Irish Standard
I.S. EN 62464-2:2011

Magnetic resonance equipment for medical imaging -- Part 2: Classification criteria for pulse sequences (IEC 62464 -2:2010 (EQV))

I.S. EN 62464-2:2011

Incorporating amendments/corrigenda issued since publication:

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I.S. xxx: Irish Standard – national specification based on the consensus of an expert panel and subject to public consultation.

S.R. xxx: Standard Recommendation - recommendation based on the consensus of an expert panel and subject to public consultation.

SWiFT xxx: A rapidly developed recommendatory document based on the consensus of the participants of an NSAI workshop.

This document replaces:	*This document is based on:* EN 62464-2:2011	*Published:* 11 February, 2011

This document was published
under the authority of the NSAI and comes into effect on:

16 February, 2011

ICS number:
11.040.55

NSAI
1 Swift Square,
Northwood, Santry
Dublin 9

T +353 1 807 3800
F +353 1 807 3838
E standards@nsai.ie
W **NSAI.ie**

Sales:
T +353 1 857 6730
F +353 1 857 6729
W standards.ie

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I.S. EN 62464-2:2011

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 62464-2

February 2011

ICS 11.040.55

English version

Magnetic resonance equipment for medical imaging - Part 2: Classification criteria for pulse sequences
(IEC 62464-2:2010)

Appareils à résonance magnétique utilisés pour l'imagerie médicale -
Partie 2: Critères de classification pour les séquences d'impulsions
(CEI 62464-2:2010)

Magnetresonanzgeräte für die medizinische Bildgebung -
Teil 2: Klassifizierungskriterien für Pulssequenzen
(IEC 62464-2:2010)

This European Standard was approved by CENELEC on 2011-02-01. 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.

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 Central Secretariat has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Bulgaria, Croatia, 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

Management Centre: Avenue Marnix 17, B - 1000 Brussels

Ref. No. EN 62464-2:2011 E

Foreword

The text of document 62B/807/FDIS, future edition 1 of IEC 62464-2, 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 62464-2 on 2011-02-01.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN and CENELEC shall not be held responsible for identifying any or all such patent rights.

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)	2011-11-01
– latest date by which the national standards conflicting with the EN have to be withdrawn	(dow)	2014-02-01

In this standard, the following print types are used:

– Requirements and definitions: roman type.

– *Test specifications: italic type.*

– Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.

– TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

– “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;

– “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;

– “may” is used to describe a permissible way to achieve compliance with a requirement or test.

Annex ZA has been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 62464-2:2010 was approved by CENELEC as a European Standard without any modification.

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 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 + corr. October	2010 2010
IEC/TR 60788	2004	Medical electrical equipment - Glossary of defined terms	-	-

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MAGNETIC RESONANCE EQUIPMENT FOR MEDICAL IMAGING –

Part 2: Classification criteria for pulse sequences

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 62464-2 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/807/FDIS	62B/816/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:

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The committee has decided that the contents of this publication will remain unchanged until the stability 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

Presently the MANUFACTURERS of MR EQUIPMENT use names for PULSE SEQUENCES which are adopted from the literature (e.g. SPIN-ECHO) or are defined by the MANUFACTURER (e.g. FISP: fast imaging with steady state precession). In the absence of a classification standard for PULSE SEQUENCES, the MANUFACTURER-specific terminology complicates comparison of PULSE SEQUENCES.

The DICOM standard allows the inclusion of PULSE SEQUENCE information with digital MAGNETIC RESONANCE (MR) images. This information helps with the interpretation of images. However, the DICOM standard allows MANUFACTURER-specific terminology.

This International Standard specifies a concise MANUFACTURER-independent classification scheme for MR imaging PULSE SEQUENCES.

In terms of MR imaging, the PULSE SEQUENCE is a chronology of RF-pulses, switching of gradient fields and data acquisition with the intention to create one or more images. As the exact chronology determines the image contrast, image artefacts and other properties of the image, it is necessary to define a consistent and accurate PULSE SEQUENCE classification.

The proposed PULSE SEQUENCE classification notation could be implemented as a new DICOM tag in addition to the existing MANUFACTURER-specific PULSE SEQUENCE name. This would facilitate end users' access to this information. Implementation as a new tag would ensure backward compatibility.