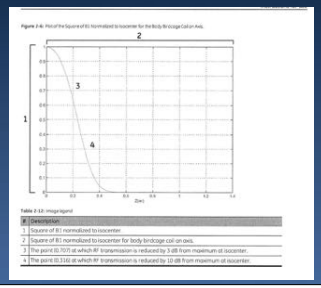
Radio Frequency Field

William Faulkner & Associates
www.t2star.com

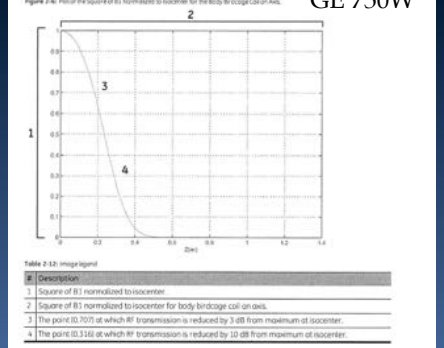
Radio Frequency Coils and
RF Power Distribution

RF Coil Maps

Distribution of RF Power



GE 750W



#	Description
1	Square of B1 normalized to isocenter
2	Square of B1 normalized to isocenter for body birdcage coil on axis.
3	The point (0.707) at which RF transmission is reduced by 3 dB from maximum at isocenter.
4	The point (0.316) at which RF transmission is reduced by 10 dB from maximum at isocenter.

Ratio of the RF power deposition along the long axis of the magnet relative to the value at the isocenter.

The following information may support assessment of SAR exposure of workers if present at the system during scanning.

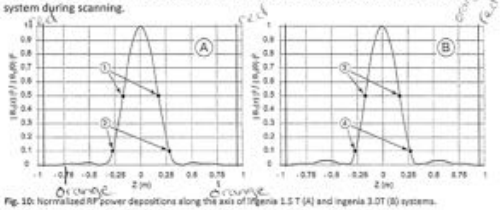
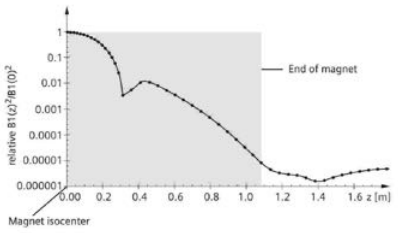


Fig. 10: Normalized RF power depositions along the axis of Ingenia 1.5 T (A) and Ingenia 3.0T (B) systems.

RF maps courtesy of Tobias Gilk

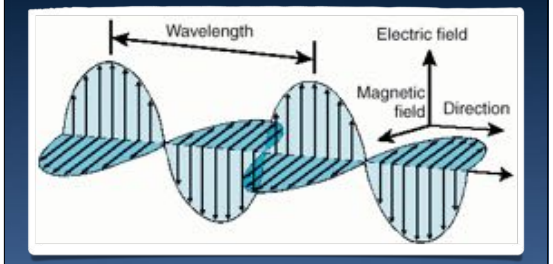
RF power distribution relevant for assessing exposure to MR workers

The diagram shows the RF power distribution along the patient axis of the MAGNETOM Prisma/Prisma^{fit} according to the requirements of the IEC 60601-2-33 standard.



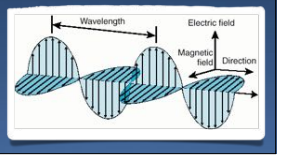
Siemens Prisma (courtesy Siemens)

Radio Frequency Field (B_1)



Radio Frequency Field (B_1)

- Frequency
- Wavelength
- Amplitude



Field Strength and Frequency

$$\omega_0 = B_0 \cdot \gamma$$

Nuclei and Frequency

$$\omega_0 = B_0 \cdot \gamma$$

Hydrogen (H^1) = 42.58 MHz/T

Sodium (Na^{23}) = 11.27 MHz/T

Phosphorus (P^{31}) = 17.25 MHz/T

Field Strength and Frequency

$$\omega_0 = B_0 \cdot \gamma$$

1.5 T x 42.6 MHz/T = 64 MHz

3.0 T x 42.6 MHz/T = 128 MHz

Frequency and Wavelength

Wavelength is based on Frequency

$$\lambda = \frac{c}{f}$$

As frequency (B_0) increases, wavelength decreases

Frequency and Wavelength

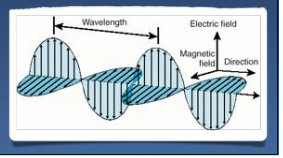
Wavelength is based on Frequency

$$\lambda = \frac{c}{f}$$

Optimal current induction in an elongated conductor is achieved when the length of the conductor matches a major harmonic of the RF wavelength

