MRI SAFETY, TEST METHODS AND CONSTRUCTION OF A DATABASE

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ABSTRACT

Magnetic Resonance Imaging, MRI, is a diagnostic tool in progress which has been available at major hospitals since the mid eighties. Today almost all hospitals worldwide may depict the human body with their own MRI scanner. MRI is dependent on a uniform magnetic field inside the scanner tunnel and Radio frequent (RF) waves used for excitation of the magnetic dipole moments in the body. These properties along with the magnetic field surrounding the scanner are associated with dangerous effects - when interacting with medical implants made of metals. These dangerous effects are twisting forces or torques, heating and translational forces respectively. A database containing information about known implants behaviour regarding these effects among with earlier documentation and information concerning MRI patient safety at Karolinska hospital, Huddinge was constructed.

Also a phantom used for heating effect measurements was constructed and heating effect measurements were performed at a SPC4129 locking titanium Peritoneal Dialysis (PD) catheter adapter and a Deep Brain Stimulator (DBS) in order to test the phantom and confirm the theory about RF induced heating on medical implants. Evidence for heating effects caused by the implants was found.

A torque measurement apparatus was constructed and measurements were performed. All measurements where performed in order to investigate the functionality of the apparatus and also the theory behind dangerous magnetically induced torques (twisting movements). Substantial torque were measured on the ferromagnetic device used for the test.

The heating phantom and torque measurement apparatus is slightly modified models of those proposed by ASTM (American Society for Testing and Materials).

Key words: MRI; Safety; Implants; Fringe field; Ferromagnetism; Database; Torque; Translational force; Heating
1. INTRODUCTION

1.1 Background

The progress in medical healthcare during the last decades has resulted in an increasing number of treatments involving implants or other medical devices prescribed to the patients. This constitute a potential risk during an MRI examination since some of the devices might contain ferromagnetic parts or are supported by electronic parts that may fail in functionality when present in an MRI environment. Except restrictions regarding the Specific Absorption Ratio (SAR) values there are no medical device safety standards regarding MRI examinations postulated from the Swedish authorities. The SAR value states the amount of energy absorbed in the patient in watts per kilo when exposed to non ionisation radiation such as the radio waves used during MR imaging.

The overall safety is mainly built upon common sense and routines developed at the MRI departments. The urge for adequate safety routines and information has resulted in some sort of international safety standards developed by the Institute for Magnetic Resonance Safety, Education, and Research (IMRSER). The main purpose of IMRSER is to distribute up-to-date information, give recommendations and guidelines to the MR community. This information is available at www.imrs.org or at www.mrisafety.com. The need for MRI compatible medical devices in a world of increasing usage of MRI has made the manufacturers aware of the economical benefits of constructing devices made of MRI compatible (both regarding safety and artefacts) materials. However, some problems still need to be considered. Patients fitted with implants (especially aneurysm clips) a few years ago, may have implants strongly contra indicated for MR imaging in their body (due to hazardous movements or heating effects). Problem arises when the information about the device is inadequate which the case is when the responsible surgeon does not state the vendor of, or complete name of the product in question. At least one lethal accident has been reported due to an aneurysm clip that was moved and rupturing the blood vessel when the patient entered the MRI environment (McRobbie et 2003) due to misleading information.
1.2 Purpose

At big hospitals like Karolinska university hospital, Huddinge, hundreds of MRI examinations are performed each week. Some of the patients may have been treated for deceases or injuries which required implants such as stents, clips, shunts or other medical devices such as pacemakers, denture, or catheters attached to or placed inside their body. This thesis is dealing with the hazards that may occur when those patients are examined by the MR scanner. The main purpose was to construct a database over medical devices which will simplify the hazard evaluation.

The benefits of having tools for measurements on medical devices and tools that make it easy to control if it is safe are obvious. Without any possibility to control the safety parameters the physicist was restricted to the information available at the MRI safety homepage and some times forced to contact the vendor or surgeon when investigating the hazards of an MRI examination for the patient. The result, printouts, handwritten notes etc, was saved in folders and the task of finding a particular device within these folders was cumbersome. One other common way was to hold the device in the hand while entering the MR scanner environment and simply try to notify any force on the device. The ability to use a torque measurement apparatus, as the one constructed for this thesis, makes the evaluation more stringent in terms of rejecting or allowing patients MRI since a more exact parameter value (translational force ([N] or torque [Nm]) is obtained. These values are compared to threshold limit values in order to reject (the measured value is above the threshold limit) or allow (the measured value is below the threshold limit) the patient MRI.

The contact with vendors or surgeons will always be necessary when gathering information about the devices, information needed in order to know exactly which kind of medical device the patient has been fitted with. MRI-safety in hospitals is highly dependent on communication and access to reliable information. Before any risk evaluation may begin information needs to be gathered. A typical scenario is that a patient, who is fitted with an implant or any other kind of medical device, has a journal explaining the surgical procedure but with very little, if any, information about the implant. The lack of proper information regarding the implant is a major source of fatal decisions thus finding proper and specific information about the fitted implant is decisive. The patient or relatives to the patient are asked whether any known metallic objects are present in the body. The reliability of the
patient or the patient’s relative’s knowledge about the type of implant is quite low. The
information gathering process starts with the surgeon who fitted the implant and therefore is
the most reliable source of information.

The process of finding proper and accurate information is quite cumbersome and starts with a
phone call to the hospital where the implant was fitted where the surgeon finds the patients
journal and description of the implant. The implant, found in the patient journals at the
hospital it was fitted, may sometimes be explained in very general terms by the surgeon. One
example could be - ‘‘Tsunami 3.0x15 stent for coronary by-pass’’ - which makes it difficult to
find the exact and correct type of implant and therefore evaluate the safety for the patient. The
next step is to find out if the implant has been tested, either by the manufacturer which then
needs to be known, or by any other reliable independent source. Almost all the tested implants
are available at MRIsafety.com. In some cases the risks are neglectable but the images
become useless due to reduced diagnostic value caused by artefacts. In this case the implant is
considered safe i.e. the device adds no risk for the patient or other individuals but the image
quality (due to artefacts caused by the device) is reduced. If the device is safe and also no
artefacts are caused by the device it is considered compatible.

The aim is to gather safety related information i.e. information about torque, translational
forces and heating effects in a database so that the procedure of searching for that same
medical device again is done within seconds and the risk evaluation becomes easy and not as
time consuming as before. The aim is also to be able to use the graphical interface of the
database in order to find additional information such as links to the manufacturer’s homepage
or links to documents gathered at the MRI department at Karolinska in Huddinge.
2. MRI SAFETY THEORY

As mentioned in the introduction there are three properties of interest when evaluating the risk: translational force, torque and heating. Induced translational force and torque depends on the shape and magnetic properties of the device/implant and the strength and fluctuations of the external magnetic field. Heating is mainly dependent of the energy deposited by the RF pulses and the shape of the device.

**Figure 2.1:** MRI imaging is associated with three properties. Each property is responsible for a specific dangerous effect.

Since it is interaction with metallic and especially ferromagnetic implants that causes the most dangerous effects, the next chapter explains the ferromagnetic properties that are of importance.
2.1 Ferromagnetism

In contrary to paramagnetic and diamagnetic materials, ferromagnetic materials may be permanently magnetized which simply means that a vast majority of the atomic or molecular magnetic moments are aligned or nearly aligned even without any applied external field and the result is that the material becomes a permanent magnet.

The ability to become a permanent magnet originates in the interactions between individual atoms within the material. The net result of all interactions (including the external field) is the hysteresis effect which is a consequence of the configuration of energies that takes place when the magnetization changes within the object. The magnetic moments within the object align themselves with the applied external magnetic field – causing a net magnetization as in the case of paramagnetic materials. Ferromagnetic materials have, however, cells or individual volumes (domains), which already are spontaneously magnetized, preferably along the domains crystal axis, which counteract the alignment toward the external magnetic field.

