Health Effects

Exposure Guidelines for Magnetic Resonance Imaging: The Most Successful Application of Electromagnetics in Biology and Medicine

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The International Nonionizing Radiation Protection Commission (ICNIRP) is an independent group of experts with the responsibility to evaluate the state of knowledge about the effects of nonionizing radiation (NIR) on human health and well being and to provide science-based advice and recommendations on protection against harmful effects of NIR that include static electric and magnetic fields, RF waves, visible light, and ultraviolet radiation.

The ICNIRP began as the International NIR Committee through an initiative of the International Radiation Protection Association (IRPA) in 1977 and was reorganized as an independent commission with a charter adopted by the IRPA General Assembly held in Montreal, Canada, in May 1992.

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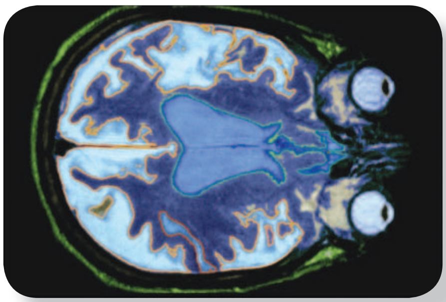
The ICNIRP's Role

The ICNIRP's scope of activity includes analyzing physical characteristics of NIR and reports of biological effects from exposure to NIR; recommending appropriate terminology, quantities, units, and methods of measurement; developing protection criteria; recommending systems of protection against NIR, including appropriate exposure limits; providing guidance for the protection of workers, members of the public, patients, and the environment; and issuing statements, recommendations, and papers on selected topics as appropriate, including reports on the application of ICNIRP recommendations.



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The ICNIRP operates through a main (SC) commission, four standing committees, and a large group of consulting experts. The main commission consists of a chair, vice chair, and up to 12 members. Commission members are individual experts representing neither their countries nor their institution. Current members of the commission come from 11 different countries and are elected upon nomination by members of the commission, the Executive Council of IRPA, or IRPA associate societies. The election takes place every four years at the last Annual General Meeting before the IRPA Congress. The four standing committees are SCI on epidemiology, SCII on biology and medicine, SCIII on physics and engineering, and SCIV on optical radiation. The scientific expertise of ICNIRP members includes medicine, dermatology, ophthalmology, epidemiology, biology, photobiology, physiology, physics, electrical engineering, and metrology.

The ICNIRP performs its work in collaboration with a number of regional and international partners and scientific organizations. ICNIRP works closely with the World Health Organization (WHO) through two NIR and health programs—the International EMF Project and the INTERSUN Project. The ICNIRP also collaborates closely with the International Labor Organization

(ILO) on matters relating to occupational NIR protection. It is officially recognized by the WHO and the ILO as the international independent advisory body for NIR protection. The ICNIRP also collaborates with the European Council, principally DG SANCO (Health), the European Society for Skin Cancer Prevention (EUROSKIN), the International Commission on Illumination (CIE), and the International Commission for Occupational Hygiene (ICOH), among others.

The products of the ICNIRP in fulfilling its aims to disseminate information and advice on the potential health hazards from exposure to NIR are published in the form of scientific reviews and reports and the proceedings of scientific meetings. The reviews, combined with risk assessments conducted in collaboration with the WHO, result in the recommendation by the ICNIRP of exposure guidelines. Examples of these are guidelines limiting exposure to electromagnetic fields, lasers and incoherent optical radiation, and ultraviolet radiation. The ICNIRP also publishes statements providing information and advice on specific topics of NIR protection and/or radiation protection issues related to specific devices or exposure situations.

Relevant Magnetic Resonance Exposure Guidelines

Operation of magnetic resonance (MR) equipment for clinical applications involves static, gradient, and RF magnetic fields. Relevant ICNIRP guidelines are briefly summarized in the following.

Guidelines for Exposure to Static Magnetic Fields

There are two very challenging questions when developing guidelines for static fields. These are the transient sensory effects with no known long term or deleterious consequences and the concern about lack of knowledge about human exposure to static fields higher than those for which there are data. In recommending the exposure limits, the ICNIRP considers that there are occupational situations where, with appropriate instruction and guidance, it is realistic for workers voluntarily and knowingly, to come across possible momentary sensory effects such as nausea, since they are not deemed to lead to health effects. The ICNIRP considers that the exposures allowed under the guidelines should be based on scientific data and that exposures should not go higher than those for which there is information. However, it accepts that, for investigational purposes, it might be desirable to explore possible effects at higher levels; such experimental exposures should be a matter for institutional ethics committees.

