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Dentistry — Test methods for machining accuracy of computer-aided milling machines

Médecine bucco-dentaire — Méthodes d'essai pour l'exactitude d'usinage des fraiseuses à commande numérique

Reference number
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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).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 9, *Dental CAD/CAM systems,* in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 55, *Dentistry,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This first edition of ISO 23298 cancels and replaces ISO/TR 18845:2017, which has been technically revised.

The main changes are as follows:

— the type of document has been changed from Technical Report to International Standard;

— two test methods have been specified using metal dies and software as the normative test methods;

— the selection guidance of test methods has been clarified;

— the details of the procedures of both test methods based on the inter-laboratory test have been revised.

Any feedback or questions on this document should be directed to the user’s national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

Dental CAD/CAM systems have been successfully used for the fabrication of indirect dental restorations such as inlays, crowns and bridges. The accuracy of these restorations is one of the most important factors for their clinical success. This document provides standardized test methods to evaluate the machining accuracy of computer-aided milling machines which are used as a part of dental CAD/CAM systems and the information to be provided by the manufacturer. Flow charts of the test methods are given in Figures A.1 and A.2.

There are two methods using metal dies or software to evaluate machining accuracy of the target restoration(s). Either or both test methods should be selected to evaluate the machining accuracy.

Dentistry — Test methods for machining accuracy of computer-aided milling machines

1 Scope

This document specifies the test methods to evaluate the machining accuracy of computer-aided milling machines as a part of dental CAD/CAM systems, which fabricate dental restorations, such as inlays, crowns and bridges.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 1942, *Dentistry — Vocabulary*

ISO 18739, *Dentistry — Vocabulary of process chain for CAD/CAM systems*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 1942, ISO 18739 and the following apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
computer-aided milling machine
computer-aided machining device designed for subtractive manufacturing of dental prostheses using rotary instruments for cutting and grinding

3.2
blank
material to be machined by a *computer-aided milling machine* (3.1)

Note 1 to entry: A blank can be a *block* (3.3) or a *disc* (3.4).

3.3
block
cuboidal material with holding device to be machined by a *computer-aided milling machine* (3.1)

3.4
disc
flat circular-shaped material to be machined by a *computer-aided milling machine* (3.1)

3.5
stock material
material *blanks* (3.2) that are in stock to be machined by a *computer-aided milling machine* (3.1)

4 General

There are two methods to evaluate accuracy of the target restoration(s). The accuracy of target restoration(s) shall be evaluated using one or both of the test methods described in Clause 5. The test method(s) selected and corresponding results shall be provided in the instructions for use, the technical manual or other means. When the machining accuracy is affected by the material, appropriate material(s) shall be tested. Testing shall be performed on each material type that the manufacturer indicates for use by the device. The metal die method (5.1) is a measurement method based on the marginal adaptability of a machined restoration to a master die. Measurements obtained using this method can be used to assess the adaptability at restoration margins. The software method (5.2) is a measurement method based on a comparison of the scanned file of a milled restoration to a master manufacturing file using reverse engineering software. Measurements obtained using this method can be used to assess restoration margin, intaglio and external surface accuracy.

5 Test methods

5.1 Metal die method

5.1.1 Target restorations

Three types of restorations are the targets of this test method:

a) class II inlay,

b) crown, and

c) four-unit bridge.

Choose the restoration type(s) specified in the manufacturer's instructions for use and technical manual. If any of the restoration types are not specified by the manufacturer's technical manual for the equipment being tested, this restoration type shall be eliminated from the test procedure.

NOTE This test method is designed by adopting the same principle as the examination method of clinical marginal adaptation. The clinical adaptation is examined by checking the discrepancy between the restoration and the cavity margin or between it and the shoulder margin of the abutment.

5.1.2 Apparatus

5.1.2.1 Metal dies

Two types of metal dies given in Figure 1 (class II inlay) and Figure 2 (crown and four-unit bridge dies) are used both for the preparation of three-dimensional data (manufacturing data set) and the evaluation of the accuracy of restorations. Dies shall be constructed based on the drawings in Figure 1 and Figure 2. These dies consist of a non-malleable base part and one or more removable structure(s) used for the evaluation of accuracy.

The diameter of the removable occlusal part, measured at the transition between the occlusal part and the abutment, shall be not less than the diameter of the abutment at this transition and the difference of diameter shall be not more than 10 µm.

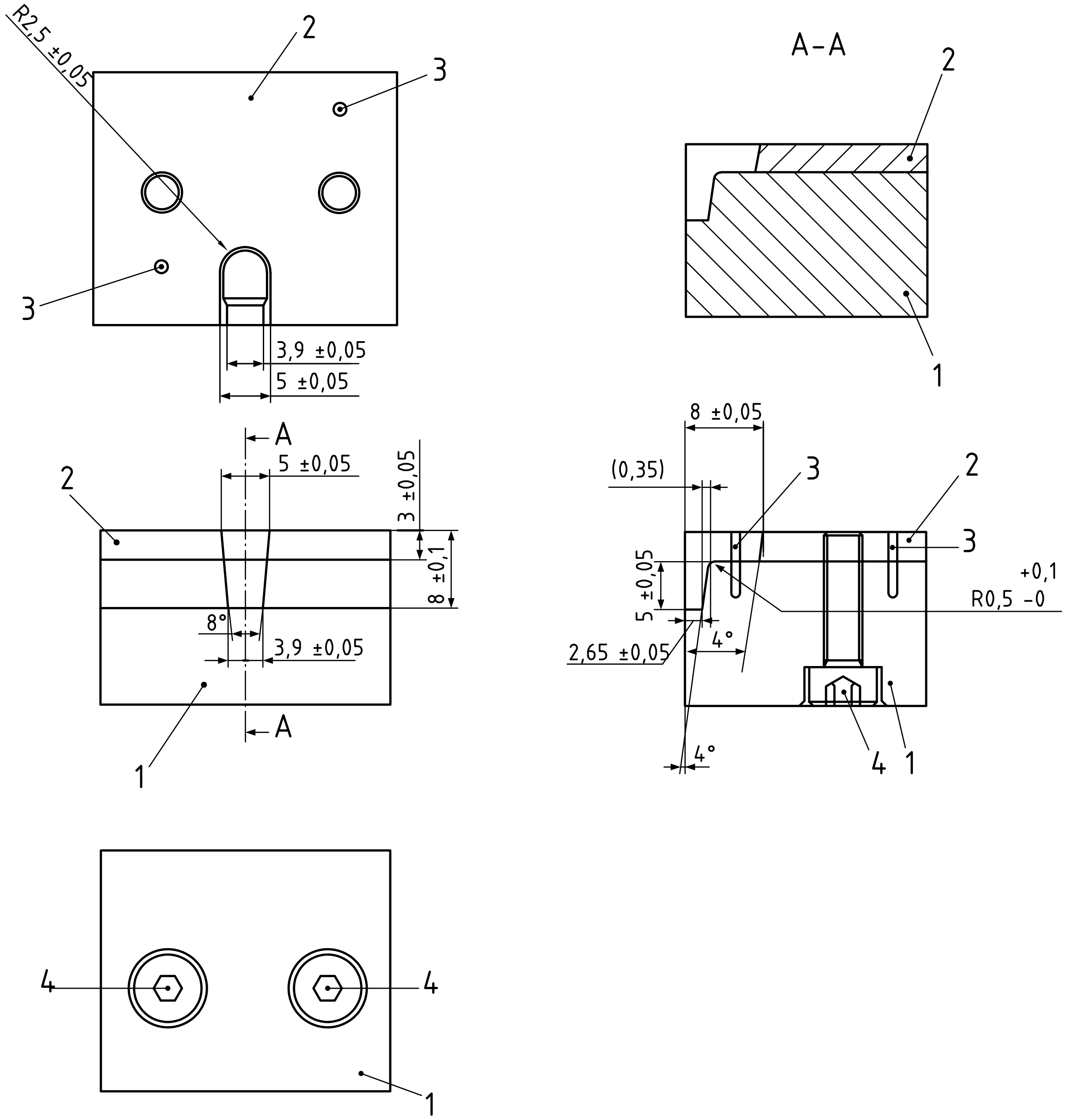
The surface roughness (S_a) of the die, excepting the surfaces which do not come in contact with the test specimens/machined restorations, shall be less than 2 µm. Refer to ISO 25178-2 and other parts for test methods.

If a mark for reference point is necessary, either a groove or a ridge, or both, may be placed on the part, but shall be placed so as to not influence the evaluation of the results.

The removable occlusal part and removable shoulder are used for preparation of three-dimensional data, but not used for evaluation of accuracy.

NOTE An example of the machining device to fabricate the dies is VERTICAL CENTER NEXUS 410B[1)].

Dimensions in millimetres



Key

1 base part

2 removable part

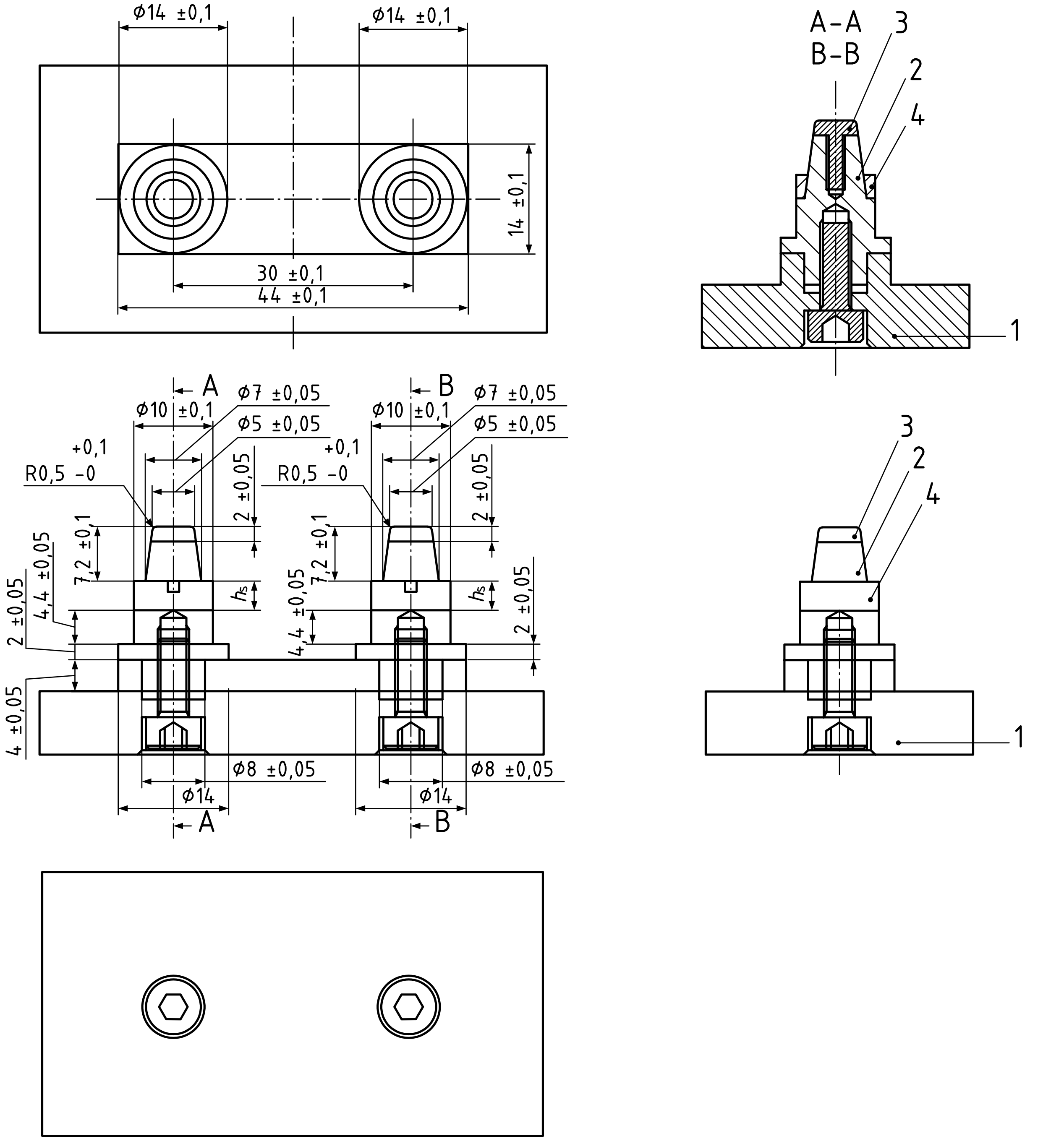
3 positioning pin

4 fixing screw

Figure 1 — Die for class II inlay specimen

1) VERTICAL CENTER NEXUS 410B is the trade name of a product supplied by Yamazaki Mazak. This information is given for the convenience of users of this document 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 results.

Dimensions in millimetres



Key

1 base part

2 abutment

3 removable occlusal part

4 removable shoulder

h_s height of the removable shoulder

The recommended size of the height of the removable shoulder is (3,6 ± 0,05) mm.

Figure 2 — Die for the crown and bridge specimen

5.1.2.2 Measuring devices used for metal dies

Measuring devices with accuracy of ≤2 µm shall be used for measurement of metal dies (5.1.3). Coordinate measuring machine (CMM) can be useful to measure the size of a die.

NOTE An example of a CMM is America Strato-Apex 574[2)].

5.1.2.3 Measuring devices used for discrepancy measurement

Measuring devices with accuracy of ≤5 µm shall be used for discrepancy measurement in 5.1.4. Three-dimensional measuring microscopes, displacement meters and digital micrometers can be used.

5.1.3 Measurement of metal dies

Each die shall be measured using a measuring device specified in 5.1.2.2 to confirm the shape and dimensions specified in Figure 1 or Figure 2. The specified dimensions of constructed die necessary to prepare CAD data shall be measured in accordance with Annex B. The measured data are used to prepare the three-dimensional data (see 5.1.4).

In case of a metal die for crown and bridge specimen, the height of the removable shoulder (h_s in Figure 2), and the height from the upper surface of the removable shoulder (Key 4 in Figure 2) to the upper surface of the removable occlusal part (Key 3 in Figure 2) shall be measured.

5.1.4 Preparation of three-dimensional data

5.1.4.1 General

The surface to be in contact with the metal die of each specimen type is determined by the measurements of the dies made in 5.1.3. The external surfaces of each specimen type are determined by 5.1.4.2 and 5.1.4.3.

5.1.4.2 Class II inlay

The shapes and sizes of test specimen of class II inlay shall conform to the cavity of metal die (see Figure 1). The occlusal and proximal surfaces shall be the same planes with the corresponding surface of the metal die.

5.1.4.3 Crown and bridges

The shapes and sizes of test specimen of the crown and the bridge shall conform to Figure 3 (crown) and Figure 4 (bridge). A mark to distinguish direction when placing the restoration on the metal die shall be made on the top surface of the crown. In case of bridges, the mark shall be made on either crown.

5.1.4.4 Preparation of CAD data (STL data)

To fabricate the target restorations, CAD data (STL data) for each of the restorations specified in 5.1.4.2 and 5.1.4.3 shall be prepared in accordance with Annex B. This CAD data shall then be processed by CAM software to prepare the manufacturing data set.

