
**Dentistry — Test Method for
Determining Radio-Opacity of Materials**

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

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Reference number
ISO 13116:2014(E)

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Published in Switzerland

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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*.

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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.