

ISO/TC 106/SC 4

Secretariat: DIN

Voting begins on:
2020-12-18

Voting terminates on:
2021-02-12

Dentistry — Excavators

Médecine bucco-dentaire — Excavateurs

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ISO/FDIS 23940:2020(E)

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Published in Switzerland

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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 4, *Dental instruments*.

This first edition cancels and replaces the first edition (ISO 13397-4:1997), which has been technically revised. The main changes compared to the previous edition are as follows:

- new shapes have been added — see [Figures 5 to 10](#) and [Table 3](#);
- test values for connection between working end and handle have been reduced from 600 N to 450 N (tensile load) and from 400 Ncm to 0,25 Nm (torque) (see [6.7](#));
- a requirement for UDI-code has been added in [Clause 8](#);
- a requirement for instructions for use has been added in [8.3](#).

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.

Dentistry — Excavators

1 Scope

This document specifies dimensions and performance requirements for excavators used in dentistry.

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 6507-1, *Metallic materials — Vickers hardness test — Part 1: Test method*

ISO 15223-1:2016, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

ISO 17664, *Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices*

ISO 21850-1, *Dentistry — Materials for dental instruments — Part 1: Stainless steel*

3 Terms and definitions

ISO/FDIS 23940

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

ISO and IEC maintain terminological 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

excavator

handheld dental instrument for excavating caries

3.2

datum point

section point between the centreline of the *handle* (3.3), at a right angle to the centreline, and the *blade* (3.6)

3.3

handle

area used for holding the dental explorer during use

3.4

shank

part of the dental explorer that connects the *working end* (3.5) to the *handle* (3.3)

3.5

working end

part of the dental explorer after the first bend of the *shank* (3.4) including the working tip

3.6 blade

active part of the *working end* (3.5) which first contacts the tooth surface

4 Symbols

The following symbols are used in this document:

- b_1 blade width
- b_2 blade thickness
- b_3 blade length
- b_4 neck thickness
- h_1 blade height
- h_2 shank height
- α blade angle
- β offset angle

5 Classification

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The classification of forms of excavators is given in Table 1.

Table 1 — Classification of excavator forms

| Form | Figure | Shape of working end | | Classification |
|------|--------------------------|----------------------|---------|----------------|
| | | Overall | Top | |
| A | Figure 1 | Straight | Discoid | 100 |
| B | Figure 2 | Angled | Discoid | 200 |
| C | Figure 3 | Contra-angled | Discoid | 300 |
| D | Figure 4 | Angled, complex | Discoid | 400 |
| E | Figure 5 | Spoon | Pear | 500 |

6 Requirements for excavators

6.1 Design and dimensions

Excavators shall have the designs shown in [Figures 1](#) to [10](#) and the dimensions as given in [Tables 2](#) and [3](#).

The points of measurement associated with the dimensions are listed in [Table 4](#).

Table 2 — Dimensions of excavators (Form A to Form D)

Dimensions in millimetres
Angles in degree

| Type | b_1 | b_2 | b_3 | b_4 | h_1 | h_2 | α | β |
|-----------------------------------|-------|-------|-------|-------|-------|-------|----------|---------|
| Tolerance | ±0,1 | ±0,1 | ±0,1 | ±0,1 | ±0,3 | ±0,3 | ±5 | ±5 |
| Form A: 100 = Straight | | | | | | | | |

Table 2 (continued)

| Type | b_1 | b_2 | b_3 | b_4 | h_1 | h_2 | α | β |
|--|-------|-------|-------|-------|-------|-------|----------|---------|
| 101 | 2,5 | 0,9 | — | 1,2 | — | — | 40 | — |
| 102 | 1,7 | 0,7 | — | 0,9 | — | — | 40 | — |
| Form B; 200 = Angled | | | | | | | | |
| 201 | 1,1 | 0,5 | — | 0,7 | 6,4 | — | 35 | 72 |
| 202 | 1,0 | 0,5 | — | 0,7 | 6,4 | — | 36 | 72 |
| Form C; 300 = Contra-angled | | | | | | | | |
| 301 | 2,5 | 0,8 | — | 1,2 | 2,0 | 3,7 | 35 | 30 |
| 302 | 2,5 | 0,7 | — | 1,2 | 2,0 | 3,7 | 35 | 40 |
| 303 | 2,0 | 0,7 | — | 1,1 | 2,1 | 3,4 | 35 | 30 |
| 304 | 1,7 | 0,7 | — | 0,9 | 1,9 | 3,5 | 35 | 30 |
| 305 | 1,4 | 0,6 | — | 0,8 | 1,7 | 3,5 | 35 | 30 |
| 306 | 1,1 | 0,6 | — | 0,7 | 1,6 | 3,6 | 35 | 30 |
| 307 | 1,0 | 0,5 | — | 0,7 | 2,5 | 1,8 | 35 | 30 |
| 308 | 0,8 | 0,5 | — | 0,6 | 2,7 | 3,6 | 35 | 35 |
| Form D; 400 = Angled, complex | | | | | | | | |
| 401 | 1,4 | 0,7 | 2,5 | 0,8 | 2,9 | 3,0 | 35 | 83 |

