

INTERNATIONAL STANDARD

NORME INTERNATIONALE

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

**Appareils à résonance magnétique pour imagerie médicale –
Partie 1: Détermination des principaux paramètres de qualité d'image**



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

**Appareils à résonance magnétique pour imagerie médicale –
Partie 1: Détermination des principaux paramètres de qualité d'image**

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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.

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

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

- c) 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.

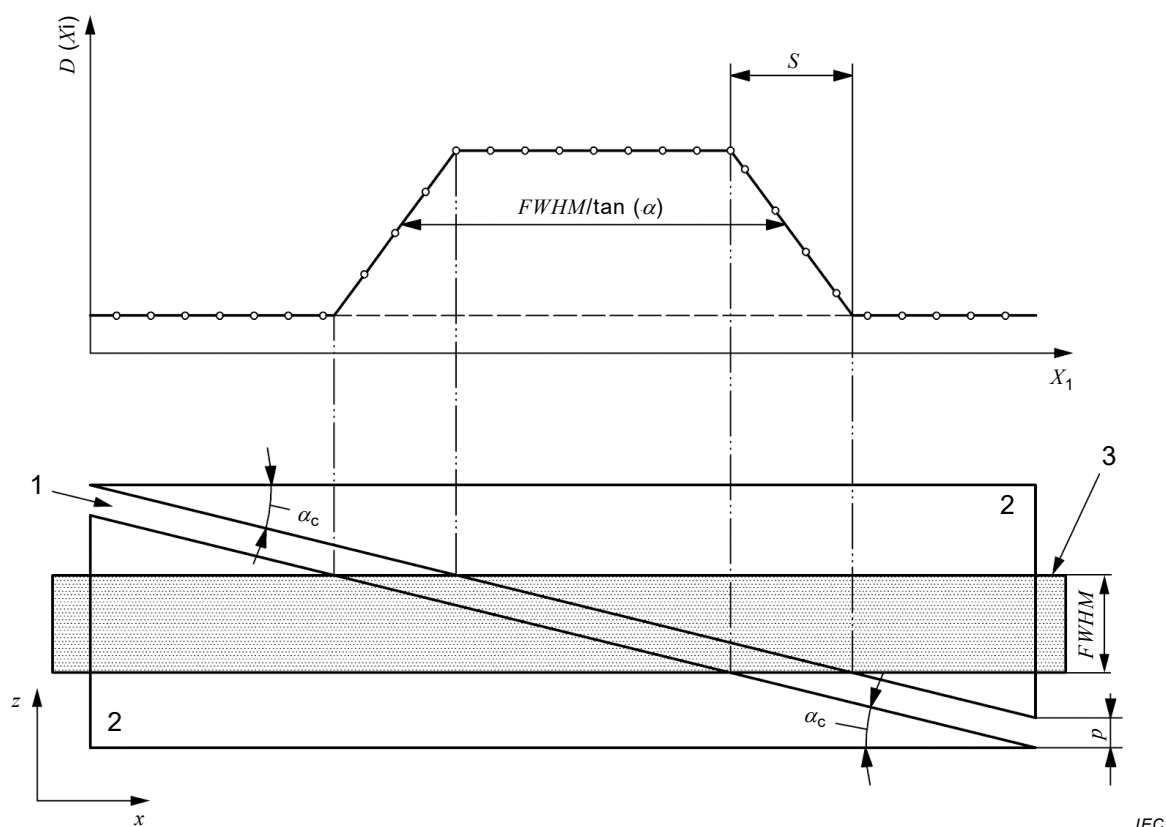
4.4.2 Requirements for the TEST DEVICE

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

$$p \leq FWHM / 5$$

**Key**

- 1 signal-producing slab
- 2 TEST DEVICE insert
- 3 slice in the x - y plane for measuring SLICE THICKNESS along the z axis

NOTE The opposing second slab is not included in the image for clarity purposes.

Figure 1 – Signal intensity profile in the inclined slab method

RF COIL loading need not be considered in the design of the TEST DEVICE since RF COIL loading will not affect the SLICE PROFILE and SLICE THICKNESS measurement.

4.4.3 Scan parameters

The following sequence shall be used:

- 2D single spin echo;
- three slices, middle slice centred at ISOCENTRE ± 30 mm with slice centres spaced at twice the nominal SLICE THICKNESS;
- 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 shall be chosen such that the nominal SLICE THICKNESS is imaged over a region of at least 20 pixels, i.e.

$$FOV < \frac{256 FWHM}{20 \tan \alpha}$$

- matrix 256×256 ;
- nominal SLICE THICKNESS 5 mm,;
- signal averaging and PHASE OVERSAMPLING are permitted.

To obtain reliable results, the SNR of the SLICE PROFILE (i.e. average signal at the top of the plateau vs. standard deviation well removed from the plateau – not the SNR of image) shall be greater than 20. In general, the SNR resulting from a single average will be too low. The SNR can be improved by using multiple averages (which increases measurement time).

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

4.4.4 Measurement procedure

Scans shall be performed in the transverse, sagittal and coronal planes. Means shall be taken to ensure that the TEST DEVICE is aligned with the imaging slice. Alignment can be verified by comparing the SLICE THICKNESS measured with the opposed inclined slabs.

4.4.5 Data analysis and tolerances

For the inclined slab method, plot the pixel intensities in the direction of the surface inclination of the slab, x for the central slice. The pixel intensity at location x_i is denoted by $D(x)$. The accuracy of FWHM of $D(x)$ is improved by linear interpolation. Averaging the SLICE PROFILES in adjacent rows perpendicular to the direction of the surface inclination, if the TEST DEVICE is not rotated, improves SLICE PROFILE SNR and the accuracy of the measurement.

The SLICE THICKNESS is then calculated as the product of the FWHM of the stretched profile, $D(x)$, and $\tan(\alpha_C)$.

Potential sources of error in the measurements include the following:

- inadequate SNR;
- lack of interpolation to determine the FWHM;
- determination of the half-maximum signal level;
- truncation error due to pixel dimensions;
- error in slab angle α_C ;
- rotation of the TEST DEVICE around the x - and z -axis;
- image non-UNIFORMITY.

Certain rotations of the TEST DEVICE will introduce errors:

- rotation of the TEST DEVICE around the z axis (see Figure 2) causes a rotation of the image of the slab, which makes it difficult to average the signal in adjacent rows in the y direction;
- rotation of the TEST DEVICE around the x axis causes a similar problem.

However, the largest error is caused by a rotation of the TEST DEVICE about the y axis, because it causes a shift in the angle of inclination of the slab.

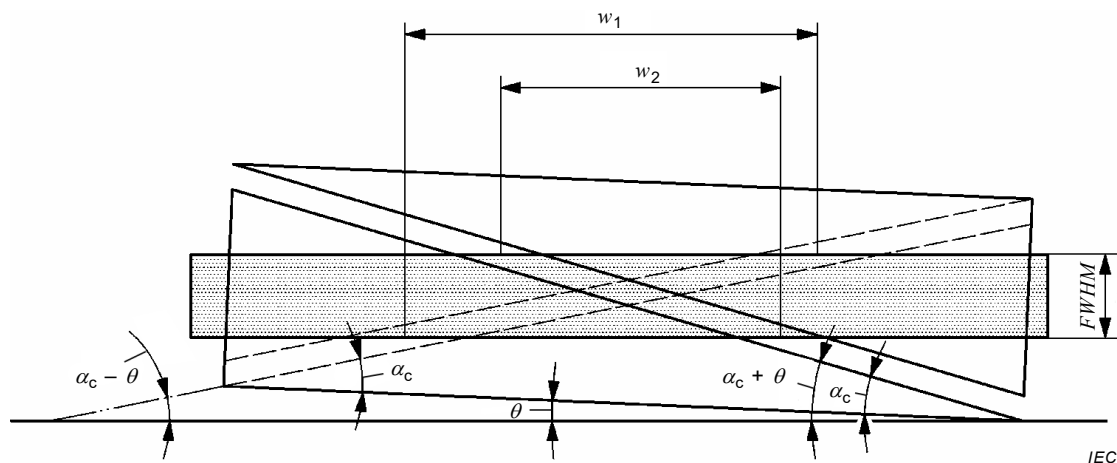
EXAMPLE For a 1:5 slab, α_C is $11,3^\circ$, and a rotation of only 1° produces a 9 % error in the SLICE THICKNESS.