When the external field is applied the domains with its crystal axis aligned, or almost aligned, to the external field expands i.e. interacts with neighbouring domains, and finally all magnetic moments is turned toward the external field i.e. deviates from preferable crystal axis. When the process is completed the ferromagnetic material is saturated which means that no further magnetization is possible. Once saturated the linear relation between $B$ and $H$ with constant $\mu_r$ and $\chi_B$ (equation A.4) becomes inaccurate. When the external magnetic field is turned off, the domains does not go back to the original state but stays in the new configuration – the material ‘’remember’’ primer exposure i.e. hysteresis effect appears.
Figure 2.2: No external field - the magnetic moments follows the crystal axis in each domain $(t = 0)$. External field applied - the domains with moment vectors close to the applied field expands, at the cost of all others $(t = 1)$. Domains with moment vectors close to the applied field, $B$ dominates the object $(t = 2)$. When saturated all moment vectors are turned in the $B$ direction $(t = 3)$.

The models describing ferromagnetism in a modern scientific fashion are all of quantum mechanic nature and the main reason for this is the complexity of this phenomena. The complexity originates in all the different kinds of energy transitions needed in the explanation. As a first step one may think that the spontaneous magnetization occurs due to interaction between the individual dipole moments which aligns them so that the object becomes magnetized. The magnetic field from a single dipole moment is however so weak that the energy transition between any two dipoles becomes extremely small compared to the atomic thermal energy which means that any alignment would be distorted by the thermal motion.

The solution to this problem is quite cumbersome and complex since if we introduce some kind of interaction that are strong enough to magnetize the object, it should become spontaneous magnetized as long as its below some kind of threshold temperature since the thermal energy depends on the temperature as well as the magnetic susceptibility, $\chi_B$ where $\chi_B > 1$ corresponds to spontaneous magnetization. Ferromagnetic objects below this threshold temperature also known as the Curie temperature, $T_C$ are however in most cases not
spontaneously magnetized since in absence of any external field, the sum of the magnetization from all domains i.e. the objects total magnetization may become zero since the magnetization vector in each domain deviates relative all other thus the vector sum becomes zero.

There are three competitive interactions taking place inside an ideal ferromagnetic object where the *exchange interaction* is the strongest at short distances. *Exchange interactions* are strong electrostatic interactions between the electrons and depend on the electrons magnetic moments and give strong enough magnetic interactions to align neighbouring moments. The other interaction, which tends to reduce the magnetization, is called *magnetic dipolar interactions* and as the name reveals it is the pure interaction between magnetic moments (Cyrot et al. 2005). These interactions are much weaker then the exchange interactions but have the advantage of a much longer interaction range. Whereas the exchange interactions only act upon neighbouring moments the dipolar interaction becomes dominant at long distances.

Ideal magnetic objects are crystalline which will make the exchange interaction go ‘ smoother’ in some favourable direction. Within the object the battle between the two interactions are raging and in some parts the exchange interactions are dominant and in others the dipolar interactions dominates and in some others the situation is something in between hence in some domains the dipoles might go in one direction and in the next some other direction and so on.

The ability to become magnetized varies a lot among the ferromagnetic materials. The main reason to this is the magnetocrystalline anisotropy which is associated to the crystalline structure and geometry of the object. In ferromagnetic systems the magnetocrystalline anisotropy and exchange energies act together in favour of spontaneous magnetisation in various degrees depending on the object symmetry.

A ferromagnetic system tries to achieve some kind of equilibrium and in order to explain how this is done we need to look at the energies associated with the three interactions stated above as well as the volumes or domain walls which separate the domains seen in figure 2.2. If the domains are separated with a thin wall it means that at the interface the magnetic moments between neighbouring atoms make a significant angle with each other. The result is a strong increase in exchange energy which becomes higher with increasing strength of the exchange interactions [J/m]. If the domain walls are wide the angle between two neighbouring magnetic moments becomes small and the exchange energy becomes insignificant. The anisotropy
energy becomes huge however since almost all moments will deviate from the favourable easy direction.

The equilibrium state becomes a minimization of energy configuration corresponding to a compromise between all configurations:

\[ F_{\text{dip}} = \text{Dipolar interaction energy density} \ [\text{J/m}^3] \]
\[ F_{\text{ex}} = \text{Exchange interaction energy density} \ [\text{J/m}^3] \]
\[ F_{\text{ani}} = \text{Anisotropy energy density} \ [\text{J/m}^3] \]
\[ F_H = \text{External applied field energy density} \ [\text{J/m}^3] \]

The compromise minimization energy density is called the total free energy density and is the sum of all energy densities involved:

\[ F_{\text{tot}} = F_{\text{dip}} + F_{\text{ex}} + F_{\text{ani}} + F_H \ [\text{J/m}^3] \]

When a ferromagnetic object is exposed to an external magnetic field, and its corresponding energy density \( F_H \) which varies in space outside the tunnel of the scanner, the total system (i.e. the object and the external magnetic field) wants to minimize the energy density. Since the resultant minimized energy density is the sum of all interactions; interactions with the external magnetic field included, and depend on the specific ferromagnetic properties of the object (the anisotropy for example) this also means that the forces acting upon the object differ among different ferromagnetic materials. Examples of ferromagnetic elements are Fe and Co. This phenomenon also leads to strange behaviours regarding alloys commonly used in implants. For example are the dominating elements in the nonferromagnetic alloy Elgiloy, which is common in modern aneurysm clips and stents, Fe and Co.
2.4 Magnetically induced displacement force

The motion from the charged particles in an atom or molecule in some kind of matter may be represented as a closed current loop as in the figure below where $I$ [A] is the current loop along the surface $S$ periphery, $m$ [Am$^2$] is the magnetic dipole moment which is perpendicular to the surface $S$ and $B$ [T] is the external magnetic field displaced with the angle $\theta$ from $m$.

![Figure 2.3: Current loop with associated dipole moment, $m$ and external magnetic field, $B$.](image)

The current loops mechanical potential magnetic energy may be expressed as $U_{\text{mec}} = -I\Phi$ [Nm] (Hultqvist, 2004) where $\Phi$ [Tm$^2$] is the flow from the external magnetic field through the surface $S$ and $I$ [A] is the current. Since the loop is extremely small $B$ is considered constant through the surface $S$ which means that $\Phi = B \cdot \hat{n} S$ where $\hat{n}$ is the normal vector to the surface $S$. The mechanical potential magnetic energy for the loop becomes:

$$U_{\text{mec}} = -IS \hat{n} \cdot B$$

where the magnetic dipole moment is defined as:

$$m = IS \hat{n}$$ [Am$^2$] thus the mechanical potential magnetic energy becomes:

$$U_{\text{mec}} = -m \cdot B$$ [Nm] \hspace{1cm} (1)

It is the rapid variations of the external magnetic field strength in the MR environment that create the translational force. Modern MR Scanners use active shielding which minimize the extension of the magnetic fields to the surrounding areas thus preventing magnetic field contamination. This minimization results unavoidable to vast field gradients close to the scanner since the magnetic field strength inside the scanner is in the order of Tesla whereas only a couple of centimetres or so further out it is in milliTesla.
The magnetic field surrounding the MR scanner varies in space. Each line corresponds exactly to one field strength. The field strength decreases with the distance from the scanner thus magnetic field gradients are present in the scanner room. 1 gauss = $10^{-4}$ Tesla.

The force becomes:

$$ F = \text{grad}(- U_{\text{mec}}) = \nabla (m \cdot B) \ [N] \quad (2) $$

This means that if the magnetic field in the room is constant the force on the loop becomes zero since the flow through the loop is independent of the position. The field surrounding the MR scanner is however, as mentioned and seen in figure 2.4, varies very rapidly in space so magnetic objects brought into the room will experience very strong forces.

Since the magnetisation, $M$ depends on the material and the fact that $m$ is proportional to $M$ (see appendix 1), the displacement force for diamagnetic, paramagnetic and ferromagnetic objects below its saturation point (where the linearity between $B$ and $M$ still is a linear approximation), the force may be written as $F \propto \nabla (M \cdot B)$ and since $M$ is proportional to $B$ according to equation 1, the force becomes proportional to the product of the field strength and the field strength gradient $F \propto |B| \cdot |\Delta B|$. For ferromagnetic objects which have reached the saturation point the force becomes proportional to the field gradient $\Delta B$ (the magnetization, $M$ becomes independent of $B$ since $M$ does not increase above the saturation point). This means that the location of maximum displacement force depends on the composition since ferromagnetic objects above the saturation point will experience maximum force where the field gradient is greatest and below saturation point maximum force is experienced where the product of the external magnetic field and field gradient is greatest.
2.5 Magnetically induced torque

Contrary to movements caused by translational forces, the rotational movement caused by magnetically induced torques may appear in a uniform magnetic field. The magnetically induced torque is caused by the interaction between the objects magnetic dipole moments and the external uniform magnetic field.

