INTERNATIONAL STANDARD

ISO 14457

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Dentistry — Handpieces and motors

Médecine bucco-dentaire — Pièces à main et moteurs

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ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web 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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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

ISO 14457 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 4, *Dental instruments*.

ISO 14457 cancels and replaces ISO 7785-1:1997, ISO 7785-2:1995, ISO 11498:1997 and ISO 13294:1997, which have been technically revised.

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This International Standard combines the content of the following four ISO standards, which have now been withdrawn.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

3.8
electrical powered scaler
handpiece powered by electrical energy, with an oscillating working part

3.9
working part
part of a fixed or interchangeable instrument connected to a handpiece

3.10
handpiece
powered handheld instrument used to operate a rotary, oscillating or reciprocating working part

3.11
handpiece attachment
extension part of a handpiece designed to hold a working part

3.12
handpiece chuck
part of the handpiece designed to securely hold the shank of a working part

3.13
high-speed air turbine handpiece
handpiece propelled by a small air-powered turbine (or rotor), capable of high speed, which is integrated into the head of the handpiece and has a chucking device coaxial with the turbine

3.14
intraoral camera handpiece
handpiece designed to take optical images in the oral cavity of the patient

3.15
motor
device, powered by air or electricity supplied by a dental unit, designed to transform energy into movement

3.16
polymerization handpiece
handpiece producing light that is applied directly to polymerizable dental materials in the oral cavity of a patient

3.17
prophy handpiece
angle handpiece used for dental prophylaxis, driven by an air motor or an electrical motor

3.18
rotary instrument
rotating instrument used in a high-speed air turbine handpiece or in a straight and geared-angle handpiece, consisting of a shank and a working end used for dental procedures

3.19
reciprocating instrument
oscillating instrument used in a high-speed air turbine handpiece, or in a straight and geared-angle handpiece, consisting of a shank and a working end used for dental procedures

3.20
straight handpiece
handpiece with the input and output axes in alignment, driven by an air motor or an electrical motor or with an internal power supply

3.21
transmission part
small tool (rotary or reciprocating) designed to transmit energy from the shank to the working end

3.22
working end
distal end of a rotary or oscillating instrument intended for direct use in the oral cavity of the patient

4 Classification of handpieces

Handpieces are classified according to their gear ratio into three types as given in Table 1.

Table 1 — Gear ratios for handpieces

Type	Gear ratio	Resulting rotating speed	Resulting torque	Colour
1	>1:1	lower	higher	green
2	1:1	constant	constant	blue
3	1:>1	higher	lower	red

5 Requirements and performance

5.1 General

The construction of handpieces shall provide for their safe and reliable operation. Their use and manipulation shall be easy and comfortable for the operator. These requirements shall be compliant with IEC 62366.

If field-repairable, the handpieces shall be capable of being easily disassembled and reassembled for maintenance and repair utilizing either readily available tools or special tools supplied by the manufacturer.

Electrical requirements are only applicable to electrically powered handpieces.

5.2 Materials

Tests for biocompatibility shall be in accordance with ISO 7405 and ISO 10993-1.

5.3 Drop test

IEC 60601-1:2005, 15.3.4.1, applies.

5.4 Noise level

The A-weighted sound pressure value generated by the handpiece shall not exceed 80 dB.

Test in accordance with 7.16.

NOTE This test applies to each handpiece as a system in actual use, i.e. each attachment used with its respective drive motor.

5.5 Surfaces

Particular attention should be given to providing secure gripping surfaces for operator manipulation under normal conditions of use.

Test in accordance with IEC 62366.

NOTE In order to reduce glare, highly polished surfaces should be avoided.

5.6 Power supply

5.6.1 Electrical power supply

The following requirements are applicable for:

a) electrical motors;

b) handpieces, integrated with the motor;

c) prophy handpieces, integrated with the motor.

The requirements shall be specified by the manufacturer and shall comply with ISO 7494-1.

Test in accordance with 7.3.

5.6.2 Air supply

5.6.2.1 Air-powered handpiece

The following requirements are applicable for:

a) high-speed air turbine handpieces;

b) air motors;

c) handpieces, integrated with the air motor;

d) prophy handpieces, integrated with the air motor.

Air-powered handpieces shall be operated by a pressurized air supply in accordance with the manufacturer's instructions. The necessary flow rate shall be < 66 Nl/min in a pressure range of (300 ± 100) kPa [(3,0 ±1,0) bar].

Test in accordance with 7.4.

5.6.2.2 Motor cooling air

The following requirement is applicable for electrical motors.

If the electrical motor is equipped with an air cooling system, the maximum air flow rate should not be more than 40 Nl/min and the pressure range should be 250 kPa to 500 kPa (2,5 bar to 5,0 bar). The electrical motor should have an outlet connection for motor air cooling.

Test in accordance with 7.8.

5.6.2.3 Spray air supply

Spray air coolant capability may be provided at the discretion of the manufacturer. Handpieces having spray air coolant capability shall direct air to the operating area of the rotary instrument. If water and air are used simultaneously, a cooling mist shall be created and transmitted to the cutting area of a rotary instrument. The handpiece shall be capable of attaining an air flow rate of at least 1,5 Nl/min at 200 kPa (2,0 bar).

Motors shall be equipped, if applicable, to transmit air to a handpiece attachment. The equipment shall be capable of attaining an air flow rate of at least 1,5 Nl/min at 200 kPa (2,0 bar).

Test in accordance with 7.5.

5.6.3 Water supply

The handpiece, if applicable, shall provide a water coolant capability to the operating area of the working part at a flow rate of at least 50 ml/min at 250 kPa (2,5 bar).

Test in accordance with 7.6.

5.7 Air and water pressure

Applicable motors and handpieces shall remain intact, i.e. shall not rupture or burst, when subjected to a pressure 50 % above the manufacturer’s maximum recommended operating pressure.

Test in accordance with 7.7.

5.8 Temperature

5.8.1 Temperature rise of housing

IEC 80601-2-60:2012, 201.11.1.1, applies.

Test in accordance with 7.18.

5.8.2 Temperature, excessive

IEC 80601-2-60:2012, 201.11.1.2.2, applies.

Test in accordance with 7.19.

5.9 Vibrations

ISO 5349-1 and ISO 5349-2 apply.

5.10 Resistance to reprocessing

All handpieces or parts of handpieces shall withstand 250 reprocessing cycles, internally and externally, as defined by the manufacturer’s instructions, without deterioration in performance or showing signs of corrosion. The reprocessing cycle shall include the recommended methods of cleaning, disinfection and sterilization.

If the manufacturer states a lower number of permitted reprocessing cycles, then this shall be used in place of the 250 stated above.

Test in accordance with 7.20.

5.11 Leakage and/or ingress of water

IEC 60601-1:2005, 11.6, applies.

5.12 Electromagnetic compatibility

Test in accordance with 5.6.1.

5.13 Operating controls

The following requirements are applicable for all handpieces and motors described in this International Standard.

Operating controls shall be designed and located to minimize accidental activation. Graphical symbols for operating controls and performance shall be in accordance with ISO 9687.

By the use of operating controls, air motors shall be capable of changing speed as specified by the manufacturer. The controls shall be provided at the air motor itself or at the dental unit.

The motor, or motor connected to a dental unit, shall be provided with operator controls to allow clockwise and anticlockwise rotation, as described by the manufacturer. The controls shall be provided at the motor itself or at the dental unit.