The limits recommended by the ICNIRP for general public and occupational exposures to static magnetic fields are summarized in Table 1 [4], which supersede those published by the ICNIRP in 1994 [1]. Based on available scientific data on the direct effects of static fields on humans, acute exposure of the general public should not exceed a spatial peak magnetic flux density of 400 mT for any part of the body and all members of the population. However, the ICNIRP recognizes that practical policies need to be implemented to avoid potential harmful exposure of persons with implanted electronic medical devices and implants containing ferromagnetic materials, and injuries due to flying ferromagnetic objects. These considerations can lead to much lower restriction levels, such as 0.5 mT [7]. The exposure limits to be set with regard to these inadvertent effects are beyond the purview of the ICNIRP. The exposure limit for the general public represents a reduction of a factor of five with respect to the occupational limit for the head and trunk, which is 2 T. When restricted to the limbs, maximum exposures of up to 8 T are permissible. For work related circumstances for which exposures above 2 T are deemed necessary, exposure up to 8 T can be accepted if the situation is managed and appropriate work practices are implemented to control movement-induced effects.

Recommendation for Patients in a Static Magnetic Field

An ICNIRP statement on the protection of patients undergoing medical MR procedures was published in 2004 [3]. Since its publication, there have been many studies on the health effects of exposure to the high-strength static magnetic field used in newer generations of MR systems. Although the advice concerning patient exposure to gradient magnetic fields remains unchanged, the ICNIRP has decided to issue an amendment of the statement concerning patient exposure to static magnetic fields in 2009. As in 2004, the statement is intended for use by national and international medical device regulatory authorities, MR users and health professionals, and those involved in the design and manufacture of MR equipment for clinical applications.

The recommendation for protection of patients in static magnetic fields is summarized in Table 2 [5]. The three-tiered approach used previously is still considered appropriate including routine diagnostic imaging. Additionally, it provides flexibility for new investigations and for further development of clinical procedures at higher field strengths. Based on this scheme a whole-body limit of 4 T is recommended for routine MR examinations for all patients for under the normal operating mode. It is noted that a knowledge gap remains of the effects of static magnetic fields in excess of 4 T on the growth and development of fetuses and infants, and therefore some

TABLE 1. ICNIRP guidelines on limits of exposure to static magnetic fields (2009a) [4].

	Exposure Domain	Magnetic Flux Density
Occupational	Head and Trunk	2 T
	Limbs	8 T
General Public	Any Part of the Body	400 mT

TABLE 2. ICNIRP recommendation for patients in static magnetic field [5].

Operating Mode	Exposure Limit (Whole Body)	Comment
Normal (Routine)	4 T	Including fetus and infant
Controlled (Specific)	8 T	Under medical supervision (potential discomfort/adverse effect)
Experimental	> 8 T	special ethical approval (cardiovascular flow potential)

Threshold for motion-induced vertigo and nausea: 1 T/s for 1 s

caution may be warranted regarding their imaging above 4 T. Note that specific MR examinations of all patients outside the normal operating range, where discomfort and/or adverse effects for some patients may occur. A clinical decision must be taken to balance perceived medical benefits against the adverse effects and the exposure must be conducted under direct medical supervision. The upper limit for whole-body exposure is 8 T, in view of uncertainties regarding the effects of higher fields. The ICNIRP recognizes the potential risks and need for providing flexibility in new investigations and for further development of clinical procedures at field strengths higher than 8 T. It therefore suggests that for experimental MR procedures at these levels a special ethical approval is required.

In addition, it is cautioned that patients should be moved slowly into the magnet bore, to avoid the possibility of vertigo and nausea. Thresholds for motion-induced vertigo have been estimated to be around 1 T/s for durations > 1 s; avoiding these sensations is likely to afford protection against other effects of induced electric fields and currents that arise as a consequence of motion in a strong static magnetic field.

Guidelines for Radio-Frequency Dosimetry and Heating

General Public and Occupational Exposures

ICNIRP's "Guidelines for Limiting Exposure to Time-Varying Electric, Magnetic, and Electromagnetic Fields (up to 300 GHz)" was published with the objective of limiting exposure to electromagnetic fields that will provide protection against known adverse health effects [2]. It was mentioned then that the guidelines will be periodically revised and updated as advances are made in identifying the adverse health effects of time-varying electric, magnetic, and electromagnetic fields. In view of the time elapsed and the many scientific studies of the effects of such fields published in recent years, the ICNIRP currently is in the process of reviewing and assessing the new data with respect to possible health hazards. In the interim, it is the opinion of the ICNIRP that the scientific literature published to date do not furnish any compelling data showing adverse effects below the basic restrictions. Thus, the data do not necessitate an immediate revision of the ICNIRP guidance on limiting exposure to RF electromagnetic fields [6].

