Physical principles for the assessment of MRI safety at high fields

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Introduction

A number of fatal incidents have been reported the past 20 years. These, however all relate to situations that were avoidable, such as the scanning of patients with contra-indicated implants (pacemaker, deep brain stimulator, surgical clip), or the use of MR unsafe devices in the MR environment (infusion pump), the missile effect of a ferromagnetic object brought in the vicinity of the magnet and a wrongly constructed RF room, which caused the fact that a service engineer could not escape in time from the room when it filled up with cold helium gas resulting from a quench of the magnet.
The number of serious incidents reported that must be contributed to the basic properties of the MR system is very limited. In clinical practice serious incidents related to human exposure to the applied static magnetic fields or the dynamic gradient magnetic field of MR systems are not known, but incidents related to the RF transmission during scanning are known. These RF incidents result when uncontrolled and thus unwanted local RF absorption occurs, resulting in excessive local heating of the patient and subsequently can result in RF burns. This local RF absorption results from unwanted resonant RF antennas, which can be created by conductors present in the system (such as ecg leads, RF coil cables). Many of these situations are reported resulting in 1^{st} and 2^{nd} degree RF burns, including a smaller number of more serious incidents where 3^{rd} degree RF burns are seen.

In this contribution the physical principles for the assessment of MRI safety related to exposure to the Electro Magnetic Fields (EMF) of MRI: the Static Magnetic Field (SMF) at 0Hz, the dynamic Gradient Magnetic Fields (GMF) in the kHz range and the RF field in the MHz range are discussed. For each of these fields the basic physical principles resulting in the interaction with the human body are shortly described. The question is raised whether we know the actual physiologic process that determines the maximum allowed value for each field. Furthermore it is questioned whether the parameters controlled in the MRI scanners correctly assure the safety of the patients and the MR workers. For the latter group this includes their safety when working with the system at the MR manufacturer and in the hospital. The currently allowed maximum values for these safety parameters for the patients are described in the IEC60601-2-33 standard [1] a future extension will also include the safety of the MR worker.
An important observation is that all the observed and known health effects that result from exposure to the EMF generated during an MRI examination are not long term effects. All observed effects reported in the literature disappear shortly after the exposure of the person involved has ended. Up till now no scientific data has been published that claims any long-term effect.

The Static Magnetic Field.

The forces that are caused by the Static magnetic Field, $\mathbf{B_o}$, are proportional to the $\mathbf{B_o}^{\mathbf{2}}$ and are the largest for ferromagnetic materials and less for partially saturated ferromagnetic, diamagnetic or paramagnetic objects. It is important to realize that these directional forces are the result of the product of $\mathbf{B_o}$ and the inhomogeneity of $\mathbf{B_o}$, the spatial derivative $d\mathbf{B_o}/dx$,

$$F \propto \chi B_0 \frac{dB_0}{dx}$$

where χ is the susceptibility of the object. For MR scanners these forces are thus higher for high field systems and are observed in the spatial gradient of the magnetic field around the scanner. The forces are largest at the position where this gradient field is maximal and are especially large when the magnet is an active shielded magnet. The forces can also result in aligning forces along the magnetic field lines resulting in torques on asymmetric ferromagnetic objects. This can be especially dangerous for ferromagnetic implants (surgical clips) and tools applied by engineers.

Already since the introduction in the early eighties of MR scanners with a SMF ≥ 1.5T negative health effects related exposure to the SMF are known and have been published frequently. The effects reported are to a large extent subjective and include dizziness, nausea, metal taste and magnetophosphenes [2]. While some people do experience these effects, many others are not at all affected by the magnetic field. Since the observations were first reported when high field systems were introduced, these health effects are often related to the high value of the SMF. This however is not at all truly demonstrated by scientific data and in fact the ultimate safe limit of SMF strength is not known and the factors that eventually may determine the maximum permissible field strength are yet to be determined [2]. More and more often it is suggested (but not proven) that not the exposure to the SMF by itself but in fact the motion of the person in the SMF is the relevant contributing factor for the observed health effects. This fits in with the observation that typically patients do not suffer from these health effects once they are positioned in the bore of the magnet, even when the SMF is as high as 7T. More often it is the MR worker doing his job around and sometimes inside the magnet bore who observes and reports these effects. Since also the physiological process that creates the listed health observations is not identified, there is still discussion on the exact physics parameters that must be controlled to minimize the observed health effects. Often the involvement of the human balance organ is suggested, but the exact mechanism is not known. Is it an electric current introduced in the galvanic vestibular system; is it a pressure difference introduced in the fluids in the labyrinth as a result of magnetohydrodynamic effects; is it the acceleration detected as a result of susceptibility inhomogeneities in this organ or is it yet another physiological effect? Is it the SMF itself; is it the spatial gradient of the magnetic field around the magnet, or is it may be the product of the SMF and its gradient? Is it the exposure only or is the movement and possibly even the acceleration in one or all of these stray fields relevant?
The observation that patients laying still in the magnet typically do not suffer from these health effects and the known fact that patient or volunteers must be transported into the bore of the high field magnets with a sufficiently low speed to avoid the effects seem to indicate that not just the exposure to the SMF is the source of the effects, but that motion is involved.

