Compliance with

EMF Directive EU 2013 / 35 / EU

Information for operators of Siemens Healthineers MR systems

The following article discusses the application of Directive 2013 / 35 / EU of the European Parliament and of the Council of 26 June 2013 on the minimum health and safety requirements regarding the exposure of operators to the risks arising from physical agents (electromagnetic fields), [1] in the following abbreviated as EMF Directive, with respect to magnetic resonance imaging.

It is intended to help organizations operating MRI systems to comply with requirements of the EMF Directive.

Note: National laws may deviate from the EMF Directive, and such deviations must be carefully considered. This is not covered by this paper.

The EMF Directive defines maximum electromagnetic field values to which employees are allowed to be exposed at the workplace (frequency range up to 300 GHz). This paper focusses on MR workers only (all persons working in the MR environment).

SIEMENS Healthineers

1. Action Levels (ALs) and Exposure Limit Values (ELVs)

To classify the impact of EMF exposure, the following structure is used:

Action levels (ALs), divided into:

- Low ALs
- High ALs

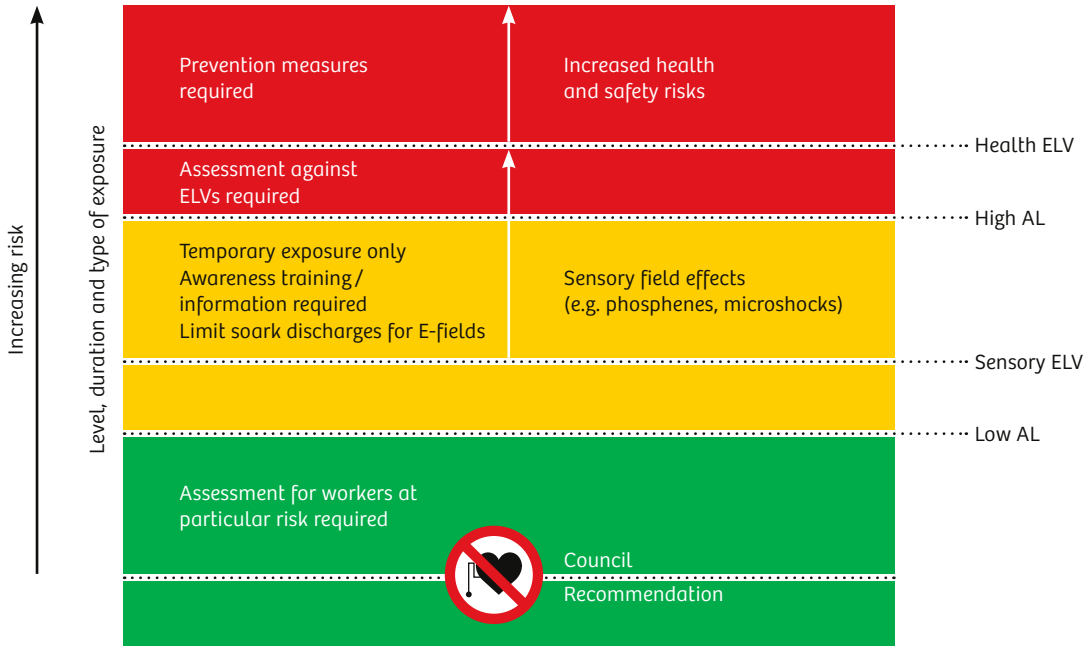
The ALs are physical quantities which can be easily determined (such as external field in V / m or T). If ALs are exceeded, the directive requires certain actions to be taken.

Exposure limit values (ELVs), divided into:

- Sensory effects ELVs
- Health effects ELVs

The ELVs are expressed in quantities that cannot be measured easily, such as induced electrical field strength, current density inside the human tissue, or absorbed energy in W / kg. Sensory effects ELVs are values above those which workers risk experiencing transient disturbed sensory perceptions. Health effects ELVs are values above those which workers might suffer short-term or acute direct effects such as thermal tissue heating, or nerve and muscle stimulation.

Note: EMF exposure for people with implants needs special assessment and is not considered here.



