

INTERNATIONAL STANDARD

ISO
7785-2

Second edition
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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 7785-2:1995(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*, Subcommittee SC 4, *Dental instruments*.

This second edition cancels and replaces the first edition (ISO 7785-2:1991), of which it constitutes a technical revision.

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

As handpieces are complex constructions, it is not possible to specify all details even though they are important. Sometimes 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.

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 apply.

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 2:

Straight and geared angle handpieces

1 Scope

This part of ISO 7785 specifies requirements and test methods for straight and geared angle handpieces for application to patients. It also contains specifications on manufacturer's instructions, marking and packaging. These handpieces are operated by electrical or air-driven motors. In addition to these specified requirements, there are several other 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.

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 1797-1:1992, *Dental rotary instruments — Shanks — Part 1: Shanks made of metals*.

ISO 1797-2:1992, *Dental rotary instruments — Shanks — Part 2: Shanks made of plastics*.

ISO 1942-3:1989, *Dental vocabulary — Part 3: Dental instruments*.

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 7785-1:1992, *Dental handpieces — Part 1: High-speed air-turbine handpieces*.

ISO 9687:1993, *Dental equipment — Graphical symbols*.

IEC 601-1:1988, *Medical electrical equipment — Part 1: General requirements for safety*.

IEC 651:1979, *Sound level meters*.

3 Definitions

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

4 Classification

Straight and geared angle handpieces are dental handpieces driven by dental low-voltage or dental air motors.

Straight and geared angle handpieces are classified as given in table 1 of ISO 7785-1.

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 provide 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 5.8 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 5.8 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 5.8 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 and nose dimensions and terminology

If the manufacturer includes the head and nose dimensions in the operator's manual (see 8.2) they shall be the dimensions 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 terminology of figure 1.

Testing shall be carried out in accordance with 7.2.

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 and ISO 1797-2.

5.2.2 Test mandrels

5.2.3 Spring-type chuck, friction grip

The force to insert into, or withdraw the test mandrel type 3 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 type 3 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 for extracting the test mandrel type 1 and type 2 from the mechanical locking chuck shall be at least 45 N and the force for extracting the test mandrel type 3 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 type 1 and type 2 shall transmit a torque of at least 2 N-cm and the test mandrel type 3 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.

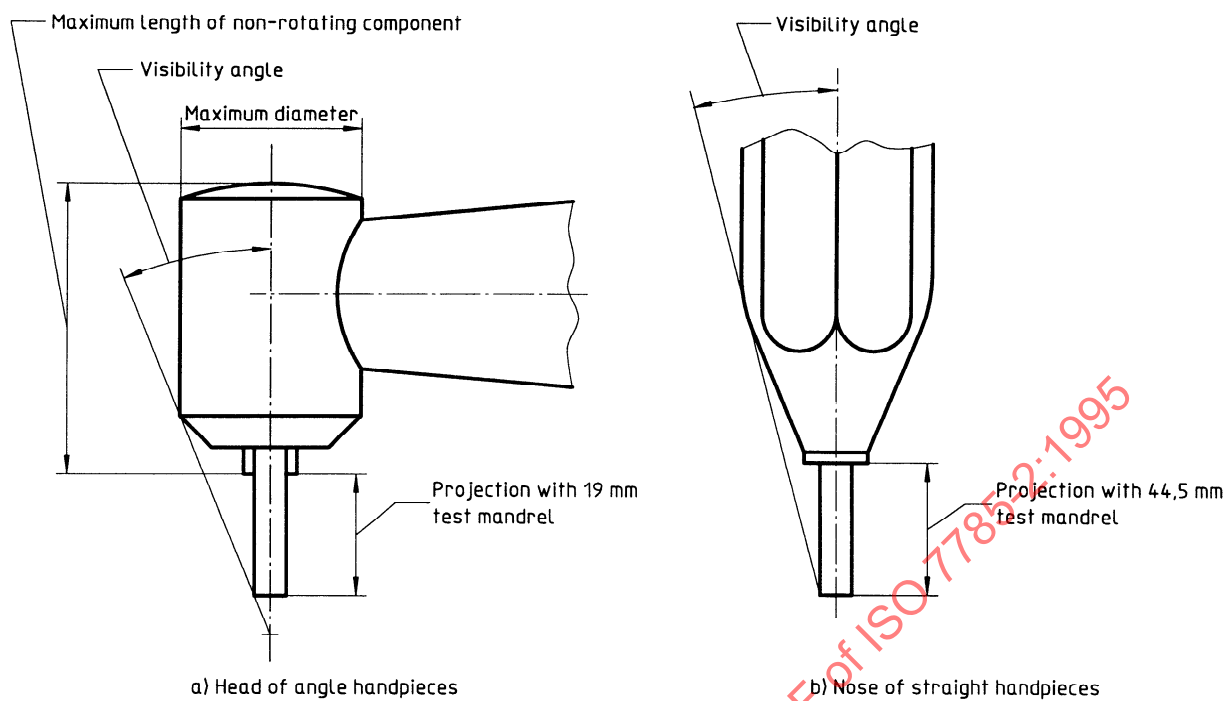


Figure 1 — Terminology for measuring head and nose dimensions

5.2.5 Latch-type chuck

The force for extracting the test mandrel type 1 from the locking chuck system shall be at least 45 N.

Testing shall be carried out in accordance with 7.3.1.

The latch mechanism shall hold the test mandrel type 1 without slipping (in rotation and linear movement) when the test mandrel is subjected to a torque of at least 4 N·cm.

Testing shall be carried out in accordance with 7.3.2.

5.2.6 Push-button locking chucks and other systems

5.2.6.1 For mandrel type 1 and type 2

The force for extracting the test mandrel type 1 or type 2 from the locking chuck system shall be at least 45 N.