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 Table 3 — Dimensions of excavators (Form E)

Dimensions in millimetres
 Angles in degree

| Type | b_1 | b_2 | b_3 | h_1 | h_2 | α |
|--------------------------------|-----------|--------------|---------------|--------------|--------------|----------|
| Tolerance | $\pm 0,1$ | — | — | — | — | — |
| Form E; 500 = Spoon | | | | | | |
| 501 (63-64 or #1) | 1,5 | 1,1 - 2,0 | 7,0 - 8,0 | 2,6 - 4,5 | 3,1 - 4,2 | 40 - 50 |
| 502 (65-66 or #2) | 1,0 | 0,8 - 1,5 | 4,5 - 8,0 | 2,0 - 3,3 | 2,5 - 4,0 | 40 - 50 |
| 503 (17-18 or #3) | 1,2 | 0,8 - 1,2 | 2,0 - 3,0 | 5,0 - 6,0 | 2,3 - 2,8 | 65 - 80 |
| 504 (21-22 or #4) | 1,5 | 1,3 - 1,5 | 2,8 - 3,6 | 2,0 - 3,0 | 2,4 - 3,0 | 35 - 45 |
| 505 (65A-66A or #5) | 1,1 | 0,8 - 1,9 | 6,0 - 11,0 | 1,8 - 4,7 | 3,0 - 5,0 | 40 - 50 |
| 506 (19-20 or #6) | 1,2 | 0,8 - 1,3 | 2,0 - 3,0 | 2,5 - 5,0 | 2,0 - 3,0 | 45 - 65 |

Table 4 — Measurement points for excavators

| | Dimension | Measurement point |
|-------|-------------|---|
| b_1 | Blade width | Measured at the widest point, unless a specific cross-section is indicated by AA, BB, ..., ZZ at a set distance from the datum point. |

Table 4 (continued)

| | Dimension | Measurement point |
|----------|------------------|--|
| b_2 | Blade thickness | Measured at the thickest part of the blade. |
| b_3 | Blade length | Distance measured from the extreme tip of the blade, parallel to the intersection of the shank and the first bend. |
| b_4 | Neck thickness | Measured immediately behind the blade at the smallest point, at a right angle to the centreline of the instrument. |
| h_1 | Blade height | Distance measured from the datum point, at a right angle to the centreline of the instrument, to the farthest extremity of the blade. |
| h_2 | Shank height | Distance measured from the datum point, at a right angle to the centreline of the instrument, to the farthest external surface of the first bend of the shank. |
| α | Blade angle | Angle of glaze surface to the centreline of the blade, shank or instrument, whichever is appropriate. |
| β | Offset angle | With the instrument viewed at 90° to the standard position (i.e. a plan view), the angle between the centreline of the shank and a line parallel to the centreline of the instrument, forming a tangent with the first bend of the instrument. |

