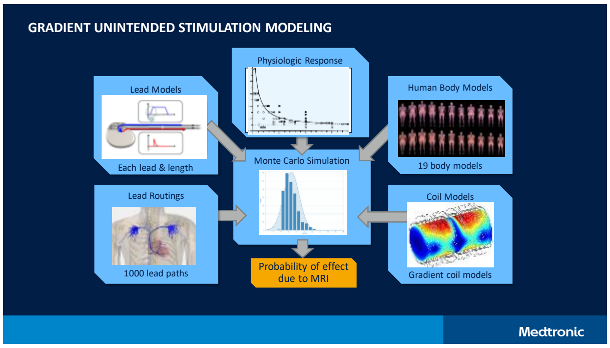

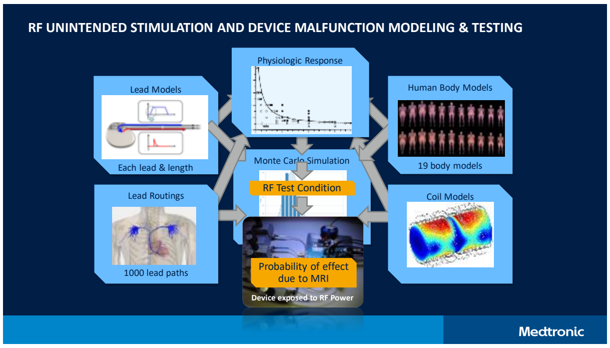

CONCLUSION

- Modeling provides an invaluable means to predict In-vivo MRI exposure conditions to AIMDs
- Heavily relied on for RF-induced heating assessments and RF exposure conditions
- Commonly used to inform gradient hazards such as unintended stimulation
- Clinical studies cannot demonstrate safety alone as they cannot ensure worst case conditions have been assessed
- Modeling utilized to support world wide approvals of many MR conditional AIMDs

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