

BS EN ISO 13116:2014



BSI Standards Publication

Dentistry — Test Method for Determining Radio-Opacity of Materials

bsi.

...making excellence a habit.™

National foreword

This British Standard is the UK implementation of EN ISO 13116:2014.

The UK participation in its preparation was entrusted to Technical Committee CH/106/1, Dental restorative and orthodontic materials.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

© The British Standards Institution 2014. Published by BSI Standards Limited 2014

ISBN 978 0 580 82429 6

ICS 11.060.10

Compliance with a British Standard cannot confer immunity from legal obligations.

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 30 November 2014.

Amendments issued since publication

Date	Text affected
------	---------------

ICS 11.060.10

English Version

Dentistry - Test Method for Determining Radio-Opacity of Materials (ISO 13116:2014)

Médecine bucco-dentaire - Méthodes de détermination de
la radio opacité des matériaux (ISO 13116:2014)

Zahnheilkunde - Prüfverfahren zur Bestimmung der
Röntgensichtbarkeit von Materialien (ISO 13116:2014)

This European Standard was approved by CEN on 6 September 2014.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.



EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

Foreword

This document (EN ISO 13116:2014) has been prepared by Technical Committee ISO/TC 106 "Dentistry" in collaboration with Technical Committee CEN/TC 55 "Dentistry" the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by May 2015, and conflicting national standards shall be withdrawn at the latest by May 2015.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 13116:2014 has been approved by CEN as EN ISO 13116:2014 without any modification.

Contents

Page

Foreword	iv
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Requirements	1
5 Sampling	1
6 Apparatus	2
6.1 Suitable moulds for constructing samples of the test-material.....	2
6.2 Screw micrometer gauge, or equivalent device.....	2
6.3 Aluminium step wedge.....	2
6.4 Dental X-ray unit.....	2
6.5 Dental X-ray sensor.....	2
7 Test conditions and procedures	3
7.1 Test conditions.....	3
7.2 Preparation of test specimens.....	3
7.3 Test procedure for analogue equipment.....	3
7.4 Test procedure for digital equipment.....	3
8 Treatment of results	4

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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 sensing 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 sensing equipment.

6.5 Dental X-ray sensor

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

6.5.1 Analogue sensing

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 $(2,5 \pm 0,5)$ known to an accuracy of $\pm 0,01$, and using an aperture of $(2,0 \pm 0,1)$ mm. The densitometer must be prepared to be stable to $\pm 0,01$ at an optical density of $(2,5 \pm 0,5)$ over 30 min or a recalibration shall be performed before each set of readings.

6.5.2 Digital sensing

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 sensor¹⁾.

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 scanner¹⁾

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 $(1,0 \pm 0,1)$ 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.

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).

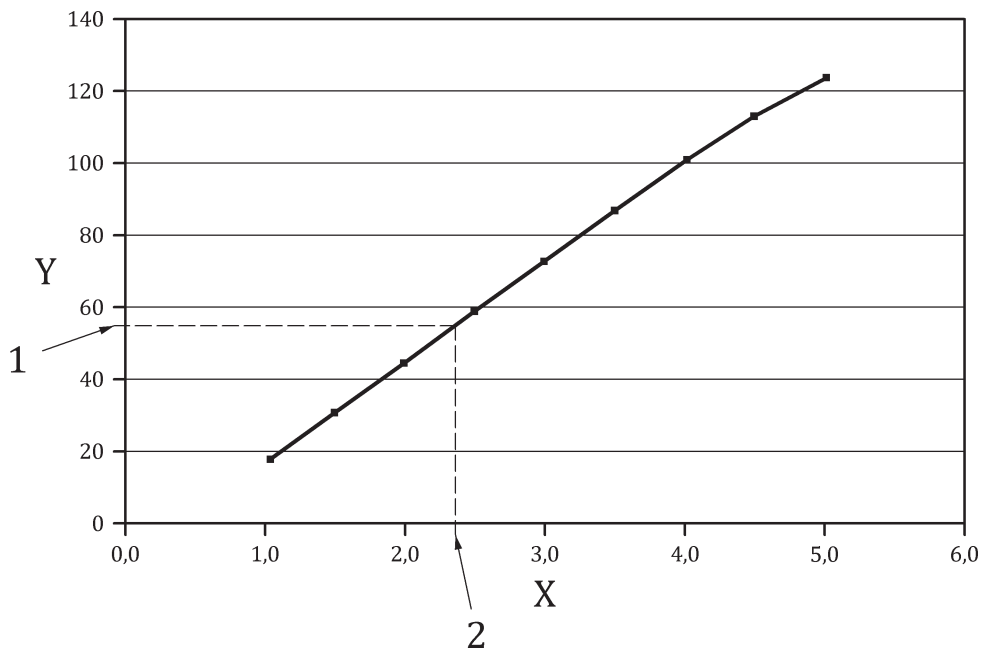
The radio-opacity (aluminium equivalent) value of a specimen of 1,0 mm thickness is then given by (T_a/T_s).

