

INTERNATIONAL STANDARD

ISO
13294

First edition
1997-05-01

Dental handpieces — Dental air-motors

Pièces à main dentaires — Moteurs dentaires à air

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Reference number
ISO 13294:1997(E)

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Printed in Switzerland

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 13294 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 4, *Dental instruments*.

Annex A of this International Standard is for information only.

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Dental handpieces – Dental air-motors

1 Scope

This International Standard specifies requirements and test methods for dental air-motors, operated by dental units, and used for straight and geared angle handpieces for application on patients.

It also contains specifications on manufacturer's instructions, marking and packaging.

This International Standard 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.

This International Standard takes priority over IEC 601-1:1988 as specified in the individual clauses of this International Standard.

Only the specifications laid down in this International Standard are applicable.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this International Standard 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,	<i>Standard atmospheres for conditioning and/or testing — Specifications.</i>
ISO 1942-3:1989,	<i>Dental vocabulary — Part 3: Dental instruments.</i>
ISO 3696:1987,	<i>Water for analytical laboratory use — Specification and test methods.</i>
ISO 4211:1979,	<i>Furniture — Assessment of surface resistance to cold liquids.</i>
ISO 7494:1996,	<i>Dental units.</i>
ISO 7785-2:1995,	<i>Dental handpieces — Straight and geared angle handpieces.</i>
ISO 9168:1991,	<i>Dental handpieces — Hose connectors.</i>
ISO 9687:1993,	<i>Dental equipment — Graphical symbols.</i>
ISO 13402:1995,	<i>Surgical and dental hand instruments — Determination of resistance against autoclaving, corrosion and thermal exposure.</i>
IEC 601-1:1988,	<i>Medical electrical equipment — Part 1: General requirements for safety.</i>
IEC 651:1979,	<i>Sound level meters.</i>

3 Definitions

For the purposes of this International Standard, the definitions given in ISO 1942-3 and in IEC 601-1:1988, clause 2, apply.

4 Classification

4.1 Speed range

Dental air-motors are classified according to the free-running speed range of the dental air motor without a dental handpiece or with a dental handpiece as described in 5.2.7.

Table 1 — Free-running speed range

Type	Free-running speed range r/min
1	up to 10 000
2	up to 20 000
3	up to 40 000

4.2 Mode of operation

Dental air-motors are a type of equipment which is usually operated intermittently.

Testing shall be carried out in accordance with 8.1.

4.3 Environmental conditions

The requirements given in IEC 601-1:1988, clause 2.2.2 apply.

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

5 Requirements

5.1 General design

5.1.1 Construction and layout

Dental air-motors shall be constructed to 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.

These requirements cannot be objectively assessed. They are considered as fulfilled if the tests in 5.1 and 5.2 are passed.

5.1.1.1 Mechanical strength

Dental air-motors which are hand-held during normal use shall not present a safety hazard as a result of a free fall from a height of 1 m onto a hard surface, if not otherwise specified by the manufacturer.

Testing shall be carried out in accordance with 7.2.1 and, if applicable, IEC 601-1:1988, clause 21.5.

5.1.1.2 Outer surfaces, corners and edges

Surfaces, corners and edges which may cause injury shall be avoided or covered.

Testing shall be carried out in accordance with 7.2.1.

5.1.2 Connection and supply

Dental air-motors shall be capable of being easily disconnected from and reconnected to the services.

The services shall be supplied by a dental unit in accordance with ISO 7494.

5.1.3 Operating controls

5.1.3.1 General

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.

Testing shall be carried out in accordance with 7.2.1.

5.1.3.2 Speed

By the use of operating controls, dental air-motors shall be capable of changing speed as specified by the manufacturer.

The controls shall be provided at the dental air-motor itself or at the dental unit.

Testing shall be carried out in accordance with 7.2.1.

5.1.3.3 Direction of rotation (if applicable)

Dental air-motors shall provide operating controls for clockwise and anticlockwise rotation, if applicable, as specified by the manufacturer.

The controls shall be provided at the dental air-motor itself or at the dental unit.

Testing shall be carried out in accordance with 7.2.1.

5.1.4 Cleaning and disinfection

All touchable parts of dental air-motors shall be capable of being cleaned and disinfected, without deterioration of the dental air-motor surface or markings, by using agents recommended by the manufacturer.

Testing shall be carried out in accordance with the manufacturer's instructions, 8.1 i) and 7.1.2.

5.1.5 Sterilizability

If it is claimed that the touchable surface of the dental air-motor is capable of withstanding sterilization, it shall be capable of withstanding 250 sterilization cycles under the manufacturer's recommended sterilization procedure without signs of deterioration.

NOTE — This test is not a test of lifetime.

Visual inspection to indicate any signs of deterioration shall be carried out in accordance with 7.2.1.

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

5.1.6 Temperatures

5.1.6.1 Excessive temperatures

The requirements given in IEC 601-1:1988, clause 42 apply.

5.1.6.2 Temperature rise of housing

The difference between ambient temperature and the temperature of the touchable surface of the housing under no-load running conditions shall not exceed 20 °C.

Testing shall be carried out in accordance with 7.1.3.

