



BSI Standards Publication

Medical electrical equipment

Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy (IEC 60601-2-54:2009)

National foreword

This British Standard is the UK implementation of EN 60601-2-54:2009+A2:2019. It is identical to IEC 60601-2-54:2009, incorporating amendment 1:2015 and amendment 2:2018. It supersedes BS EN 60601-2-54:2009+A1:2015, which will be withdrawn on 24 May 2022.

The start and finish of text introduced or altered by amendment is indicated in the text by tags. Tags indicating changes to IEC text carry the number of the IEC amendment. For example, text altered by IEC amendment A1 is indicated by A1 A1.

The UK participation in its preparation was entrusted to Technical Committee CH/62/2, Diagnostic imaging equipment.

A list of organizations represented on this committee can be obtained on request to its secretary.

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Amendments/corrigenda issued since publication

Date	Text affected
30 April 2010	Supersession details amended
31 July 2015	Implementation of IEC amendment 1:2015 with CENELEC endorsement A1:2015. Annex ZA amended
30 September 2019	Implementation of IEC amendment 2:2018 with CENELEC endorsement A2:2019. Annex ZA amended

**Medical electrical equipment -
Part 2-54: Particular requirements
for the basic safety and essential performance of X-ray equipment
for radiography and radioscopy
(IEC 60601-2-54:2009)**

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
(CEI 60601-2-54:2009)

Medizinische elektrische Geräte -
Teil 2-54: Besondere Festlegungen
für die Sicherheit und die wesentlichen
Leistungsmerkmale
von Röntgeneinrichtungen
für Radiographie und Radioskopie
(IEC 60601-2-54:2009)

This European Standard was approved by CENELEC on 2009-08-01. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CENELEC member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the Central Secretariat has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Bulgaria, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

CENELEC

European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

Central Secretariat: Avenue Marnix 17, B - 1000 Brussels

European Foreword

The text of document 62B/735/FDIS, future edition 1 of IEC 60601-2-54, prepared by SC 62B, Diagnostic imaging equipment, of IEC TC 62, Electrical equipment in medical practice, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as EN 60601-2-54 on 2009-08-01.

EN 60601-2-54 was developed for use with EN 60601-1:2006.

This European Standard supersedes EN 60601-2-7:1998, EN 60601-2-32:1994 and EN 60601-2-28:1993 (partially).

The following dates were fixed:

- latest date by which the EN has to be implemented
at national level by publication of an identical
national standard or by endorsement (dop) 2010-05-01
- latest date by which the national standards conflicting
with the EN have to be withdrawn (dow) 2012-08-01

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and covers essential requirements of EC Directive MDD (93/42/EEC). See Annex ZZ.

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.

Annexes ZA and ZZ have been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 60601-2-54:2009 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following notes have to be added for the standards indicated:

[1] IEC 60627	NOTE Harmonized as EN 60627:2001 (not modified).
[2] IEC 61267	NOTE Harmonized as EN 61267:2006 (not modified).
[3] ISO 4090	NOTE Harmonized as EN ISO 4090:2004 (not modified).
[10] IEC 60601-2-7	NOTE Harmonized as EN 60601-2-7:1998 (not modified).
[11] IEC 60601-2-28	NOTE Harmonized as EN 60601-2-28:1993 (not modified).
[12] IEC 60601-2-32	NOTE Harmonized as EN 60601-2-32:1994 (not modified).
[13] IEC 60601-1-8	NOTE Harmonized as EN 60601-1-8:2007 (not modified).
[14] IEC 60601-1-10	NOTE Harmonized as EN 60601-1-10:2008 (not modified).
[15] IEC 60601-2-43	NOTE Harmonized as EN 60601-2-43:2000 (not modified).

European foreword to amendment A1

The text of document 62B/929/CDV, future IEC 60601-2-54:2009/A1, prepared by SC 62B "Diagnostic imaging equipment" of IEC/TC 62 "Electrical equipment in medical practice" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN 60601-2-54:2009/A1:2015.

