

Australian/New Zealand Standard™

**Evaluation and routine testing in
medical imaging departments**

**Part 2.11: Constancy tests—Equipment
for general direct radiography
(IEC 61223-2-11:1999, MOD)**



AS/NZS 4184.2.11:2002

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Australian/New Zealand Standard™

Evaluation and routine testing in medical imaging departments

Part 2.11: Constancy tests—Equipment for general direct radiography (IEC 61223-2-11:1999, MOD)

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PREFACE

This Standard was prepared by the Joint Standards Australia/Standards New Zealand Committee HE-008, Diagnostic Ionizing Imaging Equipment.

This Standard has been reproduced, with national modifications, from IEC 61223-2-11:1999, *Evaluation and routine testing in medical departments, Part 2.11: Constancy tests—Equipment for general direct radiography*.

Appendix ZZ lists the variations between this Standard and IEC 61223-2-11. These changes are indicated by a rule in the margin against each Clause affected.

In the text of this Standard, the following print types are used:

- (a) Requirements, compliance with which can be tested and definitions
.....in large roman type
- (b) Explanations, advice, introductions, general statements, exceptions and references
.....in smaller roman type
- (c) Headings of sub-clauses and text specifications
.....in *italic type*
- (c) Terms used throughout the Standard, which have been defined in Clause 3 or the Index of Defined Terms (see Annex A)
.....IN SMALL CAPITALS

As this publication has been reproduced from an international Standard, the following modifications apply:

- (i) Its number does not appear on each page and its identity is shown on the cover and title page.
- (ii) The words 'this Australian/New Zealand Standard' should replace the words 'this part of IEC 61223' wherever they appear.
- (iii) The substitution of a full point (.) for a comma (,) where it appears as a decimal marker.

The terms 'normative' and 'informative' have been used in this Standard to define the application of the annex or appendix to which they apply. A 'normative' annex or appendix is an integral part of a Standard, whereas an 'informative' annex or appendix is for information and guidance only.

The references to international Standards should be replaced by references to the following Australian or Joint Australian/New Zealand Standards:

<i>Reference to International Standard or other publication *</i>		<i>Australian/New Zealand Standard</i>	
IEC		AS/NZS	
60601	Medical electrical equipment	3200	Medical electrical equipment
60601-1-3	Part 1: General requirements for safety	3200.1.3	Part 1.3: General requirements for safety
	3. Collateral standard: General requirements for radiation protection in diagnostic X-ray equipment		Collateral Standard: Requirements for radiation protection in diagnostic X-ray equipment
61223	Evaluation and routine testing in medical imaging departments	4184	Evaluation and routine testing in medical imaging departments
61223-1	Part 1: General aspects	4184.1	Part 1: General aspects
61223-2-1	Part 2-1: Constancy tests – Film processors	4184.2.1	Part 2.1: Constancy tests – Film processors

* Any international Standards not listed do not have an Australian/New Zealand equivalent.

IEC		AS/NZS	
61223-2-2	Part 2-2: Constancy tests – Radiographic cassettes and film changers – Film-screen contact and relative sensitivity of the screen-cassette assembly	4184.2.2	Part 2.2: Constancy tests – Radiographic cassettes and film changers – Film-screen contact and relative sensitivity of the screen-cassette assembly
61223-2-3	Part 2-3: Constancy tests – Darkroom safelight conditions	4184.2.3	Part 2.3: Constancy tests – Darkroom safelight conditions

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AUSTRALIAN/NEW ZEALAND STANDARD

Evaluation and routine testing in medical imaging departments

Part 2.11:

Constancy tests—Equipment for general direct radiography (IEC 61223-2-11:1999, MOD)

1 Scope and object

1.1 Scope

This part of IEC 61223 applies to those components of X-RAY EQUIPMENT which

- generate, influence the propagation of, and detect X-RADIATION; and
- process, present and store radiographic information in RADIOLOGICAL INSTALLATIONS with diagnostic X-ray systems using RADIOGRAPHIC FILM in DIRECT RADIOGRAPHY.

This standard is a part of a series of Particular Publications (international standards and technical reports), which define methods of testing the constancy of operation of various subsystems of diagnostic X-RAY EQUIPMENT.

This standard does not apply to equipment for special applications such as mammographic X-RAY EQUIPMENT or dental X-RAY EQUIPMENT; see complete list of all parts 2 of IEC 61223 in the foreword.

This standard gives methods of tests for the constancy of properties of diagnostic X-RAY EQUIPMENT as described in IEC 61223-1 (see clause 2).

