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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

First edition

Date: ~~2022-08~~2023-01-17

~~FDIS stage~~

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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).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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:

— changing the type of document from Technical Report ~~(TR)~~ to International Standard ~~(IS);~~;

— specifying two test methods using metal dies and software as the normative test methods;

— clarification of the selection guidance of test methods;

— revision of the detail procedures of both test methods based on the inter-laboratory test.

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. ~~A flow chart~~Flow charts of the test ~~method is shown~~methods are given in ~~Annex~~ 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 ~~*disk*~~*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
~~disc~~flat circular-shaped material ~~to be~~that is 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~~, are the targets of this test method.~~ .

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.

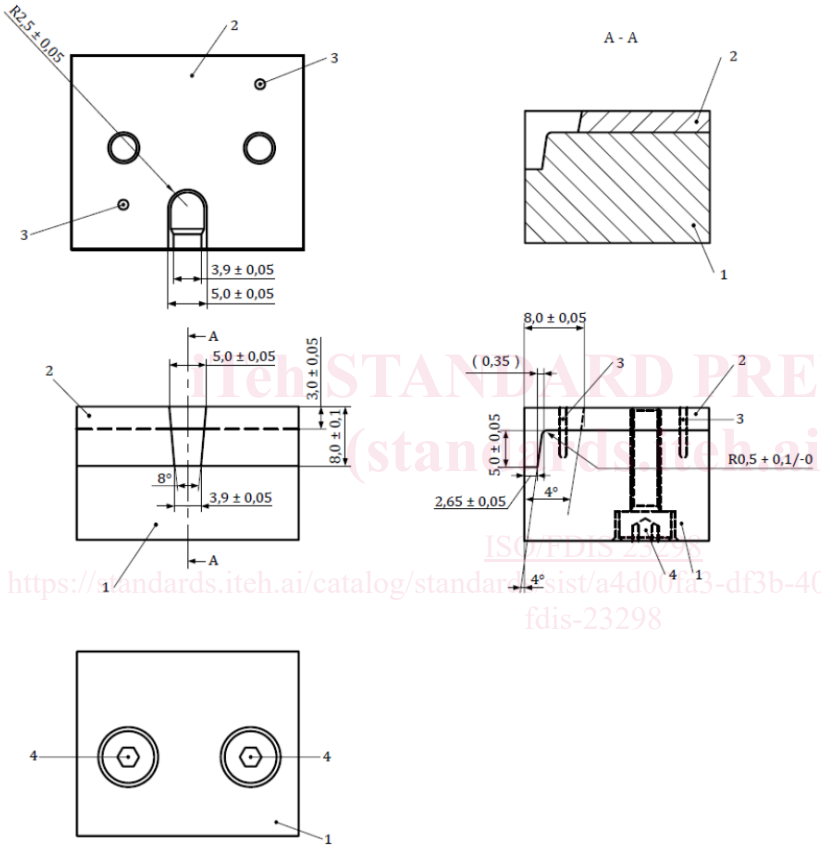
The surface roughness (S_a) of the die, excepting the surfaces which do not come in contact with the test specimens/machined restorations, shall be less than 2 µm. Refer to ISO 25178~~-~~-2 and other parts for test methods.

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.