The following dates are fixed:

- latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2016-02-22
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2018-05-22

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC [and/or CEN] shall not be held responsible for identifying any or all such patent rights.

This document has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For the relationship with EU Directive 93/42/EEC, see informative Annex ZZ, included in EN 60601-2-54:2009.

Endorsement notice

The text of the International Standard IEC 60601-2-54:2009/A1:2015 was approved by CENELEC as a European Standard without any modification.

In the Bibliography of EN 60601-2-54:2009, **replace** notes [1] and [15] by the following notes:

- | | | | |
|------|----------------|------|------------------------------|
| [1] | IEC 60627 | NOTE | Harmonized as EN 60627. |
| [15] | IEC 60601-2-43 | NOTE | Harmonized as EN 60601-2-43. |

In the Bibliography of EN 60601-2-54:2009, the following notes have to be **added** for the standards indicated:

- | | | | |
|------|----------------|------|------------------------------|
| [16] | IEC 60601-1-11 | NOTE | Harmonized as EN 60601-1-11. |
| [17] | IEC 60601-1-12 | NOTE | Harmonized as EN 60601-1-12. |

European foreword to amendment A2

The text of document 62B/1089/FDIS, future IEC 60601-2-54/A2, prepared by SC 62B "Diagnostic imaging equipment" of IEC/TC 62 "Electrical equipment in medical practice" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN 60601-2-54:2009/A2:2019.

The following dates are fixed:

- latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2019-11-24
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2022-05-24

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC shall not be held responsible for identifying any or all such patent rights.

Endorsement notice

The text of the International Standard IEC 60601-2-54:2009/A2:2018 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following notes have to be added for the standards indicated:

IEC 62220-1-3:2008 NOTE Harmonized as EN 62220-1-3:2008 (not modified)

IEC 62563-1:2009 NOTE Harmonized as EN 62563-1:2010 (not modified)

IEC 60601-1-9 NOTE Harmonized as EN 60601-1-9

Annex ZA (normative)

Normative references to international publications with their corresponding European publications

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE When an international publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

Annex ZA of EN 60601-1:2006 applies, except as follows:

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
Replace the reference to IEC 60601-1-3 by:				
IEC 60601-1-3	2008	Medical electrical equipment -	EN 60601-1-3	2008
-	-	Part 1-3: General requirements for basic	+ corrigendum Mar.	2010
+ A1	2013	safety and essential performance - Collateral	+ A1	2013
-	-	Standard: Radiation protection in diagnostic	+ A1/AC	2014
-	-	X-ray equipment		
Addition:				
IEC 60336	- ¹⁾	Medical electrical equipment - X-ray tube	EN 60336	2005 ²⁾
		assemblies for medical diagnosis -		
		Characteristics of focal spots		
IEC 60580	2000	Medical electrical equipment - Dose area	EN 60580	2000
		product meters		
IEC/TR 60788	2004	Medical electrical equipment - Glossary of	—	—
		defined terms		
IEC 60806	- ¹⁾	Determination of the maximum symmetrical	EN 60806	2004 ²⁾
		radiation field from a rotating anode X-ray tube		
		for medical diagnosis		
IEC 62220-1-1	2015	Medical electrical equipment -	EN 62220-1-1	2015
		Characteristics of digital X-ray imaging		
		devices - Part 1-1: Determination of the		
		detective quantum efficiency - Detectors		
		used in radiographic imaging		
IEC 60601-1	2005	Medical electrical equipment -	EN 60601-1	2006
-	-	Part 1: General requirements for basic	+ corrigendum Mar.	2010
+ A1	2012	safety and essential performance	+ A1	2013
-	-		+ A1/AC	2014
-	-		+ A12	2014
IEC 61910-1	2014	Medical electrical equipment - Radiation	EN 61910-1	2014
		dose documentation - Part 1: Radiation		
		dose structured reports for radiography		
		and radioscopy		
IEC 62494-1	2008	Medical electrical equipment - Exposure	EN 62494-1	2008
		index of digital X-ray imaging systems -		
		Part 1: Definitions and requirements for		
		general radiography		

¹⁾ Undated reference.