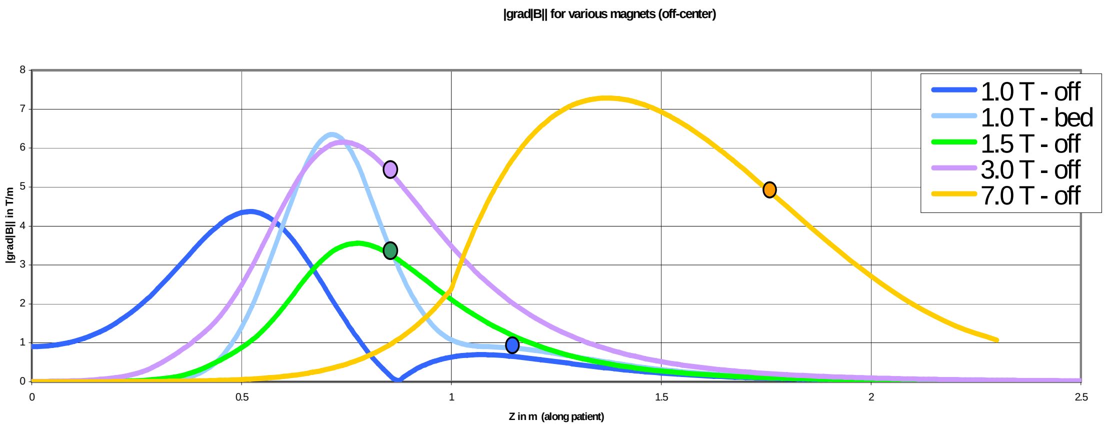

Fig.1: The spatial gradient of the static field of cylindrical 1.5T, 3.0T and 7.0T and the open 1.0T magnets. The fields are measured along the patient axis. In the cylindrical systems this was done at 25 cm above the table. In the open system it was done at 50cm off center (1.0T off) and 50 cm off center + 10cm above the table (1.0T bed). The circles in the graphs indicate the edge of the magnet.

This is supported by the observation that MR workers moving in the relatively high spatial gradient magnetic field of the relative low SMF (1.0T) of the shielded open magnet, see Fig. 1, frequently observe the reported health effects. Also comparison of the observations of MR workers working in the stray field of the 3.0T and the 7.0T systems supports this assumption. The gradient of the static fields around the shielded 3.0T magnet and the unshielded 7.0T magnet are of the same order of magnitude and the frequency of the subjective complaints of the workers are comparable (and thus not dramatically higher at 7.0T).
As a result it can be postulated that safety limits for exposure to SMF must be expressed in maximum dB/dt values, being the result combination of a movement (dx/dt) in a gradient magnetic field (dB/dx). The dB/dt value at which the observed health effects are observed can be estimated from the speed of motion of the patient into the magnet and the threshold appears to be higher than a few T/s.
On the other hand the question may be raised what the exposure limit value of the SMF would be and which physiological process would determine this limit value. A possible effect is the force in the large blood vessels that results from the magnetohydrodynamic effect of the SMF perpendicular to the flowing blood in the aorta. Simulations have indicated that when the magnetic field is orthogonal to the flow in the aorta, this force will be of the same order of magnitude as the gravitational force at about 10T [3]. Also other effects such as cellular disorder induced by high SMF have been studied recently and cultured cell exposure to SMF>10T has been demonstrated to affect the cell cytoskeleton. Whether such perturbations have consequences for human beings is not determined [4]. Physiological parameters of persons subjected to the static field of an 8T MRI system were measured [5]. No clinically significant changes were observed apart form a slight increase in the systolic blood pressure with increasing SMF.
Another possible limiting class of effects resulting from the exposure of the human brain to SMF are the effects on physiologic or neuro-cognitive functions. Results described in [6] however suggest that the cognitive-motor (eye-hand coordination) and the sensory (near-visual contrast sensitivity) are negatively influenced by exposure to SMF as low as 700mT. Although these effects are undesirable in interventional MRI procedures, it is not clear how these transient effects relate to the actual performance in a clinical setting.
In conclusion it may be stated that the fact that the IEC has introduced a maximum value of 4T for the SMF for scanning of patients [1] is based on precautionary principles and must be reconsidered.