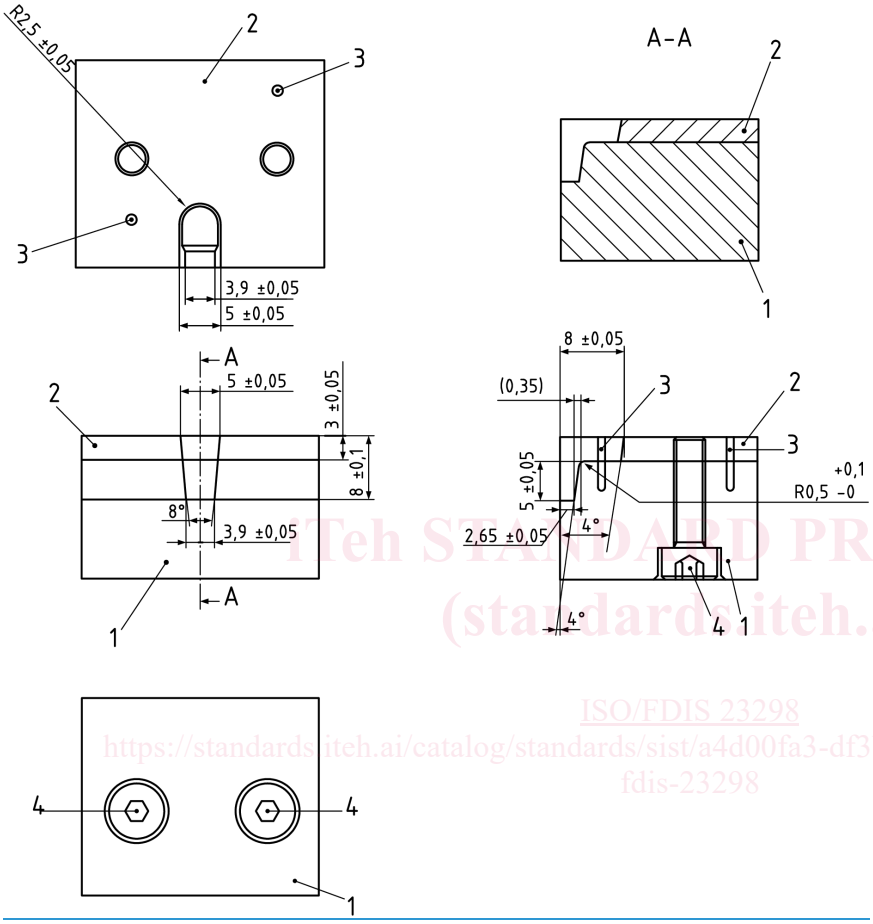
The removable occlusal part and removable shoulder are used for preparation of three-dimensional data, but not used for evaluation of accuracy.

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

Dimensions in millimetres



[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.

