INTERNATIONAL STANDARD

ISO 23298

First edition
2023-05

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
ISO 23298:2023(E)

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Published in Switzerland

Contents

Page

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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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.

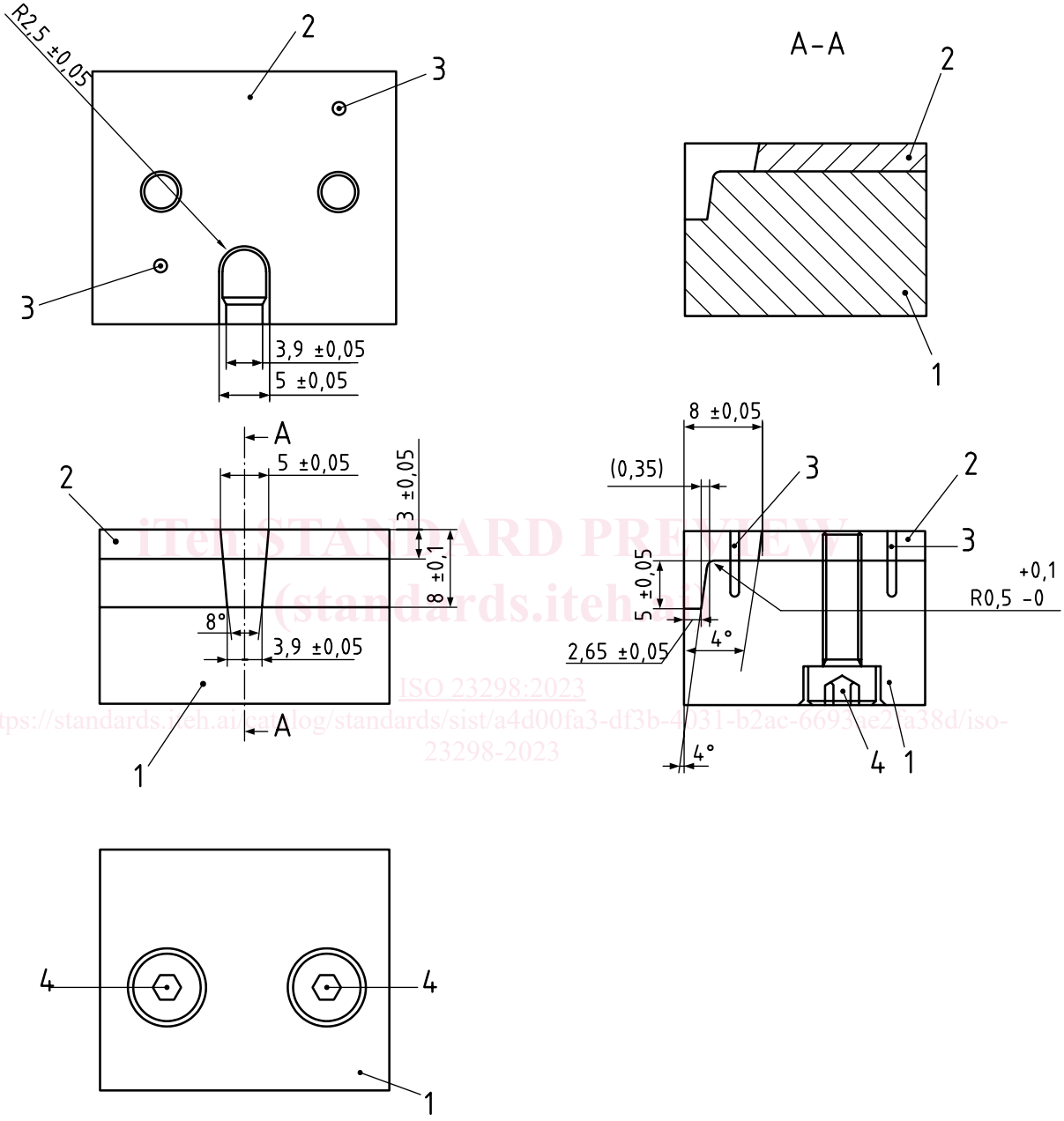
The surface roughness (S_a) of the die, excepting the surfaces which do not come in contact with the test specimens/machined restorations, shall be less than 2 µm. Refer to ISO 25178-2 and other parts for test methods.

