ICS 11.040.50 SLOVENSKÁ TECHNICKÁ NORMA Máj 2016

STN	**Rádionuklidové zobrazovacie prístroje. Charakteristiky a skúšobné podmienky. Časť 2: Gamakamery na plošné zobrazovanie, celotelové zobrazovanie a zobrazovanie SPECT.**	**STN EN 61675-2** 36 4767

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

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. 04/16

Obsahuje: EN 61675-2:2015, IEC 61675-2:2015

Oznámením tejto normy sa od 10.09.2018 ruší
STN EN 60789 (36 4765) z augusta 2006

STN EN 61675-2 (36 4767) z júla 2002

STN EN 61675-3 (36 4767) z apríla 2002

122707

Úrad pre normalizáciu, metrológiu a skúšobníctvo SR, 2016
Podľa zákona č. 264/1999 Z. z. v znení neskorších predpisov sa môžu slovenské technické normy rozmnožovať a rozširovať iba so súhlasom Úradu pre normalizáciu, metrológiu a skúšobníctvo SR.

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 61675-2

November 2015

ICS 11.040.50

Supersedes EN 60789:2005, EN 61675-2:1998, EN 61675-3:1998

English Version

Radionuclide imaging devices - Characteristics and conditions - Part 2: Gamma cameras for planar, wholebody, and SPECT imaging (IEC 61675-2:2015)

Dispositifs d'imagerie par radionucléides - Caractéristiques et conditions d'essai - Partie 2: Gamma-caméras pour l'imagerie planaire, l'imagerie du corps entier et l'imagerie SPECT
(IEC 61675-2:2015)

Bildgebende Systeme in der Nuklearmedizin - Merkmale und Prüfbedingungen - Teil 2: Gammakameras für planare Bildgebung, mit Ganzkörper-Zusatz und Gammakameras zur Einzelphotonen-Emissions-Tomographie (SPECT)
(IEC 61675-2:2015)

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European foreword

The text of document 62C/616/FDIS, future edition 2 of IEC 61675-2, prepared by IEC/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 61675-2:2015.

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)	2016-06-10
• latest date by which the national standards conflicting with the document have to be withdrawn	(dow)	2018-09-10

This document supersedes EN 61675-2:1998 and A1:2005, EN 60789:2005 and EN 61675-3:1998.

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IEC 60601-1:2005 A1:2012	NOTE Harmonized as EN 60601-1:2006 (not modified). A1:2013
IEC 61675-1:2013	NOTE Harmonized as EN 61675-1:2014 (not modified).

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

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NOTE 1 When 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	2013	Radionuclide imaging devices - Characteristics and test conditions -- Part 1: Positron emission tomographs	EN 61675-1	2014

IEC 61675-2

Edition 2.0 2015-08

INTERNATIONAL STANDARD

NORME INTERNATIONALE

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

Dispositifs d'imagerie par radionucléides – Caractéristiques et conditions d'essai – Partie 2: Gamma-caméras pour l'imagerie planaire, l'imagerie du corps entier et l'imagerie SPECT

IEC 61675-2:2015-08(en-fr)

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IEC 61675-2

Edition 2.0 2015-08

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ICS 11.040.50

ISBN 978-2-8322-2819-7

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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

FOREWORD

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International Standard IEC 61675-2 has been prepared by subcommittee 62C: Equipment for radiotherapy, nuclear medicine and radiation dosimetry, of IEC technical committee 62: Electrical equipment in medical practice.

This second edition of IEC 61675-2 cancels and replaces the first edition published in 1998 and its Amendment 1 published in 2004, as well as IEC 60789:2005, IEC 60789:2005/COR1:2009, and IEC 61675-3:1998. It has been reformatted, updated, and partly aligned with NEMA NU 1-2007. Due to the lack of market share of SPECT-systems operated in coincidence mode all such tests have been removed.

The text of this standard is based on the following documents:

FDIS	Report on voting
62C/616/FDIS	62C/623/RVD

Full information on the voting for the approval of this standard can be found in the report on voting indicated in the above table.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

In this standard, the following print types are used:

– TERMS DEFINED IN CLAUSE 2 OF THIS STANDARD OR LISTED IN THE INDEX OF DEFINED TERMS: SMALL CAPITALS.

The requirements are followed by specifications for the relevant tests.

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- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

INTRODUCTION

The test methods specified in this part of IEC 61675 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.

RADIONUCLIDE IMAGING DEVICES – CHARACTERISTICS AND TEST CONDITIONS –

Part 2: Gamma cameras for planar, wholebody, and SPECT imaging

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 planar imaging. Additional tests are specified for those GAMMA CAMERAS that are capable of planar wholebody imaging (PLANAR WHOLEBODY IMAGING EQUIPMENT) or SINGLE PHOTON EMISSION COMPUTED TOMOGRAPHY (SPECT). 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 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.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

IEC 60788:2004, *Medical electrical equipment – Glossary of defined terms*

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