SLOVENSKI STANDARD
SIST EN 61675-2:2016

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Nadomešča:
SIST EN 60789:2007
SIST EN 61675-2:1998
SIST EN 61675-2:1998/A1:2005
SIST EN 61675-3:1998

Naprave za opazovanje radioaktivnih elementov - Karakteristike in preskusni pogoji - 2. del: Gama kamere za planarno slikanje in slikanje SPECT (IEC 61675-2:2015)

Radionuclide imaging devices - Characteristics and test conditions - Part 2: Gamma cameras for planar imaging and spect imaging (IEC 61675-2:2015)

Dispositifs d'imagerie par radionucléides - Caractéristiques et conditions d'essai - Partie 2: gamma caméras pour l'imagerie planaire et l'imagerie spect

Ta slovenski standard je istoveten z: **EN 61675-2:2015**

ICS:

11.040.50	Radiografska oprema	Radiographic equipment

SIST EN 61675-2:2016 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 61675-2

November 2015

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English Version

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

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

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

This European Standard was approved by CENELEC on 2015-09-10. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CENELEC member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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

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

European foreword

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

The following dates are fixed:

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

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

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

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

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

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

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

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

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

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

IEC 61675-2

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INTERNATIONAL STANDARD

NORME INTERNATIONALE

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

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

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RADIONUCLIDE IMAGING DEVICES – CHARACTERISTICS AND TEST CONDITIONS –

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

FOREWORD

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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International Standard IEC 61675-2 has been prepared by subcommittee 62C: Equipment for radiotherapy, nuclear medicine and radiation dosimetry, of IEC technical committee 62: Electrical equipment in medical practice.

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

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

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

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

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

In this standard, the following print types are used:

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

The requirements are followed by specifications for the relevant tests.

Annex A is for information only.

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

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

INTRODUCTION

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

RADIONUCLIDE IMAGING DEVICES – CHARACTERISTICS AND TEST CONDITIONS –

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

1 Scope

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

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

2 Normative references

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

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

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

3 Terms and definitions

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

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

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

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

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

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

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

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

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

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

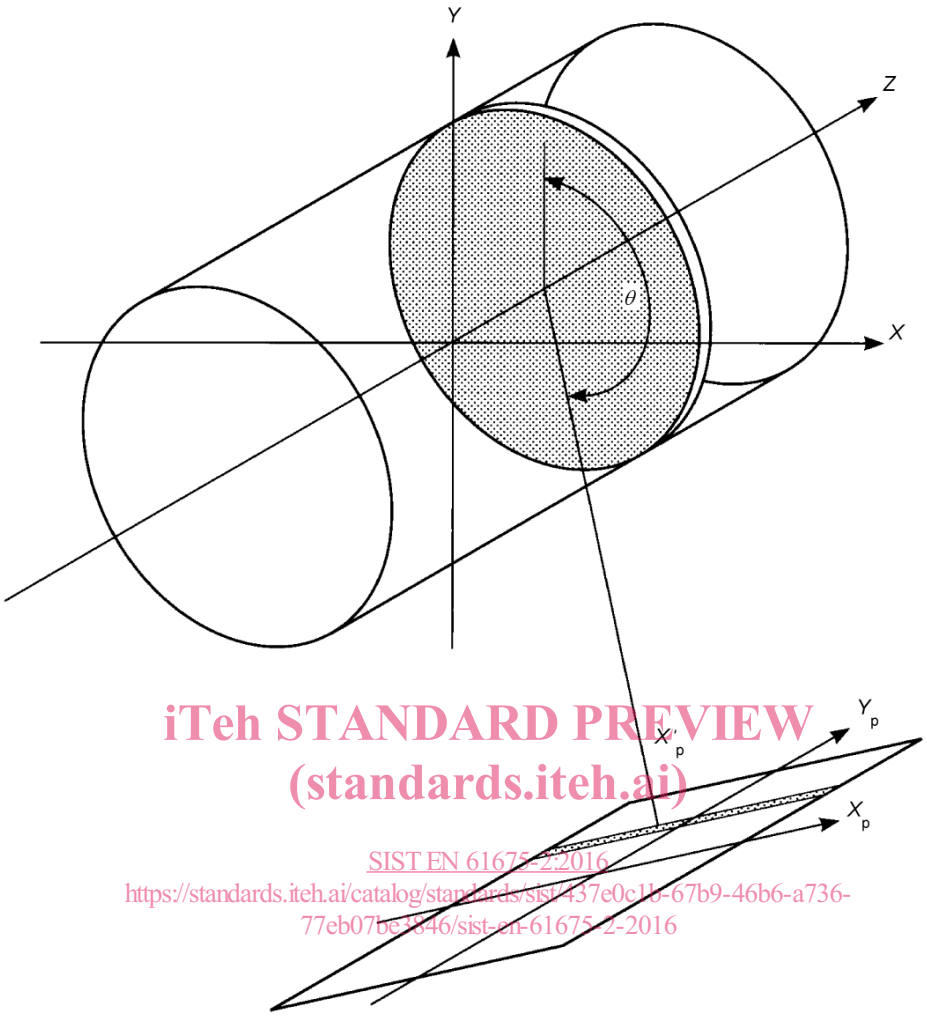
3.7
COORDINATE SYSTEM OF PROJECTION

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

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

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

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



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

Figure 1 – Geometry of PROJECTIONS

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

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

3.9
COUNT RATE
number of counts per unit of time

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

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