The dimensions of any surfaces in contact with the die surfaces are obtained from the measuring process in 5.1.3. Other dimensions are determined from Figure 3 and Figure 4.

The CAD data shall be prepared to ensure that the restoration meets the die without an allowance for cement space.

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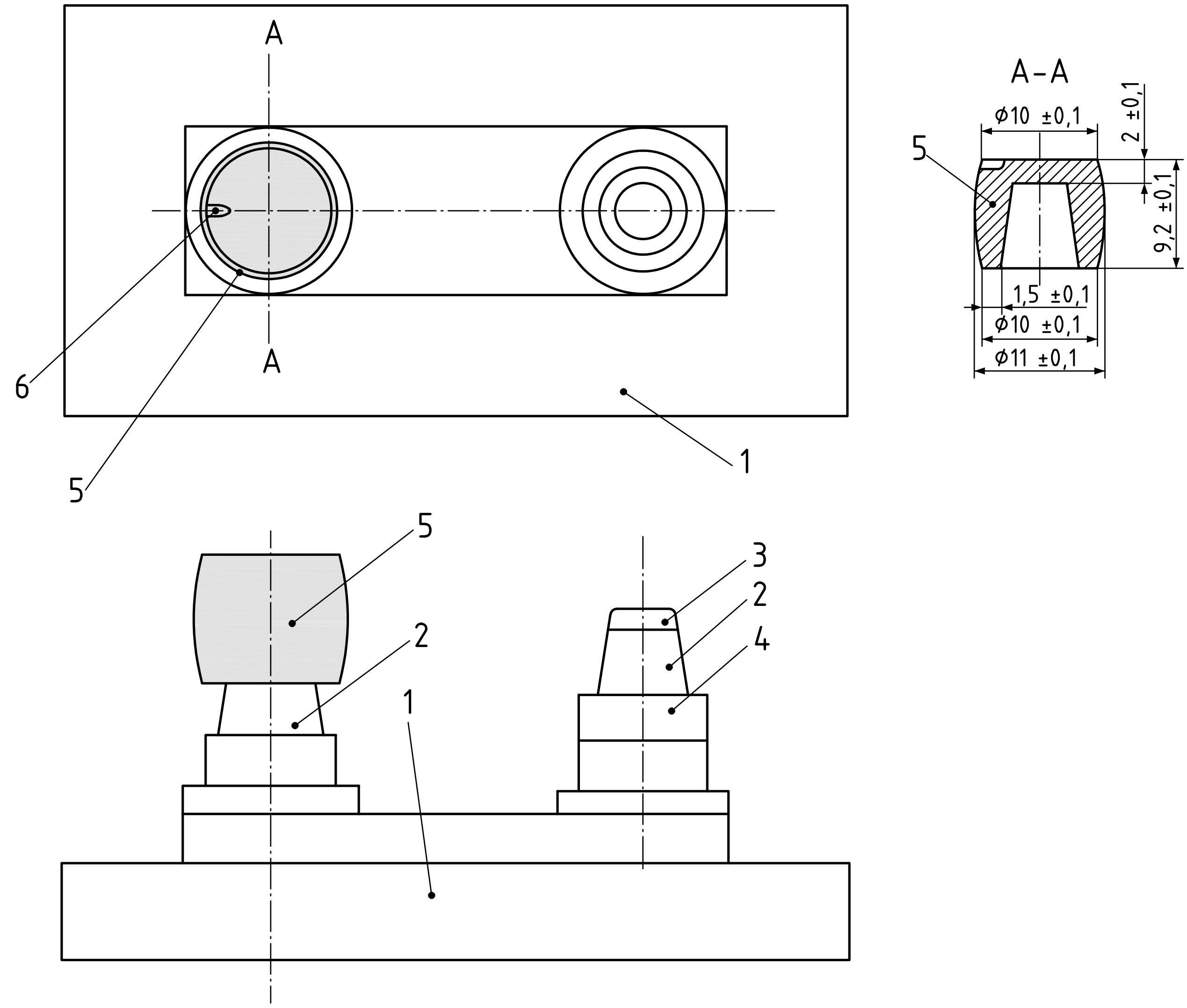
2) STRATO-Apex 574 is the trade name of a product supplied by Mitsutoyo. This information is given for the convenience of users of this document and does not constitute an endorsement by ISO of the product named. Equivalent products may be used if they can be shown to lead to the same results.

Dimensions in millimetres



Key

1 base part

2 abutment

3 removable occlusal part

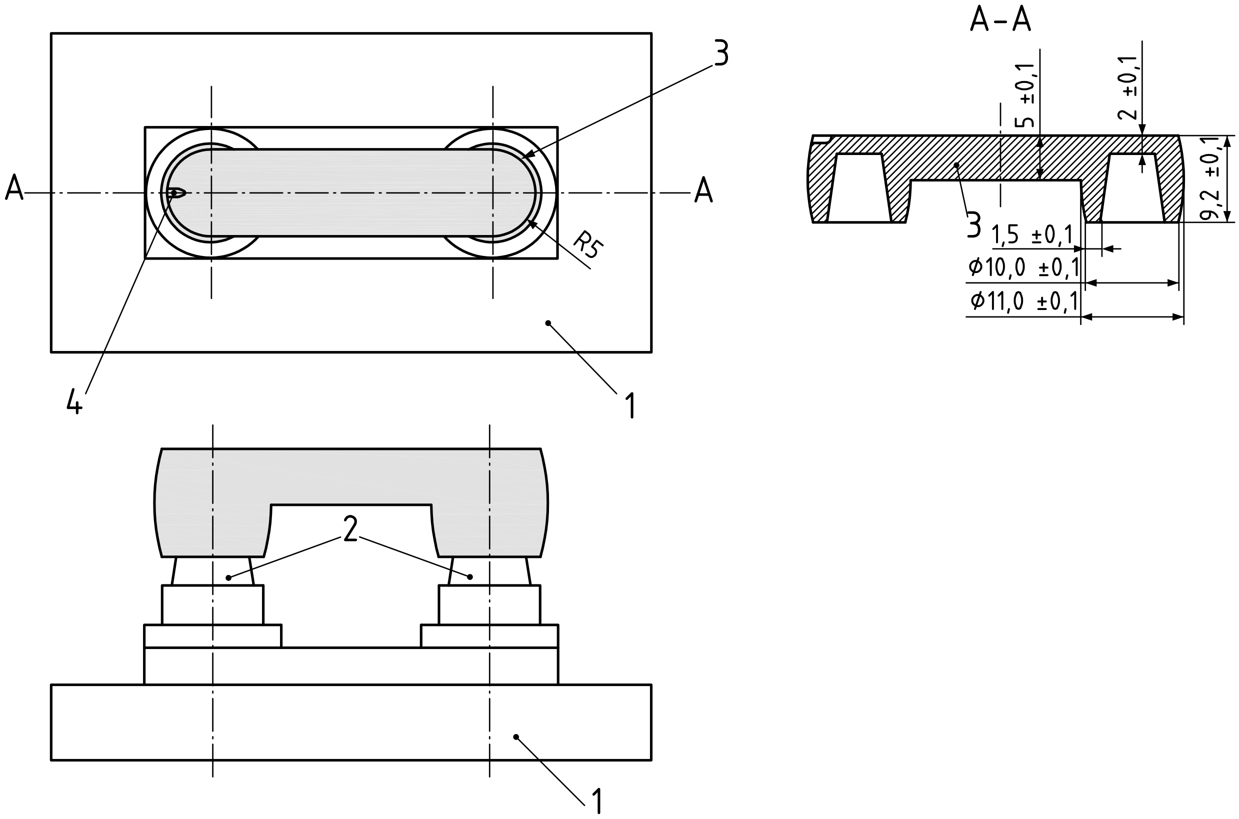
4 removable shoulder

5 test specimen

6 mark to distinguish direction

Figure 3 — Test specimen of the crown

Dimensions in millimetres



Key

1 base part

2 abutment

3 test specimen

4 mark to distinguish direction

Figure 4 — Test specimen of the bridge

5.1.5 Machining of restorations

The prepared manufacturing data set shall be input into the computer-aided milling machine following the manufacturer's instruction. The CAM software shall use the same configuration and parameters as is usually delivered. The target restoration shall be machined using the material specimen (blank) following the manufacturer's instruction.

NOTE 1 A manufacturer refers to a natural person actually manufacturing a computer-aided milling machine, or a natural person supplying necessary information to use the computer-aided milling machine.

The target restoration shall be the same size of the prepared manufacturing data set. CAM software contains a scaling factor to compensate for shrinkage of material during an additional process such as sintering. The CAM software scaling factor used in this test shall be 1,00.

This test is carried out using a computer-aided milling machine maintained according to the manufacturer's instruction.

The evaluation of accuracy (see 5.1.6) is carried out using the restoration without any after treatment such as a sintering process. If any support structures are necessary for fabrication, they shall not be positioned on the surface contacting the die and shall be removed before the measurement.

NOTE 2 Support structures are carefully removed using an appropriate rotary instrument such as a carbide laboratory cutter.

Fabricate six specimens for each of the target restorations.

5.1.6 Evaluation of accuracy

5.1.6.1 General

The accuracy of the restorations is expressed by the discrepancy between the margin of a restoration and baseline (cavity margin for inlays and the abutment shoulder for the crown and bridge).

The measurement of discrepancy is carried out using a measuring device specified in 5.1.2.3. The measured value shall be expressed in millimetre to three decimal places. After each measurement, the surface of metal die shall be cleaned to remove all particles and dust.

When two or more dies for each restoration type are prepared, evaluation of accuracy shall always be performed using restorations prepared from measurement data specific to that die set.

5.1.6.2 Class II inlay

Place the inlay in the cavity of a metal die and apply a load of (25 ± 1) N, distributed evenly on the centres of occlusal and proximal surfaces simultaneously. Round edges of the loading tip are preferred. Remove the load after (30 ± 1) s and examine where the margin of the inlay is located.

V-shaped or M-shaped pressing device having inner corner of 90° and width of (4,5 ± 0,2) mm shall be used for applying the load onto the occlusal and proximal surfaces of inlay simultaneously.

If necessary, the removable part of the inlay die should be retained with the fixation screw. See Figure 1.

NOTE The use of weighing paper or a thin elastomeric sheet can be used at the interface of the loading tip and inlay specimen.

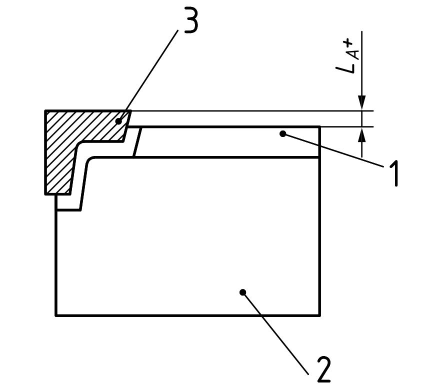
When the occlusal margin of the inlay is located higher than the occlusal baseline (occlusal margin of the die cavity), measure the discrepancy between the inlay margin and the occlusal baseline [L_{A+} in Figure 5 a)]. Similarly, when the proximal margin of the inlay extends past the proximal baseline (proximal margin of the die cavity), measure the discrepancy between the inlay margin and the proximal baseline [L_{B+} in Figure 5 b)]. The measured values for both occlusal and the proximal discrepancies are expressed as positive values.

When the occlusal and proximal margins of the inlay are located at the same level of the baseline or beneath the baseline, remove the base part (Key 2 in Figure 5) and place the inlay in the removable part (Key 1 in Figure 5). Apply a load of (25 ± 1) N, distributed evenly on the occlusal and proximal surfaces simultaneously, and remove it after (30 ± 1) s. Measure the discrepancies between the occlusal inlay margin and the occlusal baseline [L_{A-} and L_{B-} in Figure 5 c)] and between the proximal inlay margin and the proximal baseline [L_{B-} in Figure 5 d)]. The measured values are expressed as negative values. If the inlay margin is located at the same level of the baseline, the discrepancy is 0,000 mm.

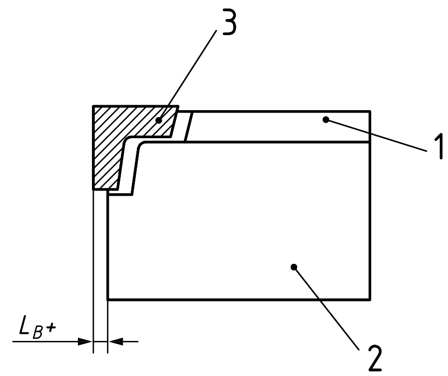
For both cases, measurements with and without base part, the measurement shall be carried out at three points for the occlusal discrepancy [see Figure 5 e)] and at four points for the proximal discrepancy [see Figure 5 f)]. A discrepancy shall be measured as horizontal discrepancy judging from the top.

NOTE 3 When a measuring microscope is used, the discrepancy in the Z-direction in the vertical direction cannot be precisely measured because of its poor focusing accuracy.

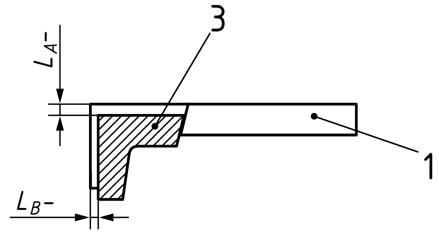
The measured discrepancy data (three points for the occlusal discrepancy and four points for the proximal discrepancy) of one inlay are averaged to represent the discrepancy of that inlay. Calculate the average of the six representative discrepancy values and the standard deviations to express the accuracy of the inlay.



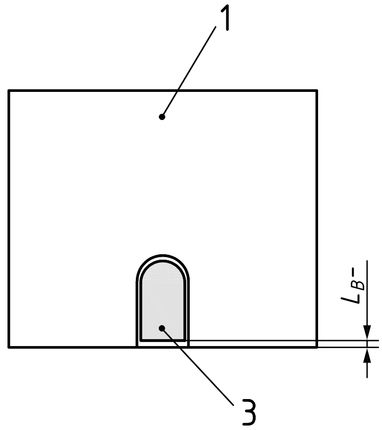
a) Occlusal discrepancy with base part



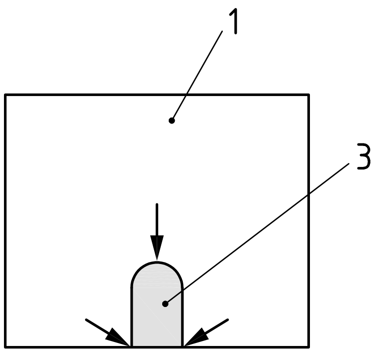
b) Proximal discrepancy with base part



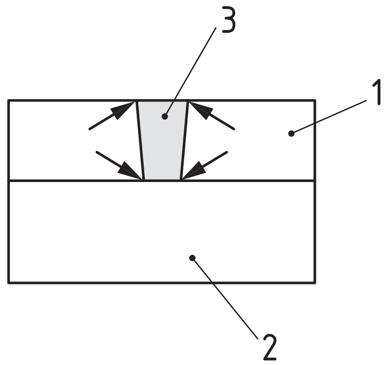
c) Occlusal and proximal discrepancy measurements without base part



d) Proximal discrepancy measurements without base part



e) Measurement points for occlusal discrepancy



f) Measurement points for proximal discrepancy

Key

1 removable part
2 base part
3 inlay
L_{A+} discrepancy between the occlusal baseline and the inlay margin which is higher than the occlusal baseline
L_{A-} discrepancy between the occlusal baseline and the inlay margin which is lower than the occlusal baseline
L_{B+} discrepancy between the proximal baseline and the inlay margin which locates outside of the proximal baseline
L_{B-} discrepancy between the proximal baseline and the inlay margin which locates inside of the proximal baseline

Figure 5 — Discrepancy measurement of class II inlay

5.1.6.3 Crown

Remove the removable occlusal part (Key 3 in Figure 2) and the removable shoulder (Key 4 in Figure 2) from the metal die. Place the crown on the abutment of a metal die (Key 2 in Figure 2) referencing the mark which distinguishes the direction on the upper surface of crown, [see 5.1.4.3 and Figure 6 e)]. Each crown to be measured shall be oriented in the same direction. Apply a load of (25 ± 1) N for (30 ± 1) s, distributed evenly across the occlusal surface of a crown. The abutment of metal die used for the preparation of design data shall be used. Remove the load and measure the apparent vertical discrepancy without the removal part (L_{By}) between the second baseline (Key 6 in Figure 6) and the margin of the crown.

