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## Dentistry — Excavators

*Médecine bucco-dentaire — Excavateurs*

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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](http://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](http://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](http://www.iso.org/iso/foreword.html).

This document was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 4, *Dental instruments*.

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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](http://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

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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 *excavator* (3.1) during use

### 3.4

#### **shank**

part of the *excavator* (3.1) that connects the *working end* (3.5) to the *handle* (3.3)

### 3.5

#### **working end**

part of the *excavator* (3.1) 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
- $\alpha$  blade angle
- $\beta$  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	<a href="#">Figure 1</a>	Straight	Discoid	100
B	<a href="#">Figure 2</a>	Angled	Discoid	200
C	<a href="#">Figure 3</a>	Contra-angled	Discoid	300
D	<a href="#">Figure 4</a>	Angled, complex	Discoid	400
E	<a href="#">Figure 5</a>	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	$b_1$	$b_2$	$b_3$	$b_4$	$h_1$	$h_2$	$\alpha$	$\beta$
<b>Tolerance</b>	±0,1	±0,1	±0,1	±0,1	±0,3	±0,3	±5	±5
<b>Form A: 100 = Straight</b>								

Table 2 (continued)

Type	$b_1$	$b_2$	$b_3$	$b_4$	$h_1$	$h_2$	$\alpha$	$\beta$
101	2,5	0,9	—	1,2	—	—	40	—
102	1,7	0,7	—	0,9	—	—	40	—
<b>Form B; 200 = Angled</b>								
201	1,1	0,5	—	0,7	6,4	—	35	72
202	1,0	0,5	—	0,7	6,4	—	36	72
<b>Form C; 300 = Contra-angled</b>								
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
<b>Form D; 400 = Angled, complex</b>								
401	1,4	0,7	2,5	0,8	2,9	3,0	35	83

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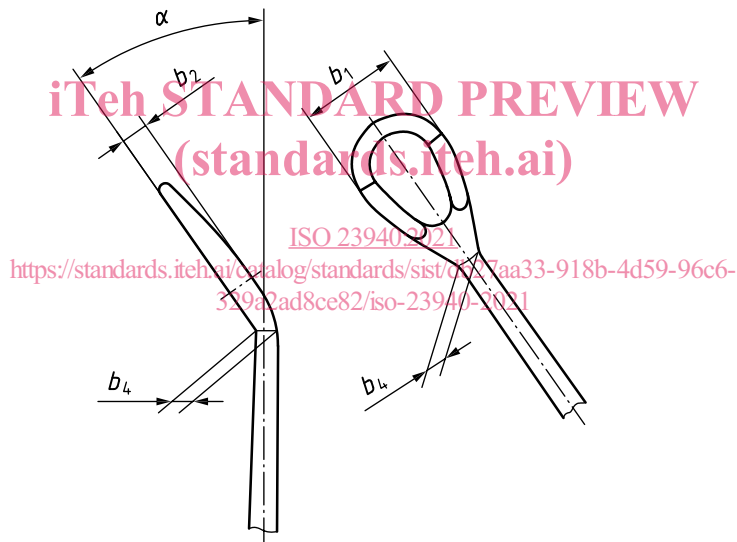
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**Table 3 — Dimensions of excavators (Form E)**

Dimensions in millimetres  
Angles in degree

Type	$b_1$	$b_2$	$b_3$	$h_1$	$h_2$	$\alpha$
<b>Tolerance</b>	±0,1	—	—	—	—	—
<b>Form E; 500 = Spoon</b>						
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**

	<b>Dimension</b>	<b>Measurement point</b>
$b_1$	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.
$b_2$	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.
$\alpha$	Blade angle	Angle of the excavator surface to the centreline of the blade, shank or instrument, whichever is appropriate.
$\beta$	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**



