Electro Magnetic Fields and Implanted Medical Devices: MRI compatibility

ESSCIRC 2010 Workshop 17 September

Medtronic Bakken Research Center Volkert Zeijlemaker Sept 17, 2010 ULTRAsponder project Workshop ESSCIRC 2010

1

Overview

- Introduction
- MRI physics
- Clinical value of MRI
- Electro magnetic compatibility challenges.
- Design "guidelines"
- Regulatory requirements

Introduction

ULTRAsponder project is an effort to avoid electromagnetic waves as transmission medium.

Magnetic resonance imaging MRI is a harsh environment that challenge all implanted electronic circuits. Specially the Radiofrequency Communication.

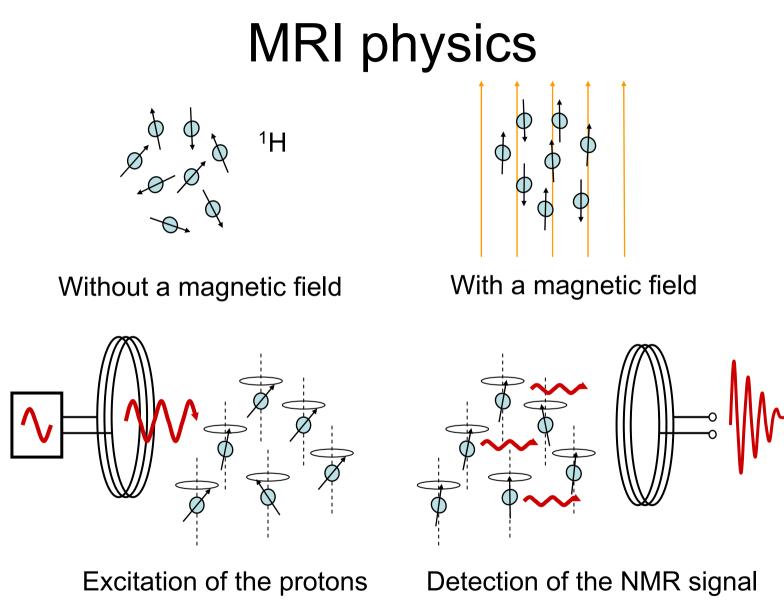
The RF communication is a highly regulated environment, a disadvantage for medical devices. Unfortunately Electromagnetic Field density is not controlled yet.

But there are others treats for medical devices: exponentially growing remote data and energy transmission.

 Magnetic resonance imaging device align proton spins with a <u>strong</u> <u>magnetic</u> field. (0.1T to about 10T)

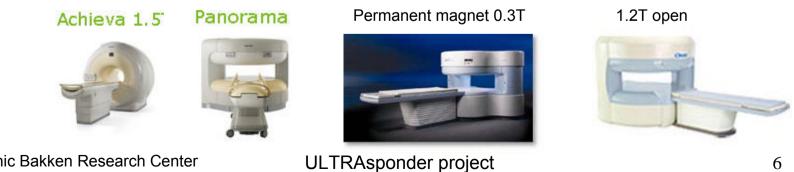
Active magnetic shielding often used to limit the spatial magnetic field.

- The MR device brings (a part of) the protons in resonance with a radio frequency field. (43 MHz per Tesla ~ kW)
 Cage of Faraday to shield the RF.
- Magnetic gradients are needed to make a 3D measurement. (Current-~100 A) Gradients in x,y and z direction.



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- Static magnetic field ۲
 - 0.3T to 3T commercial devices, up to 10T (research only).
 - $(1T \sim 30.000)$ times earth magnetic field at the equator)
- Superconducting magnet. (difficult to switch off) ٠
- Active shielding. (to limit the field outside the bore) ٠

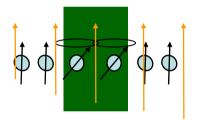


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- Radio Frequency (RF) power
 - High RF power is needed to rotate hydrogen nuclei or protons.
 - In the order of kW. (Like a microwave)
 - Power limited Specific Absorption Rate (SAR) by repetition time of RF pulses
 - Depends on static magnetic field strength.
 - Frequency depends on static magnetic field strength

Spatial encoding use additional magnetic fields which change along an axis.

