INTERNATIONAL STANDARD

IEC 61675-3

First edition
1998-02

Radionuclide imaging devices – Characteristics and test conditions –

Part 3: Gamma camera based wholebody imaging systems

Dispositifs d'imagerie par radionucléides – Caractéristiques et conditions d'essais –

Partie 3: Systèmes d'imagerie du corps entier à gamma-caméra

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For general terminology, readers are referred to IEC 60050: *International Electro-technical Vocabulary* (IEV).

For graphical symbols, and letter symbols and signs approved by the IEC for general use, readers are referred to publications IEC 60027: *Letter symbols to be used in electrical technology*, IEC 60417: *Graphical symbols for use on equipment. Index, survey and compilation of the single sheets* and IEC 60617: *Graphical symbols for diagrams.*

IEC publications prepared by the same technical committee

The attention of readers is drawn to the end pages of this publication which list the IEC publications issued by the technical committee which has prepared the present publication.

* See web site address on title page.

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Международная Электротехническая Комиссия

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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RADIONUCLIDE IMAGING DEVICES – CHARACTERISTICS AND TEST CONDITIONS –

Part 3: Gamma camera based wholebody imaging systems

FOREWORD

1) The IEC (International Electrotechnical Commission) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of the 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, the IEC publishes International Standards. 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. The IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
2) The formal decisions or agreements of the IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested National Committees.
3) The documents produced have the form of recommendations for international use and are published in the form of standards, technical reports or guides and they are accepted by the National Committees in that sense.
4) In order to promote international unification, IEC National Committees undertake to apply IEC International Standards transparently to the maximum extent possible in their national and regional standards. Any divergence between the IEC Standard and the corresponding national or regional standard shall be clearly indicated in the latter.
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6) Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. The IEC shall not be held responsible for identifying any or all such patent rights.

International Standard IEC 61675-3 has been prepared by subcommittee 62C: Equipment for radiotherapy, nuclear medicine and radiation dosimetry, of IEC technical committee 62: Electrical equipment in medical practice.

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

FDIS	Report on voting
62C/211/FDIS	62C/221/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.

In this standard the following print types are used:

– requirements, compliance with which can be tested, and definitions: in roman type;
– explanation, advice, introductions, general statements, exceptions and reference: in smaller roman type;
– *test specifications: in italic type;*
– TERMS USED THROUGHOUT THIS STANDARD WHICH HAVE BEEN DEFINED IN CLAUSE 2 OF THIS STANDARD OR LISTED IN ANNEX A; SMALL CAPITALS.

The requirements are followed by specifications for the relevant tests.

Annex A is for information only.

A bilingual version of this standard may be issued at a later date.

RADIONUCLIDE IMAGING DEVICES – CHARACTERISTICS AND TEST CONDITIONS –

Part 3: Gamma camera based wholebody imaging systems

1 General

1.1 Scope and object

The object of this part of IEC 61675 is to specify test methods for describing the characteristics of GAMMA CAMERA BASED WHOLEBODY IMAGING SYSTEMS. As these systems are based on Anger type GAMMA CAMERAS this part of IEC 61675 should be read in conjuction with IEC 60789.

Two additional tests, scanning speed constancy, and system SPATIAL RESOLUTION without scatter, shall be performed. Measurement of system uniformity for wholebody imaging systems is possible but difficult to perform because of the requirement for large and uniform sources. Most of the potential problems that could affect uniformity will also affect the system resolution, and therefore such a uniformity test is not included in this standard.

The test methods specified in this part of IEC 61675 have been selected to reflect as much as possible the clinical use of GAMMA CAMERA BASED WHOLEBODY IMAGING SYSTEMS. It is intended that the test methods be carried out by manufacturers, thereby enabling them to describe the characteristics of GAMMA CAMERA BASED WHOLEBODY IMAGING SYSTEMS.

