SLOVENSKI STANDARD
SIST EN 61675-1:2016

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Naprave za slikanje z radionuklidi - Karakteristike in preskusni pogoji - 1. del: Pozitronska emisijska tomografija (IEC 61675-1:2013)

Radionuclide imaging devices - Characteristics and test conditions - Part 1: Positron emission tomographs (IEC 61675-1:2013)

Dispositifs d'imagerie par radionucléides - Caractéristiques et conditions d'essai - Partie 1: Tomographes à émission de positrons (IEC 61675-1:2013)

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11.040.50	Radiografska oprema	Radiographic equipment

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EUROPEAN STANDARD

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English Version

Radionuclide imaging devices - Characteristics and test conditions - Part 1: Positron emission tomographs (IEC 61675-1:2013)

Dispositifs d'imagerie par radionucléides - Caractéristiques et conditions d'essai - Partie 1: Tomographes à émission de positrons (CEI 61675-1:2013)

Bildgebende Systeme in der Nuklearmedizin - Merkmale und Prüfbedingungen - Teil 1: Positronen-Emissions-Tomographen (IEC 61675-1:2013)

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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

Ref. No. EN 61675-1:2014 E

Foreword

The text of document 62C/550/CDV, future edition 2 of IEC 61675-1, 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 61675-1:2014.

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)	2014-12-13
• latest date by which the national standards conflicting with the document have to be withdrawn	(dow)	2016-10-30

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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 When an international publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

Publication	Year	Title	EN/HD	Year
IEC/TR 60788	2004	Medical electrical equipment - Glossary of defined terms	-	-

IEC 61675-1

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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