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Magnetisk resonansutrustning för medicinsk bildframställning – Del 1: Bestämning av väsentliga bildkvalitetsparametrar

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

Som svensk standard gäller europastandarden EN IEC 62464-1:2019. Den svenska standarden innehåller den officiella engelska språkversionen av EN IEC 62464-1:2019.

Nationellt förord

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- **IEC 62464-1, Second edition, 2018 - Magnetic resonance equipment for medical imaging - Part 1: Determination of essential image quality parameters**

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English Version

**Magnetic resonance equipment for medical imaging - Part 1:
Determination of essential image quality parameters
(IEC 62464-1:2018)**

Appareils à résonance magnétique pour imagerie médicale
- Partie 1: Détermination des principaux paramètres de
qualité d'image
(IEC 62464-1:2018)

Magnetresonanzgeräte für die medizinische Bildgebung -
Teil 1: Bestimmung der wesentlichen Bildqualitätsparameter
(IEC 62464-1:2018)

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Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CENELEC member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

European foreword

The text of document 62B/1068/CDV, future edition 2 of IEC 62464-1, prepared by SC 62B "Diagnostic imaging equipment" of IEC/TC 62 "Electrical equipment in medical practice" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN IEC 62464-1:2019.

The following dates are fixed:

- latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2019-10-17
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2022-01-17

This document supersedes EN 62464-1:2007.

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Endorsement notice

The text of the International Standard IEC 62464-1:2018 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following note has to be added for the standard indicated:

IEC 61223-3-5:2004 NOTE Harmonized as EN 61223-3-5:2004 (not modified)

Annex ZA (normative)

Normative references to international publications with their corresponding European publications

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.

NOTE 1 Where an International Publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

NOTE 2 Up-to-date information on the latest versions of the European Standards listed in this annex is available here: www.cenelec.eu.

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
IEC 60601-1	2005	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	EN 60601-1	2006
-	-		+ corrigendum Mar.	2010
-	-		+ A12	2014
+A1	2013		+A1	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	EN 60601-2-33	2010
-	-		+ corrigendum Oct.	2010
-	-		+ A11	2011
-	-		+ A12	2016
IEC/TR 60788	-	Medical electrical equipment - Glossary of defined terms	-	-

CONTENTS

FOREWORD.....	6
INTRODUCTION.....	8
1 Scope.....	10
2 Normative references	11
3 Terms, definitions, symbols and abbreviated terms.....	11
3.1 Terms and definitions.....	11
3.2 Symbols and abbreviated terms	15
4 * Procedures for the determination of essential image parameters.....	16
4.1 General requirements for all procedures	16
4.1.1 Requirements for the system	16
4.1.2 Requirements for the TEST DEVICE	16
4.1.3 Scan parameters	16
4.1.4 Reporting of results	17
4.2 * SIGNAL TO NOISE RATIO	20
4.2.1 Objectives and rationale	20
4.2.2 Requirements for the TEST DEVICE	20
4.2.3 Scan parameters	20
4.2.4 Measurement procedure	20
4.2.5 Data analysis and tolerances	21
4.2.6 Reporting of results	21
4.3 * UNIFORMITY	22
4.3.1 Objectives and rationale	22
4.3.2 Requirements for the TEST DEVICE	22
4.3.3 Scan parameters	22
4.3.4 Measurement procedure	23
4.3.5 Data analysis and tolerances	23
4.3.6 Reporting of results	23
4.4 SLICE THICKNESS in 2-D scanning.....	24
4.4.1 Objectives and rationale	24
4.4.2 Requirements for the TEST DEVICE	24
4.4.3 Scan parameters	25
4.4.4 Measurement procedure	26
4.4.5 Data analysis and tolerances	26
4.4.6 Reporting of results	27
4.4.7 Reporting of acceptance results.....	27
4.5 * Two-dimensional GEOMETRIC DISTORTION.....	27
4.5.1 Objectives and rationale	27
4.5.2 * Requirements for the TEST DEVICE	28
4.5.3 Scan parameters	30
4.5.4 * Measurement procedure.....	30
4.5.5 * Data analysis and tolerances	31
4.5.6 Reporting of results	32
4.6 * SPATIAL RESOLUTION.....	32
4.6.1 Objectives and rationale	32
4.6.2 Requirements for the TEST DEVICE	32
4.6.3 Scan parameters	33
4.6.4 Measurement procedure	34