The angle of rotation of the TEST DEVICE about the y axis, θ , may be computed from w_1 and w_2 , as measured with two opposed slabs using the following equation:

$$\theta = \frac{1}{2} \sin^{-1} \left(\frac{w_2 - w_1}{w_2 + w_1} \sin(2\alpha_C) \right)$$

The corrected SLICE THICKNESS is then computed from the following equation:

$$FWHM = w_1 \tan(\alpha_c + \theta)$$



NOTE The dotted lines show the location of the opposing slab.

Figure 2 – Correcting for rotation of TEST DEVICE

4.4.6 Reporting of results

The report shall contain the information of Table 5, and any additional information necessary to ensure repeatability.

Table 5 – Reporting of results for SLICE THICKNESS

Parameter	Value/Units
Scan plane orientation	
Direction of phase encoding	
Hot plate angle of inclination (α_c)	
Hot plate thickness (p)	
SNR of SLICE PROFILE plateau	
REFERENCE POSITION	
Nominal SLICE THICKNESS (TH_n)	
Measured SLICE THICKNESS (TH_M)	
$100 \times (TH_M - TH_n) / TH_n$	%

4.4.7 Reporting of acceptance results

The SLICE THICKNESS test is passed when the measured SLICE THICKNESS is within 15 % of the nominal SLICE THICKNESS.

4.5 * Two-dimensional GEOMETRIC DISTORTION

4.5.1 Objectives and rationale

4.5 presents a method for measuring and reporting two-dimensional GEOMETRIC DISTORTION. Two-dimensional GEOMETRIC DISTORTION is measured as follows:

- scale GEOMETRIC DISTORTION δ : the ratio of the mean value of N radial measured distances in an image to the actual TEST DEVICE radius;
- aberration GEOMETRIC DISTORTION σ_{δ} : the standard deviation of the N radial measured distances;
- maximum GEOMETRIC DISTORTION: the maximum difference between the value of radial measured distances in an image and the actual TEST DEVICE radius.

The scale GEOMETRIC DISTORTION and the aberration GEOMETRIC DISTORTION give complementary information. When $\delta = 0$ and $\sigma_{\delta} \neq 0$, there are radius modulations or GEOMETRIC DISTORTIONS. When $\delta \neq 0$ and $\sigma_{\delta} = 0$, there are scale variations.

This test may be performed with or without gradient distortion correction filters.

Use a homogenous RF COIL with good SNR and UNIFORMITY (e.g. a receive head coil with body transmit coil), if available in the basic system configuration. This procedure does not need to be performed for other RF COILS.

NOTE The methods presented in this document do not distinguish between GEOMETRIC DISTORTIONS induced by the phantom (e.g. susceptibility issues) and the system distortions (B_0 , gradient nonlinearity, etc.). Methods to separate distortion component sources are outside the scope of this document.

4.5.2 * Requirements for the TEST DEVICE

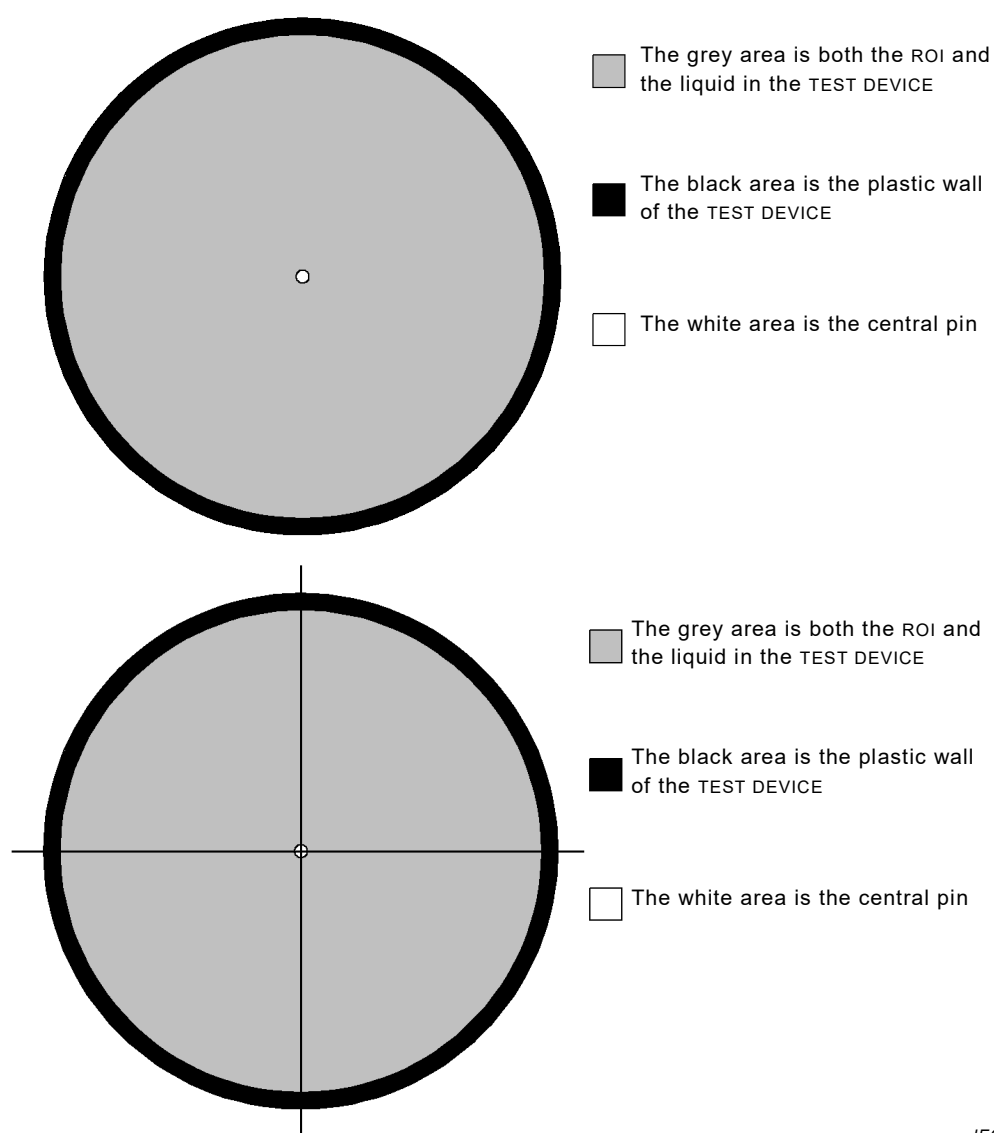
The TEST DEVICE shall be designed so that GEOMETRIC DISTORTION can be measured over the perimeter of an ROI enclosing at least 85 % of the SPECIFICATION AREA.

The perimeter of the ROI shall be matched to the TEST DEVICE shape, and can be a circle for a spherical or cylindrical specification volume. The TEST DEVICE may be either a cylinder, or sphere, where the liquid/wall boundary defines measurement point position (Figure 3 and Figure 4). The TEST DEVICE may also use a series of equally spaced fiducials such as holes, pins, vials or other well defined regular objects or structures on the perimeter, with a maximum angular separation of $22,5^\circ$ (Figure 4). A pin, or other structure, should also be positioned at the geometric centre of the TEST DEVICE to assist in accurately determining the TEST DEVICE centre. A pin diameter of approximately 1 mm helps to minimise the error in identifying the reference centre for all radial measurements. If there is no central pin, the centre of the TEST DEVICE may be defined by geometrical methods within the image.

