INTERNATIONAL STANDARD

IEC 60601-2-43

First edition
2000-06

Medical electrical equipment –

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

Appareils électromédicaux –

Partie 2-43:
Règles particulières de sécurité pour les appareils radiologiques lors d'interventions

Reference number
IEC 60601-2-43:2000(E)

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL ELECTRICAL EQUIPMENT –

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

FOREWORD

1) The IEC (International Electrotechnical Commission) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of the 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, the IEC publishes International Standards. 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. The 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 the 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 National Committees.
3) The documents produced have the form of recommendations for international use and are published in the form of standards, technical specifications, technical reports or guides and they are accepted by the National Committees in that sense.
4) In order to promote international unification, IEC National Committees undertake to apply IEC International Standards transparently to the maximum extent possible in their national and regional standards. Any divergence between the IEC Standard and the corresponding national or regional standard shall be clearly indicated in the latter.
5) The IEC provides no marking procedure to indicate its approval and cannot be rendered responsible for any equipment declared to be in conformity with one of its standards.
6) Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. The IEC shall not be held responsible for identifying any or all such patent rights.

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

The text of this Particular Standard is based on the following documents:

FDIS	Report of voting
62B/401/FDIS	62B/408/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.

Annexes AA, EE and FF form an integral part of this standard.

Annexes BB, CC and DD are for information only.

In this Particular Standard, the following print types are used:

– requirements, compliance with which can be tested and definitions: roman type;
– notes, explanations, advice, introductions, general statements, exceptions and references: smaller type;
– *test specifications: italic type;*
– TERMS USED THROUGHOUT THIS PARTICULAR STANDARD WHICH HAVE BEEN DEFINED IN CLAUSE 2 OF THE GENERAL STANDARD, IN IEC 60788 OR IN THIS STANDARD: SMALL CAPITALS.

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This publication has been drafted in accordance with the ISO/IEC Directives, Part 3.

The committee has decided that the contents of this publication will remain unchanged until 2005. At this date, the publication will be

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

A bilingual version of this standard may be issued at a later date.

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INTRODUCTION

In recent years, there have been major developments in the use of X-RAY EQUIPMENT for RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES. These procedures may involve prolonged IRRADIATIONS and may subject PATIENTS and OPERATORS to higher levels of risk than those which normally prevail.

A consequence is the occurrence of deterministic injury when procedures involve the delivery of substantial amounts of RADIATION to localized areas on the PATIENT. Another consequence is the large contribution to the stochastic risk for the RADIATION induced cancers etc. collectively to the PATIENT.

This Particular Standard deals with these additional risks and thereby complements the General Standard with special provisions for this particular domain. Interventional procedures of the type envisaged are well established in clinical fields such as:

– invasive cardiology;

– interventional RADIOLOGY;

– interventional neuroradiology.

These procedures also include many newly developing and emerging applications in a wide range of medical and surgical specialities.

NOTE Attention is drawn to the existence of legislation in some countries concerning RADIOLOGICAL PROTECTION, which may not align with the provisions of this standard.

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MEDICAL ELECTRICAL EQUIPMENT –

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

SECTION 1: GENERAL

The clauses and subclauses of this section of the General Standard apply, except as follows:

1 Scope and object

This clause of the General Standard applies, except as follows:

1.1 Scope

Addition:

This Particular Standard applies to X-RAY EQUIPMENT declared by the MANUFACTURER to be suitable for prolonged RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES. Its scope excludes, in particular:

– equipment for RADIOTHERAPY;
– equipment for COMPUTED TOMOGRAPHY;
– ACCESSORIES intended to be introduced into the PATIENT;
– mammographic X-RAY EQUIPMENT.

NOTE 1 Examples of prolonged RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES, for which the use of EQUIPMENT complying with this standard is recommended, are given in annex BB.

NOTE 2 The particular requirements of this standard are not essential for EQUIPMENT used in all RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES. Examples of procedures, for which the use of EQUIPMENT complying with this standard is considered not to be essential, are given in annex BB.

EQUIPMENT declared by the MANUFACTURER to be suitable for RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES, which does not include a PATIENT SUPPORT as part of the system, is exempt from the PATIENT SUPPORT provisions of this standard.

1.2 Object

Replacement:

The object of this standard is:

– to establish safety requirements for the design and manufacture of X-RAY EQUIPMENT for prolonged RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES;
– to specify information which is to be provided with such EQUIPMENT for the assistance of the USER and OPERATOR in managing the RADIATION risk arising from these procedures which could affect PATIENTS and staff.

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1.3 Particular standards

Addition:

This Particular Standard, hereinafter referred to as "this standard", amends and supplements a set of IEC publications, hereinafter referred to as the "General Standard", consisting of IEC 60601-1: 1988, *Medical electrical equipment – Part 1: General requirements for safety,* its amendments 1 (1991) and 2 (1995), and all Collateral Standards.

The numbering of sections, clauses and subclauses of this standard corresponds to that of the General Standard. 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 is replaced completely by the text of this standard.

"Addition" means that the text of this standard is additional to the requirements of the General Standard.

"Amendment" means that the clause or subclause of the General Standard is amended as indicated by the text of this standard.

Subclauses or figures which are additional to those of the General Standard are numbered starting from 101, additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Where there is no corresponding section, clause or subclause in this standard, the section, clause or subclause of the General Standard applies without modification.

Where it is intended that any part of the General Standard, although possibly relevant, is not to be applied, a statement to that effect is given in this standard.

A requirement of this standard replacing or modifying requirements of the General Standard takes precedence over the original requirements concerned.

2 Terminology and definitions

This clause of the General Standard applies, except as follows:

Addition before 2.1:

An index of defined terms used in this standard is given in annex AA.

In this standard, terms printed in small capitals are used in accordance with their definitions in the General Standard, in this standard, in IEC 60788 or in other IEC standards referenced in annex AA.

NOTE Attention is drawn to the fact that where some terms, although listed in annex AA, are not printed in small capitals, the concept addressed is not strictly confined to the formal definition.

In this standard, unless otherwise indicated:

– the values of X-RAY TUBE VOLTAGE refer to peak values, transients being disregarded;

– the values of X-RAY TUBE CURRENT refer to average values;

– qualifying conditions for certain defined terms, as listed in 2.202.1 to 2.202.5 of IEC 60601-1-3, apply.

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Additional definitions:

2.101
RADIOSCOPICALLY GUIDED INVASIVE PROCEDURE
invasive procedure (involving the introduction of a device, such as a needle or a catheter into the body of the PATIENT) using RADIOSCOPIC imaging as the principal means of guidance

2.102
RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURE
RADIOSCOPICALLY GUIDED INVASIVE PROCEDURE indented to effect treatment on the medical condition of the PATIENT

2.103
INTERVENTIONAL X-RAY EQUIPMENT
X-RAY EQUIPMENT for RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES

2.104
INTERVENTIONAL REFERENCE POINT
for INTERVENTIONAL X-RAY EQUIPMENT, specified point on the REFERENCE AXIS used as a reference location for the indication of PATIENT-incident AIR KERMA and AIR KERMA RATE

2.105
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 ($Gy \cdot m^2$).

– DOSE AREA PRODUCT RATE, with the unit $Gy \cdot m^2 \cdot s^{-1}$;

– DOSE AREA PRODUCT (RATE), used for brevity where either DOSE AREA PRODUCT or DOSE AREA PRODUCT RATE apply, according to the context.

NOTE The SI unit $Gy \cdot m^2$ may be expressed with a prefix e.g. as $\mu Gy \cdot m^2$ to retain earlier used numeric dimensions of values displayed to the OPERATOR.

2.106
REFERENCE AIR KERMA
AIR KERMA of the primary X-RAY BEAM measured under specific conditions and expressed as an equivalent value at the INTERVENTIONAL REFERENCE POINT

– REFERENCE AIR KERMA RATE, AIR KERMA RATE expressed as above

– REFERENCE AIR KERMA (RATE), used for brevity where either REFERENCE AIR KERMA or REFERENCE AIR KERMA RATE apply, according to the context.

