IEC 60601-2-54

Edition 2.0 2022-09

INTERNATIONAL STANDARD

NORME INTERNATIONALE

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 60601-2-54:2022-09(en-fr)

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MEDICAL ELECTRICAL EQUIPMENT –

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

FOREWORD

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IEC 60601-2-54 has been prepared by subcommittee 62B: Diagnostic imaging equipment, of IEC technical committee 62: Electrical equipment in medical practice. It is an International Standard.

This second edition cancels and replaces the first edition published in 2009, Amendment 1:2015 and Amendment 2:2018. This edition constitutes a technical revision.

This edition includes editorial and technical changes to reflect the IEC 60601-1:2005/AMD2:2020. It also contains corrections and technical improvements. Significant technical changes with respect to the previous edition are as follows:

a) a new specific term DOSIMETER is introduced to replace the general term DOSEMETER;
b) terms and definitions taken exclusively from IEC TR 60788:2004 and which are specifically applicable in this document have been moved to 201.3;
c) the collateral standards IEC 60601-1-11:2015, IEC 60601-1-11:2015/AMD1:2020, IEC 60601-1-12:2014 and IEC 60601-1-12:2014/AMD1:2020 are applicable if MANUFACTURER so declares;

d) the subclause 201.11.101 “Protection against excessive temperatures of X-ray tube assemblies” has been removed from this document as its requirements are sufficiently and clearly covered by IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020 and IEC 60601-2-28:2017;

e) to adopt changes which are introduced with respect to indicator lights in 7.8.1 of the IEC 60601-1:2005/AMD2:2020 clarification of requirements is provided to avoid conflicts with requirements of indicator lights stipulated for X-RAY EQUIPMENT;

f) explanation of the term ESSENTIAL PERFORMANCE is provided in Annex AA to emphasize the performance of the clinical function under NORMAL and SINGLE FAULT CONDITIONS.

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

Draft	Report on voting
62B/1285/FDIS	62B/1293/RVD

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

The language used for the development of this International Standard is English.

This document was drafted in accordance with ISO/IEC Directives, Part 2, and developed in accordance with ISO/IEC Directives, Part 1 and ISO/IEC Directives, IEC Supplement, available at www.iec.ch/members_experts/refdocs. The main document types developed by IEC are described in greater detail at www.iec.ch/standardsdev/publications.

In this document, the following print types are used:

– requirements and definitions: roman type;

– *test specifications: italic type*;

– informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type;

– TERMS DEFINED IN CLAUSE 3 OF IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 AND IEC 60601-1:2005/AMD2:2020, IN THIS DOCUMENT OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this document, the term

– “clause” means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);

– “subclause” means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

References to clauses within this document are preceded by the term “Clause” followed by the clause number. References to subclauses within this document are by number only.

In this document, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

The verbal forms used in this document conform to usage described in Clause 7 of the ISO/IEC Directives, Part 2. For the purposes of this document, the auxiliary verb:

– “shall” means that compliance with a requirement or a test is mandatory for compliance with this document;

– “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this document;

– “may” is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex AA.

A list of all parts of the IEC 60601 and IEC 80601 series, published under the general title *Medical electrical equipment*, can be found on the IEC website.

The committee has decided that the contents of this document will remain unchanged until the stability date indicated on the IEC website under webstore.iec.ch in the data related to the specific document. At this date, the document will be

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

INTRODUCTION

This document has been prepared to provide, based on IEC 60601-1:2005 (third edition) and its collaterals, a complete set of safety requirements for ME EQUIPMENT for RADIOGRAPHY and RADIOSCOPY. The purpose of this second edition is to introduce changes to reference the second amendment (2020) to IEC 60601-1:2005 and associated collateral standards. Moreover, in Annex AA a clarification of the term for ESSENTIAL PERFORMANCE is provided. This document addresses the system level of X-RAY EQUIPMENT, which consists of a combination of an X-RAY GENERATOR, ASSOCIATED EQUIPMENT and ACCESSORIES. Component functions are addressed as far as necessary.

The minimum safety requirements specified in this document are considered to provide for a practical degree of safety in the operation of ME EQUIPMENT for RADIOGRAPHY and RADIOSCOPY. Requirements for additional provisions for ME EQUIPMENT for interventional applications are covered by IEC 60601-2-43.

MEDICAL ELECTRICAL EQUIPMENT –

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201.1 Scope, object and related standards

Clause 1 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

201.1.1 Scope

Replacement:

This document applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of ME EQUIPMENT and ME SYSTEMS intended to be used for projection RADIOGRAPHY and INDIRECT RADIOSCOPY. IEC 60601-2-43 applies to ME EQUIPMENT and ME SYSTEMS intended to be used for interventional applications and refers to applicable requirements in this document.

ME EQUIPMENT and ME SYSTEMS intended to be used for bone or tissue absorption densitometry, computed tomography, mammography or dental or radiotherapy applications are excluded from the scope of this document. The scope of this document also excludes radiotherapy simulators.

If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, or to ME SYSTEMS only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to ME EQUIPMENT and to ME SYSTEMS, as relevant.

201.1.2 Object

Replacement:

The object of this document is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for ME EQUIPMENT and ME SYSTEMS for RADIOGRAPHY and RADIOSCOPY.

201.1.3 Collateral standards

Addition:

This document refers to those applicable collateral standards that are listed in Clause 2 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 as modified in 201.2.

IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020, IEC 60601-1-3:2008 and IEC 60601-1-3:2008/AMD1:2013 and IEC 60601-1-3:2008/AMD2:2021 apply, as modified in Clauses 202 and 203 respectively. If the MANUFACTURER declares that the ME EQUIPMENT or ME SYSTEM is intended to be operated in a HOME HEALTHCARE ENVIRONMENT, then IEC 60601-1-11:2015 and IEC 60601-1-11:2015/AMD1:2020 apply and if the MANUFACTURER declares that the ME EQUIPMENT or ME SYSTEM is intended to be operated in an EMERGENCY MEDICAL SERVICES ENVIRONMENT, then IEC 60601-1-12:2014 and IEC 60601-1-12:2015/AMD1:2020 apply. IEC 60601-1-8, IEC 60601-1-9, IEC 60601-1-10 do not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

NOTE 1 OPERATORS of X-RAY EQUIPMENT are used to audible signals as specified in this document rather than to the concepts of IEC 60601-1-8. Therefore IEC 60601-1-8 does not apply.