The TEST DEVICE shall be sufficiently thick to account for in-plane distortion within the specification volume to minimise the influence of slice curvature and partial volume effects, and sufficiently rigid to exclude TEST DEVICE deformation.

RF COIL loading need not be considered in the design of the TEST DEVICE since RF COIL loading will not affect the GEOMETRIC DISTORTION measurement.

Examples of TEST DEVICES for a spherical specification volume are shown in Figure 3 and Figure 4. They consist of an acrylic cylinder (Figure 3) whose internal wall defines the ROI perimeter or a number of fiducials (Figure 4) distributed on the ROI perimeter.



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Figure 3 – Example of a boundary wall TEST DEVICE for a spherical specification volume with two lines passing through the centre

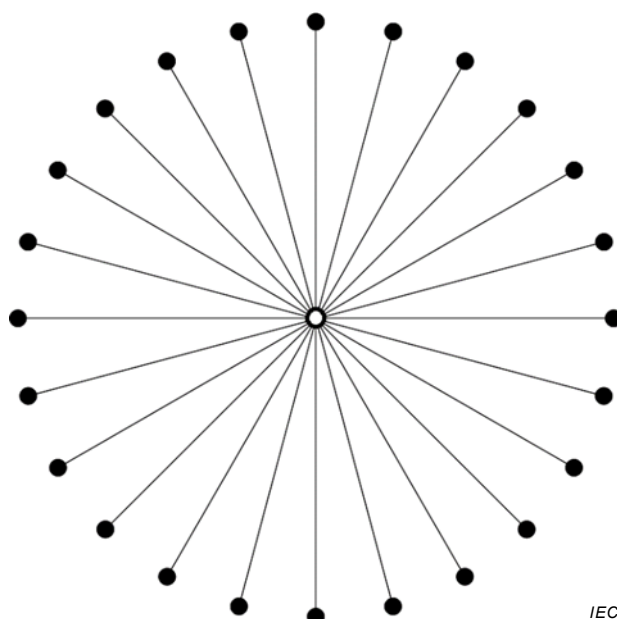


Figure 4 – Example of a fiducial marker TEST DEVICE for a spherical specification volume

4.5.3 Scan parameters

The following sequence shall be used:

- 2D single spin echo;
- single slice centred at ISOCENTRE ± 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);
NOTE This ensures a clinically typical representation for B_0 distortion in read-out direction.
- matrix size and FIELD OF VIEW (FOV) shall be selected such that both pixel dimensions are equal and sufficiently small to accurately resolve boundaries, and/or fiducials (e.g. 1 mm pixel for 2 mm fiducial pins) and the TEST DEVICE boundary is entirely within the FOV;
- SLICE THICKNESS 5 mm;
- signal averaging and PHASE OVERSAMPLING is permitted.

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

4.5.4 * Measurement procedure

The TEST DEVICE shall be positioned with its centre at the ISOCENTRE in the three orthogonal orientations: transverse, sagittal, coronal (in turn).

Since the display window width and level settings determine the apparent visual location of boundary edges or fiducial centroids and therefore affect length measurements, window width and level settings shall be set consistently utilizing an appropriate method to eliminate arbitrary settings, obtain clear boundaries for consistent position determination and therefore eliminate avoidable length measurement variance between scans.

Since automated methods of determining boundary edges or fiducial centroids based on pixel values eliminate inter- and intra-observer variations, and are independent of window width

and level settings, they are recommended. If an automated method is used, it shall be indicated.

The following manual method may be used:

- set window level = $\frac{1}{2}$ mean signal value $\bar{S}$ within the TEST DEVICE;
- set window width = mean signal value $\bar{S}$ within the TEST DEVICE.

The window width and level settings shall be recorded to ensure repeatability.

The distance between the geometric centre and points on the perimeter of the ROI shall be measured as shown in Figure 5. The measurement shall be repeated for N points that are situated uniformly on the ROI perimeter, giving the N measurement values r_i . The angle between pairs of adjacent, radially measured distances shall be less than or equal to $22,5^\circ$.

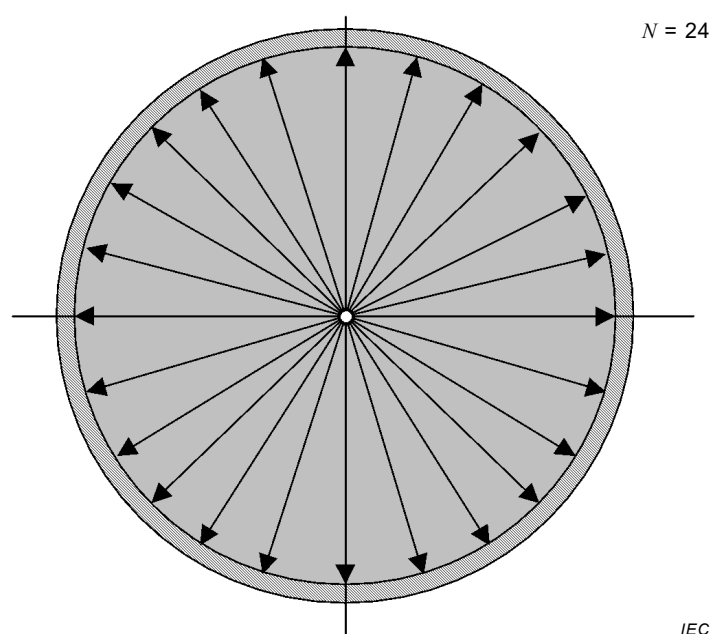


Figure 5 – Distances to be determined

4.5.5 * Data analysis and tolerances

- Calculate the average radius value as follows:

$$\bar{r} = \frac{1}{N} \sum_{i=1}^N r_i$$

- Calculate the scale GEOMETRIC DISTORTION as the relative difference between the mean value $\bar{r}$ of the N radial measured distances in each acquired image and the actual TEST DEVICE radius R , as follows:

$$\delta = \left(\frac{\bar{r}}{R} - 1 \right)$$

- Calculate the aberration GEOMETRIC DISTORTION σ_δ as the standard deviation of the N radial measured distances distribution normalised to the nominal radius, as follows:

$$\sigma_{\delta} = \frac{1}{R} \sqrt{\frac{\sum_{i=1}^N (r_i - \bar{r})^2}{N-1}}$$

- Calculate the maximum GEOMETRIC DISTORTION as follows:

$$r_{\max} = \max(r_i)$$

4.5.6 Reporting of results

The report shall contain the information of Table 6, and any additional information necessary to ensure repeatability.

Table 6 – Reporting of results for GEOMETRIC DISTORTION

Parameter	Value/Units
Scan plane orientation	
Direction of phase encoding	
ROI shape	
ROI SIZE	
REFERENCE POSITION	
ROI as a percentage of SPECIFICATION AREA	
N measurement values (r_i)	
Scale GEOMETRIC DISTORTION (δ)	
Aberration GEOMETRIC DISTORTION (σ_{δ})	
Maximum GEOMETRIC DISTORTION	
Automated or manual method used to find window width/level?	
Manual window width/level method used, if applicable	
Window width/level settings used	

4.6 * SPATIAL RESOLUTION

4.6.1 Objectives and rationale

4.6 presents a method for measuring the SPATIAL RESOLUTION using a specially designed TEST DEVICE.

This test determines whether a specified SPATIAL RESOLUTION has been achieved by measuring the modulation of a periodic pattern.

Use a homogenous RF COIL with good SNR and UNIFORMITY (e.g. a receive head coil with body transmit coil), if available in the basic system configuration.

Testing for one specific SPATIAL RESOLUTION is sufficient due to the linear behaviour of the gradients at different resolutions.

This test is configured with acceptance criteria.

