INTERNATIONAL STANDARD

ISO 14457

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Dentistry — Handpieces and motors

Médecine bucco-dentaire — Pièces à main et moteurs

Reference number
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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This International Standard combines the content of the following four ISO standards, which have now been withdrawn.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 [$(3{,}0 \pm 1{,}0)$ 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.

IEC 60601-1:2005, 15.1, applies.

5.14 Usability

IEC 62366 applies.

5.15 Connection and supply

5.15.1 General

The following requirements are applicable for:

a) high-speed air turbine handpieces;

b) handpiece attachments;

c) air motors;

d) electrical motors.

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

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 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 is made by a quick connector, the connector shall be in accordance with ISO 9168.

Test in accordance with 7.10.

5.15.3 Connector for handpiece attachments and motors

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

Test in accordance with 7.9.

5.15.4 Connections for prophy handpieces

5.15.4.1 General

The following requirements are applicable for prophy handpieces.

5.15.4.2 Dimensions

The dimensional aspects of the housing shall comply with the specifications listed in Figure 1 and Figure 2. Test in accordance with 7.10.

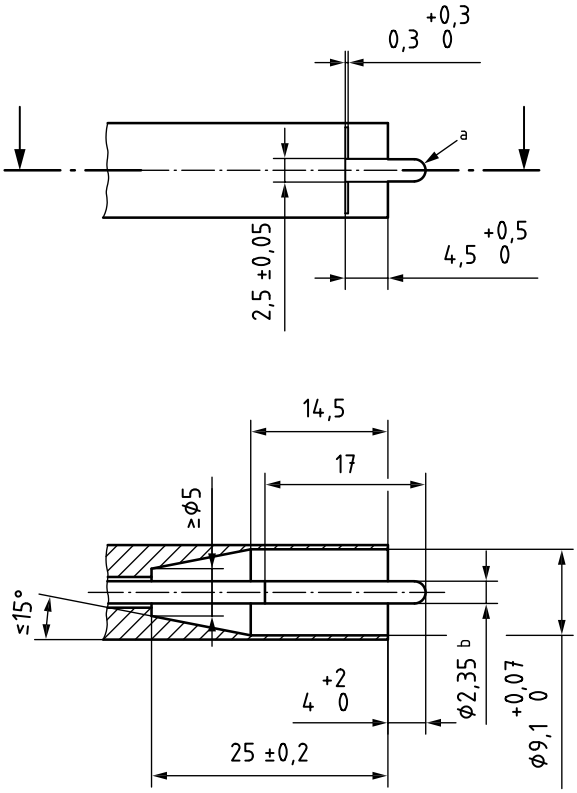
5.15.4.3 Mandrel

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 $\frac{+0}{-0,016}$ mm for metallic materials and 2,350 mm $\frac{+0}{-0,05}$ mm for

plastic materials, measured at a distance 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 is required to fall within the allowable range.

Test in accordance with 7.10.

Dimensions in millimetres



[a] Corner or round cut.

[b] Tolerances: 1) for metallic materials: $^{0}_{0,016}$ 2) for plastic materials: $^{0}_{0,05}$.

Figure 1 — Angle end dimensions for connection

Dimensions in millimetres

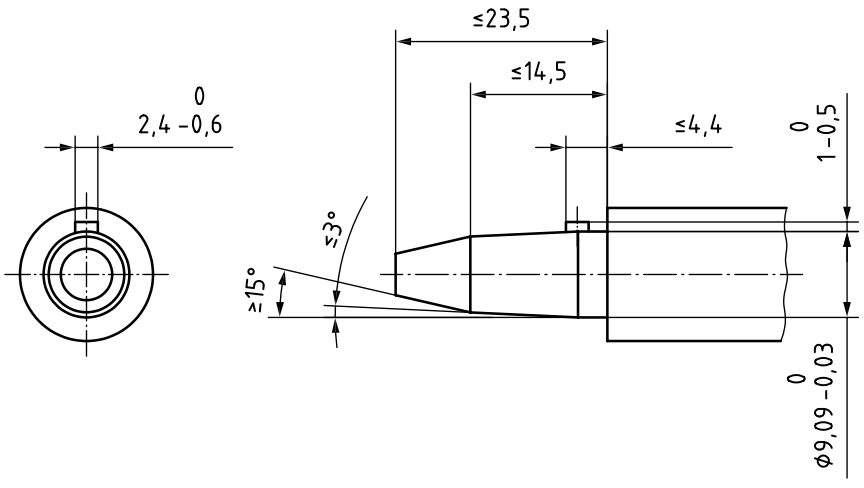


Figure 2 — Handpiece nose dimensions for connection

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, Type 4 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 45 N for 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 (in rotation and linear movement) or showing visible signs of destruction.

