



BSI Standards Publication

Dentistry - Handpieces and motors

National foreword

This British Standard is the UK implementation of EN ISO 14457:2017. It is identical to ISO 14457:2017. It supersedes BS EN ISO 14457:2012, which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/106/4, Dental Instruments and Equipment.

A list of organizations represented on this committee can be obtained on request to its secretary.

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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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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of an identical text or by endorsement, at the latest by June 2018, and conflicting national standards shall be withdrawn at the latest by June 2018.

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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)

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)

3.11

handpiece chuck

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

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)

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.

Table 1 — Classification for handpieces

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.

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

5.6.1 Electrical power supply

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) prophylaxis 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 $<80 \text{ NL/min}$ at a pressure of $(300 \pm 100) \text{ kPa}$ [$(3,0 \pm 1,0) \text{ bar}$].

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](#).

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).

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.

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

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.

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”	$t < 1 \text{ min}$	51	56	60	X	X
Having contact with patient for a time “t”	$1 \text{ min} \leq t < 10 \text{ min}$	48	48	48	X	X
Having contact with patient for a time “t”	$10 \text{ min} \leq t$	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.

5.9 Vibrations

ISO 5349-1 and ISO 5349-2 shall apply.

A manufacturer may refrain from providing a test report according to ISO 5349-1 and ISO 5349-2 with justification.

5.10 Resistance to reprocessing

All dental handpieces and motors or parts of dental handpieces and motors shall withstand 250 reprocessing cycles as specified by the manufacturer without deterioration in performance. This entails that all other requirements in this document be met after the necessary reprocessing cycles have been completed.

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

Test in accordance with [7.21](#).

5.11 Leakage and/or ingress of water

IEC 60601-1:2005+AMD1:2012, 11.6 applies.

5.12 Electromagnetic compatibility

IEC 60601-1-2 applies, if applicable.

5.13 Operating controls

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

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

The motor, or motor connected to a dental unit, if applicable, 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.

IEC 60601-1:2005+AMD1:2012, 15.1 applies.

5.14 Usability

Evaluation shall be carried out following IEC 62366-1.

5.15 Connection and supply

5.15.1 General

The following requirements are applicable for:

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

Handpieces and motors shall be capable of being disconnected from and reconnected to interfaces without any special tool.

Test in accordance with [7.2](#).

5.15.2 Connections for high-speed air turbine handpiece and air motor connectors

The following requirements are applicable for:

- a) high-speed air turbine handpieces;
- b) air motors.

The configuration, dimensions and tolerances of connections of the dental handpieces for drive air, exhaust air, spray air, cooling water and fibre-optic light, as appropriate, shall be in accordance with ISO 9168.

If the connection of the handpieces and/or motor is made by a quick connector, the connection shall be in accordance with the manufacturer's specification. In addition, if the quick connector is independent from the hose, the quick connector shall be in accordance with ISO 9168.

Test in accordance with [7.10](#).

5.15.3 Connection for handpieces and motors

5.15.3.1 General

The configuration, dimensions and tolerances of the back end of the handpieces and front end of the air motor or electrical motor shall comply with ISO 3964.

Test in accordance with [7.10](#).

5.15.3.2 Connections for prophylaxis handpieces

5.15.3.2.1 Overview

The following requirements are applicable for prophylaxis handpieces.

5.15.3.2.2 Dimensions

The dimensional aspects of the housing shall comply with the specifications listed in [Figure 1](#) and [Figure 2](#).

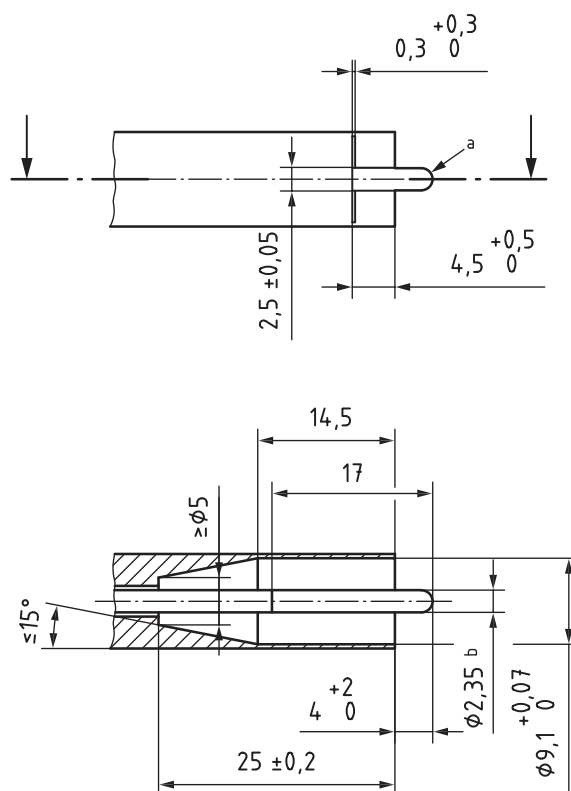
Test in accordance with [7.11](#).

