Influence of patient head definition on induced E-fields during MR examination

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TECHNICAL NOTE

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Influence of patient head definition on induced E-fields during MR examination

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Abstract

Purpose: Radiofrequency (RF) exposure during MR examination is limited by IEC 60601-2-33 to prevent thermal hazards to patients. These limits are also the basis to derive the maximum induced field for the demonstration of MR safety of implants per ISO/TS 10974 (2018). One limit is the head-averaged specific absorption rate (SAR), for which the head extent is defined differently by MR and implant vendors. The purpose of this technical note is to inform MR safety stakeholders on the sensitivity of safety evaluations due to different head extent definitions.

Methods: RF distributions from the validated MRIxViP exposure libraries of 12 high-resolution human anatomical models were scaled to the normative SAR limits for different definitions of the head extent to compare the corresponding induced SAR and electric (E-)field levels.

Results: The definitions of the head extent used by major implant vendors and defined in ISO/TS 10974 (2018) are larger than those introduced in IEC 60601-2-33 (2022), resulting in lower RF head exposure by up to 2.4 dB (factor 1.7). Other proposed definitions of the head result in intermediate values.

Conclusion: The different head extents result in different maximum RF exposures affecting the risk assessment by up to a factor of 1.7. The results of this study can be used to estimate the additional uncertainty in safety assessments. Future revisions of MR standards should eliminate this inconsistency.

KEYWORDS

head, IEC 60601-2-33, implant testing, ISO 10974, MR safety, numerical simulation, RF exposure, RF-induced heating

1 | INTRODUCTION

The operating requirements of MR systems defined in IEC 60601-2-33[1] include definitions of the maximum whole-body and partial body averaged specific absorption rate (SAR) in order to prevent thermal hazards in patients exposed to radiofrequency (RF) electromagnetic fields. The limit for the averaged SAR in the head is 3.2 W/kg for both the Normal and First Level Controlled operating modes defined in IEC 60601-2-33. From these limits, the RF field distributions in patients are computed as a

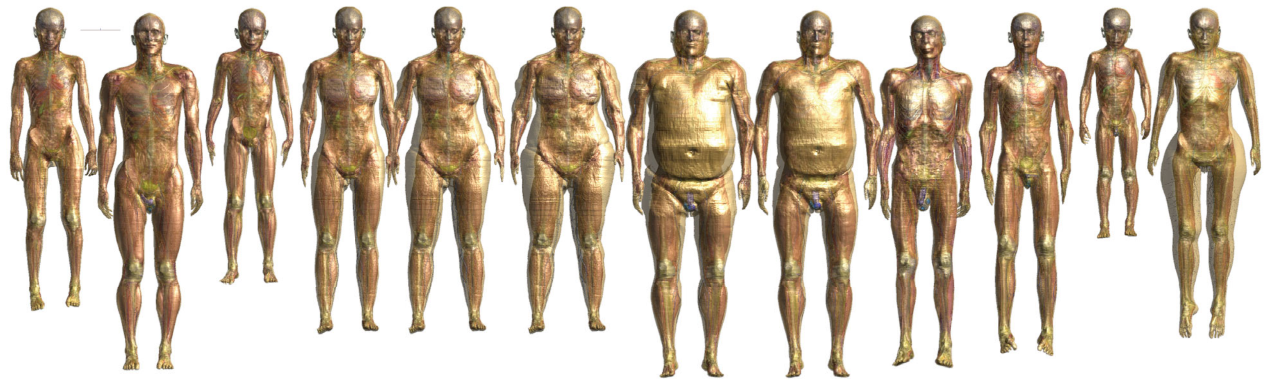

FIGURE 1 The 12 Virtual Population (ViP) phantoms included in MRIxViP V2.1, used in this study. From left to right: Billie, Duke, Eartha, Ella, EllaBMI26, EllaBMI30, Fats, FatsBMI29, Glenn, Louis, Thelonious, YoonSun. Landmark $z = 0$ cm is indicated with a horizontal line.

function of head anatomy and position to determine the thermal load in sensitive tissues, such as the eye and brain, as well as the worst-case exposure conditions of passive[2] and/or active[3] medical implants.