4.6.2 Requirements for the TEST DEVICE

The TEST DEVICE shall contain a periodic pattern, as illustrated in Figure 6. This pattern consists of n parallel plates of periodicity L and n shall be at least 10. The distance between

adjacent plates is d , the thickness of the plates is $(L - d)$ and the ratio d/L shall be between 0,61 and 0,70. The plates, which do not produce any MR signal, are surrounded by MR-signal producing material of sufficient size to enable a 25 pixel minimum ROI for SNR determination purposes. The surrounding MR-signal producing region shall also be dimensioned such that a 25 pixel minimum ROI background region outside the TEST DEVICE can be assessed. The width of the plates (a) shall be at least twice the SLICE THICKNESS, and the length of the plates (b) shall be at least 10 times L . Such TEST DEVICE will produce n linepairs with 1 linepair/ L .

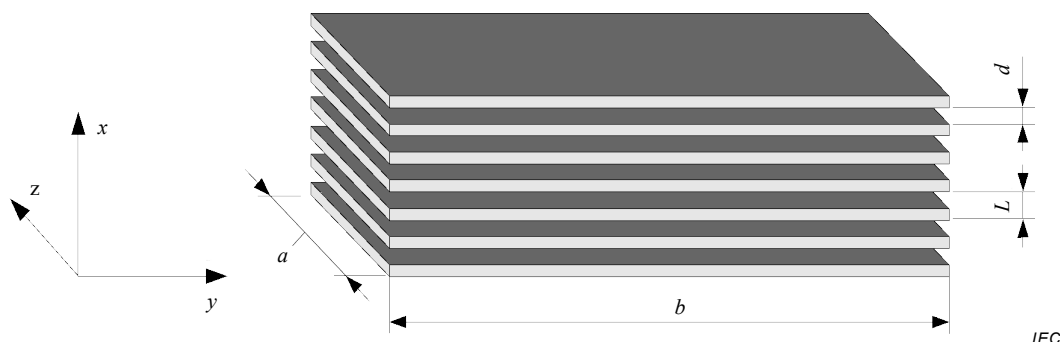


Figure 6 – Periodic pattern

RF COIL loading does not affect the SPATIAL RESOLUTION measurement. An unloaded TEST DEVICE is recommended in order to improve SNR.

4.6.3 Scan parameters

The following sequence shall be used:

- 2D single spin echo;
- single slice centred at ISOCENTRE ± 30 mm (displacement in slice selection direction);
- scan plane: transverse, sagittal, coronal (in turn);
- phase encode direction: both for each plane (see Table 7)
- $T_R \geq 3 T_1$ 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);
- pixel dimension and FIELD OF VIEW (pixel size $\Delta x = \text{FIELD OF VIEW}/\text{matrix size}$) are controlled by the following requirement:

$$4\Delta x > L;$$

- isotropic in-plane resolution;
SLICE THICKNESS 5 mm;
NOTE SLICE THICKNESS can be adjusted within limits identified in 4.6.2.
- signal averaging and PHASE OVERSAMPLING is permitted.

All smoothing or resolution enhancing filters shall be disabled. Any deviation from the parameters above shall be clearly stated and justified by a rationale.

Table 7 – Phantom, plane and gradient orientation for resolution assessment

Scan no.	Scan plane	PATIENT axis measured	Gradient encoding on PATIENT axis	Phantom orientation
1	Transverse	Left/Right	Read	Image appears as in Figure 8
2	Transverse	Left/Right	Phase	Image appears as in Figure 8
3	Sagittal	Anterior/Posterior	Read	Image appears as in Figure 8
4	Sagittal	Anterior/Posterior	Phase	Image appears as in Figure 8
5	Coronal	Superior/Inferior	Read	Image appears as in Figure 7
6	Coronal	Superior/Inferior	Phase	Image appears as in Figure 7

4.6.4 Measurement procedure

The most uniform RF COIL over the REGION OF INTEREST for this TEST DEVICE shall be used.

In total six tests shall be performed to evaluate resolution for all three axes, with frequency- and phase encoding direction alternatively on each axis. Each physical axis shall be tested exactly once, as shown in Table 7. The long axis of the TEST DEVICE shall be rotated 10° to 15°, as shown in Figure 7 and Figure 8. The pattern allows the determination of the SPATIAL RESOLUTION only perpendicular to the plates. The direction of phase encoding shall be swapped, to evaluate the SPATIAL RESOLUTION for a single gradient axis both as frequency and phase encoding directions. In order to evaluate the SPATIAL RESOLUTION for the remaining axes, the TEST DEVICE as well as the scan plane shall be rotated.

The SNR shall be at least 50. The SNR may be assessed using the single image method used in 4.7.5 for the ghosting analysis, excluding the ghosting ROI placement. The 25 pixel minimum signal ROI shall be placed in a uniform signal region beside the plates, and the 25 pixel minimum noise ROI shall be placed in a background region free of ARTEFACTS. Increase the number of averages of the sequence until the SNR reaches the target SNR.

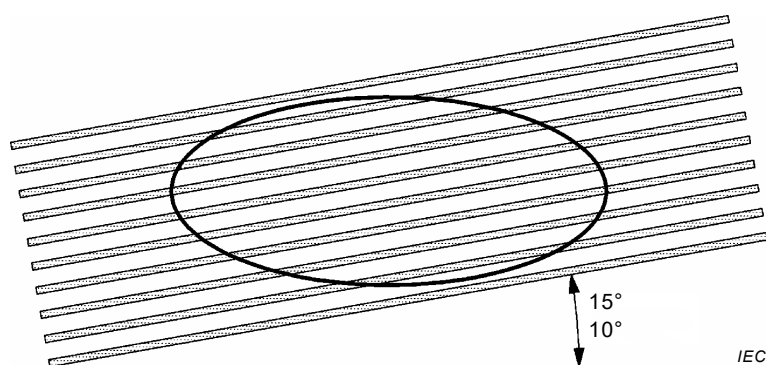


Figure 7 – Image of periodic pattern and position of ROI for coronal scans

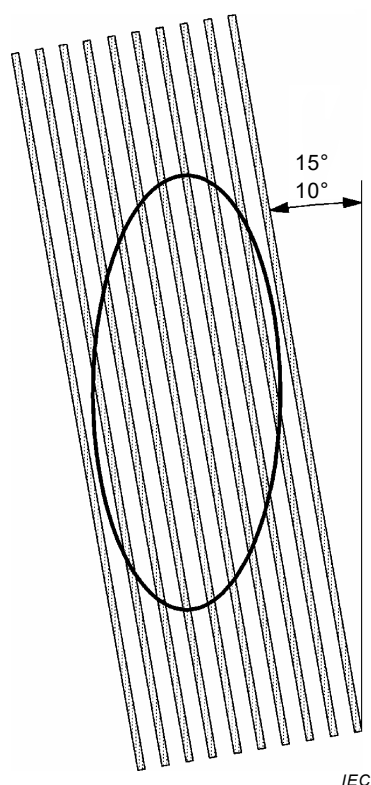


Figure 8 – Image of periodic pattern and position of ROI for transverse and sagittal scans

4.6.5 Data analysis and tolerances

An elliptical ROI shall be chosen on the periodic pattern. If elliptical ROIs are not possible, use a round, rectangular or square ROI. The ROI should be as large as possible, but shall not touch the outer two plates of the TEST DEVICE in the y direction and cover no more than 90 % of the length of the TEST DEVICE, as shown in Figure 7. The mean (S) and the standard deviation (σ) of all pixels in the ROI are determined. The modulation $m(\nu)$ at the spatial frequency $\nu = 1/L$ is calculated by using the standard deviation (σ) and the mean value:

$$m(\nu = \frac{1}{L}) = \frac{\sigma}{S}$$

4.6.6 Reporting of results

The report shall contain the information of Table 8, and any additional information necessary to ensure repeatability.

Table 8 – Reporting of results for SPATIAL RESOLUTION

Parameter	Value/Units
ROI shape	
ROI size	
REFERENCE POSITION	
Spatial frequency $\nu = 1/L$	mm^{-1}
Mean signal level S beside plates	
Noise standard deviation	
Image SNR	
Mean signal level S in ROI	
Standard deviation in ROI	
Modulation m ($\nu = 1/L$)	
Structure resolved (i.e. $m \geq 0,56$)	Yes / No

4.6.7 Reporting of acceptance results

The SPATIAL RESOLUTION test is passed when the measured modulation is above 0,56.

