



BSI Standards Publication

Magnetic resonance equipment for medical imaging

Part 1: Determination of essential image quality parameters

National foreword

This British Standard is the UK implementation of EN IEC 62464-1:2019. It is identical to IEC 62464-1:2018. It supersedes BS EN 62464-1:2007, which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/62/2, Diagnostic imaging equipment.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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Amendments/corrigenda issued since publication

Date	Text affected
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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)

This European Standard was approved by CENELEC on 2019-01-17. 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 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.

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

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	-	-

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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*

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.]

3.1.18

PHASE OVERSAMPLING

acquisition technique increasing by the same factor both the phase-encoding FIELD OF VIEW and the number of phase encodings, to avoid aliasing ARTEFACTS in the phase encoding direction

Note 1 to entry: The additional acquired part of the phase-encoding FIELD OF VIEW is cropped away.

Note 2 to entry: The technique has various commercial names, such as "oversampling" (Esaote), "no phase-wrap" (GE), "anti-wrap" (Hitachi), "fold-over suppression" (Philips), "PHASE OVERSAMPLING" (Siemens), "phase-wrap suppression" (Toshiba). This information is given for the convenience of users of this document and does not constitute an endorsement by IEC of the companies named.

3.1.19

RADIO FREQUENCY COIL

RF COIL

coil or probe used to transmit and/or receive radio frequency electromagnetic fields

3.1.20

RECONSTRUCTION PARAMETERS

ensemble of all parameters that uniquely define the transformation of the digitized signals into an image

3.1.21

REFERENCE POSITION

predefined point within the SPECIFICATION VOLUME

Note 1 to entry: Normally, the REFERENCE POSITION lies on the symmetry axis of the RF COIL and corresponds to the centre of gravity of the SPECIFICATION VOLUME.

3.1.22

REGION OF INTEREST

ROI

localised part of an image, which is of particular interest at a given time

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

[SOURCE: IEC 61223-3-5:2004, 3.15]

3.1.23

RESPONSIBLE ORGANISATION

entity accountable for the use and maintenance of an ME EQUIPMENT or an ME SYSTEM

Note 1 to entry: The accountable entity can be, for example, a hospital, an individual clinician or a layperson. In home use applications, the PATIENT, OPERATOR and RESPONSIBLE ORGANIZATION can be one and the same person.

Note 2 to entry: Education and training is included in "use".

[SOURCE: IEC 60601-1:2005, 3.101]

3.1.24

RF COIL SPECIFICATION AREA

intersection of the RF COIL SPECIFICATION VOLUME and the image plane

3.1.25

RF COIL SPECIFICATION VOLUME

imaging volume, defined relative to a specific RF COIL, within which a MANUFACTURER characterizes image performance

Note 1 to entry: Each RF COIL has its own appropriately shaped specification volume.

3.1.26**SIGNAL TO NOISE RATIO****SNR**

ratio of the signal level to the noise level

3.1.27**SLICE PROFILE**

plot of the signal intensity in a direction perpendicular to the scanned slice

3.1.28**SLICE THICKNESS**

FULL WIDTH AT HALF MAXIMUM of the SLICE PROFILE

3.1.29**SPATIAL RESOLUTION**

one half of the inverse of the highest spatial frequency where the magnitude of the MODULATION TRANSFER FUNCTION (MTF) exceeds a required threshold

3.1.30**SYSTEM SPECIFICATION VOLUME**

imaging volume within which a MANUFACTURER characterises image performance

Note 1 to entry: Images or portions of images outside this volume will not necessarily meet performance specifications, but can still be useful for diagnostic purposes.

Note 2 to entry: The SYSTEM SPECIFICATION VOLUME may be different per image quality parameter.

3.1.31**TEST DEVICE**

object for imaging test purposes

3.1.32**TYPE TEST**

test on a representative sample of the equipment with the objective of determining if the equipment, as designed and manufactured, can meet the requirements of IEC 60601-1

[SOURCE: IEC 60601-1:2005, 3.135]

3.1.33**UNIFORMITY**

spatial constancy of intensity in the image of a homogeneous TEST DEVICE excluding the effect of noise or finite data collection (truncation ARTEFACT)

3.2 Symbols and abbreviated terms

B_0	static magnetic field
B_1	radio frequency magnetic field
FT	Fourier transform
T_1	longitudinal relaxation time
T_2	transversal relaxation time
T_E	echo time
T_R	repetition time

4 * Procedures for the determination of essential image parameters

4.1 General requirements for all procedures

4.1.1 Requirements for the system

It is a prerequisite that the system is properly calibrated when performing any of the procedures.

