

Magnetic resonance equipment for medical imaging —

Part 1: Determination of essential image quality parameters

The European Standard EN 62464-1:2007 has the status of a
British Standard

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National foreword

This British Standard is the UK implementation of EN 62464-1:2007. It is identical to IEC 62464-1:2007.

The UK participation in its preparation was entrusted by Technical Committee CH/62, Electromedical equipment in medical practice, to Subcommittee 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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**Magnetic resonance equipment for medical imaging -
Part 1: Determination of essential image quality parameters
(IEC 62464-1:2007)**

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

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

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CENELEC

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

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Foreword

The text of document 62B/641/FDIS, future edition 1 of IEC 62464-1, prepared by SC 62B, Diagnostic imaging equipment, of IEC TC 62, Electrical equipment in medical practice, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as EN 62464-1 on 2007-04-01.

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In this standard, the following print types are used:

- requirements, compliance with which can be tested, and definitions: roman type;
- explanations, advice, notes, general statements and exceptions: smaller roman type;
- test specifications: *italic type*;
- terms defined in Clause 3 of EN 60601-1:2006, in this standard or in IEC/TR 60788: SMALL CAPITALS.

Annex ZA has been added by CENELEC.

Endorsement notice

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

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INTRODUCTION

This international standard is written at a moment in which MAGNETIC RESONANCE EQUIPMENT is already present in the market place for more than 20 years. It is estimated that more than 20 000 scanners are operational and more than 0,5 billion PATIENTS have been scanned. A number of standards on quality assurance and quality control have been developed by national committees to address the need for quantitative addressing of system performance and system maintenance. It is therefore felt to be necessary to introduce this IEC standard in addition to the existing standard on MAGNETIC RESONANCE (MR) safety, because the IEC standards have a true international character and this IEC standard is the first start to process and combine current best practices together and provide guidance on how to address the various questions on quality control and quality assurance testing of MAGNETIC RESONANCE EQUIPMENT together. Having a standardized set of test methods minimizes the amount of work for the MR MANUFACTURERS to demonstrate the performance characteristics of the MR scanners for many different countries and in addition, these countries do not have to formulate their own requirements for the performance testing.

Since MR scanners have been around for some time, this international standard is an attempt to consolidate the current way of working for the quality control of the performance characteristics concerning essential image quality parameters, and does not introduce major new development efforts for the established MR equipment to fulfil the requirements of this standard. This objective is achieved by introducing preferred methods in the main text of the standard, while allowing acceptable alternative test methods, described in Annex A of the standard. A number of the ACCEPTANCE TEST methods described in the standard have already been described earlier, mainly as NEMA technical MR standards, while new methods have been developed since then. For this standard, it is attempted to select the best method as the preferred method, although for a number of specific tests good alternatives are available and are therefore also acceptable.

Also for the quality assurance tests and the CONSTANCY TESTS, each MANUFACTURER has developed its own test device and related test procedures and data analysis in the past years. For the CONSTANCY TESTS it was therefore decided not to describe detailed test methods but only prescribe the parameters to be measured and essential conditions for these measurements in the main standard. This provides the necessary latitude to account for the many unique MR designs (extremity scanners, whole body scanners, cylindrical versus open scanners, various field strengths, phantom design, data analysis) and examples for possible CONSTANCY TESTS for the required parameters in the annex. This allows the user to use as many of the tools supplied by MR MANUFACTURERS as possible, appropriate and useful and still fulfill the requirements for quality control and quality assurance.

MAGNETIC RESONANCE EQUIPMENT FOR MEDICAL IMAGING –

Part 1: Determination of essential image quality parameters

1 Scope

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

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

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

This standard does not address:

- required levels of performance for ACCEPTANCE TEST and CONSTANCY TEST;
- image quality assessment of high field MR EQUIPMENT greater than 4 T, if not otherwise stated;
- image quality affected by MR-compatibility issues;
- special diagnostic procedures such as flow imaging, perfusion, diffusion, radiotherapy and image-guided therapy applications;
- type tests.

