

INTERNATIONAL STANDARD

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Dental handpieces —

Part 1:

High-speed air turbine handpieces

Pièces à main dentaires —

Partie 1: Pièces à main à turbines à air comprimé pour grandes vitesses



Reference number
ISO 7785-1:1997(E)

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.

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.

International Standard ISO 7785-1 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 4, *Dental instruments*.

This second edition cancels and replaces the first edition (ISO 7785-1:1992), which has been technically revised.

ISO 7785 consists of the following parts, under the general title *Dental handpieces*.

- *Part 1: High-speed air turbine handpieces*
- *Part 2: Straight and geared angle handpieces*

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Introduction

This part of ISO 7785 takes priority over IEC 601-1:1988 as specified in the individual clauses of this part of ISO 7785.

Only the specifications laid down in this part of ISO 7785 are applicable.

This part of ISO 7785 refers to IEC 601-1:1988, the basic standard on safety of medical electrical equipment wherever relevant, by stating the respective clause numbers of IEC 601-1:1988.

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Dental handpieces —

Part 1:

High-speed air turbine handpieces

1 Scope

This part of ISO 7785 specifies requirements and test methods for the application of high-speed air turbine dental handpieces (hereafter termed handpieces) to patients. It also contains specifications on manufacturer's instructions, packaging and marking.

This part of ISO 7785 is not applicable to single-use dental handpieces.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 7785. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this part of ISO 7785 are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 554:1976,	Standard atmospheres for conditioning and/or testing - Specifications.
ISO 1797-1:1992,	Dental rotary instruments - Shanks - Part 1: Shanks made of metals.
ISO 1942-3:1989,	Dental vocabulary - Part 3: Dental instruments.
ISO 3696:1987,	Water for analytical laboratory use - Specification and test methods.
ISO 6507-2:1983,	Metallic materials - Hardness test - Vickers test - Part 2: HV 0,2 to less than HV 5.
ISO 9168:1991,	Dental handpieces - Hose connectors.
ISO 9687: 1993,	Dental equipment - Graphical symbols.
ISO 13402:1995,	Surgical and dental hand instruments - Determination of resistance against autoclaving, corrosion and thermal exposure.
IEC 651:1979,	Sound level meters.
IEC 601-1:1988,	Medical electrical equipment - Part 1: General requirements for safety.

3 Definitions

For the purposes of this part of ISO 7785, the definitions given in ISO 1942-3 apply.

4 Classification

High-speed air turbine handpieces are dental handpieces with a minimum free-running speed of 160 000 min⁻¹ (r/min).

Dental handpieces are classified according to their gear ratio (see table 1).

High-speed air turbine handpieces are usually type 2 handpieces.

Table 1 - Gear ratio

Type	Gear ratio
1	1 : < 1
2	1 : 1
3	1 : > 1

5 Requirements

5.1 General design

5.1.1 General

The handpiece should be comfortable for the operator to use and easy to manipulate. The outside surface should be easy to clean and particular attention should be given to providing secure gripping surfaces for operator manipulation.

Compliance with these requirements cannot be objectively assessed.

If in addition the requirements of 5.1.2, 5.1.3 and 5.2 to 5.10 are complied with, the requirements of 5.1.1 are considered to be fulfilled.

Testing shall be carried out in accordance with 7.1.

5.1.2 Materials

All materials used in the construction of the handpieces should be suitable for their intended use and should be resistant to cleaning, disinfecting and sterilizing procedures recommended by the manufacturer.

Compliance with these requirements cannot be objectively assessed.

If in addition the requirements of 5.1.1, 5.1.3 and 5.2 to 5.10 are complied with, the requirements of 5.1.2 are considered to be fulfilled.

Testing shall be carried out in accordance with 7.1.

5.1.3 Construction and layout

The construction of the handpiece should provide for safe and reliable operation and, if field-repairable, should be capable of being easily disassembled and reassembled for maintenance and repair, using readily available tools or those supplied by the manufacturer.

Compliance with these requirements cannot be objectively assessed.

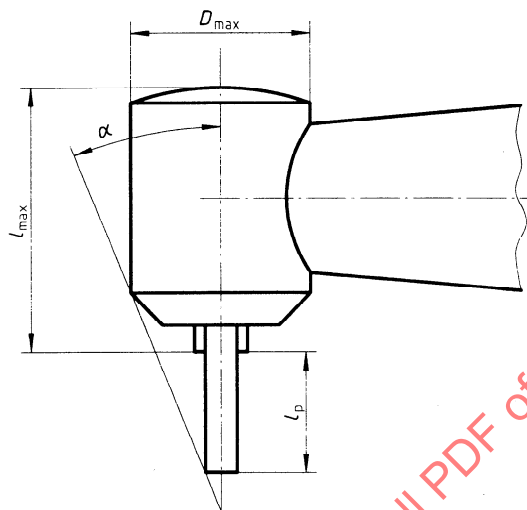
If in addition the requirements of 5.1.1, 5.1.2 and 5.2 to 5.10 are complied with, the requirements of 5.1.3 are considered to be fulfilled.

Testing shall be carried out in accordance with 7.1.