4.1.2 Requirements for the TEST DEVICE

The TEST DEVICE shall consist of a container (made of e.g. polypropylene carboy, Perspex®¹) of appropriate shape and size for the specific test and fit inside the receive coil. It shall be filled with the appropriate MR TEST DEVICE filler, (e.g. water, or silicon oil) for the specific test and B_0 static magnetic field strength under test.

Some, but not all, tests require TEST DEVICE filler properties (spin density ρ , T_1 , T_2) similar to that of a PATIENT's body (typical values: $T_1 < 1\ 200$ ms, $T_2 > 50$ ms, spin density $\rho = \rho_{H_2O}(1\ \% \pm 30\ \%)$). This can be achieved by doping the signal-producing material (e.g. water, mineral oil, gels) with appropriate relaxation modifiers (paramagnetic ions). It is suggested to use values similar to the PATIENT's body and avoid extreme values. The TEST DEVICE temperature shall be (22 ± 4) °C.

The loading of receive coils can vary substantially with application, PATIENT size/composition and coil placement. Because of these variations, a generic coil loading scheme is not included in this document and the option to test in a loaded or unloaded condition is specified for each test. Each test clause provides separate recommendations as necessary. When choosing for a loaded versus unloaded scheme, the following considerations apply:

- a loaded condition is more representative of a specific clinical situation;
- the actual loading condition may be difficult to assess, especially in case of multi-element coils;
- reproducibility of the measurement results.

In order to approximate the IMAGE NOISE performance that would be typically encountered in a clinical situation, the receive RADIO FREQUENCY COIL (RF COIL) of interest shall be electrically loaded to approximate a 50 kg to 90 kg human, if loading is required for the specific test. Loading may be accomplished by TEST DEVICES or other reproducible means.

The load is considered to be equivalent if either the following electrical parameters, or other methods (e.g. total RF power needed to achieve a certain flip angle for transmit/receive coils) that demonstrate loading equivalent to a 50 kg to 90 kg human, match within the stated errors:

- coil 3 dB bandwidth: $\pm 15\ \%$;
- coil impedance: $\pm 20\ \%$ magnitude, $\pm 20^\circ$ phase;
- coil centre frequency shift: $\pm 1\ \%$ of centre frequency.

Exceptions to these requirements are specified where necessary.

4.1.3 Scan parameters

All images shall be processed with the MR EQUIPMENT's standard clinical reconstruction algorithm (e.g. GEOMETRIC DISTORTION correction ON or OFF). The state (e.g. ON, OFF, standard settings) of all filters and other RECONSTRUCTION PARAMETERS that are changed by

¹ Perspex® is an example of a suitable product available commercially. This information is given for the convenience of users of this document and does not constitute an endorsement by IEC of this product.

the OPERATOR (e.g. smoothing/edge enhancing, image UNIFORMITY correction) shall be reported. The images to be analyzed shall be substantially free of ARTEFACTS.

All image acquisitions shall be preceded by the standard clinical prescan calibration.

Image planes and orientations will reference to a supine PATIENT positioning with head first entry; the PATIENT setup shall be set accordingly before acquisition.

Exceptions to these requirements are specified where necessary.

Reduced k -space, accelerated imaging acquisition methods (e.g. asymmetric k -space acquisition, parallel imaging) shall not be used. Cartesian k -space sampling methods shall be used.

4.1.4 Reporting of results

Portions of result reporting are common to all tests, excluding CONSTANCY TESTS, and pertain to system configuration, SPECIFICATION VOLUME/AREA, and TEST DEVICE details. All reports shall contain the information listed in Table 1, and any additional information necessary to ensure repeatability.

Table 1 – Common parameters

Parameter	Value/Units
General	
Scanner vendor/model	
Software version	
Protocol ID (optional)	
Field strength	Tesla
Specification volume	
Shape	Sphere, ellipsoid, cuboid, other (specify)
Size	$d[x,y,z]$, mm
Centre (w.r.t. ISOCENTRE)	(x,y,z) , mm
Specification area	
Shape	Circle, ellipse, rectangle, other (specify)
Size	$d[x,y,z]$, mm
Centre (w.r.t. ISOCENTRE)	(x,y,z) , mm
Transmit coil	
Type	
Name	
Number of Tx channels	
Dimensions	$d[x,y,z]$, mm
Tx mode	Linear, circularly polarized, other (specify)
Receive coil	
Type	
Name	
Number of Rx channels	
Dimensions	$d[x,y,z]$, mm
TEST DEVICE	
Filler material description	
Filler T_1	ms
Filler T_2	ms
Filler salt type	Chemical name
Filler salt concentration	g/l
Cross sectional shape	Circle, ellipse, rectangle, other (specify)
Cross sectional area	mm ²
Slab thickness	mm
Loading type	Loaded/unloaded
Drawing w/dimensions, tolerances	
Relative location w.r.t. ISOCENTRE	(x,y,z) , mm and (SI,RL,AP), and tilt