1.2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this part of IEC 61675. At the time of publication, the editions indicated were valid. All normative documents are subject to revision, and parties to agreements based on this part of IEC 61675 are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

IEC 60788:1984, *Medical radiology – Terminology*

IEC 60789:1992, *Characteristics and test conditions of radionuclide imaging devices – Anger type gamma cameras*

IEC 61675-2: *Radionuclide imaging devices – Characteristics and test conditions – Part 2: Single photon emission computed tomographs*

2 Terminology and definitions

For the purposes of this part of IEC 61675, the definitions given in IEC 60789 and IEC 60788, and IEC 61675-2 (see annex A), and the following definition apply.

2.1
GAMMA CAMERA BASED WHOLEBODY IMAGING SYSTEM
equipment for scintigraphy, employing one or two DETECTOR HEAD(S), in which the image is formed by moving the DETECTOR HEAD(S) and the object relative to each other and relating output information of the RADIOLOGICAL IMAGE

3 Test methods

All measurements shall be performed with PULSE AMPLITUDE ANALYSER WINDOW as specified in table 1 of IEC 60789. Additional measurements with other settings as specified by the manufacturer can be performed.

Before the measurements are performed, the system 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.

Measurements of performance parameters in the planar mode of operation are a prerequisite. A complete set of performance parameters shall be measured as specified in IEC 60789.

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

3.1 Scanning constancy

Scanning constancy shall be measured using a POINT SOURCE attached to the DETECTOR HEAD and expressed as COUNT RATE deviation along the full scanning length.

3.1.1 RADIONUCLIDE

The RADIONUCLIDE to be employed for this measurement shall be ^{99m}Tc or ^{57}Co.

3.1.2 Source

The source shall be a POINT SOURCE attached to the COLLIMATOR at the centre of the field of view. The ACTIVITY of the source shall be adjusted to yield a COUNT RATE between 10 000 and 20 000 counts per second, through a 20 % analyzer window, in the DETECTOR FIELD OF VIEW.

3.1.3 Data acquisition and analysis

The scan speed and the acquisition matrix shall be in the range recommended for clinical use. Two scans shall be performed along the full scanning length using different speeds. The image of the POINT SOURCE shall be recorded.

A profile through the image of the POINT SOURCE in the direction of the motion should yield a constant count value. This profile shall have a width between 20 mm and 30 mm in the direction perpendicular to the direction of motion, and shall contain at least 10 000 counts per pixel. The analysis shall exclude the areas at the ends of the profile which are affected by the spatial resolution in the scanning direction.

3.1.4 Report

For the region of analysis, report a graph of the percent deviation from the mean count value. In addition report the value of the maximum percent deviation from the mean. Any deviation greater than expected from Poisson statistics standard deviations is indicative of non-uniform scanning motion and shall be stated. The COLLIMATOR and the scan speeds used in performing the measurements shall be also reported.

3.2 SPATIAL RESOLUTION without scatter

SPATIAL RESOLUTION without scatter shall be measured parallel and perpendicular to the direction of motion, and expressed as FULL WIDTH AT HALF MAXIMUM (FWHM) of the LINE SPREAD FUNCTION.

3.2.1 RADIONUCLIDE

The RADIONUCLIDE to be employed for this measurement shall be ^{99m}Tc or ^{57}Co.

3.2.2 Source

The sources shall consist of two capillary tubes, each having an inside diameter of less than or equal to 1 mm and a length equal to the width of the scanned field of view perpendicular to the direction of motion.

NOTE – If a line source of the length specified above is difficult to manufacture or to handle, either a shorter line can be used and scanned in the required number of positions to cover the specified length, or a number of shorter lines spanning the field of view can be scanned simultaneously.

The activity of both sources shall be approximately equal and shall be adjusted to yield a COUNT RATE between 10 000 and 20 000 counts per second, through a 20 % analyzer window, with both capillary tubes in the detector field of view.

3.2.3 Location of sources

The sources shall be placed on the wholebody scanning table. For the measurement of resolution parallel to the direction of motion, one capillary tube shall be placed at the centre of the scanned field of view, perpendicular to the direction of motion to within 1 mm; the second source shall be placed parallel to the first one, at a distance of 100 mm as shown in figure 1.

