

INTERNATIONAL ELECTROTECHNICAL COMMISSION

IEC 60601-2-33
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**Medical electrical equipment -
 Part 2-33: Particular requirements for the basic safety and essential
 performance of magnetic resonance equipment for medical diagnosis**
INTERPRETATION SHEET 2

This interpretation sheet has been prepared by subcommittee 62B: Medical imaging equipment, software, and systems, of IEC technical committee 62: Medical equipment, software, and systems.

The text of this interpretation sheet is based on the following documents:

DISH	Report on voting
62B/1393/DISH	62B/1402/RVDISH

Full information on the voting for the approval of this interpretation sheet can be found in the report on voting indicated in the above table.

201.9.6.2.1.101 Acoustic noise requirements inside the MR EXAMINATION ROOM

The requirement is clarified as follows:

Exposure of the PATIENT, MR WORKERS and other persons is expressed as acoustic noise emission value, produced by MR EQUIPMENT, or the emission levels specified. Thus, exposure is not the sound level at or inside the ear, but the sound level to which the means for hearing protection is exposed.

The compliance section is clarified as follows:

The following expression shall be evaluated:

$$99 + \text{hearing protection value} > L_{Aeq,1h}$$

where $L_{Aeq,1h}$ is derived using the measured $L_{Aeq,20s}$ from NEMA MS4.

ICS 11.040.55

This implies that the PATIENT, MR WORKER and other persons will be protected from a 1-hour exposure at the loudest acoustic emission when measured in accordance with NEMA MS4, for 20 s.

201.7.9.3.101 Technical description of MR EQUIPMENT

b) Compatibility technical specification sheet (CTSS):

The requirement with respect to the magnet is clarified as follows:

The technical description discloses NOMINAL B_0 VALUE at MR ISOCENTRE in [T] with +/- 5 % accuracy.

The same tolerance is applicable for disclosure of the NOMINAL B_0 VALUE in the “About function” (201.7.2.2 Identification).

The requirement with respect to Gradient system is clarified as follows:

The technical description discloses maximum amplitude (in [mT/m]), MAXIMUM GRADIENT SLEW RATE (in [T/m/s]), under NORMAL CONDITION and in NORMAL USE

These values are intended to be identical to those for maximum spatial encoding gradient amplitude [mT/m] and MAXIMUM GRADIENT SLEW RATE [T/m/s] as displayed in the “About function” (201.7.2.2 Identification), and are specified for a (single) axis.

Such consistent use is intended for any parameter disclosed on the About Function UI.