The apparent vertical discrepancy (L_{By}) shall be measured at four points (margin at the centre of medial, distal, buccal and lingual surfaces) specified in Figure 6 e) for each crown.

The vertical discrepancy (L_{Ay+} or L_{Ay-} in Figure 6) between the margin of the crown and the baseline (Key 3 in Figure 6) is obtained by subtracting the height of the removable shoulder (Key 4 in Figure 2) from L_{By}. When the crown margin is located higher than the baseline (Key 3 in Figure 6), the vertical discrepancy [L_{Ay+} in Figure 6 a)] between the crown margin and the baseline is expressed as a positive value. When the crown margin is located lower than the baseline (Key 3 in Figure 6), the vertical discrepancy [L_{Ay-} in Figure 6 b)] between the crown margin and the baseline is expressed as a negative value. When the crown margin is located on the baseline, the vertical discrepancy is 0,000.

The vertical discrepancy (L_{Ay+} or L_{Ay-}) shall be averaged to represent the vertical discrepancy of that crown.

When the crown margin is located higher than the baseline (Key 3 in Figure 6), calculate the lateral accuracy (L_{Ly+}) using Formula (1).

When the crown margin is located lower than the baseline (Key 3 in Figure 6) or at it, calculate the lateral accuracy (L_{Ly-}) using Formula (2).

$$g = \frac{L_d \times (D_a - D_b)}{D_a \times h_a} \times 100 \qquad (1)$$

$$g = \frac{L_e \times (D_b - D_a)}{D_a \times h_a} \times 100 \qquad (2)$$

where

D_a is the diameter of abutment at the baseline [see Figure 6 c) and d)];

D_b is the diameter of abutment at the top line [see Figure 6 c) and d)];

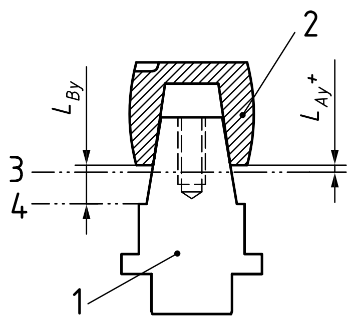
h_a is the height of abutment [see Figure 6 c) and d)];

L_d is the vertical discrepancy [see L_{Ay+} in Figure 6 c)];

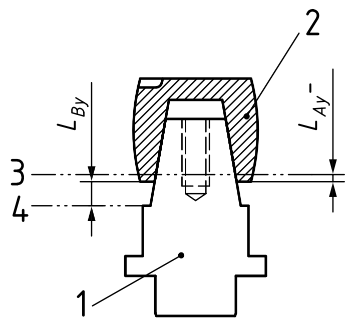
L_e is the vertical discrepancy [see L_{Ay-} in Figure 6 d)];

g is the lateral accuracy (L_{Ly+} or L_{Ly-}) (%).

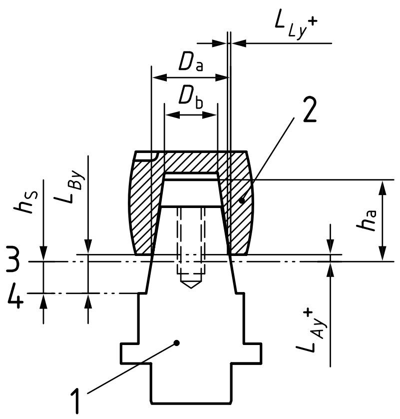
Calculate the average of the six representative lateral accuracies (%) and the standard deviation to express the accuracy of the crown.



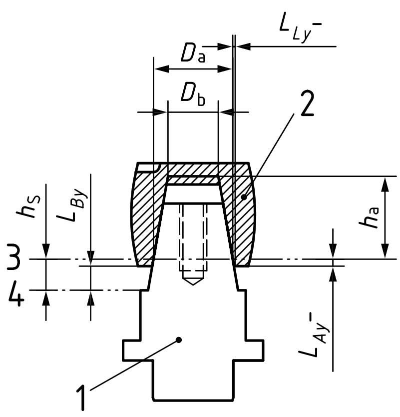
a) Vertical discrepancy, L_{Ay+}, measurement of crown when its margin locates higher than the baseline



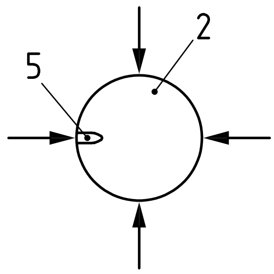
b) Vertical discrepancy, L_{Ay-}, measurement of crown when its margin locates lower than the baseline or at it



c) Lateral discrepancy, L_{Ly+}, of crown



d) Lateral discrepancy, L_{Ly-}, of crown



e) Measurement points (margin at the centre of medial, distal, buccal and lingual surfaces)

Key

1 metal die

2 crown

3 baseline (upper plane of the removable shoulder)

4 second baseline (lower plane of the removable shoulder)

5 mark to distinguish direction

D_a diameter of abutment at the baseline

D_b diameter of abutment at the top line

h_a height of abutment

h_s height of the removable shoulder which is the distance between the baseline and the second baseline

L_{Ay+} vertical discrepancy of crown when its margin is higher than the baseline, which is used as d in Formula (1)

L_{Ay-} vertical discrepancy of crown when its margin is lower than the baseline, which is used as e in Formula (2)

L_{By} measured vertical discrepancy of crown without removable parts

L_{Ly+} lateral discrepancy when its margin locates higher than the baseline

L_{Ly-} lateral discrepancy when its margin locates lower than the baseline or at it

Figure 6 — Discrepancy measurement of the crown

5.1.6.4 Four-unit bridge

Remove the removable occlusal part (Key 3 in Figure 2) and the removable shoulder (Key 4 in Figure 2) from the metal die. Place both crowns on the abutments of a metal die (Key 2 in Figure 2) referencing the mark which distinguishes the direction on the upper surface of the bridge, [see 5.1.4.3 and Figure 7 c)]. Each bridge measured shall be oriented in the same direction. Apply a load of (25 ± 1) N, distributed evenly across the occlusal surface of the two crowns for (30 ± 1) s. The total load is approximately 50 N.

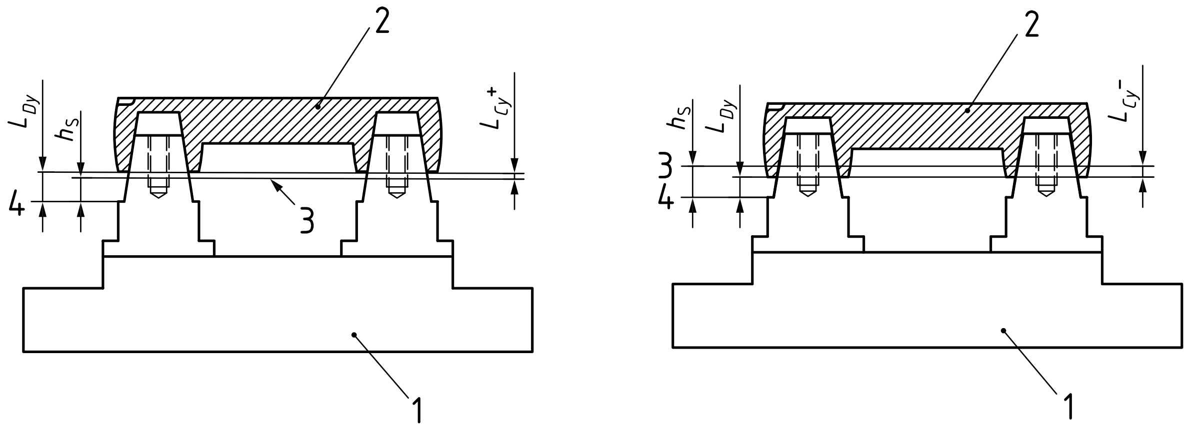
Remove the load and measure the apparent vertical discrepancy (L_{Dy}) between the second baseline (Key 4 in Figure 7) and the margin of the crowns.

The apparent vertical discrepancy (L_{Dy}) shall be measured at three points for each of two crowns [see Figure 7 c)] of one bridge.

The vertical discrepancy (L_{Cy+} or L_{Cy-} in Figure 7) between the margin of the crown and the baseline (Key 3 in Figure 7) is obtained by subtracting the height of the removable shoulder (h_s in Figure 7) from L_{Dy}. The vertical discrepancy (L_{Cy+} or L_{Cy-} in Figure 7) between the margin of the crown and the baseline (Key 3 in Figure 7) is obtained by subtracting the height of the removable shoulder (h_s in Figure 7) from L_{Dy}. When the crown margin is located higher than the baseline (Key 3 in Figure 7), the vertical discrepancy [L_{Cy+} in Figure 7 a)] between the crown margin and the baseline is expressed as a positive value. When the crown margin is located lower than the baseline (Key 3 in Figure 7), the vertical discrepancy [L_{Cy-} in Figure 7 b)] between the crown margin and the baseline is expressed as a negative value. When the crown margin is located on the baseline, the vertical discrepancy is 0,000.

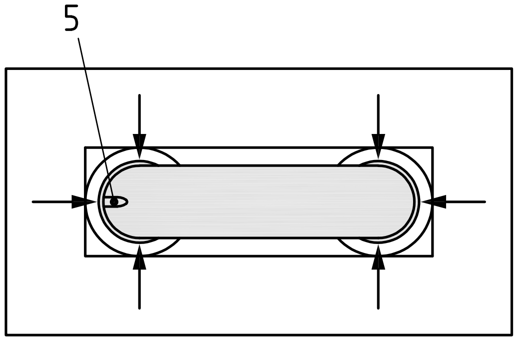
Obtain the average of the six measured values of vertical discrepancy (L_{Cy+} or L_{Cy-}) in total to represent the discrepancy of that bridge.

Calculate the average of the six representative discrepancy values and the standard deviation to express the accuracy of the four-unit bridge.



a) Discrepancy measurement when its margin locates higher than the baseline

b) Discrepancy measurement when its margin locates lower than the baseline



c) Measurement points

Key

1 base part
2 bridge
3 baseline (upper plane of the removable shoulder)
4 second baseline (lower plane of the removable shoulder)
5 mark to distinguish direction
h_s height of the removable shoulder which is the distance between the baseline and the second baseline
L_{Cy+} vertical discrepancy between the margin of the crown and the baseline
L_{Cy-} vertical discrepancy between the margin of the crown and the baseline
L_{Dy} apparent vertical discrepancy between the second baseline and the margin of the crowns

Figure 7 — Discrepancy measurement of the four-unit bridge

5.2 Test methods for software method

5.2.1 General

Four test objects are the targets of the test methods for software method:

a) crown,

b) short span bridge,

c) medium span bridge, and

d) cross-arch bridge.

The crown specimen (see Figure 8) has similar dimensions and shape with respect to a molar crown restoration. It is used as an example for crowns and other smaller-sized restorations. The three bridge specimens are used to represent examples of short span (see Figure 9), medium span (see Figure 10) and cross-arch bridges (see Figure 11) which can use different CAM software templates and challenge the accuracy of the milling machine.

Milling machines can have restrictions on stock material dimensions and thus not be capable of milling all bridge restoration specimens.

The crown specimen and the largest bridge specimen which fits in the dental mill manufacturer’s largest stock material shall be used for accuracy evaluation. For example, if a machining device only accepts small blocks for machining, and only the crown specimen fits in the block, then the crown specimen is the only specimen milled and measured for accuracy. If the three-unit bridge fits in a block compatible with the machining device and is indicated by the device manufacturer, then the crown and three-unit bridge specimen (short span bridge) is milled and measured for accuracy. If a machining device accepts large disc stock material for machining crowns and cross-arch bridges, then the crown specimen and only the cross-arch bridge specimens is milled and measured for accuracy.

The single crown specimen has a diameter of about 12,9 mm, and a height of approximately 10 mm. The design is shaped like a sphere with a cylindrical section. The cylinder walls are conical with a wall angle of 6° from vertical. The wall thickness of the specimen is 1 mm overall except for one flat plane which has a wall thickness of 0,75 mm.

The design consists of curved surfaces and flat surfaces, which are used partly for measuring and partly for placing the support pins to connect the specimen to the stock material. The three lateral flat surfaces are used for attaching the pins. They are not evenly distributed around the circumference. In addition, one surface is larger and has a smaller wall thickness to allow clear orientation to the machine axes.

The three-dimensional data (STL) of the specimen (see Table 1) shall be downloaded from: https://standards.iso.org/iso/23298/ed-1/en, and shall not be generated from the drawings shown in Figure 8 to Figure 11.