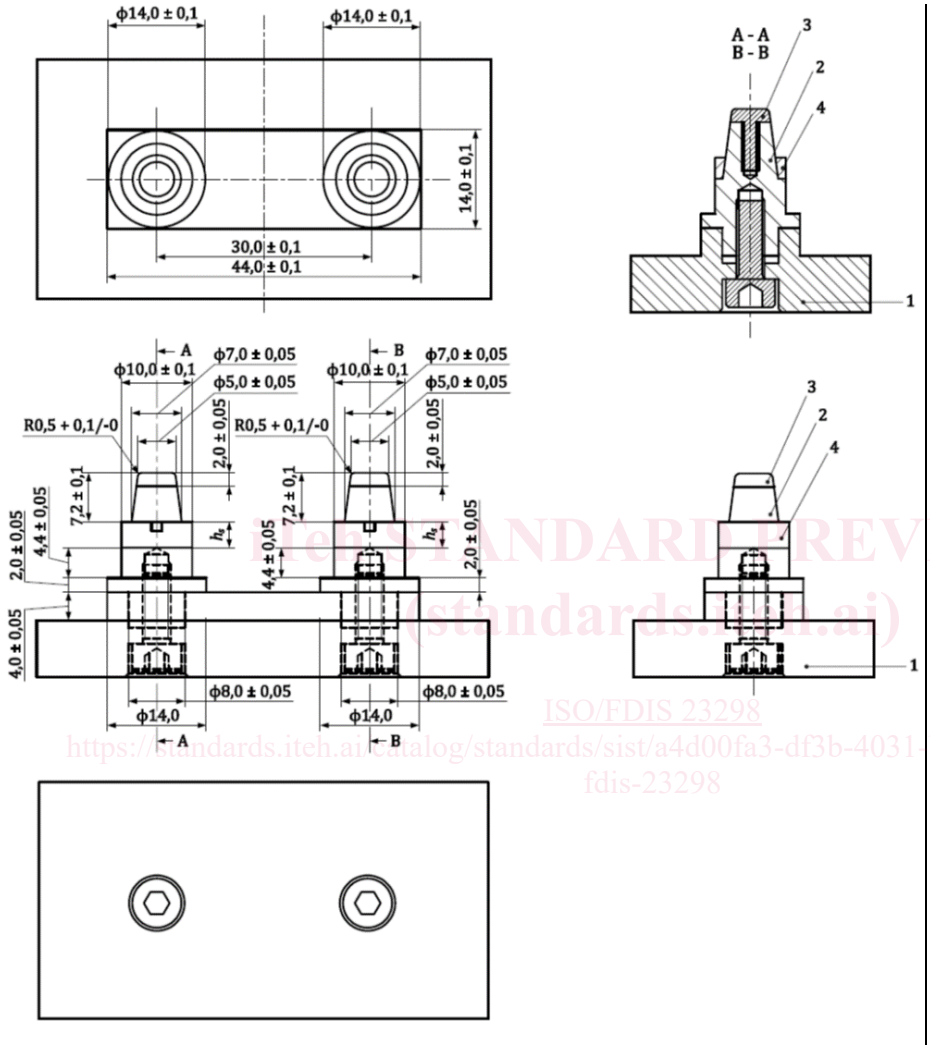


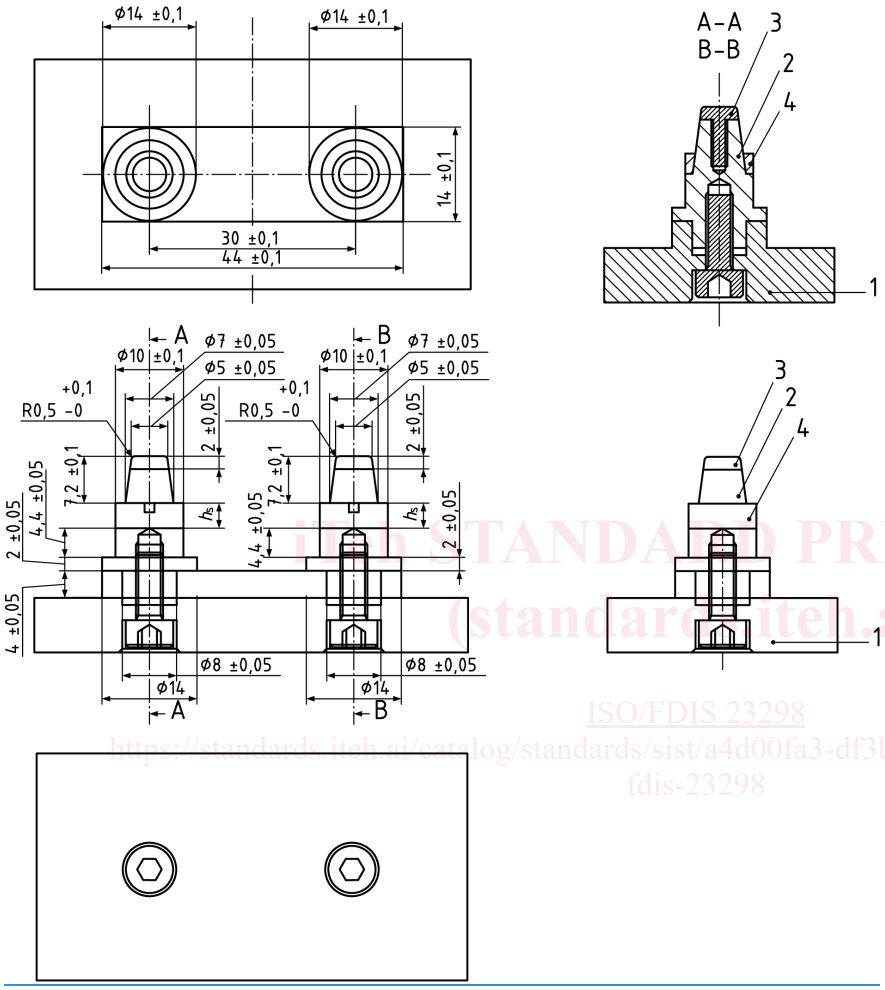
Key

1 base part
2 removable part
3 positioning pin
4 fixing screw

Figure 1 — Die for class II inlay specimen

Dimensions in millimetres





Key

1 base part
2 abutment
3 removable occlusal part
4 ~~removable shoulder~~
~~h_s~~ The recommended size of the height of the removable shoulder is (3,6 ± 0,05) mm.
~~The recommended size of the height of removable shoulder (h_s) is (3,6 ± 0,05) mm.~~

4 removable shoulder
h_s height of the removable shoulder

Figure 2 — Die for crown and bridge specimen

5.1.2.2 Measuring devices ~~to be~~ 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 ~~to be~~ 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 the 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 crown. In case of bridges, the mark shall be made on either crown.