The figure is a quantitative depiction of the different protection zones [2].

2. Impact for MRI operators

MR operators are exposed to the following:

- Static magnetic fields (i.e., with frequencies of 0 Hz)
- Magnetic fields at very low frequencies due to movement in static field (i.e., frequencies up to approx. 2 Hz)
- Magnetic fields due to switched gradients (up to 3 kHz)
- RF electromagnetic fields (42 MHz per Tesla)

In every case, a risk assessment must be performed that takes account of the specific working conditions around the MR system. The risk assessment must consider the following:

- Specific exposure conditions (type of exposure, frequency, duration, spatial distribution)
- Exposure zones in line with ALs and ELVs
- Indirect effects (e.g., interaction with implants, projectile risk from ferromagnetic objects)
- Direct effects (e.g., dizziness, nausea, nerve stimulation, tissue heating))
- Access measures (e.g., controlled access area, warning signs)
- Workflow situation (to minimize duration and level of exposure)

MRI operators must be informed and trained regarding the following:

- The levels of exposure for different workflow conditions
- Possible effects of exposure
- The result of the risk assessment
- Any effects on operators at particular risk (e.g., those with implants, pregnant woman)
- Behavior to avoid / minimize effects of exposure (e.g., moving slowly in static magnetic fields)
- Reporting any adverse health effects experienced

If exposure levels are below the ALs:

No further action is required (except special consideration for operators at particular risk, e.g., those with implants).

If exposure levels exceed the ALs but are below the ELVs:

Operators must perform a risk assessment and implement resulting measures, especially regarding minimization of EMF exposure by technical and organizational means. This comprises the following:

- Informing operators about expected EMF exposure levels and distribution
- Educating and training MR operators
- Taking organizational measures to minimize exposure levels and duration
- Health surveillance

Note: Organizational aspects are already addressed when following instructions for use (e.g., controlled access areas, warning signs, emergency plans, etc.).

If exposure levels exceed ELVs:

In rare cases, ELVs can be exceeded with certain MRI procedures (e.g., interventional procedures). Article 10 (Derogations) of the EMF Directive [1] allows this for MRI operators if the following conditions are all met:

(i) The risk assessment carried out in accordance with Article 4 has shown that the ELVs are exceeded

(ii) According to the state of technology, all technical and / or organizational measures have been applied

(iii) The specific characteristics of the workplace, work equipment, or work practices have been taken into account

(iv) The employer demonstrates that operators are still protected against adverse health effects and safety risks, including using comparable, more specific, and internationally recognized standards and guidelines

Siemens Healthineers provides all necessary information for employers to fulfill the requirements of the EMF Directive with respect to the MR workplace. Please refer to the chapter entitled MR Compatibility Datasheet [3] in the System Owner Manual (SOM).

The following sections summarize the different conditions for MR-specific EMF exposure scenarios.

