

INTERNATIONAL STANDARD



**Radionuclide imaging devices – Characteristics and test conditions –
Part 1: Positron emission tomographs**

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INTERNATIONAL STANDARD



Radionuclide imaging devices – Characteristics and test conditions – Part 1: Positron emission tomographs

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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CHARACTERISTICS AND TEST CONDITIONS –****Part 1: Positron emission tomographs****FOREWORD**

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IEC 61675-1 has been prepared by subcommittee 62C: Equipment for radiotherapy, nuclear medicine and radiation dosimetry, of IEC technical committee 62: Electrical equipment in medical practice. It is an International Standard.

This third edition cancels and replaces the second edition published in 2013. This edition constitutes a technical revision.

This edition includes the following significant technical change with respect to the previous edition: requirements have been changed or newly created regarding the technical aspects of SPATIAL RESOLUTION, sensitivity measurement, SCATTER FRACTION, COUNT RATE performance, image quality, PET/CT registration accuracy and time-of-flight resolution.

The text of this International Standard is based on the following documents:

Draft	Report on voting
62C/811/CDV	62C/828/RVC

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

The language used for the development of this International Standard is English.

In this document, the following print types are used: terms defined in Clause 3 of this document or as noted: small capitals.

This document was drafted in accordance with ISO/IEC Directives, Part 2, and developed in accordance with ISO/IEC Directives, Part 1 and ISO/IEC Directives, IEC Supplement, available at www.iec.ch/members_experts/refdocs. The main document types developed by IEC are described in greater detail at www.iec.ch/standardsdev/publications.

A list of all parts in the IEC 61675 series, published under the general title *Radionuclide imaging devices – Characteristics and test conditions*, can be found on the IEC website.

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

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

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INTRODUCTION

Further developments of POSITRON EMISSION TOMOGRAPHS allow most of the tomographs to be operated in fully 3D acquisition mode. To comply with this trend, this document describes test conditions in accordance with this acquisition characteristic. In addition, today a POSITRON EMISSION TOMOGRAPH often includes X-RAY EQUIPMENT for COMPUTED TOMOGRAPHY (CT). For this document, PET-CT hybrid devices are considered to be state of the art, dedicated POSITRON EMISSION TOMOGRAPHS not including the X-ray component being special cases only.

While the test methods specified herein are optimized for the PET component of PET-CT hybrid devices, they may also be used for the PET component of PET-MR hybrid devices.

The test methods specified in this document have been selected to reflect as much as possible the clinical use of POSITRON EMISSION TOMOGRAPHS. It is intended that the tests be carried out by MANUFACTURERS, thereby enabling them to declare the characteristics of POSITRON EMISSION TOMOGRAPHS in the ACCOMPANYING DOCUMENTS. This document does not indicate which tests will be performed by the MANUFACTURER on an individual tomograph or which class-standards may be used to characterize the performance of POSITRON EMISSION TOMOGRAPHS by the MANUFACTURER.

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RADIONUCLIDE IMAGING DEVICES – CHARACTERISTICS AND TEST CONDITIONS –

Part 1: Positron emission tomographs

1 Scope

This part of IEC 61675 specifies terminology and test methods for declaring the characteristics of POSITRON EMISSION TOMOGRAPHS. POSITRON EMISSION TOMOGRAPHS detect the ANNIHILATION RADIATION of positron emitting RADIONUCLIDES by COINCIDENCE DETECTION.

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

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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

3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC TR 60788:2004 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at <http://www.electropedia.org/>
- ISO Online browsing platform: available at <http://www.iso.org/obp>

3.1

tomography

radiography of one or more layers within an object

[SOURCE: IEC TR 60788:2004, rm-41-15]

3.1.1

transverse tomography

~~TOMOGRAPHY that slices a three-dimensional object into a stack of OBJECT SLICES which are considered as being two-dimensional and independent from each other and at which the IMAGE PLANES are perpendicular to the SYSTEM AXIS~~

3.1.1

emission computed tomography

ECT

imaging method for the representation of the spatial distribution of incorporated RADIONUCLIDES in selected two-dimensional slices through the object

3.1.1.1

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 (along the LINE OF RESPONSE) and called "Radon transform".

3.1.1.2

projection beam

beam that determines the smallest possible volume in which the physical property which determines the image is integrated during the measurement process

Note 1 to entry: The PROJECTION BEAM's shape is limited by SPATIAL RESOLUTION in all three dimensions.

Note 2 to entry: The PROJECTION BEAM mostly has the shape of a long thin cylinder or cone. In POSITRON EMISSION TOMOGRAPHY, it is the sensitive volume between two detector elements operated in coincidence.

3.1.1.3

projection angle

angle at which the PROJECTION is measured or acquired

3.1.1.4

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, and the linear projection coordinate is displayed on the abscissa.

3.1.1.5

object slice

physical property that corresponds to a slice in the object and that determines the measured information and which is displayed in the tomographic image

3.1.1.6

image plane

plane assigned to a plane in the OBJECT SLICE

Note 1 to entry: Usually, the IMAGE PLANE is the midplane of the corresponding OBJECT SLICE.

3.1.1.7

system axis

axis of symmetry, characterized by geometrical and physical properties of the arrangement of the system

Note 1 to entry: For a circular POSITRON EMISSION TOMOGRAPH, the SYSTEM AXIS is the axis through the centre of the detector ring. For tomographs with rotating detectors, it is the axis of rotation.

3.1.1.8

tomographic volume

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

3.1.1.8.1

transverse field of view

dimensions of a slice through the TOMOGRAPHIC VOLUME, perpendicular to the SYSTEM AXIS

Note 1 to entry: For a circular TRANSVERSE FIELD OF VIEW, it is described by its diameter.

Note 2 to entry: For non-cylindrical TOMOGRAPHIC VOLUMES, the TRANSVERSE FIELD OF VIEW may depend on the axial position of the slice.

3.1.1.8.2

axial field of view

AFOV

field which is characterized by dimensions of a slice through the TOMOGRAPHIC VOLUME, parallel to and including the SYSTEM AXIS

Note 1 to entry: In practice, the AXIAL FIELD OF VIEW is specified only by its axial dimension, given by the distance between the centre of the outmost defined IMAGE PLANES plus the average of the measured AXIAL RESOLUTION.

3.1.1.8.3

total field of view

field which is characterized by dimensions (three-dimensional) of the TOMOGRAPHIC VOLUME

3.1.2

positron emission tomography

PET

EMISSION COMPUTED TOMOGRAPHY utilizing the ANNIHILATION RADIATION of positron emitting RADIONUCLIDES by COINCIDENCE DETECTION

3.1.2.1

positron emission tomograph

tomographic device, which detects the ANNIHILATION RADIATION of positron emitting RADIONUCLIDES by COINCIDENCE DETECTION

3.1.2.2

annihilation radiation

ionizing radiation that is produced when a particle and its antiparticle interact and cease to exist

3.1.2.3

coincidence detection

method which checks whether two opposing detectors have detected one photon each simultaneously

Note 1 to entry: By this method, the two photons are concatenated into one event.

Note 2 to entry: The COINCIDENCE DETECTION between two opposing detector elements serves as an electronic collimation to define the corresponding PROJECTION BEAM or LINE OF RESPONSE (LOR), respectively.

3.1.2.4

coincidence window

time interval during which two detected photons are considered being simultaneous

3.1.2.5

line of response

LOR

axis of the PROJECTION BEAM

Note 1 to entry: In PET, the LINE OF RESPONSE is the line connecting the centres of two opposing detector elements operated in coincidence.

3.1.2.6

total coincidences

sum of all coincidences detected

3.1.2.6.1

true coincidence

result of COINCIDENCE DETECTION of two gamma events originating from the same positron annihilation

3.1.2.6.2

scattered true coincidence

TRUE COINCIDENCE where at least one participating photon was scattered before the COINCIDENCE DETECTION

3.1.2.6.3

unscattered true coincidence

the difference between TRUE COINCIDENCES and SCATTERED TRUE COINCIDENCES

3.1.2.6.4

random coincidence

result of a COINCIDENCE DETECTION in which participating photons do not originate from the same positron annihilation.

3.1.2.7

singles rate

COUNT RATE measured without COINCIDENCE DETECTION, but with energy discrimination

3.1.3

two-dimensional reconstruction

image reconstruction at which data are rebinned prior to reconstruction into SINOGRAMS, which are the PROJECTION data of transverse slices, which are considered being independent of each other and being perpendicular to the SYSTEM AXIS

3.1.4

three-dimensional reconstruction

image reconstruction at which the LINES OF RESPONSE are not restricted to being perpendicular to the SYSTEM AXIS so that a LINE OF RESPONSE may pass several transverse slices

3.2

image matrix

<nuclear medicine> matrix in which each element corresponds to the measured or calculated physical property of the object at the location described by the coordinates of this MATRIX ELEMENT

3.2.1

matrix element

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

3.2.2

pixel

MATRIX ELEMENT in a two-dimensional IMAGE MATRIX

3.2.1.2

trixel

MATRIX ELEMENT in a three-dimensional IMAGE MATRIX

3.2.3

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.

3.3

point spread function

PSF

scintigraphic image of a POINT SOURCE

3.3.1

physical point spread function

<tomographs> two-dimensional POINT SPREAD FUNCTION in planes perpendicular to the PROJECTION BEAM at specified distances from the detector

Note 1 to entry: The PHYSICAL POINT SPREAD FUNCTION characterizes the purely physical (intrinsic) imaging performance of the tomographic device and is independent of for example sampling, image reconstruction and image processing. A PROJECTION BEAM is characterized by the entirety of all PHYSICAL POINT SPREAD FUNCTIONS as a function of distance along its axis.

3.3.2

axial point spread function

profile passing through the peak of the PHYSICAL POINT SPREAD FUNCTION in a plane parallel to the SYSTEM AXIS

3.3.3

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.

3.4

spatial resolution

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

3.4.1

transverse resolution

SPATIAL RESOLUTION in a reconstructed plane perpendicular to the SYSTEM AXIS

3.4.1.1

radial resolution

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

3.4.1.2

tangential resolution

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

3.4.2

axial resolution

SPATIAL RESOLUTION along a line parallel to the SYSTEM AXIS

Note 1 to entry: AXIAL RESOLUTION only applies for tomographs with sufficiently fine axial sampling fulfilling the sampling theorem.

3.4.3

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

Note 1 to entry: EW better reflects scatter tails of the response function than FWHM or FWTM.

[SOURCE: IEC TR 60788:2004, rm-34-45, modified – Note to entry added.]

3.4.4 full width at half maximum FWHM

for a bell-shaped curve, distance parallel to the abscissa axis between the points where the ordinate has half of its maximum value

[SOURCE: IEC TR 60788:2004, rm-73-02]

3.5 recovery coefficient

measured (image) ACTIVITY concentration of an active volume divided by the true ACTIVITY concentration of that volume, neglecting ACTIVITY calibration factors

Note 1 to entry: For the actual measurement, the true ACTIVITY concentration is replaced by the measured ACTIVITY concentration in a large volume.

3.6 slice sensitivity

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

Note 1 to entry: In PET, the measured counts are numerically corrected for scatter by subtracting the SCATTER FRACTION.

3.7 volume sensitivity

sum of the individual SLICE SENSITIVITIES

3.8 count rate characteristic

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

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

3.8.1 count loss

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

3.8.2 count rate

number of counts per unit of time

3.8.3 true count rate

COUNT RATE that would be observed if the RESOLVING TIME of the device were zero

[SOURCE: IEC TR 60788:2004, rm-34-20]

3.9 scatter fraction SF

ratio between SCATTERED TRUE COINCIDENCES and the sum of SCATTERED plus UNSCATTERED TRUE COINCIDENCES for a given experimental set-up

3.10 point source

RADIOACTIVE SOURCE approximating a δ -function in all three dimensions

3.11

line source

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

3.12

calibration

<emission computed tomography> process to establish the relation between COUNT RATE per volume element locally in the image and the corresponding ACTIVITY concentration in the object for object sizes not requiring RECOVERY CORRECTION

Note 1 to entry: In order to have this CALIBRATION fairly independent of the object under study, the application of proper corrections to the data, e.g., ATTENUATION, scatter, COUNT LOSS, radioactive decay, detector normalization, RANDOM COINCIDENCES (PET), and branching ratio (PET) is mandatory. The independency of the object is required to scale clinical images in terms of kBq/ml or standardized uptake values (SUV).

3.13

PET count rate performance

relationship between the measured COUNT RATE of TRUE COINCIDENCES, RANDOM COINCIDENCES, TOTAL COINCIDENCES, and noise equivalent count rate versus ACTIVITY

3.14

time-of-flight resolution

TOF resolution

uncertainty of the measurement of the difference of the arrival time of the two photons from the same annihilation event

4 Test methods

4.1 General

For all measurements, the acquisition parameters of the tomograph shall be set up according to its normal mode of operation, i.e., it shall not be adjusted specially for the measurement of specific parameters. If the tomograph is specified to operate in different modes influencing the performance parameters, for example with different axial acceptance angles, ~~with and without septa,~~ with TWO-DIMENSIONAL RECONSTRUCTION and THREE-DIMENSIONAL RECONSTRUCTION, the test results shall be reported for every mode of operation. The tomograph configuration (e.g. energy thresholds, axial acceptance angle, reconstruction algorithm) shall be chosen according to the MANUFACTURER's recommendation and clearly stated. If any test cannot be carried out exactly as specified in this document, the reason for the deviation and the exact conditions under which the test was performed shall be stated clearly.

It is postulated that a POSITRON EMISSION TOMOGRAPH is capable ~~of measuring to estimate~~ RANDOM COINCIDENCES and ~~performing to perform~~ the appropriate correction. In addition, a POSITRON EMISSION TOMOGRAPH ~~shall provide~~ provides corrections for scatter, ATTENUATION, COUNT LOSS, branching ratio, radioactive decay, and CALIBRATION.

The test phantoms shall be centred within the tomograph's AXIAL FIELD OF VIEW, if not specified otherwise.

4.2 SPATIAL RESOLUTION

4.2.1 General

SPATIAL RESOLUTION measurements describe partly the ability of a tomograph to reproduce the spatial distribution of a tracer in an object in a reconstructed image. The measurement ~~is~~ shall be performed by imaging POINT SOURCES in air and reconstructing images, using a sharp reconstruction filter. Although this does not represent the condition of imaging a PATIENT, where tissue scatter is present and limited statistics require the use of a smooth reconstruction filter

and/or iterative reconstruction methods, the measured SPATIAL RESOLUTION provides an objective comparison between tomographs.

4.2.2 Purpose

The purpose of this measurement is to characterize the ability of the tomograph to recover small objects.

The ~~TRANSVERSE~~ SPATIAL RESOLUTION ~~is~~ shall be characterized by the width of the reconstructed TRANSVERSE POINT SPREAD FUNCTIONS of radioactive POINT SOURCES. The width of the point spread function ~~is~~ shall be measured by the FULL WIDTH AT HALF MAXIMUM (FWHM) and the EQUIVALENT WIDTH (EW).

~~The AXIAL RESOLUTION is defined for tomographs with sufficiently fine axial sampling (volume detectors) and could be measured with a stationary POINT SOURCE. These systems (fulfilling the sampling theorem in the axial direction) are characterized by the fact that the AXIAL POINT SPREAD FUNCTION of a stationary POINT SOURCE would not vary if the position of the source is varied in the axial direction for half the axial sampling distance.~~

4.2.3 Method

4.2.3.1 General

For all systems, the SPATIAL RESOLUTION shall be measured in the transverse IMAGE PLANE in two directions (i.e., radially and tangentially) and in the axial direction. ~~In addition, for those systems having sufficiently fine axial sampling, the AXIAL RESOLUTION also shall be measured.~~

~~The TRANSVERSE FIELD OF VIEW and the IMAGE MATRIX size determine the PIXEL size in the transverse IMAGE PLANE. In order to measure accurately the width of the spread function, its FWHM should span at least 5 PIXELS.~~

~~For volume imaging systems, the TRIAXIAL size, in both the transverse and axial dimensions, should be made close to one fifth of the expected FWHM.~~

4.2.3.2 RADIONUCLIDE

The RADIONUCLIDE for the measurement shall be ^{18}F or ^{22}Na , with an ACTIVITY such that the percent COUNT LOSS is less than 5 % or the RANDOM COINCIDENCE rate is less than 5 % of the TOTAL COINCIDENCE rate.

4.2.3.3 RADIOACTIVE SOURCE distribution

4.2.3.3.1 General

POINT SOURCES shall be used with the largest dimension less than or equal to 1 mm.

4.2.3.3.2 Source positioning

~~Tomographs shall use~~ POINT SOURCES, suspended in air, shall be used to minimize scatter, for measurements of TRANSVERSE RESOLUTION. Resolution measurements shall be made on two planes perpendicular to the LONG AXIS of the tomograph, one at the centre of the AXIAL FIELD OF VIEW and the second on a plane offset from the central plane by 3/8 of the AXIAL FIELD OF VIEW (i.e., one-eighth of the AXIAL FIELD OF VIEW from the end of the tomograph). On each plane, sources shall be positioned at 1 cm, 10 cm, and 20 cm from the SYSTEM AXIS (the 20 cm location shall may be omitted if it is not covered by the TRANSVERSE FIELD OF VIEW). The sources shall be positioned on either the horizontal or vertical line intersecting the SYSTEM AXIS, so that the radial and tangential directions are aligned with the image grid.

4.2.3.4 Data collection

Data shall be collected for all sources in ~~all~~ each of the six positions specified in 4.2.3.3.2, either singly or in groups of multiple sources, to minimize the data acquisition time. At least 100 000 counts for each POINT SOURCE shall be acquired.

4.2.3.5 Data processing

Filtered backprojection reconstruction using a ramp filter with the cutoff at the Nyquist frequency of the PROJECTION data or its 3D equivalent shall be employed for all SPATIAL RESOLUTION data. No resolution enhancement methods shall be used. The pixel size in the transverse plane shall be chosen to allow at least 3 pixels per FWHM.

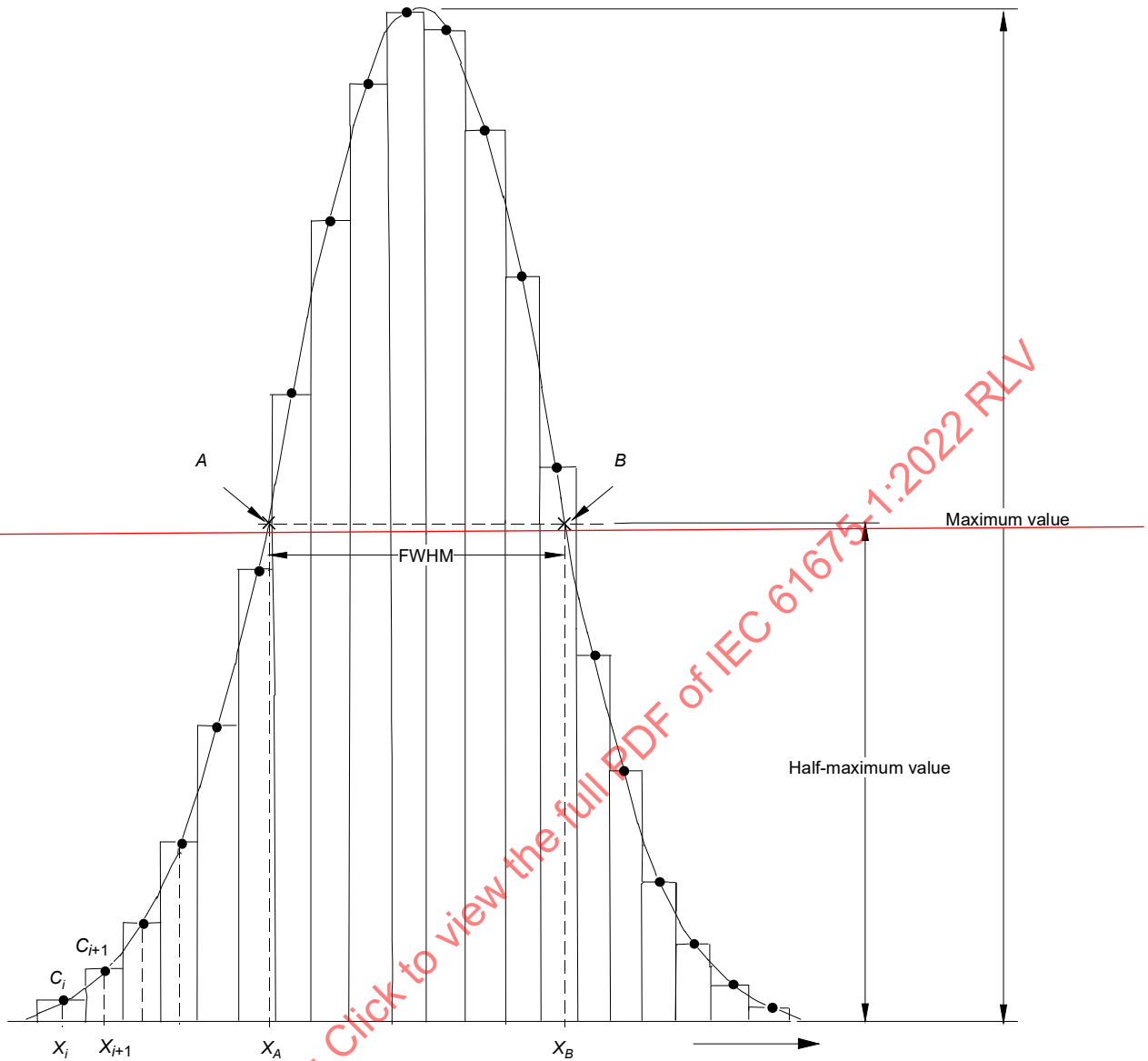
Results obtained using alternate reconstruction algorithms may be reported in addition to the filtered backprojection results, provided that the alternate reconstruction methods and their parameters are described in sufficient detail to reproduce the study results.

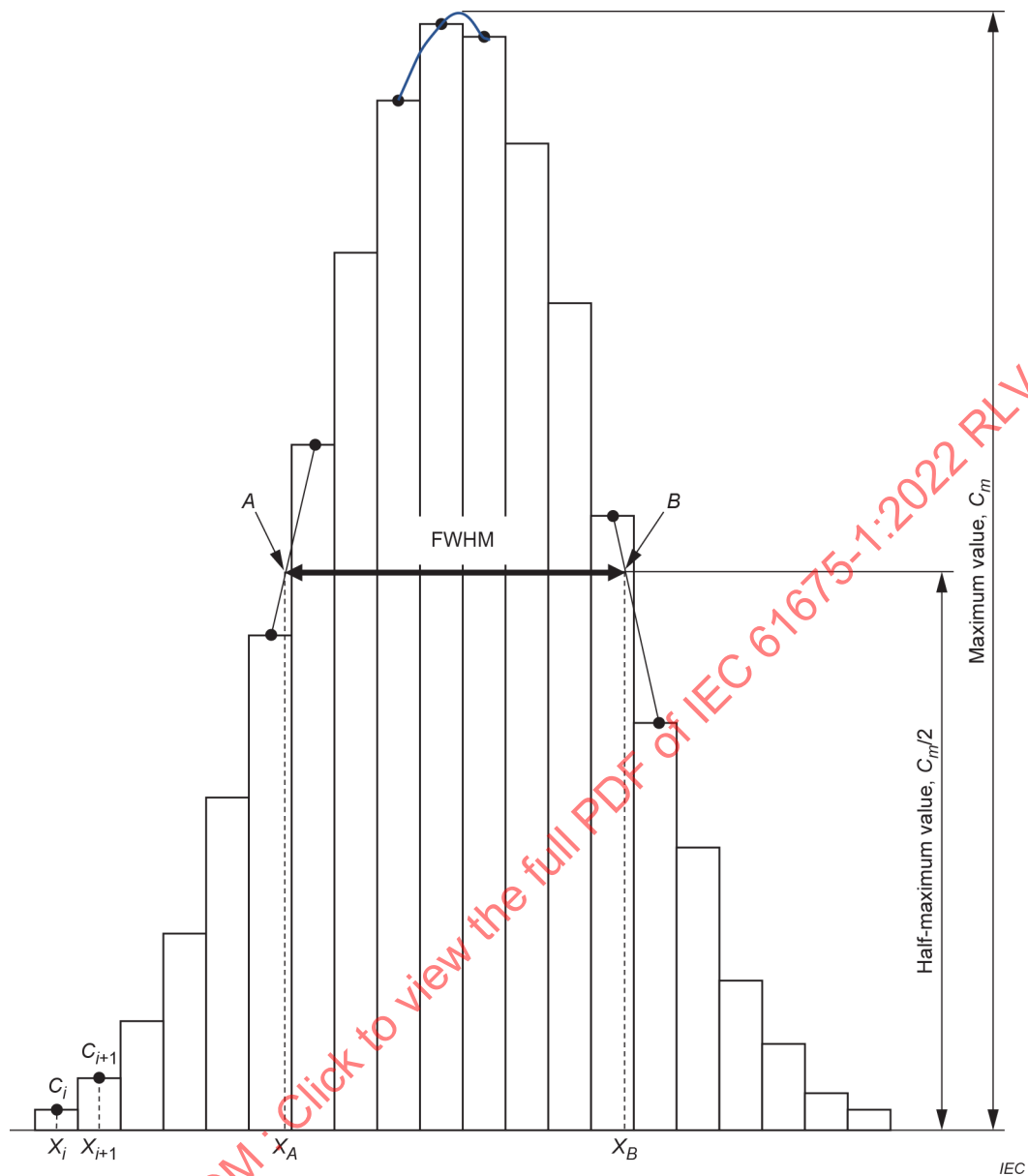
4.2.4 Analysis

The RADIAL RESOLUTION and the TANGENTIAL RESOLUTION shall be determined by forming one-dimensional response functions. These response functions ~~are~~ shall be created by taking profiles from the TRANSVERSE POINT SPREAD FUNCTION through the reconstructed 3D-image of each POINT SOURCE in radial and tangential directions passing through the peak of the distribution. The width of each profile shall be two times the expected FWHM in both directions perpendicular to the direction of the analysis.

The AXIAL RESOLUTION of the POINT SOURCE measurements ~~is~~ shall be determined by forming one-dimensional response functions (AXIAL POINT SPREAD FUNCTIONS), which result from taking profiles through the reconstructed 3D-image in the axial direction passing through the peak of the distribution. The width of each profile shall be two times the expected FWHM in both directions perpendicular to the direction of the analysis.

Each 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 1). The maximum PIXEL value C_m shall be determined by a parabolic fit using the peak point and its two nearest neighbours. Values shall be converted to millimetre units by multiplication with the appropriate PIXEL width.





NOTE C_m is the maximum value of the interpolation curve, A and B are the points where the interpolation count curve cuts the line of half-maximum value. Then $FWHM = X_B - X_A$.

Figure 1 – Evaluation of FWHM

Each EQUIVALENT WIDTH (EW) shall be measured from the corresponding response function. EW is shall be calculated from Formula (1):

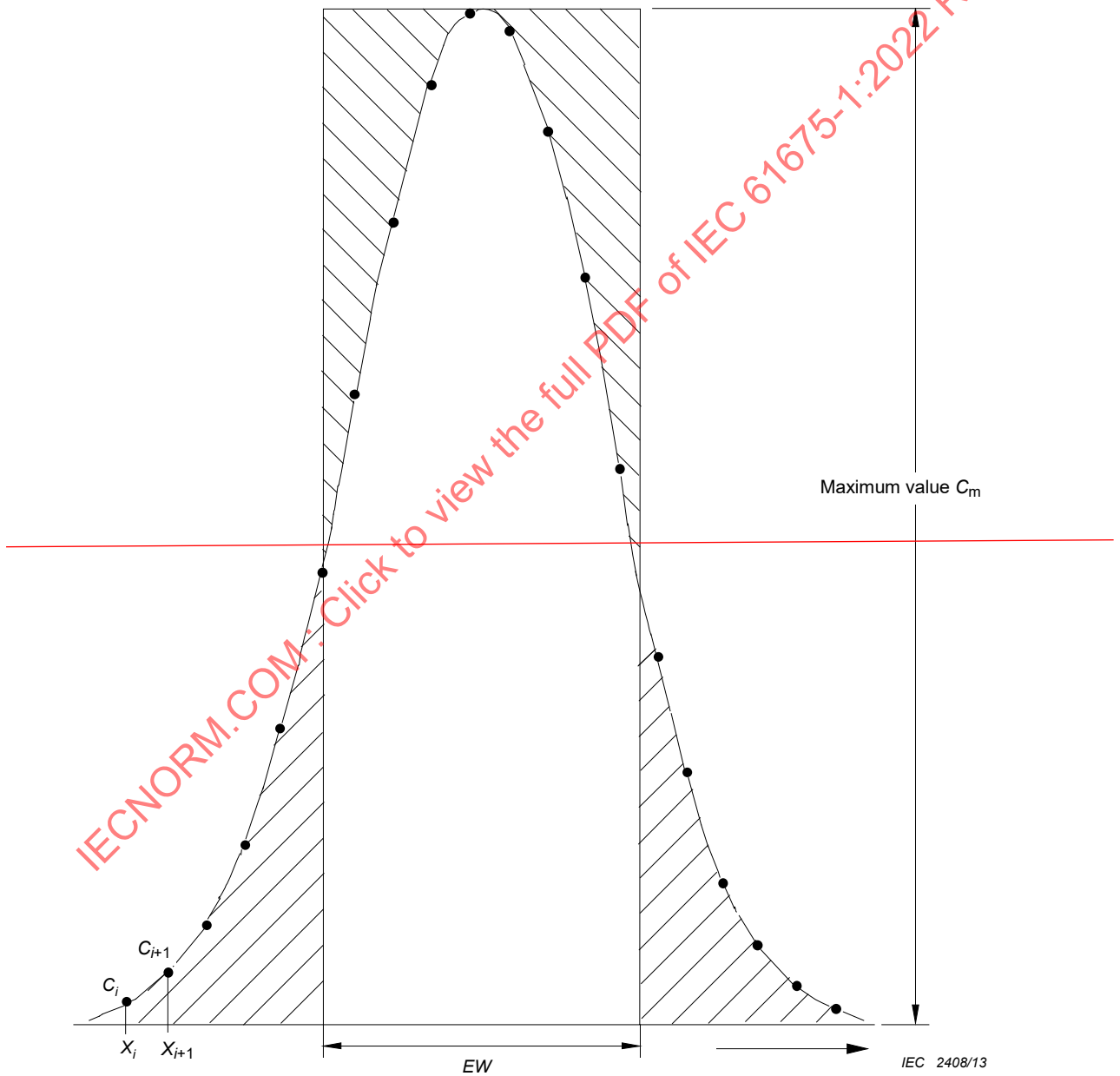
$$\underline{EW = \sum_i \frac{C_i \times PW}{C_m}} \quad EW = \frac{PW}{C_m} \sum_i C_i \quad (1)$$

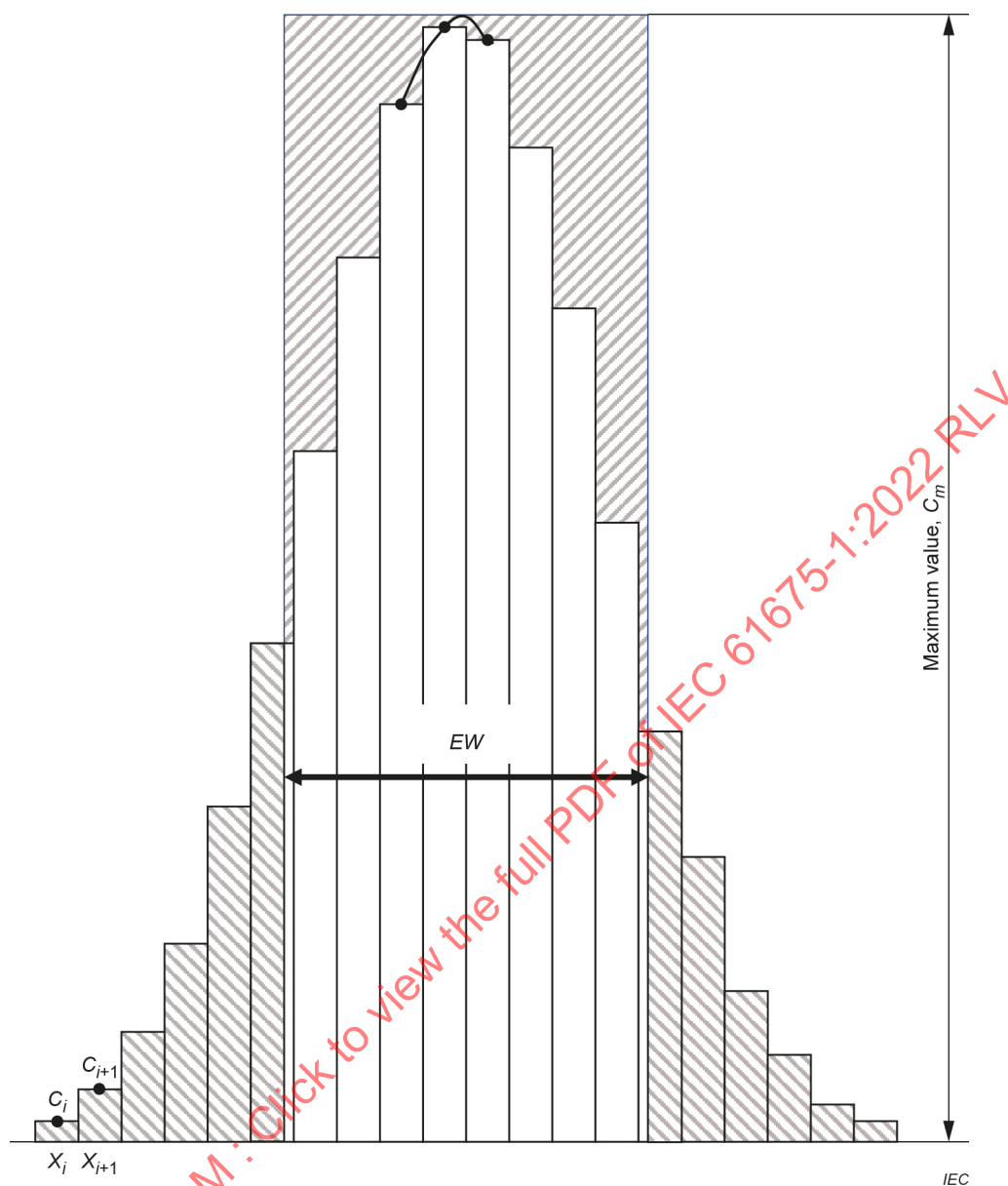
where

$\sum_i C_i$ 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 of the profile as determined in the FWHM calculation above, as opposed to the maximum pixel value among the pixel locations;

PW is the PIXEL width in millimetres (see Figure 2).





