



Edition 1.0 2009-06

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





THIS PUBLICATION IS COPYRIGHT PROTECTED

Copyright © 2009 IEC, Geneva, Switzerland

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either IEC or IEC's member National Committee in the country of the requester.

If you have any questions about IEC copyright or have an enquiry about obtaining additional rights to this publication, please contact the address below or your local IEC member National Committee for further information.

Droits de reproduction réservés. Sauf indication contraire, aucune partie de cette publication ne peut être reproduite ni utilisée sous quelque forme que ce soit et par aucun procédé, électronique ou mécanique, y compris la photocopie et les microfilms, sans l'accord écrit de la CEI ou du Comité national de la CEI du pays du demandeur. Si vous avez des questions sur le copyright de la CEI ou si vous désirez obtenir des droits supplémentaires sur cette publication, utilisez les coordonnées ci-après ou contactez le Comité national de la CEI de votre pays de résidence.

IEC Central Office 3, rue de Varembé CH-1211 Geneva 20 Switzerland Email: inmail@iec.ch Web: www.iec.ch

About the IEC

The International Electrotechnical Commission (IEC) is the leading global organization that prepares and publishes International Standards for all electrical, electronic and related technologies.

About IEC publications

The technical content of IEC publications is kept under constant review by the IEC. Please make sure that you have the latest edition, a corrigenda or an amendment might have been published.

Catalogue of IEC publications: www.iec.ch/searchpub

The IEC on-line Catalogue enables you to search by a variety of criteria (reference number, text, technical committee,...). It also gives information on projects, withdrawn and replaced publications.

IEC Just Published: www.iec.ch/online news/justpub

Stay up to date on all new IEC publications. Just Published details twice a month all new publications released. Available on-line and also by email.

Electropedia: <u>www.electropedia.org</u>

The world's leading online dictionary of electronic and electrical terms containing more than 20 000 terms and definitions in English and French, with equivalent terms in additional languages. Also known as the International Electrotechnical Vocabulary online.

Customer Service Centre: <u>www.iec.ch/webstore/custserv</u>

If you wish to give us your feedback on this publication or need further assistance, please visit the Customer Service Centre FAQ or contact us:

Email: <u>csc@iec.ch</u> Tel.: +41 22 919 02 11

Fax: +41 22 919 03 00

A propos de la CEI

La Commission Electrotechnique Internationale (CEI) est la première organisation mondiale qui élabore et publie des normes internationales pour tout ce qui a trait à l'électricité, à l'électronique et aux technologies apparentées.

A propos des publications CEI

Le contenu technique des publications de la CEI est constamment revu. Veuillez vous assurer que vous possédez l'édition la plus récente, un corrigendum ou amendement peut avoir été publié.

Catalogue des publications de la CEI: www.iec.ch/searchpub/cur_fut-f.htm

Le Catalogue en-ligne de la CEI vous permet d'effectuer des recherches en utilisant différents critères (numéro de référence, texte, comité d'études,...). Il donne aussi des informations sur les projets et les publications retirées ou remplacées.

Just Published CEI: www.iec.ch/online_news/justpub

Restez informé sur les nouvelles publications de la CEI. Just Published détaille deux fois par mois les nouvelles publications parues. Disponible en-ligne et aussi par email.

Electropedia: <u>www.electropedia.org</u>

Le premier dictionnaire en ligne au monde de termes électroniques et électriques. Il contient plus de 20 000 termes et définitions en anglais et en français, ainsi que les termes équivalents dans les langues additionnelles. Egalement appelé Vocabulaire Electrotechnique International en ligne.

