INTERNATIONAL STANDARD

ISO 7785-2

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Dental handpieces —

Part 2:
Straight and geared angle handpieces

Pièces à main dentaires —

Partie 2: Pièces à main rectilignes et à contre-angles

Reference number
ISO 7785-2:1991(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 7785-2 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*

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Dental handpieces —

Part 2:
Straight and geared angle handpieces

1 Scope

This part of ISO 7785 specifies requirements and test methods for straight and geared angle handpieces. These handpieces are operated by electrical or air driven motors. In addition to these specified requirements, there are several other essential aspects of the materials, construction, and general design of handpieces which cannot be objectively specified or assessed. They are considered to be complied with if the series of objectively verifiable requirements are fulfilled.

NOTE 1 As handpieces are complex constructions, it is not possible to specify all details even though they are important. In these latter cases only general specifications are possible, and it is the responsibility of the manufacturer to make the relevant decisions to achieve a safe and reliable product.

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 3964:1982, *Dental handpieces — Coupling dimensions.*

ISO 6507-2:1983, *Metallic materials — Hardness test — Vickers test — Part 2: HV 0,2 to less than HV 5.*

ISO 9687:—[1], *Dental equipment — Graphical symbols.*

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 3.10 are complied with, the requirement of 3.1 is considered to be fulfilled.

3.2 Construction

The construction of the handpiece shall 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.

1) To be published.

Testing shall be carried out in accordance with 4.1. If in addition the requirements of 3.5 to 3.10 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 3.10 are complied with, the requirement of 3.3 is considered to be fulfilled.

3.4 Head and nose dimensions and terminology

If the manufacturer includes the head and nose dimensions in the operator's manual (see note to 5.1), they shall be the dimensions shown in figure 1 and shall be expressed, using the terminology in figure 1, to an accuracy of $\pm 0{,}1$ mm on lengths and $\pm 1°$ 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 3 (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.

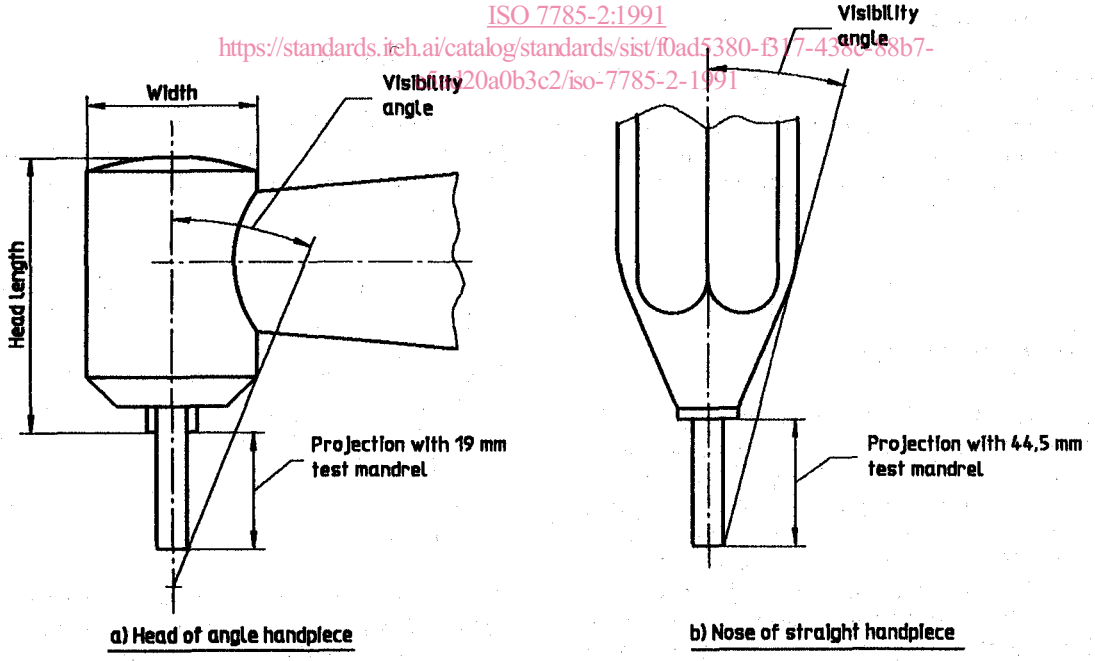

Figure 1 — Terminology for measuring head and nose dimensions

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.

3.5.4 Latch-type chuck

When locked in the chuck, the force for extracting the test mandrel 1 (see figure 2) shall be at least 45 N.

Testing shall be carried out in accordance with 4.3.1.

The latch mechanism shall hold the test mandrel 1 (see figure 2) without slipping when the mandrel is subjected to a torque of at least 4 N·cm.

Testing shall be carried out in accordance with 4.3.2.

3.5.5 Push-button locking chucks and other systems

3.5.5.1 For mandrels types 1 and 2

When locked in the chuck, the force for extracting the test mandrel 1 or 2 (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 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.