Test in accordance with 7.12.

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 5.

The manufacturer of a non-metallic chuck system shall describe in the risk management documentation any potentially increased risk particular to using the non-metallic chuck.

The force required to extract test mandrel Type 3 from the non-metallic chuck system shall be at least 12 N. When held in the chuck, test mandrel Type 3 shall transit a torque of at least 0,008 N·m.

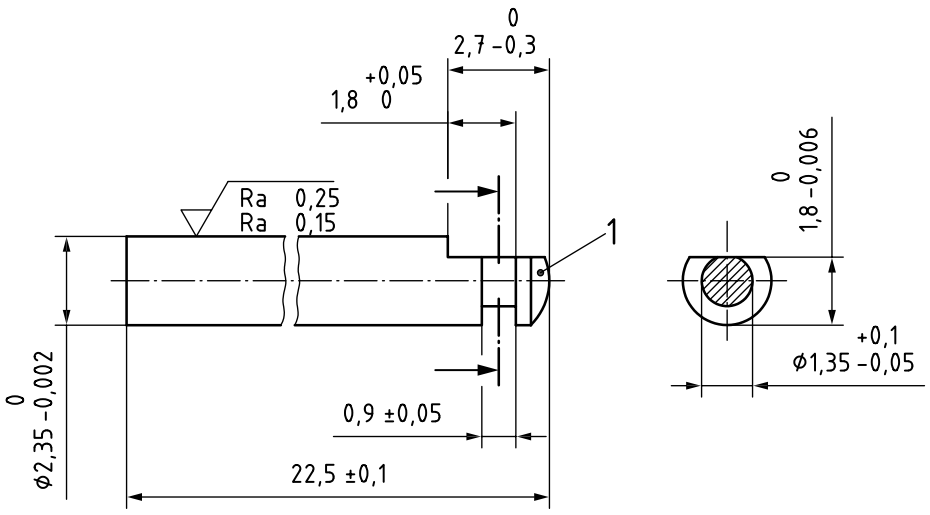
Test in accordance with 7.12.

5.17 Test mandrel

The test mandrel shall have the dimensions shown in Figure 3.

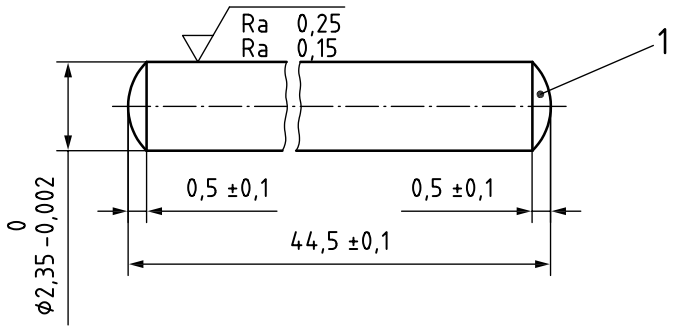
Test in accordance with 7.11.