The mechanical work needed in order to rotate the object is related to the potential mechanical magnetic energy defined by equation 1 and to the torque:

\[ dU_{mec} = -m \cdot B = -m \cdot B \cos \theta = -dW_{mec} \]
\[ dW_{mec} = \tau d\theta \]  

(3)  

(4)  

The magnetic interactions minimize the potential mechanical magnetic energy. By combining equation 3 and 4 the magnetically induced torque may be expressed as:

\[ \tau = - \frac{dU_{mec}}{d\theta} = -m \cdot B \sin \theta \]  

(5)  

Equation 5 is the definition of the vector product between \( m \) and \( B \) and the torque becomes:

\[ \tau = m \times B \text{ [Nm]} \]

(6)  

Figure 2.4: Schematic representation of a dipole moment vector, \( m \) in an external magnetic field \( B \).
2.6 Radiofrequent induced heating

RadioFrequent (RF) waves are nonionizing electromagnetic waves covering the spectrum from radar and FM radio to television and microwave communications. When the body is exposed to RF radiation the majority of the power deposited is transformed into heat.

Except for the eyes and testis, which are considered as heat sensitive organs due to the relatively low capability for heat dissipation, exposure of RF radiation does not necessarily lead to excessive heating due to the thermoregulatory system which includes convection, conduction, radiation and evaporation.

Enhanced RF induced heating caused by medical implants may occur in two ways, interaction with the oscillating magnetic component, $B_1$ or the corresponding electric component, $E_1$ of the RF wave. The $B_1$ component causes eddy currents in electric conductive materials due to Faraday’s law of induction. It is however during resonance with the $E_1$ field the most excessive heating effects occur. Resonance effect occurs when the major part of the objects impedance becomes pure resistive which happens when a standing wave, which also creates electric potentials within the object, is formed. Ohmic heating occurs at the interface between the surface of the device and the surrounding tissue or at locations where the object is narrowed or deformed where there is a sudden change in conductivity. Severe heating effects may also occur if conductive wires are formed as closed loops, and effects may even occur if the patient in some way forms loops with there own body by holding his or her hands together or holding one hand at the side while the elbow is extended from the torso e.g.

**Figure 2.5:** RF induced heating occurs due to interaction either with the oscillating magnetic component, $B_1$ or with the electric component, $E_1$. These interactions lead to electrical currents at the implants conductive surface. The heating is then caused by the Ohmic resistance.
Higher static magnetic fields require higher RF frequencies. One of the characteristics of RF heating is the correlation between the physical dimensions of the body and the incident wavelength. If the tissue size is large compared to the wavelength the RF energy is predominantly absorbed on the surface and if the tissue size is small relative the wavelength there is little absorption of RF power (Shellock 2000). The maximum absorption occurs at resonant frequency which is the frequency when the size of the tissue becomes 50% of the size of the incident wavelength. It is during resonant conditions the heating becomes most dangerous due to the deep and often uneven absorption patterns during those conditions. Elongated metallic objects become resonant if the length is an odd number of half the wavelength (Konings et al. 2000), (Kainz 2006). The critical length for 1.5 T is about 25 cm and about 12 cm for 3.0 T. Vast heating effects may also occur near resonance as tests performed by ASTM (Kainz 2006) showed. In the test a 20 cm long insulated object with bare ends was exposed to normal mode 1.5 T sequences which resulted in additional heating, $\Delta T$ as high as 34 °C.

Tests regarding heating effects caused by the static magnetic field alone or by the spatial encoding gradients associated with MRI have shown that powerful static fields may cause temperature changes. However, data from Shellock (1986) revealed that in a 1.5 T scanner no statistically significant alterations in temperature occurred. The risk of heating effects caused by the spatial encoding gradients during conventional imaging is considered neglectable (Shellock 2000).

The dosimetric term describing the amount of energy absorbed by the body is the Specific Absorption Rate (SAR). There are two kinds of SAR. The whole body SAR which is defined as the total power deposition in the patient divided by the mass, and the partial body SAR which is the power deposition divided with the patient mass within the effective volume of the RF transmit coil. The effective volume within the RF coil is defined as the volume of which no more then 95% of the total RF power is deposited inside a homogeneous material which fills the volume normally accessible by the patient. The Swedish radiation protection authority, SSI, has no legislation towards SAR values except those regarding mobile phones which states that the highest SAR allowed in Sweden and EU is 2 W/kg to the head. The international safety standard for MR systems, IEC 60601-2-33, Ed 2.0 also limits the whole body average SAR to 2 W/kg for a 6 min exposure. The partial body SAR limits ranges from 2 to 10 W/kg depending on how much of the patient that is exposed.
Table 2.1: IEC limits for whole body and partial body heating during MRI.

<table>
<thead>
<tr>
<th></th>
<th>Whole body heating °C</th>
<th>SAR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal mode limit (suitable for all patients)</td>
<td>0.5</td>
<td>0.2</td>
</tr>
<tr>
<td>First level controlled mode (Medical supervision)</td>
<td>1.0</td>
<td>4.0</td>
</tr>
<tr>
<td>Second level controlled mode</td>
<td>&gt;1.0</td>
<td>4.0</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Localised heating °C</th>
<th>SAR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Head: Normal mode limit, average over head mass</td>
<td>38</td>
<td>3.2</td>
</tr>
<tr>
<td>Torso: Normal mode limit, over any 10 grams</td>
<td>39</td>
<td>10</td>
</tr>
<tr>
<td>Extremities: Normal mode limit, over any 10 grams</td>
<td>40</td>
<td>10</td>
</tr>
</tbody>
</table>

When conductive products, especially elongated conductive products are attached to the patient, the RF $E_1$ component may cause vast additional heating which exceeds the localised heating limits.

4. HEATING EFFECT MEASUREMENTS

Heating effects are caused when the magnetic or electric part from the radio wave used during MRI interacts with the implant fitted to the patient. In order to try to predict heating effects and also test the phantom, measurements was performed on a Perional Dialysis catheter adapter (PD catheter adapter) and on a Deep Brain Stimulator (DBS).

4.1 Methods and materials

The ASTM designation: F 2182 – 02a standardization includes a torso and head shaped PMMA box. The box is filled with a gelled, tissue equivalent, solution.

Table 4.1: Electric and thermal properties of the human body (ASTM designation). The dielectric constant is the ratio between the materials static permittivity $[As/Vm]$, when a potential is applied, and the permittivity of vacuum thus it becomes dimension less.

<table>
<thead>
<tr>
<th>Conductivity [S/m]</th>
<th>Dielectric constant</th>
<th>Diffusivity [m²/s]</th>
<th>Heat capacity, C [J/(Kg K)]</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.4 – 0.8</td>
<td>60 – 100</td>
<td>$1.3\cdot10^{-11}$</td>
<td>4184</td>
</tr>
</tbody>
</table>

* siemens per meter, $1S = \Omega^{-1}$.

The viscosity shall be sufficient enough so that phantom materials do not allow bulk transport or convection currents. The appropriate gelled formula, stated by ASTM, where made from 0.8 g/l NaCl and 5.85 g/l polyacrylic acid into distilled water. This formulation has a room temperature conductivity of about 0.25 S/m according to ASTM. 31 dm³ of solution was made. The phantom box was constructed at MTA (medicinsk teknisk avdelning) in
Karolinska university hospital, Solna and the gelled solution was prepared and added at the nuclear medicine department at Karolinska university hospital, Huddinge.

![Image: Phantom used for heating measurements consists of a torso and head shaped PMMA box filled with a tissue equivalent solution.]

**Figure 4.1**: Phantom used for heating measurements consists of a torso and head shaped PMMA box filled with a tissue equivalent solution.

The first measurement was performed at a Baxter locking titanium PD catheter adapter (ref model SPC4129). The SPC4129 locking titanium PD catheter adapter is for use in peritoneal dialysis and is not available in the database at MRIsafety.com and no information about contraindication for MRI is available at the manufacturer (Baxter) homepage. The second measurement was performed on a Medtronic Deep Brain Stimulator (DBS) model 3387 which is contraindicated for MRI sequences that gives a SAR above 0.1 W/kg. Heating measurements performed by Medtronic, where the DBS electrode was embedded in tissue equivalent material and exposed to RF waves which gave an SAR of 0.4 W/kg, resulted in a 5°C temperature increase which is close to the level that can cause tissue damage (Shellock 2001).