This part of IEC 61223 is designed to be applicable to equipment for general direct radiography without digital imaging devices.

1.2 Object

This standard defines

- the essential parameters which describe or affect the performance of the above components of X-RAY EQUIPMENT;
- methods of checking that variations in measured quantities related to those parameters are within acceptable limits, in order to maintain adequate standards of imaging whilst reducing unnecessary IRRADIATION of the PATIENT.

The methods are based upon assessments of RADIOGRAMS of appropriate TEST DEVICES.

The purpose of the methods is

- to establish a reference level of performance when such equipment is accepted;
- to detect and verify any significant variation in performance which may require corrective action.

Because RADIOLOGICAL INSTALLATIONS differ widely from each other, it is not possible in this standard to specify target values and tolerances for the parameters which would be generally applicable as criteria of acceptable performance. Guidance is given, however, as to the degree of variation in single measurements which might require appropriate action.

This standard does not deal with

- aspects of mechanical and electrical safety;
- checks of the effectiveness of the direct means of protection against X-RADIATION;
- optimization of imaging performance.

With regard to the measurements, reference is made to methods described in related publications, which for practical reasons should be carried out prior to the application of the methods described in this standard (see clause 2).

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of IEC and ISO maintain registers of currently valid International Standards.

IEC 60601-1-3:1994, *Medical electrical equipment – Part 1: General requirements for safety*
3. *Collateral standard: General requirements for radiation protection in diagnostic X-ray equipment*

IEC 60788:1984, *Medical radiology – Terminology*

IEC 61223-1:1993, *Evaluation and routine testing in medical imaging departments – Part 1: General aspects*

IEC 61223-2-1:1993, *Evaluation and routine testing in medical imaging departments – Part 2-1: Constancy tests – Film processors*

IEC 61223-2-2:1993, *Evaluation and routine testing in medical imaging departments – Part 2-2: Constancy tests – Radiographic cassettes and film changers – Film-screen contact and relative sensitivity of the screen-cassette assembly*

IEC 61223-2-3:1993, *Evaluation and routine testing in medical imaging departments – Part 2-3: Constancy tests – Darkroom safelight conditions*

3 Terminology

3.1 Degree of requirements

In this standard, certain terms (which are not printed in SMALL CAPITALS) have particular meanings, as follows:

- "shall" indicates a requirement that is mandatory for compliance;
- "should" indicates a strong recommendation that is not mandatory for compliance;
- "may" indicates a permitted manner of complying with a requirement or of avoiding the need to comply;
- "specific" is used to indicate definitive information stated in this standard or referenced in other standards, usually concerning particular operating conditions, test arrangements or values connected with compliance;

- "specified" is used to indicate definitive information stated by the manufacturer in accompanying documents or in other documentation relating to the equipment under consideration, usually concerning its intended purpose, or the parameters or conditions associated with its use or with testing to determine compliance.

3.2 Use of terms

In this standard, terms printed in SMALL CAPITALS are used as defined in IEC 60788 or other IEC publications; see annex A. Where a defined term is used as a qualifier in another defined or undefined term, it is not printed in SMALL CAPITALS, unless the concept thus qualified is defined, or recognized as a "derived term without definition". Test specifications are in italics.

NOTE – Attention is drawn to the fact that, in cases where the concept addressed is not strongly confined to the definition given in one of the publications listed above, a corresponding term is printed in lower-case letters.

4 General aspects of CONSTANCY TESTS

The methods for testing the constancy described in this standard are intended to enable the OPERATOR to detect changes in image quality of images produced by X-RAY EQUIPMENT.

For the results of the CONSTANCY TESTS described in this standard to be valid, it is essential to ensure that they are not significantly influenced by anything other than changes in the parameters under test.

In particular, attention shall be paid to darkroom safelight conditions, according to IEC 61223-2-3, and proper film processing, according to IEC 61223-2-1 (see clause 2). When using FILM ILLUMINATORS special attention should also be paid to lighting conditions.

Careful consideration shall be given to the operating and test conditions under which the equipment is checked, including environmental influences.

All equipment under test and the test equipment shall be identified at the initial CONSTANCY TEST in order to ensure that the same items are used in subsequent CONSTANCY TESTS.

Appropriate individual TEST DEVICES are described in detail in annex D for each of the test measurements described in clause 5 of this standard. In practice, a composite TEST DEVICE may be used, which combines the properties of some of the individual TEST DEVICES. Furthermore, some of the test procedures described separately in clause 5 may be performed simultaneously.

