

Radionuclide imaging devices - Characteristics and test conditions - Part 1: Positron emission tomographs

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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 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

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**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

Dispositifs d'imagerie par radionucléides – Caractéristiques et conditions d'essai – Partie 1: Tomographes à émission de positrons

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

**RADIONUCLIDE IMAGING DEVICES –
CHARACTERISTICS AND TEST CONDITIONS –****Part 1: Positron emission tomographs**

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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.

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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*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC TR 60788:2004 and the following apply.

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- IEC Electropedia: available at <http://www.electropedia.org/>
- ISO Online browsing platform: available at <http://www.iso.org/obp>

3.1

tomography

radiography of one or more layers within an object

[SOURCE: IEC TR 60788:2004, rm-41-15]

3.1.1

emission computed tomography

ECT

imaging method for the representation of the spatial distribution of incorporated RADIONUCLIDES in selected two-dimensional slices through the object

3.1.1.1

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

Note 1 to entry: This process is mathematically described by line integrals in the direction of PROJECTION (along the LINE OF RESPONSE) and called "Radon transform".