²⁾ Valid edition at date of issue.

Annex ZZ (informative)

Coverage of Essential Requirements of EC Directives

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and within its scope the standard covers all relevant essential requirements as given in Annex I of the EC Directive 93/42/EEC.

Compliance with this standard provides one means of conformity with the specified essential requirements of the Directive concerned.

WARNING: Other requirements and other EC Directives may be applicable to the products falling within the scope of this standard.

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CONTENTS

FOREWORD.....	4
INTRODUCTION.....	6
A₁ INTRODUCTION TO AMENDMENT 1.....	6 A₁
A₂ INTRODUCTION TO AMENDMENT 2.....	6 A₂
201.1 Scope, object and related standards	8
201.2 Normative references	9
201.3 Terms and definitions	10
201.4 General requirements	12
201.5 General requirements for testing of ME EQUIPMENT	13
201.6 Classification of ME EQUIPMENT and ME SYSTEMS	13
201.7 ME EQUIPMENT identification, marking and documents	13
201.8 Protection against electrical HAZARDS from ME EQUIPMENT	16
201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS.....	19
201.10 Protection against unwanted and excessive radiation HAZARDS	23
201.11 Protection against excessive temperatures and other HAZARDS	23
201.12 Accuracy of controls and instruments and protection against hazardous outputs	24
201.13 HAZARDOUS SITUATIONS and fault conditions	24
201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS).....	24
201.15 Construction of ME EQUIPMENT	24
201.16 ME SYSTEMS.....	24
201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS	25
202 Electromagnetic compatibility – Requirements and tests	25
203 Radiation protection in diagnostic X-ray equipment.....	25
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 particular standard	74
Figure 203.101 – Zone of EXTRA-FOCAL RADIATION	46
Figure 203.102 – Discrepancies in covering the IMAGE RECEPTION AREA	48
Figure 203.103 – Discrepancies in visual indication of the X-RAY FIELD	52
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).....	61
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 – A₁ Distributed potential ESSENTIAL PERFORMANCE requirements A₁	12
Table 203.101 – Tests for verifying reproducibility and linearity.....	33
Table 203.102 – Loadings for testing AUTOMATIC EXPOSURE CONTROLS	35
Table 203.103 – ATTENUATION for the measurement of AIR KERMA.....	37
Table 203.104 – ATTENUATION EQUIVALENT of items in the X-RAY BEAM	54
Table 203.105 – Application categories	56
Table 203.106 – Requirements for PRIMARY PROTECTIVE SHIELDING	57
Table 203.107 – STRAY RADIATION in SIGNIFICANT ZONES OF OCCUPANCY	59
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.....	65

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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- 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 [A1](#) parts of IEC 60601-2-28:1993 [A1](#), 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.

The contents of the corrigenda of March 2010 and June 2011 have been included in this copy.

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 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. 

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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

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 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 particular standard.

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

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.

 *Text deleted* 

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, 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 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.

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

201.1.4 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 72.

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*

▣_{A1} IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
IEC 60601-1:2005/AMD1:2012 ▣_{A1}

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*

▣_{A2} 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* ▣_{A2}

Amendment:

▣_{A1} *Text deleted* ▣_{A1}

▣_{A1} 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 ▣_{A1}

▣_{A2} 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* ▣_{A2}

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in ▣_{A1} IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012 ▣_{A1}, applicable collateral standards and IEC 60788:2004 apply, except as follows:

NOTE An index of defined terms is found beginning on page 72.

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 ($\text{Gy}\cdot\text{m}^2$)

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

201.3.205

INDIRECT RADIOGRAPHY

RADIOGRAPHY in which the permanent recording is effected after TRANSFER of the information obtained at an IMAGE RECEPTION AREA

Examples: CR systems, digital detector systems, image intensifier systems.

