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Dentistry — Handpieces and motors

Médecine bucco-dentaire — Pièces à main et moteurs

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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).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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) prophy 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](#).

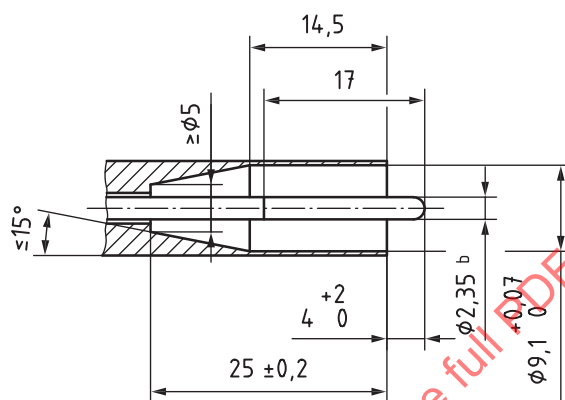
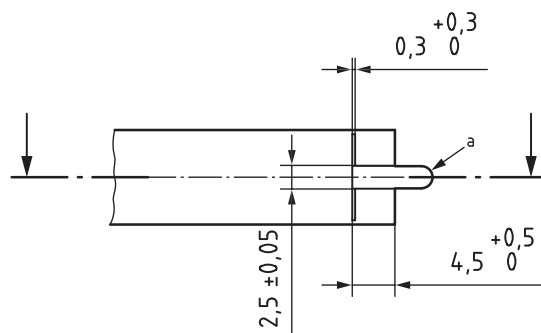
Test in accordance with [7.11](#).

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

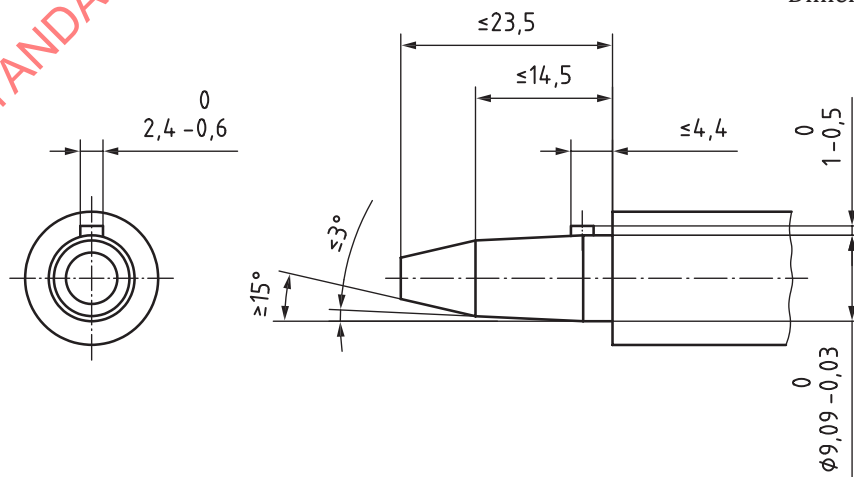
**Key**

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](#).

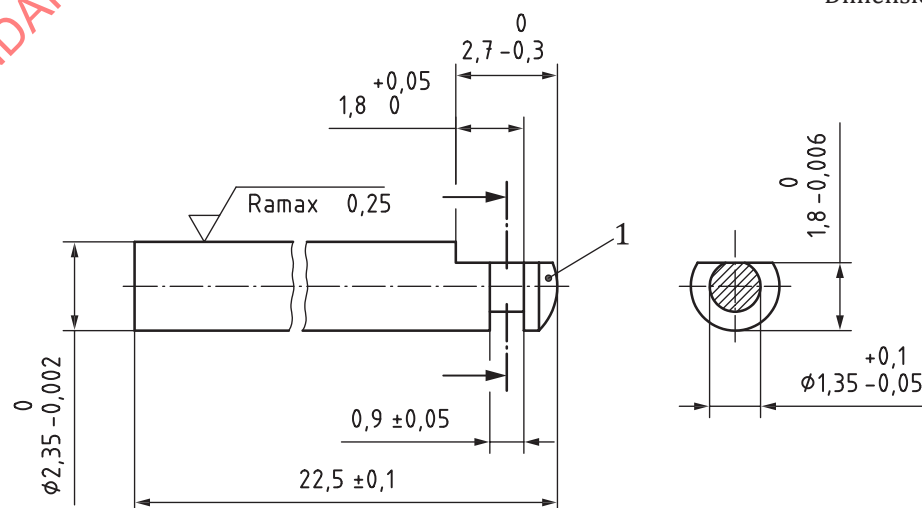
The shape of the shank end for all types of test mandrels shall be either conical or rounded at the discretion of the manufacturer or test house to avoid damaging of the chuck system.

