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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 7785-1:1992(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*, Sub-Committee SC 4, *Dental instruments*.

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*

Dental handpieces —

Part 1: High-speed air-turbine handpieces

1 Scope

This part of ISO 7785 specifies requirements and test methods for high-speed air-turbine 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 1797:1985, *Dental rotary instruments — Shanks*.

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 9687:1992, *Dental equipment — Graphical symbols*.

IEC 651:1979, *Sound level meters*.

3 Requirements

3.1 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.

Testing shall be carried out in accordance with 4.1. If in addition the requirements of 3.5 to 3.12 are complied with, the requirement of 3.1 is considered to be fulfilled.

3.2 Construction

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.

Testing shall be carried out in accordance with 4.1. If in addition the requirements of 3.5 to 3.12 are complied with, the requirement of 3.2 is considered to be fulfilled.

3.3 General design

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 provide secure gripping

surfaces for operator manipulation. In order to reduce glare, highly polished surfaces should be avoided.

Compliance with these requirements cannot be objectively assessed.

Testing shall be carried out in accordance with 4.1. If in addition the requirements of 3.5 to 3.12 are complied with, the requirement of 3.3 is considered to be fulfilled.

3.4 Head dimensions and nomenclature

If the manufacturer includes the head dimensions in the operator's manual (see note 1 in 5.1) they shall be the dimensions shown in figure 1 and shall be expressed, using the nomenclature in figure 1, to an accuracy of $\pm 0,1$ mm on lengths and of $\pm 1^\circ$ on angles.

Testing shall be carried out using measurement devices as specified in 4.2.

3.5 Chuck

3.5.1 General

The chuck shall be capable of accepting rotary instruments complying with ISO 1797.

3.5.2 Spring-type chuck, friction grip

When the test mandrel (see figure 2) is inserted into, or withdrawn from, the spring-type chuck, the force required shall be between 25 N and 45 N.

Testing shall be carried out in accordance with 4.3.1.

3.5.3 Mechanical locking chuck

When locked in the chuck, the force for extracting the relevant test mandrel (see figure 2) shall be at least 45 N.

Testing shall be carried out in accordance with 4.3.1.

When locked in the chuck, the relevant test mandrel (figure 2) shall transmit a torque of at least 4 N·cm without slipping.

Testing shall be carried out in accordance with 4.3.2.

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.

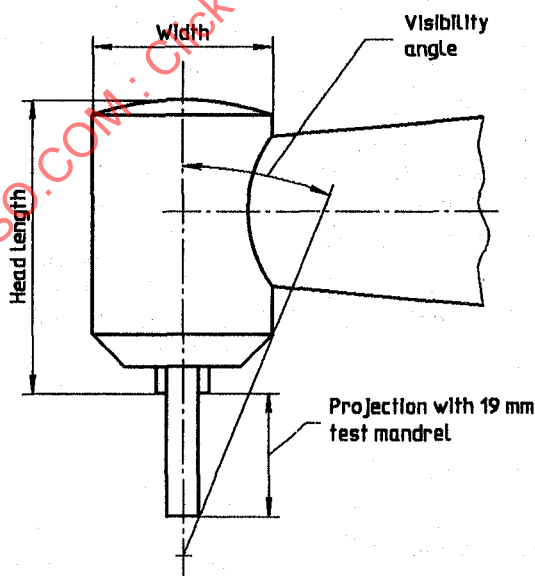


Figure 1 — Nomenclature of head dimensions

Dimensions in millimetres
surface roughness values in micrometres

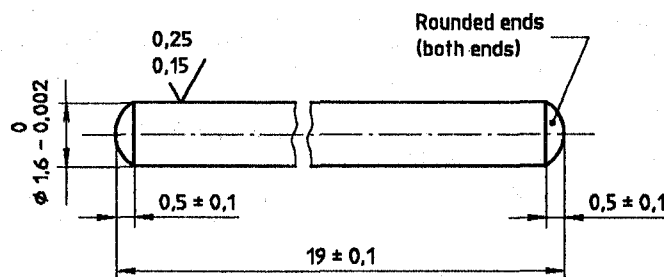


Figure 2 — Test mandrel

3.5.4 Push-button locking chucks and other systems

When locked in the chuck, the force for extracting the test mandrel (figure 2) shall be at least 25 N.

Testing shall be carried out in accordance with 4.3.1.

When locked in the chuck, the test mandrel shall transmit a torque of at least 4 N·cm without slipping.

Testing shall be carried out in accordance with 4.3.2.

3.5.5 Eccentricity

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

Testing shall be carried out in accordance with 4.3.3.

3.6 Performance

3.6.1 Speed

The rotational speed of the test mandrel (figure 2) shall not be below the minimum free-running speed stated by the manufacturer in the operator's manual (see clause 5), with a minimum of 160 000 min⁻¹ (r/min).

Testing shall be carried out in accordance with 4.7.

3.6.2 Stall torque

The stall torque shall not be below 0,05 N·cm.