Dimensions in millimetres



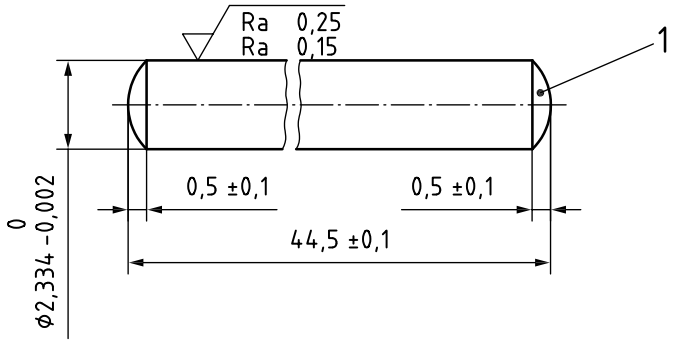
a) Test mandrel Type 1

Dimensions in millimetres



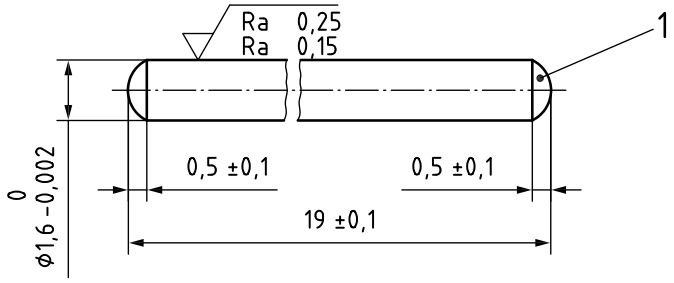
b) Test mandrel Type 2

Dimensions in millimetres



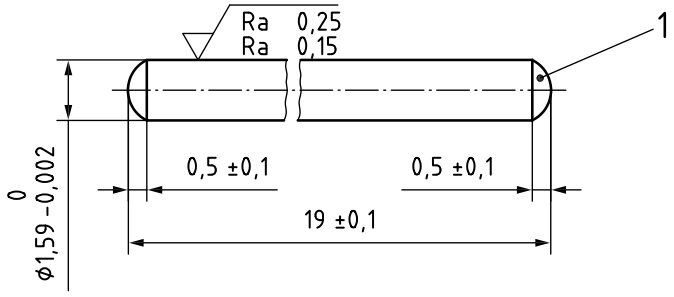
c) Test mandrel Type 3

Dimensions in millimetres



d) Test mandrel Type 4

Dimensions in millimetres



e) Test mandrel Type 5

Key

1 rounded end

Figure 3 — Types of test mandrel

5.18 Speed

The free-running speed of the handpieces shall be in accordance with the manufacturer's instructions at a tolerance of ±10 % as specified.

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

Test in accordance with 7.17.

5.19 Eccentricity

The following requirements are applicable for:

a) air-powered turbines;

b) handpiece attachments;

c) prophy handpieces.

The eccentricity of test mandrel Type 4 for air-powered turbines, Types 1, 2 and 4 for handpiece attachments and Type 2 for prophy handpieces in rotation and without applied load shall not exceed a total indicated run-out of 0,03 mm for turbines and 0,08 mm for handpiece attachments and prophy handpieces.

Test in accordance with 7.14.

5.20 Torque

The following requirements are applicable for air-powered turbines.

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

Test in accordance with 7.15.

5.21 Dimensions of head and nose

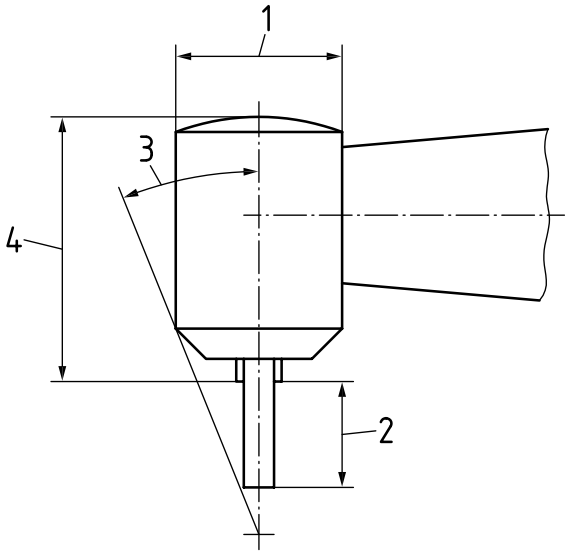
The following requirements are applicable for:

a) air-powered turbines;

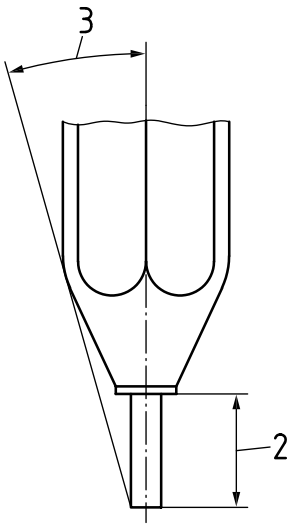
b) handpiece attachments.

If the manufacturer includes the head dimensions in the operator's manual, they shall be the dimensions as shown in Figure 4 and shall be expressed to an accuracy of ±0,1 mm of the length or ±1° on angles.

Test in accordance with 7.13.1.



a) Projection with test mandrel 19 mm



b) Projection with test mandrel 44,5 mm

Key

1 maximum diameter
2 projection with test mandrel length = 19 mm (a) or 44,5 mm (b)
3 visibility angle
4 maximum length of handpiece head including the rotor shaft

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

6 Sampling

At least one handpiece for each model series shall be evaluated for compliance with this International Standard.