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

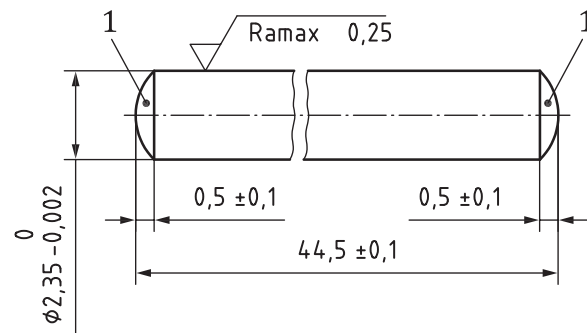
Test in accordance with [7.12](#).

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

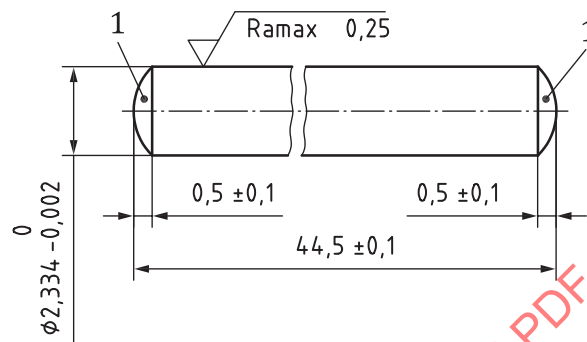
Dimensions in millimetres



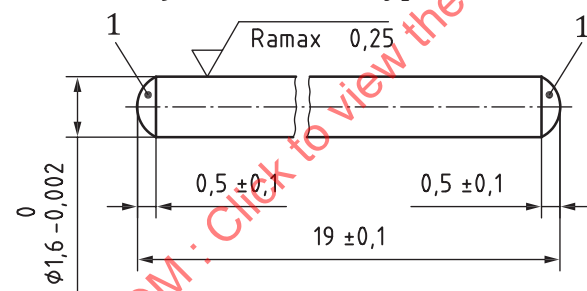
a) Test mandrel Type 1



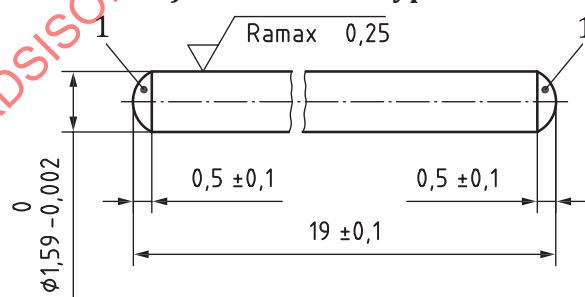
b) Test mandrel Type 2



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](#).

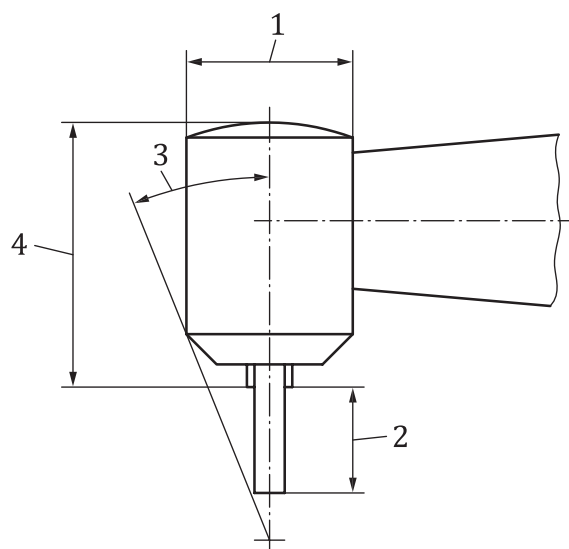
5.21 Dimensions of head and nose

The following requirements are applicable for:

