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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

Reference number
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ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

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Foreword

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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 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 cone 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

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

Note 2 to entry: 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

Note 1 to entry: Precision is a qualitative concept. The operational definition that applies in this International Standard is the standard deviation described in 5.3.2.

[SOURCE: ISO 5725-1:1994, 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, 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 principle of measurement, method of measurement, observer, measuring instrument, reference standard, location, conditions of use, 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 differences in conditions are intended to be specified.

[SOURCE: ISO 5725-1:1994, 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 error of measurement 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 20 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.

Note 3 to entry: A reference data set obtained by the procedures of A.4.2 or B.4.2 is used as a true value in A.6.2 or B.6.2. Dimensions described in C.4 are used as a true value in C.6.2.

Note 4 to entry: The magnitude of an angle or a dimension of a test object described in A.4.1 or B.4.1 obtained by an independent method of measurement may be taken as a true value, provided that the object has been manufactured in a process qualified and calibrated to the precision specified in A.4.1 or B.4.1.

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. The operational definition that applies for this International Standard is given in 5.3.3.

[SOURCE: ISO 5725-1:1994, 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 Annex A, Annex B, or Annex 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 Annex A, Annex B, and Annex 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, Annex B, or Annex 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, Annex B, or Annex 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 a true value obtained independently according to the respective annex. (See A.6.2, B.6.2, or C.6.2).

6 Test report

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

a) a reference to this International Standard, i.e. ISO 12836:2015;

b) a 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.

Annex A
(normative)

Inlay-cavity die

A.1 General

This annex specifies the measurement of a die which simulates an inlay-cavity. This test procedure uses a negative geometry.

A.2 Principle

An inlay-cavity die is first measured with a reference measurement system in order to produce a reference data set (calibration of the measurement object).

Then, the digitizing device under investigation is used to capture the inlay-shaped physical object. The resulting measurement data are compared to the reference data set.

A.3 Apparatus

A.3.1 Test specimen, in the form of an inlay-shaped physical object, as specified in Figure A.1. The material of the physical object shall be a dimensionally stable material. It shall be resistant to handling wear. It shall be compatible with spray when indicated as necessary for the use of the digitizing device.

NOTE The selection of a material which fulfils the condition of being a dimensional stable material depends on the digitizing device.

A.3.2 Reference measurement system, with an accuracy of ±2 µm.

A.3.3 Travelling microscope, with at least 20 × magnification, accurate to 0,01 mm.

A.3.4 Digitizing device under investigation.

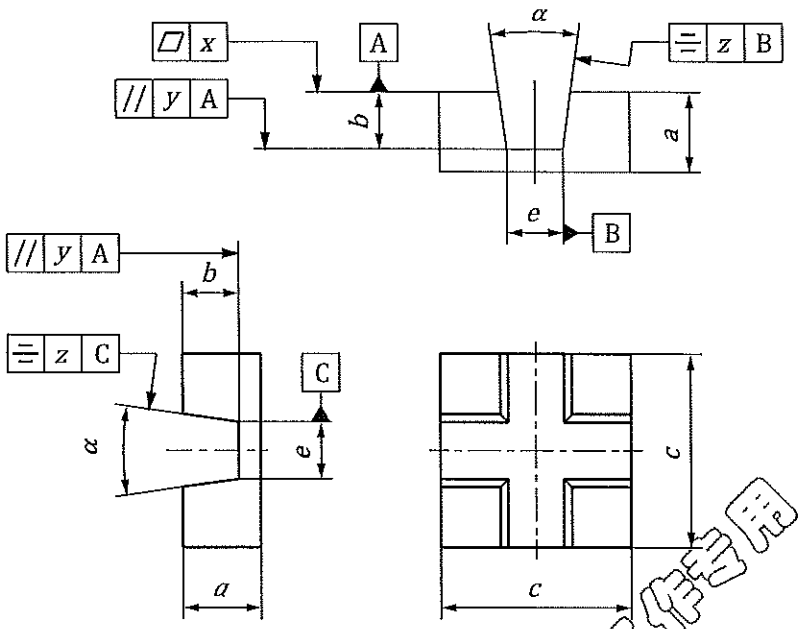
A.4 Preparation of test specimen

A.4.1 Geometry, dimensions, and tolerances

Figure A.1 gives three primary views of the inlay-cavity die.

The precisely machined die shall be produced with a defined edge radius.

The specimen consists of the die itself and a computer-aided design model. Either the die itself is produced with a manufacturing accuracy of ±2 µm or the die is measured with a measuring device with an accuracy of ±2 µm.



