



IEC 60601-2-54

Edition 2.0 2022-09
REDLINE VERSION

INTERNATIONAL STANDARD



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

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

ICS 11.040.50

ISBN 978-2-8322-5784-5

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CONTENTS

FOREWORD	4
INTRODUCTION	2
INTRODUCTION TO AMENDMENT 1	2
INTRODUCTION TO AMENDMENT 2	2
201.1 Scope, object and related standards	9
201.2 Normative references	11
201.3 Terms and definitions	11
201.4 General requirements	14
201.5 General requirements for testing ME EQUIPMENT	15
201.6 Classification of ME EQUIPMENT and ME SYSTEMS	15
201.7 ME EQUIPMENT identification, marking and documents	15
201.8 Protection against electrical HAZARDS from ME EQUIPMENT	19
201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS	22
201.10 Protection against unwanted and excessive radiation HAZARDS	26
201.11 Protection against excessive temperatures and other HAZARDS	26
201.12 Accuracy of controls and instruments and protection against hazardous outputs	27
201.13 HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT	27
201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)	27
201.15 Construction of ME EQUIPMENT	28
201.16 ME SYSTEMS	28
201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS	28
202 Electromagnetic compatibility disturbances – Requirements and tests	28
202.101 * Immunity testing of ESSENTIAL PERFORMANCE	28
203 RADIATION PROTECTION in diagnostic X-RAY EQUIPMENT	29
203.4 General requirements	29
203.5 ME EQUIPMENT identification, marking and documents	30
203.6 RADIATION management	33
203.7 RADIATION QUALITY	48
203.8 Limitation of the extent of the X-RAY BEAM and relationship between X-RAY FIELD and IMAGE RECEPTION AREA	49
203.9 FOCAL SPOT TO SKIN DISTANCE	57
203.10 ATTENUATION of the X-RAY BEAM between the PATIENT and the X-RAY IMAGE RECEPTOR	58
203.11 Protection against RESIDUAL RADIATION	59
203.12 Protection against LEAKAGE RADIATION	61
203.13 Protection against STRAY RADIATION	61
Annexes	67
Annex C (informative) Guide to marking and labelling requirements for ME EQUIPMENT and ME SYSTEMS	68
Annex AA (informative) Particular guidance and rationale	70
Bibliography	75

Index of defined terms used in this document	78
Figure 203.101 – Zone of EXTRA-FOCAL RADIATION	50
Figure 203.102 – Discrepancies in covering the IMAGE RECEPTION AREA.....	52
Figure 203.103 – Discrepancies in visual indication of the X-RAY FIELD	56
Figure 203.104 – Testing for STRAY RADIATION (X-RAY BEAM horizontal with X-RAY SOURCE ASSEMBLY below the PATIENT SUPPORT)	64
Figure 203.105 – Testing for STRAY RADIATION (X-RAY BEAM vertical with X-RAY SOURCE ASSEMBLY below the PATIENT SUPPORT)	65
Figure 203.106 – Testing for STRAY RADIATION (X-RAY BEAM horizontal with X-RAY SOURCE ASSEMBLY above the PATIENT SUPPORT)	65
Figure 203.107 – Testing for STRAY RADIATION (X-RAY BEAM vertical with X-RAY SOURCE ASSEMBLY above the PATIENT SUPPORT)	66
Table 201.101 – Distributed potential ESSENTIAL PERFORMANCE requirements	15
Table 203.101 – Tests for verifying reproducibility and linearity	37
Table 203.102 – LOADINGS for testing automatic exposure controls	38
Table 203.103 – ATTENUATION for the measurement of AIR KERMA.....	40
Table 203.104 – ATTENUATION EQUIVALENT of items in the X-RAY BEAM.....	58
Table 203.105 – Application categories.....	60
Table 203.106 – Requirements for PRIMARY PROTECTIVE SHIELDING	61
Table 203.107 – STRAY RADIATION in SIGNIFICANT ZONES OF OCCUPANCY	63
Table 201.C.101 – Marking on the outside of ME EQUIPMENT or its parts	68
Table 201.C.102 – Subclauses requiring statements in ACCOMPANYING DOCUMENTS	68

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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

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.
- 2) The formal decisions or agreements of 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 IEC National Committees.
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This redline version of the official IEC Standard allows the user to identify the changes made to the previous edition IEC 60601-2-54:2009+AMD1:2015+AMD2:2018 CSV. A vertical bar appears in the margin wherever a change has been made. Additions are in green text, deletions are in strikethrough red text.

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.

IMPORTANT – The "colour inside" logo on the cover page of this document indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this document using a colour printer.
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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. ~~While the previously existing standards for such equipment were dedicated to components and subsystems,~~ 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.