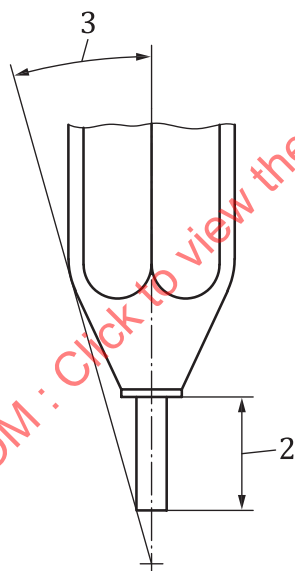
- a) high-speed air turbine handpieces;
- b) straight and angle handpieces;
- c) electrical motor handpieces, angle;
- d) electrical motor handpieces, straight.

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.

The measured maximum power output of the handpiece shall be at least 90 % of the value provided by the manufacturer when tested at the given supply air pressure.

Test in accordance with [7.22](#).

5.23 Handpieces with light

The following requirements are applicable for handpieces with any light functionality.

The measured illuminance of the handpiece light shall be at least 7 000 lx when operated at the manufacturer's recommended settings.

If a handpiece does not have an internal light source, but does contain elements for light transmission, the following requirement for the efficiency of light transmission shall be met. If the elements for light transmission are illuminated on the input side with a light source of no more than 65 000 lx, the light at the output side shall be no less than 7 000 lx.

Test in accordance with [7.23](#).

6 Sampling

At least one handpiece and motor for each model series shall be evaluated for compliance with this document.

7 Testing

7.1 General test conditions

All tests described in this document are type tests.

Unless otherwise specified, the 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 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 %, to measure high-speed air turbine handpiece or air motor supply air flow rate.

7.4.1.2 Pressure gauges, with an accuracy of ± 5 %, to measure high-speed air turbine handpiece or air motor supply air pressure.

7.4.2 Procedure

The pressure gauge shall be installed as close to the drive air inlet of the handpiece or motor as possible. Operate the handpiece at the value given in [5.6.2.1](#) and record the flow rate.

For measuring flow rate, the type of flowmeter used affects the allowable setup for the testing. If a mass flowmeter is used, it can be installed at any point between the air supply and the handpiece or motor. If a volumetric flowmeter is used, it shall be installed as close to the pressure gauge as possible, and temperature and pressure shall be used to correct from volumetric flow (e.g. l/min) to mass flow (NL/min).

7.5 Spray air supply

7.5.1 Apparatus

7.5.1.1 Flowmeter, with an accuracy of ± 5 %, to measure the spray airflow rate.

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

7.5.2 Procedure

The pressure gauge shall be installed as close to the spray air inlet of the handpiece or motor as possible. Operate the handpiece or motor as specified in [5.6.2.4](#).

For measuring flow rate, the type of flowmeter used affects the allowable setup for the testing. If a mass flowmeter is used, it can be installed at any point between the air supply and the handpiece or motor. If a volumetric flowmeter is used, it shall be installed as close to the pressure gauge as possible, and temperature and pressure shall be used to correct from volumetric flow (e.g. l/min) to mass flow (NL/min).

Record the measured airflow rate.

7.6 Water supply

7.6.1 Apparatus

7.6.1.1 Volumetric measuring jar, with an accuracy of ± 5 %, to measure the volume of the water or a flowmeter, with an accuracy of ± 5 %.

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

7.6.2 Procedure

Install the pressure gauge as close to the spray water inlet of the handpiece or motor as possible.

The supplied water pressure shall be adjusted such that the reading of the pressure gauge near the handpiece or motor is consistent with [5.6.3](#).

Operate the handpiece or motor for 1 min and record the volume of water collected.

In case the flowmeter method is employed, flowmeter shall be installed in the coolant water line.

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 %.

7.7.2 Procedure

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

Observe whether the handpiece or motor ruptures or bursts.