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

The measurement procedures specified in this standard are directed to:

- a) MANUFACTURERS, who can demonstrate compliance by performing acceptance and constancy methods as described by this standard,
- b) test houses, which can confirm performance of MR EQUIPMENT using methods described in this standard,
- c) regulatory authorities, who can reference this standard, and
- d) RESPONSIBLE ORGANISATIONS who want to perform ACCEPTANCE and CONSTANCY TESTS using methods described in this standard.

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

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

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

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

This standard also presents requirements for CONSTANCY TESTS suitable for MR EQUIPMENT quality assurance programs concerning essential image quality parameters. There are no preferred CONSTANCY TEST methods, to provide flexibility in using existing automated procedures where available, but suggested examples of test methods are found in Annex A. If necessary, other CONSTANCY TEST methods not described in this standard may be used. Since the needs of RESPONSIBLE ORGANISATIONS' quality assurance programs may vary, RESPONSIBLE ORGANISATIONS are encouraged to determine the necessary scope of tests, quality of the tests, and the sensitivity of the data analysis etc. This standard places an emphasis on consistently repeatable, automated measuring tools that facilitate trend analysis and the frequent quick testing of a small set of important parameters which are sensitive to the overall operating characteristics of the MR EQUIPMENT.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

IEC 60788, *Medical electrical equipment – Glossary of defined terms*

3 Terms, definitions and symbols

3.1 Terms and definitions

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

3.1.1

acceptance test

test carried out after new EQUIPMENT has been installed, or major modifications have been made to existing EQUIPMENT, in order to verify compliance with contractual specifications

[IEC 61223-1, definition 3.2.4]

3.1.2**accompanying document**

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

[IEC 60601-1:2005, definition 3.4]

3.1.3**artefact**

apparent structure visible in the image that does not represent a structure at the corresponding position within the object and that cannot be explained by noise

3.1.4**bandwidth per pixel**

reciprocal of the duration of the sampling window

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

3.1.5**body test device**

TEST DEVICE representing the PATIENT'S body

3.1.6**constancy test**

each of a series of tests, carried out:

- to ensure that the functional performance of EQUIPMENT meets ESTABLISHED CRITERIA; or
- to enable the early recognition of changes in the properties of components of the EQUIPMENT.

[IEC 61223-1:1993, definition 3.2.6]

3.1.7**extremity test device**

TEST DEVICE representing the PATIENT's extremities

3.1.8**field of view****FOV**

size of the imaging area requested by OPERATOR

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

3.1.9**geometric distortion**

spatial position deviation of the imaged structure from expected position of real object structure

3.1.10**ghosting artefact**

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

3.1.11**head test device**

TEST DEVICE representing the PATIENT's head

3.1.12

image data

reconstructed acquisition data

3.1.13

image noise

random fluctuations from the expected signal values in an image

3.1.14

intended use/intended purpose

use of a product, process or service in accordance with the specifications, instructions and information provided by the MANUFACTURER

[IEC 60601-1:2005, definition 3.44]

3.1.15

isocentre

in MR EQUIPMENT null point of the spatially encoding gradients

NOTE Typically, this also corresponds to the region of highest magnet homogeneity.

3.1.16

magnetic resonance equipment

MR equipment

MEDICAL ELECTRICAL EQUIPMENT that is intended for in-vivo MAGNETIC RESONANCE EXAMINATION of a PATIENT. The MR EQUIPMENT comprises all parts in hardware and software from the SUPPLY MAINS to the display monitor. The MR EQUIPMENT is a Programmable Electrical Medical System (PEMS)

[IEC 60601-2-33:2002, definition 2.2.101]

3.1.17

magnetic resonance system

MR system

ensemble of MR EQUIPMENT, ACCESSORIES including means for display, control, energy supplies, and the CONTROLLED ACCESS AREA, where provided

[IEC 60601-2-33:2002, definition 2.2.102]

3.1.18

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

[IEC 60601-1:2005, definition 3.55]

3.1.19

operator

person handling EQUIPMENT

[IEC 60601-1:2005, definition 3.73]

3.1.20

radio frequency coil

RF coil

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

3.1.21**reconstruction parameters**

in MR EQUIPMENT ensemble of all parameters that uniquely define the transform of the digitized signals to an image

3.1.22**reference position**

predefined point within the SPECIFICATION VOLUME

NOTE Normally the REFERENCE POSITION lies on the symmetry axis of the coil and corresponds to the centre of gravity of the SPECIFICATION VOLUME.