The dimensions are:

a (7 ± 0,5) mm

b (5 ± 0,5) mm

c (16 ± 1) mm

e (5 ± 0,5) mm

α (16 ± 1)°

x 0,02 mm

y 0,02 mm

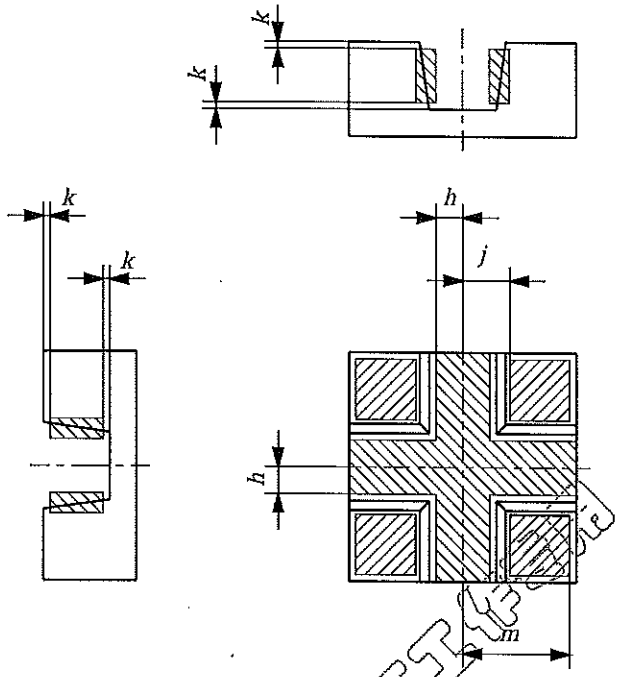
z 0,02 mm

Figure A.1 — Test specimen: Inlay-cavity die

The parallelism of the planes shall be ±0,01 mm and the deviation between the angles shall be ±0,01°.

NOTE The roughness should range between that of a prepared tooth using a medium coarse diamond (about 50 microns) and that of the surface finish of an epoxy and stone die material for laboratory-based scanners.

The edges at the top and the bottom of the valleys are generally difficult to manufacture precisely. Therefore, include only the hatched areas shown in Figure A.2 when computing the values of interest.



Dimensions of the hatched areas:

h 2 mm

j 3,5 mm

k 0,5 mm

m 8 mm

Figure A.2 — Hatched areas to be considered

The following data are of specific interest:

a) the height b, which is the distance between the upper and lower planes;

b) the angle α.

A.4.2 Reference data set and calibration of measurement object

Measure the inlay-cavity die (A.3.1) with a reference measurement system (A.3.2) in order to produce a reference data set (calibration of the measurement object). This reference data set is deemed to be the true value.

A.5 Test procedure

Visually inspect the die (A.3.1) with a travelling microscope (A.3.3) using 20 × magnification for surface damage. If necessary, remake the die.

Use the digitizing device under investigation (A.3.4) to capture the inlay-cavity die (A.3.1). Digitize the die (A.3.1) according to the recommended procedure specified in the manufacturer's instructions for digitizing inlay cavities.

Evaluate the processed data (output data) set without any further manipulation of the data handling beyond the manufacturer's procedure description for the intended end user.

If necessary, convert the processed data into ASCII or STL format and compare using 3D analysis software[1)] with the CAD model resulting from precise measurement of the physical object.

The proprietary software algorithms for best fit alignment of the measured data set to the computer-aided design model are to be applied before extracting the data which are to be recorded.

The following data shall be recorded:

a) the height b, which is the distance between the upper and lower planes;

b) the angle α.

Include only the hatched areas shown in Figure A.2 when computing b and α.

A.6 Assessment

A.6.1 Reproducibility

To assess the reproducibility, repeat the measurements 30 times. Calculate the mean of the 30 measurements and the standard deviation.

A.6.2 Repeatability and trueness

To assess the repeatability and trueness, repeat the measurements 30 times.

Calculate the mean of the 30 measurements and the standard deviation. Calculate the differences between the true value (that is, the computer-aided model) and the mean of the 30 measured values (trueness).

1) A 3D analysis programme is commercially available from Surfacer, Imageware Inc., Ann Arbor, MI, USA, or Geomagic Studio and Qualify, Geomagic Inc., NC, USA. This information is given for the convenience of the user of this International Standard and does not constitute an endorsement by ISO of the product named. Equivalent products may be used if they can be shown to lead to the same result.