5.15.3.2.3 Mandrel

The outer diameter of the long-gear mandrel shall be compatible with the coupling specifications listed in [Figure 1](#). The allowable range will be 2,350 mm $\begin{smallmatrix} +0 \\ -0,016 \end{smallmatrix}$ mm for metallic materials and 2,350 mm $\begin{smallmatrix} +0 \\ -0,05 \end{smallmatrix}$ mm for plastic materials, measured at a distance of 17 mm from the terminal end of the mandrel. Should the mandrel be shaped such that there exists a minimum and maximum diameter, the maximum diameter shall fall within the allowable range.

Test in accordance with [7.12](#).

Dimensions in millimetres



Key

a Corner or round cut.

b Tolerances:

for metallic and ceramic materials: $\begin{matrix} +0 \\ -0,016 \end{matrix}$;

for plastic materials: $\begin{matrix} +0 \\ -0,05 \end{matrix}$.

Figure 1 — Angle end dimensions for connection

Dimensions without tolerances in [Figure 1](#) shall be in accordance with ISO 2768-1 and ISO 2768-2.

Dimensions in millimetres

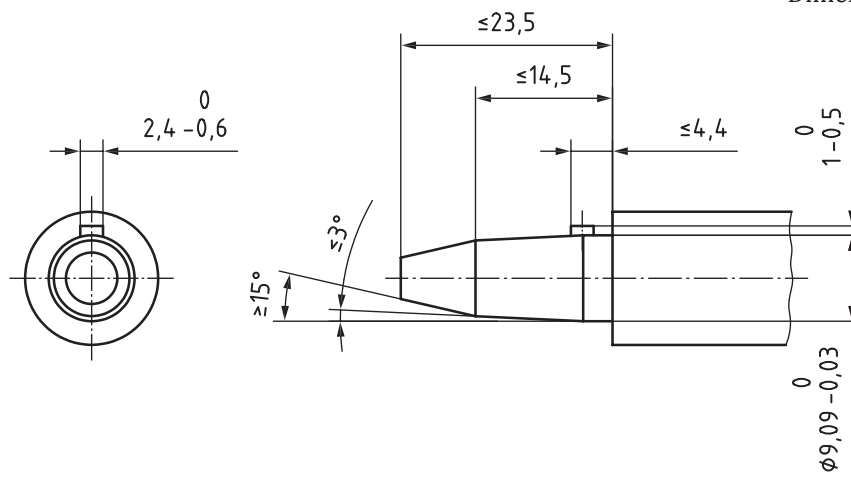


Figure 2 — Handpiece nose dimension for connection

Dimensions without tolerances in [Figure 2](#) shall be in accordance with ISO 2768-1 and ISO 2768-2.

5.16 Chuck system for shanks

5.16.1 Metallic chuck system

Handpieces with metallic chuck systems shall be capable of accepting rotary instruments of corresponding mandrels of Type 1, Type 2 and Type 4 in this document or test mandrel Type 5 as described in ISO 13295.

The force required to extract the test mandrels (see [Figure 3](#)) from the chuck system shall be at least 22 N for Type 5 and 32 N for Type 1 and Type 3. When locked in the chuck system, test mandrel Type 5 shall transmit a torque of at least 0,016 N·m; Type 1 and Type 3 shall transmit a torque of at least 0,02 N·m without slipping or showing visible signs of destruction.

Test in accordance with [7.13](#).

5.16.2 Non-metallic chuck system

Handpieces with non-metallic chuck systems shall be capable of accepting rotary instruments of corresponding mandrels of Type 4.

The force required to extract test mandrel Type 5 from the non-metallic chuck system shall be at least 12 N. When held in the chuck, test mandrel Type 5 shall transmit a torque of at least 0,008 N·m.

Test in accordance with [7.13](#).

