SLOVENSKI STANDARD
oSIST prEN IEC 61675-2:2024

01-julij-2024

Naprave za opazovanje radioaktivnih elementov - Karakteristike in preskusni pogoji - 2. del: Gama kamere za planarno slikanje, slikanje celega telesa in slikanje SPECT

Radionuclide imaging devices - Characteristics and test conditions - Part 2: Gamma cameras for planar, wholebody, and SPECT imaging

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

Dispositifs d'imagerie par radionucléides - Caractéristiques et conditions d'essai - Partie 2: Gamma-caméras pour l'imagerie planaire, l'imagerie du corps entier et l'imagerie spect

Ta slovenski standard je istoveten z: **prEN IEC 61675-2:2024**

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62C/912/CDV

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IEC SC 62C : EQUIPMENT FOR RADIOTHERAPY, NUCLEAR MEDICINE AND RADIATION DOSIMETRY			
SECRETARIAT: Germany		SECRETARY: Ms Regina Geierhofer	
OF INTEREST TO THE FOLLOWING COMMITTEES:		PROPOSED HORIZONTAL STANDARD: ☐ Other TC/SCs are requested to indicate their interest, if any, in this CDV to the secretary.	
FUNCTIONS CONCERNED: ☐ EMC	☐ ENVIRONMENT	☒ QUALITY ASSURANCE	☐ SAFETY
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TITLE:

Radionuclide imaging devices - Characteristics and test conditions - Part 2: Gamma cameras for planar, wholebody, and SPECT imaging

PROPOSED STABILITY DATE: 2031

NOTE FROM TC/SC OFFICERS:

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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RADIONUCLIDE IMAGING DEVICES – CHARACTERISTICS AND TEST CONDITIONS –

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

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IEC 61675-2 has been prepared by subcommittee 62C: Equipment for radiotherapy, nuclear medicine and radiation dosimetry, of IEC technical committee 62: Medical equipment, software, and systems. It is an International Standard.

This third edition cancels and replaces the second edition published in 2015. It combines IEC 60789:1992, IEC 61675-2:1998, IEC 61675-2:1998/AMD1:2004, and IEC 61675-3:1998. It has been modified to address systems based on pixelated semi-conductor detectors. Tests for wholebody SPECT performance and quantitative SPECT image accuracy have been added. It has been reformatted, updated, and partly aligned with NEMA NU 1-2018. Due to the lack of market share of SPECT-systems operated in coincidence mode all such tests have been removed. This edition constitutes a technical revision.

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

Draft	Report on voting
XX/XX/FDIS	XX/XX/RVD

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.

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/publications.

In this standard, the following print types are used:

– TERMS DEFINED IN CLAUSE 3 OF THIS STANDARD OR LISTED IN THE INDEX OF DEFINED TERMS: SMALL CAPITALS.

The requirements are followed by specifications for the relevant tests.

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.

INTRODUCTION

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

RADIONUCLIDE IMAGING DEVICES – CHARACTERISTICS AND TEST CONDITIONS –

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

1 Scope

This part of IEC 61675 specifies terminology and test methods for describing the characteristics of GAMMA CAMERAS equipped with PARALLEL HOLE COLLIMATORS that are capable of planar imaging. Additional tests are specified for those GAMMA CAMERAS that are capable of SINGLE PHOTON EMISSION COMPUTED TOMOGRAPHY (SPECT) or planar wholebody imaging (PLANAR WHOLEBODY IMAGING EQUIPMENT) or SPECT wholebody imaging. SPECT systems may also be equipped with a CT system for hybrid imaging.

These GAMMA CAMERAS consist of a gantry, single or multiple DETECTOR HEADS, and a computer for data acquisition, processing, storage, and display. The DETECTOR HEADS may contain single or multiple scintillation crystals or solid state detectors.

Novel camera designs with multiple DETECTOR HEADS that are not capable of planar acquisition are not included in the scope of this standard.

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*

IEC 61675-1:2022, *Radionuclide imaging devices – Characteristics and test conditions – Part 1: Positron emission tomographs*

IEC 63073-1:2020, *Dedicated radionuclide imaging devices – Characteristics and test conditions – Part 1: Cardiac SPECT*

3 Terms and definitions

For the purposes of this document the terms and definitions given in IEC TR 60788:2004, IEC 63071-1:2020 and IEC 61675-1:2022 (some of which are repeated here for convenience), and the following terms and definitions apply.

