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Dentistry — Handpieces and motors

Médecine bucco-dentaire — Pièces à main et moteurs

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Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
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Foreword

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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.

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

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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.

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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) prophy 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).

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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*

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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*

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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)

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3.5
contra-angle handpiece
angle handpiece (3.4) with one or more additional angles placed so as to bring the *working part* (3.9) of the instrument or tool approximately into line with the main axis of the *handpiece* (3.10)

3.6
non-metallic chuck
handpiece (3.10) chuck with non-metallic material on the contact surface of the shank holding mechanism

3.7
electrical motor
motor (3.14) powered by electrical energy, which is supplied by a dental unit

3.8
electrical-powered scaler
handpiece (3.10) powered by electrical energy, with an oscillating working part

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

3.10
handpiece
powered handheld instrument used to operate a rotary, oscillating or reciprocating *working part* (3.9)

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3.11
handpiece chuck
part of the *handpiece* (3.10) designed to securely hold the shank of a *working part* (3.9)

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3.12
high-speed air turbine handpiece
handpiece (3.10) 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

3.13
intraoral camera handpiece
handpiece (3.10) designed to take optical images from the oral cavity of the patient

3.14
motor
device, powered by air or electricity supplied by a dental unit, designed to transform energy into movement

3.15
multifunction handpiece
syringe
handpiece (3.10), which is supplied with air and water, and transfers the water and air directly or as air-water mixture (spray) in a cold or warm state in the patient's mouth

3.16
polymerization handpiece
handpiece (3.10) producing light that is applied directly in the oral cavity of a patient, mainly to polymerize dental materials

3.17
prophy handpiece
angle handpiece (3.4) used for dental prophylaxis, driven by an *air motor* (3.1) or an *electrical motor* (3.7)

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3.18
rotary instrument
rotating instrument used for dental procedures in a *high-speed air turbine handpiece* (3.12), a straight or a geared-angle handpiece, consisting of a shank and a *working end* (3.21)

3.19
reciprocating instrument
oscillating instrument used in a straight or geared-angle handpiece, consisting of a shank and a *working end* (3.21) used for dental procedures

3.20
straight handpiece
handpiece (3.10) with the input axe and the output axe are colinear, 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)

3.21
working end
distal end of a rotary, oscillating or *reciprocating instrument* (3.19) intended for direct use in the oral cavity of the patient

4 Classification of handpieces

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

This classification applies only to handpieces for rotary and reciprocating instruments.

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Table 1 — Classification for handpieces

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Class	Gear ratio	Resulting speed	Resulting torque	Colour
1	>1:1	lower	higher	green
2	1:1	constant	constant	blue
3	1:>1	higher	lower	red
4	—	Movement as given by the manufacturer		yellow
NOTE Colour marking is optional.				

5 Requirements and performance

5.1 General

The construction of handpieces and motors 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 80601-2-60 and IEC 62366-1.

If field-repairable, the handpieces and motors 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 and motors.

All pressure values given in the requirements are flow pressure values.

5.2 Materials

Materials for the handpiece and/or motor shall meet all requirements of this document. Choice of materials shall be at the discretion of the manufacturer.

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Material tests for biocompatibility shall be in accordance with 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 level generated by the handpiece and motor or by the high-speed air turbine handpiece shall not exceed 80 dB.

Test in accordance with 7.17.

NOTE This test applies to each handpiece and motor as a system in actual use, i.e. each handpiece 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 62366-1.

In order to reduce glare, highly polished surfaces are intended to be avoided.

5.6 Power supply

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5.6.1 Electrical power supply

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This requirement applies to all the electric-powered handpieces and motors not only for the movement power but also lighting or revolution speed feedback.

The requirements for electrical power supply shall be specified by the manufacturer and shall comply with IEC 60601-1 and IEC 80601-2-60. If applicable ISO 7494-1 shall apply.

Test in accordance with 7.3.

5.6.2 Air supply

5.6.2.1 Air-powered handpieces and motors

The following requirements are applicable for:

a) high-speed air turbine handpieces;

b) air motors;

c) handpieces with integrated air motor;

d) prophy handpieces with integrated air motor.

