BS EN 61675-2:2015

BSI Standards Publication

Radionuclide imaging devices — Characteristics and conditions

Part 2: Gamma cameras for planar, wholebody, and SPECT imaging

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National foreword

This British Standard is the UK implementation of EN 61675-2:2015. It is identical to IEC 61675-2:2015. It supersedes BS EN 61675-2:1998, BS EN 61675-3:1998 and BS EN 60789:2005, which will be withdrawn on 10 September 2018.

The UK participation in its preparation was entrusted by Technical Committee CH/62, Electrical Equipment in Medical Practice, to Subcommittee CH/62/3, Equipment for radiotherapy, nuclear medicine and radiation dosimetry.

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

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Published by BSI Standards Limited 2015

ISBN 978 0 580 84670 0
ICS 11.040.50

Compliance with a British Standard cannot confer immunity from legal obligations.

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 30 November 2015.

Amendments/corrigenda issued since publication

Date	Text affected

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 61675-2

November 2015

ICS 11.040.50

Supersedes EN 60789:2005, EN 61675-2:1998, EN 61675-3:1998

English Version

Radionuclide imaging devices - Characteristics and conditions - Part 2: Gamma cameras for planar, wholebody, and SPECT imaging (IEC 61675-2:2015)

Dispositifs d'imagerie par radionucléides - Caractéristiques et conditions d'essai - Partie 2: Gamma-caméras pour l'imagerie planaire, l'imagerie du corps entier et l'imagerie SPECT
(IEC 61675-2:2015)

Bildgebende Systeme in der Nuklearmedizin - Merkmale und Prüfbedingungen - Teil 2: Gammakameras für planare Bildgebung, mit Ganzkörper-Zusatz und Gammakameras zur Einzelphotonen-Emissions-Tomographie (SPECT)
(IEC 61675-2:2015)

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

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

Ref. No. EN 61675-2:2015 E

European foreword

The text of document 62C/616/FDIS, future edition 2 of IEC 61675-2, prepared by IEC/SC 62C "Equipment for radiotherapy, nuclear medicine and radiation dosimetry" of IEC/TC 62 "Electrical equipment in medical practice" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN 61675-2:2015.

The following dates are fixed:

• latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement	(dop)	2016-06-10
• latest date by which the national standards conflicting with the document have to be withdrawn	(dow)	2018-09-10

This document supersedes EN 61675-2:1998 and A1:2005, EN 60789:2005 and EN 61675-3:1998.

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The text of the International Standard IEC 61675-2:2015 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following notes have to be added for the standards indicated:

IEC 60601-1:2005 A1:2012	NOTE Harmonized as EN 60601-1:2006 (not modified). A1:2013
IEC 61675-1:2013	NOTE Harmonized as EN 61675-1:2014 (not modified).

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

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

NOTE 1 When an International Publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

NOTE 2 Up-to-date information on the latest versions of the European Standards listed in this annex is available here: www.cenelec.eu.

Publication	Year	Title	EN/HD	Year
IEC/TR 60788	2004	Medical electrical equipment - Glossary of defined terms	-	-
IEC 61675-1	2013	Radionuclide imaging devices - Characteristics and test conditions -- Part 1: Positron emission tomographs	EN 61675-1	2014

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

RADIONUCLIDE IMAGING DEVICES – CHARACTERISTICS AND TEST CONDITIONS –

Part 2: Gamma cameras for planar, wholebody, and SPECT imaging

FOREWORD

International Standard IEC 61675-2 has been prepared by subcommittee 62C: Equipment for radiotherapy, nuclear medicine and radiation dosimetry, of IEC technical committee 62: Electrical equipment in medical practice.

This second edition of IEC 61675-2 cancels and replaces the first edition published in 1998 and its Amendment 1 published in 2004, as well as IEC 60789:2005, IEC 60789:2005/COR1:2009, and IEC 61675-3:1998. It has been reformatted, updated, and partly aligned with NEMA NU 1-2007. Due to the lack of market share of SPECT-systems operated in coincidence mode all such tests have been removed.

The text of this standard is based on the following documents:

FDIS	Report on voting
62C/616/FDIS	62C/623/RVD

Full information on the voting for the approval of this standard can be found in the report on voting indicated in the above table.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

In this standard, the following print types are used:

– TERMS DEFINED IN CLAUSE 2 OF THIS STANDARD OR LISTED IN THE INDEX OF DEFINED TERMS: SMALL CAPITALS.

The requirements are followed by specifications for the relevant tests.

Annex A is for information only.

The committee has decided that the contents of this publication will remain unchanged until the stability date indicated on the IEC website under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

INTRODUCTION

The test methods specified in this part of IEC 61675 have been selected to reflect as much as possible the clinical use of GAMMA CAMERAS for planar imaging, PLANAR WHOLEBODY IMAGING EQUIPMENT, and SINGLE PHOTON EMISSION COMPUTED TOMOGRAPHY (SPECT). It is intended that the test methods are carried out by manufacturers thereby enabling them to describe the characteristics of the systems on a common basis.

RADIONUCLIDE IMAGING DEVICES – CHARACTERISTICS AND TEST CONDITIONS –

Part 2: Gamma cameras for planar, wholebody, and SPECT imaging

1 Scope

This part of IEC 61675 specifies terminology and test methods for describing the characteristics of GAMMA CAMERAS equipped with PARALLEL HOLE COLLIMATORS for planar imaging. Additional tests are specified for those GAMMA CAMERAS that are capable of planar wholebody imaging (PLANAR WHOLEBODY IMAGING EQUIPMENT) or SINGLE PHOTON EMISSION COMPUTED TOMOGRAPHY (SPECT). These GAMMA CAMERAS consist of a gantry, single or multiple DETECTOR HEADS, and a computer for data acquisition, processing, storage, and display. The DETECTOR HEADS may contain single or multiple scintillation crystals or solid state detectors.

No test has been specified to characterize the uniformity of reconstructed images because all methods known so far will mostly reflect the noise of the image.

2 Normative references

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

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

IEC 61675-1:2013, *Radionuclide imaging devices – Characteristics and test conditions – Part 1: Positron emission tomographs*

3 Terms and definitions

For the purposes of this document the terms and definitions given in IEC 60788 and IEC 61675-1 (some of which are repeated here for convenience), and the following terms and definitions apply.

3.1
ADDRESS PILE UP
<GAMMA CAMERA> false address calculation of an artificial event which passes the ENERGY WINDOW, but is formed from two or more events by the PILE UP EFFECT

3.2
AXIAL FIELD OF VIEW
dimensions of a slice through the TOMOGRAPHIC VOLUME parallel to and including the SYSTEM AXIS

Note 1 to entry: In practice it is specified only by its axial dimension given by the distance between the centres of the outermost defined IMAGE PLANES plus the average of the measured AXIAL SLICE WIDTH measured as EQUIVALENT WIDTH (EW).

3.3
AXIAL RESOLUTION
for tomographs with sufficiently fine axial sampling fulfilling the sampling theorem, SPATIAL RESOLUTION along a line parallel to the SYSTEM AXIS

3.4
CENTRE OF ROTATION
COR
origin of that coordinate system, which describes the PROJECTIONS of a transverse slice with respect to their orientation in space

Note 1 to entry: The CENTRE OF ROTATION of a transverse slice is given by the intersection of the SYSTEM AXIS with the mid-plane of the corresponding OBJECT SLICE.

Note 2 to entry: The second note to entry concerns the French text only.

3.5
COLLIMATOR AXIS
straight line which passes through the geometrical centre of the exit field and entrance field of the COLLIMATOR

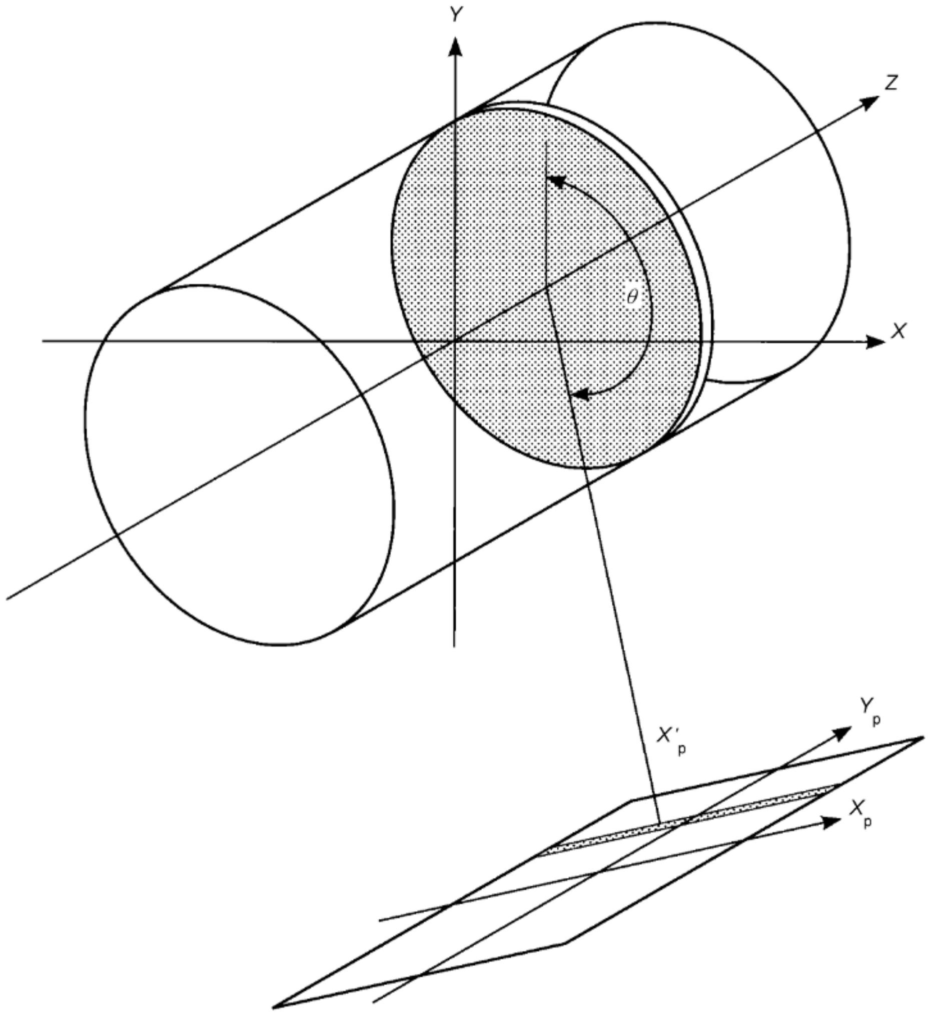
3.6
COLLIMATOR FRONT FACE
surface of the COLLIMATOR which is closest to the object being imaged

3.7
COORDINATE SYSTEM OF PROJECTION
Cartesian system of the IMAGE MATRIX of each two-dimensional PROJECTION with axes X_p and Y_p

Note 1 to entry: Axes X_p and Y_p are defined by the axes of the IMAGE MATRIX.

Note 2 to entry: The Y_p axis and the PROJECTION of the SYSTEM AXIS onto the detector front face have to be in parallel.

Note 3 to entry: The origin of the COORDINATE SYSTEM OF PROJECTION may be the centre of the IMAGE MATRIX (see Figure 1).



NOTE The FIXED COORDINATE SYSTEM X, Y, Z has its origin at the centre of the TOMOGRAPHIC VOLUME (shown as a cylinder), the Z-axis being the SYSTEM AXIS. The COORDINATE SYSTEM OF PROJECTION X_p, Y_p is shown for a PROJECTION ANGLE θ. For each θ, the one-dimensional PROJECTION of the marked OBJECT SLICE has the address range shown (hatched). Within this range the CENTRE OF ROTATION is projected onto the address X_p (offset).

Figure 1 – Geometry of PROJECTIONS

3.8
COUNT LOSS
difference between measured COUNT RATE and TRUE COUNT RATE, which is caused by the finite RESOLVING TIME of the instrument

[SOURCE: IEC 61675-1:2013, 3.8.1]

3.9
COUNT RATE
number of counts per unit of time

[SOURCE: IEC 61675-1:2013, 3.8.2]

3.10
COUNT RATE CHARACTERISTIC
function giving the relationship between observed COUNT RATE and TRUE COUNT RATE

[SOURCE: IEC 60788:2004, rm-34-21]

3.11
DETECTOR FIELD OF VIEW
FOV
region of the detector within which events are included in the display image, and for which all performance specifications are provided

Note 1 to entry: The note to entry regarding the abbreviation concerns the French text only.

3.12
DETECTOR HEAD TILT
deviation of the COLLIMATOR AXIS from orthogonality with the SYSTEM AXIS

3.13
DETECTOR POSITIONING TIME
fraction of the total time spent on an acquisition which is not used in collecting data

3.14
EMISSION COMPUTED TOMOGRAPHY
ECT
imaging method for the representation of the spatial distribution of RADIONUCLIDES in selected two-dimensional slices through the object

3.15
ENERGY WINDOW
range defining the energy signals accepted by the device for further processing

3.16
EQUIVALENT WIDTH
EW
width of that rectangle having the same area and the same height as the response function, e.g. the POINT SPREAD FUNCTION

[SOURCE: IEC 60788:2004, rm-34-45]

3.17
FIXED COORDINATE SYSTEM
Cartesian system with axes *X*, *Y*, and *Z*

Note 1 to entry: *Z* being the SYSTEM AXIS.

Note 2 to entry: The origin of the FIXED COORDINATE SYSTEM is defined by the centre of the TOMOGRAPHIC VOLUME (see Figure 1).

Note 3 to entry: The SYSTEM AXIS is orthogonal to all transverse slices.

3.18
IMAGE MATRIX
arrangement of MATRIX ELEMENTS in a preferentially Cartesian coordinate system

3.19
IMAGE PLANE
plane assigned to a plane in the OBJECT SLICE

Note 1 to entry: Usually the IMAGE PLANE is the mid-plane of the corresponding OBJECT SLICE.

3.20
INTRINSIC ENERGY RESOLUTION
FULL WIDTH AT HALF MAXIMUM of the full energy absorption peak in the INTRINSIC ENERGY SPECTRUM for a specified RADIONUCLIDE

3.21
INTRINSIC ENERGY SPECTRUM
measured histogram of pulse heights for the DETECTOR HEAD without COLLIMATOR

Note 1 to entry: The pulse height should be expressed as corresponding energy.

3.22
INTRINSIC NON-UNIFORMITY OF RESPONSE
NON-UNIFORMITY OF RESPONSE of the DETECTOR HEAD without COLLIMATOR

3.23
INTRINSIC SPATIAL NON-LINEARITY
SPATIAL NON-LINEARITY of the DETECTOR HEAD without COLLIMATOR

3.24
INTRINSIC SPATIAL RESOLUTION
<GAMMA CAMERA> SPATIAL RESOLUTION in air for a specified RADIONUCLIDE measured without the COLLIMATOR

3.25
LINE SOURCE
straight RADIOACTIVE SOURCE approximating a δ-function in two dimensions and being constant (uniform) in the third dimension

3.26
MATRIX ELEMENT
smallest unit of an IMAGE MATRIX, which is assigned in location and size to a certain volume element of the object (VOXEL)

3.27
MULTIPLE WINDOW SPATIAL REGISTRATION
measured position of a source as a function of the ENERGY WINDOW setting

3.28
NORMALIZED VOLUME SENSITIVITY
VOLUME SENSITIVITY divided by the AXIAL FIELD OF VIEW of the tomograph or the phantom length, whichever is the smaller

3.29
OBJECT SLICE
slice in the object

Note 1 to entry: The physical property of this slice that determines the measured information is displayed in the tomographic image.

3.30
OFFSET
deviation of the position of the PROJECTION of the COR (X'_p) from $X_p = 0$ (see Figure 1)

3.31
PARALLEL HOLE COLLIMATOR
COLLIMATOR with a number of apertures, the axes of which are parallel

3.32
PILE UP EFFECT
false measurement of the pulse amplitude, due to the absorption of two or more gamma rays, reaching the same radiation detector within the RESOLVING TIME

3.33
PIXEL
MATRIX ELEMENT in a two-dimensional IMAGE MATRIX

3.34
PLANAR WHOLEBODY IMAGING EQUIPMENT
<GAMMA CAMERA> GAMMA CAMERA, with one or two DETECTOR HEAD(S), in which the image of an extended object is formed by moving the DETECTOR HEAD(S) or the object in the axial direction relative to each other

3.35
POINT SOURCE
RADIOACTIVE SOURCE approximating a δ-function in all three dimensions

3.36
POINT SPREAD FUNCTION
PSF
scintigraphic image of a POINT SOURCE

3.37
PROJECTION
transformation of a three-dimensional object into its two-dimensional image or of a two-dimensional object into its one-dimensional image, by integrating the physical property which determines the image along the direction of the PROJECTION BEAM

Note 1 to entry: This process is mathematically described by line integrals in the direction of PROJECTION and called the Radon-transform.

3.38
PROJECTION ANGLE
angle at which the PROJECTION is measured or acquired

Note 1 to entry: See Figure 1.

3.39
PROJECTION BEAM
determines the smallest possible volume in which the physical property which determines the image is integrated during the measurement process

Note 1 to entry: Its shape is limited by the SPATIAL RESOLUTION in all three dimensions.

Note 2 to entry: In SPECT the PROJECTION BEAM usually has the shape of a long thin diverging cone.

3.40
RADIAL RESOLUTION
TRANSVERSE RESOLUTION along a line passing through the position of the source and the SYSTEM AXIS

[SOURCE: IEC 61675-1:2013, 3.4.1.1]

3.41
RADIOACTIVE SOURCE
quantity of radioactive material having both an ACTIVITY and a specific ACTIVITY above specific levels

[SOURCE: IEC 60788:2004, rm-20-02]

3.42
RADIUS OF ROTATION
distance between the SYSTEM AXIS and the COLLIMATOR FRONT FACE

3.43
SCATTER FRACTION
SF
<GAMMA CAMERA> ratio between the number of scattered photons and the sum of scattered plus unscattered photons for a given experimental set-up

3.44
SINGLE PHOTON EMISSION COMPUTED TOMOGRAPHY
SPECT
EMISSION COMPUTED TOMOGRAPHY utilizing single photon detection of gamma-ray emitting RADIONUCLIDES

Note 1 to entry: The note to entry regarding the abbreviation concerns the French version only.

3.45
SINOGRAM
two-dimensional display of all one-dimensional PROJECTIONS of an OBJECT SLICE, as a function of the PROJECTION ANGLE

Note 1 to entry: The PROJECTION ANGLE is displayed on the ordinate, the linear PROJECTION coordinate is displayed on the abscissa.