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

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

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

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

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

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

3.4
BAD PIXEL
detector pixel within the DETECTOR FIELD OF VIEW of the detector that has been physically or electronically turned off such that gamma rays which interact in that pixel are not recorded by the camera

[SOURCE: IEC 63073-1:2020, 3.2]

3.5
CENTRE OF ROTATION
COR
origin of that coordinate system, which describes the PROJECTIONS of a transverse slice with respect to their orientation in space

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

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

3.6
COLLIMATOR AXIS
straight line which passes through the geometrical centre of the exit field and entrance field of the COLLIMATOR

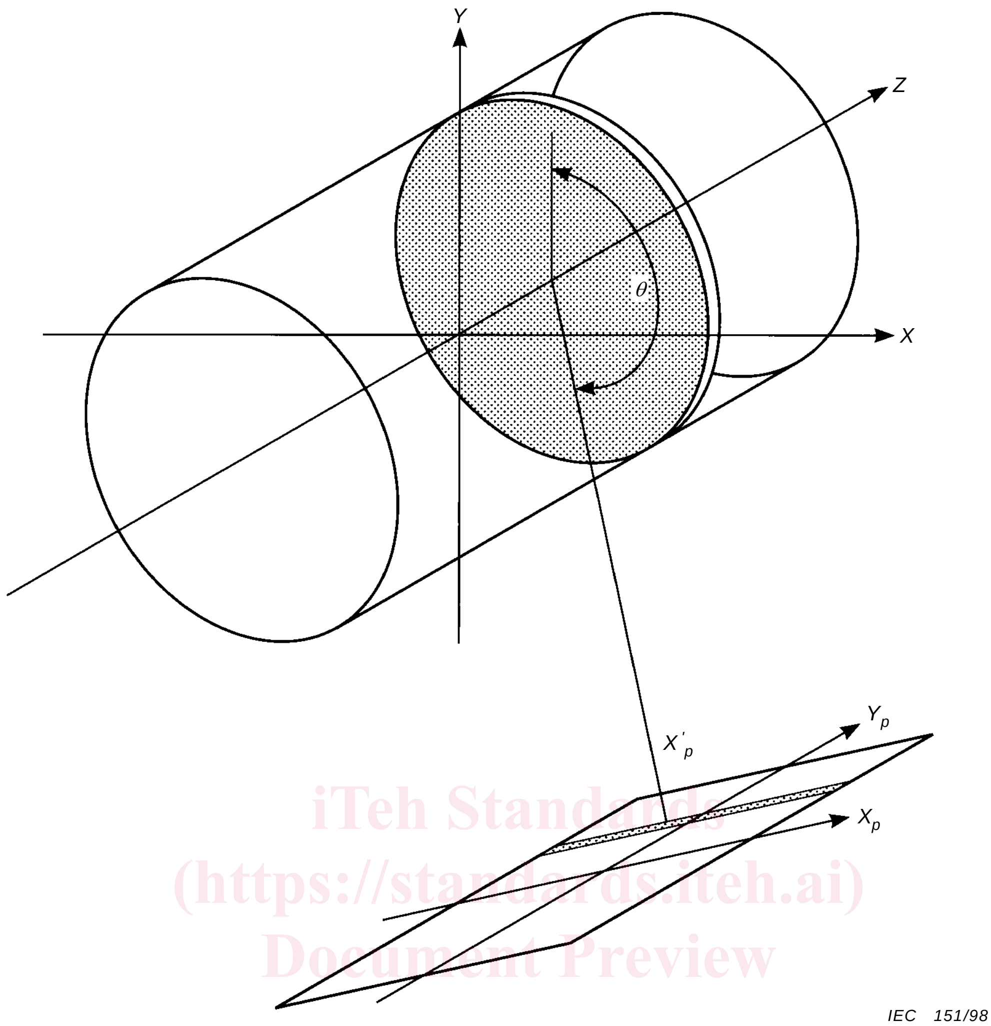
3.7
COLLIMATOR FRONT FACE
surface of the COLLIMATOR which is closest to the object being imaged

3.8
COORDINATE SYSTEM OF PROJECTION
Cartesian system of the IMAGE MATRIX of each two-dimensional PROJECTION with axes X_p and Y_p

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

Note 2 to entry: The Y_p axis and the PROJECTION of the SYSTEM AXIS onto the COLLIMATOR FRONT FACE have to be in parallel.