3.1.23**region of interest****ROI**

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

[IEC 61223-2-6, definition 3.3.9]

3.1.24**responsible organisation**

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

NOTE 1 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 Education and training is included in "use."

[IEC 60601-1:2005, definition 3.101]

3.1.25**signal to noise ratio****SNR**

the quotient of the signal level divided by the noise level

3.1.26**slice profile**

in MR EQUIPMENT, plot of the MAGNETIC RESONANCE signal intensity perpendicular to the scanned slice

3.1.27**slice thickness**

in MR EQUIPMENT, FULL WIDTH AT HALF MAXIMUM (FWHM) of the SLICE PROFILE

3.1.28**spatial resolution**

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

3.1.29**specification area**

in MR EQUIPMENT the intersection of the SPECIFICATION VOLUME and the image plane

3.1.30

specification volume

in MR EQUIPMENT, imaging volume within which a MANUFACTURER guarantees image performance specifications

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

3.1.31

test device

object for imaging test purposes

3.1.32

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

For the purposes of this document, the following symbols apply.

3.2.1

a

width of the plates

3.2.2

AAD

average absolute deviation of pixel signal values

3.2.3

b

length of plates

3.2.4

$|b(y)|$

magnitude image of a periodic box function

3.2.5

b_0 , b_1 , b_2 , and b_3

curve fit constants

3.2.6

B_0

static magnetic field

3.2.7

B_1

radio frequency magnetic field

3.2.8

BW

BANDWIDTH

3.2.9

BW_{pix}

BANDWIDTH PER PIXEL

3.2.10**BW_{im}**

Bandwidth of the image

3.2.11**BW_{GE}**

bandwidth defined by GE

3.2.12**BW_{Siemens}**

bandwidth defined by Siemens

3.2.13**C**

mean pixel signal value of a ROI in the centre of the image

3.2.14 **d_p**

distance between adjacent plates

3.2.15 **d**

TEST DEVICE diameter

3.2.16 **d^m**

diameter of the spherical TEST DEVICE measured in the image

3.2.17 **$D(X_i)$**

stretched SLICE PROFILE

3.2.18**ESF(x)**

edge spread function

3.2.19 **$F(v)$**

Fourier transform of a box function

3.2.20**FT{}**

Fourier transform

3.2.21**FWHM**

full width half maximum

3.2.22 **$g(x)$**

periodic box function

3.2.23 **$G(t)$**

B_0 -field gradient

3.2.24

$G_{\text{rd, ph, sel}}$

B_0 -field gradient in read, phase-encoding and slice-selection direction

3.2.25

I_G

intensity of ghost signal

3.2.26

I_N

noise level

3.2.27

L

periodicity of plates

3.2.28

$\text{LSF}(x)$

line spread function

3.2.29

$m(\nu)$

modulation at the spatial frequency ν

3.2.30

$\text{MTF}(\nu)$

modulation transfer function

3.2.31

n

number of plates

3.2.32

N

the total number of pixels in the ROI

3.2.33

N_d

number of radial measured distances

3.2.34

N_{tot}

number of pixels within the histogram ROI which have a pixel value larger than T

3.2.35

NU

non-uniformity

3.2.36

P

slab thickness parallel to the slice

3.2.37

R

TEST DEVICE radius

3.2.38 **RD**

relative GEOMETRIC DISTORTION

3.2.39 **$r_{\max}$**

maximum GEOMETRIC DISTORTION

3.2.40 **$\bar{r}$** mean value of the N radial measured distances**3.2.41** **$\bar{r}$**

distance of the pixel from the magnet centre

3.2.42 **s**

sides of trapezoid

3.2.43 **S**

mean pixel signal value

3.2.44 **S_i**

individual pixel signal value

3.2.45 **$S(X_i)$** pixel signal value at location X_i **3.2.46** **S_{echo}**

signal intensities for the 'regular echo'

