

INTERNATIONAL STANDARD

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**Evaluation and routine testing in medical imaging departments –
Part 3-8: Acceptance and constancy tests – Imaging performance of X-ray
equipment for radiography and radioscopy**

**Essais d'évaluation et de routine dans les services d'imagerie médicale –
Partie 3-8: Essais d'acceptation et de constance – Performance d'imagerie des
appareils à rayonnement X pour la radiographie et la radioscopie**



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**EVALUATION AND ROUTINE TESTING
IN MEDICAL IMAGING DEPARTMENTS –****Part 3-8: Acceptance and constancy tests –
Imaging performance of X-ray equipment for radiography and radioscopy****FOREWORD**

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INTRODUCTION

The IEC 61223 series gives methods for ACCEPTANCE TESTS and CONSTANCY TESTS for diagnostic X-RAY EQUIPMENT.

IEC 60601-2-54:2022 and IEC 60601-2-43:2022 state that the MANUFACTURER provides ACCOMPANYING DOCUMENTS with instructions for MANUFACTURER-recommended QUALITY CONTROL PROCEDURES and tests to be performed on the X-RAY EQUIPMENT by the RESPONSIBLE ORGANIZATION. In this document, these instructions are referred to as a QUALITY CONTROL manual.

This part of IEC 61223 provides guidance on the content to be considered for inclusion in the QUALITY CONTROL manual for X-RAY EQUIPMENT for RADIOGRAPHY and RADIOSCOPY, including INTERVENTIONAL X-RAY EQUIPMENT. The QUALITY CONTROL manual is intended to be used independently by the RESPONSIBLE ORGANIZATION to ensure safe and effective equipment performance during its EXPECTED SERVICE LIFE, without the need to consult IEC standards.

This document provides parameters to be evaluated, examples of test methods, recommended minimum frequencies of evaluation and tools intended to be used by the RESPONSIBLE ORGANIZATION on installed X-RAY EQUIPMENT within the scope of this document. For the parameters applicable to the specific X-RAY EQUIPMENT to be tested, specific acceptance criteria are supplied by MANUFACTURERS, which can be superseded with contractual criteria with the RESPONSIBLE ORGANIZATION and further superseded with locally applicable regulatory criteria.

A major purpose of this document is that of facilitating technical communication between stakeholders in the areas of ACCEPTANCE and CONSTANCY TESTING. The three major stakeholders responsible for assuring the safety and efficacy of X-RAY EQUIPMENT are the MANUFACTURER, the RESPONSIBLE ORGANIZATION and the regulatory authorities.

Generally, equipment installed in accordance with the MANUFACTURER'S QUALITY CONTROL PROCESS will comply with applicable IEC standards as well as meeting both local regulatory requirements and the MANUFACTURER'S general specifications and contractual specifications by the RESPONSIBLE ORGANIZATION.

The performance of installed equipment that is tested is assessed by the RESPONSIBLE ORGANIZATION and regulators using a wide variety of PROCESSES and tools. Acceptability criteria and PROCESSES can differ from those of equipment MANUFACTURERS.

EVALUATION AND ROUTINE TESTING IN MEDICAL IMAGING DEPARTMENTS –

Part 3-8: Acceptance and constancy tests – Imaging performance of X-ray equipment for radiography and radioscopy

1 Scope and object

This part of IEC 61223 applies to evaluation of the imaging performance and related QUALITY CONTROL parameters of X-RAY EQUIPMENT for RADIOGRAPHY and RADIOSCOPY that conform to IEC 60601-2-54:2022 or IEC 60601-2-43:2022.

NOTE Cone-beam CT is a MODE OF OPERATION in INTERVENTIONAL X-RAY EQUIPMENT. This document discusses such MODE OF OPERATION in the informative Annex F.

This document applies to the evaluation of the imaging performance of the entire imaging chain from image acquisition, image processing and image display.

This document applies to ACCEPTANCE TESTS and CONSTANCY TESTS, which are part of the QUALITY ASSURANCE PROGRAM in medical imaging departments and are intended to be performed by or under the responsibility of the RESPONSIBLE ORGANIZATION. A detailed discussion of the position of these tests within the medical radiological equipment lifecycle is provided in Clause A.2. The methods included rely mainly on non-invasive measurements that use appropriate test equipment and are performed after the installation is completed in accordance with the MANUFACTURER'S installation instructions.

IEC 60601-2-54:2022 and IEC 60601-2-43:2022 require information to be provided to the RESPONSIBLE ORGANIZATION with respect to QUALITY CONTROL. This document provides guidance to MANUFACTURERS regarding the ACCEPTANCE and CONSTANCY TESTS for the X-RAY EQUIPMENT in a MANUFACTURER supplied QUALITY CONTROL manual. Annex G provides guidance for such a manual.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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.

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

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
IEC 60601-1:2005/AMD1:2012
IEC 60601-1:2005/AMD2:2020

IEC 60601-1-3:2008, *Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral standard: Radiation protection in diagnostic X-ray equipment*
IEC 60601-1-3:2008/AMD1:2013
IEC 60601-1-3:2008/AMD2:2021

IEC 60601-2-43:2022, *Medical electrical equipment – Part 2-43: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures*

IEC 60601-2-54:2022, *Medical electrical equipment – Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy*

IEC 61267:2005, *Medical diagnostic X-ray equipment – Radiation conditions for use in the determination of characteristics*

IEC 61674:2012, *Medical electrical equipment – Dosimeters with ionization chambers and/or semi-conductor detectors as used in X-ray diagnostic imaging*

IEC 61676:2023, *Medical electrical equipment – Dosimetric instruments used for non-invasive measurement of X-ray tube voltage in diagnostic radiology*

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

3 Terms, definitions, symbols and abbreviated terms

3.1 Terms and definitions

For the purposes of this document, the terms and definitions in IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020, IEC 60601-1-3:2008, IEC 60601-1-3:2008/AMD1:2013, IEC 60601-1-3:2008/AMD2:2021, IEC 60601-2-54:2022, IEC 60601-2-43:2022 and the following apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

- IEC Electropedia: available at <https://www.electropedia.org/>
- IEC Glossary; available at <http://std.iec.ch/glossary>
- ISO Online browsing platform: available at <https://www.iso.org/obp>

3.1.1

ACCEPTANCE TEST

ACCEPTANCE TESTING

test carried out after new equipment has been installed, or major modifications have been made to existing equipment, in order to verify compliance with specifications

Note 1 to entry: The specifications could include contractual specifications, requirements enforced by legislation, the MANUFACTURER's specifications or requirements from standards, for example in the IEC 60601 series.

[SOURCE: IEC 61223-1:1993, 3.2.4, modified – Words "contractual specifications" replaced with "specifications" and Note 1 to entry added.]

3.1.2

ACTUAL FOCAL SPOT

area on the surface of the anode that intercepts the beam of accelerated particles

[SOURCE: IEC 60336:2020, 3.1, modified – Word "target" replaced with "anode" and Note 1 to entry removed.]

3.1.3

ANTI-SCATTER GRID

device to be placed before the IMAGE RECEPTION AREA in order to reduce the incidence of SCATTERED RADIATION upon that area and thus increase the contrast in the X-RAY PATTERN

[SOURCE: IEC 60627:2013, 3.1.1]

3.1.4

ARTEFACT

apparent structure visible in the image, which does not represent a structure within the object and which cannot be explained by noise or the MODULATION TRANSFER FUNCTION of the system

[SOURCE: IEC 61223-3-3:1996, 3.3.1, modified – Term "artifact" changed to "ARTEFACT".]

3.1.5

ASSOCIATED EQUIPMENT

ME EQUIPMENT, in a RADIOLOGICAL INSTALLATION, other than those for the production and control of IONIZING RADIATION, but essential for its application

[SOURCE: IEC TR 60788:2004, rm-30-01, modified – Word "equipment" replaced with "ME EQUIPMENT" and definition rephrased.]

3.1.6

BASELINE VALUE

reference value of functional parameter, which is either:

- the value obtained for this parameter in the initial CONSTANCY TEST immediately following an ACCEPTANCE TEST, or
- where described in a corresponding particular standard, the mean value of values obtained in a series of initial CONSTANCY TESTS, immediately following an ACCEPTANCE TEST

Note 1 to entry: The CONSTANCY TEST method can be different from the ACCEPTANCE TEST method. In case the methods are the same, the value obtained in the ACCEPTANCE TEST can be used.

[SOURCE: IEC 61223-3-6:2020, 3.1.5, modified – Term "status test" replaced with "ACCEPTANCE TEST" and Note 1 to entry added.]

3.1.7

CONSTANCY TEST

CONSTANCY TESTING

each of a series of tests, carried out following ACCEPTANCE TESTING, to ensure that the functional performance of the equipment continues to meet ESTABLISHED CRITERIA

Note 1 to entry: For each CONSTANCY TEST, the ACCEPTANCE TEST method or an alternative test method can be used.

3.1.8

DIGITAL DRIVING LEVEL

DDL

digital value given as input to an IMAGE DISPLAY SYSTEM producing a LUMINANCE

[SOURCE: IEC 62563-1:2009, 3.1.7]

3.1.9

DIGITAL SUBTRACTION ANGIOGRAPHY

DSA

SUBTRACTION IMAGING to visualize vessels using RADIOGRAPHY or SERIAL RADIOGRAPHY

3.1.10

DIGITAL X-RAY IMAGING DEVICE

device consisting of a digital X-ray detector including the protective layers installed for use in practice, the amplifying and digitizing electronics, and a computer providing the original data of the image

Note 1 to entry: A DIGITAL X-RAY IMAGING DEVICE can include protecting parts, such as ANTI-SCATTER GRIDS and components for AUTOMATIC EXPOSURE CONTROL.

[SOURCE: IEC 62220-1-1:2015, 3.6]

3.1.11

DOSIMETER

equipment which uses IONIZATION CHAMBERS and/or semiconductor detectors for the measurement of AIR KERMA, AIR KERMA length product and/or AIR KERMA RATE in the beam of an X-RAY EQUIPMENT used for medical radiological procedures

Note 1 to entry: A DOSIMETER contains the following components:

- one or more detector assemblies which can or cannot be an integral part of the measuring assembly; and/or
- a measuring assembly.

[SOURCE: IEC 61674:2012, 3.1, modified – Word "diagnostic" deleted twice from the definition and third item of Note 1 to entry deleted.]

3.1.12

DYNAMIC RANGE

range between the highest and lowest value of the thickness of a specified material, which can be differentiated by an X-RAY IMAGE RECEPTOR and displayed artefact-free on an IMAGE DISPLAY DEVICE

3.1.13

ENTRANCE PLANE

plane, for an X-RAY IMAGE RECEPTOR, perpendicular to its axis of symmetry and grazing the part which protrudes most in the direction of the FOCAL SPOT of the X-RAY TUBE

[SOURCE: IEC TR 60788:2004, rm-32-42, modified – Words "electro-optical X-ray image intensifier" changed to "X-RAY IMAGE RECEPTOR" and "radiation source" changed to "FOCAL SPOT of the X-RAY TUBE" and definition rephrased.]

3.1.14

ESTABLISHED CRITERIA

limits, in a QUALITY ASSURANCE PROGRAMME, to acceptable variation in the results of a CONSTANCY TEST

Note 1 to entry: Values within ESTABLISHED CRITERIA are consistent with satisfactory functional performance of the equipment tested.

Note 2 to entry: ESTABLISHED CRITERIA can include target values.

[SOURCE: IEC 61223-3-6:2020, 3.1.8, modified – Definition rephrased and notes to entry added.]

3.1.15

FOCAL SPOT

EFFECTIVE FOCAL SPOT

perpendicular PROJECTION of the ACTUAL FOCAL SPOT on the REFERENCE PLANE

[SOURCE: IEC 60336:2020, 3.4]

3.1.16**FOCAL SPOT PINHOLE RADIOGRAM**

RADIOGRAM obtained by means of a PINHOLE CAMERA, showing the shape and orientation of an EFFECTIVE FOCAL SPOT, and the spatial distribution of intensity of RADIATION across it

[SOURCE: IEC 60336:2020, 3.5]

3.1.17**FOCAL SPOT SLIT RADIOGRAM**

RADIOGRAM obtained by means of a SLIT CAMERA, showing the distribution, across an EFFECTIVE FOCAL SPOT, in the direction normal to the length of the slit, of the intensity of the RADIATION emitted

[SOURCE: IEC 60336:2020, 3.6]

3.1.18**GREYSCALE STANDARD DISPLAY FUNCTION****GSDf**

mathematically defined mapping of input, DIGITAL DRIVING LEVEL (DDL) to LUMINANCE values based on the Barten model

[SOURCE: IEC 62563-1:2009, 3.1.11]

3.1.19**HIGH-VOLTAGE GENERATOR**

combination of all components, in an X-RAY GENERATOR, for control and production of the electrical energy to be supplied to an X-RAY TUBE, usually consisting of a high-voltage transformer assembly and a control assembly

[SOURCE: IEC TR 60788:2004, rm-21-01, modified – Definition rephrased]

3.1.20**IMAGE DISPLAY DEVICE**

specific hardware/medium used to display images presented through an analogue or digital interface

[SOURCE: IEC 62563-1:2009, 3.1.13]

3.1.21**IMAGE DISPLAY SYSTEM**

workstation consisting of an IMAGE DISPLAY DEVICE, display controller and computer hardware and software, capable of displaying images

[SOURCE: IEC 62563-1:2009, 3.1.14]

3.1.22**IMAGE RECEPTION PLANE**

plane containing the greatest dimensions of the IMAGE RECEPTION AREA

[SOURCE: IEC TR 60788:2004, rm-37-15]

3.1.23

INTENSIFYING SCREEN

layer of material used in DIRECT RADIOGRAPHY to convert the incident X-RADIATION or gamma RADIATION into RADIATION more suitable for the RADIATION-sensitive emulsion of the RADIOGRAPHIC FILM

[SOURCE: IEC TR 60788:2004, rm-32-38]

3.1.24

IONIZATION CHAMBER

IONIZING RADIATION detector consisting of a chamber filled with air, in which an electric field insufficient to produce gas multiplication is provided for the collection at the electrodes of charges associated with the ions and the electrons produced in the measuring volume of the detector by IONIZING RADIATION

[SOURCE: IEC 61674:2012, 3.1.1.1.1, modified – Notes to entry deleted.]