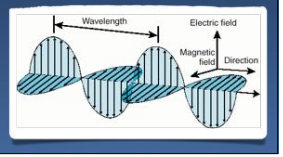
Electromagnetic Energy

- Magnetic (B-field) — Excites
- Electric (E-field)



Electromagnetic Energy

- Magnetic (B-field)
- Electric (E-field) — Tissue Heating



SAR: Specific Absorption Rate

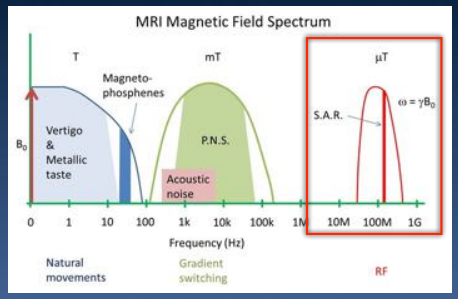
Specific to the body part and tissue

Absorption of the RF into the body/tissues

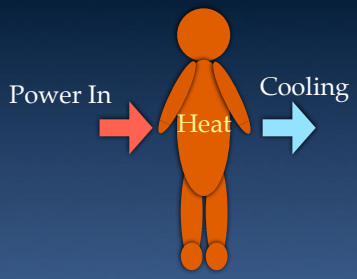
Rate of RF exposure and absorption

Units of Watts/kg

Biologic Effects

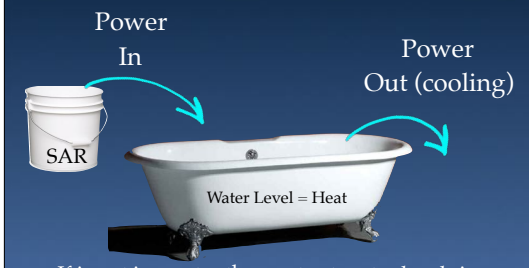


https://www.nottingham.ac.uk/magres/research/safety.aspx



If input is greater than output, heating occurs

SAR is the rate at which energy gets deposited in the body (specific for each scan)



If input is greater than output water level rises

NEMA* Standards (MS 8-2008)

"It is not considered prudent to raise the core temperature in a patient above 39.2^0 C (roughly a 2.2 degree rise from thermoneutral). If patient exposure to radio frequency magnetic fields during MR scanning is insufficient to produce a core temperature rise in excess of 1^0 C and localized heating greater than 38^0 C in the head, 39^0 C in the trunk, and 40^0 C in the extremities, RF heating is considered to be within safe levels."

*National Electrical Manufacturers Association

Original FDA

- 0.4 W/kg
- Exposure sufficient to produce a core body temperature increase of 1^0 C (normal core temp is 37^0 C)

We now know that we can scan at SAR levels of 4 W/kg without incurring a core temp rise of 1^0

SAR is estimated based on RF power (B_1) along with patient-related factors (assumed)

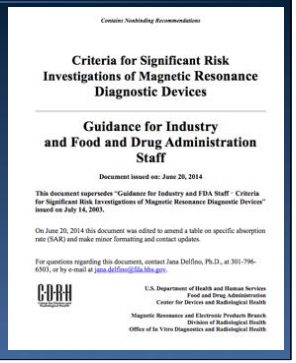
Power In – Power Out = SAR

SAR Limits

- FDA: provides guidelines
  - Manufacturers can use those guidelines or there own but must show they are safe
- IEC*: provides standards
  - Manufacturers follow IEC standards

*International Electrotechnical Commission

FDA Guidelines



Contains Nonbinding Recommendations

Criteria for Significant Risk Investigations of Magnetic Resonance Diagnostic Devices

Guidance for Industry and Food and Drug Administration Staff

Document issued on: June 20, 2014

This document supersedes "Guidance for Industry and FDA Staff – Criteria for Significant Risk Investigations of Magnetic Resonance Diagnostic Devices" issued on July 14, 2003.

On June 20, 2014 this document was edited to amend a table on specific absorption rate (SAR) and make minor formatting and contact updates.

