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● *IRPA/INIRC Guidelines*

PROTECTION OF THE PATIENT UNDERGOING A MAGNETIC RESONANCE EXAMINATION

International Non-Ionizing Radiation Committee of the International Radiation Protection Association

PREFACE

MAGNETIC resonance imaging (MRI) has become an established diagnostic modality. The clinical usefulness of *in-vivo* magnetic resonance spectroscopy (MRS) was demonstrated in several instances and is being explored further. These techniques involve exposure of the patient to static and time-varying magnetic fields and radiofrequency electromagnetic fields. In particular exposure situations, these fields may pose a health hazard.

The International Non-Ionizing Radiation Committee of the International Radiation Protection Association (IRPA/INIRC) in cooperation with the Environmental Health Division of the World Health Organization (WHO) has developed health criteria documents on magnetic fields (UNEP/WHO/IRPA 1987) and radiofrequency fields (UNEP/WHO/IRPA in press). Guidelines on limits of exposure to radiofrequency electromagnetic fields have been published by IRPA/INIRC (1988).

These publications, in conjunction with other reviews and recent literature, form the basis for this document. During its preparation, the IRPA/INIRC was composed of the following:

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The IRPA Associate Societies, as well as a number of competent institutions and individual experts, were consulted in the preparation of this document. Their cooperation is gratefully acknowledged.

PURPOSE AND SCOPE

The purpose of this document is to provide information on levels of exposure and health effects from magnetic and radiofrequency electromagnetic fields associated with MR diagnostic devices, and on precautions to be taken to minimize health hazards to patients undergoing MR examinations.

The present document does not apply to the occupational safety of the operator or to the safety of the general public. Guidelines on occupational and general public exposure limits to radiofrequency electromagnetic fields have been published (IRPA/INIRC 1988). Guidance on occupational and public exposure limits to static magnetic fields is in preparation. This document is intended for use by international or national medical device regulatory authorities, MR users and health professionals, and those involved in the design and manufacture of MR equipment for clinical applications. Contraindications, warnings, precautions, and safety considerations for the patients are given.

RATIONALE

A review of the biological effects from exposure to magnetic fields is contained in UNEP/WHO/IRPA

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(1987). Additional data and references can be found in Budinger (1981), Mansfield and Morris (1982), Saunders and Orr (1983), Budinger and Lauterbur (1984), Tenforde and Budinger (1985), Bernhardt (1986, 1988), Grandolfo (1987), Mathur-De Vre' (1987a, 1987b), Podo (1987), and Czerski (1988). Recommendations for radiofrequency exposure levels are based on the data contained in reports by the EPA (1984), NCRP (1986), UNEP/WHO/IRPA (in press), and on the rationale appended to IRPA/INIRC (1988).

Following is a brief summary of conclusions drawn from the review of scientific literature.

Static magnetic fields

The basic interaction mechanisms of static magnetic fields are the electrodynamic interactions with moving electrolytes, magnetomechanical effects (translation and orientation), and effects on electron spin states of chemical reaction intermediates.

Effects that are explained as magnetomechanical effects on molecular and cellular substances such as DNA, retinal rods, and sickle cells have been observed in experiments with fields of more than 1 tesla (T). Flow potentials can be induced in volume conductors in motion, such as flowing blood, by electrodynamic interactions with static magnetic fields. Such flow potentials caused by fields of more than 0.1 T have been confirmed to affect the T-wave in the electrocardiogram (ECG) of animals. The magnetically induced flow potential is a reversible effect and in humans does not lead to health effects at levels of up to 2.5 T (NRPB 1981, 1983).

Contractions of the heart lead to induced potential differences. When the magnetic flux density is below 2 T, the induced potential differences will be below the threshold for depolarization of cardiac muscle.