[SOURCE: IEC 61675-1:2013, 3.1.2.4]

3.46
SLICE SENSITIVITY
ratio of COUNT RATE as measured on the SINOGRAM to the ACTIVITY concentration in the phantom

Note 1 to entry: In SPECT the measured counts are not numerically corrected for scatter by subtracting the SCATTER FRACTION.

[SOURCE: IEC 61675-1:2013, 3.6]

3.47
SPATIAL NON-LINEARITY
deviations of the image of a straight LINE SOURCE from a straight line

3.48
SPATIAL RESOLUTION
<nuclear medicine> ability to concentrate the count density distribution in the image of a POINT SOURCE to a point

[SOURCE: IEC 61675-1:2013, 3.4]

3.49
SYSTEM AXIS
axis of symmetry characterized by geometrical and physical properties of the arrangement of the system

Note 1 to entry: The SYSTEM AXIS of a GAMMA CAMERA with rotating detectors is the axis of rotation.

[SOURCE: IEC 61675-1:2013, 3.1.2.7, modified – The note to entry has been changed]

3.50
SYSTEM NON-UNIFORMITY OF RESPONSE
NON-UNIFORMITY OF RESPONSE of the DETECTOR HEAD with COLLIMATOR

3.51
SYSTEM SENSITIVITY
<GAMMA CAMERA> with a specified COLLIMATOR and ENERGY WINDOW, the ratio of the COUNT RATE of the DETECTOR HEAD to the ACTIVITY of a plane source of specific dimensions and containing a specified RADIONUCLIDE placed perpendicular to and centred on the COLLIMATOR AXIS under specified conditions

Note 1 to entry: See also Figure 2.

Dimensions in millimetres

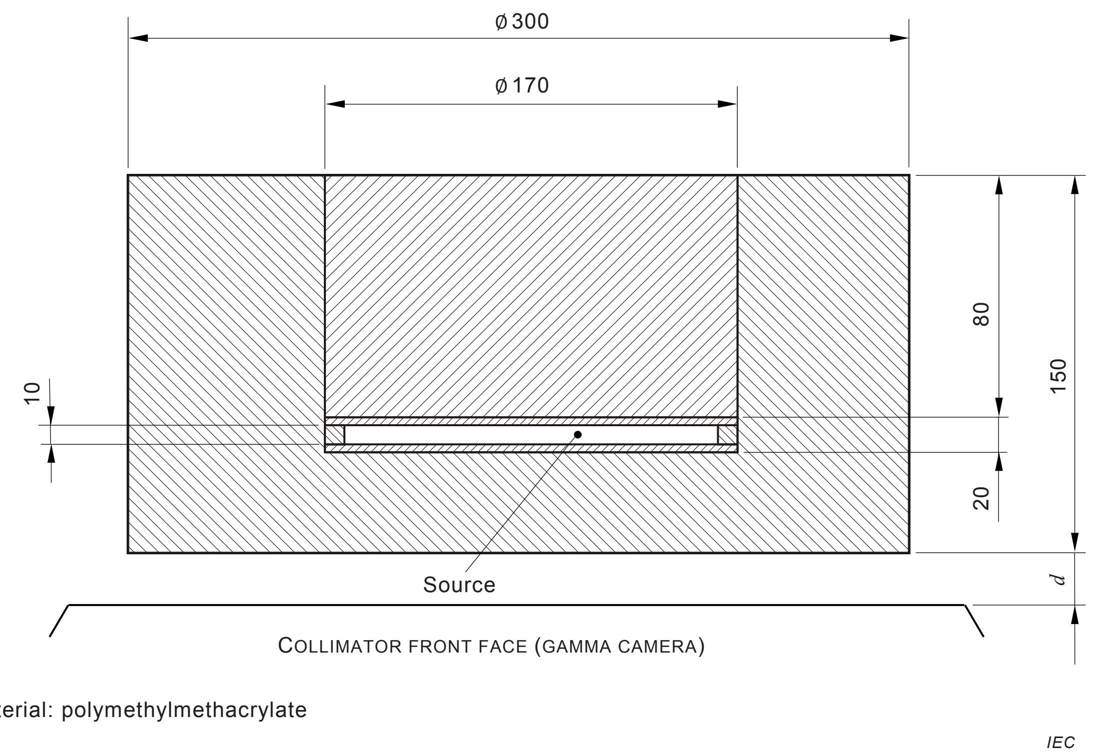


Figure 2 – Cylindrical phantom

3.52
SYSTEM SPATIAL RESOLUTION
<GAMMA CAMERA> SPATIAL RESOLUTION in a scattering medium for a specified COLLIMATOR, or a specified RADIONUCLIDE, and at a specified distance from the COLLIMATOR FRONT FACE

3.53
TANGENTIAL RESOLUTION
TRANSVERSE RESOLUTION in the direction orthogonal to the direction of RADIAL RESOLUTION

[SOURCE: IEC 61675-1:2013, 3.4.1.2]

3.54
TOMOGRAPHIC VOLUME
juxtaposition of all volume elements which contribute to the measured PROJECTIONS for all PROJECTION ANGLES

Note 1 to entry: For a rotating GAMMA CAMERA with a circular field of view the TOMOGRAPHIC VOLUME is a sphere provided that the RADIUS OF ROTATION is larger than the radius of the field of view. For a rectangular field of view, the TOMOGRAPHIC VOLUME is a cylinder.

[SOURCE: IEC 61675-1:2013, 3.1.2.8, modified – A note to entry has been added.]

3.55
TRANSVERSE POINT SPREAD FUNCTION
reconstructed two-dimensional POINT SPREAD FUNCTION in a tomographic IMAGE PLANE

Note 1 to entry: In TOMOGRAPHY, the TRANSVERSE POINT SPREAD FUNCTION can also be obtained from a LINE SOURCE located parallel to the SYSTEM AXIS.

[SOURCE: IEC 61675-1:2013, 3.3.3]

3.56
TRANSVERSE RESOLUTION
SPATIAL RESOLUTION in a reconstructed plane perpendicular to the SYSTEM AXIS

[SOURCE: IEC 61675-1:2013, 3.4.1]

3.57
VOLUME SENSITIVITY
sum of the individual SLICE SENSITIVITIES

[SOURCE: IEC 61675-1:2013, 3.7]

3.58
VOXEL
volume element in the object which is assigned to a MATRIX ELEMENT in a two- or three-dimensional IMAGE MATRIX

Note 1 to entry: The dimensions of the VOXEL are determined by the dimensions of the corresponding MATRIX ELEMENT via the appropriate scale factors and by the systems SPATIAL RESOLUTION in all three dimensions.

[SOURCE: IEC 61675-1:2013, 3.2.2]

4 Test methods

4.1 General

All measurements shall be performed with the PULSE AMPLITUDE ANALYSER WINDOW set as specified in Table 1. Additional measurements with other settings as specified by the manufacturer can be performed. Before the measurements are performed, the tomographic system shall be adjusted by the procedure normally used by the manufacturer for an installed unit and shall not be adjusted specially for the measurement of specific parameters. If any test cannot be carried out exactly as specified in the standard, the reason for the deviation and the exact conditions under which the test was performed shall be stated clearly.

Table 1 – RADIONUCLIDES and ENERGY WINDOWS to be used for performance measurements

RADIONUCLIDE	ENERGY WINDOW keV
^{99m}Tc	141 (± 7,5 %)
^{131}I	364 (± 10 %)
^{67}Ga	93, 184, 300 (± 10 %)
^{57}Co	122 (± 10 %)
NOTE Because the characteristics of a GAMMA CAMERA may change noticeably between 122 keV (^{57}Co) and 141 keV (^{99m}Tc), the former is not included as a suitable RADIONUCLIDE. However, it may be useful in some circumstances, e.g. for quality control.	

Unless otherwise specified, each DETECTOR HEAD in the system shall be characterized by a full data set.

Unless otherwise specified, SPECT characterization shall be provided for an acquisition covering the minimal rotation required to obtain a complete set of data (e.g. 120° for a three-headed system). If the tomograph is specified to operate in a non-circular orbiting mode influencing the performance parameters, test results for the non-circular orbiting mode shall be reported in addition.

Unless otherwise specified, measurements shall be carried out at COUNT RATES not exceeding 20 000 counts per second.

4.2 Planar imaging

4.2.1 SYSTEM SENSITIVITY

4.2.1.1 General

SYSTEM SENSITIVITY is a parameter that characterizes the effectiveness of a system to identify the radiation emitted from a RADIOACTIVE SOURCE, i.e. the rate at which events are detected in the presence of a RADIOACTIVE SOURCE with low ACTIVITY where COUNT LOSSES are negligible. The measured COUNT RATE for a given ACTIVITY and RADIONUCLIDE depends on many factors, including the detector material, its size and thickness, the size and shape of the RADIOACTIVE SOURCE including its absorption and scatter properties, and instrument's dead time, energy thresholds and COLLIMATOR.

4.2.1.2 Purpose

The purpose of this measurement is to determine the detected rate of events per unit of ACTIVITY for a standard volume source of given dimensions and a specified COLLIMATOR.

4.2.1.3 Method

The SYSTEM SENSITIVITY test places a known amount of ACTIVITY of a specified RADIONUCLIDE within the DETECTOR FIELD OF VIEW of the GAMMA CAMERA and observes the resulting COUNT RATE. From these values the SYSTEM SENSITIVITY is calculated. The test is critically dependent upon accurate assays of ACTIVITY as measured in a dose calibrator or well counter. It is difficult to maintain an absolute calibration with such devices to accuracies better than ±10 %. Absolute reference standards of the appropriate RADIONUCLIDE should be considered if higher degrees of accuracy are required.

4.2.1.4 RADIONUCLIDE

The RADIONUCLIDE used for this measurement shall be appropriate for the COLLIMATOR energy specification and chosen from Table 1.

4.2.1.5 RADIOACTIVE SOURCE distribution

The cylindrical phantom of polymethylmethacrylate as specified in Figure 2 shall be used. The source cuvette shown in Figure 3 shall be filled with the appropriate RADIONUCLIDE and shall be placed in the cylindrical hole with the dimensions shown in Figure 2; the remainder of the hole shall then be filled by the cylindrical insert, the dimensions of which are also shown in Figure 2. The phantom, including the source, shall then be placed on the COLLIMATOR FRONT FACE (distance d = 0) and centred on the COLLIMATOR AXIS.

Dimensions in millimetres

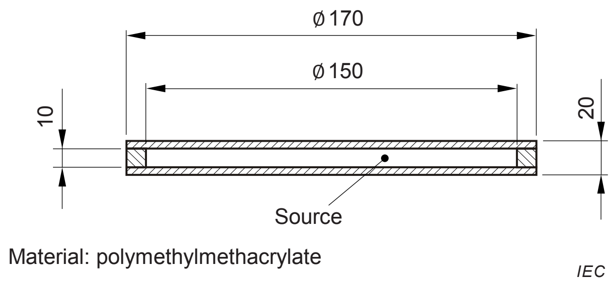


Figure 3 – Cuvette

NOTE Measurements of SYSTEM SENSITIVITY without scatter, using the source cuvette of Figure 3 placed at a distance of 10 cm from the COLLIMATOR FRONT FACE, may be carried out in addition to this test.

4.2.1.6 Data collection

With an ENERGY WINDOW setting as specified in Table 1, at least 200 000 counts shall be acquired and the data acquisition time recorded to calculate the COUNT RATE C_s for all events collected in the image.

4.2.1.7 Data processing

The ACTIVITY in the phantom shall be corrected for decay to determine the average ACTIVITY, A_{ave}, during the data acquisition time interval, T_{acq}, by the following equation

$$A_{\mathrm{ave}} = \frac{A_{\mathrm{cal}}}{\ln 2}\frac{T_{1/2}}{T_{\mathrm{acq}}}\exp\left[\frac{T_{\mathrm{cal}} - T_0}{T_{1/2}}\ln 2\right]\left[1 - \exp\left(-\frac{T_{\mathrm{acq}}}{T_{1/2}}\ln 2\right)\right] \quad (1)$$

where

A_{cal} is the ACTIVITY measured at time T_{cal};

T_0 is the acquisition start time;

$T_{1/2}$ is the RADIOACTIVE HALF-LIFE of the RADIONUCLIDE.

4.2.1.8 Data analysis

The SYSTEM SENSITIVITY S for the COLLIMATOR used shall then be found by

$$S = \frac{C_s}{A_{\mathrm{ave}}} \quad (2)$$

and shall be expressed in counts · s^{-1}· MBq^{-1}.

4.2.1.9 Report

Report the SYSTEM SENSITIVITY together with the COLLIMATOR and the RADIONUCLIDE used.

4.2.2 SPATIAL RESOLUTION

4.2.2.1 General

SPATIAL RESOLUTION determines the ability of an imaging system to reproduce the spatial distribution of a RADIONUCLIDE in an object. The measurement is performed by imaging LINE SOURCES in air without COLLIMATOR (INTRINSIC SPATIAL RESOLUTION) and with COLLIMATOR using scattering material (SYSTEM SPATIAL RESOLUTION), respectively. The measurement of SYSTEM SPATIAL RESOLUTION including scatter is more representative of the clinical situation when measuring a patient, whereas the INTRINSIC SPATIAL RESOLUTION characterizes the DETECTOR HEAD performance without the COLLIMATOR.

4.2.2.2 Purpose

The purpose of this measurement is to describe the ability of the camera to characterize small objects.

4.2.2.3 Method

For all systems, the SPATIAL RESOLUTION shall be measured in IMAGE PLANES parallel to the COLLIMATOR FRONT FACE by characterizing the width of the LINE SPREAD FUNCTIONS using LINE SOURCES. The width of the LINE SPREAD FUNCTION is measured by the FULL WIDTH AT HALF MAXIMUM (FWHM) and the EQUIVALENT WIDTH (EW). In order to accurately measure the width of the LINE SPREAD FUNCTION, its FWHM shall span at least ten PIXELS in the test image. Some GAMMA CAMERAS, for example GAMMA CAMERAS with detectors composed of multiple crystals, may not be able to achieve ten PIXELS in the FWHM in the test image. In this case the matrix used for the test shall be specified and proper interpolation shall be used and stated.

4.2.2.4 RADIONUCLIDE

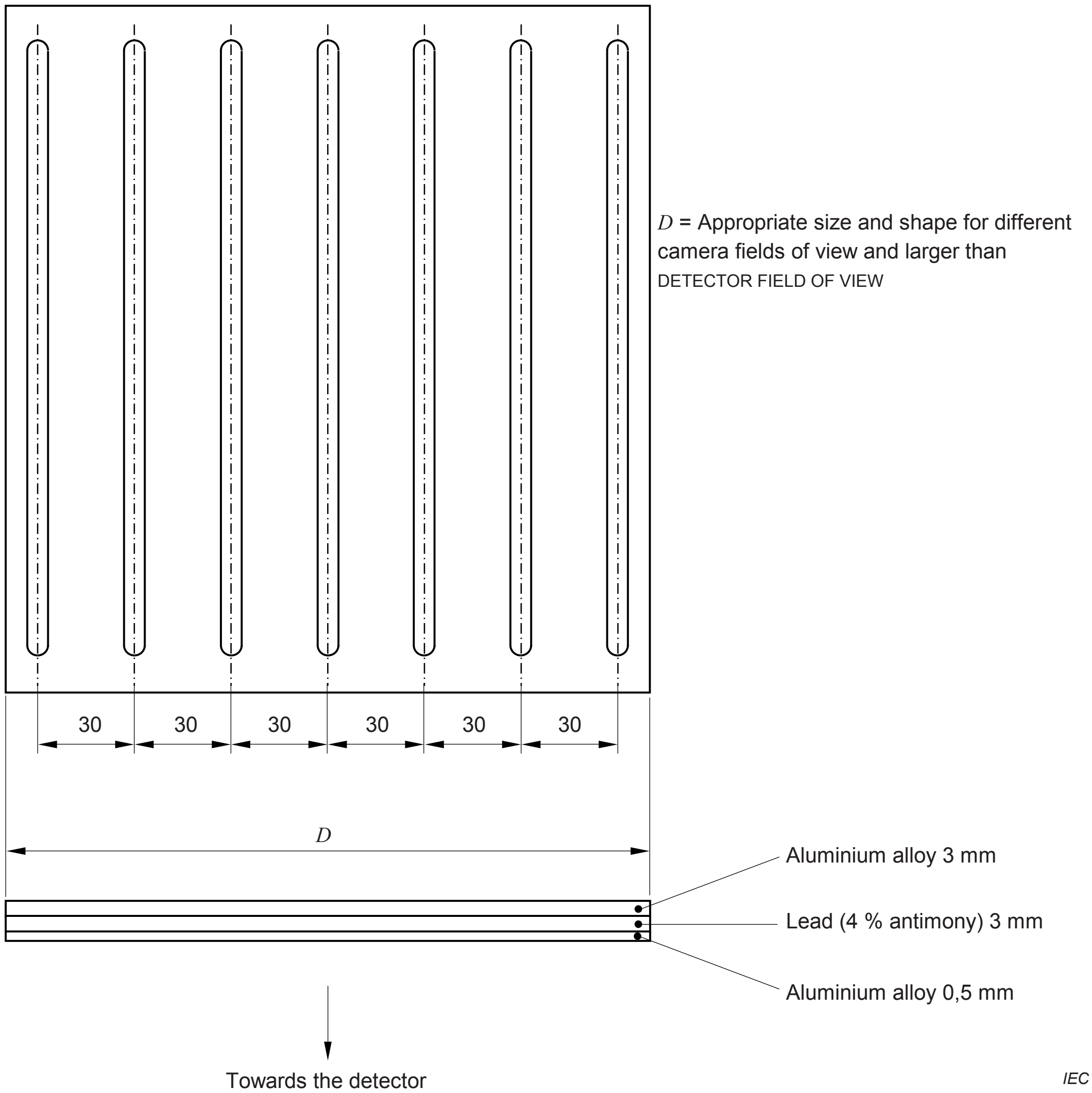
For the measurement of SYSTEM SPATIAL RESOLUTION the RADIONUCLIDE for the measurement shall be chosen from Table 1 according to the COLLIMATOR used. For the measurement of INTRINSIC SPATIAL RESOLUTION the RADIONUCLIDE shall be ^{99m}Tc.

4.2.2.5 RADIOACTIVE SOURCE distribution

For the measurement of SYSTEM SPATIAL RESOLUTION, a LINE SOURCE shall be prepared by placing a solution containing the selected RADIONUCLIDE in a tube with an inner diameter of 1 mm and length at least equal to the longer detector axis.

For the measurement of INTRINSIC SPATIAL RESOLUTION, a multiple slit transmission phantom shall be used as shown in Figure 4.