For questions regarding this document, contact Jana Delfino, Ph.D., at 301-796-6503, or by e-mail at jana.delfino@fda.hhs.gov.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Magnetic Resonance and Electronic Products Branch
Division of Radiological Health
Office of In Vitro Diagnostics and Radiological Health

FDA Guidelines

Specific Absorption Rate (SAR)

Site	Dose	Time (min) equal to or greater than:	SAR (W/kg)
whole body	averaged over	15	>4
head	averaged over	10	>3.2

Criteria for Significant Risk Investigations of Magnetic Resonance Diagnostic Devices

Guidance for Industry and Food and Drug Administration Staff

IEC: Standards

Operating Modes

Averaging time	6 minutes					
	Whole body SAR	Partial body SAR	Head SAR	Local SAR		
Body Region	whole body	exposed body part	head	head	trunk	extremities
Operating Mode ↓	(W/kg)	(W/kg)	(W/kg)	(W/kg)	(W/kg)	(W/kg)
Normal	2	2 - 10 (b)	3.2	10 (c)	10	20
1st Level Controlled	4	4 - 10 (b)	3.2	10 (c)	10	20
2nd Level Controlled	>4	>(4 - 10) (b)	>3.2	>10 (c)	>10	>20
Short term SAR	The SAR limit over any 10 s period shall not exceed three times the stated values					

Normal ≤ 2 W/kg: No physiologic stress is expected

1st Level > 2 W/kg up to 4 W/kg: Physiologic stress is possible

IEC: Standards

Operating Modes

Averaging time	6 minutes					
	Whole body SAR	Partial body SAR	Head SAR	Local SAR		
Body Region	whole body	exposed body part	head	head	trunk	extremities
Operating Mode ↓	(W/kg)	(W/kg)	(W/kg)	(W/kg)	(W/kg)	(W/kg)
Normal	2	2 - 10 (b)	3.2	10 (c)	10	20
1st Level Controlled	4	4 - 10 (b)	3.2	10 (c)	10	20
2nd Level Controlled	>4	>(4 - 10) (b)	>3.2	>10 (c)	>10	>20
Short term SAR	The SAR limit over any 10 s period shall not exceed three times the stated values					

Normal and 1st Level ≤ 3.2 W/kg: No physiologic stress is expected

SAR is Proportional To

- The power of two for a system's resonant frequency
- The power of two for the B1 amplitude of the RF field
- The power of five for the patient's circumference
- The patients average conductivity

Clinical 3T Magnetic Resonance, Val Runge, M.D., et al; Thieme 2007

Cooling Influenced By

- *Bore Temperature*
- *Ambient Temperature*
- *Relative Humidity*
- *Air Flow Rate*
- *Perspiration*
- *Blood Flow*

Some systems will reduce SAR limits if temp increases above 24^0 C (75^0 F)

Cooling Influenced By

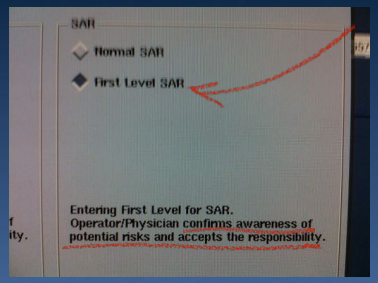
- *Bore Temperature*
- *Ambient Temperature*
- *Relative Humidity*
- *Air Flow Rate*
- *Perspiration*
- *Blood Flow*

Patient Dependant

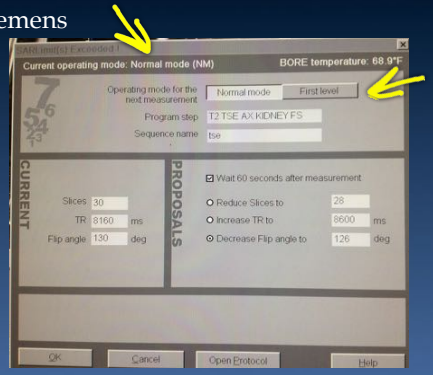
www.mrisafety.com

"Various underlying health conditions may affect an individual's ability to tolerate a thermal challenge including cardiovascular disease, hypertension, diabetes, fever, old age, and obesity. In addition, medications including diuretics, beta-blockers, calcium blockers, amphetamines, and sedatives can alter thermoregulatory responses to a heat load. Importantly, certain medications have a synergistic effect with RF radiation with respect to tissue heating. The environmental conditions (i.e., ambient temperature, relative humidity, and airflow) that exist in the MR system will also affect tissue temperature changes associated with RF energy-induced heating."

