

Evaluation and routine testing in medical imaging departments —

Part 2: Constancy tests —

Section 2.1 Method for film processors

Committees responsible for this British Standard

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- British Institute of Radiology
- College of Radiographers
- Department of Health
- Institute of Physical Sciences in Medicine (IPSM)
- Royal College of Radiologists
- Society of X-ray Technology

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National foreword

This Section of BS 7725 has been prepared under the direction of the Health Care Standards Policy Committee. It is identical with IEC 1223-2-1:1993 *Evaluation and routine testing in medical imaging departments — Part 2-1: Constancy tests — Film processors*, prepared by the Technical Committee 62 Electrical equipment in medical practice and published by the International Electrotechnical Commission (IEC).

Cross-references

International Standard	Corresponding British Standard
IEC 601-1:1988 (without amendment No. 1, 1991)	BS 5724 <i>Medical electrical equipment</i> Part 1:1989 <i>General requirements for safety</i> (Identical)
IEC 788:1984	BS 6641:1985 <i>Glossary of medical radiological terms</i> (Identical)
IEC 1223-1:1993	BS 7725 <i>Evaluation and routine testing in medical imaging departments</i> Part 1:1994 <i>General</i> (Identical)
IEC 1223-2-3:1993	Section 2.3:1994 <i>Method for darkroom conditions</i> (Identical)

NOTE ISO 4090:1991, ISO 8374:1986 and ISO 8402:1986 referenced in clause 2 are not quoted in this Technical Report. This error has been reported to the relevant body for action.

A British Standard does not purport to include all the necessary provisions of a contract. Users of British Standards are responsible for their correct application.

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Summary of pages

This document comprises a front cover, an inside front cover, pages i and ii, pages 1 to 18, an inside back cover and a back cover.

This standard has been updated (see copyright date) and may have had amendments incorporated. This will be indicated in the amendment table on the inside front cover.

Introduction

Some provisions or statements in the body of this technical report require additional information. Such information is presented in Annex D, Rationale. An asterisk in the left margin of a clause or subclause indicates the presence of such additional information.

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

NOTE 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.

NOTE 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:

- within the range 0,8 to 1,2 above FILM BASE PLUS FOG DENSITY, and
- 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 $\pm 0,02$.

4.2.4 Thermometer*

The temperatures of the processing solutions are measured by a metal stem or digital thermometer to within $\pm 0,1$ °C.

A mercury in glass thermometer shall not be used.

4.3 FILM PROCESSOR: Cleaning, maintenance and log book*

Prior to any CONSTANCY TEST, it shall be ensured that

- the FILM PROCESSOR is set up in accordance with the instructions given in the ACCOMPANYING DOCUMENTS for the radiographic materials, the FILM PROCESSOR and the chemicals;
- the optimum developer temperature is known either as determined, see Annex E, or as given in the ACCOMPANYING DOCUMENTS for the radiographic materials;
- the FILM PROCESSOR is maintained in accordance with the instructions given in the ACCOMPANYING DOCUMENTS for the radiographic materials, the FILM PROCESSOR and the chemicals.

A maintenance log-book attached to each FILM PROCESSOR is essential in order to record:

- when maintenance is carried out;
- when the processing solutions are changed,
- when new replenishment solution is added, and
- when any other changes relevant to the performance of the FILM PROCESSOR were made.

4.4 Darkroom safelight conditions

Where, during a CONSTANCY TEST according to this technical report, radiographic or photographic materials are openly handled prior to the test, it must be insured that the darkroom conditions as well as the film storage conditions are satisfactory, and, if necessary, that CONSTANCY TESTS according to IEC 1223-2-3 have been carried out.

5 Test procedure

5.1 Determination of constancy of FILM PROCESSOR performance

5.1.1 Method

- a) It should be assured that:
 - the FILM PROCESSOR has undergone routine maintenance; and
 - its performance is satisfactory; see Annex E.
- b) The FILM PROCESSOR is set at the selected optimum temperature for the development solution.
- c) The “start-up” procedure recommended in the ACCOMPANYING DOCUMENTS is followed, and a period of 30 min allowed for the solution temperatures to stabilize.
- d) The solution and wash water temperatures are checked. If feasible, the replenishment rates, wash water flow rate, and dryer temperatures are measured. Temperatures and flow rates are adjusted if necessary and allowed to stabilize.
- e) Using the sensitometer, a series of two to six control films are exposed. It is sufficient to expose only one side of a DOUBLE EMULSION FILM.
- f) *After at least 30 min but no longer than 4 h, the control films are processed. The control films are processed so that the leading edge is the least exposed end of the stepwedge pattern.

