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Dentistry — Test methods for rotary instruments

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

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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

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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*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 55, *Dentistry*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

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

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

a) some definitions have been added such as for rotary instruments;

b) list of suitable measuring instruments have been deleted from 4.3;

c) tolerances for the measuring instruments have been clarified in 5.1;

d) the formula for neck strength test has been replaced in 5.11 by a technically based Formula in 5.11.4;

e) Annex A has been added for the deduction of Formula (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.

Introduction

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

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, grinding instruments and rotary instruments used for oral surgery such as drills and countersinks.

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

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

NOTE For materials used for rotary instruments, see ISO 21850-1 and respective instrument standards.

This document is not applicable to endodontic instruments. For 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) — Surface texture: Profile method — Nominal characteristics of contact (stylus) instruments*

ISO 13295, *Dentistry — Mandrels for rotary instruments*

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

ISO 21920-3, *Geometrical product specifications (GPS) — Surface texture: Profile — Part 3: Specification operators*

3 Terms and definitions

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

ISO and IEC maintain terminology 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
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," has been deleted from the definition.]

3.2
run-out
inaccuracy of *rotary instrument* (3.1), 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* (3.1) 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 can be used; they can render similar test results.

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

For the evaluation of the test results, see the relevant instrument standards.

4.2 Ambient conditions

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

4.3 Measurements

Lengths and diameters shall be measured and calculated in millimetres, angles in degrees, forces in Newton or milliNewton and torques in milliNewtonmetres.

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 manufacturer shall determine and provide the measuring devices needed to ensure valid and reliable results when measuring is used to verify the conformity of products to requirements.

5.2 Shape of the working part

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

Determine the shape of the working part of the rotary instrument visually.

The location of measurement points shall be as follows, unless specified differently in the respective instrument 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.

Use an instrument as specified in 5.1.

Conduct one set of measurement.

5.3.2 Procedure

Measure the diameter of the working part of the rotary instrument using an instrument as specified in 5.1.

Conduct measurements on the peripheral surface, for example, 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

Calculate the average diameter of the rotary instrument by using Formula (1):

$$d = \frac{d_1 + d_2 + d_3}{3} \tag{1}$$

where

d_1 is the diameter of measurement 1;

d_2 is the diameter of measurement 2;

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 as specified in 5.1.

Conduct one measurement.

5.5 Dimensions of shanks

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

5.5.1 Shank diameter

The measurement locations shall be determined in accordance with ISO 1797.

5.5.2 Shank length

The locations of measurements shall be the points from the end of the shank to the shortest length where shank diameter enlargement or reduction occurs.

5.6 Dimensions of mandrels

The dimensions of the mandrel shall be determined in accordance with ISO 13295.

5.7 Length of working part

5.7.1 Location of measurement points

The location of measurement points shall be the points at the ends of the shortest length of the working part, including, where applicable, the coated neck.

5.7.2 Procedure

Measure the length of the working part using an instrument as specified in 5.1.

Conduct one measurement.

5.8 Overall length

5.8.1 Location of measurement points

The location of measurement points shall be the two ends of the rotary instrument, including tip and shank end.

5.8.2 Procedure

Measure the overall length of the rotary instrument using an instrument as specified in 5.1.

Conduct one measurement.

5.9 Angle of taper of working part

5.9.1 Location of measurement points

The location of measurement points shall be on the taper surface of the working part of the test piece. Use at least two measurement points, which are apart from each other as far as possible.

5.9.2 Procedure

Determine the included angle with an instrument as specified in 5.1.

Measure the relevant diameters and the length of the taper. Then calculate the angle of the taper.

Conduct one measurement.