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Radionuclide imaging devices - Characteristics and test conditions - Part 2: Gamma cameras for planar, wholebody, and SPECT imaging

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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Radionuclide imaging devices - Characteristics and test conditions - Part 2: Gamma cameras for planar, wholebody, and SPECT imaging

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This redline version of the official IEC Standard allows users to identify the changes made since the previous edition, IEC 61675-2:2015. A vertical bar appears in the margin wherever a change has been made. Additions are shown in green text, and deletions are shown in red strikethrough text.

IEC 61675-2 has been prepared by subcommittee 62C: Equipment for radiotherapy, nuclear medicine and radiation dosimetry, of IEC technical committee 62: Medical equipment, software, and systems. It is an International Standard.

This third edition cancels and replaces the second edition published in 2015. This edition constitutes a technical revision.

This edition includes the following significant technical changes with respect to the previous edition:

a) addition of systems based on pixelated semi-conductor detectors;
b) addition of tests for wholebody SPECT performance and quantitative SPECT image accuracy;
c) alignment with NEMA NU 1-2018;
d) deletion of tests for SPECT-systems operated in coincidence mode due to the lack of market share of these systems.

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

Draft	Report on voting
62C/990/FDIS	62C/998/RVD

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.

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/publications.

In this document, the following print types are used:

– terms defined in Clause 0 of this document or listed in the index of defined terms: SMALL CAPITALS.

The requirements are followed by specifications for the relevant tests.

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, or
– revised.

INTRODUCTION

The test methods specified in this document have been selected to reflect as much as possible the clinical use of GAMMA CAMERAS for planar imaging, PLANAR WHOLEBODY IMAGING EQUIPMENT, and SINGLE PHOTON EMISSION COMPUTED TOMOGRAPHY (SPECT). It is intended that the test methods are carried out by manufacturers thereby enabling them to describe the characteristics of the systems on a common basis.

This document combines IEC 60789:1992, IEC 61675-2:1998, IEC 61675-2:1998/AMD1:2004, and IEC 61675-3:1998[1].

[1] These publications have been withdrawn.

1 Scope

This part of IEC 61675 specifies terminology and test methods for describing the characteristics of GAMMA CAMERAS equipped with PARALLEL HOLE COLLIMATORS ~~for~~ that are capable of planar imaging. Additional tests are specified for those GAMMA CAMERAS that are capable of SINGLE PHOTON EMISSION COMPUTED TOMOGRAPHY (SPECT) or planar wholebody imaging (PLANAR WHOLEBODY IMAGING EQUIPMENT) or SPECT wholebody imaging. SPECT systems can also be equipped with a CT system for hybrid imaging.

These GAMMA CAMERAS consist of a gantry, single or multiple DETECTOR HEADS, and a computer for data acquisition, processing, storage, and display. The DETECTOR HEADS ~~may~~ can contain single or multiple scintillation crystals or solid state detectors.

~~No test has been specified to characterize the uniformity of reconstructed images because all methods known so far will mostly reflect the noise of the image.~~

Novel camera designs with multiple DETECTOR HEADS that are not capable of planar acquisition are not included in the scope of this document.

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*

IEC 61675-1:~~2013~~2022, *Radionuclide imaging devices - Characteristics and test conditions - Part 1: Positron emission tomographs*

IEC 63073-1:2020, *Dedicated radionuclide imaging devices - Characteristics and test conditions - Part 1: Cardiac SPECT*

Bibliography

IEC 60601-1:2005, *Medical electrical equipment - Part 1: General requirements for basic safety and essential performance*
IEC 60601-1:2005/AMD1:2012
IEC 60601-1:2005/AMD2:2020

IEC 60789:1992, *Characteristics and test conditions of radionuclide imaging devices; Anger type gamma cameras*[2]

~~IEC 61675-1:2013, *Radionuclide imaging devices – Characteristics and test conditions – Part 1: Positron emission tomographs*~~

IEC 61675-2:1998, *Radionuclide imaging devices - Characteristics and test conditions - Part 2: Single photon emission computed tomographs*[3]
IEC 61675-2:1998/AMD1:2004

IEC 61675-3:1998, *Radionuclide imaging devices - Characteristics and test conditions - Part 3: Gamma camera based wholebody imaging systems*[4]

IEC TR 61948-2:~~2001~~2019, *Nuclear medicine instrumentation - Routine tests - Part 2: Scintillation cameras and single photon emission computed tomography imaging*

NEMA NU 1-~~2012~~2018, *Performance measurements of gamma cameras*

NEMA NU 2-2007, *Performance measurements of positron emission tomographs (PETS)*

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[2] This publication has been withdrawn and replaced with IEC 60789:2005.

[3] This publication has been withdrawn and replaced with IEC 61675-2:2015.

[4] This publication has been withdrawn and replaced with IEC 61675-2:2015.