Table 1 — Three-dimensional data (STL) of the specimen

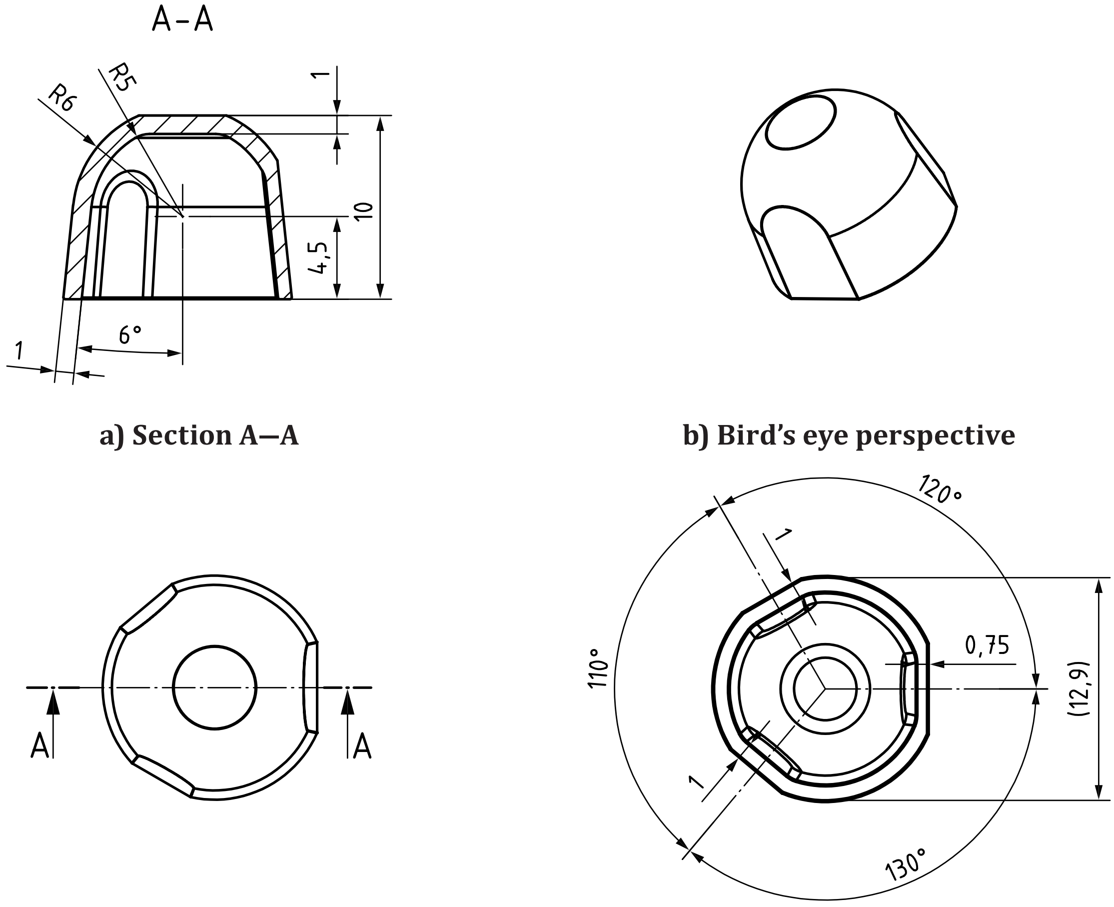
Specimen	STL-file	Used for
Crown	Crown_Specimen.stl	Manufacturing
	Crown_Specimen_Alignment.stl	Alignment procedure
	Crown_Specimen_External.stl	Analysis of external surface
	Crown_Specimen_Intaglio.stl	Analysis of intaglio surface
	Crown_Specimen_Prepline.stl	Analysis of prepline-surface
Short span bridge	Short_Span_Bridge_Specimen.stl	Manufacturing
	Short_Span_Bridge_Specimen_Alignment.stl	Alignment procedure
	Short_Span_Bridge_Specimen_External.stl	Analysis of external surface
	Short_Span_Bridge_Specimen_Intaglio.stl	Analysis of intaglio surface
	Short_Span_Bridge_Specimen_Prepline.stl	Analysis of prepline-surface
Medium span bridge	Medium_Span_Bridge_Specimen.stl	Manufacturing
	Medium_Span_Bridge_Specimen_Alignment.stl	Alignment procedure
	Medium_Span_Bridge_Specimen_External.stl	Analysis of external surface
	Medium_Span_Bridge_Specimen_Intaglio.stl	Analysis of intaglio surface
	Medium_Span_Bridge_Specimen_Prepline.stl	Analysis of prepline-surface
Cross-arch bridge	Cross_Arch_Bridge_Specimen.stl	Manufacturing
	Cross_Arch_Bridge_Specimen_Alignment.stl	Alignment procedure
	Cross_Arch_Bridge_Specimen_External.stl	Analysis of external surface
	Cross_Arch_Bridge_Specimen_Intaglio.stl	Analysis of intaglio surface
	Cross_Arch_Bridge_Specimen_Prepline.stl	Analysis of prepline-surface

5.2.2 Test object

5.2.2.1 Crown specimen

To determine crown accuracy, the single crown test specimen (see Figure 8) shall be used.

Dimensions in millimetres



a) Section A—A

b) Bird’s eye perspective

c) Top view

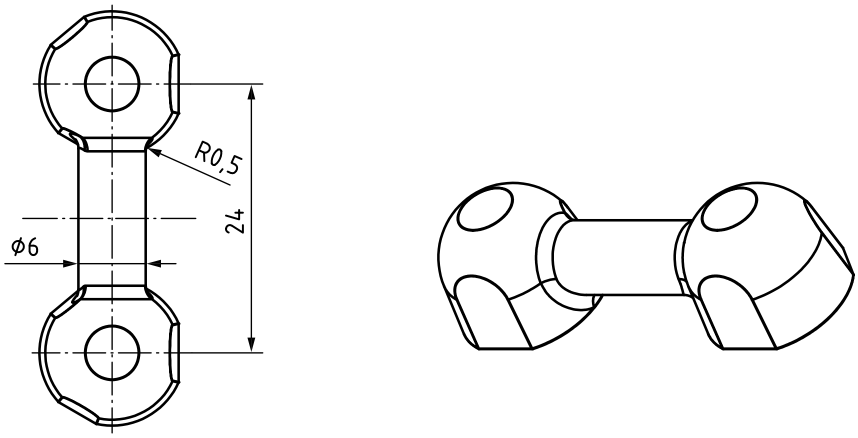
d) Bottom view

Figure 8 — Crown specimen

5.2.2.2 Short span bridge specimen

To determine the short span accuracy, the short span bridge model (see Figure 9) is used for small stock machining devices. Two single crown specimens are connected with a bar and simulate a three-unit bridge.

Dimensions in millimetres



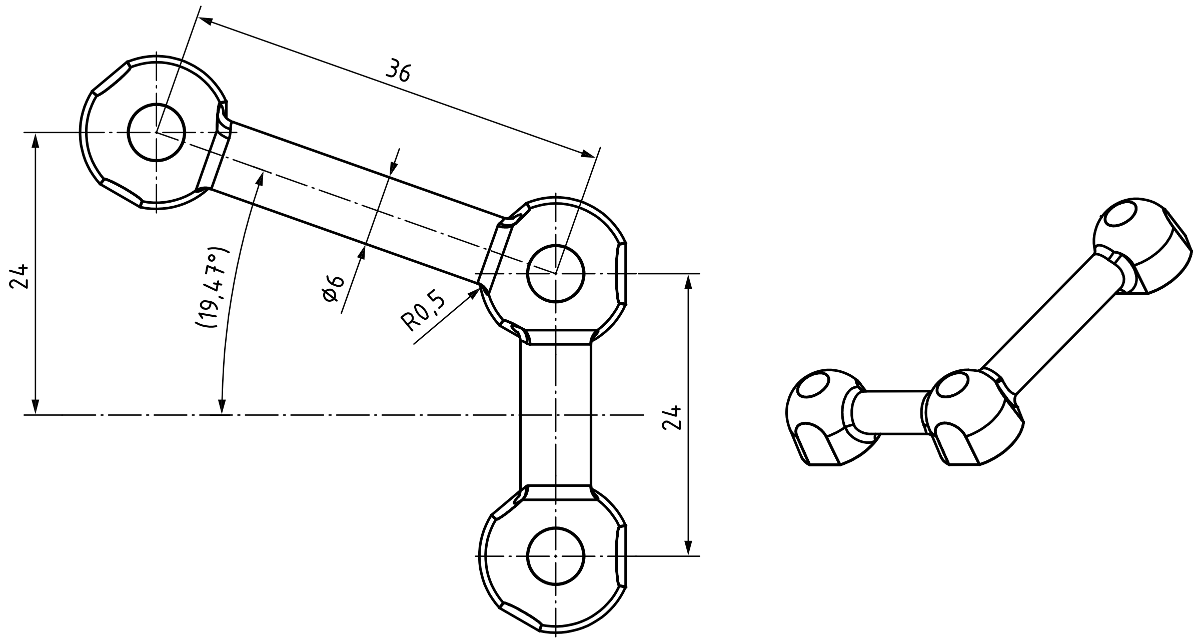
NOTE Shapes and dimensions of crown part are indicated in Figure 8.

Figure 9 — Short span bridge specimen for the small block (simulates three-unit bridge)

5.2.2.3 Medium span bridge specimen

To determine the medium span accuracy, the medium span bridge model (see Figure 10) is used for machining devices which accommodate medium blocks as stock material. The three single crown specimens are connected with two bars and simulate a six-unit bridge.

Dimensions in millimetres



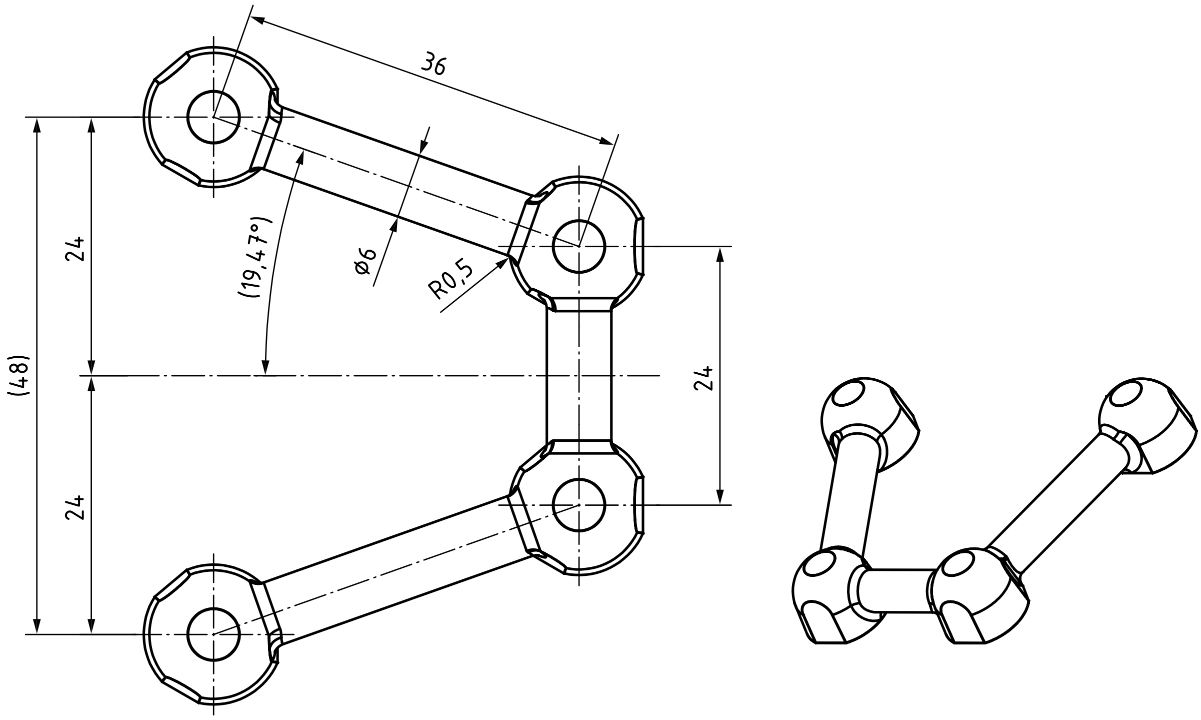
NOTE Shapes and dimensions of crown part are indicated in Figure 8.

Figure 10 — Medium span bridge specimen for the medium block

5.2.2.4 Cross-arch bridge specimen

To determine the cross-arch accuracy, the cross-arch bridge specimen (see Figure 11) is used for machining devices that accommodate large blocks or discs as stock material. The four single crown specimens are connected with three bars and simulate a nine-unit bridge.

Dimensions in millimetres



NOTE Shapes and dimensions of crown part are indicated in Figure 8.

Figure 11 — Cross-arch bridge specimen for the large block or disc

5.2.3 Equipment and apparatus

5.2.3.1 Milling equipment

The dental mill under evaluation shall be used for milling the appropriate test objects. The system shall be operated during the tests in accordance with the instructions for use or technical manual supplied with the equipment. If a specific fixture is required for milling a specific stock material, tests shall be performed using the appropriate fixture and material stock as recommended in the instructions for use or technical manual supplied with the equipment.

5.2.3.2 Measuring apparatus

The milled specimens shall be scanned or measured with a 3D measurement device such as a CMM, optical scanner or computed tomography (CT) scanner. The 3D measurement device shall have a confirmed accuracy and resolution of less than 5 µm.

NOTE 1 CMM is a device defined by ISO 10360-1.

NOTE 2 America Strato-Apex 574 and Leitz PMM-C are examples of a suitable CMM products available commercially. This information is given for the convenience of users of this document and does not constitute an endorsement by ISO of these products.

5.2.4 Machining of specimens

5.2.4.1 General

The three-dimensional data (STL) for manufacturing of each specimen (Crown specimen and largest bridge specimen capable of being milled in the milling machine) – [Crown_Specimen.stl / Short_Span_Bridge_Specimen.stl / Medium_Span_Bridge_Specimen.stl / Cross-Arch_Bridge_Specimen.stl] shall be imported or loaded into CAM software program for the machining device. Scaling of the stock material shall be set to 1,0 for the purposes of this evaluation. Any post-processing steps such as sintering, curing, crystallization, etc., which can change the dimensions of the machined specimens shall not be performed prior to analysis. The CAM software version, machining template version and material shall be recorded for each type of specimen machined and included in the test report. The CAM software shall use the same configuration, templates and parameters as is normally supplied with the milling system. The standard crown template shall be used to mill the crown specimen. The standard bridge template if one is supplied with the system shall be used to mill the selected bridge specimen. Six specimens of each size as determined in 5.2.1 shall be milled for accuracy measurements.

5.2.4.2 Positioning in the stock material

The test specimens shall be placed into the stock material with the orientation of the large lateral plane with thin wall thickness in the X+ axis direction. The occlusal surface of the crown specimen shall be oriented in the Z+ axis. The bridge specimen shall be placed in the stock material with the orientation of all large lateral planes with thin wall thickness in the X+ axis direction. See Figure 12.

If the X+ axis direction of the milling machine is not known, or the size of stock material is not sufficient to allow for orientation in the X+ axis, the specimen shall be placed in an orientation which allows it to fit in the stock material. In this case, each specimen of the same size shall be placed in the same orientation in the stock material.

Use the machining device manufacturer’s recommendation for the number of support pins and support pin size. Support pins shall be placed only on the plane lateral surfaces of the test specimen as those surfaces are not used for accuracy measurements.