Dimensions in millimetres



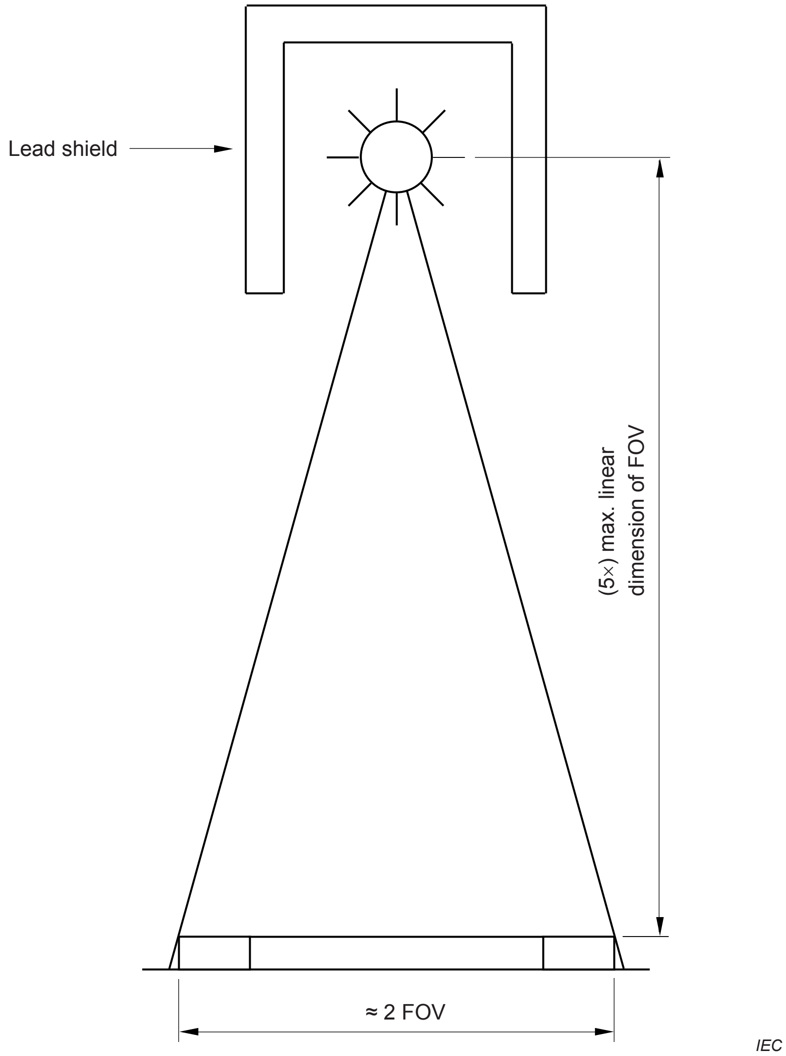
NOTE 1 Slit width 1,0 mm ± 0,05 mm.

NOTE 2 Slit straightness ± 0,05 mm over any 30 mm length.

NOTE 3 Slit centre separation 30,0 mm ± 0,05 mm.

Figure 4 – Slit phantom

This phantom covers the entire DETECTOR FIELD OF VIEW and shall be placed at the centre of the detector face (COLLIMATOR removed). A POINT SOURCE shall be positioned in front of the centre of the detector at a distance of at least five times the maximum linear dimension of the DETECTOR FIELD OF VIEW (Figure 5).



Lead shield prevents uncontrolled scatter.

Figure 5 – Source arrangement for intrinsic measurements

4.2.2.6 Data collection

4.2.2.6.1 SYSTEM SPATIAL RESOLUTION (with scatter)

The GAMMA CAMERA shall be equipped with the COLLIMATOR under study. The LINE SOURCE shall be placed with its axis perpendicular to the COLLIMATOR AXIS and aligned parallel to one of the X- or Y-axes at the depth of measurement in water or water-equivalent material covering the whole field of view. The air gap between the COLLIMATOR FRONT FACE and the surface of the scattering medium shall be less than 5 mm. The depth of the scattering medium along the COLLIMATOR AXIS shall be 200 mm in total. The measurement shall be carried out in three parallel planes with the centre of the source at 50 mm, 100 mm and 150 mm from the COLLIMATOR FRONT FACE. The measurement shall be repeated with the source aligned parallel to the other electronic axis. Data shall be acquired with a PIXEL size equal to or less than 10 % of the FWHM at the depth of measurement. At least 10 000 counts shall be collected in the peak point of each LINE SPREAD FUNCTION.

4.2.2.6.2 INTRINSIC SPATIAL RESOLUTION

The slit transmission phantom shall be placed on the GAMMA CAMERA, with the COLLIMATOR removed. Two sets of data shall be obtained. The orientation of the slit transmission phantom shall be adjusted until its slit axis is aligned parallel to the X- or Y-axis, respectively. At least 1 000 counts shall be collected in the peak point of each LINE SPREAD FUNCTION.

4.2.2.7 Data processing

4.2.2.7.1 Data processing for SYSTEM SPATIAL RESOLUTION

The SYSTEM SPATIAL RESOLUTION profiles of width 30 mm ± 5 mm shall be obtained at right angles to the LINE SOURCE. The lateral extension of profiles shall be to a point where the measured quantity is 5 % of the maximum value, or up to the edge of the DETECTOR FIELD OF VIEW, whichever lateral extension is the smaller. The profiles shall abut each other.

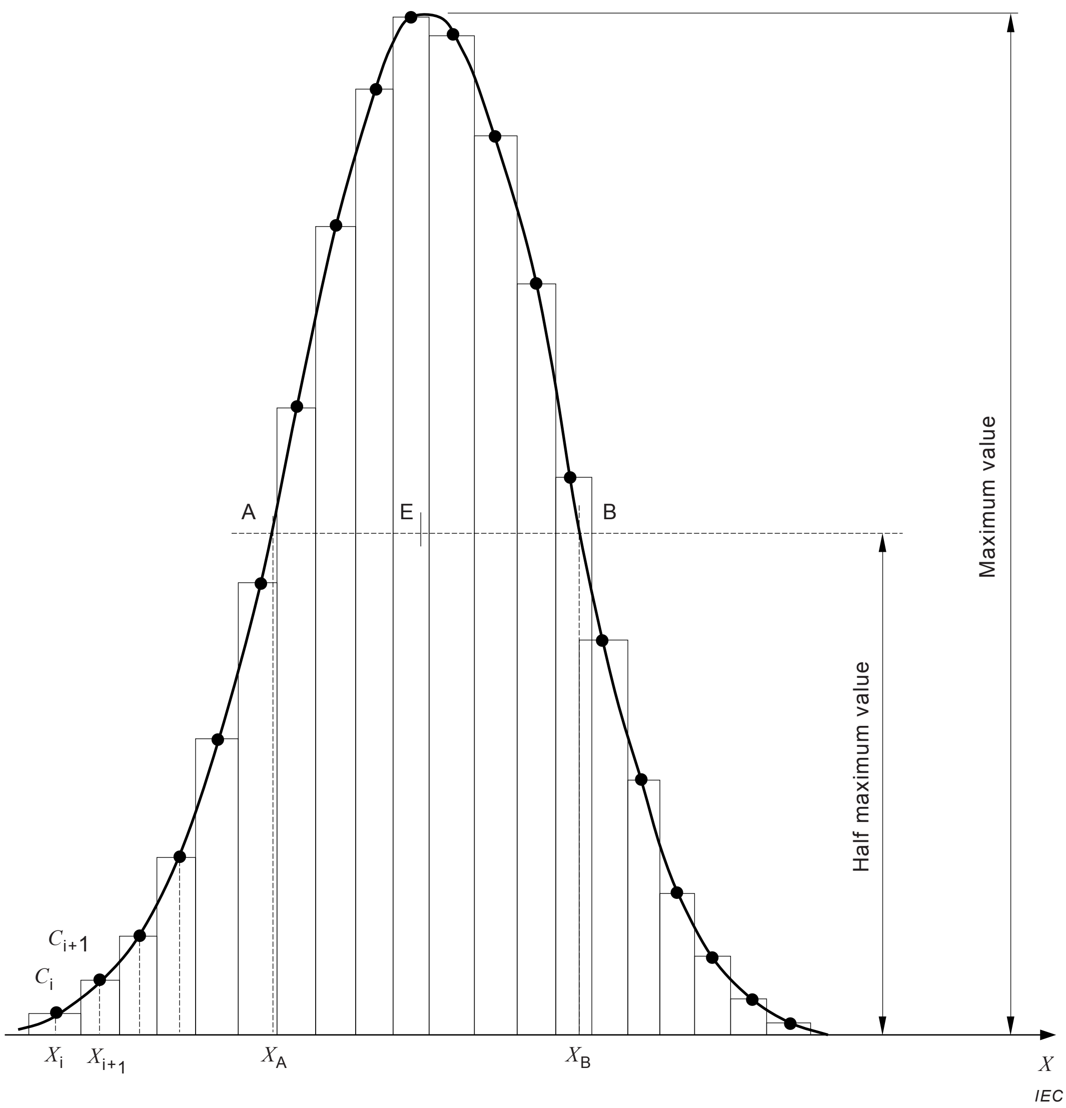
4.2.2.7.2 Data processing for INTRINSIC SPATIAL RESOLUTION

For the INTRINSIC SPATIAL RESOLUTION profiles of width 30 mm ± 5 mm shall be obtained at right angles to the direction of the slit. The profiles shall abut each other.

4.2.2.8 Data analysis

4.2.2.8.1 General

FULL WIDTH AT HALF MAXIMUM (FWHM) shall be determined by linear interpolation between adjacent PIXELS at half the maximum PIXEL value, which is the peak of the response function (see Figure 6). Values shall be converted to millimetre units by multiplication with the appropriate PIXEL size.



A and B are the points where the interpolated curve cuts the line of half maximum value.

FWHM = $X_B - X_A$

Figure 6 – Calculation of FWHM

EQUIVALENT WIDTH (EW) shall be measured from the corresponding response function. *EW* is calculated from the formula (see Figure 7)

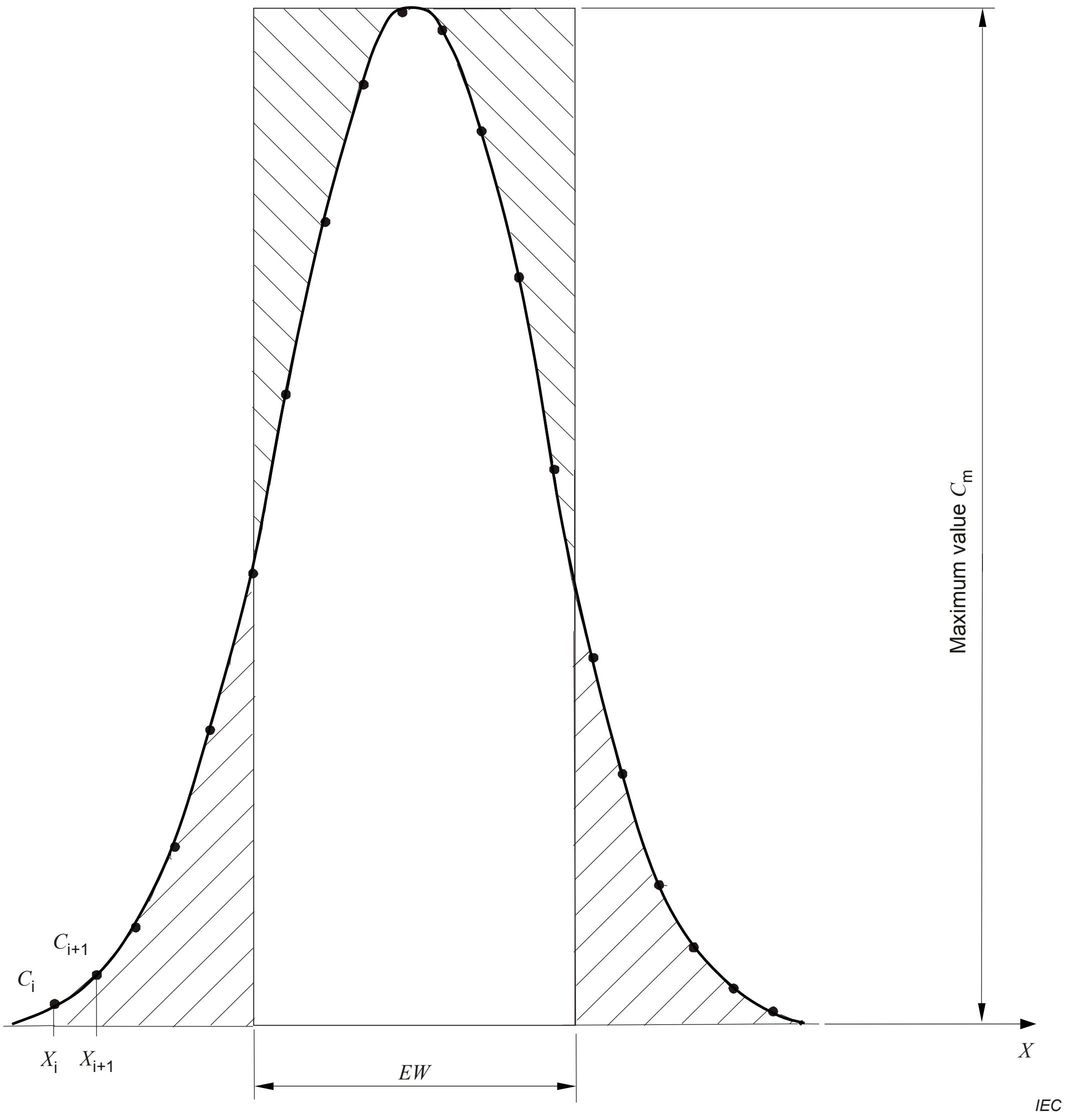
$$EW = \sum_i \frac{C_i \times PW}{C_\mathrm{m}} \tag{3}$$

where

$\sum_i C_i$ is the sum of the counts in the profile between the limits defined by 1/20 C_m on either side of the peak;

C_m is the maximum PIXEL value;

PW is the PIXEL width in millimetres (see Figure 7).



NOTE *EW* is given by the width of the rectangle having the area of the LINE SPREAD FUNCTION and its maximum value C_m.

$$EW = \sum (C_i \times PW)/C_\mathrm{m}$$

The PIXEL width PW is $x_{i+1} - x_i$.

The areas shaded differently are equal.

Figure 7 – Evaluation of equivalent width (EW)

4.2.2.8.2 SYSTEM SPATIAL RESOLUTION

From the measured LINE SPREAD FUNCTIONS (4.2.2.6.1) the following data shall be obtained:

a) the calculated MODULATION TRANSFER FUNCTION (MTF), presented as a set of graphs with linear scaling, for the most central profile;

b) the FWHM, FULL WIDTH AT TENTH MAXIMUM (FWTM) and EQUIVALENT WIDTH (EW) for each LINE SPREAD FUNCTION measured. Then, for each source-to-COLLIMATOR distance the indices calculated shall be averaged separately in the x- or in the y-direction, respectively. Finally, the x- and y-indices shall be averaged to yield the SPATIAL RESOLUTION specifications.

4.2.2.8.3 INTRINSIC SPATIAL RESOLUTION

From the measured LINE SPREAD FUNCTIONS (4.2.2.6.2) the FWHM and EW shall be calculated as described in 4.2.2.8.1.

4.2.2.9 Report

For each COLLIMATOR the SYSTEM SPATIAL RESOLUTION including scatter expressed as FWHM, FWTM, and EW shall be reported as a function of source-to-COLLIMATOR distance according to 4.2.2.6.1. In addition, graphs of the matching MODULATION TRANSFER FUNCTIONS shall be given.

The PIXEL size shall be reported

The INTRINSIC SPATIAL RESOLUTION, expressed as FWHM and EW, according to 4.2.2.6.2 shall be reported.

4.2.3 SPATIAL NON-LINEARITY

4.2.3.1 General

Spatial linearity describes the ability of the system to reproduce the geometric properties of the object.

4.2.3.2 Purpose

SPATIAL NON-LINEARITY measurements provide information about the geometric distortion of a straight line.

4.2.3.3 Method

For all systems, the SPATIAL NON-LINEARITY shall be measured in an IMAGE PLANE parallel to the detector front face by measuring the deviations from a straight line of the lines in the image of the slit phantom.

NOTE For pixelized detectors this method also applies

4.2.3.4 RADIONUCLIDE

For the measurement of SPATIAL NON-LINEARITY the RADIONUCLIDE shall be ^{99m}Tc.

4.2.3.5 RADIOACTIVE SOURCE distribution

For the measurement of SPATIAL NON-LINEARITY, a multiple slit transmission phantom shall be used as shown in Figure 4. This phantom covers the entire DETECTOR FIELD OF VIEW and shall be placed at the centre of the detector face (COLLIMATOR removed). A POINT SOURCE shall be positioned in front of the centre of the detector at a distance of at least five times the maximum linear dimension of the DETECTOR FIELD OF VIEW (Figure 5).

4.2.3.6 Data collection

The data acquired in the measurement of INTRINSIC SPATIAL RESOLUTION (4.2.2.6.2) shall be analysed.

4.2.3.7 Data processing

From each of the two sets of data, profiles shall be obtained from slices at right angles to the slit axis extending not more than 30 mm in the direction of the slit axis. The slices shall abut each other.

4.2.3.8 Data analysis

4.2.3.8.1 Differential non-linearity

The location of each peak in each profile shall be determined according to Figure 6 (position E). In each profile the distances between adjacent peak locations shall be found. The differential non-linearity for the DETECTOR FIELD OF VIEW shall be determined as the standard deviation of all measured distances obtained from the two data sets (X and Y oriented).

4.2.3.8.2 Absolute non-linearity

Absolute non-linearity shall be determined by least squares fitting to equally spaced parallel lines for each of the two data sets separately (X and Y oriented). Absolute non-linearity shall be determined as the largest value of the X or Y displacement in mm between observed and fitted lines over the DETECTOR FIELD OF VIEW.

4.2.3.9 Report

The differential non-linearity for the DETECTOR FIELD OF VIEW shall be reported according to 4.2.3.8.1 for X and Y.

Absolute non-linearity shall be reported according to 4.2.3.8.2 for X and Y.

4.2.4 NON-UNIFORMITY OF RESPONSE

4.2.4.1 General

Uniformity describes the ability of an imaging system to reproduce the object with a local sensitivity which is constant all over the DETECTOR FIELD OF VIEW.

The measurement is performed by imaging a uniform flux incident to the GAMMA CAMERA in air without COLLIMATOR (INTRINSIC NON-UNIFORMITY OF RESPONSE) and with COLLIMATOR using scattering material (SYSTEM NON-UNIFORMITY OF RESPONSE), respectively. The measurement of SYSTEM NON-UNIFORMITY OF RESPONSE including scatter is more representative of the clinical situation when measuring a patient, whereas the INTRINSIC NON-UNIFORMITY OF RESPONSE characterizes the DETECTOR HEAD performance without the COLLIMATOR and the influence of scatter.