3.1.25

ISOCENTRE

centre of the smallest sphere through which the RADIATION BEAM AXIS passes, in X-RAY EQUIPMENT with several modes of movement of the REFERENCE AXIS around a common centre

[SOURCE: IEC TR 60788:2004, rm 37-32, modified – Words "radiological equipment" replaced with "X-RAY EQUIPMENT" and definition rephrased.]

3.1.26

LIGHT FIELD

area illuminated by light, being the locus of points at which the illumination exceeds a specific or specified level, simulating the RADIATION FIELD, in X-RAY EQUIPMENT

[SOURCE: IEC TR 60788:2004, rm-37-09, modified – Word "equipment" replaced with "X-RAY EQUIPMENT" and definition rephrased.]

3.1.27

LIGHT FIELD-INDICATOR

device, in X-RAY EQUIPMENT, to delineate by means of visible light the extent of the field to be irradiated

[SOURCE: IEC TR 60788:2004, rm 37-31, modified – Words "radiological equipment" replaced with "X-RAY EQUIPMENT" and definition rephrased.]

3.1.28

LINE PAIR RESOLUTION

highest SPATIAL FREQUENCY of the specified line-group TEST PATTERN imaged under specified conditions which is distinguishable in the image

Note 1 to entry: The unit is lp/mm.

Note 2 to entry: Generally, SPATIAL RESOLUTION is used for the system property, whereas the term LINE PAIR RESOLUTION is often used in relation to test methods and TEST DEVICES.

[SOURCE: IEC 61223-3-1:1999, 3.3.2, modified – Unit information moved to a new note to entry, and details given in the existing note.]

3.1.29**LOW CONTRAST RESOLUTION**

lowest contrast detail object of a specified shape and area that can be resolved from an uniform background under defined IRRADIATION conditions

[SOURCE: IEC TR 60788:2004, rm-32-56, modified – Words "under defined IRRADIATION conditions" added.]

3.1.30**LUMINANCE**

ratio of luminous flux penetrating (impinging on) a surface area in a specified direction to the product of the irradiated solid angle and the PROJECTION of the surface area onto a plane perpendicular to the viewing direction

Note 1 to entry: The unit is candela per square meter (cd/m^2)

[SOURCE: IEC 62563-1:2009, 3.1.15, modified – Note 1 to entry replaced with unit information which was in the definition.]

3.1.31**MEASUREMENT UNCERTAINTY**

non-negative parameter characterizing the dispersion of the quantity values being attributed to a measurand, based on the information used

[SOURCE: ISO/IEC Guide 99:2007, 2.26, modified – Notes to entry deleted.]

3.1.32**MODULATION TRANSFER FUNCTION**

$MTF(u, v)$

modulus of the generally complex optical transfer function, expressed as a function of SPATIAL FREQUENCIES u and v

[SOURCE: IEC 62220-1-1:2015, 3.10]

3.1.33**NOMINAL FOCAL SPOT VALUE**

dimensionless numerical value having a specific relation to the dimensions of the EFFECTIVE FOCAL SPOT of an X-RAY TUBE, measured under specific conditions

[SOURCE: IEC 60336:2020, 3.8]

3.1.34**PATIENT SUPPORT**

component such as a table top or arm rest, in X-RAY EQUIPMENT, serving to support the PATIENT in order to allow the part of his/her body which is to be irradiated to be positioned or to be displaced

[SOURCE: IEC TR 60788:2004, rm-30-02, modified – Words "radiological equipment" replaced with "X-RAY EQUIPMENT" and definition rephrased.]

3.1.35**PINHOLE CAMERA**

assembly of equipment used to obtain a FOCAL SPOT PINHOLE RADIOGRAM

[SOURCE: IEC 60336:2020, 3.9]

3.1.36

PROJECTION

transformation of a three-dimensional object into its two-dimensional image or of a two-dimensional object into its one-dimensional image, by integrating the physical property which determines the image along the direction of the projection beam

[SOURCE: IEC TR 60788:2004, rm-32-61, modified – Note deleted.]

3.1.37

QUALITY ASSURANCE

planned and systematic actions necessary to provide adequate confidence by ensuring that a product or service will satisfy given requirements for quality

[SOURCE: IEC TR 60788:2004, rm-70-05]

3.1.38

QUALITY ASSURANCE PROGRAMME

detailed instruction for carrying out actions of QUALITY ASSURANCE for individual items of equipment, systems of equipment or facilities, including quality administrative elements and QUALITY CONTROL techniques

Note 1 to entry: The QUALITY ASSURANCE PROGRAMME is broader than the QUALITY CONTROL of the X-RAY EQUIPMENT and includes for example QUALITY CONTROL of the facility and training of the personnel. The IEC 61223 series focusses only on the QUALITY CONTROL of the X-RAY EQUIPMENT.

[SOURCE: IEC 61223-3-6:2020, 3.1.14, modified – Note 1 to entry added.]

3.1.39

QUALITY CONTROL

part of the QUALITY ASSURANCE, including tests of instruments with appropriate test methods

Note 1 to entry: Includes both ACCEPTANCE TEST and CONSTANCY TEST.

[SOURCE: IEC TR 61948-3:2018, 3.11, modified – Domain <nuclear medicine> removed and “routine test” replaced with “constancy test” in Note 1 to entry.]

3.1.40

RADIOGRAM

RECORD, in RADIOLOGY, of an X-RAY PATTERN

[SOURCE: IEC TR 60788:2004, rm-32-02, Modified – definition rephrased.]

3.1.41

RADIOGRAPHIC CASSETTE

light-tight receptacle with a RADIATION-transparent front cover, intended to house one or more stationary RADIOGRAPHIC FILMS, usually with one or more INTENSIFYING SCREENS

[SOURCE: IEC TR 60788:2004, rm-35-14]

3.1.42

RADIOGRAPHIC FILM

sheet or roll material consisting of a transparent carrier covered with RADIATION-sensitive emulsion on one or usually both sides and designed for use in DIRECT RADIOGRAPHY

[SOURCE: IEC TR 60788:2004, rm-32-32]

3.1.43**READY STATE**

state of equipment in which all conditions, such as carrying out of confirming operations and any other satisfaction of interlocks are prevailing so that the intended operation of such equipment can be initiated by a single action

[SOURCE: IEC TR 60788:2004, rm-84-05]

3.1.44**REFERENCE AXIS**

<RADIATION SOURCE> line in the REFERENCE DIRECTION through the centre of the RADIATION SOURCE

[SOURCE: IEC 60336:2020, 3.10]

3.1.45**REFERENCE DIRECTION**

<RADIATION SOURCE> specified direction to which characteristics such as TARGET ANGLE, RADIATION FIELD and specifications with respect to the imaging quality of the RADIATION SOURCE are referenced

[SOURCE: IEC 60336:2020, 3.11]

3.1.46**REFERENCE PLANE**

<diagnostic X-RAY EQUIPMENT for an EFFECTIVE FOCAL SPOT> plane perpendicular to the REFERENCE DIRECTION containing the point at which the REFERENCE AXIS intersects with the ACTUAL FOCAL SPOT

Note 1 to entry: By convention, the point of intersection forms the centre of the EFFECTIVE FOCAL SPOT.

[SOURCE: IEC 60336:2020, 3.12]

3.1.47**SIMPLE CHECK**

test that can be performed routinely and uses simple means and methods to enable the early detection of changes in the functional performance of equipment

Note 1 to entry: SIMPLE CHECKS are intended to be performed by the RESPONSIBLE ORGANIZATION frequently and without any measurement instruments (e.g., DOSIMETER, LUMINANCE meter).

3.1.48**SLIT CAMERA**

assembly of equipment used to obtain a FOCAL SPOT SLIT RADIOGRAM

[SOURCE: IEC 60336:2020, 3.13]

3.1.49**SPATIAL FREQUENCY** **u or v**

inverse of the period of a repetitive spatial phenomenon

Note 1 to entry: The dimension of the SPATIAL FREQUENCY is inverse length.

[SOURCE: IEC 62220-1-1:2015, 3.17]

3.1.50

SPATIAL RESOLUTION

ability of the system to display small structures of high contrast

Note 1 to entry: SPATIAL RESOLUTION depends both on technical and observer performance.

3.1.51

SPOTFILM DEVICE

device for taking one or more RADIOGRAMS for which the choice of object and moment is made during RADIOSCOPY

Note 1 to entry: A RADIOGRAPHIC CASSETTE holder attached to a radioscopic device is not considered as a SPOTFILM DEVICE.

[SOURCE: IEC TR 60788:2004, rm-31-05]

3.1.52

SUBTRACTION IMAGING

MODE OF OPERATION to visualize differences between images or image series

Note 1 to entry: SUBTRACTION IMAGING includes DIGITAL SUBTRACTION ANGIOGRAPHY (see 3.1.9) which is a RADIOGRAPHY MODE OF OPERATION, but also includes a RADIOSCOPY MODE OF OPERATION.

3.1.53

TARGET ANGLE

acute angle between the plane of the ACTUAL FOCAL SPOT and the REFERENCE AXIS

[SOURCE: IEC TR 60788:2004, rm-20-11]

3.1.54

TEST DEVICE

specific structure, for tests requiring an X-RAY PATTERN, of one or more suitable materials to be placed in a RADIATION BEAM in order to produce such a pattern

[SOURCE: IEC TR 60788:2004, rm-71-04]

3.1.55

TEST PATTERN

image for testing or verifying the IMAGE DISPLAY SYSTEMS

[SOURCE: IEC 62563-1:2009, 3.1.21]

3.1.56

X-RAY BEAM AXIS

RADIATION BEAM AXIS

line through the centre of the RADIATION SOURCE, for a symmetrical RADIATION BEAM, and half way between the effective edges of the BEAM LIMITING DEVICE

Note 1 to entry: Usually, the RADIATION BEAM AXIS coincides within required tolerances with the REFERENCE AXIS of the RADIATION SOURCE

[SOURCE: IEC TR 60788:2004, rm-37-06, modified – Second sentence of the definition moved to a note to entry, and examples of beam axis removed as are not relevant in this document.]

3.1.57

TISSUE EQUIVALENT MATERIAL

material which absorbs and scatters a specified IONIZING RADIATION to the same degree as a particular biological tissue

[SOURCE: IEC TR 60788:2004, rm-35-16]

3.2 Symbols and abbreviated terms

Physical quantity/description	Symbol/abbreviated term	Typical unit
(REFERENCE) AIR KERMA	K	mGy
(REFERENCE) AIR KERMA RATE	$\dot{K}$	mGy/min mGy/s
AUTOMATIC EXPOSURE CONTROL	AEC	-
computed RADIOGRAPHY	CR	-
CURRENT TIME PRODUCT	Q	mAs
DIGITAL DRIVING LEVEL	DDL	-
digital RADIOGRAPHY	DR	-
DIGITAL SUBTRACTION ANGIOGRAPHY	DSA	-
DOSE AREA PRODUCT ^a	DAP/KAP/ P_{KA}	Gy·cm ² μGy·m ² cGy·cm ² mGy·cm ²
GREYSCALE STANDARD DISPLAY FUNCTION	GSDF	-
HALF-VALUE LAYER	HVL	mm Al
LINE PAIR RESOLUTION	R	lp/mm
LOADING TIME	t	s, ms
LOW CONTRAST RESOLUTION	C	%
MODULATION TRANSFER FUNCTION	MTF	-
polymethylmethacrylate	PMMA	-
X-RAY IMAGE RECEPTOR AIR KERMA (RATE)	K_B $\dot{K}_B$	mGy mGy/s
X-RAY TUBE VOLTAGE	U	kV
X-RAY TUBE CURRENT	I	mA
^a The quantity (AIR) KERMA-area product (KAP) is historically known as DOSE AREA PRODUCT (DAP). The symbol recommended in ICRU report 74 [1] ¹ is P_{KA}		

4 General aspects of ACCEPTANCE TESTING

4.1 General

Clause 4 focuses on general aspects of ACCEPTANCE TESTING. A detailed discussion on the relation between ACCEPTANCE TESTING and CONSTANCY TESTING, as part of the QUALITY ASSURANCE PROGRAM in medical imaging departments is provided in Annex A.

ACCEPTANCE TESTING shall be performed after installation of new X-RAY EQUIPMENT. Consideration shall be given to performing ACCEPTANCE TESTING upon change or after repair of the X-RAY EQUIPMENT, depending on the nature of the change or repair.

¹ Numbers in square brackets refer to the Bibliography.

4.2 Levels of requirements

4.2.1 General

The ACCEPTANCE TESTS described in this document cover a range of X-RAY EQUIPMENT. Only those test PROCEDURES relevant for the equipment under test and provided with acceptance criteria determined from 4.2.2, 4.2.3 and 4.2.4 shall be applicable.

4.2.2 Local regulatory requirements

For the RESPONSIBLE ORGANIZATION, local regulatory requirements, including test PROCEDURES and acceptance values, can apply.