For the measurement of resolution perpendicular to the direction of motion, one capillary tube shall be placed at the centre of the scanned field of view, parallel to the direction of motion to within 1 mm; the second source shall be placed parallel to the first one, at a distance of 100 mm as shown in figure 2.

3.2.4 Data acquisition

The scan speed shall be in the range recommended for clinical use. Scans shall be performed both above and below the table for the two source positions described in 3.2.3. The camera shall be positioned at a distance of 100 mm from the sources to the face of the COLLIMATOR.

The sampling, perpendicular to the tubes, shall be no coarser than 25 % of the FWHM of the SPATIAL RESOLUTION with the COLLIMATOR being used. The measured quantity, i.e. number of counts, shall be integrated in the direction parallel to the sources within sets of areas with lengths not more than 30 mm. The areas shall abut each other.

3.2.5 Calculation of FWHM

The FWHM shall be calculated in each segment (length of integrated area as specified in 3.2.4) of the central capillary tube, using a gaussian fit method. The values of the FWHM shall be averaged separately for the tubes parallel and perpendicular to the direction of motion, for the measurement above and below the table. The values shall be stated in millimetres.

3.2.6 Report

The FWHM values shall be reported separately for the measurements above and below the table and in the directions parallel and perpendicular to the direction of motion. The COLLIMATOR and scan speed used in performing the measurements shall be reported.

4 ACCOMPANYING DOCUMENTS

A document shall accompany each GAMMA CAMERA BASED WHOLEBODY IMAGING SYSTEM and shall include the following information.

4.1 All items described in clause 4 of IEC 60789.
4.2 Scanning constancy as specified in 3.1 of this standard.
4.3 SPATIAL RESOLUTION as specified in 3.2 of this standard.

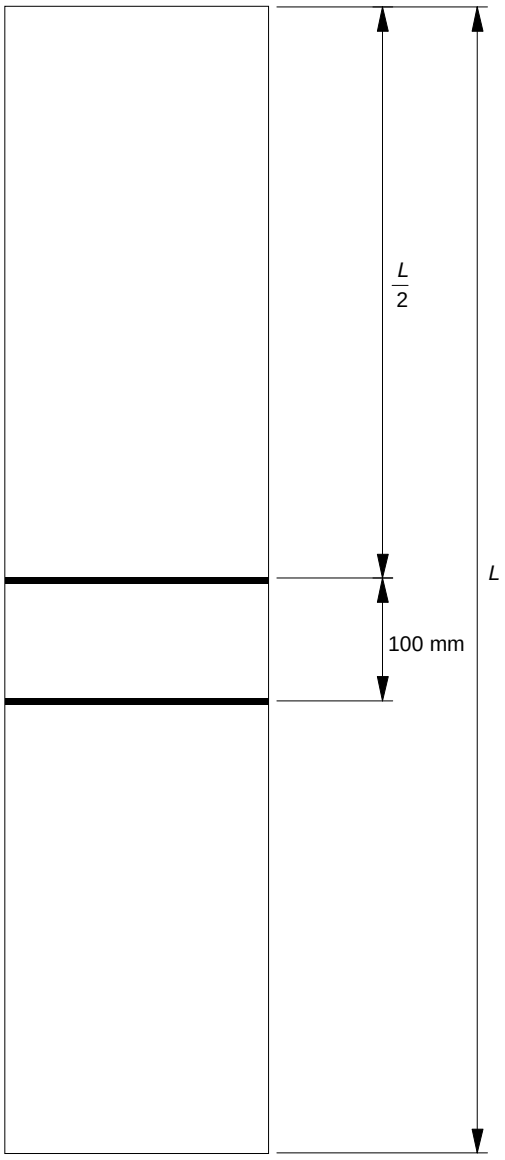

Figure 1 – Source position for resolution measurement parallel to the direction of motion