2.1 Assessment Regarding Exposure to Static Magnetic Field (B_0) and Movement Through B_0

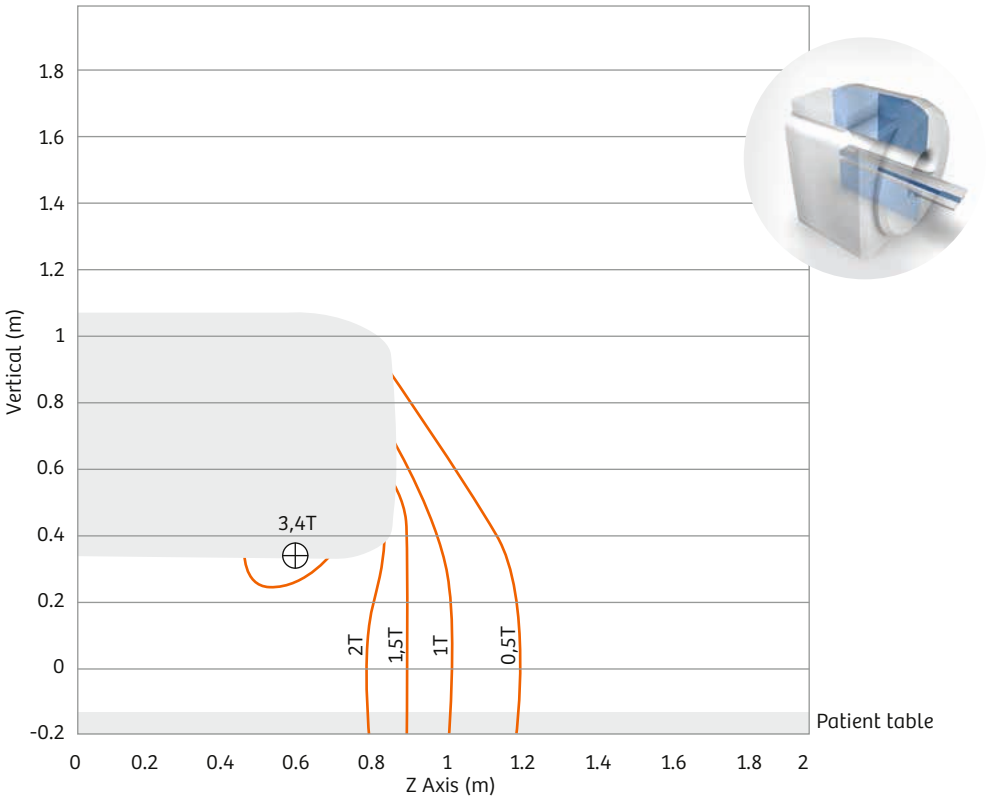
Static magnetic field

Criteria	MR relevance	Expected effects
Static magnetic field < 2T, below sensory effects ELV: green	1.5T systems, i.e., MAGNETOM Vision, MAGNETOM Symphony, MAGNETOM Symphony a Tim System, MAGNETOM Sonata, MAGNETOM Avanto, MAGNETOM Avanto^{fit}, MAGNETOM Espree, MAGNETOM ESSENZA, MAGNETOM Aera, MAGNETOM Amira, MAGNETOM Sempra 3T systems in areas < 2T (outside patient bore, see B_0 field distribution as shown in the SOM), i.e., MAGNETOM Spectra, MAGNETOM Skyra, MAGNETOM Prisma, MAGNETOM Vida	Indirect effects (interaction with implants, projectile risk)
Static magnetic field of 2T to 8T, below health effects ELV: yellow	3T systems in areas close to or inside patient bore, i.e., MAGNETOM Allegra, MAGNETOM Trio, MAGNETOM Trio A Tim System, MAGNETOM Verio, MAGNETOM Spectra, MAGNETOM Skyra, MAGNETOM Skyra^{fit}, MAGNETOM Prisma, MAGNETOM Prisma^{fit}, MAGNETOM Vida, Biograph mMR 7T system e.g. MAGNETOM Terra	Indirect effects as above, plus sensory effects (dizziness, nausea)
8T and higher, above health effects ELV: red	n.a.	n.a.

Movement in static magnetic field

Criteria	MR relevance	Expected effects
Movement in static magnetic field, below sensory effects ELV: 0.7 V / m	Example: 0.7 V / m corresponds to approx. 2 T / s e.g., a rotation around the head of 180° in a stray field of 1T in 1 s (MAGNETOM Skyra: 0.2 m from magnet cover) At higher stray fields, movement must be reduced further.	Sensory effects (dizziness, nausea)

Example taken from MAGNETOM Skyra SOM:



⊕ At this location, the value of the magnetic field B_0 is greatest.

This plot represents the 0.5T, 1T, 1.5T, and 2T iso-magnetic contours at positions accessible to and relevant for the MR operator as far as the static magnetic field in the isocenter exceeds any of these values.