7.8 Motor cooling air

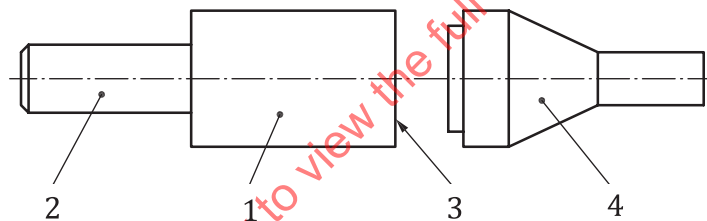
7.8.1 Apparatus

7.8.1.1 Flowmeter, with an accuracy of ± 5 %, to measure the motor cooling airflow rate.

7.8.1.2 Pressure gauge, with an accuracy of ± 5 %, to measure the air supply pressure at the inlet of the electrical motor or electrical motor handpiece.

7.8.2 Procedure

An example of the electrical motor with its interface is given in [Figure 5](#). Install the flowmeter between the hose coupling of electrical motor or electrical motor handpiece and the motor hose. Measure the motor cooling airflow rate while operating the electrical motor or electrical motor handpiece at the maximum speed recommended by the manufacturer.



Key

- 1 electric motor
- 2 handpiece coupling (nozzle)
- 3 hose coupling
- 4 motor hose

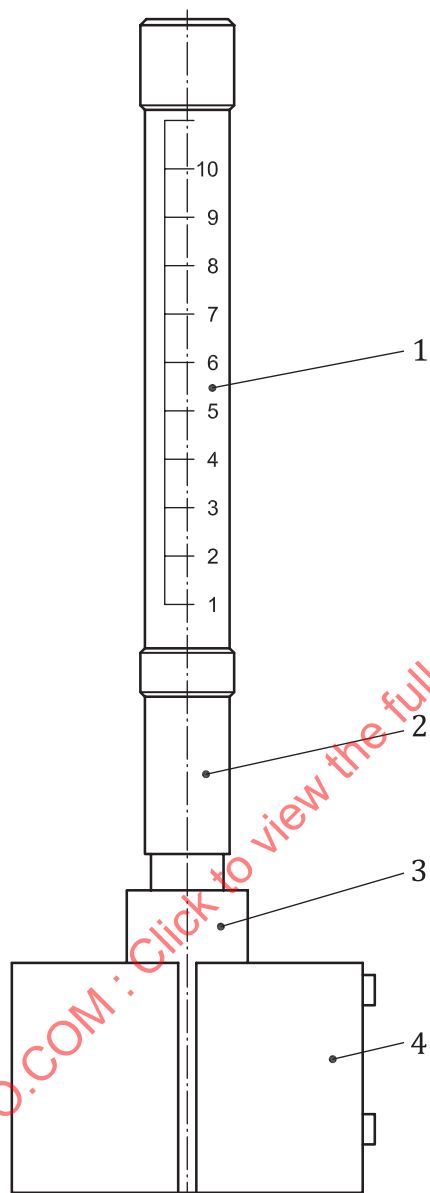
Figure 5 — Electrical motor with its interfaces

7.9 Handpiece cooling air

7.9.1 Apparatus

7.9.1.1 Flowmeter, with an accuracy of ± 5 %, to measure the handpiece cooling airflow rate; see [Figure 6](#).

7.9.1.2 Pressure gauge, with accuracy of $\pm 5\%$, to measure the air supply pressure at the inlet of the handpiece; see [Figure 6](#).



Key

- 1 airflow measuring tube
- 2 measuring tube connector
- 3 motor
- 4 motor bracket

Figure 6 — Measurement device for handpiece cooling air (example)

7.9.2 Procedure

Install the flowmeter at the supply line (nozzle) of the handpiece coupling of the motor so that only the inner bore is covered and measure the instrument air cooling flow rate coming through the bore while operating the motor at the maximum recommended speed.

7.10 Connection for handpieces and motors

Testing shall be carried out by visual inspection and measurement using appropriate measuring instruments.

7.11 Connection and supply

7.11.1 Apparatus

7.11.1.1 Measuring device, such as a gauge or dial indicator, with an accuracy of 0,01 mm for linear dimension and $\pm 1^\circ$ on angles.

7.11.2 Procedure

Measure and record the dimensions as shown in [Figure 1](#) and [Figure 2](#).

7.12 Test mandrels

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 [5.15.3.2.3](#), [5.17](#) and [Figure 3](#).