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



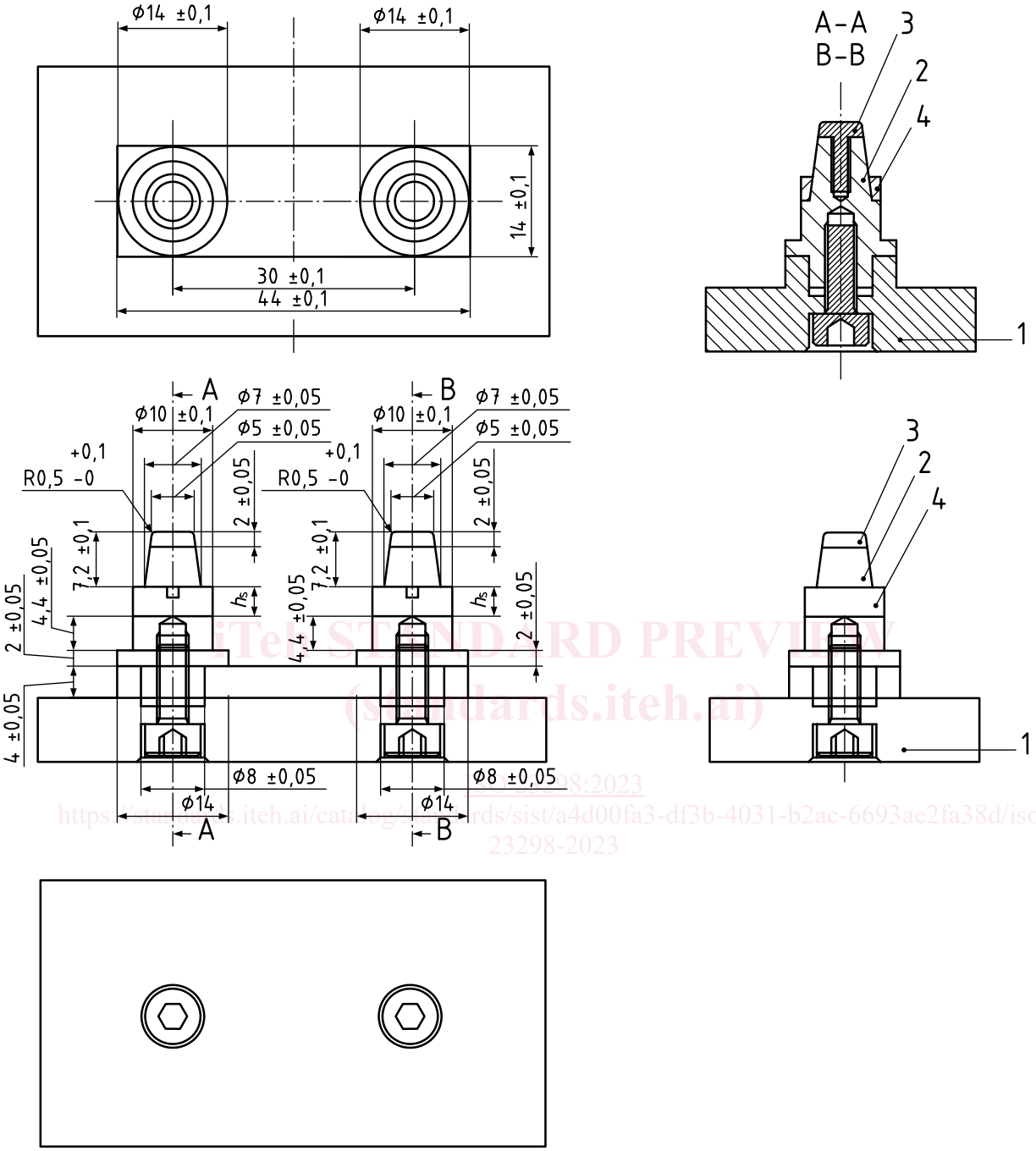
Key

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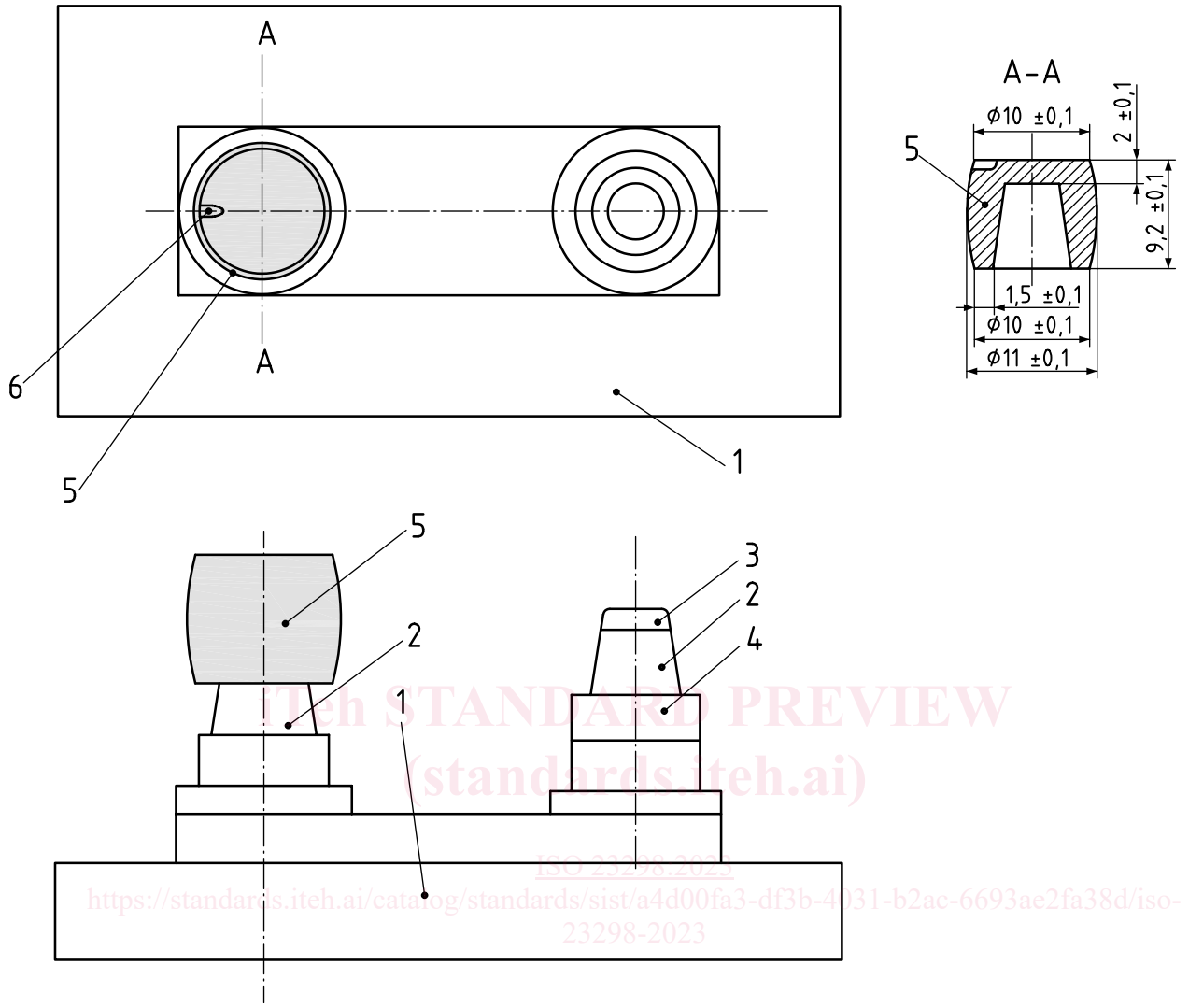
2) STRATO-Apex 574 is the trade name of a product supplied by Mitsutoyo. This information is given for the convenience of users of this document and does not constitute an endorsement by ISO of the product named. Equivalent products may be used if they can be shown to lead to the same results.

