IEC 60601-2-54

Edition 1.0 2015-04

INTERNATIONAL STANDARD

NORME INTERNATIONALE

AMENDMENT 1
AMENDEMENT 1

Medical electrical equipment –
Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy

Appareils électromédicaux –
Partie 2-54: Exigences particulières pour la sécurité de base et les performances essentielles des appareils à rayonnement X utilisés pour la radiographie et la radioscopie

IEC 60601-2-54:2009-06/AMD1:2015-04(en-fr)

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FOREWORD

This amendment has been prepared by subcommittee 62B: Diagnostic imaging equipment, of IEC technical committee 62: Electrical equipment in medical practice.

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

CDV	Report on voting
62B/929/CDV	62B/956/RVC

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

The committee has decided that the contents of this amendment and the base publication will remain unchanged until the stability date indicated on the IEC website 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- withdrawn,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 TO AMENDMENT 1

The purpose of this first amendment to IEC 60601-2-54:2009 is to introduce changes to reference the first amendment (2012) to IEC 60601-1:2005. As neither IEC 60601-2-54:2009 nor this amendment refers to specific elements of IEC 60601-1-2, the introduction of a dated reference to the latter document has been removed. In addition, a number of technical errors have been corrected.

FOREWORD

Replace, in the existing second paragraph, the phrase "IEC 60601-2-28:1993 (currently under revision)" *with* "parts of IEC 60601-2-28:1993".

201.1 Scope, object and related standards

Amend the footnote to read as follows:

1) *The general standard is IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*

201.1.3 Collateral standards

Replace the existing second sentence of the second paragraph with the following:

IEC 60601-1-8, IEC 60601-1-10, IEC 60601-1-11 and IEC 60601-1-12 do not apply.

201.2 Normative references

Add the following new reference:

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

Delete the following reference:

IEC 60601-1-2:2007, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance– Collateral standard: Electromagnetic compatibility – Requirements and tests*

Replace the existing reference to IEC 60601-1-3 with the following:

IEC 60601-1-3:2008 *Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral standard: Radiation protection in diagnostic X-ray equipment*
IEC 60601-1-3:2008/AMD1:2013

201.3 Terms and definitions

Replace, in the introductory paragraph, the reference to "IEC 60601-1:2005" *by* "IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012".

201.4.3 ESSENTIAL PERFORMANCE

201.4.3.101 * Additional ESSENTIAL PERFORMANCE requirements

Replace the existing title with the following:

201.4.3.101 * Additional potential ESSENTIAL PERFORMANCE requirements

*Replace, in the first sentence, the term "*ESSENTIAL PERFORMANCE*" by "*potential ESSENTIAL PERFORMANCE*".*

Table 201.101 – Distributed ESSENTIAL PERFORMANCE requirements

Amend the existing title of the table to read as follows:

Table 201.101 – Distributed potential ESSENTIAL PERFORMANCE requirements

201.7 ME EQUIPMENT identification, marking and documents

201.7.2 Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts

201.7.2.101 BEAM LIMITING DEVICE

Replace the existing third dash with the following:

– QUALITY EQUIVALENT FILTRATION of all materials together that are permanently fixed and intercept the X-RAY BEAM.

201.7.9 ACCOMPANYING DOCUMENTS

201.7.9.2 Instructions for use

Add the following new subclause:

201.7.9.2.17 ME EQUIPMENT emitting radiation

Replacement:

For X-RAY EQUIPMENT the instructions for use shall provide information as required in 203.5.

201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS

201.9.2 HAZARDS associated with moving parts

Replace the existing title with the following:

201.9.2 MECHANICAL HAZARDS associated with moving parts

Add the following header:

201.9.2.2 TRAPPING ZONE

201.9.2.2.4 GUARDS and protective measures

Replace the existing title with the following:

201.9.2.2.4 GUARDS and other RISK CONTROL measures

201.9.2.2.4.4 Protective measures

Replace the existing title with the following:

201.9.2.2.4.4 Other RISK CONTROL measures

201.9.2.3 Other HAZARDS associated with moving parts

Replace the existing title with the following:

201.9.2.3 Other MECHANICAL HAZARDS associated with moving parts

201.9.2.3.1 Unintended movement

Add the following new paragraph between the penultimate paragraph and the compliance statement:

The configurations shall be considered in the USABILITY ENGINEERING PROCESS.

Replace the final paragraph (compliance statement) by the following:

Compliance is checked by functional tests and by inspection of the instructions for use and the USABILITY ENGINEERING FILE.