NOTE – If the MANUFACTURER provides proposals for the method and frequency of CONSTANCY TESTS in the ACCOMPANYING DOCUMENTS, they should preferably be followed.

4.1 General conditions affecting test procedures

The CONSTANCY TESTS described in this standard have been designed to be easily reproducible, i.e., their results should be affected only by changes in the parameters under investigation. The number of test tools and test equipment has been kept to a minimum and restricted where possible to devices that are passive, inherently simple or reasonably stable. It is important

- to perform CONSTANCY TESTS with LOADING FACTORS which are the same as those used most frequently in clinical practice;
- to record and reproduce all significant settings of the X-RAY EQUIPMENT and ACCESSORIES each time a test is undertaken and to check that the same equipment, components and ACCESSORIES are being used;
- to consider particularly variations in supply voltage, on the results;
- to use RADIOGRAPHIC FILM which is handled, processed and viewed in accordance with the standards and technical reports referenced in clause 2;
- to check the performance of the test instrumentation regularly, particularly when any significant variation in the X-RAY EQUIPMENT is suspected.

NOTE – When appropriate national standards exist, measuring equipment should be referable to them.

Before the CONSTANCY TESTS are started, the constancy of the radiographic cassettes, the radiographic film, the film processing and the film viewing conditions shall be checked.

4.2 Establishment of BASELINE VALUES

When new X-RAY EQUIPMENT is brought into use, or any component of the X-RAY EQUIPMENT, ACCESSORIES or test equipment is changed, which may cause a variation in the test result, an initial CONSTANCY TEST shall be carried out immediately after an ACCEPTANCE TEST or STATUS TEST has indicated that the performance is satisfactory. The purpose of the initial CONSTANCY TEST is to establish new BASELINE VALUES for the parameters tested.

4.3 Frequency of CONSTANCY TESTS

The CONSTANCY TESTS shall be repeated as directed in the appropriate subclauses of this standard. In addition, the CONSTANCY TESTS should be repeated

- whenever malfunction is suspected;
- immediately after the equipment has undergone maintenance that could affect the performance parameter under test;
- to confirm the test results, whenever the results are outside the criteria.

Records of the BASELINE VALUES shall be kept until a new initial CONSTANCY TEST is performed. The results of the CONSTANCY TESTS shall be kept at least two years.

4.4 Identification of equipment, instrumentation and test conditions

All X-RAY EQUIPMENT under test or used for testing shall be unequivocally identified.

Interchangeable components of X-RAY EQUIPMENT such as

- ADDED FILTERS;
- BEAM LIMITING DEVICE;
- PATIENT SUPPORT or other attenuating material in the RADIATION BEAM;
- RADIATION DETECTOR of the AUTOMATIC CONTROL SYSTEM;
- ANTI-SCATTER GRID;

together with items of test instrumentation such as

- combination of RADIOGRAPHIC CASSETTE and INTENSIFYING SCREENS;
- TEST DEVICES;
- RADIOGRAPHIC FILM type and emulsion number;
- FILM PROCESSOR;
- sensitometer;
- densitometer;

and settings of variables such as

- FOCAL SPOT TO IMAGE RECEPTOR DISTANCE;
- AUTOMATIC CONTROL SYSTEM density control and sensor position;
- LOADING FACTORS;
- nominal FOCAL SPOT size, if applicable;

shall be marked and/or recorded so that the items and settings used in the initial CONSTANCY TEST can be used with the equipment under test.

NOTE 1 – Most of the tests should be performed with the particular RADIOGRAPHIC CASSETTE used for the initial CONSTANCY TEST. This cassette, hereafter referred to as the "test cassette", may be kept exclusively for test procedures or identified among those used regularly in clinical work. Whereas the first is more likely to provide a stable tool for revealing changes in the equipment, the second approach will be more representative of changes of the whole system, including those due to the ageing of the cassette itself.

NOTE 2 – It is essential that any RADIOGRAPHIC FILM used in the test is of the same type as the film used for the CONSTANCY TEST for the FILM PROCESSOR.

RADIOGRAMS of a TEST DEVICE shall be taken with the test cassette, with the same INTENSIFYING SCREENS and film type. The RADIOGRAPHIC FILM shall be processed under known comparable conditions and appropriate allowance shall be made for any changes in film batch according to the method specified in IEC 61223-2-1. If the film type and/or associated processing conditions are changed, a new initial CONSTANCY TEST shall be carried out.