The solution formulation proposed by ASTM (table 4.1 at page 26) contains polycyclic acid which is added in order to prevent convective heat transport. The amount of polyacrylic acid proposed by ASTM was however not sufficient enough thus the solution properties were close to water in terms of viscosity. The catheter adapter measurement described above, which was the first measurement, was performed during those conditions. Due to the potential risk of leakage of solution during the examination, which would lead to severe damage to the MR scanner, more polyacrylic acid was added in order to thicken the solution and therefore decrease the risk of leakage. The additional amount of polyacrylic acid (about 0.5 g/litre) is assumed to change the conductivity properties within the acceptable range (0.4 – 0.8 S/m, 0.25 S/m before additional acid – see Table 4.1).
The deep brain stimulator used in the measurements was borrowed from the centre of neurology at Karolinska university hospital, Solna and consists of the four parts displayed in figure 4.7. The screener, which transmits the electrical signals to the electrode pad thus stimulating the nerves, is excluded from the figures since it is not allowed into the scanner room where the measurements were performed (it contains ferromagnetic parts). DBS are mainly used in order to ease the uncontrolled spasms associated to patients with Parkinson’s disease.

### 4.2 Heating measurement at the catheter adapter

**Figure 4.2:** The Baxter SPC4129 locking titanium PD catheter adapter consists of two parts (picture to the right) which are joined together (picture to the left).

The elongated shape of the catheter adapter leads to the assumption that the concentration of eddy currents, and therefore greatest heating effects, occur at the narrowing tip of the device. Due to the relatively small size of the implant, resonance effects are considered insignificant (see chapter 2.6). A calibrated (Swedac number 0076-06371) Luxotron® I652 industrial fluoroptic thermometer with two sensors was used to measure the temperature. The accuracy of the thermometer is ±0.2 °C and the output resolution is 0.01 °C.

**Figure 4.3:** One of the thermometer sensors were attached at the intersection between the tip of the device and the tissue equivalent solution.
Whilst the gelled solution was stirred, in order to homogenize it, the temperature in the MR scanner room was measured. The temperature in the room was measured in order to reveal any deviation from steady state temperature. One of the temperature sensors was placed at the MR-table just outside the tunnel and the thermometer sampled two signals/s for about 20 minutes. The temperatures were extrapolated to one hour in order to make sure that the variation stayed below one degree during a one hour period as stated by ASTM. The measurement showed that the temperature stayed within 1 °C variation during a full hour.

When the gelled solution was homogenized the device-temperature sensor setup, seen in Figure 4:3, was lowered into the phantom and the reference sensor was placed in an opposite position as seen in the figure 4.4 below:

![Figure 4.4: The device was lowered at the phantoms right side (A) and the reference at the left (B). Both in FOV thus exposed to RF pulses.](image)

Two “worst case scenario” measurements were performed. In this case “worst case scenario” means Fast Spin Echo (FSE) sequences with high turbofactor and as short as possible TR which will induce as high SAR and heating as possible. It is considered better to overestimate then underestimate the SAR since the measurements are used for safety reasons. The temperature increase was also extrapolated to a value corresponding to the temperature that would occur if the whole body SAR was 2.0 watts per kilo.

<table>
<thead>
<tr>
<th>Sequence</th>
<th>TR [ms]</th>
<th>TE [ms]</th>
<th>Pulses / s</th>
<th>Flip angle</th>
<th>Turbo factor</th>
<th>SAR [W/kg]</th>
</tr>
</thead>
<tbody>
<tr>
<td>FSE</td>
<td>5230</td>
<td>97</td>
<td>2.9</td>
<td>180°</td>
<td>15</td>
<td>4.9</td>
</tr>
</tbody>
</table>
The MR-scanner used was a 1.5 T Siemens Avanto and the software installed was Syngo MR 2004. The estimated whole body SAR, produced by a body coil embracing the test and reference position, reported by the MR system was 4.9 W/kg.

### 4.2.1 Results from adapter heating measurement

The temperature in the phantom material was lower than the room temperature which means that the temperature of the phantom material increases naturally. In the ideal setup the temperature of the phantom material would have been acclimatized to the room temperature but the phantom is not allowed to be in the scanner room (due to risk of leakage). This and the limited amount time for non clinical tests make the temperature difference unavoidable. The natural increase is however estimated by extrapolation of the temperature before the RF pulse was applied. The temperature increase at the catheter adapter site, A is compared to the increase at the reference point, B (see figure 4.4) where the increase only depends on the energy deposited directly to the phantom material.

![Catheter adapter heating measurement](image)

**Figure 4.6:** Measured and extrapolated changes in temperature versus time.

The temperature at the test site was about 0.5 °C lower than at the reference site before the sequence was applied. The extrapolated increase due to acclimatisation towards room temperature is also greater at the reference point then at the test site. Even though the phantom
solution was stirred methodically before the measurement there is no other explanation to the temperature difference then insufficient stirring. But even with insufficient stirring a difference of about 0.5 °C seems much since the temperature within the phantom solution should acclimatize to itself. Except for the difference in increase rate this is however not a huge problem since it is the relative temperature increase, ΔT caused by the RF pulse that is of importance.

**Table 4.3:** Difference between extrapolated temperature and measured temperature at the end of the FSE sequence and the difference in temperature increase due to the applied sequence between reference site and test site.

<table>
<thead>
<tr>
<th>Temperature at test site [°C]</th>
<th>Temperature at reference site [°C]</th>
<th>Increase difference test site – ref site [°C]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Measured</td>
<td>Extrapolated</td>
<td>Difference ΔT&lt;sub&gt;Test&lt;/sub&gt;</td>
</tr>
<tr>
<td>23,7</td>
<td>22,4</td>
<td>1,3</td>
</tr>
<tr>
<td>Measured</td>
<td>Extrapolated</td>
<td>Difference ΔT&lt;sub&gt;ref&lt;/sub&gt;</td>
</tr>
<tr>
<td>23,6</td>
<td>22,9</td>
<td>0,7</td>
</tr>
<tr>
<td>A – B</td>
<td>ΔT&lt;sub&gt;Test-ref&lt;/sub&gt;</td>
<td></td>
</tr>
<tr>
<td>0,6</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 4.3 shows that heating effects due to RF energy deposited directly into the tissue becomes 0.7 °C and that the SPC4129 locking titanium PD catheter adapters induce an additional temperature increase of 0,6 °C during sequence parameters according to table 4.2.

The maximal temperature rise extrapolated to a whole body SAR of 2 W/kg becomes:

ΔT<sub>2.0 SAR</sub> = ΔT<sub>Test</sub> · (SAR<sub>2.0</sub> / SAR<sub>4.9</sub>) = 1.3 · (2.0 / 4.9) = 0.5 °C.

The additional heating effect caused by the adapter extrapolated to a whole body SAR of 2.0 W/kg becomes:

ΔT<sub>2.0 SAR</sub> = ΔT<sub>test-ref</sub> · (SAR<sub>2.0</sub> / SAR<sub>4.9</sub>) = 0.6 · (2.0 / 4.9) = 0.2 °C.
4.3 Heating measurement at the Deep Brain Stimulator

The screener plug (seen in figure 4.7 below) is placed outside the body and is connected to the one of the extension connectors which exits behind one of the patients ears. The plug is, however, placed inside the phantom material which is assumed to simulate the closed loop scenario that would occur if the plug is in close contact with the skin. At the second measurement the sensor probe was attached to the electrode pad.

Figure 4.7: The DBS contains of the four parts, the lead wire, extension wire, screener plug and the electrode pad. RF induced heating effects was first measured by the screener plug and secondly by the electrode pad.

ASTM recommends a Fast Spin Echo (FSE) sequence (appendix 4) for use at heating measurements and the parameters used (table 4.5) is as close as it gets with the MR scanner used (Siemens Avanto) for these measurements.

Table 4.5: Sequence parameters applied at the DBS measurement. Same sequences where applied during both measurements.