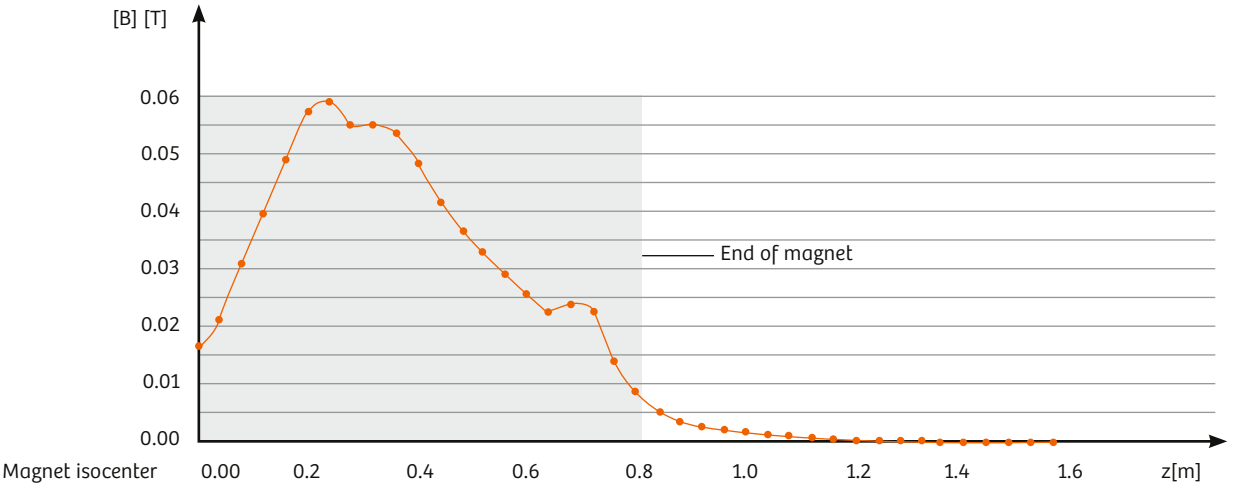
The diagram shows that outside the patient bore the static field is below 2T and thus below the sensory effects ELV. Sensory effects due to movement are not expected when movement speed corresponds to a field change of less than 2T / s (e.g., rotation around the head by 180° at 20 cm in front of the magnet cover in no less than 1 s).

2.2 Assessment Regarding Exposure to Switched Gradient Fields

The limit values depend on frequency and body area. For simplicity, we have used the worst-case scenario of 3 kHz, which relates to an AL of 100 µT for the head and torso.

Criteria	MR relevance	Expected effects
< 100 µT @ < 3 kHz, below AL: green	All systems, when head or torso is outside the patient bore	none
>> 100 µT or > 1.1 V / m, above ELF: red	All systems, when head or torso is inside the patient bore	Mild nerve or muscle stimulation

Example taken from MAGNETOM Skyra SOM:



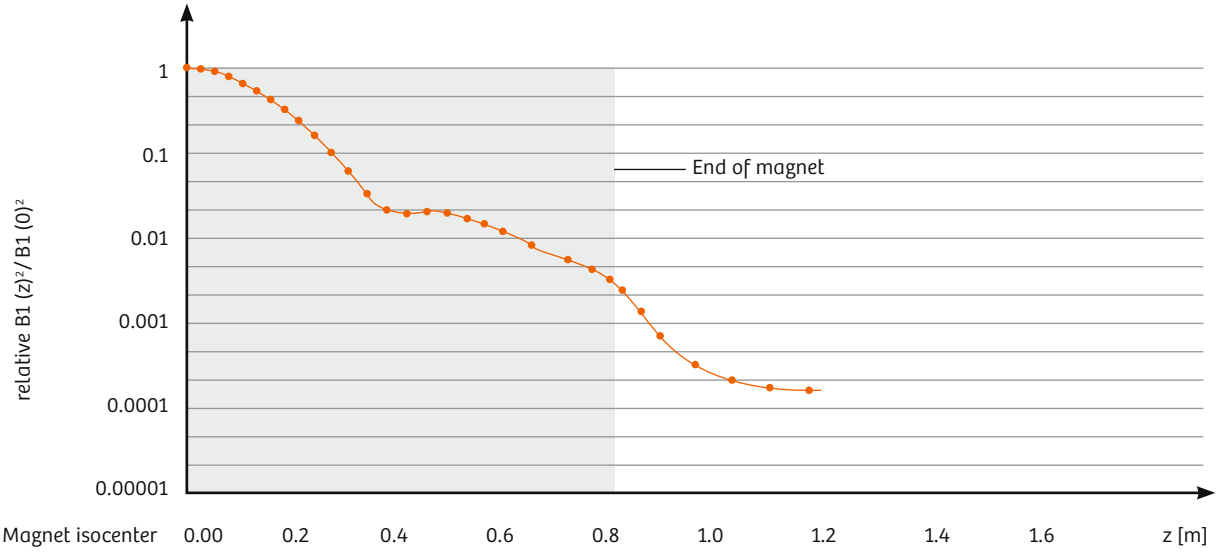
The area shaded in grey indicates the length of the magnet.

