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IEC 61675-1

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REDLINE VERSION

# INTERNATIONAL STANDARD



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

INTERNATIONAL  
ELECTROTECHNICAL  
COMMISSION

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## INTERNATIONAL ELECTROTECHNICAL COMMISSION

### 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](http://www.iec.ch/members_experts/refdocs). The main document types developed by IEC are described in greater detail at [www.iec.ch/standardsdev/publications](http://www.iec.ch/standardsdev/publications).

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**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.

~~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 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*

# 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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## COMMISSION ÉLECTROTECHNIQUE INTERNATIONALE

### DISPOSITIFS D'IMAGERIE PAR RADIONUCLÉIDES – CARACTÉRISTIQUES ET CONDITIONS D'ESSAI –

#### Partie 1: Tomographes à émission de positrons

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Cette troisième édition annule et remplace la deuxième édition parue en 2013. Cette édition constitue une révision technique.

Cette édition inclut les modifications techniques majeures suivantes par rapport à l'édition précédente: des exigences ont été modifiées ou ajoutées quant aux aspects techniques de la RESOLUTION SPATIALE, du mesurage de la sensibilité, de la FRACTION DE DIFFUSION, de la performance du TAUX DE COMPTAGE, de la qualité d'image et de l'exactitude de la superposition d'images en TEP ou CT.

Le texte de cette Norme internationale est issu des documents suivants:

Projet	Rapport de vote
62C/811/CDV	62C/828/RVC

Le rapport de vote indiqué dans le tableau ci-dessus donne toute information sur le vote ayant abouti à son approbation.

La langue employée pour l'élaboration de cette Norme internationale est l'anglais.

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Une liste de toutes les parties de la série IEC 61675, publiées sous le titre général *Dispositifs d'imagerie par radionucléides – Caractéristiques et conditions d'essai*, peut être consultée sur le site web de l'IEC.

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## INTRODUCTION

Après les progrès réalisés dans le domaine des TOMOGRAPHES A EMISSION DE POSITRONS, la plupart des tomographes peuvent maintenant être utilisés en mode d'acquisition totalement 3D. Afin de satisfaire à cette tendance, le présent document décrit les conditions d'essai en tenant compte de cette caractéristique d'acquisition. En outre, les TOMOGRAPHES A EMISSION DE POSITRONS modernes intègrent souvent des EQUIPEMENTS A RAYONNEMENT X pour TOMODENSITOMETRIE (CT). Dans le présent document, les dispositifs hybrides TEP-CT sont considérés comme représentatifs de l'état de l'art, les TOMOGRAPHES A EMISSION DE POSITRONS spécialisés n'intégrant pas le rayonnement X constituant seulement des cas particuliers.

Bien que les méthodes d'essai spécifiées dans le présent document soient optimisées pour le composant TEP des dispositifs hybrides TEP-CT, elles peuvent être également utilisées pour le composant TEP des dispositifs hybrides TEP-RM (tomographie par émission de positrons-résonance magnétique).

Les méthodes d'essai spécifiées dans le présent document ont été sélectionnées afin de refléter, autant que possible, l'utilisation clinique des TOMOGRAPHES A EMISSION DE POSITRONS. L'objectif est de faire en sorte que les essais soient réalisés par les FABRICANTS et de permettre à ces derniers de décrire les caractéristiques des TOMOGRAPHES A EMISSION DE POSITRONS dans les DOCUMENTS D'ACCOMPAGNEMENT. Le présent document n'indique pas quels essais sont effectués par le FABRICANT sur un tomographe particulier ou quelles normes de classification peuvent être utilisées par le FABRICANT pour caractériser les performances des TOMOGRAPHES A EMISSION DE POSITRONS.

## DISPOSITIFS D'IMAGERIE PAR RADIONUCLÉIDES – CARACTÉRISTIQUES ET CONDITIONS D'ESSAI –

### Partie 1: Tomographes à émission de positrons

#### 1 Domaine d'application

La présente partie de l'IEC 61675 spécifie la terminologie et les méthodes d'essai relatives à la description des caractéristiques des TOMOGRAPHES A EMISSION DE POSITRONS. Les TOMOGRAPHES A EMISSION DE POSITRONS détectent le RAYONNEMENT D'ANNIHILATION des RADIONUCLEIDES qui émettent des positrons par la DETECTION EN COÏNCIDENCE.

#### 2 Références normatives

Les documents suivants sont cités dans le texte de sorte qu'ils constituent, pour tout ou partie de leur contenu, des exigences du présent document. Pour les références datées, seule l'édition citée s'applique. Pour les références non datées, la dernière édition du document de référence s'applique (y compris les éventuels amendements).

IEC TR 60788:2004, *Medical electrical equipment – Glossary of defined terms* (disponible en anglais seulement)