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Edition 2.0 2018-12

INTERNATIONAL STANDARD

NORME INTERNATIONALE

Magnetic resonance equipment for medical imaging – Part 1: Determination of essential image quality parameters

Appareils à résonance magnétique pour imagerie médicale – Partie 1: Détermination des principaux paramètres de qualité d'image

IEC 62464-1:2018-12(en-fr)

IEC Central Office
3, rue de Varembé
CH-1211 Geneva 20
Switzerland

Tel.: +41 22 919 02 11
info@iec.ch
www.iec.ch

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Magnetic resonance equipment for medical imaging – Part 1: Determination of essential image quality parameters

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MAGNETIC RESONANCE EQUIPMENT FOR MEDICAL IMAGING –

Part 1: Determination of essential image quality parameters

FOREWORD

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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International Standard IEC 62464-1 has been prepared by subcommittee 62B: Diagnostic imaging equipment, of IEC technical committee 62: Electrical equipment in medical practice.

This second edition cancels and replaces the first edition published in 2007. This edition constitutes a technical revision.

This edition includes the following significant technical changes with respect to the previous edition:

a) the tests have been revised to comply with the technical progress;
b) the range of B_0 was increased from 4 T to 8 T.

The text of this International Standard is based on the following documents:

CDV	Report on voting
62B/1068/CDV	62B/1078/RVC

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

This document has been drafted in accordance with the ISO/IEC Directives, Part 2.

In this document, the following print types are used:

- requirements, compliance with which can be tested, and definitions: roman type;
- explanations, advice, notes, general statements and exceptions: smaller roman type;
- *test specifications: italic type;*
- TERMS DEFINED IN CLAUSE 3 OR IN OTHER INTERNATIONAL STANDARDS: SMALL CAPITALS.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex B.

A list of all the parts in the IEC 62464 series, published under the general title *Magnetic resonance equipment for medical imaging*, can be found on the IEC website.

The committee has decided that the contents of this document will remain unchanged until the stability date indicated on the IEC website under "http://webstore.iec.ch" in the data related to the specific document. At this date, the document will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

INTRODUCTION

This part of IEC 62464 is written at a moment in which the magnetic resonance (MR) equipment is already present in the market place for more than 30 years. It is estimated that more than 30 000 scanners are operational and more than 0,5 billion PATIENTS have been scanned. A number of standards on quality assurance and quality control have been developed by National Committees to address the need for quantitative assessment of system performance and system maintenance. It is therefore felt to be necessary to introduce this document in addition to the existing standards on MR safety, because the IEC standards have a true international character and this document combines current best practices together and provides guidance on how to address the various questions on quality control and quality assurance testing of MAGNETIC RESONANCE EQUIPMENT together. Having a standardised set of test methods minimises the amount of work for the MR MANUFACTURERS to demonstrate the performance characteristics of the MR scanners for many different countries and, in addition, these countries do not have to formulate their own requirements for the performance testing.

Since MR scanners have been used for some time, this document is an attempt to consolidate the current way of working for the quality control of the performance characteristics concerning essential image quality parameters, and does not introduce major new development efforts for the established MR EQUIPMENT to fulfil the requirements of this document. This objective is achieved by introducing preferred methods in the main text, while allowing acceptable alternative test methods, described in Annex A. A number of the ACCEPTANCE TEST methods described in this document are already described earlier, mainly as NEMA technical MR standards, and new methods have been developed since then. For this document, it is attempted to select the best method as preferred method, whereas for a number of specific tests, good alternatives are available and are therefore also acceptable.

Also, for the quality assurance tests, the CONSTANCY TESTS, each MANUFACTURER has developed its own TEST DEVICE and related test procedures and data analysis in the past years. For the CONSTANCY TESTS, it was therefore decided not to describe detailed test methods but only prescribe the parameters to be measured and essential conditions for these measurements in the main text. This provides the necessary latitude to account for the many unique MR designs (extremity scanners, whole body scanners, cylindrical versus open scanners, various field strengths, TEST DEVICE design, and data analysis) and examples for possible CONSTANCY TESTS for the required parameters in Annex A.

This document draws on the practical experiences gained in the implementation of IEC 62464-1:2007 and benefits from the continued improvements found in the associated updated NEMA MS series of standards. The utility in implementing the various tests found herein was improved by clarifying the relationship between the tests, the parameters used, the analysis of results, the expected calibration state of the scanner and the reporting of results. Two tests, with no known sensitivity to, for example, field strength considerations (SPATIAL RESOLUTION, SLICE THICKNESS in 2-D scanning), now have acceptance criteria. The Annex A GEOMETRIC DISTORTION test suite now includes 3-D test methods.