5.17 Test mandrel

The test mandrel shall have the dimensions shown in [Figure 3](#).

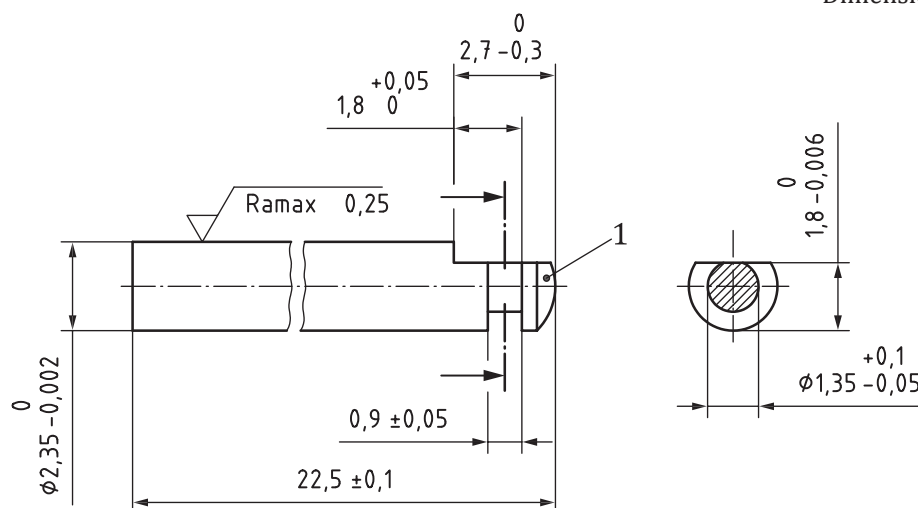
The shape of the shank end for all types of test mandrels shall be either conical or rounded at the discretion of the manufacturer or test house to avoid damaging of the chuck system.

The mandrel cylindricity shall not exceed a value of 2,5 µm and its hardness shall exhibit a value of at least 610 HV5.

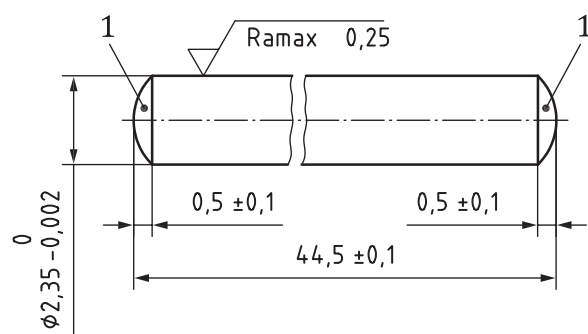
Test in accordance with [7.12](#).

Dimensions without tolerances in [Figure 3](#) shall be in accordance with ISO 2768-1 and ISO 2768-2.

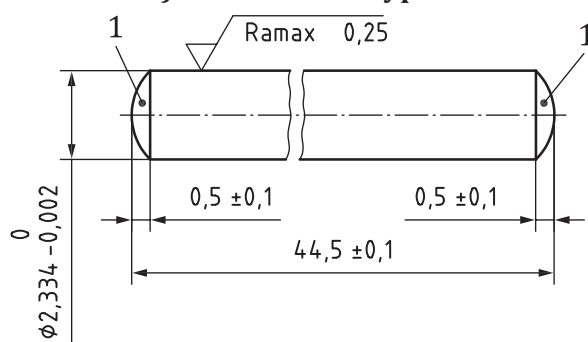
Dimensions in millimetres



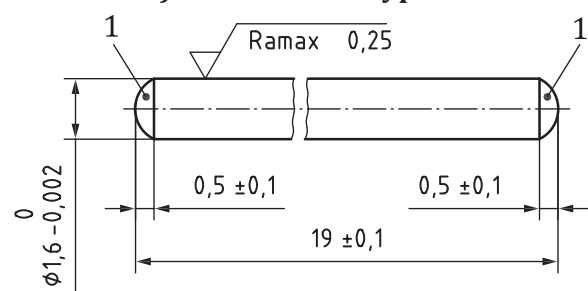
a) Test mandrel Type 1



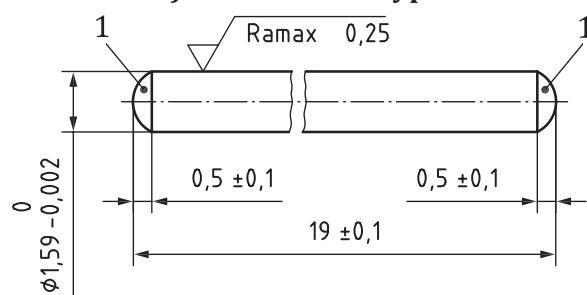
b) Test mandrel Type 2



c) Test mandrel Type 3



d) Test mandrel Type 4



e) Test mandrel Type 5

Key

1 conical or rounded end

Figure 3 — Five types of test mandrel

5.18 Speed

The free-running speed of the handpieces and motors shall be within $\pm 10\%$ of that specified in the manufacturer's instructions for use.

