

AS/NZS 4184.2.1:1994

IEC 1223-2-1:1993

AS/NZS 4184.2.1

Australian/New Zealand Standard

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

**Part 2.1: Constancy tests—Film
processors**

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This Joint Australian/New Zealand Standard was prepared by Joint Technical Committee HT/23, Medical Diagnostic Imaging Equipment. It was approved on behalf of the Council of Standards Australia on 14 February 1994 and on behalf of the Council of Standards New Zealand on 28 February 1994. It was published on 16 May 1994.

The following interests are represented on Committee HT/23:

Australian Academy of Dento-Maxillo-Facial Radiologists
Australian College of Physical Scientists and Engineers in Medicine
Australian and New Zealand Society of Nuclear Medicine
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AS/NZS 4184.2.1:1994

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Evaluation and routine testing in medical imaging departments

Part 2.1: Constancy tests—Film processors

First published as Joint Standard AS/NZS 4184.2.1:1994.

PUBLISHED JOINTLY BY:

STANDARDS AUSTRALIA
1 The Crescent,
Homebush NSW 2140 Australia

STANDARDS NEW ZEALAND
6th Floor, Wellington Trade Centre,
181-187 Victoria Street,
Wellington 1 New Zealand

ISBN 0 7262 8833 0



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PREFACE

This Standard was prepared by the Joint Standards Australia/Standards New Zealand Committee HT/23 on Medical Diagnostic Imaging Equipment and issued as a Joint Standard under the terms of the Active Cooperation Agreement between Standards Australia and Standards New Zealand.

This Standard is identical with, and has been reproduced from, IEC 1223-2-1:1993, *Evaluation and routine testing in medical imaging departments*, Part 2-1: *Constancy tests—Film processors*.

Under arrangements made between Standards Australia/Standards New Zealand and ISO/IEC, as well as certain other Standards organizations, users of this Standard are advised that the number of this Standard is not reproduced on each page, its identity is shown only on the cover and title page.

For the purpose of this Standard, the IEC text should be modified as follows:

- (a) *Terminology* The words ‘this Australian/New Zealand Standard’ should replace the word ‘this International Standard’ wherever they appear.
- (b) *Decimal marker* Substitute a full point for a comma where it appears as a decimal marker.
- (c) *References* The references to international Standards should be replaced by references to the following Australian or Joint Australian/New Zealand Standards:

Reference to International Standard or other publication		Joint Australian/New Zealand Standard	
IEC		AS	
601	Medical electrical equipment	3200	Approval and test specification— Medical electrical equipment
601-1	Part 1: General requirements for safety Amendment No. 1, 1991	3200.1	General requirements for safety (NZS 6150:1990) Amdt 1 December 1992
788	Medical radiology—Terminology	—	
		AS/NZS	
1223	Evaluation and routine testing in medical imaging departments	4184	Evaluation and routine testing in medical imaging departments
1223.1	Part 1: General aspects	4184.1	Part 1: General aspects
1223-2-3	Part 2-3: Constancy tests—Dark- room safelight conditions	4184.2.3	Part 2.3 Constancy tests—Dark- room safelight conditions
ISO			
4090	Photography—Film dimensions— Medical radiography	—	
8374	Photography—Determination of ISO safelight conditions	—	
8402	Quality—Vocabulary	—	

The Annexes to this Standard, A, B and C, are for information purposes only.

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STANDARDS AUSTRALIA/STANDARDS NEW ZEALAND

Australian/New Zealand Standard**Evaluation and routine testing in medical imaging departments****Part 2.1: Constancy tests—Film processors****1 Scope and object****1.1 Scope**

This technical report applies to those components of X-RAY EQUIPMENT which process RADIOGRAPHIC FILM and other photographic materials in X-ray facilities in which any of the following radiographic or photographic materials are handled:

- all types of SCREEN FILM;
- NON-SCREEN FILM;
- photographic film for INDIRECT RADIOGRAPHY, as used for recording
 - OUTPUT IMAGES of X-RAY IMAGE INTENSIFIERS,
 - other transferred RADIOLOGICAL IMAGES;
- photographic material for copying RADIOGRAMS;
- photographic material for making permanent images of information recorded by electronic means, and presented on display tubes, for example: hard copy cameras, or printed by other electronic means, for example: laser; as used in diagnostic equipment such as for general RECONSTRUCTIVE TOMOGRAPHY, digital imaging, ultrasound, NUCLEAR MEDICINE, magnetic resonance.

The method described in this technical report is intended primarily for automatic FILM PROCESSORS, but may be adapted for testing equipment for manual processing.

This technical report is a part of a series of Particular Publications (standards and technical reports) which will describe test methods for the constancy of properties of various subsystems of diagnostic X-RAY EQUIPMENT, as described in IEC 1223-1.

• 1.2 Object

This technical report describes constancy parameters in FILM PROCESSORS, and a method to check these parameters, in order to ensure that the conditions for producing consistent RADIOGRAMS of adequate quality on radiographic and photographic materials are maintained.