201.11 Protection against excessive temperatures and other HAZARDS

201.11.101 Protection against excessive temperatures of X-RAY TUBE ASSEMBLIES

Add the following note after the first paragraph:

NOTE Examples of such means are covers, handles for operation etc.

202 Electromagnetic compatibility – Requirements and tests

Replace the dated reference by an undated reference in the first paragraph as follows:

IEC 60601-1-2 applies, except as follows.

202.101 Immunity testing of ESSENTIAL PERFORMANCE

Add the following two new paragraphs before the existing first paragraph:

The MANUFACTURER may minimize the test requirements of the additional potential ESSENTIAL PERFORMANCE requirements listed in Table 201.101 to a practical level through the RISK MANAGEMENT PROCESS.

When selecting the requirements to be tested, the MANUFACTURER needs to take into account the sensitivity to the EMC environment, probability of EMC condition and severity, and probability and contribution to unacceptable RISK through the RISK MANAGEMENT PROCESS.

Add, after the last paragraph, the following new text:

ME EQUIPMENT being tested shall not be modified to perform this immunity test.

Compliance is checked by the inspection of RISK MANAGEMENT FILE.

203 Radiation protection in diagnostic X-ray equipment

Replace, in the first paragraph, the reference to "IEC 60601-1-3:2008" *by* "IEC 60601-1-3:2008 and IEC 60601-1-3:2008/AMD1:2013".

203.6 RADIATION management

203.6.4 Indication of operational states

203.6.4.5 *Dosimetric indications

Replace, in the third paragraph, the second, third and fourth dashes with the following:

– The value of the cumulative REFERENCE AIR KERMA resulting from RADIOSCOPY and RADIOGRAPHY since the last reset operation shall be
  - continuously displayed at the working position of the OPERATOR in mGy together with this unit and updated at least once every 5 s; or
  - displayed not later than 5 s after the interruption or termination of LOADING.

– The values for the REFERENCE AIR KERMA RATE and the cumulative REFERENCE AIR KERMA shall be clearly distinguishable from each other.

203.7 RADIATION QUALITY

203.7.1 HALF-VALUE LAYERS and TOTAL FILTRATION in X-RAY EQUIPMENT

Add the following note after the first paragraph:

NOTE An appropriate permanently mounted FILTER, not removable by the OPERATOR, satisfies the above requirement.

203.7.1.101 FILTRATION in X-RAY SOURCE ASSEMBLIES

In the first paragraph, first dashed item, add the following text at the beginning of the first sentence:

Unless solely intended for use in MOBILE X-RAY EQUIPMENT specified for RADIOSCOPY during surgery,

Bibliography

Replace in reference [1] "IEC 60627:2001" *by* "IEC 60627" *and in reference [15]* "IEC 60601-2-43:2010" *by* "IEC 60601-2-43"

Add the following new references:

[16] IEC 60601-1-11, *Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment*

[17] IEC 60601-1-12, *Medical electrical equipment – Part 1-12: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment*

Index of defined terms used in this collateral standard

In the note replace the reference to "IEC 60601-1:2005" *by* "IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012".

Amend the references to the following terms:

EARTH LEAKAGE CURRENT ..... IEC 60601-1:2005/AMD1:2012, 3.25
ESSENTIAL PERFORMANCE ..... IEC 60601-1:2005/AMD1:2012, 3.27
HAZARD ..... IEC 60601-1:2005/AMD1:2012, 3.39
INTENDED USE ..... IEC 60601-1:2005/AMD1:2012, 3.44
MAINS PART ..... IEC 60601-1:2005/AMD1:2012, 3.49
MANUFACTURER ..... IEC 60601-1:2005/AMD1:2012, 3.55
MOBILE ..... IEC 60601-1:2005/AMD1:2012, 3.65
NORMAL USE ..... IEC 60601-1:2005/AMD1:2012, 3.71
PATIENT ..... IEC 60601-1:2005/AMD1:2012, 3.76
PROCEDURE ..... IEC 60601-1:2005/AMD1:2012, 3.88
RISK ..... IEC 60601-1:2005/AMD1:2012, 3.102
RISK MANAGEMENT ..... IEC 60601-1:2005/AMD1:2012, 3.107
RISK MANAGEMENT FILE ..... IEC 60601-1:2005/AMD1:2012, 3.108
SINGLE FAULT CONDITION ..... IEC 60601-1:2005/AMD1:2012, 3.116
TRANSPORTABLE ..... IEC 60601-1:2005/AMD1:2012, 3.130