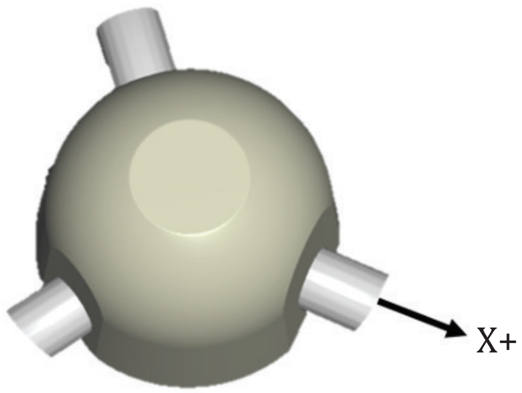
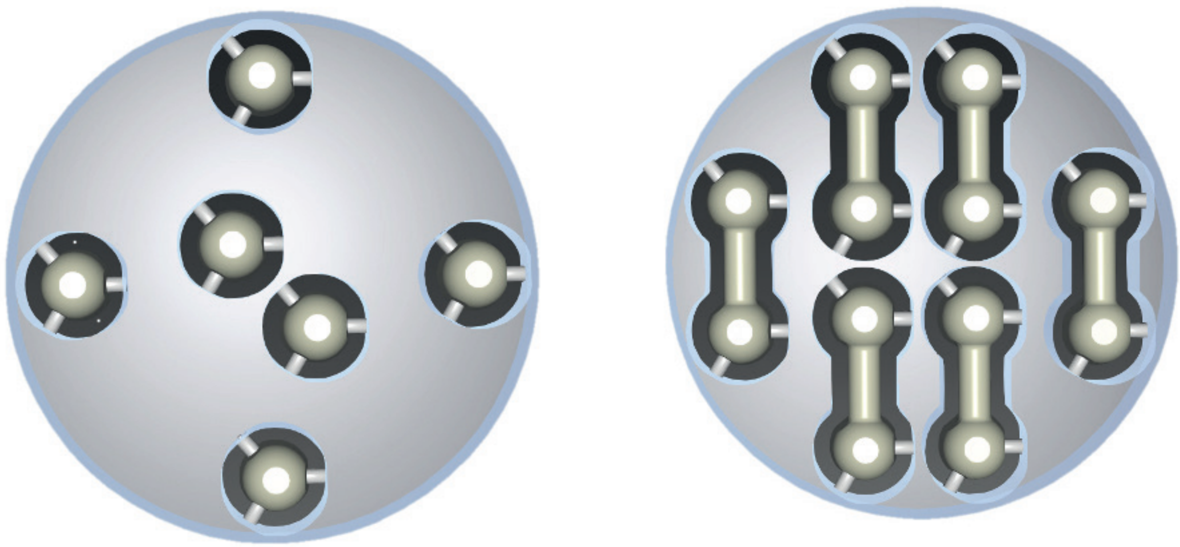


Figure 12 — Large lateral plane oriented in the X+ direction

In order to detect local differences in machine accuracy, the six objects being milled shall be evenly distributed throughout the stock material when a disc-type blank or a large block for more than one unit is used. See Figures 13 a) and b).



a) Crowns

b) Bridges

Figure 13 — Placement of crowns and bridges in the disc-type blank

The manufacturing data set for the specimens shall be calculated and delivered to the milling machine in accordance with the milling machine manufacturer's instructions.

5.2.4.3 Milling of specimens

The stock material shall be placed in the milling machine following the manufacturer's instructions. The milling machine manufacturer's recommended stock material retaining screws, fixtures and tooling shall be used during the evaluation process. If the equipment supplier/manufacturer specifies a specific calibration interval or tool replacement interval which occurs during the course of the evaluation, calibration or tool replacement shall be done in accordance with the supplier/manufacturer's instructions.

5.2.4.4 Specimen removal

After milling the specimens shall be removed from the stock material. Follow the methods of removing milled objects from stock as outlined in the milling machine manufacturer's instructions for use or technical manual. Care shall be taken in the removal and handling of the milled specimens as some materials can deform or fracture if handled inappropriately.

5.2.5 Measurement

Measure the shapes and dimensions using the measuring apparatus (5.2.3.2).

Data collected shall include all internal and external surfaces of the specimens. Follow the 3D measurement device manufacturer's instructions for use and best practice to obtain 3D data sets of each milled specimen. Exact procedures will vary by the 3D measurement device manufacturer.

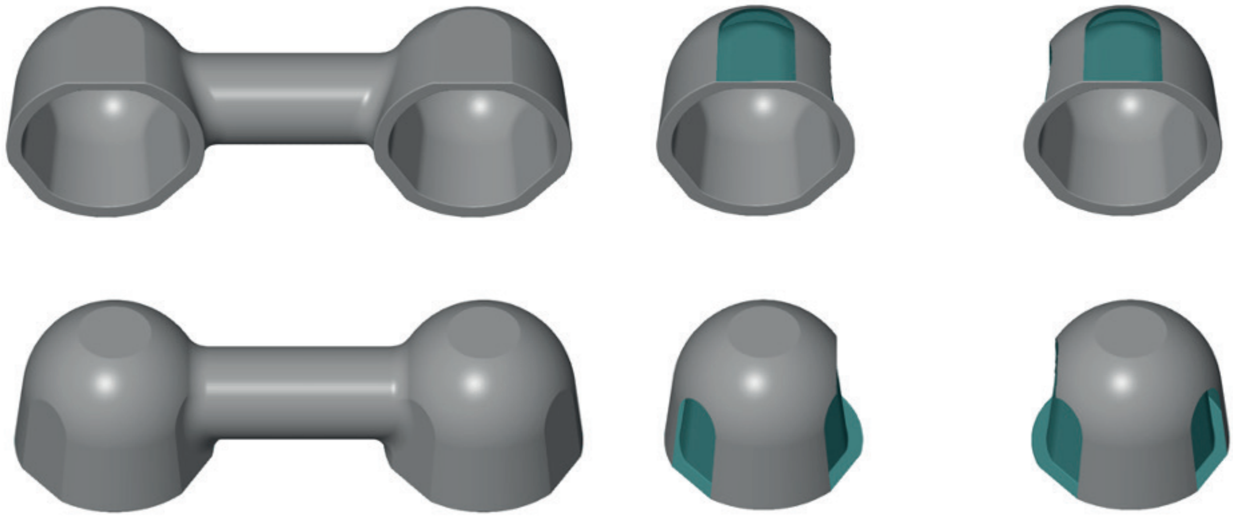
The data resulting from the measurements shall be converted to an STL format.

5.2.6 Data alignment procedures

5.2.6.1 General

Prior to analysis, each measured or scanned STL object shall be aligned with the appropriate specimen alignment STL. Reverse engineering or inspection software shall be used to align STL files.

Milling supports or sprue locations represent areas on the target specimens which have unique contours or surfaces not part of the original reference STL. These surfaces shall be ignored during the alignment and analysis processes. Therefore, in the STL-file for alignment, these surfaces have been eliminated. See Figure 14.



a) STL-file for manufacturing — b) STL-file for alignment

Figure 14 — Alignment data set using the short span bridge specimen

For alignment, all surfaces of the alignment file (Crown_Specimen_Alignment.stl, Short_Span_Bridge_Specimen_Alignment.stl, Medium_Span_Bridge_Specimen_Alignment.stl, Cross_Arch_Bridge_Specimen_Alignment.stl) shall be used. Alignment shall be performed using an acceptable algorithm such as best fit/least square error. The position of the alignment file (Crown_Specimen_Alignment.stl, Short_Span_Bridge_Specimen_Alignment.stl, Medium_Span_Bridge_Specimen_Alignment.stl, Cross_Arch_Bridge_Specimen_Alignment.stl) shall not change during the alignment process. Scanned STL files are aligned to the appropriate alignment STL file, i.e. scanned STL files move to the alignment-file position.

NOTE Geomagic Control and Qualify or GOM-Inspect are an examples of suitable reverse engineering or inspection software programs available commercially. This information is given for the convenience of users of this document and does not constitute an endorsement by ISO of these products.

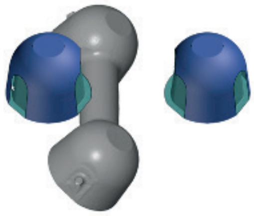
5.2.6.2 Alignment steps

For alignment of the alignment STL and scanned STLs, a reverse engineering or inspection analysis software with a “Local Best Fit” or “Least Squares” algorithm is needed. This algorithm shall be performed with all surfaces of the alignment STL. Depending on the software product, set maximum distance for alignment to 0,5 mm to avoid aligning errors due to opposite walls, as the minimum wall thickness of the specimen is 0,75 mm.

The algorithm aligns the objects by calculating the least square error between alignment STL and scanned STL using all surfaces. In most cases, a rough pre-alignment shall be performed in advance.

The following procedure is based on the example of the short span bridge specimen using the GOM-Inspect software. Specific steps or terminology can vary with other software products, but the basic procedure is the same.

— Step 1: Import the alignment STL and scanned STL (not aligned).



— Step 2: Perform pre-alignment.

Make sure that after alignment the lateral planes of alignment STL and scanned STL point in the same direction.

— Step 3: Select all surfaces of alignment STL for precision-alignment (local best fit).

Set the maximum distance to 0,5 mm.

— Step 4: Run main alignment with local best fit algorithm on selected surfaces.

After the above steps, the alignment STL and scanned STL have been aligned and the analysis procedure can be performed. This alignment process shall be repeated for each specimen.

5.2.7 Data analysis procedure

5.2.7.1 General

The prerequisite for the analysis procedure is the correct alignment of the scanned STL. During the analysis, the deviation between the specific analysis STL and scanned STL is calculated for all surfaces of the analysis STL using the analysis software. In the analysis software, the analysis STL shall be identified as the reference or original object file. The scanned STL shall be identified as the "test" or "challenge" object file.

The analysis software calculates the deviation using the following algorithm.

— Each surface is represented by a group of triangles. Each selected surface consists of a subset of triangles that describe the area. To calculate the total error of the area, the distance between each triangle of the reference object surface and the closest corresponding surface on the test object in a perpendicular (normal) direction is computed. The distances of all triangles are cumulated to determine a mean or average distance and a standard deviation.

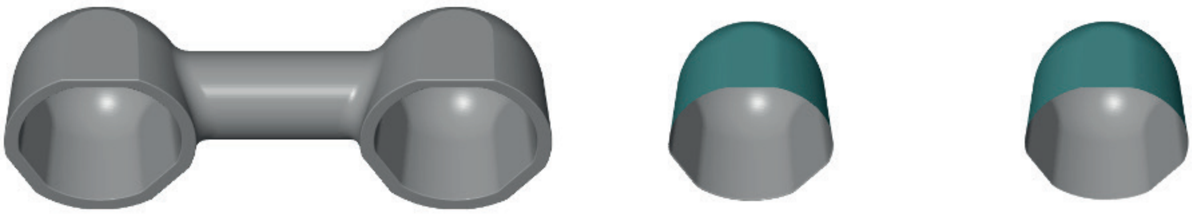
— Depending on the software product, set the maximum distance to 0,5 mm to avoid analysis errors due to opposite walls, as the minimum wall thickness of the specimen is 0,75 mm.

— Depending on the software product, set the maximum deviation of normal to 30°.

— Depending on the software product, perform the analysis on reference data.

5.2.7.2 Specimen intaglio surface

Select the analysis STL file for the intaglio surfaces (Crown_Specimen_Intaglio.stl / Short_Span_Bridge_Specimen_Intaglio.stl / Medium_Span_Bridge_Specimen_Intaglio.stl / Cross_Arch_Bridge_Specimen_Intaglio.stl) to determine the mean or average distance and the standard deviation for the intaglio surface. Perform the analysis step and document the computed mean deviation and standard deviation of the selected surface. See Figure 15.



a) STL-file for manufacturing

b) STL-file for intaglio analysis

Figure 15 — Analysis data set for intaglio surfaces using the example of the short span bridge specimen

The following procedure is based on the example of the short span bridge specimen using the GOM-Inspect software. Specific steps or terminology can vary with other software products, but the basic procedure is the same.

— Step 1: Import the analysis STL for intaglio surfaces. The scanned STL shall be aligned in accordance with 5.2.6.2.

— Step 2: Select all surfaces of analysis STL.

— Step 3: Perform inspection step on selected reference surface.

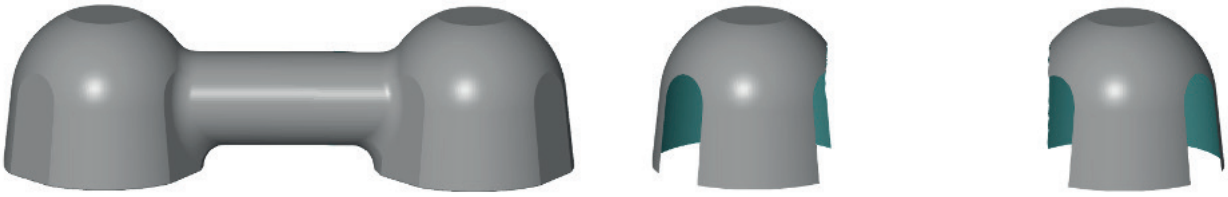
Set the maximum distance to 0,5.

Set the maximum deviation of normal to 30°.

— Step 4: Save the mean accuracy (average value of discrepancy) and standard deviation values.

5.2.7.3 Specimen external surface

Select the analysis STL file for the external surfaces (Crown_Specimen_External.stl / Short_Span_Bridge_Specimen_External.stl / Medium_Span_Bridge_Specimen_External.stl / Cross_Arch_Bridge_Specimen_External.stl) to determine the mean or average distance and the standard deviation for the external surface. Perform the analysis step and document the computed mean deviation and standard deviation of the selected surface. See Figure 16.



a) STL-file for manufacturing **b) STL-file for external analysis**

Figure 16 — Analysis data set for external surfaces using the example of the short span bridge specimen

The following procedure is based on the example of the short span bridge specimen using the GOM-Inspect software. Specific steps or terminology can vary with other software products, but the basic procedure is the same.

— Step 1: Import the analysis STL for external surfaces. The scanned STL shall be aligned in accordance with 5.2.6.2.

— Step 2: Select all surfaces of analysis STL.

— Step 3: Perform inspection step on selected reference surface.

Set the maximum distance to 0,5.

Set the maximum deviation of normal to 30°.

— Step 4: Save the mean accuracy (average value of discrepancy) and standard deviation values.

5.2.7.4 Specimen margin (prep-line) surface

Select the analysis STL file for the margin (prep-line) surfaces (Crown_Specimen_Prepline.stl / Short_Span_Bridge_Specimen_Prepline.stl / Medium_Span_Bridge_Specimen_Prepline.stl / Cross_Arch_Bridge_Specimen_Prepline.stl) to determine the mean or average distance and the standard deviation for the margin (prep-line) surfaces. Perform the analysis step and document the computed mean deviation and standard deviation of the selected surface. See Figure 17.

a) STL-file for manufacturing **b) STL-file for margin (prep-line) analysis**

Figure 17 — Analysis data set for margin (prep-line) surfaces using the short span bridge specimen

The following procedure is based on the example of the short span bridge specimen using the GOM-Inspect software. Specific steps or terminology can vary with other software products, but the basic procedure is the same.

— Step 1: Import the analysis STL for margin (prep-line) surfaces. The scanned STL shall be aligned in accordance with 5.2.6.2.

— Step 2: Select all surfaces of analysis STL.

— Step 3: Perform inspection step on selected reference surface.

Set the maximum distance to 0,5.

Set the maximum deviation of normal to 30°.

— Step 4: Save the mean accuracy (average value of discrepancy) and standard deviation values.

5.2.8 Calculation of total errors

5.2.8.1 Discrepancy values

The discrepancy values (mean and standard deviation) of intaglio and external surfaces shall be reported separately:

a) specimen intaglio surfaces;

b) specimen external surfaces;

c) specimen intaglio margin (prep-line) surface.

5.2.8.2 Calculation of total values for all six specimens

The total mean value and the total standard deviation shall be calculated from all six fabricated specimens.

This shall be done for all three surfaces [a), b), c)] separately.

The total mean value (average) shall be calculated based on Formula (3):

$$\bar{e} = \frac{1}{\sum_{i=1}^{N} A_i} * \sum_{i=1}^{N} e_i * A_i \tag{3}$$

where

$\bar{e}$ is the resulting mean value;

e_i is the individual error of the analysed surface on specimen i;

A_i is the individual area size of the analysed surface on specimen i;

N is the number of specimens, therefore $N = 6$.

