

## INTERNATIONAL ELECTROTECHNICAL COMMISSION

### IEC 60601-2-33 Edition 4.0 2022-08

#### MEDICAL ELECTRICAL EQUIPMENT –

#### Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis

### INTERPRETATION SHEET 1

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/1315/DISH	62B/1319/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.

#### Definition 201.3.214 (EFFECTIVE STIMULUS DURATION $t_{s,eff}$ )

The definition is clarified by the following:

- It is important to consider that the magnetic field gradient displayed in Figure 201.101 can be realized by simultaneous activation of multiple GRADIENT UNITS.
- The concept of  $t_{s,eff}$  applies both to cardiac stimulation and peripheral nerve stimulation.
- The appropriate timescale for evaluating the duration of monotonic increase or decrease of the GRADIENT OUTPUT is in the order of the chronaxie. When a discrete time-segment based approach is used for numerical evaluation, one or more discrete time segments deviating from monotonic increase or decrease will likely not reset  $t_{s,eff}$  nor modify the likelihood of stimulation. Application of a filter as suggested in Annex AA (Formula AA.22) can prevent unintentional misinterpretation of monotonicity.

**Definition 201.3.219 (HEAD SAR)**

Note 1 to entry is clarified as follows:

Extent of the head as provided in the note to entry represents a common understanding of medical professionals. Variation in assessment volume for HEAD SAR is acceptable for use by the MR MANUFACTURER when implementing IEC 60601-2-33. For example, these volumes could be (tilted) axial demarcations of cervical vertebrae C3, C5, or C7.