The scientific literature does not indicate adverse effects from exposure of the whole body to 2 T and of the extremities to 5 T. For whole-body exposure at 5 T, magnetoelectrodynamic and magnetohydrodynamic interactions with blood flow may lead to effects on the cardiocirculatory system (Tenforde and Budinger 1985; UNEP/WHO/IRPA 1987). Volunteers who were exposed to 10 T without adverse effects reported discomfort (Beischer 1962). Animals exposed to the same flux density also did not show adverse effects but exhibited behavioral modifications (UNEP/WHO/IRPA 1987). Theoretical analyses indicate that at 24 T, direct interference with ionic conduction current is likely. Some predictions indicate the possibility of interaction at lower levels with conduction loops within the central nervous system. Hence, the recommendation is to monitor patients for symptoms referable to the nervous system at levels above 2 T.

Time-varying magnetic fields

Recommendations on limiting the exposure to time-varying magnetic fields were based primarily on effects of induced currents on excitable cell membranes in the nervous system and muscles, and to a certain extent on more subtle effects in other cells (Tenforde and Budinger 1985; Bernhardt 1986; Czerski and Athey 1987; Reilly 1987; UNEP/WHO/IRPA 1987; Athey and Czerski 1988).

In the absence of adverse health effects, it may be assumed that current densities on the order of 1–10 mA m^{-2} induced by continuous sinusoidal magnetic fields are of no concern. Current densities of 10–100 mA m^{-2} can have effects that are strongly dependent on the frequency but are not considered adverse. For example, at 10–50 Hz and at fields of more than 5 mT, sensations of light flashes in the eyes (magnetophosphenes) have been observed; 100–1000 mA m^{-2} is the range where stimulation of excitable cell membranes is observed and where health hazards are possible. A current density of more than 1 A m^{-2} in the vicinity of the heart or an electric field strength exceeding 5 V m^{-1} in tissue may cause ventricular fibrillation (UNEP/WHO/IRPA 1987).

It is difficult to correlate the induced body currents with the magnetic flux change of the different magnetic field gradients occurring in pulse sequences from MR equipment. When wave shapes deviate from sinusoidal, it is difficult to predict the biological effectiveness in causing stimulation. As a result, in case of non-sinusoidal currents, each specific situation must be evaluated on the basis of the shape and frequency of the wave.

It can be estimated that a magnetic flux change of 3 T s^{-1} induces a maximum current density of 30 to 60 mA m^{-2} in the head or trunk, respectively (Budinger 1981). A flux change of 20 T s^{-1} induces a maximum current density of 400 mA m^{-2} at the periphery of the trunk inside MRI equipment. For a single pulse, under worst-case assumptions, Reilly (1987) calculated that this current density remains below the threshold for peripheral nerve stimulation by a factor of at least 3. As the pulse duration of dB/dt is shortened to less than 0.1 ms, higher flux change rates can be permitted. In the MR environment, peripheral nerve stimulation occurs before effects on the function of the heart are induced (McRobbie and Foster 1984, 1985) and can be used as a primary criterion for the assessment of MR safety (Czerski and Athey 1987). Because of the smaller induction loops in magnets used for MR examinations of limbs, the values for exposure of limbs alone can be increased compared with the trunk.

Radiofrequency fields

Limitations on radiofrequency energy deposition are intended to eliminate the elevation of temperature to levels at which local thermal injury or systemic thermal overload may occur. They are based on experimental and human data, including experimental, clinical, and modelling studies on thermal effects of MR exposure (Borup and Gandhi 1984; Spiegel 1984; Bottomley et al. 1985; Adair and Berglund 1986; Shellock et al. 1986; Shellock and Crues 1987; Athey and Czerski 1988; Grandolfo et al. 1990). Thus, the primary criterion for radiofrequency exposure is based on elevation of temperature in the skin, body core, or in spatially limited volumes of tissues where local temperature increases ("hot spots") may occur under conditions of MR exposure. Nonuniformities in RF en-

ergy deposition, particularly in vascular or hypovascular structures characterized by a higher radiofrequency absorption and lower heat dissipation, such as the eyes, brain ventricles, hydrocephalus, tumors, and hemorrhagic foci (De Ford et al. 1983; Athey 1989; Shellock and Crues 1988), were considered in the recommendations that follow. The values for the specific absorption rates and total energy absorption over time indicated below were derived under worst-case assumptions and represent conservative approximations.