2.107
MODE OF OPERATION
for INTERVENTIONAL X-RAY EQUIPMENT, the technical state defined by a configuration of several predetermined LOADING FACTORS, technique factors or other settings for RADIOSCOPY or RADIOGRAPHY, selectable simultaneously by the operation of a single control

NOTE 1 Selection of a particular mode does not necessarily define the values of all the parameters affecting its use.

NOTE 2 Values defined by selection of a particular mode are not necessarily invariable during its use.

6 Identification, marking and documents

This clause of the General Standard applies, except as follows:

6.1 Marking on the outside of EQUIPMENT or EQUIPMENT parts

Additional items:

aa) *PATIENT SUPPORT load*

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The PATIENT SUPPORT shall be marked with the maximum permissible mass (“load”) in kilograms for NORMAL USE, other than use for cardiopulmonary resuscitation.

bb) *Cardiopulmonary resuscitation (CPR)*

The PATIENT SUPPORT shall be marked with abbreviated instructions on configuring the EQUIPMENT for CPR.

cc) *Marking of compliance*

If, for INTERVENTIONAL X-RAY EQUIPMENT, compliance with this standard is to be marked on the outside of the EQUIPMENT, the marking shall be made in combination with the MODEL OR TYPE REFERENCE as follows:

INTERVENTIONAL X-RAY EQUIPMENT [model or type reference] IEC 60601-2-43:2000.

6.8.2 INSTRUCTIONS FOR USE

a) General information

Addition:

Add the following sentence to the first dash (as created in amendment 2 of the General Standard):

The statement shall mention that the EQUIPMENT is intended for procedures in which skin dose levels can be high enough in NORMAL USE to constitute a risk of deterministic effects.

d) Cleaning, disinfection and sterilization of parts in contact with the PATIENT

Amendment:

Replace "or, where necessary, identify suitable sterilization agents," with "shall identify suitable agents for these purposes,".

Addition:

For INTERVENTIONAL X-RAY EQUIPMENT the scope of this information shall include details concerning the cleaning and disinfection of all parts that, although not necessarily in direct contact with the PATIENT, can become soiled or contaminated, especially with body fluids, in NORMAL USE.

NOTE 1 It is advisable for MANUFACTURERS to ensure that the information given is sufficient to exclude commonly used but possibly corrosive substances, such as sodium hypochlorite, if the use of such substances would present a risk of damage to the parts of the EQUIPMENT concerned.

NOTE 2 General information concerning the importance of cleaning and disinfection of INTERVENTIONAL X-RAY EQUIPMENT is given in annex DD.

Additional items:

aa) *Skin dose levels*

The instructions shall draw attention to the need to manage the risk of skin dose levels being high enough in NORMAL USE to cause deterministic effects and to the availability of several selectable settings in both RADIOSCOPY and RADIOGRAPHY having a considerable effect on the RADIATION QUALITY, the delivered AIR KERMA or AIR KERMA RATE and the image quality.

bb) *Available settings*

Information shall be provided as delivered from the MANUFACTURER concerning available configurations, MODES OF OPERATION, settings of LOADING FACTORS, technique factors and

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operating parameters that affect the RADIATION QUALITY or the prevailing value of REFERENCE AIR KERMA (RATE) in NORMAL USE. This information shall include:

1) the values applying to the MODES OF OPERATION in RADIOSCOPY designated normal and low in accordance with 51.101.4;
2) details of all other MODES OF OPERATION, giving the default values and the available ranges of any factors that can be varied after the mode has been selected;
3) the values in RADIOSCOPY delivering the highest available REFERENCE AIR KERMA RATE;
4) the values in RADIOGRAPHY delivering the highest available REFERENCE AIR KERMA per frame;
5) one set of values typical of RADIOGRAPHY for distinctive types of procedure for which the EQUIPMENT is intended to be used.

NOTE This would, for example, include a typical vascular setting and a typical cardiac setting for EQUIPMENT intended to be used for both applications.

Compliance is determined by inspection, functional tests and measurements of REFERENCE AIR KERMA (RATE) as appropriate (see item cc) below).

cc) *RADIATION data*

For the MODES OF OPERATION and sets of values described in accordance with item bb) above, values of REFERENCE AIR KERMA (RATE) shall be given, based on measurement by the method described in annex EE.

In addition, for each of the available MODES OF OPERATION described in items bb) 1) and bb 2), information shall be given, based on the use of the 20 cm PHANTOM, concerning the effect on the REFERENCE AIR KERMA(rate) of changing the following factors, if these factors are variable by the OPERATOR in the MODE OF OPERATION concerned:

– selectable ADDED FILTERS;
– ENTRANCE FIELD SIZE;
– pulse repetition frequency.

Particulars shall be given of the configurations of the EQUIPMENT and the test geometries that can be used in the procedure described in annex EE to verify the values given.

Although it is required to provide details to enable verification by measurement in accordance with annex EE, the stated values may be determined originally by other methods, including calculation, leading to values that are in compliance, subject to the permitted tolerances, when verified by the method given in annex EE.

Compliance is determined by inspection, functional tests and examination of the INSTRUCTIONS FOR USE. The stated values of REFERENCE AIR KERMA (RATE) and statements concerning the variation of these values are verified by the method described in annex EE, using validated configurations and test geometries described in the INSTRUCTIONS FOR USE.

dd) *PROTECTIVE DEVICES and ACCESSORIES*

A list of PROTECTIVE DEVICES and ACCESSORIES for use when the EQUIPMENT is employed for RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES shall be provided. There may be different lists for different types of procedures. The listing may include PROTECTIVE DEVICES such as PROTECTIVE CLOTHING, recommended for use but not part of the EQUIPMENT.

ee) *Provisions for CPR*

Instructions shall be given for at least one method of configuring the EQUIPMENT for the performance of CPR including the use of any necessary ACCESSORIES provided with the EQUIPMENT. These instructions shall not call for the use of ACCESSORIES that are not provided with the EQUIPMENT.

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ff) *INTERVENTIONAL REFERENCE POINT*

The concept of the INTERVENTIONAL REFERENCE POINT shall be explained, and its location, designated in accordance with 50.101.3, shall be described. Any statement required in 50.101.3 to justify the choice of location shall be included.

gg) *IRRADIATION disabling switch*

The instructions shall recommend that the IRRADIATION disabling switch (see 50.101.6) be used at all times, except when a procedure is in progress, to prevent the possibility of RADIATION being emitted through the inadvertent actuation of an IRRADIATION SWITCH.

hh) *Collision protection*

The instructions shall describe the anti-collision features, including the operation of the measures provided to prevent unnecessary interruption of a procedure arising from a collision.

jj) *Dosimetry calibration*

Instructions shall be given for maintaining the calibration of all dosimetric indications provided on the EQUIPMENT.

Table 101 – Subclauses containing normative references to the ACCOMPANYING DOCUMENTS

Subclause	Heading
21.3	Mechanical strength – untitled
29.208.101	Isokerma maps
44.1	Overflow, spillage, etc. – General
51.101.3	Position of the INTERVENTIONAL REFERENCE POINT
51.102.2	Management of image storage capacity
59.102	Attachment of protective drapes

6.8.3 Technical description

a) General

Addition:

The technical description shall state that the EQUIPMENT is intended for the performance of prolonged RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES including those in which there is a risk of skin dose levels being high enough to cause deterministic effects.

Additional items:

aa) *Installation*

The technical description shall contain the following recommendations concerning the installation of the EQUIPMENT:

– INTERLOCKS should not be provided on the doors of the room containing the EQUIPMENT. No other measures, whether or not employed for RADIATION PROTECTION, should be able to cause the interruption of IRRADIATION or any other disturbance of a procedure in progress, unless the OPERATOR has the means to prevent such action from occurring during the procedure;
– all emergency stop controls in the system should be protected against accidental actuation;
– sufficient space should be provided around the PATIENT SUPPORT for the unimpeded conduct of CPR;

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– one or more warning lights should be provided in order to indicate the LOADING STATE to persons at all positions in the room containing the EQUIPMENT; see also requirement of 29.208.3.

