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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Dentistry — Excavators

Médecine bucco-dentaire — Excavateurs

ICS: 11.060.25

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Contents

Page

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).

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 on 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 the following URL: www.iso.org/iso/foreword.html.

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

This second 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:

— 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 Figure 5 to Figure 10, and Table 3;

— 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 Clause 7;

— requirement for instructions for use has been added in 7.3.

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 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

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 https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

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

1) 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;

α blade angle;

$ß$ offset angle.

4 Classification

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

5 Requirements for excavators

5.1 Design and dimensions

Excavators shall have the designs shown in Figures 1 to 10 and the dimensions as given in Table 2 and Table 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
Angels 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**								
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

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	±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.

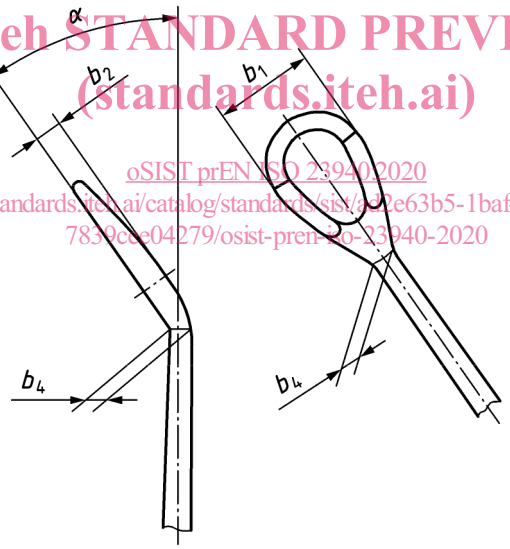

Figure 1 — Form A: Straight