Prior to Ed 4.0 (2022) of IEC 60601-2-33, the anatomical extent of the head was not defined; whereas the technical specification ISO/TS 10974 ED 2 (2018) informative Annex P defines the head to be “within a region including the cranial and cervical vertebrae superior to C7 as necessary based on head tilt.”[3] IEC 60601-2-33 ED4.0 (2022) added a new note to the definition of head SAR: “The lower extent of the head is generally considered to be a line drawn from the foramen magnum anteriorly along the inferior border of the body of the mandible in closed mouth position,”[1] a definition which does not include any cervical vertebrae. None of these definitions are normative, as according to ISO/IEC guidelines “Notes shall not contain requirements … or any information considered indispensable for the use of the document, for example instructions (imperative mood), recommendations … or permission … ”.[4] Therefore, each vendor can use their own definition loosely following the notes in the standards.

On the other hand, it is obvious that the head extent affects the RF exposure and the associated risk assessment. Hence, the objective of this study is to determine the sensitivity of the induced fields upon different head definitions, allowing vendors and regulators to consider the differences in their uncertainty and risk assessments and to guide future revisions of the standards.

2 | METHODS

The deviation in the scaling of the induced electric (E-)fields, resulting from differing definitions of the head region, was determined for 12 high-resolution human anatomical models of the Virtual Population (ViP, IT’IS Foundation, Figure 1).[5] These anatomical phantoms were exposed to the RF fields of ten different sizes of whole-body volume transmit birdcage coils over imaging landmarks from the center of the head to the lower extremities, as part of the MRIxViP1.5T and MRIxViP3.0T exposure libraries qualified by the US Food and Drug Administration (FDA).[6] All assessments were performed at circular polarization and Normal Operating Mode.

The models were positioned as described in Annex P of ISO 10974, namely, with their arms along the sides of their bodies, at different landmarks along the axis of the bore (the z-axis). The reference point at the center of the cranium, used to define the head imaging position, was set between the eyebrows in longitudinal and horizontal axes, with allowance for head tilt, and aligned with the ears in anteroposterior direction. This reference point coincides with the RF-coil iso-center at the head imaging position, and is typically about 10 cm below the top of the head, depending on the anatomical model. We defined this position as $z = 0$ cm.

The exposure was evaluated from head to foot imaging positions, with each exposure simulating the intermediate imaging position along the longitudinal axes starting from $z = 0$ cm with the 5 cm (1.5 T) and 2.5 cm (3 T) steps of MRIxViP. Each landmark position refers to the location of the reference point with respect to the center of the RF coil.

The fields were computed with the IMAnalytics Module V3.0 of Sim4Life V7.0, using the MRIxViP1.5T and MRIxViP3.0T V2.1 exposure libraries of RF-induced E-field distributions inside the ViP anatomical phantoms for the defined birdcage, shown in Figure S1.[6] The results were previously validated by direct simulation of the ViP model Duke with the verified electromagnetic

