# MAYO CLINIC

## MRI Safety - 7 T and Beyond

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### Overview

- 1. Ultra High Field MRI current state-of-play
- 2. Safety concerns relating to  $\mathsf{B}_{\mathsf{0}}$  and Gradients
- 3. Safety concerns relating to RF @  $\geq$  300 MHz
- 4. Scanning of implanted medical devices
- 5. Ensuring Safety logistics & practicalities

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### 1. Ultra High Field MRI – current state-of-play

Early UHF systems

- 8 T installed in 1998 (Ohio State university)
- 7 T installed ~ 2000 (CMRR, Univ. Minnesota)
- Current install base (UHF human scanners currently at field):
- ~ 75 x 7 T (approx. 20-30% performing some degree of clinical scanning

• ~ 5 x 9.4

- 10.5 T (Uni. Minnesota)
- Roadmap for UHF MRI scanners:

	FDA 2003 <sup>1</sup>	- MRI up to 8 T constitutes a non-significant risk for adults,
		children and infants > 1 month
	ICNIRP 2009 <sup>2</sup>	- no serious health effects from exposure to static magnetic
		fields up to 8 T
	IEC 2015 <sup>3</sup>	- increased the first-level controlled operating mode for the
IAYO LINIC	(60601-2-33)	static magnetic field to 8 T

### 1. Ultra High Field MRI – current state-of-play

• 7 T Regulatory status

- Clinical diagnostic scanning Siemens Magnetom Terra
- CE Labelling
- Head & knee imaging



### 1. Ultra High Field MRI – current state-of-play

 > 8 T – U.S. FDA Investigational Device Exemption (IDE) required → granted already for 9.4 and 10.5 T systems



2. Safety concerns relating to B<sub>0</sub> and Gradients

· Forces (translational, torque) on objects

material force	paramagnetic and unsaturated ferromagnetic	saturated ferromagnetic
translational	$F_{trans}  \propto  B_0   \nabla B_0 $	$F_{trans} ~ \varpropto ~ B_{S} ~  \nabla B_{0} $
torque	$F_{torque}  \propto B_0$	$F_{torque}$ insensitive to $B_0$

- inversely proportional to length hence, most concern for short, elongated objects

2 B <sub>e</sub> & Gradients		max   <b>⊽</b> B <sub>o</sub>	max B <sub>o</sub>	max B₀   <b>V</b> B₀
2. 50 a cradionio	Shielded 7 T	12.2	7.2	87.8
	3 T 4	19	3.7	62.9
	1.5 T <sup>4</sup>	17	2.4	45.6
0.6 B <sub>0</sub> Plot 0.4 T <sub>72T</sub> 0.2			⊀ Wood AST7	s et al, J Testing Eval, M International, 2019
$-0.2$ $0.6$ $\nabla B_0$ Plot	I Z Avis (m)		Shielded 7 T magnet	
	6019m	\$ 8 6 6 7 7	c patient table 2	

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### 2. B<sub>0</sub> & Gradients

Bioeffects - exposure to static  ${\rm B}_{\rm 0}$  and movement through spatial gradients

- Differentiate between long-term and transitory effects
- Potential long-term effects DNA damage <sup>5</sup>
  - inconsistent / conflicting data in literature
  - Potential source (if even present) not clear
  - RF quantum energy at 7T is 10,000 times smaller than Boltzmann thermal energy
    ? Disruption of DNA repair mechanisms due to low-frequency EM fields in MRI?
  - Long history of safe use of MRL (including ~ 55,000 scans at 7 T)
  - Likely to be significantly smaller than for ionizing radiation (2017 ICNIRP statement 6)



### 2. B<sub>0</sub> & Gradients

### Potential Transitory effects - all exacerbated at UHF

- Cognitive effects 8,9
  - conflicting data in literature
  - possible that any effect present may be due to disturbance of the vestibular system <sup>10,11</sup>
- ECG waveform distortion
  - magnetohydynamic effect, significantly elevated T-wave
  - issue for cardiac gating
- Physiological effects <sup>12,13</sup>, e.g. heart rate, blood pressure
  - + Modelling of magnetohydynamic equations suggest < 0.2% change in blood pressure in human vasculature at 10 T  $^{14}$
  - No effects in animal models measured up to 10.5 T<sup>15</sup>
- Most studies report subjects willing to undergo further UHF scan (> 90%)
- May be more relevant for occupational exposure of staff
  - e.g. workers performing maintenance or cleaning in the bore
  - advice to avoid activities such as driving immediately afterwards....