4.2.4.2 Purpose

The purpose of this measurement is to characterize the ability of the camera to reproduce a uniform input signal without random local changes in count density.

4.2.4.3 Method

This is done by characterizing the uniformity of the image of a uniform photon flux by specifying differential non-uniformity, integral non-uniformity, and non-uniformity distribution. The test reports the maximum deviation from the average count density, locally (differential non-uniformity) and over the entire DETECTOR FIELD OF VIEW (integral non-uniformity). Additionally a three-class histogram of PIXEL deviations (non-uniformity distribution) is specified.

4.2.4.4 RADIONUCLIDE

For the measurement of SYSTEM NON-UNIFORMITY OF RESPONSE the RADIONUCLIDE shall be chosen from Table 1 according to the COLLIMATOR used. For the measurement of INTRINSIC NON-UNIFORMITY OF RESPONSE the RADIONUCLIDE shall be ^{99m}Tc.

NOTE In addition other than the nuclides listed can be used.

4.2.4.5 RADIOACTIVE SOURCE distribution

4.2.4.5.1 Measurement of INTRINSIC NON-UNIFORMITY OF RESPONSE

A source holder and source shall be positioned as shown in Figure 5.

4.2.4.5.2 Measurement of SYSTEM NON-UNIFORMITY OF RESPONSE

The measurement shall be performed using a PARALLEL HOLE COLLIMATOR appropriate to the RADIONUCLIDE used. The source configuration shown in Figure 8, with a RADIONUCLIDE selected from Table 1, shall be placed as close as possible to the COLLIMATOR FRONT FACE.

Dimensions in millimetres

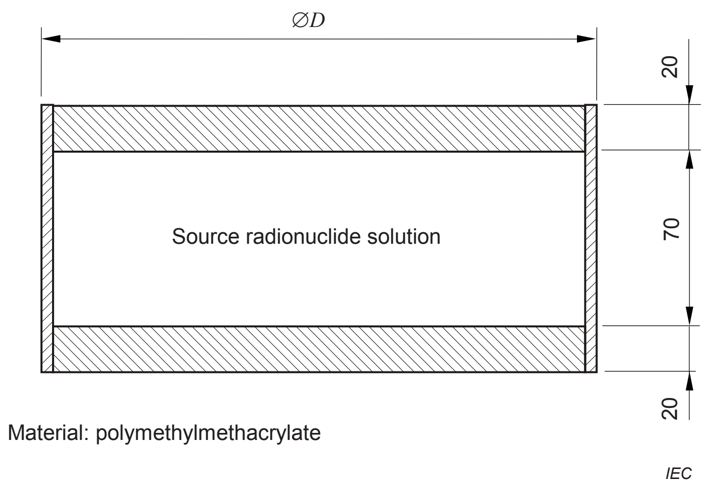


Figure 8 – Uniform source

4.2.4.6 Data collection

4.2.4.6.1 Measurement of INTRINSIC NON-UNIFORMITY OF RESPONSE

Regions outside the DETECTOR FIELD OF VIEW shall be shielded with lead. The PIXELS shall be square. The PIXEL size shall be equal to or less than twice the INTRINSIC SPATIAL RESOLUTION measured in terms of FWHM, and stated. The mean number of counts per PIXEL shall be 10 000 ± 10 %. The COUNT RATE shall not exceed 40 000 counts per second.

4.2.4.6.2 Measurement of SYSTEM NON-UNIFORMITY OF RESPONSE

The photon flux reaching the COLLIMATOR FRONT FACE shall be uniform within ± 1 %, measured over areas of 1 cm^2.

The PIXELS shall be square. The PIXEL size shall be equal to or less than the SYSTEM SPATIAL RESOLUTION measured in terms of FWHM at 50 mm from the COLLIMATOR FRONT FACE and stated. The mean number of counts per PIXEL shall be greater than 10 000 ± 10 %.

NOTE For a low energy PARALLEL HOLE COLLIMATOR the count density specified corresponds to approximately 20 000 counts/cm^2 or better.

4.2.4.7 Data processing

Before evaluation of the measurements described in 4.2.4.6.1 and 4.2.4.6.2, the mean number of counts per PIXEL shall be determined in a square area with side dimensions equal to 75 % of the shortest dimension of the DETECTOR FIELD OF VIEW. Then, PIXELS shall be selected for inclusion in the analysis as follows:

First, all PIXELS at the edge that contain less than 75 % of the mean number of counts shall be set to zero.

Second, PIXELS that have one of the four directly abutted neighbours containing zero count shall be excluded from the analysis and also set to zero. The remaining data (i.e. non-zero PIXELS) obtained from the image of the uniform flux shall be smoothed once by convolution with a nine-point filter function of the following weights:

$$\begin{matrix} 1 & 2 & 1 \\ 2 & 4 & 2 \\ 1 & 2 & 1 \end{matrix}$$

In those cases where a PIXEL with zero count was included in the smoothing operation, the normalization coefficient shall be adjusted accordingly.

4.2.4.8 Data analysis

4.2.4.8.1 Non-uniformity distribution

The distribution of non-uniformity over the DETECTOR FIELD OF VIEW shall be evaluated in the following way:

a) The number of PIXELS for which the number of counts deviates by 10 % or more from the mean number of counts per PIXEL shall be determined and expressed as a percentage of the total number of non-zero PIXELS;

b) The number of PIXELS for which the number of counts deviates by 5 % or more, but less than 10 %, from the mean number of counts per PIXEL shall be determined and expressed as a percentage of the total number of non-zero PIXELS;

c) The number of PIXELS for which the number of counts deviates by 2,5 % or more, but less than 5 %, from the mean number of counts per PIXEL shall be determined and expressed as a percentage of the total number of non-zero PIXELS.

4.2.4.8.2 Integral non-uniformity

The maximum and minimum value of all non-zero PIXELS shall be determined. From these data the integral non-uniformity shall be calculated using the following equation:

$$\text{Integral non-uniformity} = \pm \frac{\text{Max.value} - \text{Min.value}}{\text{Max.value} + \text{Min.value}} \times 100\ \% \qquad (4)$$

4.2.4.8.3 Differential non-uniformity

The image of the uniform flux shall be treated as individual rows and columns (lines). Each horizontal line (X direction) shall be processed by starting at one end, examining a set of five PIXELS including the first PIXEL**,** and noting the PIXELS with the maximum and minimum counts. The differential non-uniformity shall be calculated using the following equation:

$$\text{Differential non-uniformity} = \pm \frac{\text{Max.value} - \text{Min.value}}{\text{Max.value} + \text{Min.value}} \times 100\ \% \qquad (5)$$

The set is moved forward one PIXEL and those five PIXELS are examined, and the differential non-uniformity is calculated. This process is continued until the outermost PIXEL is included. Then all other horizontal lines are processed in the same way and the differential non-uniformity is expressed as the maximum absolute value.

This process is repeated for all vertical lines (Y direction) independently. Then the averages of both X and Y values are reported.

4.2.4.9 Report

For each COLLIMATOR, the SYSTEM NON-UNIFORMITY OF RESPONSE shall be reported in terms of non-uniformity distribution (4.2.4.8.1), integral non-uniformity (4.2.4.8.2), and differential non-uniformity (4.2.4.8.3). The PIXEL size used for analysis has to be stated.

The same data have to be reported for the INTRINSIC NON-UNIFORMITY OF RESPONSE.

4.2.5 INTRINSIC ENERGY RESOLUTION

4.2.5.1 General

Energy resolution describes the ability of the detector to properly identify the energy of the detected photons.

4.2.5.2 Purpose

The INTRINSIC ENERGY RESOLUTION is measured to characterize the ability of a GAMMA CAMERA to separate photons with different energies.

4.2.5.3 Method

Measure an energy spectrum in low scatter configuration using a uniform irradiation of the DETECTOR FIELD OF VIEW to yield an average energy resolution.

4.2.5.4 RADIONUCLIDE

The source shall be ^{99m}Tc.

4.2.5.5 RADIOACTIVE SOURCE distribution

A source holder and a source shall be positioned as in Figure 5. The COUNT RATE shall not exceed 20 000 counts per second.

4.2.5.6 Data collection

The pulse height spectrum shall be obtained with a channel width less than or equal to 5 % of the expected photopeak FWHM. The number of counts in the peak channel shall be greater than 10 000.

4.2.5.7 Data processing

The channel number shall be expressed in terms of energy by calibrating the GAMMA CAMERA with an additional RADIONUCLIDE.

4.2.5.8 Data analysis

The INTRINSIC ENERGY RESOLUTION shall be the FWHM of the full energy absorption peak expressed as a percentage of this energy.

4.2.5.9 Report

The INTRINSIC ENERGY RESOLUTION shall be reported.

4.2.6 Intrinsic MULTIPLE WINDOW SPATIAL REGISTRATION

4.2.6.1 General

MULTIPLE WINDOW SPATIAL REGISTRATION is a measure of the ability of a GAMMA CAMERA to accurately position photons of different energies when imaged through different photopeak ENERGY WINDOWS.

4.2.6.2 Purpose

The purpose of the test is to determine the energy dependence of the source localization in the image which may result in an energy dependent spatial scaling.

4.2.6.3 Method

Measurements shall be made at nine specified points on the entrance plane of the scintillation camera.

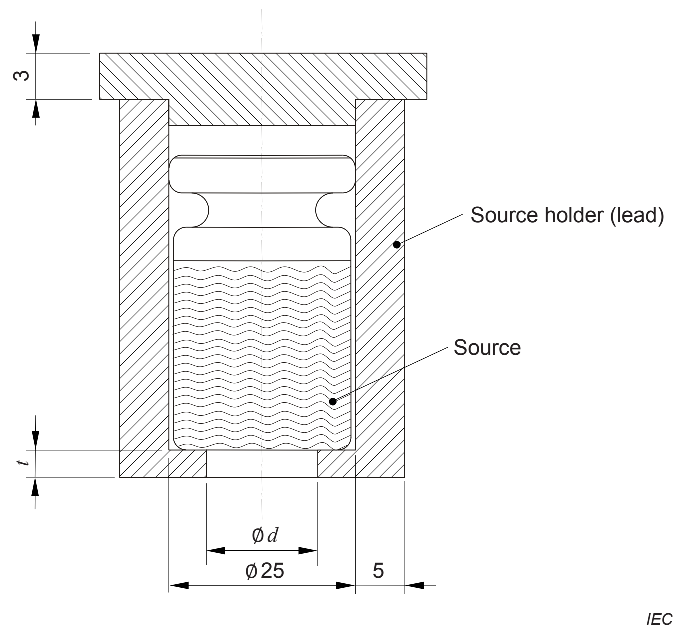
4.2.6.4 RADIONUCLIDE

The RADIONUCLIDE used to measure MULTIPLE WINDOW SPATIAL REGISTRATION shall be ^{67}Ga. The ENERGY WINDOW settings for each of the three ^{67}Ga photopeaks shall be set as specified in Table 1. The COUNT RATE shall not exceed 10 000 counts per second through each photopeak ENERGY WINDOW.

4.2.6.5 RADIOACTIVE SOURCE distribution

A lead-lined source holder shall collimate the ^{67}Ga source through a cylindrical hole in the lead. This hole shall be d = 5 mm in diameter and t = 25 mm in length. See Figure 9 for a sketch of the ^{67}Ga source inside a source holder. To minimize penetration through the side walls the source height should be 5 mm.

Dimensions in millimetres



NOTE 1 Drawing not to scale.

NOTE 2 See 4.2.6.5 and 4.2.8.5 for recommended values for d and t.

Figure 9 – Small shielded liquid source

4.2.6.6 Data collection

Images shall be acquired using the above described collimated ^{67}Ga source (see Figure 9), positioned at nine specific points on the surface of the detector without COLLIMATOR. These nine points shall be the central point, four points on the X-axis and four points on the Y-axis. The off-centre points shall be located 0,4 times and 0,8 times the distance from the central point to the edge of the FOV of the camera along the respective axes. Separate images of the collimated ^{67}Ga source shall be acquired through separate ENERGY WINDOWS of the ^{67}Ga photopeaks at each of these source locations. The images shall be acquired with a PIXEL size of not more than 2,5 mm. For cameras with two ENERGY WINDOWS, two images shall be acquired at each point, one using the 93 keV photopeak and the second using the 300 keV photopeak. For cameras with three or more ENERGY WINDOWS, the 184 keV photopeak shall also be imaged. At least 1 000 counts shall be acquired in the peak PIXEL of each photopeak image.

4.2.6.7 Data processing

The displacement of the count centroids from each other in the X and Y directions shall be determined for each measurement point's photopeak images. A square region of interest (ROI) centred on the maximum count PIXEL associated with each photopeak image shall be used to analyse the individual photopeak images.

The PIXEL dimensions of the square ROI shall be approximately four times the expected FWHM of the image count profile to be analysed. Each image shall be integrated in the Y direction to determine the X count profile and integrated in the X direction to determine the Y count profile. The centroid of counts in the X and Y directions shall be determined for each image from that direction's count profile by the method described below.

4.2.6.8 Data analysis

The maximum difference in position of the centroid of counts acquired from each photopeak shall be determined. The largest PIXEL displacement shall then be converted to millimetres.

The centroid of counts in the X and Y direction for the count profiles in each photopeak shall be determined as follows. Find the maximum count PIXEL in the integrated X or Y profile and calculate the centroid of counts using the following formula:

$$L_j = \sum_{i=1}^{n}(X_i \times C_i) / \sum_{i=1}^{n} C_i \qquad (6)$$

where

L_j is the calculated centroid location for energy window where j can equal 1,2 or 3;

X_i is the X or Y count profile pixel at the i^{th} location;

C_i are the counts at the X_i or Y_i location;

$\sum_{i=1}^{n}$ is the sum over the profile pixels centred on the maximum count profile pixel. The exact number of pixels will depend on the FWHM of the count profile and the pixel size. The minimum number of pixels in this sum shall include both the left and right half maximum counts.

The displacement D_{ij} between ENERGY WINDOWS i and j is then:

$$D_{ij} = | L_i - L_j | \qquad (7)$$

where

i = 1, 2 or 3;

j = 1, 2 or 3.

The maximum displacement is simply the largest D_{ij}.

4.2.6.9 Report

The MULTIPLE WINDOW SPATIAL REGISTRATION shall be reported as the maximum difference in spatial positions for different ENERGY WINDOWS in either the X or Y direction of the photopeak count centroids for the nine points measured. The values shall be reported in millimetres.

4.2.7 COUNT RATE performance

4.2.7.1 General

COUNT RATE performance depends in a complex manner on the spatial distribution of ACTIVITY and scattering materials, which therefore should simulate clinical imaging situations. Therefore the tests are conducted with COLLIMATOR and scattering material.

COUNT RATE performance includes:

a) the relationship between registered COUNT RATE and ACTIVITY, i.e. the COUNT RATE CHARACTERISTIC;

   The COUNT RATE CHARACTERISTIC describes the constancy of the GAMMA CAMERA sensitivity at different ACTIVITY levels and is highly dependent on the set-up of the measurement conditions.

b) a check for address errors caused by ADDRESS PILE UP.

   The ADDRESS PILE UP results in spatial distortion in the image and is highly dependent on the set-up of the measurement conditions.

4.2.7.2 Purpose

The procedure described here is designed to evaluate deviations from the linear relationship between COUNT RATE and ACTIVITY, caused by COUNT LOSSES, and the evaluation of image distortions at high COUNT RATES, especially those leading to spatially misplaced events by ADDRESS PILE UP.

4.2.7.3 Method

Measurements of the COUNT RATE are performed at various ACTIVITY levels. The variation of ACTIVITY is normally achieved by radioactive decay. No correction is made for COUNT LOSSES and scatter. Each measured count shall be taken into account only once.

4.2.7.4 RADIONUCLIDE

The RADIONUCLIDE for the measurement shall be ^{99m}Tc with ENERGY WINDOW setting according to Table 1.

4.2.7.5 RADIOACTIVE SOURCE distribution

A cylindrical phantom as described in 4.2.1.5 and Figure 2 shall be used. The air gap d between the surface of the phantom and the COLLIMATOR FRONT FACE shall not be more than 20 mm.

4.2.7.6 Data collection

A COUNT RATE CHARACTERISTIC (measured COUNT RATE versus incident COUNT RATE or ACTIVITY) is to be measured by acquiring a series of images over time (e.g. frames). The variation of ACTIVITY is accomplished by radioactive decay with measurements continuing over approximately 10 RADIOACTIVE HALF-LIVES. The time per frame shall be less than one-half of the RADIOACTIVE HALF-LIFE with the exception of the last three frames, which can be longer. The initial amount of ACTIVITY shall be chosen so that COUNT RATE saturation is exceeded, and the last frame shall be acquired with a COUNT LOSS of less than 1 %.

A background acquisition shall be performed.

4.2.7.7 Data processing

The total counts acquired in each image shall be processed. Background correction shall be performed for all frames.

The average of the decaying ACTIVITY, $A_{ave,i,}$ during the data acquisition interval for time frame i, $T_{acq,i,}$ shall be determined by the following equation:

$$A_{\mathrm{ave},i} = A_{\mathrm{cal}} \frac{1}{\ln 2} \frac{T_{1/2}}{T_{\mathrm{acq},i}} \exp\left[\frac{T_{\mathrm{cal}} - T_{0,i}}{T_{1/2}} \ln 2\right]\left[1 - \exp\left(-\frac{T_{\mathrm{acq},i}}{T_{1/2}} \ln 2\right)\right] \tag{8}$$

where

A_{cal} is the ACTIVITY measured at time T_{cal};

$T_{0,i}$ is the acquisition start-time of the time frame i;

$T_{1/2}$ is the RADIOACTIVE HALF-LIFE of the RADIONUCLIDE in use.

From the above measurements, plot the COUNT RATE CHARACTERISTIC (i.e. measured COUNT RATE versus ACTIVITY).

The conversion factor between ACTIVITY and COUNT RATE without COUNT LOSS shall be determined from each of the three frames with lowest ACTIVITY and averaged. Care shall be taken to acquire enough counts in these frames to ensure a statistical precision of 1 % or better.

4.2.7.8 Data analysis

The measured COUNT RATE, which corresponds to 80 % of the TRUE COUNT RATE, shall be read from the graph and stated.

To check for address errors caused by ADDRESS PILE UP, profiles shall be drawn in the X- and Y-directions over the centre of the image of the source for selected images: one pair of profiles at a measured COUNT RATE of approximately 5 000 counts per second, one pair at a measured COUNT RATE of approximately 20 000 counts per second, and one pair at the maximum measured COUNT RATE.