4.2.3 Contractual requirements

Individual contractual requirements with the RESPONSIBLE ORGANIZATION can specify more stringent test PROCEDURES and acceptance values than items in this document.

Tests needed to verify the contractual requirements should be included in these requirements.

4.2.4 MANUFACTURER specifications

The RESPONSIBLE ORGANIZATION shall apply the acceptance values and tolerances that are provided by the MANUFACTURER in the ACCOMPANYING DOCUMENTS. Local regulatory requirements or contractual requirements can apply.

4.3 General conditions in test procedures

Prior to the ACCEPTANCE TEST, an inventory of the delivered X-RAY EQUIPMENT shall be established by the RESPONSIBLE ORGANIZATION.

The X-RAY EQUIPMENT and its components shall be unambiguously identified by the RESPONSIBLE ORGANIZATION, for example with respect to type and serial number, and checked against the order contract. The check shall also encompass ascertaining that the delivery is complete, that the ACCOMPANYING DOCUMENTS are included and that these documents relate to the equipment delivered.

Testing of IMAGE DISPLAY DEVICES that are a part of the X-RAY EQUIPMENT, used in ACCEPTANCE and CONSTANCY TESTS, is a prerequisite to perform any image quality related test specified in this document. It shall be assured that the IMAGE DISPLAY DEVICES perform as specified, for example with respect to contrast, brightness and absence of ARTEFACTS.

Non-invasive measurements are preferred for the ACCEPTANCE TEST. Whenever invasive tests are part of the programme, the equipment shall be restored to its original condition and safety confirmed after the invasive test has been completed.

Before the ACCEPTANCE TEST, the X-RAY EQUIPMENT shall be completely installed and calibrated according to the MANUFACTURER'S specifications.

4.4 Documents and data for the tests

Together with the X-RAY EQUIPMENT used for RADIOGRAPHY or RADIOSCOPY, the following documentation is required to complete the ACCEPTANCE TEST:

- list of equipment/parts of equipment ordered and actual delivery list;
- list of applicable tests and acceptance criteria according to this document as agreed upon between the RESPONSIBLE ORGANIZATION and the supplier of the equipment;

- results supplied by the MANUFACTURER from tests performed at the MANUFACTURER'S site or during installation covering items of importance to quality, such as the X-RAY TUBE CURRENT or CURRENT TIME PRODUCT and the confirmation of the FOCAL SPOT dimensions;
- ACCOMPANYING DOCUMENTS;
- reports on previous tests on the equipment where applicable;
- documentation of technical changes performed on the equipment since previous testing;
- list of agreed technical modifications between the order contract and the ACCEPTANCE TEST, if applicable.

4.5 Test conditions

Different categories of tests can be identified:

- visual inspection;
- functional tests;
- system performance tests.

The measuring arrangements which can be used for performing tests are illustrated in Figure 1 and Figure 2.

Figure 1 includes the measuring arrangement for the AIR KERMA (RATE) at the IMAGE RECEPTION PLANE and the test parameters derived from them.

Figure 2 includes the measuring arrangement to test geometry and image quality, for example LOW CONTRAST RESOLUTION, DYNAMIC RANGE or SPATIAL RESOLUTION.

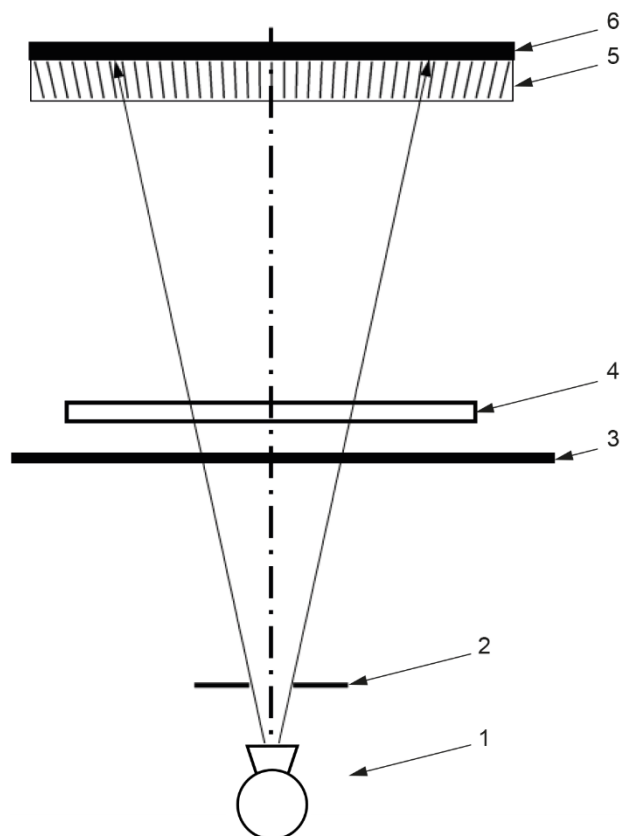
The arrangements in Figure 1 and Figure 2 are indicative only. The test can be carried out in the vertical or the horizontal position according to the MODE OF OPERATION of the equipment. The figures show an under-table X-RAY TUBE configuration by default. The PATIENT SUPPORT and PHANTOM are interchanged in an over-table configuration. Not every component in the figures is needed in every test. The QUALITY CONTROL manual of the specific equipment can provide actual details for the equipment under test, as required by IEC 60601-2-54:2022, 201.7.9.1, and IEC 60601-2-43:2022, 201.7.9.1. See also Annex G.

In the actual measuring arrangements, the effects of SCATTERED RADIATION should be considered (see also 4.7.6 c) for general aspects and the applicable subclauses in Clause 7 for specific details on the test methods).

The tests should yield information sufficient for a demonstration of performance over the range of OPERATOR accessible variables corresponding to the INTENDED USE of the equipment.

All relevant data, such as the identification of the X-RAY EQUIPMENT under test, identification of the test equipment used, geometrical set-up, operating characteristics (e.g., MODE OF OPERATION), correction factors and test results of the ASSOCIATED EQUIPMENT shall be recorded with the test results. The RECORD shall include the identification of the location, the date and the names of the persons performing the tests.

For testing purposes, a MANUFACTURER supplied QUALITY CONTROL mode can be used, as mentioned in IEC 60601-2-54:2022, 203.6.5.



IEC

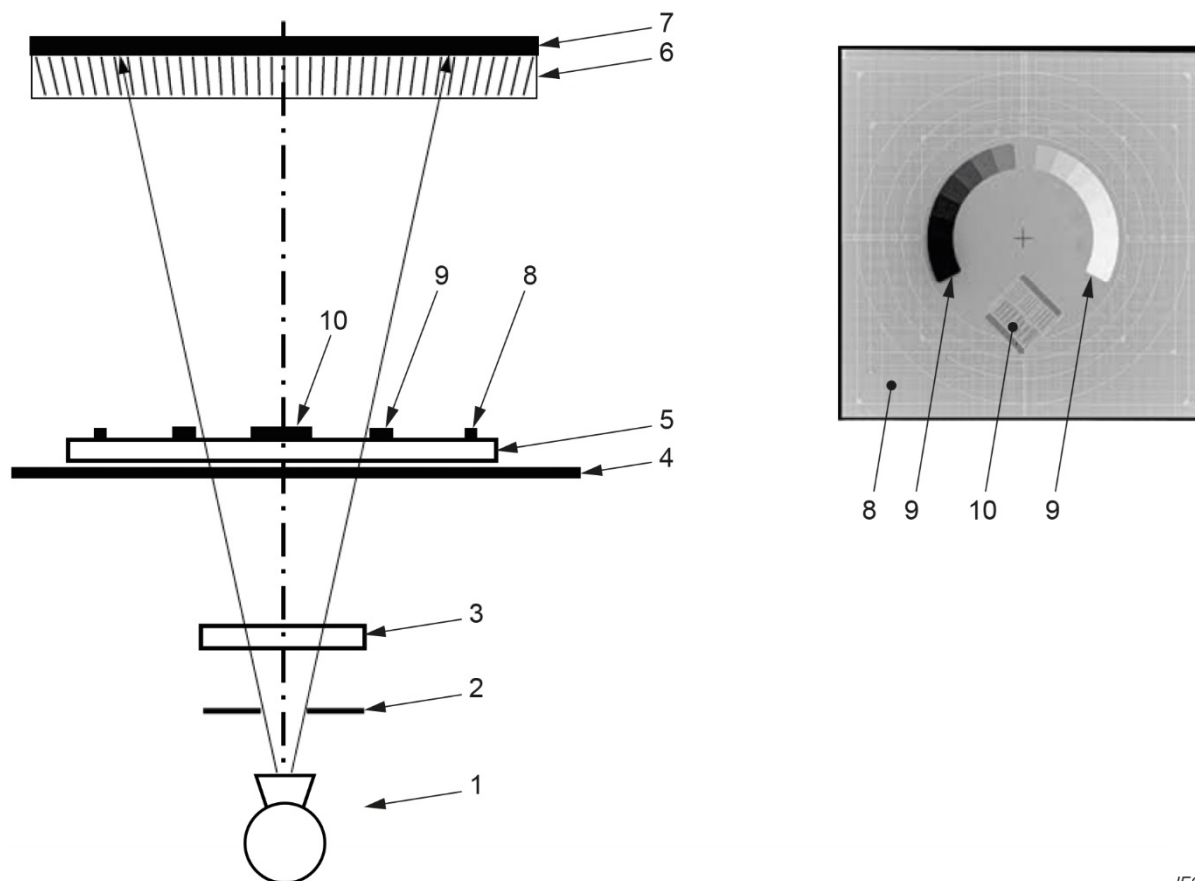
Key

- 1 X-RAY TUBE
- 2 DIAPHRAGM (BEAM LIMITING DEVICE)
- 3 PATIENT SUPPORT
- 4 additional ATTENUATION layer / PHANTOM
- 5 ANTI-SCATTER GRID
- 6 IMAGE RECEPTION PLANE (of X-RAY IMAGE RECEPTOR)

NOTE 1 The position of the detector of the DOSIMETER is not indicated in the figure, since it can be placed in multiple positions depending on the actual tests defined in Clause 7.

NOTE 2 The exact measuring arrangement can be adapted to the specific configuration under test.

Figure 1 – Indicative measuring arrangement for RADIOGRAPHY and RADIOSCOPY equipment for AIR KERMA measurements



IEC

Key

- 1 X-RAY TUBE
- 2 DIAPHRAGM (BEAM LIMITING DEVICE)
- 3 additional ATTENUATION layer / PHANTOM (e.g., 25 mm Al)
- 4 PATIENT SUPPORT
- 5 TEST DEVICE
- 6 ANTI-SCATTER GRID
- 7 IMAGE RECEPTION PLANE (of X-RAY IMAGE RECEPTOR)
- 8 markings for field geometry (LIGHT FIELD – structural elements)
- 9 contrast details (DYNAMIC RANGE and LOW CONTRAST RESOLUTION)
- 10 LINE PAIR RESOLUTION TEST DEVICE (under 45° of the X-RAY IMAGE RECEPTOR axes)

Figure 2 – Indicative measuring arrangement for RADIOGRAPHY and RADIOSCOPY equipment to test geometry and resolutions

4.6 Scope of tests

An overview of tests possible for X-RAY EQUIPMENT is given in Table 1. Tests shall be performed for each imaging chain available, where relevant. Only tests applicable to the system under test shall be performed.

If equipment can be configured by the MANUFACTURER to enable or disable specific functionality, only those functions enabled in the normal MODE OF OPERATION shall be tested. However, if changes are made to enable additional functionality, then additional tests can be necessary at that time.

4.7 Test equipment including PHANTOMS and TEST DEVICES

4.7.1 General

The measurement equipment used shall be certified as calibrated against a national or international standard where such a standard exists. The uncertainty of measuring instruments shall be suitable for the measurement. Additional discussion on uncertainty is provided in Annex H. Details on test conditions, test equipment, PHANTOMS and TEST DEVICES are discussed below.

4.7.2 Analysis software

The use of validated automated analysis software can facilitate the test PROCEDURES. For establishment of BASELINE VALUES and CONSTANCY TESTING, the same software type and version should be used consistently.

NOTE The validation of the software can be verified by the inspection of the documentation and test RECORDS provided by the supplier of this software.

4.7.3 Viewing conditions

The ambient lighting in the room shall be maintained at clinically used conditions unless permitted otherwise in the QUALITY CONTROL manual. Room lights, windows, viewing devices etc. shall not cause any disturbing reflections on the IMAGE DISPLAY DEVICE. If, due to visual impairment, the tester shall to use optical devices, then the appropriate devices shall be used, particularly for evaluating of images on the IMAGE DISPLAY DEVICE.

The IMAGE DISPLAY DEVICE controls that can be modified by the OPERATOR (e.g. brightness, contrast, window width and window levels), shall be set according to the instructions in the ACCOMPANYING DOCUMENTS.

4.7.4 High-voltage measuring instrument

The high-voltage measuring instrument shall determine the X-RAY TUBE VOLTAGE within the specified range. Instruments complying with IEC 61676:2023 shall be used. The overall MEASUREMENT UNCERTAINTY for non-invasive measurement instruments shall be less than $\pm 2\%$ or ± 1 kV, whichever is larger. Additional discussion on uncertainty is provided in Annex H.

4.7.5 DOSIMETER

The DOSIMETER used to test the equipment according to this document shall have a range sufficient to measure the AIR KERMA (RATE) within the required accuracy for the system under test and shall be calibrated for the applied RADIATION QUALITY. The DOSIMETER shall conform to IEC 61674:2012. Additional discussion on uncertainty is provided in Annex H.