An original goal of IEC 62464-1:2007 was linkage of the SNR, SLICE THICKNESS and resolution tests in order to characterize the system in a consistent configuration. However, increasing the range of B_0 covered in this document from 4 T to 8 T (consistent with the recent changes in IEC 60601-2-33) required additional flexibility in the TEST DEVICE filler composition in order to eliminate confounding wavelength ARTEFACTS. Therefore, the various test clauses are decoupled in this document. This permits the flexibility to perform each test in an optimal configuration and does not require a retest of other parameters. For example, it is not necessary to repeat a resolution test for a RF COIL, which is not a function of the RF COIL, when the objective is to measure only SNR.

It was not possible to establish a full set of TEST DEVICE and scan parameter requirements appropriate for all MRI systems at the full range of B_0 permitted in this document. Instead, this document was modified to state that testing shall be performed in an MRI system that has been properly calibrated for routine clinical scanning. Calibration is specific to the make and model of MRI scanner and no requirements are listed in this document.The flexibility in the

definition of specification areas and volumes was improved to support the increasing specialization of receive coils. The standard encourages reuse of phantoms for multiple applications where possible, as long as the phantom provides signal in the specification area and/or volume as required, unless instructed otherwise.

This document has also been modified regarding the use of reconstruction and image filters. The intent of IEC 62464-1:2007 was to disable all user controlled filters, and record the condition of all other filters, in order to characterize the system in the most basic possible configuration. However, systems continue to evolve and the presence and configuration of some filters are not known to the end user (e.g. image reconstruction), whereas other filters might be known to the end user, beyond their control, and always applied (e.g. GEOMETRIC DISTORTION correction). This document formally introduces two mechanisms for addressing this situation: 1) the concept of "clinically relevant" to provide guidance on filter settings and 2) an emphasis on the accurate recording of all parameters used in the acquisition and reconstruction of the images sufficient to enable a faithful reproduction of results on another unit of the same make, model and software revision. The intent of "clinically relevant" is to enable a known and properly identified protocol from a given software revision to be used as the basis for the tests. Factory set defaults are assumed to be applied, and filters considered not essential can be turned on or off as clinically appropriate. All adjustments made from default setting should be recorded in the reporting of results. By carefully recording the base system configuration and any additional acquisition parameter adjustments, all known and unknown filter settings are reproducible and all results should be repeatable. Note that "clinically relevant" also enables the user of this document to appropriately select parameters (e.g. acquisition bandwidth) that may vary with B_0 or other system attributes.

MAGNETIC RESONANCE EQUIPMENT FOR MEDICAL IMAGING –

Part 1: Determination of essential image quality parameters

1 Scope

This part of IEC 62464 specifies measurement procedures for the determination of many essential image quality parameters for MR EQUIPMENT. Measurement procedures as addressed in this document are suitable for

– quality assessment in the ACCEPTANCE TEST, and
– quality assurance in the CONSTANCY TEST.

Required levels of performance for ACCEPTANCE TESTS are not provided for all tests.

This document does not address

– image quality assessment of MR EQUIPMENT with a static magnetic field intensity greater than 8 Tesla, if not otherwise stated,
– image quality affected by MR-compatibility issues,
– special diagnostic procedures such as flow imaging, perfusion, diffusion, radiotherapy and image-guided therapy applications, and
– TYPE TESTS.

The scope of this document is also limited to measuring image quality characteristics in images acquired on TEST DEVICES, not in PATIENT images.

The measurement procedures specified in this document are directed to

– MANUFACTURERS, who can demonstrate compliance by performing ACCEPTANCE and CONSTANCY TESTS as described by this document,
– test houses, who can confirm performance of MR EQUIPMENT using methods described in this document,
– regulatory authorities, who can reference this document, and
– RESPONSIBLE ORGANISATIONS who want to perform ACCEPTANCE and CONSTANCY TESTS using methods described in this document.

The essential image quality parameters and measurement methodologies defined in this document are

– SIGNAL TO NOISE RATIO,
– UNIFORMITY,
– SLICE THICKNESS in 2-D scanning,
– 2-D GEOMETRIC DISTORTION,
– SPATIAL RESOLUTION, and
– GHOSTING ARTEFACTS.

Each of these procedures can be performed standalone or in combination with any of the other procedures.

This document describes the preferred measurement procedures. It also describes alternative normative methods in Annex A. The preferred test methods may be substituted with these

alternative normative methods. If necessary, other methods not described in this document can be used, provided those other test methods are documented and validated against the methods described in the document: it means an analysis is done by comparison to the original method that demonstrates a similar, or better, level of sensitivity to the same parameter of interest and a similar, or better, level of robustness against unrelated parameters. All methods will produce quantitative results.

The rationale to the preferred and alternate methods, and their pitfalls, are described in Annex B.