Caution about the exposure of pregnant women, particularly during the first trimester, is based on questions on the efficacy of fetus imaging and on its thermal vulnerability (Tenforde and Budinger 1985; UNEP/WHO/IRPA 1987). Safety of MR examinations during pregnancy has not been established.

There is virtually no information about any delayed effects that may result from long or repeated exposure, and no guidance can be derived in this area other than the benefits to the patients.

GENERAL RECOMMENDATIONS

Until now, most MRI or MRS examinations have been made using static magnetic fields up to 2 T; however, higher magnetic flux densities offer potential diagnostic advantages, particularly for MRS. From the review of the biological effects of magnetic fields, it can be concluded that no adverse health effects are to be expected from short-term (hours) exposure to static fields up to 2 T (UNEP/WHO/IRPA 1987). Also, there are many gaps in our knowledge of biological effects and interaction mechanisms of static magnetic fields with tissues. The Committee emphasizes that in the application of MR, the following issues deserve special attention:

(1) Magnetic resonance (MR) *in-vivo* examinations should be performed only when there is a potential clinical advantage to the patient.

(2) An assessment of risks and benefits of the MR examination should be made, and the decision to proceed must be based on the relationship between the patient and the physician.

(3) Consideration should be given to the clinical advantages and disadvantages of MR compared with other diagnostic techniques.

(4) Where MR examinations form part of a research project, the project should be guided by rules of human ethics; informed consent of the patient should be obtained.

(5) MR equipment users must be adequately trained in the principles and operation of the equipment, indications and contraindications for use, recordkeeping requirements, safety aspects, and precautions.

(6) Manufacturers should supply complete documentation about patient exposure levels for their equipment, and these safety guidelines should be considered in the design of equipment and facility layout so that exposures to magnetic and radiofrequency fields are within the levels recommended for patients.

RECOMMENDATIONS ABOUT EXPOSURE LEVELS

Clinical experience currently indicates that adequate diagnostic information can be obtained while examining a patient for periods ranging from 15 min to 1 h and may be repeated several times over the course of the disease. The exposure levels below refer to patient studies from 15 min to less than 1 h, and where none of the contraindications listed below exist. Exposure levels are stated in SI quantities and units (IRPA/INIRC 1985).

Static magnetic fields

No adverse health effects are expected from exposures of the head and/or trunk to magnetic flux densities up to 2 T, or from exposure of the limbs to magnetic flux densities up to 5 T.

Exposures of the head and trunk to magnetic flux densities above 2 T require an assessment of the potential adverse effects vs. the likely benefit to the patient. Short-term whole-body exposures to fields of 5 T may pose health hazards, particularly for people with cardiovascular diseases, including high blood pressure. Therefore, monitoring the patient's cardiovascular function must be undertaken whenever exposures are above 2 T for the head or trunk, and above 5 T for limbs. Experimental data above 5 T are sparse; until further information is available, magnetic flux densities above 10 T should not be used.

Time-varying magnetic fields

Clinical experience indicates that no adverse health effects are to be expected when the rate of change of magnetic flux density does not exceed 6 T s^{-1}. However, patients with changes in the electrocardiogram (ECG) indicative of abnormalities in conduction may be particularly susceptible to exposure to magnetic fields. Therefore, an assessment of cardiac function (i.e., an ECG) should be made when exposures above 6 T s^{-1} are contemplated, and the patient's cardiovascular function should be monitored during exposure above 6 T s^{-1}. There is no widespread clinical experience above 6 T s^{-1}; theoretical calculations (Czerski and Athey 1987; Reilly 1989) indicate that above 20 T s^{-1} peripheral nerve stimulation could occur. Therefore, 20 T s^{-1} should not be exceeded.