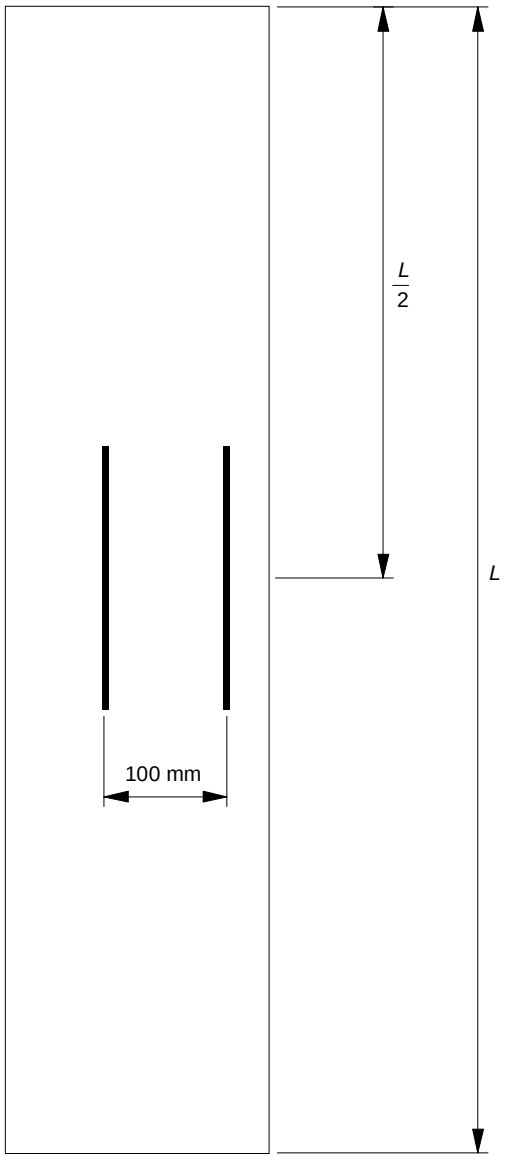

Figure 2 – Source position for resolution measurement perpendicular to the direction of motion

Annex A
(informative)

Index of defined terms

Standards Survey

We at the IEC want to know how our standards are used once they are published.

The answers to this survey will help us to improve IEC standards and standard related information to meet your future needs

Would you please take a minute to answer the survey on the other side and mail or fax to:

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1211 Geneva 20
Switzerland

or

Fax to: CSC at +41 22 919 03 00

Thank you for your contribution to the standards making process.

Nicht frankieren
Ne pas affranchir

Non affrancare
No stamp required

A Prioritaire

RÉPONSE PAYÉE

SUISSE

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International Electrotechnical Commission
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Case postale 131
1211 GENEVA 20
Switzerland

1.

No. of IEC standard:

.....

2.

Tell us why you have the standard. (check as many as apply). I am:

- ☐ the buyer
- ☐ the user
- ☐ a librarian
- ☐ a researcher
- ☐ an engineer
- ☐ a safety expert
- ☐ involved in testing
- ☐ with a government agency
- ☐ in industry
- ☐ other.....

3.

This standard was purchased from?

.....

4.

This standard will be used (check as many as apply):

- ☐ for reference
- ☐ in a standards library
- ☐ to develop a new product
- ☐ to write specifications
- ☐ to use in a tender
- ☐ for educational purposes
- ☐ for a lawsuit
- ☐ for quality assessment
- ☐ for certification
- ☐ for general information
- ☐ for design purposes
- ☐ for testing
- ☐ other.....

5.

This standard will be used in conjunction with (check as many as apply):

- ☐ IEC
- ☐ ISO
- ☐ corporate
- ☐ other (published by.....)
- ☐ other (published by.....)
- ☐ other (published by.....)

6.

This standard meets my needs (check one)

- ☐ not at all
- ☐ almost
- ☐ fairly well
- ☐ exactly

7.

Please rate the standard in the following areas as (1) bad, (2) below average, (3) average, (4) above average, (5) exceptional, (0) not applicable:

- ☐ clearly written
- ☐ logically arranged
- ☐ information given by tables
- ☐ illustrations
- ☐ technical information

8.