7 Testing

7.1 General test conditions

All tests described in this International Standard are type tests.

Unless otherwise specified, tests shall not be repeated.

7.2 Visual inspection

Visually inspect without magnification to determine compliance with the requirements.

7.3 Power supply — Electrical

The requirements given in IEC 60601-1:2005 and IEC 80601-2-60 apply.

7.4 Power supply — Air

7.4.1 Apparatus

7.4.1.1 Flowmeter, with an accuracy of 5 % of expected value, to measure the motor supply air flow rate.

7.4.1.2 Pressure gauges, with an accuracy of 5 % of expected value, to measure the air supply pressure at the inlet of the air motor.

7.4.2 Procedure

Install the flowmeter at the handpiece air connector and measure the motor air supply flow rate while operating the handpiece at the maximum recommended operating pressure. Air flow measurements shall be corrected to standard flow rates.

7.5 Spray air supply

7.5.1 Apparatus

7.5.1.1 Flowmeter, with an accuracy of 5 % of expected value, to measure the spray air flow rate.

7.5.1.2 Pressure gauge, with an accuracy of 5 % of expected value, to measure the air supply pressure to the handpiece inlet.

7.5.2 Procedure

To measure the cooling air flow of handpieces, adjust the air supply pressure at the handpiece inlet to 200 kPa (2,0 bar) and connect a flowmeter to the handpiece air outlet tube.

For motors, install the flowmeter at the motor connector and measure the spray air flow rate while operating the motor at 250 kPa. Air flow rate shall be corrected to standard flow rates. Record the air flow rate.

7.6 Spray water supply

7.6.1 Apparatus

7.6.1.1 Volumetric measuring jar, with an accuracy of 5 % of expected value, to measure the volume of cooling water.

7.6.1.2 Pressure gauge, with an accuracy of 5 % of expected value, to measure the water supply pressure to the handpiece inlet.

7.6.2 Procedure

To measure the cooling water flow of handpieces, adjust the water supply pressure at the handpiece inlet to 200 kPa (2,0 bar) and operate the handpiece for 1 min.

For motors, adjust the water supply pressure at the motor inlet to 250 kPa (2,5 bar) and operate the motor for 1 min. Record the volume of water collected.

7.7 Air and water pressure

7.7.1 Apparatus

7.7.1.1 Pressure gauge, capable of measuring the supply pressure to an accuracy of 5 % of the expected value.

7.7.2 Procedure

Operate the handpiece at 50 % above the recommended operating pressure for a period of 10 min.

Observe whether the handpiece ruptures or bursts.

7.8 Motor cooling air

7.8.1 Apparatus

7.8.1.1 Flowmeter, to measure with an accuracy of ±10 % (of expected value) the motor cooling air flow rate.

7.8.1.2 Pressure gauge, to measure with an accuracy of ±5 % (of expected value) the air supply pressure at the inlet of the low-voltage electrical motor.

7.8.2 Procedure

Install the flowmeter at the electrical motor connector and measure the motor cooling air flow rate while operating the motor at the maximum recommended speed. Air flow measurements shall be corrected to standard flow rates.

7.9 Connector for handpiece attachment and for air-powered handpiece

Testing shall be carried out by inspection and measurement, using appropriate measuring instruments, to fulfill the requirements given in ISO 3964 for handpiece attachments and ISO 9168 for air-powered handpieces, or according to the manufacturer's instructions.

7.10 Connection and supply

7.10.1 Apparatus

7.10.1.1 Measuring device, such as a gauge or dial indicator, with an accuracy of 0,01 mm for linear dimension and ±1° on angles.

7.10.2 Procedure

Measure and record the dimensions as shown in Figure 1 and Figure 2.

7.11 Test mandrels

The test mandrels shall be straight to within 0,002 5 mm and shall have a hardness of at least 610 HV 5.

Testing of hardness shall be carried out in accordance with ISO 6507-1.

Testing of dimensions shall be carried out by inspection and measurement, using readily available measuring instruments, to fulfil the requirements given in 5.15.4.3 and Figure 3.