4.6.5	Data analysis and tolerances	35
4.6.6	Reporting of results	35
4.6.7	Reporting of acceptance results.....	36
4.7	* GHOSTING ARTEFACTS	36
4.7.1	Objectives and rationale	36
4.7.2	* Requirements for the TEST DEVICE	36
4.7.3	Scan parameters	36
4.7.4	Measurement procedure	37
4.7.5	Data analysis and tolerances	37
4.7.6	Reporting of results	38
5	* CONSTANCY TEST	39
5.1	Objectives and rationale	39
5.2	Requirements for the TEST DEVICE	39
5.3	Scan characteristics.....	39
5.4	Measurement procedure	39
5.5	Data analysis, reporting of results and tolerances	40
Annex A	(normative) Alternative methods	41
A.1	Pertaining to 4.2 SIGNAL TO NOISE RATIO.....	41
A.1.1	General	41
A.1.2	Alternative method: SNR measurements using alternative noise determination.....	41
A.1.3	Alternative method: SNR "single image"	42
A.2	Pertaining to 4.3 UNIFORMITY.....	43
A.2.1	General	43
A.2.2	Alternative method "grey-scale map"	43
A.2.3	Alternative method "ACR method"	45
A.3	Pertaining to 4.4 SLICE THICKNESS in 2-D scanning	45
A.3.1	General	45
A.3.2	Alternative method: SLICE THICKNESS in 2-D scanning: wedge method	46
A.4	Pertaining to 4.5 Two-dimensional GEOMETRIC DISTORTION.....	48
A.4.1	General	48
A.4.2	Alternative method: GEOMETRIC DISTORTION measurements using elliptical boundary TEST DEVICES	48
A.4.3	Alternative method: 3D GEOMETRIC DISTORTION component measurement method	49
A.5	Pertaining to 4.6 SPATIAL RESOLUTION	56
A.5.1	General	56
A.5.2	Alternative method: determination of the full MODULATION TRANSFER FUNCTION	57
A.6	Pertaining to 5 CONSTANCY TESTS.....	58
A.6.1	Alternative CONSTANCY TEST methods.....	58
A.6.2	Pitfalls	61
Annex B	(informative) Rationale.....	62
B.1	Pertaining to 4 * Procedures for the determination of essential image parameters	62
B.2	Pertaining to 4.2 SIGNAL TO NOISE RATIO	62
B.2.1	Rationale	62
B.2.2	References	75
B.3	Pertaining to 4.3 UNIFORMITY.....	75
B.3.1	Rationale	75

B.3.2	AAD method	75
B.3.3	Standing waves	75
B.4	Pertaining to 4.5 Two-dimensional GEOMETRIC DISTORTION.....	76
B.4.1	Rationale	76
B.4.2	Pitfalls	77
B.5	Pertaining to 4.6 SPATIAL RESOLUTION.....	81
B.5.1	Rationale	81
B.5.2	Pitfalls	82
B.6	Pertaining to 4.7 GHOSTING ARTEFACTS	83
B.6.1	Rationale	83
B.6.2	Pitfalls	83
B.6.3	References	84
B.7	Pertaining to 5 CONSTANCY TEST – Rationale	84
	Index of defined terms	86
	Bibliography.....	87
	Figure 1 – Signal intensity profile in the inclined slab method	25
	Figure 2 – Correcting for rotation of TEST DEVICE	27
	Figure 3 – Example of a boundary wall TEST DEVICE for a spherical specification volume with two lines passing through the centre.....	29
	Figure 4 – Example of a fiducial marker TEST DEVICE for a spherical specification volume.....	30
	Figure 5 – Distances to be determined.....	31
	Figure 6 – Periodic pattern.....	33
	Figure 7 – Image of periodic pattern and position of ROI for coronal scans	34
	Figure 8 – Image of periodic pattern and position of ROI for transverse and sagittal scans.....	35
	Figure 9 – Example image of the TEST DEVICE and region of interest (ROI) for signal, ghost, and noise measurements.....	38
	Figure A.1 – Wedge TEST DEVICE.....	46
	Figure A.2 – Measurement of SLICE PROFILE and SLICE THICKNESS using wedge TEST DEVICE.....	47
	Figure A.3 – Determination of radius length of an ellipse with semi axis length a and b forming an angle α with respect to the X axis	49
	Figure A.4 – Possible TEST DEVICE configurations for measuring GEOMETRIC DISTORTION.....	51
	Figure A.5 – Two elements with an apparent spacing of $A_i(x,y)$ but a true spacing of $T_i(x,y)$	53
	Figure A.6 – A schematic of a spatial mapping GEOMETRIC DISTORTION plot	55
	Figure A.7 – Scatter plot of GEOMETRIC DISTORTION error	56
	Figure B.1 – Relaxation times T_1 and T_2 in dependency on the concentration of $\text{CuSO}_4 \times 5 \text{H}_2\text{O}$	64
	Figure B.2 – Centring error	78
	Table 1 – Common parameters	18
	Table 2 – Acquisition parameters	19
	Table 3 – Reporting of results for SNR.....	22
	Table 4 – Reporting of results for UNIFORMITY.....	23

Table 5 – Reporting of results for SLICE THICKNESS	27
Table 6 – Reporting of results for GEOMETRIC DISTORTION	32
Table 7 – Phantom, plane and gradient orientation for resolution assessment.....	34
Table 8 – Reporting of results for SPATIAL RESOLUTION.....	36
Table 9 – Reporting of results for GHOSTING ARTEFACTS.....	38
Table 10 – Required CONSTANCY TESTS – Parameter settings	40
Table A.1 – Reporting of results for UNIFORMITY "grey-scale map"	44
Table A.2 – Recommended fiducial volumes	52
Table A.3 – Example of error table.....	56
Table A.4 – Reporting of results for SPATIAL RESOLUTION (MTF method).....	58
Table A.5 – Reporting of results for centre frequency.....	59
Table A.6 – Reporting of results for RF calibration	60
Table A.7 – Reporting of results for geometric accuracy	61
Table B.1 – TEST DEVICE conductivity and dielectric properties	65
Table B.2 – Bandwidth-related quantities as provided by different vendors	67
Table B.3 – Relaxation fit parameters for Gd(TMHD) at concentrations ≤ 4 parts per thousand by weight	68
Table B.4 – Noise correction factors by number of complex channels	69

INTERNATIONAL ELECTROTECHNICAL COMMISSION

MAGNETIC RESONANCE EQUIPMENT FOR MEDICAL IMAGING –

Part 1: Determination of essential image quality parameters

FOREWORD

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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*