

### SLOVENSKI STANDARD SIST EN 61675-2:2016

01-april-2016

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)

### iTeh STANDARD PREVIEW

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

<u>SIST EN 61675-2:2016</u> https://standards.iteh.ai/catalog/standards/sist/437e0c1b-67b9-46b6-a736-77eb07be3846/sist-en-61675-2-2016

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



## iTeh STANDARD PREVIEW (standards.iteh.ai)

<u>SIST EN 61675-2:2016</u> https://standards.iteh.ai/catalog/standards/sist/437e0c1b-67b9-46b6-a736-77eb07be3846/sist-en-61675-2-2016

### SIST EN 61675-2:2016

## EUROPEAN STANDARD NORME EUROPÉENNE EUROPÄISCHE NORM

### EN 61675-2

November 2015

ICS 11.040.50

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

**English Version** 

### Radionuclide imaging devices - Characteristics and 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. 77eb07be3846/sist-en-61675-2-2016

CENELEC members are the national electrotechnical committees of Austria, Belgium, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.



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

© 2015 CENELEC All rights of exploitation in any form and by any means reserved worldwide for CENELEC Members.

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	document have to be withdrawn		

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

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC [and/or CEN] shall not be held responsible for identifying any or all such patent rights.

### iTeh STEndorsement notice VIEW

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: indicated: 77eb07be3846/sist-en-61675-2-2016

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).

EN 61675-2:2015

### 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	<u>EN/HD</u>	Year
IEC/TR 60788	2004	Medical electrical equipment - Glossary of defined terms	-	-
IEC 61675-1	2013	Radionuclide imaging devices - <b>REVI</b> Characteristics and test conditions Part 1: Positron emission tomographs <b>a</b>	EN 61675-1	2014

<u>SIST EN 61675-2:2016</u> https://standards.iteh.ai/catalog/standards/sist/437e0c1b-67b9-46b6-a736-77eb07be3846/sist-en-61675-2-2016



## iTeh STANDARD PREVIEW (standards.iteh.ai)

<u>SIST EN 61675-2:2016</u> https://standards.iteh.ai/catalog/standards/sist/437e0c1b-67b9-46b6-a736-77eb07be3846/sist-en-61675-2-2016



Edition 2.0 2015-08

# INTERNATIONAL STANDARD

## NORME INTERNATIONALE

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

INTERNATIONAL ELECTROTECHNICAL COMMISSION

COMMISSION ELECTROTECHNIQUE INTERNATIONALE

ICS 11.040.50

ISBN 978-2-8322-2819-7

Warning! Make sure that you obtained this publication from an authorized distributor. Attention! Veuillez vous assurer que vous avez obtenu cette publication via un distributeur agréé.

 Registered trademark of the International Electrotechnical Commission Marque déposée de la Commission Electrotechnique Internationale

### – 2 – IEC 61675-2:2015 © IEC 2015

### CONTENTS

FC	DREWC	RD	4
IN	TRODU	ICTION	6
1	Scop	е	7
2	Norm	native references	7
3	Term	s and definitions.	7
4	Test	methods	15
Т	1 1	General	15
	4.1	Planar imaging	15
	421	System sensitivity	10
	422	SPATIAL RESOLUTION	18
	4.2.3	SPATIAL NON-LINEARITY	24
	4.2.4	Non-uniformity of response	25
	4.2.5	INTRINSIC ENERGY RESOLUTION	28
	4.2.6	Intrinsic MULTIPLE WINDOW SPATIAL REGISTRATION	29
	4.2.7	COUNT RATE performance	31
	4.2.8	Shield leakage test	33
	4.3	Wholebody imaging	33
	4.3.1	Scanning constancy ANDARD PREVIEW	33
	4.3.2	SPATIAL RESOLUTION without scatter	36
	4.4	Tomographic imaging (SPECT)	37
	4.4.1	Test of PROJECTION geometry	37
	4.4.2	Measurement of SPECT SYSTEM SENSITIVITY	41
	4.4.3	Scatter measurement7be3846/sist-en-61675-2-2016	44
	4.4.4	SPECT SYSTEM SPATIAL RESOLUTION	48
	4.4.5	Tomographic image quality	50
5	Acco	mpanying documents	57
	5.1	General	57
	5.2	General parameters for GAMMA CAMERAS	58
	5.2.1	Collimators	58
	5.2.2	Shield leakage values	58
	5.2.3	Pre-set PULSE AMPLITUDE ANALYSER WINDOWS	58
	5.2.4	INTRINSIC ENERGY RESOLUTION	58
	5.2.5	COLLIMATOR dependent quantities	58
	5.2.6	COUNT RATE CHARACTERISTICS	58
	5.2.7	Measured COUNT RATE that is 80 % of the corresponding TRUE COUNT RATE	58
	5.2.8	Dimensions of the DETECTOR FIELD OF VIEW	58
	5.2.9	Non-uniformity characteristics	58
	5.2.1	0 INTRINSIC SPATIAL RESOLUTION (FWHM and EW) of the DETECTOR HEAD without COLLIMATOR	58
	5.2.1	1 INTRINSIC SPATIAL NON-LINEARITY	58
	5.2.1	2 Intrinsic MULTIPLE WINDOW SPATIAL REGISTRATION	59
	5.3	GAMMA CAMERA based wholebody imaging system	59
	5.3.1	Scanning constancy	59
	5.3.2	SPATIAL RESOLUTION	59
	5.4	SPECT	59