3.2.47 **$S_{\text{stim.echo}}$**

signal intensities for the 'stimulated echo'

3.2.48 **SD**

standard deviation of pixel signal values

3.2.49 **T**

threshold value

3.2.50 **T_1**

longitudinal relaxation time

3.2.51 **T_2**

transversal relaxation time

3.2.52

T_E

echo time

3.2.53

T_R

repetition time

3.2.54

T_{RF}

duration of RF-pulse

3.2.55

U

UNIFORMITY

3.2.56

V

threshold used for colour coding

3.2.57

$w(x,y,z)$

relative weighting function of the signal intensity at the location (x,y,z)

3.2.58

w_i

SLICE THICKNESS measured at measurement i

3.2.59

w_d

weighting factor to remove the effect of discrete differentiation

3.2.60

WFS

water-fat shift

3.2.61

X_i

location

3.2.62

α

flip angle

3.2.63

α_s

slab inclination angle

3.2.64

γ

gyromagnetic ratio

3.2.65

δ

scale GEOMETRIC DISTORTION

3.2.66 **δ'**

effective scale geometric distortion

3.2.67 **$\Delta_i(P)$**

geometric error caused by choosing the measurement points not precisely on the ROI perimeter

3.2.68 **$\Delta_i(\varepsilon)$**

geometric error caused by centring error

3.2.69 **$\Delta_i(\delta)$**

geometric error contribution of the geometric distortion

3.2.70 **$\Delta B_0(\vec{r})$**

static field inhomogeneity at the location of the pixel

3.2.71 **Δf**

frequency difference

3.2.72 **$\Delta G(\vec{r})$** B_0 -field gradient linearity error at the location of the pixel**3.2.73** **$\Delta r(\vec{r})$**

geometrical shift of the pixel

3.2.74 **ΔT**

time delay

3.2.75 **Δx**

pixel size in x dimension

3.2.76 **Δy**

pixel size in y dimension

3.2.77 **ε**

centering error

3.2.78 **θ**

angle of rotation of the TEST DEVICE about the y axis

3.2.79

θ_r

angle between r and x-axis

3.2.80

σ_δ

aberration GEOMETRIC DISTORTION

3.2.81

ν

spatial frequency

3.2.82

ν_c

cut off frequency

3.2.83

ν_N

Nyquist frequency

3.2.84

ϕ

constant phase of the signals

4 Procedures for the determination of essential image parameters

4.1 General requirements for all procedures

4.1.1 Requirements for the TEST DEVICE

The TEST DEVICE shall consist of a volume (e.g. polypropylene carboy, Perspex) of appropriate shape and size to fit inside the receive coil to be tested. It shall be filled with a MR signal-producing material, (e.g. water, or silicon oil) with a sufficiently small dielectric constant and conductivity to reduce standing wave phenomena.

The MR specific properties of the signal-producing material (spin density ρ , T_1 , T_2) shall be similar to that of a PATIENT's body. (Typical values: $T_1 < 1\,200$ ms, $T_2 > 50$ ms, Spin density $\rho = \rho_{H_2O} \pm 20\%$). This can be achieved by doping pure water 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 $22\,^\circ\text{C} \pm 4\,^\circ\text{C}$.

Exceptions to these requirements are specified where necessary.

4.1.2 Requirements for image reconstruction

All images shall be processed with the MR EQUIPMENT's standard clinical reconstruction algorithm. All such filters that can be selected by the OPERATOR shall be disabled unless otherwise specified. Filters include distortion corrections, smoothing and edge enhancement, for example. If this is not possible, identify all remaining filters in the results. The images to be analysed shall be substantially free of image ARTEFACTS.