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

British Standards Institution (BSI)

BSI is the national body responsible for preparing British Standards and other standards-related publications, information and services.

BSI is incorporated by Royal Charter. British Standards and other standardization products are published by BSI Standards Limited.

About us

We bring together business, industry, government, consumers, innovators and others to shape their combined experience and expertise into standards-based solutions.

The knowledge embodied in our standards has been carefully assembled in a dependable format and refined through our open consultation process. Organizations of all sizes and across all sectors choose standards to help them achieve their goals.

Information on standards

We can provide you with the knowledge that your organization needs to succeed. Find out more about British Standards by visiting our website at bsigroup.com/standards or contacting our Customer Services team or Knowledge Centre.

Buying standards

You can buy and download PDF versions of BSI publications, including British and adopted European and international standards, through our website at bsigroup.com/shop, where hard copies can also be purchased.

If you need international and foreign standards from other Standards Development Organizations, hard copies can be ordered from our Customer Services team.

Subscriptions

Our range of subscription services are designed to make using standards easier for you. For further information on our subscription products go to bsigroup.com/subscriptions.

With **British Standards Online (BSOL)** you'll have instant access to over 55,000 British and adopted European and international standards from your desktop. It's available 24/7 and is refreshed daily so you'll always be up to date.

You can keep in touch with standards developments and receive substantial discounts on the purchase price of standards, both in single copy and subscription format, by becoming a **BSI Subscribing Member**.

PLUS is an updating service exclusive to BSI Subscribing Members. You will automatically receive the latest hard copy of your standards when they're revised or replaced.

To find out more about becoming a BSI Subscribing Member and the benefits of membership, please visit bsigroup.com/shop.

With a **Multi-User Network Licence (MUNL)** you are able to host standards publications on your intranet. Licences can cover as few or as many users as you wish. With updates supplied as soon as they're available, you can be sure your documentation is current. For further information, email bsmusales@bsigroup.com.

BSI Group Headquarters

389 Chiswick High Road London W4 4AL UK

Revisions

Our British Standards and other publications are updated by amendment or revision.

We continually improve the quality of our products and services to benefit your business. If you find an inaccuracy or ambiguity within a British Standard or other BSI publication please inform the Knowledge Centre.

Copyright

All the data, software and documentation set out in all British Standards and other BSI publications are the property of and copyrighted by BSI, or some person or entity that owns copyright in the information used (such as the international standardization bodies) and has formally licensed such information to BSI for commercial publication and use. Except as permitted under the Copyright, Designs and Patents Act 1988 no extract may be reproduced, stored in a retrieval system or transmitted in any form or by any means – electronic, photocopying, recording or otherwise – without prior written permission from BSI. Details and advice can be obtained from the Copyright & Licensing Department.

Useful Contacts:

Customer Services

Tel: +44 845 086 9001

Email (orders): orders@bsigroup.com

Email (enquiries): cservices@bsigroup.com

Subscriptions

Tel: +44 845 086 9001

Email: subscriptions@bsigroup.com

Knowledge Centre

Tel: +44 20 8996 7004

Email: knowledgecentre@bsigroup.com

Copyright & Licensing

Tel: +44 20 8996 7070

Email: copyright@bsigroup.com



...making excellence a habit.™