4.7 * GHOSTING ARTEFACTS

4.7.1 Objectives and rationale

This test measures ghost signal amplitude and compares it to the average signal amplitude and the noise floor.

Use a homogenous RF COIL with good SNR and UNIFORMITY (e.g. a receive head coil with body transmit coil), if available in the basic system configuration. This procedure does not need to be performed for other RF COILS.

4.7.2 * Requirements for the TEST DEVICE

The TEST DEVICE size in the phase-encoding direction shall not exceed 50 % of the image FIELD OF VIEW. The TEST DEVICE shall be sufficiently large to permit proper signal ROI measurements. The TEST DEVICE size in the frequency-encoding direction shall not exceed 80 % of the image FIELD OF VIEW. Since both loaded and unloaded measurements are sensitive to changes in the remainder of the MR system (although the loaded condition may be more representative of clinical conditions), either is permitted in this measurement procedure, and the chosen option shall be reported in the results table.

4.7.3 Scan parameters

The following sequence shall be used:

- 2D single gradient echo;
- single slice centred at ISOCENTRE ± 30 mm (displacement in slice selection direction);
- scan plane: transverse (phase encoding direction: left/right), sagittal (phase encoding direction: anterior/posterior), coronal (phase encoding direction: superior/inferior);
- $T_R = 603$ ms;
- $T_E = 25$ ms;
- 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 shall be square;

- matrix size: 192×192 or higher;
- no signal averaging is permitted;
- turn off all smoothing or resolution enhancing filters;
- no PHASE OVERSAMPLING is permitted; to check this assumption, the scan time shall be checked to be approximately equal to the number of phase encodings multiplied by the T_R .

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

To ensure accurate results, the minimum SNR, as determined in 4.7.5, shall be at least 100. If necessary, the pulse sequence parameters indicated below can be adjusted to achieve the required SNR level, in order of preference:

- SLICE THICKNESS;
- flip angle
- FIELD OF VIEW; or
- number of phase encodings.

4.7.4 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) after positioning the TEST DEVICE before scanning to prevent swirling ARTEFACTS. To check the stability of the TEST DEVICE's filler fluid, the acquisition may be repeated until the fluid shows no signal inhomogeneity due to swirling.

4.7.5 Data analysis and tolerances

Three measurements are required on the image to characterize ghosting levels:

- mean ghost level I_G ;
- mean signal level S ;
- noise level I_N .

Set the window width to 1 and change the window level until the brightest ghost appears outside the TEST DEVICE area in the phase-encoding direction. Place an ROI of 25 pixels on the ghost. Make sure that the ROI does not contain any portion of the possible "digital zero" pixels generated by the gradient distortion correction filters (if applied).

Measure and record the ROI mean as the mean ghost signal, I_G .

The noise standard deviation is determined in a region outside the TEST DEVICE area in the frequency-encoding direction (Figure 9). Make sure that the ROI does not contain any portion of the possible "digital zero" pixels generated by the gradient distortion correction filters (if applied). Measure the standard deviation within an ROI of at least 25 pixels and compute I_N as follows:

$$I_N = \sigma / 0,655$$

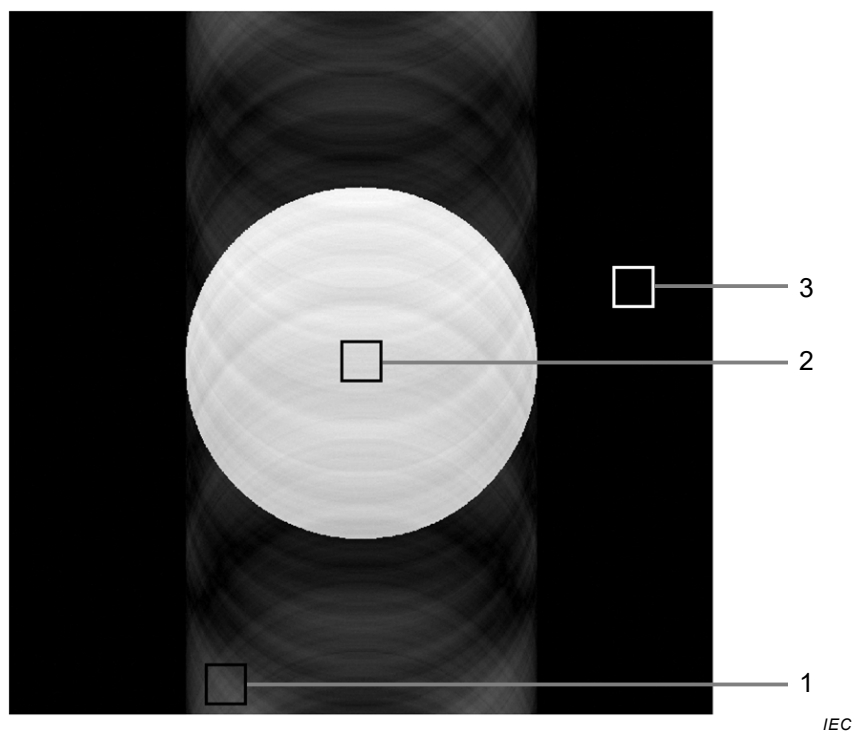
where the 0,655 factor corrects for the rectification of noise by the magnitude image reconstruction process for single channel RF COILS. For multi channel RF COILS, other correction factors depending on the reconstruction are necessary as described in B.2.1.8.

Measure the average signal level (S) within the TEST DEVICE using an ROI of at least 25 pixels.

Calculate the ghost to signal ratio = I_G / S .

Calculate the ghost to noise ratio = I_G / I_N .

Calculate the SIGNAL TO NOISE RATIO = S / I_N .



Key

- 1 ROI for mean ghost measurements
- 2 ROI for mean signal measurements
- 3 ROI for noise measurements

Figure 9 – Example image of the TEST DEVICE and region of interest (ROI) for signal, ghost, and noise measurements

4.7.6 Reporting of results

The report shall contain the information of Table 9, and any additional information necessary to ensure repeatability.

Table 9 – Reporting of results for GHOSTING ARTEFACTS

Parameter	Value/Units
ROI shape	
ROI size	
REFERENCE POSITION	
Mean signal level, S	
Mean ghost level, I_G	
Noise standard deviation, I_N	
I_G/S	
I_G/I_N	
S/I_N	

5 * CONSTANCY TEST

5.1 Objectives and rationale

Clause 5 describes the minimum requirements for a set of CONSTANCY TESTS, to be used within a quality assurance programs concerning essential image quality parameters, suitable for MR EQUIPMENT. This test offers a procedure for assessing image quality over time.

CONSTANCY TESTS check the general condition of the MR EQUIPMENT with a series of quick, simple, sensitive, robust and effective tests. The intent of such tests is not necessarily to diagnose what the problem is, but to identify a problem or verify that the machine is performing properly. Once a performance degradation has been detected by these tests, extra diagnostic tests can be run by the service engineer to isolate and correct the problem. It is not the intent of these measurements to perform an ACCEPTANCE TEST, re-accredit the MR EQUIPMENT, or necessarily diagnose the problem. The intent is to ensure that the machine is continuing to perform at approximately the same level as when the MR EQUIPMENT was accepted. It is important that the measurements be implemented periodically and consistently so that trends can be monitored.

NOTE There is no specific test of magnet homogeneity (e.g., to determine whether ferromagnetic objects are present in the MR EQUIPMENT). The only reason for this "omission" is the fact that no simple fast sequence or phase field mapping technique could be defined that fulfils the boundary conditions (useful CONSTANCY TESTS are quick, simple, sensitive, robust and effective).

