SLOVENSKI STANDARD
SIST EN ISO 12836:2015

01-oktober-2015

Nadomešča:
SIST EN ISO 12836:2012

Zobozdravstvo - Pripomočki za za uporabo sistemov CAD/CAM za posredne zobne preureditve - Preskusne metode za ugotavljanje točnosti (ISO 12836:2015)

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

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

Ta slovenski standard je istoveten z: **EN ISO 12836:2015**

ICS:

11.060.01	Zobozdravstvo na splošno	Dentistry in general
35.240.80	Uporabniške rešitve IT v zdravstveni tehniki	IT applications in health care technology

SIST EN ISO 12836:2015 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 12836

July 2015

ICS 11.060.01

Supersedes EN ISO 12836:2012

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)

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This European Standard was approved by CEN on 7 May 2015.

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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.

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

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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.

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Endorsement notice

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

INTERNATIONAL STANDARD

ISO 12836

Second edition
2015-07-01

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

Médecine bucco-dentaire — Dispositifs de numérisation des systèmes de CFAO pour restaurations dentaires — Méthodes d'essai pour l'évaluation de l'exactitude

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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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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 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 Tesselation 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.