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(JSRT/JSA)

**Evaluation and routine testing in
medical imaging departments—
Part 2-10 : Constancy tests—
X-ray equipment for mammography**

ICS 11.040.50

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Foreword

This translation has been made based on the original Japanese Industrial Standard established by the Minister of Health, Labour and Welfare and the Minister of Economy, Trade and Industry through deliberations at the Japanese Industrial Standards Committee according to the proposal of establishing a Japanese Industrial Standard from Japanese Society of Radiological Technology (JSRT)/Japanese Standards Association (JSA), with a draft of Industrial Standard based on the provision of Article 12 Clause 1 of the Industrial Standardization Law.

This Standard has been made based on IEC 61223-2-10 : 1999 *Evaluation and routine testing in medical imaging departments—Part 2-10 : Constancy tests—X-ray equipment for mammography* for the purposes of making it easier to compare this Standard with International Standard; to prepare Japanese Industrial Standard conforming with International Standard; and to propose a draft of an International Standard which is based on Japanese Industrial Standard.

Attention is drawn to the possibility that some parts of this Standard may conflict with a patent right, application for a patent after opening to the public, utility model right or application for registration of utility model after opening to the public which have technical properties. The relevant Minister and the Japanese Industrial Standards Committee are not responsible for identifying the patent right, application for a patent after opening to the public, utility model right or application for registration of utility model after opening to the public which have the said technical properties.

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Contents

	Page
Introduction	1
1 Scope and object.....	1
1.1 Scope.....	1
1.2 Object.....	2
2 Normative references.....	2
3 Terminology	3
3.1 Degree of requirements	3
3.2 Use of terms.....	4
3.3 Definitions	4
4 General aspects of constancy tests	4
4.1 General conditions affecting test procedures	4
4.2 Establishment of baseline values	5
4.3 Frequency of constancy tests.....	5
4.4 Identification of equipment, instrumentation and test conditions.....	5
5 Performance tests	7
5.1 X-ray equipment—Imaging performance	7
5.2 Radiation beam—Geometric characteristics	11
5.3 Compression device	12
5.4 Mammographic cassettes and intensifying screens.....	13
5.5 Mammographic film	17
6 Statement of compliance.....	17
Annex A (normative) Terminology — Index of defined terms	22
Annex B (informative) Example of a form for the standardized test report.....	25
Annex C (informative) Guidance on action to be taken.....	27
Annex D (informative) Rationale.....	29
Annex E (informative) Bibliography.....	32
Annex F (normative) Phantoms and test devices	33
Annex 1 (informative) Comparison table between JIS and corresponding International Standard	35

Evaluation and routine testing in medical imaging departments—Part 2-10 : Constancy tests— X-ray equipment for mammography

Introduction This Japanese Industrial Standard has been prepared based on the first edition of IEC 61223-2-10 *Evaluation and routine testing in medical imaging departments—Part 2-10 : Constancy tests—X-ray equipment for mammography* published in 1999 with some modifications of the technical contents. In addition, for the subclauses with marks (*) on the left shoulder of their own in this Standard, these supplements are described in annex D (informative).

The portions underlined with dots are the matters not stated in the original International Standard.

1 Scope and object

1.1 Scope This part of JIS Z 4752 applies to those components of X-ray equipment which

- generate, influence the propagation of and detect X-radiation;
- process, record and present radiographic information in radiological installations with mammographic X-ray equipment using intensifying screens with radiographic film.

Special accessories of mammographic X-ray equipment such as biopsy plates and stereotactic devices are not within the scope of this Standard.

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 gives methods of tests for the constancy of properties of diagnostic X-ray equipment as described in JIS Z 4752-1 (see clause 2).

This part of JIS Z 4752 is designed to be applicable to X-ray equipment for mammography without digital imaging devices.

Remarks : The International Standard corresponding to this Standard is as follows.

In addition, symbols which denote the degree of correspondence in the contents between the relevant International Standard and JIS are IDT (identical), MOD (modified), and NEQ (not equivalent) according to ISO/IEC Guide 21.

IEC 61223-2-10 : 1999 *Evaluation and routine testing in medical imaging departments—Part 2-10 : Constancy tests—X-ray equipment for mammography (MOD)*

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 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 standard contain provisions which, through reference in this text, constitute provisions of this Standard. The most recent editions of the standards (including amendments) indicated below shall be applied.

JIS Z 4005 *Medical radiology—Terminology*

Remarks : IEC 60788 : 1984 *Medical radiology—Terminology* is equivalent to the said standard.

JIS Z 4752-1 *Evaluation and routine testing in medical imaging departments—Part 1 : General aspects*

Remarks : IEC 61223-1 : 1993 *Evaluation and routine testing in medical imaging departments—Part 1 : General aspects* is identical with the said standard.

