

Dentistry - Handpieces and motors (ISO 14457:2017)

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

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| See Eesti standard EVS-EN ISO 14457:2017 sisaldab Euroopa standardi EN ISO 14457:2017 ingliskeelset teksti. | This Estonian standard EVS-EN ISO 14457:2017 consists of the English text of the European standard EN ISO 14457:2017. |
| Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas | This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation. |
| Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 06.12.2017. | Date of Availability of the European standard is 06.12.2017. |
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ICS 11.060.25

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English Version

Dentistry - Handpieces and motors (ISO 14457:2017)

Médecine bucco-dentaire - Pièces à main et moteurs
(ISO 14457:2017)

Zahnheilkunde - Handstücke und Motoren (ISO
14457:2017)

This European Standard was approved by CEN on 17 August 2017.

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COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

European foreword

This document (EN ISO 14457:2017) has been prepared by Technical Committee ISO/TC 106 "Dentistry" in collaboration with Technical Committee CEN/TC 55 "Dentistry" the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by June 2018, and conflicting national standards shall be withdrawn at the latest by June 2018.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 14457:2012.

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Endorsement notice

The text of ISO 14457:2017 has been approved by CEN as EN ISO 14457:2017 without any modification.

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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 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 14457:2012), which has been technically revised.

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

- use of terms for handpieces and motors has been clarified;
- output power for high-speed air turbine handpieces has been added;
- light for handpieces has been added;
- a few technical data have been corrected;
- an example for the test report has been added in [Annex B](#).

Dentistry — Handpieces and motors

1 Scope

This document specifies requirements and test methods for handpieces and motors used in dentistry for treatment of patients and having patient contact, regardless of their construction. It also specifies requirements for manufacturer's information, marking and packaging.

This document is applicable to the following:

- a) straight and angle handpieces;
- b) high-speed air turbine handpieces;
- c) air motors;
- d) electrical motors;
- e) prophylaxis handpieces.

This document is not applicable to the following:

- intraoral camera handpieces;
- powered polymerization handpieces;
- air-powered scalers;
- electrical-powered scalers;
- powder jet handpieces;
- multifunction handpieces (syringes).

NOTE See [Annex A](#) for clarification of handpieces and motor types covered by this document.

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 2768-1, *General tolerances — Part 1: Tolerances for linear and angular dimensions without individual tolerance indications*

ISO 2768-2, *General tolerances — Part 2: Geometrical tolerances for features without individual tolerance indications*

ISO 3964, *Dentistry — Coupling dimensions for handpiece connectors*

ISO 5349-1, *Mechanical vibration — Measurement and evaluation of human exposure to hand-transmitted vibration — Part 1: General requirements*

ISO 5349-2, *Mechanical vibration — Measurement and evaluation of human exposure to hand-transmitted vibration — Part 2: Practical guidance for measurement at the workplace*

ISO 6507-1, *Metallic materials — Vickers hardness test — Part 1: Test method*

ISO 7494-1, *Dentistry — Dental units — Part 1: General requirements and test methods*

ISO 9168, *Dentistry — Hose connectors for air driven dental handpieces*

ISO 9687, *Dentistry — Graphical symbols for dental equipment*

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 13295, *Dentistry — Mandrels for rotary instruments*

ISO 15223-1, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

ISO 17664, *Sterilization of medical devices — Information to be provided by the manufacturer for the processing of resterilizable medical devices*

ISO 21531, *Dentistry — Graphical symbols for dental instruments*

IEC 60601-1:2005+AMD1:2012, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

IEC 61672-1, *Electroacoustics — Sound level meters — Part 1: Specifications*

IEC 62366-1, *Medical devices — Part 1: Application of usability engineering to medical devices*

IEC 80601-2-60:2012, *Medical electrical equipment — Part 2-60: Particular requirements for basic safety and essential performance of dental equipment*

3 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:

- IEC Electropedia: available at <http://www.electropedia.org/>
- ISO Online browsing platform: available at <http://www.iso.org/obp>

3.1

air motor

motor (3.14) powered by compressed air, which is supplied by a dental unit

3.2

powder jet handpiece

handpiece (3.10) powered by compressed air, designed to deliver powder to the patient's oral cavity at high velocity

3.3

air-powered scaler

handpiece (3.10) powered by compressed air, with an oscillating working part

3.4

angle handpiece

handpiece (3.10) with an angle between the input and output axes, driven by an *air motor* (3.1) or an *electrical motor* (3.7) or with an internal power supply, including extension part of a handpiece designed to hold a *working part* (3.9)