SLOVENSKI STANDARD
SIST EN 62464-1:2010

01-september-2010

Oprema za magnetno resonanco za medicinsko slikanje - 1. del: Ugotavljanje bistvenih parametrov za kakovost slike (IEC 62464-1:2007)

Magnetic resonance equipment for medical imaging - Part 1: Determination of essential image quality parameters (IEC 62464-1:2007)

Magnetresonanzgeräte für die medizinische Bildgebung - Teil 1: Bestimmung der wesentlichen Bildqualitätsparameter (IEC 62464-1:2007)

Appareils à résonance magnétique pour imagerie médicale - Partie 1: Détermination des principaux paramètres de qualité d'image (CEI 62464-1:2007)

Ta slovenski standard je istoveten z: **EN 62464-1:2007**

ICS:

11.040.50	Radiografska oprema	Radiographic equipment

SIST EN 62464-1:2010 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 62464-1

May 2007

ICS 11.040.50

English version

Magnetic resonance equipment for medical imaging - Part 1: Determination of essential image quality parameters
(IEC 62464-1:2007)

Appareils à résonance magnétique pour imagerie médicale - Partie 1: Détermination des principaux paramètres de qualité d'image (CEI 62464-1:2007)

Magnetresonanzgeräte für die medizinische Bildgebung - Teil 1: Bestimmung der wesentlichen Bildqualitätsparameter (IEC 62464-1:2007)

This European Standard was approved by CENELEC on 2007-04-01. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

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

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CENELEC members are the national electrotechnical committees of Austria, Belgium, Bulgaria, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

CENELEC

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

Central Secretariat: rue de Stassart 35, B - 1050 Brussels

Ref. No. EN 62464-1:2007 E

Foreword

The text of document 62B/641/FDIS, future edition 1 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 was approved by CENELEC as EN 62464-1 on 2007-04-01.

The following dates were fixed:

– latest date by which the EN has to be implemented at national level by publication of an identical national standard or by endorsement	(dop)	2008-01-01
– latest date by which the national standards conflicting with the EN have to be withdrawn	(dow)	2010-04-01

In this standard, 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 of EN 60601-1:2006, in this standard or in IEC/TR 60788: SMALL CAPITALS.

Annex ZA has been added by CENELEC.

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Endorsement notice

The text of the International Standard IEC 62464-1:2007 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following notes have to be added for the standards indicated:

IEC 60601-1	NOTE	Harmonized as EN 60601-1:2006 (not modified).
IEC 60601-1-2	NOTE	Harmonized as EN 60601-1-2:2001 (not modified).
IEC 60601-2-33	NOTE	Harmonized as EN 60601-2-33:2002 (not modified).
IEC 61223-2-6	NOTE	Harmonized as EN 61223-2-6:2007 (not modified).

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Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

The following referenced documents are indispensable for the application 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 When an international publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

Publication	Year	Title	EN/HD	Year
IEC/TR 60788	-[1)]	Medical electrical equipment - Glossary of defined terms	-	-

[1)] Undated reference.

NORME INTERNATIONALE

INTERNATIONAL STANDARD

CEI
IEC
62464-1

Première édition
First edition
2007-01

Appareils à résonance magnétique pour imagerie médicale –

Partie 1: Détermination des principaux paramètres de qualité d'image

Magnetic resonance equipment for medical imaging –

Part 1: Determination of essential image quality parameters

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International Electrotechnical Commission
Международная Электротехническая Комиссия

CODE PRIX
PRICE CODE XC

Pour prix, voir catalogue en vigueur
For price, see current catalogue

CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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.

The text of this standard is based on the following documents:

FDIS	Report on voting
62B/641/FDIS	62B/646/RVD

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

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

In this standard, 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 2 of the General Standard, in this standard or in IEC 60788: SMALL CAPITALS

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

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

INTRODUCTION

This international standard is written at a moment in which MAGNETIC RESONANCE EQUIPMENT is already present in the market place for more than 20 years. It is estimated that more then 20 000 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 addressing of system performance and system maintenance. It is therefore felt to be necessary to introduce this IEC standard in addition to the existing standard on MAGNETIC RESONANCE (MR) safety, because the IEC standards have a true international character and this IEC standard is the first start to process and combine current best practices together and provide guidance on how to address the various questions on quality control and quality assurance testing of MAGNETIC RESONANCE EQUIPMENT together. Having a standardized set of test methods minimizes 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 around for some time, this international standard 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 standard. This objective is achieved by introducing preferred methods in the main text of the standard, while allowing acceptable alternative test methods, described in Annex A of the standard. A number of the ACCEPTANCE TEST methods described in the standard have already been described earlier, mainly as NEMA technical MR standards, while new methods have been developed since then. For this standard, it is attempted to select the best method as the preferred method, although for a number of specific tests good alternatives are available and are therefore also acceptable.

