

Dentistry - Digitizing devices for CAD/CAM systems for indirect dental restorations - Test methods for assessing accuracy (ISO 12836:2015)

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 12836:2015 sisaldab Euroopa standardi EN ISO 12836:2015 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 12836:2015 consists of the English text of the European standard EN ISO 12836:2015.
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English Version

Dentistry - Digitizing devices for CAD/CAM systems for indirect dental restorations - Test methods for assessing accuracy (ISO 12836:2015)

Médecine bucco-dentaire - Dispositifs de numérisation des systèmes de CFAO pour restaurations dentaires - Méthodes d'essai pour l'évaluation de l'exactitude (ISO 12836:2015)

Zahnheilkunde - Digitalisierungsgeräte für CAD/CAM-Systeme für indirekte dentale Restaurationen - Prüfverfahren zur Beurteilung der Genauigkeit (ISO 12836:2015)

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European foreword

This document (EN ISO 12836:2015) 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of an identical text or by endorsement, at the latest by January 2016, and conflicting national standards shall be withdrawn at the latest by January 2016.

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.

This document supersedes EN ISO 12836:2012.

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 12836:2015 has been approved by CEN as EN ISO 12836:2015 without any modification.

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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).

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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 9, *Dental CAD/CAM systems*.

This second edition cancels and replaces the first edition (ISO 12836:2012), of which it constitutes a minor revision.

Introduction

The application of dental computer-aided design and manufacturing (CAD/CAM) systems is increasing throughout the world.

This International Standard specifies three test methods for assessing the accuracy of dental digitizing devices used for CAD/CAM systems.

This International Standard is based on the premise that only the matched point cloud and the resulting tessellation thereof conforming to the StereoLithography Interface Specification (also known as Standard Tessellation Language or STL) be regarded as the product of scanning the physical object.

This International Standard includes the measurement of the image that is digitized from dental scanners (lab-based optical scanners and lab-based mechanical contact scanners). Digitized images are not only used for the fabrication of restorative products but also applied to teaching and research in dentistry, in such areas as occlusion, tooth and gingival contour change measurements, and so forth.

It was felt that, besides the sphere, more physical objects are required, for example, a surface with an inlay-shaped cavity with a sharp edge to simulate the edge of an inlay preparation. When no means (for example, software algorithm) are available to calculate a standard deviation of discrepancies between the points of the point cloud or STL surface and the physical object's surface as a measure for accuracy, some software is required to match the CAD STL format file of the physical object with the point cloud or STL surface and visualize discrepancies, resulting in a qualitative assessment.

The following three specimens (two dental and one technical), which are specified in [Annex A](#), [Annex B](#), and [Annex C](#), can be used for assessing digitizing devices:

- a) specimen shaped to simulate a cavity for an inlay;
- b) multi-unit specimen, consisting of two core dies for coverage by a full crown with a centre-to-centre distance of 30 mm, being designed to simulate digitizing a four-unit bridge;
- c) a sphere, the measurement of which is limited to the hemisphere lying above the horizontal plane.

ISO 5725-1 uses two terms, "trueness" and "precision", to describe the accuracy of a measurement method. "Trueness" refers to the closeness of agreement between the arithmetic mean of a large number of test results and the true or accepted value. "Precision" refers to the closeness of agreement between test results. The general term "accuracy" is used to refer to both trueness and precision.

Dentistry — Digitizing devices for CAD/CAM systems for indirect dental restorations — Test methods for assessing accuracy

1 Scope

This International Standard specifies test methods for the assessment of the accuracy of digitizing devices for computer-aided design/computer-aided manufacturing (CAD/CAM) systems for indirect dental restorations. The methods described in this International Standard require a digitizing device in which the object is mounted relative to the optical or mechanical-contact system and therefore do not apply to hand-held scanning devices.

These test methods are not applicable to digitization by radiographic (X-ray) methods or by magnetic resonance imaging (MRI) methods.

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 554, *Standard atmospheres for conditioning and/or testing — Specifications*

ISO 1942, *Dentistry — Vocabulary*

ISO 3290-2, *Rolling bearings — Balls — Part 2: Ceramic balls*

ISO 5725-1, *Accuracy (trueness and precision) of measurement methods and results — Part 1: General principles and definitions*

ISO/IEC Guide 99, *International vocabulary of metrology — Basic and general concepts and associated terms (VIM)*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 1942, ISO 5725-1, ISO Guide 99, and the following apply.

3.1

accuracy

(measurement) closeness of agreement between a result of a measurement and a true value of the measurand

Note 1 to entry: Accuracy is a qualitative concept. See [3.8](#) and [3.17](#) for quantification of its two constituent components: precision and trueness.

[SOURCE: ISO 5725-1:1994, 3.6, modified]

3.2

calibration

set of operations that establish, under specified conditions, the relationship between values of quantities indicated by a measuring instrument or measuring system or values represented by a material measure or a reference material and the corresponding values realized by standards