4.2.7.9 Report

The ACTIVITY shall be specified as the total amount of ACTIVITY within the phantom.

Report the graph showing the COUNT RATE CHARACTERISTIC and the ACTIVITY level at 20 % COUNT LOSS.

Report the profiles in the X- and Y-direction over the centre of the source: one pair of profiles at a measured COUNT RATE of approximately 5 000 counts per second, one pair at a measured COUNT RATE of approximately 20 000 counts per second and one pair at the maximum measured COUNT RATE.

4.2.8 Shield leakage test

4.2.8.1 General

The DETECTOR SHIELD prevents the detection of unwanted photons originated from outside the entrance field of view of the COLLIMATOR.

4.2.8.2 Purpose

The purpose of this test is to identify the locations of the highest leakage and its magnitude.

4.2.8.3 Method

The complete surface of the DETECTOR SHIELD and the joints shall be swept with a collimated source searching for the maximum leakage COUNT RATES at the rear and the side of the DETECTOR SHIELD and the joints (particularly the joint between the COLLIMATOR and the DETECTOR SHIELD).

4.2.8.4 RADIONUCLIDE

The RADIONUCLIDE is selected from Table 1 according to the COLLIMATOR under study.

4.2.8.5 RADIOACTIVE SOURCE distribution

A small collimated source, as illustrated in Figure 9, with *d* not larger than 20 mm and *t* not less than 10 mm, totally filled with the RADIONUCLIDE.

4.2.8.6 Data collection

The source shall be placed in contact with the external surface of the DETECTOR SHIELD and the joints. The entire surface of the DETECTOR SHIELD shall be swept and the COUNT RATES measured.

The reference COUNT RATE shall be measured with the source placed on the COLLIMATOR AXIS at 100 mm distance from the COLLIMATOR FRONT FACE.

4.2.8.7 Data processing

The maximum leakage COUNT RATES at the rear and the side of the DETECTOR SHIELD shall be recorded. Also the maximum leakage COUNT RATE at joints in the shield shall be recorded.

4.2.8.8 Data analysis

Express the ratios of the three maximum leakage COUNT RATES as a percentage of the reference COUNT RATE.

4.2.8.9 Report

The three maximum leakage ratios shall be reported.

The RADIONUCLIDE and the COLLIMATOR used shall be stated.

4.3 Wholebody imaging

4.3.1 Scanning constancy

4.3.1.1 General

For wholebody image creation with a PLANAR WHOLEBODY IMAGING EQUIPMENT the speed of the relative movement of the GAMMA CAMERA and the object shall be constant.

4.3.1.2 Purpose

The purpose of this measurement is to test the constancy of GAMMA CAMERA motion in the scanning direction

4.3.1.3 Method

With a RADIOACTIVE SOURCE attached to the DETECTOR HEAD of a GAMMA CAMERA, the wholebody image creation process will produce in the final image a constant number of counts per unit of axial distance provided that the scanning speed is constant.

4.3.1.4 RADIONUCLIDE

The RADIONUCLIDE to be employed for this measurement shall be ^{99m}Tc.

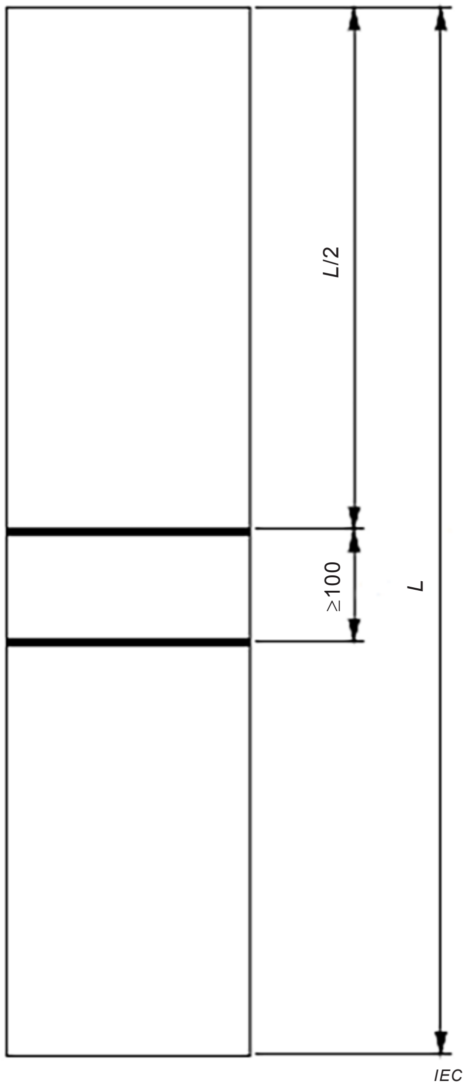
4.3.1.5 RADIOACTIVE SOURCE distribution

A small source shall be attached to the COLLIMATOR at the centre of the DETECTOR FIELD OF VIEW. The ACTIVITY of the source shall be adjusted to yield a COUNT RATE of approximately 10 000 counts per second, through a 20 % PULSE AMPLITUDE ANALYSER WINDOW, in the DETECTOR FIELD OF VIEW.

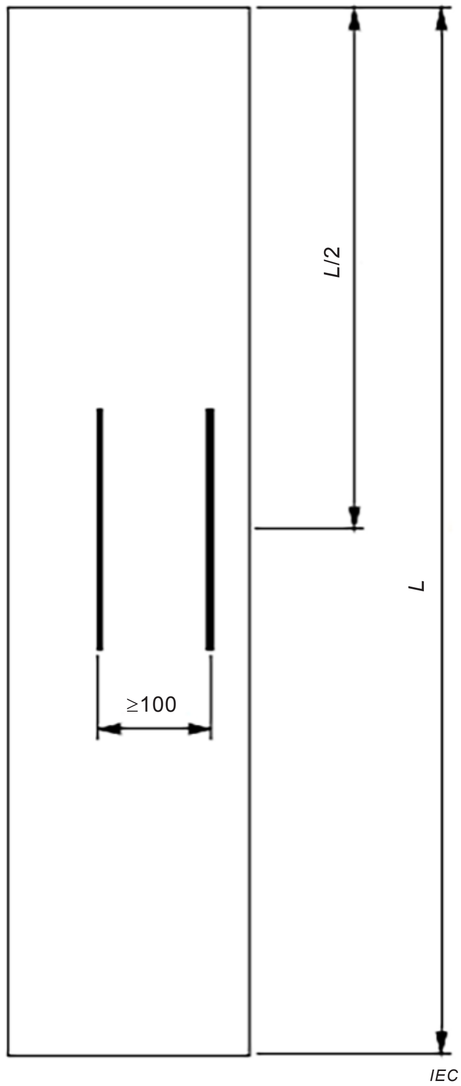
4.3.1.6 Data collection

The scan speed and the acquisition matrix shall be in the range recommended for clinical use. Two scans shall be performed along the full scanning length *L* (Figure 10) as specified by the MANUFACTURER using different speeds. The image of the source shall be recorded.

Dimensions in millimetres



a) Source position for resolution measurement parallel to the direction of motion



b) Source position for resolution measurement perpendicular to the direction of motion

Key

L full wholebody scanning length (as specified by the manufacturer)

Figure 10 – Source positions for scanning constancy for wholebody imaging

4.3.1.7 Data processing

A profile through the image of the source in the direction of the motion is drawn. This profile shall have a width between 20 mm and 30 mm in the direction perpendicular to the direction of motion, and shall contain at least 10 000 counts per profile bin.

4.3.1.8 Data analysis

The analysis shall be performed over *L*, excluding 20 mm at the ends of the profile. For this region of analysis the mean value *M* of the counts per profile bin shall be calculated. For each bin the percent deviation from *M* is determined and the maximum percent deviation from M identified.

Any deviation greater than ± 4 standard deviations of *M* (assuming Poisson statistics) is indicative of non-uniform scanning motion. The locations of such deviations and their values shall be noted.

4.3.1.9 Report

Report shall include a graph of the percent deviation from the mean value of counts and the maximum percent deviation from this mean. The deviations greater than ± 4 standard deviations shall be stated.

The COLLIMATOR and the scan speeds used in performing the measurements shall be also reported.

4.3.2 SPATIAL RESOLUTION without scatter

4.3.2.1 General

SPATIAL RESOLUTION determines the ability of an imaging system to reproduce the spatial distribution of a RADIONUCLIDE in an object. The measurement is performed by imaging LINE SOURCES in air with COLLIMATOR. It is assumed that the motion associated with the wholebody scan will not affect the SPATIAL RESOLUTION in the final image.

4.3.2.2 Purpose

The purpose of this test is to validate the consistency of SPATIAL RESOLUTION in wholebody scans.

4.3.2.3 Method

SPATIAL RESOLUTION without scatter shall be measured parallel and perpendicular to the direction of motion, and expressed as FULL WIDTH AT HALF MAXIMUM (FWHM) of the LINE SPREAD FUNCTION.

4.3.2.4 RADIONUCLIDE

The RADIONUCLIDE to be employed for this measurement shall be ^{99m}Tc.

4.3.2.5 RADIOACTIVE SOURCE distribution

The sources shall consist of capillary tubes, each having an inside diameter of less than or equal to 1 mm and a length of at least 120 mm.

The activity of the sources shall be approximately equal and shall be adjusted to yield a COUNT RATE between 3 000 and 10 000 counts per second, using an PULSE AMPLITUDE ANALYSER WINDOW set according to Table 1, with both capillary tubes in the DETECTOR FIELD OF VIEW.

The sources shall be placed on the wholebody scanning table on a flat support with low attenuation.

For the measurement of resolution parallel to the direction of motion, both capillary tubes shall be placed in the centre of the scanned field of view, perpendicular to the direction of motion; the second source shall be placed parallel to the first one at a known distance of at least 100 mm as shown in Figure 10a.

For the measurement of resolution perpendicular to the direction of motion, both capillary tubes shall be placed in the scanned field of view, parallel to the direction of motion; the second source shall be placed parallel to the first one at a known distance of at least 100 mm as shown in Figure 10b.

NOTE It may be possible to position four sources simultaneously in the DETECTOR FIELD OF VIEW of the GAMMA CAMERA and to combine the two measurements into one scan.

4.3.2.6 Data collection

The scan speed shall be in the range recommended for clinical use. Scans shall be performed both above and below the table for the two source positions described in 4.2.2.5. The camera shall be positioned at a distance of 100 mm from the sources to the COLLIMATOR FRONT FACE. The PIXEL size shall be no larger than 20 % of the FWHM of the SPATIAL RESOLUTION with the COLLIMATOR being used. The scan range shall be at least three times the axial length of the detector and shall cover all sources.

4.3.2.7 Data processing

Profiles of width 30 mm ± 5 mm shall be obtained at right angles to the direction of each LINE SOURCE. The profiles shall abut each other.

The FWHM shall be calculated for each profile using a Gaussian fit method. Additionally, for each LINE SOURCE the corresponding peak position shall be calculated from the profile.

For both pairs of LINE SOURCES and each detector head the PIXEL size shall be determined from the known LINE SOURCE spacing and the corresponding peak positions.

4.3.2.8 Data analysis

The values of the FWHM shall be averaged separately for the tubes parallel and perpendicular to the direction of motion, for the measurement above and below the table. The values shall be stated in millimetres.

4.3.2.9 Report

The FWHM values shall be reported separately for the measurements above and below the table and in the directions parallel and perpendicular to the direction of motion. The COLLIMATOR and scan speed used in performing the measurements shall be reported.

4.4 Tomographic imaging (SPECT)

4.4.1 Test of PROJECTION geometry

4.4.1.1 General

The reconstruction of SPECT data sets requires a precise knowledge of the geometry of the PROJECTIONS. In particular all lines of response must be perpendicular to the axis of rotation.

The four key factors that influence the consistency of the geometry of acquired PROJECTIONS are the correctness of CENTRE OF ROTATION, the DETECTOR HEAD TILT, COLLIMATOR hole alignment, and multiple-head co-registration.

An error-free reconstruction requires the knowledge of the position of the PROJECTION of the COR into the coordinate system X_p, Y_p for each PROJECTION (i.e. for each PROJECTION ANGLE) of that slice. For a circular rotation of the detector and for an ideal system, the PROJECTION of a POINT SOURCE at the COR will be at the same position X'_p in the PROJECTION matrix for all angles of PROJECTION (see Figure 1).

An error-free reconstruction requires that the direction of the COLLIMATOR holes is orthogonal to the SYSTEM AXIS for each angle of PROJECTION. Deviations from this requirement are called DETECTOR HEAD TILT.

If all holes of a PARALLEL HOLE COLLIMATOR are parallel, the OFFSET is constant for all source positions within the measuring volume, assuming linearity of the positioning electronics.

Additionally for multiple-head systems all detectors must be matched to image the same volume, for example have the same PIXEL size, OFFSET, and coordinates in the z-direction. Especially the OFFSET of the individual DETECTOR HEADS need to be aligned to each other.

4.4.1.2 Purpose

To assure the consistency of the geometry of acquired PROJECTIONS.

4.4.1.3 Method

The tests shall be performed for all COLLIMATORs. For multiple-head systems all angular DETECTOR HEAD configurations and all COLLIMATOR combinations shall be tested.

4.4.1.4 RADIONUCLIDE

The RADIONUCLIDE for the measurement shall be ^{99m}Tc with ENERGY WINDOW setting according to Table 1.

4.4.1.5 RADIOACTIVE SOURCE distribution

4.4.1.5.1 CENTRE OF ROTATION (COR) and DETECTOR HEAD TILT

Three POINT SOURCES locations are required. The sources shall be positioned radially at least 5 cm from the SYSTEM AXIS. The axial location (Z) shall be at the centre of the DETECTOR FIELD OF VIEW and the other two, ± 1/3 of the AXIAL FIELD OF VIEW from the centre. If more than one POINT SOURCE is used at the same time, assure that the location of each source is selected in such a way that the centroid of its PROJECTION can be evaluated independently.

4.4.1.5.2 COLLIMATOR HOLE MISALIGNMENT

A POINT SOURCE shall be placed sequentially at all intersections of an orthogonal grid, lying in the X, Z plane, covering the field of view. The distance of the grid lines shall be 10 cm apart.

4.4.1.6 Data collection

For each DETECTOR HEAD a minimum of 32 PROJECTIONS equally spaced over 360° are acquired and displayed as a SINOGRAM. The RADIUS OF ROTATION shall be set to 20 cm or higher.

At least 10 000 counts per view shall be acquired. The PIXEL size shall be less than 4 mm.

4.4.1.7 Data processing

4.4.1.7.1 CENTRE OF ROTATION (COR)

For the calculation of the centroid $X_p(\theta)$ of the source in the X_p direction, 50 mm wide strips in the Y direction centred around the Y_p position of each source shall be used. This shall be done for each PROJECTION ANGLE θ.

NOTE If there is a DETECTOR HEAD TILT the position of the image of the POINT SOURCE will move not only in the X_p direction, but also in the Y_p direction. To determine the X_p movement not influenced by the Y_p movement (for a reasonable amount of head tilt), the centroid is calculated using the 50 mm wide strip. The subscript p refers to the projection space (see Figure 1).

4.4.1.7.2 DETECTOR HEAD TILT

The DETECTOR HEAD TILT is determined by calculating the centroid $Y_p(\theta)$ of the image of one POINT SOURCE in the Y_p direction, using the data full field-of-view in the X_p direction. This calculation shall be done for each PROJECTION ANGLE.

4.4.1.7.3 COLLIMATOR hole misalignment

The centroids $X_p(\theta)$ and $Y_p(\theta)$ are calculated according to 4.4.1.7.1 and 4.4.1.7.2, respectively.

4.4.1.8 Data analysis

4.4.1.8.1 CENTRE OF ROTATION (COR)

A sine function is fitted to the calculated centroids $X_p(\theta)$ for each source position *i*

$$X_{p,i}(\theta) = A_i \sin(\theta + \varphi_i) + C_i \tag{9}$$

where

θ is the PROJECTION ANGLE;

A_i is the amplitude of the sine function for source position *i*;

φ_i is the phase shift of the sine function for source position *i*;

C_i is the base shift of the sine function for source position *i*.

Then the OFFSET is calculated as the average of the C_i over the three source positions.

In addition, the difference between fit and data shall be plotted (showing the error) as a function of θ. The maximum difference for each axial position shall be determined.

4.4.1.8.2 DETECTOR HEAD TILT

One source is selected for the evaluation of DETECTOR HEAD TILT.

A sine function is fitted to the calculated centroid $Y_p(\theta)$ for the selected source

$$Y_p(\theta)= B \sin(\theta + \psi) + D \tag{10}$$

where

θ is the PROJECTION ANGLE;

B is the amplitude of the sine function for the selected source;

ψ is the phase shift of the sine function for the selected source.

D is the base shift of the sine function for the selected source

The head tilt angle value *a* is calculated as *a* = arcsin *B/A*, where *A* is the amplitude for the selected source as obtained in 4.4.1.8.1.

In addition the difference between fit and data shall be plotted (showing the error) as a function of θ.

4.4.1.8.3 COLLIMATOR hole misalignment

The following analysis is performed for all source positions *i*.

A sine function is fitted to the calculated centroids $X_{p,i}(\theta)$

$$X_{p,i}(\theta) = A_i \sin(\theta + \varphi_i) + C_i \tag{11}$$

where

θ is the PROJECTION ANGLE;

A_i is the amplitude of the sine function for source position i;

φ_i is the phase shift of the sine function for source position i;

C_i is the base shift of the sine function for source position i.

The mean value of all C_i, (which are the local hole misalignments in X_p-direction) shall be calculated and the maximum deviation from this mean value identified.

A sine function is fitted to the calculated centroid $Y_{p,i}(\theta)$

$$Y_{p,i}(\theta) = B_i \sin(\theta + \psi_i) + D_i \qquad (12)$$

where

θ is the PROJECTION ANGLE;

B_i is the amplitude of the sine function for source position i;

ψ_i is the phase shift of the sine function for source position i.

D_i is the base shift of the sine function for source position i

The local hole misalignment in the Y_p-direction a_i is calculated as $a_i = \arcsin B_i/A_i$

The mean value of all a_i shall be calculated and the maximum deviation from this mean value identified.

4.4.1.9 Report

4.4.1.9.1 General

The DETECTOR HEAD and COLLIMATOR used shall be stated. For multiple head systems the configuration of the DETECTOR HEADS shall be reported.

The PIXEL size used shall be reported.

4.4.1.9.2 CENTRE OF ROTATION

Report the OFFSET of the CENTRE OF ROTATION as calculated according to 4.4.1.8.1 in millimetres.