The measurement procedures presented in the following allow the use of fast automated algorithms which analyse the images in a consistent, repeatable fashion.

5.2 Requirements for the TEST DEVICE

Since only concepts and requirements for CONSTANCY TESTS are described, no specific TEST DEVICE definition is given. Consequently, the TEST DEVICE provided by the MANUFACTURER or any other TEST DEVICE may be used if it is suitable for the required tests and the related protocols. If the MANUFACTURER'S TEST DEVICE is used, the automated features provided by the MANUFACTURER can be used, simplifying operation and data reporting. The MANUFACTURER's automated features are often optimised for the MR EQUIPMENT and may result in a more sensitive test.

5.3 Scan characteristics

No specific sequences are defined, but it should be possible to complete all of the required tests with 3-4 scans in approximately 5 min to 10 min. Automation of the entire scan process is strongly recommended in order that all tests are consistently applied.

5.4 Measurement procedure

Different methods and algorithms for the various standard CONSTANCY TESTS (even included in this document) are in common use today. Where possible, it is recommended to use fast, automated algorithms, which analyse the QA images in a consistent, repeatable fashion. A possible set of measurement procedures is given in Clause A.6.

The CONSTANCY TEST requires the following procedures listed in Table 10.

Table 10 – Required CONSTANCY TESTS – Parameter settings

Required CONSTANCY TESTS – Parameter settings	TEST DEVICE, scan characteristics
Centre frequency	RF system frequency (^1H)
RF calibration	RF power or voltage of a reference pulse
Geometric accuracy	Size of the TEST DEVICE
Ghosting level	Minimum SNR, T_R limitation
SIGNAL TO NOISE RATIO (SNR)	Maximum SNR

Tests may also share a single scan. For instance, the SNR measurement may be combined with a ghosting test and a part of the geometric accuracy test.

EXAMPLE If the ghosting sequence defined in 4.7.3 is used twice, in orthogonal directions, it is possible to generate enough data to measure SNR twice, ghosting twice and geometric accuracy along each axis at least once within a total scan time of approximately 5 min.

The measurement procedures for the parameters listed may vary for each type of MR EQUIPMENT and may be based on the procedures described in this document. It is important to use fast, automated algorithms, which analyse the QA images in a consistent, repeatable fashion whenever possible. Therefore, no specific test methodologies are defined and consequently no recommended methods are listed in 5.4. Alternative measurement procedures suitable for CONSTANCY TESTS are provided in A.6.1.

5.5 Data analysis, reporting of results and tolerances

Typically, the CONSTANCY TESTS should be performed shortly after installation of the MR EQUIPMENT and the results of this first test should be used as base reference values for subsequent trend analysis.

The output of the tests should be expressed numerically and not in acceptance ("pass/fail") criteria. The report shall contain the data necessary to support the CONSTANCY TEST, and any additional information necessary to ensure repeatability, such as base software and automated protocol version. Numeric results may permit the user to observe trends and proactively diagnose the MR EQUIPMENT before QA tests start to fail.

Annex A (normative)

Alternative methods

A.1 Pertaining to 4.2 SIGNAL TO NOISE RATIO

A.1.1 General

Clause A.1 presents alternative methods for measuring the SNR in TEST DEVICES. Reporting of results shall follow the main methods, with modifications as necessary to enable the duplication of results produced by the alternative methods.

A.1.2 Alternative method: SNR measurements using alternative noise determination

A.1.2.1 Objectives and rationale

A.1.2 presents a method for measuring the SIGNAL TO NOISE RATIO in TEST DEVICES where the noise is measured differently than in 4.2. A minimum- T_R noise scan image is acquired with the TEST DEVICE in its original position but with no RF excitation. T_R may be reduced to a minimum without any effect on the results on the measured noise.

This alternate method is faster than the method described in Clause 4, and thus possibly less sensitive to any system drift that produce significant signal patches in the "differences of images" image. However, the alternate method is more sensitive to subtle background ARTEFACTS that may not be visible.

This method cannot be used if the standard clinical image reconstruction software suppresses or otherwise alters the characteristics of image background noise regions (e.g. noise-only region masking methods). GEOMETRIC DISTORTION correction algorithms potentially violate this requirement, but are exempted if the measurements are near ISOCENTRE where the corrections are presumed minimal.

A.1.2.2 Requirements for the TEST DEVICE

The requirements for the TEST DEVICE are identical to the general requirements noted in 4.1.1 and the specific requirements noted in 4.2.2.

A.1.2.3 Scan parameters

The scan parameters for the noise scan are identical to the requirements specified in 4.2.3, with the exception that T_R may be reduced to the minimum consistent with all the other requirements (e.g. bandwidth, matrix size).

Shut off or otherwise suppress the output from the RF amplifier while acquiring the noise image. Ensure that the receiver attenuation (or gain control) and any scaling of the image reconstruction are identical to that of the signal image (first scan).

The images shall also be reconstructed following the general guidelines specified in 4.2.

A.1.2.4 Measurement procedure

The measurement procedure shall be identical to the procedure described in 4.2.4.

A.1.2.5 Data analysis and tolerances

The same method of analysis as described in 4.2.5 shall be used, but steps 2 to 4 will be substituted as follows:

- Step 2) Not applicable.
- Step 3) Measure the standard deviation, σ , of the pixel values within the ROI on the magnitude noise image (second scan) in a ghost free part of the background of the image. The ROI can be increased in the second image to improve accuracy.
- Step 4) Estimate the IMAGE NOISE.
 - For single-channel magnitude images, use [1]²:

$$I_N = \frac{\sigma}{\sqrt{(4-\pi)/2}} \approx \frac{\sigma}{0,655}$$

- For a real image, $I_N = \sigma$.
 - If magnitude images from multi-channel array coils are used, the appropriate correction factor for the number of channels shall be used as provided in B.2.1.8.
- Step 5) The SNR is:

$$SNR = \frac{S}{I_N}$$

A.1.2.6 Reporting of results

The reporting of results shall match the requirements of 4.2.6.

A.1.2.7 References

Information on SNR measurements and noise determination can be found in [1] and [2].

A.1.3 Alternative method: SNR "single image"

A.1.3.1 Objective and rationale

A single image measurement is acquired with the TEST DEVICE in its original position. The advantage of this method is that only one image acquisition needs to be performed. This alternative method is therefore faster than the method described in 4.2, and less sensitive to any system drift issues that produce significant signal patches in the difference image. However, the alternative method is more sensitive to any noise contamination in the background of the image.

A.1.3.2 Requirements for the TEST DEVICE

See 4.2.2.

A.1.3.3 Scan parameters

See 4.2.3.

A.1.3.4 Measurement procedure

See 4.2.4, apart from the fact that only one scan is executed.

A.1.3.5 Data analysis and tolerances

See A.1.2.5, but replace steps 3 and 4 by

² Numbers in square brackets refer to the Bibliography.

- Step 3) Estimate the IMAGE NOISE.
 - For single-channel magnitude images, use [1]:

$$I_N = \frac{\sigma}{\sqrt{(4-\pi)/2}} \approx \frac{\sigma}{0,655}$$

- For a real image, $I_N = \sigma$.
- If magnitude images from multi-channel array coils are used, the appropriate correction factor for the number of channels shall be used. See B.2.1.8.

A.2 Pertaining to 4.3 UNIFORMITY

A.2.1 General

UNIFORMITY can be measured in a variety of ways. Two alternate methods for UNIFORMITY measurements are given. Reporting of results shall follow the main methods, with modifications as necessary to enable the duplication of results produced by the alternative methods.

A.2.2 Alternative method "grey-scale map"

A.2.2.1 Objectives and rationale

The requirements for the TEST DEVICE, scan parameters and measurement procedure as described in this document can be used to analyse the data in a specific way, also referred to as the "contour method". Many different types of RF COILS are used for signal detection: linear coils, volume coils, and combination coils (i.e. phased array). All coil types have become very useful to optimize imaging within the diverse range of clinical applications for MR. However RF COILS do not detect the same level of MR signal throughout their coverage area or volume. This variation of signal level detection can be characterized by the term "signal UNIFORMITY". This measurement procedure provides a practical figure of UNIFORMITY, for comparing one RF COIL's detection performance against another RF COIL's.