~~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.~~

~~INTRODUCTION TO AMENDMENT 2~~

~~The purpose of this second amendment to IEC 60601-2-54:2009 is to introduce changes which take the current state of the art into account. Therefore, X-RAY EQUIPMENT specified for DIRECT RADIOSCOPY is no longer in the scope of this document. The normative references were also updated in this amendment, and editorial clarifications and new terms and definitions were added. Provisions for QUALITY CONTROL PROCEDURES to be recommended by the MANUFACTURER are emphasized. Specific attention is paid to EXAMINATION PROTOCOLS in a new subclause which differentiate between adult and paediatric applications, in particular for X-RAY EQUIPMENT without an AUTOMATIC CONTROL SYSTEM. In addition, fixed periods for termination of LOADING after release of the RADIATION control by the OPERATOR are stipulated for RADIOSCOPY.~~

~~A new subclause on electronic documentation of EXAMINATION PROTOCOLS is introduced. It recommends providing access to electronic documentation containing relevant parameters of the PRE-PROGRAMMED EXAMINATION PROTOCOL. In another new subclause, the creation of basic documentation of the RADIATION DOSE STRUCTURED REPORT (RDSR) according to IEC 61910-1 is recommended. Furthermore, the subclause describing the LAST IMAGE HOLD RADIOGRAM has been revised and requires that the last image in RADIOSCOPY be displayed rather than provide just a means to display it.~~

~~This amendment recommends providing a graphical DISPLAY of the position of the BEAM LIMITING DEVICE blades on the IMAGE DISPLAY DEVICE in the subclause "Indication on the X-RAY EQUIPMENT".~~

~~Finally, the requirement for providing means to limit the FOCAL SPOT TO SKIN DISTANCES for radiosopic X-RAY EQUIPMENT differentiates between MOBILE and FIXED EQUIPMENT and extends, in the latter case, the minimum distance in possible clinical applications.~~

MEDICAL ELECTRICAL EQUIPMENT –

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

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, ~~IEC 60601-1-11 and IEC 60601-1-12~~ 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 ~~required~~ specified in this document rather than to the concepts of IEC 60601-1-8. Therefore IEC 60601-1-8 does not apply.

201.1.4 Particular standards

Replacement:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 and collateral standards as appropriate for the particular ME EQUIPMENT under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.

A requirement of a particular standard takes priority over IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020.

~~For brevity, IEC 60601-1 is referred to in this particular standard as the general standard. Collateral standards are referred to by their document number.~~

The numbering of clauses and subclauses of this document corresponds to that of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 with the prefix “201” (e.g. 201.1 in this document addresses the content of Clause 1 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020) or applicable collateral standard with the prefix “20x” where x is the final digit(s) of the collateral standard document number (e.g. 202.4 in this document addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 203.4 in this document addresses the content of Clause 4 of the IEC 60601-1-3 collateral standard, etc.). The changes to the text of the IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 are specified by the use of the following words:

“*Replacement*” means that the clause or subclause of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or the applicable collateral standard is replaced completely by the text of this document.

“*Addition*” means that the text of this document is additional to the requirements of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or the applicable collateral standard.

“*Amendment*” means that the clause or subclause of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or the applicable collateral standard is amended as indicated by the text of this document.

Subclauses, figures or tables which are additional to those of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 are numbered starting from 201.101. However, due to the fact that definitions in IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 are numbered 3.1 through 3.139154, additional definitions in this document are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses, figures or tables which are additional to those of a collateral standard are numbered starting from 20x, where “x” is the number of the collateral standard, e.g. 202 for IEC 60601-1-2, 203 for IEC 60601-1-3, etc.

~~The term “this standard” is used to make reference to the general standard, any applicable collateral standards and this particular standard taken together.~~

Where there is no corresponding clause or subclause in this document, the clause or subclause of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or the applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC

60601-1:2005/AMD2:2020 or the applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this document.

201.2 Normative references

NOTE Informative references are listed in the Bibliography.

Clause 2 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

Addition:

IEC 60336:2020, *Medical electrical equipment – X-ray tube assemblies for medical diagnosis – ~~Characteristics of focal spots~~ Focal spot dimensions and related characteristics*

IEC 60580:20002019, *Medical electrical equipment – Dose area product meters*

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

IEC 60601-1:2005/AMD1:2012

IEC 60601-1:2005/AMD2:2020

IEC TR 60788:2004, *Medical electrical equipment – Glossary of defined terms*

IEC 60806, *Determination of the maximum symmetrical radiation field ~~from a rotating anode~~ of X-ray tube assemblies and X-ray source assemblies for medical diagnosis*

~~IEC 62220-1-1:2015, Medical electrical equipment – Characteristics of digital X-ray imaging devices – Part 1-1: Determination of the detective quantum efficiency – Detectors used in radiographic imaging~~

IEC 61910-1:2014, *Medical electrical equipment – Radiation dose documentation – Part 1: Radiation dose structured reports for radiography and radioscopy*

IEC 62494-1:2008, *Medical electrical equipment – Exposure index of digital X-ray imaging systems – Part 1: Definitions and requirements for general radiography*

Amendment:

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

IEC 60601-1-3:2008/AMD2:2021

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**

CONTENTS

FOREWORD	4
INTRODUCTION.....	7
201.1 Scope, object and related standards	8
201.2 Normative references.....	10
201.3 Terms and definitions.....	10
201.4 General requirements	13
201.5 General requirements for testing ME EQUIPMENT	14
201.6 Classification of ME EQUIPMENT and ME SYSTEMS.....	14
201.7 ME EQUIPMENT identification, marking and documents	14
201.8 Protection against electrical HAZARDS from ME EQUIPMENT	18
201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS	20
201.10 Protection against unwanted and excessive radiation HAZARDS	24
201.11 Protection against excessive temperatures and other HAZARDS	24
201.12 Accuracy of controls and instruments and protection against hazardous outputs	25
201.13 HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT	25
201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)	25
201.15 Construction of ME EQUIPMENT	25
201.16 ME SYSTEMS	26
201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS	26
202 Electromagnetic disturbances – Requirements and tests.....	26
202.101 * Immunity testing of ESSENTIAL PERFORMANCE.....	26
203 RADIATION PROTECTION in diagnostic X-RAY EQUIPMENT.....	26
203.4 General requirements	27
203.5 ME EQUIPMENT identification, marking and documents	28
203.6 RADIATION management	31
203.7 RADIATION QUALITY.....	46
203.8 Limitation of the extent of the X-RAY BEAM and relationship between X-RAY FIELD and IMAGE RECEPTION AREA	47
203.9 FOCAL SPOT TO SKIN DISTANCE	54
203.10 ATTENUATION of the X-RAY BEAM between the PATIENT and the X-RAY IMAGE RECEPTOR.....	55
203.11 Protection against RESIDUAL RADIATION	56
203.12 Protection against LEAKAGE RADIATION	58
203.13 Protection against STRAY RADIATION.....	58
Annexes	64
Annex C (informative) Guide to marking and labelling requirements for ME EQUIPMENT and ME SYSTEMS.....	65
Annex AA (informative) Particular guidance and rationale	67
Bibliography.....	72
Index of defined terms used in this document	74

Figure 203.101 – Zone of EXTRA-FOCAL RADIATION	47
Figure 203.102 – Discrepancies in covering the IMAGE RECEPTION AREA.....	49
Figure 203.103 – Discrepancies in visual indication of the X-RAY FIELD	53
Figure 203.104 – Testing for STRAY RADIATION (X-RAY BEAM horizontal with X-RAY SOURCE ASSEMBLY below the PATIENT SUPPORT)	61
Figure 203.105 – Testing for STRAY RADIATION (X-RAY BEAM vertical with X-RAY SOURCE ASSEMBLY below the PATIENT SUPPORT)	62
Figure 203.106 – Testing for STRAY RADIATION (X-RAY BEAM horizontal with X-RAY SOURCE ASSEMBLY above the PATIENT SUPPORT)	62
Figure 203.107 – Testing for STRAY RADIATION (X-RAY BEAM vertical with X-RAY SOURCE ASSEMBLY above the PATIENT SUPPORT).....	63
Table 201.101 – Distributed potential ESSENTIAL PERFORMANCE requirements	13
Table 203.101 – Tests for verifying reproducibility and linearity	34
Table 203.102 – LOADINGS for testing automatic exposure controls	36
Table 203.103 – ATTENUATION for the measurement of AIR KERMA.....	38
Table 203.104 – ATTENUATION EQUIVALENT of items in the X-RAY BEAM.....	55
Table 203.105 – Application categories.....	57
Table 203.106 – Requirements for PRIMARY PROTECTIVE SHIELDING	58
Table 203.107 – STRAY RADIATION in SIGNIFICANT ZONES OF OCCUPANCY	60
Table 201.C.101 – Marking on the outside of ME EQUIPMENT or its parts	65
Table 201.C.102 – Subclauses requiring statements in ACCOMPANYING DOCUMENTS.....	66

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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

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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- 9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

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 –

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

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.

201.1.4 Particular standards

Replacement:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 and collateral standards as appropriate for the particular ME EQUIPMENT under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.

A requirement of a particular standard takes priority over IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020.

The numbering of clauses and subclauses of this document corresponds to that of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 with the prefix “201” (e.g. 201.1 in this document addresses the content of Clause 1 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020) or applicable collateral standard with the prefix “20x” where x is the final digit(s) of the collateral standard document number (e.g. 202.4 in this document addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 203.4 in this document addresses the content of Clause 4 of the IEC 60601-1-3 collateral standard, etc.). The changes to the text of the IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 are specified by the use of the following words:

“*Replacement*” means that the clause or subclause of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or the applicable collateral standard is replaced completely by the text of this document.

“*Addition*” means that the text of this document is additional to the requirements of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or the applicable collateral standard.

“*Amendment*” means that the clause or subclause of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or the applicable collateral standard is amended as indicated by the text of this document.

Subclauses, figures or tables which are additional to those of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 are numbered starting from 201.101. However, due to the fact that definitions in IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 are numbered 3.1 through 3.154, additional definitions in this document are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses, figures or tables which are additional to those of a collateral standard are numbered starting from 20x, where “x” is the number of the collateral standard, e.g. 202 for IEC 60601-1-2, 203 for IEC 60601-1-3, etc.

Where there is no corresponding clause or subclause in this document, the clause or subclause of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or the applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or the applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this document.

201.2 Normative references

NOTE Informative references are listed in the Bibliography.