The current ICNIRP guidelines for RF electromagnetic fields in the magnetic-resonance-pertinent, 10 MHz to 10 GHz frequency range are given in Table 3. For example, at 1.5, 3.0 7.0, 9.4, and 11.7 T, the corresponding frequencies for hydrogen protons are 64, 128, 300, 400, and 500 MHz, respectively. The basic restrictions on the specific absorption rate (SAR) limit for general public and occupational exposures are provided to avoid whole-body heat stress and excessive localized tissue heating. These restrictions will, specifically, prevent biological and health effects in responses to a body temperature rise of 1 °C or more for an averaging time of 6 min. This level of temperature increase results from exposure of individuals under moderate environmental conditions to a whole-body SAR of approximately 4 W/kg for about 30 min. A whole-body average SAR of 0.4 W/kg was chosen as the restriction that provides adequate protection for occupational exposure. An additional reduction factor of five is introduced for exposure of the public, giving an average whole-body SAR limit of 0.08 W/kg.

Patients Undergoing Magnetic Resonance Procedures

In addition to the guidelines on general public and occupational exposure limits promulgated since 1998, the ICNIRP has published guidelines on protection of patients undergoing MR examinations [3]. The recommended SAR limits for environmental temperatures below 24 °C and averaging time of 6 min are summarized in Table 4 for whole-body, partial-body and for the head, the trunk, and the extremities. These SAR levels should not be exceeded in order to limit temperature elevation to the values given in Table 5. Whole-body SARs are applicable at environmental temperatures at or below 24 °C. At higher temperatures, they should be reduced depending on actual environmental temperature and humidity. The recommended SAR restrictions do not pertain to any individual MR sequence, but rather to running SAR averages computed over

TABLE 3. Basic restrictions for time-varying electric and magnetic fields in the 10 MHz–10 GHz frequency range.

Exposure Type	Whole-Body Average SAR (W/kg)	Local SAR* (Head and Trunk) (W/kg)	Local SAR (Limbs) (W/kg)
General public	0.08	2	4
Occupational	0.4	10	20

*Local SAR is based on an averaging mass of 10 g of contiguous tissue.

TABLE 4. Recommended SAR limits valid at environmental temperatures below 24 °C and averaging time of 6 min.

Body Region	Whole-Body SAR (W/kg)	Partial-Body SAR (W/kg)		Local SAR* (W/kg)		
MR Operation	Whole body	Head	Other	Head	Trunk	Extremities
Normal	2	3	2–10	10	10	20
Controlled	4	3	4–10	10	10	20
Restricted	>4	>3	>4–10	>10	>10	>20
Short-term SAR**	<3 times above	<3 times above	<3 times above	<3 times above	<3 times above	<3 times above

*Local SAR (averaged over 10 g of contiguous tissue).
**The SAR limit over any 10 s period should not exceed 3 times the corresponding average SAR limit.

each 6-min period, which is assumed to be a typical thermal equilibration time of smaller masses of tissue.

Partial-body SARs scale with the ratio between the tissue mass exposed and the total patient mass. For a ratio approaching one, the ratio converges toward the corresponding whole-body values; but for ratios approaching zero, they converge toward the localized SAR level of 10 W/kg specified by the ICNIRP for occupational exposure of head and trunk (see above).

As mentioned in the "General Public and Occupational Exposures" section, for whole-body exposures, available data suggest that adverse health effects are not expected if the increase in body core temperature does not exceed 1 °C. In the case of infants, pregnant women, and persons with cardiovascular impairment, it is desirable to limit body core temperature increases to 0.5 °C. Similarly, local temperature under exposure to the head, trunk, or extremities should be limited to the values given in Table 5 for the three types of MR operations.

Remarks on Specific Absorption Rate and Temperature

The metric SAR in W/kg is defined as the time rate of change of the incremental energy absorbed by or deposited in an incremental mass contained in a volume of a given density [8]. The total amount of or whole-body energy deposited or absorbed and is given by the integral of SAR over a finite interval of time. The whole-body SAR as a metric corresponds to the average value obtained by dividing mass of the body into whole-body energy absorption. The whole-body absorption of RF electromagnetic energy by humans and laboratory animals is of interest because it is related to the energy required to alter the thermoregulatory responses of the exposed subject.

