Magnetic resonance equipment for medical imaging - Part 2: Classification criteria for pulse sequences

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NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN 62464-2:2011 sisaldab Euroopa standardi EN 62464-2:2011 ingliskeelset teksti.	This Estonian standard EVS-EN 62464-2:2011 consists of the English text of the European standard EN 62464-2:2011.
Standard on kinnitatud Eesti Standardikeskuse 28.02.2011 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.	This standard is ratified with the order of Estonian Centre for Standardisation dated 28.02.2011 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.
Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 11.02.2011.	Date of Availability of the European standard text 11.02.2011.
Standard on kättesaadav Eesti standardiorganisatsioonist.	The standard is available from Estonian standardisation organisation.

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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

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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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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.

MAGNETIC RESONANCE EQUIPMENT FOR MEDICAL IMAGING –

Part 2 – Classification criteria for pulse sequences

1 Scope

This International Standard specifies the description of PULSE SEQUENCES of MAGNETIC RESONANCE imaging.

NOTE The classification in this standard is suitable for:

– tender texts;

– image annotation;

– protocol definition;

– technical publications.

This International Standard does not apply to MAGNETIC RESONANCE spectroscopy. The classification does not focus on image contrast (T1, T2, proton density), as this is defined by PULSE SEQUENCE parameters (e.g. repetition time, echo time) and is not a property of the PULSE SEQUENCE alone. The PULSE SEQUENCE classification does not specify the K-SPACE acquisition scheme, reconstruction algorithm or post-processing.

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 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 60788:2004, *Medical electrical equipment – Glossary of defined terms*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-2-33:2010, IEC 60788:2004 and the following apply.

3.1
pulse sequence
chronology of radiofrequency-pulses, switching of magnetic field gradients, and data acquisition for the generation of one or more MAGNETIC RESONANCE images

NOTE The terms “imaging sequence” or “sequence” are sometimes used as synonyms for PULSE SEQUENCE.

3.2
transverse magnetisation
magnetisation component perpendicular to the direction of the static magnetic field

3.3
longitudinal magnetisation
magnetisation component parallel to the direction of the static magnetic field