This document also presents requirements for CONSTANCY TESTS suitable for MR EQUIPMENT quality assurance programs concerning essential image quality parameters. There are no preferred CONSTANCY TEST methods, to provide flexibility in using existing automated procedures where available, but suggested examples of test methods can be found in Annex A. This document places an emphasis on consistently repeatable, automated measuring tools that facilitate trend analysis and the frequent quick testing of a small set of important parameters that are sensitive to the overall operating characteristics of the MR EQUIPMENT.

NOTE None of the methods found in this document have been extensively tested at a static magnetic field intensity above 3 T. Initial tests indicate the methods function correctly when appropriate TEST DEVICE fillers are used.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
IEC 60601-1:2005/AMD1:2013

IEC 60601-2-33:2010, *Medical electrical equipment – Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis*

IEC TR 60788, *Medical electrical equipment – Glossary of defined terms*

3 Terms, definitions, symbols and abbreviated terms

3.1 Terms and definitions

For the purposes of this document, the terms and definitions in IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, IEC 60601-2-33, IEC TR 60788 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp

NOTE 1 See also the IEC Glossary available at http://std.iec.ch/glossary.

NOTE 2 An index of defined terms is found beginning on page 86.

3.1.1
ACCEPTANCE TEST
test carried out after new equipment has been installed, or major modifications have been made to existing equipment, in order to verify compliance with contractual specifications

[SOURCE: IEC 61223-3-5:2004, 3.1]

3.1.2
ARTEFACT
apparent structure visible in the image that does not represent a structure at the corresponding position within the object and that cannot be explained by noise

3.1.3
BANDWIDTH PER PIXEL
BPP
reciprocal of the duration of the sampling window

Note 1 to entry: Instead of BANDWIDTH PER PIXEL, alternate values may be stated on the control console in a MANUFACTURER-specific format. For a rationale on how to convert the MANUFACTURER-specific information into the required BANDWIDTH PER PIXEL, see B.2.1.5.

Note 2 to entry: This definition is only applicable when standard, constant-gradient readout is used.

Note 3 to entry: This note applies to the French text only.

3.1.4
CONSTANCY TEST

each of a series of tests carried out to ensure that the functional performance of equipment meets established criteria; or to enable the early recognition of changes in the properties of components of the equipment

[SOURCE: IEC 61223-3-5:2004, 3.2]

3.1.5
EDGE SPREAD FUNCTION
ESF
discrete profile of the image data, taken across a sharp edge

Note 1 to entry: This note applies to the French text only.

3.1.6
FIELD OF VIEW
FOV
size of the imaging area requested by the OPERATOR

Note 1 to entry: To be specified with one or two linear measures (in mm), if imaging area is square or rectangular respectively.

3.1.7
FULL WIDTH AT HALF-MAXIMUM
FWHM
interval parallel to the abscissa between the points on a curve with the value of one-half of the maximum of the curve

[SOURCE: IEC 61223-2-6:2004, 3.9]

3.1.8
GEOMETRIC DISTORTION
spatial position deviation of the imaged structure from expected position of real object structure

3.1.9
GHOSTING ARTEFACT
ARTEFACT showing a replica or part of a replica of an existing structure in a wrong position

3.1.10
IMAGE NOISE
amplitude of the random fluctuations from the expected signal values in an image

3.1.11
ISOCENTRE
null point of the spatially encoding gradients

Note 1 to entry: Typically, this also corresponds to the region of highest magnet homogeneity.

3.1.12
LINE SPREAD FUNCTION
LSF
complex derivative of the EDGE SPREAD FUNCTION

Note 1 to entry: This note applies to the French text only.

3.1.13
MAGNETIC RESONANCE EQUIPMENT
MR EQUIPMENT
MEDICAL ELECTRICAL EQUIPMENT which is intended for in vivo magnetic resonance examination of a PATIENT comprising all parts in hardware and software from the SUPPLY MAINS to the display monitor

Note 1 to entry: The MR EQUIPMENT is a PROGRAMMABLE ELECTRICAL MEDICAL SYSTEM (PEMS).

[SOURCE: IEC 60601-2-33:2010, 201.3.218]

3.1.14
MANUFACTURER
natural or legal person with responsibility for the design, manufacture, packaging, or labelling of ME EQUIPMENT, assembling an ME SYSTEM, or adapting ME EQUIPMENT or an ME SYSTEM, regardless of whether these operations are performed by that person or on that person's behalf by a third party

[SOURCE: IEC 60601-1:2005, 3.55, modified – The notes have been deleted.].

3.1.15
MODULATION TRANSFER FUNCTION
MTF
normalised magnitude of the Fourier transform of the LINE SPREAD FUNCTION

3.1.16
OPERATOR
person handling equipment

[SOURCE: IEC 60601-1:2005, 3.73]

3.1.17
PATIENT
living being (person or animal) undergoing a medical, surgical or dental procedure

Note 1 to entry: A PATIENT can be an OPERATOR.

[SOURCE: IEC 60601-1:2005, 3.76, modified – The note has been added.]