Radiofrequency fields

Radiofrequency energy at frequencies between 10 and 100 MHz deposited in the body during an MR examination will be converted to heat, which will be distributed largely by convective heat transfer through blood flow. As the body temperature increases, there will be an increase in blood flow and cardiac output, as well as an increase in sweat secretion and evaporation.

For whole-body exposures or exposures to the head and trunk, no adverse health effects are expected if the increase in body temperature does not exceed 1°C. In the case of infants, pregnant women, and persons with cardiocirculatory impairment, it is desirable to limit temperature increases to 0.5°C.

In practice, due to its thermal capacity, no tissue will increase in temperature at a rate more than 1°C h^{-1} for each W kg^{-1} of power deposition. In persons (infants, aged persons, patients with local or systemic cardiovascular impairment) in whom the thermoregulatory mechanisms are less efficient than in a healthy human adult, signs of distress may appear at a whole-body average SAR of 2 W kg^{-1} after 10 min of exposure (Budinger et al. 1985). Considering the modifying effects of blood flow and environmental heat exchange, no adverse health effects are to be expected in persons without cardiovascular abnormalities exposed to 2 W kg^{-1} for 1 h. In persons with cardiovascular abnormalities, 1 W kg^{-1} for 1 h is an acceptable level, provided proper monitoring is instituted.

In MR exposures up to 1 h, the total body exposure should be limited to a total energy deposition of 120 W min kg^{-1} (7.2 J g^{-1}) in order not to overload the thermoregulatory system. To avoid overheating any local area, the product of time and local SAR should not exceed:

60 W min kg^{-1} (3.6 J g^{-1}) averaged over the head, or
120 W min kg^{-1} (7.2 J g^{-1}) averaged over the trunk, or
180 W min kg^{-1} (10.8 J g^{-1}) averaged over the extremities,

provided that the instantaneous SAR does not exceed:
4 W kg^{-1} averaged over the head, or
8 W kg^{-1} averaged over the trunk, or
12 W kg^{-1} averaged over the extremities.

To protect poorly perfused tissues, the eyes for example, such tissues should not be exposed to a local SAR of more than 10 W kg^{-1}, averaged over 0.01 kg (0.1 W/10 g) for more than 10 min.

For exposures of infants, pregnant women, or persons with cardiocirculatory and/or cerebral vascular impairment, a reduction of these values by a factor of two is recommended. For an RF-emitting surface coil, the average should be taken over the volume affected by the coil.

Users of diagnostic magnetic resonance devices usually do not have adequate resources to determine energy deposition within the patient's body. Such information should be supplied by the manufacturer, and it is recommended that the user requests reliable and detailed data from the manufacturer.

CONTRAINDICATIONS

Examinations of patients who have electrically, magnetically, or mechanically activated implants (e.g., cardiac pacemakers), or who rely on electrically, magnetically, or mechanically activated life-support systems, are contraindicated. Examinations of patients with ferromagnetic aneurysm clips or metallic implants (e.g., intrauterine contraceptive devices, prostheses) are also contraindicated.

WARNINGS AND SAFETY CONSIDERATIONS

Exposure during pregnancy

There is no firm evidence that mammalian embryos are sensitive to the magnetic fields encountered in magnetic resonance systems. However, pending the accumulation of more data regarding MR in pregnancy, it is recommended that elective examination of pregnant women should be postponed until after the first trimester. Because ultrasound is the modality of choice for fetal and uterine examination during pregnancy, an MR examination should be limited to cases in which unique diagnostic information can be obtained. Exposure duration should be reduced to the minimum, consistent with obtaining useful diagnostic information (Weinreb et al. 1985; NIH 1988).