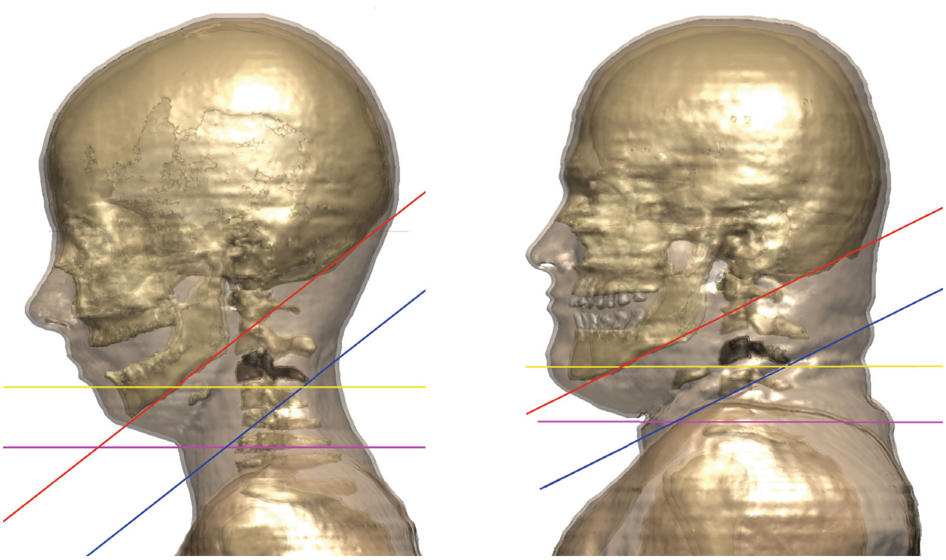

FIGURE 2 ViP phantoms Ella (left) and Fats (right) demonstrating the four possible lower extents of the definition of the head considered in this study: the reference definition from Annex P of ISO/TS 10974 (2018) (purple); a line angled along the jawline from the opisthion ("Op," red), considered to satisfy the definition note of IEC 60601-2-33 ED4.0 (2022); a horizontal line which fully includes the third cervical vertebra ("C3," yellow); and a line matching the opisthion definition but extended to fully include C3 ("Op→C3," blue). The C3 vertebrae are colored black for reference.

finite-difference time-domain (EM-FDTD) solver of SEMCAD/Sim4Life 7.0, exposed to a Huygens' field from the same RF coil model driven in circular polarization.[3,6]

The peak E_{rms} fields over the adjustment volume are normalized to the MR examination limit following the procedure previously reported[7]: the B_1 field is increased until one of the head SAR (as defined with the corresponding head SAR mask, see Annex), the whole-body SAR, or partial-body SAR in the model at the landmark reaches the limit specified by IEC 60601-2-33 for Normal Operating Mode. The scaling of the B_1 field strength to reach this limit is compared for the different definitions of the head, and the results are presented in decibels relative to the reference head definition.

The results were calculated for both operating frequencies, all ten RF coils, and all 12 anatomical phantoms available in MRIxViP V2.1, at circular polarizations. Generalization to other anatomical models, coil designs, polarizations and/or operating frequencies is not possible from these results.

Four definitions of the head were considered in this study, as shown in Figure 2. The reference head definition for each anatomical phantom was taken to be the set of masks described in Annex P of ISO/TS 10974 (2018), indicated in Figure 2 by a purple line. A survey of major implant vendors participating in IEC 60601-2-33 and ISO 10974 confirmed that they used this definition, with minimal variations, for SAR-based risk assessments. The definition of the lower extent of the head which includes the whole skull and complies with the definition note of IEC 60601-2-33 ED4.0 (2022) was taken to be a line angled along the jaw from the opisthion ("Op", red). Two further definitions were considered: a horizontal mask that fully includes the third cervical vertebra ("C3", yellow), and a line matching the opisthion definition but extended to fully include C3 ("Op→C3", blue).

3 | RESULTS

The exposure is illustrated in Figure 3 and the resulting differences are presented in Table 1. It shows the maximum deviation, in decibels, in the RF fields at the Normal Operating Mode SAR limit for the indicated head definition, from that of Annex P of ISO 10974, over all ten RF body coils of the MRIxViP libraries in circular polarizations. As the assessed definitions of the head are all smaller in extent than the reference definition, the deviations are positive, *i.e.*, resulting in higher predictions of E-fields at the Normal Operating Mode SAR limit than the definition used by implant vendors and defined in ISO/TS 10974 (2018).

The results show that estimating the patient head SAR using the opisthion ("Op") definition of the head, representing the definition note of IEC 60601-2-33 ED4.0 (2022), permits RF exposures at Normal Operating Mode which are 2.4 dB (factor 1.7 in E^2) greater than the head definition used by implant vendors, in ViP phantom Fats. The alternative definitions, which include the C3 vertebra, result in deviations of 1.2 – 1.9 dB (factor 1.3 – 1.5 in E^2) greater than the reference definition in the same phantom. The differences in other phantoms are lesser, and are tabulated in Table S1.