Legal regulations requiring the use of other dosimetric quantities can apply.

If the DOSIMETER does not have a negligible ATTENUATION, the DOSIMETER should be placed outside the sensitive area of the imaging surface used for the AUTOMATIC CONTROL SYSTEM. For systems where the whole imaging area is used as a sensitive area, the DOSIMETER can influence the results. Always follow the MANUFACTURER guidance, if available.

4.7.6 PHANTOMS, TEST DEVICES and their application

PHANTOMS and TEST DEVICES can consist of attenuating material (PHANTOM part of the object) and/or structural elements (TEST DEVICE part of the object) that can be arranged in combination or separately.

The following applies.

a) External dimensions

ATTENUATION layer dimensions should be at least large enough to intercept the entire RADIATION BEAM for all test conditions applicable; see Figure 1 and Figure 2.

b) ATTENUATION layers

For tests that determine HALF-VALUE LAYER or TOTAL FILTRATION, calibrated thicknesses of aluminium ATTENUATION layers are required. For these tests, the required purity of aluminium shall be 99,9 % or higher.

For all test procedures requiring some form of ATTENUATION layer, the attenuating material to be used should consist of either one of the following.

- Aluminium with a thickness of up to 25 mm (or more if required by local regulations, for example [2]) with a purity of at least 99,5 %. Some tests will require an additional homogeneous ATTENUATION layer of up to 1,5 mm Cu.
- Copper with a thickness of up to 3 mm.
- Low atomic number material (for example polymethyl-methacrylate (PMMA), TISSUE EQUIVALENT MATERIAL or water). Typical thickness will include for example 10 cm, 15 cm or 20 cm.

For some tests, lead (Pb) layers of between 1 mm and 2 mm, or equivalent high atomic number attenuating materials, are required to protect the detector from unattenuated primary RADIATION.

NOTE 1 The required purity of aluminium in this document for tests other than HALF-VALUE LAYER or TOTAL FILTRATION differs from IEC 60601-1-3:2008, IEC 60601-1-3:2008/AMD1:2013 and IEC 60601-1-3:2008/AMD2:2021 and IEC 61267:2005 where 99,9 % is used. This is to keep the cost of test objects for the RESPONSIBLE ORGANIZATION low without a significant impact on reproducibility and accuracy [3][1].

If PMMA is used for TEST DEVICES or PHANTOMS, the density shall be 1,18 g/cm³, with a relative tolerance of ± 5 %.

NOTE 2 A standard RADIATION QUALITY, such as RQA 5 (IEC 61267:2005), can be specified. If other thicknesses and combinations of ATTENUATION layers are specified, consideration can be given to the thicknesses required to ensure users can easily obtain such thicknesses without excessive cost.

c) Effects of SCATTERED RADIATION with various measuring arrangements

Tests should be designed such that they either minimise the effect of SCATTERED RADIATION or they utilise scatter to reflect the clinical situation.

For measuring arrangements that minimise SCATTERED RADIATION, the test geometry should pay attention to issues such as NARROW BEAM GEOMETRY, distance between ATTENUATION layers and measuring devices or image quality test objects to minimise the effects of SCATTERED RADIATION reaching the measuring device or DOSIMETER.

For tests utilising SCATTERED RADIATION to reflect the clinical situation, the measurement geometry should be repeatable as SCATTERED RADIATION is strongly dependent upon factors such as limitation of the RADIATION BEAM, FOCAL SPOT to object distance and object to detector distance. Measures such as insisting BEAM LIMITING DEVICE are fully open can reduce variability in set-up.

d) Beam limiting TEST DEVICE

The beam limiting TEST DEVICE should comprise structural elements for testing the centring, limitation and indication of the extent of the X-RAY BEAM as marking elements and a matrix with intervals of 1 cm made of RADIATION absorbing material. Alternatively lead rulers can be used to evaluate the beam limitation.

The design of the TEST DEVICE should be of such material and arranged in such a way that possible interactions with the function of the AUTOMATIC CONTROL SYSTEM are minimized.

e) LINE PAIR RESOLUTION TEST DEVICE

The TEST DEVICE should comprise line-group TEST PATTERNS with a thickness of, for example, 0,05 mm Pb and test groups with SPATIAL FREQUENCIES of 0,6 lp/mm to 5,0 lp/mm. The steps between the groups should not exceed 20 %. The outer dimensions are for example 50 mm by 50 mm; see Figure 3.

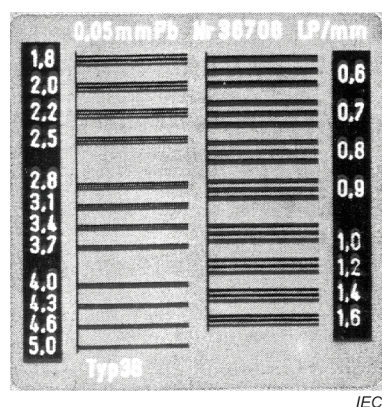
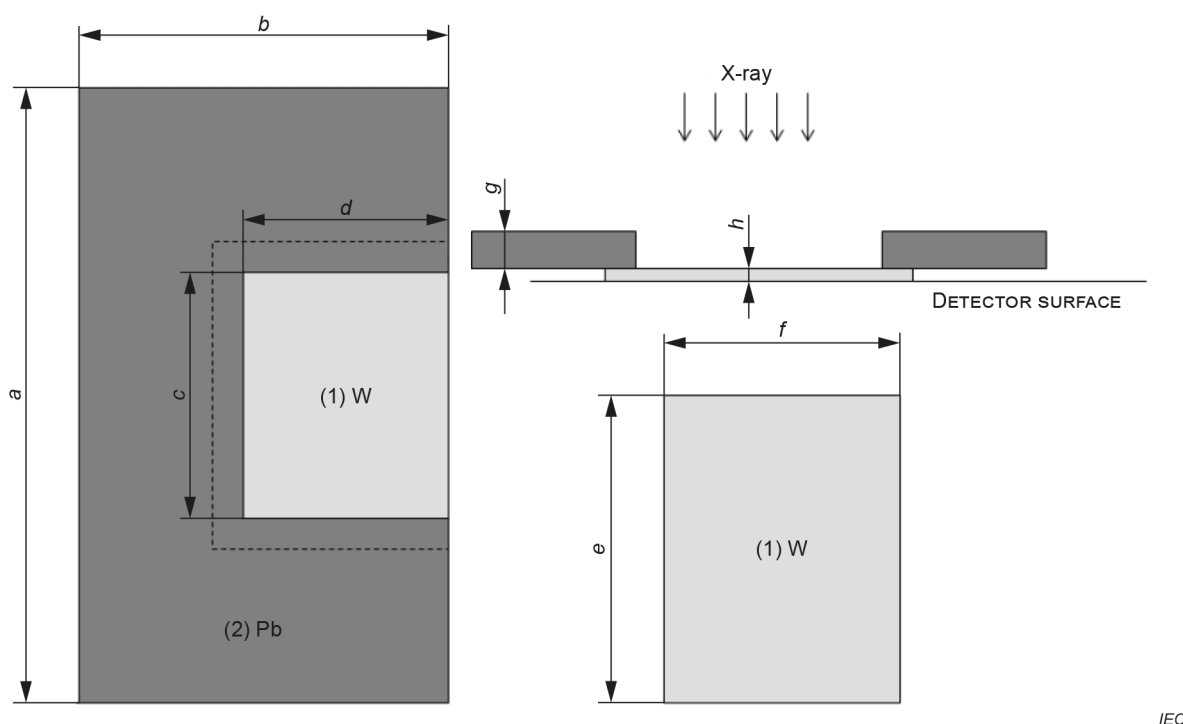


Figure 3 – Example of a LINE PAIR RESOLUTION TEST DEVICE

f) MODULATION TRANSFER FUNCTION TEST DEVICE

For a MODULATION TRANSFER FUNCTION TEST DEVICE, the device as described in IEC 62220-1-1:2015, 4.4, can be used (see Figure 4). The tungsten plate is used as an edge TEST DEVICE. Therefore, the edge which is used for the test IRRADIATION should be carefully polished straight and at 90° to the plate. This arrangement is suitable to measure the MODULATION TRANSFER FUNCTION of the X-RAY EQUIPMENT in one direction.



The TEST DEVICE consists of a tungsten plate (1) fixed on a lead plate (2). Dimension of the lead plate: a: 200 mm, b: 100 mm, c: 90 mm, d: 70 mm, g: 3 mm. Dimension of the tungsten plate: e: 100 mm, f: 75 mm, h: 1 mm.

Figure 4 – MODULATION TRANSFER FUNCTION TEST DEVICE

For more characteristics of the TEST DEVICE, see IEC 62220-1-1:2015. Alternatively, an absorbing metal plate (e.g., 1,5 mm copper (Cu) [4]), can be used, as long as the edge of the plate is carefully polished straight and at 90° to the plate.

g) LOW CONTRAST RESOLUTION TEST DEVICE

There are many devices available to measure the LOW CONTRAST RESOLUTION. If this parameter is measured, the results should be recorded together with the description of the TEST DEVICE used.

The contrast detail diameters should be such that their resolution is neither enhanced nor degraded by the frequency response of the X-RAY EQUIPMENT. For examples, see Annex D.

h) DSA PHANTOM

A DSA PHANTOM incorporates two test functions.

- Step wedge to test DSA DYNAMIC RANGE

Generally, a DSA PHANTOM has a number of steps of equal thickness of material, to cover the DYNAMIC RANGE using an X-RAY TUBE VOLTAGE typical for the INTENDED USE of the X-RAY EQUIPMENT, for example, 70 kV.

- Vascular simulation pattern

The PHANTOM generally contains test objects to simulate the presence of contrast media in blood vessels. The test objects should be sufficiently large so that their detectability is not significantly influenced by the SPATIAL RESOLUTION.

Examples of suitable DSA PHANTOMS are shown in Annex E.

4.8 Evaluating the test results

Whenever specified limiting values or tolerances are exceeded, verify the results by making at least two additional measurements.

In the evaluation of the results, the RESPONSIBLE ORGANIZATION shall

- take the acceptance criteria provided by the MANUFACTURER into account, if provided, and
- determine how the uncertainty in the measurement shall be taken into consideration.

Additional discussion on uncertainty is provided in Annex H.

5 Specific aspects of CONSTANCY TESTING

5.1 General

General aspects of ACCEPTANCE TESTING, as described in Clause 4, are also applicable to CONSTANCY TESTING. A detailed discussion on the relation between ACCEPTANCE TESTING and CONSTANCY TESTING is provided in Annex A.

5.2 Establishment of BASELINE VALUES

For those parameters subject to CONSTANCY TESTING, the initial BASELINE VALUES shall be established when the ACCEPTANCE TEST is done. The same test equipment and PROCEDURES as used to establish the BASELINE VALUES should be used for the CONSTANCY TEST.

When utilizing test equipment and/or PROCEDURES which are different, the RESPONSIBLE ORGANIZATION shall validate them against the test equipment and PROCEDURES specified for ACCEPTANCE TESTING.

New BASELINE VALUES shall be established, or existing BASELINE VALUES reviewed, when

- a) the new X-RAY EQUIPMENT is brought into use, or
- b) any component relevant to imaging performance of the X-RAY EQUIPMENT or its ACCESSORIES is exchanged or repaired, or
- c) test equipment is changed that can cause a variation.

In case a), ACCEPTANCE TESTING shall be performed. In case b), it shall be considered to perform relevant ACCEPTANCE TESTING, based on the nature of the change.

Examples of system changes and relevant ACCEPTANCE TESTS that can be performed upon system changes can be found in Annex J.

NOTE Software can be regarded as a component that is relevant to imaging performance, but the actual change of the software determines whether new BASELINE VALUES need to be established and for which tests. This can be determined from the notification of the MANUFACTURER.

5.3 CONSTANCY TESTING and SIMPLE CHECKS

CONSTANCY TESTING requires dedicated measurement equipment, for example LUMINANCE measurement of an IMAGE DISPLAY DEVICE. SIMPLE CHECKS require only simple methods and tools, for example visual check using a TEST PATTERN on an IMAGE DISPLAY DEVICE. SIMPLE CHECKS are designed to be performed more frequently than CONSTANCY TESTS and in an economical way.

CONSTANCY TESTS and SIMPLE CHECKS are intended to be performed by or under the responsibility of the RESPONSIBLE ORGANIZATION.

In practice, SIMPLE CHECKS can include for example DICOM parameters (such as kV, mA, dose, etc.) that can be tracked over time using a known PHANTOM or attenuator and known LOADING FACTORS. Additional information is provided in Annex I.

NOTE An example of a methodology for SIMPLE CHECKS is used in the Netherlands (QC-light protocol) [5].

If there is a difference in the setup used for SIMPLE CHECKS compared with the setup used for CONSTANCY TESTING, then separate BASELINE VALUES shall be established.

5.4 Frequency of CONSTANCY TESTS

The CONSTANCY TESTS shall be repeated as prescribed in the individual test methods (refer to Table 1).

In addition, the appropriate tests should be performed

- a) whenever malfunction is suspected, or
- b) immediately after the X-RAY EQUIPMENT has undergone maintenance that could affect the performance parameter under test.

6 Summary of tests for X-RAY EQUIPMENT

Table 1 lists the parameters to be evaluated by the RESPONSIBLE ORGANIZATION and the recommended frequencies of evaluation. Only tests applicable to the system under test shall be performed.