Other safety considerations related to patient's condition

Communication with the patient or monitoring of the anesthetized patient must be assured throughout the examination.

Certain patients may experience claustrophobia. Claustrophobic reactions should be explored before an examination is undertaken.

Because some individuals may exhibit hypersensitivity to heating, it is advisable to ascertain if the patient's history comprises incidents indicative of hypersensitivity to heat and, if necessary, limit the duration of the examination.

Metallic inclusions

Ferromagnetic objects are attracted by magnetic fields. Depending on size, composition, and location of metallic implants or inclusions, serious injuries may result because of motions and displacement of such objects. Large metallic objects, such as hip prostheses, may become heated because of preferential radiofrequency absorption, leading to local thermal injury. Moreover, the presence of such objects results in artifacts in diagnostic information because of magnetic distortion.

The presence or absence of such objects in the body has to be ascertained and the consequences evaluated before an examination is undertaken.

Collision hazards and electromagnetic interference

The field near the magnet may be strong enough to attract ferromagnetic objects and to cause them to fly towards the magnet. Thus, metallic objects, particularly with sharp edges, may become dangerous projectiles. All such objects have to be eliminated from the examination room and proper warning signs must be posted. Such hazards may arise also during installation or transport of magnets. Proper precautions should be taken, with warning signs posted in the area and placed on crates and packages during transport.

The manufacturer should provide information regarding the extent of the zone in which collision hazards and danger of uncontrolled movements of objects exist

(e.g., uncontrolled movement of hospital carts, trolleys, loose tools, medical instruments, etc.).

Various medical and non-medical equipment and magnetic data carriers may be affected by magnetic fields. X-ray imaging equipment may be affected at magnetic flux densities above 0.05 mT, and cathode-ray devices and tubes affected at 0.2 mT. Patient monitoring equipment and emergency equipment may be affected at magnetic flux densities of 0.2 mT and above. Electronic implants, such as cardiac pacemakers, may be affected above 0.5 mT. Computers and magnetic storage media may be affected above 0.5 mT, and credit cards and analog watches affected at fields above 1 mT. The extent of zones in which such fields exist must be determined, and proper warning signs must be posted.

Quench

For MR facilities using superconducting magnets, there is a rare possibility that the liquid helium will suddenly become gaseous. This can occur if the superconductor becomes "normal," resulting in the dissipation of heat and evaporation of cryogens. An appropriate exhaust system should be attached to the magnet so that in the event of a quench, the gases will be vented to the outside and the helium does not become an asphyxiation hazard. If this system fails, the patient must be removed very quickly. An emergency procedure should be established to remove the patient from the examination room in the event of a quench.

Patient monitoring

Special requirements apply to the equipment and methods used for the monitoring of the patient under MR exposure conditions. Cardiorespiratory function may be monitored using non-ferromagnetic transducers to register the heart beat rate, blood pressure, and respiratory rate. The ECG is subject to distortion because of electrodynamic interactions and does not yield useful information. Non-perturbing fiber-optic probes for measurement of temperature are available. Under MR exposure conditions, oral temperature and the temperature of the skin of exposed body parts, possibly supplemented by rectal temperature measurement, are suitable for patient monitoring. Detailed information on body temperature measurements may be found in the review by Togawa (1985).

Resuscitation and emergency procedures

In view of the problems associated with collision hazards and electromagnetic interference, it may be impractical to institute resuscitation procedures and intensive care for the patient in the examining room. All necessary equipment should be assembled and tested in an adjoining room, outside the zone of interference. Speedy transport of the patient to an emergency area must be readily available.

Recordkeeping and patient follow-up

Examination records should be kept and patients should be monitored according to standard requirements of good medical practice. It is recommended that follow-up studies be carried out on children born following magnetic resonance examination *in utero*, or who were examined during early childhood. Observations on adverse reactions should be collected, reported according to national requirements, and published in the medical literature.

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