201.3.206

INDIRECT RADIOSCOPY

RADIOSCOPY in which the images are presented at a location outside the RADIATION BEAM after TRANSFER of the information

201.3.207

INTERLOCK

means preventing the start or the continued operation of ME EQUIPMENT unless certain predetermined conditions prevail

201.3.208

NOMINAL SHORTEST IRRADIATION TIME

shortest LOADING TIME for which a required constancy of the controlled RADIATION QUANTITY is maintained

NOTE The IRRADIATION TIME is controlled by a HIGH-VOLTAGE GENERATOR with AUTOMATIC CONTROL SYSTEMS.

201.3.209

SERIAL RADIOGRAPHY

RADIOGRAPHY in which the information is obtained and recorded in a regular or irregular series of LOADINGS with equal or unequal LOADING FACTORS



201.3.210

EXAMINATION PROTOCOL

full set of any programmed technical factors, control functions and settings, including image processing settings, designed to optimize the image acquisition and DISPLAY

201.3.211

EXAMINATION PROTOCOL SELECTION CONTROL

control to select a PRE-PROGRAMMED EXAMINATION PROTOCOL

201.3.212

LAST-IMAGE HOLD RADIOGRAM

LIH RADIOGRAM

single image obtained by sampling or temporal processing of one or more images from the end of a radiosopic IRRADIATION

Note 1 to entry: This note applies to the French language only.

201.3.213

PRE-PROGRAMMED EXAMINATION PROTOCOL

single hardware or software setting, or both, which is associated with an EXAMINATION PROTOCOL

201.3.214

RADIOLOGY REPLAY IMAGE SEQUENCE

series of the most recent images of the most recent RADIOLOGY IRRADIATION-EVENT 

201.4 General requirements

Clause 4 of the general standard applies, except as follows

201.4.3 ESSENTIAL PERFORMANCE

Additional subclause:

201.4.3.101 * Additional potential ESSENTIAL PERFORMANCE requirements

Additional  potential ESSENTIAL PERFORMANCE  requirements are found in the subclauses listed in Table 201.101.

Table 201.101 –  Distributed potential ESSENTIAL PERFORMANCE requirements 

Requirement	Subclause
Accuracy of LOADING FACTORS	203.6.4.3.104
Reproducibility of the RADIATION output	203.6.3.2
AUTOMATIC CONTROL SYSTEM	203.6.5
Imaging performance	203.6.7

201.4.10.2 Supply mains for ME EQUIPMENT and ME SYSTEMS

Addition:

The internal impedance of a SUPPLY MAINS is to be considered sufficiently low for the operation of X-RAY EQUIPMENT for RADIOGRAPHY and RADIOLOGY if the value of the APPARENT RESISTANCE OF SUPPLY MAINS does not exceed the value specified in the ACCOMPANYING DOCUMENTS.

Either the APPARENT RESISTANCE OF SUPPLY MAINS or other appropriate SUPPLY MAINS specifications used in a facility shall be specified in the ACCOMPANYING DOCUMENTS.

NOTE If a NOMINAL voltage is claimed for a mains power supply system, it is assumed that there is no voltage of a higher value between any of the conductors of the system or between any of these conductors and earth.

An alternating voltage is considered in practice to be sinusoidal if any instantaneous value of the waveform concerned differs from the instantaneous value of the ideal waveform at the same moment by no more than $\pm 2\%$ of the peak value of the ideal waveform.

A three-phase SUPPLY MAINS is considered to have a practical symmetry if it delivers symmetrical voltages and produces, when loaded symmetrically, symmetrical currents.

The requirements of this standard are based upon the assumption that three-phase systems have a symmetrical configuration of the MAINS VOLTAGE with respect to earth. Single-phase systems may be derived from such three-phase systems. Where the supply system is not earthed at the source it is assumed that adequate measures have been provided to detect, limit and remedy any disturbance of symmetry within a reasonably short time.

