

Human Subjects in fMRI Research

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Outline

- *General Information for Use of Human Subjects*
- *fMRI Specific Information for Use of Human Subjects*
 - Static B0 fields
 - RF B1 fields- tissue heating
 - Switched gradient fields- peripheral nerve stimulation
 - Acoustic Noise
- *Practicing Safe Imaging*
- *Minimizing Distress in the MR Environment*



Safety is Your Responsibility

- **Become familiar with the material posted on your institution's Human Subjects web site**
 - e.g. <http://hms.harvard.edu/integrity>
 - **Read**
 - Belmont Report
 - Title 45 Code of Federal Regulations Part 46 Protection of Human Subject
 - **Review NIH presentation from the Office of Human Research Protection**
 - <http://ohrp.osophs.dhhs.gov/humansubjects/assurance/sbirsttr/requirements.htm>
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Human Subject Considerations

- **Informed Consent**
 - **Risk/Benefit Considerations**
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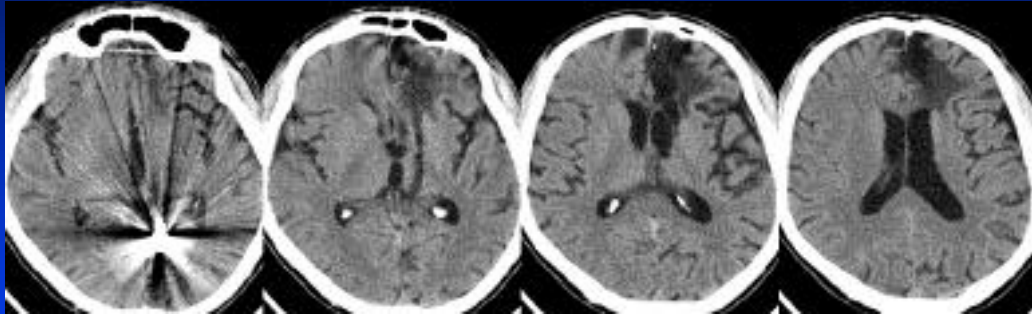
Static B_0 Fields

- No established adverse health effects
 - Projectile accidents
 - Metallic object screening
 - Magnetohydrodynamic effects
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Static B_0 fields- Projectile Accidents



45 y.o. male 2+ years s/p altercation



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RF B₁ Fields- Tissue Heating

- Ohmic heating of patient tissue is due to resistive losses from induced electric fields
 - Greatest effect at periphery or surface
 - Described in terms of Specific Absorption Rate (SAR)
 - Scanner determinants: RF frequency, type of RF pulse, TR and type of RF coil
 - Body determinants: thermoregulatory function

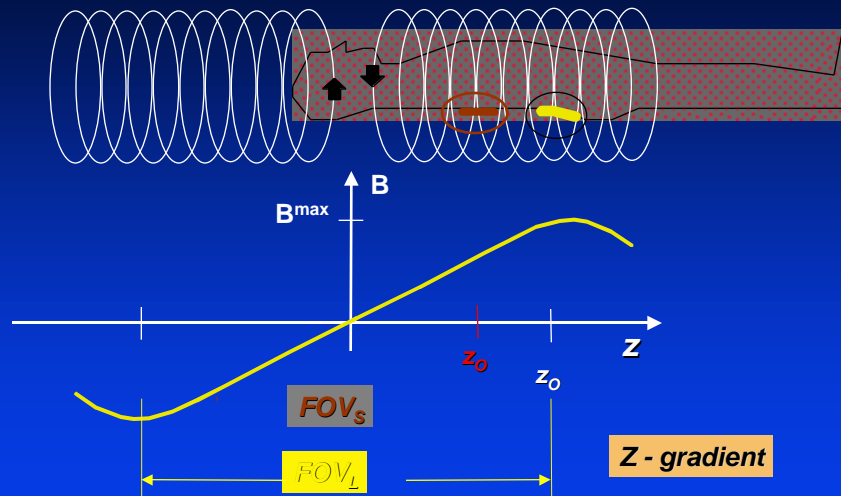
 - Electrical Burns
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Switched Gradient Fields

- Peripheral Nerve Stimulation
 - Metallic Taste
 - Magnetophosphenes
 - Skeletal Muscle Contractions

 - By Faraday's Law of Induction exposure of conductive tissue to time-varying magnetic fields will induce an electric field.
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Peripheral Nerve Stimulation



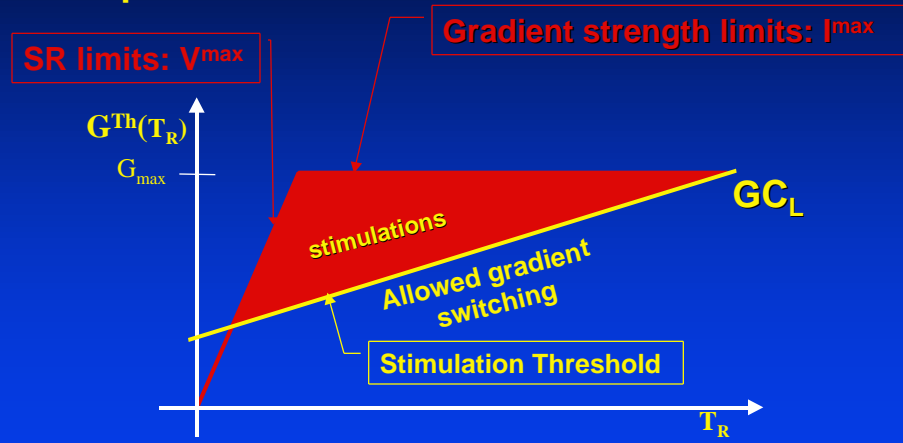
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Stimulation Aspects(I)