The diagram shows the maximum absolute field change due to the switched gradients (worst case, with all three axes superimposed at maximum amplitude). The exposure value falls below the AL of 100 µT at about 20 to 30 cm in front of the magnet cover.

2.3 Assessment Regarding Exposure to Radio Frequency Fields (RF fields)

Criteria	MR relevance	Expected effects
SAR < 0.4 W / kg, below ELV: green	Approx. > 30 cm outside isocenter	none

Example taken from MAGNETOM Skyra SOM:



RF power distribution relevant for assessing exposure to MR operators. The diagram shows the RF power distribution along the patient axis of the MAGNETOM Skyra according to the requirements of the IEC 60601-2-33 standard.

The RF field is calculated along the center line starting in the magnet isocenter. The area shaded in grey indicates the length of the magnet.

The ratio $B1(z)^2 / B1(0)^2$ provides a worst case estimation of the SAR contribution to a person who is positioned at a distance z from the isocenter. The SAR contribution is relative to the SAR that is applied to a person in the center of the patient bore.

For example, a person standing in front of the system aperture absorbs a maximum of 0.2% of the RF power, which is applied to a patient scanned in the center of the bore.

Assuming a maximum RF power corresponding to an SAR of 4 W / kg in the magnet's center, the diagram shows that SAR falls below 0.4 W / kg at a distance of 30 cm from the magnet's center. Outside the patient bore, the RF power is reduced to far less than 1% of that from the magnet's center. No workflow would make it likely that workers would enter the zone where SAR exceeds 0.4 W / kg.

3. Typical MR Use Cases

Use case	Please refer to the information in
During the MR examination, operators are outside the examination room.	
Operators prepare patient in the MR examination room.	Section 2
During the MR examination, operators are inside the examination room but outside the magnet (e.g., anesthesia).	Section 2.1
During the MR examination, operators are partially inside the magnet (e.g., interventional procedures)	Sections 2.1, 2.2, and 2.3

4. List of Siemens MR Systems

Up to 1T	MAGNETOM Impact, MAGNETOM Expert, MAGNETOM Harmony MAGNETOM C!
1,5T	MAGNETOM Vision, MAGNETOM Symphony, MAGNETOM Symphony a Tim System, MAGNETOM Sonata, MAGNETOM Avanto, MAGNETOM Avanto^{fit}, MAGNETOM Espree, MAGNETOM ESSENZA, MAGNETOM Aera, MAGNETOM Amira, MAGNETOM Sempra
3T	MAGNETOM Allegra, MAGNETOM Trio, MAGNETOM Trio A Tim System, MAGNETOM Verio, MAGNETOM Spectra, MAGNETOM Skyra, MAGNETOM Skyra^{fit}, MAGNETOM Prisma, MAGNETOM Prisma^{fit}, MAGNETOM Vida, Biograph mMR
7T	MAGNETOM Terra

5. Further Information

[1] DIRECTIVE 2013 / 35 / EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 26 June 2013 on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (electromagnetic fields).

[2] European Commission Directorate-General for Employment, Social Affairs, and Inclusion, Unit B3. Non-binding guide to good practice for implementing Directive 2013 / 35 / EU Electromagnetic Fields; Volume 1: Practical Guide, special. Luxembourg: Publications Office of the European Union. 2016. (Useful information can be found in Appendix F, Guidance on MRI, pp. 160-169)

[3] Siemens AG. System Owner Manual (part of the user documentation for Siemens MAGNETOM systems). Erlangen: Siemens AG. 2010-2012

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Notes

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