X-RAY EQUIPMENT is considered to comply with the requirements of this standard only if its specified NOMINAL ELECTRIC POWER can be demonstrated at an APPARENT RESISTANCE OF SUPPLY MAINS having a value not less than the APPARENT RESISTANCE OF SUPPLY MAINS specified by the MANUFACTURER in the ACCOMPANYING DOCUMENTS.

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS.

201.5 General requirements for testing of ME EQUIPMENT

Clause 5 of the general standard applies.

201.6 Classification of ME EQUIPMENT and ME SYSTEMS

Clause 6 of the general standard applies.

201.7 ME EQUIPMENT identification, marking and documents

Clause 7 of the general standard applies, except as follows:

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

201.7.2.7 Electrical input power from the SUPPLY MAINS

Addition:

For ME EQUIPMENT that is specified to be PERMANENTLY INSTALLED, the information may be stated in the ACCOMPANYING DOCUMENTS only.

The information on the input power shall be specified in terms of combinations of

- a) the RATED MAINS VOLTAGE of the ME EQUIPMENT in volts; see 7.2.1 and 7.2.6 of the general standard,
- b) the number of phases; see 7.2.1 and 7.2.6 of the general standard,
- c) the frequency, in hertz; see 7.2.1 and 7.2.6 of the general standard,
- d) the maximum permissible value for APPARENT RESISTANCE OF SUPPLY MAINS, in ohms;
- e) the characteristics of OVER-CURRENT RELEASES required in the SUPPLY MAINS.

NOTE These requirements are adapted from 6.1j) of IEC 60601-2-7:1998.

201.7.2.15 Cooling conditions

Addition:

If cooling is necessary for safe operation of ME EQUIPMENT, or a subassembly thereof, the cooling requirements shall be indicated in the ACCOMPANYING DOCUMENT, including as appropriate:

- the maximum heat dissipation into the surrounding air, given separately for each subassembly that dissipates more than 100 W and might be separately located on installation;
- the maximum heat dissipation into forced air cooling devices, and the corresponding flow rate and temperature rise of the forced air stream;
- the maximum heat dissipation into a cooling medium utility and the permissible input temperature range, minimum flow rate and pressure requirements for the utility.

NOTE These requirements are adapted from 6.1t) of IEC 60601-2-7:1998.

Additional subclause:

201.7.2.101 Beam limiting device

BEAM LIMITING DEVICES shall be provided with the following markings:

- those required in subclause 7.2.2 of the general standard;

- serial designation or individual identification;

- A1** – QUALITY EQUIVALENT FILTRATION of all materials together that are permanently fixed and intercept the X-RAY BEAM. **A1**

NOTE These requirements are adapted from 6.1 of IEC 60601-2-28:1993.

201.7.8.1 Colours of indicator lights

Addition:

The indication of X-RAY related states shall be excluded from subclause 7.8 in the general standard. Subclauses 203.6.4.2 and 203.6.4.101 shall apply instead.

201.7.9 ACCOMPANYING DOCUMENTS

201.7.9.1 General

Addition:

- A2** The ACCOMPANYING DOCUMENTS shall contain instructions for MANUFACTURER-recommended QUALITY CONTROL PROCEDURES and tests to be performed on the X-RAY EQUIPMENT by the RESPONSIBLE ORGANIZATION. These shall include acceptance criteria for each test and frequency for each test.

NOTE The intention is to perform these QUALITY CONTROL PROCEDURES and tests using only the supplied information. **A2**

Additionally for X-RAY EQUIPMENT provided with an integrated digital X-RAY IMAGE RECEPTOR, the ACCOMPANYING DOCUMENTS shall contain:

- A2** – an identification of adjustable or selectable image processing applied to ORIGINAL DATA including the version number or how to determine it; **A2**
- a description of the file transfer format of the images acquired with this unit and of any data associated with these images;

The performance of means required to present the images for diagnostic purpose shall be stated according to the INTENDED USE.