4.5 Measured functional parameters

The imaging performance of a direct radiographic system is considered to be constant if the variations of the following functional parameters are found to meet applicable criteria:

- RADIATION output from the X-RAY SOURCE ASSEMBLY; see 5.1;
- RADIATION input to the IMAGE RECEPTION AREA; see 5.2;
- geometric characteristics; see 5.3;
- resolution of high-contrast detail; see 5.4;
- variation in optical density throughout a RADIOGRAM; see 5.5.

The constancy of the imaging performance may be affected by variations in one or more of the following parameters:

- value and wave-form of the mains voltage;
- value and wave-form of the X-RAY TUBE VOLTAGE;
- X-RAY TUBE CURRENT;
- LOADING TIME;
- IRRADIATION TIME under AUTOMATIC EXPOSURE CONTROL;
- FILTRATION and ATTENUATION by layers in the RADIATION BEAM;
- roughening of the TARGET in the ANODE of the X-RAY TUBE;

- distances of planes of interest from the FOCAL SPOT;
- limitation of the RADIATION BEAM;
- direction of the RADIATION BEAM;
- alignment of the RADIATION BEAM with the IMAGE RECEPTION AREA;
- coincidence of the RADIATION FIELD with the field indicated by the LIGHT FIELD-INDICATOR;
- movement of the MOVING GRID;
- positioning of the ANTI-SCATTER GRID;
- imaging properties of the FOCAL SPOT;
- mechanical stability.

5 Performance tests

5.1 RADIATION output from the X-RAY SOURCE ASSEMBLY

5.1.1 Summary

The RADIATION output from the X-RAY SOURCE ASSEMBLY is measured by means of a RADIATION METER. The measurements are carried out under manual and/or AUTOMATIC EXPOSURE CONTROL, depending upon the type and use of the X-RAY EQUIPMENT.

5.1.2 Test equipment

Measurements are performed using an integrating RADIATION METER having an overall reproducibility of ± 5 % (including long-term stability, instrument noise and read-out ability).

As a substitute for the PATIENT when testing under AUTOMATIC EXPOSURE CONTROL, the ATTENUATION PHANTOM shall be used. This is intended to provide appropriate ATTENUATION and hardening of the X-RAY BEAM. A detailed description including consideration for the correct choice of an ATTENUATION PHANTOM is provided in annex D.

5.1.3 Test procedure

Place the RADIATION DETECTOR of the RADIATION METER in the RADIATION BEAM emerging from the X-RAY SOURCE ASSEMBLY. Measurement geometry shall be such that

- *the distance of the RADIATION DETECTOR from the FOCAL SPOT;*
- *the position of the RADIATION DETECTOR within the RADIATION FIELD;*

are reproduced to within ± 1 % of the FOCAL SPOT to RADIATION DETECTOR distance used in the initial CONSTANCY TEST. The same RADIATION FIELD size shall be used.

Whenever possible, carry out this test under both manual and AUTOMATIC EXPOSURE CONTROL. If a measurement according to 5.2.3.2 is performed, a measurement according to 5.1.3.2 may be regarded as redundant.

5.1.3.1 Testing under manual control

Operate the X-RAY EQUIPMENT using manual settings of the LOADING FACTORS identical to those used in the initial CONSTANCY TEST.

Record the reading of the RADIATION METER.

5.1.3.2 Testing under AUTOMATIC EXPOSURE CONTROL

Align the X-RAY SOURCE ASSEMBLY with the X-RAY IMAGE RECEPTOR as in normal clinical practice.

Place the ATTENUATION PHANTOM in the RADIATION BEAM between the RADIATION DETECTOR of the RADIATION METER and the RADIATION DETECTORS of the AUTOMATIC CONTROL SYSTEM.

Position the RADIATION DETECTOR of the RADIATION METER so as not to affect the operation of the AUTOMATIC CONTROL SYSTEM.

NOTE – For every RADIATION DETECTOR, a specific instruction has to be given as to where it has to be positioned in order to minimize the effect on the AUTOMATIC EXPOSURE CONTROL. If ATTENUATION PHANTOMS are used which are attached to the X-RAY SOURCE ASSEMBLY (A2 or A3), making the measurement behind the PHANTOM (if the sensitivity of the RADIATION DETECTOR allows it) has to be considered.

Place an unloaded RADIOGRAPHIC CASSETTE in the CASSETTE CHANGER and operate the X-RAY EQUIPMENT in conjunction with the AUTOMATIC CONTROL SYSTEM using settings of the X-RAY TUBE VOLTAGE identical to those used in the initial CONSTANCY TEST. Use the same RADIOGRAPHIC CASSETTE.