Plot the difference between fitted sine function and the locations of the centroids as a function of θ for each axial position.

The maximum difference for each axial position shall be reported in millimetres.

4.4.1.9.3 DETECTOR HEAD TILT

The head tilt angle value α shall be reported.

Plot the difference between fitted sine function and the locations of the centroids as a function of θ.

4.4.1.9.4 Detector hole misalignment

The mean values of all C_i and all A_i and the corresponding maximum deviations from these mean values shall be reported.

Report all C_i and A_i values and their positions.

4.4.2 Measurement of SPECT SYSTEM SENSITIVITY

4.4.2.1 DETECTOR POSITIONING TIME

4.4.2.1.1 General

In combination with the acquisition time chosen, the DETECTOR POSITIONING TIME determines that fraction of the total time spent on an acquisition which is not useful in collecting data. Therefore it will influence the sensitivity of a tomographic device. This is especially true for a rotating detector working in "step and shoot" mode.

4.4.2.1.2 Purpose

This test provides a measure to determine the idle time of the system during the acquisition that is not used for data acquisition.

4.4.2.1.3 Method

The result of the test is based on a standard SPECT acquisition.

4.4.2.1.4 RADIONUCLIDE

The RADIONUCLIDE for the measurement shall be ^{99m}Tc with ENERGY WINDOW setting according to Table 1.

4.4.2.1.5 RADIOACTIVE SOURCE distribution

A POINT SOURCE of ^{99m}Tc shall be placed at the CENTRE OF ROTATION in air.

4.4.2.1.6 Data collection

The COUNT RATE shall be greater than 1 000 cps. Two 360° tomographic acquisitions of a stated number, $P_{j,}$ PROJECTIONS (one with at least 60, the other with at least 120 PROJECTIONS) shall be performed using an acquisition time ΔT_{acq} per PROJECTION of 10 s. The subscript j is either "low" or "high" corresponding to the range of approximately 60 or 120 PROJECTIONS. The time T_j from the start of acquisition of the first PROJECTION to the end of the acquisition of the last PROJECTION shall be measured. A corresponding static acquisition of duration T_j shall also be performed directly after the tomographic acquisition. The data shall be decay corrected for the different starting times.

4.4.2.1.7 Data processing

The total DETECTOR POSITIONING TIME T_{pos} shall be calculated according to:

$$T_{\text{pos},j} = \frac{\left(N_{\text{static},j} - N_{\text{total},j}\right)T_j}{N_{\text{static},j}} \tag{13}$$

where

N_{total} is the sum of the counts in all PROJECTIONS;

N_{static} is the number of counts in the static acquisition.

4.4.2.1.8 Data analysis

The mean DETECTOR POSITIONING TIME per PROJECTION ΔT_{pos} is then calculated by dividing T_{pos} by the number of transitions between PROJECTION steps actually used.

$$\Delta T_{\text{pos},j} = \frac{T_{\text{pos},j}}{\left(P_j - 1\right)} \tag{14}$$

The correction factor c_j for the calculation of the VOLUME SENSITIVITY is then given by

$$c_j = \frac{\Delta T_{\text{acq},j}}{\Delta T_{\text{acq},j} + \Delta T_{\text{pos},j}} \tag{15}$$

The correction factor c_j shall be calculated for the subscript j with corresponding acquisition times per PROJECTION $\Delta T_{acq,j}$ of 20 s (low) and 10 s (high), respectively.

4.4.2.1.9 Report

The correction factor c_j shall be reported for the subscript j with corresponding acquisition times per PROJECTION $\Delta T_{acq,j}$ of 20 s (low) and 10 s (high), respectively. This corresponds to a typical clinical situation of total acquisition time of 30 min.

4.4.2.2 NORMALIZED VOLUME SENSITIVITY

4.4.2.2.1 General

The VOLUME SENSITIVITY of a SPECT system may only provide an indirect measure of the clinical performance of a SPECT system.

4.4.2.2.2 Purpose

The test determines the VOLUME SENSITIVITY and relates it to the AXIAL FIELD OF VIEW.

4.4.2.2.3 Method

A standard SPECT acquisition of a uniform phantom is used to calculate the NORMALIZED VOLUME SENSITIVITY.

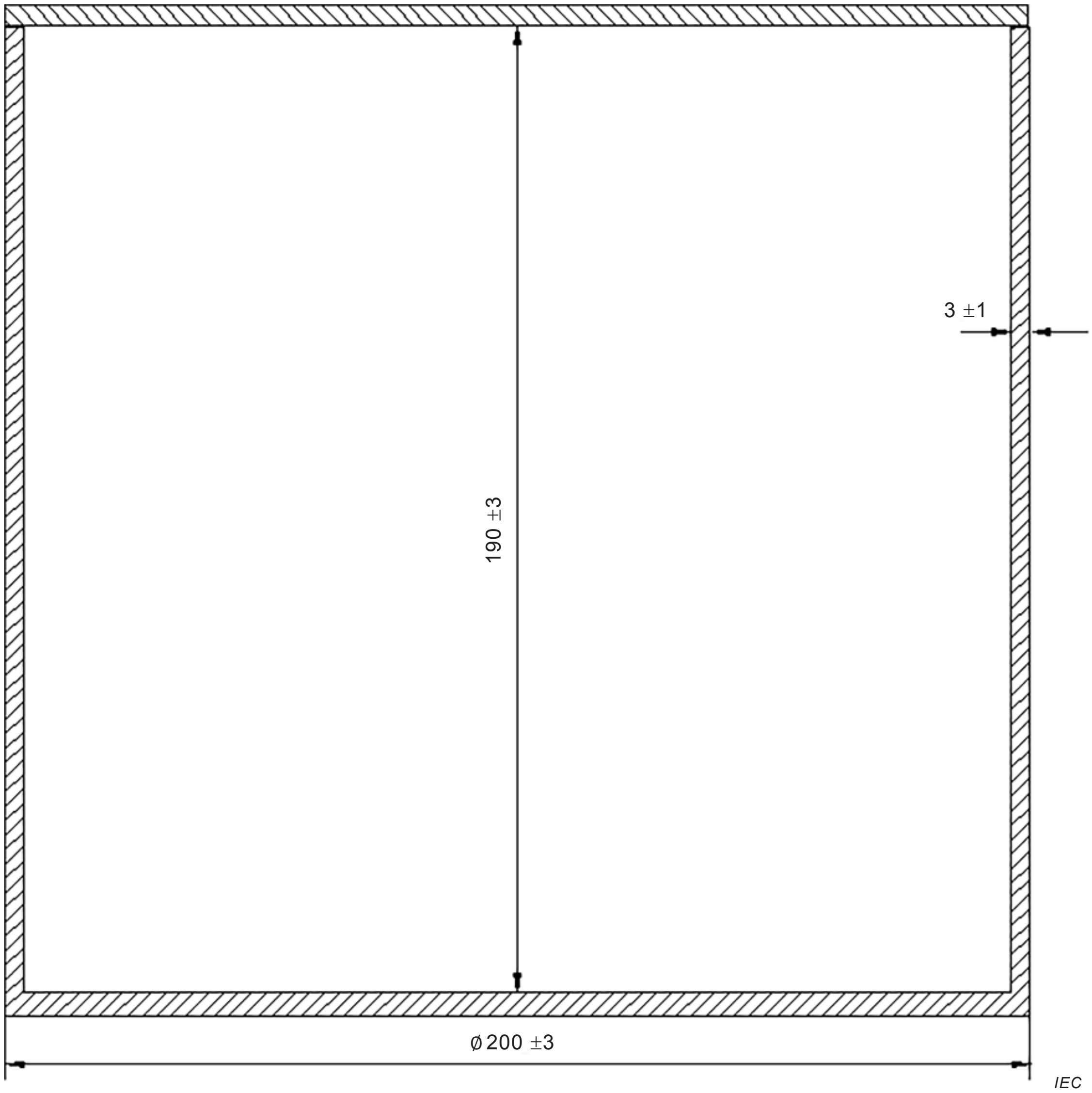
4.4.2.2.4 RADIONUCLIDE

The RADIONUCLIDE for the measurement shall be ^{99m}Tc with ENERGY WINDOW setting according to Table 1.

4.4.2.2.5 RADIOACTIVE SOURCE distribution

The measurement shall be carried out using a cylindrical phantom of 200 mm ± 3 mm outside diameter, of wall thickness 3 mm ± 1 mm, and 190 mm ± 3 mm inside length (see Figure 11), filled homogeneously with a water solution of ^{99m}Tc.

Dimensions in millimetres



Material: polymethylmethacrylate

Figure 11 – Cylindrical phantom

The ACTIVITY concentration a_{ave} (kBq/cm^3) shall be accurately determined by counting at least two samples from that solution in a calibrated well counter and correcting the result for radioactive decay to the time of measurement (midpoint of acquisition interval).

NOTE The test is critically dependent upon accurate assays of radioactivity as measured in a dose calibrator or well counter. It is difficult to maintain an absolute calibration with such devices to accuracies better than 10 %. Absolute reference standards using appropriate γ-emitters are to be considered if higher degrees of accuracy are required.

4.4.2.2.6 Data collection

The phantom shall be positioned so that its long axis coincides with the SYSTEM AXIS (parallel to and as close as possible to the SYSTEM AXIS). The RADIUS OF ROTATION R shall be 20 cm. For each COLLIMATOR used routinely for SPECT imaging at least one million counts shall be acquired in static imaging mode and the acquisition time T_a recorded.

4.4.2.2.7 Data processing

For a rectangular region of interest (ROI) centred on the image of the phantom the number of counts N_{ROI} shall be determined. The width of the ROI shall be at most 240 mm to cover the cylinder diameter, and the length l shall be at least 150 mm in the axial direction and centred to the phantom.

4.4.2.2.8 Data analysis

The NORMALIZED VOLUME SENSITIVITY S_{norm} is then calculated by dividing the number of counts N_{ROI} registered from the ROI by the ACTIVITY concentration a_{ave}, the acquisition time T_a, the axial length l of the ROI, and by multiplying by the correction factor c_j (see 4.4.2.1.8) according to the following equation:

$$S_{\mathrm{norm}} = \frac{N_{\mathrm{ROI}}}{a_{\mathrm{ave}} T_a l} c_j \left[\mathrm{cps/}\left(\mathrm{kBq/cm^2}\right)\right] \tag{16}$$

NOTE For a given phantom set-up and PARALLEL HOLE COLLIMATOR, the NORMALIZED VOLUME SENSITIVITY and the SYSTEM SENSITIVITY measured according to 4.2.1 are related by a fixed ratio and the correction factor c_j.

4.4.2.2.9 Report

The values shall be specified and stated for the subscript j of low and high respectively.

4.4.3 Scatter measurement

4.4.3.1 General

The scattering of primary gamma rays results in events with false information for radiation source localization. Variations in design and implementation cause emission tomographs to have different sensitivities to scattered radiation. The purpose of this procedure is to measure the relative SYSTEM SENSITIVITY to scattered radiation, expressed by the SCATTER FRACTION (SF), as well as the values of the SCATTER FRACTION in each slice (SF_i).

4.4.3.2 Purpose

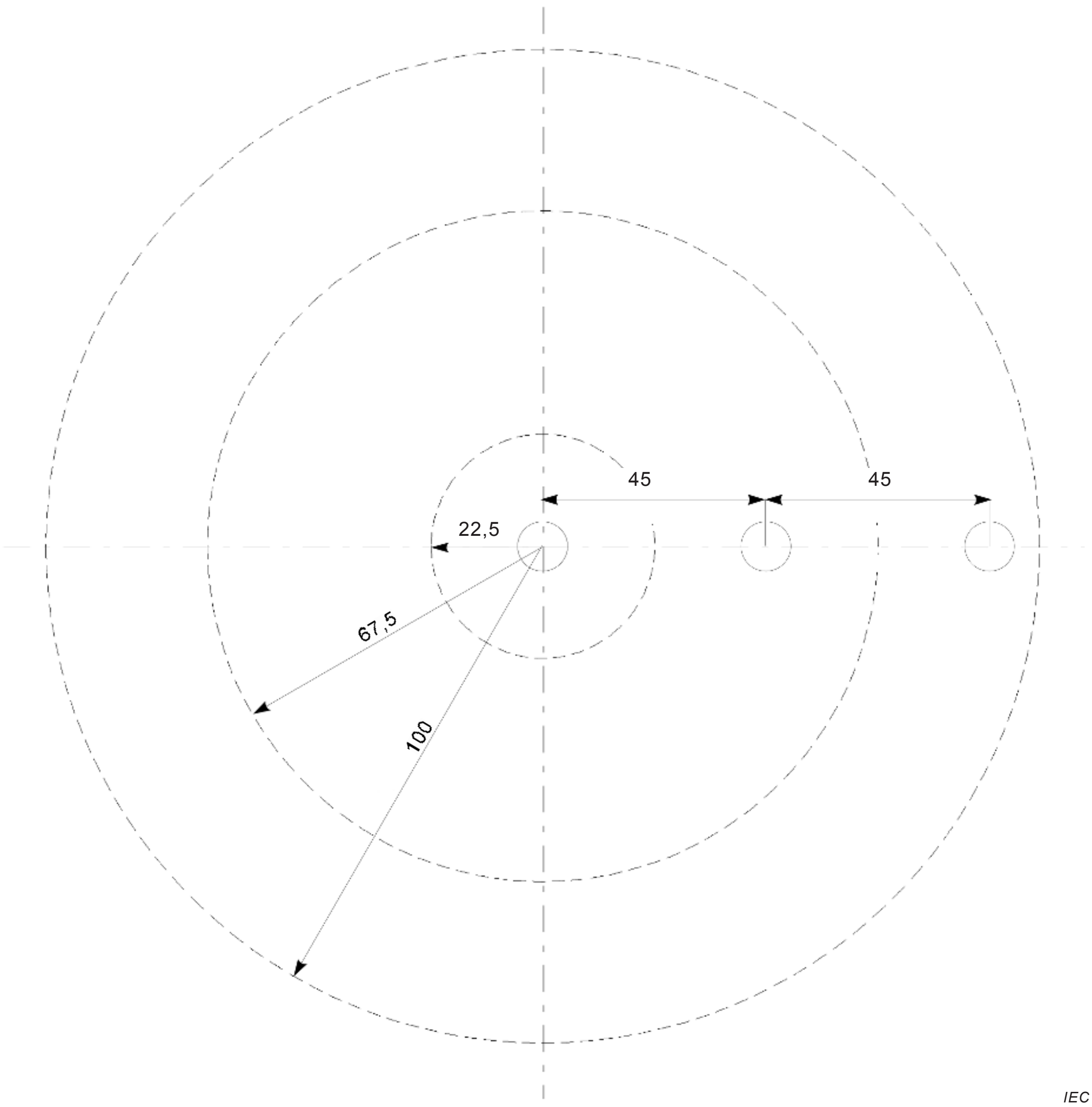
Unscattered events are assumed to lie within a 2 × $FWHM$ wide strip centred on the image of the LINE SOURCE in each SINOGRAM. This region width is chosen because the scatter value is insensitive to the exact width of the region, and a negligible number of unscattered events lie more than one $FWHM$ from the line image.

4.4.3.3 Method

The width of the scatter response function allows a simplified analysis method. A linear interpolation across the strip from the points of intersection of the scatter tails and the edges of the 2 × $FWHM$ wide strip is used to estimate the amount of scatter present in the strip. The area under the line of interpolation plus the contributions outside the strip constitute the estimated scatter.

Estimates of the SCATTER FRACTION for uniform source distributions are made under the assumption of its low radial dependence. Under this assumption, the measure of SCATTER FRACTION for a LINE SOURCE on-axis is applied to a cross-sectional area out to a radius of 22,5 mm. The SCATTER FRACTION for a LINE SOURCE of 45 mm off-axis is applied to an annulus between 22,5 mm and 67,5 mm. Likewise, the SCATTER FRACTION for a LINE SOURCE 90 mm off-axis is applied to an annulus between 67,5 mm and 100 mm (see Figure 12). The three values for SCATTER FRACTION are weighted by the areas to which they are applied, yielding a weighted average. The annular areas are in the ratios of 1:8:10,75 respectively.

Dimensions in millimetres



Material: polymethylmethacrylate

NOTE The mounting plate replaces the cover of the cylindrical phantom.

The source holders consist of tubes of lengths sufficient to fill the inside length of the cylindrical phantom.

In addition, the drawing shows the weighting areas (bounded by the dashed lines) for the scatter measurement.

Figure 12 – Phantom insert with holders for the scatter source

4.4.3.4 RADIONUCLIDE

The RADIONUCLIDE for the measurement shall be ^{99m}Tc with ENERGY WINDOW setting according to Table 1, with an ACTIVITY less than that at which the percent dead-time losses exceed 5 %.

4.4.3.5 RADIOACTIVE SOURCE distribution

The test phantom shall be filled with non-radioactive water as a scatter medium. The test phantom LINE SOURCE shall be inserted, parallel to the axis of the cylinder, sequentially at radial distances of 0 mm, 45 mm, and 90 mm. The phantom shall be centred axially. For tomographs with an AXIAL FIELD OF VIEW greater than 165 mm, the phantom shall be centred within the AXIAL FIELD OF VIEW.

4.4.3.6 Data collection

The measurements shall be performed by imaging a single LINE SOURCE at three different radial positions within a water-filled test phantom, using the COLLIMATOR used for SPECT imaging, a circular orbit and a 200 mm RADIUS OF ROTATION.

Data shall be taken with the source at the specified radial distances from the long axis of the tomograph. SINOGRAM data shall be acquired for each of the radial locations of the LINE SOURCE. At least 200 000 counts per slice shall be acquired for each slice within:

a) the AXIAL FIELD OF VIEW;

b) the central 165 mm;

where the phantom was placed, whichever is the smaller.