Service Clients: <u>www.iec.ch/webstore/custserv/custserv_entry-f.htm</u>

Si vous désirez nous donner des commentaires sur cette publication ou si vous avez des questions, visitez le FAQ du Service clients ou contactez-nous:

Email: <u>csc@iec.ch</u> Tél.: +41 22 919 02 11

Fax: +41 22 919 03 00



Edition 1.0 2009-06

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

INTERNATIONAL ELECTROTECHNICAL COMMISSION

COMMISSION ELECTROTECHNIQUE INTERNATIONALE

PRICE CODE CODE PRIX

ICS 11.040.50

ISBN 2-8318-1047-5

CONTENTS

FOREWO	RD	.4	
INTRODU	CTION	.6	
201.1	Scope, object and related standards	.7	
201.2	Normative references	.8	
201.3	Terms and definitions	.9	
201.4	General requirements	10	
201.5	General requirements for testing of ME EQUIPMENT	11	
201.6	Classification of ME EQUIPMENT and ME SYSTEMS	11	
201.7	ME EQUIPMENT identification, marking and documents	11	
201.8	Protection against electrical HAZARDS from ME EQUIPMENT	14	
201.9	Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS	17	
201.10	Protection against unwanted and excessive radiation HAZARDS	21	
201.11	Protection against excessive temperatures and other HAZARDS	21	
201.12	Accuracy of controls and instruments and protection against hazardous outputs	22	
201.13	HAZARDOUS SITUATIONS and fault conditions	22	
201.14	PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)	22	
201.15	Construction of ME EQUIPMENT	22	
201.16	ME SYSTEMS	22	
201.17	Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS	22	
202	Electromagnetic compatibility – Requirements and tests	22	
203	Radiation protection in diagnostic X-ray equipment	23	
Annexes .		58	
Annex C (and ME SY	informative) Guide to marking and labelling requirements for ME EQUIPMENT	59	
Annex AA	(informative) Particular guidance and rationale	31	
Bibliography			
Index of defined terms used in this particular standard			
Figure 20:	3 101 – Zone of EXTRA-EOCAL RADIATION	41	
Figure 203,102 – Discrepancies in covering the IMAGE RECEPTION AREA			
Figure 203	3.103 – Discrepancies in visual indication of the X-RAY FIELD	47	
Figure 203 SOURCE AS	3.104 – Testing for STRAY RADIATION (X-RAY BEAM horizontal with X-RAY SSEMBLY below the PATIENT SUPPORT)	55	
Figure 203 ASSEMBLY	3.105 – Testing for STRAY RADIATION (X-RAY BEAM vertical with X-RAY SOURCE below the PATIENT SUPPORT)	55	
Figure 203 SOURCE AS	3.106 – Testing for STRAY RADIATION (X-RAY BEAM horizontal with X-RAY SSEMBLY above the PATIENT SUPPORT)	56	
Figure 203.107 – Testing for STRAY RADIATION (X-RAY BEAM vertical with X-RAY SOURCE ASSEMBLY above the PATIENT SUPPORT)			
Table 201	.101 – Distributed ESSENTIAL PERFORMANCE requirements	10	
Table 203	.101 – Tests for verifying reproducibility and linearity	29	

able 203.102 – Loadings for testing AUTOMATIC EXPOSURE CONTROLS	31
able 203.103 – ATTENUATION for the measurement of AIR KERMA	33
able 203.104 – Attenuation equivalent of items in the X-ray beam	49
able 203.105 – Application categories	51
able 203.106 – Requirements for PRIMARY PROTECTIVE SHIELDING	51
able 203.107 – Stray radiation in significant zones of occupancy	53
able 201.C.101 – Marking on the outside of ME EQUIPMENT or its parts	59
able 201.C.102 – Subclauses requiring statements in ACCOMPANYING DOCUMENTS	59
0.	
\odot	
0	
	L
	(\mathbf{r})

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 committee; 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.
- 3) IEC Publications have the form of recommendations for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user.
- 4) In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible in their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter.
- 5) IEC provides no marking procedure to indicate its approval and cannot be rendered responsible for any equipment declared to be in conformity with an IEC Publication.
- 6) All users should ensure that they have the latest edition of this publication.
- 7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.
- 8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
- 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.

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

IEC 60601-2-54 has been developed for use with the third edition of IEC 60601-1 (2005). It replaces and supersedes IEC 60601-2-7 and IEC 60601-2-32, as well as IEC 60601-2-28:1993 (currently under revision), all of which were developed to amend earlier editions of IEC 60601-1 and consequently no longer apply to this particular standard.

