SLOVENSKI STANDARD
SIST EN ISO 12836:2012/oprA1:2014

01-marec-2014

Zobozdravstvo - Digitalne naprave za uporabo sistemov CAD/CAM za posredne zobne restavracije/obnovo - Preskusne metode za ugotavljanje točnosti (ISO 12836:2012/DAM 1:2014)

Dentistry - Digitizing devices for CAD/CAM systems for indirect dental restorations - Test methods for assessing accuracy (ISO 12836:2012/DAM 1:2014)

Zahnheilkunde - Digitalisierungsgeräte für CAD/CAM-Systeme für indirekte dentale Restaurationen - Prüfverfahren zur Beurteilung der Genauigkeit (ISO 12836:2012/DAM 1:2014)

Médecine bucco-dentaire - Dispositifs de numérisation des systèmes de CFAO pour restaurations dentaires - Méthodes d'essai pour l'évaluation de l'exactitude (ISO 12836:2012/DAM 1:2014)

Ta slovenski standard je istoveten z: EN ISO 12836:2012/prA1

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 12836:2012/oprA1:2014   en

DRAFT AMENDMENT
ISO 12836:2012/DAM 1

ISO/TC **106**/SC **9**

Secretariat: **JISC**

Voting begins on:
2014-01-09

Voting terminates on:
2014-06-09

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

AMENDMENT 1

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

AMENDEMENT 1

ICS: 11.060.01

ISO/CEN PARALLEL PROCESSING

This draft has been developed within the International Organization for Standardization (ISO), and processed under the **ISO lead** mode of collaboration as defined in the Vienna Agreement.

This draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel five month enquiry.

Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month approval vote in ISO and formal vote in CEN.

To expedite distribution, this document is circulated as received from the committee secretariat. ISO Central Secretariat work of editing and text composition will be undertaken at publication stage.

Reference number
ISO 12836:2012(E)/DAM 1

ISO 12836:2012(E)/DAM 1

ISO 12836:2012(E)

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 12836 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 9, *Dental CAD/CAM systems.*

Amendment 1 to ISO 12836: was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 9, *Dental CAD/CAM Systems*.

[f1]: Replace

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ISO 12836:2012(E)

Introduction

The application of dental 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 Standard Tesselation Language surface (STL surface) thereof 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 (intra-oral 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.

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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 formatfile 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 Annexes A, B and C, can be used for assessing digitizing devices:

a) inlay-shaped specimen in order to simulate inlay-shaped cavities; specimen shaped to stimulate a cavity for an inlay

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b) multi-unit specimen, consisting of two full coverage dies 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 4-unit-bridge;

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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.

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INTERNATIONAL STANDARD   **ISO 12836:2012(E)**

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 standard require that a digitizing device in which the object is mounted relative to the optical system, and therefore do not apply to hand-held scanning devices.

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

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 and 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. Its quantitative counterpart is trueness.~~ Accuracy is a qualitative concept. See 3.8 and 3.17 for quantification of its two constituent components: precision and trueness.

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[SOURCE: ISO 5725-1:1994, definition 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

3.3
digitizing device
dental surface data acquisition device
device for computer-aided design and manufacturing of custom-made indirect dental restorations used to record the topographical characteristics of teeth and surrounding tissues, implant connecting components, dental impressions, dental moulds or stone models by analogue or digital methods

NOTE 1 to entry: These systems consist of a scanning device, hardware and software.

NOTE 2 to entry: A surface digitization procedure starts with the generation of actually measured surface points (or their conversion, for example, in STL format), which are the measured digitization data. In most digitizing systems, the measured points are mathematically processed by operations such as:

— matching

— filtering

— weighing

— selective removal

— smoothing, etc.

This results in the processed digitization data (or surface data). These data depend very much on, for example, the digitization protocol (for example the number of passes), the extraction method of a surface from the raw data points and the matching of point clouds.

3.4
error
⟨measurement⟩ result of a measurement minus a true value of the measurand

NOTE 1   When it is necessary to distinguish "error" from "relative error", the former is sometimes called "absolute trueness".

NOTE 2   In many instances, the trueness is called "total error".

3.5
indirect dental restoration
any kind of restoration manufactured extraorally which replaces intra-oral hard and/or soft tissues

EXAMPLE   Crowns, bridges, inlays, implant superstructures, prostheses, provisional restorations.

NOTE 1 to entry: Epitheses that involve the oral cavity are included; devices for short-term use, for example surgical guides, are excluded.

3.6
measurand
particular quantity subject to measurement

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