NOTE Subclause 29.1.102 of IEC 60601-2-7 contains a requirement for HIGH-VOLTAGE GENERATORS to be provided with means for the connection of external warning lights.

bb) *Failure of SUPPLY MAINS*

The technical description shall describe the functional response and re-starting procedure for the EQUIPMENT in the event of failure of the SUPPLY MAINS. Details shall be given of the possibilities for provisions being made in the installation for emergency RADIOSCOPY and for the preservation of stored images, so that the USER is able to decide on an appropriate level of protection to be provided against such failures.

6.8.101 Statement of compliance

If, for INTERVENTIONAL X-RAY EQUIPMENT, compliance with this standard is to be stated, the statement shall be made in the following form:

INTERVENTIONAL X-RAY EQUIPMENT .... *) IEC 60601-2-43:2000***), or

.... **) .... *) IEC 60601-2-43:2000***) .

*) MODEL OR TYPE REFERENCE

**) Name of the EQUIPMENT

***) Year of publication of this standard

SECTION 2: ENVIRONMENTAL CONDITIONS

The clauses and subclauses of this section of the General Standard apply, except as follows:

10 Environmental conditions

This clause of the General Standard applies, except as follows:

10.2.1 Environment (see also 4.5)

Amendment:

The ambient temperature range in item a) is amended to +15 °C to +35 °C.

SECTION 3: PROTECTION AGAINST ELECTRIC SHOCK HAZARDS

The clauses and subclauses of this section of the General Standard apply.

SECTION 4: PROTECTION AGAINST MECHANICAL HAZARDS

The clauses and subclauses of this section of the General Standard apply, except as follows:

21 Mechanical strength

This clause of the General Standard applies, except as follows:

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21.3

Addition:

Add the following paragraph after the third paragraph:

In INTERVENTIONAL X-RAY EQUIPMENT, the load for which the PATIENT SUPPORT is designed shall be the normal load imposed by the PATIENT (as specified and marked, or otherwise as required in this subclause), with the addition of a mass of not less than 50 kg to provide for additional mass imposed in the performance of CPR. This additional load shall be assumed to be applied uniformly over a length of 1 500 mm from the head-end of the PATIENT SUPPORT, or over the whole length if it is less than 1 500 mm, when the EQUIPMENT is configured for CPR in accordance with the INSTRUCTIONS FOR USE, including the fitting of any ACCESSORIES specified for use in CPR.

Addition:

Add the following to the first paragraph of the description of the compliance test:

For INTERVENTIONAL X-RAY EQUIPMENT, the test shall be carried out in the least favourable position other than when configured for CPR, and also in the least favourable position when configured for CPR. When configured for CPR, the test shall include the application of additional weight evenly over the portion of the PATIENT SUPPORT from the head-end up to a length of 1 500 mm or the maximum available length if less than 1 500 mm. This additional weight shall be applied after an interval of 1 min or more subsequent to the application of the testing weight representing the normal load.

Amendment:

Delete the third paragraph of the description of the compliance test and substitute the following:

The weight shall be equal to the required SAFETY FACTOR (see clause 28 of the General Standard and also 21.101.1 and Table 102 in IEC 60601-2-32) times the specified normal load. Where no normal load is specified, a weight that exerts a force of 1,35 kN shall be considered the normal load. The full load shall act on the support system for a period of 1 min. The additional weight applied subsequently for tests in the CPR configuration shall be 50 kg and shall act on the support system for 1 min after its application.

Addition:

Add the following sentence to the fifth paragraph of the description of the compliance test:

For a test of INTERVENTIONAL X-RAY EQUIPMENT in the CPR configuration, the system shall be free from flexing or resonance effects that would impede the conduct of CPR.

22 Moving parts

This clause of the General Standard applies, except as follows:

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22.7

Addition:

Add a fifth dash, as follows:

– In order to prevent hazards arising from the unintended interruption of RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES, the operation of anti-collision devices in INTERVENTIONAL X-RAY EQUIPMENT shall not automatically switch off IRRADIATION and shall not impair other functions of the EQUIPMENT, except movements connected with the potential collision. Means shall be provided for any movement disabled by the actuation of an anti-collision device to be caused to recover from collision within 5 s after a positive action taken at the working position of the OPERATOR.

NOTE In INTERVENTIONAL X-RAY EQUIPMENT, hazards can arise if functionality is unnecessarily affected by the operation of safety devices such as anti-collision devices.

SECTION 5: PROTECTION AGAINST HAZARDS FROM UNWANTED OR EXCESSIVE RADIATION

The clauses and subclauses of this section of the General Standard apply, except as follows:

29 X-RADIATION

This clause of the Collateral Standard 60601-1-3 applies, except as follows:

29.201.2 HALF-VALUE LAYERS in X-RAY EQUIPMENT

Replacement:

The contents of table 204 are replaced by the following:

Table 204 – HALF-VALUE LAYERS in X-RAY EQUIPMENT

Application	X-RAY TUBE VOLTAGE		Minimum permissible first HALF-VALUE LAYER
	Operating range for NORMAL USE kV	Selected value (see note 1) kV	mm Al (see note 3)
INTERVENTIONAL X-RAY EQUIPMENT		<50	See note 2
		50	1,8
		60	2,2
		70	2,5
		80	2,9
		90	3,2
		100	3,6
		110	3,9
		120	4,3
		>120	See note 2

NOTE 1 HALF-VALUE LAYERS for intermediate selected voltages are to be obtained by linear interpolation.

NOTE 2 Linear extrapolation is to be used here.

NOTE 3 These HALF-VALUE LAYER values correspond to a TOTAL FILTRATION of 2,5 mm Al for X-RAY EQUIPMENT operating at constant potential.

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29.201.4 FILTRATION in X-RAY SOURCE ASSEMBLIES

Amendment:

In the first line of the first dashed item in the list, replace "may" by "shall".

29.203.4 Correspondence between X-RAY FIELD and IMAGE RECEPTION AREA

Addition:

In perpendicular position of the X-RAY BEAM AXIS to the IMAGE RECEPTOR PLANE, the maximum area of the X-RAY FIELD shall conform to the following requirements:

a) at least 80 % of the area of the X-RAY FIELD shall overlie the effective IMAGE RECEPTION AREA. Effective IMAGE RECEPTION AREAS smaller than 10 cm in diameter or on one side of their shape are exempted;

b) the X-RAY FIELD measured along a diameter in the direction of greatest misalignment with the IMAGE RECEPTION AREA shall not extend beyond the boundary of the effective IMAGE RECEPTION AREA by more than 2 cm.

NOTE 1 Attention is drawn to the qualifying conditions applying to the definitions of the terms X-RAY FIELD and effective IMAGE RECEPTION AREA in this addition, as stated in 2.202.1 and 2.202.3 of IEC 60601-1-3 respectively.

NOTE 2 This amendment requires higher precision for small X-RAY FIELDS in INTERVENTIONAL X-RAY EQUIPMENT as compared with the original subclause in IEC 60601-1-3, reflecting the applicable working conditions for such equipment and the current state of the technology.

Compliance is checked by inspection and test of the equipment, by measurement of the X-RAY FIELDS. When automatic adjustment of the RADIATION APERTURE is provided, allow a period of at least 5 s before measurements are made, for the automatic mechanism to complete any adjustment occurring during the tests.

29.208.3 Designated SIGNIFICANT ZONES OF OCCUPANCY

Addition:

Add the following as the fourth dash in the list that follows the third paragraph:

– for INTERVENTIONAL X-RAY EQUIPMENT, means to switch into and out of the LOADING STATE shall be available for use by an OPERATOR located in the following positions:

  a) in any of the designated SIGNIFICANT ZONES OF OCCUPANCY, with the EQUIPMENT appropriately configured; a single footswitch with a sufficiently long cable may be used for several SIGNIFICANT ZONES OF OCCUPANCY near the PATIENT;

  b) at least 2 m from the irradiated region of the PATIENT, or within a PROTECTED AREA if provided in the installation;

– for INTERVENTIONAL X-RAY EQUIPMENT, a signal indicating the LOADING STATE shall be provided in such a way that it is perceptible to the OPERATOR in all the locations of items a) and b) above. The presence of an image on the monitor shall not be considered as satisfying this requirement.