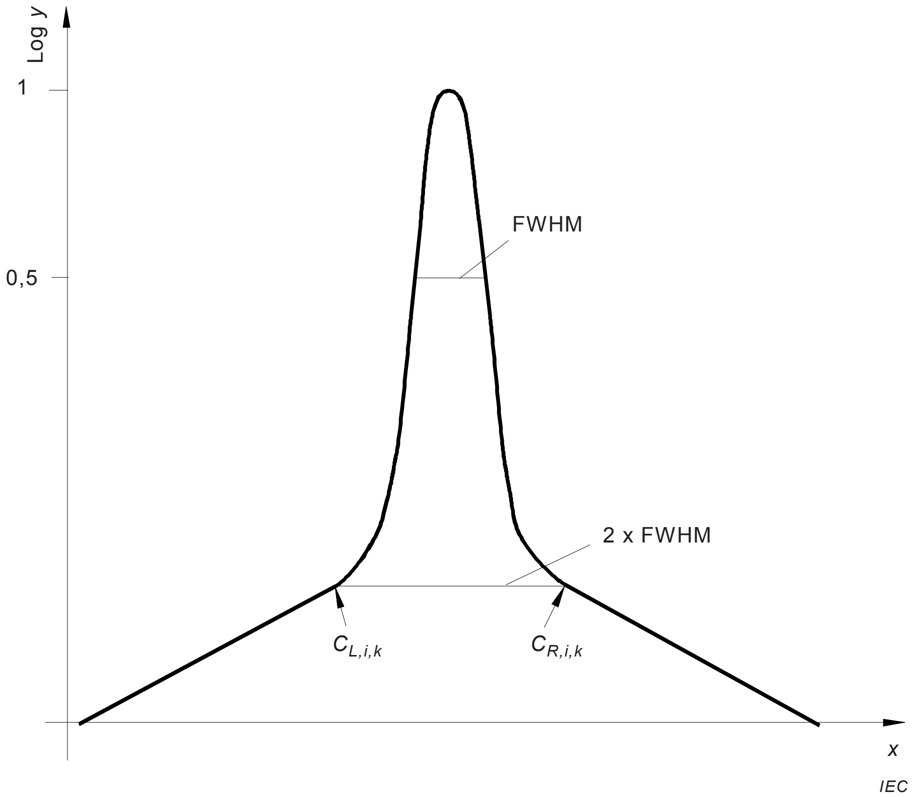
4.4.3.7 Data processing

Data shall not be corrected for scatter or ATTENUATION.

4.4.3.8 Data analysis

All SINOGRAMS corresponding to slices at least 10 mm from either end of the phantom shall be processed. Thus for tomographs with an AXIAL FIELD OF VIEW less than 165 mm, all slices shall be processed.

All PIXELS in each SINOGRAM which correspond to points which are located further than 120 mm from the centre shall be set to zero. For each PROJECTION ANGLE within the SINOGRAM, the location of the centre of the LINE SOURCE shall be determined by finding the PIXEL with the largest value. Each PROJECTION shall be shifted so that the PIXEL containing the maximum value aligns with the central PIXEL row of the SINOGRAM. After realignment, a sum PROJECTION shall be produced. The counts in the PIXELS at the left and right edges of the 2 × *FWHM* wide strip $C_{L,i,k}$ and $C_{R,i,k}$, respectively shall be obtained from the sum PROJECTION (see Figure 13). Linear interpolation shall be used to find the count levels at ±1 × FWHM from the central PIXEL of the PROJECTION. The average of the two count levels $C_{L,i,k}$ and $C_{R,i,k}$ shall be multiplied by the fractional number of PIXELS between the edges of the 2 × FWHM wide strip, with the product added to the counts in the PIXELS outside the strip, to yield the number of scattered counts $C_{s,i,k}$, for the slice *i* and the source position *k*. The total counts (scattered plus unscattered) $C_{tot,i,k}$ is the sum of the counts in all PIXELS in the sum PROJECTION.



NOTE In the summed PROJECTION the scatter is estimated by the counts outside the 2 × *FWHM* wide strip plus the area of the LSF below the line $C_{L,i,k}$ – $C_{R,i,k}$.

Figure 13 – Evaluation of scatter fraction

The average ACTIVITY $A_{ave,k}$ during data acquisition over the time interval $T_{acq,k}$ for the LINE SOURCE at position *k*, shall be calculated by correcting for decay (each midpoint of the time intervals $T_{acq,k}$ is related to a common starting time).

The SCATTER FRACTION SF_i for each slice, *i*, due to a uniform source distribution shall be calculated as follows:

$$SF_i = \frac{\left[\dfrac{C_{\mathrm{s},i,1}}{A_{\mathrm{ave},1}}\right] + 8\left[\dfrac{C_{\mathrm{s},i,2}}{A_{\mathrm{ave},2}}\right] + 10{,}75\left[\dfrac{C_{\mathrm{s},i,3}}{A_{\mathrm{ave},3}}\right]}{\left[\dfrac{C_{\mathrm{tot},i,1}}{A_{\mathrm{ave},1}}\right] + 8\left[\dfrac{C_{\mathrm{tot},i,2}}{A_{\mathrm{ave},2}}\right] + 10{,}75\left[\dfrac{C_{\mathrm{tot},i,3}}{A_{\mathrm{ave},3}}\right]} \tag{17}$$

where the subscripts 1, 2 and 3 refer to LINE SOURCES at radial distances 0 mm, 45 mm and 90 mm, respectively.

4.4.3.9 Report

For each slice, *i*, that was processed, the value of SF_i shall be tabulated. The average *SF* of the set of values of SF_i shall also be reported as the system SCATTER FRACTION for uniform sources.

4.4.4 SPECT SYSTEM SPATIAL RESOLUTION

4.4.4.1 General

4.4.4.2 Purpose

The SPECT SYSTEM SPATIAL RESOLUTION characterizes the ability of the SPECT system to identify small details and high contrasts.

4.4.4.3 Method

SPECT acquisition and reconstruction of a set of POINT SOURCES.

4.4.4.4 RADIONUCLIDE

The RADIONUCLIDE selected from Table 1.

4.4.4.5 RADIOACTIVE SOURCE distribution

The IEC cylindrical phantom (see Figure 11) shall be used with the mounting plate according to Figure 12.

Three POINT SOURCES, prepared from a RADIONUCLIDE selected from Table 1 and stated, of dimensions not to exceed 2 mm in any direction, shall be placed within the water-filled cylinder. The axis of the cylinder shall coincide with the SYSTEM AXIS. The first POINT SOURCE shall be placed inside the tube on the axis of the cylinder (see Figure 12) and at the central plane in the *Z* direction (see Figure 1).

The second POINT SOURCE shall be placed at the radial position of 45 mm and –50 mm from the central plane in the *Z* direction. The third POINT SOURCE shall be placed at the radial position of 90 mm and +50 mm from the central plane in the *Z* direction.

4.4.4.6 Data collection

To measure the SPECT SYSTEM SPATIAL RESOLUTION the axis of the phantom shall be aligned with the SYSTEM AXIS and oriented such that the two off-centre POINT SOURCES will intercept either the *X* or *Y* axis of the reconstructed transverse slice. Measurements shall be carried out with a 200 mm RADIUS OF ROTATION unless otherwise specified. For those systems that cannot achieve 200 mm, the maximum possible RADIUS OF ROTATION shall be set and stated. Data shall be acquired with a PIXEL size equal to or less than 30 % of the system FWHM at 200 mm from the face of the COLLIMATOR using at least 120 equally spaced PROJECTION ANGLES over 360° acquisition. A minimum of 250 000 counts shall be acquired into each reconstructed slice.

4.4.4.7 Data processing

The three slices to be analysed shall be positioned so as to include the centre of the phantom, and the points ± 50 mm distant along the axis of the phantom. Profiles of the TRANSVERSE POINT SPREAD FUNCTIONS of each reconstructed transverse slice shall be obtained both in the *X* and *Y* direction (see Figure 14) to yield PIXEL size, RADIAL and TANGENTIAL RESOLUTION. From the coronal or sagittal slice containing the three POINT SOURCES, profiles of the POINT SPREAD FUNCTIONS shall be obtained in the *Z* direction to yield PIXEL size and AXIAL RESOLUTION.

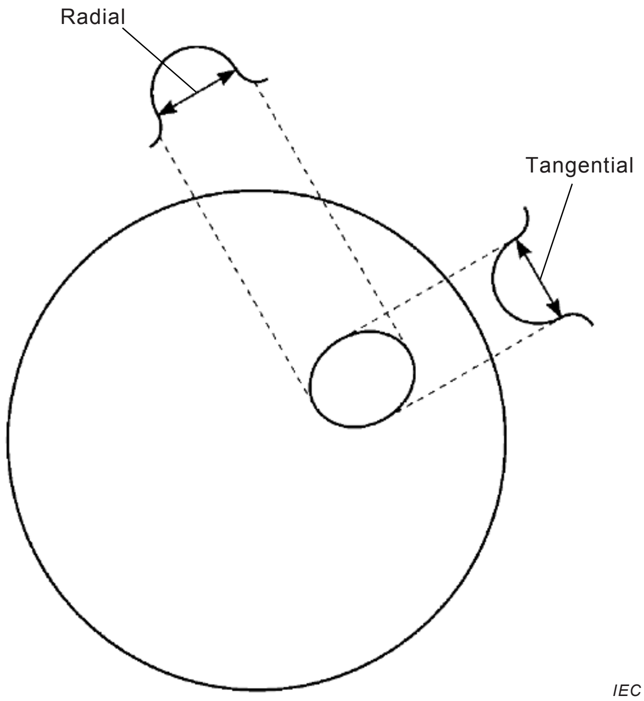


Figure 14 – Reporting transverse resolution

Three transverse slices, 10 mm ± 3 mm thick shall be reconstructed using filtered backprojection a ramp filter with a cut-off at the Nyquist frequency as determined by the acquisition PIXEL size.

4.4.4.8 Data analysis

From the measured POINT SPREAD FUNCTIONS (see 4.4.4.7), the following data shall be obtained:

a) the RADIAL RESOLUTION (FWHM and EW) for each position in the radial direction from the measurements described in 4.4.4.6 (see Figures 6, 7, 14);
b) the TANGENTIAL RESOLUTION (FWHM and EW) in the tangential direction from the measurements for each position described in 4.4.4.6 (see Figures 6, 7, 14);
c) the AXIAL RESOLUTION (FWHM and EW) in the axial direction from the measurements for each position described in 4.4.4.6 (see Figures 6, 7).

4.4.4.9 Report

The PIXEL size and the number of PROJECTIONS shall be stated.

From the measured POINT SPREAD FUNCTIONS (see 4.4.4.7), the following data shall be reported:

a) the RADIAL RESOLUTION (FWHM and EW) for each position in the radial direction from the measurements described in 4.4.4.6 (see Figures 6, 7, 14);
b) the TANGENTIAL RESOLUTION (FWHM and EW) in the tangential direction from the measurements for each position described in 4.4.4.6 (see Figures 6, 7, 14);
c) the AXIAL RESOLUTION (FWHM and EW) in the axial direction from the measurements for each position described in 4.4.4.6 (see Figures 6, 7).

4.4.5 Tomographic image quality

4.4.5.1 General

Contrast and noise are factors that affect image quality; their combination determines lesion detectability. Contrast depends on the lesion-to-background ACTIVITY concentration ratio. Image contrast is further compromised by finite SPATIAL RESOLUTION and scatter. The visibility of a lesion at low contrast is affected by the noise present in the background surrounding the lesion.

4.4.5.2 Purpose

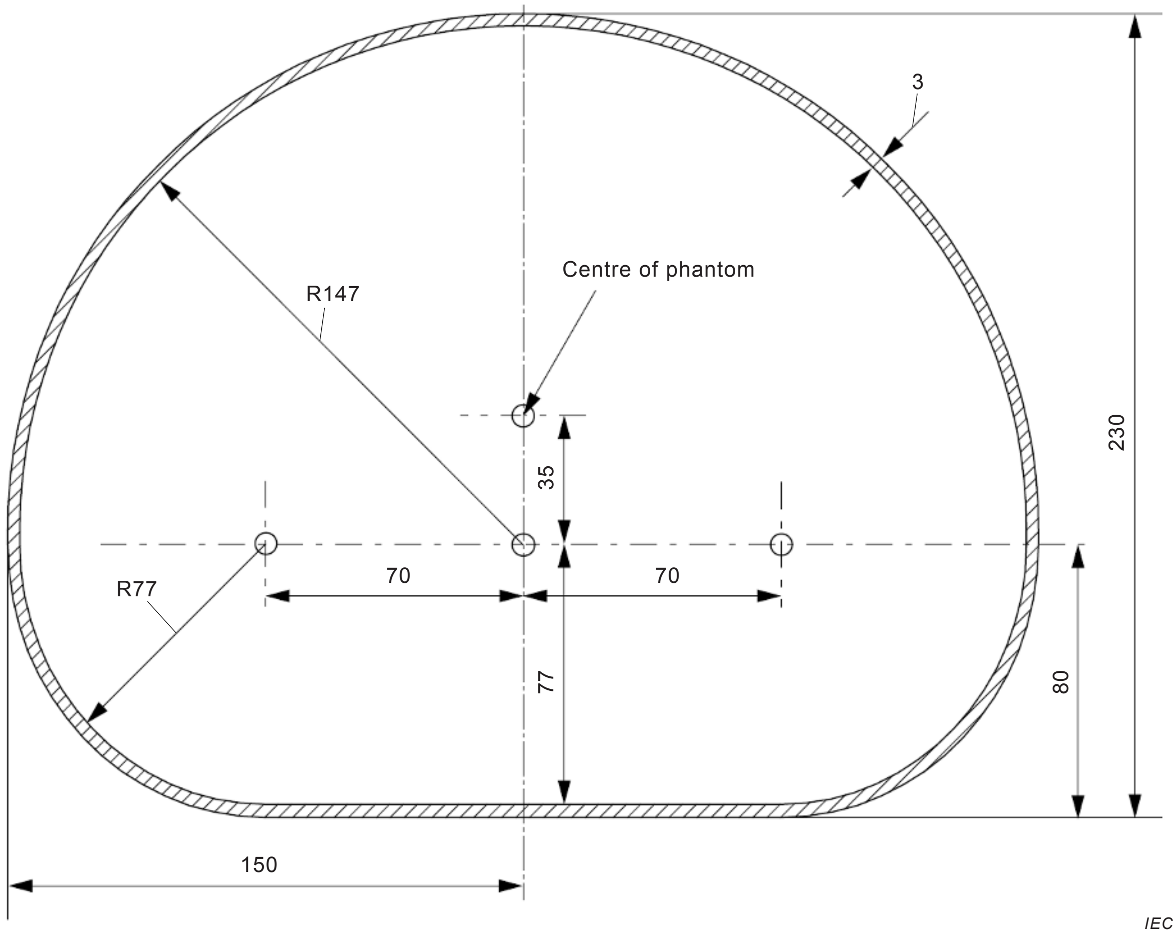
The purpose of this subclause 4.4.5 is to measure image quality factors of the SPECT and of the SPECT/CT scanner under normal imaging conditions. To mimic such normal imaging conditions, a torso shaped phantom shall be used containing multiple hot spheres of decreasing diameters and a cold cylinder insert in a warm background.

The contrast of the hot spheres is measured and compared to the noise in the background to assess lesion detectability. Additional measurements include assessing the ability of the scanner to recover contrast as a function of sphere size.

4.4.5.3 Method

The wholebody phantom is to be used for all measurements (see Figure 15) into which hollow spheres and lung insert are placed (see Figure 16).

Dimensions are in millimetres and are given within ±1 mm

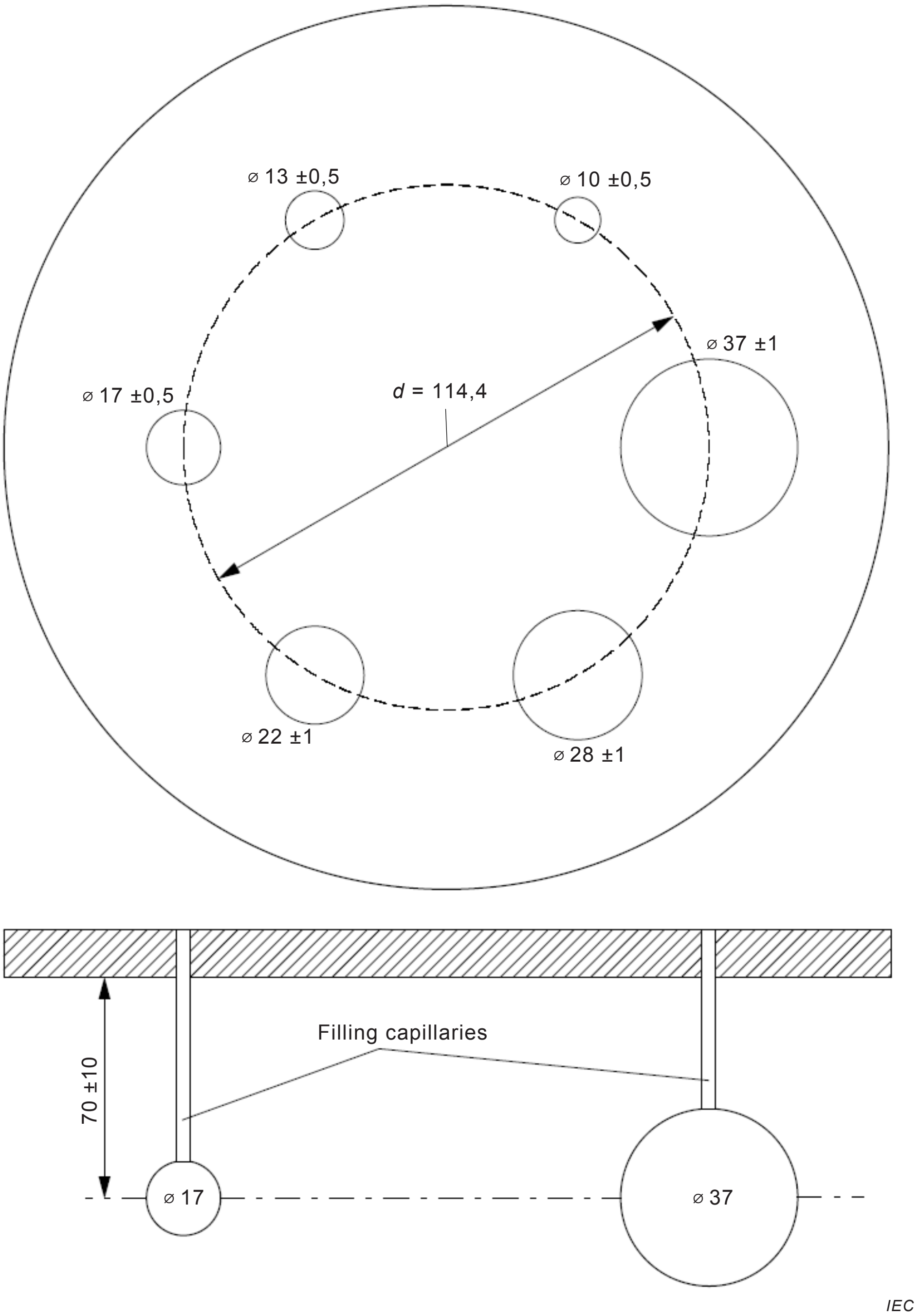


Material: polymethylmethacrylate

NOTE The phantom length shall be at least 180 mm ± 5 mm.