All reports shall also contain confirmation of the pre-defined acquisition parameters listed in Table 1, and completion of the remaining acquisition parameters (see Table 2).

Table 2 – Acquisition parameters

Parameter	Test (subclause number)						
		SNR (4.2)	UNIFORMITY (4.3)	SLICE THICKNESS (4.4)	GEOMETRIC DISTORTION (4.5)	SPATIAL RESOLUTION (4.6)	Ghosting (4.7)
PATIENT entry	Head or Feet first	Head first	Head first	Head first	Head first	Head first	Head first
PATIENT position	Supine, Prone, etc.	Supine	Supine	Supine	Supine	Supine	Supine
PATIENT weight							
Imaging mode	2D or 3D	2D	2D	2D	2D	2D	2D
Pulse sequence	SE or GRE	SE	SE	SE	SE	SE	GRE
Plane	Transverse/ Axial, Sagittal, Coronal	All 3	All 3	All 3	All 3	All 3	All 3
Frequency encode FOV	mm						
Phase encode FOV	mm						
Number of slices	slices	1	1	3	1	1	1
SLICE THICKNESS	mm	5	5	5	5	5	See 4.7.3
Slice spacing (centre-to-centre)	mm	N/A	N/A	10	N/A	N/A	N/A
Centre slice position	mm (SI,RL or AP) w.r.t. either ISOCENTRE or REFERENCE POSITION	ref ±30	ref ±30	ISO ±30	ISO ±30	ISO ±30	ISO ±30
FOV centre coord	mm (SI,RL or AP)						
Phase encode direction	SI, RL, AP					Both for each plane See 4.6.3	Trans: L/R Sagittal: A/P Coronal: S/I
T_R	ms	$> 3 \times T_1$	$> 3 \times T_1$	$> 3 \times T_1$	$> 3 \times T_1$	$> 3 \times T_1$	603
T_E	ms	30 or $< T_{2/3}$	30 or $< T_{2/3}$	30 or $< T_{2/3}$	30 or $< T_{2/3}$	30 or $< T_{2/3}$	25
Number echoes	echoes	1	1	1	1	1	1
Flip angle (if GRE)	degrees	N/A	N/A	N/A	N/A	N/A	
Acquisition matrix (frequency encode)	samples	256	256	256			
Acquisition matrix (phase encode)	samples	256	256	256			
Number of averages	averages	1	≥ 1	≥ 1	≥ 1	≥ 1	1
Bandwidth/pixel	Hz/pixel	Clinical typical	Clinical typical	Clinical typical	Clinical typical	Clinical typical	Clinical typical
Phase oversample factor (1 = none)	factor of FOV	1	≥ 1	≥ 1	≥ 1	≥ 1	
GEOMETRIC DISTORTION correction	On/off, Type (2D, 3D)						
Smoothing/edge enhancement	Identify: on, off						

	Test (subclause number)						
Parameter		SNR (4.2)	UNIFORMITY (4.3)	SLICE THICKNESS (4.4)	GEOMETRIC DISTORTION (4.5)	SPATIAL RESOLUTION (4.6)	Ghosting (4.7)
UNIFORMITY/shading correction	Identify: on, off						
Additional filters	Identify: on, off						

The reporting of measurement results are discussed in the individual test clauses.

4.2 * SIGNAL TO NOISE RATIO

4.2.1 Objectives and rationale

Image SIGNAL TO NOISE RATIO (SNR) is a parameter that relates to clinical usefulness of MRI and is also a sensitive measure of hardware performance. Experience has shown that variations in system calibration, transmit and receive gain, RF COIL tuning, RF shielding, RF COIL loading or other similar parameters may cause a corresponding change in image SNR. Furthermore, SNR is to a great extent defined by the receive RF COIL.

4.2.2 Requirements for the TEST DEVICE

Per receive coil, either a loaded or unloaded condition may be selected for this measurement procedure.