<table>
<thead>
<tr>
<th>Sequence</th>
<th>TR [ms]</th>
<th>TE [ms]</th>
<th>Pulses / s</th>
<th>Flip angle</th>
<th>Turbo factor</th>
<th>SAR [W/kg]</th>
</tr>
</thead>
<tbody>
<tr>
<td>FSE</td>
<td>83</td>
<td>14</td>
<td>60</td>
<td>180</td>
<td>5</td>
<td>1.9</td>
</tr>
</tbody>
</table>
4.3.1 Results from DBS heating measurement

The screener plug (seen in figure 4.7) is located outside the body. In this test a situation where the plug is in contact with the skin, creating a closed circuit is simulated. The intention is to see if any heating effects occur if the plug is lowered into the phantom material. The setup is seen in figure 4.8 below.

![Figure 4.8](image)

**Figure 4.8**: The screener plug measurement resulted in vast temperature increase (12.5 °C) plotted as 2 in the figure a. The thermometer sensor setup is seen in figure b.

Figure 4.8 shows at least three distinctive patterns corresponding to following events:

1. **Temperature before any applied sequence.** These data points are used for the extrapolation of temperature to the time when the main sequence is has ended.
2. **A pre-test sequence is applied.** The temperature increases and deviate relative the extrapolated – natural temperature increase.
3. **Sequence stated in table 4.5 is applied with the setup position seen in figure 4.8 b (the reference location -1R and the screener location - 1T).** The green line shows the temperature increase near the screener plug.

The increase in temperature is probably caused by resonance effects as described in chapter 2.6. At the end of the measurement the temperature near the screener plug has increased to 32.2 °C which is compared to the extrapolated temperature 19.7 °C (the temperature it should be at that time without any applied RF field). In this case the body received a SAR of 1.9 watts per kilo which will increase the temperature in the phantom material. We are however
interested in the additional heating caused by the screener plug and the difference in temperature increase at the reference point (a single thermometer sensor lowered directly into the phantom material) is subtracted from the temperature increase by the screener plug. In order to be able to compare these results with other measurements, the temperature was extrapolated to what it should have been if the phantom material was exposed to RF waves that gave a SAR of 2.0 watts per kilo.

Table 4.5: Results from the DBS screener plug measurement.

<table>
<thead>
<tr>
<th>Temperature at test site [°C]</th>
<th>Temperature at reference site [°C]</th>
<th>Increase difference. test site – ref site [°C]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Measured</td>
<td>Extrapolated</td>
<td>ΔT Test</td>
</tr>
<tr>
<td>32.2</td>
<td>19.7</td>
<td>12.5</td>
</tr>
<tr>
<td>Measured</td>
<td>Extrapolated</td>
<td>ΔT Ref</td>
</tr>
<tr>
<td>21.2</td>
<td>20.0</td>
<td>1.2</td>
</tr>
<tr>
<td>ΔT test-ref</td>
<td></td>
<td>11.3</td>
</tr>
</tbody>
</table>

An additional heating of 12.5 °C occurred at the test site and the additional heating effect caused by DBS at the screener plug location is 11.3 °C.

The maximal temperature rise extrapolated to a whole body SAR of 2 W/kg becomes:

$$\Delta T_{2.0\text{ SAR}} = \Delta T_{\text{Test}} \cdot \left(\text{SAR}_{2.0} / \text{SAR}_{1.9}\right) = 12.5 \cdot (2.0 / 1.9) = 13.2 \, ^\circ C.$$  

The additional heating effect caused by the adapter extrapolated to a whole body SAR of 2.0 W/kg becomes:

$$\Delta T_{2.0\text{ SAR}} = \Delta T_{\text{test-ref}} \cdot \left(\text{SAR}_{2.0} / \text{SAR}_{1.9}\right) = 11.3 \cdot (2.0 / 1.9) = 11.9 \, ^\circ C.$$  

Heating measurements were also performed near the electrode pad. The electrode pad is connected to the screener plug as seen in figure 4.7. The electrodes are placed deep inside the brain with stereotactic surgery. Patients with Parkinson disease (PD) for instance may be fitted with a DBS where the electrodes stimulate the SubThalamic Nucleus (STN) which control complex movement. The DBS suppresses the activity in STN in such way that the characteristic spasms associated to PD is reduced or even eliminated.
It is the heating effects that are measured during this test and a thermometer sensor is placed at the electrode pad as seen in figure 4.7. The electrode is lowered approximately 9 cm into the phantom which means that it is in the middle of the phantom head. The location within the phantom is seen in figure 4.9 (the electrode location is denoted as 2T and the reference location 2R).

![Temperature vs. Time Diagram](image)

**Figure 4.9:** Only moderate temperature increase (0.2 °C) is obtained near the electrode pad. The thermometer sensor setup is seen in the figure to the right. The electrode location is labelled 2T and the reference location is labelled 2R. No temperature increase occurs at the reference point which is located about 20 cm from FOV.

**Table 4.6:** Results from the DBS electrode pad measurement.

<table>
<thead>
<tr>
<th>Temperature at test site [°C]</th>
<th>Temperature at reference site [°C] (no exposure to RF energy)</th>
<th>Increase difference. test site – ref site [°C]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Measured</td>
<td>Extrapolated</td>
<td>ΔT_{Test}</td>
</tr>
<tr>
<td>20.6</td>
<td>20.4</td>
<td>0.2</td>
</tr>
</tbody>
</table>

The maximal temperature rise extrapolated to a whole body SAR of 2 W/kg becomes:

\[ ΔT_{2.0\, \text{SAR}} = ΔT_{\text{Test}} \times \left( \frac{\text{SAR}_{2.0}}{\text{SAR}_{1.9}} \right) = 0.2 \times (2.0 / 1.9) = 0.2 \, ^o\text{C}. \]
The minor heating effect by the electrodes does not correspond to the 5 °C (25 °C when extrapolated to SAR = 2.0 W/kg), increase measured by the manufacturer (see page 19). Such huge increase should have been reproduced (or at least greater heating effects then 0.2 °C) in our measurement which indicates that the measurement may be invalid. The most probable cause is that the connectors were inappropriately connected since some of them were broken and rejoined by hand.

In fact none of the heating effect measurements performed on the DBS is relevant for real hazard evaluations. The main reason is that it was not in the same condition as it should be when used clinically (inserted to the brain and electrically stimulating the nerves) which is one criteria which much be fulfilled in order to validate the measurement. The other reason is that the screener plug was placed inside the phantom head but the real location is outside the patients head (the most common way is to let the extension wire, which is connected to the screener plug – see figure 4.7, exit behind the patients ear). An anatomically correct placement of the implant is the other criteria which must be fulfilled according to the ASTM guidelines.

The measurements was however not intended to be regarded as real hazard evaluation measurements but rather to test the phantom and find evidence for heating effects. Also no other implants were available (then the broken DBS and the catheter adapter) which means that a real DBS hazard evaluation was not possible.

4.6 Significance and use

All kinds of temperature measurements are troubled with a vast number of problems and uncertainties. The first problem is that the measured temperature is always the temperature of the thermometer sensors and not the temperature of the object (except for radiation pyrometers which measure the heat radiation from the object) (Loyd 2004). The sensor temperature may also differ from the temperature displayed (due to electronic noise) and there is always a time lag occurring between measured temperature and real temperature. These effects may however be minimized as long as the individual uncertainties are known.

Much more problematic effects to solve are those emerging from unknown events such as unnatural convection cells resulting in heat transport caused by the presence of the sensor, or other improper measurement setups or other spurious errors which in this case could mean
that we are measuring the sensor temperature when located in a bubble of air instead of tissue equivalent phantom material.

Temperature measurements, performed in order to evaluate heating effects on medical devices, by using a phantom exposed to RF energy adds a couple of uncertainties where the first is that each MR scanner is unique. The relevance of uniqueness in this case is that the $B_1$ field rotation may differ among different scanners, even those of same type. This depends on how the static magnet was damped during the installation (IEC Standard 60601-2-33, 2004). Since the field inside the ASTM phantom is asymmetric and depends on the direction of the $B_1$ field rotation the anatomical placement of the medical device in a patient can not be translated to a phantom worst case heating test. According to a FDA (Food and Drug Administration) draft (Kainz 2007) an evaluation for the whole patient population under worst case assumptions is needed in order to determine the worst case local magnetic and electric field distribution. This should be achieved by computer modelling, using anatomically correct models of the whole population and when the worst case field distribution is known the medical device may be appropriately placed in the phantom.

