

Index des termes définis utilisés dans la présente norme particulière

Terme dérivé IEC 60601-1:2005, 3.3
Terme abrégé IEC 60601-1:2005, 3.3

ACCESSOIRE IEC 60601-1:2005, 3.3

AFFICHAGE IEC TR 60788:2004, rm-84-01

APPAREIL ELECTROMEDICAL (APPAREIL EM) IEC 60601-1:2005, 3.63

APPAREIL A RAYONNEMENT X D'INTERVENTION 201.3.202

APPLICATION D'UNE CHARGE IEC 60601-1-3:2008, 3.34

AXE DU FAISCEAU DE RAYONNEMENT X IEC TR 60788:2004, rm-37-06+

BARRIÈRE IEC 60601-1:2005 et IEC 60601-1:2005/AMD1:2012, 3.36

CLAIREMENT LISIBLE IEC 60601-1:2005 et IEC 60601-1:2005/AMD1:2012, 3.15

CARTE DE DOSE SUR LA PEAU 201.3.207

CARTE DE DOSE 201.3.205

CHAMP DE RAYONNEMENT X IEC 60601-1-3:2008, 3.58

CHAMP DE RAYONNEMENT IEC 60601-1-3:2008, 3.58

CHARGE DE FONCTIONNEMENT EN SECURITE IEC 60601-1:2005, 3.109

COMMANDE D'IRRADIATION IEC 60601-1-3:2008, 3.31

CONDITION DE PREMIER DEFECT IEC 60601-1:2005 et IEC 60601-1:2005/AMD1:2012, 3.116

DANGER IEC 60601-1:2005 et IEC 60601-1:2005/AMD1:2012, 3.39

DANGER MÉCANIQUE IEC 60601-1:2005 et IEC 60601-1:2005/AMD1:2012, 3.39

DEBIT DE KERMA DANS L'AIR DE REFERENCE IEC 60601-1-3:2008, 3.71

DEBIT DE KERMA DANS L'AIR IEC 60601-1-3:2008, 3.5

DELAI D'AFFICHAGE DE L'IMAGE 201.3.201

DIMENSIONS DU CHAMP D'ENTREE IEC 60601-2-54:2009, 201.3.204

DISPOSITIF DE PROTECTION RADIOLOGIQUE IEC 60601-1-3:2008, 3.50

DISTANCE FOYER-PEAU IEC 60601-1-3:2008, 3.26

DISTANCE FOYER-RECEPTEUR D'IMAGES IEC 60601-1-3:2008, 3.25

DOCUMENT D'ACCOMPAGNEMENT IEC 60601-1:2005, 3.4

DOMMAGE IEC 60601-1:2005 et IEC 60601-1:2005/AMD1:2012, 3.38

~~DONNEES ORIGINALES IEC 62220-1-1:2015, 3.13~~

DOSE ABSORBEE IEC TR 60788:2004, rm-13-08

DOSE SUR LA PEAU 201.3.206

DOSIMETRE IEC TR 60788:2004, rm-50-02

DOSSIER DE GESTION DES RISQUES IEC 60601-1:2005 et IEC 60601-1:2005/AMD1:2012, 3.108

ENSEMBLE RADIOGENE IEC 60601-1-3:2008, 3.62

ENVELOPPE IEC 60601-1:2005, 3.26

EQUIPEMENT A RAYONNEMENT X IEC 60601-1-3:2008, 3.78

ETAT EN CHARGE IEC 60601-1-3:2008, 3.36

FABRICANT	IEC 60601-1:2005 et IEC 60601-1:2005/AMD1:2012, 3.55
FAISCEAU DE RAYONNEMENT X	IEC 60601-1-3:2008, 3.55+
FANTOME	IEC 60601-1-3:2008, 3.46
FENETRE	IEC 60601-1-3:2008, 3.54
FILTRE ADDITIONNEL	IEC 60601-1-3:2008, 3.2
FILTRE EN COIN	IEC TR 60788:2004, rm-35-10
FIXE	IEC 60601-1:2005 et IEC 60601-1:2005/AMD1:2012, 3.30
FOYER	IEC TR 60788:2004, rm-20-13s
GAINE EQUIPEE	IEC 60601-1-3:2008, 3.84
GESTION DES RISQUES	IEC 60601-1:2005 et IEC 60601-1:2005/AMD1:2012, 3.107
GRAVITE	IEC 60601-1:2005 et IEC 60601-1:2005/AMD1:2012, 3.114
GRILLE ANTIDIFFUSANTE	IEC TR 60788:2004, rm-32-06
HAUTE TENSION NOMINALE	IEC 60601-1-3:2008, 3.42
HAUTE TENSION RADIOGENE	IEC 60601-1-3:2008, 3.88
INSTALLE DE FAÇON PERMANENTE	IEC 60601-1:2005, 3.84
INTERVENTION GUIDEE PAR RADIOSCOPIE	201.3.203
IRRADIATION	IEC 60601-1-3:2008, 3.30
ISOCENTRE	IEC TR 60788:2004, rm-37-32
KERMA DANS L'AIR DE REFERENCE	IEC 60601-1-3:2008, 3.70