The dynamic Gradient Magnetic Field.

The health effects related to exposure to the dynamic Gradient Magnetic Field, G, are the result of the electric fields induced by the time-variation of this field, dG/dt in T/s, during switching of the gradient coils in the kHz range. This field can affect excitable tissue and can result in Peripheral Nerve Stimulation (PNS) in the human body. For whole body gradient subsystems, the theory satisfactorily explains the effects of the GMF on the human body [7,8,9]. Compared to peripheral nerves, the cardiac nerves have a much higher threshold value for stimulation and at PNS threshold cardiac nerve stimulation still is avoided by a large safety factor. In practice the PNS is therefore a very good practical limiter to avoid cardiac stimulation. The models [7] in a hyperbolic equation, which relate the time rate of chance of the flux to the effective stimulus duration,

$$\frac{dG}{dt} = rheobase\left(\frac{1 + chronaxie}{t_s}\right)$$

whereby t_s is the duration of the decreasing or increasing GMF applied during MR scanning. The rheobase is the threshold for stimulation for infinitely long stimuli and the chronaxie is the duration for which the stimulation threshold is twice the rheobase. The best experimental fit for the mean threshold level for PNS as found in the literature [9] results in a rheobase value of 20T/s and a chronaxie of 0.36ms. It is interesting to see that the research of the last decade has resulted in an increase of the allowed values for the gradient output of modern MR scanners. It is also allowed, following the requirements of the IEC standard [1], for the MR manufacturers to determine the mean threshold level for PNS for each system (gradient coil design). In this way it may be expected that somewhat higher values of the gradient output can be applied than the default values as given by the hyperbolic equation, without creating intolerable PNS (as opposed to mild or painful PNS) in the patient. Since the mean threshold level for PNS again varies considerably between individuals (with a standard deviation of about 20% of the mean threshold, [9]), it is in practice possible that very sensitive patients do experience a painful level of PNS on modern scanners. The number of reports is however very minimal and no reports are known which report the occurrence of any form of serious injury for the patient.

It is important to realize that the threshold level for PNS is independent of the value of the SMF. In fact in practice the experiments done to determine the threshold level on volunteers are done outside the MR magnet or in a system with the magnet field switched off in order to not influence the observation by the volunteer by the knocking sound of the gradients [9].

An open issue related to the health effect caused by the GMF is the discussion of the exposure limits proposed specifically for MR workers. The actual proposed limit values for workers for exposure to EMF in the kHz range are given by ICNIRP [10] and are based the observation of visual phosphenes and as such on the threshold current density estimated for minor effects on nervous system functions. Visual phosphenes are however observed at lower frequency values than applied during MR scanning and therefore the extrapolation of the ICNIRP guidelines to the kHz range should be discussed [11, 12]. A direct consequence of this situation is that the limit values as proposed by ICNIRP for workers in general (not specific MR workers) are much lower than the values allowed by IEC for patients [1] (for patients values identical to those of IEC are adopted by ICNIRP in a more recent publication [13]). When the low limits recommended by ICNIRP for the MR workers are used in national regulations (and such regulations are expected soon in the EEG), this may hamper the development of MR scanners and will certainly limit the application of interventional MR, whereby the medical doctor sometimes has to be present near the bore of the scanner during scanning).

The RF radiation.