5. MAGNETICALLY INDUCED TORQUE MEASUREMENTS

The torque measurement apparatus constructed is a slightly modified model of the one proposed by ASTM (designation F 2213 – 04). The ASTM model has two torsion springs supporting a basket in plastic (the device holder) but the model constructed at the department has one torsion spring supporting a device holder in wood. The idea is that since the device holder only is supported by the spring, any magnetically induced torque will cause a deflection from the state of equilibrium.

The deflection is measured as the deviation between the marker on the device holder and the $0^\circ$ marker (pre-set as the equilibrium configuration) at a protractor. ASTM uses two torsion springs (one from the top and one from below) in order to stabilize the device holder. The model constructed in this project stabilizes the device holder by using one torsion spring from the top and at the bottom the device holder rotates around a small cylindrical piece of wood (seen just below the device holder in figure 5.2) which prevents all movements, except circular motions, in the horizontal plane.
5.1 Methods and materials

Figure 5.1: The wooden frame of the torque measurement apparatus has a shape that allows it to perfectly fit the scanner tunnel. The frame supports the functional parts used in order to determine the magnetically induced torque.

Figure 5.2: There are four functional parts operating during the measurement. The cog-wheels attached to the top and bottom wooden plates (see figure 5.1), one turning knob which is used in order to turn the cog-wheels. Protractors only attached to the bottom cog-wheels and a device holder which is only attached to the top cog-wheels via the torsion spring.
The idea is to strap the elongated metallic implant (only devices with a well defined major axis experience torque) to the device holder. Since the device holder is attached to the torsion spring alone it may easily be rotated relative the top protractor. When the implant has been strapped on to the device holder the entire apparatus (see figure 5.1) is moved into the iso-center i.e. into the scanner tunnel. At the beginning the major principal axis of the device is aligned with the uniform magnetic field present in the surroundings of the iso-center. This means, since the torque works so that the implant align itself to the external field (see equation 6), that the implant initially is in a state of equilibrium.

By turning the cog-wheels (by turning the turning knob in figure 5.2) the device holder and therefore the device will deviate from the state of equilibrium. The cog-wheels are turned in increments of $10^0$ which are guaranteed by watching the protractor at the bottom (attached to the bottom wooden plate). Each time the cog-wheels are turned, the torsion spring forces the implant out of its equilibrium state. For each $10^0$ increment the force from the torsion spring acting upon the implant increases since it create a bigger angle between the implants' equilibrium (i.e. when pointing in the same direction as the external field) and the angle actually turned – the degrees turned by the turning knob increases from 10, 20, 30… By measuring the angle deviation between the device (implant) holder and the top protractor (which has been turned exactly the same degrees as the bottom protractor i.e. 10, 20, 30…) the magnetically induced torque – which works against the torsion spring (any deviation from equilibrium creates a torque acting on the implant towards the implants' equilibrium location $(x,y,z)$ i.e. with the main principal axis aligned with the uniform magnetic field) creates a deviation in degrees between the actual number of degrees turned by the turning knob and the real number of degrees the device/device holder has been turned. This deviation or difference in degrees is used in order to calculate the torque since it represents the magnetically induced torque acting on the torsion spring.

The deviation angle $\theta$ is proportional to the torque, $M$ induced on the medical device by the static magnetic field:

$$M = \theta \cdot k \ [\text{Nm}] \quad (10)$$

$k$ is the spring constant which is 0.0002 [Nm/degrees].

The force becomes:

$$F = \frac{M}{L} \ [\text{N}] \quad (11)$$
Where \( L = 0.05 \) is the leg length in meters.

It is the magnetically induced torque (eq 10) that is the measurand and it is by comparing the magnetically induced torque to the device gravitational torque – the length of the implants principal major axis in meters times the weight in kilos and the acceleration of gravity constant \( g = 9.81 \, [m/s^2] \) the hazard is evaluated. If the gravitational torque is greater than any measured magnetically induced torque after a whole \( 360^0 \) measurement, the implant is considered compatible for MR imaging.

Every torsion spring has a maximum deflection angle, which is the maximum acceptable rotation angle for the spring in degrees. This means that if the legs of the springs are originally perpendicular to each other (one leg sticks out in both ends of the spring) this angle can only be decreased (by force) a given number of degrees without risk of damaging the spring. The spring during these measurements has its legs perpendicular \( (90^0) \) in its originally state and the maximum deflection angle from this is \( 25^0 \) as proposed by ASTM.

### 5.2 Torque measurements

In order to verify the apparatus four measurements was performed. The procedure follows the method described by ASTM which means that the cog-wheels are turned in increments of \( 10^0 \).

Four non-ferromagnetic devices (screws made of stainless steel in different sizes) was tested without any significant deflection. The reason for this result is that the magnetic susceptibility factor (eq A3) is extremely small thus the magnetization and torque becomes insignificant.

Ferromagnetic objects, however, becomes extremely magnetized which means that vast deflection forces and torque occurs. No ferromagnetic medical device was available so a ferromagnetic switch contact was used.

The switch contact was attached to the device holder and aligned with the static magnetic field produced by the scanner. In this position the system is in equilibrium and the spring do not experience any torque and the marker attached to the device holder points at the \( 0^0 \) marking at the top protractor. The system is turned in increments of 10 degrees and the relative deflection is observed.
Figure 5.3: Switch contact and measurement setup. The switch contact is attached to the device holder with plastic bands. In the figure the device holder points at 0° i.e. the system is in equilibrium. The weight of the switch contact is 1.4 g.

5.2 Results from torque measurement

Two measurements were performed with almost identical result. The torque and force is calculated with equation 10 and 11. Maximum torque occurs when the device swings back to the next equilibrium position i.e. when the angular derivative of the torque changes sign. The torque induced on the device is about 10 times above the safety threshold limit of 0.0005 Nm when the cog-wheels i.e. the protractors had been turned 40 degrees. Due to the low spring constant, the device precession relative the magnetic field, $B$ becomes quite low i.e. the protractor is moved but the device is almost stationary (compare the angles in figure 5.1).
If the device was perfectly stationary when the cog-wheels are turned, the deviation between the protractor and device holder would be exactly the same as the angle turned from equilibrium (see figure 5.1 and figure 5.2). When the cog-wheels has been turned 240° the device holder – protractor deviation is 180° which means that the device is deviating 60° (240° – 180°) relative the magnetic field, B. Since the torsion spring is constructed so that the maximum deflection angle is 25° the measurement was ended when the deviation reached 180° in order to prevent damage on the spring. The maximal torque is probably occurring when the angle between the device principal axis and B is higher then 60° but it is not necessary to force the spring to that deflection angle in order to state that the device is contraindicated for MR – torque greater the gravitational torque is achieved before a 10° increment.

5.3 Significance and use

The torque considered during the measurements is the magneto-static torque caused by the interaction between the MRI static field and the magnetisation in the implant. If the greatest torque measured is less then the gravity torque - the product of device weight and the largest linear dimensions, it is assumed that the risk of getting injured, due to magnetically induced torque, is not greater then any risk imposed by normal daily activity in the earth normal magnetic field.

Eddy currents may be induced in an implant that is rotated within the static field. Interaction between the static magnetic field and the field produced by the eddy currents may cause dynamic torque which is not addressed in this method. Currents in lead wires, such as wires from pace makers, may induce torque as well.

ASTM also states in the designation that the sensitivity of the torque measurement must be greater then 1/10 of the gravity torque.

It was noticed that there are small deviations between the top protractor and the device holder when the cog wheels was turned even when the device holder was empty. This implies that there are some systematic errors present during the measurements. The deviation goes in a negative direction (the device holder marker travels along the protractor in opposite direction
or in other words: the device holder lags behind the protractor) which would give lower torques (see equation 10).

Six measurements were performed in order to get an approximation of the errors. The cog wheels were turned in increments of $10^\circ$ with an empty basket. It became clear that there are small systematic errors between 1 and 3 degrees occurring in the interval between the $40^\circ$ and $70^\circ$ turning points (the cogwheels are turned in increments of $10^\circ$ i.e. $10^\circ$, $20^\circ$, $30^\circ$ … $360^\circ$ and in the interval $40^\circ$ and $70^\circ$ there is a deviation that should not be there since there are no magnetically induced torque acting upon the device holder). These errors are caused by an unbalancing or mismatch between the torsion spring attachment point and the centre of the top protractor.