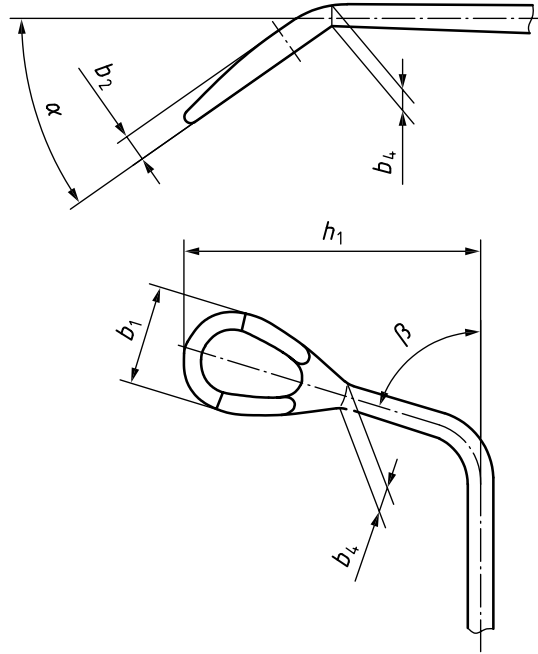


Figure 2 — Form B: Angled

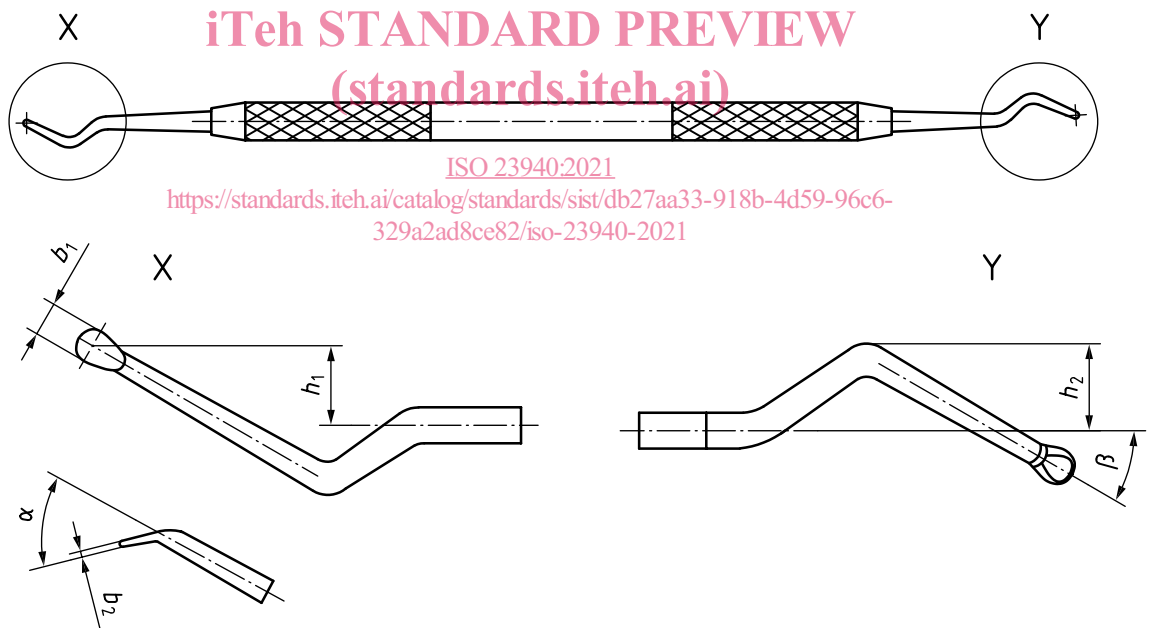


Figure 3 — Form C: Contra-angled

