

STN	Rádionuklidové zobrazovacie prístroje Charakteristiky a skúšobné podmienky Časť 1: Pozitrónové emisné tomografy	STN EN IEC 61675-1 36 4767
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Radionuclide imaging devices - Characteristics and test conditions - Part 1: Positron emission tomographs

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 06/22

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EN IEC 61675-1

April 2022

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Supersedes EN 61675-1:2014

English Version

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

Dispositifs d'imagerie par radionucléides - Caractéristiques
et conditions d'essai - Partie 1: Tomographes à émission de
positrons
(IEC 61675-1:2022)

Bildgebende Systeme in der Nuklearmedizin - Merkmale
und Prüfbedingungen - Teil 1: Positronen-Emissions-
Tomographen
(IEC 61675-1:2022)

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EN IEC 61675-1:2022 (E)**European foreword**

The text of document 62C/811/CDV, future edition 3 of IEC 61675-1, prepared by 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 IEC 61675-1:2022.

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IEC 60601-1:2005 NOTE Harmonized as EN 60601-1:2006 (not modified) +A11:2011

Annex ZA (normative)

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

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



IEC 61675-1

Edition 3.0 2022-03

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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IEC 61675-1

Edition 3.0 2022-03

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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CONTENTS

FOREWORD	4
INTRODUCTION	6
1 Scope	7
2 Normative references	7
3 Terms and definitions	7
4 Test methods.....	13
4.1 General.....	13
4.2 SPATIAL RESOLUTION	13
4.2.1 General	13
4.2.2 Purpose	14
4.2.3 Method	14
4.2.4 Analysis.....	15
4.2.5 Report	17
4.3 Tomographic sensitivity	18
4.3.1 General	18
4.3.2 Purpose.....	18
4.3.3 Method	18
4.3.4 Analysis.....	20
4.3.5 Report	20
4.4 Scatter measurement.....	20
4.4.1 General	20
4.4.2 Purpose.....	20
4.4.3 Method	20
4.4.4 Analysis.....	21
4.4.5 Report	23
4.5 PET COUNT RATE PERFORMANCE	23
4.5.1 General	23
4.5.2 Purpose.....	23
4.5.3 Method	23
4.5.4 Analysis.....	24
4.5.5 Report	26
4.6 Time-of-flight resolution	26
4.6.1 General	26
4.6.2 Purpose.....	27
4.6.3 Method	27
4.6.4 Radionuclide, source distribution and data collection	27
4.6.5 Data processing.....	27
4.6.6 Analysis.....	28
4.6.7 Scatter and random removal.....	29
4.6.8 FWHM analysis.....	29
4.6.9 Report	29
4.7 Image quality and quantification accuracy of source ACTIVITY concentrations and PET/CT registration accuracy.....	30
4.7.1 General	30
4.7.2 Purpose.....	30
4.7.3 Method	30

4.7.4	Data analysis.....	35
4.7.5	Report	38
5	ACCOMPANYING DOCUMENTS	39
5.1	General.....	39
5.2	Design parameters and configuration	39
5.3	SPATIAL RESOLUTION	40
5.4	Sensitivity	40
5.5	SCATTER FRACTION.....	40
5.6	COUNT RATE performance	40
5.7	TIME-OF-FLIGHT resolution.....	40
5.8	Image quality and quantification accuracy of source ACTIVITY concentrations	40
	Bibliography.....	41
	Index of defined terms	42
	Figure 1 – Evaluation of FWHM	16
	Figure 2 – Evaluation of EQUIVALENT WIDTH (<i>EW</i>).....	17
	Figure 3 – Scatter phantom configuration and position on the imaging bed	19
	Figure 4 – Evaluation of SCATTER FRACTION	22
	Figure 5 – Determination of LOR distance from line source.....	27
	Figure 6 – Cross-section of body phantom	31
	Figure 7 – Phantom insert with hollow spheres	32
	Figure 8 – Image quality phantom and scatter phantom position for whole body scan acquisition	33
	Figure 9 – Placement of ROIs in the phantom background.....	36

INTERNATIONAL ELECTROTECHNICAL COMMISSION

RADIONUCLIDE IMAGING DEVICES – CHARACTERISTICS AND TEST CONDITIONS –

Part 1: Positron emission tomographs

FOREWORD

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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. It is an International Standard.

This third edition cancels and replaces the second edition published in 2013. This edition constitutes a technical revision.

This edition includes the following significant technical change with respect to the previous edition: requirements have been changed or newly created regarding the technical aspects of SPATIAL RESOLUTION, sensitivity measurement, SCATTER FRACTION, COUNT RATE performance, image quality, PET/CT registration accuracy and time-of-flight resolution.

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

Draft	Report on voting
62C/811/CDV	62C/828/RVC

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.

In this document, the following print types are used: terms defined in Clause 3 of this document or as noted: small capitals.

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/standardsdev/publications.

A list of all parts in the IEC 61675 series, published under the general title *Radionuclide imaging devices – Characteristics and test conditions*, can be found on the IEC website.

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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 document 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 document, 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.

While the test methods specified herein are optimized for the PET component of PET-CT hybrid devices, they may also be used for the PET component of PET-MR hybrid devices.

The test methods specified in this document 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 document does not indicate which tests will be performed by the MANUFACTURER on an individual tomograph or which class-standards may be used to characterize the performance of POSITRON EMISSION TOMOGRAPHS by the MANUFACTURER.

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.

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*

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