-> Excitation only in one slice

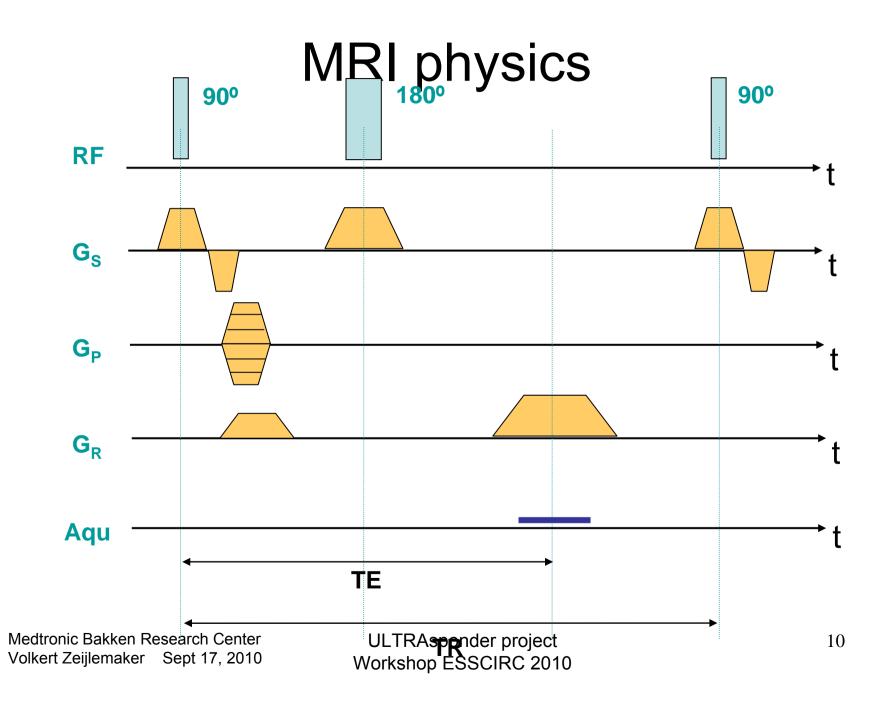


The use of three so called gradient fields allow the excitation of arbitrary slices

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Gradient fields.

- Up to 100 mT/m. Power limited by to avoid peripheral nerve stimulation
- Noise due to gradient coil movement.
- Induction of currents in conducting material.
- Vibration in metal objects.



Clinical value of MRI

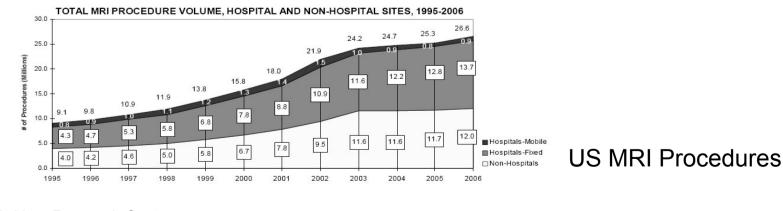
- MRI is safe to use. No ionizing radiation.
- Excellent soft tissue imaging.
- A number of effects can be used to image.
- Spectroscopy (tissue properties)
- More than half of the patients with implants need once MRI.

Clinical value of MRI

Increase.

lack of adverse side effect. variety of applications.

Contraindication for active medical implantable devices under discussion! (Often no good alternative)



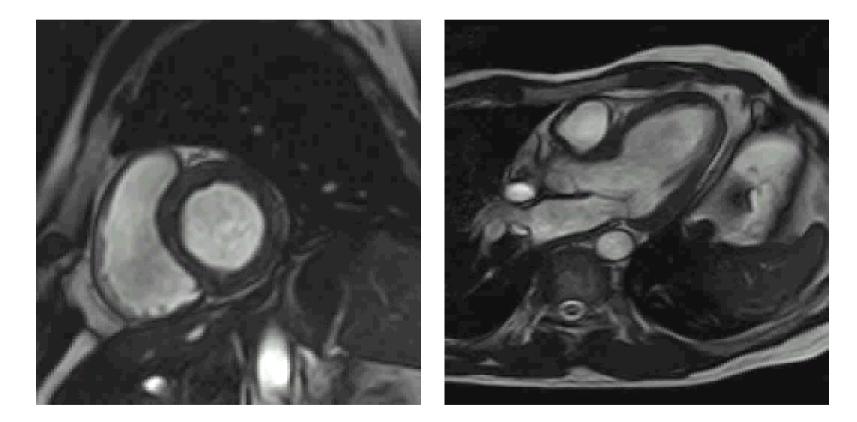
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MRI characteristics.