Annex B
(normative)

Crown-and-bridge preparation die

B.1 General

This annex specifies the measurement of a die simulating abutments prepared for a four-unit fixed prosthesis (FP) with a centre-to-centre distance of 30 mm. The measurement may be performed either on one abutment (single crown) or both abutments (four-unit FP).

This test procedure uses a positive geometry.

B.2 Principle

A crown-and-bridge preparation die is first measured with a reference measurement system in order to produce a reference data set (calibration of the measurement object).

Then, the digitizing device under investigation is used to capture the crown-and-bridge preparation die. The resulting measurement data are compared to the reference data set.

B.3 Apparatus

B.3.1 Test specimen, in the form of a multi-unit physical object consisting of two dies with a centre-to-centre distance of (30 ± 1) mm, as specified in Figure B.1. The material of the die shall be dimensionally stable. It shall be resistant to handling wear. It shall be compatible with spray when indicated as necessary for the use of the digitizing device.

NOTE The selection of a material which fulfils the condition of being a dimensional stable material depends on the digitizing device.

B.3.2 Reference measurement system, with an accuracy of ±2 µm.

B.3.3 Travelling microscope, with at least 20 × magnification, accurate to 0,01 mm.

B.3.4 Digitizing device under investigation.

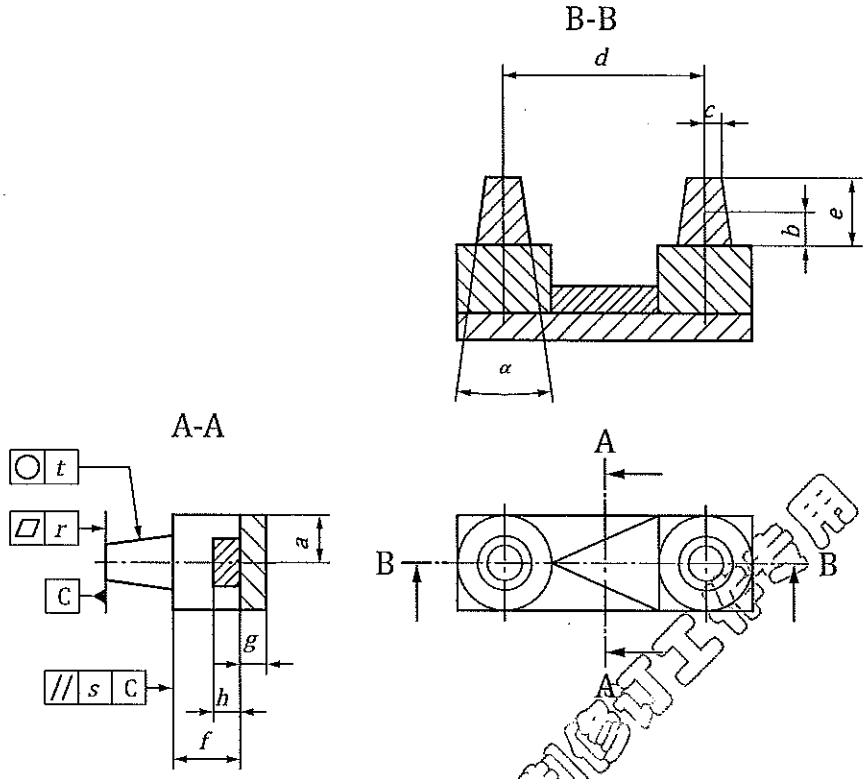
B.4 Preparation of test specimen

B.4.1 Geometry, dimensions, and tolerances

Figure B.1 gives three primary views of the crown-and-bridge preparation die.

The precision-machined die shall be produced with a defined edge radius.

The specimen consists of the die itself and a computer-aided design model. Either the physical object itself is produced with a manufacturing accuracy of ±2 µm or the physical object is measured with a measuring device with an accuracy of ±2 µm.



The dimensions are:

a (7 ± 0,5) mm

b *e*/2

c (2,6 ± 0,1) mm

d (30 ± 1) mm

e (10 ± 0,5) mm

f (10 ± 0,5) mm

g (4 ± 0,5) mm

h (4 ± 0,5) mm

r 0,02 mm

s 0,02 mm

t 0,02 mm

α (16 ± 1)°

Figure B.1 — Test specimen: Crown-and-bridge preparation die

The roughness should range between that of a prepared tooth using a medium coarse diamond (about 50 microns) and that of an epoxy and stone die material for laboratory-based scanners.

Any digitizing device with a measurement volume smaller than the specimen might require several scans in order to capture the complete specimen. Typically, these scans will be combined to give the complete set of measurement data. This combination typically requires some characteristic landscape.