Figure 15 – Cross-section of body phantom

Dimensions in millimetres



Material: polymethylmethacrylate

The wall thickness of the spheres shall be ≤ 1 mm.

The centres of the spheres shall be at the same distance from the surface of the mounting plate.

The spheres can also be made from glass.

The lung insert cylinder is centred within the image quality phantom and has length that extends through the entire chamber and diameter of 50 ± 2 mm.

NOTE All diameters given are inside diameters.

Figure 16 – Phantom insert with hollow spheres

The hollow spheres of decreasing diameter are arranged circularly and centred on a single plane and have hollow stems that extend through the outer plate to permit filling of the spheres with a radioactive liquid. The lung cylinder insert has a diameter of (50 ± 2) mm and extends through the length of the phantom chamber. The cylinder is filled with a low atomic number material of density of (0,30 ± 0,10) g/cm^3, is void of ACTIVITY and simulates the ATTENUATION of the lung.

A SPECT acquisition covering the length of the wholebody phantom shall be obtained.

The algorithms used for image reconstruction, scatter and ATTENUATION correction shall be those corresponding to the routine SPECT clinical image protocol for bone or cardiac imaging. Results for additional image reconstructions with enhancements may be reported separately.

Following the acquisitions and image reconstruction, ROIs are drawn on selected image slices over the hot spheres, cold cylinder insert, and image quality phantom background. The average ROI PIXEL values are used for analysis.

4.4.5.4 RADIONUCLIDE

The RADIONUCLIDE for the measurement shall be ^{99m}Tc.

4.4.5.5 RADIOACTIVE SOURCE distribution

The total ACTIVITY in the wholebody phantom background should be 500 MBq. This corresponds to a concentration of approximately 80 kBq/ml. The spheres shall be filled with an ACTIVITY concentration that is between 7,6 and 8,4 times the ACTIVITY concentration in the background. All ACTIVITY concentrations are specified for the time at the start of acquisition.

The relative ACTIVITY concentrations in the phantom background and spheres shall be determined independently by planar imaging of 5 cm^3 aliquots of the two solutions using the same DETECTOR HEAD.

4.4.5.6 Data collection

The wholebody phantom is placed on the patient bed of the tomograph and is centred within the TRANSVERSE FIELD OF VIEW. A line drawn through the centre of the wholebody phantom shall be parallel to the SYSTEM AXIS.

A SPECT acquisition over the length of the wholebody phantom shall be performed. If the AXIAL FIELD OF VIEW is sufficient to cover the phantom length, the acquisition is performed in a single scan position. Additional scan positions in either direction shall be necessary if the AXIAL FIELD OF VIEW of the scanner is insufficient to cover the required length.

The acquisition shall use

– a circular orbit with a RADIUS OF ROTATION of 25 cm or more;
– a low-energy high resolution PARALLEL HOLE COLLIMATOR appropriate for clinical imaging of ^{99m}Tc;

The number of PROJECTIONS obtained over a 360°acquisition shall be 120 or 128, corresponding to 3° or 2,8° rotation between steps. If the SPECT system has a limited angular range of less than 360°, then the maximum permitted angular range shall be used and the number of PROJECTIONS obtained has a corresponding 3° or 2,8° rotation between steps. For multiple detector SPECT systems, each detector shall contribute towards the total number of PROJECTIONS obtained. For example each detector in a dual-detector system will contribute half the images to the total acquisition.

The acquisition is designed to collect approximately 50 million counts. The time per angular stop T_p shall be determined from the measured COUNT RATE and calculated as follows:

$$T_p = 50 \times 10^6 \text{ counts} / (CR \times \text{number of PROJECTIONS}) \quad (19)$$

where CR is the measured COUNT RATE in counts/s. T_p should then be rounded up to the nearest whole number of seconds.

The IMAGE MATRIX and acquisition zoom applied should be chosen to store PROJECTIONS with PIXEL size of 3,0 mm to 3,5 mm.

Any data necessary for creating the attenuation map and for scatter correction should be acquired or calculated using the standard clinical protocol.

4.4.5.7 Data processing

Tomographic reconstruction shall be performed over the axial length of the image quality phantom. The standard reconstruction method for the clinical imaging protocol used shall be applied.

4.4.5.8 Data analysis

4.4.5.8.1 Regions of interest

4.4.5.8.1.1 General

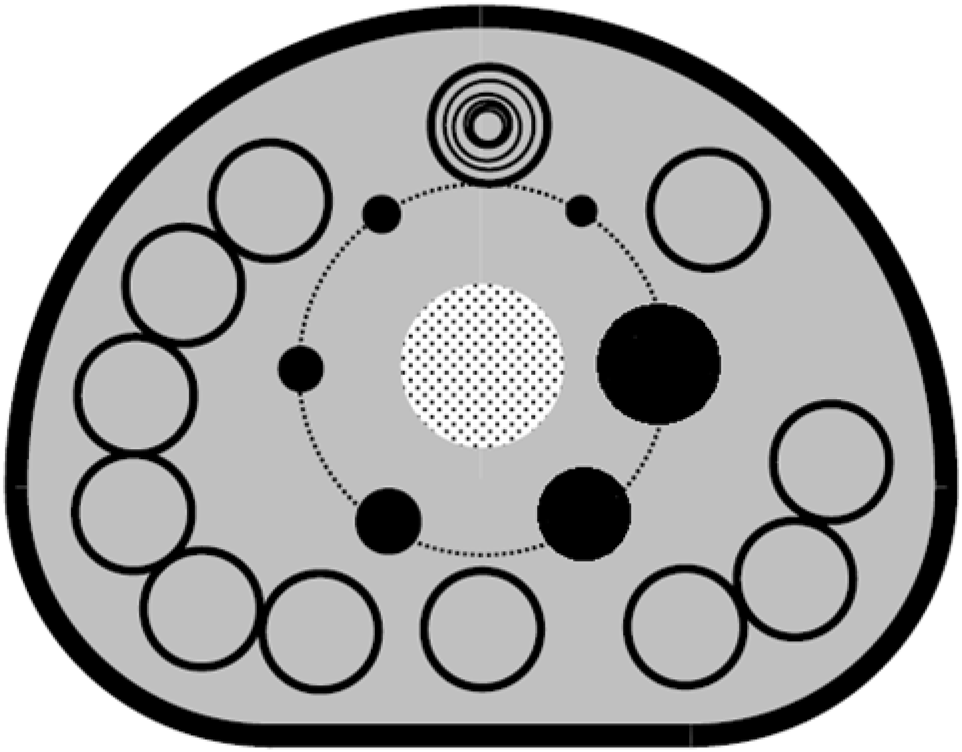
For image quality analysis 2D circular ROIs drawn on selected transverse slices are used.

4.4.5.8.1.2 HOT SPHERES ROIS

The transverse slice coinciding with the central plane of the hot spheres shall be identified (this slice will be referred to as the “S-slice”). Circular ROIs shall be drawn over the six spheres in the S-slice. The ROI diameter should be as close as possible to the sphere inner diameter, but shall not exceed the inner diameter. The average PIXEL value P_i for each ROI shall be computed.

4.4.5.8.1.3 BACKGROUND ROIS

The transverse slices shall be identified at a distance as close as possible to ± 1 cm and ± 2 cm from the S-slice. On these four slices and the S-slice, twelve 37 mm diameter ROIs shall be drawn throughout the background at a distance of at least 15 mm from the edge of the phantom (see Figure 17 for an example of background ROI placement on the S-slice). ROIs corresponding to the five smaller diameter spheres shall then be drawn concentric within each of the 37 mm diameter ROIs, producing a total of 60 background ROIs for each sphere diameter (12 ROIs on each of the five slices).



Twelve locations are specified. At each location, six ROIs, identical in size to the sphere ROIs, are placed concentrically. (adapted from NEMA Standards Publication NU 2-2007 *Performance Measurements of Positron Emission Tomographs*; used with permission.)

Figure 17 – Placement of ROIs in the phantom background

For each sphere diameter, compute the average PIXEL value for each of the 60 ROIs, then compute the mean and standard deviation of those 60 ROI values.

4.4.5.8.1.4 LUNG AND BACKGROUND ROIs

Draw a 25 mm diameter ROI inside the lung insert on every transverse slice over the entire length of the image quality phantom. Likewise, draw a 25 mm diameter ROI in the phantom background positioned 15 mm from the left edge of the phantom edge. Record the average PIXEL values for all regions and label as $WBBkg_k$ and $WBLung_k$, respectively for slice $k = 1,n$ where n is the last slice in the phantom. Calculate the average of *all* $WBBkg_k$ and record as $WBBkg_{avg}$.

4.4.5.8.2 Image quality calculations

The contrast recovery coefficient CR_j for each sphere j with a diameter of 10 mm, 13 mm, 17 mm, 22 mm, 28 mm, and 37 mm, respectively, shall be computed. The index j is either 10, 13, 17, 22, 28, or 37 and matched to the diameter of the corresponding sphere.

$$CR_j = (P_j/B_j - 1)/(A_S/A_B - 1) \quad (20)$$

where

P_j is the ROI value for sphere j, as computed in 4.4.5.8.1.1;

B_j is the average of the background ROI values for sphere j, as computed in section 4.4.5.8.1.2;

A_S is the ACTIVITY concentration in the spheres;

A_B is the ACTIVITY concentration in the background.

The noise coefficient of variation CN_j for each sphere diameter shall be computed as:

$$CN_j = S_j/B_j \tag{21}$$

where

B_j is the average of the background ROI values for sphere *j*, as computed in section 4.4.5.8.1.2;

S_j is the standard deviation of the background ROI values for sphere *j*, as computed in section 4.4.5.8.1.2.

The contrast-to-noise ratio CNR_j for each sphere diameter shall be computed as:

$$CNR_j = (P_j/B_j - 1)/CN_j \tag{22}$$

where

P_j is the ROI value for sphere *j*, as computed in 4.4.5.8.1.1;

B_j is the average of the background ROI values for sphere *j*, as computed in 4.4.5.8.1.2;

CN_j is the noise coefficient of variation for sphere *j,* as computed in Equation (12).

4.4.5.8.3 Accuracy of ATTENUATION correction and scatter correction

Accuracy of corrections for ATTENUATION and scatter is assessed using the ROIs from the background and the lung insert according to 4.4.5.8.1.3.

The residual error in the lung insert is calculated as follows:

$$\Delta LR_k = 100\ \% \times WBLung_k\ /\ WBBkg_{avg} \tag{23}$$

where

ΔLR_k is the percent residual error in slice *k*;

$WBLung_k$ is the average PIXEL value in the lung insert ROI in slice *k*;

$WBBkg_{avg}$ is the average PIXEL value in the phantom background.

4.4.5.8.4 Accuracy of the SPECT and CT image registration for SPECT/CT

Alignment of the SPECT and CT image volumes is crucial for diagnosis and for ATTENUATION correction. X, Y, and Z-centroids of each sphere on the SPECT and CT scans should be calculated using a 3D ROI tool. If a 3D ROI tool is not available, then 2D ROIs are to be drawn on all slices which contain the sphere. The image quality SPECT scan and corresponding CT scan will be used for comparison of the two image volumes.

On the SPECT scan, completely encircle the spheres. Set all PIXELS in the ROI that are greater than 1,25 times the average background (B_j for sphere *j* as defined in 4.4.5.8.1.1) within the ROI to one, otherwise set them to zero. The X, Y, and Z-centroids are then calculated as follows:

$$C_{X,j} = \Sigma\ x \times ROI_{\mathrm{SPECT,j}}(x,y,z)/\Sigma\ ROI_{\mathrm{SPECT,j}}(x,y,z);\ \text{for all } x,y,z \text{ of ROI} \tag{24}$$

$$C_{Y,j} = \Sigma\ y \times ROI_{\mathrm{SPECT,j}}(x,y,z)/\Sigma\ ROI_{\mathrm{SPECT,j}}(x,y,z);\ \text{for all } x,y,z \text{ of ROI} \tag{25}$$

$$C_{Z,j} = \Sigma\ z \times ROI_{\mathrm{SPECT,j}}(x,y,z)/\Sigma\ ROI_{\mathrm{SPECT,j}}(x,y,z);\ \text{for all } x,y,z \text{ of ROI} \tag{26}$$

Then identify $C_{SPECT,j} = (C_{X,j}, C_{Y,j}, C_{Z,j})$ as the centroid coordinate for sphere *j* for SPECT.

For the CT scan, completely encircle the spheres. Set all PIXELS in the ROI which belong to the sphere wall to one and the others to zero. The X, Y, and Z-centroids are then calculated as follows:

$$C_{X,j} = \Sigma\, x \times ROI_{\mathrm{CT},j}(x,y,z)/\Sigma\, ROI_{\mathrm{CT},j}(x,y,z);\ \text{for all } x,y,z \text{ of ROI} \quad (27)$$

$$C_{Y,j} = \Sigma\, y \times ROI_{\mathrm{CT},j}(x,y,z)/\Sigma\, ROI_{\mathrm{CT},j}(x,y,z);\ \text{for all } x,y,z \text{ of ROI} \quad (28)$$

$$C_{Z,j} = \Sigma\, z \times ROI_{\mathrm{CT},j}(x,y,z)/\Sigma\, ROI_{\mathrm{CT},j}(x,y,z);\ \text{for all } x,y,z \text{ of ROI} \quad (29)$$

Then identify $C_{CT,j} = (C_{X,j}, C_{Y,j}, C_{Z,j})$ as the centroid coordinate for sphere j for CT.

Calculate the distance between the SPECT and CT centroids for each sphere.

4.4.5.9 Report

4.4.5.9.1 Scan set up and phantom ACTIVITY concentrations

Report scan set up parameters:

- total ACTIVITY in the phantom background, concentrations of the ACTIVITY in the spheres and background, and the ratio of the concentrations at the start time of scanning;
- COLLIMATOR and RADIUS OF ROTATION
- total angle of acquisition, number of PROJECTIONS, matrix size and PIXEL size;
- acquisition time per stop and the total acquired counts;
- CT acquisition parameters: kVp, mAs, slice-thickness;
- reconstruction algorithm, methods used for ATTENUATION and scatter corrections, post reconstruction image filter and all associated parameters.

4.4.5.9.2 Image quality

Report the noise coefficient of variation CN_j for all spheres.

Report the contrast recovery coefficients CR_j for all spheres.

Report the contrast-noise-ratio CNR_j for all spheres.

4.4.5.9.3 Accuracy of ATTENUATION correction and scatter correction

Plot the residual error ΔLR_k for every slice k.

4.4.5.9.4 Accuracy of SPECT and CT image registration

Report the deviation distance in mm between the SPECT and CT centroids for each sphere.

5 Accompanying documents

5.1 General

A document shall accompany each GAMMA CAMERA for planar imaging, PLANAR WHOLEBODY IMAGING EQUIPMENT, and SINGLE PHOTON EMISSION COMPUTED TOMOGRAPHY and shall include the information indicated in 5.2 to 5.4.

5.2 General parameters for GAMMA CAMERAS

5.2.1 COLLIMATORS

- photon energy range;
- type (parallel holes, pin-hole, converging, diverging, slit, etc.);
- type of construction (e.g. foil, cast);
- number, shape and size of holes;
- minimum septal thickness;
- COLLIMATOR thickness.

5.2.2 Shield leakage values

- as specified in 4.2.8;

5.2.3 Pre-set PULSE AMPLITUDE ANALYSER WINDOWS

5.2.4 INTRINSIC ENERGY RESOLUTION

as described in 4.2.5, for the selected RADIONUCLIDE;

5.2.5 COLLIMATOR dependent quantities

For each COLLIMATOR the following quantities shall be given:

- SYSTEM SENSITIVITY and RADIONUCLIDE used;
- EW, FWHM and FWTM as a function of depth as specified in 4.2.2;
- MTF as a function of depth as specified in 4.2.2;

5.2.6 COUNT RATE CHARACTERISTICS

- as described in 4.2.7;

5.2.7 Measured COUNT RATE that is 80 % of the corresponding TRUE COUNT RATE

- as described in 4.2.7.8;

5.2.8 Dimensions of the DETECTOR FIELD OF VIEW

- as defined in 3.1;

5.2.9 Non-uniformity characteristics

Values for the following non-uniformity characteristics with a selected RADIONUCLIDE as specified in 4.2.4

- non-uniformity distribution;
- integral non-uniformity;
- differential non-uniformity.

If an instrument incorporates facilities for uniformity correction, other than those based on spatial and spectrum corrections (e.g. flood field correction), the results shall be provided with and without these other corrections.

5.2.10 INTRINSIC SPATIAL RESOLUTION (FWHM and EW) of the DETECTOR HEAD without COLLIMATOR

- as specified in 4.2.2.6.2;

5.2.11 INTRINSIC SPATIAL NON-LINEARITY

- as specified in 4.2.3

5.2.12 Intrinsic MULTIPLE WINDOW SPATIAL REGISTRATION

– as specified in 4.2.6

5.3 GAMMA CAMERA based wholebody imaging system

5.3.1 Scanning constancy

– as specified in 4.3.1

5.3.2 SPATIAL RESOLUTION

– as specified in 4.3.2

5.4 SPECT

5.4.1 Calibration measurements of COR

– as specified in 4.4.1

5.4.2 Measurement of head tilt

– as specified in 4.4.1

5.4.3 Measurement of COLLIMATOR hole misalignment

– as specified in 4.4.1

5.4.4 TRANSVERSE RESOLUTION (radial and tangential)

– as specified in 4.4.4

5.4.5 AXIAL RESOLUTION

– as specified in 4.4.4

5.4.6 Axial PIXEL size

– as specified in 4.4.4

5.4.7 Transaxial PIXEL size

– as specified in 4.4.4

5.4.8 DETECTOR POSITIONING TIME

– as specified in 4.4.2

5.4.9 NORMALIZED VOLUME SENSITIVITY

– as specified in 4.4.2

5.4.10 SCATTER FRACTIONS SF_i and SF

– as specified in 4.4.3

5.4.11 Scan set up and phantom ACTIVITY concentration

– as specified in 4.4.5.9.1

5.4.12 Image quality

– as specified in 4.4.5.9.2

5.4.13 Accuracy of ATTENUATION correction and scatter correction

– as specified in 4.4.5.9.3

5.4.14 Accuracy of SPECT and CT image registration

– as specified in 4.4.5.9.4

Index of defined terms

Bibliography

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
IEC 60601-1:2005/AMD1:2012

IEC 61675-1:2013, *Radionuclide imaging devices – Characteristics and test conditions – Part 1: Positron emission tomographs*

IEC TR 61948-2:2001, *Nuclear medicine instrumentation – Routine tests – Part 2: Scintillation cameras and single photon emission computed tomography imaging*

NEMA NU 1-2012, *Performance measurements of gamma cameras*

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