4 | DISCUSSION

The motivation for specifying a separate head SAR limit was to enable higher field power while protecting sensitive

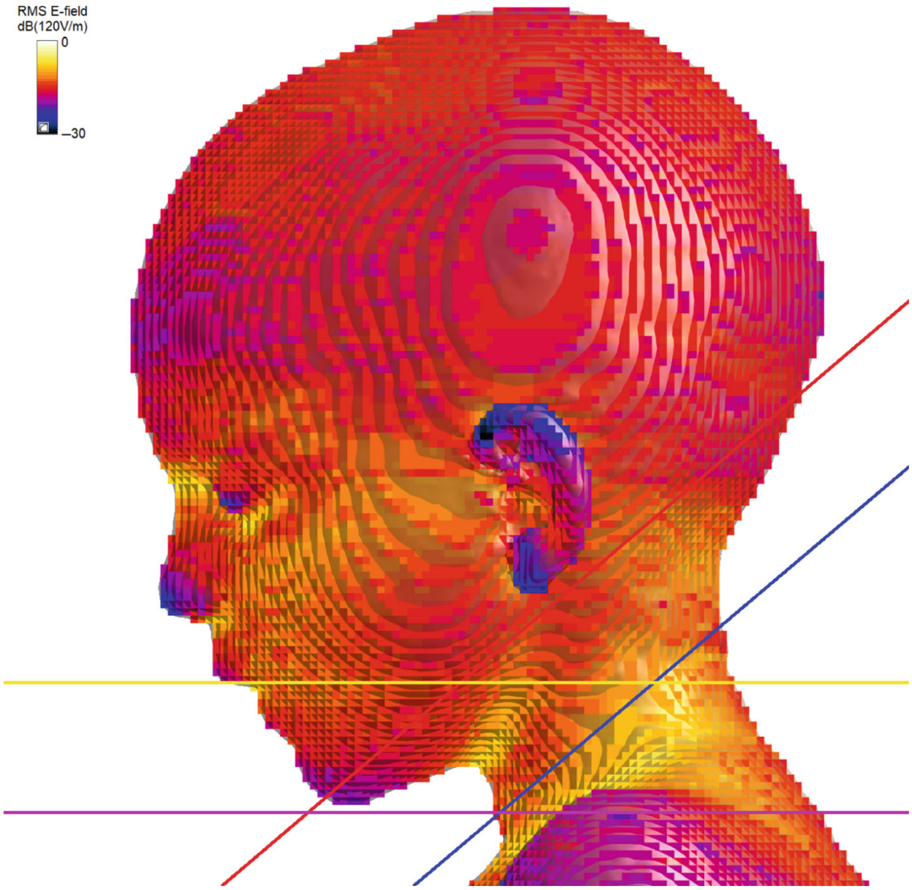

FIGURE 3 Representative head exposure of ViP phantom Thelonious at 64 MHz. The colored lines indicate the head definitions as described in Figure 2. Typical hotspots at the bridge of the nose, around the eye socket, and near the collarbone are visible.

tissues, especially the eye and brain, from excessive local SAR and corresponding temperature rise. Earlier editions of IEC 60601-2-33, and corresponding FDA guidance,[8] specified local SAR limits in the head; these limits were subsequently removed, with the rationale from literature (e.g., Reference 9) that a 3.2 W/kg head SAR limit was sufficient to limit local temperature rise in the brain and eye. It is thus noteworthy that the local SAR throughout the head, *e.g.* in the eye, is sensitive to the definition of head extents as demonstrated in this study; it is not "merely" tissues located between different head extent definitions, such as the brain stem, which are affected. The demonstrated approach could be also used to specifically assess the impact on local SAR of sensitive tissues, such as the eye or the brain stem, due to different definitions of the head.

Obviously the extent of the head affects the averaged SAR. Due to the hot spots in the shoulders, the maximum RF field to maintain the limits of 3.2 W/kg is lower if the head extent is enlarged, hence the head extent is the dominant factor for maximum field strength.

The primary reason behind the larger deviation in ViP phantom Fats is likely the low position of the C7 vertebra with respect to the shoulder line. The neck region is a characteristic SAR hotspot during MR examination,[10] and the fact that the presented head extents variously include, partially include, or fully exclude this hotspot results in large variations.

