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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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RADIONUCLIDE IMAGING DEVICES – CHARACTERISTICS AND TEST CONDITIONS –

Part 1: Positron emission tomographs

FOREWORD

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International Standard 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.

This second edition replaces the first edition of IEC 61675-1, published in 1998. This edition constitutes a technical revision. Requirements have been changed regarding the following technical aspects:

– SPATIAL RESOLUTION;
– sensitivity measurement;
– SCATTER FRACTION;
– COUNT RATE performance;
– image quality.

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

CDV	Report on voting
62C/550/CDV	62C/561/RVC

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

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

In this standard, the following print types are used:

– Requirements and definitions: roman type.

– *Test specifications: italic type.*

– Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.

– TERMS DEFINED IN CLAUSE 3 OF IEC 60601-1, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

References to clauses within this standard are preceded by the term “clause” followed by the clause number. References to subclauses within this particular standard are by number only.

In this standard, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

– “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;

– “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;

– “may” is used to describe a permissible way to achieve compliance with a requirement or test.

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

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

INTRODUCTION

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 standard 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 standard 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.

The test methods specified in this part of IEC 61675 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 standard does not indicate which tests will be performed by the MANUFACTURER on an individual tomograph.

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

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

3 Terms and definitions

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

3.1
tomography
radiography of one or more layers within an object

[SOURCE: IEC 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

3.1.2
emission computed tomography
ECT
imaging method for the representation of the spatial distribution of incorporated RADIONUCLIDES in selected two-dimensional slices through the object

3.1.2.1
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.

3.1.2.2
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: Its 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.

3.1.2.3
projection angle
angle at which the PROJECTION is measured or acquired

3.1.2.4
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, the linear projection coordinate is displayed on the abscissa.

3.1.2.5
object slice
physical property that correspondes to a slice in the object and that determines the measured information and which is displayed in the tomographic image

3.1.2.6
image plane
a 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.

3.1.2.7
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.

3.1.2.8
tomographic volume
juxtaposition of all volume elements which contribute to the measured PROJECTIONS for all PROJECTION ANGLES

3.1.2.8.1
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.

3.1.2.8.2
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, it 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.

3.1.2.8.3
total field of view
field which is characterized by dimensions (three-dimensional) of the TOMOGRAPHIC VOLUME

3.1.3
positron emission tomography
PET
EMISSION COMPUTED TOMOGRAPHY utilizing the ANNIHILATION RADIATION of positron emitting RADIONUCLIDES by COINCIDENCE DETECTION

3.1.3.1
positron emission tomograph
tomographic device, which detects the ANNIHILATION RADIATION of positron emitting RADIONUCLIDES by COINCIDENCE DETECTION

3.1.3.2
annihilation radiation
ionizing radiation that is produced when a particle and its antiparticle interact and cease to exist

3.1.3.3
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.

3.1.3.4
coincidence window
time interval during which two detected photons are considered as being simultaneous

3.1.3.5
line of response
LOR
axis of the PROJECTION BEAM

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

3.1.3.6
total coincidences
sum of all coincidences detected

3.1.3.6.1
true coincidence
result of COINCIDENCE DETECTION of two gamma events originating from the same positron annihilation

3.1.3.6.2
scattered true coincidence
TRUE COINCIDENCE where at least one participating photon was scattered before the COINCIDENCE DETECTION

3.1.3.6.3
unscattered true coincidence
difference between TRUE COINCIDENCES and SCATTERED TRUE COINCIDENCES

3.1.3.6.4
random coincidence
result of a COINCIDENCE DETECTION in which participating photons do not originate from the same positron annihilation.

3.1.3.7
singles rate
COUNT RATE measured without COINCIDENCE DETECTION, but with energy discrimination

3.1.4
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 as being independent of each other and being perpendicular to the SYSTEM AXIS

3.1.5
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)

3.2.1.1
pixel
MATRIX ELEMENT in a two-dimensional IMAGE MATRIX

3.2.1.2
trixel
MATRIX ELEMENT in a three-dimensional IMAGE MATRIX

3.2.2
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 the rectangle that has the same area and the same height as the response function

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 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 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 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> the 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

4 Test methods

4.1 General

For all measurements, 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 standard, 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 RANDOM COINCIDENCES and performing the appropriate correction. In addition, a POSITRON EMISSION TOMOGRAPH shall provide 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 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 RESOLUTION is characterized by the width of the reconstructed TRANSVERSE POINT SPREAD FUNCTIONS of radioactive POINT SOURCES. The width of the spread function is measured by the FULL WIDTH AT HALF MAXIMUM (FWHM) and the EQUIVALENT WIDTH (EW).