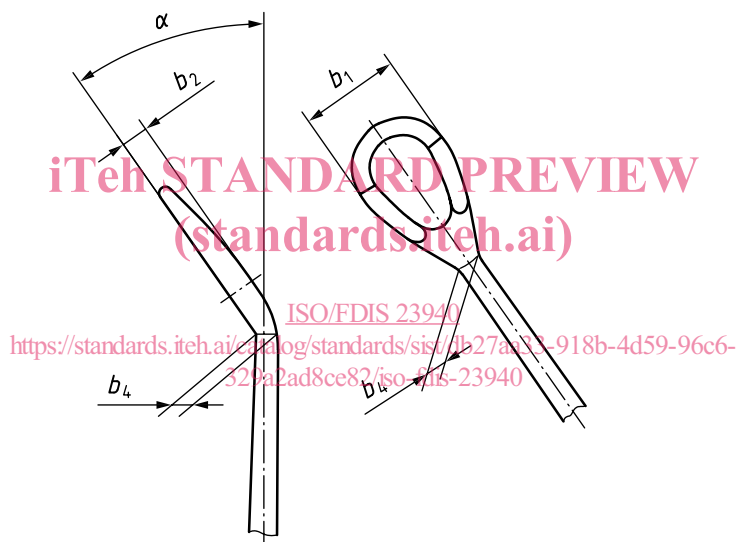


Figure 1 — Form A: Straight

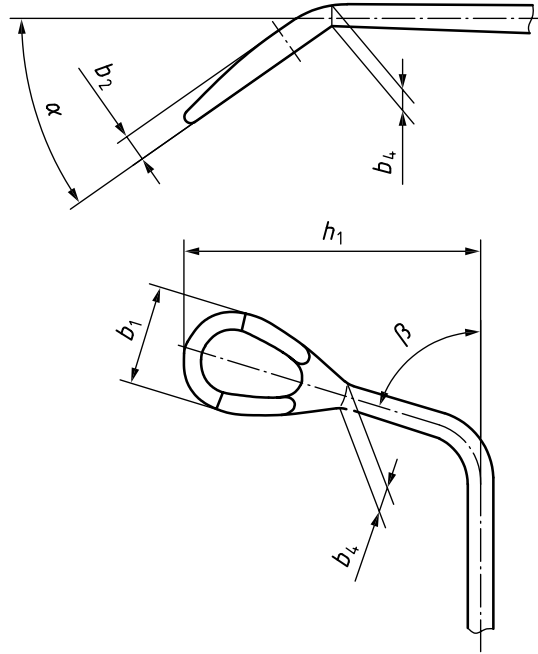


Figure 2 — Form B: Angled

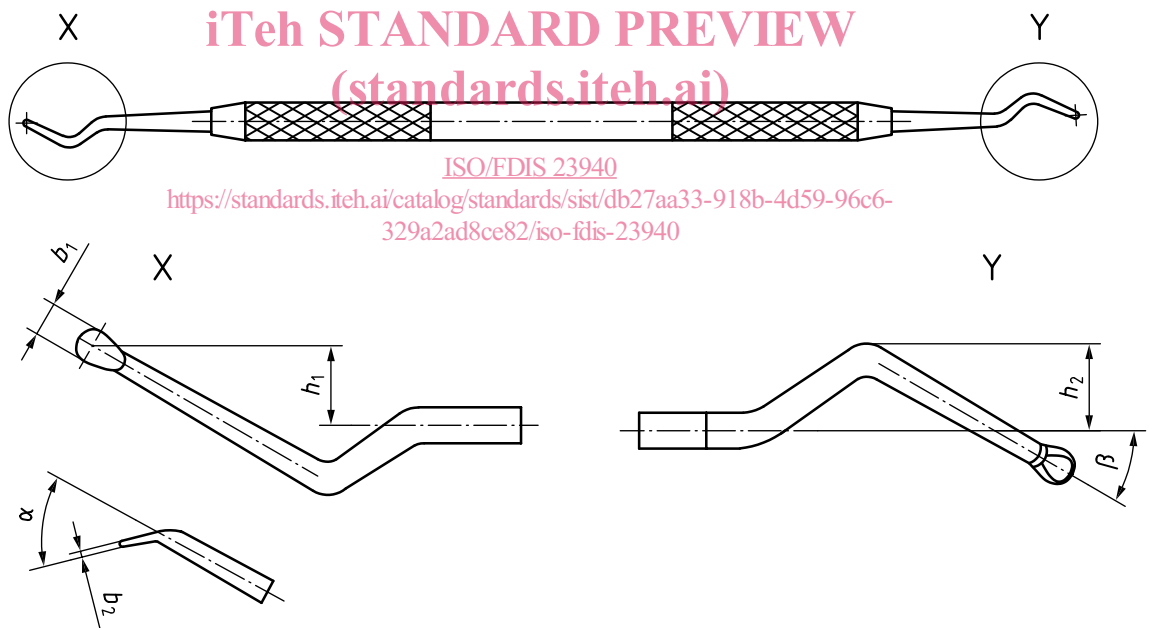


Figure 3 — Form C: Contra-angled