GE

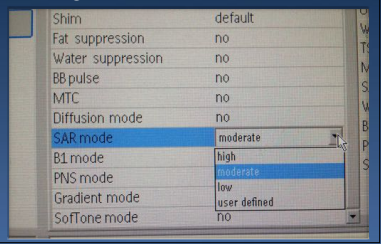


Siemens



Philips

- Low = 2.0 W/kg
- Moderate = 3.2 W/kg
- High = 4.0 W/kg



Parameters Effecting SAR

- TR
- Echo Train Length / Turbo Factor
- Echo Spacing / Receiver Bandwidth
- Flip Angle (GRE)
- Refocusing Angle (FSE)
- Specific Pulse Sequence

Managing SAR and Pt Warming

- Scan in Normal Operating Mode as much as possible
- Do not use minimum TR for maximum number of slices (long TR sequences)
- Pause between sequences
- Do not wrap patients in blankets
- Alternate between high and low SAR sequences
- Use vendor specific options

SED: Specific Energy Dose

Specific to the body part and tissue
Energy of the RF
Dose into the body

May also be referred to as "specific absorbed energy"

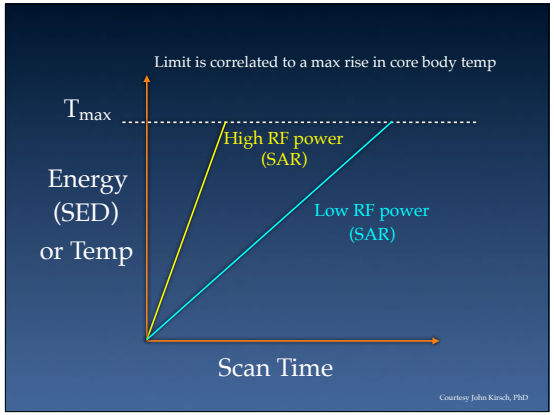
Units of Joules/kg

SAR is the rate at which energy gets deposited in the body (specific for each scan)

SED is the total accumulated amount of energy that gets deposited in the body

SED = SAR x time

Joules/kg = Watts/kg x sec



SED Limits

240 W-min/kg (14440 J/kg)*

Research shows that this level will produce a temperature rise to 43^0 C (109^0 F) above which patient with normal thermal regulation may suffer tissue damage[1]

*IEC 60601-2-33 edition 3 (2010) requirement

[1]Magn Reson Med, 71, 421-431, 2014

SED Limits

100 W-min/kg (6000 J/kg)

Above this level patients with compromised thermal regulation may suffer physiological stress or even tissue damage[1]

[1]Magn Reson Med, 71, 421-431, 2014

SED Limits

240 W-min/kg (14400 J/kg)

- 1 Hr continuous scanning at 4 W/kg (1st Level Controlled)
- 2 Hr continuous scanning at 2 W/kg (Normal Mode)

100 W-min/kg (6000 J/kg)

- 25 min continuous scanning at 4 W/kg (1st Level Controlled)
- 50 min continuous scanning at 2 W/kg (Normal Mode)

