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

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The UK participation in its preparation was entrusted to Technical Committee CH/106, Dentistry.

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

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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)

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

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Foreword

This document (EN ISO 12836:2012) 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of an identical text or by endorsement, at the latest by March 2013, and conflicting national standards shall be withdrawn at the latest by March 2013.

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Endorsement notice

The text of ISO 12836:2012 has been approved by CEN as a EN ISO 12836:2012 without any modification.

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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 Tessellation 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.

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;
- b) multi-unit specimen, consisting of two full coverage dies with a centre-to-centre distance of 30 mm, being designed to simulate digitizing a 4-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.

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.

[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.