

# SLOVENSKI STANDARD oSIST prEN ISO 23940:2020

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### Zobozdravstvo - Ekskavatorji (ISO/DIS 23940:2019)

Dentistry - Excavators (ISO/DIS 23940:2019)

Zahnheilkunde - Exkavatoren (ISO/DIS 23940:2019)

Médecine bucco-dentaire - Excavateurs (ISO/DIS 23940:2019)

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# DRAFT INTERNATIONAL STANDARD ISO/DIS 23940

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### **Dentistry** — Excavators

*Médecine bucco-dentaire* — *Excavateurs* 

ICS: 11.060.25

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## ISO/CEN PARALLEL PROCESSING



Reference number ISO/DIS 23940:2019(E)

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#### Foreword

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This second edition cancels and replaces the first pedition (HSO  $^{\circ}$ 13397-4:1997), which has been technically revised.

The main changes compared to the previous edition are as follows:

- publication under a separate standard number (ISO 23940) and therefore no longer as part of the ISO 13397 standard series;
- addition of new shapes, see <u>Figure 5</u> to <u>Figure 10</u>, and <u>Table 3</u>;
- test values for connection between working end and handle were reduced from 600 N to 450 N (tensile load) and from 400 Ncm to 0,25 Nm (torque) (see 5.7);
- requirement for UDI-code has been added in <u>Clause 7</u>;
- requirement for instructions for use has been added in <u>7.3</u>.

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 <a href="https://www.iso.org/members.html">www.iso.org/members.html</a>.

### **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 6508-1, Metallic materials — Rockwell hardness test — Part 1: Test method

ISO 7153-1, Surgical instruments — Materials — Part 1: Metals

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

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

## 3 Terms, definitions and symbols standards/sist/ad2e63b5-1baf-4611-97fl-

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#### 3.1 Terms and definitions

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 <a href="https://www.iso.org/obp">https://www.iso.org/obp</a>
- IEC Electropedia: available at <a href="https://www.electropedia.org/">https://www.electropedia.org/</a>

#### 3.1.1

#### excavator

handheld dental instrument for excavating caries

#### 3.1.2

#### datum point

section point between the centreline of the handle, at right angle to the centreline, and the blade

#### 3.1.3

#### handle

area used for holding the dental explorer during tactile exploration

#### 3.1.4

#### shank

part of the dental explorer that connects the working end to the handle

<sup>1)</sup> Currently at FDIS-stage.

#### 3.1.5

#### working end

part of the dental explorer after the first bend of the shank including the working tip

#### 3.1.6

#### blade

active part of the working end which will be first to contact the tooth surface

#### 3.2 Symbols and abbreviated terms

The following symbols and abbreviated terms 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;
- ß offset angle.

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#### 4 Classification

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The classification of forms of excavators is given in the classification of forms of excavators is given in the classification of forms of excavators is given in the classification of forms of excavators is given in the classification of forms of excavators is given in the classification of forms of excavators is given in the classification of forms of excavators is given in the classification of forms of excavators is given in the classification of forms of excavators is given in the classification of forms of excavators is given in the classification of the classi

Table 1 — Classification of excavator forms

Form	Eiguno	Shape of work	Classification	
FOLIII	Figure	Overall	Тор	Classification
A	Figure 1	Straight	Discoid	100
В	Figure 2	Angled	Discoid	200
С	Figure 3	Contra-angled	Discoid	300
D	Figure 4	Angled, complex	Discoid	400
Е	Figure 5	Spoon	Pear	500

#### 5 Requirements for excavators

#### 5.1 Design and dimensions

Excavators shall have the designs shown in Figures 1 to  $\underline{10}$  and the dimensions as given in Table 2 and Table 3.

The points of measurement associated with the dimensions are listed in <u>Table 4</u>.

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

Dimensions in millimetres
Angels in degree

							_	
Type	<i>b</i> 1	<i>b</i> 2	<i>b</i> 3	<i>b</i> 4	h1	h2	α	β
Tolerance	±0,1	±0,1	±0,1	±0,1	±0,3	±0,3	±5	±5
Form A:								
100 = Straight								
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	DĒ.	0,9	1,9	3,5	35	30
305 11 en S	1,4	0,6	KD)	0,8	1,7	3,5	35	30
306	stan	0,6	ds <del>.i</del> te	h0,7ai	1,6	3,6	35	30
307	1,0	0,5	_	0,7	2,5	1,8	35	30
308		Гр <b>0,5</b> \ I			2,7	3,6	35	35
Form D; https://standards.iteh.ai/catalog/standards/sist/ad2e63b5-1baf-4611-97f1-7839cee04279/osist-pren-iso-23940-2020								
400 = Angled,		L / 9/OSISI-	preiris0-2	L394U-2U	20			
complex								
401	1,4	0,7	2,5	0,8	2,9	3,0	35	83

Table 3 — Dimensions of excavators (Form E)

Dimensions in millimetres
Angles in degree

Туре	<i>b</i> 1	<i>b</i> 2	<i>b</i> 3	h1	h2	α
Tolerance	±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.
$b_2$	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 right angles to the centreline of the instrument.
$h_1$	Blade height	Distance measured from the datum point, at right angles to the centreline of the instrument, to the farthest extremity of the blade.
$h_2$	Shank height	Distance measured from the datum point, at right angles 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.
ß	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.

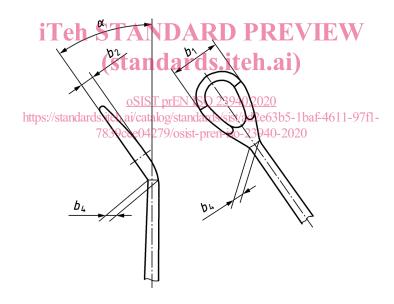


Figure 1 — Form A: Straight