Exceptions to these requirements are specified where necessary.

4.1.3 Requirements for scanning

All image acquisitions shall be preceded by the standard clinical prescan calibration, unless otherwise specified.

4.2 SIGNAL TO NOISE RATIO

4.2.1 Objectives and rational

Image SNR is a parameter that relates to clinical usefulness of MRI and also is a sensitive measure of hardware performance. Experience has shown that variations in system calibration, gain, coil tuning, RF shielding, or other similar parameters are usually demonstrated by a corresponding change in image SNR.

It is also a further objective of the SNR, SLICE THICKNESS and SPATIAL RESOLUTION tests to use the identical sequence and parameters, with some specific exceptions for the number of averages, to control the close relationship between the results of these three tests.

4.2.2 Requirements for the TEST DEVICE

In order to approximate the IMAGE NOISE performance that would be typically encountered in a clinical situation, the receive coil of interest shall be electrically loaded to approximate a 50 kg – 90 kg human. Loading may be accomplished by TEST DEVICES or other reproducible means. Experimentally verify that the loading is similar to a 50 kg – 90 kg human properly positioned for clinical scanning. The load is considered to be equivalent if the following electrical parameters 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

Alternatively, or additionally, other methods (total RF power needed to achieve a certain flip angle, etc.) can be used to verify the compliance of the loading with a 50 kg – 90 kg human.

The BODY TEST DEVICE containing the signal-producing material can be a cylinder, sphere or an ellipsoid. The minimum cross sectional area is a 200 mm diameter circle.

The HEAD TEST DEVICE containing the signal-producing material can be a cylinder, sphere or an ellipsoid. The minimum cross sectional area is a 150 mm diameter circle.

The EXTREMITY TEST DEVICE containing the signal-producing material can assume any shape. The minimum cross sectional area will be 85 % of the SPECIFICATION AREA.

4.2.3 Scan parameters

The following sequence should be used:

- 2D single spin echo, single slice sequence centred at ISOCENTRE ± 30 mm,
- scan plane: transverse, sagittal, coronal (in turn),

- $T_R = 1\,000\text{ ms}$ or $\geq 3 T_1$ of the signal-producing material whichever is larger,
- $T_E = 30\text{ ms}$ or $\leq 1/3 T_2$ of the signal-producing material whichever is smaller,
- pixel bandwidth $(100 \pm 3)\text{ Hz}$,
- FIELD OF VIEW 250 mm for head coil,
- FIELD OF VIEW 440 mm for body coil,
- FIELD OF VIEW of 250 mm for the head coil, FIELD OF VIEW of 440 mm for the body coil, for all other coils FIELD OF VIEW shall not exceed 110 % of the largest RF COIL dimension in the image plane,
- matrix 256×256 ,
- SLICE THICKNESS 5 mm, and
- no signal averaging is permitted.

Use the identical sequence and RECONSTRUCTION PARAMETERS for SLICE THICKNESS and SPATIAL RESOLUTION measurements, apart signal averaging is permitted.

4.2.4 Measurement procedure

The placement of the TEST DEVICE in the 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. The scanned slice shall be set through the REFERENCE POSITION to give the largest SPECIFICATION AREA; preferably along or perpendicular to a symmetry axis of the coil.

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. Verify the SPATIAL RESOLUTION and SLICE THICKNESS for the sequence in SNR determination. Use the methods described in 4.4 and 4.6 of this standard.

NOTE This verification confirms that the nominal SLICE THICKNESS and SPATIAL RESOLUTION were realised.

4.2.5 Data analysis and tolerances

The REGION OF INTEREST (ROI) has to be a centred, regular geometric area enclosing at least 85 % of the area of the image of the signal-producing volume of the TEST DEVICE.

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:
image 3 = image 1 - image 2.

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 (i.e. negative values).

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 (SD). Divide SD by the square root of two, eliminating the noise amplification of the image subtraction process, to give the IMAGE NOISE.