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

$$EW = \sum (C_i \times PW) / C_m$$

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

The areas shaded differently are equal.

Figure 2 – Evaluation of EQUIVALENT WIDTH (EW)

4.2.5 Report

RADIAL RESOLUTION, TANGENTIAL RESOLUTION, and AXIAL RESOLUTION ($FWHM$ and EW) for each POINT SOURCE position shall be calculated and reported. Transverse and axial PIXEL dimensions shall be reported.

If special reconstruction methods were used, the results of the tests ~~should~~ shall be reported together with the exact description of the methodology.

4.3 Tomographic sensitivity

4.3.1 General

Tomographic sensitivity is a parameter that characterizes the rate at which coincidence events are detected in the presence of a RADIOACTIVE SOURCE in the limit of low ACTIVITY where COUNT LOSSES and RANDOM COINCIDENCES are negligible. The measured rate of TRUE COINCIDENCES for a given distribution of the RADIOACTIVE SOURCE depends upon many factors, including the detector material, size, and packing fraction, tomograph ring diameter, axial acceptance window and septa geometry, ATTENUATION, scatter, dead-time, and energy thresholds.

4.3.2 Purpose

The purpose of this measurement is to determine the detected rate of UNSCATTERED TRUE COINCIDENCES per unit of ACTIVITY concentration for a standard volume source, i.e., a cylindrical phantom of given dimensions.

4.3.3 Method

4.3.3.1 General

The tomographic sensitivity test places a specified volume of radioactive solution of known ACTIVITY ~~concentration~~ in the TOTAL FIELD OF VIEW of the POSITRON EMISSION TOMOGRAPH and observes the resulting COUNT RATE. The system's sensitivity ~~is~~ shall be calculated from these values. 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 finer than 10 %. Absolute reference standards using positron emitters should be considered if higher degrees of accuracy are required.

~~The last frame of the PET COUNT RATE PERFORMANCE test (4.6) can also be used to determine the SLICE SENSITIVITY and VOLUME SENSITIVITY.~~

One of the later frames of the PET COUNT RATE PERFORMANCE test (4.5) can be used to determine the SLICE SENSITIVITY and VOLUME SENSITIVITY if the RADIONUCLIDE used for these measurements is ^{18}F .

4.3.3.2 RADIONUCLIDE

The RADIONUCLIDE used for these measurements shall be ^{18}F . The amount of ACTIVITY ~~used~~ at the time of the tomographic sensitivity measurement shall be such that the percentage of COUNT LOSSES is less than 2 %.

4.3.3.3 RADIOACTIVE SOURCE distribution

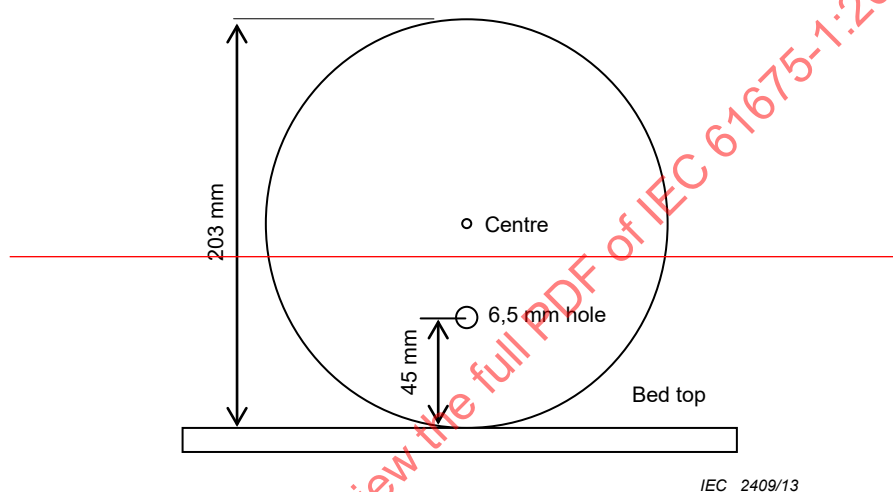
The test phantom ~~is~~ shall be a solid right circular cylinder composed of polyethylene with a specific density of $(0,96 \pm 0,01) \text{ g/cm}^3$, with an outside diameter of $(203 \pm 3) \text{ mm}$, and with an overall length of $(700 \pm 5) \text{ mm}$. A $(6,5 \pm 0,3) \text{ mm}$ hole is drilled parallel to the central axis of the cylinder, at a radial distance of $(45 \pm 1) \text{ mm}$. For ease of fabrication and handling, the cylinder may consist of several segments that are assembled together during testing. However, in both design and assembly of the completed phantom ~~one must insure a tight fit between~~, adjacent segments shall be fit tightly together, as even very small gaps will allow narrow axial regions of scatter-free radiation.

The test phantom LINE SOURCE insert ~~is~~ shall be a clear polyethylene or polyethylene coated plastic tube $(800 \pm 5) \text{ mm}$ in length, with an inside diameter of $(3,2 \pm 0,2) \text{ mm}$ and an outside diameter of $(4,8 \pm 0,2) \text{ mm}$.

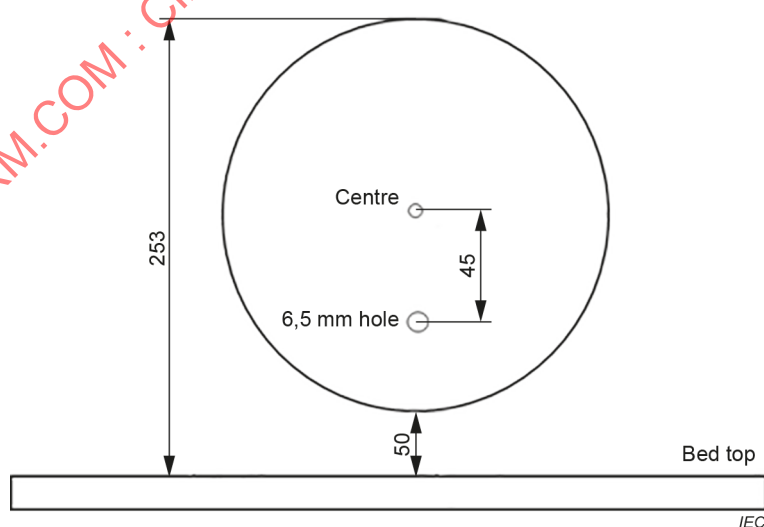
The test phantom LINE SOURCE insert shall be filled with water well mixed with the measured amount of ACTIVITY to a length of $(700 \pm 5) \text{ mm}$ and sealed at both ends. This LINE SOURCE shall be inserted into the hole of the test phantom such that the ACTIVITY of the LINE SOURCE matches

the length of the polyethylene phantom. The test phantom with LINE SOURCE ~~is~~ shall be mounted on the standard patient bed supplied by the MANUFACTURER. The phantom shall be raised ($5 \pm 0,5$) cm above the patient bed, using a mounting means such as foam blocks placed outside the AXIAL FIELD OF VIEW, and rotated such that the LINE SOURCE insert is positioned nearest to the patient bed (see Figure 3). ~~The phantom shall be centred in the TRANSVERSE FIELD OF VIEW and to within 5 mm or if the phantom cannot be centred in the TRANSVERSE FIELD OF VIEW by elevation of the patient bed alone, additional mounting means as foam blocks placed outside the AXIAL FIELD OF VIEW can be used. In this case the actual mounting means and the actual table elevation shall be reported.~~ The patient bed shall be positioned ($15,2 \pm 0,5$) cm below the centre of the TRANSVERSE FIELD OF VIEW, so that the phantom is centred in the TRANSVERSE FIELD OF VIEW.

If the phantom cannot be centred as described above, then mounting blocks of other dimensions may be used to centre the phantom in the transverse field of view. The distance of the table from the centre of the transverse field of view shall be reported.



Dimensions in millimetres



NOTE The 6,5 mm hole is for insertion of the LINE SOURCE.

Figure 3 – Scatter phantom configuration and position on the imaging bed

4.3.3.4 Data collection

Each coincident event between individual detectors shall be taken into account only once. Data ~~shall be~~ **are** assembled into SINOGRAMS. All events shall be assigned to the transverse slice passing the midpoint of the corresponding LINE OF RESPONSE.

At least 500 000 true coincident counts ~~shall be~~ **are** acquired.

4.3.3.5 Data processing

The ACTIVITY concentration in the phantom shall be corrected for decay to determine the average ACTIVITY concentration, a_{ave} , during the data acquisition time, T_{acq} , by the following Formula (2):

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

where

V is the **nominal** volume of the **test** phantom (**22 700 cm³**);

A_{cal} is the ACTIVITY times branching ratio ("positron activity") measured at time T_{cal} ;

T_0 is the acquisition start time;

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

No corrections for detector normalization, COUNT LOSS, SCATTERED TRUE COINCIDENCES, and ATTENUATION shall be applied. The data shall be corrected for RANDOM COINCIDENCES.

4.3.4 Analysis

All PIXELS in the SINOGRAM located further than 25 cm from the SYSTEM AXIS shall be set to zero.

The total counts $C_{i,tot}$ on each slice i shall be obtained by summing all PIXELS in the corresponding SINOGRAM. The SLICE SENSITIVITY S_i for unscattered events shall be found by the following Formula (3):

$$S_i = \frac{C_{i,tot}}{T_{acq}} \frac{(1 - SF_i)}{a_{ave}} \quad (3)$$

where

SF_i is the corresponding SCATTER FRACTION (see 4.4).

The VOLUME SENSITIVITY, S_{tot} , shall be the sum of S_i over all slices of the tomograph within the AXIAL FIELD OF VIEW.

4.3.5 Report

~~For each slice i , report the values of S_i . The VOLUME SENSITIVITY S_{tot} shall also be reported.~~

The VOLUME SENSITIVITY S_{tot} shall be reported. A graph of SLICE SENSITIVITY S_i values shall be reported.

~~4.4 — Uniformity~~

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

4.4 Scatter measurement

4.4.1 General

The scattering of ~~primary gamma rays~~ photons created in the annihilation of positrons results in coincidence events with false information for radiation source localization. Variations in design and implementation cause POSITRON EMISSION TOMOGRAPHS to have different sensitivities to scattered radiation.

4.4.2 Purpose

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_j .

4.4.3 Method

4.4.3.1 General

The test phantom ~~is~~ shall be a solid right circular cylinder composed of polyethylene with a specific density of $(0,96 \pm 0,01)$ g/cm³, with an outside diameter of (203 ± 3) mm, and with an overall length of (700 ± 5) mm. A $(6,5 \pm 0,3)$ mm hole ~~is~~ shall be drilled parallel to the central axis of the cylinder, at a radial distance of (45 ± 1) mm. For ease of fabrication and handling, the cylinder may consist of several segments that ~~are~~ shall be assembled together during testing. However, in both design and assembly of the completed phantom ~~one shall insure a tight fit between~~, adjacent segments shall fit tightly together, as even very small gaps will allow narrow axial regions of scatter-free radiation.

~~The last frame of the COUNT RATE CHARACTERISTIC test (4.6) may be used to determine the SCATTER FRACTION if the test is performed with ¹⁸F.~~

One of the later frames of the PET COUNT RATE PERFORMANCE test (4.5) may be used to determine the SCATTER FRACTION.

4.4.3.2 RADIONUCLIDE

The RADIONUCLIDE for the measurement shall be ¹⁸F or ¹¹C with an ACTIVITY such that the percentage of COUNT LOSSES is less than 5 %.

4.4.3.3 RADIOACTIVE SOURCE distribution

The test phantom LINE SOURCE insert ~~is~~ shall be a clear polyethylene or polyethylene coated plastic tube (800 ± 5) mm in length, with an inside diameter of $(3,2 \pm 0,2)$ mm and an outside diameter of $(4,8 \pm 0,2)$ mm. This tube ~~will~~ shall be filled with a known quantity of ACTIVITY and threaded through the 6,5 mm hole in the test phantom.

The test phantom LINE SOURCE insert shall be filled with water well mixed with the measured amount of ACTIVITY to a length of (700 ± 5) mm and sealed at both ends. This LINE SOURCE shall be inserted into the hole of the test phantom such that the ACTIVITY of the LINE SOURCE matches the length of the polyethylene phantom. ~~The test phantom with LINE SOURCE is mounted on the standard patient bed supplied by the MANUFACTURER and rotated such that the LINE SOURCE insert is positioned nearest to the patient bed (see Figure 3). The phantom shall be centred in the TRANSVERSE FIELD OF VIEW and AXIAL FIELD OF VIEW to within 5 mm or if the phantom cannot be centred in the TRANSVERSE FIELD OF VIEW by elevation of the patient bed alone, additional~~

~~mounting means as foam blocks placed outside the AXIAL FIELD OF VIEW can be used. In this case the actual mounting means and the actual table elevation shall be reported.~~

The test phantom with LINE SOURCE shall be mounted on the standard patient bed supplied by the MANUFACTURER. The phantom shall be raised ($5 \pm 0,5$) cm above the patient bed, using a mounting means such as foam blocks placed outside the AXIAL FIELD OF VIEW, and shall be rotated such that the LINE SOURCE insert is positioned nearest to the patient bed (see Figure 3). The phantom shall be centred in the TRANSVERSE FIELD OF VIEW by raising or lowering the bed.

If the phantom cannot be centred as described above, then mounting blocks of other dimensions may be used to centre the phantom in the transverse field of view. The distance of the table from the centre of the transverse field of view shall be reported.

4.4.3.4 Data collection

Each coincident event between individual detectors shall be taken into account only once. Data shall be assembled into SINOGRAMS. All events ~~will~~ shall be assigned to the slice at the midpoint of the corresponding LINE OF RESPONSE. The acquisition ~~should~~ shall contain a minimum of 500 000 true coincident counts.

4.4.3.5 Data processing

No corrections for variations in detector sensitivity, SCATTERED TRUE COINCIDENCES, COUNT LOSS, or ATTENUATION shall be applied to the measurements.

The data shall be corrected for RANDOM COINCIDENCES.

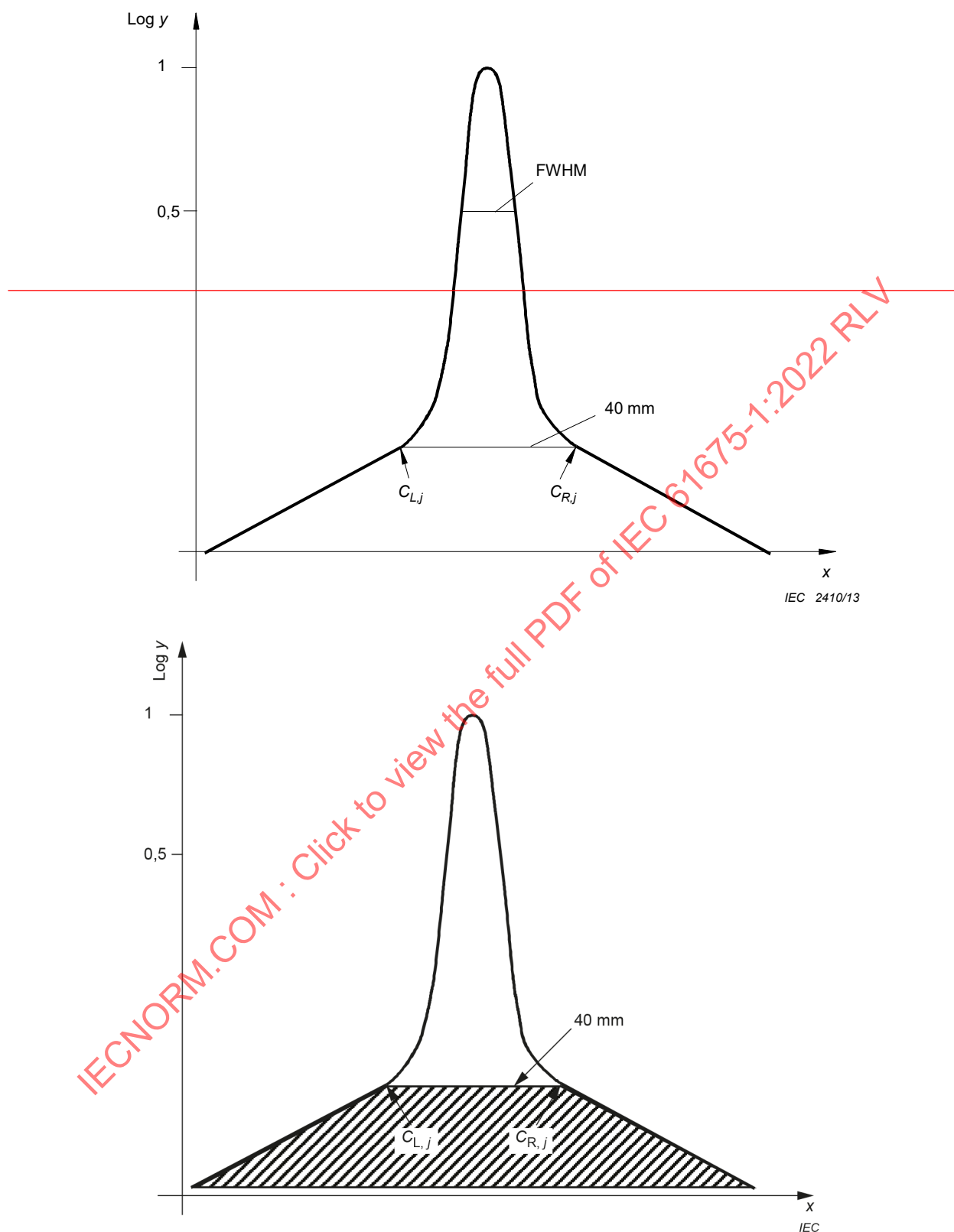
4.4.4 Analysis

For tomographs with an AXIAL FIELD OF VIEW of 65 cm or less, SINOGRAMS of TRUE COINCIDENCES shall be generated for each acquisition j of slice j . For tomographs with an AXIAL FIELD OF VIEW greater than 65 cm, SINOGRAMS of TRUE COINCIDENCES shall be generated for each acquisition for slices within the central 65 cm.

Oblique SINOGRAMS ~~are~~ shall be collapsed into a single SINOGRAM for each respective slice (by single-slice rebinning) while conserving the number of counts in the SINOGRAM.

The SINOGRAM j of TRUE COINCIDENCES shall be processed as follows.

- a) All PIXELS located further than 25 cm from the SYSTEM AXIS shall be set to zero.
- b) For each PROJECTION ANGLE ϕ within the SINOGRAM, the location of the centre of the LINE SOURCE response shall be determined by finding the PIXEL having the greatest value. Each PROJECTION shall be shifted so that the PIXEL containing the maximum value is aligned with the central PIXEL of the SINOGRAM.
- c) After alignment, a sum projection shall be produced. A PIXEL in the sum projection ~~is~~ shall be the sum of the PIXELS in each angular PROJECTION having the same radial offset as the PIXEL in the sum projection.
- d) The counts $C_{L,j}$ and $C_{R,j}$, the left and right PIXEL intensities at the edges of the strip with a width of ± 20 mm from the centre of the profile calculated in (b), shall be obtained (see Figure 4). Linear interpolation shall be employed to find $C_{L,j}$ and $C_{R,j}$.



NOTE—In the summed projection, the scatter ~~is~~ shall be estimated by the counts outside the 40 mm wide strip plus the area ~~of the LSF~~ below the line $C_{L,j} - C_{R,j}$.

Figure 4 – Evaluation of SCATTER FRACTION

- e) The average of the two PIXEL intensities $C_{L,j}$ and $C_{R,j}$ shall be multiplied by the number of PIXELS, including fractional values, corresponding to the width of the strip, and the product

shall be added to the sum of counts in the PIXELS outside the strip, to yield the number of scatter counts $C_{s,j}$ for the slice j .

- f) The TRUE COINCIDENCES $C_{TOT,j}$ shall be computed as the sum of all counts in the sum projection for slice j . The TRUE COINCIDENCES include SCATTERED TRUE COINCIDENCES and UNSCATTERED TRUE COINCIDENCES.

The SCATTER FRACTION SF_j for each slice shall be calculated as shown in Formula (4):

$$SF_j = \frac{C_{s,j}}{C_{TOT,j}} \quad (4)$$

The SCATTER FRACTION SF shall be computed by Formula (5):

$$SF = \frac{\sum_j C_{s,j}}{\sum_j C_{TOT,j}} \quad (5)$$

4.4.5 Report

~~For each slice j that was processed, SF_j shall be reported (Equation (4)). The SCATTER FRACTION SF shall also be reported (Equation (5)).~~

The SCATTER FRACTION SF shall be reported (Formula (5)). A graph of SF_j values shall be reported (calculated from Formula (4)).

4.5 PET COUNT RATE PERFORMANCE

4.5.1 General

PET COUNT RATE PERFORMANCE depends in a complex manner on the spatial distribution of ACTIVITY and scattering materials, on the trues-to-singles ratio, on the COUNT RATE CHARACTERISTIC of the SINGLES RATE, and on the setup of the measurement conditions. In addition, COUNT RATE performance is strongly influenced by the amount of RANDOM COINCIDENCES and by the accuracy of the subtraction of these events.

4.5.2 Purpose

The procedure described here is designed to evaluate deviations from the linear relationship between COUNT RATE of TRUE COINCIDENCES and ACTIVITY, caused by COUNT LOSSES. As modern PET tomographs are operated with COUNT LOSS correction schemes, the accuracy of these correction algorithms ~~shall~~ is also ~~be~~ tested.

4.5.3 Method

4.5.3.1 General

The test phantom ~~is~~ shall be a solid right circular cylinder composed of polyethylene with a specific density of $(0,96 \pm 0,01) \text{ g/cm}^3$, with an outside diameter of $(203 \pm 3) \text{ mm}$, and with an overall length of $(700 \pm 5) \text{ mm}$. A $(6,5 \pm 0,3) \text{ mm}$ hole is drilled parallel to the central axis of the cylinder, at a radial distance of $(45 \pm 1) \text{ mm}$. For ease of fabrication and handling, the cylinder may consist of several segments that ~~are~~ shall be assembled together during testing. However, in both design and assembly of the completed phantom, one ~~must insure~~ shall ensure a tight fit between adjacent segments, as even very small gaps will allow narrow axial regions of scatter-free radiation.

4.5.3.2 RADIONUCLIDE and ACTIVITY-~~18F~~

The RADIONUCLIDE for the measurement shall be ^{18}F or ^{11}C . The variation of ACTIVITY-~~is~~ shall be obtained by radioactive decay-~~over approximately 10 HALF LIVES~~. The last frame shall be acquired with a COUNT LOSS of less than 1 %. The initial amount of ACTIVITY shall be high enough to allow for the following two rates to be measured:

- a) $R_{t,\max}$ – maximum COUNT RATE of TRUE COINCIDENCES;
- b) $R_{\text{NEC},\max}$ – maximum noise equivalent count rate.

Recommendations for the initial ACTIVITY required to meet these objectives-~~should~~ shall be supplied by the MANUFACTURER.

4.5.3.3 RADIOACTIVE SOURCE distribution

The test phantom LINE SOURCE insert-~~is~~ shall be a clear polyethylene or polyethylene coated plastic tube (800 ± 5) mm in length, with an inside diameter of ($3,2 \pm 0,2$) mm and an outside diameter of ($4,8 \pm 0,2$) mm. This tube shall be filled with a known quantity of ACTIVITY and threaded through the 6,5 mm hole in the test phantom.

The test phantom LINE SOURCE insert shall be filled with water well mixed with the measured amount of ACTIVITY to a length of (700 ± 5) mm and sealed at both ends. ~~This LINE SOURCE shall be inserted into the hole of the test phantom such that the ACTIVITY of the LINE SOURCE matches the length of the polyethylene phantom.~~ The test phantom with LINE SOURCE ~~is~~ shall be mounted on the standard patient bed supplied by the MANUFACTURER. The phantom shall be raised ($5 \pm 0,5$) cm above the patient bed, using a mounting means such as foam blocks placed outside the AXIAL FIELD OF VIEW, and shall be rotated such that the LINE SOURCE insert is positioned nearest to the patient bed (see Figure 3). The phantom shall be centred in the TRANSVERSE FIELD OF VIEW-~~and the AXIAL FIELD OF VIEW to within 5 mm or if the phantom cannot be centred in the TRANSVERSE FIELD OF VIEW by elevation of the patient bed alone, additional mounting means such as foam blocks placed outside the AXIAL FIELD OF VIEW can be used by raising or lowering the bed. In this case the actual mounting means and the actual table elevation shall be reported.~~

If the phantom cannot be centred as described above, then mounting blocks of other dimensions may be used to centre the phantom in the transverse field of view. The distance of the table from the centre of the transverse field of view shall be reported.

~~To begin the test, a source of relatively high ACTIVITY is~~ The test phantom shall be placed in the field of view of the POSITRON EMISSION TOMOGRAPH. Regular measurements (at least two per RADIOACTIVE HALF LIFE)-~~are~~ shall then be taken while the ACTIVITY in the phantom decays over several RADIOACTIVE HALF-LIVES. A decrease in the event rate accompanies the ACTIVITY decay. In addition, the efficiency of the system in processing coincident events improves as the ACTIVITY decays, until COUNT LOSSES may be effectively neglected. Thus, by waiting long enough, one obtains a measurement of the COUNT RATE of TRUE COINCIDENCES that is effectively free from processing losses. By extrapolating this COUNT RATE of TRUE COINCIDENCES back to higher ACTIVITY levels and comparing it to the COUNT RATE of TRUE COINCIDENCES measured at these higher ACTIVITY levels, one may estimate COUNT LOSSES suffered by the system at higher ACTIVITY levels. The accuracy of this technique depends critically on adequate statistics being gathered at sufficiently low levels of ACTIVITY. This may require repeated measurements at the lower COUNT RATES. Recommendations for the acquisition protocol required to meet these objectives shall be supplied by the MANUFACTURER.

4.5.3.4 DATA COLLECTION

Each coincident event between individual detectors shall be taken into account only once.

If the data are also to be used to calculate TOF RESOLUTION for 4.6, then the data shall be acquired in TOF acquisition mode.

4.5.4 Analysis

4.5.4.1 Test of the PET COUNT RATE PERFORMANCE

4.5.4.1.1 General

Data shall be assembled into SINOGRAMS. All events ~~will~~ shall be assigned to the slice at the midpoint of the corresponding LINE OF RESPONSE.

No corrections for variations in detector sensitivity, scatter, COUNT LOSS, or ATTENUATION shall be applied to the measurements.

For tomographs with an AXIAL FIELD OF VIEW of 65 cm or less, SINOGRAMS of TRUE COINCIDENCES shall be generated for each acquisition i of slice j . For tomographs with an AXIAL FIELD OF VIEW greater than 65 cm, SINOGRAMS of TRUE COINCIDENCES shall be generated for each acquisition for slices within the central 65 cm.