5.1.4.4 Preparation of CAD data (STL data)

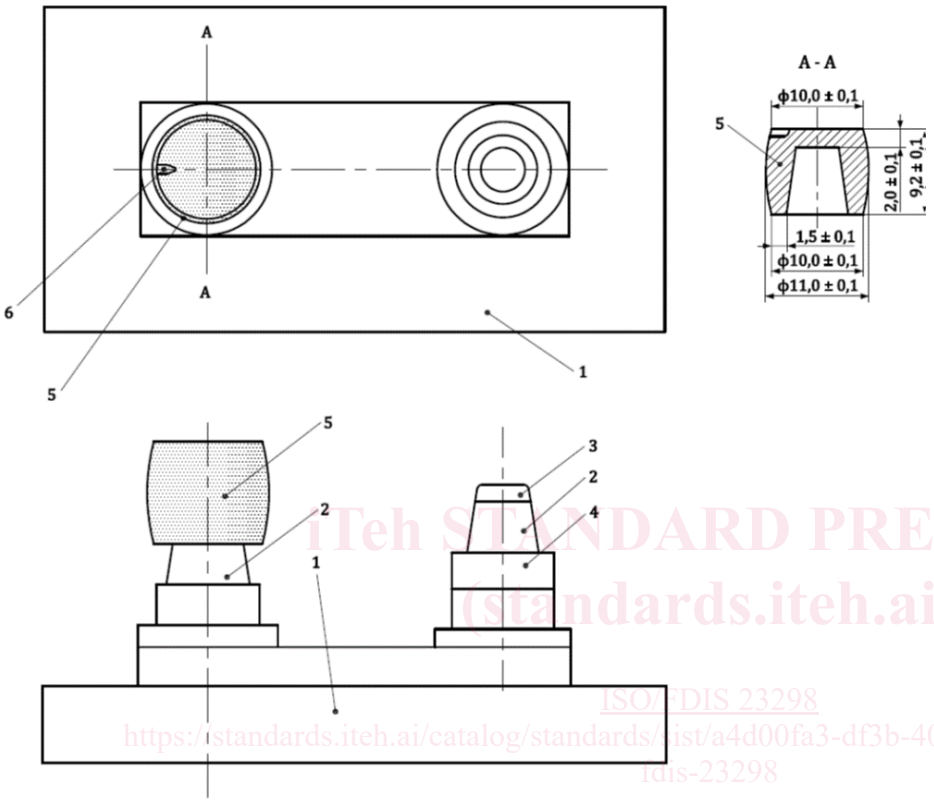
To fabricate the target restorations, CAD data (STL data) for each of the restorations specified in 5.1.4.2 and 5.1.4.3 shall be prepared in accordance with Annex B. This CAD data shall then be processed by ~~the~~ CAM software to prepare the manufacturing data set.

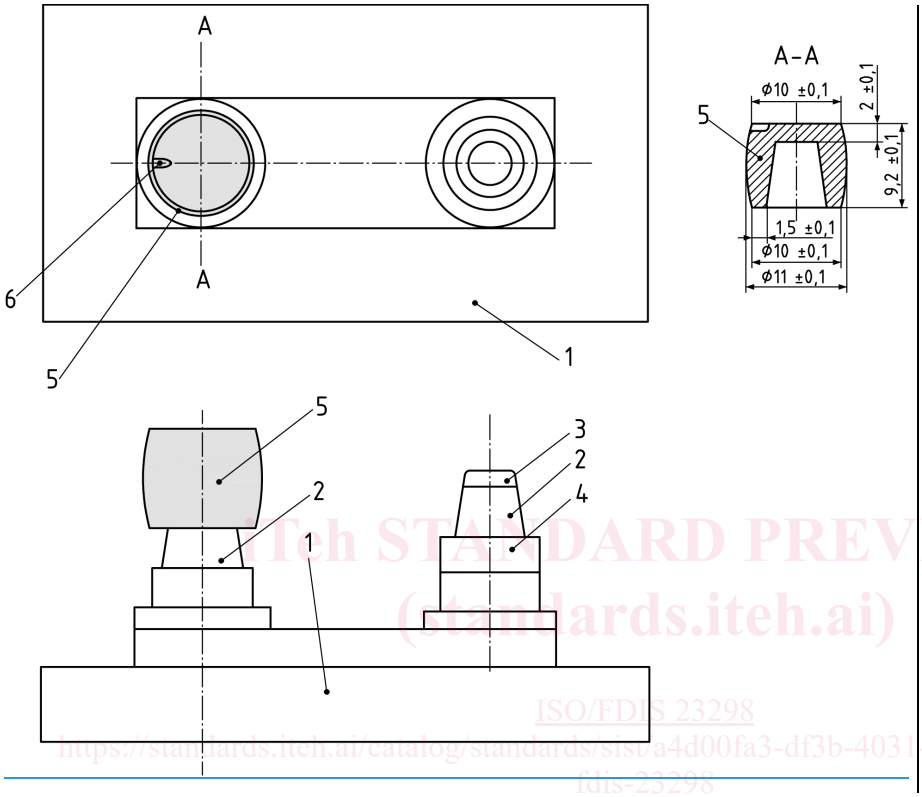
The dimensions of any surfaces in contact with the die surfaces are obtained from the measuring process in 5.1.3. Other dimensions are determined from Figure 3 and Figure 4.

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

Dimensions in millimetres

[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.





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 crown

Dimensions in millimetres