

ICS:

SLOVENSKI STANDARD oSIST prEN ISO 8325:2022

01-april-2022

Zobozdravstvo - Preskusne metode za vrtilne instrumente (ISO/DIS 8325:2022)

Dentistry - Test methods for rotary instruments (ISO/DIS 8325:2022)

Zahnheilkunde – Prüfverfahren für rotierende Instrumente (ISO/DIS 8325:2022)

iTeh STANDARD

Médecine bucco-dentaire - Méthodes d'essai pour instruments rotatifs (ISO/DIS 8325:2022)

Ta slovenski standard je istoveten z: prEN ISO 8325

<u>oSIST prEN ISO 8325:2022</u>

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11.060.25 Zobotehnični instrumenti ²⁰Dental instruments

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DRAFT INTERNATIONAL STANDARD ISO/DIS 8325

ISO/TC **106**/SC **4** Secretariat: **DIN**

Voting begins on: Voting terminates on:

2022-02-04 2022-04-29

Dentistry — Test methods for rotary instruments

Médecine bucco-dentaire — Méthodes d'essai pour instruments rotatifs

ICS: 11.060.20

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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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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.

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

This third edition cancels and replaces the second edition (ISO 8325:2004), which has been technically revised.

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

- a) addition of definitions, e.g. for rotary instruments (3.1);
- b) deletion of list of suitable measuring instruments (4.3);
- c) clarification of tolerances for the measuring instruments (5.1);
- d) replacement of formula for neck strength test (5.9) by a technically based formula (5.9.4);
- e) addition of Annex A for deduction of formula 5.9.4.

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.

Introduction

To check the conformity of dental rotary instruments against relevant product standards, it is indispensable, to conduct tests on the basis of harmonised test methods in order to achieve comparable test results. In the respective product standards for dental rotary instruments, reference is made to the test methods specified in this document.

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Dentistry — Test methods for rotary instruments

1 Scope

This document specifies general test methods for rotary instruments used in dentistry. These test methods are used for measuring the dimensional characteristics, neck strength and surface roughness of rotary instruments, such as burs, cutters, polishers, diamond instruments, abrasive instruments and rotary instruments used for oral surgery such as drills, countersinks.

Specific tests are specified in the respective product standards, if available.

This document does not specify test methods for materials used for rotary instruments.

NOTE For these materials see ISO 21850-1 and the respective product standards.

This document is not applicable to endodontic instruments (see ISO 3630-1).

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 1797, Dentistry — Shanks for rotary and oscillating instruments

ISO 1942, Dentistry — Vocabulary

ISO 3274, Geometrical Product Specifications (GPS) 25: Surface texture: Profile method — Nominal characteristics of contact (stylus) instruments atalog/standards/sist/7fd98d26-

9261-4058-b9d5-b08bae079c9e/osist-pren-iso-8325-ISO 4288, Geometrical Product Specifications (GPS) — Surface texture: Profile method — Rules and procedures for the assessment of surface texture

ISO 13295, Dentistry — Mandrels for rotary instruments

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

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 1942 and ISO 21850-1 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/

[SOURCE: ISO 21850-1:2020, 3.1]

3.1

rotary instrument

instrument used with a continuous rotation in a handpiece used for dental procedures

[SOURCE: ISO 1942:2020, 3.4.1.3, modified — "consisting of a shank and a working part," was deleted in the definition.]

3.2

run-out

inaccuracy of rotary instrument, specifically that the working end or shank does not rotate exactly in line with the main axis

3.3

bending moment

reaction induced in a rotary instrument when an external force (e.g. by the hand of the dentist) is applied to the rotary instrument, causing the instrument to bend

4 Measurement and test methods

4.1 General

The measurement and test methods specified in this document refer to the main characteristics of rotary instruments used in dentistry. They are demonstrated by describing the test procedures for the single characteristics of rotary instruments.

In addition to the measurement and test methods specified other equivalent measurement and test methods and test devices exist and may be used; they may render similar test results.

In case of dispute, however, the measurement and test methods specified in this document become reference.

For evaluation of test results, see the relevant product standards. /

4.2 Ambient conditions

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Tests shall be conducted at ambient temperature of 18 °C to 28 °C.

4.3 Measurements

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Lengths and diameters shall be measured and calculated in millimetres, angles in degrees.

5 Measurement of single characteristics

5.1 Measuring instrument

A measuring instrument with a measuring resolution of ≤ 10 % of the tolerance range of the intended dimensions shall be used.

The applied measuring force shall not exceed 1,5 N, unless otherwise stated in this document.

5.2 Shape of the working part

5.2.1 Procedure

Determine the shape of the working part of the rotary instrument visually or by using a measuring instrument specified in 5.1.

Conduct one set of measurements.

5.3 Diameter of the working part

5.3.1 Location of measurement points

The location of measurement points shall be as follows, unless specified differently in the respective product standard:

- a) for cylindrical rotary instruments: the middle of the working part;
- b) for non cylindrical rotary instruments: the largest diameter of the working part.

5.3.2 Procedure

Measure the diameter of the working part of the rotary instrument using a measuring instrument as specified in <u>5.2.1</u>.

Conduct measurements on the peripheral surface, e. g. on the diameter of the largest cutting blade.

Conduct three or four measurements, as appropriate, at angles of approximately 120°, or 90° as appropriate, apart on the circumference of the test piece. Lift the blade before rotating the test piece to the next measurement point. Record the three measuring results as d_1 , d_2 and d_3 .

5.3.3 Evaluation of test results STANDARD

Calculate the average diameter of the rotary instrument by using the following formula:

$$d = \frac{d_1 + d_2 + d_3}{3}$$
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where

- $d_1 \qquad \text{is the diameter of measurement 1:} \\ \frac{\text{oSIST prEN ISO }8325:2022}{\text{inttps://standards.nteh.ai/catalog/standards/sist/7fd98d26-}}$
- d_2 is the diameter of measurement 2, ae079c9e/osist-pren-iso-8325-
- d_3 is the diameter of measurement 3.

5.4 Neck diameter

5.4.1 Location of measurement points

The location of measurement points shall be the smallest diameter just behind the working part, or just behind the collar, where applicable.

5.4.2 Procedure

Measure the neck diameter of the rotary instrument by using an instrument of 5.3.1.

Conduct one measurement.

5.5 Dimensions of shanks

The dimensions of the shank shall be determined in accordance with ISO 1797.