This could constitute a risk but since the spring constant is so low any magnetically induced torque would most likely make the device holder deviate much more than that in this interval (the device holder is turned / forced away from the equilibrium by the torsion spring quite a lot and any magnetically induced torque at this angle would create a relatively big deviation) thus a mismatch of 1 to 3 degrees would still give a substantial torque. Also the systematic error only occurs in a relative small interval of the total $360^\circ$. Since the systematic error is known it can also be corrected for. No correction was made for the measurement presented in figure 5.4 since the safety threshold limit was reached even before the $20^\circ$ turned.
6. THE DATABASE

The purpose of the database is to minimize the time for both finding additional proper information about the medical device and make it easy and less time consuming to find information about medical devices which already is know, i.e. which are in the database. The aim is that the database is continuously filled with new products permitting fast evaluations. Many medical devices within the database are not available at the MRI safety.com list but have been encountered with earlier at the MRI department at Karolinska university hospital in Huddinge.

6.1: Access

The database is constructed in the windows based program, Microsoft Access. Microsoft Access is based upon different tables filled with relevant information. The idea is to store specific information (for example only info about vendors in one table, product name in one and so on) and relate all these tables in such way that the specific information in one table becomes uniquely related to all other tables. The tables, and the relations between them, are transferred to queries which enable filtration. Figure 6.1 below shows the relations between the tables gathered in the query used in this database. All the tables are related via a specific id number created each time any new product is added to the database.
Figure 6.1: The query used to sort the information in the database. This means that if information about one specific implant is wanted this information is scattered in all six tables and put together when the user demands it. This is possible since all tables are related in a specific way.

Access enables the user to create forms containing almost all standard applications used in Windows (command buttons, list boxes, labels and so on). Since the aim was to create a database that was easy to handle both regarding finding and adding information, a Graphical Unit Interface (GUI) was created in order to achieve just that. The first form displayed when the database is opened is the main menu form which gives the user three alternatives, searching products, adding products or closing the database. Figure 6.2 below shows the main menu form interface.
The first form that meets the user is the main menu form offering three alternatives: searching, adding or closing.

Each button is related to Structured Query Language (SQL) action codes which will run as soon as the user clicks a button. The Sök (search) and Lägg till nytt (add new) button are related to SQL codes that opens a search form or alternatively a add new data form.

### 6.2 Searching devices

The Figure 6.3 below shows the graphical interface of the search form which offers five different search criteria and one internet link to MRIsafety.com and one link to more general safety documentation saved at the computer:
Figure 6.3: The search form interface displays the search alternatives.

Each of the five search options seen in figure 6.3 are all related to the tables in figure 6.1. Once the device has been selected in one, or a couple, of the search alternatives the search button is activated which runs the SQL code that finds and sorts the specific information wanted. When procedure is completed a new form is opened automatically which only displays this relevant information. For example, say a patient has a heart valve from Medtronic (and this is all we know). This gives us seven options, the search for vendor list where Medtronic is selected, search for general type list where heart valve is selected and search for specified type list where heart valve from Medtronic is selected, and then of course all these three options in combinations. If the product is not to be found in the database or if the user wants to double check the information an MRIsafety.com internet link is available in the bottom right corner. If any general information about MRI and safety concerning some particular type of medical device the link “Allmän information” (general information) is clicked on and all such available information gathered from the folders at the MR scanner facility is opened.
The new form opened after filtration is shown in the figure below and displays all relevant information about the products corresponding to the search criteria.

![Resultat av sökning](image)

**Figure 6.4:** The search result form displays all relevant safety information for every device in the database.

The search results are displayed in five sections as seen in figure 6.4. The section at the upper left corner contains *product information* i.e. name, type and serial number. The middle section contains *test result information* i.e. the MR-scanner field strength, measured force, torque and heating effects and known artefacts. The section “Övrigt” (Other) displays other relevant safety information. The two grey coloured sections at the bottom displays information about the manufacturer or vendor i.e. telephone number and address. They also contain internet links to MRI Safety.com, vendors and a link to a scanned copy of the original document of the device which also is saved in folders at the MR-scanner reception.
The medical device is allocated in *one* of the following MRI safety categories:

**Ja** which means that the device is made of such materials that no magnetically induced displacement force, torque or excessive heating may occur. Some metallic devices are also considered safe if tests have shown that the three device properties are below the safety limitations. In this case the magnetic field strength or SAR values used during the test must be stated.

**Nej** The medical device is contraindicated for MRI! This means that the device is ferromagnetic or that at least one of the properties is above the safety threshold limit. Some non-passive implants such as pace-makers may also be in this category.

**Vilkor** MRI examination may be performed but under strict conditions such as limited SAR values, field strength or that the surgical convalescence is finished.

Once all relevant information has been found i.e. the device is among the products in the search result form, a paper print out might be preferable. This is achieved by first clicking the ‘preview report’ button which opens a report, as seen in the figure below, containing all relevant info.
**Figure 6.5:** Report made for paper printouts which includes all relevant information.

The report might be saved among the patient’s other journals as basis during the risk evaluation made by the responsible physician.
4.3 Adding devices

One criterion was a simple and straightforward usage of the database. Adding information to the database is just that whereas the information collection part may be quite cumbersome. Once all relevant information is gathered we want to store it properly for easy admittance in future and the first step is to open the ‘Add new data sheet’ seen below:

**Figure 6.6:** Any new information is typed into the text boxes. Information already stored in the database (in the tables) may be found in the list boxes.
All the text and list boxes in all forms are, of course, related to the tables. Specific information like artefacts and MR compability categories are fixed parameters which only can be selected in respective list box. The type (“Typ, Allmänt” and “Typ, specfierat”) of device and vendor (Tillverkare) selection list boxes holds all previous added info. If the list boxes do not hold information which corresponds to the new device it can be added to the database by double clicking respective list box which enables the user to add all brand new information in an additional form which will save the text in the related tables.

There are three types of forms available for this reason:

![Figure 6.7: Forms used to add brand new types of devices. The type is simply edited to respective text box and will be saved in the tables so it becomes available in the list box in the ‘‘add new data’’ form (figure 6.6).]
Figure 6.8: The form used to add new manufacturers. The form is used every time any new manufacturer or vendor is encountered. The information is stored in the table for manufacturers.

Before any new information is added to the database the user needs to double check the text typed into the form as a safety barrier towards misleading information when evaluating the hazards.

In the main form (figure 6.6) all text boxes except ‘related documents’ and ‘Övrigt’ needs to contain information. If not, following message box appears:

Figure 6.9: ‘lack of info’ Message box which is one part of the safety buffer towards misleading data within the database. This one makes sure that all relevant information is typed into the tables.
If data is simply not available, which is the case when no safety measurements have been performed, it is enough to type a hyphen (-) into the relevant text box which then ensures that the user has notified all text labels.

When all information is typed into the form and the user clicks at the ‘’Klar/Avsluta’’ (Finished/Close) button in order to save it in the tables, the message box displayed in figure 6.10 appears:

![Message Box](image)

**Figure 6.10:** ‘‘Check added info’’ message box which appears when the Finished/close button is clicked. Click ‘‘Ok’’ if the information is correct and may be saved in the tables and the ‘‘Avbryt’’ (Abort) button if anything needs to be changed.

### 7. CONCLUSIONS

The aim was to construct a database that enabled easy and fast safety evaluations regarding patients fitted with medical devices entering the MRI environment. The database constructed is (until this date) the only of its kind in Sweden. The nurses and other medical staff at the MR department at Karolinska, Huddinge have approved the functionality of the database and appreciate it as a tool which will be used frequently during safety evaluations. 244 medical devices are gathered in the database but every time any new devices are encountered it will be added. However, the database is only used locally at the MRI department and by the physicist thus a future work is to transform the database into an intranet or even internet based tool for usage by all personal involved with implants and MRI. An additional search option which enables the user to search by field strength may also be added.

The conclusion is that the aim of the database has been fulfilled.

The other task of this thesis was to build one heating measurement phantom and one torque measurement apparatus for the cases when the hazards are unknown thus permitting safety
measurements of our own. A displacement force apparatus has been constructed earlier at the department.