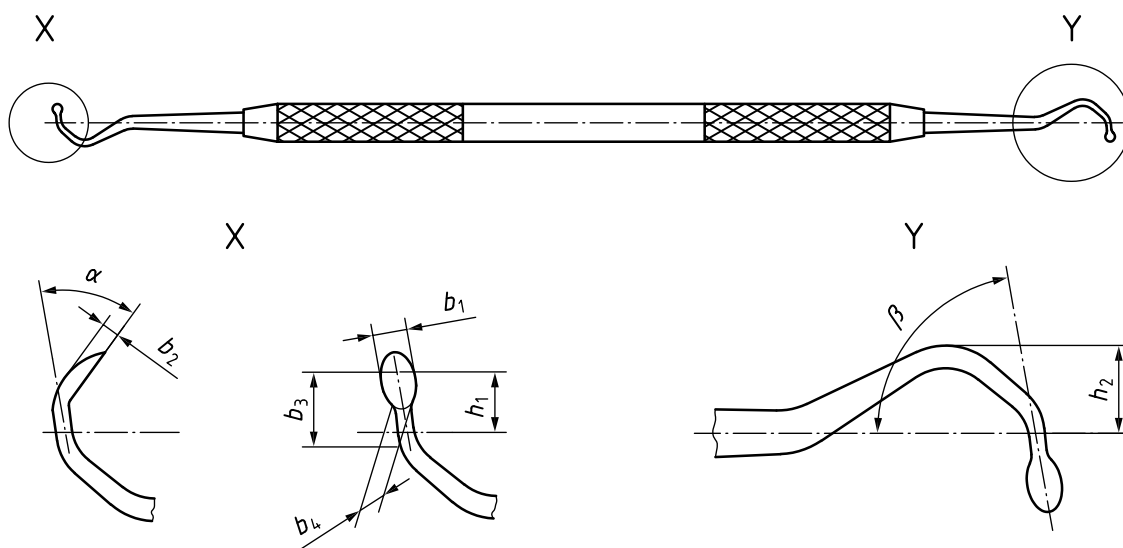


Figure 4 — Form D: Angled, complex

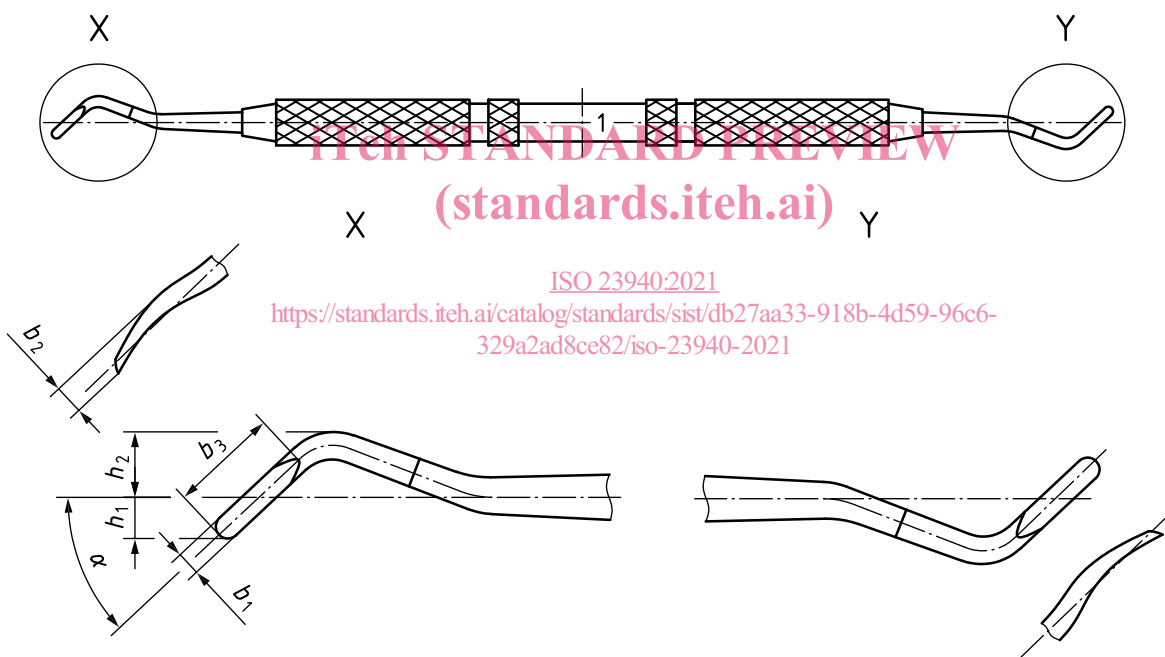


Figure 5 — Form E: Spoon type 501 (63-64 or #1)