7.13 Chuck for shanks

7.13.1 Extraction test

7.13.1.1 Apparatus

7.13.1.1.1 Spring force gauge, with an accuracy of $\pm 0,5$ N, to measure the extraction forces.

7.13.1.1.2 Test mandrel, as shown in [Figure 3](#).

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

7.13.1.2 Procedure

Adjust the force gauge on the test mandrel. The force to extract the test mandrel shall be increased gradually until the test mandrel moves at least 0,2 mm. Record the maximum force.

The following procedure may be conducted before testing. Install the test mandrel in the handpiece in accordance with the manufacturer's instructions. Operate the handpiece at the recommended maximum speed for at least 10 s and brake the test mandrel through a radial force so that the speed is reduced by no more than 50 %.

7.13.2 Torque test

Apply the torque stated in [5.16.1](#) and [5.16.2](#) at which the mandrel shall not slip in the chuck.

7.13.2.1 Apparatus

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

7.13.2.1.2 Test mandrel, as stated in [5.16.1](#) and [5.16.2](#) and shown in [Figure 3](#).

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

7.13.2.2 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.

7.14 Dimensions of head and nose

7.14.1 Apparatus

7.14.1.1 Measuring device, such as a gauge or dial indicator, with an accuracy of 0,01 mm for linear dimension and $\pm 1^\circ$ on angles.

7.14.1.2 Test mandrel, as shown in [Figure 3](#).

7.14.2 Procedure

Fully insert the test mandrel in the chuck. Measure and record the dimensions as shown in [Figure 4](#).

7.15 Eccentricity

7.15.1 Apparatus

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

7.15.1.2 Test mandrel, as given in [5.17](#) and shown in [Figure 3](#), to measure the dynamic eccentricity.

7.15.2 Procedure

Measure the eccentricity at a distance of ≥ 6 mm from the spindle of the instrument. Measure the diameter of the mandrel face or distal end with the handpiece at no speed. Operate the handpiece in accordance with the manufacturer's instructions at the maximum operating speed. Measure the diameter of the mandrel face or distal end at maximum operating speed. Calculate the total dynamic eccentricity as the difference of diameter between the maximum operating speed and no speed.

7.16 Stall torque

7.16.1 Apparatus

7.16.1.1 Torque watch or dynamometer, with an accuracy of $\pm 10\%$.

7.16.2 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 airflow 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.

7.17 Noise level

7.17.1 Apparatus

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

7.17.1.2 Non-rigid suspension system.

7.17.2 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 with a test mandrel in the head or motor under test. Foam or non-reflective material may be used to reduce reflections from hard surfaces.

7.17.3 Procedure

Suspend the handpiece and/or motor in the centre of the chamber by means of a non-rigid suspension system. Operate the handpiece and/or motor as recommended by the manufacturer at the maximum recommended air pressure for air-powered handpieces and/or motors or the maximum recommended speed for electric handpieces or motors under unloaded conditions for at least 30 s. Then, using the sound level meter, measure the maximum A-weighted sound pressure level generated from the handpiece for at least 5 s at a distance of 0,45 m from the head, perpendicular to the long axis of the handpiece and/or motors.

7.18 Speed

7.18.1 Apparatus

7.18.1.1 Non-contact tachometer, such as a magnetic proximity gauge or photo-optic tachometer or spectrum analyser with appropriate transducer with an accuracy of ±5 %.

7.18.1.2 Test mandrel, Type 1 or Type 2 or Type 4 as shown in [Figure 3](#).

7.18.2 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).

7.19 Temperature rise of housing

7.19.1 Temperature rise of motors

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

7.19.2 Temperature rise for handpieces

Operate the handpiece in the condition of reasonable foreseeable misuse:

- The handpiece shall be at room temperature (20 °C + 5 °C) prior testing.
- Spray air, if applicable, in the lowest setting permitted by the manufacturer.

- Spray water, if applicable, set to not more than 10 ml/min.
- Handpiece cooling air, if applicable, is set to no more than 5 NL/min.
- Insert a fitting test mandrel according to [Figure 3](#).

For prophylactic handpieces, if applicable, the test shall be done using other adequate test mandrel.