The sheets of control film are passed into the FILM PROCESSOR always at the same side of the feeding slit.

- g) In the three areas of each control film the optical densities are measured; see 4.2.2.
- h) for each constancy parameter, the average value is determined of the optical densities measured in the six RADIOGRAMS.

In an initial CONSTANCY TEST, these three average values are the BASELINE VALUES for FILM BASE PLUS FOG DENSITY, SPEED INDEX and CONTRAST INDEX.

5.1.2 Data evaluation

In a subsequent CONSTANCY TEST, the average values of the constancy parameters are determined and compared with the BASELINE VALUES, determined as described in item h) of 5.1.1.

This comparison is facilitated by the use of a control chart for each FILM PROCESSOR on which the constancy parameters are plotted as a function of time. An example is shown in Figure 2, which also indicates the BASELINE VALUES and the limits of acceptable performance.

The test results and conditions should be recorded in a uniform manner, examples of which are given in Figure 2 and Annex B.

5.1.3 ESTABLISHED CRITERIA

The performance of the FILM PROCESSOR is of adequate constancy if variations in the constancy parameters are within the following limits:

- a) the FILM BASE PLUS FOG DENSITY shall be within $\pm 0,05$ of the BASELINE VALUE;
- b) the SPEED INDEX shall be within $\pm 0,15$ of the BASELINE VALUE, and should be within $\pm 0,10$ of this value.

5.1.4 Further action

If any of the constancy parameters are outside the ESTABLISHED CRITERIA described in 5.1.3 the CONSTANCY TEST should be repeated.

If any of the constancy parameters still remain outside these limits, or if the results of the last three CONSTANCY TESTS indicate a tendency for any index to consistently decrease or increase in value, then appropriate action should be taken as described in clause 6.

5.1.5 Frequency of CONSTANCY TEST

- a) Once per day at the same time, if use of the FILM PROCESSOR is intense;
- b) prior to use, if the FILM PROCESSOR has not been used for at least 24 h;
- c) each time the processing solutions are changed;
- d) after maintenance or repair of the FILM PROCESSOR.

5.2 Consistency of control films

When the current batch of control films is about to become exhausted, a replacement batch of control films should be introduced in accordance with the following procedure.

- a) At least three control films from the current batch, together with at least three control films from the replacement batch, are exposed as described in 5.1.1.
- b) The control films are processed and evaluated as described in 5.1.1.
- c) The average values of the constancy parameters for the two batches of control films are compared. The differences in these average values should be used to establish the new BASELINE VALUES for the constancy parameters.
- d) If the difference in any single constancy parameter is outside the limits described in 5.1.3, an investigation should be carried out into the reason for the change in film characteristics. This investigation is beyond the scope of this technical report.

5.3 Hypo retention test*

In order to ensure that radiographic materials are fixed and washed adequately, a hypo retention test should be performed at least annually, as follows.

- a) An unexposed control film is processed, and then a few drops of hypo test solution are placed on the RADIOGRAM. This normally produces a stain on the RADIOGRAM ranging in colour from pale yellow to dark brown.
- b) The hue of the coloured stain is compared against a standard estimator. This shall be within the limit specified in the ACCOMPANYING DOCUMENTS for the film used, otherwise corrective action is necessary.

*NOTE The standard estimator may be obtained from the film manufacturer. The hypo test solution may also be obtained from the film manufacturer or can be made up as described in Annex C.

6 Action to be taken

The control charts according to 5.1.2, and records of test results according to Annex B, will clearly show any trend in the values of the constancy parameters with time, and will indicate any tendency to exceed the ESTABLISHED CRITERIA described in 5.1.3.

Should such a trend occur, or should the value of any constancy parameter fall outside the limits described in 5.1.3, the following checks should be carried out in order to determine what corrective action should be taken to halt the deterioration in processing conditions:

- a) The temperature of the development solution is measured.
- b) The replenishment rates are measured.
- c) The radiographic materials currently being processed are checked for changes in batch numbers, types and sizes.
- d) The replenishment solutions are checked for correct preparation.
- e) The expiry dates of control film and the radiographic materials currently in use in the X-ray department are checked.
- f) The wash water flow rate is measured.
- g) The wash water temperature is measured.
- h) The operation of the recirculatory system is checked.
- i) The developer filters are inspected.
- j) The expiry dates of the chemicals in use are checked, if applicable.