5.1.4 Head dimensions and nomenclature

If the manufacturer includes the head dimensions in the operator's manual (see note in clause 8) they shall be the dimensions as shown in figure 1 and shall be expressed to an accuracy of $\pm 0,1$ mm on lengths and $\pm 1^\circ$ on angles using the nomenclature of figure 1.

Testing shall be carried out in accordance with 7.2.



$D_{\max}$	Maximum diameter
$l_{\max}$	Maximum length of non-rotating component
α	Visibility angle
l_p	Projection using 19 mm test mandrel

Figure 1 — Terminology for measuring head dimensions

5.2 Chuck

5.2.1 General

The chuck shall be capable of accepting rotary instruments the shanks of which comply with ISO 1797-1.

5.2.2 Test mandrel

The test mandrel shall have the dimensions shown in figure 2.

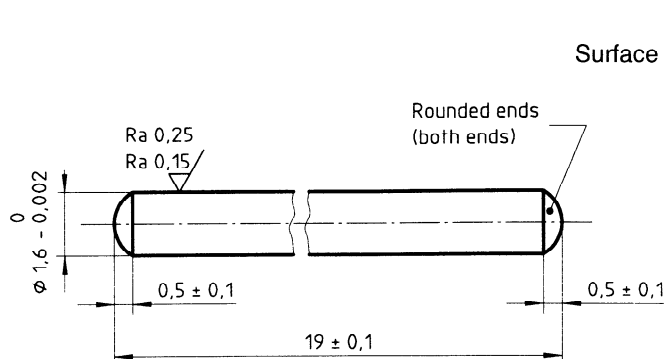


Figure 2 - Test mandrel

5.2.3 Spring-type chuck, friction grip

The force to insert into, or to withdraw the test mandrel from, the spring-type chuck shall be between 22 N and 45 N.

Testing shall be carried out in accordance with 7.3.1.

When locked in the chuck, the test mandrel shall transmit a torque of at least 1,6 N·cm without slipping.

Testing shall be carried out in accordance with 7.3.2.

5.2.4 Mechanical locking chuck

The force to extract the test mandrel from the mechanical locking chuck shall be at least 22 N.

Testing shall be carried out in accordance with 7.3.1.

When locked in the chuck, the test mandrel shall transmit a torque of at least 1,6 N·cm without slipping.

Testing shall be carried out in accordance with 7.3.2.

The locking or unlocking force required to position the rotary instrument in the chuck should be the minimum force sufficient to prevent accidental unlocking in use.

5.2.5 Push-button locking chucks and other systems

The force to extract the test mandrel from the chuck system shall be at least 22 N.

Testing shall be carried out in accordance with 7.3.1.

When locked in the chuck, the test mandrel shall transmit a torque of at least 1,6 N·cm without slipping.

Testing shall be carried out in accordance with 7.3.2.

5.2.6 Eccentricity

The eccentricity of the test mandrel in rotation and without applied load shall not exceed a total indicated run-out of 0,03 mm.

Testing shall be carried out in accordance with 7.3.3.

5.3 Performance

5.3.1 Speed

The rotational speed of the test mandrel shall be at least the minimum free-running speed stated by the manufacturer in the operator's manual, with a minimum of 160 000 min⁻¹ (r/min).

Testing shall be carried out in accordance with 7.4.

5.3.2 Stall torque

The stall torque shall be at least 0,05 N·cm.

Testing shall be carried out in accordance with 7.5.

5.4 Water and spray air supply

5.4.1 General

The handpiece shall provide cooling capability at the operating area.

Testing shall be carried out in accordance with 7.1 and 7.6.

5.4.2 Water cooling

The handpiece shall provide water coolant capability at the operating area of the rotary instrument. The handpiece shall have a capability of attaining a water flowrate of at least 50 ml/min at 200 kPa (2,0 bar).

Testing shall be carried out in accordance with 7.6.2.1.

5.4.3 Air cooling

Air coolant capability may be provided at the discretion of the manufacturer. Handpieces having 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 the rotary instrument. The handpiece shall be capable of attaining an air flowrate of at least 1,5 l/min at 200 kPa (2,0 bar).

Testing shall be carried out in accordance with 7.6.2.2.

5.5 Handpiece connector

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

Testing shall be carried out by inspection and measurement in accordance with 7.1.

5.6 Air pressure

Handpieces shall remain intact, i.e. it shall not rupture or burst, when subjected to an air pressure 50 % above the recommended operating pressure.

Testing shall be carried out in accordance with 7.7.

5.7 Noise level

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

NOTE — It is recommended to reduce the noise level to 65 dB.

Testing shall be carried out in accordance with 7.9.

5.8 Resistance to corrosion

Handpieces shall be corrosion-resistant, i.e. the construction materials shall show no visible signs of corrosion after having been subjected to the autoclave procedure specified in 7.8.

Visual inspection shall be carried out in accordance with 7.1.

5.9 Resistance to sterilizing procedure

Handpieces shall be capable of being subjected to a minimum of 250 cycles of the manufacturer's recommended sterilizing procedure without signs of deterioration.

