



COCIR Position Paper

Healthcare Industry wants MRI taken out of new EMF Directive

Global Healthcare Industry Leaders, Members of COCIR are calling urgently on the European Commission for a full exemption of Magnetic Resonance Imaging (MRI) from the scope of the EMF Directive (2004/40/EC).

The EMF Directive (2004/40/EC) will be transposed into national legislation by April 2008. As a consequence of its transposition, maintenance of all the 7000 MRI's in European hospitals will no longer be possible. This would mean that healthcare professionals can no longer use MRI, a lifesaving technology for the diagnosis and treatment of diseases such as cancer and heart disease. There is no scientific, health or safety need for this to happen.

Users and manufacturers of MR equipment are affected by the EMF Directive in numerous ways as described in the Annex below. In the 30 years' history of the use of MR for medical purposes with more than 500 million patients treated, no negative health effects have been reported that relate to EMF exposure.

The EMF Directive contains limit values for frequencies between 0 and 300 GHz which would restrict the use of MR equipment and may prevent certain applications. These exposure limits will apply to MR workers. This will affect the use of MR for medical diagnosis and treatment as well as the service, maintenance, development and manufacturing of equipment.

As a result of the Directive's implementation, MR diagnostic tools **would no longer be available**. Secondly, it would result in an increase in the use of X-ray based imaging modalities or lead to increased medical tourism outside the EU. Finally, we expect Europe to lose innovation leadership position in the development of future medical technology.

COCIR members are committed to maintaining high levels of safety for both patients and users. COCIR members are actively involved in developing international safety standards.

COCIR supports recent publications (see annex) where it is claimed that the limit values set in this Directive are not substantiated by sound scientific and clinical data.

COCIR is calling for **an exemption from the scope** of this Directive for people working with MRI and that the **safety of MR workers** should be ensured by the application of **the International MRI Safety Standard IEC 60601-2-33, amendment 2**, specifically developed for protection of MR workers.

COCIR Company Members: Agfa HealthCare, Canon Europe, Dräger Medical, GE Healthcare, Hitachi Medical Systems Europe, IBA Ion Beam Applications, IBM, ICW, Intel, iSoft, Kodak Health Group, Philips, Quovadx, Siemens Medical Solutions, Toshiba Medical Systems Europe. ***COCIR National Associations Members:*** AGORIA (Belgium), ANIE (Italy), SNITEM (France), ZVEI (Germany), SPECTARIS (Germany), Holland Healthcare Technology Association (Netherlands), FENIN (Spain), Swedish Medtech (Sweden), AXREM (UK), FiHTA (Finland)

Annex

Examples of impact on users and manufacturers of MR equipment caused by the requirements of the EMF Directive

- Although there is currently no limit value for the static magnetic field, people have to move in this field (for patient positioning, service, maintenance etc). In these cases currents are induced in the body. It is not possible to measure these currents. However, simulations show that they by far exceed the authorised limit values.
- With interventional procedures, the physician or other medical professionals must be near the equipment during scanning to perform the intervention. This kind of interventional procedures is likely to become more common in the near future.
- During maintenance and repair, the service engineer may be exposed to EMF fields higher than the limits set out in the EMF Directive.
- During the development and manufacturing cycle of MR equipment, system engineers may be exposed to EMF fields higher than the limits set out in the EMF Directive.

References:

Impact of Electromagnetic Field Exposure limits in Europe: Is the future of Interventional MRI Safe?, DLG Hill, K Mcleish, SF Keevil, Academic Radiology, Vol.12, No 9, p1135-1142, September 2005.

An analysis of differences in the low-frequency electric and magnetic field exposure standards of ICES and ICNIRP, JP Reilly, Health Physics, Vol. 89, Number 1, p71-80, July 2005.

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