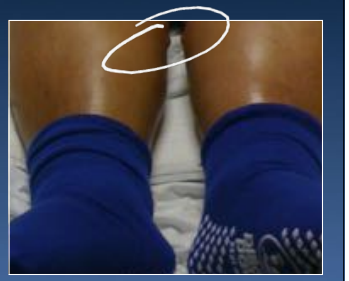
Courtesy John Kirsch, PhD

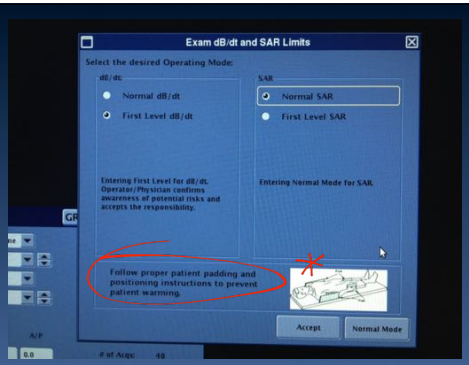
RF-Related Burns




Skin-to-Skin Contact

E-field is focused in a small area

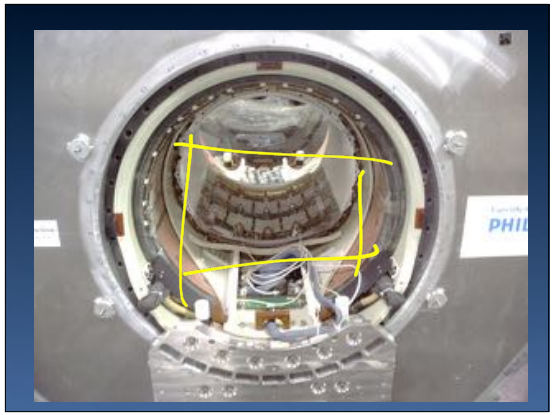


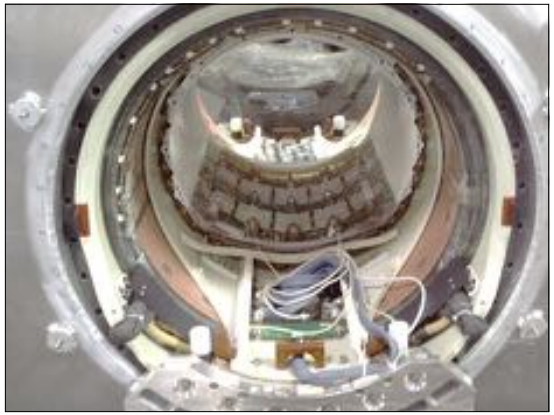


Newer GE UI: Exam dB/dt and SAR Limits Page

Gap (space) or insulating padding between the patient and side of the magnet

0.5 - 1.0 cm of padding





FDA MAUDE Database

Event Date 12/29/2014
Event Type Injury
Manufacturer Narrative

Ge healthcare's investigation is ongoing. A follow up report will be submitted once the investigation has been completed.

Event Description

It was reported that a patient undergoing an mri of the left shoulder sustained a 2cmx3cm full thickness burn to their right elbow. Pads were initially placed to isolate skin contact to the side of the magnet bore, however due to the patient's body habitus the pads were observed to be very compressed to the sides of the bore. It was reported that the pads shifted during the exam and the patient was in contact with the sides of the magnet bore during the exam. The patient was provided the patient alert ball, and did not report any warming during the exam. Upon completion of the exam, the patient did not report any burns or areas of injury, and left the mri department without incident. The patient's referring physician contacted the (b)(6) two weeks after the patient's mri exam. The physician communicated that the patient had an observed wound on his elbow. The patient has received treatment that included augmentin, percocet, and outpatient wound debridement.

Manufacturer Narrative

The ge healthcare investigation indicates that the incident appears to be the result of insufficient and shifting padding between the patient's elbow and the magnet bore during the scan. The patient's size did not allow for adequate padding. System log and configuration files were reviewed. The data indicates that the system was operating normally and within performance specifications. The information reviewed did not indicate there was any system malfunction that may have contributed to this incident. No further actions are planned at this time.

- Insufficient and shifting padding
- Pt size did not allow for adequate padding
- Delayed burn (approx 2 wks)

Study: Brain and Whole Spine

1.5 T, Head/Neck/Spine coil

Short obese patient with shoulders touching the side of the bore

Patient under GA

ECG monitored - "a lot of wires"

Total scan time
2 Hrs

Courtesy Frank Shellock, PhD

Conductive Metal Contacting Pt.

"Space Blanket"

prayfornoah.com

Immediate Release
Contact: Victoria Young
214.948.5940, 214.948.6940
vicki@theencompassgroup.net

Encompass Group Voluntarily Recalls Thermoflect Product Line.

McDonough, GA- (December 24, 2059)- Jan R. Gackowski, Encompass Group Corporate Compliance Officer announced today the company is voluntarily recalling the Thermoflect product line for relabeling regarding its use in the MR (Magnetic Resonance) environment.

"We are voluntarily recalling the product line from use in the Magnetic Resonance (MR) environment," Gackowski said. "We are requesting Thermoflect Blankets and other products not be used in MR conditional or MR compatible environments. We are in the process of sending labels to our customers to be attached per instructions to remind the hospitals the product line should not be used in the MR environment."

"In the past, we have stated the Thermoflect product may be used in the MR environment. However, after being informed by the FDA, at this time we will not promote the products for use in the Magnetic Resonance Environment. However, the product is still safe and effective for use in treating hypothermia."

We have been advised by the FDA that a report has been filed of an injury to an (MRI) patient. Several items are under consideration, including all of the blankets used in the MRI environment, of which Thermoflect is one. There is no evidence the Thermoflect blanket caused the injury but as a precautionary measure we are voluntarily recalling the product line for relabeling.