The TEST DEVICE shall fill the RF COIL SPECIFICATION VOLUME or RF COIL SPECIFICATION AREA.

4.2.3 Scan parameters

The following sequence shall be used:

- 2D single spin echo;
- single slice centred at REFERENCE POSITION ± 30 mm (displacement in slice selection direction);
- scan plane: transverse, sagittal, coronal (in turn);
- $T_R = \geq 3 T_1$ of the signal producing material;
- $T_E = 30$ ms or $\leq 1/3 T_2$ of the signal producing material, whichever is smaller;
- BANDWIDTH PER PIXEL shall be set to a clinically relevant value, that may be dependent on the field strength (e.g. 100 Hz/pixel at 0,5 T, 300 Hz/pixel at 1,5 T, 600 Hz/pixel at 3 T);
- FIELD OF VIEW large enough to cover the TEST DEVICE;
- matrix 256×256 ;
- SLICE THICKNESS 5 mm;
- signal averaging or PHASE OVERSAMPLING are not permitted.

Any deviation from the parameters above shall be clearly stated and justified by a rationale.

4.2.4 Measurement procedure

The placement of the TEST DEVICE and RF COIL shall simulate the typical diagnostic procedure.

Wait appropriate time (e.g. 15 min for a large TEST DEVICE) after positioning the TEST DEVICE before scanning to prevent swirling ARTEFACTS.

Execute two sequential scans (image 1 and image 2) of the slice with less than 5 min from the end of the first scan to the beginning of the second. No adjustment or calibration shall be performed between the scans.

4.2.5 Data analysis and tolerances

The REGION OF INTEREST (ROI) shall cover at least 85 % of the RF COIL SPECIFICATION AREA.

Step 1: Determine the mean pixel value within the ROI in image 1. The resulting number (minus any baseline pixel offset value) shall be called the image signal, S .

Step 2: Calculate a pixel by pixel signed difference image (image 3) as follows:

$$\Theta_3 = \Theta_1 - \Theta_2$$

where

$\Theta_1, \Theta_2, \Theta_3$ is image 1, 2, 3 respectively.

The subtraction process shall avoid errors resulting from the generation of pixel values that exceed the minimum (or maximum) pixel values allowed on the particular MR EQUIPMENT.

Step 3: Transfer the ROI used to measure S in step 1 to the same location in image 3 and compute the ROI standard deviation σ .

Step 4: Calculate SNR as:

$$SNR = \frac{S}{\left(\frac{\sigma}{\sqrt{2}} \right)}$$

where

σ is the standard deviation.

NOTE In the SNR calculation, the measured σ will be divided by the square root of two, eliminating the noise amplification of the image subtraction process, to give the IMAGE NOISE.

4.2.6 Reporting of results

The report shall contain the information showed in Table 3, and any additional information necessary to ensure repeatability.

Table 3 – Reporting of results for SNR

Parameter	Value/Units
Scan plane orientation	
Direction of phase encoding	
ROI shape	
ROI SIZE	mm ²
REFERENCE POSITION	
Mean signal level S	
Noise standard deviation	
SNR	

4.3 * UNIFORMITY

4.3.1 Objectives and rationale

4.3 presents a measurement procedure for computing a UNIFORMITY figure of merit. As a result, the low spatial frequency non-uniformities typical for MRI images, from all sources, can be characterized. However, UNIFORMITY is typically dominated by the RF COILS used in both transmit and receive. The measurements are made over a volume that is representative of the region used for typical clinical studies.

Due to image ARTEFACT concerns (e.g. Gibbs' ringing ARTEFACT), the TEST DEVICE size shall, at a minimum, equal the RF COIL SPECIFICATION AREA, but the measurements shall be derived from an ROI that is at least 85 % of the SPECIFICATION AREA .

4.3.2 Requirements for the TEST DEVICE

A homogeneous TEST DEVICE shall be used. The TEST DEVICE, at a minimum, shall have a size at least equal the RF COIL SPECIFICATION VOLUME or RF COIL SPECIFICATION AREA. RF COIL loading is not a requirement for the TEST DEVICE.

UNIFORMITY is sensitive to coil loading and the unloaded condition is the most reproducible test configuration. The improved SNR associated with an unloaded test condition will also improve UNIFORMITY measurement precision.