Landscapes are an optional structure and can, for example, be:

a) the negative shape of two different spheres;

b) a triangular shape, as shown in Figure B.1.

Should the assessment come to the conclusion that the measurement was not precise enough, then this failure could mean that the landscape does not offer enough information for a correct combination of the single scans.

The lower box and the triangular shape may be manufactured independently of each other and then combined.

The following data are of specific interest:

— the height, e;

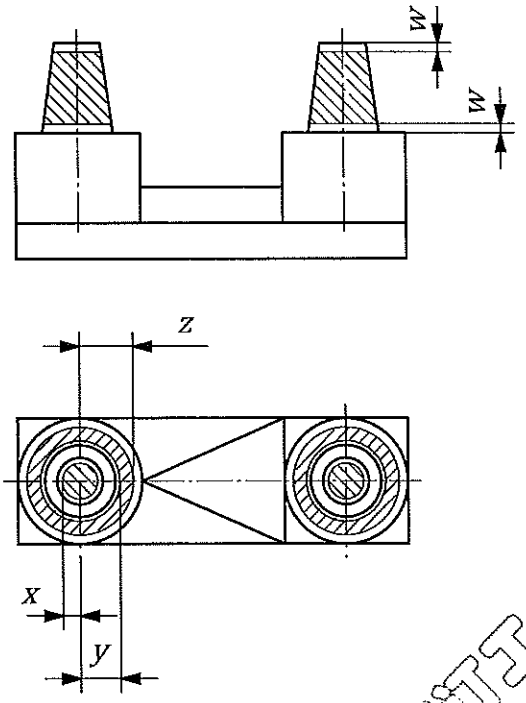
— the angle, α;

— The distance, d, between the corresponding midpoints of the circular sections at the half-height, $b = e/2$, of the two dies.

NOTE This measurement of the dimension, d, does not apply for digitizing devices designed only for single crowns.

The circular edges at the very top and the circular edges that form the step are generally difficult to manufacture precisely. Therefore, include only the hatched areas shown in Figure B.2 when computing the values of interest.

The distance, d, of the circular sections at half the height has been selected as it is uniquely determined by the measurement data. These values should match the values obtained from the reference measurement system.



The dimensions are:

w 1 mm

x 2 mm

y 4,5 mm

z 6 mm

Figure B.2 — Hatched areas to be considered

To test for the ability of the scan and extraction software delivered with the digitizing device under investigation (B.3.4) to cope with sharp edges and measurement of distance, two calibrated dies with a maximum edge round-off of 0,02 mm are used.

B.4.2 Reference data set and calibration of measurement object

Measure the crown-and-bridge preparation die (B.3.1) with a reference measurement system (B.3.2) in order to produce a reference data set (calibration of the measurement object). This reference data set is deemed to be the true value.

B.5 Test procedure

Visually inspect the physical object (B.3.1) with a travelling microscope (B.3.3) using 20 × magnification for surface damage. If necessary, remake the physical object.

Use the digitizing device under investigation (B.3.4) to capture the physical object (B.3.1). Digitize the physical object (B.3.1) according to the recommended procedure specified in the manufacturer's instructions for digitizing single dies or bridges.

Evaluate the processed data (output data) set without any further manipulation of the data handling beyond the manufacturer's procedure description for the intended end user.

If necessary, convert the processed data into STL format and compare using 3D analysis software[2)] with the CAD model resulting from precise measurement of the die.

The proprietary software algorithms for best fit alignment of the measured data set to the computer-aided design model are to be applied before extracting the data which are to be recorded.

The following data shall be recorded:

a) the height, e;

b) the angle, α;

c) the distance, d, between the corresponding midpoints of the circular sections at the half height, $b = e/2$, of the two dies.

Include only the hatched areas shown in Figure B.2 when computing d, e, and α.

B.6 Assessment

B.6.1 Reproducibility

To assess the reproducibility, repeat the measurements 30 times. Calculate the mean of the 30 measurements and the standard deviation.

B.6.2 Repeatability and trueness

To assess the repeatability and trueness, repeat the measurements 30 times.

Calculate the mean of the 30 measurements and the standard deviation. Calculate the differences between the true value (that is, the computer-aided model) and the mean of the 30 measured values (trueness).

2) A 3D analysis programme is commercially available from Surfacer, Imageware Inc., Ann Arbor, MI, USA or Geomagic Studio and Qualify, Geomagic Inc., NC, USA. This information is given for the convenience of the user of this International Standard and does not constitute an endorsement by ISO of the product named. Equivalent products may be used if they can be shown to lead to the same result.