4.5.4.1.2 Test

The relationship between COUNT RATE and ACTIVITY within the TOTAL FIELD OF VIEW of the tomograph shall be measured. 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~~ may be longer. For each of these last three frames, a minimum of 500 000 true coincident counts shall be acquired.

The initial ACTIVITY in the phantom shall be determined from the ACTIVITY injected into the phantom as measured in a calibrated dose calibrator.

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 Formula (6):

$$A_{ave,i} = A_{cal} \frac{1}{\ln 2} \frac{T_{1/2}}{T_{acq,i}} \exp \left[\frac{T_{cal} - T_{0,i}}{T_{1/2}} \ln 2 \right] \left[1 - \exp \left(- \frac{T_{acq,i}}{T_{1/2}} \ln 2 \right) \right] \quad (6)$$

where

A_{cal} is the ACTIVITY times branching ratio ("positron 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 ^{18}F or ^{11}C , respectively.

The SINOGRAMS shall be analysed without COUNT LOSS correction. All PIXELS in the **acquired SINOGRAM** and in the **corresponding randoms estimate SINOGRAMS** located further than 25 cm from the SYSTEM AXIS shall be set to zero.

For each time frame i , compute:

- ~~the total event rate $R_{TOT,i,j}$ for each slice j , i.e. the number of TOTAL COINCIDENCES in slice j divided by the acquisition time for frame i .~~
- ~~the random event rate $R_{r,i,j}$ for each slice j , i.e. the number of RANDOM COINCIDENCES in slice j divided by the acquisition time for frame i .~~
- ~~the true event rate $R_{t,i,j}$ for each slice j , i.e. the number of TRUE COINCIDENCES in slice j divided by the acquisition time for frame i .~~
- ~~the noise equivalent count rate $R_{NEC,i,j}$ for each slice j (equation (7)).~~

$$R_{\text{NEC},i,j} = \frac{(1 - SF_j)^2 R_{t,i,j}^2}{R_{\text{TOT},i,j} + R_{r,i,j}} \quad (7)$$

~~NOTE For this evaluation the NEC formula (Equation (7)) accounts for randoms and scatter corrections, and does not account for other effects like time of flight.~~

~~Total system COUNT RATES $R_{\text{TOT},i}$, $R_{t,i}$, $R_{r,i}$ and $R_{\text{NEC},i}$ are computed as the sum of the corresponding slice COUNT RATES over all slices j .~~

For each time frame i , the total counts acquired, $N_{\text{TOT},i}$, and the total randoms estimated, $N_{r,i}$, shall be computed as the sum of the remaining data.

For each time frame i , $R_{\text{TOT},i}$, $R_{r,i}$ and $R_{t,i}$ shall be computed:

- a) $R_{\text{TOT},i} = N_{\text{TOT},i} / T_i$
- b) $R_{r,i} = N_{r,i} / T_i$
- c) $R_{t,i} = (1 - SF) \times (N_{\text{TOT},i} - N_{r,i}) / T_i$

where

SF is the scatter fraction as calculated in 4.4.4;

T_i is the acquisition time for frame i .

The noise equivalent count rate (NECR), $R_{\text{NEC},i}$ for each time frame shall be calculated as:

$$R_{\text{NEC},i} = R_{t,i}^2 / (R_{\text{TOT},i} + R_{r,i}) \quad (7)$$

The maximum NECR, $R_{\text{NEC},\text{max}}$ shall be reported, as well as the corresponding ACTIVITY, $A_{\text{NEC},\text{max}}$.

4.5.4.2 Test of COUNT LOSS correction scheme

4.5.4.2.1 General

For tomographs with an AXIAL FIELD OF VIEW of 65 cm or less, all slices shall be reconstructed. For tomographs with an AXIAL FIELD OF VIEW greater than 65 cm, only slices in the central 65 cm shall be reconstructed. Attenuation, scatter, COUNT LOSS and randoms correction shall be applied to the data. Images shall be reconstructed using standard methods without decay correction.

4.5.4.2.2 Test

All analyses shall be performed on each reconstructed image i,j . The average ACTIVITY $A_{\text{ave},i}$ for each acquisition i shall be calculated. The average effective ACTIVITY concentration $A_{\text{eff},i}$ for each acquisition i shall be computed by dividing $A_{\text{ave},i}$ by ~~22000~~ 22 700 cm³, which is the volume of the test phantom.

A circular REGION OF INTEREST (ROI) centred on the TRANSVERSE FIELD OF VIEW (*not* centred on the LINE SOURCE) with a diameter of 18 cm shall be drawn on the reconstructed image for each slice j . ~~The number of TRUE COINCIDENCES $C_{\text{ROI},i,j}$ in this ROI for each slice j and acquisition i shall be measured. The COUNT RATE of TRUE COINCIDENCES $R_{\text{ROI},i,j}$ shall be calculated as the ratio of $C_{\text{ROI},i,j}$ and $T_{\text{acq},i}$.~~

~~For each slice j , the extrapolated COUNT RATE of the TRUE COINCIDENCES $R_{\text{Extr},i,j}$, shall be calculated. This rate would have been obtained for acquisition i if there were no COUNT LOSSES. To minimize the effects of statistics, $R_{\text{Extr},i,j}$ shall be obtained by the following equation (8):~~

$$R_{\text{Extr},i,j} = \frac{A_{\text{ave},i}}{3} \sum_{k=1}^3 \frac{R_{\text{ROI},j,k}}{A_{\text{ave},k}} \quad (8)$$

~~where~~

~~$k = 1$ is the acquisition with the lowest ACTIVITY, and the sum is computed over the three lowest ACTIVITY acquisitions.~~

~~For each slice j of each acquisition i , the relative COUNT RATE error $\Delta r_{i,j}$ in percentage units shall be calculated by the following equation (9):~~

$$\Delta r_{i,j} = 100 \left(\frac{R_{\text{ROI},i,j}}{R_{\text{Extr},i,j}} - 1 \right) \% \quad (9)$$

$\Gamma_{\text{ROI},i,j}$ is the average activity concentration in the ROI for each slice j and acquisition i .

For each slice j , the best fit ROI value $\Gamma_{\text{Fit},i,j}$, shall be calculated by the following Formula (8):

$$\Gamma_{\text{Fit},i,j} = \frac{A_{\text{ave},i}}{I} \sum_{k=1}^I \frac{\Gamma_{\text{ROI},i,k}}{A_{\text{ave},k}} \quad (8)$$

where I shall be the total number of acquisitions with activity at or below maximum NECR ($R_{\text{NEC,max}}$) as determined in 4.5.4.1.2, and the sum shall be computed over each acquisition k .

For each slice j of each acquisition i , the relative COUNT RATE error $\Delta \gamma_{i,j}$ in percentage units shall be calculated by the following Formula (9):

$$\Delta \gamma_{i,j} = \Gamma_{\text{ROI},i,j} / \Gamma_{\text{Fit},i,j} - 1 \quad (9)$$

4.5.5 Report

4.5.5.1 PET COUNT RATE PERFORMANCE (see 4.5.4.1)

For the system, the following four quantities as a function of the average effective ACTIVITY concentration $A_{\text{ave},i}$ shall be plotted:

- a) $R_{t,i}$ – COUNT RATE of TRUE COINCIDENCES;
- b) $R_{r,i}$ – COUNT RATE of RANDOM COINCIDENCES;
- c) $R_{\text{NEC},i}$ – noise equivalent count rate NECR;
- d) $R_{\text{TOT},i}$ – COUNT RATE of TOTAL COINCIDENCES.

The following values, derived from the above plot, shall be reported:

- a) $R_{t,\text{max}}$ – maximum COUNT RATE of TRUE COINCIDENCES;
- b) $R_{\text{NEC},\text{max}}$ – maximum noise equivalent count rate;

- c) $A_{t,\max}$ – the ACTIVITY concentration at which $R_{t,\max}$ is reached;
- d) $A_{\text{NEC},\max}$ – the ACTIVITY concentration at which $R_{\text{NEC},\max}$ is reached.

The method used for estimating RANDOM COINCIDENCES shall be reported.

4.5.5.2 Accuracy of COUNT LOSS correction (see 4.5.4.2)

A graph of the highest and lowest values among the slices of $-A_{t,j} \Delta\gamma_{i,j}$ versus $-a_{\text{eff},t} A_{\text{eff},i}$ shall be ~~created~~ plotted using a linear scale. The data points may be joined to form a continuous curve.

The maximum value of the bias $-A_{t,j} \Delta\gamma_{i,j}$ in the ACTIVITY range up to the $A_{\text{NEC},\max}$ shall be reported.

4.6 Time-of-flight resolution

4.6.1 General

Time-of-flight data are used to localize the annihilation point along the LINE-OF-RESPONSE during reconstruction.

NOTE 1 The measurement of TOF RESOLUTION is only applicable to those systems that offer TOF acquisition.

NOTE 2 TOF resolution does not characterize the reconstruction process or effect of TOF reconstruction on the image.

4.6.2 Purpose

The purpose of this procedure is to characterize the TOF RESOLUTION.

4.6.3 Method

TOF RESOLUTION shall be measured from the data acquired in 4.5.

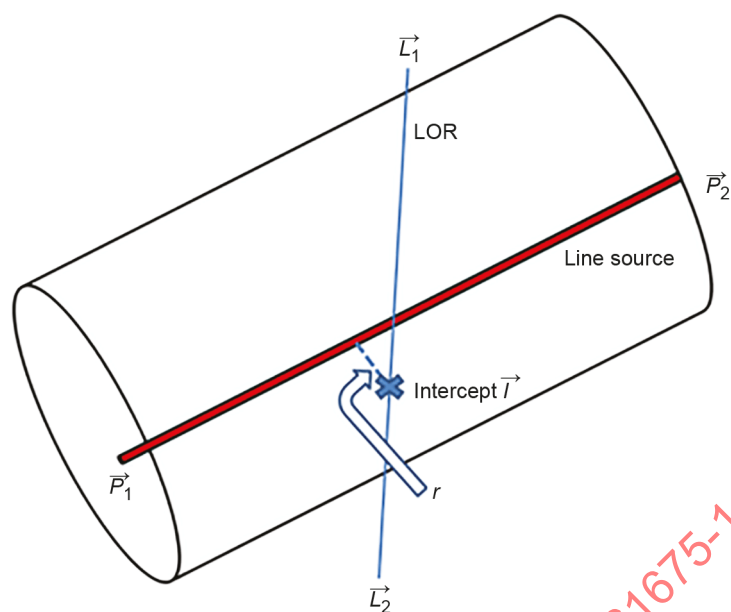
Figure 5 shows the geometry used in the processing and analysis of the coincidence data.

4.6.4 Radionuclide, source distribution and data collection

See 4.5.

4.6.5 Data processing

For PET scanners with an AXIAL FIELD OF VIEW of 65 cm or less, data from all slices shall be considered. For PET scanners with an AXIAL FIELD OF VIEW greater than 65 cm, only axial slices in the central 65 cm shall be considered. No corrections for detector sensitivity variation, scatter, random, deadtime or attenuation shall be applied to the measurements, except while reconstructing the images used to localize the line source in 4.6.6.1.



IEC

Key

r shortest distance between LOR and line source

The intercept of the LOR with the line source shall be defined as the point along the LOR with the shortest distance to the line source.

Figure 5 – Determination of LOR distance from line source

4.6.6 Analysis

4.6.6.1 Identifying the line source position

The first frame of the dynamic sequence where the activity is below the maximum NECR, $R_{NEC,max}$, shall be reconstructed with all available corrections except for decay correction and a pixel size in the transverse slice not to exceed 2,5 mm, forming images in the PET coordinate system. The location of the line source shall be determined by a centroid calculation on all transverse slices, except for those within 10 mm of either end of the axial field of view. A line shall be used to fit with these centroid positions. The intersection of the line with the first and the last transverse slices defines the two points $\vec{P}_1$ and $\vec{P}_2$, respectively. The unit vector $\vec{v}$ for the line shall be calculated as:

$$\vec{v} = \frac{\vec{P}_2 - \vec{P}_1}{|\vec{P}_2 - \vec{P}_1|}$$

Images reconstructed for the count rate correction accuracy test in 4.5.4.2 may be used.

4.6.6.2 Evaluation of time differences

4.6.6.2.1 General

The following analysis shall be performed on each time frame of the test phantom data beginning with the last frame acquired above the maximum NECR, $R_{NEC,max}$ as measured in 4.5, and continuing through all frames with at least 500 000 prompt events acquired.

4.6.6.2.2 2-D histogram formation

Each event shall be accumulated into one 2-D histogram for each acquisition j . The 2-D histograms shall be centred on zero in both the time and spatial dimensions. The bin sizes Δt and Δr shall be less than one-fourth of the expected FWHM of the timing and spatial distributions, respectively.

For each coincidence event in the data set, $\vec{L}_1$ and $\vec{L}_2$ shall be defined as three-dimensional coordinates of two points along the line in PET coordinates representing the coincidence event, as used in image reconstruction (see Figure 5). Then, the following calculations shall be performed.

- a) Compute the unit vector $\vec{u}$ from $\vec{L}_1$ to $\vec{L}_2$:

$$\vec{u} = \frac{\vec{L}_2 - \vec{L}_1}{|\vec{L}_2 - \vec{L}_1|}.$$

- b) Compute the distance r' between the coincidence line and the line source:

$$r = (\vec{L}_1 - \vec{P}_1) \cdot \frac{\vec{u} \times \vec{v}}{|\vec{u} \times \vec{v}|}.$$

If $|r'| > (20 + \Delta r)$ mm, this event shall be excluded from the 2-D histogram formation. Otherwise, continue.

- c) Compute the point $\vec{I}$ on the coincidence line closest to the line source:

$$\vec{I} = \vec{L}_1 + \frac{(\vec{L}_1 - \vec{P}_1) \cdot (\vec{u} - \vec{v}(\vec{u} \cdot \vec{v}))}{|\vec{u} \cdot \vec{v}|^2 - 1} \vec{u}.$$

- d) Compute the timing error t' as the difference between the measured timing data for the event and its expected timing offset:

$$t' = (t_1 - t_2) - \frac{|\vec{L}_1 - \vec{I}| - |\vec{L}_2 - \vec{I}|}{c}.$$

- e) Compute τ and ρ as:

$$\tau = \text{int}\left(\frac{t' - \Delta t}{\Delta t}\right)$$

$$\rho = \text{int}\left(\frac{r' - \Delta r}{\Delta r}\right).$$

In this context, the function "int" means "round to the nearest integer". Each event shall be accumulated into one 2-D histogram $C_j(\tau, \rho)$ for each acquisition j .

4.6.7 Scatter and random removal

For each timing bin τ of each acquisition j , the following shall be done.

- a) Determine the counts per pixel, $C_{L,T,j}$ and $C_{R,T,j}$, at the left and right edges, respectively, of the 40 mm wide strip at the centre of $C_j(\tau, \rho)$. If these points do not correspond to sample locations of $C_j(\tau, \rho)$, these values are found by linear interpolation (see Figure 4).
- b) Form the 1D timing histogram $C_j(\tau)$ by summing contributions from all radial bins in the 40 mm wide strip and correcting for the background:

$$C_j(\tau) = \sum_{\rho} \left\{ C_j(\tau, \rho) - \left[\frac{20 - \rho}{40} \right] C_{L,T,j} + \left[\frac{\rho + 20}{40} \right] C_{R,T,j} \right\}$$

4.6.8 FWHM analysis

Each 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 1). The maximum PIXEL value $C_j(t)$ shall be determined by a parabolic fit using the peak point and its two nearest neighbours. Values are converted to time units by multiplication with Δt .

4.6.9 Report

The following items shall be reported.

- a) TOF resolution ($FWHM_{TOF}(j)$), plotted as a function of the effective radioactivity concentration $A_{ave}(j)$, where the volume V is the total volume of the cylindrical phantom (22 700 ml).
- b) TOF resolution ($FWHM_{TOF}$) at effective radioactivity concentration of 5,0 kBq/ml, determined by linear interpolation from the values of $A_{ave}(j)$ immediately above and below 5,0 kBq/ml.

4.7 Image quality and quantification accuracy of source ACTIVITY concentrations and PET/CT registration accuracy

4.7.1 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, scatter and randoms. The contrast resolution is affected by the noise present in the background surrounding a lesion.

4.7.2 Purpose

The purpose of 4.7 is to measure image quality factors and quantification accuracy of the PET scanner under normal imaging conditions. To mimic such normal imaging conditions, a torso shaped phantom ~~shall be~~ is used containing multiple hot spheres of decreasing diameters and a cold cylinder insert in a warm background.

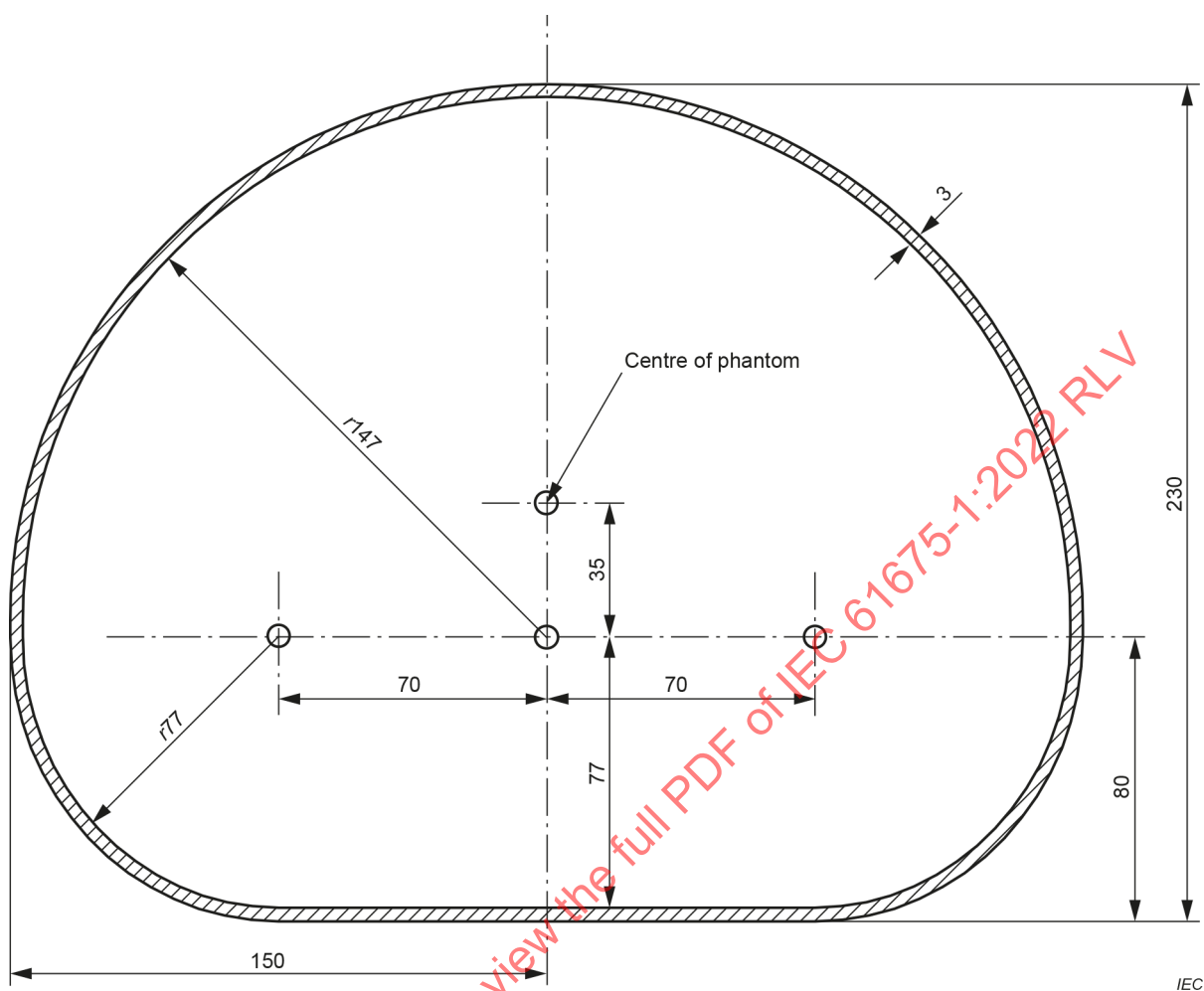
The contrast of the hot spheres is measured and compared to the noise in the background to assess lesion detectability. Quantification accuracy is determined by comparing the measured concentrations in the spheres, background, and lung cylinder insert to their true ACTIVITY concentrations. Additional measurements include assessing the ability of the scanner to quantify ACTIVITY concentration as a function of sphere size.

4.7.3 Method

4.7.3.1 General

The whole-body phantom ~~is to~~ shall be used for all measurements (see Figure 6) into which hollow spheres and lung insert ~~are~~ shall be placed (see Figure 7).

Dimensions are in millimetres and are given within ± 1 mm

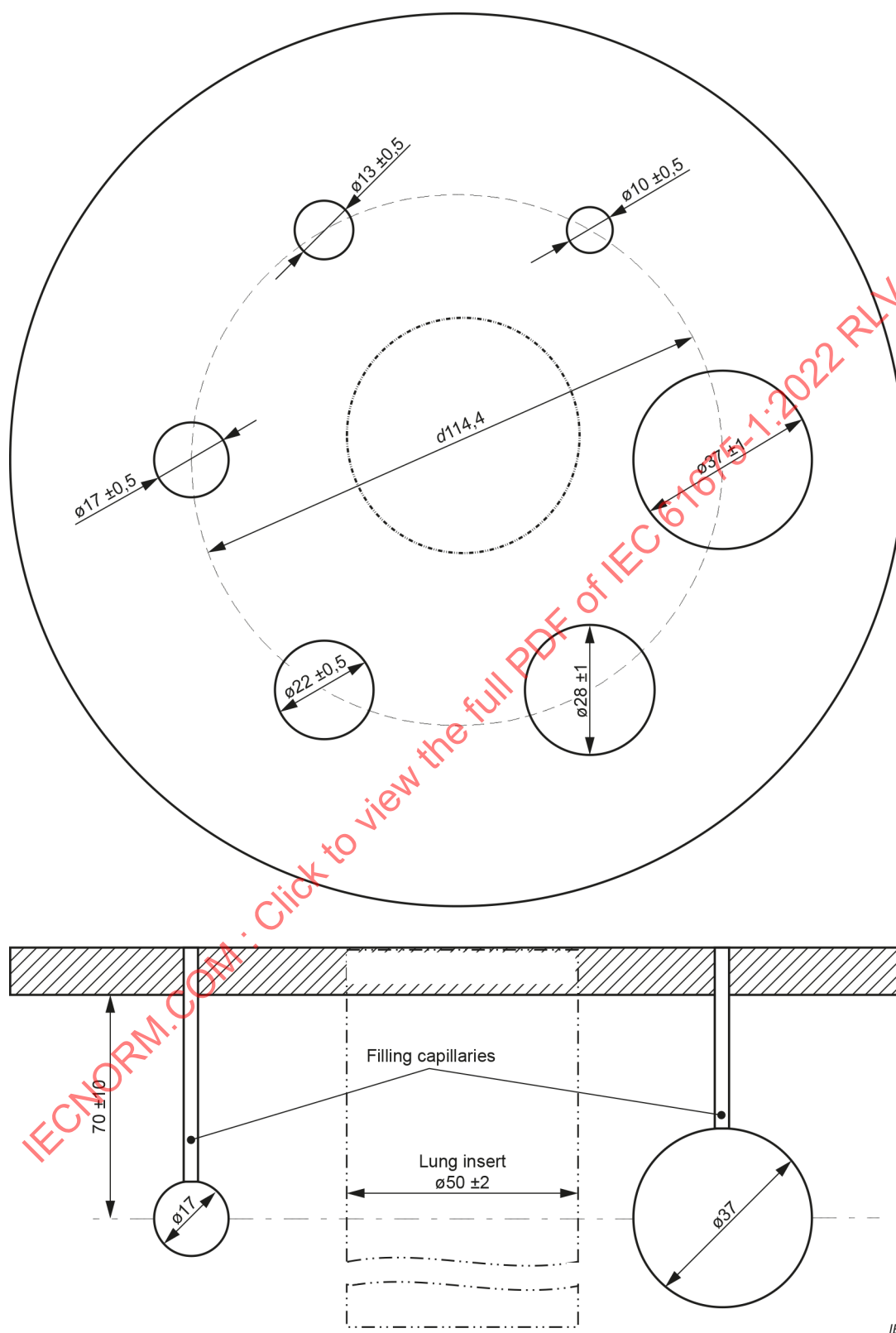


Material: polymethylmethacrylate.

The phantom length shall be at least 180 mm $\pm$ 5 mm.

Figure 6 – Cross-section of body phantom

Dimensions in millimetres



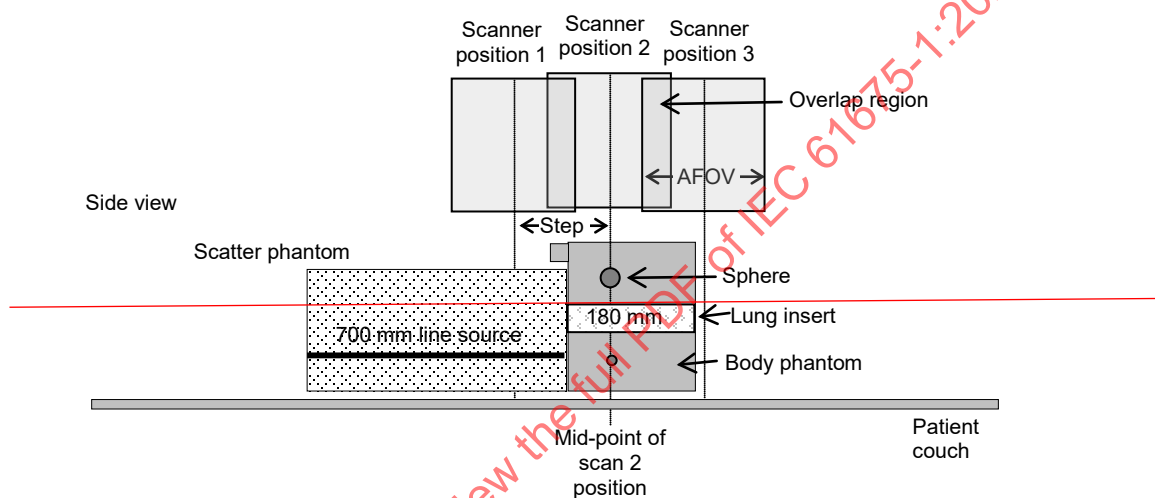
Material: polymethylmethacrylate.

All diameters given are inside diameters. The wall thickness of the spheres ~~shall be~~ is ≤ 1 mm. The centres of the spheres ~~shall be~~ are 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 $50 \text{ mm} \pm 2 \text{ mm}$.

Figure 7 – Phantom insert with hollow spheres

The hollow spheres of decreasing diameter ~~are~~ shall be arranged circularly and centred on a single plane and shall have hollow stems that extend through the outer plate to permit filling of the spheres with a radioactive liquid. The lung cylinder insert ~~has~~ shall have a diameter of (50 ± 2) mm and extends through the length of the phantom chamber. The cylinder ~~is~~ shall be filled with a low atomic number material of density of $(0,30 \pm 0,10)$ g/cm³, ~~is~~ shall be void of ACTIVITY and ~~simulates~~ shall simulate the ATTENUATION of the lung.

Abutted to the whole-body phantom at the head end (closer to the spheres) ~~is~~ the scatter phantom with LINE SOURCE shall be inserted – see Figure 8 a) – and ~~is~~ shall be used to simulate outside field of view source ACTIVITY. Known source ACTIVITY concentrations ~~are~~ shall be added to all the fillable spheres, image quality phantom background, and scatter phantom with LINE SOURCE inserted. The ~~average~~ ACTIVITY in the LINE SOURCE shall be chosen so that the effective ACTIVITY concentration in the scatter phantom including the LINE SOURCE ~~shall be~~ is equal to the background ACTIVITY concentration in the image quality phantom.



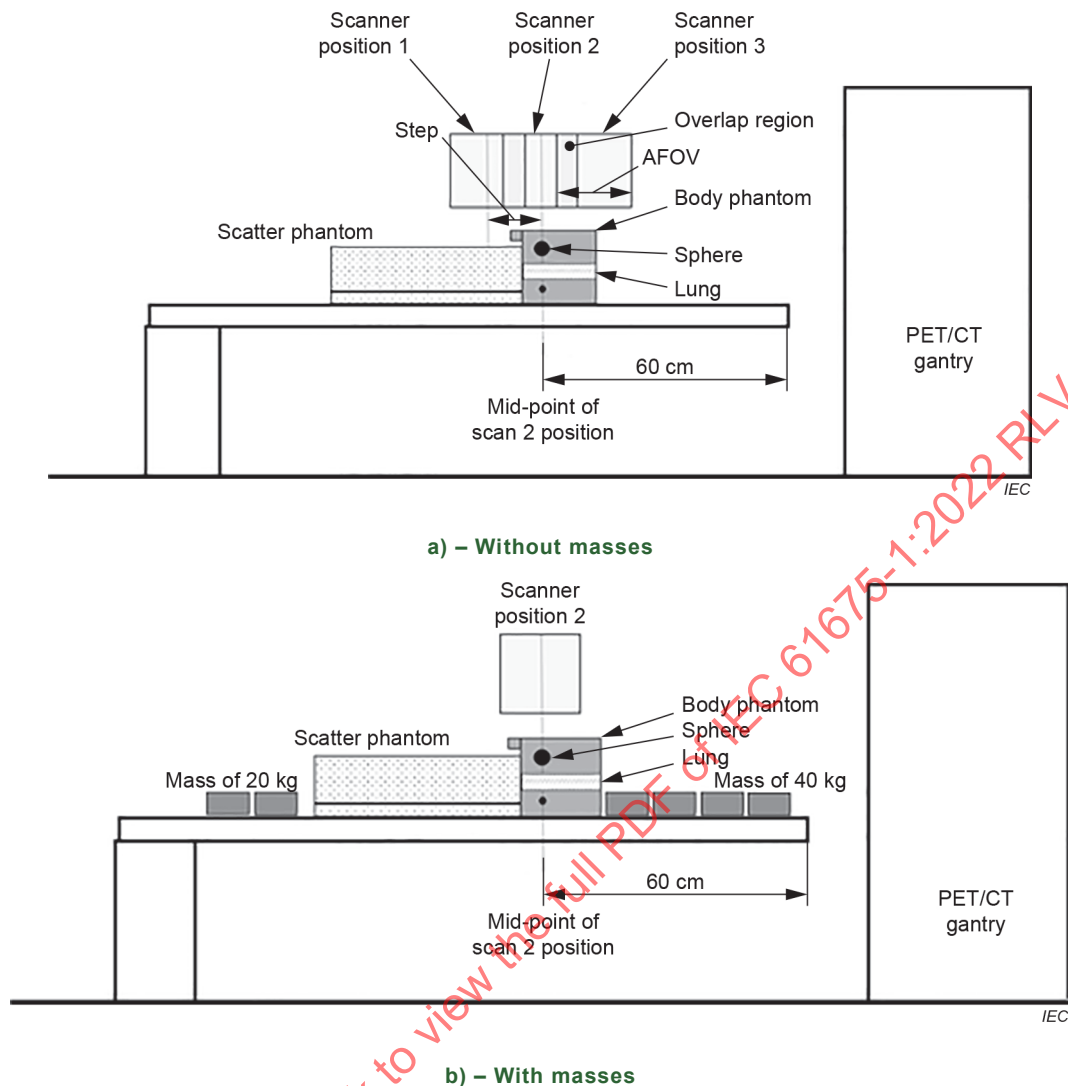


Figure 8 – Image quality phantom and scatter phantom position for whole body scan acquisition

A whole-body acquisition covering the length of the whole-body phantom shall be obtained.