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

FDIS	Report on voting
62B/735/FDIS	62B/750/RVD

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

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

In this standard, 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 THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this standard, 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 standard are preceded by the term "Clause" followed by the clause number. References to subclauses within this particular standard are by number only.

In this standard, 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 standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

- "shall" means that compliance with a requirement or a test is mandatory for compliance with this standard;
- "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;
- "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 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 publication will remain unchanged until the maintenance result date indicated on the IEC web site 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

This particular standard 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. While the previously existing standards for such equipment were dedicated to components and subsystems, this particular standard 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 particular standard are considered to jre, nis k by IEC 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 the general standard¹⁾ applies, except as follows:

201.1.1 Scope

Replacement:

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of ME EQUIPMENT and ME SYSTEMS intended to be used for projection RADIOGRAPHY and 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 particular standard.

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

NOTE Taking into account economic and social factors, the scope of this particular standard includes ME EQUIPMENT intended to be used for DIRECT RADIOSCOPY. In some countries examinations performed with DIRECT RADIOSCOPY are prohibited.

201.1.2 Object

Replacement:

The object of this particular standard 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 particular standard refers to those applicable collateral standards that are listed in Clause 2 of the general standard and Clause 201.2 of this particular standard.

IEC 60601-1-2 and IEC 60601-1-3 apply as modified in Clauses 202 and 203 respectively. IEC 60601-1-8 and IEC 60601-1-10 do not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

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

NOTE OPERATORS of X-RAY EQUIPMENT are used to audible signals as required in this particular standard 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 the general standard 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 the general standard.

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 particular standard corresponds to that of the general standard with the prefix "201" (e.g. 201.1 in this standard addresses the content of Clause 1 of the general standard) 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 particular standard addresses the content of Clause 4 of the 60601-1-2 collateral standard, 203.4 in this particular standard addresses the content of Clause 4 of the 60601-1-3 collateral standard, etc.). The changes to the text of the general standard are specified by the use of the following words:

"Replacement" means that the clause or subclause of the general standard or applicable collateral standard is replaced completely by the text of this particular standard.

"Addition" means that the text of this particular standard is additional to the requirements of the general standard or applicable collateral standard.

"Amendment" means that the clause or subclause of the general standard or applicable collateral standard is amended as indicated by the text of this particular standard.

Subclauses, figures or tables which are additional to those of the general standard are numbered starting from 201.101. However due to the fact that definitions in the general standard are numbered 3.1 through 3.139, additional definitions in this standard 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 particular standard, the clause or subclause of the general standard or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of the general standard or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this particular standard.

201.2 Normative references

NOTE Informative references are listed in the bibliography on page 64.

Clause 2 of the general standard applies, except as follows:

Addition:

IEC 60336, Medical electrical equipment – X-ray tube assemblies for medical diagnosis – Characteristics of focal spots

IEC 60580:2000, Medical electrical equipment – Dose area product meters

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

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

IEC 62220-1:2003, Medical electrical equipment – Characteristics of digital X-ray imaging devices – Part 1: Determination of the detective quantum efficiency

Amendment:

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

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

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005, applicable collateral standards and IEC 60788:2004 apply, except as follows:

NOTE An index of defined terms is found beginning on page 65.

Addition:

201.3.201

DIRECT RADIOGRAPHY

RADIOGRAPHY in which the permanent recording is effected at an IMAGE RECEPTION AREA

Example: film-screen or film radiography.

201.3.202

DIRECT RADIOSCOPY

RADIOSCOPY in which the visible images are presented at the IMAGE RECEPTION AREA, or close to it, in the RADIATION BEAM

201.3.203

DOSE AREA PRODUCT

product of the area of the cross-section of an X-RAY BEAM and the averaged AIR KERMA over that cross-section. The unit is the gray square metre $(Gy \cdot m^2)$

201.3.204

ENTRANCE FIELD SIZE

dimensions of the field in the entrance plane of an X-RAY IMAGE RECEPTOR that can be used for the transmission of an X-RAY PATTERN under specific conditions