Operate the handpiece for 3 min at the maximum speed permitted by the manufacturer without interruption. External cooling of the handpiece is not permitted. Verify that the value of the temperature gradient is equal or less the value stated in [5.8.2.2](#).

7.20 Excessive temperature

7.20.1 Excessive temperature for motors

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

7.20.2 Excessive temperature for handpieces

For the handpieces, the manufacturer shall define the temperatures and the test conditions and the test procedure regarding the requirements as described in this document.

7.20.2.1 Test in normal conditions

Operate the handpiece in the condition of normal use:

- The handpiece shall be at room temperature ($20\text{ °C} + 5\text{ °C}$) prior testing.
- Spray air, if applicable, in the lowest setting permitted by the manufacturer.
- Spray water, if applicable, set to lowest setting permitted by the manufacturer.
- Handpiece cooling air, if applicable, is set to no more than 5 NL/min.
- Insert a fitting test mandrel according to [Figure 3](#).

For prophylactic handpieces, if applicable, the test shall be done using other adequate test mandrel.

Operate the handpiece for 3 min at the maximum speed permitted by the manufacturer without interruption. If the handpiece does not have cooling air, the time of operation is reduced to 1 min. External cooling of the handpiece is not permitted.

7.20.2.2 Test in reasonably foreseeable misuse conditions

Operate the handpiece in the condition of reasonable foreseeable misuse:

- The handpiece shall be at room temperature ($20\text{ °C} + 5\text{ °C}$) prior testing.
- Spray air, if applicable, in the lowest setting permitted by the manufacturer.
- Spray water, if applicable, set to not more than 10 ml/min.
- Handpiece cooling air, if applicable, is set to no more than 5 NL/min.
- Insert a fitting test mandrel according to [Figure 3](#).

For prophylactic handpieces, if applicable, the test shall be done using other adequate test mandrel.

Operate the handpiece for 3 min at the maximum speed permitted by the manufacturer without interruption. If the handpiece does not have cooling air, the time of operation is reduced to 1 min. External cooling of the handpiece is not permitted.

7.21 Resistance to reprocessing

Carry out 250 reprocessing cycles according to the reprocessing instructions given by the manufacturer in the instructions for use.

If the manufacturer recommends a maximum of less than 250 in the instructions, this maximum figure shall be used.

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

All requirements of this document shall be met subsequent to this test.

NOTE For accelerated testing, it is permissible to carry out the required substeps of reprocessing in a block-by-block manner. For example, blocks of 10-x thermal disinfection followed by 10-x sterilization until the 250 reprocessing cycles are reached.

7.22 Output power of high-speed air turbine handpieces

7.22.1 Apparatus

7.22.1.1 Dynamic torque meter, capable of simultaneously measuring dynamic torque and rotation speed with an accuracy of $\pm 10\%$ (e.g. Eddy current dynamometer, thread loading torque meter).

7.22.1.2 Pressure gauges, with an accuracy of $\pm 5\%$, to measure the air supply pressure at the inlet to the handpiece.

7.22.1.3 Output power measuring setup, example of a measuring setup for the output power is given in [Figure 7](#).

7.22.2 Procedure

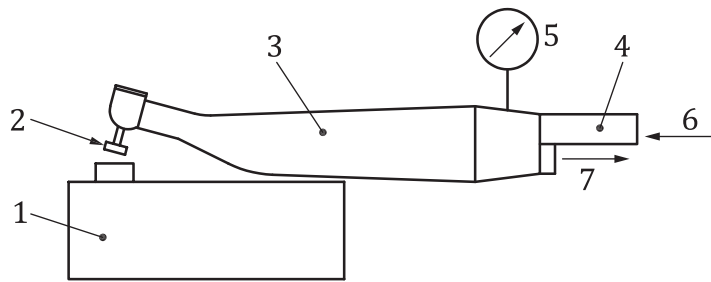
Secure the handpiece appropriately for measurement with the torque testing device.

Operate the handpiece with the supply pressure set to match the pressure corresponding to the power output stated by the manufacturer in the instructions for use.

If applicable for the handpiece under test, any exhaust air being returned from the handpiece via the hose connection shall be vented to atmosphere as close to the handpiece connection as possible to minimize exhaust resistance.