Testing shall be carried out in accordance with 4.8.

3.7 Water and spray air supply

3.7.1 General

The handpiece shall provide cooling capability at the operating point.

Testing shall be carried out in accordance with 4.1 and 4.4.

3.7.2 Water cooling

The handpiece shall provide water cooling capability to the cutting portion of the rotary instrument. The handpiece shall be capable of attaining a water flow-rate of at least 50 cm³/min at 200 kPa (2 bar).

Testing shall be carried out in accordance with 4.4.2.1.

3.7.3 Air cooling

Handpieces having air coolant capability shall direct air to the cutting portion of the rotary instrument. Simultaneous use with cooling water shall permit the creation of a cooling mist. The handpiece shall be capable of attaining an air flow-rate of at least 1,5 STD (Standard flow-rate) l/min.

Testing shall be carried out in accordance with 4.4.2.2.

3.8 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.

3.9 Air pressure

The handpiece shall remain intact, i.e. it shall not rupture or burst, when subjected to an air pressure 50 % above the recommended operating pressure [see item d) in clause 5].

Testing shall be carried out in accordance with 4.5.

3.10 Noise level

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

Testing shall be carried out in accordance with 4.9.

3.11 Resistance to corrosion

Dental 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 4.6.

Visual inspection shall be carried out in accordance with 4.1.

3.12 Sterilizability

Dental handpieces shall be sterilizable, i.e. they shall be capable of being subjected to a minimum of 250 cycles of the manufacturer's recommended sterilizing procedure without significant signs of deterioration.

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

Visual inspection shall be carried out in accordance with 4.1.

4 Test methods

All tests described in this part of ISO 7785 are type tests.

4.1 Visual inspection

Visual inspection shall be carried out at normal visual acuity without magnification.

4.2 Head dimensions

4.2.1 Equipment

- a) **Measuring devices** such as gauges, dial indicators, etc. with an accuracy of 0,01 mm for linear dimensions and $\pm 1^\circ$ for angles;
- b) **Test mandrel** for all handpiece tests as shown in figure 2. The test mandrel shall be straight to

within 0,002 5 mm and shall have a hardness of not less than 610 HV 5.

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

4.2.2 Procedure

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

4.3 Chuck

4.3.1 Insertion and extraction forces

4.3.1.1 Equipment

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

4.3.1.2 Procedure

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 exerted either to insert or to extract the test mandrel.

4.3.2 Torque test

Apply the torque stated in 3.5.3 or 3.5.4 at which the mandrel shall not slip in the chuck.

4.3.3 Eccentricity

4.3.3.1 Equipment

A **non-contacting gauging system** (such as a magnetic proximity gauge) with an accuracy of within 10 % of the measured value and the **test mandrel** shown in figure 2 is required to measure the dynamic eccentricity.

4.3.3.2 Procedure

Install the test mandrel in the handpiece in accordance with the manufacturer's instructions. Operate the handpiece through the recommended speed range and record the maximum total indicated run-out at a point on the mandrel 6 mm from the proximal face of the spindle.

4.4 Water and spray air supply

4.4.1 Equipment

- a) **Volumetric measuring jar** with an accuracy of within 5 %, to measure the cooling water.

- b) **Flow meter** with an accuracy of within 2 %, to measure the spray air.
- c) **Pressure gauges** with an accuracy of within 2 %, to measure the air and water supply pressures to the handpiece inlet.

4.4.2 Procedure

4.4.2.1 Measurement of cooling water flow

Adjust the water supply pressure at the handpiece inlet to 200 kPa and operate the handpiece for 1 min. Record the volume of water collected.

4.4.2.2 Measurement of cooling air flow

Adjust the air supply at the handpiece inlet to 200 kPa. Connect a flow meter to the handpiece air outlet tube, record the air flow-rate and correct it to the standard flow-rate.

4.5 Air pressure

4.5.1 Equipment

Precision pressure gauge capable of measuring the supply pressure to an accuracy of 2 % of the measured value.

4.5.2 Procedure

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

4.6 Resistance to corrosion

4.6.1 Equipment

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

4.6.2 Procedure

Using distilled or deionized water, subject the handpiece to an autoclave test of 10 cycles at $(136 \pm 2) ^\circ\text{C}$, each cycle being of $(3^{+0,5}_0)$ min duration at 220 kPa (2,2 bar).

4.7 Speed

4.7.1 Equipment

- a) **Test mandrel**, as specified in figure 2.

- b) **Non-contacting tachometer**, e.g. magnetic proximity gauge or photo-optic tachometer, accurate to within 5 %.

4.7.2 Procedure

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

4.8 Stall torque

4.8.1 Equipment

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

4.8.2 Procedure

Rotate the torque watch slowly and read the maximum value.

4.9 Noise level

4.9.1 Equipment

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

4.9.2 Test environment

The measurements shall be taken in a room with dimensions greater than 2,5 m $\times$ 2,5 m $\times$ 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.

4.9.3 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 pressure. 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.