- Excellent Soft tissue imaging.
- 3D images.
- Multiple applications of the NMR effect.
 - Magnetic resonance spectroscopy.
 - Functional MRI.
 - Interventional MRI.
 - Cardiac MRI (Multiple options for functional diagnosis).
- No adverse effects. (no radiation like x-ray)

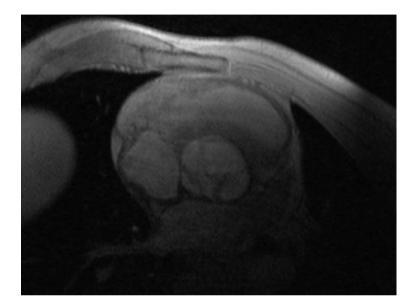
Heart (Sense)

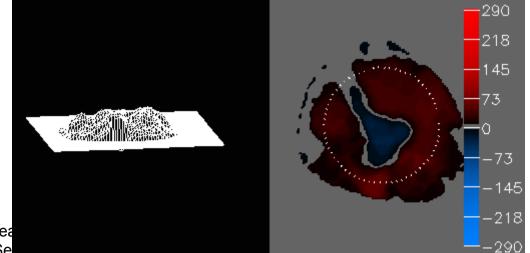
Balanced FFE, SENSE reduction Faktor 1.5



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Heart (Flow)

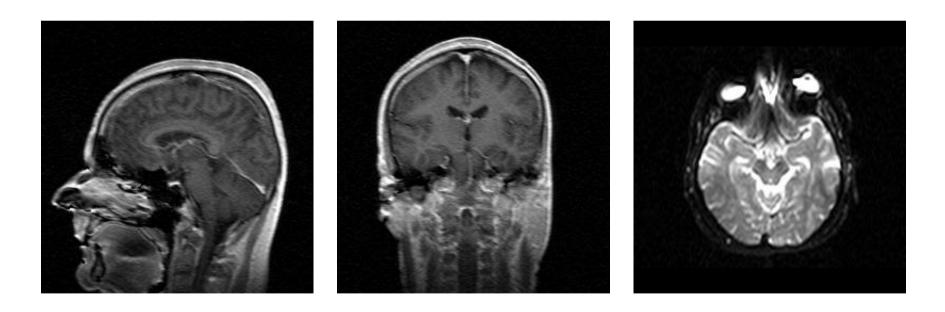




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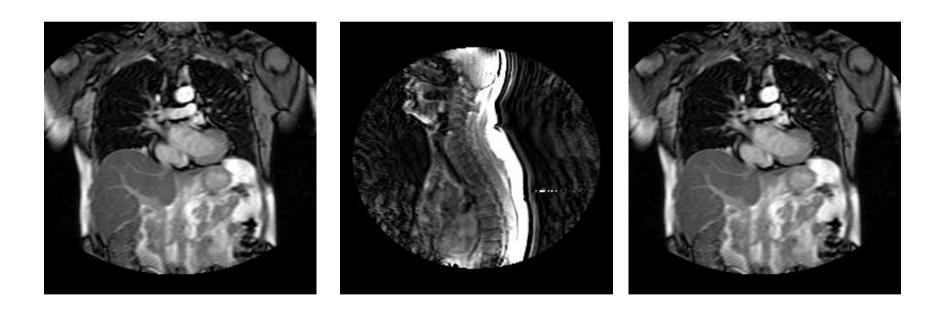
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Head



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Thorax



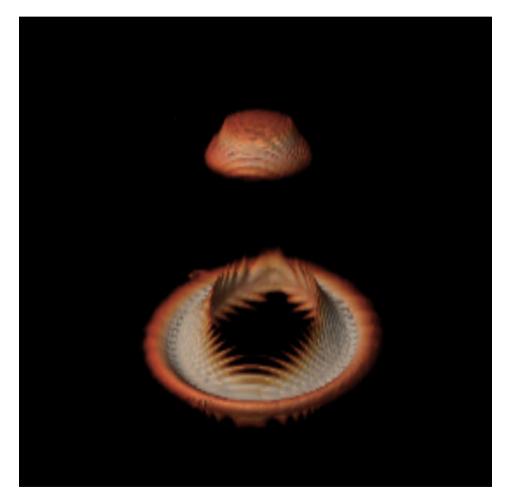
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Electro magnetic compatibility challenges

- Static magnetic field: Force and torque.
- Gradients: Induction of voltages in conductors. dB/dt max ~
- RF Larmor frequency 42.58 MHz/*Tesla* 8.5 MHz (0.2 T) to 127.7 MHz (3T) Power About 1KW

- Static magnetic Avoid ferromagnetic material. field Avoid "ferrite" materials in inductors
- Gradient fields: -Avoid inductive loops: wire loops that may form a conducting loop through the body fluid.
 Structures with electrodes may stimulate nerves or muscles.
 Eddy currents may Heat conducting shields and Vibrate conducting shields
- Gradient induced artifacts.