Note that in RF exposure the externally applied electric field induces electric field inside the biological body. Indeed, the induced electric field is the primary driving force underlying the interaction of electromagnetic energy with biological systems. Once the induced electric field is known, SAR can be derived from it by a simple conversion formula. Specifically, for an induced electric field E in V/m,

$$\mathrm{SAR} = \frac{\sigma E^2}{\rho_m}, \tag{1}$$

where σ is the bulk electrical conductivity (S/m) and ρ_m is the mass density (kg/m^3) of tissue.

TABLE 5. Basic restrictions for whole body temperature elevation and localized partial body temperatures.

MR Operation	Elevation of Body Core Temperature (°C)	Spatially Localized Temperature Limits (°C)		
		Head	Trunk	Extremities
Normal	0.5	38	39	40
Controlled	1.0	38	39	40
Restricted	>1.0	>38	>39	>40

However, at present, a small, isotropic, implantable electric-field sensor with sufficient sensitivity is not widely available. Fortunately, at sufficiently high intensity, the induced electric field generates heat in biological tissues, with finite electrical conductivity. Consequently, a common practice in experimental dosimetry relies on the use of small field insensitive temperature probes to measure the temperature elevation produced under a short-duration (~30 s), high-intensity exposure condition. The short duration is not enough for significant conductive or convective heat transfer to contribute to tissue temperature rise. In this case, the time rate of initial rise in temperature (slope of transient temperature response curve) can be related to SAR through a secondary procedure, i.e.,

$$\mathrm{SAR} = \frac{c\,\Delta T}{\Delta t}, \tag{2}$$

where c is the specific heat capacity of tissue (J/kg°C), ΔT is the temperature increment (°C) and Δt is the short duration (s) over which ΔT is measured. Thus, the rise in tissue temperature during the initial transient period of RF energy absorption is linearly proportional to the value of SAR.

It is important to distinguish the use of SAR and its derivation from transient temperature measurements. The derived quantity of SAR is merely a metric for energy deposition or absorption and it should not be construed to imply any mechanism of interaction, thermal or otherwise. Moreover, it is a quantity that pertains to a macroscopic phenomenon by virtue of the use of bulk electrical conductivity and specific heat capacity in its derivation from (1) and (2), respectively [8].

Challenges in Setting Guidelines for RF Exposure in MRI

High magnetic-field-strength MR systems are becoming more common and new open designs and interventional and intraoperative procedures increasingly have become routine at many sites. While exposure guidelines have been promulgated for MR operations, there are a number of challenges that warrant further consideration.

- *Differences in SAR and temperature distributions within heterogeneous human anatomies, which have been well-documented [9], [10].* Mammalian thermoregulatory responses can modify tissue temperature elevations and distribution under high SAR conditions, especially for the whole body and for pregnant women. Given the limitations in measuring in vivo temperature distribution and heating, computational prediction of SAR and temperature over typical MR examination periods continues to be a challenge in developing safety limits.
- *Mass of averaging volume for SAR and temperature.* It is significant to note the use of bulk electrical conductivity, specific heat capacity, and the mass density (kg/m^3) of tissue in the computation and derivation of SAR from electric field strength or from measurement of temperature elevation. Their use in the definition meant that a volume of tissue mass must be selected over which SAR is determined. A problem arises when the SAR distribution is highly nonuniform or when tissues with differing properties and conductivities are within the same volume. Thus, in general, a smaller averaging mass, or volume would allow SAR as a metric to provide a more precise representation of the true values of RF absorption and its variation inside the body or tissue medium. Similarly, the size of the mass within the averaging volume will impact temperature predictions.
- *Dosimetry and thermal models of pregnant women.* It is important to accurately characterize SAR and the heating of tissues during MR imaging of pregnant women and fetuses. It should be noted that thermal and dosimetry models of pregnant women and fetuses have only recently become available for SAR and temperature studies. Computer methods for prediction and validation of SAR and temperature distributions will be critical

to ensure safe MR operation involving this population group.

- *Features of SAR and heating distributions for high-field MR imaging.* Many studies have demonstrated SAR and temperature differences from high-field MR operations, compared to the current generation of MR systems. Comprehensive investigations are needed for safety assurance in high-field MR operations.
- *Epidemiological studies of health effects in patients or MR workers.* There have been no epidemiological studies performed to assess possible long-term health effects in patients, volunteers, or MR workers. It is important that such research be conducted, particularly on individuals with extended and high levels of exposure. There is a paucity of specific information regarding possible long-term health effects, although current understanding suggests that any effects are likely to be acute.

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