I would like to know how I can legally reproduce this standard for:

- ☐ internal use
- ☐ sales information
- ☐ product demonstration
- ☐ other.....

9.

In what medium of standard does your organization maintain most of its standards (check one):

- ☐ paper
- ☐ microfilm/microfiche
- ☐ mag tapes
- ☐ CD-ROM
- ☐ floppy disk
- ☐ on line

9A.

If your organization currently maintains part or all of its standards collection in electronic media, please indicate the format(s):

- ☐ raster image
- ☐ full text

10.

In what medium does your organization intend to maintain its standards collection in the future (check all that apply):

- ☐ paper
- ☐ microfilm/microfiche
- ☐ mag tape
- ☐ CD-ROM
- ☐ floppy disk
- ☐ on line

10A.

For electronic media which format will be chosen (check one)

- ☐ raster image
- ☐ full text

11.

My organization is in the following sector (e.g. engineering, manufacturing)

.....

12.

Does your organization have a standards library:

- ☐ yes
- ☐ no

13.

If you said yes to 12 then how many volumes:

.....

14.

Which standards organizations published the standards in your library (e.g. ISO, DIN, ANSI, BSI, etc.):

.....

15.

My organization supports the standards-making process (check as many as apply):

- ☐ buying standards
- ☐ using standards
- ☐ membership in standards organization
- ☐ serving on standards development committee
- ☐ other.....

16.

My organization uses (check one)

- ☐ French text only
- ☐ English text only
- ☐ Both English/French text

17.

Other comments:

.....

.....

.....

.....

.....

.....

18.

Please give us information about you and your company

name: .....

job title:.....

company: .....

address:.....

.....

.....

.....

No. employees at your location:.....

turnover/sales:.....

Publications de la CEI préparées par le Comité d'Etudes n° 62

60336 (1993) Gaines équipées pour diagnostic médical – Caractéristiques des foyers.

60406 (1997) Cassettes pour la radiographie médicale – Cassettes radiographiques et cassettes mammographiques.

60513 (1994) Aspects fondamentaux des normes de sécurité pour les appareils électromédicaux.

60522 (1976) Filtration inhérente d'une gaine équipée.

60526 (1978) Raccordements par fiche et réceptacle des câbles haute tension pour équipements à rayons X à usage médical.

60580 (1977) Radiamètre de produit exposition-surface.

60601: — Appareils électromédicaux.

60601-1 (1988) Première partie: Règles générales de sécurité.
Amendement n° 1 (1991).
Amendement n° 2 (1995).

60601-1-1 (1992) Première partie: Règles générales de sécurité. 1. Norme collatérale: Règles de sécurité pour systèmes électromédicaux.
Amendement 1 (1995).

60601-1-2 (1993) Première partie: Règles générales de sécurité. 2. Norme collatérale: Compatibilité électromagnétique – Prescriptions et essais.

60601-1-3 (1994) Première partie: Règles générales de sécurité. 3. Norme collatérale: Règles générales pour la radioprotection dans les équipements à rayonnement X de diagnostic.

60601-1-4 (1996) Partie 1: Règles générales de sécurité. 4. Norme collatérale: Systèmes électromédicaux programmables.

60601-2-1 (1981) Deuxième partie: Règles particulières pour accélérateurs médicaux d'électrons dans la gamme 1 MeV à 50 MeV. Section un: Généralités. Section deux: Sécurité radiologique des appareils.
Modification n° 1 (1984).
Modification n° 2 (1990).

60601-2-2 (1991) Deuxième partie: Règles particulières de sécurité pour appareils d'électrochirurgie à courant haute fréquence.

60601-2-3 (1991) Deuxième partie: Règles particulières de sécurité pour appareils de thérapie à ondes courtes.

60601-2-4 (1983) Deuxième partie: Règles particulières de sécurité pour appareils cardiaques et moniteurs-défibrillateurs cardiaques.