JIS Z 4752-2-1 *Evaluation and routine testing in medical imaging departments—
Part 2-1 : Constancy tests—Film processors*

Remarks : IEC 61223-2-1 : 1993 *Evaluation and routine testing in medical imaging departments—Part 2-1 : Constancy tests—Film processors* is equivalent to the said standard.

JIS Z 4752-2-2 *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*

Remarks : 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* is equivalent to the said standard.

JIS Z 4752-2-3 *Evaluation and routine testing in medical imaging departments—
Part 2-3: Constancy tests—Darkroom safelight conditions*

Remarks : IEC 61223-2-3 : 1993 *Evaluation and routine testing in medical imaging departments—Part 2-3 : Constancy tests—Darkroom safelight conditions* is identical with the said standard.

JIS Z 4752-2-5 *Evaluation and routine testing in medical imaging departments—
Part 2-5 : Constancy tests—Imaging display devices*

Remarks : IEC 61223-2-5 : 1994 *Evaluation and routine testing in medical imaging departments—Part 2-5 : Constancy tests—Image display devices* is identical with the said standard.

JIS Z 4905 *Radiographic cassettes for medical use*

3 Terminology

3.1 Degree of requirements In this Standard certain terms 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 boldfaced letters are used as defined in JIS Z 4005 or in 3.3 of this Standard or annex A.

3.3 Definitions

3.3.1 film base plus fog density for constancy tests in X-ray equipment, the optical density in an area of the radiogram, on the processed control film, that has not been exposed to light from a sensitometer (This definition has been taken from JIS Z 4752-2-1.)

3.3.2 net optical density density above film base plus fog density

4 General aspects of constancy tests 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 JIS Z 4752-2-3 and proper film processing, according to JIS Z 4752-2-1 (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 the influences of environmental changes.

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.

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.

However, it is important

- to perform constancy tests with loading factors which are the same as those used most frequently in clinical practice;

- to reproduce and record 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 the influence of environmental changes on the results. Variations in mains voltage and, if evaluating images from **image display device**, room lighting conditions are of special importance;
- 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 : Where appropriate national standards exist, measuring equipment should be referable to them.

Before the constancy tests are started, the constancy of the **radiographic film**, the film processing and the film viewing conditions have to 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 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 shall be repeated

- whenever malfunction is suspected;
- immediately after the **X-ray 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;
- anode materials;
- beam limiting devices;
- compression plates, **patient support** or other attenuating material in the radiation beam;

- **anti-scatter grid**;
 - **radiographic film** type and emulsion number;
 - **film processor**;
- together with items of test instrumentation such as:
- combination of a **radiographic cassette** and **intensifying screens**;
 - **test devices**;
 - **sensitometer**;
 - **densitometer**;
 - **force balance**;
- and settings of variables such as
- **focal spot to image receptor distance**;
 - **automatic control system density control** and **sensor position**;
 - **loading factors**;
 - **magnification position**;
 - **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 **mammographic X-ray equipment** under test.

NOTES 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 systems, including those due to the ageing of the cassette itself.

2 It is essential that any **radiographic film** used in the test is of the same type as the film used in clinical practice for mammography.

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 **JIS Z 4752-2-1**.

If the film type and/or associated processing conditions are changed, a new initial constancy test shall be carried out.

Test devices are described for each of the performance tests described in clause 5 of this Standard. In practice, some tests, for example those described in 5.1 through 5.4, may be performed simultaneously by using a composite **test device** which combines the properties of a number of individual test devices. Test devices are discussed in detail in annex F.

5 Performance tests

5.1 X-ray equipment—Imaging performance

*5.1.1 Image density

5.1.1.1 Summary A standard test device is exposed under standard conditions and the net optical density of the image is measured at a specific position in the radiogram. Radiograms are made under both manual and automatic exposure control. Evaluation may reveal changes in the performance under automatic exposure control as well as changes in the radiation output, radiation quality, attenuation in the radiation beam and sensitivity of the imaging system.

5.1.1.2 Test equipment

- The test cassette.
- An optical densitometer (measurement range: between 0 and 3.5, accuracy: within ± 0.02)
- The reference thickness of the attenuation phantom (40 mm) is used to simulate a patient during the test under manual control.
- Three different thickness (preferably 20 mm, 40 mm, 60 mm) of the attenuation phantom shall be used for the test under automatic exposure control.

5.1.1.3 Test procedure Ensure that all interchangeable parts and the geometric arrangement of the X-ray equipment are as in the initial constancy test. Place the loaded test cassette in the radiographic cassette holder, and the attenuation phantom in the same position as in the initial constancy test, centred from side to side and aligned with the proximal (chest wall) edge of the breast support table.