This area size can either be measured within the analysis software or be provided in Table 2.

Table 2 — Area sizes

Surface	Crown mm^2	Short span bridge mm^2	Medium span bridge mm^2	Cross arch bridge mm^2
intaglio	300	600	900	1 200
external	310	530	780	1 010
margin (prep-line)	35	70	105	140

The total standard deviation shall be calculated based on Formula (4):

$$\bar{\sigma} = \sqrt{\left(\frac{1}{\sum_{i=1}^{N} A_i} * \sum_{i=1}^{N} \left(\sigma_i^{\,2} + e_i^{\,2} \right) * A_i \right) - \bar{e}^2} \tag{4}$$

where

$\bar{\sigma}$ is the resulting standard deviation;

σ_i is the individual standard deviation of the analysed surface on specimen i;

$\bar{e}$ is the resulting mean value;

e_i is the individual error of the analysed surface on specimen i;

A_i is the individual area size of the analysed surface on specimen i;

N is the number of specimens, therefore $N = 6$.

6 Test report

6.1 General information

Examples of test reports are given in Annex C.

The test report shall contain at least the following information:

a) name of computer-aided milling machine (include serial number of the machine) and CAM software (include version number and machining template version details);

b) intended target restoration, for example, inlay, crown, bridge;

c) International Standard used (i.e. ISO 23298:2023);

d) test method used (e.g. die method, software method);

e) tested material and its lot number (batch designation);

f) type of milling bur/tool and its condition (e.g. period of service);

g) specific information specified in 6.2;

h) evaluation method and results (i.e. results, including a reference to the clause which explains how the results were calculated);

i) any deviations from the procedure;

j) any unusual features observed;

k) date of test;

l) date of report, name and signature of the test inspector.

6.2 Specific information

6.2.1 Die method

The test report shall contain at least the following information:

a) dimension of the die used and device for die dimensional measurement;

b) device for evaluating accuracy of restoration;

c) averaged characteristic accuracy values specified in 6.3.1.

6.2.2 Software method

The test report shall contain at least the following information:

a) device and software for evaluating accuracy of milled restorations;

b) calculated mean and standard deviation of discrepancy measurements for each specimen type milled (crown, short span bridge, medium span bridge, cross-arch specimen) specified in 6.3.2.

6.3 Averaged characteristic accuracy values

6.3.1 Die method

6.3.1.1 Inlay specimen (see 5.1.6.2)

The test report shall contain at least the following information:

a) occlusal accuracy:

   1) average value,

   2) standard deviation;

b) proximal accuracy:

   1) average value,

   2) standard deviation.

6.3.1.2 Crown specimen (see 5.1.6.3)

A test report shall contain at least the following information:

a) average value of lateral accuracy;

b) standard deviation of lateral accuracy.

6.3.1.3 Bridge specimen (see 5.1.6.4)

The test report shall contain at least the following information:

a) average value of vertical accuracy;

b) standard deviation of vertical accuracy.

6.3.2 Software method

The test report shall contain at least the following information:

a) intaglio discrepancy in millimetre:

   1) average value,

   2) standard deviation;

b) external discrepancy in millimetre:

   1) average value,

   2) standard deviation;

c) margin (prep-line) discrepancy in millimetre:

   1) average value,

   2) standard deviation.

Annex A
(informative)

Flow chart of test method

A.1 Die method

Table A.1 — Flow chart of the test method for the die method

Test method subclauses	Steps of the test method	Remarks
5.1.1 Target restorations	Selection of types of restorations ↓	
5.1.2 Apparatus	Preparation of die ↓	a) A die consists of a base part and removable part(s). b) Each die shall be prepared based on the shape and dimensions of applicable figure (see 5.1.2.1).
	Measurement of dimensions and surface roughness of die ↓	a) The dimensions of each die shall be measured using a measuring device with an accuracy of ±2 µm. b) The surface roughness (S_a) of die, excepting the surfaces which do not come in contact with the test specimens/machined restorations, is less than 2 µm.
5.1.4 Preparation of three-dimensional data set	Preparation of three-dimensional data set of restoration ↓	a) Three-dimensional data set shall be prepared for each target restoration using the dimensions measured in the “measurement of dimensions and surface roughness of die” step.
5.1.5 Machining of restorations	Machining of restoration ↓	a) The prepared three-dimensional data are input into the computer-aided milling machine. b) Target restorations shall be machined.
5.1.6 Evaluation of accuracy	Evaluation of accuracy	Each restoration shall be evaluated using the same die used for the preparation of three-dimensional data.

A.2 Software method

Table A.2 — Flow chart of the test method for the software method

Test method subclauses	Steps of the test method	Remarks
5.2.1 General	Selection of types of restorations ↓	
5.2.2 Test object	Download of three-dimensional data set of restoration ↓	The three-dimensional data set (design data set) (STL) for the target restoration shall be downloaded from the ISO server.
5.2.4 Machining of specimens	Machining of restoration ↓	a) Milling equipment specified in 5.2.3.1 shall be used. b) Target restorations shall be machined (see 5.2.1, 5.2.4).
5.2.5 Measurement	Measurement of machined restoration ↓	Each machined specimen shall be measured using an appropriate 3D measurement device with an accuracy and resolution of ±5 µm or better (see 5.2.3.2).
5.2.6 Data alignment procedures 5.2.7 Data analysis procedure 5.2.8 Calculation of total errors	Evaluation of accuracy	a) Align scanned STL file to the corresponding alignment STL file (see 5.2.6.1, 5.2.6.2). b) Perform the deviation measurements using each corresponding analysis STL file (see 5.2.7.1 to 5.2.7.4). c) Calculate the errors for each surface (see 5.2.8).

Annex B
(normative)

Measurement of die set(s) and preparation of CAD data of target restoration(s)

B.1 General

A CMM shall be calibrated in accordance with the instructions provided by the manufacturer before measuring. If CMM consists of a probe contacting the object, the diameter of tip contacting the object shall be 1,0 mm or less.

The metal die shall be fixed on the measuring table. A reference point shall be registered on the appropriate point on the metal die, and then the x-axis, the y-axis and the Z-axis shall be registered.

The design data set of restorations shall be prepared using the measured value of metal die.

B.2 Metal die for class II inlay

B.2.1 Measuring procedures

Measure the coordinate values of planes of the metal die shown in Figure B.1 using CMM in accordance with the following procedures. The coordinate values of the x-axis, the y-axis and the Z-axis at the four points of each plane or truncated cone shape shown in Figure B.2 shall be measured and stored in the CMM.

a) Measure the coordinate values at the upper surface of metal die as a plane [see Figure B.2 a)].

b) Measure the coordinate values at the cavity floor of metal die as a plane [see Figure B.2 b)].

c) Measure the coordinate values at the gingival floor of metal die as a plane [see Figure B.2 c)].

d) Measure the coordinate values at the cavity wall 0,5 mm to 1,0 mm below from the upper surface of metal die as a truncated cone shape [see Figure B.2 d)].

e) Measure the coordinate values at the cavity wall 0,5 mm to 1,0 mm upper from the cavity floor of metal die as a truncated cone shape [see Figure B.2 e)].

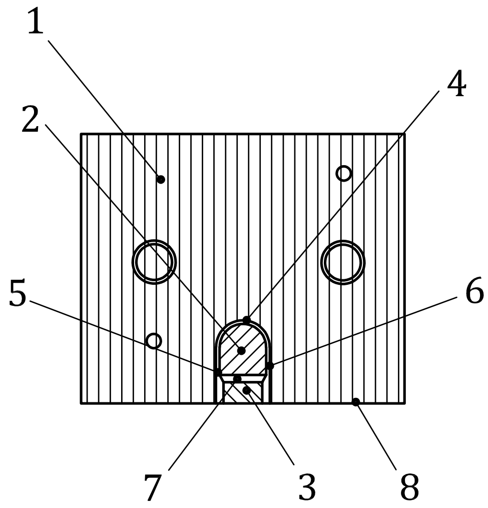
f) Determine the shape of truncated cone from the coordinated values obtained in the steps d) and e).

g) Measure the coordinate values at the left axial wall of metal die as a plane [see Figure B.2 f)].

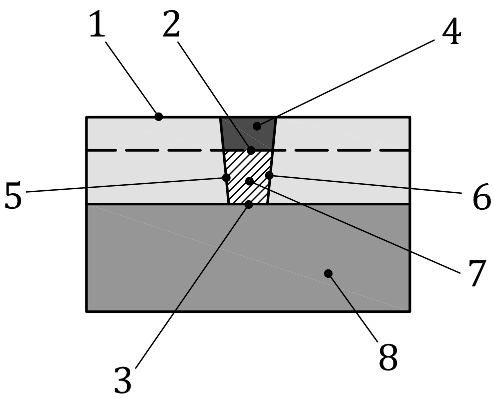
h) Measure the coordinate values at the right axial wall of metal die as a plane [see Figure B.2 f)].

i) Measure the coordinate values at the pulpal wall of proximal cavity of metal die as a plane [see Figure B.2 g)].

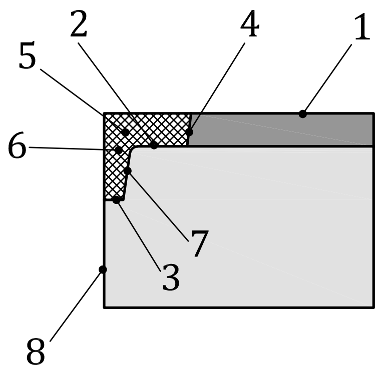
j) Measure the coordinate values at the proximal surface of metal die near the cavity as a plane [see Figure B.2 h)].



a) Top view



b) Front view



c) Side view

Key

1 upper surface

2 cavity floor

3 gingival floor

4 cavity wall

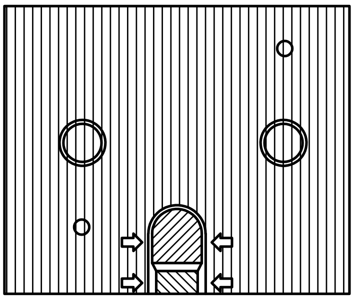
5 left axial wall of cavity

6 right axial wall of cavity

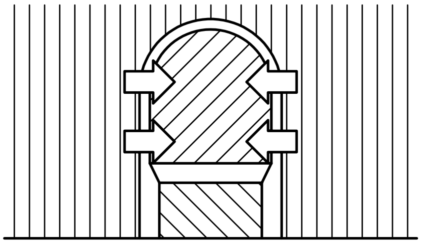
7 pulpal wall of proximal cavity

8 proximal surface

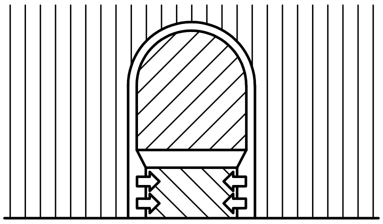
Figure B.1 — Measuring planes on metal die for class II inlay



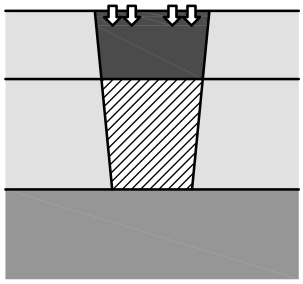
a) Upper surface



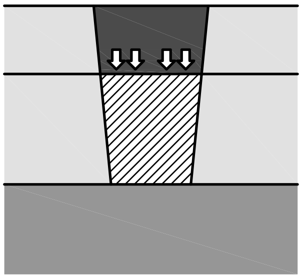
b) Cavity floor



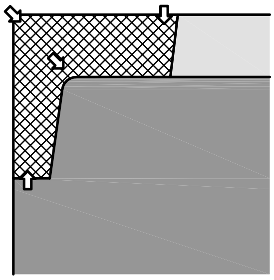
c) Gingival floor of cavity



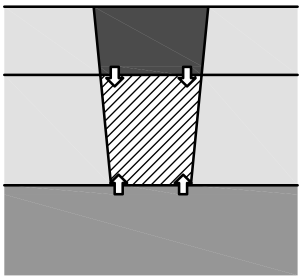
d) Cavity wall near upper surface



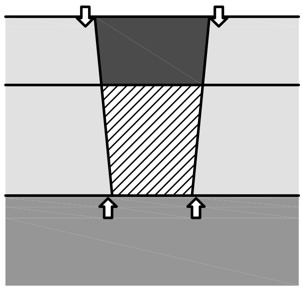
e) Cavity wall near cavity floor



f) Axial walls of cavity



g) Pulpal wall of proximal cavity



h) Proximal surface

Figure B.2 — Measuring points on the die for class II inlay

B.2.2 Calculation of the sizes for class II inlay

Calculate the specific values shown in Figure B.3 necessary to determine the shape of class II inlay from the coordinate values of planes or truncated cone shape obtained in B.2.1. Normally, the specific values are calculated by the calculation algorithm installed in CMM. If difficult, they may be calculated with the following procedure.

a) The isthmus width (B_I) is calculated as the distance from the intersection point of planes a, e and h and that of planes a, f and h. These planes are designated in Figure B.1.

b) The taper of left axial wall of cavity (T_A) is calculated as the angle between the plane a and the plane e in Figure B.1. The taper of right axial wall of cavity (T_B) is calculated as the angle between the plane a and the plane f in Figure B.1.

c) The radius at the upper side of half truncated cone (R_{TC}) is calculated as the radius of upper circle of truncated cone which is formed by the curved surface d and the plane a in Figure B.1.

d) The horizontal depth of occlusal cavity (H_{OC}) is calculated as the distance between the intersectional point between the plane a and the centre line of truncated cone and the intersectional line between the plane a and the plane h in Figure B.1.

e) The distance between cavity floor and gingival floor (d_{PG}) is calculated as the vertical distance between the plane b and the plane c in Figure B.1.

f) The depth of gingival floor (H_{GF}) is calculated as the distance between the plane a and the plane c in Figure B.1.

g) The width of gingival floor (B_{GF}) is calculated as the distance between the intersectional point of the planes c, e and h and the intersectional line of the planes c and g in Figure B.1.

h) The taper of pulpal wall of proximal cavity (T_C) is calculated as the angle between the plane c and the plane g in Figure B.1.

a) Bird's eye view **b) Side view**

Figure B.3 — Specific values for class II inlay

B.2.3 Preparation of CAD data

Prepare the data set of target restoration with the values calculated in B.2.2 using the following procedures. There shall be no spacer or cement gap between the values determined in B.2.2 and the target restoration.

Prepare the data set of 3D model which is designed using the values calculated in B.2.2 in accordance with the following procedures.

a) Draw the upper surface of inlay using B_I, R_{TC} and H_{OC} [see Figure B.4 a)].

b) When the value B_I is larger than twice of the value R_{TC}, a little step exists at intersectional point. Eliminate the step by a circle with a corner radius of 0,5 mm [see Figure B.4 b)].

c) When the value B_I is lower than twice of the value R_{TC}, a little step exists at intersectional point. Eliminate the bulging area from rectangle [see Figure B.4 c)].

d) Extrude the sketch and make solid body with the height H_{GF} [see Figure B.4 d)].

e) Draw a rectangle having the value B_I as a width and the value B_{GF} as a length [see Figure B.4 e)].