The actual frequency of evaluation depends on local regulations and/or MANUFACTURER specifications. MANUFACTURERS can specify increased or reduced frequencies. Depending on the INTENDED USE of the X-RAY EQUIPMENT, the RESPONSIBLE ORGANIZATION can apply higher evaluation frequencies, for example for INTERVENTIONAL X-RAY EQUIPMENT.

NOTE All applicable evaluations below can be included as ACCEPTANCE TESTS. CONSTANCY TESTS can include all, a part of, or modified test methods described in Clause 7.

Table 1 – QUALITY CONTROL tests and recommended frequencies

Subcl. No.	Test	Recommended frequency for CONSTANCY TEST	
		RADIOGRAPHY MODE OF OPERATION	RADIOSCOPY MODE OF OPERATION
7.2	Functional properties	Annually	Annually
7.3	Image display device performance	Annually / Semi-annually ^a	Annually ^a
7.4	X-RAY TUBE VOLTAGE	Annually	Annually
7.5	X-RAY TUBE CURRENT or CURRENT TIME PRODUCT	Annually	Annually
7.6	HALF-VALUE LAYER of the X-RAY SOURCE ASSEMBLY	ACCEPTANCE TEST only	ACCEPTANCE TEST only
7.7	* QUALITY equivalent FILTRATION OF ADDED filters	Annually	Annually
7.8	* ATTENUATION EQUIVALENT of materials between the PATIENT and the X-RAY IMAGE RECEPTOR	ACCEPTANCE TEST only	ACCEPTANCE TEST only
7.9	FOCAL SPOT of the X-RAY TUBE	ACCEPTANCE TEST only	ACCEPTANCE TEST only
7.10	Assessing geometrical properties of the X-RAY EQUIPMENT	ACCEPTANCE TEST only	ACCEPTANCE TEST only
7.11	AUTOMATIC CONTROL SYSTEM – Performance	Annually	Annually
7.12	AUTOMATIC CONTROL SYSTEM – Reproducibility	Annually	Annually
7.13	* AUTOMATIC CONTROL SYSTEM – NOMINAL SHORTEST IRRADIATION TIME	ACCEPTANCE TEST only	Not applicable
7.14	Correspondence between the X-RAY FIELD and EFFECTIVE IMAGE RECEPTION AREA	Annually	Annually
7.15	Accuracy of indication of the LIGHT FIELD-INDICATOR	Annually	Annually
7.16	Accuracy of marked and written indications of the X-RAY FIELD size	ACCEPTANCE TEST only	ACCEPTANCE TEST only
7.17	AIR KERMA RATE at the ENTRANCE PLANE of the X-RAY IMAGE RECEPTOR for RADIOSCOPY	Not applicable	Annually
7.18	REFERENCE AIR KERMA RATE for RADIOSCOPY	Not applicable	Annually
7.19	AIR KERMA at the ENTRANCE PLANE of the X-RAY IMAGE RECEPTOR for RADIOGRAPHY	Annually	Not applicable
7.20	REFERENCE AIR KERMA for SERIAL RADIOGRAPHY	Annually	Not applicable
7.21	Limitation of the REFERENCE AIR KERMA RATE in RADIOSCOPY	Not applicable	Annually
7.22	SPATIAL RESOLUTION for RADIOSCOPY and RADIOGRAPHY	Annually	Annually
7.23	LOW CONTRAST RESOLUTION for RADIOSCOPY and RADIOGRAPHY	Annually	Annually
7.24	DYNAMIC RANGE for RADIOSCOPY and RADIOGRAPHY	ACCEPTANCE TEST only	ACCEPTANCE TEST only
7.25	DOSE AREA PRODUCT and REFERENCE AIR KERMA (RATE) indicator	Annually	Annually
7.26	Back-up timer and safety measures	Annually	Not applicable
7.27	ARTEFACTS	Annually	Annually
7.28	Accuracy of image measuring functions	ACCEPTANCE TEST only	ACCEPTANCE TEST only
7.29	DYNAMIC RANGE for SUBTRACTION IMAGING	ACCEPTANCE TEST only	ACCEPTANCE TEST only
7.30	Contrast sensitivity for SUBTRACTION IMAGING	ACCEPTANCE TEST only	ACCEPTANCE TEST only
7.31	SPATIAL RESOLUTION for SUBTRACTION IMAGING	ACCEPTANCE TEST only	ACCEPTANCE TEST only
7.32	ARTEFACTS in SUBTRACTION IMAGING	ACCEPTANCE TEST only	ACCEPTANCE TEST only

Subcl. No.	Test	Recommended frequency for CONSTANCY TEST	
		RADIOGRAPHY MODE OF OPERATION	RADIOSCOPY MODE OF OPERATION
7.33	X-RAY IMAGE RECEPTOR EXPOSURE INDEX	Annually	Not applicable
7.34	Leakage radiation	ACCEPTANCE TEST only	ACCEPTANCE TEST only
^a Depending on the classification of the monitor as specified in IEC 62563-2:2021, Clause 5, the monitor shall be tested annually or semi-annually as specified in IEC 62563-2:2021, 7.2. NOTE With the term "annually", it is meant that the test is performed at least within 13 months of the previous test.			

7 Requirements and test methods

7.1 General

Clause 7 describes evaluation methods for the parameters indicated in Table 1. MANUFACTURERS can define alternative methods after evaluation of the equivalence of the test method. The RESPONSIBLE ORGANIZATION can use the alternative methods provided that they adequately evaluate the intended system parameter(s). Likewise, evaluations can be combined if the MANUFACTURER or others provide the hardware and/or software required to perform the combined evaluations (e.g., a MANUFACTURER can provide a PHANTOM that tests several required parameters in one image acquisition).

NOTE 1 Requirements for the availability of tools which are needed for the test are described in IEC 60601-2-54:2022, 201.7.9.1.

Additionally, MANUFACTURERS can provide information in the QUALITY CONTROL manual indicating the recommended ACCEPTANCE TESTS to perform after a major repair or major upgrade (hardware or software) as appropriate to ensure the safe and effective use of the equipment.

MANUFACTURERS can define alternative SIMPLE CHECKS and their associated tolerances that are deemed necessary for the safe and effective use of the X-RAY EQUIPMENT. Examples of such SIMPLE CHECKS that MANUFACTURERS can consider are provided in Annex I. If the result of a SIMPLE CHECK repeatedly breaches tolerance levels, repeats of CONSTANCY TESTS can be needed.

It is assumed that, prior to performing the ACCEPTANCE TEST, the RESPONSIBLE ORGANIZATION has performed the following:

- inventory of equipment under test, for example, catalogue number, software version, serial number;

NOTE 2 This includes availability and proper setup of PROTECTIVE DEVICES supplied or installed by the MANUFACTURER.

- check on the presence of all documents according to 4.4;
- review of the ACCOMPANYING DOCUMENTS.

7.2 Functional properties

7.2.1 Test requirements

As required in IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, the ACCOMPANYING DOCUMENTS describe how the X-RAY EQUIPMENT under test shall be operated. Depending on the type of equipment, the following shall apply:

- markings shall conform to the MANUFACTURER specifications,
- control elements shall function as specified by the MANUFACTURER,
- mechanical movements and interlocks shall function as specified by the MANUFACTURER,
- the system shall be installed with mechanical integrity,
- electronic documentation of EXAMINATION PROTOCOLS shall be available.

7.2.2 Test method for ACCEPTANCE TEST

These tests are performed by visual inspection and functional test. Depending on the type of equipment, they comprise of:

- *visual inspection of the markings on the X-RAY EQUIPMENT, for example, FOCAL SPOT size, warning signs;*
- *visual inspection and functional test of the control elements, for example, functional evaluation of all controls (buttons, switches, tableside controls, etc...), indication of the LOADING STATE, indication of the READY STATE, emergency power off switches;*
- *functional test of the mechanical movements and interlocks, for example, locking mechanisms, detents, PATIENT SUPPORT handling and locking, overrides as applicable, collision sensors functionality;*
- *visual and functional test of the mechanical integrity of the X-RAY EQUIPMENT, for example, mechanical motions of the C-arm (both driven and freely moving), PATIENT SUPPORT, suspension for IMAGE DISPLAY DEVICE, and any other ceiling mounted devices that can interfere with the clinical use of the X-RAY EQUIPMENT;*
- *inspection of the electronic documentation of the PRE-PROGRAMMED EXAMINATION PROTOCOLS for X-RAY EQUIPMENT that includes an EXAMINATION PROTOCOL SELECTION CONTROL. See Annex C for a detailed discussion on assessing clinical protocol performance.*

7.2.3 Test method for CONSTANCY TEST

A modified or reduced set of evaluations can be recommended for CONSTANCY TESTING and should be limited to elements needed to ensure the safe and effective operation of the imaging equipment. It is possible that not all elements of 7.2.2 can be included as part of the test method for CONSTANCY TESTING and for others a higher frequency than specified in Table 1 can be appropriate.

7.3 IMAGE DISPLAY DEVICE performance

7.3.1 Test requirements

Before performing any image quality test, it shall be assured that the IMAGE DISPLAY DEVICE performance is within the specified tolerances. Tests only apply to IMAGE DISPLAY DEVICES that are part of the X-RAY EQUIPMENT and used for diagnostic and/or interventional procedures.

7.3.2 Test method for ACCEPTANCE TEST

IEC 62563-1:2009, IEC 62563-1:2009/AMD1:2016 and IEC 62563-1:2009/AMD2:2021 describe various evaluation methods without dictating what particular tests shall be used for ACCEPTANCE and/or CONSTANCY TESTS. It is intended as a reference to other standards and guidelines to provide evaluation methods and to mention limiting values and frequencies for ACCEPTANCE and CONSTANCY TESTS.

Furthermore IEC 62563-1:2009, 6.4, provides examples of TEST PATTERNS. A subset of these examples or elements from these examples should be used to form composite TEST PATTERNS depending on the INTENDED USE of each modality being tested.

Practical tests, performance criteria for ACCEPTANCE TESTING of IMAGE DISPLAY DEVICES are given in IEC 62563-2:2021 that defines application categories of IMAGE DISPLAY DEVICE(S), based on display resolution and GSDF LUMINANCE response. To select the appropriate category, the ACCOMPANYING DOCUMENTS of the X-RAY EQUIPMENT shall be consulted.

Check the performance results with the specified tolerances. Examples of appropriate tests are:

- minimum and maximum LUMINANCE;
- minimum LUMINANCE ratio;
- LUMINANCE uniformity;
- chromaticity uniformity;
- ARTEFACTS in the IMAGE DISPLAY DEVICE;
- TEST PATTERN evaluation (SPATIAL RESOLUTION, LOW CONTRAST RESOLUTION, etc.).

For large IMAGE DISPLAY DEVICES which incorporate configurable view ports, check the QUALITY CONTROL manual whether a specific pixel matrix size is recommended for testing.

7.3.3 Test method for CONSTANCY TEST

Performance criteria for CONSTANCY TESTING of IMAGE DISPLAY DEVICES are given in IEC 62563-2:2021.

7.4 X-RAY TUBE VOLTAGE

7.4.1 Test requirements

The MEASURED VALUES of the X-RAY TUBE VOLTAGE shall agree with the values indicated at the CONTROL PANEL within the specified tolerances.

7.4.2 Test method for ACCEPTANCE TEST

For systems where the X-RAY TUBE VOLTAGE can be manually set by the OPERATOR (including those systems having a QUALITY CONTROL mode per IEC 60601-2-54:2022, 203.6.5, or IEC 60601-2-43:2022, 203.6.5), the requested X-RAY TUBE VOLTAGES shall be set. In this case the measurements should be carried out using the arrangement in Figure 1 without the ATTENUATION layer. Adequate protection of the X-RAY IMAGE RECEPTOR should be provided.

For systems with only an AUTOMATIC CONTROL SYSTEM, where the X-RAY TUBE VOLTAGE cannot be manually set by the OPERATOR, the X-RAY TUBE VOLTAGE can be influenced by varying the thickness of the ATTENUATION layer placed between the high-voltage measuring instrument and the X-RAY IMAGE RECEPTOR, according to the arrangement in Figure 1. The values of the LOADING FACTORS which are controlled by the AUTOMATIC CONTROL SYSTEM are recorded.

NOTE 1 For systems with only an AUTOMATIC CONTROL SYSTEM, the RADIATION QUALITY of the X-RAY BEAM can vary by adding or removing one or more ADDED FILTERS. If this is the case, this can be specified by the MANUFACTURER, so that test instrument readings can be correctly interpreted.

Place the detector of the high-voltage measuring instrument in the X-RAY BEAM and measure the X-RAY TUBE VOLTAGE. At least three standard X-RAY TUBE VOLTAGE measurements shall be performed to span approximately equally the X-RAY TUBE VOLTAGE range.

NOTE 2 The choice of LOADING FACTORS can be made considering the nature of the equipment under test and its clinical application, so as to explore enough of the X-RAY TUBE VOLTAGE/LOADING TIME/X-RAY TUBE CURRENT relationship to establish the conformance of the equipment to its specification and the needs of the user.

The maximum ratings of the X-RAY TUBE ASSEMBLY shall not be exceeded.

NOTE 3 Most radioscopic systems with X-RAY IMAGE RECEPTOR systems are equipped with an AUTOMATIC CONTROL SYSTEM. This control system consists of a kV or mA control or a combined kV/mA control. Generally, separate measurement of the individual LOADING FACTORS is only possible with invasive measurements, or, if available, with a MANUFACTURER supplied QUALITY CONTROL mode that supports such functionality.

Compare the MEASURED VALUES of the X-RAY TUBE VOLTAGE with the values indicated at the CONTROL PANEL and the specified tolerances.