Pacemaker artifact



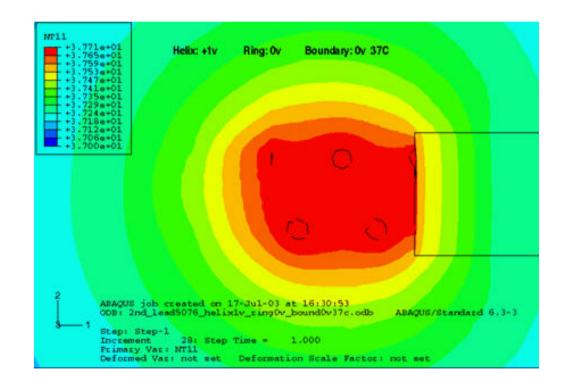
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RF electro magnetic fields: electrical vector + magnetic vector

The magnetic field rotates around the z axis. So the electrical field is in the z direction elongated conducting (insulated) structures function as antenna in the field. The received power may generate currents in the electrode tissue interface and generate local tissue heating.

• To spoil RF antenna properties it is important to keep structures relative short with respect to the wave length. (1/9 th of λ_{air}) Epsilon r water is 81 c= 1/ SQRT($\epsilon\mu$) so $\lambda_{water} = 1/9 \lambda_{air}$

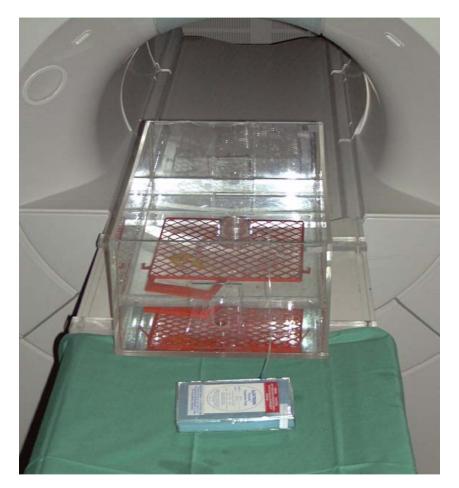
• Temperature profile around an electrode during MRI



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- Transmission line properties apply for conducting structures.
- Perform in-vitro testing with the device in different positions.
- Perform Field simulations to evaluate worse case positions.

Initial Investigations: In-vitro



Phantom at opening of 1.5T MRI system

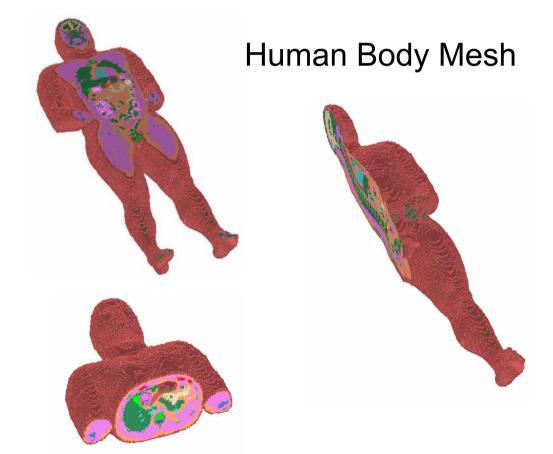
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Modeling EM fields

FTDT simulation of the EM field distribution in a human.

Model of Human Body

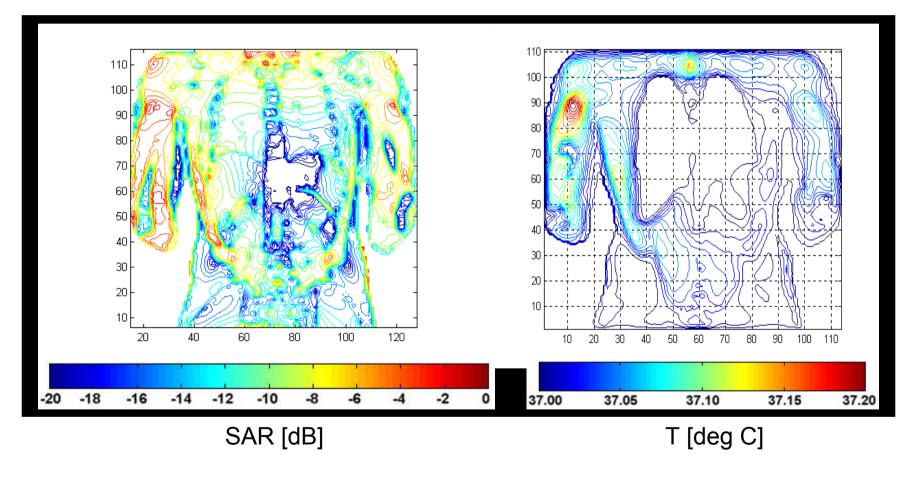




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Modeling EM fields

Heat transfer



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Regulatory requirements

• ISO IEC requirements are under construction. Technical specification is about to be distributed.

Requirements for the safety and compatibility of magnetic resonance imaging for patients with an active implantable medical device.

- This future standard requires evaluation of the medical device on most adverse effects from implantable devices during MRI
- Clinical evaluation may part of regulatory submission