4.3.3 Scan parameters

The following sequence shall be used:

- 2D single spin echo;
- single slice centred at REFERENCE POSITION ± 30 mm (displacement in slice selection direction);
- scan plane: transverse, sagittal, coronal (in turn);
- $T_R = \geq 3 T_1$ of the signal producing material;
- $T_E = 30$ ms or $\leq 1/3 T_2$ of the signal producing material, whichever is smaller;
- BANDWIDTH PER PIXEL shall be set to a clinically relevant value, that may be dependent on the field strength (e. g. 100 Hz/pixel at 0,5 T, 300 Hz/pixel at 1,5 T, 600 Hz/pixel at 3 T);
- FIELD OF VIEW large enough to cover the TEST DEVICE;
- matrix 256×256 ;
- SLICE THICKNESS 5 mm;
- signal averaging and PHASE OVERSAMPLING is permitted.

NOTE The UNIFORMITY measurement sensitivity to noise is reduced with high SNR images.

Any deviation from the parameters above shall be clearly stated and justified by a rationale.

4.3.4 Measurement procedure

The placement of the TEST DEVICE in the appropriate RF COIL shall simulate the typical diagnostic procedure.

Wait appropriate time (e.g. 15 min for a large TEST DEVICE) after positioning the TEST DEVICE before scanning to prevent swirling ARTEFACTS.

4.3.5 Data analysis and tolerances

The normalized average absolute deviation (NAAD) of the signal in an ROI is defined as

$$\eta = 100 \left(1 - \frac{1}{NS} \sum_{i=1}^N |S_i - S| \right)$$

where

S_i is the individual pixel value in the ROI;

S is the mean of all pixels in the ROI;

$|S_i - S|$ is the absolute deviation for pixel i ;

N is the total number of pixels in the ROI

η is NAAD.

For each RF COIL to be assessed, the UNIFORMITY shall be calculated by placing one ROI in the TEST DEVICE area for each image.

- Draw an ROI to include at least 85 % of the SPECIFICATION AREA.
- Calculate $NAAD$ from ROI, which is the measure of UNIFORMITY (U)

$$U = \eta \quad (1)$$

- Alternatively, non-UNIFORMITY (NU) is defined as:

$$NU = 100 - U \quad (2)$$

4.3.6 Reporting of results

The report shall contain the information of Table 4, and any additional information necessary to ensure repeatability.

Table 4 – Reporting of results for UNIFORMITY

Parameter	Value/Units
Scan plane orientation	
Direction of phase encoding	
ROI shape	
ROI SIZE	mm ²
REFERENCE POSITION	
ROI as percentage of SPECIFICATION AREA	
UNIFORMITY U or non-UNIFORMITY NU	

4.4 SLICE THICKNESS in 2-D scanning

4.4.1 Objectives and rationale

4.4 describes a method for measuring the SLICE THICKNESS for multi-slice 2D imaging. All three orientations are assessed at one intersecting location and considered representative of the SYSTEM SPECIFICATION VOLUME. SLICE THICKNESS is determined by measurement of the signal intensity profile over a thin inclined slab of signal producing material (the so-called "hot plate" method). A method is provided to correct for rotational errors caused by any tilting of the TEST DEVICE.

Since it depends on the RF pulse shape, transmit gain, and other parameters, the SLICE THICKNESS is a significant measure of the proper adjustment of an MRI system and its image quality.

Use a homogenous RF COIL with good SNR and UNIFORMITY, such as a receive head coil with body transmit coil, if available in the basic system configuration. A single test set is considered representative of the system operating with any combination of Rx, Tx coils.

This test is configured with acceptance criteria.

4.4.2 Requirements for the TEST DEVICE

The TEST DEVICE consists of two thin opposed inclined slabs of MR signal producing material enclosed by MR-inactive material. The inclined surfaces of both slabs form an angle, α_C , with one of the axes of the image (typical range for α_C : from 5° to 12°).

EXAMPLE When $\alpha_C = 5,71^\circ$, a 10:1 ramp is created, expanding all SLICE THICKNESS features 10-fold ($1/\tan(\alpha_C)$).

The inclined slab produces a trapezoidal signal intensity profile (see Figure 1; note that only one of the opposed inclined slabs is shown). The direction perpendicular to the slice is denoted by Z, the direction of wedge inclination is denoted by X, and Y is perpendicular to X and Z. The sides of the trapezoid, s , become larger with respect to the FULL WIDTH AT HALF-MAXIMUM (FWHM) of the measured profile as the thickness of the slab, p , is increased. To ensure that the full height of the SLICE PROFILE is established (top plateau) under the scan parameter conditions specified in 4.4.3, the plate separation distance p should be

$$p \leq FWHM / 5$$