Clause 2 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

Addition:

IEC 60336:2020, *Medical electrical equipment – X-ray tube assemblies for medical diagnosis – Focal spot dimensions and related characteristics*

IEC 60580:2019, *Medical electrical equipment – Dose area product meters*

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

IEC 60601-1:2005/AMD1:2012

IEC 60601-1:2005/AMD2:2020

IEC TR 60788:2004, *Medical electrical equipment – Glossary of defined terms*

IEC 60806, *Determination of the maximum symmetrical radiation field of X-ray tube assemblies and X-ray source assemblies for medical diagnosis*

IEC 61910-1:2014, *Medical electrical equipment – Radiation dose documentation – Part 1: Radiation dose structured reports for radiography and radioscopy*

IEC 62494-1:2008, *Medical electrical equipment – Exposure index of digital X-ray imaging systems – Part 1: Definitions and requirements for general radiography*

Amendment:

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

IEC 60601-1-3:2008/AMD2:2021

SOMMAIRE

AVANT-PROPOS	82
INTRODUCTION.....	85
201.1 Domaine d'application, objet et normes connexes	86
201.2 Références normatives	88
201.3 Termes et définitions	88
201.4 Exigences générales.....	91
201.5 Exigences générales relatives aux essais des APPAREILS EM	92
201.6 Classification des APPAREILS EM et des SYSTEMES EM	93
201.7 Identification, marquage et documentation des APPAREILS EM	93
201.8 Protection contre les DANGERS d'origine électrique provenant des APPAREILS EM	96
201.9 Protection contre les DANGERS MECANQUES des APPAREILS EM et des SYSTEMES EM.....	99
201.10 Protection contre les DANGERS dus aux rayonnements involontaires et excessifs.....	104
201.11 Protection contre les températures excessives et les autres DANGERS	104
201.12 Précision des commandes et des instruments et protection contre les caractéristiques de sortie présentant des risques.....	105
201.13 SITUATIONS DANGEREUSES et conditions de défaut pour les APPAREILS EM	105
201.14 SYSTEMES ELECTROMEDICAUX PROGRAMMABLES (SEMP)	105
201.15 Construction de l'APPAREIL EM	105
201.16 SYSTEMES EM	105
201.17 Compatibilité électromagnétique des APPAREILS EM et des SYSTEMES EM.....	105
202 Perturbations électromagnétiques – Exigences et essais	105
202.101 *Essais d'immunité des PERFORMANCES ESSENTIELLES	106
203 RADIOPROTECTION dans les APPAREILS A RAYONNEMENT X de diagnostic	106
203.4 Exigences générales.....	106
203.5 Identification, marquage et documentation des APPAREILS EM.....	108
203.6 Gestion des RAYONNEMENTS	111
203.7 QUALITE DE RAYONNEMENT	128
203.8 Limitation de l'étendue du FAISCEAU DE RAYONNEMENT X et relation entre FAISCEAU DE RAYONNEMENT X et SURFACE RECEPTRICE DE L'IMAGE	128
203.9 DISTANCE FOYER-PEAU	136
203.10 ATTENUATION du FAISCEAU DE RAYONNEMENT X entre le PATIENT et le RECEPTEUR D'IMAGE RADIOLOGIQUE	137
203.11 Protection contre le RAYONNEMENT RESIDUEL.....	139
203.12 Protection contre le RAYONNEMENT DE FUITE	141
203.13 Protection contre les RAYONNEMENTS PARASITES	142
Annexes	147
Annexe C (informative) Guide pour le marquage et exigences d'étiquetage pour les APPAREILS et les SYSTEMES EM.....	148
Annexe AA (informative) Recommandations particulières et justification	150
Bibliographie.....	155

Index des termes définis utilisés dans le présent document	157
Figure 203.101 – Zone de RAYONNEMENT EXTRAFOCAL	129
Figure 203.102 – Écart de couverture de la SURFACE RECEPTRICE DE L'IMAGE	131
Figure 203.103 – Écart dans l'indication visuelle du CHAMP DE RAYONNEMENT X	135
Figure 203.104 – Essai pour RAYONNEMENT PARASITE (FAISCEAU DE RAYONNEMENT X horizontal, l'ENSEMBLE RADIOGENE étant situé au-dessous du SUPPORT PATIENT)	145
Figure 203.105 – Essai pour RAYONNEMENT PARASITE (FAISCEAU DE RAYONNEMENT X vertical, l'ENSEMBLE RADIOGENE étant situé au-dessous du SUPPORT PATIENT)	145
Figure 203.106 – Essai pour RAYONNEMENT PARASITE (FAISCEAU DE RAYONNEMENT X horizontal, l'ENSEMBLE RADIOGENE étant situé au-dessus du SUPPORT PATIENT)	146
Figure 203.107 – Essai pour RAYONNEMENT PARASITE (FAISCEAU DE RAYONNEMENT X vertical, l'ENSEMBLE RADIOGENE étant situé au-dessus du support patient)	146
Tableau 201.101 – Références des exigences relatives aux PERFORMANCES ESSENTIELLES potentielles	92
Tableau 203.101 – Essais destinés à vérifier la reproductibilité et la linéarité	115
Tableau 203.102 – Applications de CHARGE pour les essais des commandes automatiques d'exposition	117
Tableau 203.103 – ATTENUATION pour le mesurage du KERMA DANS L'AIR	119
Tableau 203.104 – ÉQUIVALENT D'ATTENUATION des éléments dans le FAISCEAU DE RAYONNEMENT X	138
Tableau 203.105 – Catégories d'application	140
Tableau 203.106 – Exigences relatives à la BARRIERE DE PROTECTION CONTRE LE FAISCEAU	141
Tableau 203.107 – RAYONNEMENT PARASITE dans les ZONES SIGNIFICATIVES D'OCCUPATION	143
Tableau 201.C101 – Marquage sur l'extérieur des APPAREILS EM ou de leurs parties	148
Tableau 201.C.102 – Paragraphes exigeant des indications qui doivent figurer dans les DOCUMENTS D'ACCOMPAGNEMENT	149