The algorithms used for image reconstruction, scatter and ATTENUATION correction shall be those corresponding to the routine whole-body clinical image protocol. PIXEL values in units of kBq/ml shall be produced. Prior to this, a scanner CALIBRATION ~~is required~~ shall be conducted. Results for additional image reconstructions with enhancements may ~~be~~ reported separately.

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

4.7.3.2 RADIONUCLIDE

The RADIONUCLIDE for the measurement shall be ^{18}F .

4.7.3.3 Source distribution

The ACTIVITY concentration in the whole-body phantom background shall be $(5 \pm 0,3)$ kBq/ml. The spheres shall be filled with an ACTIVITY concentration that is between 3,8 and 4,2 times the ACTIVITY concentration in the background. The LINE SOURCE in the scatter phantom shall be filled

with an ACTIVITY of (110 ± 5) MBq. All ACTIVITY concentrations ~~are~~ shall be specified for the time at the start of acquisition. The RADIONUCLIDE in all phantoms shall be well mixed.

NOTE These concentrations correspond to a typical clinical dosage of 350 MBq in a 70 kg PATIENT for whole body imaging.

The test is critically dependent upon the accurate assays of ACTIVITY to be used. The dose calibrator, where it is difficult to maintain an absolute CALIBRATION to accuracies finer than 10 %, may be used to assay starting ACTIVITY levels. Absolute reference standards using positron emitters ~~should~~ may be considered if higher degrees of accuracy are required.

If the MANUFACTURER recommends a lower dosage for this test, the ACTIVITY concentration in all phantoms may be lowered proportionately. The report shall include the MANUFACTURER recommended dosage.

4.7.3.4 Data collection

The whole-body phantom ~~is~~ shall be placed on the patient bed of the tomograph and ~~is~~ shall be centred within the TRANSVERSE FIELD OF VIEW. The plane passing through the centre of the spheres in the whole-body phantom shall be aligned to the centre of the AXIAL FIELD OF VIEW. The line-source scatter phantom, set directly on the patient bed, ~~abuts~~ shall abut to the head-end of the image quality phantom – see Figure 8 a). The distance of the centre of the spheres to the end of the bed shall be 60 cm.

A whole-body acquisition over the length of the whole-body phantom shall be performed. It is assumed that whole-body acquisition scan consists of multiple stationary scans with the standard overlap between scan positions. The "step size" is the axial distance the bed translates between positions and may be less than the AXIAL FIELD OF VIEW. At least three scan positions are required. Start position 1 ~~is~~ shall be determined by scan position 2 which ~~shall be~~ is axially centred over the transverse plane of the spheres. Position 1 ~~is~~ shall be located towards the scatter phantom at a distance equal to the "step size" used in clinical whole body scans. The end scan at position 3 ~~is~~ shall be where the scanner is moved a "step size" distance toward the opposite end of the image quality phantom so that the centre of the AXIAL FIELD OF VIEW is located beyond the end of the phantom. 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 in three steps.

The acquisition time T_p for a single position shall be computed as follows:

$$T_p = (d_{ax}/100 \text{ cm}) \cdot 30 \text{ min} \quad (10)$$

where

d_{ax} is the axial distance in centimetres the bed translates between positions (step size).

Additional measurements ~~can~~ may be taken for different values of scan time and axial coverage. If additional measurements are taken, those values shall be included in the final report.

Prior to the start of the emission acquisition, a CT scan over the entire whole-body scan length ~~is~~ shall be obtained with X-ray technique factors as prescribed per whole-body clinical protocol. If the scanner does not have a CT component, then the prescribed method of transmission imaging ~~must~~ shall be applied and reported.

For the emission scan, ~~use~~ an acquisition matrix, field of view size, slice thickness, acquisition mode as 2D or 3D, and multiple scan overlap as prescribed for routine clinical whole-body scans shall be used.

Corrections for RANDOM COINCIDENCES shall be performed and the method used ~~must~~ shall be clearly reported. Enhancements such as time-of-flight information, depth-of-interaction may also be enabled, and the enhancement method ~~must~~ shall be reported. The start-time of the emission scans ~~is~~ shall be used as the reference time for computation of phantom ACTIVITY concentrations and reporting.

Masses shall be added to the table as indicated in Figure 8 b). The PET and the CT acquisition shall be repeated for bed position 2 only. The acquisition time T_{2p} shall be two times of T_p .

4.7.3.5 Data processing

Transverse slices shall be reconstructed over the length of the image quality phantom. The standard reconstruction protocol for whole-body imaging shall be applied. The reconstruction algorithm, methods used for ATTENUATION, scatter, and COUNT LOSS corrections, and post reconstruction image filter and all associated parameters shall be reported. ~~If the PET system provides reconstruction software with enhancements such as time of flight and resolution recovery these results may be reported separately.~~ Results from alternate reconstruction protocols may be reported separately.

4.7.4 Data analysis

4.7.4.1 Data analysis for image quality and quantification accuracy of source ACTIVITY concentrations

4.7.4.1.1 General

The following analysis for the measurements without weights present shall be performed.

4.7.4.1.2 Regions-of-interest

4.7.4.1.2.1 General

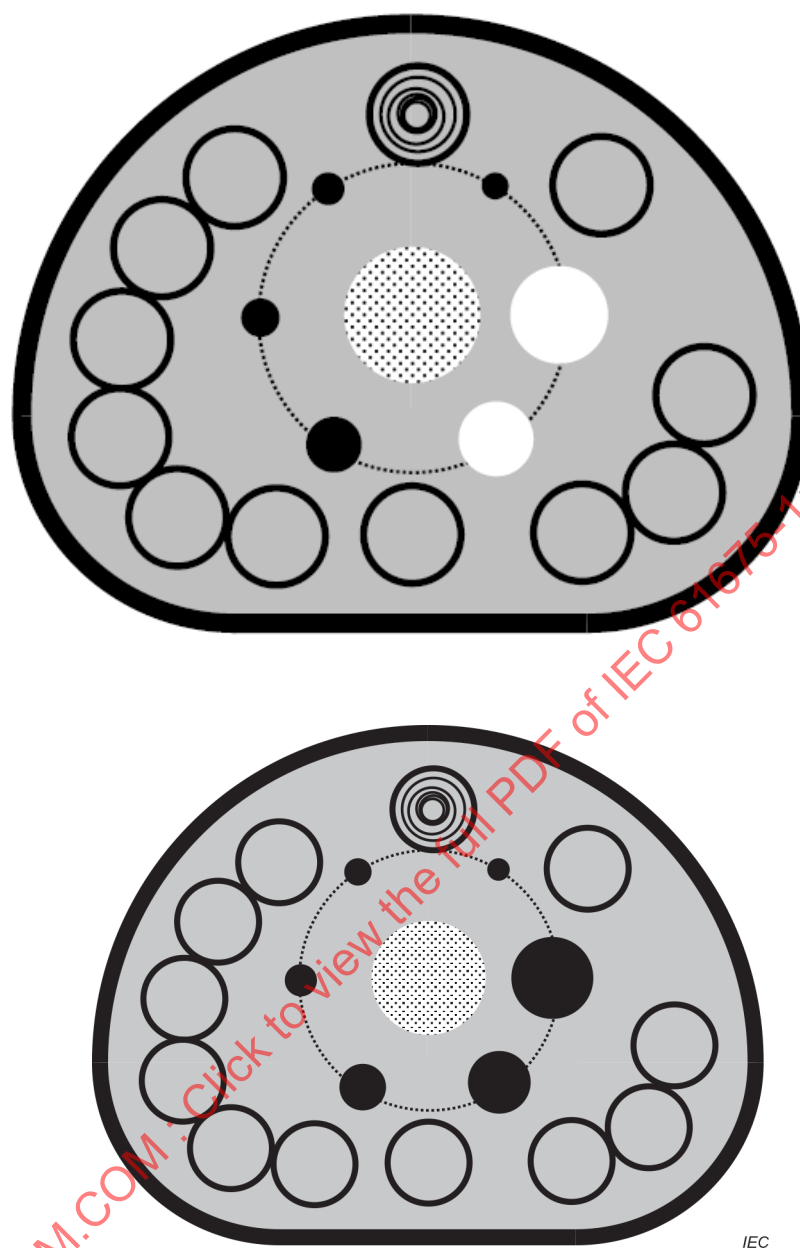
For image quality and quantitative accuracy analyses, 2D circular ROIs ~~are~~ shall be drawn over the spheres and whole-body phantom background on selected slices.

4.7.4.1.2.2 Hot sphere 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 regions-of-interest (ROIs) shall be drawn over the six spheres in the S-slice. The ROI diameter ~~should~~ shall be made as close as possible to the sphere inner diameter, ~~but shall not exceed~~ without exceeding the inner diameter. The average PIXEL value P_j for each sphere shall be computed.

4.7.4.1.2.3 Background ROIs

The transverse slices as close as possible to ± 1 cm and ± 2 cm from the S-slice shall be identified. 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 9 for an example of background ROI placement on the S-slice). ROIs corresponding to the five smaller diameter spheres shall 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~~ shall be placed concentrically.

SOURCE: [1]¹, used with permission.

Figure 9 – Placement of ROIs in the phantom background

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

4.7.4.1.2.4 Whole-body scan lung and background ROIs

~~Draw~~ A 37 mm diameter ROI shall be drawn inside the lung insert on every transverse slice over the entire length of the image quality phantom. Likewise, ~~draw~~ a 37 mm diameter ROI shall be drawn in the phantom background positioned 15 mm from the left edge of the phantom edge.

¹ Numbers in square brackets refer to the Bibliography.

~~Record~~ The average PIXEL values shall be recorded for all regions and label as $WBBg_k$ and $WBLung_k$, respectively for slice $k = 1, n$ where n is the last slice.

4.7.4.1.3 Image quality

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.

$$CR_j = (P_j/B_j - 1) / (A_S/A_B - 1) \quad (11)$$

where

P_j is the ROI value for sphere j , as computed in 4.7.4.1.2.2;

B_j is the average of the background ROI values for sphere j , as computed in 4.7.4.1.2.3;

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:

$$CN_j = S_j/B_j \quad (12)$$

where

B_j is the average of the background ROI values for sphere j , as computed in 4.7.4.1.2.3;

S_j is the standard deviation of the background ROI values for sphere j , as computed in 4.7.4.1.2.3.

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

$$CNR_j = (P_j/B_j - 1) / CN_j \quad (13)$$

where

P_j is the ROI value for sphere j , as computed in 4.7.4.1.2.2;

B_j is the average of the background ROI values for sphere j , as computed in 4.7.4.1.2.3;

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

4.7.4.1.4 Quantification accuracy

~~Compute the~~ Percent deviation shall be computed from true ACTIVITY concentration in the phantom background as showed in Formula (14):

$$\Delta Q_B = 100 \% \cdot (B_{37} - A_B) / A_B \quad (14)$$

where

ΔQ_B is the percent deviation from true ACTIVITY concentration in the background;

B_{37} is the average PIXEL value for 37 mm ROI in the background (see 4.7.4.1.2.3) in units of kBq/ml;

A_B is the ACTIVITY concentration in the phantom background in units of kBq/ml.

4.7.4.1.5 Accuracy of scatter and ATTENUATION corrections

Accuracy of scatter and ATTENUATION corrections ~~is shall be~~ measured in the background and the lung insert along the entire length of the phantom. A residual error in the lung insert ~~is shall be~~ calculated for every slice. Quantification accuracy ~~is shall be~~ calculated for the background ROI for every slice.

The residual error in the lung insert ~~is shall be~~ calculated as showed in Formula (15):

$$\Delta LR_k = 100 \% \cdot WBLung_k / A_B \quad (15)$$

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 in units of kBq/ml;

A_B is the ACTIVITY concentration in the phantom background in units of kBq/ml.

The quantification accuracy in the background is calculated as showed in Formula (16):

$$\Delta QWB_k = 100 \% \cdot (WBBkg_k - A_B) / A_B \quad (16)$$

where

ΔQWB_k is the percent residual error in slice k ;

$WBBkg_k$ is the average PIXEL value in the background in slice k in units of kBq/ml;

A_B is the ACTIVITY concentration in the phantom background in units of kBq/ml.

4.7.4.2 ~~Accuracy of PET and CT image registration~~ Data analysis for PET/CT registration accuracy

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

The following analysis shall be performed for the measurements with masses added according to Figure 8 b).

On the PET scan, ~~completely encircle~~ the spheres shall be encircled completely. ~~Set~~ All PIXELS in the ROI that are greater than 1,25 times the average background (B_j for sphere j as defined in 4.7.4.1.2.3) within the ROI shall be set to one, otherwise they shall be set ~~them~~ to zero. The X, Y, and Z-centroids ~~are shall~~ then calculated as showed in Formula (17), Formula (18), and Formula (19):

$$C_{X,j} = \Sigma x \cdot ROI_{PET,j}(x,y,z) / \Sigma ROI_{PET,j}(x,y,z); \text{ for all } x,y,z \text{ of ROI} \quad (17)$$

$$C_{Y,j} = \Sigma y \cdot ROI_{PET,j}(x,y,z) / \Sigma ROI_{PET,j}(x,y,z); \text{ for all } x,y,z \text{ of ROI} \quad (18)$$

$$C_{Z,j} = \Sigma z \cdot ROI_{PET,j}(x,y,z) / \Sigma ROI_{PET,j}(x,y,z); \text{ for all } x,y,z \text{ of ROI} \quad (19)$$

Then ~~identify~~ $C_{PET,j} = (C_{X,j}, C_{Y,j}, C_{Z,j})$ shall be identified as the centroid coordinate for sphere j for PET.

For the CT scan, ~~completely encircle~~ the spheres shall be encircled completely. ~~Set~~ All PIXELs in the ROI which belong to the sphere wall shall be set to one and the others to zero. The X, Y, and Z-centroids ~~are~~ shall then be calculated as showed in Formula (20), Formula (21) and Formula (22):

$$C_{X,j} = \Sigma x \cdot ROI_{CT,j}(x,y,z) / \Sigma ROI_{CT,j}(x,y,z); \text{ for all } x,y,z \text{ of ROI} \quad (20)$$

$$C_{Y,j} = \Sigma y \cdot ROI_{CT,j}(x,y,z) / \Sigma ROI_{CT,j}(x,y,z); \text{ for all } x,y,z \text{ of ROI} \quad (21)$$

$$C_{Z,j} = \Sigma z \cdot ROI_{CT,j}(x,y,z) / \Sigma ROI_{CT,j}(x,y,z); \text{ for all } x,y,z \text{ of ROI} \quad (22)$$

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

~~Calculate~~ The distance between the PET and CT centroids shall be calculated for each sphere.

4.7.5 Report

4.7.5.1 Scan set up and phantom ACTIVITY concentrations

~~Report~~ The following scan set up parameters shall be reported:

- scanner axial field of view;
- bed "step size" between multiple acquisitions;
- acquisition time per bed position;
- total whole-body scan length;
- CT acquisition parameters: kVp, mAs, slice-thickness;
- PET acquisition parameters: reconstructed field of view diameter, slice thickness, acquisition mode as 2D or 3D, and method of randoms correction;
- reconstruction algorithm, methods used for ATTENUATION, scatter, and dead-time count loss corrections, post reconstruction image filter and all associated parameters.

~~Report~~ The sphere and phantom background ACTIVITY concentrations at start of the first measurement made with the phantom positioned according to Figure 8 a) shall be reported.

4.7.5.2 Image quality

~~Report~~ The noise coefficient of variation for all spheres shall be reported.

~~Report~~ The contrast recovery coefficients for all spheres shall be reported. ~~Identify~~ The smallest sphere that has a recovery coefficient greater than 0,90 shall be identified and reported.

~~Report~~ The contrast-noise-ratio for all spheres shall be reported. ~~Identify~~ The smallest sphere for which the contrast-noise-ratio exceeds four shall be identified and reported.

4.7.5.3 Quantification accuracy

~~Report~~ The percent deviation from true ACTIVITY concentration for the background for the average PIXEL values in the region shall be reported.

4.7.5.4 Accuracy of scatter and ATTENUATION corrections

~~Plot~~ The residual error in the lung insert and background shall be reported for every slice.

~~Report~~ The length of any portion of the phantom where the magnitude of the residual error exceeds 10 % ~~shall be reported~~.

4.7.5.5 Accuracy of PET and CT image registration

~~Report~~ The deviation distance in mm between the PET and CT centroids for each sphere ~~shall be reported~~.

5 ACCOMPANYING DOCUMENTS

5.1 General

A document shall accompany each POSITRON EMISSION TOMOGRAPH ~~and shall include~~ that ~~includes~~ the information contained in 5.2 to 5.8.

5.2 Design parameters and configuration

- detector element dimensions and number of elements;
- detector material;
- ~~— Number and configuration of detector elements per block, if applicable~~
- ~~— Number of detector blocks per ring, if applicable~~
- COINCIDENCE WINDOW;
- detector ring diameter;
- ~~— Patient port diameter~~
- TRANSVERSE FIELD OF VIEW;
- AXIAL FIELD OF VIEW;
- SINOGRAM sampling (linear and angular);
- axial sampling;
- ~~— Septal length~~
- ~~— Septal thickness~~
- ~~— Length of side shields~~
- ~~— Type of transmission source and source ACTIVITY (nominal and recommended range)~~
- ~~— Detector movement (e.g. rotational speed, angular range), if any~~
- energy window;
- axial acceptance angle;
- reconstruction algorithm;
- method of RANDOM COINCIDENCE estimation;
- any additional information being considered essential by the MANUFACTURER to characterize normal operation.

~~5.3 Configuration of the tomograph~~

- ~~— Energy threshold~~
- ~~— Axial acceptance angle (2D mode, 3D mode)~~
- ~~— Reconstruction algorithm~~
- ~~— Method of RANDOM COINCIDENCE estimation~~
- ~~— Any additional information being considered essential by the MANUFACTURER to characterize normal operation~~

5.3 SPATIAL RESOLUTION

- TRANSVERSE RESOLUTION (radial and tangential) according to 4.2.5;

- AXIAL RESOLUTION according to 4.2.5;
- axial PIXEL dimension according to 4.2.5;
- transverse PIXEL dimensions according to 4.2.5.

5.4 Sensitivity

- SLICE SENSITIVITY according to 4.3.5;
- VOLUME SENSITIVITY according to 4.3.5.

5.5 SCATTER FRACTION

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5.6 COUNT RATE performance

- COUNT RATE CHARACTERISTIC and derived quantities according to 4.5.5.1;
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5.7 TIME-OF-FLIGHT resolution

- TOF-resolution ($FWHM_{TOF(i)}$, $FWHM_{TOF}$) and derived quantities according to 4.6.9.

5.8 Image quality and quantification accuracy of source ACTIVITY concentrations

- scan set up and phantom ACTIVITY concentrations according to 4.7.5.1;
- image quality according to 4.7.5.2;
- quantification accuracy according to 4.7.5.3;
- accuracy of scatter and ATTENUATION corrections according to 4.7.5.4;
- accuracy of PET and CT image registration according to 4.7.5.5;

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INTERNATIONAL STANDARD

NORME INTERNATIONALE



**Radionuclide imaging devices – Characteristics and test conditions –
Part 1: Positron emission tomographs**

**Dispositifs d'imagerie par radionucléides – Caractéristiques et conditions
d'essai –
Partie 1: Tomographes à émission de positrons**

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

**RADIONUCLIDE IMAGING DEVICES –
CHARACTERISTICS AND TEST CONDITIONS –****Part 1: Positron emission tomographs**

FOREWORD

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IEC 61675-1 has been prepared by subcommittee 62C: Equipment for radiotherapy, nuclear medicine and radiation dosimetry, of IEC technical committee 62: Electrical equipment in medical practice. It is an International Standard.

This third edition cancels and replaces the second edition published in 2013. This edition constitutes a technical revision.

This edition includes the following significant technical change with respect to the previous edition: requirements have been changed or newly created regarding the technical aspects of SPATIAL RESOLUTION, sensitivity measurement, SCATTER FRACTION, COUNT RATE performance, image quality, PET/CT registration accuracy and time-of-flight resolution.

The text of this International Standard is based on the following documents:

Draft	Report on voting
62C/811/CDV	62C/828/RVC

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

The language used for the development of this International Standard is English.

In this document, the following print types are used: terms defined in Clause 3 of this document or as noted: small capitals.

This document was drafted in accordance with ISO/IEC Directives, Part 2, and developed in accordance with ISO/IEC Directives, Part 1 and ISO/IEC Directives, IEC Supplement, available at www.iec.ch/members_experts/refdocs. The main document types developed by IEC are described in greater detail at www.iec.ch/standardsdev/publications.

A list of all parts in the IEC 61675 series, published under the general title *Radionuclide imaging devices – Characteristics and test conditions*, can be found on the IEC website.

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

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

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INTRODUCTION

Further developments of POSITRON EMISSION TOMOGRAPHS allow most of the tomographs to be operated in fully 3D acquisition mode. To comply with this trend, this document describes test conditions in accordance with this acquisition characteristic. In addition, today a POSITRON EMISSION TOMOGRAPH often includes X-RAY EQUIPMENT for COMPUTED TOMOGRAPHY (CT). For this document, PET-CT hybrid devices are considered to be state of the art, dedicated POSITRON EMISSION TOMOGRAPHS not including the X-ray component being special cases only.

While the test methods specified herein are optimized for the PET component of PET-CT hybrid devices, they may also be used for the PET component of PET-MR hybrid devices.

The test methods specified in this document have been selected to reflect as much as possible the clinical use of POSITRON EMISSION TOMOGRAPHS. It is intended that the tests be carried out by MANUFACTURERS, thereby enabling them to declare the characteristics of POSITRON EMISSION TOMOGRAPHS in the ACCOMPANYING DOCUMENTS. This document does not indicate which tests will be performed by the MANUFACTURER on an individual tomograph or which class-standards may be used to characterize the performance of POSITRON EMISSION TOMOGRAPHS by the MANUFACTURER.

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RADIONUCLIDE IMAGING DEVICES – CHARACTERISTICS AND TEST CONDITIONS –

Part 1: Positron emission tomographs

1 Scope

This part of IEC 61675 specifies terminology and test methods for declaring the characteristics of POSITRON EMISSION TOMOGRAPHS. POSITRON EMISSION TOMOGRAPHS detect the ANNIHILATION RADIATION of positron emitting RADIONUCLIDES by COINCIDENCE DETECTION.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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

3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC TR 60788:2004 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at <http://www.electropedia.org/>
- ISO Online browsing platform: available at <http://www.iso.org/obp>

3.1

tomography

radiography of one or more layers within an object

[SOURCE: IEC TR 60788:2004, rm-41-15]

3.1.1

emission computed tomography

ECT

imaging method for the representation of the spatial distribution of incorporated RADIONUCLIDES in selected two-dimensional slices through the object

3.1.1.1

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 (along the LINE OF RESPONSE) and called "Radon transform".

3.1.1.2

projection beam

beam that determines the smallest possible volume in which the physical property which determines the image is integrated during the measurement process

Note 1 to entry: The PROJECTION BEAM's shape is limited by SPATIAL RESOLUTION in all three dimensions.

Note 2 to entry: The PROJECTION BEAM mostly has the shape of a long thin cylinder or cone. In POSITRON EMISSION TOMOGRAPHY, it is the sensitive volume between two detector elements operated in coincidence.

3.1.1.3

projection angle

angle at which the PROJECTION is measured or acquired

3.1.1.4

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, and the linear projection coordinate is displayed on the abscissa.

3.1.1.5

object slice

physical property that corresponds to a slice in the object and that determines the measured information and which is displayed in the tomographic image

3.1.1.6

image plane

plane assigned to a plane in the OBJECT SLICE

Note 1 to entry: Usually, the IMAGE PLANE is the midplane of the corresponding OBJECT SLICE.

3.1.1.7

system axis

axis of symmetry, characterized by geometrical and physical properties of the arrangement of the system

Note 1 to entry: For a circular POSITRON EMISSION TOMOGRAPH, the SYSTEM AXIS is the axis through the centre of the detector ring. For tomographs with rotating detectors, it is the axis of rotation.

3.1.1.8

tomographic volume

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

3.1.1.8.1

transverse field of view

dimensions of a slice through the TOMOGRAPHIC VOLUME, perpendicular to the SYSTEM AXIS

Note 1 to entry: For a circular TRANSVERSE FIELD OF VIEW, it is described by its diameter.

Note 2 to entry: For non-cylindrical TOMOGRAPHIC VOLUMES, the TRANSVERSE FIELD OF VIEW may depend on the axial position of the slice.

3.1.1.8.2

axial field of view

AFOV

field which is characterized by dimensions of a slice through the TOMOGRAPHIC VOLUME, parallel to and including the SYSTEM AXIS

Note 1 to entry: In practice, the AXIAL FIELD OF VIEW is specified only by its axial dimension, given by the distance between the centre of the outmost defined IMAGE PLANES plus the average of the measured AXIAL RESOLUTION.

3.1.1.8.3

total field of view

field which is characterized by dimensions (three-dimensional) of the TOMOGRAPHIC VOLUME

3.1.2

positron emission tomography

PET

EMISSION COMPUTED TOMOGRAPHY utilizing the ANNIHILATION RADIATION of positron emitting RADIONUCLIDES by COINCIDENCE DETECTION

3.1.2.1

positron emission tomograph

tomographic device, which detects the ANNIHILATION RADIATION of positron emitting RADIONUCLIDES by COINCIDENCE DETECTION

3.1.2.2

annihilation radiation

ionizing radiation that is produced when a particle and its antiparticle interact and cease to exist

3.1.2.3

coincidence detection

method which checks whether two opposing detectors have detected one photon each simultaneously

Note 1 to entry: By this method, the two photons are concatenated into one event.

Note 2 to entry: The COINCIDENCE DETECTION between two opposing detector elements serves as an electronic collimation to define the corresponding PROJECTION BEAM or LINE OF RESPONSE (LOR), respectively.

3.1.2.4

coincidence window

time interval during which two detected photons are considered being simultaneous

3.1.2.5

line of response

LOR

axis of the PROJECTION BEAM

Note 1 to entry: In PET, the LINE OF RESPONSE is the line connecting the centres of two opposing detector elements operated in coincidence.

3.1.2.6

total coincidences

sum of all coincidences detected

3.1.2.6.1

true coincidence

result of COINCIDENCE DETECTION of two gamma events originating from the same positron annihilation

3.1.2.6.2

scattered true coincidence

TRUE COINCIDENCE where at least one participating photon was scattered before the COINCIDENCE DETECTION

3.1.2.6.3

unscattered true coincidence

the difference between TRUE COINCIDENCES and SCATTERED TRUE COINCIDENCES

3.1.2.6.4

random coincidence

result of a COINCIDENCE DETECTION in which participating photons do not originate from the same positron annihilation.

3.1.2.7

singles rate

COUNT RATE measured without COINCIDENCE DETECTION, but with energy discrimination

3.1.3

two-dimensional reconstruction

image reconstruction at which data are rebinned prior to reconstruction into SINOGRAMS, which are the PROJECTION data of transverse slices, which are considered being independent of each other and being perpendicular to the SYSTEM AXIS

3.1.4

three-dimensional reconstruction

image reconstruction at which the LINES OF RESPONSE are not restricted to being perpendicular to the SYSTEM AXIS so that a LINE OF RESPONSE may pass several transverse slices

3.2

image matrix

<nuclear medicine> matrix in which each element corresponds to the measured or calculated physical property of the object at the location described by the coordinates of this MATRIX ELEMENT

3.2.1

matrix element

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

3.2.2

pixel

MATRIX ELEMENT in a two-dimensional IMAGE MATRIX

3.2.3

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.

3.3

point spread function

PSF

scintigraphic image of a POINT SOURCE

3.3.1

physical point spread function

<tomographs> two-dimensional POINT SPREAD FUNCTION in planes perpendicular to the PROJECTION BEAM at specified distances from the detector

Note 1 to entry: The PHYSICAL POINT SPREAD FUNCTION characterizes the purely physical (intrinsic) imaging performance of the tomographic device and is independent of for example sampling, image reconstruction and image

processing. A PROJECTION BEAM is characterized by the entirety of all PHYSICAL POINT SPREAD FUNCTIONS as a function of distance along its axis.

3.3.2

axial point spread function

profile passing through the peak of the PHYSICAL POINT SPREAD FUNCTION in a plane parallel to the SYSTEM AXIS

3.3.3

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.

3.4

spatial resolution

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

3.4.1

transverse resolution

SPATIAL RESOLUTION in a reconstructed plane perpendicular to the SYSTEM AXIS

3.4.1.1

radial resolution

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

3.4.1.2

tangential resolution

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

3.4.2

axial resolution

SPATIAL RESOLUTION along a line parallel to the SYSTEM AXIS

Note 1 to entry: AXIAL RESOLUTION only applies for tomographs with sufficiently fine axial sampling fulfilling the sampling theorem.

3.4.3

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

Note 1 to entry: EW better reflects scatter tails of the response function than FWHM or FWTM.

[SOURCE: IEC TR 60788:2004, rm-34-45, modified – Note to entry added.]

3.4.4

full width at half maximum

FWHM

for a bell-shaped curve, distance parallel to the abscissa axis between the points where the ordinate has half of its maximum value

[SOURCE: IEC TR 60788:2004, rm-73-02]

3.5

recovery coefficient

measured (image) ACTIVITY concentration of an active volume divided by the true ACTIVITY concentration of that volume, neglecting ACTIVITY calibration factors

Note 1 to entry: For the actual measurement, the true ACTIVITY concentration is replaced by the measured ACTIVITY concentration in a large volume.

3.6

slice sensitivity

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

Note 1 to entry: In PET, the measured counts are numerically corrected for scatter by subtracting the SCATTER FRACTION.