- A2** If the test or PROCEDURE requires a device-specific TOOL that is only available from the MANUFACTURER, the MANUFACTURER shall make this TOOL available to the RESPONSIBLE ORGANIZATION. **A2**

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS.

201.7.9.2 Instructions for use

201.7.9.2.1 General

Addition:

201.7.9.2.1.101 LOADING FACTORS

In the instructions for use the LOADING FACTORS shall be stated as described below. The following combinations and data shall be stated:

- a) The corresponding NOMINAL X-RAY TUBE VOLTAGE for RADIOSCOPY and RADIOGRAPHY together with the highest X-RAY TUBE CURRENT obtainable from the ME EQUIPMENT when operated at that X-RAY TUBE VOLTAGE.

- b) The corresponding highest X-RAY TUBE CURRENT for RADIOSCOPY and RADIOGRAPHY together with the highest X-RAY TUBE VOLTAGE obtainable from the ME EQUIPMENT when operating at that X-RAY TUBE CURRENT.
- c) The corresponding combination of X-RAY TUBE VOLTAGE for RADIOSCOPY and RADIOGRAPHY, and X-RAY TUBE CURRENT which results in the highest electric power in the high-voltage circuit (see 203.4.101).
- d) The NOMINAL ELECTRIC POWER given as the highest constant electric power in kilowatts which the ME EQUIPMENT can produce/generate, for a LOADING TIME of 0,1 s at an X-RAY TUBE VOLTAGE of 100 kV or, if these values are not selectable, with nearest parameters (see 203.4.101).

The NOMINAL ELECTRIC POWER shall be given together with the combination of X-RAY TUBE VOLTAGE and X-RAY TUBE CURRENT and the LOADING TIME.

- e) For ME EQUIPMENT indicating precalculated or measured CURRENT TIME PRODUCT, the lowest CURRENT TIME PRODUCT or the combinations of LOADING FACTORS resulting in the lowest CURRENT TIME PRODUCT.

If the value of the lowest CURRENT TIME PRODUCT depends upon the X-RAY TUBE VOLTAGE or upon certain combinations of values of LOADING FACTORS, the lowest CURRENT TIME PRODUCT may be given as a table or curve showing the dependence.

- f) The NOMINAL SHORTEST IRRADIATION TIME used in AUTOMATIC EXPOSURE CONTROL systems of ME EQUIPMENT.

If the NOMINAL SHORTEST IRRADIATION TIME depends upon LOADING FACTORS such as X-RAY TUBE VOLTAGE and X-RAY TUBE CURRENT, the ranges of these LOADING FACTORS for which the NOMINAL SHORTEST IRRADIATION TIME is valid shall be stated.

The maximum possible range of the X-RAY TUBE VOLTAGE and/or the X-RAY TUBE CURRENT during IRRADIATIONS, controlled with the AUTOMATIC EXPOSURE CONTROL SYSTEMS, shall be stated in the instructions for use.

NOTE These requirements are adapted from 6.8.2 a) of IEC 60601-2-7:1998.

201.7.9.2.1.102 X-RAY SOURCE ASSEMBLY

The instructions for use shall state the maximum symmetrical RADIATION FIELD of the integrated X-RAY SOURCE ASSEMBLY determined according to IEC 60806.

NOTE This requirement is adapted from 6.8.2 (dd) of IEC 60601-2-28:1993.

201.7.9.2.1.103 Integrated X-RAY IMAGE RECEPTOR

For X-RAY EQUIPMENT provided with an integrated X-RAY IMAGE RECEPTOR, the instructions for use shall contain a description of the particular handling and maintenance of the X-RAY IMAGE RECEPTOR.

Compliance is checked by inspection of the instructions for use.