COMMISSION ÉLECTROTECHNIQUE INTERNATIONALE

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

AVANT-PROPOS

- 1) La Commission Électrotechnique Internationale (IEC) est une organisation mondiale de normalisation composée de l'ensemble des comités électrotechniques nationaux (Comités nationaux de l'IEC). L'IEC a pour objet de favoriser la coopération internationale pour toutes les questions de normalisation dans les domaines de l'électricité et de l'électronique. À cet effet, l'IEC – entre autres activités – publie des Normes internationales, des Spécifications techniques, des Rapports techniques, des Spécifications accessibles au public (PAS) et des Guides (ci-après dénommés "Publication(s) de l'IEC"). Leur élaboration est confiée à des comités d'études, aux travaux desquels tout Comité national intéressé par le sujet traité peut participer. Les organisations internationales, gouvernementales et non gouvernementales, en liaison avec l'IEC, participent également aux travaux. L'IEC collabore étroitement avec l'Organisation Internationale de Normalisation (ISO), selon des conditions fixées par accord entre les deux organisations.
- 2) Les décisions ou accords officiels de l'IEC concernant les questions techniques représentent, dans la mesure du possible, un accord international sur les sujets étudiés, étant donné que les Comités nationaux de l'IEC intéressés sont représentés dans chaque comité d'études.
- 3) Les Publications de l'IEC se présentent sous la forme de recommandations internationales et sont agréées comme telles par les Comités nationaux de l'IEC. Tous les efforts raisonnables sont entrepris afin que l'IEC s'assure de l'exactitude du contenu technique de ses publications; l'IEC ne peut pas être tenue responsable de l'éventuelle mauvaise utilisation ou interprétation qui en est faite par un quelconque utilisateur final.
- 4) Dans le but d'encourager l'uniformité internationale, les Comités nationaux de l'IEC s'engagent, dans toute la mesure possible, à appliquer de façon transparente les Publications de l'IEC dans leurs publications nationales et régionales. Toutes divergences entre toutes Publications de l'IEC et toutes publications nationales ou régionales correspondantes doivent être indiquées en termes clairs dans ces dernières.
- 5) L'IEC elle-même ne fournit aucune attestation de conformité. Des organismes de certification indépendants fournissent des services d'évaluation de conformité et, dans certains secteurs, accèdent aux marques de conformité de l'IEC. L'IEC n'est responsable d'aucun des services effectués par les organismes de certification indépendants.
- 6) Tous les utilisateurs doivent s'assurer qu'ils sont en possession de la dernière édition de cette publication.
- 7) Aucune responsabilité ne doit être imputée à l'IEC, à ses administrateurs, employés, auxiliaires ou mandataires, y compris ses experts particuliers et les membres de ses comités d'études et des Comités nationaux de l'IEC, pour tout préjudice causé en cas de dommages corporels et matériels, ou de tout autre dommage de quelque nature que ce soit, directe ou indirecte, ou pour supporter les coûts (y compris les frais de justice) et les dépenses découlant de la publication ou de l'utilisation de cette Publication de l'IEC ou de toute autre Publication de l'IEC, ou au crédit qui lui est accordé.
- 8) L'attention est attirée sur les références normatives citées dans cette publication. L'utilisation de publications référencées est obligatoire pour une application correcte de la présente publication.
- 9) L'attention est attirée sur le fait que certains des éléments du présent document de l'IEC peuvent faire l'objet de droits de brevet. L'IEC ne saurait être tenue pour responsable de ne pas avoir identifié de tels droits de brevets.

L'IEC 60601-2-54 a été établie par le sous-comité 62B: Appareils d'imagerie de diagnostic, du comité d'études 62 de l'IEC: Équipements électriques dans la pratique médicale. Il s'agit d'une Norme internationale.

Cette deuxième édition annule et remplace la première édition parue en 2009, l'Amendement 1:2015 et l'Amendement 2:2018. Cette édition constitue une révision technique.