3.7

volume sensitivity

sum of the individual SLICE SENSITIVITIES

3.8

count rate characteristic

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

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

3.8.1

count loss

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

3.8.2

count rate

number of counts per unit of time

3.8.3

true count rate

COUNT RATE that would be observed if the RESOLVING TIME of the device were zero

[SOURCE: IEC TR 60788:2004, rm-34-20]

3.9

scatter fraction

SF

ratio between SCATTERED TRUE COINCIDENCES and the sum of SCATTERED plus UNSCATTERED TRUE COINCIDENCES for a given experimental set-up

3.10

point source

RADIOACTIVE SOURCE approximating a δ -function in all three dimensions

3.11

line source

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

3.12 calibration

<emission computed tomography> process to establish the relation between COUNT RATE per volume element locally in the image and the corresponding ACTIVITY concentration in the object for object sizes not requiring RECOVERY CORRECTION

Note 1 to entry: In order to have this CALIBRATION fairly independent of the object under study, the application of proper corrections to the data, e.g., ATTENUATION, scatter, COUNT LOSS, radioactive decay, detector normalization, RANDOM COINCIDENCES (PET), and branching ratio (PET) is mandatory. The independency of the object is required to scale clinical images in terms of kBq/ml or standardized uptake values (SUV).

3.13 PET count rate performance

relationship between the measured COUNT RATE of TRUE COINCIDENCES, RANDOM COINCIDENCES, TOTAL COINCIDENCES, and noise equivalent count rate versus ACTIVITY

3.14 time-of-flight resolution TOF resolution

uncertainty of the measurement of the difference of the arrival time of the two photons from the same annihilation event

4 Test methods

4.1 General

For all measurements, the acquisition parameters of the tomograph shall be set up according to its normal mode of operation, i.e., it is not adjusted specially for the measurement of specific parameters. If the tomograph is specified to operate in different modes influencing the performance parameters, for example with different axial acceptance angles, with TWO-DIMENSIONAL RECONSTRUCTION and THREE-DIMENSIONAL RECONSTRUCTION, the test results shall be reported for every mode of operation. The tomograph configuration (e.g. energy thresholds, axial acceptance angle, reconstruction algorithm) shall be chosen according to the MANUFACTURER's recommendation and clearly stated. If any test cannot be carried out exactly as specified in this document, the reason for the deviation and the exact conditions under which the test was performed shall be stated clearly.

It is postulated that a POSITRON EMISSION TOMOGRAPH is capable to estimate RANDOM COINCIDENCES and to perform the appropriate correction. In addition, a POSITRON EMISSION TOMOGRAPH provides corrections for scatter, ATTENUATION, COUNT LOSS, branching ratio, radioactive decay, and CALIBRATION.

The test phantoms shall be centred within the tomograph's AXIAL FIELD OF VIEW, if not specified otherwise.

4.2 SPATIAL RESOLUTION

4.2.1 General

SPATIAL RESOLUTION measurements describe partly the ability of a tomograph to reproduce the spatial distribution of a tracer in an object in a reconstructed image. The measurement shall be performed by imaging POINT SOURCES in air and reconstructing images, using a sharp reconstruction filter. Although this does not represent the condition of imaging a PATIENT, where tissue scatter is present and limited statistics require the use of a smooth reconstruction filter and/or iterative reconstruction methods, the measured SPATIAL RESOLUTION provides an objective comparison between tomographs.

4.2.2 Purpose

The purpose of this measurement is to characterize the ability of the tomograph to recover small objects.

The SPATIAL RESOLUTION shall be characterized by the width of the reconstructed TRANSVERSE POINT SPREAD FUNCTIONS of radioactive POINT SOURCES. The width of the point spread function shall be measured by the FULL WIDTH AT HALF MAXIMUM (FWHM) and the EQUIVALENT WIDTH (EW).

4.2.3 Method

4.2.3.1 General

For all systems, the SPATIAL RESOLUTION shall be measured in the transverse IMAGE PLANE in two directions (i.e., radially and tangentially) and in the axial direction.

4.2.3.2 RADIONUCLIDE

The RADIONUCLIDE for the measurement shall be ^{18}F or ^{22}Na , with an ACTIVITY such that the percent COUNT LOSS is less than 5 % or the RANDOM COINCIDENCE rate is less than 5 % of the TOTAL COINCIDENCE rate.

4.2.3.3 RADIOACTIVE SOURCE distribution

4.2.3.3.1 General

POINT SOURCES shall be used with the largest dimension less than or equal to 1 mm.

4.2.3.3.2 Source positioning

POINT SOURCES, suspended in air, shall be used to minimize scatter, for measurements of TRANSVERSE RESOLUTION. Resolution measurements shall be made on two planes perpendicular to the LONG AXIS of the tomograph, one at the centre of the AXIAL FIELD OF VIEW and the second on a plane offset from the central plane by 3/8 of the AXIAL FIELD OF VIEW (i.e., one-eighth of the AXIAL FIELD OF VIEW from the end of the tomograph). On each plane, sources shall be positioned at 1 cm, 10 cm, and 20 cm from the SYSTEM AXIS (the 20 cm location may be omitted if it is not covered by the TRANSVERSE FIELD OF VIEW). The sources shall be positioned on either the horizontal or vertical line intersecting the SYSTEM AXIS, so that the radial and tangential directions are aligned with the image grid.

4.2.3.4 Data collection

Data shall be collected for all sources in each of the six positions specified in 4.2.3.3.2, either singly or in groups of multiple sources, to minimize the data acquisition time. At least 100 000 counts for each POINT SOURCE shall be acquired.

4.2.3.5 Data processing

Filtered backprojection reconstruction using a ramp filter with the cutoff at the Nyquist frequency of the PROJECTION data or its 3D equivalent shall be employed for all SPATIAL RESOLUTION data. No resolution enhancement methods shall be used. The pixel size in the transverse plane shall be chosen to allow at least 3 pixels per FWHM.

Results obtained using alternate reconstruction algorithms may be reported in addition to the filtered backprojection results, provided that the alternate reconstruction methods and their parameters are described in sufficient detail to reproduce the study results.

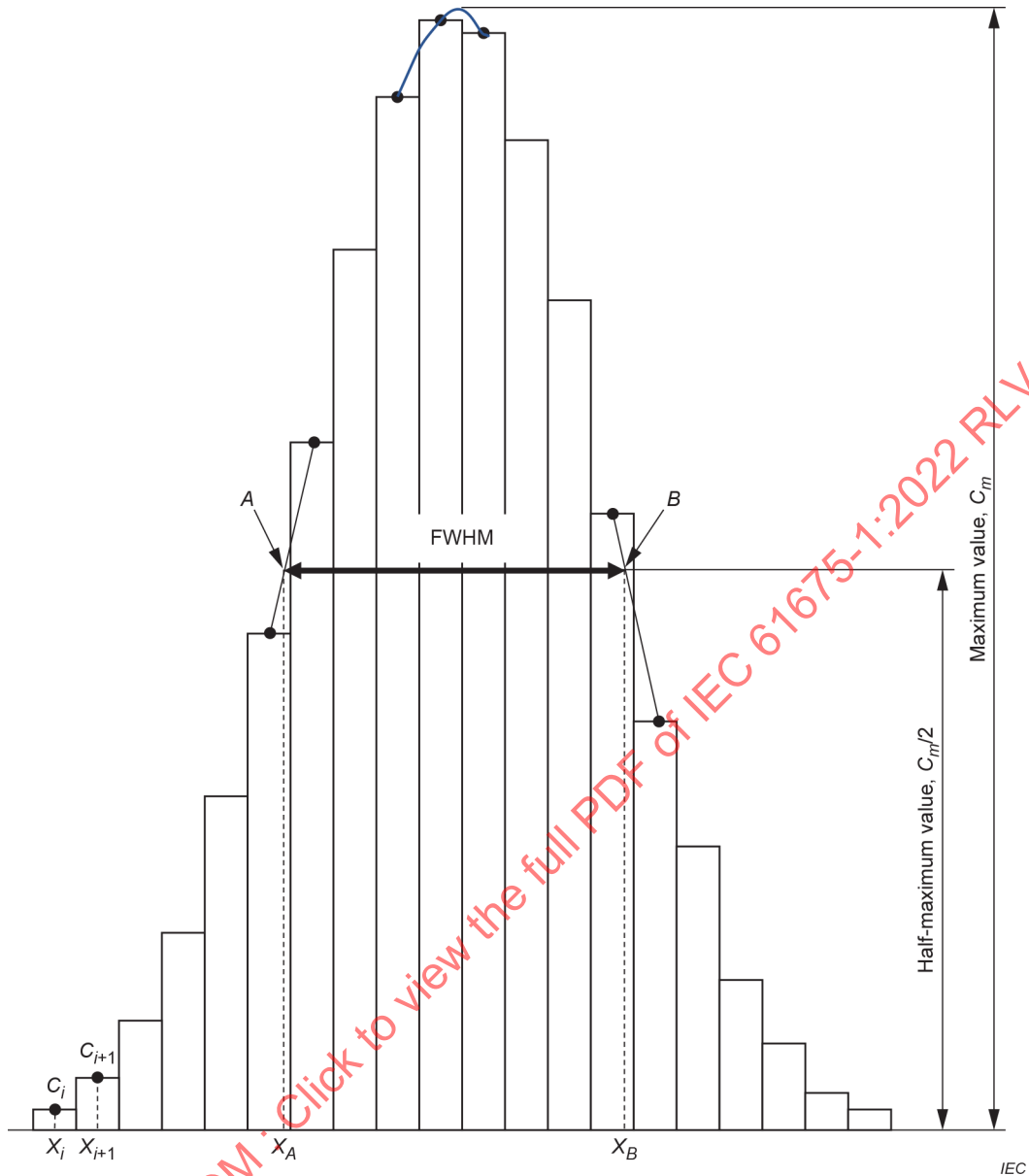
4.2.4 Analysis

The RADIAL RESOLUTION and the TANGENTIAL RESOLUTION shall be determined by forming one-dimensional response functions. These response functions shall be created by taking profiles from the TRANSVERSE POINT SPREAD FUNCTION through the reconstructed 3D-image of each POINT SOURCE in radial and tangential directions passing through the peak of the distribution. The width of each profile shall be two times the expected FWHM in both directions perpendicular to the direction of the analysis.

The AXIAL RESOLUTION of the POINT SOURCE measurements shall be determined by forming one-dimensional response functions (AXIAL POINT SPREAD FUNCTIONS), which result from taking profiles through the reconstructed 3D-image in the axial direction passing through the peak of the distribution. The width of each profile shall be two times the expected FWHM in both directions perpendicular to the direction of the analysis.

Each 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 1). The maximum PIXEL value C_m shall be determined by a parabolic fit using the peak point and its two nearest neighbours. Values shall be converted to millimetre units by multiplication with the appropriate PIXEL width.

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NOTE C_m is the maximum value of the interpolation curve, A and B are the points where the interpolation count curve cuts the line of half-maximum value. Then $FWHM = X_B - X_A$.

Figure 1 – Evaluation of FWHM

Each EQUIVALENT WIDTH (EW) shall be measured from the corresponding response function. EW shall be calculated from Formula (1):

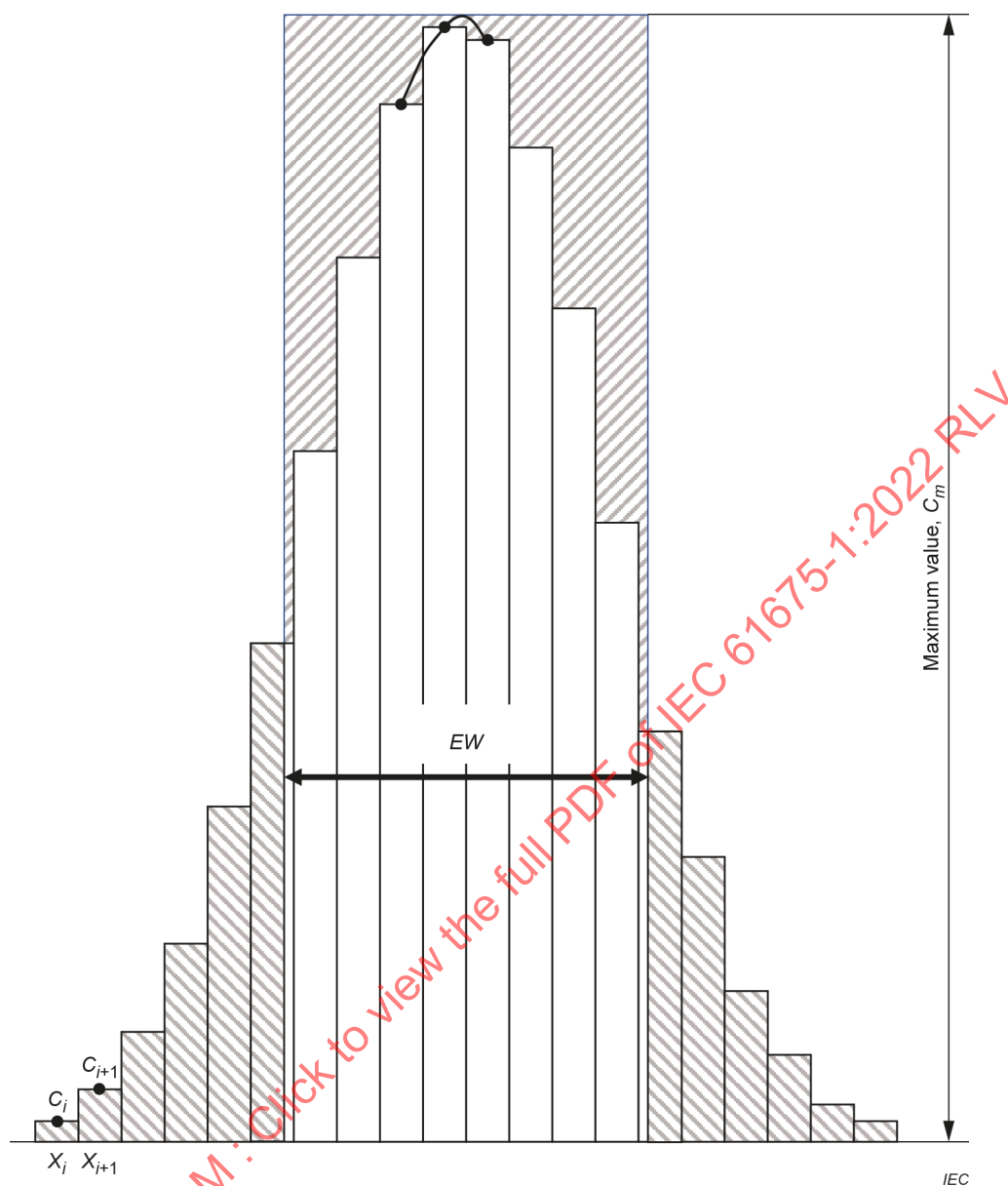
$$EW = \frac{PW}{C_m} \sum_i C_i \quad (1)$$

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 of the profile as determined in the FWHM calculation above, as opposed to the maximum pixel value among the pixel locations;

PW is the PIXEL width in millimetres (see Figure 2).



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

$$EW = \sum (C_i \times PW) / C_m$$

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

The areas shaded differently are equal.

Figure 2 – Evaluation of EQUIVALENT WIDTH (EW)

4.2.5 Report

RADIAL RESOLUTION, TANGENTIAL RESOLUTION, and AXIAL RESOLUTION ($FWHM$ and EW) for each POINT SOURCE position shall be calculated and reported. Transverse and axial PIXEL dimensions shall be reported.

If special reconstruction methods were used, the results of the tests shall be reported together with the exact description of the methodology.

4.3 Tomographic sensitivity

4.3.1 General

Tomographic sensitivity is a parameter that characterizes the rate at which coincidence events are detected in the presence of a RADIOACTIVE SOURCE in the limit of low ACTIVITY where COUNT LOSSES and RANDOM COINCIDENCES are negligible. The measured rate of TRUE COINCIDENCES for a given distribution of the RADIOACTIVE SOURCE depends upon many factors, including the detector material, size, and packing fraction, tomograph ring diameter, axial acceptance window and septa geometry, ATTENUATION, scatter, dead-time, and energy thresholds.

4.3.2 Purpose

The purpose of this measurement is to determine the detected rate of UNSCATTERED TRUE COINCIDENCES per unit of ACTIVITY concentration for a standard volume source, i.e., a cylindrical phantom of given dimensions.

4.3.3 Method

4.3.3.1 General

The tomographic sensitivity test places a specified volume of radioactive solution of known ACTIVITY in the TOTAL FIELD OF VIEW of the POSITRON EMISSION TOMOGRAPH and observes the resulting COUNT RATE. The system's sensitivity shall be calculated from these values. 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 finer than 10 %. Absolute reference standards using positron emitters should be considered if higher degrees of accuracy are required.

One of the later frames of the PET COUNT RATE PERFORMANCE test (4.5) can be used to determine the SLICE SENSITIVITY and VOLUME SENSITIVITY if the RADIONUCLIDE used for these measurements is ^{18}F .

4.3.3.2 RADIONUCLIDE

The RADIONUCLIDE used for these measurements shall be ^{18}F . The amount of ACTIVITY at the time of the tomographic sensitivity measurement shall be such that the percentage of COUNT LOSSES is less than 2 %.

4.3.3.3 RADIOACTIVE SOURCE distribution

The test phantom shall be a solid right circular cylinder composed of polyethylene with a specific density of $(0,96 \pm 0,01) \text{ g/cm}^3$, with an outside diameter of $(203 \pm 3) \text{ mm}$, and with an overall length of $(700 \pm 5) \text{ mm}$. A $(6,5 \pm 0,3) \text{ mm}$ hole is drilled parallel to the central axis of the cylinder, at a radial distance of $(45 \pm 1) \text{ mm}$. For ease of fabrication and handling, the cylinder may consist of several segments that are assembled together during testing. However, in both design and assembly of the completed phantom, adjacent segments shall be fit tightly together, as even very small gaps will allow narrow axial regions of scatter-free radiation.

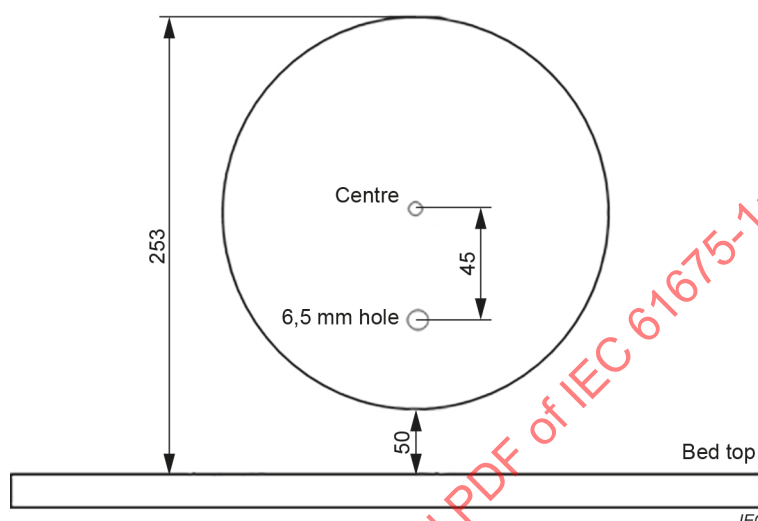
The test phantom LINE SOURCE insert shall be a clear polyethylene or polyethylene coated plastic tube $(800 \pm 5) \text{ mm}$ in length, with an inside diameter of $(3,2 \pm 0,2) \text{ mm}$ and an outside diameter of $(4,8 \pm 0,2) \text{ mm}$.

The test phantom LINE SOURCE insert shall be filled with water well mixed with the measured amount of ACTIVITY to a length of $(700 \pm 5) \text{ mm}$ and sealed at both ends. This LINE SOURCE shall be inserted into the hole of the test phantom such that the ACTIVITY of the LINE SOURCE matches the length of the polyethylene phantom. The test phantom with LINE SOURCE shall be mounted on the standard patient bed supplied by the MANUFACTURER. The phantom shall be raised $(5 \pm 0,5) \text{ cm}$ above the patient bed, using a mounting means such as foam blocks placed outside the AXIAL FIELD OF VIEW, and rotated such that the LINE SOURCE insert is positioned nearest to

the patient bed (see Figure 3). The patient bed shall be positioned $(15,2 \pm 0,5)$ cm below the centre of the TRANSVERSE FIELD OF VIEW, so that the phantom is centred in the TRANSVERSE FIELD OF VIEW.

If the phantom cannot be centred as described above, then mounting blocks of other dimensions may be used to centre the phantom in the transverse field of view. The distance of the table from the centre of the transverse field of view shall be reported.

Dimensions in millimetres



NOTE The 6,5 mm hole is for insertion of the LINE SOURCE.

Figure 3 – Scatter phantom configuration and position on the imaging bed

4.3.3.4 Data collection

Each coincident event between individual detectors shall be taken into account only once. Data are assembled into SINOGRAMS. All events shall be assigned to the transverse slice passing the midpoint of the corresponding LINE OF RESPONSE.

At least 500 000 true coincident counts are acquired.

4.3.3.5 Data processing

The ACTIVITY concentration in the phantom shall be corrected for decay to determine the average ACTIVITY concentration, a_{ave} , during the data acquisition time, T_{acq} , by the following Formula (2):

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

where

- V is the nominal volume of the test phantom ($22\,700\text{ cm}^3$);
- A_{cal} is the ACTIVITY times branching ratio ("positron activity") measured at time T_{cal} ;
- T_0 is the acquisition start time;
- $T_{1/2}$ is the RADIOACTIVE HALF-LIFE of the RADIONUCLIDE.

No corrections for detector normalization, COUNT LOSS, SCATTERED TRUE COINCIDENCES, and ATTENUATION shall be applied. The data shall be corrected for RANDOM COINCIDENCES.

4.3.4 Analysis

All PIXELS in the SINOGRAM located further than 25 cm from the SYSTEM AXIS shall be set to zero.

The total counts $C_{i,tot}$ on each slice i shall be obtained by summing all PIXELS in the corresponding SINOGRAM. The SLICE SENSITIVITY S_i for unscattered events shall be found by the following Formula (3):

$$S_i = \frac{C_{i,tot}}{T_{acq}} \frac{(1 - SF_i)}{a_{ave}} \quad (3)$$

where

SF_i is the corresponding SCATTER FRACTION (see 4.4).

The VOLUME SENSITIVITY, S_{tot} , shall be the sum of S_i over all slices of the tomograph within the AXIAL FIELD OF VIEW.

4.3.5 Report

The VOLUME SENSITIVITY S_{tot} shall be reported. A graph of SLICE SENSITIVITY S_i values shall be reported.

4.4 Scatter measurement

4.4.1 General

The scattering of photons created in the annihilation of positrons results in coincidence events with false information for radiation source localization. Variations in design and implementation cause POSITRON EMISSION TOMOGRAPHS to have different sensitivities to scattered radiation.

4.4.2 Purpose

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_j .

4.4.3 Method

4.4.3.1 General

The test phantom shall be a solid right circular cylinder composed of polyethylene with a specific density of $(0,96 \pm 0,01)$ g/cm³, with an outside diameter of (203 ± 3) mm, and with an overall length of (700 ± 5) mm. A $(6,5 \pm 0,3)$ mm hole shall be drilled parallel to the central axis of the cylinder, at a radial distance of (45 ± 1) mm. For ease of fabrication and handling, the cylinder may consist of several segments that shall be assembled together during testing. However, in both design and assembly of the completed phantom, adjacent segments shall fit tightly together, as even very small gaps will allow narrow axial regions of scatter-free radiation.

One of the later frames of the PET COUNT RATE PERFORMANCE test (4.5) may be used to determine the SCATTER FRACTION.

4.4.3.2 RADIONUCLIDE

The RADIONUCLIDE for the measurement shall be ^{18}F or ^{11}C with an ACTIVITY such that the percentage of COUNT LOSSES is less than 5 %.

4.4.3.3 RADIOACTIVE SOURCE distribution

The test phantom LINE SOURCE insert shall be a clear polyethylene or polyethylene coated plastic tube (800 ± 5) mm in length, with an inside diameter of ($3,2 \pm 0,2$) mm and an outside diameter of ($4,8 \pm 0,2$) mm. This tube shall be filled with a known quantity of ACTIVITY and threaded through the 6,5 mm hole in the test phantom.

The test phantom LINE SOURCE insert shall be filled with water well mixed with the measured amount of ACTIVITY to a length of (700 ± 5) mm and sealed at both ends. This LINE SOURCE shall be inserted into the hole of the test phantom such that the ACTIVITY of the LINE SOURCE matches the length of the polyethylene phantom.

The test phantom with LINE SOURCE shall be mounted on the standard patient bed supplied by the MANUFACTURER. The phantom shall be raised ($5 \pm 0,5$) cm above the patient bed, using a mounting means such as foam blocks placed outside the AXIAL FIELD OF VIEW, and shall be rotated such that the LINE SOURCE insert is positioned nearest to the patient bed (see Figure 3). The phantom shall be centred in the TRANSVERSE FIELD OF VIEW by raising or lowering the bed.

If the phantom cannot be centred as described above, then mounting blocks of other dimensions may be used to centre the phantom in the transverse field of view. The distance of the table from the centre of the transverse field of view shall be reported.

4.4.3.4 Data collection

Each coincident event between individual detectors shall be taken into account only once. Data shall be assembled into SINOGRAMS. All events shall be assigned to the slice at the midpoint of the corresponding LINE OF RESPONSE. The acquisition shall contain a minimum of 500 000 true coincident counts.

4.4.3.5 Data processing

No corrections for variations in detector sensitivity, SCATTERED TRUE COINCIDENCES, COUNT LOSS, or ATTENUATION shall be applied to the measurements.

The data shall be corrected for RANDOM COINCIDENCES.

4.4.4 Analysis

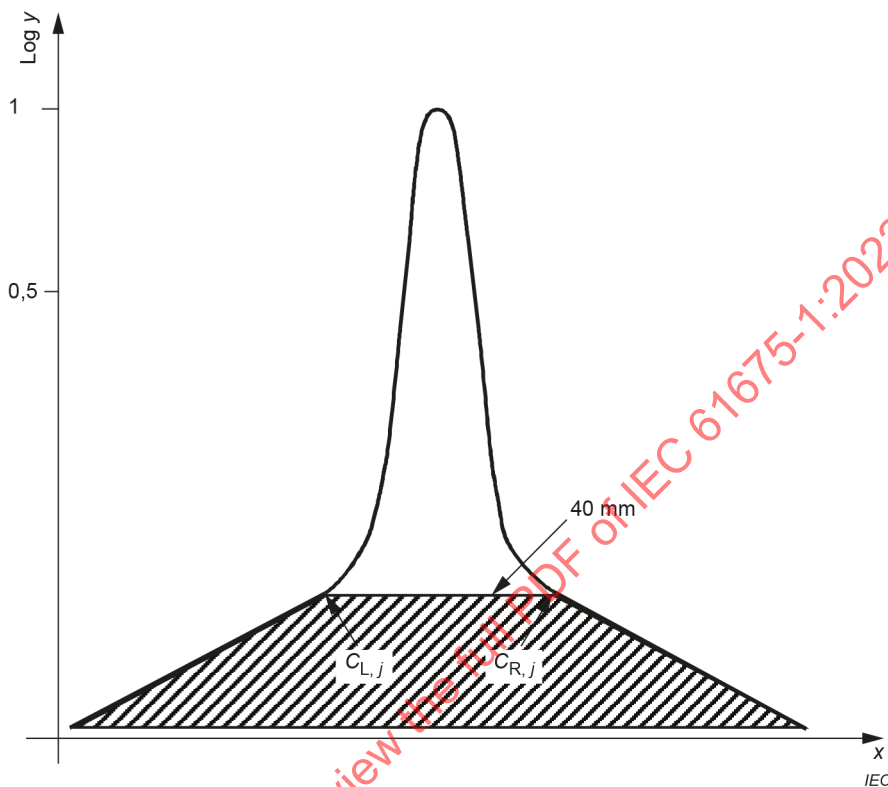
For tomographs with an AXIAL FIELD OF VIEW of 65 cm or less, SINOGRAMS of TRUE COINCIDENCES shall be generated for each acquisition i of slice j . For tomographs with an AXIAL FIELD OF VIEW greater than 65 cm, SINOGRAMS of TRUE COINCIDENCES shall be generated for each acquisition for slices within the central 65 cm.

Oblique SINOGRAMS shall be collapsed into a single SINOGRAM for each respective slice (by single-slice rebinning) while conserving the number of counts in the SINOGRAM.

The SINOGRAM j of TRUE COINCIDENCES shall be processed as follows.

- a) All PIXELS located further than 25 cm from the SYSTEM AXIS shall be set to zero.
- b) For each PROJECTION ANGLE ϕ within the SINOGRAM, the location of the centre of the LINE SOURCE response shall be determined by finding the PIXEL having the greatest value. Each PROJECTION shall be shifted so that the PIXEL containing the maximum value is aligned with the central PIXEL of the SINOGRAM.

- c) After alignment, a sum projection shall be produced. A PIXEL in the sum projection shall be the sum of the PIXELS in each angular PROJECTION having the same radial offset as the PIXEL in the sum projection.
- d) The counts $C_{L,j}$ and $C_{R,j}$, the left and right PIXEL intensities at the edges of the strip with a width of ± 20 mm from the centre of the profile calculated in (b), shall be obtained (see Figure 4). Linear interpolation shall be employed to find $C_{L,j}$ and $C_{R,j}$.



In the summed projection, the scatter shall be estimated by the counts outside the 40 mm wide strip plus the area below the line $C_{L,j} - C_{R,j}$.

Figure 4 – Evaluation of SCATTER FRACTION

- e) The average of the two PIXEL intensities $C_{L,j}$ and $C_{R,j}$ shall be multiplied by the number of PIXELS, including fractional values, corresponding to the width of the strip, and the product shall be added to the sum of counts in the PIXELS outside the strip, to yield the number of scatter counts $C_{s,j}$ for the slice j .
- f) The TRUE COINCIDENCES $C_{TOT,j}$ shall be computed as the sum of all counts in the sum projection for slice j . The TRUE COINCIDENCES include SCATTERED TRUE COINCIDENCES and UNSCATTERED TRUE COINCIDENCES.

The SCATTER FRACTION SF_j for each slice shall be calculated as shown in Formula (4):

$$SF_j = \frac{C_{s,j}}{C_{TOT,j}} \quad (4)$$

The SCATTER FRACTION SF shall be computed by Formula (5):

$$SF = \frac{\sum_j C_{s,j}}{\sum_j C_{TOT,j}} \quad (5)$$

4.4.5 Report

The SCATTER FRACTION SF shall be reported (Formula (5)). A graph of SF_j values shall be reported (calculated from Formula (4)).

4.5 PET COUNT RATE PERFORMANCE

4.5.1 General

PET COUNT RATE PERFORMANCE depends in a complex manner on the spatial distribution of ACTIVITY and scattering materials, on the trues-to-singles ratio, on the COUNT RATE CHARACTERISTIC of the SINGLES RATE, and on the setup of the measurement conditions. In addition, COUNT RATE performance is strongly influenced by the amount of RANDOM COINCIDENCES and by the accuracy of the subtraction of these events.