Dimensions in millimetres

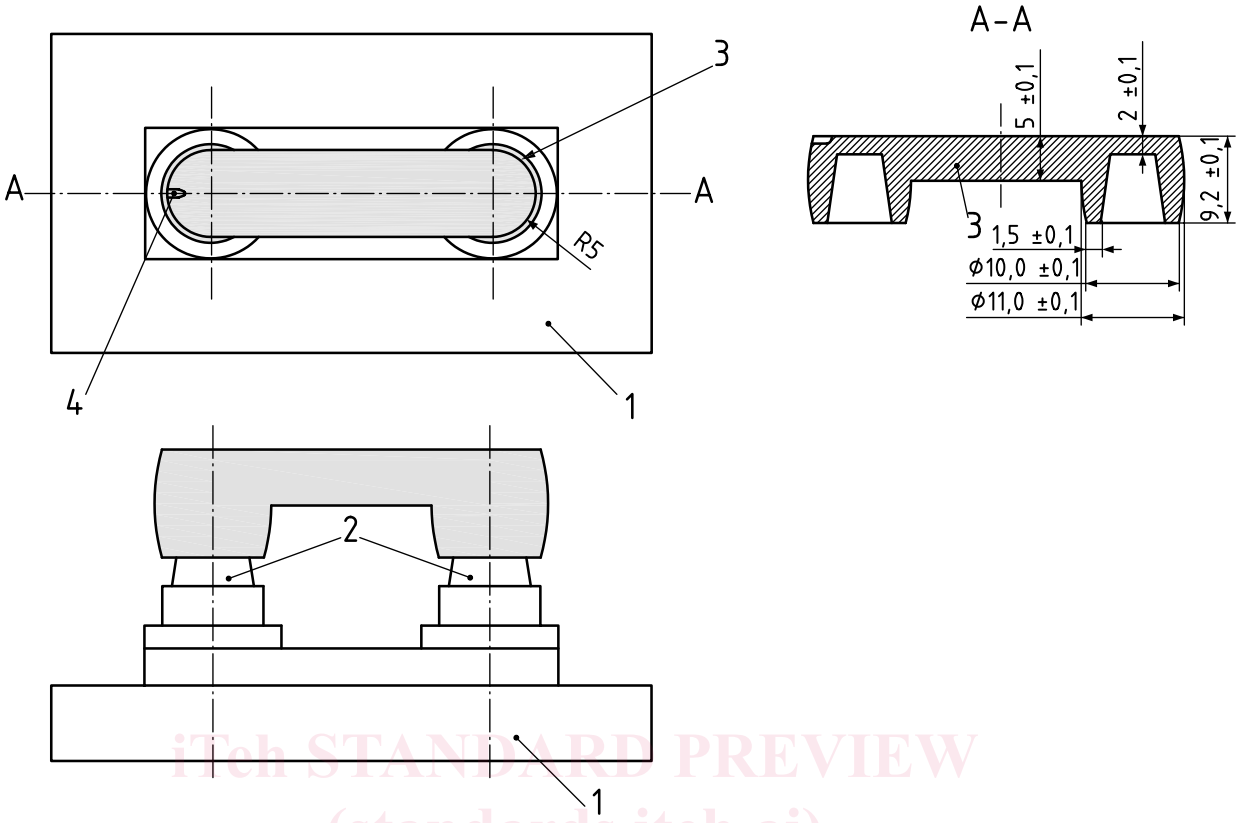


Key

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.