La présente édition comprend des modifications techniques et rédactionnelles destinées à représenter l'IEC 60601-1:2005/AMD2:2020. Elle contient également des corrections et des améliorations techniques. Les modifications techniques majeures par rapport à l'édition précédente sont les suivantes:

- a) déplacement en 201.3 des termes issus exclusivement de l'IEC TR 60788:2004 et qui sont spécifiquement applicables dans le présent document;
- b) si le FABRICANT le déclare, les normes collatérales IEC 60601-1-11:2015, IEC 60601-1-11:2015/AMD1:2020, IEC 60601-1-12:2014 et IEC 60601-1-12:2014/AMD1:2020 s'appliquent;
- c) le paragraphe 201.11.101 "Protection contre les températures excessives des gaines équipées" a été supprimé du présent document, car ses exigences sont suffisamment et clairement traitées par l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012, l'IEC 60601-1:2005/AMD2:2020 et l'IEC 60601-2-28:2017;
- d) clarification des exigences pour l'adoption des modifications introduites concernant les voyants lumineux au paragraphe 7.8.1 de l'IEC 60601-1:2005/AMD2:2020 afin d'éviter les conflits avec les exigences relatives aux voyants lumineux stipulées pour les APPAREILS A RAYONNEMENT X;
- e) explication du terme PERFORMANCE ESSENTIELLE fournie dans l'Annexe AA afin de mettre l'accent sur la fonction clinique en CONDITION NORMALE ET DE PREMIER DEFAULT.

Le texte de ce document est issu des documents suivants:

Projet	Rapport de vote
62B/1285/FDIS	62B/1293/RVD

Le rapport de vote indiqué dans le tableau ci-dessus donne toute information sur le vote ayant abouti à son approbation.

La langue employée pour l'élaboration de cette Norme internationale est l'anglais.

Le présent document a été rédigé selon les Directives ISO/IEC, Partie 2, il a été développé selon les Directives ISO/IEC, Partie 1 et les Directives ISO/IEC, Supplément IEC, disponibles sous www.iec.ch/members_experts/refdocs. Les principaux types de documents développés par l'IEC sont décrits plus en détail sous www.iec.ch/standardsdev/publications.

Dans le présent document, les caractères d'imprimerie suivants sont utilisés:

- exigences et définitions: caractères romains;
- *modalités d'essais: caractères italiques;*
- indications de nature informative apparaissant hors des tableaux, comme les notes, les exemples et les références: petits caractères. Le texte normatif à l'intérieur des tableaux est également en petits caractères ;
- LES TERMES DEFINIS A L'ARTICLE 3 DE L'IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 ET DE L'IEC 60601-1:2005/AMD2:2020, DANS LE PRESENT DOCUMENT OU LORSQUE MENTIONNES: PETITES MAJUSCULES.

Concernant la structure du présent document, le terme

- "article" désigne l'une des dix-sept sections numérotées dans la table des matières, avec toutes ses subdivisions (par exemple, l'Article 7 inclut les paragraphes 7.1, 7.2, etc.);
- "paragraphe" désigne une subdivision numérotée d'un article (par exemple, 7.1, 7.2 et 7.2.1 sont tous des paragraphes appartenant à l'Article 7).

Dans le présent document, les références à des articles sont précédées du mot "Article" suivi du numéro de l'article concerné. Dans le présent document, les références aux paragraphes utilisent uniquement le numéro du paragraphe concerné.

Dans le présent document, la conjonction "ou" est utilisée avec la valeur d'un "ou inclusif", ainsi un énoncé est vrai si une combinaison des conditions quelle qu'elle soit est vraie.

Les formes verbales utilisées dans le présent document sont conformes à l'usage donné à l'Article 7 des Directives ISO/IEC, Partie 2. Pour les besoins le présent document:

- "devoir" mis au présent de l'indicatif signifie que la satisfaction à une exigence ou à un essai est obligatoire pour la conformité au présent document;
- "il convient/il est recommandé" signifie que la satisfaction à une exigence ou à un essai est recommandée mais n'est pas obligatoire pour la conformité au présent document;
- "pouvoir" mis au présent de l'indicatif est utilisé pour décrire un moyen admissible pour satisfaire à une exigence ou à un essai.

Lorsqu'un astérisque (*) est utilisé comme premier caractère devant un titre, ou au début d'un titre d'alinéa ou de tableau, il indique l'existence de recommandations ou d'une justification à consulter à l'Annexe AA.

Une liste de toutes les parties de la série IEC 60601 et de la série IEC 80601, publiées sous le titre général *Appareils électromédicaux*, peut être consultée sur le site web de l'IEC.

Le comité a décidé que le contenu du présent document ne sera pas modifié avant la date de stabilité indiquée sur le site web de l'IEC sous webstore.iec.ch dans les données relatives au document recherché. À cette date, le document sera

- reconduit,
- supprimé,
- remplacé par une édition révisée, ou
- amendé.

INTRODUCTION

Le présent document a été établi pour fournir, sur la base de l'IEC 60601-1:2005 (troisième édition), et de ses normes collatérales, un ensemble complet d'exigences de sécurité applicables aux APPAREILS ELECTROMEDICAUX (EM) utilisés pour la RADIOGRAPHIE et la RADIOSCOPIE. Cette deuxième édition a pour objet d'introduire des changements qui font référence au deuxième amendement (2020) de l'IEC 60601-1 :2005 ainsi qu'aux normes collatérales associées. De plus, l'Annexe AA fournit une clarification du terme relatif aux PERFORMANCES ESSENTIELLES. Le présent document traite des APPAREILS A RAYONNEMENT X considérés au niveau système, lequel se compose d'un GROUPE RADIOGENE, d'EQUIPEMENTS ASSOCIES et d'ACCESSOIRES. Les fonctions des composants sont traitées au besoin.