Testing shall be carried out in accordance with 7.3.1.

When locked in the chuck the test mandrel type 1 shall transmit a torque of at least 4 N·cm and the test mandrel type 2 shall transmit a torque of at least 2 N·cm without slipping.

Testing shall be carried out in accordance with 7.3.2.

5.2.6.2 For test mandrel type 3

The force for extracting the test mandrel type 3 from the locking 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 type 3 shall transmit a torque of at least 1,6 N·cm without slipping.

Testing shall be carried out in accordance with 7.3.2.

5.2.7 Eccentricity

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

Testing shall be carried out in accordance with 7.3.3.

5.3 Water and spray air supply

5.3.1 Water cooling

If water cooling is provided, the handpiece shall transmit water to the cutting area of the rotary in-

strument at a rate of at least 50 ml/min at 200 kPa (2 bar).

Testing shall be carried out in accordance with 7.4.2.1.

5.3.2 Air cooling

If air cooling is provided, the handpiece shall transmit air to the cutting area of the rotary instrument at a rate of at least 1,5 l/min at 200 kPa (2 bar).

Testing shall be carried out in accordance with 7.4.2.2.

5.3.3 Water and air cooling

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

Testing shall be carried out in accordance with 7.1.

5.4 Handpiece connector

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

Visual inspection shall be carried out in accordance with 7.1.

5.5 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 the handpiece, totally or partially non-repairable, is of single-use type, the disposable part shall be sold sterile or shall be sterilizable one time before use, according to the manufacturer's instructions.

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

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

5.6 Temperature rise

The maximum temperature rise at the touchable surface of the housing under rated running conditions

shall not exceed 20 °C compared to the temperature of the environment.

Testing shall be carried out in accordance with 7.5.

5.7 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 7.6.

Visual inspection shall be carried out in accordance with 7.1.

5.8 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 a non-earthed 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 7.7.

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 Equipment

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

7.2.1.2 Test mandrels as shown in figure 2. The test mandrels shall be straight to within 0,0025 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.

Dimensions in millimetres;
surface roughness values in micrometres

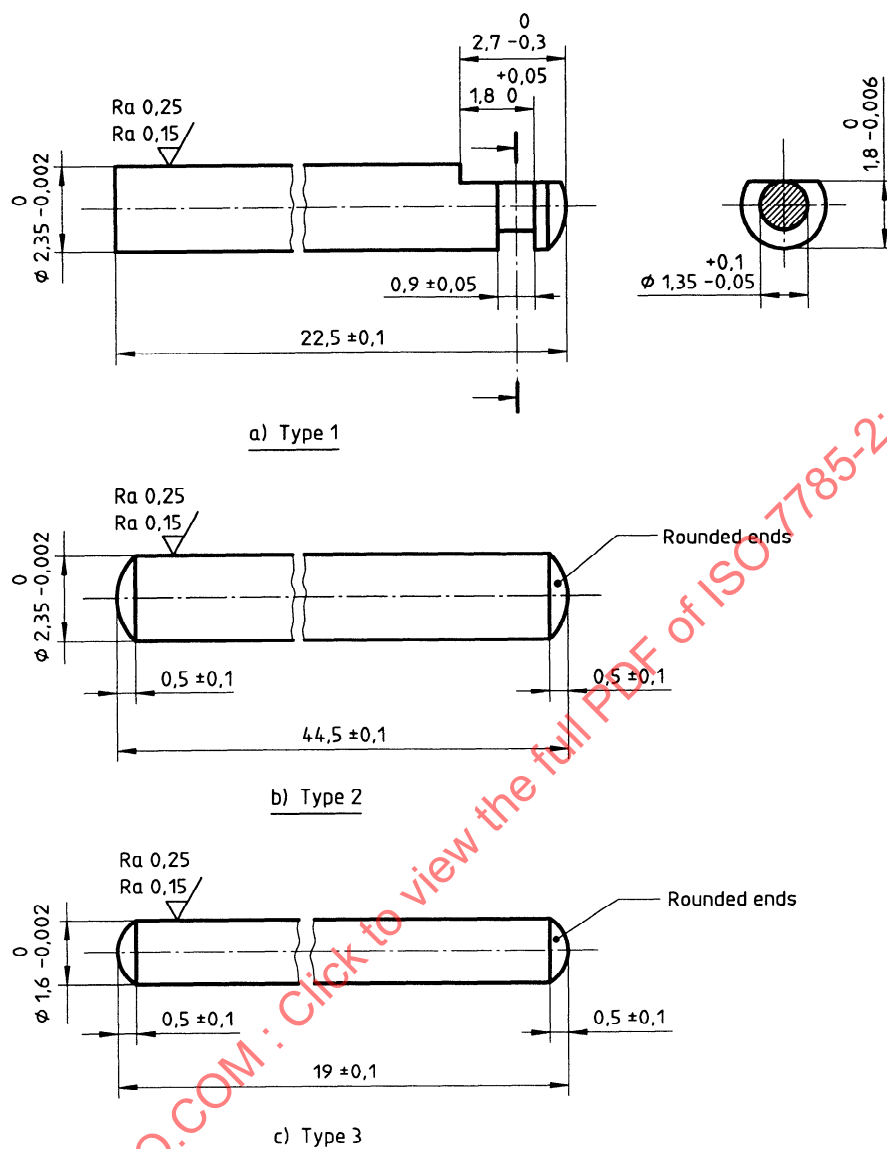


Figure 2 — Test mandrels

7.2.2 Procedure

Fully insert the relevant 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 Equipment

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

7.3.1.1.2 Test mandrels 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 exerted either to insert or to extract the test mandrel.