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STN	**Rádionuklidové zobrazovacie prístroje Charakteristiky a skúšobné podmienky Časť 1: Pozitrónové emisné tomografy**	**STN EN IEC 61675-1** 36 4767

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

Obsahuje: EN IEC 61675-1:2022, IEC 61675-1:2022

Oznámením tejto normy sa od 22.04.2025 ruší
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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN IEC 61675-1

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

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

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.

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) 2023-01-22
•	latest date by which the national standards conflicting with the document have to be withdrawn	(dow) 2025-04-22

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In the official version, for Bibliography, the following note has to be added for the standard indicated:

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

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

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.

NOTE 1 Where 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

Edition 3.0 2022-03

INTERNATIONAL STANDARD

NORME INTERNATIONALE

colour inside

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

IEC 61675-1:2022-03(en-fr)

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RADIONUCLIDE IMAGING DEVICES – CHARACTERISTICS AND TEST CONDITIONS –

Part 1: Positron emission tomographs

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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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.

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.

IMPORTANT – The "colour inside" logo on the cover page of this document indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this document using a colour printer.

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*