

Dentistry - Handpieces and motors (ISO 14457:2012)

This document is a preview generated by EVS

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 14457:2012 sisaldab Euroopa standardi EN ISO 14457:2012 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 14457:2012 consists of the English text of the European standard EN ISO 14457:2012.
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 15.09.2012.	Date of Availability of the European standard is 15.09.2012.
Standard on kättesaadav Eesti Standardikeskusest.	The standard is available from the Estonian Centre for Standardisation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

ICS 11.060.25

Standardite reprodutseerimise ja levitamise õigus kuulub Eesti Standardikeskusele

Andmete paljundamine, taastekitamine, kopeerimine, salvestamine elektroonsesse süsteemi või edastamine ükskõik millises vormis või millisel teel ilma Eesti Standardikeskuse kirjaliku loata on keelatud.

Kui Teil on küsimusi standardite autorikaitse kohta, võtke palun ühendust Eesti Standardikeskusega:
Aru 10, 10317 Tallinn, Eesti; www.evs.ee; telefon 605 5050; e-post info@evs.ee

The right to reproduce and distribute standards belongs to the Estonian Centre for Standardisation

No part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying, without a written permission from the Estonian Centre for Standardisation.

If you have any questions about copyright, please contact Estonian Centre for Standardisation:
Aru 10, 10317 Tallinn, Estonia; www.evs.ee; phone 605 5050; e-mail info@evs.ee

English Version

Dentistry - Handpieces and motors (ISO 14457:2012)

Médecine bucco-dentaire - Pièces à main et moteurs (ISO
14457:2012)

Zahnheilkunde - Handstücke und Motoren (ISO
14457:2012)

This European Standard was approved by CEN on 14 September 2012.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.



EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: Avenue Marnix 17, B-1000 Brussels

Foreword

This document (EN ISO 14457:2012) 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 March 2013, and conflicting national standards shall be withdrawn at the latest by March 2013.

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

This document supersedes EN ISO 7785-1:1999, EN ISO 7785-2:1997, EN ISO 11498:1999, EN ISO 13294:1997.

According to the CEN/CENELEC Internal Regulations, the national standards organisations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 14457:2012 has been approved by CEN as a EN ISO 14457:2012 without any modification.

Contents

Page

Foreword	v
Introduction	vi
1 Scope	1
2 Normative references	1
3 Terms and definitions	2
4 Classification of handpieces	4
5 Requirements and performance	4
5.1 General	4
5.2 Materials	4
5.3 Drop test	4
5.4 Noise level	4
5.5 Surfaces	4
5.6 Power supply	5
5.7 Air and water pressure	6
5.8 Temperature	6
5.9 Vibrations	6
5.10 Resistance to reprocessing	6
5.11 Leakage and/or ingress of water	6
5.12 Electromagnetic compatibility	6
5.13 Operating controls	6
5.14 Usability	7
5.15 Connection and supply	7
5.16 Chuck system for shanks	9
5.17 Test mandrel	9
5.18 Speed	11
5.19 Eccentricity	11
5.20 Torque	11
5.21 Dimensions of head and nose	11
6 Sampling	12
7 Testing	12
7.1 General test conditions	12
7.2 Visual inspection	13
7.3 Power supply — Electrical	13
7.4 Power supply — Air	13
7.5 Spray air supply	13
7.6 Spray water supply	13
7.7 Air and water pressure	14
7.8 Motor cooling air	14
7.9 Connector for handpiece attachment and for air-powered handpiece	14
7.10 Connection and supply	14
7.11 Test mandrels	14
7.12 Chuck for shanks	15
7.13 Dimensions (of head and nose)	15
7.14 Eccentricity	16
7.15 Torque	16
7.16 Noise level	16
7.17 Speed	17
7.18 Temperature rise of housing	17
7.19 Temperature, excessive	17
7.20 Resistance to reprocessing	17
8 Instructions for use, maintenance and service	17

9 **Technical description** 18

10 **Marking**..... 18

10.1 **General**..... 18

10.2 **Handpieces** 18

10.3 **Motors**..... 18

11 **Labelling**..... 19

12 **Packaging**..... 19

Annex A (informative) Handpiece categories..... 20

Bibliography 22

Introduction

Dental handpieces and dental motors have been used in dental treatment procedures for many years.

Technical development creates handpieces and motors that are better and easier to use. The combination of these items is very important for good performance.

This International Standard combines the content of the following four ISO standards, which have now been withdrawn.

ISO 7785-1:1997, *Dental handpieces — Part 1: High-speed air turbine handpieces*

ISO 7785-2:1995, *Dental handpieces — Part 2: Straight and geared angle handpieces*

ISO 11498:1997, *Dental handpieces — Dental low-voltage electrical motors*

ISO 13294:1997, *Dental handpieces — Dental air-motors*

Dentistry — Handpieces and motors

1 Scope

This International Standard is applicable to handpieces and motors used in dentistry for patient contact, regardless of their construction. It specifies requirements, test methods, manufacturer's information, marking and packaging.

This International Standard is applicable to:

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

This International Standard is not applicable to:

- 1) intraoral camera handpieces;
- 2) powered polymerization handpieces;
- 3) air-powered scalers;
- 4) electrical powered scalers;
- 5) air-powder polishing handpieces;
- 6) multifunction handpieces (syringes).

NOTE See Annex A for clarification of the handpieces, attachments and motor types covered by this International Standard.

2 Normative references

The following referenced documents are indispensable for the application 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 1797-1, *Dentistry — Shanks for rotary instruments — Part 1: Shanks made of metals*

ISO 1797-2, *Dental rotary instruments — Shanks — Part 2: Shanks made of plastics*

ISO 1942, *Dentistry — Vocabulary*

ISO 3964, *Dental handpieces — Coupling dimensions*

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 7405, *Dentistry — Evaluation of biocompatibility of medical devices used in dentistry*

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, *Dental equipment — Graphical symbols*

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, *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, *Medical devices — 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.

3.1

air motor

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

3.2

air-powered powder jet handpiece

handpiece powered by air, designed to transfer powder to the patient

3.3

air-powered scaler

handpiece powered by air, with an oscillating working part

3.4

angle handpiece

handpiece with an angle between the input and output axes, driven by an air motor or an electrical motor or with an internal power supply

3.5

contra-angle handpiece

angle handpiece with one or more additional angles placed so as to bring the working part of the instrument or tool approximately into line with the main axis of the handpiece

3.6

non-metallic chuck

handpiece chuck with non-metallic material on the contact surface of the shank holding mechanism

3.7

electrical motor

motor powered by electrical energy, which is supplied by a dental unit