### 2. B<sub>0</sub> & Gradients

- 10.5 T (CMRR, Uni Minnesota)
  - To determine effects of 10.5T exposure on human volunteers with respect to
  - physiologic parameters, the vestibular system and cognition
  - Some very minor effects reported to date <sup>17</sup>
    - O<sub>2</sub> saturation, nystagmus, blood pressure, cognitive executive functioning
    - biological significance under investigation
  - Most pronounced effect compared to lower fields Increases in metallic taste in mouth
- Dental amalgam 2018 study
  - reported increase of mercury from ex vivo samples after 7T scanning <sup>18</sup>
  - Several methodological issues unclear

### 2. B<sub>0</sub> & Gradients

### Switching gradient fields

- Similar amplitudes and slew rates to 3T scanners
  - 80 mT/m
  - 200 1/m/s
  - No increase in risk of cardiac ventricular fibrillation
  - Recent study reported higher incidence of PNS on one actively-shielded 7T scanner
    67% of subjects reported PNS (n = 103) <sup>16</sup>
    - · corroboration required on other scanner designs, image scan protocols, etc.

### Acoustic noise

- Not appreciably higher at 7T than 3T scanners
- Head coil is narrower fitting headphones is an iss

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### 3. Safety concerns relating to RF @ ≥ 300 MHz

- Higher RF frequency → increased power absorption in tissue
- RF wavelength is short relative to body dimensions
  - + e.g. at 7T for  $^1\!\text{H},$  300 MHz,  $\lambda$  fat is 40 cm, liquids 10 cm
  - Result
    - RF interference effects, highly dependent on Tx coil
    - configuration, tissue composition, etc.
    - RF Tx field is very inhomogeneous birdcage designs obsolete for anything larger than head
- Regional peaks in local SAR may occur
- No longer operating in the quasi-static electromagnetic regime
  - 1.5T, 3T magnetostatic approximation is useful (Biot-Savart law etc)
  - > 31 electromagnetic regime, full set of Maxwell's equations need to be solv
  - RF simulations are essential for SAR prediction & RF coil design

### 3. RF @ ≥ 300 MHz

- + Quasi-static estimates predict SAR will increase with  ${\rm B_0^2}$
- → electromagnetic regime not expected to follow this exact trend
- Regulatory limits are nonetheless the same (IEC 2015)
- However, the lack of 'volume' RF coils at UHF means we must consider Local SAR for safety assessments and RF monitoring

	Operating mode	
Normal	1 <sup>st</sup> Level Controlled	2 <sup>nd</sup> Level controlled
2	4	> 4
	4-10	> 4-10
10	20	> 20
	averaged over 6 minutes	
	Normal 2 2-10 3.2 10 20	Operating mode        Normal      1st Level Controlled        2      4        2·10      4·10        3.2      3.2        10      20        20      40        averaged over 6 minutes







### 3. RF @ ≥ 300 MHz

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		Operating mode	
	Normal	1 <sup>st</sup> Level Controlled	2 <sup>nd</sup> Level controller
Global SAR [W/kg]			
Whole body	2	4	> 4
Partial body		4-10	> 4-10
Head			
Local SAR [W/kg]			
Trunk	10	20	> 20
Limbs			> 40
		averaged over 6 minutes	

### 3. RF @ ≥ 300 MHz

- Global SAR can be determined directly from absorbed power in the exposed body region
  measurement of the [forward backward] RF power into the Tx coil
- Local SAR more difficult to assess and monitor
  - requires SAR simulations which solve full Maxwell equations in realistic
    anthropomorphic virtual human models