Addition:

29.208.101 Isokerma maps

Isokerma maps shall be provided in the ACCOMPANYING DOCUMENTS, describing the distribution of STRAY RADIATION around the EQUIPMENT. These maps shall apply to typical configurations of the EQUIPMENT when operated at the NOMINAL X-RAY TUBE VOLTAGE for RADIOSCOPY and shall satisfy the following conditions:

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– information shall be given for at least one typical configuration with the X-RAY BEAM horizontal and one with the X-RAY BEAM vertical;

– the isokerma maps shall be presented as isokerma curves normalised to a DOSE AREA PRODUCT of 1 $\mu Gy \cdot m^2$;

– the isokerma maps shall be given for horizontal planes 1,0 m and 1,5 m height above the floor and may be given additionally for other planes;

– the interval of value between adjacent curves shall not exceed a factor of 2;

– the measurement geometry on which the data are based shall be compatible with the arrangements used for verification as described in annex FF;

– the data presented shall be accurate within ±50 % at all points more than 15 cm from the EQUIPMENT or PHANTOM and within 3 m of the INTERVENTIONAL REFERENCE POINT or down to 0,001 $\mu Gy/(\mu Gy \cdot m^2)$.

The information shall also include, for each configuration, a scaled schematic representation of the arrangement of the EQUIPMENT showing the projection of the FOCAL SPOT on to the plane of the drawing. Details shall also be given of the applicable measurement geometry, FOCAL SPOT TO IMAGE RECEPTOR DISTANCE, X-RAY TUBE VOLTAGE and ENTRANCE FIELD SIZE.

NOTE Examples of the presentation of isokerma maps are given in Figures 101 and 102.

Compliance is determined by inspection of the ACCOMPANYING DOCUMENTS. The isokerma maps are checked by the procedure described in annex FF.

SECTION 6: PROTECTION AGAINST HAZARDS OF IGNITION OF FLAMMABLE ANAESTHETIC MIXTURES

The clauses and subclauses of this section of the General Standard apply.

SECTION 7: PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER SAFETY HAZARDS

The clauses and subclauses of this section of the General Standard apply, except as follows:

42 Excessive temperatures

42.1

Addition:

Add a row to Table Xa as shown in Table 102:

Table 102 – Addition to Table Xa in IEC 60601-1

Parts	Maximum temperature °C
Parts of INTERVENTIONAL X-RAY EQUIPMENT which can, in NORMAL USE, have prolonged contact with the PATIENT or the OPERATOR	41

Addition:

NOTE The addition to the maximum temperature in Table 102 is designed to take into account the added risks arising from the possibility that long periods of contact may be involved, that the PATIENT is often sedated and that the avoidance of contact during a procedure may not be possible without introducing other risks for the PATIENT.

Attention is drawn to the additions to clause 42 contained in IEC 60601-2-28.

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44 Overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization and disinfection

This clause of the General Standard applies, except as follows:

44.1 General

Addition:

RATIONALE – In RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES, there can be relatively large quantities of body and other fluids which may, directly or through deposits left behind, give rise to damage to the EQUIPMENT, or to electrical, toxic or infectious hazards to PATIENTS, OPERATORS and service personnel.

All components which can come into contact with PATIENTS' secretions, excretions, other body fluids, or fluids shall be constructed:

– so that covers or drapes can be employed to divert these fluids away from the EQUIPMENT, or

– so that the EQUIPMENT surfaces over which the fluids can flow are suitable for cleaning and disinfection.

Guidance shall be provided for the use of the cleaning and disinfecting agents listed in the ACCOMPANYING DOCUMENTS.

EQUIPMENT casings likely to be exposed to specified cleaning and disinfecting agents shall be designed so that they are protected from, or are otherwise tolerant, of the agents concerned.

NOTE Attention is drawn to the additional requirements in 6.8.2 d) concerning cleaning and disinfection

44.6 Ingress of liquids

Additional subclause:

44.6.101 Footswitches

The footswitches of INTERVENTIONAL X-RAY EQUIPMENT shall be operable even if the floor is covered with 25 mm of water.

NOTE Attention is drawn to the limitation of operating voltage imposed by 56.11 in the General Standard.

Compliance is determined by mechanically actuating and releasing the footswitch (with no electrical power source connected) 900 times in 25 mm depth of water over a period of 1 h; then checking its functionality and electrical safety in accordance with the General Standard. In addition there must be no evidence of water having reached mechanical parts that might deteriorate if they remain wet indefinitely.

SECTION 8: ACCURACY OF OPERATING DATA AND PROTECTION AGAINST HAZARDOUS OUTPUT

The clauses and subclauses of this section of the General Standard apply, except as follows:

51 Protection against hazardous output

Addition:

NOTE The provisions in the following subclauses recognize that protection against hazardous output from INTERVENTIONAL X-RAY EQUIPMENT requires flexibility in the delivery of the intended RADIATION and the avoidance of confusion in the presentation of image data to the OPERATOR during the course of a procedure.

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Additional subclauses:

51.101 Control features

51.101.1 AUTOMATIC INTENSITY CONTROL

AUTOMATIC INTENSITY CONTROL shall be provided.

Compliance is determined by inspection and functional tests.

51.101.2 Grid removal

The ANTI-SCATTER GRID should be removable without the use of TOOLS.

NOTE This is of particularly high importance in paediatric applications.

Compliance is determined by inspection and functional tests.

51.101.3 Position of the INTERVENTIONAL REFERENCE POINT

A position for the INTERVENTIONAL REFERENCE POINT shall be stated in the INSTRUCTIONS FOR USE and shall be utilised to determine all values of REFERENCE AIR KERMA (RATE) required for compliance with this standard. The position shall be:

a) for systems with an ISOCENTRE, a point on the REFERENCE AXIS 15 cm from the ISOCENTRE in the direction of the FOCAL SPOT;

   EXAMPLE For systems with the ISOCENTRE 70 cm from the FOCAL SPOT, the INTERVENTIONAL REFERENCE POINT shall be 55 cm from the FOCAL SPOT along the REFERENCE AXIS.

b) for systems without an ISOCENTRE, a point along the REFERENCE AXIS defined by the MANUFACTURER as being representative of the point of intersection of the REFERENCE AXIS with the PATIENT SURFACE. In this case, the statement in the INSTRUCTIONS FOR USE shall include the rationale for the choice of position made by the MANUFACTURER.

NOTE 1 Examples of situations where the MANUFACTURER would specify the INTERVENTIONAL REFERENCE POINT:

– the EQUIPMENT senses the actual distance to the PATIENT SURFACE;

– the EQUIPMENT has a fixed distance between FOCAL SPOT and PATIENT SURFACE.

NOTE 2 For general information concerning the INTERVENTIONAL REFERENCE POINT, see annex CC.

51.101.4 Range of AIR KERMA RATES in RADIOSCOPY

For RADIOSCOPY the MODES OF OPERATION provided for NORMAL USE shall include two modes, designated normal and low respectively, producing different REFERENCE AIR KERMA RATES, such that the value for the low mode does not exceed 50 % of the value for the normal mode. Additional MODES OF OPERATION may be provided, with REFERENCE AIR KERMA RATES less or greater than the values for the normal and low modes.

A control for the selection of any of these MODES OF OPERATION shall not also perform the function of an IRRADIATION SWITCH.

An indication of the selected MODE OF OPERATION shall be provided at the working position of the OPERATOR.

The EQUIPMENT shall not default to a setting with a REFERENCE AIR KERMA RATE higher than that of the normal setting, when the EQUIPMENT is being prepared for the commencement of a procedure.

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Compliance is determined by inspection and functional tests and also by the test procedure given in annex EE, using the 20 cm polymethyl-methacrylate (PMMA) PHANTOM in order to verify the ratio of the REFERENCE AIR KERMA RATES at the designated normal and low MODES OF OPERATION.