4.5.2 Purpose

The procedure described here is designed to evaluate deviations from the linear relationship between COUNT RATE of TRUE COINCIDENCES and ACTIVITY caused by COUNT LOSSES. As modern PET tomographs are operated with COUNT LOSS correction schemes, the accuracy of these correction algorithms is also tested.

4.5.3 Method

4.5.3.1 General

The test phantom shall be a solid right circular cylinder composed of polyethylene with a specific density of $(0,96 \pm 0,01) \text{ g/cm}^3$, with an outside diameter of $(203 \pm 3) \text{ mm}$, and with an overall length of $(700 \pm 5) \text{ mm}$. A $(6,5 \pm 0,3) \text{ mm}$ hole is drilled parallel to the central axis of the cylinder, at a radial distance of $(45 \pm 1) \text{ mm}$. For ease of fabrication and handling, the cylinder may consist of several segments that shall be assembled together during testing. However, in both design and assembly of the completed phantom, one shall ensure a tight fit between adjacent segments, as even very small gaps will allow narrow axial regions of scatter-free radiation.

4.5.3.2 RADIONUCLIDE and ACTIVITY

The RADIONUCLIDE for the measurement shall be ^{18}F or ^{11}C . The variation of ACTIVITY shall be obtained by radioactive decay. The last frame shall be acquired with a COUNT LOSS of less than 1 %. The initial amount of ACTIVITY shall be high enough to allow for the following two rates to be measured:

- a) $R_{t,\max}$ – maximum COUNT RATE of TRUE COINCIDENCES;
- b) $R_{\text{NEC},\max}$ – maximum noise equivalent count rate.

Recommendations for the initial ACTIVITY required to meet these objectives shall be supplied by the MANUFACTURER.

4.5.3.3 RADIOACTIVE SOURCE distribution

The test phantom LINE SOURCE insert shall be a clear polyethylene or polyethylene coated plastic tube $(800 \pm 5) \text{ mm}$ in length, with an inside diameter of $(3,2 \pm 0,2) \text{ mm}$ and an outside diameter of $(4,8 \pm 0,2) \text{ mm}$. This tube shall be filled with a known quantity of ACTIVITY and threaded through the $6,5 \text{ mm}$ hole in the test phantom.

The test phantom LINE SOURCE insert shall be filled with water well mixed with the measured amount of ACTIVITY to a length of (700 ± 5) mm and sealed at both ends. The test phantom with LINE SOURCE shall be mounted on the standard patient bed supplied by the MANUFACTURER. The phantom shall be raised $(5 \pm 0,5)$ cm above the patient bed, using a mounting means such as foam blocks placed outside the AXIAL FIELD OF VIEW, and shall be rotated such that the LINE SOURCE insert is positioned nearest to the patient bed (see Figure 3). The phantom shall be centred in the TRANSVERSE FIELD OF VIEW by raising or lowering the bed.

If the phantom cannot be centred as described above, then mounting blocks of other dimensions may be used to centre the phantom in the transverse field of view. The distance of the table from the centre of the transverse field of view shall be reported.

The test phantom shall be placed in the field of view of the POSITRON EMISSION TOMOGRAPH. Regular measurements (at least two per RADIOACTIVE HALF-LIFE) shall then be taken while the ACTIVITY in the phantom decays over several RADIOACTIVE HALF-LIVES. A decrease in the event rate accompanies the ACTIVITY decay. In addition, the efficiency of the system in processing coincident events improves as the ACTIVITY decays, until COUNT LOSSES may be effectively neglected. Thus, by waiting long enough, one obtains a measurement of the COUNT RATE of TRUE COINCIDENCES that is effectively free from processing losses. By extrapolating this COUNT RATE of TRUE COINCIDENCES back to higher ACTIVITY levels and comparing it to the COUNT RATE of TRUE COINCIDENCES measured at these higher ACTIVITY levels, one may estimate COUNT LOSSES suffered by the system at higher ACTIVITY levels. The accuracy of this technique depends critically on adequate statistics being gathered at sufficiently low levels of ACTIVITY. This may require repeated measurements at the lower COUNT RATES. Recommendations for the acquisition protocol required to meet these objectives shall be supplied by the MANUFACTURER.

4.5.3.4 DATA COLLECTION

Each coincident event between individual detectors shall be taken into account only once.

If the data are also to be used to calculate TOF RESOLUTION for 4.6, then the data shall be acquired in TOF acquisition mode.

4.5.4 Analysis

4.5.4.1 Test of the PET COUNT RATE PERFORMANCE

4.5.4.1.1 General

Data shall be assembled into SINOGRAMS. All events shall be assigned to the slice at the midpoint of the corresponding LINE OF RESPONSE.

No corrections for variations in detector sensitivity, scatter, COUNT LOSS, or ATTENUATION shall be applied to the measurements.

For tomographs with an AXIAL FIELD OF VIEW of 65 cm or less, SINOGRAMS of TRUE COINCIDENCES shall be generated for each acquisition i of slice j . For tomographs with an AXIAL FIELD OF VIEW greater than 65 cm, SINOGRAMS of TRUE COINCIDENCES shall be generated for each acquisition for slices within the central 65 cm.

4.5.4.1.2 Test

The relationship between COUNT RATE and ACTIVITY within the TOTAL FIELD OF VIEW of the tomograph shall be measured. The time per frame shall be less than one-half of the RADIOACTIVE HALF-LIFE with the exception of the last three frames, which may be longer. For each of these last three frames, a minimum of 500 000 true coincident counts shall be acquired.

The initial ACTIVITY in the phantom shall be determined from the ACTIVITY injected into the phantom as measured in a calibrated dose calibrator.

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 Formula (6):

$$A_{ave,i} = A_{cal} \frac{1}{\ln 2} \frac{T_{1/2}}{T_{acq,i}} \exp \left[\frac{T_{cal} - T_{0,i}}{T_{1/2}} \ln 2 \right] \left[1 - \exp \left(- \frac{T_{acq,i}}{T_{1/2}} \ln 2 \right) \right] \quad (6)$$

where

A_{cal} is the ACTIVITY times branching ratio ("positron 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 ^{18}F or ^{11}C , respectively.

The SINOGRAMS shall be analysed without COUNT LOSS correction. All PIXELS in the acquired SINOGRAM and in the corresponding randoms estimate SINOGRAMS located further than 25 cm from the SYSTEM AXIS shall be set to zero.

For each time frame i , the total counts acquired, $N_{TOT,i}$, and the total randoms estimated, $N_{r,i}$, shall be computed as the sum of the remaining data.

For each time frame i , $R_{TOT,i}$, $R_{r,i}$, and $R_{t,i}$ shall be computed.

a) $R_{TOT,i} = N_{TOT,i} / T_i$

b) $R_{r,i} = N_{r,i} / T_i$

c) $R_{t,i} = (1 - SF) \times (N_{TOT,i} - N_{r,i}) / T_i$

where

SF is the scatter fraction as calculated in 4.4.4;

T_i is the acquisition time for frame i .

The noise equivalent count rate (NECR), $R_{NEC,i}$ for each time frame shall be calculated as:

$$R_{NEC,i} = R_{t,i}^2 / (R_{TOT,i} + R_{r,i}) \quad (7)$$

The maximum NECR, $R_{NEC,max}$ shall be reported, as well as the corresponding ACTIVITY, $A_{NEC,max}$.

4.5.4.2 Test of COUNT LOSS correction scheme

4.5.4.2.1 General

For tomographs with an AXIAL FIELD OF VIEW of 65 cm or less, all slices shall be reconstructed. For tomographs with an AXIAL FIELD OF VIEW greater than 65 cm, only slices in the central 65 cm shall be reconstructed. Attenuation, scatter, COUNT LOSS and randoms correction shall be applied to the data. Images shall be reconstructed using standard methods without decay correction.

4.5.4.2.2 Test

All analyses shall be performed on each reconstructed image i,j . The average ACTIVITY $A_{ave,i}$ for each acquisition i shall be calculated. The average effective ACTIVITY concentration $A_{eff,i}$ for each acquisition i shall be computed by dividing $A_{ave,i}$ by $22\,700\text{ cm}^3$, which is the volume of the test phantom.

A circular REGION OF INTEREST (ROI) centred on the TRANSVERSE FIELD OF VIEW (*not* centred on the LINE SOURCE) with a diameter of 18 cm shall be drawn on the reconstructed image for each slice j . $\Gamma_{\text{ROI},i,j}$ is the average activity concentration in the ROI for each slice j and acquisition i .

For each slice j , the best fit ROI value $\Gamma_{\text{Fit},i,j}$, shall be calculated by the following Formula (8):

$$\Gamma_{\text{Fit},i,j} = \frac{A_{\text{ave},i}}{I} \sum_{k=1}^I \frac{\Gamma_{\text{ROI},i,k}}{A_{\text{ave},k}} \quad (8)$$

where I shall be the total number of acquisitions with activity at or below maximum NECR ($R_{\text{NEC,max}}$) as determined in 4.5.4.1.2, and the sum shall be computed over each acquisition k .

For each slice j of each acquisition i , the relative COUNT RATE error $\Delta\gamma_{i,j}$ in percentage units shall be calculated by the following Formula (9):

$$\Delta\gamma_{i,j} = \Gamma_{\text{ROI},i,j} / \Gamma_{\text{Fit},i,j} - 1 \quad (9)$$

4.5.5 Report

4.5.5.1 PET COUNT RATE PERFORMANCE (see 4.5.4.1)

For the system, the following four quantities as a function of the average effective ACTIVITY concentration $A_{\text{ave},i}$ shall be plotted:

- a) $R_{t,i}$ – COUNT RATE of TRUE COINCIDENCES;
- b) $R_{r,i}$ – COUNT RATE of RANDOM COINCIDENCES;
- c) $R_{\text{NEC},i}$ – noise equivalent count rate NECR;
- d) $R_{\text{TOT},i}$ – COUNT RATE of TOTAL COINCIDENCES.

The following values, derived from the above plot, shall be reported:

- a) $R_{t,\text{max}}$ – maximum COUNT RATE of TRUE COINCIDENCES;
- b) $R_{\text{NEC},\text{max}}$ – maximum noise equivalent count rate;
- c) $A_{t,\text{max}}$ – the ACTIVITY concentration at which $R_{t,\text{max}}$ is reached;
- d) $A_{\text{NEC},\text{max}}$ – the ACTIVITY concentration at which $R_{\text{NEC},\text{max}}$ is reached.

The method used for estimating RANDOM COINCIDENCES shall be reported.

4.5.5.2 Accuracy of COUNT LOSS correction (see 4.5.4.2)

A graph of the highest and lowest values among the slices of $\Delta\gamma_{i,j}$ versus $A_{\text{eff},i}$ shall be plotted using a linear scale. The data points may be joined to form a continuous curve.

The maximum value of the bias $|\Delta\gamma_{i,j}|$ in the ACTIVITY range up to the $A_{\text{NEC},\text{max}}$ shall be reported.

4.6 Time-of-flight resolution

4.6.1 General

Time-of-flight data are used to localize the annihilation point along the LINE-OF-RESPONSE during reconstruction.

NOTE 1 The measurement of TOF RESOLUTION is only applicable to those systems that offer TOF acquisition.

NOTE 2 TOF resolution does not characterize the reconstruction process or effect of TOF reconstruction on the image.

4.6.2 Purpose

The purpose of this procedure is to characterize the TOF RESOLUTION.

4.6.3 Method

TOF RESOLUTION shall be measured from the data acquired in 4.5.

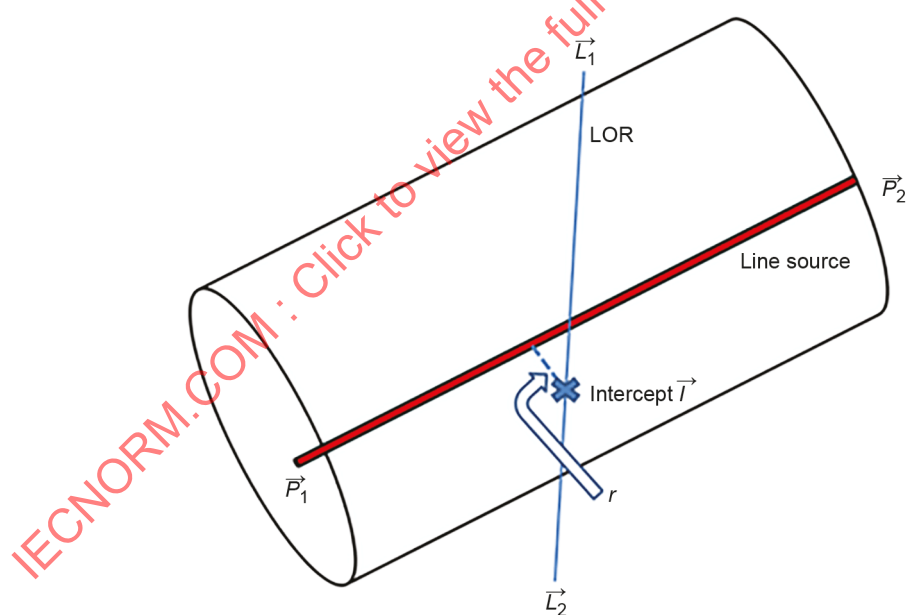
Figure 5 shows the geometry used in the processing and analysis of the coincidence data.

4.6.4 Radionuclide, source distribution and data collection

See 4.5.

4.6.5 Data processing

For PET scanners with an AXIAL FIELD OF VIEW of 65 cm or less, data from all slices shall be considered. For PET scanners with an AXIAL FIELD OF VIEW greater than 65 cm, only axial slices in the central 65 cm shall be considered. No corrections for detector sensitivity variation, scatter, random, deadtime or attenuation shall be applied to the measurements, except while reconstructing the images used to localize the line source in 4.6.6.1.



IEC

Key

r shortest distance between LOR and line source

The intercept of the LOR with the line source shall be defined as the point along the LOR with the shortest distance to the line source.

Figure 5 – Determination of LOR distance from line source

4.6.6 Analysis

4.6.6.1 Identifying the line source position

The first frame of the dynamic sequence where the activity is below the maximum NECR, $R_{\text{NEC,max}}$, shall be reconstructed with all available corrections except for decay correction and a pixel size in the transverse slice not to exceed 2,5 mm, forming images in the PET coordinate system. The location of the line source shall be determined by a centroid calculation on all transverse slices, except for those within 10 mm of either end of the axial field of view. A line shall be used to fit with these centroid positions. The intersection of the line with the first and the last transverse slices defines the two points $\vec{P}_1$ and $\vec{P}_2$, respectively. The unit vector $\vec{v}$ for the line shall be calculated as:

$$\vec{v} = \frac{\vec{P}_2 - \vec{P}_1}{|\vec{P}_2 - \vec{P}_1|}$$

Images reconstructed for the count rate correction accuracy test in 4.5.4.2 may be used.

4.6.6.2 Evaluation of time differences

4.6.6.2.1 General

The following analysis shall be performed on each time frame of the test phantom data beginning with the last frame acquired above the maximum NECR, $R_{\text{NEC,max}}$ as measured in 4.5, and continuing through all frames with at least 500 000 prompt events acquired.

4.6.6.2.2 2-D histogram formation

Each event shall be accumulated into one 2-D histogram for each acquisition j . The 2-D histograms shall be centred on zero in both the time and spatial dimensions. The bin sizes Δt and Δr shall be less than one-fourth of the expected FWHM of the timing and spatial distributions, respectively.

For each coincidence event in the data set, $\vec{L}_1$ and $\vec{L}_2$ shall be defined as three-dimensional coordinates of two points along the line in PET coordinates representing the coincidence event, as used in image reconstruction (see Figure 5). Then, the following calculations shall be performed.

a) Compute the unit vector $\vec{u}$ from $\vec{L}_1$ to $\vec{L}_2$:

$$\vec{u} = \frac{\vec{L}_2 - \vec{L}_1}{|\vec{L}_2 - \vec{L}_1|}$$

b) Compute the distance r' between the coincidence line and the line source:

$$r = (\vec{L}_1 - \vec{P}_1) \cdot \frac{\vec{u} \times \vec{v}}{|\vec{u} \times \vec{v}|}$$

If $|r'| > (20 + \Delta r)$ mm, this event shall be excluded from the 2-D histogram formation. Otherwise, continue.

c) Compute the point $\vec{l}$ on the coincidence line closest to the line source:

$$\bar{l} = \bar{L}_1 + \frac{(\bar{L}_1 - \bar{P}_1) \cdot (\bar{u} - \bar{v}(\bar{u} \cdot \bar{v}))}{|\bar{u} \cdot \bar{v}|^2 - 1} \bar{u}.$$

- d) Compute the timing error t' as the difference between the measured timing data for the event and its expected timing offset:

$$t' = (t_1 - t_2) - \frac{|\bar{L}_1 - \bar{l}| - |\bar{L}_2 - \bar{l}|}{c}.$$

- e) Compute τ and ρ as:

$$\tau = \text{int}\left(\frac{t' - \Delta t}{\Delta t}\right)$$

$$\rho = \text{int}\left(\frac{r' - \Delta r}{\Delta r}\right).$$

In this context, the function "int" means "round to the nearest integer". Each event shall be accumulated into one 2-D histogram $C_j(\tau, \rho)$ for each acquisition j .

4.6.7 Scatter and random removal

For each timing bin τ of each acquisition j , the following shall be done.

- Determine the counts per pixel, $C_{L,\tau,j}$ and $C_{R,\tau,j}$, at the left and right edges, respectively, of the 40 mm wide strip at the centre of $C_j(\tau, \rho)$. If these points do not correspond to sample locations of $C_j(\tau, \rho)$, these values are found by linear interpolation (see Figure 4).
- Form the 1D timing histogram $C_j(\tau)$ by summing contributions from all radial bins in the 40 mm wide strip and correcting for the background:

$$C_j(\tau) = \sum_{\rho} \left\{ C_j(\tau, \rho) - \left[\frac{20 - \rho}{40} \right] C_{L,\tau,j} + \left[\frac{\rho + 20}{40} \right] C_{R,\tau,j} \right\}$$

4.6.8 FWHM analysis

Each 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 1). The maximum PIXEL value $C_j(t)$ shall be determined by a parabolic fit using the peak point and its two nearest neighbours. Values are converted to time units by multiplication with Δt .

4.6.9 Report

The following items shall be reported.

- TOF resolution ($FWHM_{\text{TOF}}(j)$), plotted as a function of the effective radioactivity concentration $A_{\text{ave}}(j)$, where the volume V is the total volume of the cylindrical phantom (22 700 ml).
- TOF resolution ($FWHM_{\text{TOF}}$) at effective radioactivity concentration of 5,0 kBq/ml, determined by linear interpolation from the values of $A_{\text{ave}}(j)$ immediately above and below 5,0 kBq/ml.

4.7 Image quality and quantification accuracy of source ACTIVITY concentrations and PET/CT registration accuracy

4.7.1 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, scatter and randoms. The contrast resolution is affected by the noise present in the background surrounding a lesion.

4.7.2 Purpose

The purpose of 4.7 is to measure image quality factors and quantification accuracy of the PET scanner under normal imaging conditions. To mimic such normal imaging conditions, a torso shaped phantom is used containing multiple hot spheres of decreasing diameters and a cold cylinder insert in a warm background.

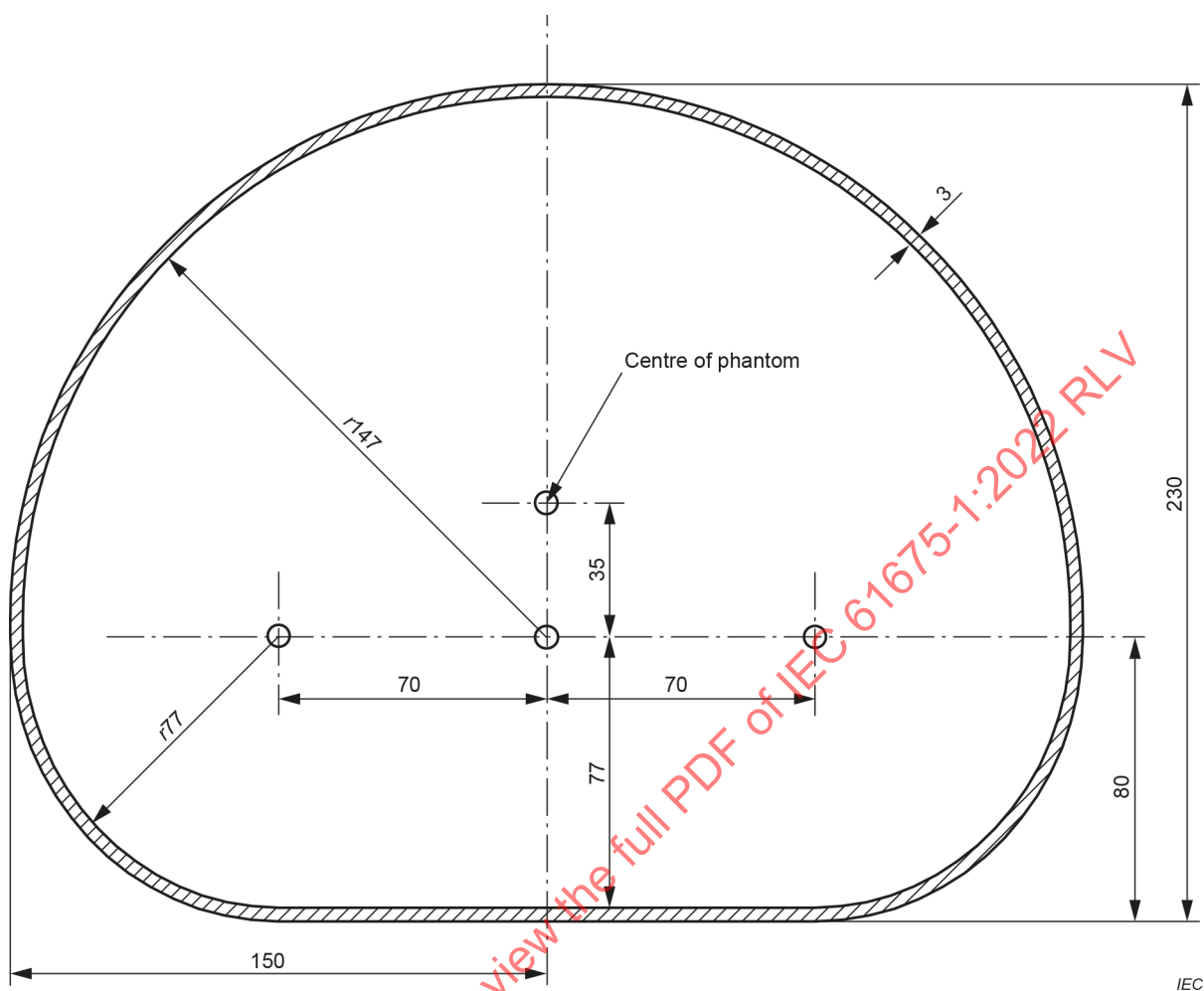
The contrast of the hot spheres is measured and compared to the noise in the background to assess lesion detectability. Quantification accuracy is determined by comparing the measured concentrations in the spheres, background, and lung cylinder insert to their true ACTIVITY concentrations. Additional measurements include assessing the ability of the scanner to quantify ACTIVITY concentration as a function of sphere size.

4.7.3 Method

4.7.3.1 General

The whole-body phantom shall be used for all measurements (see Figure 6) into which hollow spheres and lung insert shall be placed (see Figure 7).

Dimensions are in millimetres and are given within ± 1 mm

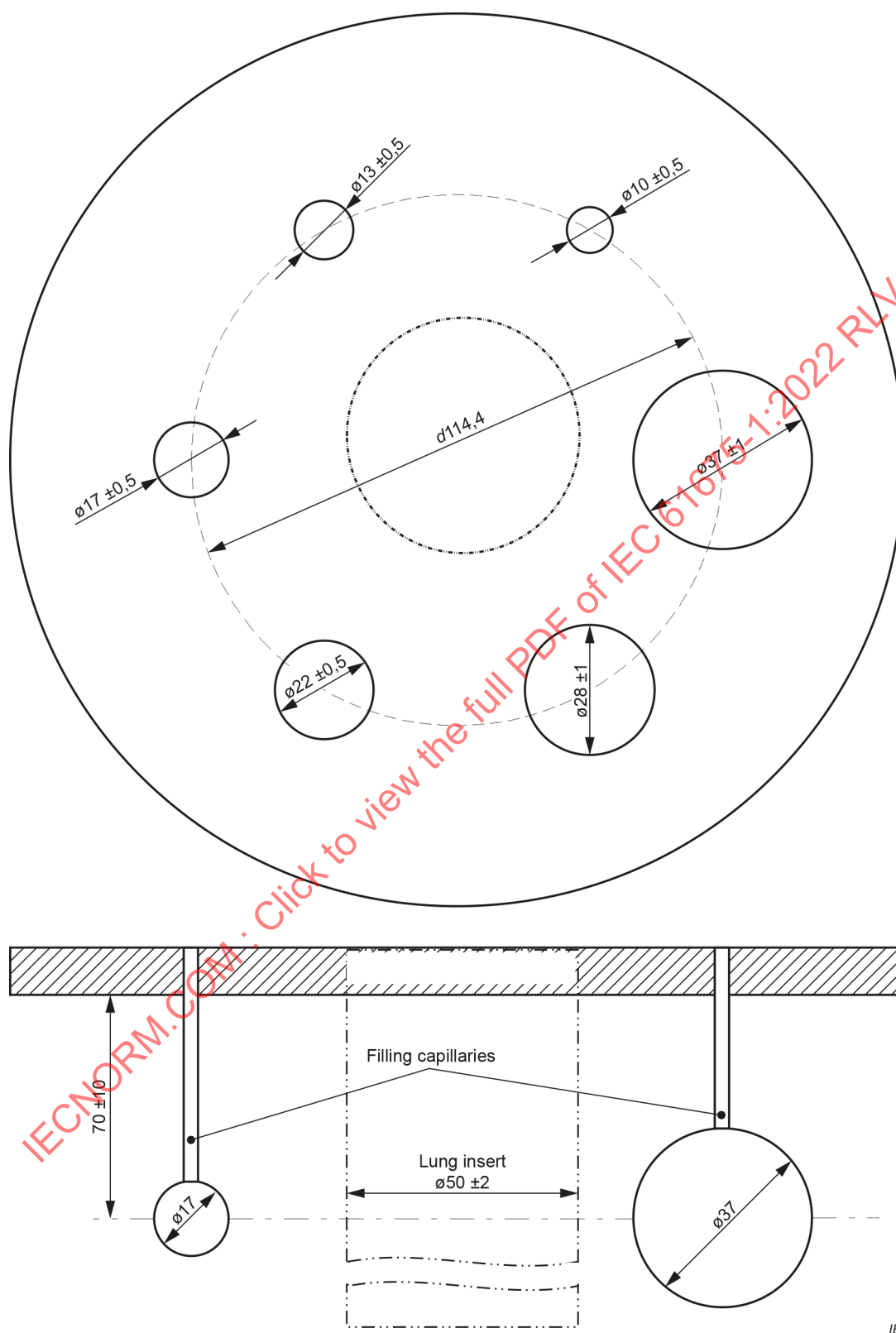


Material: polymethylmethacrylate.

The phantom length is at least $180 \text{ mm} \pm 5 \text{ mm}$.

Figure 6 – Cross-section of body phantom

Dimensions in millimetres



Material: polymethylmethacrylate.

All diameters given are inside diameters. The wall thickness of the spheres is ≤ 1 mm. The centres of the spheres are 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 $50 \text{ mm} \pm 2$ mm.

Figure 7 – Phantom insert with hollow spheres

The hollow spheres of decreasing diameter shall be arranged circularly and centred on a single plane and shall have hollow stems that extend through the outer plate to permit filling of the spheres with a radioactive liquid. The lung cylinder insert shall have a diameter of (50 ± 2) mm and extends through the length of the phantom chamber. The cylinder shall be filled with a low atomic number material of density of $(0,30 \pm 0,10)$ g/cm³, shall be void of ACTIVITY and shall simulate the ATTENUATION of the lung.

Abutted to the whole-body phantom at the head end (closer to the spheres), the scatter phantom with LINE SOURCE shall be inserted – see Figure 8 a) – and shall be used to simulate outside field of view source ACTIVITY. Known source ACTIVITY concentrations shall be added to all the fillable spheres, image quality phantom background, and scatter phantom with LINE SOURCE inserted. The ACTIVITY in the LINE SOURCE shall be chosen so that the effective ACTIVITY concentration in the scatter phantom including the LINE SOURCE is equal to the background ACTIVITY concentration in the image quality phantom.

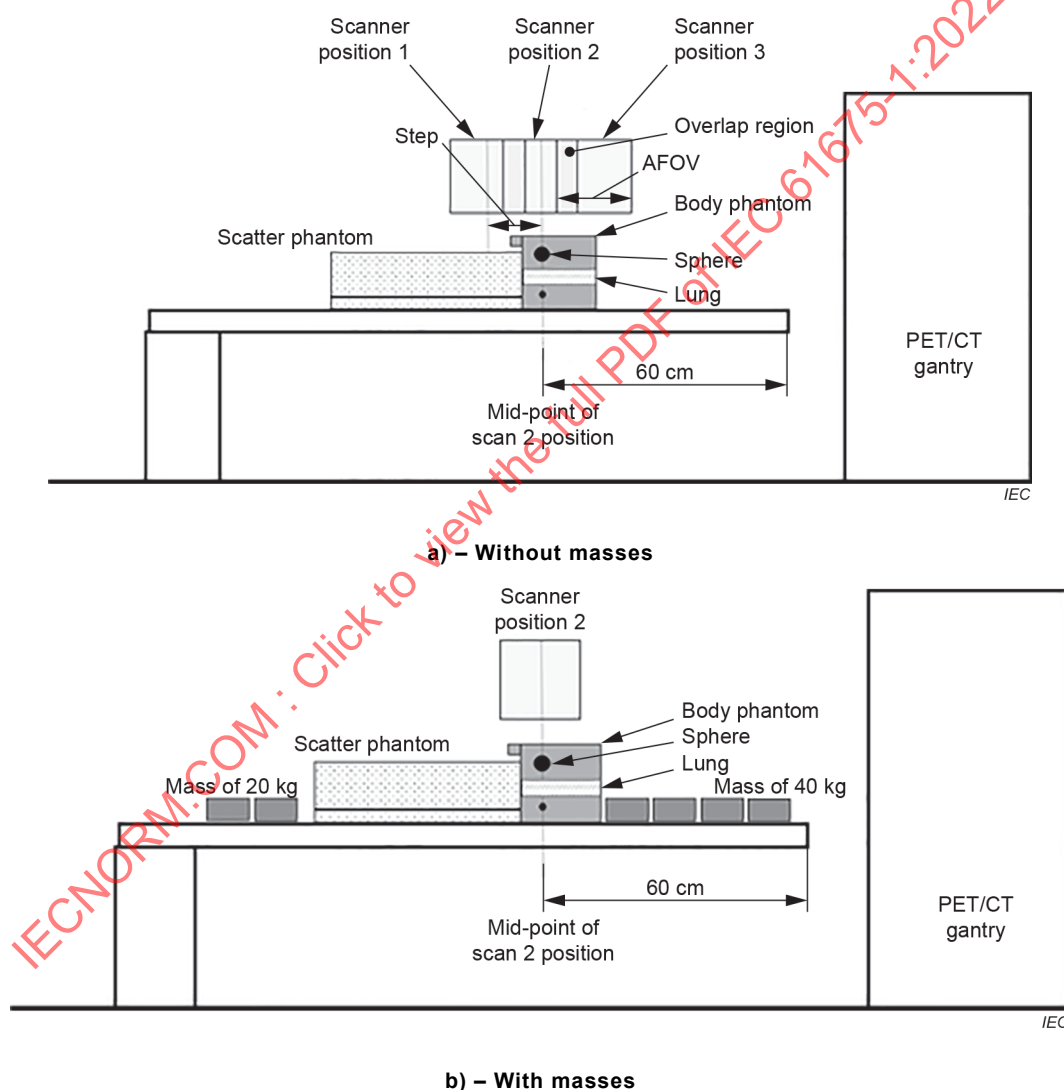


Figure 8 – Image quality phantom and scatter phantom position for whole body scan acquisition

A whole-body acquisition covering the length of the whole-body phantom shall be obtained.