201.7.9.2.17 ME EQUIPMENT emitting radiation

Replacement:

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

201.7.9.3 Technical description

Additional subclause:

201.7.9.3.101 X-RAY SOURCE ASSEMBLY

The technical description of the integrated X-RAY SOURCE ASSEMBLIES shall specify the following, in addition to the data required to be marked according to subclause 7.2 of the general standard:

- a) specification of the REFERENCE AXIS to which the TARGET ANGLE(s) and the FOCAL SPOT characteristics of the X-RAY SOURCE ASSEMBLY refer;
- b) TARGET ANGLE(s) with respect to the specified REFERENCE AXIS;
- c) position of the FOCAL SPOT and its tolerances on the REFERENCE AXIS;
- d) NOMINAL FOCAL SPOT VALUE(s) determined according to IEC 60336 for the specified REFERENCE AXIS.

NOTE These requirements are adapted from 6.8.3 dd) of IEC 60601-2-28:1993.

Additional subclause:

201.7.9.101 Additional statements in ACCOMPANYING DOCUMENTS

Additional requirements for statements in ACCOMPANYING DOCUMENTS (which include instructions for use and technical description) are found in the subclauses listed in Table 201.C.102 of Annex C.

201.8 Protection against electrical HAZARDS from ME EQUIPMENT

Clause 8 of the general standard applies, except as follows:

201.8.4 Limitation of voltage, current or energy

201.8.4.3 ME EQUIPMENT intended to be connected to a power source by a plug

Addition:

201.8.4.3.101 HIGH-VOLTAGE CABLE CONNECTIONS

Detachable HIGH-VOLTAGE CABLE CONNECTIONS shall either be designed so that the use of TOOLS is required to disconnect them or they shall be provided with INTERLOCKS so that at all times when protective covers or HIGH-VOLTAGE CONNECTIONS are removed:

- the ME EQUIPMENT is disconnected from its power supply, and
- capacitances in the high-voltage circuit are discharged within the minimum time necessary to gain access to the high-voltage circuit, and
- the discharged state is maintained.

Compliance is checked by inspection and by measurement.

NOTE These requirements are adapted from Clause 15, item aa) of IEC 60601-2-7:1998.

Additional subclause:

201.8.4.101 Limitation of X-RAY TUBE VOLTAGE

ME EQUIPMENT shall be designed so as not to deliver in INTENDED USE, to any connected X-RAY TUBE ASSEMBLY, a voltage greater than the NOMINAL X-RAY TUBE VOLTAGE for the X-RAY TUBE concerned or greater than the NOMINAL X-RAY TUBE VOLTAGE the X-RAY TUBE ASSEMBLY is designed for, whichever is the lower voltage.

NOTE This requirement is adapted from 3.1 of IEC 60601-2-7:1998.

201.8.5 Separation of parts

201.8.5.1 MEANS OF PROTECTION (MOP)

Additional subclause:

201.8.5.1.101 Additional limitation of voltage, current or energy

Provision shall be made to prevent the appearance of an unacceptably high voltage in the MAINS PART or in any other low-voltage circuit.

NOTE This may be achieved for example

- by provision of a winding layer or a conductive screen connected to the PROTECTIVE EARTH TERMINAL between high-voltage and low-voltage circuits;
- by provision of a voltage limiting device across terminals to which external devices are connected and between which an excessive voltage might arise if the external path becomes discontinuous.

Compliance is checked by inspection of design data and construction.

NOTE These requirements are adapted from 15bb) of IEC 60601-2-7:1998.

201.8.5.4 WORKING VOLTAGE

Addition:

201.8.5.4.101 Stator and stator circuit dielectric strength testing

The test voltage for the dielectric strength testing of stator and stator circuit used for the operation of the rotating anode of the X-RAY TUBE is to be referred to the voltage existing after reduction of the stator supply voltage to its steady state operating value.

NOTE This requirement is adapted from 20.4 I) of IEC 60601-2-7:1998.