51.101.5 Accessibility of switching between RADIOSCOPY and RADIOGRAPHY

Means to switch between RADIOSCOPY and RADIOGRAPHY shall be provided at the normal positions of the OPERATOR.

NOTE This requirement is intended to ensure that switching can be achieved by a sole OPERATOR without change of location and without the intervention of a second member of the operating staff.

Compliance is determined by inspection and functional tests.

51.101.6 IRRADIATION disabling switch

A switch shall be provided to disable/enable the LOADING STATE without affecting any other functions of the EQUIPMENT. The operation of this switch shall not, in itself, be capable of initiating the LOADING STATE.

NOTE For compliance with 29.1.105 of IEC 60601-2-7 (1998), HIGH-VOLTAGE GENERATORS of diagnostic X-RAY GENERATORS are required to be provided with means to connect devices performing the function described in this subclause.

Compliance is determined by inspection and functional tests.

51.102 Information to the OPERATOR

51.102.1 PATIENT data

Information shall be available on the DISPLAY concerning the identity of the PATIENT and the medical procedure to which displayed images relate.

NOTE Such information will typically include at least the name and date of birth of the PATIENT, and the date and time of the procedure.

Compliance is determined by inspection and functional tests.

51.102.2 Management of image storage capacity

Upon completion of entry of the PATIENT data at the beginning of a new case, the EQUIPMENT shall indicate the available image storage capacity.

When the operating parameters have been entered, prior to acquiring a run, the EQUIPMENT shall indicate whether there is sufficient storage space to store the run completely under the programmed conditions or shall state the number of frames possible or the acquisition time available, at the frame rate and resolution selected.

In the event of the EQUIPMENT reaching a zero storage space condition because the programmed run has been extended by the OPERATOR, at least one of the following options may be available to the OPERATOR:

– to continue the run without image storage, currently stored images remaining available;
– to continue the current run by overwriting stored images, in accordance with overwriting options, which shall be described in the INSTRUCTIONS FOR USE.

Compliance is determined by inspection and functional tests.

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51.102.3 Image DISPLAYS

During RADIOSCOPY, the live image shall always occupy the same DISPLAY location. The status of all displayed images, in particular whether they are currently live or stored and, if stored, whether they are "last-image-hold" images or previously stored reference images, shall be indicated at their relevant DISPLAY locations.

Except when the switching of the same DISPLAY location has been effected by the OPERATOR between the "last-image-hold" image and a previously stored reference image, the most recently acquired image shall be displayed after the LOADING STATE has ended, until the LOADING STATE is resumed.

NOTE 1 A DISPLAY location may be one of several separate monitor screens or a logical subdivision of the area of an individual monitor screen.

NOTE 2 These requirements arise from the extreme danger that occurs if an OPERATOR undertakes a procedure on the mistaken assumption that a currently displayed image is, for example, a live one.

Compliance is determined by inspection and functional tests.

51.102.4 Dosimetric indications

During RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES, the following indications shall be provided at the working position of the OPERATOR:

– while the equipment is in the LOADING STATE and the frame rate is more than 6 per second, the measured or estimated value of the REFERENCE AIR KERMA RATE;

– while not in the LOADING STATE, the measured or estimated value of the cumulative REFERENCE AIR KERMA. This cumulative value shall represent the sum of AIR KERMA from RADIOSCOPY and RADIOGRAPHY from the beginning of the procedure. This indication shall occur within 5 s of leaving the LOADING STATE.

In addition, an indication shall be provided of the measured or estimated value of the cumulative DOSE AREA PRODUCT, representing the sum of DOSE AREA PRODUCTS from RADIOSCOPY and from RADIOGRAPHY from the beginning of the procedure.

NOTE This indication need not be provided in the working position of the OPERATOR.

Compliance is determined by inspection and tests. The test shall be performed with a LOADING STATE of duration longer than 3 s.

51.102.5 Supplementary indications

During RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES, indications of one or more of the following items should be made available:

– cumulative LOADING TIME of RADIOSCOPY for the whole procedure;

– cumulative LOADING TIME of RADIOSCOPY for at least one part of the procedure determined by the OPERATOR;

– cumulative number of RADIOGRAPHIC IRRADIATIONS for the whole procedure;

– cumulative number of RADIOGRAPHIC IRRADIATIONS for at least one part of the procedure determined by the OPERATOR;

– integrated REFERENCE AIR KERMA for at least one part of the procedure determined by the OPERATOR.

NOTE The DOSE AREA PRODUCT, DOSE AREA PRODUCT RATE or related values may be indicated, particularly in training situations. However, the DOSE AREA PRODUCT is primarily used as an indicator for stochastic effects and is not useful for predicting deterministic effects. It may be useful to momentarily indicate the DOSE AREA PRODUCT RATE and the cumulative DOSE AREA PRODUCT at the position of the OPERATOR, by means of a toggle.

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51.102.6 Accuracy of dosimetric indications

All indications of dosimetric values on the EQUIPMENT shall be accurate to within ±50 % at values ranging from QQ to the maximum indication, where QQ is:

– 100 mGy for AIR KERMA;

– 100 $\mu Gy \cdot s^{-1}$ for AIR KERMA RATE;

– 250 $\mu Gy \cdot m^2$ for DOSE AREA PRODUCT;

– 0,25 $\mu Gy \cdot m^2 \cdot s^{-1}$ for DOSE AREA PRODUCT RATE.

Compliance is verified by tests with appropriate dosimetric calibration.

SECTION 9: ABNORMAL OPERATION AND FAULT CONDITIONS; ENVIRONMENTAL TESTS

The clauses and subclauses of this section of the General Standard apply.

SECTION 10: CONSTRUCTIONAL REQUIREMENTS

The clauses and subclauses of this section of the General Standard apply, except as follows:

59 Construction and layout

This clause of the General Standard applies, except as follows:

Additional clauses:

59.101 Configuration for cardiopulmonary resuscitation (CPR)

The EQUIPMENT shall be so constructed that it can be placed in a configuration designated for CPR within 15 s. This period may be increased by 1 s for each 15° that the current working position of the PATIENT SUPPORT deviates from the CPR position.

Compliance is determined by functional tests.

59.102 Attachment of protective drapes

Means shall be provided, and described in the INSTRUCTIONS FOR USE, for allowing protective drapes to be attached to the EQUIPMENT or its ACCESSORIES to enable procedures to be conducted with an appropriate level of sterility.

Compliance is determined by inspection of the EQUIPMENT and the INSTRUCTIONS FOR USE.

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Annexes

The appendices of the General Standard apply, except as follows:

APPENDIX L

References – Publications mentioned in this standard

Addition:

IEC 60529:1989*, Degrees of protection provided by enclosures (IP code)*

IEC 60601-2-7:1998*, Medical electrical equipment – Part* 2-7*: Particular requirements for the safety of high-voltage generators of diagnostic X-ray generators*

IEC 60601-2-28:1993, *Medical electrical equipment – Part 2: Particular requirements for the safety of X-ray source assemblies and X-ray tube assemblies for medical diagnosis*

IEC 60601-2-32:1994, *Medical electrical equipment – Part 2: Particular requirements for the safety of associated equipment of X-ray equipment*

IEC 60788:1984, *Medical radiology – Terminology*

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Annex AA
(normative)

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Annex BB
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Indications for the need to use EQUIPMENT complying with this standard

Over the past 20 years, there has been a substantial increase in the use of RADIOSCOPY for visualisation in a wide range of diagnostic and interventional procedures. All indications are that this increase will continue in the near future. These interventional procedures sometimes require long periods of RADIOSCOPIC operation with, in some cases, an unchanged position of the X-RAY FIELD on the PATIENT SURFACE. It should be noted that these procedures usually provide significant advantages over alternative therapies in terms of overall clinical outcome for the PATIENT. Table BB.1 provides examples of interventional procedures which may involve prolonged RADIOSCOPIC IRRADIATION TIMES. In addition, these procedures are performed by varieties of clinicians with different degrees of training in RADIOLOGICAL PROTECTION. Because of these characteristics, these interventional procedures are different from procedures in MEDICAL DIAGNOSTIC RADIOLOGY in that the possibility of deterministic effects such as RADIATION-induced skin injury cannot be excluded.

