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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.

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*.

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.

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.

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

3.7
measurement procedure
set of operations which are specifically used in the performance of particular measurements according to a given technique

NOTE 1 to entry: In a quality system, a measurement procedure is recorded as a working instructions document and should be described in sufficient detail to enable an operator to carry out a measurement without additional information.

3.8
precision
closeness of agreement between independent results of measurement obtained under stipulated conditions

[SOURCE: ISO 5725-1:1994, definition 3.12, modified]

3.9
random error
result of a measurement minus the mean that would result from an infinite number of measurements of the same measurand carried out under repeatable conditions

NOTE 1 to entry: Random error is equal to trueness minus systematic error.

NOTE 2 to entry: In practice, random error may be estimated from 20 or more repeated measurements of a measurand under specified conditions.

3.10
relative error
trueness divided by a true value of the measurand

3.11
repeatability
⟨results of measurements⟩ closeness of the agreement between the results of successive measurements of the same measurand carried out under the same conditions of measurement

NOTE 1 to entry: Repeatability is a qualitative concept. Its quantitative counterpart is standard deviation of repeatability or coefficient of variation of repeatability of the measurement results.

NOTE 2 to entry: Repeatability may depend on the value of the measurand.

3.12
repeatability conditions
conditions where independent results of measurements are obtained with the same measurement procedure in the same laboratory by the same operator using the same equipment within short intervals of time without new calibration

[SOURCE: ISO 5725-1:1994, definition 3.14, modified]

3.13
reproducibility
⟨results of measurements⟩ closeness of the agreement between the results of measurements of the same measurand carried out under changed conditions of measurement

NOTE 1 to entry: The changed conditions may include the observer, measuring instrument, location and time.

NOTE 2 to entry: The set of specified conditions is termed “reproducibility conditions”.

NOTE 3 to entry: Reproducibility is a qualitative concept. Its quantitative counterpart is standard deviation of reproducibility or coefficient of variation of reproducibility of the measurement results.

NOTE 4 to entry: Reproducibility may depend on the value of the measurand.

3.14
reproducibility conditions
conditions where results of measurements are obtained on the same measurand under different conditions in different laboratories

NOTE 1 to entry: The different conditions should be specified.

[SOURCE: ISO 5725-1:1994, definition 3.18, modified]

3.15
systematic error
mean that would result from an infinite number of measurements of the same measurand carried out under repeatable conditions minus a true value of the measurand

NOTE 1 to entry: Systematic error is equal to trueness minus random error.

NOTE 2 to entry: Systematic error may be constant or proportional to the value of the measurand.

NOTE 3 to entry: In practice, systematic error is estimated from 30 or more repeated measurements of a measurand under specified conditions.

3.16
true value (of a quantity)
value consistent with the definition of a given particular quantity

NOTE 1 to entry: This is a value that would be obtained by a perfect measurement. True values are by nature indeterminate.

NOTE 2 to entry: The indefinite article "a", rather than the definite article "the" is used in conjunction with "true value" because there may be many values consistent with the definition of a given particular quantity.

3.17
trueness
closeness of agreement between the mean obtained from repeated measurements and a true value or a conventional true value

NOTE 1 to entry: Trueness is a qualitative concept. Its quantitative counterpart is systematic error.

[SOURCE: ISO 5725-1:1994, definition 3.7, modified]

4 Requirements

4.1 General

The manufacturer of the digitizing device shall provide product-specific information including instructions for use.

The digitization device shall be driven by software recommended by the supplier or manufacturer for digitization and rendering of the scanned physical object surface.

4.2 Accuracy

The manufacturer of the digitizing device shall provide product-specific information on the accuracy (trueness and precision) of the digitizing device (e.g. a description of the tested object) in the instructions for use.

In order to determine the quality of a digitizing device in terms of accuracy, repeatability and reproducibility, known physical objects shall be analysed for structures that are important for the purpose of generating indirect dental restorations. The manufacturer of the digitizing device shall report on the tests carried out, for example in the instructions for use.

From the assessment performed with the test specimens specified in Annexes A, B or C, the manufacturer shall derive comprehensive documentation.

The test procedure used shall be reported.

EXAMPLE "Tested in accordance with ISO 12836:2012, Annex A, Inlay-shaped specimen."

5 Test methods

5.1 General

Use at least two of the test methods described in Annexes A, B and C.

5.2 Test conditions

Testing shall be done under the following test conditions:

a) the change of temperature during the test shall remain within ± 1 °C;

b) the ambient room temperature shall be (23 ± 2) °C in accordance with ISO 554;

c) the quality of the data set in terms of any missing or corrupted data shall be evaluated by the operator; in cases of missing or corrupted data, the test shall be repeated.

5.3 Accuracy

5.3.1 Repeatability

Repeat the measurement 30 times without removing the test specimen from the digitizing device. Use the test specimen and procedures specified in Annex A, B or C as recommended in the manufacturer's instructions for use. Calculate the mean and standard deviation of the 30 measurements. Record this value(s).

5.3.2 Reproducibility

Repeat the measurement 30 times, removing the test specimen from the digitizing device and replacing it into the digitizing device. Use the test specimen and procedures specified in Annex A, B or C as recommended in the manufacturer's instructions for use. Calculate the mean and standard deviation of the 30 measurements. Record this value(s).

5.3.3 Trueness

Calculate the difference between the mean of the 30 repeatability measurements and the true value.

6 Test report

Prepare a written test report. The test report shall contain at least the following information:

a) reference to this International Standard;

b) reference to the annexes of this International Standard used for testing;

c) identification of the test specimen (i.e. inlay-shaped specimen, crown-shaped specimen, bridge-shaped specimen, sphere specimen);

d) specimen surface preparation;

e) test conditions, including the number of scanning views manually matched, if it is necessary according to the measurement procedure as specified in the manufacturer's instructions;

f) trueness;

g) mean and standard deviation for repeatability and reproducibility of measurement;

h) software and the version of the software used for assessment;

i) full identification and qualifications of the person who performed the test;

j) full documentation of the conditions used during reproducibility testing.

In addition, the following information shall be included for tests made in accordance with Annex C:

— number of measured points;

— histogram distribution of points;

— mean radius, R_{mn};

— minimum and maximum radius;

— radius deviation.