Calculate the output power from the measured dynamic torque and rotation speed. The maximum calculated power should be recorded together with the supply air pressure.

While applying the load for the dynamic torque measurement, the load shall be gradually increased to minimize the influence of system inertia. The test time per measurement shall be longer than 10 s.



Key

- 1 dynamic torque meter (torque and rotation speed)
- 2 attachment
- 3 high-speed air turbine handpiece
- 4 hose
- 5 supply pressure gauge
- 6 supply air
- 7 exhaust air vented to atmosphere, if applicable

Figure 7 — Output power measuring setup (example)

7.23 Handpieces with light

7.23.1 Apparatus

7.23.1.1 Illuminance meter, with a photometer head and an active sensor surface diameter of 10 mm, calibrated according to CIE 69, or a similar illuminance meter (e.g. CIE S 023/E).

7.23.1.2 Power supply, with adjustable voltage, if applicable.

7.23.1.3 Light source, as described by the handpiece manufacturer or modified light source for testing, if applicable.

7.23.2 Procedure

The measurement of illuminance shall be made at an ambient illumination of no more than 500 lx and the test station in the area of the photometer shall be free from reflective surfaces.

Insert a suitable test mandrel Type 1, Type 4 or a mandrel with the recommended length specified by the manufacturer of the handpiece into the handpiece chuck system. In case the handpiece requires the use of a burr with different length from the test mandrel, use the test mandrel with the most suitable length.

Position the handpiece so that the test mandrel is perpendicular to and centred over the sensor surface and its tip is <1 mm above the sensor surface (see [Figure 8](#)). Fix the handpiece so that it remains stable and immobile in this position over the light meter for the duration of the measurement. Apply the manufacturer's maximum recommended electrical power to the handpiece, wait 5 s, and then record the mean illuminance over a test duration of 30 s.

If the handpiece has a separate or removable light source, including light transmitted from hose, the measuring light source shall be tested without the handpiece attached.

Dimensions in millimetres

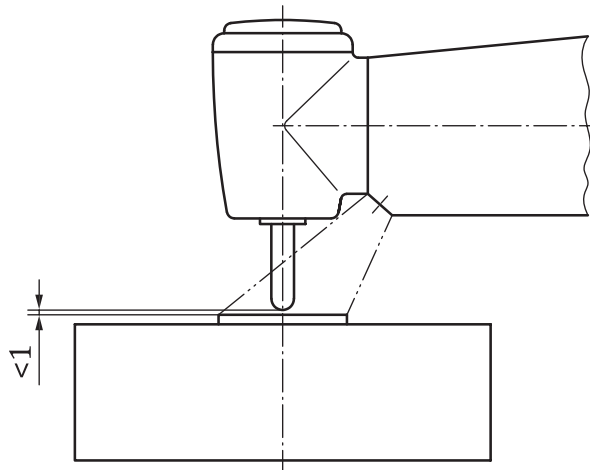


Figure 8 — Measurement position

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;
- d) allowable maximum overall length and working diameter of the rotary instruments;
- e) coupling identification for handpiece or motor connection, if applicable;
- f) recommended operating pressures of air and water, if applicable;
- g) consumption of air, in normal litres per minute (NL/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, if applicable;
- k) statement as to whether the tool for changing the handpiece or motor 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 or motor 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 handpiece model or motor model;
- r) statement that prophylactic handpieces are intended for single use only and then to be safely disposed after one patient treatment;
- s) maximum output power (W) at the supply air pressure (e.g. 20 W at 3 bar supply air pressure), if the manufacturer is providing this value.

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 autoclavability, if applicable;
- e) mark to indicate thermal disinfection ability, if applicable;
- f) for parts of single-use handpieces, if sold as a sterile product, the "use by" date on the packaging;
- g) 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;
- d) mark to indicate thermal disinfection ability, if applicable;
- e) mark to indicate autoclavability, if applicable.

11 Labelling

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

The packaging of handpieces and motors 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) mark to indicate autoclavability, if applicable;
- e) mark to indicate thermal disinfection ability, if applicable;
- f) 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 motors, or the disposable (non-reusable) parts of other handpieces or motors, shall be packaged or wrapped individually by the manufacturer to maintain cleanliness.