Step 4. Calculate *SNR* as:

$$SNR = \frac{S}{\left(\frac{SD}{\sqrt{2}}\right)} \quad (1)$$

4.2.6 Reporting of results

The report shall contain the following:

Parameter	Dimension
SNR	
SLICE THICKNESS (result of measurement according to 4.4)	mm
SPATIAL RESOLUTION (result of measurement according to 4.6)	mm
Scan plane orientation	
Direction of frequency/phase encoding	
SPECIFICATION AREA - size and shape	mm ²
Coil dimensions	mm
Coil name and type	
Cross-sectional area of TEST DEVICE - size and shape	mm ²
ROI - size and shape	mm ²
REFERENCE POSITION	
Data acquisition matrix size	
FIELD OF VIEW	mm ²
Nominal voxel dimension (Δx , Δy , selected SLICE THICKNESS)	mm
SLICE THICKNESS (measured)	mm
SPATIAL RESOLUTION (measured)	mm
TEST DEVICE filler material description	
TEST DEVICE filler T_1	ms
TEST DEVICE filler T_2	ms
TEST DEVICE salt type and concentration	g/l
BANDWIDTH PER PIXEL	Hz/pixel
Sequence repetition time (T_R)	ms
Echo delay time (T_E)	ms
Number of averages	
Pulse sequence spin echo or gradient echo	
Filter used (if any)	
The results shall be accompanied by an estimate of the measurement errors.	

List all RECONSTRUCTION PARAMETERS selected and provide other relevant information that ensures repeatability.

4.3 UNIFORMITY

4.3.1 Objectives and rationale

This subclause presents a measurement procedure for computing a UNIFORMITY figure of merit that is suitable for all MR coils. As a result the low spatial frequency non-uniformities typical for MRI images can be characterized. The measurements are made over a volume that is representative of the region used for typical clinical studies.

4.3.2 Requirements for the TEST DEVICE

For coil UNIFORMITY characterisation a homogeneous TEST DEVICE shall be used. This may differ per coil type.

TEST DEVICE dimensions and shape shall include, at a minimum, the SPECIFICATION AREA for that coil.

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

4.3.3 Scan parameters

The following sequence should be used:

- 2D single spin echo, single slice sequence centred at ISOCENTRE +/- 30 mm
- scan plane: transverse, sagittal, coronal (in turn)
- $T_R = 1\,000\text{ ms}$ or $\geq 3\, T_1$ of the signal-producing material whichever is larger,
- $T_E = 30\text{ ms}$ or $\leq 1/3\, T_2$ of the signal-producing material whichever is smaller,
- pixel bandwidth $(100 \pm 3)\text{ Hz}$,
- FIELD OF VIEW 250 mm for head coil,
- FIELD OF VIEW 440 mm for body coil,
- FIELD OF VIEW of 250 mm for the head coil, FIELD OF VIEW of 440 mm for the body coil, for all other coils FIELD OF VIEW shall not exceed 110 % of the largest RF COIL dimension in the image plane,
- matrix 256×256 ,
- SLICE THICKNESS 5 mm, and
- signal averaging is permitted.

4.3.4 Measurement procedure

The placement of the TEST DEVICE in the appropriate RF COIL (Figures 1 and 2) 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. The IMAGE PLANE shall be set through the REFERENCE POSITION to give the largest SPECIFICATION AREA, preferably along or perpendicular to a symmetry axis of the coil.