5.4.1	Calibration measurements of COR	59				
5.4.2	Measurement of head tilt	59				
5.4.3	Measurement of COLLIMATOR hole misalignment	59				
5.4.4	TRANSVERSE RESOLUTION (radial and tangential)	59				
5.4.5	Axial resolution	59				
5.4.6	5.4.6 Axial PIXEL size					
5.4.7	Transaxial PIXEL size	59				
5.4.8	DETECTOR POSITIONING TIME	59				
5.4.9	NORMALIZED VOLUME SENSITIVITY	59				
5.4.10	SCATTER FRACTIONS SF <sub>i</sub> and SF	59				
5.4.11	Scan set up and phantom ACTIVITY concentration	59				
5.4.12	Image quality	59				
5.4.13	Accuracy of ATTENUATION correction and scatter correction	59				
5.4.14	Accuracy of SPECT and CT image registration	59				
Index of defined	I terms	60				
Bibliography		62				
Figure 1 – Geor	metry of PROJECTIONS	9				
Figure 2 – Cylin	drical phantom	14				
Figure 3 – Cuve	ette	17				
Figure 4 – Slit phantom						
Figure 5 – Source arrangement for intrinsic measurements ai) 20						
Figure 6 – Calculation of FWHM22						
SIST EN 61675-2:2016 Figure 7 – Evaluation of equivalent width (EW) and visit (27.0.1) (710.400 (27.0.2)						
Figure 8 – Uniform source 77eb07be3846/sist-en-61675-2-2016 26						
Figure 9 – Small shielded liquid source						
Figure 9 – Small Shletded liquid Source						
Figure 10 – Source positions for scanning constancy for wholebody imaging						
+igure 11 – Cylindrical phantom43						
Figure 12 – Phantom insert with holders for the scatter source45						
Figure 13 – Evaluation of scatter fraction						
Figure 14 – Reporting transverse resolution						
Figure 15 – Cro	ss-section of body phantom	51				
Figure 16 – Pha	antom insert with hollow spheres	52				
Figure 17 – Pla	cement of ROIs in the phantom background	55				
J I						
Table 1 – RADIO	NUICUDES and ENERGY WINDOWS to be used for performance					
measurements		16				

### IEC 61675-2:2015 © IEC 2015 - 3 -

- 4 -

### INTERNATIONAL ELECTROTECHNICAL COMMISSION

### 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.
- 2) The formal decisions or agreements of IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested IEC National Committees, TANDARD PREVIEW
- 3) IEC Publications have the form of recommendations for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user.
- 4) In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible tim their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter.
- 5) IEC itself does not provide any attestation of conformity. Independent certification bodies provide conformity assessment services and, in some areas, access to IEC marks of conformity. IEC is not responsible for any services carried out by independent certification bodies.
- 6) All users should ensure that they have the latest edition of this publication.
- 7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.
- 8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
- 9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

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.

IEC 61675-2:2015 © IEC 2015

- 5 -

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

- iTeh STANDARD PREVIEW reconfirmed, •
- withdrawn, •
  - (standards.iteh.ai)
- replaced by a revised edition, or .
- amended. •

SIST EN 61675-2:2016 https://standards.iteh.ai/catalog/standards/sist/437e0c1b-67b9-46b6-a736-77eb07be3846/sist-en-61675-2-2016

IEC 61675-2:2015 © IEC 2015

### 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.

### iTeh STANDARD PREVIEW (standards.iteh.ai)

SIST EN 61675-2:2016 https://standards.iteh.ai/catalog/standards/sist/437e0c1b-67b9-46b6-a736-77eb07be3846/sist-en-61675-2-2016 IEC 61675-2:2015 © IEC 2015

### 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 STANDARD PREVIEW

The following documents, in whole of 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. https://standards.iteh.ai/catalog/standards/sist/437e0c1b-67b9-46b6-a736-

77eb07be3846/sist-en-61675-2-2016

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

- 8 -

#### 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

### iTeh STANDARD PREVIEW

COORDINATE SYSTEM OF PROJECTION and a consistent system of the IMAGE MATRIX of each two-dimensional PROJECTION with axes  $X_p$  and Yp

#### SIST EN 61675-2:2016

Note 1 to entry: Axes x pand y are defined by the axes of the MAGE MATRIX b9-46b6-a736-

77eb07be3846/sist-en-61675-2-2016

Note 2 to entry: The Y<sub>p</sub> 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).

-9-



7

IEC

**iTeh STANDARD PREVIEW** (standards.iteh.ai) <u>SIST EN 61675-2:2016</u> https://standards.iteh.ai/catalog/standards/stst/437e0c1b-67b9-46b6-a736-77eb07bc73646/sist-en-61675-2-2016

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  $\theta$ . For each  $\theta$ , 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