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



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

Figure 1 – Geometry of PROJECTIONS

3.9
COUNT LOSS
difference between measured COUNT RATE and TRUE COUNT RATE, which is caused by the finite RESOLVING TIME of the instrument

[SOURCE: IEC 61675-1:2022, 3.8.1]

3.10
COUNT RATE
number of counts per unit of time

[SOURCE: IEC 61675-1:2022, 3.8.2]

3.11
COUNT RATE CHARACTERISTIC
function giving the relationship between observed COUNT RATE and TRUE COUNT RATE

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

3.12
DETECTOR FIELD OF VIEW
FOV
region of the detector within which events are included in the display image, and for which all performance specifications are provided

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

3.13
DETECTOR HEAD TILT
deviation of the COLLIMATOR AXIS from orthogonality with the SYSTEM AXIS

3.14
DETECTOR POSITIONING TIME
fraction of the total time spent on an acquisition which is not used in collecting data

3.15
DETECTOR PIXEL
smallest discrete unit of a pixelated DETECTOR HEAD that is able to provide distinct energy, spatial, and timing information about detected photons

3.16
EMISSION COMPUTED TOMOGRAPHY
ECT
imaging method for the representation of the spatial distribution of RADIONUCLIDES in selected two-dimensional slices through the object

3.17
ENERGY WINDOW
range defining the energy of the signals accepted by the device for further processing

3.18
EQUIVALENT WIDTH
EW
width of that rectangle having the same area and the same height as the response function, e.g., the POINT SPREAD FUNCTION

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

3.19
FIXED COORDINATE SYSTEM
Cartesian system with axes *X*, *Y*, and *Z*

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

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

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

3.20
IMAGE MATRIX
arrangement of MATRIX ELEMENTS in a preferentially Cartesian coordinate system

3.21
IMAGE PLANE
plane assigned to a plane in the OBJECT SLICE

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

3.22

INTRINSIC ENERGY RESOLUTION

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

3.23

INTRINSIC ENERGY SPECTRUM

measured histogram of pulse heights for the DETECTOR HEAD without COLLIMATOR

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

3.24

INTRINSIC NON-UNIFORMITY OF RESPONSE

NON-UNIFORMITY OF RESPONSE of the DETECTOR HEAD without COLLIMATOR

3.25

INTRINSIC SPATIAL NON-LINEARITY

SPATIAL NON-LINEARITY of the DETECTOR HEAD without COLLIMATOR

3.26

INTRINSIC SPATIAL RESOLUTION

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

3.27

LINE SOURCE

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

3.28

LOW-ENERGY-TAIL RATIO

ratio of the counts measured in an energy window of width 2*E_{FWHM} centred at energy E_{peak} - 2* E_{FWHM} divided by the counts measured in an energy window of width 2*E_{FWHM} centred at an energy of E_{peak}, where E_{peak} is the peak energy of the RADIOISOTOPE being measured and E_{FWHM} is the energy resolution of the detector

[SOURCE: IEC 63073-1:2020, 3.12]

3.29

MATRIX ELEMENT

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

3.30

MULTIPLE WINDOW SPATIAL REGISTRATION

measured position of a source as a function of the ENERGY WINDOW setting

3.31

NORMALIZED VOLUME SENSITIVITY

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

3.32

OBJECT SLICE

slice in the object

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

3.33

OFFSET

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

3.34

PARALLEL HOLE COLLIMATOR

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

3.35

PILE UP EFFECT

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

3.36

PIXEL

MATRIX ELEMENT in a two-dimensional IMAGE MATRIX

3.37

PLANAR WHOLEBODY IMAGING EQUIPMENT

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

3.38

POINT SOURCE

RADIOACTIVE SOURCE approximating a δ-function in all three dimensions

3.39

POINT SPREAD FUNCTION

PSF

scintigraphic image of a POINT SOURCE

3.40

PROJECTION

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

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

3.41

PROJECTION ANGLE

angle at which the PROJECTION is measured or acquired

Note 1 to entry: See Figure 1.

3.42

PROJECTION BEAM

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

Note 1 to entry: Its shape is limited by the SPATIAL RESOLUTION in all three dimensions and may vary with photon energy and COLLIMATOR design.

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