201.8.6 Protective earthing, functional earthing and potential equalization of ME EQUIPMENT

201.8.6.4 Impedance and current-carrying capability

Addition:

The flexible conductive screen is not to be recognized as satisfying a requirement for a PROTECTIVE EARTH CONNECTION between the devices connected by the cable.

Additional subclause:

201.8.6.101 X-RAY TUBE ASSEMBLY

- a) Accessible high-voltage cables connecting X-RAY TUBE ASSEMBLIES to their associated HIGH-VOLTAGE GENERATOR shall incorporate a flexible conductive screen, having a resistance per unit length not exceeding $1 \Omega \text{ m}^{-1}$, and covered with a non-conductive material capable of protecting the screen against mechanical damage. The screen shall be connected to the conductive ENCLOSURE of the HIGH-VOLTAGE GENERATOR.

Compliance is checked by visual inspection and by measurement.

NOTE These requirements are adopted from Clause 16, item aa) of IEC 60601-2-28:1993.

- b) In all cases, there shall be electrical continuity between the screen of a fitted high-voltage cable and the ACCESSIBLE METAL PARTS of its receptacle on the X-RAY TUBE ASSEMBLY.

Compliance is checked by visual inspection and by measurement.

NOTE These requirements are adopted from Clause 16, item cc) of IEC 60601-2-28:1993.

201.8.7 LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS

201.8.7.3 *Allowable values

Item c) is amended as follows:

For MOBILE X-RAY EQUIPMENT and TRANSPORTABLE X-RAY EQUIPMENT, the TOUCH CURRENT under SINGLE FAULT CONDITION shall not exceed 2 mA.

Item d) is replaced by:

For MOBILE X-RAY EQUIPMENT and TRANSPORTABLE X-RAY EQUIPMENT, the allowable values of the EARTH LEAKAGE CURRENT are 2,5 mA in NORMAL CONDITION and 5 mA in SINGLE FAULT CONDITIONS. For PERMANENTLY INSTALLED ME EQUIPMENT, the allowable value of EARTH LEAKAGE CURRENT is 10 mA in NORMAL CONDITION and in SINGLE FAULT CONDITIONS.

Item e) is amended as follows:

For PERMANENTLY INSTALLED ME EQUIPMENT including HIGH-VOLTAGE GENERATORS, the allowable value of EARTH LEAKAGE CURRENT is 20 mA in NORMAL CONDITION and SINGLE FAULT CONDITION.

NOTE These requirements are adapted from 19.3 of IEC 60601-2-7:1998.

201.8.8.3 Dielectric strength

Amendment to the compliance test for high-voltage circuit:

The high-voltage circuit of the ME EQUIPMENT is tested by applying no more than half the test voltage, and then the test voltage is gradually raised over a period of 10 s to the full value, which is maintained for 3 min in RADIOGRAPHY and 15 min in RADIOSCOPY.

Addition to the test conditions for high-voltage circuit:

The test for the high-voltage circuit shall be made without an X-RAY TUBE ASSEMBLY connected and with a test voltage of 1,2 times the NOMINAL X-RAY TUBE VOLTAGE of the ME EQUIPMENT.

If the ME EQUIPMENT can be tested only with the X-RAY TUBE ASSEMBLY connected and if the X-RAY TUBE does not allow the ME EQUIPMENT to be tested with a test voltage of 1,2 times the NOMINAL X-RAY TUBE VOLTAGE, the test voltage may be lower but not less than 1,1 times that voltage.

For ME EQUIPMENT in which the NOMINAL X-RAY TUBE VOLTAGE for RADIOSCOPY does not exceed 80 % of that for RADIOGRAPHY, the test voltage for the high-voltage circuit shall be referred to the value for RADIOGRAPHY, and the test shall be carried out in that mode only.

If during the dielectric strength test there is a RISK of overheating a transformer under test, it is permitted to carry out the test at a higher supply frequency.

During the dielectric strength test, the test voltage in the high-voltage circuit should be kept as close as possible to 100 %, and is not to be outside the range of 100 % and 105 % of the value required.