7.4.3 Test method for CONSTANCY TEST

The same test method as used for ACCEPTANCE TESTING should also be used for CONSTANCY TESTING.

7.5 X-RAY TUBE CURRENT OR CURRENT TIME PRODUCT

7.5.1 Test requirements

The X-RAY TUBE CURRENT OR CURRENT TIME PRODUCT shall agree with the values indicated at the CONTROL PANEL within the specified tolerances.

7.5.2 Test method for ACCEPTANCE TEST

In most systems the X-RAY TUBE CURRENT and the CURRENT TIME PRODUCT can only be directly measured by invasive methods. Therefore, this test can only be performed by the MANUFACTURER or its representative as an on-site test. The results from the on-site test shall be compared with MANUFACTURER'S specified values and tolerances in the ACCOMPANYING DOCUMENTS.

However, if the high voltage cables are accessible without the use of tools, the X-RAY TUBE CURRENT or the CURRENT TIME PRODUCT can be measured directly.

Generally, the X-RAY TUBE CURRENT should be measured at least at one value in the lower range, the typical range and the upper range, respectively.

7.5.3 Test method for CONSTANCY TEST

CONSTANCY TESTS can use linearity of dose rate with the nominal value of X-RAY TUBE CURRENT or linearity of dose with the nominal value of CURRENT TIME PRODUCT as an alternative for X-RAY TUBE CURRENT accuracy.

Alternatively, the same test method as used for ACCEPTANCE TESTING can also be used for CONSTANCY TESTING.

7.6 HALF-VALUE LAYER of the X-RAY SOURCE ASSEMBLY

7.6.1 Test requirements

The HALF-VALUE LAYER of the X-RAY SOURCE ASSEMBLY shall be as specified.

7.6.2 Test method for ACCEPTANCE TEST

Initially, compliance with the specification is checked by inspection of the markings on the X-RAY EQUIPMENT and by examination of the ACCOMPANYING DOCUMENTS.

Measurement can conveniently be performed for systems where the LOADING FACTORS can be set by the OPERATOR. Use the arrangement in Figure 1, without the ATTENUATION layer. Adequate protection of the X-RAY IMAGE RECEPTOR should be provided. Use a DOSIMETER to evaluate the AIR KERMA at a fixed distance from the X-RAY TUBE. Perform a measurement at a fixed X-RAY TUBE VOLTAGE, for example 100 kV, and with ADDED FILTERS as specified. Add ATTENUATION layers of aluminium to reach half of the initial AIR KERMA measured. The resulting total thickness of the ATTENUATION layers added is the HALF-VALUE LAYER thickness. Alternatively, direct measurement of HALF-VALUE LAYER can be performed with the use of a suitable measuring instrument.

Compare the MEASURED VALUES with the specified values under the specified conditions.

7.6.3 Test method for CONSTANCY TEST

CONSTANCY TESTING should not include assessment of HALF-VALUE LAYER.

7.7 * QUALITY EQUIVALENT FILTRATION of ADDED FILTERS

7.7.1 Test requirements

The QUALITY EQUIVALENT FILTRATION of ADDED FILTERS shall be as specified.

7.7.2 * Test method for ACCEPTANCE TEST

The test is performed by an inspection of the ACCOMPANYING DOCUMENTS.

Generally, testing of the QUALITY EQUIVALENT FILTRATION of ADDED FILTERS is a type test that will be performed by or under supervision of the MANUFACTURER or its representative.

7.7.3 Test method for CONSTANCY TEST

CONSTANCY TESTING should not include assessment of QUALITY EQUIVALENT FILTRATION of ADDED FILTERS. If the ADDED FILTERS are controllable by the OPERATOR, the following test can be used to check the presence and/or performance of the filters.

Align the X-RAY SOURCE ASSEMBLY, the DIAPHRAGM and the DOSIMETER under NARROW BEAM CONDITION. Use an ATTENUATION layer of appropriate thickness to realise an X-RAY TUBE VOLTAGE representative of the specified INTENDED USE. Measure the dose with and without ADDED FILTERS.

Alternatively, use the test conditions specified by the MANUFACTURER.

7.8 * ATTENUATION EQUIVALENT of materials between the PATIENT and the X-RAY IMAGE RECEPTOR

7.8.1 Test requirements

The ATTENUATION EQUIVALENT of components that are part of the X-RAY EQUIPMENT and located in the path of the X-RAY BEAM between the PATIENT and the X-RAY IMAGE RECEPTOR shall comply with the requirements of IEC 60601-1-3:2008, IEC 60601-1-3:2008/AMD1:2013 and IEC 60601-1-3:2008/AMD2:2021. The ACCOMPANYING DOCUMENTS shall specify the maximum value of ATTENUATION EQUIVALENT according to the requirements stated in IEC 60601-2-54:2022 or IEC 60601-2-43:2022, as applicable.

7.8.2 * Test method for ACCEPTANCE TEST

The test is performed by an inspection of the ACCOMPANYING DOCUMENTS.

Generally, testing of the ATTENUATION EQUIVALENT is a type test that will be performed by or under supervision of the MANUFACTURER or its representative.

7.8.3 Test method for CONSTANCY TEST

CONSTANCY TESTING should not include assessment of ATTENUATION EQUIVALENT.

7.9 FOCAL SPOT of the X-RAY TUBE

7.9.1 Test requirements

The NOMINAL FOCAL SPOT VALUES as determined according to IEC 60336:2020 shall be as specified in the ACCOMPANYING DOCUMENTS.

7.9.2 Test method for ACCEPTANCE TEST

The compliance of the FOCAL SPOT dimensions for the stated NOMINAL FOCAL SPOT VALUES with IEC 60336:2020 shall be confirmed by the MANUFACTURER.

NOTE FOCAL SPOT measuring PROCEDURES by SLIT CAMERA, PINHOLE CAMERA, star pattern evaluation and Fourier transform of images of TEST DEVICES all give different results concerning size and resolution. The standard FOCAL SPOT measurement is specified according to IEC 60336:2020 by SLIT CAMERA under specified PROJECTION conditions and operating conditions.

7.9.3 Test method for CONSTANCY TEST

This test should not be included in CONSTANCY TESTING.

NOTE Other indirect tests such as system SPATIAL RESOLUTION (see 7.22) exist, are more practical and provide sufficient information.

7.10 Assessing geometrical properties of the X-RAY EQUIPMENT

7.10.1 Test requirements

The following distances shall be according to MANUFACTURER specification and tolerances:

- location of
 - FOCAL SPOT,
 - ISOCENTRE, and
 - PATIENT ENTRANCE REFERENCE POINT;
- FOCAL SPOT TO IMAGE RECEPTOR DISTANCE;
- rotation and angulation indicators.

7.10.2 Test method for ACCEPTANCE TEST

Compliance is checked by inspection of markings and functional tests, by examination of the ACCOMPANYING DOCUMENTS.

7.10.3 Test method for CONSTANCY TEST

This test should not be included in CONSTANCY TESTING.

7.11 AUTOMATIC CONTROL SYSTEM — Performance

7.11.1 Test requirements

The AUTOMATIC CONTROL SYSTEM shall function as specified. The functionality could be demonstrated, for example, by providing graphs or diagrams showing how X-RAY TUBE VOLTAGE, X-RAY TUBE CURRENT and FILTRATION vary with the ATTENUATION of a PHANTOM.

7.11.2 * Test method for ACCEPTANCE TEST

Use the PROCEDURE specified by the MANUFACTURER for testing the AUTOMATIC CONTROL SYSTEM function.

Check that the AUTOMATIC CONTROL SYSTEM functions correctly according to the MANUFACTURER specifications for a representative set of selectable parameters as recommended by the MANUFACTURER.

7.11.3 * Test method for CONSTANCY TEST

A substantially reduced subset of the test method of 7.11.2 can be incorporated into CONSTANCY TESTING.

7.12 AUTOMATIC CONTROL SYSTEM — Reproducibility

7.12.1 Test requirements

In the operation of an AUTOMATIC CONTROL SYSTEM the reproducibility shall be as specified in the ACCOMPANYING DOCUMENTS of the MANUFACTURER.

7.12.2 Test method for ACCEPTANCE TEST

Align the X-RAY SOURCE ASSEMBLY, the DIAPHRAGM and the DOSIMETER under NARROW BEAM CONDITION. Use an ATTENUATION layer of appropriate thickness to realise an X-RAY TUBE VOLTAGE representative of the specified INTENDED USE.

For RADIOGRAPHY and/or RADIOSCOPY, make 10 measurements of AIR KERMA (RATE) in one hour. Calculate the ratio between the highest and the lowest MEASURED VALUES of AIR KERMA (RATE).

NOTE A complete set of test methods for RADIOGRAPHY is discussed in IEC 60601-2-54:2022, 203.6.3.2.102 d). The methodology described can also be followed for RADIOSCOPY.

Alternatively, use the test conditions specified by the MANUFACTURER.

7.12.3 Test method for CONSTANCY TEST

The same test method as used for ACCEPTANCE TESTING should also be used for CONSTANCY TESTING.

7.13 * AUTOMATIC CONTROL SYSTEM — NOMINAL SHORTEST IRRADIATION TIME

7.13.1 Test requirements

For X-RAY EQUIPMENT provided with AUTOMATIC EXPOSURE CONTROL, the NOMINAL SHORTEST IRRADIATION TIME shall be as specified in the ACCOMPANYING DOCUMENTS of the MANUFACTURER.

7.13.2 * Test method for ACCEPTANCE TEST

Generally, testing of the NOMINAL SHORTEST IRRADIATION TIME is a type test that will be performed by or under supervision of the MANUFACTURER or its representative. The method of this test is specified in IEC 60601-2-54:2022, 203.4.101.4 and 203.6.5.101.

7.13.3 Test method for CONSTANCY TEST

CONSTANCY TESTING should not require assessment of this parameter.

7.14 Correspondence between the X-RAY FIELD and EFFECTIVE IMAGE RECEPTION AREA

7.14.1 Test requirements

The discrepancies between the edges of the X-RAY FIELD and the corresponding edges of the EFFECTIVE IMAGE RECEPTION AREA shall comply with the tolerances specified.

If the X-RAY FIELD is adjusted in the INTENDED USE for full coverage of the IMAGE RECEPTION AREA, it shall correspond to the IMAGE RECEPTION AREA within the following limits, as applicable.

- If the IMAGE RECEPTION AREA is circular, the X-RAY FIELD shall coincide with the IMAGE RECEPTION AREA as required in a) and b):
 - a) 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;
 - b) at least 80 % of the area of the X-RAY FIELD shall overlap the EFFECTIVE IMAGE RECEPTION AREA. EFFECTIVE IMAGE RECEPTION AREAS smaller than 10 cm in diameter are exempted.
- X-RAY EQUIPMENT specified for gastro-intestinal examinations with SPOTFILM DEVICES using also rectangular X-RAY IMAGE RECEPTORS need not comply with this requirement, but neither the length nor the width of the X-RAY FIELD shall exceed the diameter of the IMAGE RECEPTION AREA.
- In X-RAY EQUIPMENT specified for RADIOSCOPY during surgery at a fixed FOCAL SPOT TO IMAGE RECEPTOR DISTANCE, in which
 - a) there is provision for RADIOGRAPHY using a RADIOGRAPHIC CASSETTE holder, with beam limitation to a circular X-RAY FIELD for use on a rectangular IMAGE RECEPTION AREA; and
 - b) the orientation of the IMAGE RECEPTION AREA is selectable; and
 - c) the maximum diameter of the X-RAY FIELD does not exceed 40 cm,the diameter of the X-RAY FIELD may exceed the diagonal dimension of the IMAGE RECEPTION AREA by an amount not exceeding 2 cm.
 - In cases where the X-RAY FIELD does not correspond to the IMAGE RECEPTION AREA in accordance with one of the categories above, the following requirements apply:
 - a) along each of the two major axes of the IMAGE RECEPTION AREA, the total of the discrepancies between the edges of the X-RAY FIELD and the corresponding edges of the IMAGE RECEPTION AREA shall not exceed 3 % of the indicated FOCAL SPOT TO IMAGE RECEPTOR DISTANCE when the IMAGE RECEPTION PLANE is normal to the X-RAY BEAM AXIS;
 - b) the sum of the discrepancies on both axes shall not exceed 4 % of the indicated FOCAL SPOT TO IMAGE RECEPTOR DISTANCE.

NOTE 1 If a secondary BEAM LIMITING DEVICE is used between PATIENT and X-RAY IMAGE RECEPTOR, this requirement refers to the percentage of the RADIATION reaching the IMAGE RECEPTION AREA relative to the RADIATION in front of the secondary BEAM LIMITING DEVICE.

Additionally for INTERVENTIONAL X-RAY EQUIPMENT:

Regardless of the shape of the IMAGE RECEPTION AREA (circular and non-circular shape), when the X-RAY BEAM is perpendicular to the IMAGE RECEPTION 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 overlies the EFFECTIVE IMAGE RECEPTION AREA. EFFECTIVE IMAGE RECEPTION AREAS smaller than 10 cm in diameter or less than 10 cm in length on any side are exempted;

- b) the X-RAY FIELD measured from the centre of the IMAGE RECEPTION AREA 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.

The additional requirement is applicable for all magnification steps and for minimum and maximum positions of the FOCAL SPOT TO IMAGE RECEPTOR DISTANCE and for horizontal and vertical positions of the GANTRY.

NOTE 2 This requirement and the associated test method in 7.14.2 are taken from IEC 60601-2-54:2022, 203.8.5.3, and IEC 60601-2-43:2022, 203.8.5.3.