7.12 Chuck for shanks

7.12.1 Extraction test

7.12.1.1 Apparatus

7.12.1.1.1 Spring force gauge, with an accuracy of ±0,5 N, to measure the extraction forces.

7.12.1.1.2 Test mandrel, as shown in Figure 3.

7.12.1.1.3 Measuring device, with an accuracy of 0,01 mm for linear dimension.

7.12.1.2 Procedure

Adjust the force gauge to register the maximum force exerted. The force to extract the test mandrel shall be increased gradually until the test mandrel moves by a maximum of 2 mm. Record the maximum force required to extract/pull out the test mandrel at least 0,2 mm.

7.12.2 Torque test

Apply the torque stated in 5.16.1 and 5.16.2 at which the mandrel shall not slip in the chuck.

7.12.2.1 Apparatus

7.12.2.1.1 Torque watch, with an accuracy that allows measurement of the recommended torque.

7.12.2.1.2 Test mandrel, as stated in 5.16.1 and 5.16.2 and shown in Figure 3.

7.12.2.1.3 Measuring device, with an accuracy of 0,01 mm for linear dimension.

7.12.2.2 Procedure

Check the torque in accordance with the requirements of 5.16.1 and 5.16.2. The test mandrel shall not slip in the chuck.

7.13 Dimensions (of head and nose)

7.13.1 Apparatus

7.13.1.1 Measuring device, such as a gauge or dial indicator, with an accuracy of 0,01 mm for linear dimension and ±1° on angles.

7.13.1.2 Test mandrel, as shown in Figure 3.

7.13.2 Procedure

Fully insert the test mandrel in the chuck. Measure and record the dimensions as shown in Figure 4.

7.14 Eccentricity

7.14.1 Apparatus

7.14.1.1 Non-contacting gauging system, such as a magnetic proximity gauge, laser or optical imaging system, with an accuracy of ±10 % of the measured value.

7.14.1.2 Test mandrel, as given in 5.19 and shown in Figure 3, to measure the dynamic eccentricity.

7.14.2 Procedure

A non-contacting optical imaging system may be used to measure the total dynamic eccentricity. Operate the handpiece in accordance with the manufacturer's instructions over the entire range of operating speeds. Measure the diameter of the mandrel face or distal end with the handpiece speed at zero and the operating speed at maximum. Calculate the total indicated run-out as the difference between the measured diameter at maximum operating speed and at zero.

7.15 Torque

7.15.1 Apparatus

7.15.1.1 Torque watch or dynamometer, with an accuracy of ±10 % of expected value.

7.15.2 Procedure

Install the working part in the handpiece in accordance with the manufacturer's instructions. Operate the handpiece at the maximum recommended air pressure and the maximum recommended air/water flow rate for at least 1 min, and apply a force so that the movement of the end of the working part becomes zero. Record the torque required (in N·m) to stop the working part.

7.16 Noise level

7.16.1 Apparatus

7.16.1.1 Precision sound level meter, meeting the requirements for a Type 1 instrument as specified in IEC 61672-1.

7.16.1.2 Non-rigid suspension system.

7.16.2 Test conditions

The measurements shall be taken in a room with dimensions greater than 2,5 m × 2,5 m × 2,5 m, or in a chamber with a free-field radius of at least 1 m. The background A-weighted noise level shall be less than 65 dBA. There shall be no hard reflective surface within a 1 m envelope of the handpiece under test. Foam or non-reflective material may be used to reduce reflections from hard surfaces.

7.16.3 Procedure

Suspend the handpiece in the centre of the chamber by means of a non-rigid suspension system. Operate the handpiece at the maximum recommended air pressure, for air-powered handpieces, or the maximum recommended speed for electric handpieces. Using the sound level meter, measure the maximum A-weighted sound pressure value level generated from the handpiece at a distance of 0,45 m from the head, perpendicular to the long axis of the handpiece.

7.17 Speed

7.17.1 Apparatus

7.17.1.1 Non-contact tachometer, such as a magnetic proximity gauge or photo-optic tachometer or spectrum analyser with appropriate transducer, accurate to 5 % of expected value.

7.17.1.2 Test mandrel, Type 1 or Type 2 or Type 4, as shown in Figure 3.

7.17.2 Procedure

Operate the handpiece, fitted with the test mandrel, at the maximum recommended driving power (air pressure, electric power).

Measure the speed and record the speed in revolutions per minute (r/min).

7.18 Temperature rise of housing

IEC 80601-2-60:2012, 201.11.1.3 f), applies.

7.19 Temperature, excessive

IEC 80601-2-60:2012, 201.11.1.3 g), applies.