Air-powered handpieces and motors shall be operated by a pressurized air supply in accordance with the manufacturer's instructions. The necessary flow rate shall be <80 NL/min at a pressure of (300 ± 100) kPa [(3,0 ± 1,0) bar].

NOTE NL/min indicates normal litres per minute, the amount of air that flows through a pipe calculated back to "normal" conditions (0 °C, relative humidity 0 % and 1 atm or 1,013 25 bar).

Test in accordance with 7.4.

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5.6.2.2 Motor cooling air

The following requirements are applicable for electrical motors.

If the electrical motor is equipped with an air cooling system, the maximum airflow rate taken from the electrical motor supply hose shall be not more than 40 NL/min and the pressure range at the connector between electrical motor and supply hose shall be 250 kPa to 500 kPa (2,5 bar to 5,0 bar). The electrical motor shall have an outlet for motor cooling air.

Test in accordance with 7.8.

5.6.2.3 Handpiece cooling air provided by the motor

The following requirements are applicable for motors that are intended to supply handpieces with handpiece cooling air through the motor nozzle of a coupling system according to ISO 3964.

If the motor is equipped with an air cooling system, the motor coupling system according to ISO 3964 shall be able to transmit a cooling air flow no less than 5 NL/min and no more than 40 NL/min at the pressure recommended by the manufacturer. The recommended pressure shall be in a pressure range of 250 kPa to 500 kPa (2,5 bar to 5,0 bar).

Test in accordance with 7.9.

5.6.2.4 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 working end of the rotary instrument. If water and air are used simultaneously, a cooling mist shall be created and transmitted to the working end of the rotary instrument. If spray air functionality is separate from drive air, the handpiece shall be capable of attaining an airflow rate of at least 1,5 NL/min at 200 kPa (2,0 bar).

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The motor, if applicable, shall provide air to a handpiece at a flow rate of at least 1,5 NL/min at 250 kPa (2,5 bar).

Test in accordance with 7.5.

5.6.3 Water supply

The handpiece, if applicable, shall provide a coolant capability to the working end of the instrument at a flow rate of at least 50 ml/min at 200 kPa (2,0 bar).

The motor, if applicable, shall provide water to a handpiece 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 manufacturers maximum recommended operating pressure.

Test in accordance with 7.7.

5.8 Temperature

5.8.1 General

The following requirements are not applicable for air motors and high-speed air turbine handpieces.

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5.8.2 Temperature rise of housing

5.8.2.1 Temperature rise for motors

IEC 80601-2-60 applies.

Test in accordance with 7.19.1.

5.8.2.2 Temperature rise for handpieces

The maximum rate of temperature rise of handpiece housing on both the operator side and the patient side shall not exceed 5 °C per second in any condition of use. The test shall be performed in the condition of reasonably foreseeable misuse as defined in 7.19.2.

Test in accordance with 7.19.2.

5.8.3 Excessive temperature

5.8.3.1 Excessive temperature for motors

IEC 80601-2-60 applies.

Test in accordance with 7.20.1.

5.8.3.2 Excessive temperature for handpieces

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Handpieces have an operator side and a patient side.

Maximum allowable temperatures are given in Table 2. Test shall be performed in both normal conditions and reasonably foreseeable misuse conditions.

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Test in normal conditions in accordance with 7.20.2.1.

Test in reasonably foreseeable misuse conditions in accordance with 7.20.2.2.

Table 2 — Allowable maximum temperatures

Applied part		Allowable maximum temperature °C			Conditions	
		Metal	Glass, porcelain, vitreous material	Plastic, rubber	Normal	Reasonably foreseeable misuse
Having contact with operator		56	66	71	X	
Having contact with operator		65	80	80		X
Having contact with patient for a time "t"	$t < 1$ min	51	56	60	X	X
Having contact with patient for a time "t"	1 min ≤ t < 10 min	48	48	48	X	X
Having contact with patient for a time "t"	10 min ≤ t	43	43	43	X	X

If the surface temperature of an applied part exceeds the values in Table 2, the maximum temperature shall be disclosed in the instructions for use. The clinical effects with respect to characteristics, such as body surface, maturity of patients, medications being taken or surface pressure, shall be determined and documented in the risk management file.

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