Table BB.1 – Examples of prolonged RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES for which deterministic effects of IRRADIATION are possible

Radio-frequency cardiac catheter ablations
Transjugular intrahepatic portosystemic shunt (TIPS)
Embolizations
Cardiac and non-cardiac vascular reconstructions

The concern over confirmed RADIATION-induced skin injuries as a result of some interventional procedures has prompted some countries to issue special advice on the avoidance of injuries during RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES [1), 2)]. This special advice has included a recommendation for EQUIPMENT features that permit estimation of the ABSORBED DOSE to the skin. The purpose of this recommendation is to encourage identification of those areas of the skin which are irradiated causing levels of ABSORBED DOSE that approach or exceed the threshold for deterministic injury. Such identification would be important for communication and PATIENT care upon the onset of symptoms of RADIATION injury or where additional IRRADIATION in the same skin area is being considered. In addition, the information may assist medical practitioners and health-care organisations in improving interventional procedures, thereby reducing the potential for injury in the future.

There are also a number of interventional procedures in MEDICAL RADIOLOGY in which the same risks do not arise by the nature of the procedure and which, therefore, do not require the use of EQUIPMENT having the features specified in this standard. Some examples of these procedures are given in table BB.2.

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Table BB.2 – Examples of RADIOSCOPICALLY guided procedures for which deterministic effects are unlikely

IVC filter placement
Simple angioplasty
Biopsy
Dialysis access maintenance
RADIOSCOPICALLY assisted ERCP

The decision to offer equipment complying with this Particular Standard rests with the MANUFACTURER. The decision to use interventionally labelled EQUIPMENT rests with the USER and OPERATOR of the EQUIPMENT.

Reference documents:

1) US Food and Drug Administration – Avoidance of serious X-ray induced skin injuries to patients during fluoroscopically guided procedures. Warning issued on September 9, 1994

2) US Food and Drug Administration – Recording information in the patient's medical record that identifies the potential for serious X-ray induced skin injuries following fluoroscopically guided procedures. Advice issued on September 15, 1995

3) Shope TB, Radiation-induced skin injuries from fluoroscopy. Radiographics 1996,16:1195 – 1199

4) Vano E, Arranz L, Sastre JM, Moro C, Ledo A, Garate TM and Minguez I, Dosimetric and radiation protection considerations based on some cases of patient skin injuries in interventional cardiology. Br. J. Radiol. 1998; 71:510 – 516

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Annex CC
(informative)

The INTERVENTIONAL REFERENCE POINT

This standard allows the use of an indirect indication to estimate the ABSORBED DOSE to the skin. The estimate could be drawn from the indications of X-RAY EQUIPMENT parameters followed by a calculation of the primary AIR KERMA or AIR KERMA RATE at a point specified with reference to the FOCAL SPOT. The specified point, which has been defined here as the INTERVENTIONAL REFERENCE POINT, is intended to be representative of the point of intersection of the X-RAY BEAM AXIS with the PATIENT. For systems with an ISOCENTRE, a point on the REFERENCE AXIS 15 cm from the ISOCENTRE towards the FOCAL SPOT has been specified as the INTERVENTIONAL REFERENCE POINT. This distance is assumed to represent a good approximation of the value of the actual FOCAL SPOT TO SKIN DISTANCE during interventional procedures. If one considers currently available methods to estimate ABSORBED DOSES to selected tissues for RADIOSCOPIC and cine-angiographic examinations of the coronary arteries of adults [1),2)], these methods rely on the use of distinct operating conditions commonly used in RADIOLOGICAL examinations of the heart. These operating conditions are associated with a view, an arterial projection, and technique factors on the X-RAY EQUIPMENT such as the X-RAY TUBE VOLTAGE (kV), the HALF-VALUE LAYER (HVL), the FOCAL SPOT TO SKIN DISTANCE**,** the FOCAL SPOT TO IMAGE RECEPTOR DISTANCE and the ENTRANCE FIELD SIZE. A review of the operating conditions derived from analyses of practice [3),6)] indicates that the defined INTERVENTIONAL REFERENCE POINT is, in fact, a fair approximation of the FOCAL SPOT TO SKIN DISTANCE for each field. Unfortunately, similar data are not available for non-cardiac diagnostic and interventional procedures.

The error in estimating the total ABSORBED DOSE to the skin introduced from the defined INTERVENTIONAL REFERENCE POINT should average out as long as the interventional procedure is composed of multiple views. When the interventional procedure is limited to one or a few views, the possibility of error in estimating the ABSORBED DOSE to the skin may be higher. However, even under worst case conditions, errors should be less than a factor of two. Of course, most of this error can be eliminated by assessing the position of the PATIENT and calculating the appropriate correction factor.

The standard has the flexibility of allowing an alternative to the use of the defined INTERVENTIONAL REFERENCE POINT for systems without an ISOCENTRE. In this case, the INTERVENTIONAL REFERENCE POINT is located at a position, defined by the MANUFACTURER to be representative of the point of intersection of the REFERENCE AXIS with the PATIENT SURFACE, and stated in the ACCOMPANYING DOCUMENTS. Examples of situations where the MANUFACTURER would use this alternative method of defining the INTERVENTIONAL REFERENCE POINT, would be EQUIPMENT that senses the actual FOCAL-SPOT-TO-SKIN DISTANCE, deviates from traditional geometry or has a fixed FOCAL SPOT TO SKIN DISTANCE.

Reference documents

1) S.H. Stern, M. Rosenstein, L. Renaud, M. Zankl - Handbook of Selected Tissue Doses for Fluoroscopic and Cineangiographic Examination of the Coronary Arteries. U.S. Department of Health and Human Services Publication FDA 95-8289, May 1995

2) G.T. Nahass – Fluoroscopy and the Skin: Implications for Radiofrequency Catheter Ablation. Am. J. of Card. 76, 174-176 (1995)

3) J. Lesperance – Coronary Angiography Projections. Institut de Cardiologie de Montréal, April 1982

4) R. Haddi et L. Renaud – Projections et Conditions Techniques en Usage en Angiocardiologie, Etude Statistique. Rapport technique, Service de Génie Biomédical, Institut de Cardiologie de Montréal, March 1993

5) D.L. Hykes – Determination of Patient Radiation Doses Associated with Cardiac Catherization Procedures using Direct measurements and Monte Carlo Methods. Ph.D. dissertation. Medical College of Ohio, Toledo OH

6) C.J. Huyskens and W.A. Hummel – Data Analysis on Patient Exposures in Cardiac Angiography. Radiation Protection Dosimetry 57(1), 475-480 (1995)

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Annex DD
(informative)

Cleaning and disinfection

The need for the development of this standard in this area arises from the nature of interventional procedures and the heightened awareness of the risk of transmission of potentially lethal organisms. Whilst incisions made during interventional procedures are small, large blood vessels and collections of body fluids (for example, abscesses) are frequently directly accessed with catheters or tubes. Arising from this, blood and body fluids may spill on to or contaminate the work environment and the EQUIPMENT. Some procedures also involve copious quantities of fluids being used to wash or flush away debris during procedures. These fluids have been known to enter and lodge in cavities and crevices in the EQUIPMENT, thereby producing both electrical and infection control hazards. The latter may be a serious problem for maintenance technicians who may have to approach EQUIPMENT containing up to several litres of saline and miscellaneous body fluids of unknown origin. The possibility of such occurrences may be greatly reduced or even eliminated at the design stage of the EQUIPMENT, by giving careful thought to the issues involved.

The possibility that EQUIPMENT may become contaminated, or have fluids or deposits lodge in cracks and crevices, gives rise to the need for cleaning and disinfection. This, in turn, gives rise to the use of cleaning and disinfection agents which may achieve their own aims admirably but, in doing so, can give rise to electrical hazards or damage the EQUIPMENT surfaces to which they are applied. Again, such problems can be greatly reduced at the design stage, and by giving explicit instructions on cleaning and disinfection.