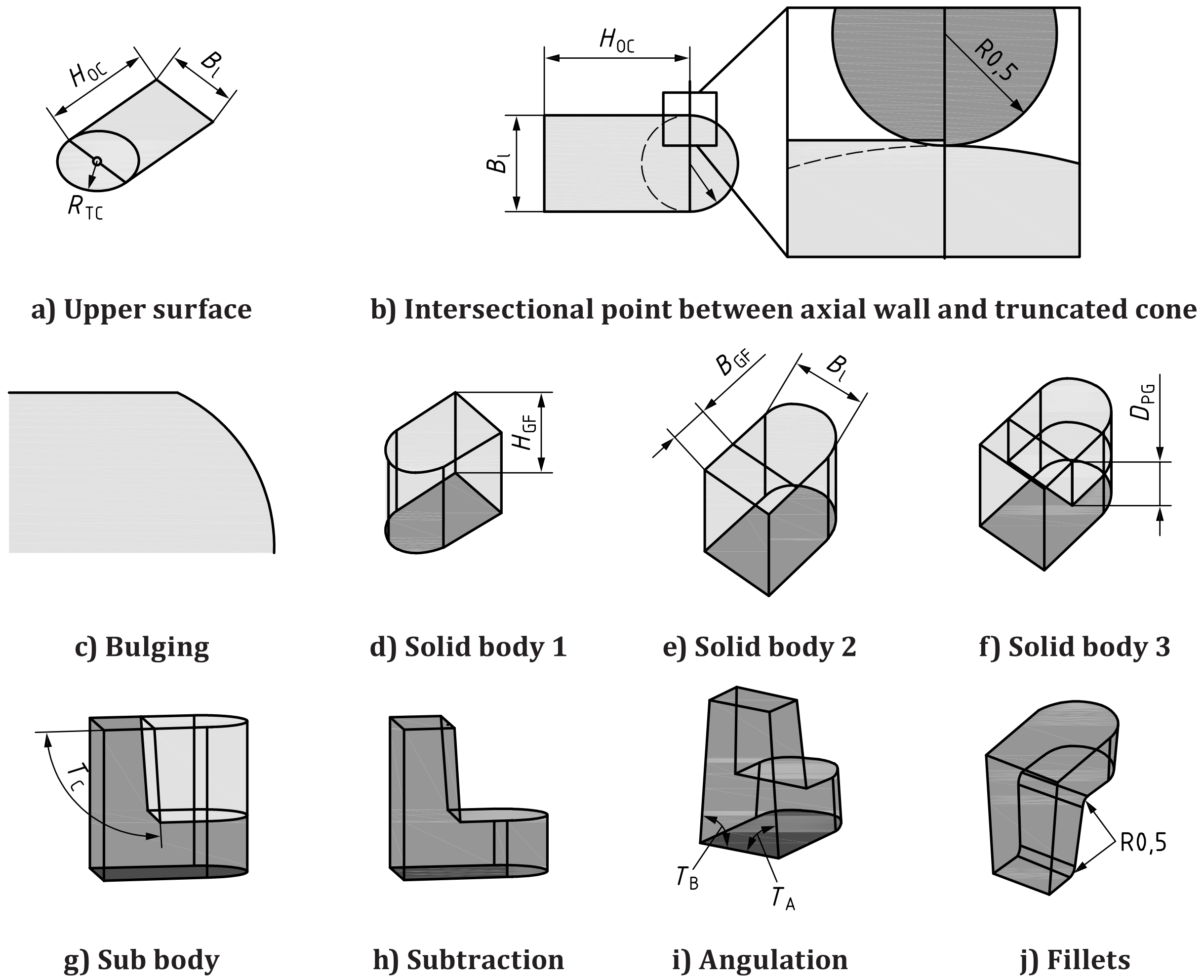
f) Extrude a solid body with the height d_{PG} [see Figure B.4 f)].

g) Make an angle at the sub body [see Figure B.4 g)].

h) Subtract the sub body from the main body [see Figure B.4 h)].

i) Make the angles T_A and T_B at the main body's side area [see Figure B.4 i)].

j) Set the fillets with a corner radius of 0,5 mm at the edge shown in Figure B.4 j).



a) Upper surface
b) Intersectional point between axial wall and truncated cone
c) Bulging
d) Solid body 1
e) Solid body 2
f) Solid body 3
g) Sub body
h) Subtraction
i) Angulation
j) Fillets

Figure B.4 — Design data set for class II inlay

B.3 Metal die for the crown and bridge

B.3.1 Measuring procedures

Measure the coordinate values of planes or surfaces of the metal die shown in Figure B.5 using CMM in accordance with the following procedures. Left and right abutments shall be measured independently. The coordinate values of the x-axis, the y-axis and the Z-axis at the four points of each plane or surface shown in Figure B.5 shall be measured and stored in the CMM.

a) All removable parts shall be fixed prior to measurements.

b) Measure the coordinate values at the upper surface of base part of metal die (see Key 1 in Figure B.5) as a plane [see Figure B.6 a)].

c) Measure the coordinate values at the outer surface of removable shoulder as a surface of cylinder [see Figure B.6 b)]. The four measuring points shall be located (90 ± 5)°.

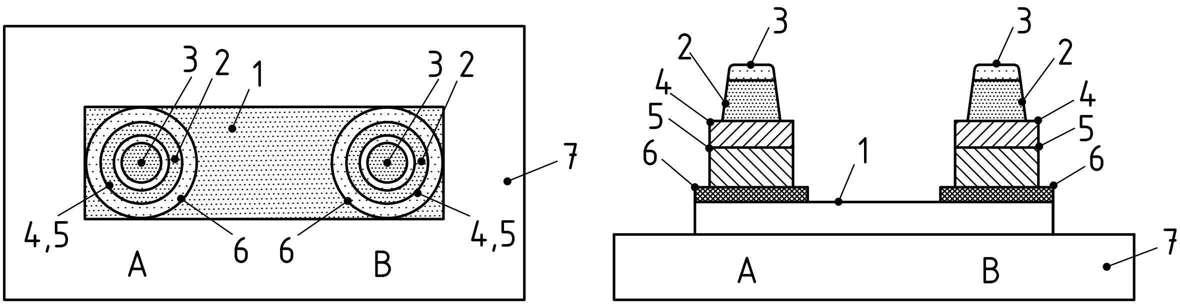
d) Measure the coordinate values at the upper plane of removable shoulder (see Key 4 in Figure B.5) as a plane [see Figure B.6 c)]. This plane will be the margin area of crown.

e) Remove the removable shoulder. Measure coordinate values at the plane between removable shoulder and abutment part (see Key 5 in Figure B.5) as a plane [see Figure B.6 c)]. This plane will be the baseline during accuracy measurements.

f) Measure the coordinate values at the base plane of abutment part (see Key 6 in Figure B.5) as a plane.

g) Measure the coordinate values at the occlusal surface of abutment (see Key 3 in Figure B.5) as a plane.

h) Measure the coordinate values at axial surface of abutment (see Key 2 in Figure B.5) as a truncated cone shape [see Figure B.6 d)]. The four measuring points are located 0,5 mm to 1,0 mm below from the occlusal plane of abutment and (90 ± 5)°. Another set of four measuring points are located 0,5 mm to 1,0 mm upper the plane between removable shoulder and abutment part, and (90 ± 5)°.



Key

1 upper surface of base part of metal die

2 axial surface of abutment

3 occlusal surface of abutment

4 upper plane of removable shoulder (margin area)

5 plane between removable shoulder and abutment part

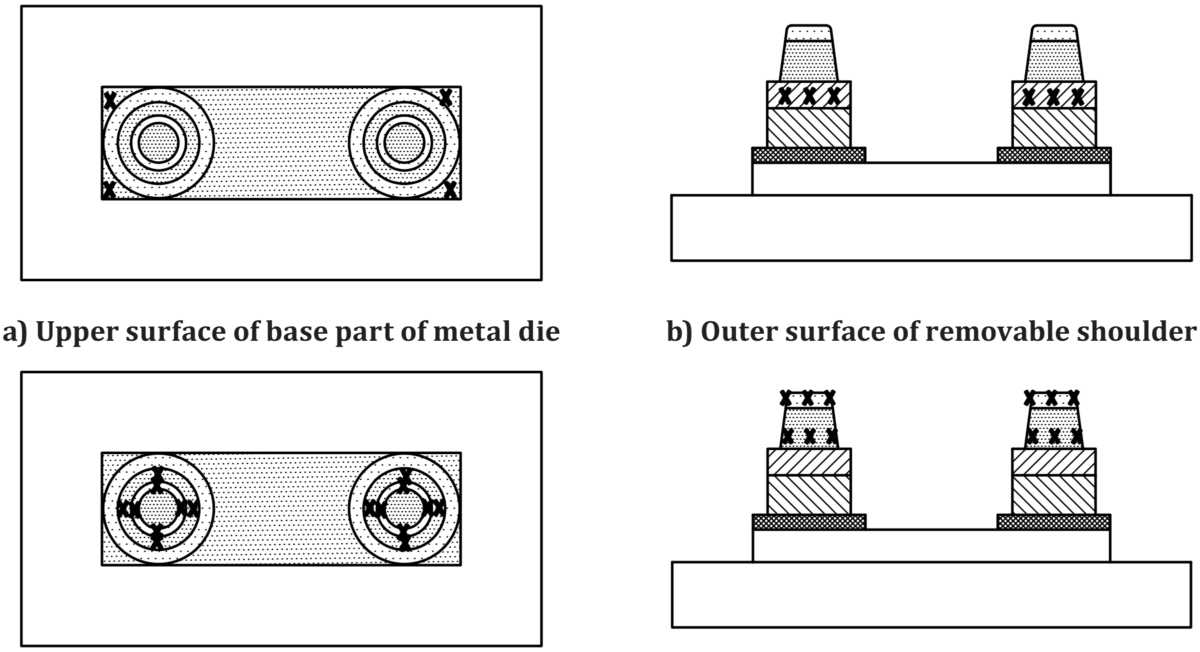
6 base plane of abutment part

7 base part of metal die

A left abutment

B right abutment

Figure B.5 — Measuring planes and surfaces on metal die for crown and bridge



a) Upper surface of base part of metal die

b) Outer surface of removable shoulder

c) Upper and bottom planes of removable shoulder

d) Axial surface of abutment

Figure B.6 — Measuring points on metal die for the crown and bridge

B.3.2 Specific values for the crown and bridge

Calculate the specific values shown in Figure B.7 necessary to determine the shape of the crown and bridge from the coordinate values of planes, surface or truncated cone shape obtained in B.3.1. Normally, the specific values are calculated by the calculation algorithm installed in the CMM. If difficult, they may be calculated as following procedures.

a) The removable shoulders and the removable occlusal parts shall be fixed to the abutment part of metal die prior to measurements.

b) The height of abutment (H_{A4} and H_{B4} in Figure B.7) shall be calculated as the distance from the upper plane of removable shoulder (see Key 4 in Figure B.5) and the occlusal surface of abutment (see Key 3 in Figure B.5).

c) The inclination of the central axis of the truncated cone shall be calculated. The inclinations are the angle between the projection line of the centre line for the Y—Z plane and the y-axis (ϕ_{Ax} or ϕ_{Bx}), and the angle between the projection line of the normal line for the Z—X plane and the z-axis (ϕ_{Ay} or ϕ_{By}). The angles ϕ_{Ax} and ϕ_{Ay} are the inclination of the left abutment of metal die. The angles ϕ_{Bx} and ϕ_{By} are the inclination of the right abutment of metal die [see Figure B.7 b)].

d) The diameter of abutment at the occlusal surface (D_{A1} and D_{B1} in Figure B.7) shall calculated as the diameter of circle formed by intersecting the outer surface of the truncated cone (see Key 2 in Figure B.5) and the occlusal surface of the abutment (see Key 3 in Figure B.5).

e) The diameter of abutment at the upper plane of removable shoulder (D_{A2} and D_{B2} in Figure B.7) shall be calculated as the diameter of circle formed by intersecting the curved surface and the plane. The curved surface is the outer surface of the truncated cone (see Key 2 in Figure B.5) and the plane is the upper plane of removable shoulder (see Key 4 in Figure B.5).

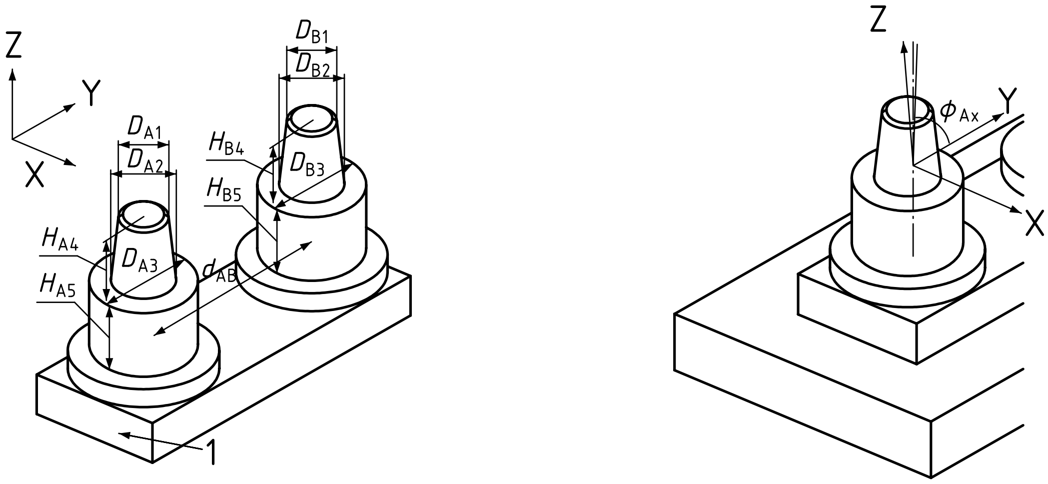
f) The height of cylinder (H_{A5} and H_{B5} in Figure B.7) shall be calculated as the distance from the base plane (see Key 6 in Figure B.5) to the upper plane of removable shoulder (see Key 4 in Figure B.5). The cylinder consists of the removal shoulder and a part of abutment of metal die.

g) The height of the removable shoulder shall be determined as the distance between the plane between removable shoulder and abutment part (see Key 5 in Figure B.5), and the upper plane of removable shoulder (see Key 4 in Figure B.5). It may be measured by another appropriate measuring device (see 5.1.2.3).

h) The outer diameter of removable shoulder (D_{A3} and D_{B3} in Figure B.7) at the upper plane of removable shoulder (see Key 4 in Figure B.5) shall be determined.

i) The normal line of the upper plane of removable shoulder (see Key 4 in Figure B.5) shall be calculated. The inclination of normal line shall be calculated. Inclinations are angle ϕ_{NAx} or ϕ_{NBx} between the projection line of normal line for the Y—Z plane and the y-axis, and angle ϕ_{NAy} or ϕ_{NBy} between the projection line of normal line for Z—X plane and the Z-axis. The angles ϕ_{NAx} and ϕ_{NAy} are the inclination of the left abutment of metal die. The angles ϕ_{NBx} and ϕ_{NBy} are the inclination of the right abutment of metal die.

j) In case of a bridge, the distance between abutments A and B shown in Figure B.5 shall be determined as the distance between the centre of the upper plane of removable shoulder of the abutments A and B (d_{AB} in Figure B.7).



a) Measuring values **b) Inclinations**

Key

D_{A1}, D_{B1}	diameter of abutment at the occlusal surface
D_{A2}, D_{B2}	diameter of abutment at the upper plane of removable shoulder
D_{A3}, D_{B3}	outer diameter of removable shoulder at the upper plane
H_{A4}, H_{B4}	height of abutment
H_{A5}, H_{B5}	height of cylinder
ϕ_{Ax}	angle between the projection line of the centre line for the Y—Z plane and the y-axis
d_{AB}	distance between the centre lines of the abutments A and B

Figure B.7 — Specific values for the crown and bridge

B.3.3 Preparation of CAD data

Prepare the data set of target restoration with the values calculated in B.3.2 using the following procedures. There shall be no spacer or cement gap between the values determined in B.2.2 and the target restoration.