NOTE 3 For X-RAY EQUIPMENT with an adjustable BEAM LIMITING DEVICE, the boundaries of the X-RAY FIELD can be configured so that these boundaries are visible on the IMAGE DISPLAY DEVICE with the X-RAY BEAM AXIS in a specified orientation. This orientation is described in the instructions for use.

7.14.2 Test method for ACCEPTANCE TEST

Compliance with the relevant requirements is checked by measurement of the X-RAY FIELDS, where appropriate.

When automatic adjustment of the RADIATION APERTURE is provided, before making any measurements, allow a period of at least 5 s for the automatic mechanism to complete any adjustments.

For visualising the X-RAY BEAM, various possibilities are available, for example, a portable X-RAY IMAGE RECEPTOR (e.g., a CR cassette or a DR detector) can be used. Alternatively, fluorescent screens, fluorescent rulers or self-developing films are commercially available for evaluation of the X-RAY BEAM alignment.

Carry out the measurements using the arrangement of Figure 2, without the ATTENUATION layer. Adjust the BEAM LIMITING DEVICE to maximum field size. Check whether the boundaries of the BEAM LIMITING DEVICE are visible on the IMAGE DISPLAY DEVICE, both in vertical and horizontal direction.

If the boundaries are not visible, perform the following test steps.

- a) *Place a portable X-RAY IMAGE RECEPTOR (e.g., a CR cassette or a DR detector) or alternative means on the PATIENT SUPPORT.*
- b) *Adjust the BEAM LIMITING DEVICE to a small field size. Centre the portable X-RAY IMAGE RECEPTOR or alternative means with the BEAM LIMITING DEVICE under RADIOGRAPHY.*
- c) *Adjust the BEAM LIMITING DEVICE to maximum field size. Position an absorbing marker (e.g., a copper or lead strip) at all four edges of the visible image of the IMAGE DISPLAY DEVICE.*
- d) *Make a radiographic image.*
- e) *In case a portable X-RAY IMAGE RECEPTOR is used, evaluate the processed radiographic image. In case alternative means are used, evaluate the X-RAY FIELD limits directly.*
- f) *Measure the X-RAY FIELD limits in four directions outside of the markers. Calculate the distances c_1 , c_2 , d_1 and d_2 taking into account the magnification factor (see Figure 5).*

Repeat this PROCEDURE for all X-RAY IMAGE RECEPTORS available and for INTERVENTIONAL X-RAY EQUIPMENT for all magnification steps available.

For CONSTANCY TESTING, the test shall only be performed at the maximum X-RAY FIELD size, not with all available field sizes.

In case of C-arm X-RAY EQUIPMENT, this test shall be performed for all worst case positions to evaluate bending of the C-arm.

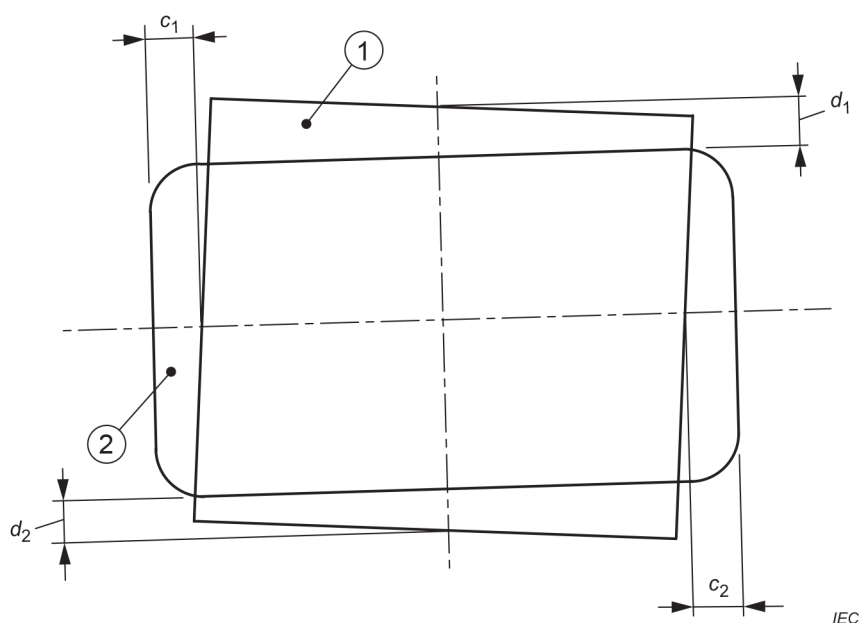
As shown in Figure 5, the measured discrepancies in the IMAGE RECEPTION PLANE are represented by c_1 and c_2 on one axis, and by d_1 and d_2 on the other. If the FOCAL SPOT TO IMAGE RECEPTOR DISTANCE is S , then for compliance, the following relationships are true:

$$|c_1| + |c_2| \leq 0,03 \times S$$

$$|d_1| + |d_2| \leq 0,03 \times S$$

$$|c_1| + |c_2| + |d_1| + |d_2| \leq 0,04 \times S$$

NOTE If the above requirements are fulfilled, the X-RAY EQUIPMENT complies with the X-RAY FIELD centring requirements.



1 X-RAY FIELD

2 IMAGE RECEPTION AREA

Figure 5 – Discrepancies in covering the IMAGE RECEPTION AREA

7.14.3 Test method for CONSTANCY TEST

The same test method as used for ACCEPTANCE TESTING should also be used for CONSTANCY TESTING.

7.15 Accuracy of indication of the LIGHT FIELD-INDICATOR

7.15.1 Test requirements

If a LIGHT FIELD-INDICATOR is provided with the X-RAY EQUIPMENT, the discrepancies in the indication of the LIGHT FIELD and the X-RAY FIELD shall comply with the tolerances specified.

Along each of the two major axes of the X-RAY FIELD in the plane of the LIGHT FIELD, the total of the discrepancies between the edges of the X-RAY FIELD and the corresponding edges of the LIGHT FIELD shall not exceed 2 % of the distance of the measurement plane of the LIGHT FIELD from the FOCAL SPOT.

NOTE This requirement and the associated test method in 7.15.2 are taken from IEC 60601-2-54:2022, 203.8.102.6.

7.15.2 Test method for ACCEPTANCE TEST

Compliance is checked by measurement, on the two major axes of the X-RAY FIELD, of the discrepancies between corresponding edges of the X-RAY FIELD and the LIGHT FIELD, in selected planes at measured distances from the FOCAL SPOT, within the range of NORMAL USE, and normal to the X-RAY BEAM AXIS within three degrees.

For visualising the X-RAY BEAM, various possibilities are available, a portable X-RAY IMAGE RECEPTOR (e.g., a CR cassette or a DR detector) can be used. Alternatively, fluorescent screens, fluorescent rulers or self-developing films are commercially available for evaluation of the X-RAY BEAM alignment.

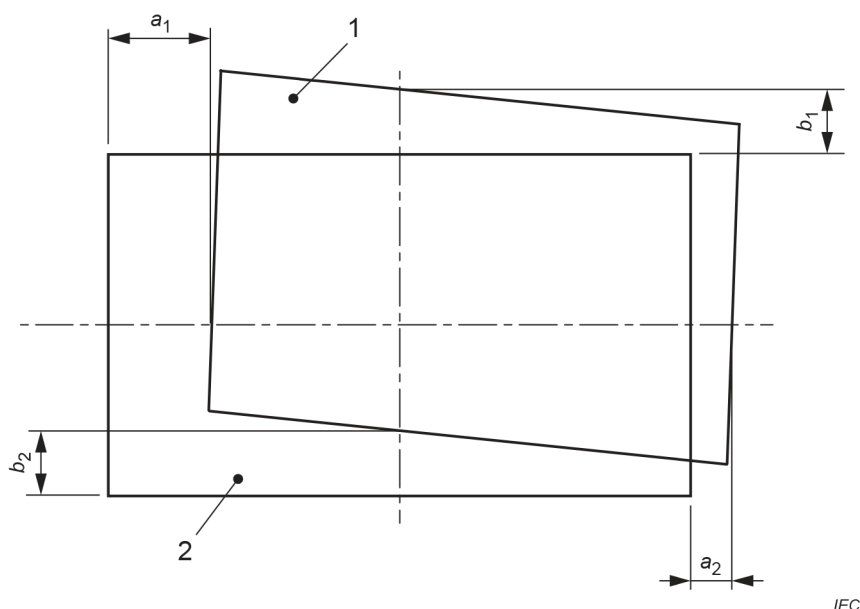
For practical implementation, position a portable X-RAY IMAGE RECEPTOR, of a size of for example 24 cm x 30 cm, on top of the PATIENT SUPPORT in the centre of the X-RAY FIELD and manually set a LIGHT FIELD of for example 18 cm x 24 cm. Alternative means can be used to visualize the X-RAY FIELD. Mark the corners of the LIGHT FIELD with radio-opaque markers, for example metal wires.

Measure the X-RAY FIELD limits on the processed radiographic image and the discrepancies from the indicated LIGHT FIELD.

In Figure 6, the measured discrepancies are represented by a_1 and a_2 on one axis, and by b_1 and b_2 on the other. If the FOCAL SPOT to the plane of the LIGHT FIELD distance is S , then, for compliance, the following relationships are true:

$$|a_1| + |a_2| \leq 0,02 \times S$$

$$|b_1| + |b_2| \leq 0,02 \times S$$



- 1 Visually defined field
- 2 X-RAY FIELD

Figure 6 – Discrepancies in visual indication of the X-RAY FIELD

7.15.3 Test method for CONSTANCY TEST

The same test method as used for ACCEPTANCE TESTING should also be used for CONSTANCY TESTING.

7.16 Accuracy of marked and written indications of the X-RAY FIELD size

7.16.1 Test requirements

If the extent of the X-RAY BEAM is indicated by display on the X-RAY EQUIPMENT, the actual size of the maximum size of the X-RAY FIELD shall comply with what is indicated on the equipment within the specified tolerances.

7.16.2 Test method for ACCEPTANCE TEST

Measure the dimensions of the X-RAY FIELD along its two major axes at selected indicated settings of the BEAM LIMITING SYSTEM, and the FOCAL SPOT TO IMAGE RECEPTOR DISTANCE, as available for NORMAL USE and at the commonly used X-RAY BEAM angulation.

Make sure that the boundaries of the BEAM LIMITING DEVICE are not configured to be visible in the X-RAY FIELD at its maximum size for each magnification mode, as this might lead to erroneous results. Consult the ACCOMPANYING DOCUMENTS for additional guidance.

Other test PROCEDURES than those described here can be used if they lead to comparable results.

Use the FOCAL SPOT TO IMAGE RECEPTOR DISTANCE at the value indicated on the equipment or stated in the ACCOMPANYING DOCUMENTS, for the setting used.

For visualising the X-RAY BEAM, various possibilities are available, a portable X-RAY IMAGE RECEPTOR (e.g., a CR cassette or a DR detector) can be used. Alternatively, fluorescent screens, fluorescent rulers or self-developing films are commercially available for evaluation of the X-RAY BEAM alignment.

Use a beam limiting TEST DEVICE with markings for field geometry. Make the measurements with a portable X-RAY IMAGE RECEPTOR arranged in the tray or on the top of the PATIENT SUPPORT in the centre of the X-RAY FIELD and using the arrangement in Figure 2, without the ATTENUATION layer. Alternative means can be used to visualize the X-RAY FIELD.

Measure the X-RAY FIELD size on the processed radiographic image and note the discrepancies with the displayed indication(s) on the X-RAY EQUIPMENT. If the cassette had been exposed on the top of the PATIENT SUPPORT, this field size shall be corrected to correspond to that at the ENTRANCE PLANE of the X-RAY IMAGE RECEPTOR.

Discrepancies between the measured X-RAY FIELD size and the displayed indications shall be within the specified tolerances.

7.16.3 Test method for CONSTANCY TEST

This test should not be included in CONSTANCY TESTING.

7.17 AIR KERMA RATE at the ENTRANCE PLANE of the X-RAY IMAGE RECEPTOR for RADIOLOGY

7.17.1 Test requirements

The AIR KERMA RATE at the ENTRANCE PLANE of the X-RAY IMAGE RECEPTOR, under the specified conditions, shall comply with the values and tolerances specified. This also applies to MODES OF OPERATION using image subtraction.

NOTE Equipment integrating one or more flat panel X-RAY IMAGE RECEPTORS do not need to follow this ACCEPTANCE TEST PROCEDURE. For such equipment however, it is still useful to apply 7.17.2 in order to establish a BASELINE VALUE for performing CONSTANCY TESTING. The use of measuring AIR KERMA RATE at the ENTRANCE PLANE of the X-RAY IMAGE RECEPTOR is further discussed in Annex B.

7.17.2 Test method for ACCEPTANCE TEST

The measurements shall be made under typical operating conditions. Carry out the measurements using the arrangement in Figure 1, with the ATTENUATION layer, for example 25 mm Al or 1,5 mm Cu (see 4.7.6), in position and the DOSIMETER as close as possible to the ENTRANCE PLANE of the X-RAY IMAGE RECEPTOR.

Select an X-RAY TUBE VOLTAGE of 70 kV to 80 kV, or another suitable value considering the type of equipment and its clinical use. If the X-RAY TUBE VOLTAGE selection is automatic, add sufficient attenuating material to drive the X-RAY TUBE VOLTAGE to within this range. Make the measurement in the stable phase of the AUTOMATIC CONTROL SYSTEM. Note that the DOSIMETER shall be placed outside the sensitive area of the imaging surface used for the AUTOMATIC CONTROL SYSTEM.

Measure the AIR KERMA RATE at the ENTRANCE PLANE, $\dot{K}_B$, of the X-RAY IMAGE RECEPTOR behind the ANTI-SCATTER GRID.