60601-2-5 (1984) Deuxième partie: Règles particulières de sécurité pour appareils à ultrasons pour thérapie.

60601-2-6 (1984) Deuxième partie: Règles particulières de sécurité pour appareils de thérapie à micro-ondes.

60601-2-7 (1998) (Publiée en langue anglaise seulement.)

60601-2-8 (1987) Deuxième partie: Règles particulières de sécurité pour groupes radiogènes de radiothérapie.
Amendement 1 (1997).

60601-2-9 (1996) Partie 2: Règles particulières de sécurité des dosimètres au contact du patient utilisés en radiothérapie avec des détecteurs de rayonnement reliés électriquement.

60601-2-10 (1987) Deuxième partie: Règles particulières de sécurité pour stimulateurs de nerfs et de muscles.

60601-2-11 (1997) Partie 2: Règles particulières de sécurité pour les appareils de gammathérapie.

(suite)

IEC publications prepared by Technical Committee No. 62

60336 (1993) X-ray tube assemblies for medical diagnosis – Characteristics of focal spots.

60406 (1997) Cassettes for medical X-ray diagnosis – Radiographic cassettes and mammographic cassettes.

60513 (1994) Fundamental aspects of safety standards for medical electrical equipment.

60522 (1976) Inherent filtration of an X-ray tube assembly.

60526 (1978) High-voltage cable plug and socket connections for medical X-ray equipment.

60580 (1977) Area exposure product meter.

60601: — Medical electrical equipment.

60601-1 (1988) Part 1: General requirements for safety.
Amendment No. 1 (1991).
Amendment No. 2 (1995).

60601-1-1 (1992) Part 1: General requirements for safety. 1. Collateral standard: Safety requirements for medical electrical systems.
Amendment 1 (1995).

60601-1-2 (1993) Part 1: General requirements for safety. 2. Collateral standard: Electromagnetic compatibility – Requirements and tests.

60601-1-3 (1994) Part 1: General requirements for safety. 3. Collateral standard: General requirements for radiation protection in diagnostic X-ray equipment.

60601-1-4 (1996) Part 1: General requirements for safety. 4. Collateral standard: Programmable electrical medical systems.

60601-2-1 (1981) Part 2: Particular requirements for medical electron accelerators in the range 1 MeV to 50 MeV. Section One: General. Section Two: Radiation safety for equipment.
Amendment No. 1 (1984).
Amendment No. 2 (1990).

60601-2-2 (1991) Part 2: Particular requirements for the safety of high frequency surgical equipment.

60601-2-3 (1991) Part 2: Particular requirements for the safety of short-wave therapy equipment.

60601-2-4 (1983) Part 2: Particular requirements for the safety of cardiac defibrillators and cardiac defibrillator-monitors.

60601-2-5 (1984) Part 2: Particular requirements for the safety of ultrasonic therapy equipment.

60601-2-6 (1984) Part 2: Particular requirements for the safety of microwave therapy equipment.

60601-2-7 (1998) Part 2: Particular requirements for the safety of high-voltage generators of diagnostic X-ray generators.

60601-2-8 (1987) Part 2: Particular requirements for the safety of therapeutic X-ray generators.
Amendment 1 (1997).

60601-2-9 (1996) Part 2: Particular requirements for the safety of patient contact dosemeters used in radiotherapy with electrically connected radiation detectors.

60601-2-10 (1987) Part 2: Particular requirements for the safety of nerve and muscle stimulators.

60601-2-11 (1997) Part 2: Particular requirements for the safety of gamma beam therapy equipment.