The algorithms used for image reconstruction, scatter and ATTENUATION correction shall be those corresponding to the routine whole-body clinical image protocol. PIXEL values in units of kBq/ml shall be produced. Prior to this, a scanner CALIBRATION shall be conducted. Results for additional image reconstructions with enhancements may reported separately.

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

4.7.3.2 RADIONUCLIDE

The RADIONUCLIDE for the measurement shall be ^{18}F .

4.7.3.3 Source distribution

The ACTIVITY concentration in the whole-body phantom background shall be $(5 \pm 0,3)$ kBq/ml. The spheres shall be filled with an ACTIVITY concentration that is between 3,8 and 4,2 times the ACTIVITY concentration in the background. The LINE SOURCE in the scatter phantom shall be filled with an ACTIVITY of (110 ± 5) MBq. All ACTIVITY concentrations shall be specified for the time at the start of acquisition. The RADIONUCLIDE in all phantoms shall be well mixed.

NOTE These concentrations correspond to a typical clinical dosage of 350 MBq in a 70 kg PATIENT for whole body imaging.

The test is critically dependent upon the accurate assays of ACTIVITY to be used. The dose calibrator, where it is difficult to maintain an absolute CALIBRATION to accuracies finer than 10 %, may be used to assay starting ACTIVITY levels. Absolute reference standards using positron emitters may be considered if higher degrees of accuracy are required.

If the MANUFACTURER recommends a lower dosage for this test, the ACTIVITY concentration in all phantoms may be lowered proportionately. The report shall include the MANUFACTURER recommended dosage.

4.7.3.4 Data collection

The whole-body phantom shall be placed on the patient bed of the tomograph and shall be centred within the TRANSVERSE FIELD OF VIEW. The plane passing through the centre of the spheres in the whole-body phantom shall be aligned to the centre of the AXIAL FIELD OF VIEW. The line-source scatter phantom, set directly on the patient bed, shall abut to the head-end of the image quality phantom – see Figure 8 a). The distance of the centre of the spheres to the end of the bed shall be 60 cm.

A whole-body acquisition over the length of the whole-body phantom shall be performed. It is assumed that whole-body acquisition scan consists of multiple stationary scans with the standard overlap between scan positions. The "step size" is the axial distance the bed translates between positions and may be less than the AXIAL FIELD OF VIEW. At least three scan positions are required. Start position 1 shall be determined by scan position 2 which is axially centred over the transverse plane of the spheres. Position 1 shall be located towards the scatter phantom at a distance equal to the "step size" used in clinical whole body scans. The end scan at position 3 shall be where the scanner is moved a "step size" distance toward the opposite end of the image quality phantom so that the centre of the AXIAL FIELD OF VIEW is located beyond the end of the phantom. 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 in three steps.

The acquisition time T_p for a single position shall be computed as follows:

$$T_p = (d_{ax}/100 \text{ cm}) \cdot 30 \text{ min} \quad (10)$$

where

d_{ax} is the axial distance in centimetres the bed translates between positions (step size).

Additional measurements may be taken for different values of scan time and axial coverage. If additional measurements are taken, those values shall be included in the final report.

Prior to the start of the emission acquisition, a CT scan over the entire whole-body scan length shall be obtained with X-ray technique factors as prescribed per whole-body clinical protocol. If the scanner does not have a CT component, then the prescribed method of transmission imaging shall be applied and reported.

For the emission scan, an acquisition matrix, field of view size, slice thickness, acquisition mode as 2D or 3D, and multiple scan overlap as prescribed for routine clinical whole-body scans shall be used.

Corrections for RANDOM COINCIDENCES shall be performed and the method used shall be clearly reported. Enhancements such as time-of-flight information, depth-of-interaction may also be enabled, and the enhancement method shall be reported. The start-time of the emission scans shall be used as the reference time for computation of phantom ACTIVITY concentrations and reporting.

Masses shall be added to the table as indicated in Figure 8 b). The PET and the CT acquisition shall be repeated for bed position 2 only. The acquisition time T_{2p} shall be two times of T_p .

4.7.3.5 Data processing

Transverse slices shall be reconstructed over the length of the image quality phantom. The standard reconstruction protocol for whole-body imaging shall be applied. The reconstruction algorithm, methods used for ATTENUATION, scatter, and COUNT LOSS corrections, and post reconstruction image filter and all associated parameters shall be reported. Results from alternate reconstruction protocols may be reported separately.

4.7.4 Data analysis

4.7.4.1 Data analysis for image quality and quantification accuracy of source ACTIVITY concentrations

4.7.4.1.1 General

The following analysis for the measurements without weights present shall be performed.

4.7.4.1.2 Regions-of-interest

4.7.4.1.2.1 General

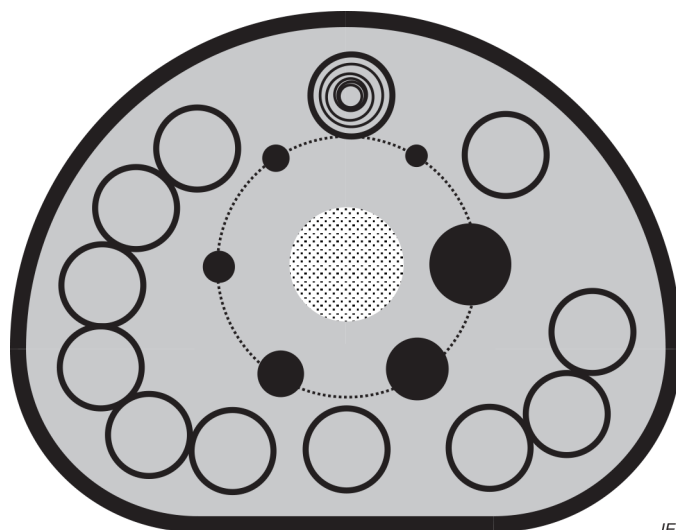
For image quality and quantitative accuracy analyses, 2D circular ROIs shall be drawn over the spheres and whole-body phantom background on selected slices.

4.7.4.1.2.2 Hot sphere 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 regions-of-interest (ROIs) shall be drawn over the six spheres in the S-slice. The ROI diameter shall be made as close as possible to the sphere inner diameter, without exceeding the inner diameter. The average PIXEL value P_j for each sphere shall be computed.

4.7.4.1.2.3 Background ROIs

The transverse slices as close as possible to ± 1 cm and ± 2 cm from the S-slice shall be identified. 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 9 for an example of background ROI placement on the S-slice). ROIs corresponding to the five smaller diameter spheres shall 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, shall be placed concentrically.

SOURCE: [1]¹, used with permission.

Figure 9 – Placement of ROIs in the phantom background

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

4.7.4.1.2.4 Whole-body scan lung and background ROIs

A 37 mm diameter ROI shall be drawn inside the lung insert on every transverse slice over the entire length of the image quality phantom. Likewise, a 37 mm diameter ROI shall be drawn in the phantom background positioned 15 mm from the left edge of the phantom edge. The average PIXEL values shall be recorded for all regions and label as $WBBkg_k$ and $WBLung_k$, respectively for slice $k = 1, n$ where n is the last slice.

4.7.4.1.3 Image quality

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.

$$CR_j = (P_j/B_j - 1) / (A_S/A_B - 1) \quad (11)$$

where

P_j is the ROI value for sphere j , as computed in 4.7.4.1.2.2;

B_j is the average of the background ROI values for sphere j , as computed in 4.7.4.1.2.3;

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 is computed as:

¹ Numbers in square brackets refer to the Bibliography.

$$CN_j = S_j/B_j \quad (12)$$

where

B_j is the average of the background ROI values for sphere j , as computed in 4.7.4.1.2.3;

S_j is the standard deviation of the background ROI values for sphere j , as computed in 4.7.4.1.2.3.

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

$$CNR_j = (P_j/B_j - 1)/CN_j \quad (13)$$

where

P_j is the ROI value for sphere j , as computed in 4.7.4.1.2.2;

B_j is the average of the background ROI values for sphere j , as computed in 4.7.4.1.2.3;

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

4.7.4.1.4 Quantification accuracy

Percent deviation shall be computed from true ACTIVITY concentration in the phantom background as showed in Formula (14):

$$\Delta Q_B = 100 \% \cdot (B_{37} - A_B)/A_B \quad (14)$$

where

ΔQ_B is the percent deviation from true ACTIVITY concentration in the background;

B_{37} is the average PIXEL value for 37 mm ROI in the background (see 4.7.4.1.2.3) in units of kBq/ml;

A_B is the ACTIVITY concentration in the phantom background in units of kBq/ml.

4.7.4.1.5 Accuracy of scatter and ATTENUATION corrections

Accuracy of scatter and ATTENUATION corrections shall be measured in the background and the lung insert along the entire length of the phantom. A residual error in the lung insert shall be calculated for every slice. Quantification accuracy shall be calculated for the background ROI for every slice.

The residual error in the lung insert shall be calculated as showed in Formula (15):

$$\Delta LR_k = 100 \% \cdot WBLung_k/A_B \quad (15)$$

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 in units of kBq/ml;

A_B is the ACTIVITY concentration in the phantom background in units of kBq/ml.

The quantification accuracy in the background is calculated as showed in Formula (16):

$$\Delta QWB_k = 100 \% \cdot (WBBkg_k - A_B)/A_B \quad (16)$$

where

ΔQWB_k is the percent residual error in slice k ;

$WBBkg_k$ is the average PIXEL value in the background in slice k in units of kBq/ml;

A_B is the ACTIVITY concentration in the phantom background in units of kBq/ml.

4.7.4.2 Data analysis for PET/CT registration accuracy

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

The following analysis shall be performed for the measurements with masses added according to Figure 8 b).

On the PET scan, the spheres shall be encircled completely. All PIXELS in the ROI that are greater than 1,25 times the average background (B_j for sphere j as defined in 4.7.4.1.2.3) within the ROI shall be set to one, otherwise they shall be set to zero. The X, Y, and Z-centroids shall then be calculated as showed in Formula (17), Formula (18), and Formula (19):

$$C_{X,j} = \sum x \cdot ROI_{PET,j}(x,y,z) / \sum ROI_{PET,j}(x,y,z); \text{ for all } x,y,z \text{ of ROI} \quad (17)$$

$$C_{Y,j} = \sum y \cdot ROI_{PET,j}(x,y,z) / \sum ROI_{PET,j}(x,y,z); \text{ for all } x,y,z \text{ of ROI} \quad (18)$$

$$C_{Z,j} = \sum z \cdot ROI_{PET,j}(x,y,z) / \sum ROI_{PET,j}(x,y,z); \text{ for all } x,y,z \text{ of ROI} \quad (19)$$

Then $C_{PET,j} = (C_{X,j}, C_{Y,j}, C_{Z,j})$ shall be identified as the centroid coordinate for sphere j for PET.

For the CT scan, the spheres shall be encircled completely. All PIXELS in the ROI which belong to the sphere wall shall be set to one and the others to zero. The X, Y, and Z-centroids shall then be calculated as showed in Formula (20), Formula (21) and Formula (22):

$$C_{X,j} = \sum x \cdot ROI_{CT,j}(x,y,z) / \sum ROI_{CT,j}(x,y,z); \text{ for all } x,y,z \text{ of ROI} \quad (20)$$

$$C_{Y,j} = \sum y \cdot ROI_{CT,j}(x,y,z) / \sum ROI_{CT,j}(x,y,z); \text{ for all } x,y,z \text{ of ROI} \quad (21)$$

$$C_{Z,j} = \sum z \cdot ROI_{CT,j}(x,y,z) / \sum ROI_{CT,j}(x,y,z); \text{ for all } x,y,z \text{ of ROI} \quad (22)$$

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

The distance between the PET and CT centroids shall be calculated for each sphere.

4.7.5 Report

4.7.5.1 Scan set up and phantom ACTIVITY concentrations

The following scan set up parameters shall be reported:

- scanner axial field of view;
- bed "step size" between multiple acquisitions;

- acquisition time per bed position;
- total whole-body scan length;
- CT acquisition parameters: kVp, mAs, slice-thickness;
- PET acquisition parameters: reconstructed field of view diameter, slice thickness, acquisition mode as 2D or 3D, and method of randoms correction;
- reconstruction algorithm, methods used for ATTENUATION, scatter, and dead-time count loss corrections, post reconstruction image filter and all associated parameters.

The sphere and phantom background ACTIVITY concentrations at start of the first measurement made with the phantom positioned according to Figure 8 a) shall be reported.

4.7.5.2 Image quality

The noise coefficient of variation for all spheres shall be reported.

The contrast recovery coefficients for all spheres shall be reported. The smallest sphere that has a recovery coefficient greater than 0,90 shall be identified and reported.

The contrast-noise-ratio for all spheres shall be reported. The smallest sphere for which the contrast-noise-ratio exceeds four shall be identified and reported.

4.7.5.3 Quantification accuracy

The percent deviation from true ACTIVITY concentration for the background for the average PIXEL values in the region shall be reported.

4.7.5.4 Accuracy of scatter and ATTENUATION corrections

The residual error in the lung insert and background shall be reported for every slice.

The length of any portion of the phantom where the magnitude of the residual error exceeds 10 % shall be reported.

4.7.5.5 Accuracy of PET and CT image registration

The deviation distance in mm between the PET and CT centroids for each sphere shall be reported.

5 ACCOMPANYING DOCUMENTS

5.1 General

A document shall accompany each POSITRON EMISSION TOMOGRAPH that includes the information contained in 5.2 to 5.8.

5.2 Design parameters and configuration

- detector element dimensions and number of elements;
- detector material;
- COINCIDENCE WINDOW;
- detector ring diameter;
- TRANSVERSE FIELD OF VIEW;
- AXIAL FIELD OF VIEW;
- SINOGRAM sampling (linear and angular);
- axial sampling;

- energy window;
- axial acceptance angle;
- reconstruction algorithm;
- method of RANDOM COINCIDENCE estimation;
- any additional information being considered essential by the MANUFACTURER to characterize normal operation.

5.3 SPATIAL RESOLUTION

- TRANSVERSE RESOLUTION (radial and tangential) according to 4.2.5;
- AXIAL RESOLUTION according to 4.2.5;
- axial PIXEL dimension according to 4.2.5;
- transverse PIXEL dimensions according to 4.2.5.

5.4 Sensitivity

- SLICE SENSITIVITY according to 4.3.5;
- VOLUME SENSITIVITY according to 4.3.5.

5.5 SCATTER FRACTION

SCATTER FRACTIONS SFi and SF according to 4.4.5.

5.6 COUNT RATE performance

- COUNT RATE CHARACTERISTIC and derived quantities according to 4.5.5.1;
- method of correction for RANDOM COINCIDENCES according to 4.5.5.1;
- accuracy of COUNT LOSS correction and associated plots according to 4.5.5.2.

5.7 TIME-OF-FLIGHT resolution

- TOF-resolution ($FWHM_{TOF(i)}$, $FWHM_{TOF}$) and derived quantities according to 4.6.9.

5.8 Image quality and quantification accuracy of source ACTIVITY concentrations

- scan set up and phantom ACTIVITY concentrations according to 4.7.5.1;
- image quality according to 4.7.5.2;
- quantification accuracy according to 4.7.5.3;
- accuracy of scatter and ATTENUATION corrections according to 4.7.5.4;
- accuracy of PET and CT image registration according to 4.7.5.5;

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- [1] NEMA NU 2-2018, *Performance measurements of positron emission tomographs (PETS)*
- [2] IEC TR 61948-3:2018, *Nuclear medicine instrumentation – Routine tests – Part 3: Positron emission tomographs*
- [3] Wang G-C, *et al*, "PET Timing Performance Measurement Method Using NEMA NEC Phantom", *IEEE Transactions on Nuclear Science*, vol. 63, no. 3, 2016. pp. 1335-1342.
- [4] IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
IEC 60601-1:2005/AMD1:2012
IEC 60601-1:2005/AMD2:2020

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COMMISSION ÉLECTROTECHNIQUE INTERNATIONALE

**DISPOSITIFS D'IMAGERIE PAR RADIONUCLÉIDES –
CARACTÉRISTIQUES ET CONDITIONS D'ESSAI –****Partie 1: Tomographes à émission de positrons****AVANT-PROPOS**

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Cette troisième édition annule et remplace la deuxième édition parue en 2013. Cette édition constitue une révision technique.

Cette édition inclut les modifications techniques majeures suivantes par rapport à l'édition précédente: des exigences ont été modifiées ou ajoutées quant aux aspects techniques de la RESOLUTION SPATIALE, du mesurage de la sensibilité, de la FRACTION DE DIFFUSION, de la performance du TAUX DE COMPTAGE, de la qualité d'image et de l'exactitude de la superposition d'images en TEP ou CT.

Le texte de cette Norme internationale est issu des documents suivants:

Projet	Rapport de vote
62C/811/CDV	62C/828/RVC

Le rapport de vote indiqué dans le tableau ci-dessus donne toute information sur le vote ayant abouti à son approbation.

La langue employée pour l'élaboration de cette Norme internationale est l'anglais.

Dans le présent document, les caractères d'imprimerie suivants sont utilisés: les termes définis à l'Article 3 du présent document ou tels qu'ils sont notés: petites majuscules.

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Une liste de toutes les parties de la série IEC 61675, publiées sous le titre général *Dispositifs d'imagerie par radionucléides – Caractéristiques et conditions d'essai*, peut être consultée sur le site web de l'IEC.

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INTRODUCTION

Après les progrès réalisés dans le domaine des TOMOGRAPHES A EMISSION DE POSITRONS, la plupart des tomographes peuvent maintenant être utilisés en mode d'acquisition totalement 3D. Afin de satisfaire à cette tendance, le présent document décrit les conditions d'essai en tenant compte de cette caractéristique d'acquisition. En outre, les TOMOGRAPHES A EMISSION DE POSITRONS modernes intègrent souvent des EQUIPEMENTS A RAYONNEMENT X pour TOMODENSITOMETRIE (CT). Dans le présent document, les dispositifs hybrides TEP-CT sont considérés comme représentatifs de l'état de l'art, les TOMOGRAPHES A EMISSION DE POSITRONS spécialisés n'intégrant pas le rayonnement X constituant seulement des cas particuliers.

Bien que les méthodes d'essai spécifiées dans le présent document soient optimisées pour le composant TEP des dispositifs hybrides TEP-CT, elles peuvent être également utilisées pour le composant TEP des dispositifs hybrides TEP-RM (tomographie par émission de positrons-résonance magnétique).

Les méthodes d'essai spécifiées dans le présent document ont été sélectionnées afin de refléter, autant que possible, l'utilisation clinique des TOMOGRAPHES A EMISSION DE POSITRONS. L'objectif est de faire en sorte que les essais soient réalisés par les FABRICANTS et de permettre à ces derniers de décrire les caractéristiques des TOMOGRAPHES A EMISSION DE POSITRONS dans les DOCUMENTS D'ACCOMPAGNEMENT. Le présent document n'indique pas quels essais sont effectués par le FABRICANT sur un tomographe particulier ou quelles normes de classification peuvent être utilisées par le FABRICANT pour caractériser les performances des TOMOGRAPHES A EMISSION DE POSITRONS.

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DISPOSITIFS D'IMAGERIE PAR RADIONUCLÉIDES – CARACTÉRISTIQUES ET CONDITIONS D'ESSAI –

Partie 1: Tomographes à émission de positrons

1 Domaine d'application

La présente partie de l'IEC 61675 spécifie la terminologie et les méthodes d'essai relatives à la description des caractéristiques des TOMOGRAPHES A EMISSION DE POSITRONS. Les TOMOGRAPHES A EMISSION DE POSITRONS détectent le RAYONNEMENT D'ANNIHILATION des RADIONUCLEIDES qui émettent des positrons par la DETECTION EN COÏNCIDENCE.

2 Références normatives

Les documents suivants sont cités dans le texte de sorte qu'ils constituent, pour tout ou partie de leur contenu, des exigences du présent document. Pour les références datées, seule l'édition citée s'applique. Pour les références non datées, la dernière édition du document de référence s'applique (y compris les éventuels amendements).

IEC TR 60788:2004, *Medical electrical equipment – Glossary of defined terms* (disponible en anglais seulement)

3 Termes et définitions

Pour les besoins du présent document, les termes et définitions de l'IEC TR 60788:2004, ainsi que les suivants s'appliquent.

L'ISO et l'IEC tiennent à jour des bases de données terminologiques destinées à être utilisées en normalisation, consultables aux adresses suivantes:

- IEC Electropedia: disponible à l'adresse <http://www.electropedia.org/>
- ISO Online browsing platform: disponible à l'adresse <http://www.iso.org/obp>

3.1

tomographie

radiographie d'une ou de plusieurs tranches d'un objet

[SOURCE: En anglais, IEC TR 60788:2004, rm-41-15]

3.1.1

tomodensitométrie par émission

TPE

méthode d'imagerie qui permet la représentation de la distribution spatiale des RADIONUCLEIDES incorporés dans des coupes bidimensionnelles sélectionnées à travers l'objet

3.1.1.1

projection

transformation d'un objet tridimensionnel en son image bidimensionnelle ou d'un objet bidimensionnel en son image unidimensionnelle, par l'intégration de la propriété physique qui détermine l'image le long de la direction du FAISCEAU DE PROJECTION

Note 1 à l'article: Ce processus est décrit mathématiquement par des intégrales de lignes dans la direction de PROJECTION (le long de la LIGNE DE REPONSE); il est appelé "transformée de Radon".

3.1.1.2

faisceau de projection

faisceau qui détermine le plus petit volume possible dans lequel la propriété physique qui détermine l'image est intégrée au cours du processus de mesure

Note 1 à l'article: La forme du FAISCEAU DE PROJECTION est limitée par la RESOLUTION SPATIALE dans chacune des trois dimensions.

Note 2 à l'article: Le FAISCEAU DE PROJECTION a généralement la forme d'un cylindre ou d'un cône long et fin. En TOMOGRAPHIE PAR EMISSION DE POSITRONS, il s'agit du volume utile entre deux éléments de détecteurs utilisés en coïncidence.

3.1.1.3

angle de projection

angle auquel la PROJECTION est mesurée ou acquise

3.1.1.4

sinogramme

affichage bidimensionnel de toutes les PROJECTIONS unidimensionnelles d'une COUPE D'OBJET en fonction de l'ANGLE DE PROJECTION

Note 1 à l'article: L'ANGLE DE PROJECTION est affiché sur l'ordonnée, et la coordonnée de la projection linéaire sur l'abscisse.

3.1.1.5

coupe d'objet

propriété physique qui correspond à une coupe dans l'objet qui détermine les informations mesurées et qui est affichée dans l'image tomographique

3.1.1.6

plan d'image

plan attribué à un plan dans la COUPE D'OBJET

Note 1 à l'article: Le PLAN D'IMAGE est généralement le plan médian de la COUPE D'OBJET correspondante.

3.1.1.7

axe du système

axe de symétrie caractérisé par les propriétés géométriques et physiques de la disposition du système

Note 1 à l'article: Dans un TOMOGRAPHE A EMISSION DE POSITRONS circulaire, l'AXE DU SYSTEME est l'axe qui passe par le centre de l'anneau du détecteur. Dans le cas des tomographes à détecteurs rotatifs, il correspond à l'axe de rotation.

3.1.1.8

volume tomographique

juxtaposition de tous les éléments volumiques qui contribuent aux PROJECTIONS mesurées pour tous les ANGLES DE PROJECTION

3.1.1.8.1

champ de visualisation transversal

dimensions d'une coupe à travers le VOLUME TOMOGRAPHIQUE, perpendiculaire à l'AXE DU SYSTEME

Note 1 à l'article: Un CHAMP DE VISUALISATION TRANSVERSAL circulaire est décrit par son diamètre.

Note 2 à l'article: Dans le cas des VOLUMES TOMOGRAPHIQUES non cylindriques, le CHAMP DE VISUALISATION TRANSVERSAL peut dépendre de la position axiale de la coupe.

3.1.1.8.2**champ de visualisation axial****AFOV**

champ caractérisé par les dimensions d'une coupe à travers le VOLUME TOMOGRAPHIQUE, parallèle à et incluant l'AXE DU SYSTEME

Note 1 à l'article: En pratique, le CHAMP DE VISUALISATION AXIAL n'est spécifié que par sa dimension axiale, donnée par la distance entre le centre des PLANS D'IMAGES les plus éloignés définis, à laquelle s'ajoute la moyenne de la RESOLUTION AXIALE mesurée.

Note 2 à l'article: L'abréviation "AFOV" est dérivée du terme anglais développé correspondant "axial field of view".

3.1.1.8.3**champ de visualisation total**

champ caractérisé par les dimensions (tridimensionnelles) du VOLUME TOMOGRAPHIQUE

3.1.2**tomographie par émission de positrons****TEP**

TOMODENSITOMETRIE PAR EMISSION qui utilise le RAYONNEMENT D'ANNIHILATION des RADIONUCLEIDES émettant des positrons par la DETECTION EN COÏNCIDENCE

3.1.2.1**tomographe à émission de positrons**

dispositif de tomographie qui détecte le RAYONNEMENT D'ANNIHILATION des RADIONUCLEIDES émettant des positrons par la DETECTION EN COÏNCIDENCE

3.1.2.2**rayonnement d'annihilation**

rayonnement ionisant produit lorsqu'une particule et son antiparticule interagissent et cessent d'exister

3.1.2.3**détection en coïncidence**

méthode qui permet de vérifier si deux détecteurs opposés ont détecté simultanément un photon chacun

Note 1 à l'article: Dans cette méthode, les deux photons sont concaténés en un seul événement.

Note 2 à l'article: La DETECTION EN COÏNCIDENCE entre deux éléments de détecteurs opposés sert de collimation électronique pour définir le FAISCEAU DE PROJECTION correspondant ou la LIGNE DE REPONSE (LOR) correspondante, respectivement.

3.1.2.4**fenêtre de coïncidence**

intervalle de temps au cours duquel deux photons détectés sont considérés comme simultanés

3.1.2.5**ligne de réponse****LOR**

axe du FAISCEAU DE PROJECTION

Note 1 à l'article: En TEP, la LIGNE DE RÉPONSE est la ligne qui relie le centre de deux éléments de détecteurs opposés utilisés en coïncidence.

Note 2 à l'article: L'abréviation "LOR" est dérivée du terme anglais développé correspondant "line of response".

3.1.2.6**coïncidences totales**

somme de toutes les coïncidences détectées

3.1.2.6.1

coïncidence réelle

résultat de la DETECTION EN COÏNCIDENCE de deux événements gamma en provenance de la même annihilation de positrons

3.1.2.6.2

coïncidence réelle diffusée

COÏNCIDENCE REELLE dans laquelle au moins un photon participant a été diffusé avant la DETECTION EN COÏNCIDENCE

3.1.2.6.3

coïncidence réelle non diffusée

différence entre les COÏNCIDENCES REELLES et les COÏNCIDENCES REELLES DIFFUSEES

3.1.2.6.4

coïncidence aléatoire

résultat d'une DETECTION EN COÏNCIDENCE dans laquelle les photons participants ne proviennent pas de la même annihilation de positrons

3.1.2.7

taux de singles

TAUX DE COMPTAGE mesuré sans DETECTION EN COÏNCIDENCE, mais avec discrimination en énergie

3.1.3

reconstitution bidimensionnelle

reconstitution d'image dans laquelle les données sont recombinaées avant la reconstitution en SINOGRAMMES, qui sont les données de PROJECTION des coupes transversales, considérées comme étant indépendantes les unes des autres et comme étant perpendiculaires à l'AXE DU SYSTEME

3.1.4

reconstitution tridimensionnelle

reconstitution d'image dans laquelle les LIGNES DE REPONSE ne se limitent pas à être perpendiculaires à l'AXE DU SYSTEME, une LIGNE DE REPONSE pouvant ainsi traverser plusieurs coupes transversales

3.2

matrice image

<médecine nucléaire> matrice dans laquelle chaque élément correspond à la propriété physique mesurée ou calculée de l'objet à l'endroit décrit par les coordonnées de cet ELEMENT DE MATRICE

3.2.1

élément de matrice

plus petite unité d'une MATRICE IMAGE, qui est attribuée en localisation et en taille à un certain élément volumique de l'objet (VOXEL)

3.2.2

pixel

ELEMENT DE MATRICE dans une MATRICE IMAGE bidimensionnelle

3.2.3

voxel

élément volumique de l'objet qui est attribué à un ELEMENT DE MATRICE dans une MATRICE IMAGE bidimensionnelle ou tridimensionnelle

Note 1 à l'article: Les dimensions du VOXEL sont déterminées par les dimensions de l'ELEMENT DE MATRICE correspondant par l'intermédiaire des facteurs d'échelle appropriés et par la RESOLUTION SPATIALE du système dans chacune des trois dimensions.

3.3

fonction de distribution de points

PSF

image scintigraphique d'une SOURCE PONCTUELLE

Note 1 à l'article: L'abréviation "PSF" est dérivée du terme anglais développé correspondant "point spread function".

3.3.1

fonction de distribution de points physique

<tomographes> FONCTION DE DISTRIBUTION DE POINTS bidimensionnelle dans des plans perpendiculaires au FAISCEAU DE PROJECTION à des distances spécifiées du détecteur

Note 1 à l'article: La FONCTION DE DISTRIBUTION DE POINTS PHYSIQUE caractérise les performances d'imagerie purement physiques (intrinsèques) du dispositif de tomographie et elle est indépendante, par exemple, de l'échantillonnage, de la reconstitution d'image et du traitement d'image. Un FAISCEAU DE PROJECTION est caractérisé par l'intégralité de toutes les FONCTIONS DE DISTRIBUTION DE POINTS PHYSIQUES en fonction de la distance le long de son axe.

