

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

The European Standard EN 60789:2005 has the status of a
British Standard

ICS 11.040.50

National foreword

This British Standard is the official English language version of EN 60789:2005. It is identical with IEC 60789:2005. It supersedes BS EN 60789:1994 which is withdrawn.

The UK participation in its preparation was entrusted by Technical Committee CH/62, Electromedical equipment in medical practice, to Subcommittee CH/62/3, Equipment for radiotherapy, nuclear medicine and radiation dosimetry, which has the responsibility to:

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Summary of pages

This document comprises a front cover, an inside front cover, the EN title page, pages 2 to 29 and a back cover.

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Amendments issued since publication

Amd. No.	Date	Comments

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 13 February 2006

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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)

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CENELEC

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

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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.

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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

3.6**EXIT 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 BACK FACE

3.7**COLLIMATOR AXIS**

straight line which passes through the geometrical centre of the EXIT and ENTRANCE FIELDS of the COLLIMATOR

3.8**PARALLEL HOLE COLLIMATOR**

COLLIMATOR with a number of apertures, the axes of which are parallel

3.9**PIN-HOLE COLLIMATOR**

COLLIMATOR with one small aperture in a plane in front of the RADIATION DETECTOR ASSEMBLY

3.10**ADDRESS PILE UP**

<GAMMA CAMERA> false address calculation of an artificial event which passes the ENERGY WINDOW, but is formed from two or more events by the PILE UP EFFECT

3.11**PILE UP EFFECT**

false measurement of the pulse amplitude, due to the absorption of two or more gamma rays, reaching the same radiation detector within the RESOLVING TIME

[IEC 61675-1, definition 2.7.4.1]

3.12**SYSTEM SENSITIVITY**

<GAMMA CAMERA> with a specified COLLIMATOR and ENERGY WINDOW, the ratio of the COUNT RATE of the DETECTOR HEAD to the ACTIVITY of a plane source of specific dimensions and containing a specified radionuclide placed perpendicular to and centred on the COLLIMATOR AXIS under specified conditions

NOTE See also Figure 2.

3.13**INTRINSIC LINE SPREAD FUNCTION**

line spread function measured with a collimated line source in front of the DETECTOR HEAD without COLLIMATOR

3.14**DETECTOR HEAD LINE SPREAD FUNCTION**

line spread function measured with an uncollimated line source at a specified distance Z from the COLLIMATOR FRONT FACE

3.15**EQUIVALENT WIDTH****EW**

width of a rectangle having the same area as the LSF and a height equal to the maximum value of the LSF

3.16

SPATIAL RESOLUTION

ability to concentrate the count density distribution in the image of a POINT SOURCE to a point

[IEC 61675-1, definition 2.4]

3.17

SYSTEM SPATIAL RESOLUTION

<GAMMA CAMERA> SPATIAL RESOLUTION in a scattering medium for a specified COLLIMATOR, or a specified radionuclide, and at a specified distance from the COLLIMATOR FRONT FACE

3.18

INTRINSIC SPATIAL RESOLUTION

<GAMMA CAMERA> SPATIAL RESOLUTION in air for a specified radionuclide excluding the COLLIMATOR

3.19

INTRINSIC ENERGY SPECTRUM

measured histogram of pulse heights for the DETECTOR HEAD without COLLIMATOR

NOTE The pulse height should be expressed as corresponding energy.

3.20

INTRINSIC ENERGY RESOLUTION

FULL WIDTH AT HALF MAXIMUM of the full energy absorption peak in the INTRINSIC ENERGY SPECTRUM for a specified radionuclide

3.21

MULTIPLE WINDOW SPATIAL REGISTRATION

measured position of a source as a function of the ENERGY WINDOW setting

3.22

INTRINSIC NON-UNIFORMITY OF RESPONSE

NON-UNIFORMITY OF RESPONSE of the DETECTOR HEAD without COLLIMATOR

3.23

SYSTEM NON-UNIFORMITY OF RESPONSE

NON-UNIFORMITY OF RESPONSE of the DETECTOR HEAD with COLLIMATOR

3.24

SPATIAL NON-LINEARITY

deviations of the image of a straight line source from a straight line

3.25

INTRINSIC SPATIAL NON-LINEARITY

SPATIAL NON-LINEARITY of the DETECTOR HEAD without COLLIMATOR

3.26

COUNT LOSS

difference between measured COUNT RATE and TRUE COUNT RATE, which is caused by the finite RESOLVING TIME of the instrument

[IEC 61675-1, definition 2.7.1]

3.27**COUNT RATE**

number of counts per unit of time

[IEC 61675-1, definition 2.7.2]

4 Test methods**4.1 General requirements**

All measurements shall be performed with the energy window settings specified in Table 1.

**Table 1 – Radionuclides and energy windows
to be used for performance measurements**

Radionuclide	Energy window keV
^{99m}Tc	141, with a tolerance of $\pm 7,5 \%$
^{131}I	364, with a tolerance of $\pm 10 \%$
^{67}Ga	93, 184, 300, with a tolerance of $\pm 20 \%$
^{68}Ga	511, with a tolerance of $\pm 10 \%$
NOTE Because the characteristics of a gamma camera may change noticeably between 122 keV (^{57}Co) and 141 keV (^{99m}Tc), the former is not included as a suitable radionuclide. However, it may be useful in some circumstances, e.g. for quality control.	

Additional measurements with other settings, as specified by the manufacturer, can be performed. Before the measurements are performed, the camera shall be adjusted by the procedure normally used by the manufacturer for an installed unit and shall not be adjusted specially for the measurement of specific parameters.

Unless otherwise specified, measurements shall be carried out at count rates not exceeding 20 000 counts per second.

4.2 SYSTEM SENSITIVITY**4.2.1 General**

Sensitivity is a parameter that characterizes the effectiveness of a system to identify the radiation emitted from a RADIOACTIVE SOURCE, i.e. the rate at which events are detected in the presence of a RADIOACTIVE SOURCE in the limit of low ACTIVITY where COUNT LOSSES are negligible. The measured COUNT RATE for a given ACTIVITY and RADIONUCLIDE depends on many factors, including the detector material, its size and thickness, the size and shape of the RADIOACTIVE SOURCE including its absorption and scatter properties, and instruments dead time, energy thresholds and COLLIMATOR.

4.2.2 Purpose

The purpose of this measurement is to determine the detected rate of events per unit of ACTIVITY for a standard volume source of given dimensions and a specified COLLIMATOR.

4.2.3 Method

The SYSTEM SENSITIVITY test places a known amount of ACTIVITY of a specified RADIONUCLIDE within the DETECTOR FIELD OF VIEW of the GAMMA CAMERA and observes the resulting COUNT RATE. From these values the SYSTEM SENSITIVITY is calculated. The test is critically dependent