7.20 Resistance to reprocessing

Carry out 250 reprocessing cycles as specified in the manufacturer's instructions.

Inspect the surfaces in accordance with 7.2 for signs of rust, pitting or any other surface defects to assess the corrosion resistance.

All requirements of this International Standard shall be met subsequent to this test.

8 Instructions for use, maintenance and service

Each handpiece and/or motor shall be accompanied by documents containing instructions for operation, operator maintenance, lubrication, safety and servicing.

Instructions shall include at least the following information, which is applicable to each type:

a) name and/or trademark and address of manufacturer or distributor;

b) model or type reference;

c) type and dimension of shank and minimum fitting length of shank in accordance with ISO 1797-1 and ISO 1797-2;

d) allowable maximum overall length and working diameter of the rotary instruments;

e) coupling identification for handpiece connection, if applicable;

f) recommended operating pressures of air and water, in SI units;

g) consumption of air, in litres per minute (l/min), and water, in millilitres per minute (ml/min), at the specified operating pressures;

h) recommended electrical power supply and rated electrical characteristics (e.g. voltage, frequency, fuse values) as given by the manufacturer, if applicable;

i) recommended spray supply, operating air pressure and capacity, if applicable;

j) rated torque and speed;

k) statement as to whether the tool for changing the handpiece and working parts is sterilizable (if required) and by what methods;

l) reprocessing instructions (cleaning, disinfecting, sterilizing) if applicable, as specified in ISO 17664;

m) statement as to whether the handpiece is field-repairable;

n) recommended lubricating instructions;

o) presence of light supply, if applicable;

p) accessories and working tools, if applicable;

q) any other instructions for safe and effective use (e.g. power setting limitations, liquid flow limitations) depending upon the specific model or handpiece;

r) statement that prophy handpieces intended for single use are to be used only once and then safely disposed of after one patient treatment.

9 Technical description

In addition, the following information shall be provided by the manufacturer:

a) list of spare parts required in general use;

b) schematic wiring diagrams, if applicable.

10 Marking

10.1 General

Graphical symbols used for marking handpieces and motors shall be in accordance with ISO 9687, ISO 15223-1 and ISO 21531.

10.2 Handpieces

Handpieces shall have at least the following marking:

a) manufacturer’s name or trademark;

b) serial number;

c) model or type reference;

d) mark to indicate autoclave ability, if applicable;

e) for parts of single-use handpieces, if sold as a sterile product, the “use by” date on the packaging;

f) for working parts or their packaging, a manufacturer’s code.

10.3 Motors

Motors shall have at least the following marking:

a) manufacturer’s name or trademark;

b) serial number;

c) model or type reference.

11 Labelling

Graphical symbols used for labelling shall be in accordance with ISO 9687, ISO 15223-1 and ISO 21531.

The packaging of handpieces and working parts shall be labelled as follows:

a) manufacturer's name or trademark;

b) serial number or lot number;

c) model or type reference (e.g. catalogue number);

d) for working parts, mark to indicate autoclaveability, if applicable;

e) for single-use devices, the symbol for "Do not re-use".

12 Packaging

Handpieces and motors shall be packaged for transportation at the discretion of the manufacturer in such a way that no damage can occur during anticipated transport conditions.

