

# SLOVENSKI STANDARD oSIST prEN ISO 7492:2019

01-februar-2019

| Zobozdravstvo - Dentalne sonde | (ISO/FDIS 7492:2018) |
|--------------------------------|----------------------|
|--------------------------------|----------------------|

Dentistry - Dental explorer (ISO/FDIS 7492:2018)

Zahnheilkunde - Zahnsonde (ISO/FDIS 7492:2018)

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Médecine bucco-dentaire - Sondes exploratrices dentaires (ISO/FDIS 7492:2018)

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# INTERNATIONAL STANDARD

# ISO/FDIS 7492

ISO/TC 106/SC 4

Secretariat: DIN

Voting begins on: **2018-12-04** 

Voting terminates on: 2019-02-26

# Dentistry — Dental explorer

Médecine bucco-dentaire — Sondes exploratrices dentaires

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Reference number ISO/FDIS 7492:2018(E)

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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 <a href="https://www.iso.org/directives">www.iso.org/directives</a>).

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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 <u>www.iso</u> .org/iso/foreword.html.

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

#### <u>SIST EN ISO 7492:2019</u>

This fourth edition cancels and replaces the third edition (ISO 7492:2018), which has been technically revised. 37509964158a/sist-en-iso-7492-2019

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

- recommendation for maximum length of a dental explorer was reduced from 178 mm to 173 mm in 4.3;
- 4.6.2 of the previous edition was removed, because it did not apply to explorers, and handle surface finish was already defined in paragraphs 1 and 2 of 4.6.1 of the previous edition;
- Sentence 1 of paragraph 2 of <u>4.7</u> was removed because reflective coatings are not an applicable property of explorers;
- Requirement for UDI code was added in <u>Clause 6</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 <u>www.iso.org/members.html</u>.

#### FINAL DRAFT INTERNATIONAL STANDARD

### **Dentistry — Dental explorer**

#### 1 Scope

This document specifies the dimensions and performance requirements for dental explorers.

This document is not applicable to endodontic explorers.

#### 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

#### **3 Terms and definitions** SIST EN ISO 7492:2019

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 <u>https://www.iso.org/obp</u>

— IEC Electropedia: available at <u>http://www.electropedia.org/</u>

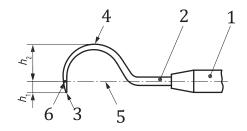
#### 3.1.1

#### dental explorer

handheld dental instrument with a pointed tip designed for tactile examination of tooth surfaces

Note 1 to entry: See Figure 1.

Note 2 to entry: Dental explorer is used to examine teeth for decay (caries), calculus, furcations, or other abnormalities.



#### Кеу

- 1 handle
- 2 shank
- 3 working tip
- 4 first bending point
- 5 centreline
- 6 datum point
- $h_1$  working end height
- $h_2$  shank height

#### Figure 1 — Designation of parts and dimensions for dental explorers

#### 3.1.2

datum point iTeh STANDARD PREVIEW.

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

Note 1 to entry: The datum point is where  $h_1$  and  $h_2$  meet. **OS ITC 1**.**21** 

#### 3.1.3 handle

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area used for holding the *dental explorer* (3.1.1) during tactile exploration 8411463d-9126

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#### 3.1.4 shank

part of the *dental explorer* (3.1.1) that connects the working end to the handle

#### 3.1.5

#### working end

part of the *dental explorer* (3.1.1) after the first bend of the shank including the working tip

Note 1 to entry: The working end is the combination of  $h_1$  and  $h_2$  directly on the explorer.

#### 3.1.6

#### working tip

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

#### 3.2 Symbols and abbreviated terms

For the purposes of this document, the following symbols and abbreviated terms apply, and are shown in <u>Figure 1</u> to <u>Figure 9</u>.

- *b* length of working tip (only used in Figure 5)
- $h_1$  working end height
- $h_2$  shank height

- *r* working end radius
- $\alpha$  working end angle
- $\beta$  secondary angle of working tip (only used in Figure 5)

#### **4** Requirements

#### 4.1 Materials

#### 4.1.1 Material of the working end

The working end of a dental explorer shall be made of metallic materials in accordance with ISO 7153-1.

#### 4.1.2 Material of the handle

The material for the handle, selected at the discretion of the manufacturer, shall meet the requirements of <u>Clause 5</u>.

5.3 does not apply.

#### 4.2 Location of measurement points

The location of the points of measurement for dental explorers shall be as shown in Figure 1 and in Table 1.

| Symbol         | Meaning SIS  | <u><b>I EN ISO 7492:201 P</b></u> oints of measurement  |
|----------------|--|---|
| b              | Length of working tip (only used in <u>Figure 5</u> )          | distance from the extreme tip of the working end, parallel to the<br>centreline of the working tip, to the first bend of the working end                                |
| h <sub>1</sub> | Working end height   | distance from the datum point, at right angles to the centreline of the shank, to the farthest extremity of the working tip   |
| h <sub>2</sub> | Shank height   | distance from the datum point, at right angles to the centreline of the<br>shank, to the furthest point on the external surface of the first bend<br>of the working end |
| r              | Working end radius   | radius of curvature of the inside of the first bend of the working end  |
| α              | Working end angle  | angle between the centreline of the shank and the working end   |
| β              | Secondary angle of working tip (only used in <u>Figure 5</u> ) | angle between the centreline of the shank and a line parallel to the tangent to the first bend of the working end   |

(standards.iteh.ai) Table 1 — Measurement of dimensions for dental explorers

#### 4.3 Shape and dimensions

The dental explorer shall have one of the forms shown in Figure 2 to Figure 9.

Commonly used dimensions are shown in <u>Table 2</u>. The column is arranged according to the increase in the dimension  $h_1$ .

The dimensions shall be measured in accordance with <u>Table 1</u> and <u>Figure 1</u>.

The working tip shall be pointed but the exact shape and design of the working end is left to the discretion of the manufacturer.

The maximum length of a dental explorer shall be at the manufacturer's discretion, but it should be noted that overall lengths in excess of 173 mm can cause difficulty in containment within a sterilization cassette.

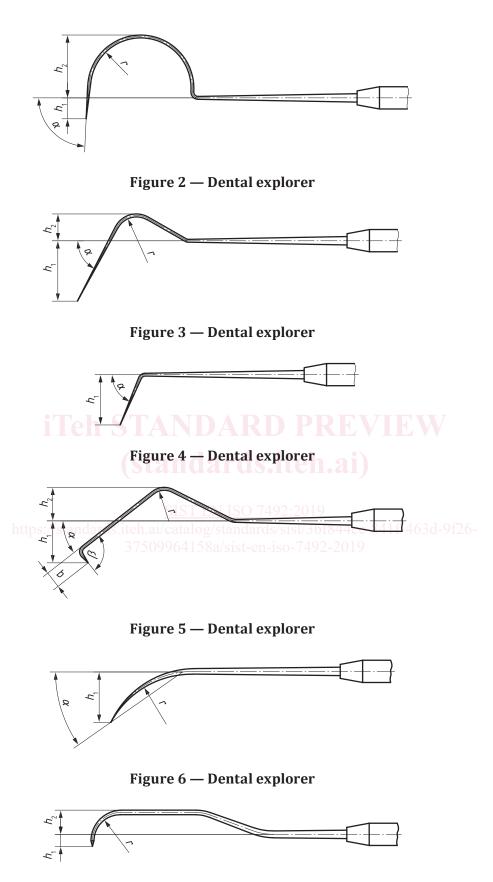


Figure 7 — Dental explorer