The presented approach and results can be used to estimate the offsets in the safety assessments caused by the differing head definitions. In other words, the definition used by the implant vendors results in lower maximum field strength, and has the potential to underestimate the risk when the MR vendors used a different definition to define their applied levels. However, it should be noted that MR vendors might use different anatomical phantoms and assignment of tissue properties than used in this study, and might use additional safety factors, which also affect the results. These unknowns clearly call for a unification of the definition. Applying the larger extent would reduce the maximum exposure and make the standard consistent with implant testing.

Alternative definitions for implant safety assessments, namely, specification of maximum B_1+ levels instead of SAR-limited operating modes, would make the assessment independent of the definition of head extents and would also address the problem; however, some regulators prefer implant vendors to utilize SAR-based limits, or both SAR and B_1+ labels, when applying for MR conditional labeling.

TABLE 1 Maximum deviation, in decibels, in radiofrequency (RF) field strength scaling to reach the Normal Operating Mode specific absorption rate (SAR) limit for the indicated head definition, from that of Annex P of ISO/TS 10974 (2018), over all 10 RF body coils and all 12 anatomical phantoms of the MRIxViP libraries in circular polarizations.

Landmark[a] (mm)	Max. deviation, 1.5 T (dB)		
	C3	Op→C3	Op
0	0.8	0.9	1.4
50	1.0	1.2	1.7
100	1.3	1.4	2.0
150	1.5	1.9	**2.4**
200	0.6	0.6	0.6
250	0.0	0.0	0.0
300	0.0	0.0	0.0
	Max. deviation, 3 T (dB)		
0	0.6	0.6	1.1
25	0.6	0.7	1.1
50	0.7	0.7	1.2
75	0.8	0.7	1.3
100	1.0	0.9	1.6
125	1.0	1.0	1.7
150	0.9	1.2	2.1
175	1.0	1.4	**2.4**
200	1.2	1.6	2.3
225	1.2	1.5	2.0
250	1.0	1.3	1.8
275	0.9	1.1	1.1
300	0.2	0.2	0.2

Notes: All the deviations are positive, that is, resulting in higher predictions of E-fields at the Normal Operating Mode SAR limit than the ISO/TS 10974 (2018) definition. The maximum deviations, occurring in ViP models Fats and FatsBMI29, are indicated in bold.
Abbreviations: C3, Axis-aligned box containing C3 vertebra; Op→C3, box angled along opisthion line shifted to contain the C3 vertebra; Op, box angled along opisthion line.
[a] The reference landmark 0 mm is defined as in Annex P of ISO 10974, that is, the center of the cranium, between the eyebrow in longitudinal and horizontal axes, and aligned with the ears in anteroposterior direction.

5 | CONCLUSIONS

The extents of the head used by major implant vendors and defined in ISO/TS 10974 (2018) are larger than those introduced in IEC 60601-2-33 (2022), resulting in lower estimates of the RF head exposure by up to 2.4 dB (factor 1.7 in E^2) at Normal and First Level Operating Mode in the twelve ViP phantoms studied. Other potential definitions of the head result in intermediate values. This mismatch may result in under- or over-estimation of the risks posed by the RF exposure in the head tissues during SAR-limited MR examinations.

These differences should be considered in the risk assessment, and requires that MR and implant vendors specify which definition of the head was applied when estimating the maximum patient RF exposure during SAR-limited head and shoulder MR examinations. Where possible, safety assessments should be referenced to B_1+ levels, if regulators and MR technicians are comfortable with such labeling.

The existence of two nonnormative, incompatible definitions of the head in two related standards should be addressed by the community, and harmonized as soon as possible.

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CONFLICT OF INTEREST STATEMENT

The authors declare no potential conflict of interest.

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SUPPORTING INFORMATION

Additional supporting information may be found in the online version of the article at the publisher's website.

Figure S1. Numerical models and dimensions of the 10 two-port radiofrequency coils in BCLib, used to generate the MRIxViP exposure library. The bore diameters are 5 cm smaller than the indicated RFcoil inner diameters.

Table S1. Maximum deviations from Table 1, broken down by anatomical phantom.

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