NOTE Perform the measurement with the ANTI-SCATTER GRID in place. If this is difficult, the DOSIMETER and ANTI-SCATTER GRID can be affixed to the X-RAY IMAGE RECEPTOR, for example by using tape. Alternatively, take the grid transmission into account. The grid transmission can be taken from the accompanying documents of the ANTI-SCATTER GRID.

Compare the results of this measurement with the specified values.

7.17.3 Test method for CONSTANCY TEST

The same test method as used for ACCEPTANCE TESTING should also be used for CONSTANCY TESTING.

7.18 REFERENCE AIR KERMA RATE for RADIOSCOPY

7.18.1 Test requirements

The REFERENCE AIR KERMA RATE shall comply with the values specified. This also applies to MODES OF OPERATION using image subtraction.

NOTE Once the initial ACCEPTANCE TEST value is determined, the reproducibility of the CONSTANCY TEST values can lead to a smaller tolerance.

7.18.2 Test method for ACCEPTANCE TEST

The measurements shall be carried out under typical operating conditions.

NOTE 1 These measurements give an indication of the effectiveness of additional X-RAY BEAM filtering devices, of the AIR KERMA at the PATIENT entrance and the SKIN DOSE. This is especially important for cardiac radioscopy systems using high dose rate RADIOSCOPY.

1) Relevant parameters

The following are examples of factors that shall be specified by the MANUFACTURER.

i) 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

ii) 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*

iii) Test geometry

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

2) Measurements and test conditions:

- *Use a 20 cm polymethyl-methacrylate (PMMA) PHANTOM (the PHANTOM can be fabricated from layers of material) comprising of rectangular blocks with sides equal to or exceeding 25 cm. Density of the nominal 20 cm PHANTOM: 1,18 g/cm³, with a relative tolerance of $\pm 5\%$.*
- *Use a DOSIMETER with a measuring detector small enough to cover not more than 80 % of the area of the X-RAY BEAM in the plane of measurement.*

NOTE 2 Place the detector of the DOSIMETER such that the beam inhomogeneity due to anode heel effect is minimized.

- *The PHANTOM is placed near the X-RAY IMAGE RECEPTOR, leaving as much of the available distance as possible between the X-RAY SOURCE ASSEMBLY and the ENTRANCE SURFACE of the PHANTOM.*
- *Position the measuring detector at a point that is either:*
 - *the PATIENT ENTRANCE REFERENCE POINT (only if there is at least 20 cm distance between the measuring detector and the PHANTOM if the measuring detector is sensitive to backscattered X-RADIATION), or*
 - *half-way between the FOCAL SPOT and the ENTRANCE SURFACE of the PHANTOM, in that case, the measured values shall include scaling to the appropriate geometrical distance based on the inverse square law, or*
 - *on the ENTRANCE SURFACE of the PHANTOM if the measuring detector does not detect backscattered X-RADIATION.*
- *Measure the REFERENCE AIR KERMA RATE for typical RADIOLOGY settings.*
- *For each of these settings, measure the AIR KERMA (RATE) using the PHANTOM described:*
 - *for representative OPERATOR selectable ENTRANCE FIELD SIZES;*
 - *for representative OPERATOR selectable ADDED FILTERS;*
 - *for representative OPERATOR selectable pulse repetition frequencies.*
- *The surface of the PHANTOM shall be aligned perpendicular to the X-RAY BEAM AXIS within $\pm 2^\circ$ in all directions.*

7.18.3 Test method for CONSTANCY TEST

The same test method as used for ACCEPTANCE TESTING should also be used for CONSTANCY TESTING. Other ATTENUATION layers, for example 25 mm Al or 1,5 mm Cu, can be used.

7.19 AIR KERMA at the ENTRANCE PLANE of the X-RAY IMAGE RECEPTOR for RADIOGRAPHY

7.19.1 Test requirements

The AIR KERMA per image at the ENTRANCE PLANE of the X-RAY IMAGE RECEPTOR shall comply with the values and tolerances specified. This also applies to MODES OF OPERATION using image subtraction.

NOTE Equipment integrating one or more flat panel X-RAY IMAGE RECEPTORS do not need to follow this ACCEPTANCE TEST PROCEDURE. For such equipment however, it is still useful to apply 7.19.2 in order to establish a BASELINE VALUE for performing CONSTANCY TESTING. The use of measuring AIR KERMA at the ENTRANCE PLANE of the X-RAY IMAGE RECEPTOR is further discussed in Annex B.

7.19.2 Test method for ACCEPTANCE TEST

Measure the AIR KERMA per image for typical RADIOGRAPHY settings with the test conditions as specified in 7.17.2.

7.19.3 Test method for CONSTANCY TEST

The same test method as used for ACCEPTANCE TESTING should also be used for CONSTANCY TESTING.

7.20 REFERENCE AIR KERMA for SERIAL RADIOGRAPHY

7.20.1 Test requirements

The REFERENCE AIR KERMA per image shall comply with the values and tolerances specified. This also applies to MODES OF OPERATION using image subtraction.

7.20.2 Test method for ACCEPTANCE TEST

Measure the AIR KERMA per image for typical SERIAL RADIOGRAPHY settings with the test conditions as specified in 7.18.2.

7.20.3 Test method for CONSTANCY TEST

Measure the AIR KERMA per image for typical SERIAL RADIOGRAPHY settings with the test conditions as specified in 7.18.3.

7.21 Limitation of the REFERENCE AIR KERMA RATE in RADIOSCOPY

7.21.1 Test requirements

The limitation of the REFERENCE AIR KERMA RATE shall comply with the values specified. The limit on the maximum REFERENCE AIR KERMA RATE depends on the local regulations.

NOTE Typically, limitation of the REFERENCE AIR KERMA RATE is defined in international and local standards (e.g., 88 mGy/min). Additionally, a high-level control mode is specified for modes exceeding the REFERENCE AIR KERMA RATE limitation, with a maximum of for example 176 mGy/min.

7.21.2 Test method for ACCEPTANCE TEST

The AUTOMATIC CONTROL SYSTEM shall be set to reach the maximum value of REFERENCE AIR KERMA RATE, for example by covering the X-RAY IMAGE RECEPTOR with a lead plate. For X-RAY EQUIPMENT without AUTOMATIC CONTROL SYSTEM, the REFERENCE AIR KERMA RATE shall be set to the maximum value.

For the application of this requirement to C-arm X-RAY EQUIPMENT, the REFERENCE AIR KERMA RATE shall be replaced with the AIR KERMA RATE measured at 30 cm from the ACCESSIBLE SURFACE of the X-RAY IMAGE RECEPTOR.

For non-C-arm X-RAY EQUIPMENT, tests shall be performed by measurement of the maximum entrance REFERENCE AIR KERMA RATE at the PATIENT ENTRANCE REFERENCE POINT.

The measurement results are compared with the specified values.

7.21.3 Test method for CONSTANCY TEST

The same test method as used for ACCEPTANCE TESTING should also be used for CONSTANCY TESTING.

7.22 SPATIAL RESOLUTION for RADIOSCOPY and RADIOGRAPHY

7.22.1 Test requirements

The SPATIAL RESOLUTION for RADIOSCOPY with X-RAY IMAGE RECEPTOR and for INDIRECT RADIOGRAPHY systems shall comply with the specified values under the specified conditions. This applies to both the system resolution and the X-RAY IMAGE RECEPTOR resolution.

NOTE X-RAY IMAGE RECEPTOR resolution is generally only performed at ACCEPTANCE TESTING; system resolution is generally performed more routinely.

7.22.2 Test method for ACCEPTANCE TEST

At least one of the following test method approaches shall be considered for testing SPATIAL RESOLUTION of the X-RAY IMAGE RECEPTOR and of the system.

a) LINE PAIR RESOLUTION approach

Use a LINE PAIR RESOLUTION TEST DEVICE. Carry out the measurements using the arrangement in Figure 2 with the LINE PAIR RESOLUTION TEST DEVICE, oriented at 45° to the X-RAY IMAGE RECEPTOR axes to minimize aliasing ARTIFACTS.

NOTE 1 The LINE PAIR RESOLUTION approach is a subjective observer-based measurement.

NOTE 2 If measurements are made with the ANTI-SCATTER GRID removed, different performance figures will be produced.

NOTE 3 Assure that the LINE PAIR RESOLUTION test device has a range of measurable resolutions that spans the resolution to be measured.

The test shall be carried out with one of the following conditions, as specified.

i) X-RAY IMAGE RECEPTOR resolution without ATTENUATION layer/PHANTOM

Place the LINE PAIR RESOLUTION TEST DEVICE near the centre of the X-RAY BEAM as close as possible to the ENTRANCE PLANE of the X-RAY IMAGE RECEPTOR, to minimize the effect of geometric magnification. Use a setting that results in a high contrast image (for example in the range of 45 kV to 50 kV).

The setting used to reduce the effect of quantum noise shall not saturate the brightest parts of the image.

ii) System resolution with ATTENUATION layer/PHANTOM

Place the line PAIR RESOLUTION TEST DEVICE near the centre of the X-RAY BEAM at a distance to the ENTRANCE PLANE of the X-RAY IMAGE RECEPTOR as specified by the MANUFACTURER.

NOTE 4 Test method i) gives information mainly about the function of the X-RAY IMAGE RECEPTOR system. It represents the highest possible SPATIAL RESOLUTION (without PATIENT, no geometric magnification and with high contrast image, mainly due to low X-RAY TUBE VOLTAGE and scatter-free setup). Test method ii) gives information mainly about the function of the X-RAY EQUIPMENT including the X-RAY IMAGE RECEPTOR system under clinical operating conditions (PATIENT simulated by a PHANTOM; including geometric magnification and SCATTERED RADIATION).

For RADIOSCOPY, when an ATTENUATION layer or PHANTOM is used, select a voltage for this measurement of 70 kV to 80 kV.

If the voltage selection is automatic, further ATTENUATION can be necessary to drive the X-RAY TUBE VOLTAGE to within this range.

For INDIRECT RADIOGRAPHY with an AUTOMATIC CONTROL SYSTEM (kV/mA control), for example with SERIAL RADIOGRAPHY technique, sufficient ATTENUATION (for example aluminium or copper according to the MANUFACTURER'S instructions) can be necessary in addition to the PHANTOM used in the arrangement of Figure 1 to achieve an X-RAY TUBE VOLTAGE of 70 kV to 80 kV.

Measure the light level on the face of the monitor under normal working conditions. If necessary, adjust the ambient light level so that the light on the face of the (unilluminated) monitor is as specified by the MANUFACTURER (for example less than 1 cd/m²).

Record the smallest line-group (highest SPATIAL RESOLUTION i.e LINE PAIR RESOLUTION) of the specified LINE PAIR RESOLUTION TEST DEVICE which can be resolved in the image while all the line-groups having smaller SPATIAL RESOLUTION can also be resolved. The lines of a group shall be detectable over the major part of the total length. Use digital zooming if needed and available.

Record the system settings and measurement conditions used: for example, FOCAL SPOT TO IMAGE RECEPTOR DISTANCE, FOCAL SPOT to TEST DEVICE distance, X-RAY FIELD size at this distance, kV, mA and FILTRATION. For the system test, it is important to record and replicate the viewing conditions used.

Compare the values with the specified values under specified conditions.

b) MODULATION TRANSFER FUNCTION approach

Generally, the MTF of the X-RAY IMAGE RECEPTOR can be taken from the ACCOMPANYING DOCUMENTS.

NOTE 5 This test is normally only performed as a type test and not part of ACCEPTANCE TESTING or CONSTANCY TESTING.

However, if measurement is required, the following should be taken into account, either in a range of SPATIAL FREQUENCIES (e.g. from 0 lp/mm up to the Nyquist frequency) or for specific SPATIAL FREQUENCIES (e.g. at 1 lp/mm etc.).

A method for measuring the presampled MTF (i.e. MTF excluding aliasing effects) of digital radiographic systems using a tilted edge TEST DEVICE has been described in literature [6].

NOTE 6 The MODULATION TRANSFER FUNCTION approach is a quantitative method described in detail in IEC 62220-1-1:2015.

A TEST DEVICE as described in 4.7.6 f) can be used. If possible for the equipment under test, the RADIATION QUALITIES shall be one or more of the following four selected RADIATION QUALITIES according to IEC 61267:2005 as specified in Table 1 of IEC 62220-1-1:2015: RQA3, RQA5, RQA7, RQA9. If only a single RADIATION QUALITY is used, RADIATION QUALITY RQA 5 should be preferred.

Carry out the measurements using the arrangement in Figure 2 with the TEST DEVICE positioned in such a way that the edge is tilted by an angle α relative to the axis of the pixel columns or pixel rows, where α is between 1,5° and 3°.

i) Determination of MODULATION TRANSFER FUNCTION of the X-RAY IMAGE RECEPTOR

Place the TEST DEVICE near the centre of the X-RAY BEAM as close as possible to the ENTRANCE PLANE of the X-RAY IMAGE RECEPTOR.

ii) Determination of system MODULATION TRANSFER FUNCTION

Place the TEST DEVICE near the centre of the X-RAY BEAM at a distance to the ENTRANCE PLANE of the X-RAY IMAGE RECEPTOR as specified by the MANUFACTURER.

NOTE 7 Test method i) minimizes the effects of SCATTERED RADIATION and geometric magnification and mainly provides information about the function of the X-RAY IMAGE RECEPTOR system. Test method ii) gives information mainly about the function of the X-RAY EQUIPMENT including the X-RAY IMAGE RECEPTOR system under practical diagnostic conditions.