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Publications de la CEI préparées par le Comité d'Etudes n° 62 *(suite)*

60601-2-12 (1988)	Deuxième partie: Règles particulières de sécurité pour ventilateurs pulmonaires à usage médical.
60601-2-13 (1989)	Deuxième partie: Règles particulières de sécurité pour appareils d'anesthésie.
60601-2-14 (1989)	Deuxième partie: Règles particulières de sécurité pour appareils de thérapie par électroconvulsions.
60601-2-15 (1988)	Deuxième partie: Règles particulières de sécurité pour groupes radiogènes à décharge de condensateur.
60601-2-16 (1998)	(Publiée en langue anglaise uniquement).
60601-2-17 (1989)	Deuxième partie: Règles particulières de sécurité des projecteurs de sources radioactives automatiques télécommandés utilisés en radiothérapie par rayonnement gamma. Amendement 1 (1996).
60601-2-18 (1996)	Partie 2: Règles particulières de sécurité pour appareils d'endoscopie.
60601-2-19 (1990)	Deuxième partie: Règles particulières de sécurité des incubateurs pour bébés. Amendement 1 (1996).
60601-2-20 (1990)	Deuxième partie: Règles particulières de sécurité des incubateurs de transport. Amendement 1 (1996).
60601-2-21 (1994)	Partie 2: Règles particulières de sécurité des incubateurs radiants pour nouveau-nés. Amendement 1 (1996).
60601-2-22 (1995)	Partie 2: Règles particulières de sécurité pour les appareils thérapeutiques et de diagnostic à laser.
60601-2-23 (1993)	Partie 2: Règles particulières de sécurité pour les appareils de surveillance de la pression partielle transcutanée.
60601-2-24 (1998)	(Publiée en langue anglaise seulement.)
60601-2-25 (1993)	Partie 2: Règles particulières de sécurité des électrocardiographes.
60601-2-26 (1994)	Partie 2: Règles particulières de sécurité pour les électroencéphalographes.
60601-2-27 (1994)	Partie 2: Règles particulières de sécurité des appareils de surveillance d'électrocardiographie.
60601-2-28 (1993)	Partie 2: Règles particulières de sécurité pour les ensembles radiogènes à rayonnement X et les gaines équipées pour diagnostic médical.
60601-2-29 (1993)	Partie 2: Règles particulières de sécurité pour les simulateurs de radiothérapie. Amendement 1 (1996).
60601-2-30 (1995)	Partie 2: Règles particulières de sécurité des appareils de surveillance de la pression sanguine prélevée indirectement, automatiquement et périodiquement.
60601-2-31 (1994)	Partie 2: Règles particulières de sécurité des stimulateurs cardiaques externes à source d'énergie interne. Amendement 1 (1998).
60601-2-32 (1994)	Partie 2: Règles particulières de sécurité pour les équipements associés aux équipements à rayonnement X.
60601-2-33 (1995)	Partie 2: Règles particulières de sécurité relatives aux appareils à résonance magnétique pour diagnostic médical.
60601-2-34 (1994)	Partie 2: Règles particulières de sécurité pour les appareils de surveillance de la pression sanguine prélevée directement.

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IEC publications prepared by Technical Committee No. 62 *(continued)*

60601-2-12 (1988)	Part 2: Particular requirements for the safety of lung ventilators for medical use.
60601-2-13 (1989)	Part 2: Particular requirements for the safety of anaesthetic machines.
60601-2-14 (1989)	Part 2: Particular requirements for the safety of electroconvulsive therapy equipment.
60601-2-15 (1988)	Part 2: Particular requirements for the safety of capacitor discharge X-ray generators.
60601-2-16 (1998)	Part 2: Particular requirements for the safety of haemodialysis, haemodiafiltration and haemofiltration equipment.
60601-2-17 (1989)	Part 2: Particular requirements for the safety of remote-controlled automatically driven gamma-ray after-loading equipment. Amendment 1 (1996).
60601-2-18 (1996)	Part 2: Particular requirements for the safety of endoscopic equipment.
60601-2-19 (1990)	Part 2: Particular requirements for safety of baby incubators. Amendment 1 (1996).
60601-2-20 (1990)	Part 2: Particular requirements for safety of transport incubators. Amendment 1 (1996).
60601-2-21 (1994)	Part 2: Particular requirements for safety of infant radiant warmers. Amendment 1 (1996).
60601-2-22 (1995)	Part 2: Particular requirements for the safety of diagnostic and therapeutic laser equipment.
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