A.2.2.2 Requirements for the TEST DEVICE

See 4.3.2

A.2.2.3 Scan parameters

See 4.3.3.

A.2.2.4 Measurement procedure

See 4.3.4.

A.2.2.5 Data analysis and tolerances

To help minimise the effects of noise on the measurements, the image may be convolved with a nine-point low pass filter function.

A grey-scale coded map is created by the following procedure.

- 1) Select a REGION OF INTEREST (ROI) on the centre of the image that encloses a sufficient number of pixels to yield the desired statistical precision (e.g. 400 pixels to provide 5 % precision), and determine its mean value. If the ROI is in a region with anomalous signal characteristics (e.g. centre of high signal intensity caused by dielectric resonance), use the mean of the ROI (S).

- 2) Examine the signal from each pixel in the entire image and assign a grey-level to each pixel according to the magnitude by which the signal differs from the mean value at the centre ROI. Pixels with signal magnitudes differing by less than V % from the mean value shall be assigned a neutral grey-level. Pixels whose signal is more than V % greater than the mean value, but less than $2 V$ % greater, shall be assigned the next lighter grey-level. Pixels, whose signals are more than V % smaller than the mean value but less than $2 V$ % smaller, shall be assigned the next darker grey-level. Pixels with signal more than $2 V$ % greater than the mean value shall be white, and pixels with signals more than $2V$ % smaller than the mean value shall be black. Practical values for V are 10 (for volume coils) or 20 (for special purpose coils).
- 3) The indicated procedure produces a five grey-level representation of the image non-UNIFORMITY with the following ranges relative to the mean value:
 - lowest signal value to $-2 V$ %;
 - $-2 V$ % through $- V$ %;
 - $- V$ % through $+ V$ %;
 - $+ V$ % through $+2 V$ %;
 - $+2 V$ % through the highest signal value.

These five unequally-sized bands visualize the location and structure of non-uniformities without showing the complex structure immediately surrounding the RF COIL elements.
- 4) Display the grey-scale coded images on the monitor. Because the shape of a contour plot can hardly be specified, a histogram calculation is performed to be able to specify flood-field UNIFORMITY. The histogram calculation proceeds as follows.
 - An ROI (REGION OF INTEREST) for histogram calculation is defined: size and shape depend on the coil type.
 - The number of pixels within the histogram ROI which have a pixel value larger than T , i.e. pixels which are not black, is determined: N_{tot} . The threshold value T is approximately 10 times the background noise level.
 - For every grey value, the percentage ratio is calculated:

$$R = N_g / N_{\text{tot}}$$

where R is the percentage ratio and N and N_g is the number of pixels with a certain grey value is the number of pixels with a certain grey value

The percentage ratios are used to specify the flood-field UNIFORMITY.

A.2.2.6 Reporting of results

The reports shall contain the information of Table A.1 as a minimum, in addition to the report given in clause 4.3.6.

Table A.1 – Reporting of results for UNIFORMITY "grey-scale map"

Parameter	Value/Units
Pixel count T to C – $2 V$	%
Pixel count C – $2 V$ to C – V	%
Pixel count C – V to C + V	%
Pixel count C + V to C + $2 V$	%
Pixel count C + $2 V$ to MAX	%

A.2.3 Alternative method "ACR method"

A.2.3.1 Objectives and rationale

The requirements for the TEST DEVICE, scan parameters and measurement procedure as described in this document can be used to analyse the data in a specific and alternate way, also referred to as the ACR-MRAP (ACR MR accreditation program) method. The ACR-MRAP procedure finds the highest and lowest small signal sub-region areas of interest (SROI) within the ROI.

A.2.3.2 Requirements for the TEST DEVICE

See 4.3.2.

A.2.3.3 Scan parameters

See 4.3.3.

A.2.3.4 Measurement procedure

See 4.3.4.

A.2.3.5 Data analysis and tolerances

Two SROI, approximately 0,5 % of the ROI described in 4.3.5, and wholly enclosed within the ROI shall be positioned at the minimum and maximum signal intensity locations within the ROI.

- 1) Set the window width to a narrow band and adjust the window level so that a small region of the highest signal intensity within the ROI is isolated. Position the SROI in the high intensity region and the average within that SROI is $S_{\max}$.
- 2) Set the window width to a narrow band and readjust the window level so that a small region of the lowest signal intensity within the ROI is isolated. Position the SROI in the low intensity region and the average within that SROI is $S_{\min}$.

The percent image UNIFORMITY (PIU, κ) shall be calculated as follows:

$$\kappa = 100 \left(1 - \frac{S_{\max} - S_{\min}}{S_{\max} + S_{\min}} \right)$$

- 3) Report PIU instead of NU in 4.3.6.

Automated implementations of this algorithm are encouraged.

A.3 Pertaining to 4.4 SLICE THICKNESS in 2-D scanning

A.3.1 General

Clause A.3 presents alternative methods for measuring the SLICE THICKNESS in TEST DEVICES. Reporting of results shall follow the main methods, with modifications as necessary to enable the duplication of results produced by the alternative methods.

The inclined slab method is simpler than the inclined wedge method, because it can be done on most MR EQUIPMENT using a feature that provides a plot of signal intensity along a specified line. However, an ideal rectangular slice will produce a trapezoidal rather than rectangular signal intensity profile (see Figure 1). The thicker the slab relative to the slice, the longer the sides of the trapezoid relative to the plateau. As the thickness of the slab approaches the thickness of the slice, the measured slice intensity profile approaches a triangular shape. If the slab is made thinner to reduce this effect, the signal intensity produced by the slab is reduced, and noise degrades the measurement accuracy. An appropriate slab

thickness may be chosen based on the SLICE THICKNESS to be measured. If this is not possible, multiple averages may be needed to increase the contrast to noise ratio.

A.3.2 Alternative method: SLICE THICKNESS in 2-D scanning: wedge method

A.3.2.1 Objectives and rationale

A.3.2 describes a method for measuring the SLICE THICKNESS from the SLICE PROFILE from 2D images using a wedge of MR-inactive material.

The wedge method is more flexible than the inclined slab method as there is no restriction on the SLICE THICKNESS that can be measured. However, the wedge method requires software for numerical differentiation of the signal intensity profile and is not found on clinical MR EQUIPMENT. Additionally, the numerical differentiation amplifies noise levels and signal non-uniformities produce baseline variations.

A.3.2.2 Requirements for the TEST DEVICE

The TEST DEVICE consists of signal-producing material in which two opposing wedges of non-signal producing material are mounted (see Figure A.1). The inclined surfaces of both wedges form an angle, α , typically 5° to 12° , with the scan plane. 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.

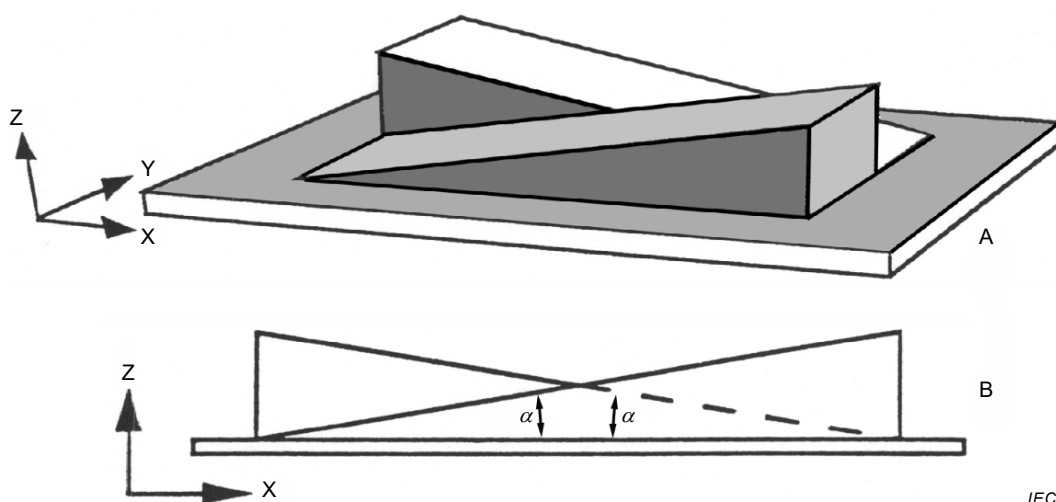


Figure A.1 – Wedge TEST DEVICE

A.3.2.3 Scan parameters

The scan parameters shall match the requirements of 4.4.3.