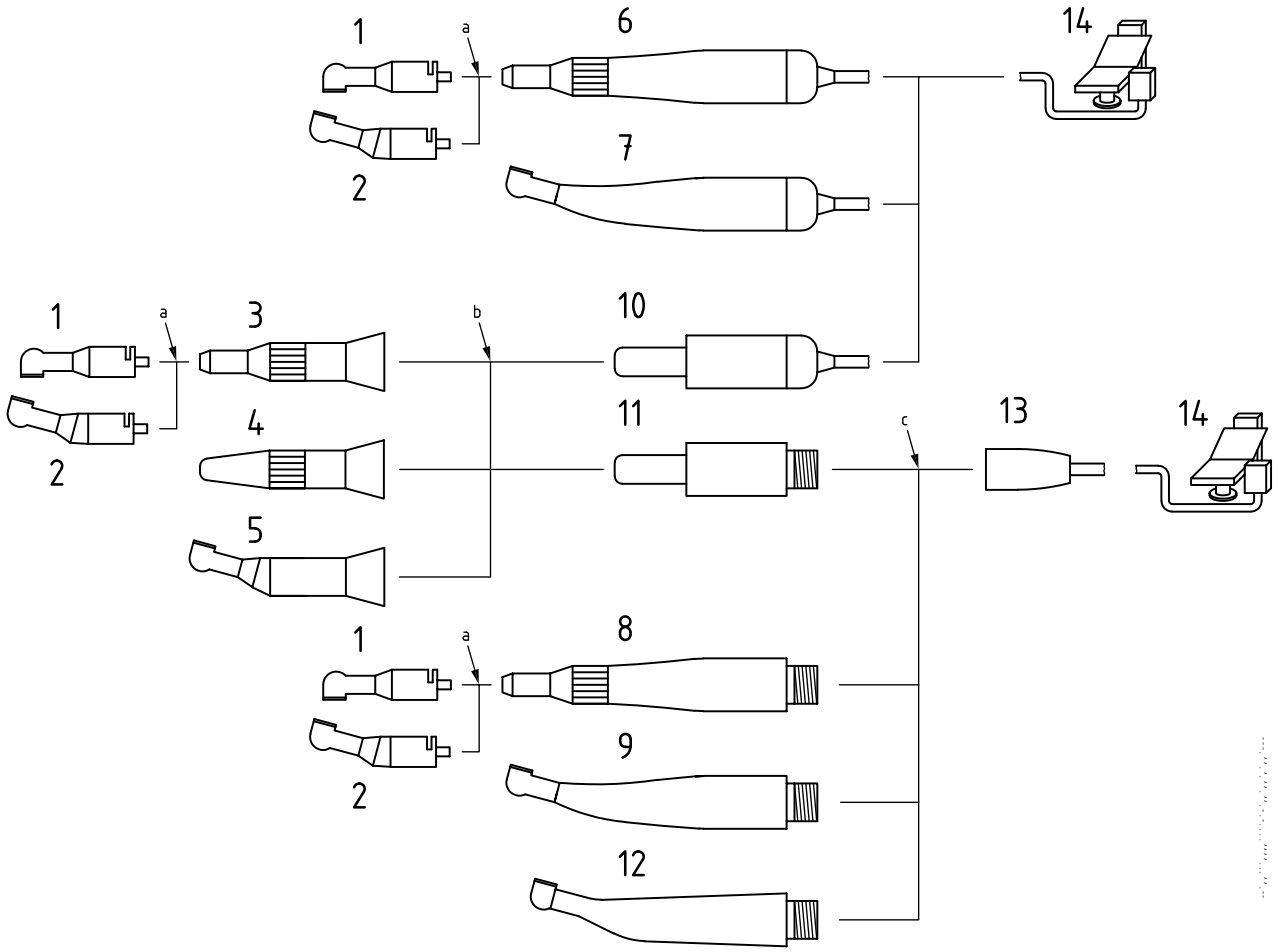
If several packages are supplied, they shall be marked on the outside to facilitate assembly and installation.

Single-use handpieces, or the disposable (non-reusable) parts of other handpieces, shall be packaged or wrapped individually by the manufacturer to maintain cleanliness.

Annex A
(informative)

Handpiece categories

Handpieces are categorized as shown in Figure A.1.



Key

1 prophy handpiece, straight
2 prophy handpiece, angle
3 straight handpiece
4 straight handpiece
5 angle handpiece
6 straight electrical motor handpiece
7 angle electrical motor handpiece
8 straight air motor handpiece
9 angle air motor handpiece
10 electrical motor
11 air motor
12 high-speed air turbine handpiece
13 hose connector
14 dental unit

a Connection according to Figure 1 and Figure 2.
b Connection according to ISO 3964.
c Connection according to ISO 9168.

Figure A.1 — Handpiece categories

Bibliography

[1] ISO 10650-1, *Dentistry — Powered polymerization activators — Part 1: Quartz tungsten halogen lamps*

[2] ISO 10650-2, *Dentistry — Powered polymerization activators — Part 2: Light-emitting diode (LED) lamps*

[3] ISO 13402, *Surgical and dental hand instruments — Determination of resistance against autoclaving, corrosion and thermal exposure*

[4] ISO 15606, *Dental handpieces — Air-powered scalers and scaler tips*

[5] ISO 22374, *Dentistry — Dental handpieces — Electrical-powered scalers and scaler tips*

[6] IEC 60601-1-2:2007, *Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral standard: Electromagnetic phenomena — Requirements and tests*

ICS 11.060.25

Price based on 21 pages