If a part of handpieces, totally or partially nonreparable, are of single-use type, the disposable part shall be sold sterile or shall be sterilizable once before use, according to the manufacturers instructions.

Testing shall be carried out in accordance with the manufacturer's instructions.

Visual inspection to indicate any signs of deterioration shall be carried out in accordance with 7.1.

5.10 Energy for light supply (if applicable)

The voltage shall not exceed a nominal value of 25 V a.c or 60 V d.c. at rated supply voltage on the transformer or converter, between conductors in an earth-free circuit which is isolated from the supply mains by a safety transformer or by a device with an equivalent separation.

Testing shall be carried out in accordance with 7.10.

6 Sampling

At least one handpiece for each model series shall be evaluated for compliance with this part of ISO 7785.

7 Test methods

All tests described are type tests.

7.1 Visual inspection

Carry out visual inspection at normal visual acuity without magnification.

7.2 Head dimensions

7.2.1 Apparatus

- a) **Measuring device** such as gauge, dial indicator, etc. with an accuracy of $\pm 0,01$ mm for linear dimension and $\pm 1^\circ$ for angles;
- b) **Test mandrel** as shown in figure 2. The test mandrel shall be straight to within 0,0025 mm and shall have a hardness of at least 610 HV 5.

Testing of hardness shall be carried out in accordance with ISO 6507-2.

7.2.2 Procedure

Fully insert the test mandrel in the chuck. Measure and record the dimensions shown in figure 1.

7.3 Chuck

7.3.1 Insertion and extraction forces

7.3.1.1 Apparatus

- a) **Spring force gauge** with an accuracy of $\pm 0,5$ N, to measure the insertion and extraction forces.
- b) **Test mandrel**, as shown in figure 2.

7.3.1.2 Procedure

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 at least 50 %. Adjust the force gauge to register the maximum force exerted. The force either to insert or to extract the test mandrel shall be increased gradually until movement of the test mandrel occurs. Record the maximum force required either to insert or to extract the test mandrel.

7.3.2 Torque test

Apply the torque stated in 5.2.3, 5.2.4 or 5.2.5, at which the mandrel shall not slip in the chuck.

7.3.3 Eccentricity

7.3.3.1 Apparatus

- a) **Non-contacting gauging system**, e.g. magnetic proximity gauge, with an accuracy of $\pm 10\%$ of the measured value.
- b) **Test mandrel**, as shown in figure 2, to measure the dynamic eccentricity.

7.3.3.2 Procedure

Install the test mandrel in the handpiece in accordance with the manufacturer's instructions. Operate the handpiece with the recommended speed range and without any applied load and record the maximum total indicated run-out at a point on the mandrel 6 mm from the proximal face of the spindle.

7.4 Speed

7.4.1 Apparatus

- a) **Non-contacting tachometer**, e.g. magnetic proximity gauge or photo-optic tachometer or spectrum analyzer with appropriate transducer, accurate to 5 %.
- b) **Test mandrel**, as shown in figure 2.

7.4.2 Procedure

Using the test mandrel, operate the handpiece at the maximum recommended operating pressure. Measure the speed and record the speed in reciprocal minutes (revolutions per minute).

7.5 Stall torque

7.5.1 Apparatus

Torque watch or **dynamometer**, capable of measuring the stall torque in newton-centimetres to an accuracy of 10 %.

7.5.2 Procedure

Rotate the torque watch slowly and record the maximum value.

7.6 Water and spray air supply

7.6.1 Apparatus

- a) **Volumetric measuring jar**, with an accuracy of 5 %, to measure the volume of cooling water.
- b) **Flow meter**, with an accuracy of 5 %, to measure the spray air flowrate.
- c) **Pressure gauge**, with an accuracy of 5 %, to measure the air and water supply pressures to the handpiece inlet.

7.6.2 Procedure

7.6.2.1 Measurement of cooling water flow

Adjust the water supply pressure at the handpiece inlet to 200 kPa (2,0 bar) and operate the handpiece for 1 min. Record the volume of water collected.

7.6.2.2 Measurement of cooling air flow

Adjust the air supply at the handpiece inlet to 200 kPa (2,0 bar). Connect a flow meter to the handpiece air outlet tube. Record the air flowrate.

7.7 Air pressure

7.7.1 Apparatus

Pressure gauge capable of measuring the supply pressure to an accuracy of 5 % of the measured value.

7.7.2 Procedure

Operate the handpiece at 50 % above the recommended operating pressure for a period of 10 min and record any signs of failure.

7.8 Resistance to corrosion

7.8.1 Apparatus

- a) **Autoclave**, capable of being operated at $(136 \pm 2) ^\circ\text{C}$ and 220 kPa (2,2 bar).
- b) Distilled or deionized water of grade 3 in accordance with ISO 3696.

7.8.2 Procedure

Subject the touchable surface of the handpiece to an autoclave test of 10 cycles at $(136 \pm 2) ^\circ\text{C}$.

Testing shall be carried out in accordance with ISO 13402.

7.9 Noise level

7.9.1 Apparatus

- a) **Precision sound level meter**, meeting the requirements for a type 1 instrument as specified in IEC 651.
- b) **Non-rigid suspension system**.