In the early days of MRI scanning on patients, it was already known that in the MHz range EMF in human tissue dissipates heat and results in a temperature rise in the human body. It was also realized that even the relative low RF energy levels available on the early MR scanners were nevertheless enough to heat up the human body locally to more than 1 ^{o}C. Since it is in practice impossible to monitor the temperature of the human body during an MRI scan, the power transmitted by the RF transmit coil has to be controlled. The RF transmit coils induces electric fields in the human tissue during an MR examination, which results in the RF magnetic field strength, B_1. For an MR scanner the RF power absorbed by the human tissue can be controlled via the Specific Absorption Rate (SAR) expressed in W/kg in the patient. The SAR value can be estimated with reasonable accuracy. For a volume transmit RF coil the B_1 field is uniform in the volume of the coil coils and the SAR value is then directly proportional to the B_1^2 and is a function of the electrical conductivity σ and density ρ of the tissue.

$$SAR \propto \frac{\sigma B_1^2}{\rho}$$

Up till now, the SAR has always been used to limit the transmitted RF power. The limit for the temperature rise in the patient body is 1 ^{o}C in any part of the human body [1]. The allowed maximum

temperature is however different for the different parts of the human body (head, 38°C, trunk, 39°C and extremities, 40°C), but these numbers are not applied on MR scanners up till now.
Since the mid nineties the maximum allowed SAR values have not been changed significantly for the MR scanners, being expressed in the whole body SAR value and the head SAR. Although limits are given for the local SAR values, its value was in practice not separately controlled by the MR system. Instead, supported by experiment and or by deduction, it was inferred that when the limits for the whole body SAR are applied, also the local SAR limits are respected. This is no longer true since the introduction of high field systems.
The limits for the allowed SAR values as given in the IEC standard [1] are independent of the value of the SMF. However, the amounts of energy needed for an MRI scan increases when the value of the B_0 is increased as can be seen from

$$SAR \propto \frac{\theta^2 B_0^2}{\tau}$$

where θ is the RF tip angle and τ the RF pulse duration. So, ignoring all other effects related to the higher frequency of the RF radiation and the interaction with the human tissue, the number of occasions in which the SAR value in practice will be the limiting factor for a specific sequence increases for higher values of the SMF. It must be realized that since the wavelength of the RF waves is shorter at higher values of the SMF, the interaction with the human body is different. Simulations applying realistic heterogeneous human body models and finite difference time domain (FDTD) calculations of the Maxwell equations have demonstrated that at these higher SMF in fact the local SAR values become more relevant [14]. As a consequence, it is no longer valid to assume that obeying the whole body SAR limits automatically fulfills the requirements for the local SAR value.
Also the averaging times applied for the SAR determination are in discussion in the MR community. It appears that both the 6 min (long term) and 10 s (short term) averaging times as given in the current version of the IEC standard [1] are not adequate and nuancing is required. In addition it is more and more realized that the limit for the allowed temperature increase of only 1°C in any part of the human body may be too rigid for the MR patient. Is it possible to allow higher temperature for specific parts of the human body? Is it possible to allow higher local SAR for specific organs, taking into account the actual cooling by perfusion or diffusion? Specifically for the human head a multi-tissue numerical model was developed, that considered thermal conductivity, heat capacity, perfusion, heat of metabolism, electrical properties and density [15]. This resulted in the observation that the local SAR limits are exceeded in the brain before the temperature in the brain increased by more than 1°C.

Conclusions and future outlook.

It is surprising to see that even after more than 20 years of experience with MR scanners, the scientific basis for the exposure limits for the EMF related parameters is still in discussion. For the static magnetic field it is not clear which parameter determines the maximum allowed field. Is it indeed the movement of the person in the gradient field of the SMF that results in the observed health effects? Can we define a practical limit to minimize these effects for patients and MR workers?
For the dynamic gradient magnetic field, the discussion is limited (and not relevant for patient scanning), since only the fact that the limits for workers are not in line with the limits for patients is open for debate.
Discussions on the allowed SAR values have started only the past few years, after results of simulations in realistic human models became available, faster and more energetic RF sequences

created complains and the relevance of the local SAR values even at SMF of the order of 1.5 T are demonstrated.

Clarity in this respect is urgently needed and resulted in the initiative to start working on the 3rd edition of the IEC 60601-2-33 standard. It may be expected that this 3rd edition will address these new aspects both for patients and for MR workers, although it must be realized that the authorized version of this edition of the standard will not become available earlier than 3 or may be even 4 years from now.

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