INTERNATIONAL STANDARD

ISO 13116

First edition
2014-11-01

Dentistry — Test Method for Determining Radio-Opacity of Materials

Médecine bucco-dentaire — Méthodes de détermination de la radio opacité des matériaux

Reference number
ISO 13116:2014(E)

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Published in Switzerland

Contents

Page

Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword — Supplementary information

The committee responsible for this document is ISO/TC 106, *Dentistry*, Subcommittee SC 1, *Filling and restorative materials*.

Dentistry — Test Method for Determining Radio-Opacity of Materials

1 Scope

This International Standard specifies test methods for determination of radio-opacity of a test material by reference to a specimen of an aluminium standard. The method is designed to discriminate radio-opacity at a clinically meaningful level and is not designed to take account of factors which may affect precise, inherent values of radio-opacity such as background noise, X-ray beam power, grey scale correction and image enhancement. It is recognized that such factors can change the value of radio-opacity but not the relative ranking compared to standard thicknesses of an internal standard such as aluminium. This test may be performed with conventional or digital sensoring techniques of dental X-ray apparatus.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 3665, *Photography — Intra-oral dental radiographic film and film packets — Manufacturer specifications*

ISO 1942, *Dentistry — Vocabulary*

ISO 8601, *Data elements and interchange formats — Information interchange — Representation of dates and times*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 1942 apply.

4 Requirements

This International Standard does not set pass/fail limits for radio-opacity. If a manufacturer claims that a material is radio-opaque, the radio-opacity, determined in accordance with Clause 7, shall have a value at least equivalent to the minimum level specified in the appropriate product standard requirements.

NOTE Aluminium has a radio-opacity equivalent to that of dentine. Thus 1 mm of material having a radio-opacity equivalent to 1 mm of aluminium has a radio-opacity equivalent to that of dentine.

5 Sampling

The relevant product standard defines the details of the sampling procedure.

NOTE Normal procedures are for a sample to be drawn from one batch to provide sufficient material to complete the prescribed test. The test sample normally consists of packages prepared for retail sale.

6 Apparatus

6.1 Suitable moulds for constructing samples of the test-material

Details of suitable moulds are specified in the appropriate product standard. Typically, moulds for specimens suitable for use in this test have a thickness ranging from 0,5 mm to 2,5 mm with straight right-angled edges. The specimens shall be homogenous and have a uniform thickness but the shape and size are not critical providing there is sufficient area for a determination to be made and that the specimens can be located near the centre of the film or sensor.

NOTE 1 10 mm diameter has been found to be suitable for disc shaped specimens.

NOTE 2 For highly radio-opaque materials (e.g. containing zirconia), thinner specimens up to a maximum of 1,5 mm thickness may be required; while for materials of low radio-opacity, thicker specimens may be required.

6.2 Screw micrometer gauge, or equivalent device

Reading and accurate to 0,01 mm.

6.3 Aluminium step wedge

With purity at least 98 % (mass fraction) of aluminium with less than 0,1 % (mass fraction) copper and less than 1,0 % (mass fraction) iron present, having a thickness range from 0,5 mm to 5,0 mm in equally spaced steps. Measure the thickness of each step with the micrometer (6.2) to an accuracy of 0,01 mm. There must be less than a 0,05 mm variation in thickness over the area of each step. The wedge must be free standing.

NOTE The overall dimensions may be adjusted for the convenience of the user.

A thickness difference of each step in the step-wedge of approximately 0,5 mm is recommended.

6.4 Dental X-ray unit

With a total filtration of 1,5 to 2 mm aluminium, and capable of operation at (60 ± 10) kV, with suitable accessories. The unit shall be used in conjunction with conventional and/or digital X-ray sensoring equipment.

6.5 Dental X-ray sensor

NOTE One of three sensoring techniques may be used to determine the radio-opacity of the test material.

6.5.1 Analogue sensoring

6.5.1.1 Dental X-ray occlusal film of speed group D, E or F (as specified in ISO 3665) and freshly-prepared developing solution and fixer prepared and used in accordance with manufacturers' instructions.

6.5.1.2 Densitometer using white light and capable of measuring in the optical density range 0 to 3,0 to a resolution of 0,01, calibrated at zero and against a reference with optical density of (2,5 ± 0,5) known to an accuracy of ± 0,01, and using an aperture of (2,0 ± 0,1) mm. The densitometer must be prepared to be stable to ± 0,01 at an optical density of (2,5 ± 0,5) over 30 min or a recalibration shall be performed before each set of readings.

6.5.2 Digital sensoring

6.5.2.1 Intra-oral X-ray sensor calibrated for use with appropriate software.

6.5.2.2 Software capable of grey scale analysis with an accuracy of ± 1 grey value and compatible with the intra-oral sensor[1)].

6.5.3 Imaging plates

6.5.3.1 Phosphor imaging plates of a size suitable for the placement of specimens of the test material and the aluminium step wedge (6.3)

6.5.3.2 Digital scanner compatible with the imaging plates.

6.5.3.3 Software capable of grey scale analysis with an accuracy of ± 1 grey value and compatible with the digital scanner[1)]

7 Test conditions and procedures

7.1 Test conditions

Use test conditions as outlined in the appropriate product standard.

7.2 Preparation of test specimens

Prepare the test specimens according to the procedure outlined in the appropriate product standard. Measure the thickness of all samples using the measuring device described in 6.2. There must be less than a 0,05 mm variation in thickness of specimens over the area in which the determination is to be made. Use a specimen thickness which complies with the appropriate product standard.