Except for small deviations in size and modification in the percentage of polyacrylic acid in the gelled solution the heating phantom follows the model proposed by ASTM. The phantom has a bigger head (14 dm$^3$) than the ASTM model (13 dm$^3$) but the torso is smaller (37 dm$^3$, ASTM 84 dm$^3$). If the difference in size will affect the result as compared to an ASTM model is not known but as mentioned in the significance and use section are RF induced temperature measurements troubled with a numerous of uncertainties and the phantom size is one of them.

The phantom should simulate some average sized human and the measure of the ASTM model was considered to wide. In fact it is so wide – 52 cm that it would not fit into the scanner which is only 49.3 cm wide at the table.

The gelled solution was modified in order to stiffen the solution preventing leakage. The additional amount of acid thickened the solution into what seems a more human tissue like substance. Also in this case no other choice than adding acid and therefore deviate from the ASTM proposal was an option due to the risk of leakage of solution which could damage the MR scanner. The importance lies within the conductive properties and properties that prevent convective heat transport that do not occur in humans. The difference in conductivity is assumed to be within the acceptable range for human tissue.

The heating effect measurements show that RF energy is deposited in the phantom material. Moderate additional heating effects are shown for the catheter adapter. Vast additional heating effects are present at the screener plug location and minor additional heating effects are obtained by the DBS electrode pad. The screener plug location was chosen in order to simulate a situation when a conductive circuit was formed by the plugs and the skin. The setup, with the plugs inside the phantom solution, might be exaggerated compared to a real life situation but the result is however alarming.

The conclusion is that heating effects are possible to detect with the phantom but a great deal of effort needs performed in order to minimize the uncertainties stated in significance and use section and that measurements are performed at devices that has not been manipulated with.
The torque measurement showed that it is possible to measure magnetically induced torque on devices which has excessive magnetic susceptibility. The maximum torque was not discovered due to the low spring constant but since ASTM states that the sensitivity of the torque measurement must be greater then 1/10 of the gravity torque it is better to have a low spring constant – which then detects even small torques. The switch contact material (and therefore magnetic susceptibility) is unknown thus theoretical calculations of magnetically induced torque, which should be compared to the result from the measurement, is not possible. If any proper device with known susceptibility is available in the future, such comparison may be performed.

The reliability of the results from the torque measurements are much higher compared to the heating effect measurement. It is both an easier setup thus spurious errors is less likely and also measuring the magnetically induced torque is a much more straight forward procedure since it is a simple interaction with the uniform magnetic field, which is the same for in the same field strength class (0.3 T, 0.8 T, 1.5 T, 3.0T e.g.) This means that it is not necessary to take into account the uniqueness of each scanner (if the device is tested in one 1.5 T scanner the result would most likely be similar as if tested in an other 1.5 T scanner) as in the case with the electric and magnetic fields responsible to heating effects.

The torque measurement apparatus constructed is considered useful and will give the physicists and physicians an improved ability to decide whether MR imaging may be performed on the patient or not.

The ability to find relevant information about implants has improved due to the database and the possibility to perform measurements of our own was the aim and result of this work. The question is whether the database, torque apparatus and heating phantom will be used during risk evaluations at department. The simple answer is yes – but with confidence and only as guidance for the total risk evaluation. The management of the torque measurement apparatus and heating phantom will be restricted to the physicists and the measurements set-up and procedure will follow the up-to-date designations stated by ASTM.
Acknowledgments

It was my supervisor Tomas Jonsson who is a medical physicist at Karolinska, Huddinge urge to find new and improved methods regarding safety evaluation for patients fitted with implants that made my thesis possible. I Am grateful for his ideas and thank him for all precious help during the measurements. I would also like to thank everyone else at the department for their support and comradeship. Thank you! Finally my most grateful appreciation goes to my friends and classmates – Klas Eriksson, Sandro de Luelmo, Sebastian Saurudis – without you these years would not have been as joyful and educational as it has been!

8. REFERENCES


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APPENDIX

A.1 Ampere’s law of circulation

Ampere’s law of circulation relates the curve integral of the $B$ field around any closed curve, $C$ to the total current, $I$ through a surface $S$ with $C$ as border.

$$\oint_{C} B \cdot dl = \mu_{0} \int_{S} \left( J_{f} + J_{b} \right) \cdot \hat{n} ds$$  \hspace{1cm} (A.1)

A.3 Magnetization

If the magnetized object is divided into partial volumes $\Delta v$, and if the magnetic moment from the $i$th atom in the volume $\Delta v$ is $m_{i}$ the magnetisation becomes:

$$M = \lim_{\Delta v \to 0} \frac{1}{\Delta v} \sum_{i} m_{i} \text{ [A/m]}$$  \hspace{1cm} (A.2)

When an object is unmagnetized the vector sum, $\Sigma_{i} m_{i}$, simply becomes zero since the distribution of $m_{i}$ is random i.e. pointing in different directions so that the summation of all direction cancels them out.

A.4 The magnetic field

It is the MR systems magnetic field gradients, static magnetic field and the RF pulses which are of importance concerning attractive forces, torque and heating of implants. All of the hazardous effects may be derived by Maxwell’s equations. The need for solenoid shape at $\geq 1.5$ Tesla scanners is a consequence described by Gauss and Amperes laws which, when combined, shows that the magnetic field inside a solenoid become homogeneous. The shape of the magnetic field from a solenoid also corresponds to the magnetic field from a magnetized rod or to the electric field from a polarized rod. (Cyrot et al 2005) (Hultqvist, 2004).
Figure A 2.1: Gauss law for the magnetic field says that the total magnetic flux through any closed surface becomes zero thus the induced magnetic field from a solenoid (cylindrical symmetry) only goes through the ends of the cylinder as in the figure. The radial component is zero.

Figure A 2.2: Amperes law says that any closed line integral of $\mathbf{B}$ is equal to the total current $I$ through the surface with the path $C$ as border. Since no current goes through the curve $C$ the integral becomes zero and since the radial component of $\mathbf{B}$ is zero as mentioned above (due to Gauss law) only the horizontal lines determines the size of closed integral. The integral is zero which means that the absolute value of $\mathbf{B}$ is equal at the top and bottom line. Since $C$ can be chosen in any way the result is clear: $\mathbf{B}$ is homogenous and has no radial component within the solenoid.

Figure A 2.3: The shape of the electric field, $\mathbf{E}$, around a uniform polarised cylinder is the same as the magnetic field around a magnetized rod or the same as the magnetic field from a solenoid i.e. a MR scanner.

Gauss law for the magnetic field also implies that the magnetic field lines form closed loops as in figure A 2.3. Compare the field lines surrounding the cylinder in figure A 2.3 to the fringe field surrounding the MR scanner in figure 2.4. Both illustrate vast gradients. These gradients cause translational forces between the scanner and any ferromagnetic object or between two ferromagnetic objects such as a fridge and a fridge magnet.
A.5 About magnetism

If the device is paramagnetic or diamagnetic, and if the susceptibility is isotropic, there is an approximately linear relationship between the magnetization, $M$, and the induced magnetic field, $B$ (not the same as the external magnetic field produced by the MR scanner, $B_0$) which according to the Amperian model becomes:

$$M = \frac{1}{\mu_0} \chi_B B$$

(A.3)

where $\chi_B$ is the magnetic susceptibility and $\mu_0 [Vs/Am]$ the permeability in vacuum.

The magnetizing field is defined as: $H \equiv \mu_0^{-1} B - M$ thus the linear relationship between the magnetic flux density, $B$ and $H$ becomes:

$$H = \frac{1}{\mu_0} (1 - \chi_B) B$$

(A.4)

or $B = \mu_0 (1 - \chi_B)^{-1} H \equiv \mu_0 \mu_r H$.

$\mu_r$ is the relative permeability and the product $\mu_0 \mu_r$ the permeability so that when $\chi_B = 0$ (vacuum), $\mu_r = 1$ and permeability $= \mu_0$.

$\chi_B$ is $< 0$ for diamagnetic materials thus $\mu_r < 1$ which means that the presence of material weakens the applied field. In paramagnetic objects $\chi_B$ is $> 0$ and $\mu_r > 1$ so that the material strengthens the applied field. The correct value of $\chi_B$ also depends on the temperature.
A.4 ASTM designation F2182-12a RF intensive imaging protocol

Table A.4: RF intensive imaging protocol proposed by ASTM

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**Table A5: Angles turned by the cog-wheel and angle deviation between device holder and protractor from which torque and force is calculated by using equation 10 and 11.**

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