Prophy handpieces shall be capable of operating between 1 200 r/min and 3 000 r/min.

Test in accordance with [7.18](#).

5.19 Eccentricity

The following requirements are applicable for:

- a) high-speed air turbine handpieces;
- b) straight and angle handpieces;
- c) electrical motor handpieces, angle;
- d) electrical motor handpieces, straight;
- e) prophy handpieces.

The eccentricity of test mandrel Type 4 for high-speed air turbine handpieces, Types 1, 2 and 4 for straight and angle handpieces and Type 2 for prophy handpieces in rotation and without applied load shall not exceed a total dynamic eccentricity of 0,03 mm for high-speed air turbine handpieces and 0,08 mm for all other handpieces.

Test in accordance with [7.15](#).

5.20 Stall torque

The following requirements are applicable for high-speed air turbine handpieces.

The torque shall be at least 0,000 5 N·m.

Test in accordance with [7.16](#).

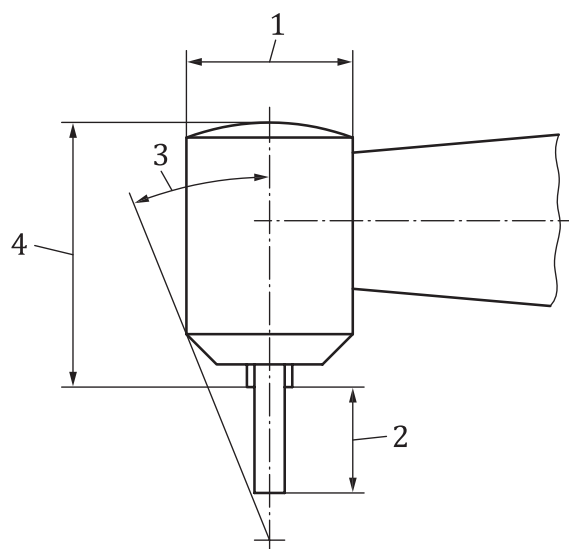
5.21 Dimensions of head and nose

The following requirements are applicable for:

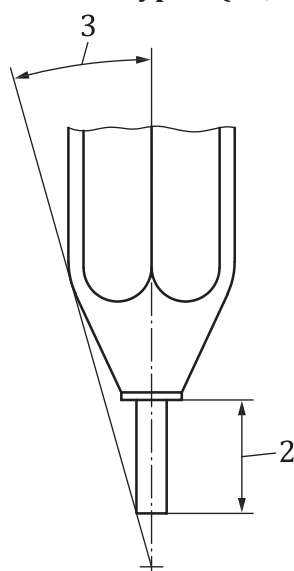
- a) high-speed air turbine handpieces;
- b) straight and angle handpieces;
- c) electrical motor handpieces, angle;
- d) electrical motor handpieces, straight.

If the manufacturer includes the head and nose dimensions in the operator's manual, they shall be the dimensions as shown in [Figure 4](#) and shall be expressed to an accuracy of $\pm 0,1$ mm of the length or $\pm 1^\circ$ on angles.

Test in accordance with [7.14](#).



a) Projection with test mandrel Type 1 (22,5 mm) or Type 4 (19 mm)



b) Projection with test mandrel Type 2 (44,5 mm)

Key

- 1 maximum diameter
- 2 projection with test mandrel length = 19 mm, 22,5 mm or 44,5 mm
- 3 visibility angle
- 4 maximum length of non-rotating component of the head

Figure 4 — Visibility angle of test mandrel used for measuring head and nose dimensions

5.22 Output power of high-speed air turbine handpiece

The following requirements apply to high-speed air turbine handpieces.

If the manufacturer provides a value for the output power of the handpiece in the instructions for use, they shall also provide the supply air pressure, as measured at the inlet to the handpiece, required to produce that power.

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