Thermoflect products are distributed nationally and internationally. A complete list of Thermoflect products and additional information can be found at www.thermoflect.com.

We have concluded there is currently no ASTM International standard to test Thermoflect in the MR environment, although we have conducted multiple laboratory and field tests. "Until an ASTM standard has been developed by ASTM International, we have removed statements on our website and in our product literature that Thermoflect is MR-Conditional or MR-Compatible."

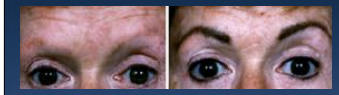
"In addition to issuing this news release to appropriate magazine and trade paper listings, we have sent letters to our customers, hospitals, and doctors in radiology and will follow up with training and verification surveys. "

"At Encompass Group, our mission is always to help healthcare and hospitality providers create safe and comfortable environments for patients, staff, residents and guests. This voluntary recall is another example of our ongoing commitment to those objectives"

For More Information, contact
Jan R. Gackowski, C.H.B., C.C.S.
Corporate Compliance Officer
770-626-2044
Monday – Friday 9 a.m. – 5 p.m. eastern

Tattoos

Permanent Cosmetics

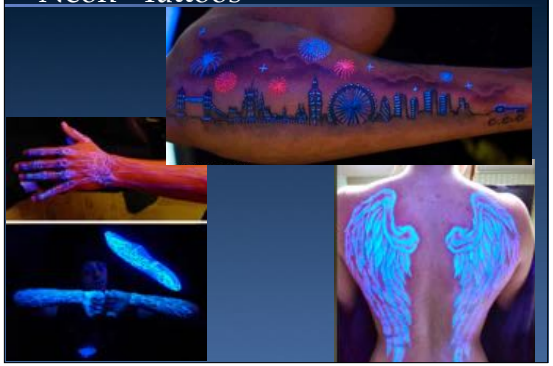


Tattoo

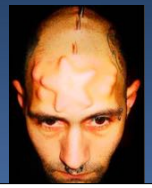
RF burn

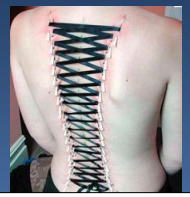
Courtesy Frank Shellock, Ph.D.

"Neon" Tattoos



Body Modifications and Piercings





Examples of patient injuries and incidents reported to the FDA in April of 2009

The site reported that a pt sustained a blister on the left arm during a mr hip exam using an 8-channel body array coil. According to the site supervisor, the pt ws sedated and placed into the bore with an intravenous (iv) line in the left arm. Due to the size of the pt, padding was not used.

The coil was positioned for a hip examination. It was observed that the coil cable was routed between the left arm and left breast. Immediately after the examination, first and second degree burns with a 17 mm and a 24 mm blister appeared on the inside of the left upper arm and left breast.

The site reported that the pt sustained quarter size blisters on both elbows during a mr exam of the sacrum using a torso array surface coil. The pt was not being monitored during the exam. The pt's hands were not clasped during the exam. Also, there was no cable or conductive material in contact with the pt during the exam. According to the site, no padding was used on the pt. Instead, the site used sheets and blankets

The operator was using a head coil to do the foot study. The hospital did not have an extremity coil at the time of the event. The operator introduced a metallic film approximately 8 inches wide which was wrapped around the patient's right leg as an rf blanket. The metallic film caused the heating and resultant fire. The patient received second degree burns when the fire occurred

Do not create loops with coil wires

Patient Injuries*

- 29.8% burns resulting from electrically conductive materials in the bore with the patient (leads, metallic clothing, coils, cables, etc.)
- 19.2% burns from contact with bore (RF coil)
- 16.3% projectiles
- 12.5% hearing damage
- 10.6% large-caliber body loops

*Personal communication Tobias Gilk: compiled from FDA reported injuries over a 2-year period

RF-Related Heating

- Unnecessary or unused electrically conductive materials
- Large-caliber conductive loops (including patient)
- Insulation/padding
- Clothing
- Skin-to-skin contact

RF-Related Heating

- Staples or superficial metallic structures
- Tattoos or Tattooed eyeliner
- Cold/ice pack
- Tattoo smearing (48 hrs post tattoo)
- Skin-to-skin contact
- Within volume of RF transmit coil


Questions?