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Annex EE
(normative)

Procedure for measuring REFERENCE AIR KERMA (RATE)

EE.1 General

EE.1.1 Introduction

In this standard, the required statements of AIR KERMA and AIR KERMA RATE are expressed as values of REFERENCE AIR KERMA (RATE), the applicable position of the INTERVENTIONAL REFERENCE POINT being designated in accordance with 51.101.3. This position generally approximates to the position of the PATIENT SURFACE, but does not necessarily coincide with it under all conditions. The concept, supported by the measuring procedure described here, is intended to provide a uniform method for stating the AIR KERMA (RATE) produced by INTERVENTIONAL X-RAY EQUIPMENT in NORMAL USE. This test method is based on the use of specific polymethyl-methacrylate (PMMA) PHANTOMS under particular conditions. The compliance criteria stated in this procedure allow for manufacturing tolerances in the stated values, when these values are verified against the MEASURED VALUES resulting from the test. For this reason and also because of factors such as PATIENT variability and the actual clinical configuration of the EQUIPMENT, the stated values are not to be regarded as accurate measures of X-RADIATION actually incident upon the skin of the PATIENT.

In addition to its purpose of verifying the compliance of statements made in accordance with this standard, the method can be adapted for use in other situations, such as those where it is required to determine or verify levels of AIR KERMA (RATE) applying at any time to examples of INTERVENTIONAL X-RAY EQUIPMENT under conditions of NORMAL USE, or to investigate the dependence of the REFERENCE AIR KERMA (RATE) on selected MODES OF OPERATION or on the settings of variable operating parameters. Such additional uses, however, are not within the normative intent of this annex.

EE.1.2 Operating conditions

INTERVENTIONAL X-RAY EQUIPMENT may be equipped with means for manually or automatically configuring the operating parameters for different intended uses. In addition, different operating parameter sets may be required to comply with differing national regulations and preferences. Requirements are given in 6.8.2 bb) for details of MODES OF OPERATION and certain other available settings to be stated. In 6.8.2 cc) the associated values of REFERENCE AIR KERMA (RATE) are required to be given, together with the configurations and test geometries by which they can be verified by the method described in this annex. The first stage of compliance testing is to check this information (other than the dosimetric values) for compliance with the requirements and compatibility with the measuring method. If the information complies, it is used in the measuring procedure to verify the compliance of the stated values of REFERENCE AIR KERMA (RATE). Otherwise, the EQUIPMENT is considered non-compliant without further testing. Thus, the EQUIPMENT is delivered with a set of verified values and also with sufficient information to enable the values to be re-checked at any time. It is emphasised that, in any circumstances, the test method is intended to be applied only in respect of conditions that are within the range of NORMAL USE.

EE.2 Test equipment

EE.2.1 PHANTOM

Material: Polymethyl-methacrylate (PMMA)

Rectangular blocks with sides equal to or exceeding 25 cm

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Nominal thickness: 20 cm and 30 cm (the PHANTOM may be fabricated from layers of material)

Area density of the nominal 20 cm PHANTOM: 23,5 g.cm^{-2} ± 5 %.

Area density of the nominal 30 cm PHANTOM: 35,5 g.cm^{-2} ± 5 %.

EE.2.2 DOSEMETER

The measuring detector must be small enough to cover not more than 80 % of the area of the X-RAY BEAM in the plane of measurement, and the area of its surface perpendicular to the source-detector axis must not exceed 30 cm^2.

EE.3 Measurement procedure

EE.3.1 Relevant parameters

It is required in 6.8.2 cc) to provide, in the INSTRUCTIONS FOR USE, a description of the configurations and test geometries applying to the stated values of REFERENCE AIR KERMA (RATE). The following are examples of factors that need to be referenced, when relevant to the EQUIPMENT settings concerned.

a) Equipment configuration

- *1 Orientation of the X-RAY BEAM*
- *2 PATIENT SUPPORT in or out*
- *3 ANTI-SCATTER GRID in or out*
- *4 Appropriate ENTRANCE FIELD SIZE selected*

b) Operating settings (representative of NORMAL USE)

- *1 Technical details of parameters included in each MODE OF OPERATION*
- *2 Frame rate*
- *3 Selectable ADDED FILTERS automatically applied*
- *4 Selectable ADDED FILTERS manually applied*

c) Test geometry

- *1 FOCAL SPOT TO IMAGE RECEPTOR DISTANCE*
- *2 Distance of FOCAL SPOT to measuring detector*
- *3 X-RAY FIELD size at the measuring detector*
- *4 Positioning of PHANTOM (see EE.3.2 below)*
- *5 Positioning of measuring detector (see EE.3.2 below)*

EE.3.2 Positioning of PHANTOM and measuring detector

The PHANTOM is placed near the IMAGE RECEPTOR, leaving as much of the available distance as possible between the X-RAY SOURCE ASSEMBLY and the ENTRANCE SURFACE of the PHANTOM. (This will minimize the effect of SCATTERED RADIATION on the measurements.)

Position the measuring detector at a point half-way between the FOCAL SPOT and the ENTRANCE SURFACE of the PHANTOM. (This will minimize the contribution of STRAY RADIATION to the reading.)

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EE.3.3 Checking the test conditions

Before any dosimetric measurements are made, verify that the particulars of the EQUIPMENT settings under test and the associated measuring arrangements given in the INSTRUCTIONS FOR USE are in compliance with 6.8.2 bb) and 6.8.2 cc). Dosimetry is not to proceed and, therefore, compliance with dosimetric requirements cannot be determined, unless the associated information is in itself compliant.

NOTE In the event of the procedure in this annex being used other than to determine compliance with requirements in this standard, the choice of EQUIPMENT settings and the test arrangements may depend on the circumstances and purpose of the test.

EE.3.4 Basic measurements

Measure the AIR KERMA RATE for each of the RADIOSCOPIC settings for which a value of REFERENCE AIR KERMA RATE is required to be stated in 6.8.2 cc).

Measure the AIR KERMA per image for each RADIOGRAPHIC setting as required to be stated in 6.8.2 cc).

Measurements are made using the 20 cm PHANTOM, or both the 20 cm and 30 cm PHANTOMS, as required in 6.8.2 cc) as the basis for the stated values concerned.

EE.3.5 OPERATOR selectable parameters

For each setting measured in EE.3.4, measure the AIR KERMA (RATE) using the nominal 20 cm PMMA PHANTOM:

– for representative OPERATOR selectable ENTRANCE FIELD SIZES;

– for representative OPERATOR selectable ADDED FILTERS;

– for representative OPERATOR selectable pulse repetition frequencies.

EE.4 Compliance criteria

From the MEASURED VALUES obtained in the tests, calculate the corresponding values of REFERENCE AIR KERMA (RATE). Compliance is verified if:

- *no value stated in the INSTRUCTIONS FOR USE differs from the corresponding calculated value by more than 50 % of the stated value;*
- *the precision of the values in any group, stated for a common test geometry, is ±15 % or better;*
- *in respect of the two RADIOSCOPIC MODES OF OPERATION described in 6.8.2 bb) 1), the ratio of the normal value to the low value is not less than 2.*

The values are only valid for the factory settings. When settings are changed they may deviate.

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Annex FF
(normative)

Distribution maps of STRAY RADIATION

FF.1 Introduction

This standard contains requirements in 29.208.101 for isokerma maps of STRAY RADIATION to be provided with INTERVENTIONAL X-RAY EQUIPMENT. The purpose is to provide information on the distribution of the STRAY RADIATION for guidance in the RADIOLOGICAL PROTECTION of staff. These maps will also be useful in the design of STRUCTURAL SHIELDING and the placement of mobile shielding. This annex describes the procedure for verifying compliance. Since dosimetric information of this kind depends considerably on the operating conditions and measuring methods employed, the annex is also intended for the guidance of MANUFACTURERS in meeting the requirements.

FF.2 Equipment configuration

The ACCOMPANYING DOCUMENTS are examined in relation to the configuration of the EQUIPMENT and other data applying to the isokerma curves. For compliance:

– *the information must be complete, as listed in 29.208.101;*

– *configurations must be typical of the NORMAL USE of the EQUIPMENT;*

– *the measuring arrangements described must be compatible with those specified in this annex for verification of the values.*

If the information is compliant, the isokerma maps are verified as in FF.3 and FF.4, with the EQUIPMENT configured and operated as described in the ACCOMPANYING DOCUMENTS.