3.3.2

fonction axiale de distribution de points

profil qui passe par le pic de la FONCTION DE DISTRIBUTION DE POINTS PHYSIQUE dans un plan parallèle à l'AXE DU SYSTEME

3.3.3

fonction transversale de distribution de points

FONCTION DE DISTRIBUTION DE POINTS bidimensionnelle reconstituée dans un PLAN D'IMAGE tomographique

Note 1 à l'article: En TOMOGRAPHIE, la FONCTION TRANSVERSALE DE DISTRIBUTION DE POINTS peut également être obtenue à partir d'une SOURCE LINEAIRE parallèle à l'AXE DU SYSTEME.

3.4

résolution spatiale

<médecine nucléaire> capacité à concentrer la distribution de densité de comptage dans l'image d'une SOURCE PONCTUELLE en un point

3.4.1

résolution transversale

RESOLUTION SPATIALE dans un plan reconstitué perpendiculaire à l'AXE DU SYSTEME

3.4.1.1

résolution radiale

RESOLUTION TRANSVERSALE le long d'une ligne qui passe par la position de la source et l'AXE DU SYSTEME

3.4.1.2

résolution tangentielle

RESOLUTION TRANSVERSALE dans la direction orthogonale à la direction de la RESOLUTION RADIALE

3.4.2

résolution axiale

RESOLUTION SPATIALE le long d'une ligne parallèle à l'AXE DU SYSTEME

Note 1 à l'article: La RESOLUTION AXIALE s'applique uniquement aux tomographes qui bénéficient d'un échantillonnage axial suffisamment précis satisfaisant au théorème d'échantillonnage.

3.4.3

largeur équivalente

EW

largeur du rectangle ayant la même superficie et la même hauteur que la fonction de réponse, par exemple, la FONCTION DE DISTRIBUTION DE POINTS

Note 1 à l'article: La EW reflète mieux les queues de diffusion de la fonction de réponse que la largeur à mi-hauteur (FWHM - full width at half maximum) ou la largeur au dixième (LD).

Note 2 à l'article: L'abréviation "EW" est dérivée du terme anglais développé correspondant "equivalent width".

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

3.4.4

largeur à mi-hauteur

FWHM

pour une courbe en forme de cloche, distance parallèle à l'axe des abscisses entre les points d'ordonnée égale à la moitié de l'ordonnée maximale

Note 1 à l'article: L'abréviation "FWHM" est dérivée du terme anglais développé correspondant "full width at half maximum".

[SOURCE: En anglais, IEC TR 60788:2004, rm-73-02]

3.5

coefficient de reprise

concentration d'ACTIVITE (d'image) mesurée d'un volume actif divisée par la concentration d'ACTIVITE réelle de ce volume, les facteurs d'étalonnage d'ACTIVITE étant négligés

Note 1 à l'article: Pour les mesurages réels, la concentration d'ACTIVITE réelle est remplacée par la concentration d'ACTIVITE mesurée dans un grand volume.

3.6

sensibilité de coupe

rapport entre le TAUX DE COMPTAGE mesuré sur le SINOGRAMME et la concentration d'ACTIVITE dans le fantôme

Note 1 à l'article: En TEP, les impulsions mesurées sont corrigées numériquement en diffusion, par le retrait de la FRACTION DE DIFFUSION.

3.7

sensibilité volumique

somme des différentes SENSIBILITES DE COUPE

3.8

caractéristique du taux de comptage

fonction établissant la relation entre le TAUX DE COMPTAGE observé et le TAUX DE COMPTAGE REEL

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

3.8.1

perte de comptage

différence entre le TAUX DE COMPTAGE mesuré et le TAUX DE COMPTAGE REEL provoquée par le TEMPS DE RESOLUTION fini de l'appareil

3.8.2

taux de comptage

nombre d'impulsions par unité de temps

3.8.3

taux de comptage réel

TAUX DE COMPTAGE qui est observé pour le TEMPS DE RESOLUTION zéro de l'instrument

[SOURCE: En anglais, IEC TR 60788:2004, rm-34-20]

3.9

fraction de diffusion

SF

rapport entre les COÏNCIDENCES REELLES DIFFUSEES et la somme des COÏNCIDENCES REELLES DIFFUSEES et NON DIFFUSEES pour un montage expérimental donné

Note 1 to entry: L'abréviation "SF" est dérivée du terme anglais développé correspondant "scatter fraction".

3.10

source ponctuelle

SOURCE RADIOACTIVE proche d'une fonction δ dans chacune des trois dimensions

3.11

source linéaire

SOURCE RADIOACTIVE droite proche d'une fonction δ dans deux dimensions et constante (uniforme) dans la troisième dimension

3.12

étalonnage

<tomodensitométrie par émission> processus d'établissement de la relation entre le TAUX DE COMPTAGE par élément volumique localement dans l'image et la concentration d'ACTIVITE correspondante dans l'objet, pour des tailles d'objets n'exigeant pas de CORRECTION DE REPRISE

Note 1 à l'article: Pour que cet ETALONNAGE soit suffisamment indépendant de l'objet à l'étude, il est obligatoire d'appliquer les corrections adéquates aux données, par exemple ATTENUATION, diffusion, PERTE DE COMPTAGE, décroissance de la radioactivité, normalisation du détecteur, COÏNCIDENCES ALEATOIRES (TEP) et rapport d'embranchement (TEP). L'indépendance de l'objet doit dimensionner les images cliniques en matière de kBq/ml ou de valeurs de fixation normalisées (SUV).

3.13

performance du taux de comptage en TEP

relation entre le TAUX DE COMPTAGE mesuré des COÏNCIDENCES REELLES, COÏNCIDENCES ALEATOIRES ET COÏNCIDENCES TOTALES, et le taux de comptage équivalent bruit, d'une part, et l'ACTIVITE, d'autre part

3.14

résolution en temps de vol

résolution TOF

incertitude de mesure de la différence du temps d'arrivée des deux photons issus du même événement d'annihilation

Note 1 à l'article: L'abréviation "TOF" est dérivée du terme anglais développé correspondant "time-of-flight".

4 Méthodes d'essai

4.1 Généralités

Pour tous les mesurages, les paramètres d'acquisition du tomographe doivent être définis conformément à son mode normal de fonctionnement, c'est-à-dire qu'il n'est pas ajusté particulièrement pour le mesurage de paramètres spécifiques. Si le tomographe est spécifié pour fonctionner dans différents modes influençant les paramètres de performance, par exemple avec des angles d'admission axiaux différents, avec une RECONSTITUTION BIDIMENSIONNELLE et une RECONSTITUTION TRIDIMENSIONNELLE, les résultats d'essai doivent être consignés pour chacun des modes de fonctionnement. La configuration du tomographe (par

exemple, seuils d'énergie, angle d'admission axial, algorithme de reconstitution) doit être choisie conformément à la recommandation du FABRICANT et établie clairement. Si un essai ne peut pas être réalisé exactement comme cela est spécifié dans le présent document, les raisons expliquant l'écart et les conditions exactes dans lesquelles l'essai a été effectué doivent être établies clairement.

Par hypothèse, un TOMOGRAPHE A EMISSION DE POSITRONS est capable d'estimer les COÏNCIDENCES ALEATOIRES et d'effectuer la correction appropriée. En outre, un TOMOGRAPHE A EMISSION DE POSITRONS permet des corrections associées à la diffusion, à l'ATTENUATION, à la PERTE DE COMPTAGE, au rapport d'embranchement, à la décroissance de la radioactivité et à l'ETALONNAGE.

Sauf spécification contraire, les fantômes d'essai doivent être centrés dans le CHAMP DE VISUALISATION AXIAL du tomographe.

4.2 RÉSOLUTION SPATIALE

4.2.1 Généralités

Les mesurages de la RESOLUTION SPATIALE décrivent en partie la capacité d'un tomographe à reproduire la distribution spatiale d'un traceur dans un objet, dans une image reconstituée. Le mesurage doit être effectué en reproduisant l'image de SOURCES PONCTUELLES dans l'air et en reconstituant les images, à l'aide d'un filtre de reconstitution fin. Bien que cela ne représente pas la condition de reproduction de l'image d'un PATIENT, dans laquelle la diffusion des tissus est présente et dans laquelle des statistiques limitées exigent l'utilisation d'un filtre de reconstitution lisse et/ou de méthodes de reconstitution itératives, la RESOLUTION SPATIALE mesurée fournit une comparaison objective entre les tomographes.

4.2.2 Objet

L'objet de ce mesurage est de caractériser la capacité du tomographe à capter de petits objets.

La RESOLUTION SPATIALE doit être caractérisée par la largeur des FONCTIONS TRANSVERSALES DE DISTRIBUTION DE POINTS reconstituées de SOURCES PONCTUELLES radioactives. La largeur de la FONCTION DE DISTRIBUTION DE POINTS doit être mesurée par la LARGEUR A MI-HAUTEUR (FWHM) et la LARGEUR EQUIVALENTE (EW).

4.2.3 Méthode

4.2.3.1 Généralités

Pour tous les systèmes, la RESOLUTION SPATIALE doit être mesurée dans le PLAN D'IMAGE transversal, dans deux directions (c'est-à-dire, radiale et tangentielle) et dans la direction axiale.

4.2.3.2 RADIONUCLÉIDE

Le RADIONUCLÉIDE utilisé pour le mesurage doit être de ^{18}F ou ^{22}Na , avec une ACTIVITE telle que la PERTE DE COMPTAGE en pourcentage soit inférieure à 5 % ou que le taux de COÏNCIDENCE ALEATOIRE soit inférieur à 5 % du taux de COÏNCIDENCE TOTALE.

4.2.3.3 Distribution de la source radioactive

4.2.3.3.1 Généralités

Des SOURCES PONCTUELLES doivent être utilisées avec la dimension la plus importante qui est inférieure ou égale à 1 mm.

4.2.3.3.2 Positionnement de la source

Les SOURCES PONCTUELLES, suspendues dans l'air, doivent être utilisées afin de réduire le plus possible la diffusion, pour les mesurages de la RESOLUTION TRANSVERSALE. Les mesurages de résolution doivent être effectués sur deux plans perpendiculaires à l'AXE LONGITUDINAL du tomographe, l'un placé au centre du CHAMP DE VISUALISATION AXIAL et l'autre situé sur un plan décalé de 3/8 du CHAMP DE VISUALISATION AXIAL (c'est-à-dire 1/8 du CHAMP DE VISUALISATION AXIAL à partir de l'extrémité du tomographe) par rapport au plan central. Sur chaque plan, des sources doivent être positionnées à 1 cm, 10 cm et 20 cm de l'AXE DU SYSTEME (la position à 20 cm peut être omise si elle ne rentre pas dans le CHAMP DE VISUALISATION TRANSVERSAL). Les sources doivent être positionnées sur la ligne horizontale ou verticale qui coupe l'AXE DU SYSTEME, de sorte que les directions radiale et tangentielle soient alignées sur la grille d'image.

4.2.3.4 Collecte de données

Les données doivent être rassemblées pour toutes les sources dans chacune des six positions spécifiées en 4.2.3.3.2, soit individuellement, soit en groupes de sources multiples, afin de réduire le plus possible le temps d'acquisition des données. Au moins 100 000 impulsions doivent être acquises pour chaque SOURCE PONCTUELLE.

4.2.3.5 Traitement des données

La reconstitution par rétroprojection filtrée à l'aide d'un filtre de rampe avec une coupure à la fréquence de Nyquist des données de PROJECTION ou de leur équivalent 3D doit être utilisée pour toutes les données de la RESOLUTION SPATIALE. Aucune méthode d'amélioration de la résolution ne doit être utilisée. La taille de pixel dans le plan transversal doit être choisie de manière à obtenir au moins 3 pixels par largeur FWHM.

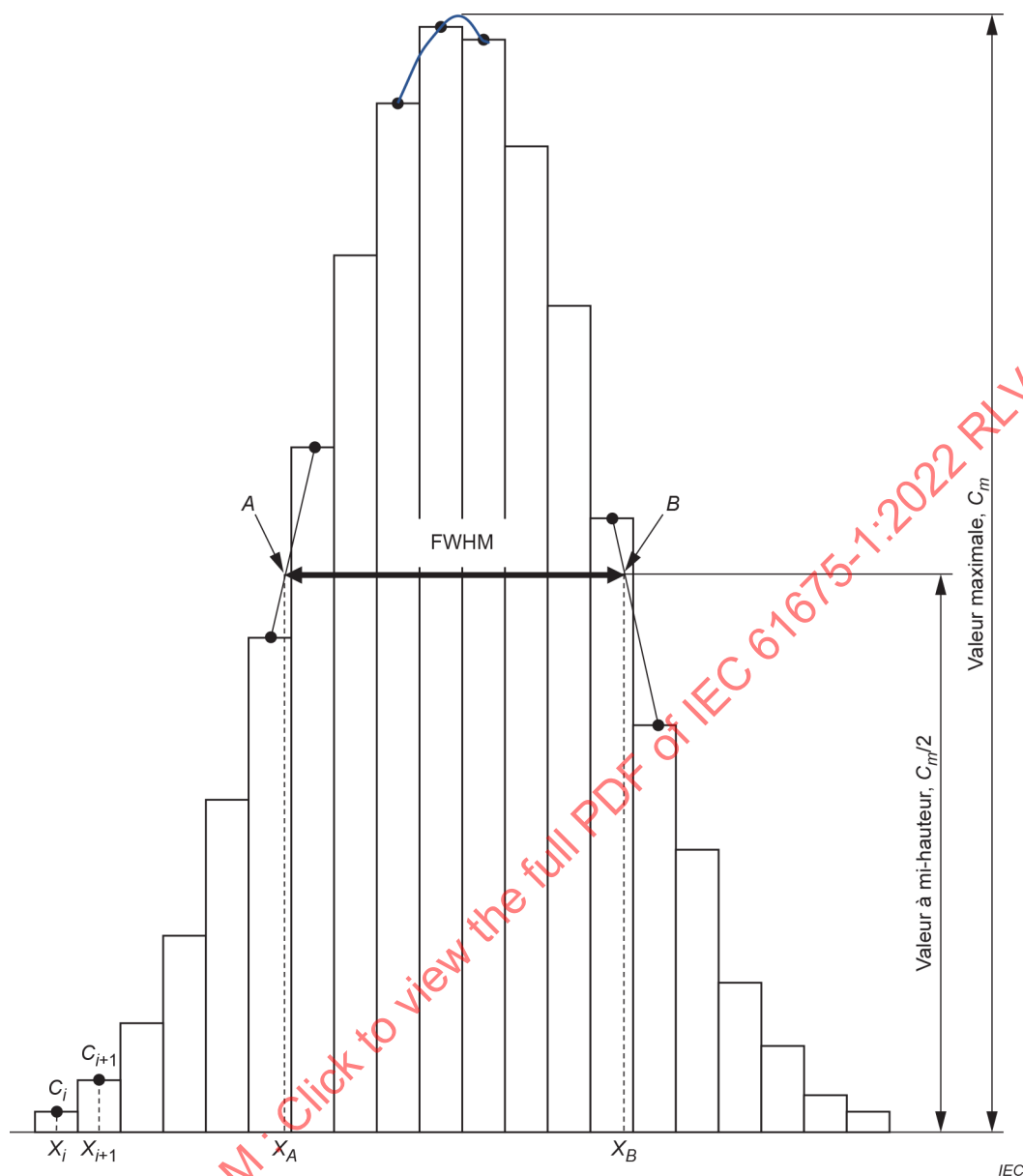
Les résultats obtenus avec d'autres algorithmes de reconstitution peuvent être consignés en complément des résultats de la rétroprojection filtrée, à condition que les méthodes de reconstitution alternatives employées et les paramètres associés soient décrits de façon suffisamment détaillée pour permettre la reproduction des résultats d'étude.

4.2.4 Analyse

La RESOLUTION RADIALE et la RESOLUTION TANGENTIELLE doivent être déterminées par la formation de fonctions de réponse unidimensionnelles. Ces fonctions de réponse doivent être créées par la prise de profils de la FONCTION TRANSVERSALE DE DISTRIBUTION DE POINTS à travers l'image 3D reconstituée de chaque SOURCE PONCTUELLE dans les directions radiale et tangentielle, passant par le pic de la distribution. La largeur de chaque profil doit être égale au double de la FWHM prévue dans les deux directions perpendiculaires à la direction de l'analyse.

La RESOLUTION AXIALE des mesurages de SOURCE PONCTUELLE doit être déterminée par la formation de fonctions de réponse unidimensionnelles (FONCTIONS AXIALES DE DISTRIBUTION DE POINTS), qui proviennent de la prise de profils à travers l'image 3D reconstituée dans la direction axiale, passant par le pic de la distribution. La largeur de chaque profil doit être égale au double de la FWHM prévue dans les deux directions perpendiculaires à la direction de l'analyse.

Chaque largeur FWHM doit être déterminée par interpolation linéaire entre les PIXELS adjacents à la moitié de la valeur maximale de PIXEL, qui correspond au pic de la fonction de réponse (voir Figure 1). La valeur maximale de PIXEL C_m doit être déterminée à l'aide d'un ajustement parabolique, à partir du point maximal et de ses deux plus proches voisins. Les valeurs doivent être converties en millimètres par multiplication avec la largeur de PIXEL appropriée.



NOTE C_m est la valeur maximale de la courbe d'interpolation, A et B sont les points d'intersection de la courbe d'impulsions d'interpolation et de la ligne de valeur à mi-hauteur. Alors $FWHM = X_B - X_A$.

Figure 1 – Évaluation de la FWHM

Chaque LARGEUR EQUIVALENTE (EW) doit être mesurée à partir de la fonction de réponse correspondante. La EW doit être calculée à partir de la Formule (1):

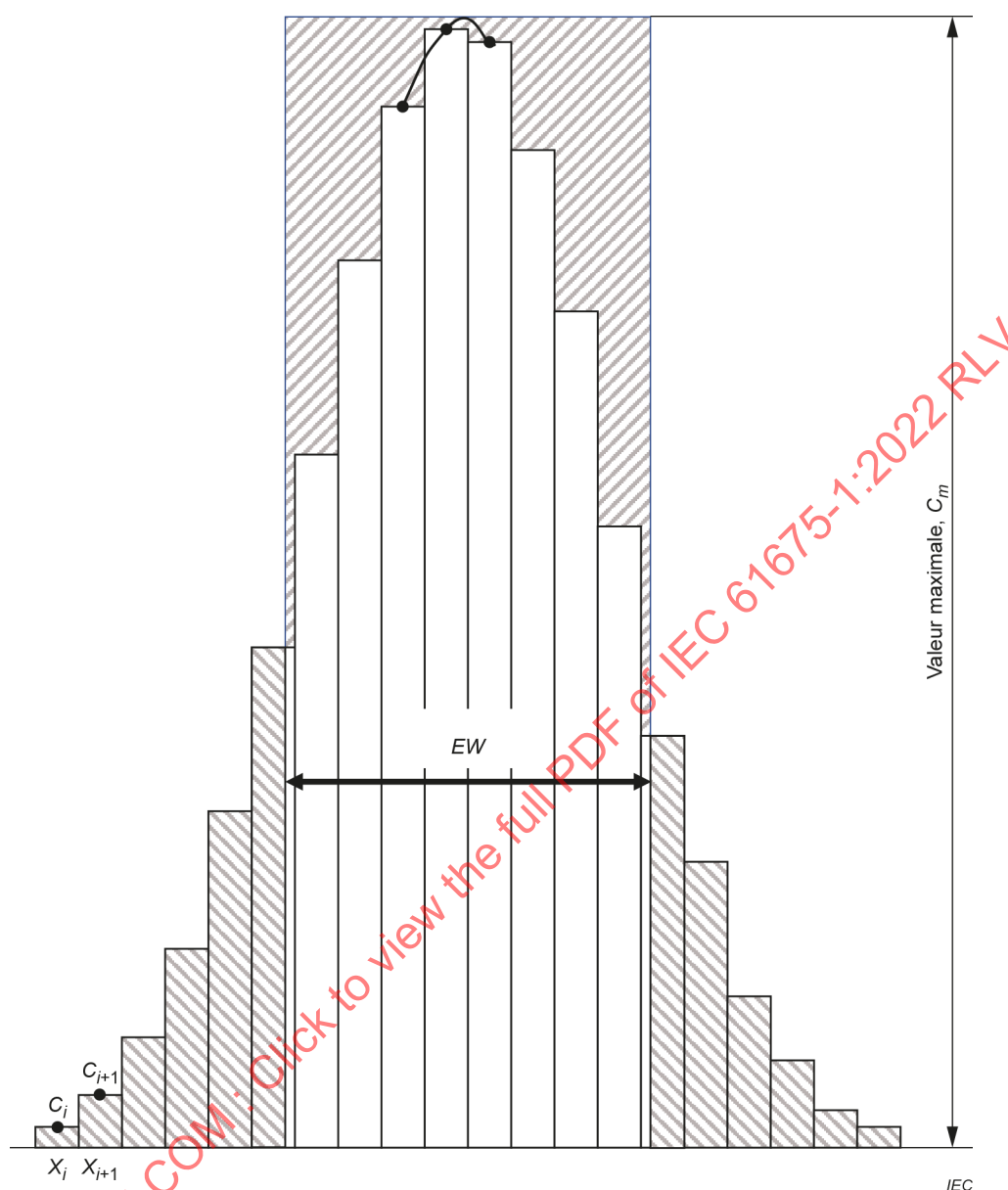
$$EW = \frac{PW}{C_m} \sum_i C_i \quad (1)$$

où

$\sum_i C_i$ est la somme des impulsions dans le profil entre les limites définies par $1/20 C_m$ de chaque côté du pic;

C_m est la valeur maximale de PIXEL du profil telle qu'elle est déterminée par le calcul de la FWHM ci-dessus, opposée à la valeur maximale de pixel à partir des localisations de pixel;

PW est la largeur de PIXEL en millimètres (voir Figure 2).



NOTE La EW est donnée par la largeur du rectangle qui présente la superficie de la FONCTION DE DISTRIBUTION LINEAIRE et sa valeur maximale C_m .

$$EW = \sum (C_i \times PW) / C_m$$

La largeur de PIXEL PW est égale à $x_{i+1} - x_i$.

Les superficies hachurées de la même manière sont égales.

Figure 2 – Évaluation DE LA LARGEUR EQUIVALENTE (EW)

4.2.5 Rapport

La RESOLUTION RADIALE, la RESOLUTION TANGENTIELLE et la RESOLUTION AXIALE ($FWHM$ et EW) associées à chaque position de SOURCE PONCTUELLE doivent être calculées et consignées. Les dimensions de PIXEL transversale et axiale doivent être consignées.

Si des méthodes de reconstitution particulières ont été utilisées, les résultats des essais doivent être consignés et la méthodologie employée doit être décrite avec exactitude.

4.3 Sensibilité tomographique

4.3.1 Généralités

La sensibilité tomographique est un paramètre qui caractérise la vitesse à laquelle les événements de coïncidence sont détectés en présence d'une SOURCE RADIOACTIVE dans la limite de faible ACTIVITE, dans laquelle les PERTES DE COMPTAGE et les COÏNCIDENCES ALEATOIRES sont négligeables. Le taux mesuré de COÏNCIDENCES REELLES pour une distribution donnée de la SOURCE RADIOACTIVE dépend de nombreux facteurs, y compris le matériau, la taille et le facteur de tassement du détecteur, le diamètre des anneaux du tomographe, la fenêtre d'admission axiale et la configuration des cloisons, l'ATTENUATION, la diffusion, le temps mort et les seuils d'énergie.

4.3.2 Objet

L'objet de ce mesurage est de déterminer le taux de COÏNCIDENCES REELLES NON DIFFUSEES détecté par unité de concentration d'ACTIVITE pour une source volumique normalisée, c'est-à-dire un fantôme cylindrique de dimensions données.

4.3.3 Méthode

4.3.3.1 Généralités

L'essai de sensibilité tomographique place un volume spécifié de solution radioactive d'ACTIVITE connue dans le CHAMP DE VISUALISATION TOTAL du TOMOGRAPHE A EMISSION DE POSITRONS et observe le TAUX DE COMPTAGE obtenu. La sensibilité du système doit être calculée à partir de ces valeurs. L'essai dépend sérieusement des analyses exactes d'ACTIVITE mesurées dans un compteur de radiation ou un compteur puits. Il est difficile de maintenir un ETALONNAGE absolu avec de tels dispositifs à des exactitudes de 10 %. Il convient de prendre en considération les normes de référence absolues qui utilisent des émetteurs de positrons si des degrés plus élevés d'exactitude sont exigés.

Une des dernières trames de l'essai de PERFORMANCE du TAUX DE COMPTAGE en TEP (4.5) peut être utilisée pour déterminer la SENSIBILITE DE COUPE et la SENSIBILITE VOLUMIQUE si le RADIONUCLÉIDE utilisé pour ces mesurages est de ^{18}F .

4.3.3.2 RADIONUCLÉIDE

Le RADIONUCLÉIDE utilisé pour ces mesurages doit être de ^{18}F . La quantité d'ACTIVITE AU MOMENT DU mesurage de la sensibilité tomographique doit être telle que le pourcentage de PERTES DE COMPTAGE soit inférieur à 2 %.

4.3.3.3 Distribution de la SOURCE RADIOACTIVE

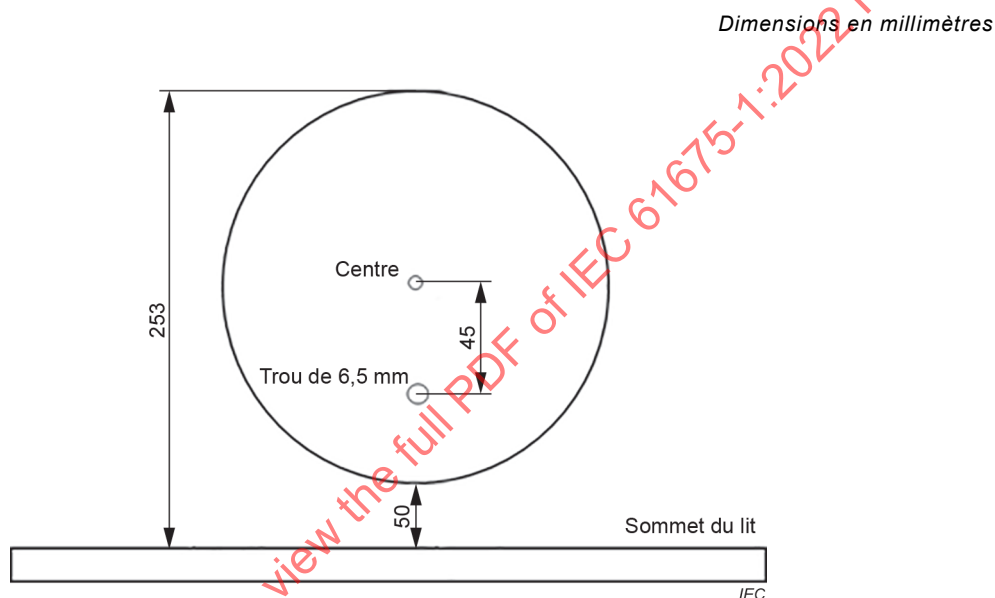
Le fantôme d'essai doit être un cylindre droit plein composé de polyéthylène qui présente une densité relative de $(0,96 \pm 0,01) \text{ g/cm}^3$, de diamètre extérieur $(203 \pm 3) \text{ mm}$ et de longueur totale $(700 \pm 5) \text{ mm}$. Un trou de $(6,5 \pm 0,3) \text{ mm}$ est percé parallèlement à l'axe central du cylindre, à une distance radiale de $(45 \pm 1) \text{ mm}$. Pour faciliter la fabrication et la manipulation, le cylindre peut se composer de plusieurs segments, assemblés au cours des essais. Cependant, au moment de la conception et de l'assemblage du fantôme complet, les segments adjacents doivent être bien serrés les uns contre les autres, le moindre espace laissé permettant la formation de régions axiales étroites de rayonnement sans diffusion.

L'élément de SOURCE LINEAIRE du fantôme d'essai doit être un tube en polyéthylène ou en plastique recouvert de polyéthylène transparent de $(800 \pm 5) \text{ mm}$ de longueur, qui présente un diamètre intérieur de $(3,2 \pm 0,2) \text{ mm}$ et un diamètre extérieur de $(4,8 \pm 0,2) \text{ mm}$.

L'élément de SOURCE LINEAIRE du fantôme d'essai doit être rempli d'eau bien mélangée avec la quantité mesurée d'ACTIVITE jusqu'à une longueur de $(700 \pm 5) \text{ mm}$ et fermé aux deux extrémités. Cette SOURCE LINEAIRE doit être insérée dans le trou percé dans le fantôme

d'essai de sorte que l'ACTIVITE de la SOURCE LINEAIRE corresponde à la longueur du fantôme en polyéthylène. Le fantôme d'essai équipé de la SOURCE LINEAIRE doit être installé sur le lit d'examen normalisé fourni par le FABRICANT. Le fantôme doit être surélevé de $(5 \pm 0,5)$ cm au-dessus du lit d'examen, à l'aide des moyens de montage tels que des blocs de mousse placés hors du CHAMP DE VISUALISATION AXIAL, et doit être pivoté de sorte que l'élément de SOURCE LINEAIRE se retrouve au plus près du lit d'examen (voir Figure 3). Le lit d'examen doit être positionné à $(15,2 \pm 0,5)$ cm en dessous du centre du CHAMP DE VISUALISATION TRANSVERSAL de sorte que le fantôme soit centré dans ce CHAMP.

Si le fantôme ne peut être centré comme cela est décrit ci-dessus, des blocs de montage d'autres dimensions peuvent être utilisés pour centrer le fantôme dans le champ de visualisation transversal. La distance entre la table utilisée et le centre du champ de visualisation transversal doit être consignée.



NOTE Le trou de 6,5 mm est destiné à l'insertion de la SOURCE LINEAIRE.

Figure 3 – Configuration du fantôme de diffusion et position sur le lit d'examen

4.3.3.4 Collecte de données

Chaque événement de coïncidence qui apparaît entre différents détecteurs ne doit être pris en compte qu'une fois. Les données sont assemblées en SINOGRAMMES. Tous les événements doivent être attribués à la coupe transversale qui passe par le centre de la LIGNE DE REPONSE CORRESPONDANTE.

Au moins 500 000 impulsions en coïncidence réelle sont acquises.

4.3.3.5 Traitement des données

La baisse de la concentration d'ACTIVITE dans le fantôme doit être corrigée afin de déterminer la concentration d'ACTIVITE moyenne a_{ave} au cours du temps d'acquisition des données T_{acq} , à partir de la formule (2) ci-dessous:

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