Les exigences de sécurité minimales spécifiées dans le présent document sont estimées assurer un degré de sécurité réalisable dans le cadre du fonctionnement des APPAREILS EM utilisés pour la RADIOGRAPHIE et la RADIOSCOPIE. Les exigences relatives aux dispositions supplémentaires concernant les procédures d'intervention applicables aux APPAREILS EM sont traitées dans l'IEC 60601-2-43.

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

201.1 Domaine d'application, objet et normes connexes

L'Article 1 de l'IEC 60601-1:2005, de l'IEC 60601-1:2005/AMD1:2012 et de l'IEC 60601-1:2005/AMD2:2020 s'applique, avec les exceptions suivantes:

201.1.1 Domaine d'application

Remplacement:

Le présent document s'applique à la SECURITE DE BASE et aux PERFORMANCES ESSENTIELLES des APPAREILS EM et des SYSTEMES EM destinés à la RADIOGRAPHIE de projection et à la RADIOSCOPIE INDIRECTE. L'IEC 60601-2-43 est applicable aux APPAREILS EM et aux SYSTEMES EM destinés à être utilisés lors de procédures d'interventions et se réfère aux exigences applicables du présent document.

Les APPAREILS EM et SYSTEMES EM destinés à l'ostéodensitométrie par absorption, à la tomodynamométrie, à la mammographie ou aux applications dentaires ou de radiothérapie, sont exclus du domaine d'application du présent document. Le domaine d'application du présent document exclut également les simulateurs de radiothérapie.

Lorsqu'un article ou un paragraphe est spécifiquement destiné à être applicable uniquement aux APPAREILS EM ou uniquement aux SYSTEMES EM, son titre et son contenu l'indiquent. Lorsque cela n'est pas le cas, l'article ou le paragraphe s'applique à la fois aux APPAREILS EM et aux SYSTEMES EM, selon le cas.

201.1.2 Objet

Remplacement:

Le présent document vise à établir des exigences particulières relatives à la SECURITE DE BASE et aux PERFORMANCES ESSENTIELLES des APPAREILS EM et des SYSTEMES EM utilisés pour la RADIOGRAPHIE et la RADIOSCOPIE.

201.1.3 Normes collatérales

Addition:

Le présent document se réfère aux normes collatérales applicables énumérées à l'Article 2 de l'IEC 60601-1:2005, de l'IEC 60601-1:2005/AMD1:2012 et de l'IEC 60601-1:2005/AMD2:2020, tel qu'il est modifié en 201.2.

L'IEC 60601-1-2:2014 et l'IEC 60601-1-2:2014/AMD1:2020, l'IEC 60601-1-3:2008 et l'IEC 60601-1-3:2008/AMD1:2013 ainsi que l'IEC 60601-1-3:2008/AMD2:2021 s'appliquent telles que modifiées respectivement par les Articles 202 et 203. Dans le cas où le FABRICANT déclare qu'il est prévu que l'APPAREIL EM ou le SYSTEME EM soit utilisé dans un ENVIRONNEMENT DE SOINS A DOMICILE, alors l'IEC 60601-1-11:2015 et l'IEC 60601-1-11:2015/AMD1:2020 s'appliquent et lorsque le FABRICANT déclare qu'il est prévu que l'APPAREIL EM ou le SYSTEME EM soit utilisé dans un ENVIRONNEMENT DE SERVICES MEDICAUX D'URGENCE, alors l'IEC 60601-1-12:2014 et l'IEC 60601-1-12:2015/AMD1:2020 s'appliquent. L'IEC 60601-1-8, l'IEC 60601-1-9, l'IEC 60601-1-10 ne s'appliquent pas. Toutes les autres normes collatérales parues dans la série IEC 60601-1 s'appliquent telles qu'elles sont publiées.

NOTE Les OPERATEURS d'APPAREILS A RAYONNEMENT X sont habitués aux signaux sonores, comme cela est spécifié dans le présent document, plutôt qu'aux concepts de l'IEC 60601-1-8. De ce fait, l'IEC 60601-1-8 ne s'applique pas.

201.1.4 Normes particulières

Remplacement:

Dans la série IEC 60601, des normes particulières peuvent modifier, remplacer ou supprimer des exigences contenues dans l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 et dans les normes collatérales en fonction de ce qui est approprié à l'APPAREIL EM considéré, et elles peuvent ajouter d'autres exigences de SECURITE DE BASE et de PERFORMANCES ESSENTIELLES.

Une exigence d'une norme particulière prévaut sur celles de l'IEC 60601-1:2005, de l'IEC 60601-1:2005/AMD1:2012 et de l'IEC 60601-1:2005/AMD2:2020.