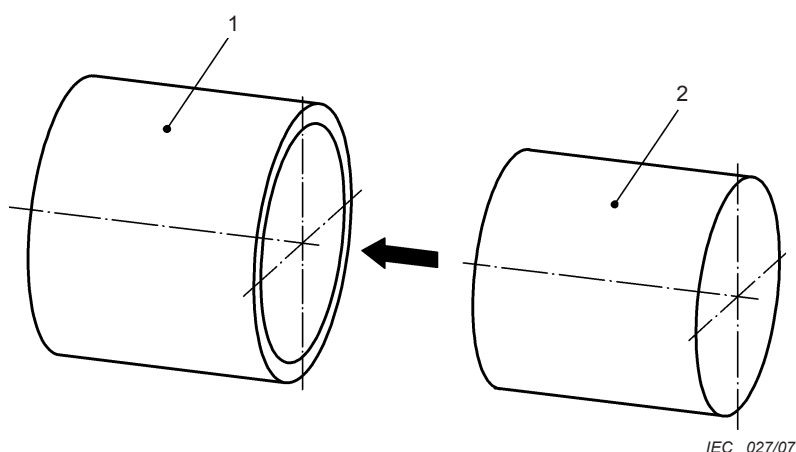
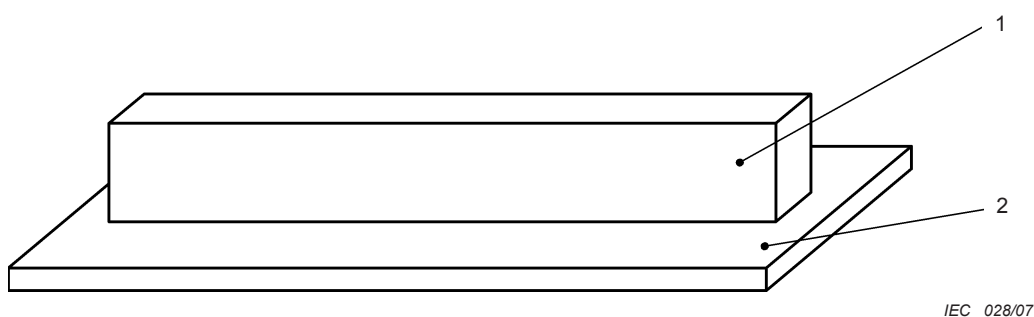


Figure 1 – Insertion of a homogenous TEST DEVICE into the RF coil



Components

- 1 TEST DEVICE
- 2 Coil

Figure 2 – Position of the TEST DEVICE on the surface coil

For volume coils one image shall be obtained from each plane, i.e. transverse, coronal and sagittal, thus recording three images per coil.

4.3.5 Data analysis and tolerances

The average absolute deviation of the signal in a ROI is defined as

$$AAD = \sum_{i=1}^N (|S_i - S|) / N \quad (2)$$

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 , and

N is the total number of pixels in the ROI.

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

- a) Draw a ROI to include 85 % of the signal-producing volume within the SPECIFICATION AREA. The signal-producing area shall exceed the SPECIFICATION AREA to avoid ARTEFACTS.
- b) Calculate the mean signal and AAD from ROI.
- c) Compute the UNIFORMITY measure U :

$$U = 1 - \frac{AAD}{S} \quad (3)$$

where U is the measure for UNIFORMITY

Dividing by the mean of the TEST DEVICE signal region S normalises the output for each coil. Record U for all assessed planes.

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

$$NU = 1 - U \quad (4)$$

4.3.6 Reporting of results

The report shall contain the following:

Parameter	Dimension
UNIFORMITY U or non-uniformity NU	
Scan plane orientation	
Direction of frequency/phase encoding	
SPECIFICATION AREA - size and shape	mm ²
Coil dimensions	mm
Coil name and type	
Cross-sectional area of TEST DEVICE - size and shape	mm ²
ROI - size and shape	mm ²
REFERENCE POSITION	
Data acquisition matrix size	
FIELD OF VIEW	mm ²
Nominal voxel dimension (Δx , Δy , selected SLICE THICKNESS)	mm
SLICE THICKNESS (measured)	mm
SPATIAL RESOLUTION (measured)	mm
TEST DEVICE filler material description	
TEST DEVICE filler T_1	ms
TEST DEVICE filler T_2	ms
TEST DEVICE salt type and concentration	g/l
BANDWIDTH PER PIXEL	Hz/pixel
Sequence repetition time (T_R)	ms
Echo delay time (T_E)	ms
Number of averages	
Pulse sequence spin echo or gradient echo	
Filter used (if any)	
The results shall be accompanied by an estimate of the measurement errors.	