Record the reading of the RADIATION METER. In addition, record the IRRADIATION TIME, CURRENT TIME PRODUCT, etc. after each IRRADIATION has been made, if these are indicated.

5.1.4 Data evaluation

Compare the measured values of RADIATION output with the established BASELINE VALUES.

5.1.5 Criteria to be applied

5.1.5.1 Testing under manual control

The RADIATION output should be within ± 20 % of the BASELINE VALUES.

5.1.5.2 Testing under AUTOMATIC EXPOSURE CONTROL

The criteria to be applied depend on material used in the ATTENUATION PHANTOM.

If materials with low atomic number (up to 14) are used (for example water, polymethyl-methacrylate (PMMA), aluminium) the RADIATION output should be within the range +25 % to –20 % of the BASELINE VALUES.

For high atomic number materials, for example copper or lead, the action levels for the RADIATION output should be within ± 25 % of the BASELINE VALUES.

When lead is used with X-RAY TUBE VOLTAGES above 90 kV, the action levels appropriate to low atomic number materials shall be applied.

5.1.6 Action to be taken

If the system fails to meet the criteria, the guidance given in annex C should be followed.

NOTE – A gradual decrease in the RADIATION output is to be expected as a result of ageing of the X-RAY TUBE. In order to allow for this, it will be necessary from time to time to determine new BASELINE VALUES. This holds especially for testing under manual control, whereas for AUTOMATIC EXPOSURE CONTROL a decrease in the RADIATION output is compensated and cannot be detected.

5.1.7 Frequency of CONSTANCY TESTS

Initially, a series of CONSTANCY TESTS should be carried out daily for at least one week in order to establish the BASELINE VALUES by calculating the mean value of the output measurements.

Subsequently, the CONSTANCY TESTS should be repeated in a two-week cycle up to six months, in order to obtain data regarding the reliability of the X-RAY SOURCE ASSEMBLY, HIGH-VOLTAGE GENERATOR and AUTOMATIC CONTROL SYSTEM. Thereafter, the CONSTANCY TESTS shall be repeated according to the INSTRUCTIONS FOR USE as provided by the MANUFACTURER. If no such information is provided, the CONSTANCY TESTS shall be performed at least quarterly.

5.2 RADIATION input to the IMAGE RECEPTION AREA

5.2.1 Summary

The RADIATION input to the IMAGE RECEPTION AREA is determined from measurements of the optical density, recorded at specific points of a RADIOGRAM. Alternatively, the RADIATION input may be directly measured by means of a RADIATION METER.

NOTE – However a RADIATION METER takes no account of the X-RAY BEAM quality. The film method should therefore be preferred.

The measurements are carried out under manual and/or AUTOMATIC EXPOSURE CONTROL, depending upon the type and use of the X-RAY EQUIPMENT.

5.2.2 Test equipment

This test shall be performed using the same ANTI-SCATTER GRID, the same dedicated RADIOGRAPHIC CASSETTE and associated screen-film combination of the type normally used with the X-RAY EQUIPMENT under test. The systematic error of the optical densitometer used shall not be higher than ± 0.02 .

If a RADIATION METER is used, the instrument shall be of the integrating type with an overall reproducibility of $\pm 5\%$ (including long-term stability, instrument noise and read-out ability).

The ATTENUATION PHANTOM shall be used as a substitute for the PATIENT. This is intended to provide appropriate ATTENUATION and hardening of the X-RAY BEAM. In addition, the film marker TEST DEVICE shall also be used in order to enable specific points in the RADIOGRAM to be identified where measurements of the optical density are to be made.

Detailed descriptions including consideration for the correct choice of the ATTENUATION PHANTOM and the film marker TEST DEVICE are provided in annex D.

5.2.3 Test procedure

If the equipment is provided with AUTOMATIC EXPOSURE CONTROL, perform the CONSTANCY TEST in automatic mode. Whenever possible, repeat this CONSTANCY TEST under manual control.

Align the X-RAY SOURCE ASSEMBLY with the X-RAY IMAGE RECEPTOR as in normal clinical practice.

If a RADIOGRAPHIC CASSETTE is used, put it into its place. If a RADIATION METER is used, place its RADIATION DETECTOR in the IMAGE RECEPTION AREA. Place the ATTENUATION PHANTOM and the film marker TEST DEVICE in the X-RAY BEAM between the FOCAL SPOT and the X-RAY IMAGE RECEPTOR.