FF.3 PHANTOM

The PHANTOM consists of a 25 cm cube of polymethyl-methacrylate (PMMA), which may be assembled from 25 cm square slabs.

FF.4 Measurement set-up

The X-RAY BEAM is aligned so that the centre of the ENTRANCE SURFACE of the PHANTOM is at the INTERVENTIONAL REFERENCE POINT. The X-RAY BEAM must not be aligned in such a way that its axis lies in the plane between adjacent slabs of PMMA. The X-RAY FIELD size shall be 100 cm^2 at the entrance of the PHANTOM.

Measurements are performed at the NOMINAL X-RAY TUBE VOLTAGE for RADIOSCOPY.

Measurements are made at all locations within 3 m of the INTERVENTIONAL REFERENCE POINT or down to 0,001 μGy/μGy·m^2), except that measurements may be omitted:

– *within 15 cm of the INTERVENTIONAL REFERENCE POINT when placement of the measuring device is impractical, and*

– *at locations vertically over the EQUIPMENT.*

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Measurements are made for two orientations of the X-RAY BEAM, one horizontal and one vertical. When the X-RAY BEAM is vertical, the X-RAY SOURCE ASSEMBLY is oriented to the beam direction corresponding to the most frequent use of the EQUIPMENT.

Example: For an isocentric system, the beam is directed vertically upward.

FF.5 Criteria for compliance

The MEASURED VALUES are normalized to a DOSE AREA PRODUCT of 1 μGy·m^2. For compliance, all values of AIR KERMA represented by the curves in the ACCOMPANYING DOCUMENTS shall be within ±50 % of the normalized MEASURED VALUES determined by the test.

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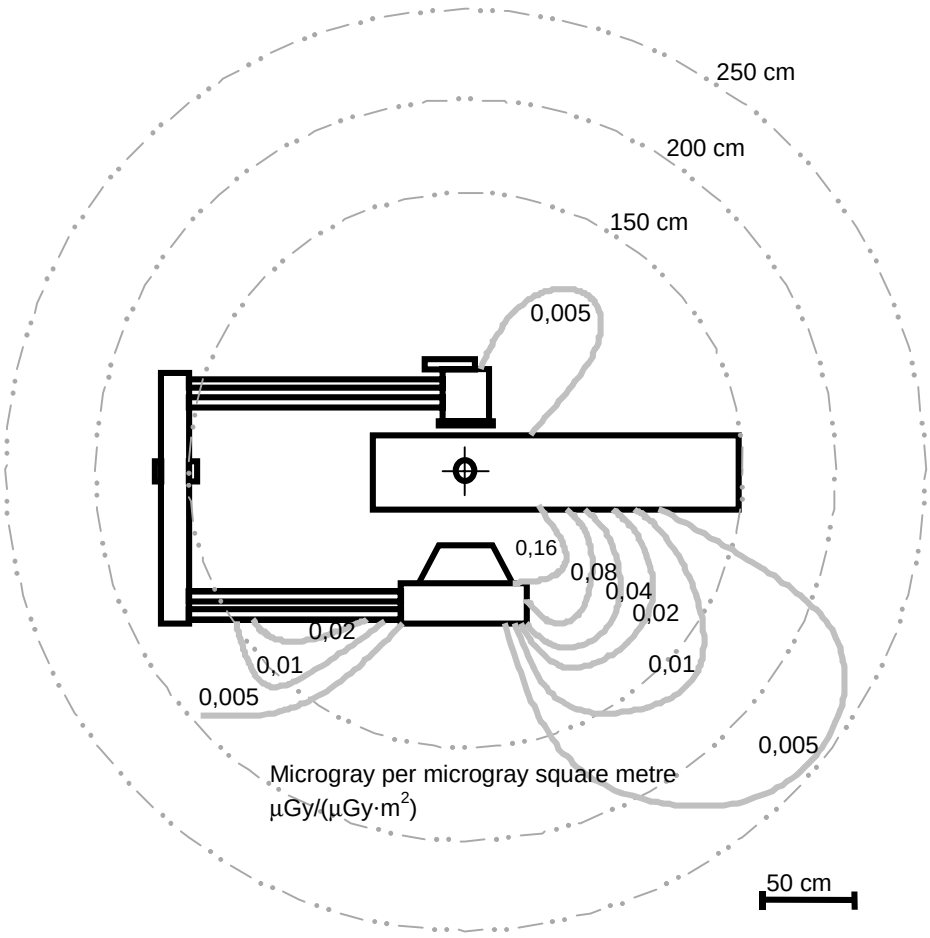


Figure 101 – Example of isokerma map at 100 cm height

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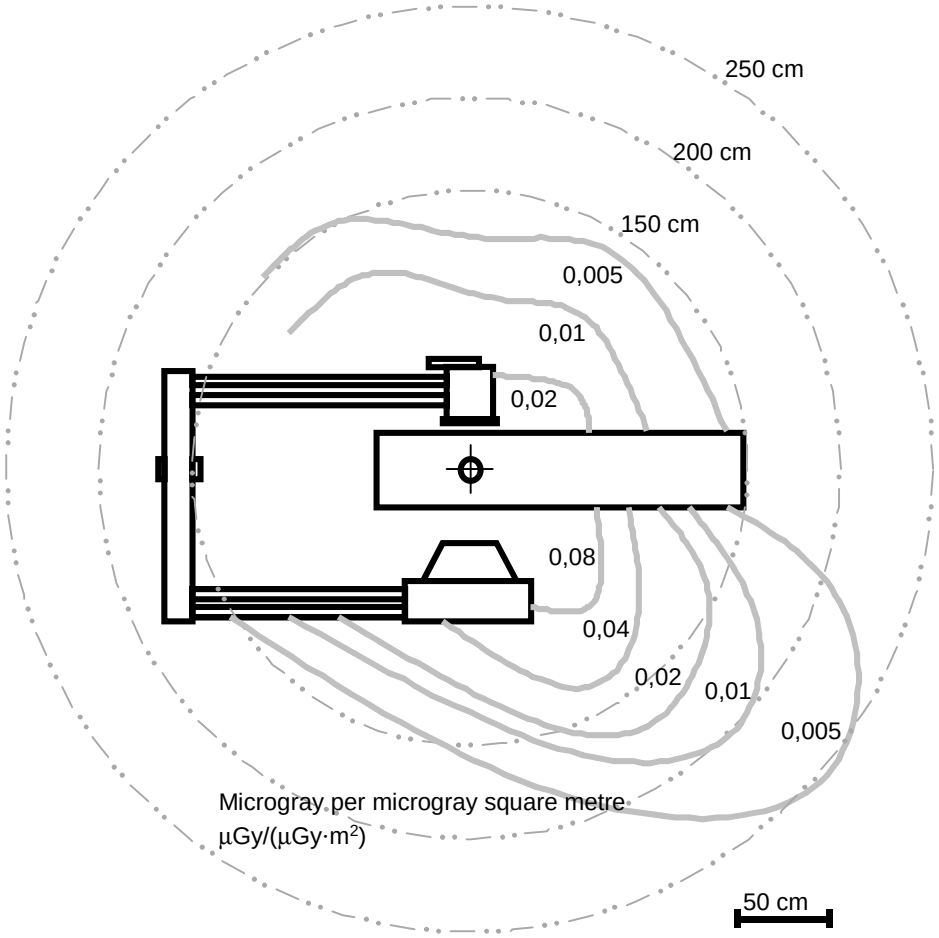


Figure 102 – Example of isokerma map at 150 cm height

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- librarian ❑
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other.....

Q3 I work for/in/as a: *(tick all that apply)*

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- nearly ❑
- fairly well ❑
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- standard is out of date ❑
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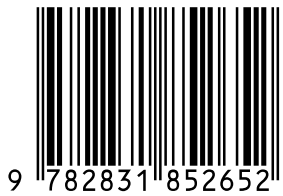
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