Dimensions in millimetres; surface roughness values in micrometres

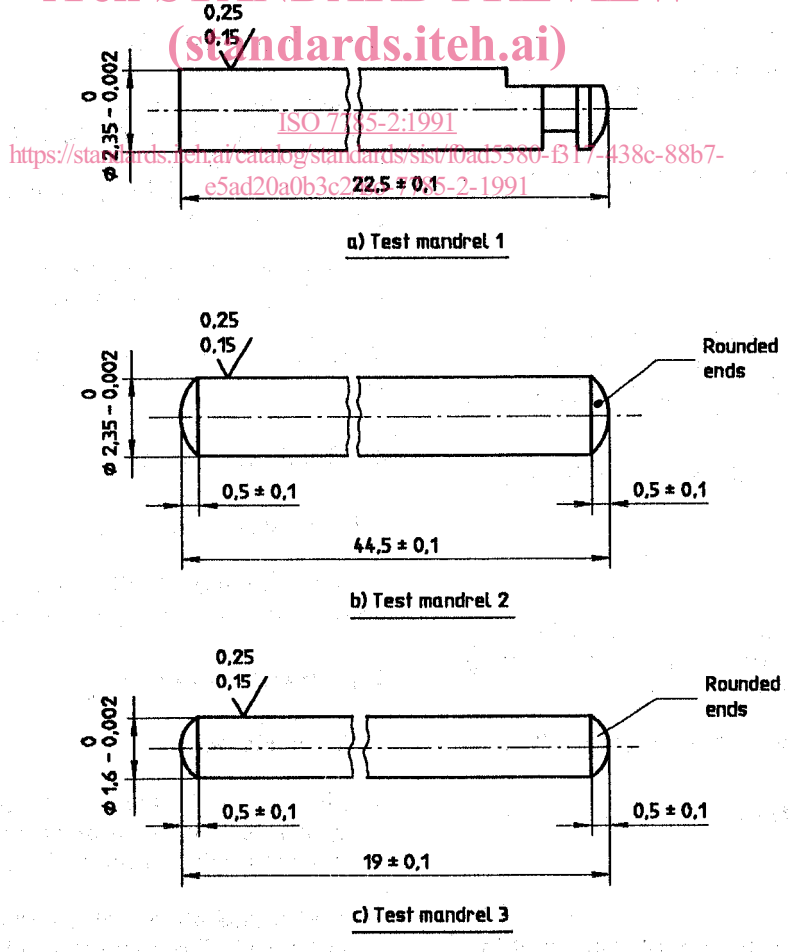

Figure 2 — Test mandrels

3.5.5.2 For mandrel type 3

When locked in the chuck, the force for extracting the test mandrel 3 (see 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.

3.5.6 Eccentricity

The eccentricity of the test mandrel without applied load shall not exceed the total indicated run-out of 0,08 mm.

Testing shall be carried out in accordance with 4.3.3.

3.6 Water and spray air supply

3.6.1 Water cooling

If water cooling is provided, the handpiece shall transmit water to the cutting portion of the rotary instrument at a rate of at least 50 cm^3/min at 200 kPa (2 bar).

Testing shall be carried out in accordance with 4.4.2.1.

3.6.2 Air cooling

If air cooling is provided, the handpiece shall transmit air to the cutting portions of the rotary instrument at a rate of at least 1,5 STD (Standard flow rate) l/min.

Testing shall be carried out in accordance with 4.4.2.2.

3.6.3 Water and air cooling

If water and air are used simultaneously, a cooling mist shall be created and transmitted to the cutting portion of the rotary instrument.

Testing shall be carried out in accordance with 4.1.

3.7 Handpiece connectors

3.7.1 Standard coupling

The configuration, dimensions and tolerances of the back end of the handpiece shall comply with ISO 3964.

3.7.2 Coupling (Doriot)

Straight handpieces shall be capable of accepting geared angle attachments or other items. See ISO 3964.

3.7.3 Doriot nose attachment

This attachment shall have dimensions and tolerances as specified in ISO 3964.

3.8 Temperature rise

The temperature rise of the casing shall not exceed 20 °C.

Testing shall be carried out in accordance with 4.5.

3.9 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.

3.10 Sterilizability

Dental handpieces shall be sterilizable, i.e. they shall be capable of being subjected to a minimum of 250 cycles under 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

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 ± 1° for angles.

b) **Test mandrels** for all handpiece tests as shown in figure 2. The test mandrels 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 mandrels 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, 3.5.4 or 3.5.5 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 relevant **test mandrel** shown in figure 2 is required to measure the dynamic eccentricity.

4.3.3.2 Procedure

Install the relevant 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 Temperature rise

4.5.1 Equipment

Electronic contact thermometer having an accuracy of within 1 %.

4.5.2 Procedure

Operate the handpiece at the maximum speed without load in accordance with the manufacturer's instructions. After 3 min, measure the maximum temperature rise at the head and centre of the shank of the handpiece casing. Perform this test at (20 ± 2) °C.

4.6 Resistance to corrosion

4.6.1 Equipment

a) **Autoclave** capable of being operated at (136 ± 2) °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 ± 2) °C, each cycle being of $(3\ ^{+0,5}_{0})$ min duration at 220 kPa (2,2 bar).

5 Instructions for use, maintenance and service

5.1 Operator's manual

Each handpiece shall be supplied with instructions detailing operation, operator maintenance, lubrication, safety and servicing. At least the following information shall also be included:

a) maximum operating speed;

b) minimum fitting length (see ISO 1797);

c) maximum length of rotary instrument;

d) sterilizing instructions;

e) type and dimension of shank;

f) type of coupling which can be used (if appropriate);

g) cleaning and lubricating instructions;

h) gear ratio, if applicable.

NOTE 2 The head and nose dimensions may be included at the discretion of the manufacturer (see 3.4).

6 Marking

Handpieces shall be marked as follows:

a) manufacturer's name or trade-mark;

b) serial number;

c) mark to indicate autoclavability, if applicable (symbol in accordance with ISO 9687).