Also for the quality assurance tests and 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 standard. 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, phantom design, data analysis) and examples for possible CONSTANCY TESTS for the required parameters in the annex. This allows the user to use as many of the tools supplied by MR MANUFACTURERS as possible, appropriate and useful and still fulfill the requirements for quality control and quality assurance.

MAGNETIC RESONANCE EQUIPMENT FOR MEDICAL IMAGING –

Part 1: Determination of essential image quality parameters

1 Scope

This international standard specifies measurement procedures for the determination of many essential medical MR EQUIPMENT image quality parameters. Measurement procedures as addressed in this standard are suitable for:

- quality assessment in the ACCEPTANCE TEST;
- quality assurance in the CONSTANCY TEST.

In addition, the measurement procedures specified in this standard may also be useful for type tests, although that is not an objective of this standard.

This standard does not address:

- required levels of performance for ACCEPTANCE TEST and CONSTANCY TEST;
- image quality assessment of high field MR EQUIPMENT greater than 4 T, 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;
- type tests.

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

The measurement procedures specified in this standard are directed to:

a) MANUFACTURERS, who can demonstrate compliance by performing acceptance and constancy methods as described by this standard,

b) test houses, which can confirm performance of MR EQUIPMENT using methods described in this standard,

c) regulatory authorities, who can reference this standard, and

d) RESPONSIBLE ORGANISATIONS who want to perform ACCEPTANCE and CONSTANCY TESTS using methods described in this standard.

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

- SIGNAL-TO-NOISE RATIO,
- UNIFORMITY,
- SLICE THICKNESS and SLICE PROFILE,
- GEOMETRIC DISTORTION,
- SPATIAL RESOLUTION, and
- ghosting.

This standard describes the preferred measurement procedures. It also describes alternative methods in Annex A. The preferred test methods may be substituted with the alternative methods. If necessary, other methods not described in this standard may be used, provided these other test methods are documented and validated against the methods described in the standard. Validation of other test methods requires an analysis of test sensitivity to the same parameter of interest and an analysis of the insensitivity of the test to other unrelated parameters and should demonstrate 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 shall produce quantitative results.

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

This standard 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 are found in Annex A. If necessary, other CONSTANCY TEST methods not described in this standard may be used. Since the needs of RESPONSIBLE ORGANISATIONS' quality assurance programs may vary, RESPONSIBLE ORGANISATIONS are encouraged to determine the necessary scope of tests, quality of the tests, and the sensitivity of the data analysis etc. This standard 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 which are sensitive to the overall operating characteristics of the MR EQUIPMENT.

2 Normative references

The following referenced documents are indispensable for the application 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 60788, *Medical electrical equipment – Glossary of defined terms*

3 Terms, definitions and symbols

3.1 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

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

[IEC 61223-1, definition 3.2.4]

3.1.2
accompanying document
document accompanying ME EQUIPMENT, an ME SYSTEM, EQUIPMENT or an ACCESSORY and containing information for the RESPONSIBLE ORGANIZATION or OPERATOR, particularly regarding BASIC SAFETY and ESSENTIAL PERFORMANCE

[IEC 60601-1:2005, definition 3.4]

3.1.3
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

3.1.4
bandwidth per pixel
reciprocal of the duration of the sampling window

NOTE Instead of BANDWIDTH PER PIXEL, equivalent values may be stated on the control console.

3.1.5
body test device
TEST DEVICE representing the PATIENT'S body

3.1.6
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.

[IEC 61223-1:1993, definition 3.2.6]

3.1.7
extremity test device
TEST DEVICE representing the PATIENT's extremities

3.1.8
field of view
FOV
size of the imaging area requested by OPERATOR

NOTE To be specified with one or two linear measures (in mm), if imaging area is square or rectangular respectively.

3.1.9
geometric distortion
spatial position deviation of the imaged structure from expected position of real object structure

3.1.10
ghosting artefact
ARTEFACT showing a replica or part of the replica of an existing structure in a wrong position

3.1.11
head test device
TEST DEVICE representing the PATIENT's head