Annex C
(normative)

Sphere

C.1 General

This annex specifies the measurement of a sphere which is limited to the hemisphere lying above the horizontal plane.

This test procedure uses a positive geometry.

C.2 Principle

A spherical physical object of known accuracy is measured with the digitizing device under investigation.

C.3 Apparatus

C.3.1 Test specimen, in the form of a sphere, as specified in Figure C.1, calibrated, with an accuracy better than 0,002 mm.

C.3.2 Travelling microscope, with at least 20 × magnification, accurate to 0,01 mm.

C.3.3 Digitizing device under investigation.

C.4 Geometry, dimensions, and tolerances of test specimen

Precision sphere of any dimensionally stable material (e.g. aluminium oxide or zirconium dioxide) with a nominal radius of (6,0 ± 0,000 5) mm shall be used as the physical object[3)] mimicking the size of a molar. The grade of the sphere shall be Grade 20 in accordance with ISO 3290-2.

NOTE 1 By using Grade 20 or better, the diameter error and the surface error are smaller than ±0,001 mm. Therefore, it is assumed that they are negligible.

NOTE 2 The Grade 20 sphere has a deviation from the spherical form of maximum 0,000 5 mm and a surface roughness tolerance of 0,000 03 mm.

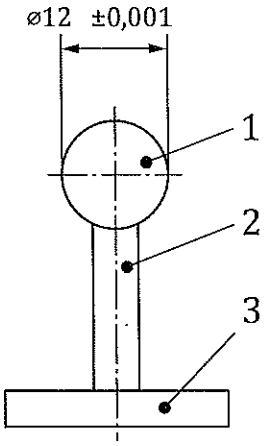
In order to establish and maintain the operational integrity, it is essential that the sphere is first calibrated by a technically competent laboratory (for example, complying with ISO/IEC 17025).

Glue the sphere onto a post (see Figure C.1). Ensure that the surface is clean and smooth. Treat the surface according to the manufacturer's instructions. If powder application is recommended in the manufacturer's instructions, it shall be coated as described. If powder application is recommended but no specific information is given in the manufacturer's instructions, spray the surface with titanium dioxide powder having a mean grain size smaller than 5 µm for reflectivity and opacity of the surface.

NOTE 3 Spraying the surface gives an error but, when applied correctly, this will be small compared to the measured error. An error is the application of too little or too much powder, causing uneven coating thickness and overlaps. This is directly visible in the measured error distribution.

3) Precision spheres are commercially available from Saphirwerk, Brügg, Switzerland. This information is given for the convenience of the user of this International Standard and does not constitute an endorsement by ISO of the product named. Equivalent products may be used if they can be shown to lead to the same result.

Dimensions in millimetres



Key

1 sphere
2 post
3 support

Figure C.1 — Test specimen: Sphere

C.5 Test procedure

Visually inspect the physical object (C.3.1) with a travelling microscope (C.3.2) using 20 × magnification for surface damage. If necessary, remake the physical object. Inspect the sphere of the test specimen (C.3.1) for a homogeneous surface without adhering particles.

Use the digitizing device under investigation (C.3.3) to capture the physical object (C.3.1). Digitize the physical object (C.3.1) according to the recommended procedure specified in the manufacturer's instructions for digitizing single crowns or teeth. Measure the upper part of the sphere including the equator.

NOTE The output is the data set used commonly for input of the CAD software.

Calculate from the processed digitization data the "best fitted" sphere.

EXAMPLE This can be done by an iterative method, beginning from a start point, given by clicking in a reference marker and start radius. No filtering takes place and the points measured by the sensor are transformed (moved and rotated) to the 3D world coordinates according to the position of the axis. Each point in the cloud, belonging to the sphere, is transformed to a polar coordinate, giving a radius and a direction. From this, the three dimensional errors of the point are calculated.

Determine the sphere centre and radius by using software tools with appropriate fitting methods.

Calculate the minimum and maximum radius by using software tools with appropriate fitting methods.

Calculate the histogram distribution by using software tools with appropriate fitting methods.

Calculate the mean angular coverage.

Calculate the mean radius and the standard deviation to an accuracy of ±0,001 mm.

C.6 Assessment

C.6.1 Reproducibility

To assess the reproducibility, repeat the measurements 30 times. Calculate the mean of the 30 measurements and the standard deviation.

C.6.2 Repeatability and trueness

To assess the repeatability and trueness, repeat the measurements 30 times.

Calculate the mean of the 30 measurements and the standard deviation. Calculate the differences between the true value and the mean of the 30 measured values (trueness).

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