SLOVENSKI STANDARD

SIST EN 60789:2007

januar 2007

Medicinska električna oprema - Karakteristike in preskusni pogoji za naprave za slikanje z radionuklidi - Kamere z žarki gama tipa Anger (IEC 60789:2005)

(istoveten EN 60789:2005)

Medical electrical equipment - Characteristics and test conditions of radionuclide imaging devices - Anger type gamma cameras (IEC 60789:2005)

ICS 11.040.50

Referenčna številka
SIST EN 60789:2007(en)

EUROPEAN STANDARD **EN 60789**

NORME EUROPÉENNE

EUROPÄISCHE NORM December 2005

ICS 11.040.50 Supersedes EN 60789:1993

English version

Medical electrical equipment – Characteristics and test conditions of radionuclide imaging devices - Anger type gamma cameras
(IEC 60789:2005)

Appareils électromédicaux - Caractéristiques et conditions d'essai des dispositifs d'imagerie par radionucléides – Gamma caméras de type Anger (CEI 60789:2005)

Medizinische elektrische Geräte - Merkmale und Prüfbedingungen für bildgebende Systeme in der Nuklearmedizin – Einkristall-Gamma-Kameras (IEC 60789:2005)

This European Standard was approved by CENELEC on 2005-11-01. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CENELEC member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the Central Secretariat has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

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

Central Secretariat: rue de Stassart 35, B - 1050 Brussels

Ref. No. EN 60789:2005 E

Foreword

The text of document 62C/388/FDIS, future edition 3 of IEC 60789, 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 was approved by CENELEC as EN 60789 on 2005-11-01.

This European Standard supersedes EN 60789:1993.

With respect to EN 60789:1993, the measurement of intrinsic point source sensitivity variation has been removed, the subclauses SYSTEM SENSITIVITY (4.2), SPATIAL RESOLUTION (4.3), NON-UNIFORMITY OF RESPONSE (4.5), INTRINSIC MULTIPLE WINDOW SPATIAL REGISTRATION (4.7) and COUNT RATE CHARACTERISTIC (4.8) have been reformulated (although the procedures are mostly unchanged) and some small editorial changes have been made.

The following dates were fixed:

– latest date by which the EN has to be implemented at national level by publication of an identical national standard or by endorsement	(dop)	2006-08-01
– latest date by which the national standards conflicting with the EN have to be withdrawn	(dow)	2008-11-01

In this standard the following print types are used:

– requirements, compliance with which can be tested, and definitions: in roman type;

– notes, explanations, advice, introductions, general statements, exceptions and reference: in smaller roman type;

– *test specifications: in italic type;*

– TERMS DEFINED IN CLAUSE 3 OF THIS STANDARD LISTED IN ANNEX B: SMALL CAPITALS.

The requirements are followed by specifications for the relevant tests.

Annex ZA has been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 60789:2005 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following notes have to be added for the standards indicated:

IEC 60601-1	NOTE	Harmonized as EN 60601-1:1990 (not modified).
IEC 61675-1	NOTE	Harmonized as EN 61675-1:1998 (not modified).
IEC 61675-2	NOTE	Harmonized as EN 61675-2:1998 (not modified).

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

The following referenced documents are indispensable for the application 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 Where an international publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

Publication	Year	Title	EN/HD	Year
IEC/TR 60788	2004	Medical electrical equipment - Glossary of defined terms	-	-

NORME INTERNATIONALE

INTERNATIONAL STANDARD

CEI
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Troisième édition
Third edition
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Appareils électromédicaux – Caractéristiques et conditions d'essai des dispositifs d'imagerie par radionucléides – Gamma caméras de type Anger

Medical electrical equipment – Characteristics and test conditions of radionuclide imaging devices – Anger type gamma cameras

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Международная Электротехническая Комиссия

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT – CHARACTERISTICS AND TEST CONDITIONS OF RADIONUCLIDE IMAGING DEVICES – ANGER TYPE GAMMA CAMERAS

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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International Standard IEC 60789 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 third edition cancels and replaces the second edition published in 1992. It constitutes a technical revision.

With respect to the second edition, the measurement of intrinsic point source sensitivity variation has been removed, the subclauses SYSTEM SENSITIVITY (4.2), SPATIAL RESOLUTION (4.3),NON-UNIFORMITY OF RESPONSE (4.5), INTRINSIC MULTIPLE WINDOW SPATIAL REGISTRATION (4.7) and COUNT RATE CHARACTERISTIC (4.8) have been reformulated (although the procedures are mostly unchanged) and some small editorial changes have been made.

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

FDIS	Report on voting
62C/388/FDIS	62C/392/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:

– requirements, compliance with which can be tested, and definitions: in roman type;

– notes, explanations, advice, introductions, general statements, exceptions and reference: in smaller roman type;

– *test specifications: in italic type;*

– TERMS DEFINED IN CLAUSE 3 OF THIS STANDARD LISTED IN ANNEX B: SMALL CAPITALS.

The requirements are followed by specifications for the relevant tests.

The committee has decided that the contents of this publication will remain unchanged until the maintenance result date indicated on the IEC web site under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

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

INTRODUCTION

The test methods specified in this standard have been selected to reflect as much as possible the clinical use of GAMMA CAMERAS. It is intended that the test methods be carried out by manufacturers, thereby enabling them to describe the characteristics of GAMMA CAMERAS on a common basis.

MEDICAL ELECTRICAL EQUIPMENT – CHARACTERISTICS AND TEST CONDITIONS OF RADIONUCLIDE IMAGING DEVICES – ANGER TYPE GAMMA CAMERAS

1 Scope

This International Standard specifies test methods for declaring the characteristics of Anger type GAMMA CAMERAS. The latter are composed of a collimator, a detector shield and a radiation detector assembly, together with recording and display devices.

It is not within the scope of this standard to address the safety requirements to be followed by manufacturers according to IEC 60601-1.

2 Normative references

The following referenced documents are for the application 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 60788:2004, *Medical electrical equipment – Glossary of defined terms*

3 Terms and definitions

For the purposes of this document, the definitions given in IEC 60788 (see Index of defined terms) and the following apply.

3.1
ENERGY WINDOW
range defining the energy signals accepted by the device for further processing

3.2
DETECTOR FIELD OF VIEW
FOV
region of the detector within which events are included in the display image, and for which all performance specifications are provided

3.3
COLLIMATOR FRONT FACE
surface of the COLLIMATOR which is closest to the object being imaged

3.4
COLLIMATOR BACK FACE
surface of the COLLIMATOR which is closest to the RADIATION DETECTOR ASSEMBLY

3.5
ENTRANCE FIELD OF A COLLIMATOR
area bounded by the shortest line which is tangential to the outside edges of the peripheral COLLIMATOR apertures on the COLLIMATOR FRONT FACE