La numérotation des articles et des paragraphes du présent document correspond à celle de l'IEC 60601-1:2005, de l'IEC 60601-1:2005/AMD1:2012 et de l'IEC 60601-1:2005/AMD2:2020 avec le préfixe "201" (par exemple, 201.1 dans le présent document couvre le contenu de l'Article 1 de l'IEC 60601-1:2005, de l'IEC 60601-1:2005/AMD1:2012 et de l'IEC 60601-1:2005/AMD2:2020) ou de la norme collatérale applicable avec le préfixe "20x", où x est (sont) le (les) dernier(s) chiffre(s) du numéro de document de la norme collatérale (par exemple, 202.4 dans le présent document couvre le contenu de l'Article 4 de la norme collatérale IEC 60601-1-2, 203.4 dans le présent document couvre le contenu de l'Article 4 de la norme collatérale IEC 60601-1-3, etc.). Les modifications apportées au texte de l'IEC 60601-1:2005, de l'IEC 60601-1:2005/AMD1:2012 et de l'IEC 60601-1:2005/AMD2:2020 sont précisées en utilisant les termes suivants:

"*Remplacement*" signifie que l'article ou le paragraphe de l'IEC 60601-1:2005, de l'IEC 60601-1:2005/AMD1:2012 et de l'IEC 60601-1:2005/AMD2:2020 ou de la norme collatérale applicable est remplacé complètement par le texte de la présente norme particulière.

"*Addition*" signifie que le texte du présent document vient s'ajouter aux exigences de l'IEC 60601-1:2005, de l'IEC 60601-1:2005/AMD1:2012 et de l'IEC 60601-1:2005/AMD2:2020 ou de la norme collatérale applicable.

"*Amendement*" signifie que l'article ou le paragraphe de l'IEC 60601-1:2005, de l'IEC 60601-1:2005/AMD1:2012 et de l'IEC 60601-1:2005/AMD2:2020 ou de la norme collatérale applicable est amendé comme cela est indiqué par le texte du présent document.

Les paragraphes, les figures ou les tableaux qui sont ajoutés à ceux de l'IEC 60601-1:2005, de l'IEC 60601-1:2005/AMD1:2012 et de l'IEC 60601-1:2005/AMD2:2020 sont numérotés à partir de 201.101. Toutefois, en raison du fait que les définitions de l'IEC 60601-1:2005, de l'IEC 60601-1:2005/AMD1:2012 et de l'IEC 60601-1:2005/AMD2:2020 sont numérotées de 3.1 à 3.154, les définitions complémentaires dans le présent document sont numérotées à partir de 201.3.201. Les annexes supplémentaires sont notées AA, BB, etc., et les alinéas supplémentaires aa), bb), etc.

Les paragraphes, les figures ou les tableaux qui sont ajoutés à une norme collatérale sont numérotés à partir de 20x, où "x" est le chiffre de la norme collatérale, par exemple 202 pour l'IEC 60601-1-2, 203 pour l'IEC 60601-1-3, etc.

Lorsque le présent document ne comprend pas d'article ou de paragraphe correspondant, l'article ou le paragraphe de l'IEC 60601-1:2005, de l'IEC 60601-1:2005/AMD1:2012 et de l'IEC 60601-1:2005/AMD2:2020 ou de la norme collatérale applicable, bien qu'il puisse être sans objet, s'applique sans modification; lorsque l'objectif est qu'une partie quelconque de l'IEC 60601-1:2005, de l'IEC 60601-1:2005/AMD1:2012 et de l'IEC 60601-1:2005/AMD2:2020 ou de la norme collatérale applicable, bien que potentiellement pertinente, ne doive pas s'appliquer, cela est expressément mentionné dans le présent document.

201.2 Références normatives

NOTE Une liste de références informatives est fournie dans la Bibliographie.

L'Article 2 de l'IEC 60601-1:2005, de l'IEC 60601-1:2005/AMD1:2012 et de l'IEC 60601-1:2005/AMD2:2020 s'applique, avec les exceptions suivantes:

Addition:

IEC 60336:2020, *Appareils électromédicaux – Gaines équipées pour diagnostic médical – Dimensions des foyers et caractéristiques connexes*

IEC 60580:2019, *Appareils électromédicaux – Radimètres de produit exposition-surface*

IEC 60601-1:2005, *Appareils électromédicaux – Partie 1: Exigences générales pour la sécurité de base et les performances essentielles*

IEC 60601-1:2005/AMD1:2012

IEC 60601-1:2005/AMD2:2020

IEC TR 60788:2004, *Medical electrical equipment – Glossary of defined terms* (disponible en anglais seulement)

IEC 60806, *Détermination du champ de rayonnement maximal symétrique des gaines équipées et des ensembles radiogènes utilisés en diagnostic médical*

IEC 61910-1:2014, *Appareils électromédicaux – Documentation sur la dose de rayonnement – Partie 1: Rapports structurés sur la dose de rayonnement pour la radiographie et la radioscopie*

IEC 62494-1:2008, *Appareils électromédicaux – Indice d'exposition des systèmes d'imagerie numérique à rayonnement X – Partie 1: Définitions et exigences pour la radiographie générale*

Amendement:

IEC 60601-1-3:2008, *Appareils électromédicaux – Partie 1-3: Exigences générales pour la sécurité de base et les performances essentielles – Norme collatérale: Radioprotection dans les appareils à rayonnement X de diagnostic*

IEC 60601-1-3:2008/AMD1:2013

IEC 60601-1-3:2008/AMD2:2021