Prepare the data set of 3D model which is designed using the values D_{A1} to H_A measured in B.3.2 in accordance with the following procedures.

a) Draw a circle (c1) with the diameter D_{A3}. In case of a bridge, draw another circle (d1) with the diameter D_{B3}. The distance between centres of two circles shall be the distance d_{AB} [see Figure B.8 a)].

b) Extrude the circle (c1) and make a solid body (cylinder-A) with the height H_{A5}. In case of a bridge, extrude another circle (d1) and make a solid body (cylinder-B) with the height H_{B5} [see Figure B.8 b)].

c) Draw a circle (c2) with the diameter D_{A2} at the centre of top of cylinder-A. In case of a bridge, draw another circle (d2) with the diameter D_{B2} at the centre of top of cylinder-B [see Figure B.8 c)]

d) Draw a circle (c3) with the diameter D_{A1} at a plane which locates with the distance H_{A4} from the upper surface of cylinder-A. The centre of circle shall be on the central axis of cylinder-A. In case of a bridge, draw another circle (d3) with the diameter D_{B1} at a plane which locates with the distance H_{B4} from the top of cylinder-B. The centre of circle shall be on the central axis of cylinder-B [see Figure B.8 d)].

e) Connect the circle (c2) and the circle (c3) and make a body of truncated cone (tc-A). In case of a bridge, connect the circle (d2) and the circle (d3) and make a body of truncated cone (tc-B). Set the fillets with a corner radius of 0,5 mm at the edge of top of truncated cones (tc-A and tc-B) [see Figure B.8 e)].

f) Give the truncated cone (tc-A) for inclination (ϕ_{Ax} and ϕ_{Ay}) [see Figure B.8 f)]. In case of a bridge, give the truncated cone (tc-B) for inclination (ϕ_{Bx} and ϕ_{By}) [see Figure B.8 f)].

g) Give the top surface of cylinder-A for inclination (ϕ_{NAx}). In case of a bridge, give the top surface of cylinder-B for inclination (ϕ_{NBx}) [see Figure B.8 g)].

h) Extend the truncated cones (tc-A and tc-B) as 1 mm longer to bottom side without changing the taper of truncated cone [see Figure B.8 h)].

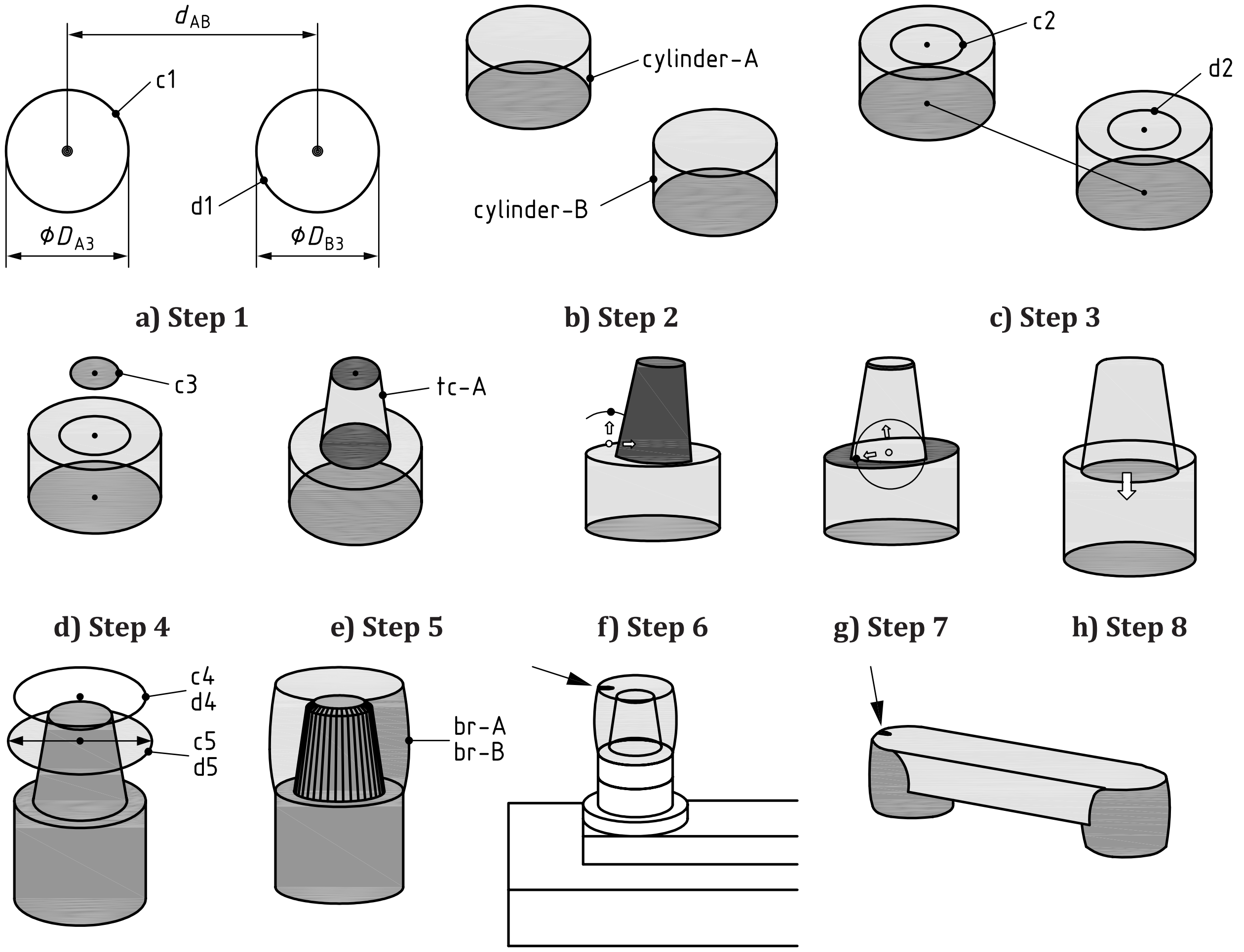
i) Draw a circle (c4) with the diameter of 10,0 mm at a plane which locates with the distance of 9,2 mm from the top of cylinder-A. Draw a circle (c5) with the diameter of 11,0 mm at the plane which locates with the distance of 5,0 mm from the top of cylinder-A. The centres of circles (c4 and c5) shall be on the central axis of cylinder-A. In case of a bridge, draw a circle (d4) with the diameter of 10,0 mm at a plane which locates with the distance of 9,2 mm from the top of cylinder-B. Draw a circle (d5) with the diameter of 11,0 mm at the plane which locates with the distance of 5,0 mm from the top of cylinder-B. The centres of circles (d4 and d5) shall be on the central axis of cylinder-B [see Figure B.8 i)].

j) Connect the circles (c4 and c5) and top circle of cylinder A and make a barrel-like body (br-A). In case of a bridge, connect the circles (d4 and d5) and top circle of cylinder B and make a barrel-like body (br-B). [see Figure B.8 j)]. The central axis of the truncated cone (tc-A or tc-B) and the barrel-like body (br-A or br-B) shall be same in both cases.

k) Subtract the truncated cone (tc-A) from the barrel-like body (br-A) to make a crown A. In case of a bridge, subtract the truncated cone (tc-B) from the barrel-like body (br-B) to make a crown B.

l) Make a mark such as a shallow groove, on the top of crown A in order to distinguish the directions when placing [see Figure B.8 k)].

m) In case of a bridge, connect two crowns A and B with a rectangular having 10 mm width and 5 mm thickness [see Figure B.8 l)].



a) Step 1 b) Step 2 c) Step 3

d) Step 4 e) Step 5 f) Step 6 g) Step 7 h) Step 8

i) Step 9 j) Crown k) Marking l) Bridge

Figure B.8 — Design data set for crown and bridge

Annex C
(informative)

Contents of test reports

C.1 Die method

Table C.1 — Contents of the test report for the die method

Contents of the test report	Examples
a) computer-aided milling machine of dental CAD/CAM systems (serial number of the computer-aided milling machine) and CAM software (version), milling template (version)	Computer-aided milling machine: XXXX manufactured by YYYY Serial number: XXXX CAM software: XXXX ver. YYYY produced by ZZZZ Milling template: xxxx (if necessary)
b) intended target restoration: e.g. Class II inlay, crown, bridge	Intended restoration: Class II inlay, crown and bridge
c) International Standard used	ISO 23298:2023
d) test method used	Die method

Table C.1 *(continued)*

Contents of the test report	Examples
e) dimension of the die used and device for die dimensional measurement	1) Measuring device: XXXX manufacture by YYYY 2) Dimensions of dies a) Die 1 for Class II inlay (see ISO 23298:2023, B.2.2 and Figure B.3) B_I: T_A: R_TC: H_OC: d_PG: H_GF: B_GF: T_C: b) Die 2 for crown and bridge (see ISO 23298:2023, B.3.2 and Figure B.7) D_A1: D_A2: D_A3: H_A4: H_A5: ϕ_{Ax}: ϕ_{Ay}: ϕ_{NAx}: ϕ_{NAy}: D_B1: D_B2: D_B3: H_B4: H_B5: ϕ_{Bx}: ϕ_{By}: ϕ_{NBx}: ϕ_{NBy}: d_AB: NOTE The dimensions of die can be explained in appropriate figures.

Table C.1 *(continued)*

Contents of the test report	Examples
f) tested material and its lot number (batch designation)	Tested material (zirconia) XXXX manufactured by YYYY Lot/Batch number: ZZZZZ (titanium) XXXX manufactured by YYYY Lot/Batch number: ZZZZZ
g) type of milling bur/tool and its condition (e.g. period of service)	Used milling bur: Carbide Bur ϕ3, ϕ2, (ball end type) Conditions: Tool used time is less than 250 min, good condition
h) device for evaluating accuracy of restoration	Measuring device: three-dimensional measuring microscope XXXX manufactured by YYYY Accuracy of device: 2 µm
i) evaluation method and results (i.e. results, including a reference to the clause which explains how the results were calculated	Evaluation method: ISO 23298:2023, 5.2.7 and 5.2.8 Results: 1) Class II inlay a) Occlusal accuracy Average value: +0,256 mm Standard deviation: ±0,018 mm b) Proximal accuracy Average value: +0,121 mm Standard deviation: 0,030 mm 2) Crown (zirconia) Lateral accuracy Average value: 0,371 % Standard deviation: 0,082 % (titanium) Lateral accuracy Average value: −0,213 % Standard deviation: 0,022 % 3) Bridge (zirconia)

Table C.1 *(continued)*

Contents of the test report	Examples
	A: Average value: −0,099 mm Standard deviation: 0,023 mm B: Average value: −0,123 mm Standard deviation: 0,016 mm (titanium) A: Average value: −0,074 mm Standard deviation: 0,023 mm B: Average value: −0,089 mm Standard deviation: 0,013 mm NOTE A positive value (+) means that the margin line of restoration is higher than the targeted baseline. A negative value (−) means that the margin line of restoration is lower than the targeted baseline.
j) any deviations from the procedure	none
k) any unusual features observed	The following unusual features were observed. 1) **************
l) date of test	YYYY-MM-DD/YYYY-MM-DD
m) date of report, name and signature of the test inspector	Date of report: YYYY-MM-DD Test inspector: *****************

C.2 Software method

Table C.2 — Contents of the test report for the software method

Contents of test report	Examples
a) computer-aided milling machine of dental CAD/CAM systems (serial number of the computer-aided milling machine) and CAM software (version) milling template (version)	Computer-aided milling machine: XXXX manufactured by YYYY Serial number: XXXX CAM software: XXXX ver. YYYY produced by ZZ xxxxx ver. yyyyy produced by zzzzz (if necessary) Milling template: xxxx (if necessary)
b) intended target restoration: e.g. crown, bridge	Intended restoration: crown and bridge
c) International Standard used	ISO 23298:2023
d) test method used	Software method
e) tested material and its lot number (batch designation)	Tested material (zirconia) XXXX manufactured by YYYY Lot/Batch number: ZZZZZ (titanium) XXXX manufactured by YYYY Lot/Batch number: ZZZZZ

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Table C.2 *(continued)*

Contents of test report	Examples
f) type of milling bur/tool and its condition (e.g. period of service)	Used milling bur: Carbide Bur ϕ3 mm, ϕ2 mm, ϕ1 mm (ball end type) Conditions: Tool used time is less than 250 min, good condition
g) device for evaluating accuracy of restoration	Measuring device: CMM XXXX manufactured by YYYY Accuracy of device: 2 µm
h) software for evaluating accuracy of restoration	Measuring device: three-dimensional measuring microscope XXXX manufactured by YYYY Accuracy of device: 5 µm Software: GOM-Inspect Professional 2018[a]
i) evaluation method and results (i.e. results, including a reference to the clause which explains how the results were calculated	Evaluation method: ISO 23298:2023, 5.1.6 Results: a) Crown (zirconia) Intaglio discrepancy Average value: 0,021 mm Standard deviation: 0,005 mm External discrepancy Average value: 0,024 mm Standard deviation: 0,007 mm Margin (prep-line) discrepancy Average value: 0,021 mm Standard deviation: 0,005 mm b) Bridge (zirconia) Intaglio discrepancy Average value: 0,034 mm Standard deviation: 0,008 mm External discrepancy Average value: 0,036 mm Standard deviation: 0,009 mm Margin (prep-line) discrepancy Average value: 0,035 mm Standard deviation: 0,009 mm
j) any deviations from the procedure	none
k) any unusual features observed	The following unusual features were observed. 1) **************
l) date of test	YYYY-MM-DD/YYYY-MM-DD
m) date of report, name and signature of the test inspector	Date of report: YYYY-MM-DD Test inspector: *****************

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Bibliography

[1] ISO 10360-1, *Geometrical Product Specifications (GPS) — Acceptance and reverification tests for coordinate measuring machines (CMM) — Part 1: Vocabulary*

[2] ISO 12836, *Dentistry — Digitizing devices for CAD/CAM systems for indirect dental restorations — Test methods for assessing accuracy*

[3] ISO 20896-1, *Dentistry — Digital impression devices — Part 1: Methods for assessing accuracy*

[4] ISO 25178-2, *Geometrical product specifications (GPS) — Surface texture: Areal — Part 2: Terms, definitions and surface texture parameters*

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