- a) **Testing under manual control** Make an irradiation with the manual settings of the loading factors of the X-ray equipment as used in the initial constancy test.

In the case of an initial constancy test, adjust the loading factors and repeat if necessary to obtain a net optical density between 1.0 and 1.6.

Record the loading factors for subsequent use.

- b) **Testing under automatic exposure control** Ensure that the automatic exposure control sensor is in the position used for the initial constancy test and completely covered by the test device, with X-ray tube voltage density control and other relevant settings identical to those used in the initial constancy test. Make radiograms of at least three different thicknesses of the attenuation phantom, in steps of not more than 20 mm and including the 40 mm “reference” thickness.

Record, if possible, the irradiation time or the current time product, the anode material and the added filter after each irradiation.

Process the exposed film in accordance with the procedure referred to in 4.4. Measure on each radiogram the net optical density at the point defined in the initial constancy test, which was preferably in the mid-line of the film and between 20 mm and 30 mm from the chest wall. This area may be marked by fixing a fibre washer to the attenuation phantom.

5.1.1.4 Date evaluation Compare the measured values of net optical density in the radiograms with the established baseline values, after correcting for changes in the film batch or the processing conditions. Compare the corrected optical densities of the radiograms obtained for the different thicknesses of the attenuation phantom (with automatic exposure control) with the respective values obtained during the initial constancy test.

NOTE : If irradiation time or current time product data are available, compare the irradiation time or current time product recorded during the test under automatic exposure control with the values obtained during the initial constancy test.

5.1.1.5 Criteria to be applied The net optical density should be within ± 0.20 of the baseline values.

NOTE : A deviation of ± 0.20 with regard to the baseline values is acceptable if variations in net optical density due to speed variations in film emulsions and film processing are not included. It is nevertheless well recognized that ± 0.15 is a common tolerance limit for breast screening services.

Under automatic exposure control, any variation in net optical density between tests should be in the same direction and closely correlated for all thicknesses of the attenuation phantom. The range of individual baseline values for different thicknesses may be greater than ± 0.20 of the value for the reference thickness.

If the measured optical densities fall within ± 0.20 of their baseline values but some have increased and others decreased, further investigation is recommended.

NOTE : If a constancy test on irradiation time or current time product is performed using the 40 mm thickness of the attenuation phantom, these parameters should normally be within ± 0.20 % of the baseline values.

5.1.1.6 Action to be taken If the systems fails to meet the criteria, the guidance given in annex C should be followed.

5.1.1.7 Frequency of constancy tests The constancy test shall be performed at least quarterly. A higher frequency is recommended if there are doubts concerning the reliability of the X-ray source assembly, the high-voltage generator or the automatic exposure control.

NOTE : If the X-ray equipment is heavily used, particularly for breast screening, a simplified test, using only the standard thickness of the attenuation phantom and the mode (manual or automatic exposure control) clinically used, should be repeated at least once a week, or, in the case of remote film processing daily.

5.1.2 Artefacts

5.1.2.1 Summary This test is intended to reveal artefacts in the imaging system that might reduce the diagnostic quality of the image. Probable sources of artefacts are anti-scatter grid failures such as misalignment, decentring, mechanical damage or incorrect movement and uneven attenuation of the radiation beam by the breast support, compression paddle or added filters.

5.1.2.2 Test equipment

- Film illuminator;
- Magnifying lens with a magnification factor between 5 and 10.

5.1.2.3 Test procedure Examine the radiograms obtained from the test in 5.1.1 together with the corresponding ones obtained in the initial constancy test. Use a film illuminator and view the radiograms.

- a) from the distance normally used in clinical practice ; and
- b) with a magnifying lens.

5.1.2.4 Data evaluation

- a) Compare the gross density variation in the radiograms with the corresponding radiograms from the initial constancy test. Examine the radiograms with respect to the occurrence of patterns, stains, dots and other phenomena that are not present in the initial constancy test.
- b) If a moving grid is used, inspect the radiogram and record any appearance of grid lines.

5.1.2.5 Criteria to be applied Any visible deterioration in the homogeneity of the film density across the radiogram, the occurrence of any pattern not present before or the more pronounced appearance of grid lines, should lead to further action.

NOTE : Grid lines should not be visible in normal clinical use, and should not be visible if the attenuation phantom has a thickness of 20 mm or greater as in the present test.

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

5.1.2.7 Frequency of constancy tests This test shall be performed with the same frequency as specified in 5.1.1.7.

5.1.3 High-contrast resolution

5.1.3.1 Summary This test checks the constancy of the spatial resolution of the X-ray equipment by producing a radiographic image of a high-contrast test device (No.1) associated with an homogeneous scattering phantom.