2 References to other publications

The following IEC/ISO publications are quoted in this technical report:

IEC 601-1: 1988, *Medical electrical equipment – Part 1: General requirements for safety*

Amendment No. 1, 1991

IEC 788: 1984, *Medical radiology – Terminology*

IEC 1223-1: 1993, *Evaluation and routine testing in medical imaging departments – Part 1: General aspects*

IEC 1223-2-3: 1993, *Evaluation and routine testing in medical imaging departments – Part 2-3: Constancy tests – Darkroom safelight conditions*

ISO 4090: 1991, *Photography – Film dimensions – Medical radiography*

ISO 8374: 1986, *Photography – Determination of ISO safelight conditions*

ISO 8402: 1986, *Quality – Vocabulary*

3 Terminology

3.1 Use of terms

This technical report contains a number of terms that are defined in IEC 788, in IEC 1223-1 and in IEC 1223-2-1 (see annex A, Terminology – Index of terms). Where these terms are used with the meanings given in their definitions, they are printed in capital letters to signify that the defined meaning applies. Words forming a part of the whole of any defined term may also appear in lower-case letters. In that event, the meaning is not intended necessarily to correspond to any formal definition, but to be derived from the customary meaning of the words in the language and from the actual context.

Terms derived from those formally defined (for example, the plural form of a term defined in the singular or the adjectival form of a term defined as a noun), are used where appropriate and, if printed in capital letters, have meanings linked to the definitions of the source terms concerned.

The term:

"specific" when used with parameters or conditions: refers to a particular value or standardized arrangement, usually to those required in an IEC publication or a legal requirement.

"specified" when used with parameters or conditions: refers to a value or arrangement to be chosen for the purpose under consideration and indicated usually in ACCOMPANYING DOCUMENTS.

3.2 Definitions

3.2.1 FILM PROCESSOR: For use in MEDICAL DIAGNOSTIC RADIOLOGY, a combination of equipment and devices to process the latent radiological information, recorded on, or transferred to, radiographic or photographic material, into a permanent, visible image.

3.2.2 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.

3.2.3 SPEED INDEX: For CONSTANCY TESTS in X-RAY EQUIPMENT, the specific value of optical density in an area of the RADIOGRAM produced by a constant exposure to a light source.

NOTE - The value of SPEED INDEX normally is established at an optical density in the range from 0,8 to 1,2 above that of FILM BASE PLUS FOG DENSITY.

3.2.4 CONTRAST INDEX: For CONSTANCY TESTS in X-RAY EQUIPMENT, difference between the SPEED INDEX and the value of optical density produced by a constant exposure from a light source, greater than that used for producing the SPEED INDEX.

NOTES

1 This exposure is normally aimed at an optical density in the range from 1,6 to 2,0 above that of FILM BASE PLUS FOG DENSITY.

2 SPEED INDEX and CONTRAST INDEX are used as constancy parameters and are intended to facilitate the routine checks described in this technical report. They must not be confused with the sensitometric definitions of sensitivity in terms of speed and average gradient.

4 General aspects of CONSTANCY TESTS

4.1 Principle of the test procedures

In an initial series of CONSTANCY TESTS, the BASELINE VALUES of the three constancy parameters of the FILM PROCESSOR (FILM BASE PLUS FOG DENSITY, SPEED INDEX and CONTRAST INDEX) are determined. This is achieved by exposing control films under specific conditions prior to processing them in the FILM PROCESSOR under test.

NOTE - Whilst it is possible to use pre-exposed films available from the manufacturers of photosensitive materials, this method is not recommended in preference to the use of freshly exposed control films because of the differences in the characteristic response of the pre-exposed films from those currently in use in the X-ray department.

The subsequent performance of the FILM PROCESSOR is monitored routinely by processing further control films, and the measured values of the constancy parameters are compared with the BASELINE VALUES in order to detect deviations from constancy.

In X-ray departments where more than one FILM PROCESSOR is in use, the performance of several FILM PROCESSORS can be harmonized by adjusting their individual developer temperatures. This is greatly facilitated if all the FILM PROCESSORS use the same chemistry; see annex E.

4.2 Test equipment

* 4.2.1 Control films

Control films of photographic or RADIOGRAPHIC FILM are produced by exposure under a stepwedge to light emitted from a calibrated and stable light source (sensitometer).

The control films should be of the same type as the radiographic material(s) normally used in the X-ray department and should be stored under the same conditions.

As far as is practicable, control films used for successive CONSTANCY TESTS should be of the same type and batch/emulsion number, and should be taken from the same package. One package should not be in use for a period exceeding six months, nor beyond its expiry date.

Prior to changing the batch or type of radiographic material used for the control films, it is necessary to adjust the BASELINE VALUES of the constancy parameters. This is achieved by simultaneously processing control films from both the current and replacement batches. The appropriate degree of adjustment is then determined from a comparison of the measured constancy parameters.

If more than one type of radiographic material is processed in the same FILM PROCESSOR, it may be necessary to use several series of control films, one representative of each type of radiographic material, in order to allow for differences in characteristic response of the different types of material.

4.2.2 Sensitometer

Control films should be exposed by means of a sensitometer equipped with a suitable stepwedge. The light output should be reproducible to within $\pm 2\%$. The sensitometer should provide at least two levels of exposure which result in optical densities on the processed control films:

- a) within the range 0,8 to 1,2 above FILM BASE PLUS FOG DENSITY, and
- b) within the range 1,6 to 2,0 above FILM BASE PLUS FOG DENSITY.

No part of the control film should be exposed to light from the sensitometer in order to permit measurement of the FILM BASE PLUS FOG DENSITY on the processed control film.

A stepwedge containing a series of steps will enable differences in the sensitivity of different types of control film to be taken into account.

4.2.3 Densitometer

Optical densities are measured with a densitometer which reads consistently within $\pm 0,02$.