7.3 Test procedure for analogue equipment

Position the X-ray source (6.4) perpendicular to the X-ray film (6.5.1.1). Place the specimen and the aluminium step wedge (6.3) in contact and upright, in the centre of the film.

Irradiate the specimen, aluminium step wedge and film with X-rays at (60 ± 10) kV at a target film distance of 300 mm to 400 mm for such a time that, after processing, the region of film beside the specimen and aluminium has an optical density of between 1,5 and 2.

NOTE Exposures of between 0,1 s and 0,4 s at 10 mA are typical.

Measure the thickness of the specimen (T_S) and the steps of the aluminium step wedge (6.3) with the micrometer (6.2) to an accuracy of 0,01 mm. The optimal thickness of the specimen is stated in the appropriate product standard.

If the thickness of the specimen is in the range specified by the product standard then, after developing and fixing the film, measure the optical density of the image of the specimen and that of each step of the aluminium using the densitometer (6.5.1.2).

NOTE For many materials a specimen thickness of (1,0 ± 0,1) mm is most appropriate.

Carry out three separate exposures or the number specified in the product standard if that is greater.

7.4 Test procedure for digital equipment

Measure the thickness of the specimen (T_S) and the steps of the aluminium step wedge (6.3) with the micrometer (6.2) to an accuracy of 0,01 mm.

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1) Adobe Photoshop is an example of a suitable product available commercially. This information is given for the convenience of users of this International Standard and does not constitute an endorsement by ISO of this product.

Position the intra oral X-ray sensor (6.5.2.1) or the phosphor imaging plate (6.5.3.1). Place the specimen and the step wedge (6.3) in contact near the centre of the sensor. Irradiate the assembly with X-rays (6.4) at a target-film distance of 300 - 400 mm. Repeat the procedure to find the appropriate exposure time to make a clear image without too great a contrast.

Export the digital image file to the grey scale analysis software (6.5.2.2).

NOTE The number of grey shades is assessed using the measuring tool in the software. The number of grey shades in the digital image is given by the number of binary digits (bits) used to define a pixel.

Using the grey scale analysis software, define a rectangular area to measure in the specimen image and measure the average grey value in that area.

Repeat this procedure with each of the steps of the step wedge.

Carry out three separate exposures or the number specified in the product standard if that is greater.

8 Treatment of results

Plot the individual optical densities/grey values of each aluminium step against the thickness of each step, (see Figure 1). Take the optical density/grey value for the specimen of thickness T_s and determine from the plot the corresponding value of aluminium (T_a).

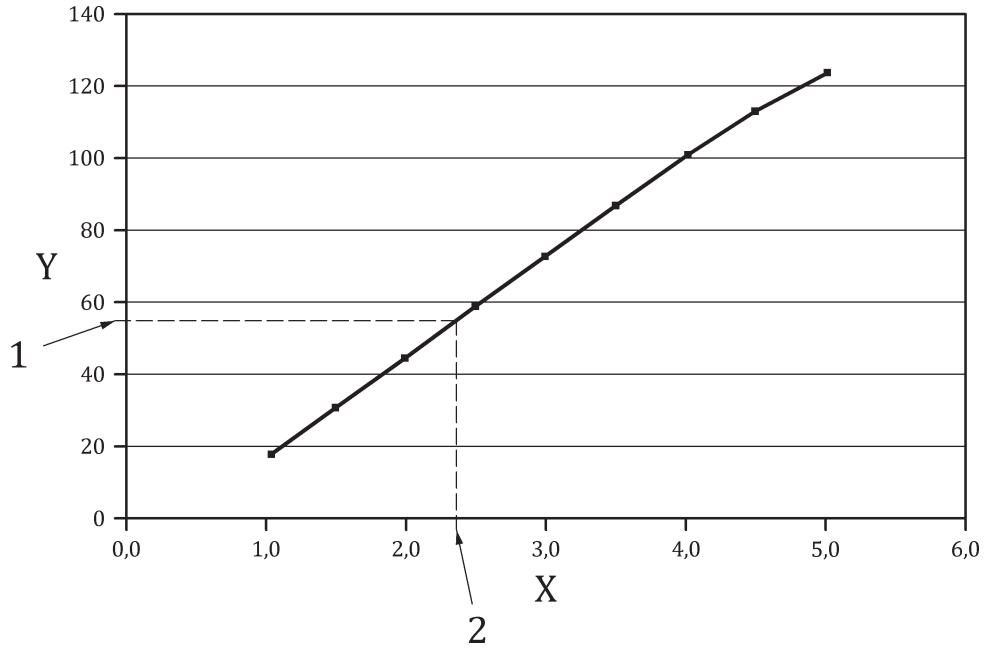
The radio-opacity (aluminium equivalent) value of a specimen of 1,0 mm thickness is then given by (T_a/T_s).

Interpret and report the result in the manner described in the appropriate product standard.

The plot of optical density against aluminium thickness of the step wedge shall be made for each radiographic exposure, since minor variations may occur due to radiographic processing.

NOTE It is common to report the result with a statement that the radio-opacity lies between x and y mm aluminium or between x and y % of aluminium.

Figure 1 — Determination of radio-opacity — Plot of optical density or grey value against aluminium step thickness and superimposition of a specimen reading used to determine equivalent radio-opacity. Diagram illustrates the principle of measurement but the actual plot would cover the whole range of aluminium and specimen thicknesses.



Key

1 specimen reading

2 aluminium equivalent

Figure 1 — Determination of radio-opacity