A.3.2.4 Measurement procedure

The measurement procedure shall match the method provided in 4.4.4.

A.3.2.5 Data analysis and tolerances

For the wedge method, plot the pixel intensities in the direction of the inclination of the wedge, X (see Figure A.2). The pixel intensity at location X_i is denoted by $S(X_i)$. Several rows of pixels may be averaged to improve the SNR. The stretched SLICE PROFILE, $D(X_i)$, is computed by numerical differentiation of the signal intensity plot with respect to distance. This is done by computing the signal intensity difference between neighbouring pixels and dividing by the distance between them, i.e.

$$D(X_i) = [S(X_i) - S(X_{i-1})]/(X_i - X_{i-1})$$

The FWHM of $D(X_i)$ is determined by linear interpolation. The SLICE THICKNESS is then calculated as the product of the FWHM of the stretched profile, $D(X_i)$, and $\tan(\alpha)$.

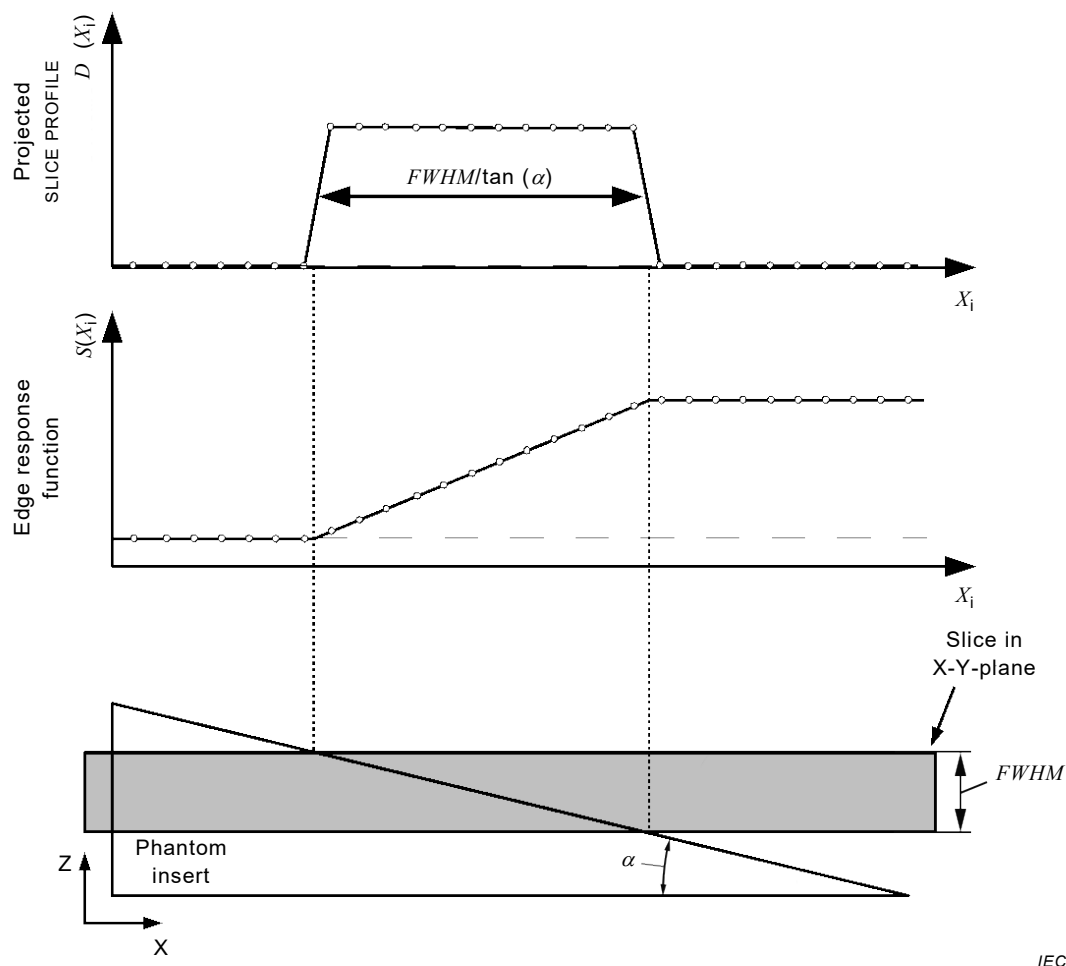


Figure A.2 – Measurement of SLICE PROFILE and SLICE THICKNESS using wedge TEST DEVICE

Since this method takes the derivative of the profile, and the derivative operation increases the noise level in the profile, the image SNR requirement needs to be higher than that specified in 4.4. Increasing the number of averages of the acquisition is a time consuming solution. The SNR may also be improved by averaging together several SLICE PROFILES in adjacent rows perpendicular to the direction of the surface inclination if the TEST DEVICE is not rotated. Ensure that the edges of the individual profiles are accurately aligned to a common point before averaging. Otherwise, the sources of error described in 4.4 are also valid for this alternate method.

In addition, the derivative operation will cause image non-uniformities to be introduced into the profile as baseline variations that may introduce errors in the determination of slice FWHM.

A.3.2.6 Reporting of results

The reporting of results shall match the requirements of 4.4.6.

A.4 Pertaining to 4.5 Two-dimensional GEOMETRIC DISTORTION

A.4.1 General

Clause A.4 presents alternative methods for measuring the GEOMETRIC DISTORTION in TEST DEVICES, including a 3-D method. Reporting of results shall follow the main methods, with modifications as necessary to enable the duplication of results produced by the alternative methods.

A.4.2 Alternative method: GEOMETRIC DISTORTION measurements using elliptical boundary TEST DEVICES

A.4.2.1 Objectives and rationale

A.4.2 presents alternative methods for measuring GEOMETRIC DISTORTION in TEST DEVICES having elliptical boundaries.

A.4.2.2 Requirements for the TEST DEVICE

The perimeter of the ROI shall be matched to the TEST DEVICE shape, and can be an ellipse for an ellipsoid or elliptical cylinder specification volume. A pin, or other structure, may also be positioned at the geometric centre of the TEST DEVICE to assist in accurately determining its centre. A pin diameter of approximately 1 mm helps minimise the error in identifying the reference centre for all radial measurements. If there is no central pin, the centre of the TEST DEVICE may be defined by geometrical methods within the image.

A.4.2.3 Scan parameters

The scan parameters shall match the requirements of 4.5.3.

A.4.2.4 Measurement procedure

The measurement procedure shall match the method provided in 4.5.4.

A.4.2.5 Data analysis and tolerances

A.4.2.5 presents a method for measuring and reporting two-dimensional GEOMETRIC DISTORTION based on an elliptical boundary. For scans resulting in an elliptical section, the measurements of radial distances shall be modified with respect to the circular case. The different values of the nominal radius length will be denoted by R_i in A.4.2.5.

The length of the radius of an ellipse with semi axis length a and b (on X and Y axis respectively) forming an angle α with respect to the X axis can easily be calculated to be:

$$R_i(\alpha) = b \sqrt{\frac{(\tan \alpha)^2 + 1}{(\tan \alpha)^2 + \frac{b^2}{a^2}}}$$

See Figure A.3.