### 3. RF @ ≥ 300 MHz

- Parallel Tx coils becoming ubiquitous at UHF
  - Useful for B<sub>1</sub><sup>+</sup> homogeneity and RF power reduction
  - Independently vary phase and amplitude of waveforms applied to each Tx channel
  - Results in very complex local SAR patterns
  - → potential for SAR hotspots, which furthermore can vary during application of the RF pulse

37 Ladd, Topics MRI 2012

### • SAR.





### 4. Implant scanning

- Several studies in literature safety testing of devices
  - Limitations results only applicable to the specific experimental set-up
  - RF coils used different design concepts with different RF distributions
  - RF Tx method



4. Implant scanning		
<sup>27</sup> Wezel et al. M	EQ. 2014 Experimental temperature rise (C) 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	Was tap Winc centra Rutenetice
Max heating occurred for wire: → max 1.5°C rise at 5	sof47mm in length (~ ½ -½ o xglobal SAR limit , i.e. at 5 x [3	ofλ) 3.2 W/kg]















### 4. Implant scanning

### Future directions

- Limit on some measure of thermal dose → likelihood of tissue damage
- Pre-calculated temperature VOPs
  - Additional parameters increases the complexity of thermal simulations
    e.g. thermal tissue properties (conductivity, specific heat), metabolism, blood
  - perfusion, heat transfer coefficient at body surface
  - Better thermoregulation / blood perfusion models required
  - Verification of numerical results difficult
- Many studies focus on RE heating only
  - Further studies required to assess other safety
  - Useful e.g. when considering implants outside the RF Tx fie

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### 4. Implant scanning

### In Practice

- Many small objects can be scanned routinely
  - Dental implants < 30 mm
    - consider lower SAR protocols for longer objects (for brain imaging)
  - Orthopedic implants located far from Tx field
    - If ferrous-free
    - Hip/knee replacements
    - · Screws, rods, spinal fusion plate
  - · Cranial fixation plates
    - < 30 mm long</li>
    - > 40 mm separation
- · Other objects considered on case-by-case basis
  - Stents, clips, IUDs, objects within/close to Tx field

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### 5. Ensuring Safety - logistics & practicalities

UHF Safety Committee

- Develop / review policies & procedures to adhere to local regulation and best practice
- Perform risk-benefit analyses as required
- Significant pre-screening of patients required
  - to identify patients/subjects suitable for 7T imaging
    - certain indications only
    - patients > 30 kg due to lack of suitable anatomical models for small childre
    - o assess any implants and weed-out contraindicated devices
    - · implant model number, location in body, proximity to other devices of
    - thermosensitive tissue, date or implantation
    - consider taking planar X-rays if no prior imaging is available
    - MR Conditionality at
- AAAA

### 5. Logistics & Practicalities

- Technologist training
  - Core group of "7T MR Technologists" who operate the scanner
  - Many items scanned without a second thought at 3T may be contraindicated at UHF
  - - use of dielectric pads
  - RF coil handling positioning important

  - Fever / thermoregulatory compromise
  - Magnet room environmental conditions (temperature, humidity)

### Summary

- UHF MRI
  - significant step-change in MR technology
- Higher B<sub>0</sub>
  - increased forces on para- and ferro-magnetic objects
  - potential for increased long-term & transient physiological effects
- RF higher  $f_0$  and shorter  $\lambda$ 

  - shorter resonant lengths near metallic implants
- ISMRM Working Group
  White Paper "7T MRI Safety"

### References

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### 3. RF @ ≥ 300 MHz

### Lack of 'body' RF coils at UHF

### Local Tx coils

- produce strong E fields close to the coil conductors
- can lead to very high local power absorption even though global SAR remains small









# A Implant scanning Implants within the RF Tx field SAR<sub>100</sub> preferred method of predicting temperature increase near metallic implants. SAR<sub>100</sub> preferred method of predicting temperature increase near metallic implants. Supervised on UHF scanners However, doubt over whether 10g (or even 1g) of tisse gives sufficient spatial resolution to detect ho spots near implants Free Werl er al. 212 Metallic field and the spots of the spot

2015 MRM