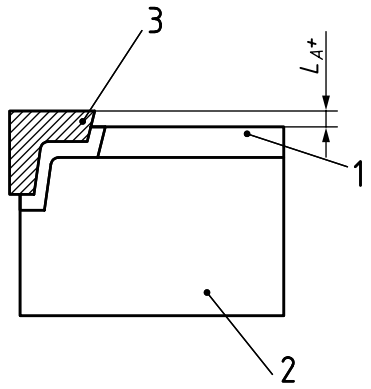
When the occlusal margin of the inlay is located higher than the occlusal baseline (occlusal margin of the die cavity), measure the discrepancy between the inlay margin and the occlusal baseline [L_{A+} in Figure 5 a)]. Similarly, when the proximal margin of the inlay extends past the proximal baseline (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.

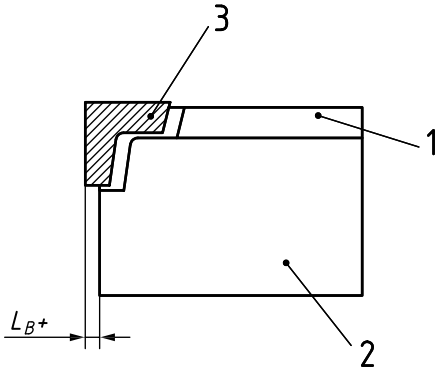
For both cases, measurements with and without base part, the measurement shall be carried out at three points for the occlusal discrepancy [see Figure 5 e)] and at four points for the proximal discrepancy [see Figure 5 f)]. A discrepancy shall be measured as horizontal discrepancy judging from the top.

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.

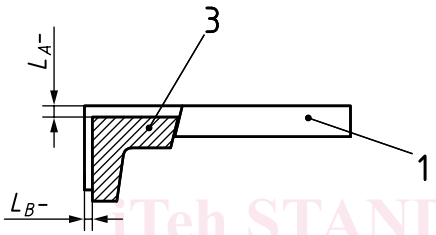
The measured discrepancy data (three points for the occlusal discrepancy and four points for the proximal discrepancy) of one inlay are averaged to represent the discrepancy of that inlay. Calculate the average of the six representative discrepancy values and the standard deviations to express the accuracy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



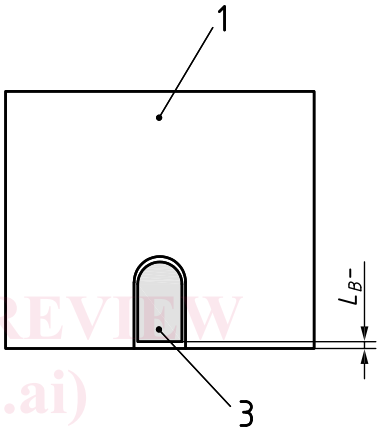
a) Occlusal discrepancy with base part



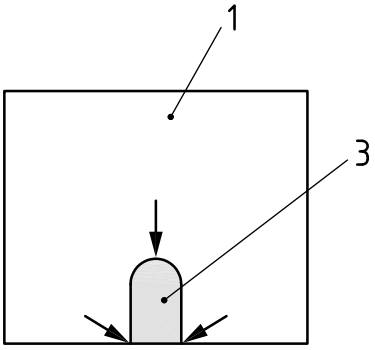
b) Proximal discrepancy with base part



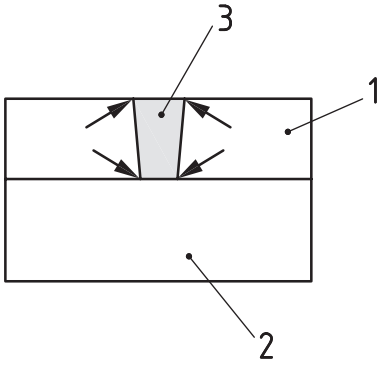
c) Occlusal and proximal discrepancy measurements without base part



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