KERMA DANS L'AIR	IEC 60601-1-3:2008, 3.4
(DEBIT DE) KERMA DANS L'AIR	IEC 60601-1-3:2008, 3.5 +
LIMITEUR DE FAISCEAU	IEC 60601-1-3:2008, 3.11
MAÎTRISE DU RISQUE	IEC 60601-1:2005 et IEC 60601-1:2005/AMD1:2012, 3.105
MOBILE	IEC 60601-1:2005 et IEC 60601-1:2005/AMD1:2012, 3.65
MODE DE FONCTIONNEMENT	IEC 60601-1-3:2008, 3.40
OPERATEUR	IEC 60601-1:2005, 3.73
ORGANISME RESPONSABLE	IEC 60601-1:2005, 3.101
OUTIL	IEC 60601-1:2005, 3.127
PARAMETRE DE CHARGE	IEC 60601-1-3:2008, 3.35
PARTIE APPLIQUEE	IEC 60601-1:2005, 3.8
PATIENT	IEC 60601-1:2005 et IEC 60601-1:2005/AMD1:2012, 3.76
PERFORMANCE ESSENTIELLE	IEC 60601-1:2005 et IEC 60601-1:2005/AMD1:2012, 3.27
PLAN DU RECEPTEUR D'IMAGE	IEC TR 60788:2004, rm-37-15

POINT DE REFERENCE D'ENTREE PATIENT	IEC 60601-1-3:2008, 3.43
PORTIQUE	IEC TR 60788:2004, rm-30-04
PROCEDURE	IEC 60601-1:2005 et IEC 60601-1:2005/AMD1:2012, 3.88
PROCESSUS.....	IEC 60601-1:2005 et IEC 60601-1:2005/AMD1:2012, 3.89
PRODUIT EXPOSITION-SURFACE	IEC 60601-2-54:2009, 201.3.203
(DEBIT DE) PRODUIT EXPOSITION-SURFACE	IEC 60601-2-54:2009, 201.3.203+
PROTECTION RADIOLOGIQUE.....	IEC TR 60788:2004, rm-60-03
PROTOCOLE D'EXAMEN	IEC 60601-2-54:2009/AMD2:2018, 201.3.210
QUALITE DE RAYONNEMENT	IEC 60601-1-3:2008, 3.60
RADIOMETRE DE PRODUIT EXPOSITION-SURFACE.....	IEC 60580 3.8
RADIOGRAMME A DERNIERE IMAGE MEMORISEE	
(RADIOGRAMME LIH)	IEC 60601-2-54:2009/AMD2:2018, 201.3.212
RADIOGRAPHIE DIRECTE	IEC 60601-2-54:2009, 201.3.201
RADIOGRAPHIE INDIRECTE	IEC 60601-2-54:2009, 201.3.205
RADIOGRAPHIE.....	IEC 60601-1-3:2008, 3.64
RADIOLOGIE.....	IEC TR 60788:2004, rm-40-01
RADIOPROTECTION	IEC 60601-1-3:2008, 3.59
RADIOSCOPIE DIRECTE	IEC 60601-2-54:2009, 201.3.202
RADIOSCOPIE.....	IEC 60601-1-3:2008, 3.69
RADIOSCOPIE D'URGENCE	201.3.204
RADIOTHERAPIE	IEC TR 60788:2004, rm-40-05
RAPPORT STRUCTURÉ DE DOSE DE RAYONNEMENT (RDSR).....	IEC 61910-1:2014, 3.3
RAYONNEMENT DIFFUSE.....	IEC 60601-1-3:2008, 3.73
RAYONNEMENT PARASITE	IEC 60601-1-3:2008, 3.75
RAYONNEMENT X.....	IEC 60601-1-3:2008, 3.53
RAYONNEMENT	IEC 60601-1-3:2008, 3.53
RECEPTEUR D'IMAGE RADIOLOGIQUE	IEC 60601-1-3:2008, 3.81
REFERENCE DU MODELE OU DU TYPE.....	IEC 60601-1:2005, 3.66
RESEAU D'ALIMENTATION	IEC 60601-1:2005, 3.120
RISQUE	IEC 60601-1:2005 et IEC 60601-1:2005/AMD1:2012, 3.102
SECURITE DE BASE	IEC 60601-1:2005, 3.10
SEQUENCE DE REPETITION DE LECTURE D'IMAGES	
DE RADIOSCOPIE	IEC 60601-2-54:2009/AMD2:2018, 201.3.214
SERIOGRAPHIE.....	IEC 60601-2-54:2009, 201.3.209
SITUATION DANGEREUSE.....	IEC 60601-1:2005 et IEC 60601-1:2005/AMD1:2012, 3.40
SUPPORT PATIENT	IEC TR 60788:2004, rm-30-02
SURFACE D'ENTREE.....	IEC 60601-1-3:2008, 3.21
SURFACE DU PATIENT	IEC TR 60788:2004, rm-37-18
SURFACE RECEPTRICE DE L'IMAGE EFFICACE.....	IEC 60601-1-3:2008, 3.20
SURFACE RECEPTRICE DE L'IMAGE	IEC 60601-1-3:2008, 3.28
SYSTEME ELECTROMEDICAL (SYSTEME EM)	IEC 60601-1:2005, 3.64