- Stimulation thresholds vary
 - linearly with rise time
 - ramp shape
 - fct (#pulses)

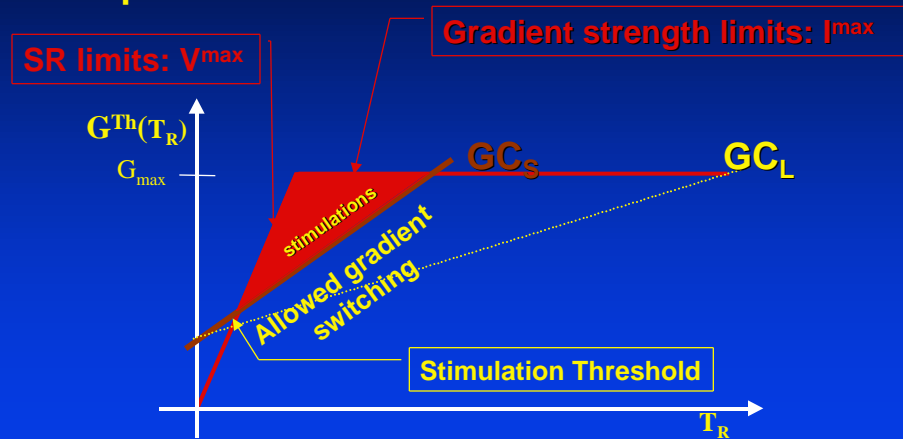
How to Place the Gradient Coil Performance?

- GPA performance
- g Peripheral Nerve/Muscle Stimulation



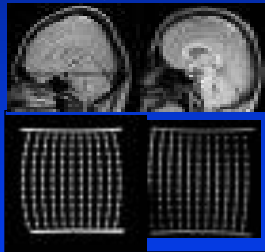
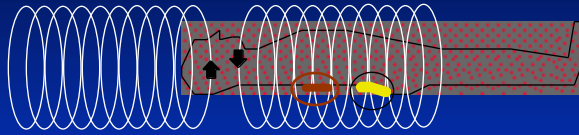
How to Place the Gradient Coil Performance?

- GPA performance
- Peripheral Nerve/Muscle Stimulation



Faster & Stronger Gradients

- “shorten” the gradient coil typically results in
 - higher stimulation thresholds, when expressed in mT/m
 - lower inductance
 - i.e. higher SR, G_{\max}
 - but more geometric image distortions



FOV_s

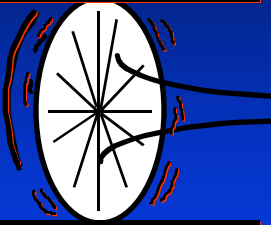
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Z - gradient

Why does EPI make so MUCH noise?

Strong, Static Magnetic Field

Current pulse
to create
gradient
fields

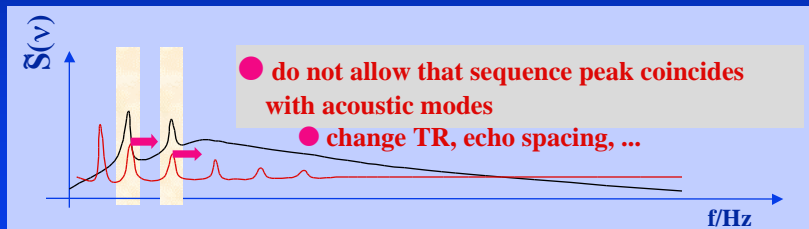


Together, these
produce mechanical
forces on the coils
that create the
gradient fields;
so the coils move.

The result is
acoustic noise.

Acoustic Noise .. and how to avoid?

- **passive damping** ~ 10 - 15 dB
 - acoustic insulation
 - more mass & stiffer
- **encapsulation & vacuum** ~ 20 - 30 dB
 - cooling
 - MRI system becomes longer
- **“active” damping** ~ 20 dB
 - avoid mechanical / acoustical resonance



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Current FDA Criteria for Non-significant Risk

- Field strength < 4T
- SAR < 3 W/kg averaged over 10 minutes in head
- SAR < 8 W/Kg in any 1 cc of tissue in head averaged over 5 minutes
- Acoustic Noise <140 dB peak and 99 dB average with ear protection
- No painful or severe peripheral nerve stimulation

Subjective Distress in the MRI Environment

- Incidence of distress among clinical MRI is high
 - Distress can be caused by many factors including: confined space, noise, restriction of movement
 - Distress can range from mild anxiety to full blown panic attack
 - Distress can result in subject motion and disrupt image quality
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Minimizing Subjective Distress

- Careful screening
 - Complete explanations
 - Make them comfortable in the scanner
 - Maintain verbal contact
 - Give them the panic button
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