SYSTEME DE COMMANDE AUTOMATIQUE	IEC 60601-1-3:2008, 3.9
TEMPS D'IRRADIATION	IEC 60601-1-3:2008, 3.32
TEMPS DE CHARGE	IEC 60601-1-3:2008, 3.37
TOMODENSITOMETRIE	IEC TR 60788:2004, rm-41-20
TRANSMISSION DE FIN DE PROCÉDURE DU RDSR	IEC 61910-1:2014, 3.5
UTILISATION NORMALE	IEC 60601-1:2005 et IEC 60601-1:2005/AMD1:2012, 3.71
UTILISATION PREVUE	IEC 60601-1:2005 et IEC 60601-1:2005/AMD1:2012, 3.44
VALEUR MESUREE	IEC 60601-1-3:2008, 3.38
VERROUILLAGE	IEC 60601-2-54:2009, 201.3.207
VETEMENT DE PROTECTION RADIOLOGIQUE	IEC 60601-1-3:2008, 3.50
ZONE DE PIÉGEAGE	IEC 60601-1:2005, 3.131
ZONE PROTEGEE	IEC 60601-1-3:2008, 3.48
ZONE SIGNIFICATIVE D'OCCUPATION	IEC 60601-1-3:2008, 3.74

FINAL VERSION

VERSION FINALE



Medical electrical equipment –

Part 2-43: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures

Appareils électromédicaux –

Partie 2-43: Exigences particulières pour la sécurité de base et les performances essentielles des appareils à rayonnement X lors d'interventions

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CONTENTS

FOREWORD	4
INTRODUCTION	7
INTRODUCTION to Amendment 1	7
INTRODUCTION to Amendment 2	7
201.1 Scope, object and related standards	9
201.2 Normative references	11
201.3 Terms and definitions	12
201.4 General requirements	13
201.5 General requirements for testing of 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	19
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	23
201.13 HAZARDOUS SITUATIONS and fault conditions	26
201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)	26
201.15 Construction of ME EQUIPMENT	26
201.16 ME SYSTEMS	27
201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS	27
202 Electromagnetic disturbances – Requirements and tests	27
203 Radiation protection in diagnostic X-ray equipment	28
Annexes	40
Annex AA (informative) Particular guidance and rationale	41
Annex BB (normative) Distribution maps of STRAY RADIATION	52
Annex CC (informative) Mapping between this Edition 2 of IEC 60601-2-43 and Edition 1	55
Bibliography	57
Index of defined terms used in this particular standard	60
Figure BB.1 – Example of isokerma map at 100 cm height in lateral configuration	53
Figure BB.2 – Example of isokerma map at 100 cm height in vertical configuration	54
Table 201.101 – Additional list of potential ESSENTIAL PERFORMANCE to be considered by MANUFACTURER in the RISK MANAGEMENT analysis	13
Table 201.102 – Other subclauses requiring statements in ACCOMPANYING DOCUMENTS	19
Table 2 – Subclauses requiring statements in ACCOMPANYING DOCUMENTS	28
Table AA.1 – Examples of prolonged RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES for which deterministic effects of IRRADIATION are possible	41
Table AA.2 – Examples of RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES for which deterministic effects are unlikely	42

Table AA.3 – Examples of isodose boundaries and colour codes for SKIN DOSE MAP and air kerma map.....	50
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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –**Part 2-43: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures**

FOREWORD

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This Consolidated version of IEC 60601-2-43 bears the edition number 2.2. It consists of the second edition (2010-03) [documents 62B/779/FDIS and 62B/792/RVD], its amendment 1 (2017-05) [documents 62B/1012/CDV and 62B/1037/RVC] and its amendment 2 (2019-10) [documents 62B/1137/FDIS and 62B/1146/RVD]. The technical content is identical to the base edition and its amendments.

This Final version does not show where the technical content is modified by amendments 1 and 2. A separate Redline version with all changes highlighted is available in this publication.

International standard IEC 60601-2-43 has been prepared by IEC subcommittee 62B: Diagnostic imaging equipment, of IEC technical committee 62: Electrical equipment in medical practice.

This second edition constitutes a technical revision.

This particular standard has been revised to provide a complete set of safety requirements for X-RAY EQUIPMENT for RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES, based on the third edition of IEC 60601-1 and relevant collaterals. The present edition is extended to become a system standard for X-RAY EQUIPMENT designed for the use during interventional procedures using X-ray imaging, whether of prolonged or normal duration.

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.

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

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