5.1.7 Resistance to corrosion

The touchable surface of dental air-motors as specified from the manufacturer shall be corrosion-resistant, i.e. the materials used shall show no visible signs of corrosion after having been subjected to autoclave procedures.

Visual inspection to indicate any signs of deterioration shall be carried out in accordance with 7.2.1.

Testing shall be carried out in accordance with 7.1.4.

5.2 Technical requirements

5.2.1 Spray water supply

Dental air-motors shall be equipped, if applicable, to transmit water to a dental handpiece in accordance with ISO 7785-2. The equipment shall be capable of attaining a water flowrate of at least 50 ml/min at 250 kPa (2,5 bar).

Testing shall be carried out in accordance with 7.2.2.

5.2.2 Spray air supply

Dental air-motors shall be equipped, if applicable, to transmit air to a dental handpiece in accordance with ISO 7785-2. The equipment shall be capable of attaining an air flowrate of at least 1,5 l/min at 250 kPa (2,5 bar).

Testing shall be carried out in accordance with 7.2.3.

5.2.3 Motor air supply

Dental air-motors shall be operated by a pressure air supply in accordance with the manufacturer's instructions. The necessary flowrate should be ≤ 65 l/min in a pressure range of 200 kPa to 400 kPa (2,0 bar to 4,0 bar).

If the dental air-motor has a connection of type B, C or D in accordance with ISO 9168, it shall have an exhaust air connection.

Testing shall be carried out in accordance with 7.2.4.

5.2.4 Handpiece connector

The configuration, dimensions and tolerances of the dental air-motor to be connected to a dental handpiece should comply with ISO 3964.

Testing shall be carried out by inspection and measurement using readily available measuring instruments.

5.2.5 Air-motor connector

The configuration, dimensions and tolerances of connections of the dental air-motor 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 is made by a quick connector, the connector shall be in accordance with ISO 9168.

Testing shall be carried out by inspection and measurement using readily available measuring instruments.

5.2.6 Energy for light supply (if applicable)

Dental air-motors shall be supplied with voltage which does 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 7.3.2.

5.2.7 Speed

The free-running speed of the dental air-motor shall be in accordance with the manufacturer's instructions at a tolerance of $\pm 10\%$ for both directions.

Testing shall be carried out in accordance with 7.2.5.

5.2.8 Rotation

Dental air-motors should be capable of being operated clockwise or anticlockwise as indicated by the manufacturer.

Testing shall be carried out in accordance with 7.2.1.

5.2.9 Stall torque

For dental air-motors of type 1, the generated torque shall be more than 2,5 N·cm at a minimum air pressure of 200 kPa (2,0 bar).

For dental air-motors of type 2, the generated torque shall be more than 1,5 N·cm at a minimum air pressure of 200 kPa (2,0 bar).

For dental air-motors of type 3, the generated torque shall be more than 1,0 N·cm at a minimum air pressure of 200 kPa (2,0 bar).

Testing shall be carried out in accordance with 7.2.6.

5.2.10 Noise level

The A-weighted sound pressure level generated by dental air-motors shall not exceed 80 dB.

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

Testing shall be carried out in accordance with 7.2.7.

5.2.11 Air pressure

Dental air-motors shall remain intact, i.e. 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 7.2.8.

6 Sampling

At least one dental air-motor for each model series shall be evaluated for compliance with this International Standard.

7 Testing

7.1 General tests

7.1.1 General provisions

The sequence of tests shall be in accordance with IEC 601-1:1988, appendix C.

All tests described in this International Standard are type tests. Unless otherwise specified, tests shall not be repeated.

Since some of the tests described are destructive tests, the dental air-motor tested shall not be used afterwards.

The rating of components shall be inspected to check that they are appropriate for the application intended.

Where a component or equipment part has specified ratings exceeding those appropriate to its use in the equipment, testing over such a wider range is not required.

Dental air-motors, or parts thereof, using materials or having forms of construction different from those detailed in this International Standard shall be acceptable if it can be demonstrated that an equivalent degree of safety is obtained.

7.1.2 Cleaning and disinfection

The cleaning and disinfection test shall be carried out in accordance with ISO 4211.

Cleaning and disinfecting agents shall be applied for 24 h.

7.1.3 Temperature rise of housing

7.1.3.1 Apparatus

Electronic contact thermometer, having an accuracy of $\pm 1\%$.

7.1.3.2 Procedure

Operate the dental air-motor at the maximum speed, without load, in accordance with the manufacturer's instructions. After 3 min, measure the temperature at the head and the centre of the touchable surface of the dental air-motor housing. Perform this test at an ambient temperature of $(23 \pm 2)^\circ\text{C}$ in accordance with ISO 554.

7.1.4 Resistance to corrosion

7.1.4.1 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.

7.1.4.2 Procedure

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

Testing shall be carried out in accordance with ISO 13402.

7.2 Technical tests

7.2.1 Visual inspection

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

7.2.2 Spray water supply

7.2.2.1 Apparatus

- a) **Volumetric measuring jar**, graduated with an accuracy of 5 %, to measure the spray water volume.
- b) **Pressure gauges**, with an accuracy of 5 %, to measure the water supply pressure at the inlet of the dental air-motor.

7.2.2.2 Procedure

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

7.2.3 Spray air supply

7.2.3.1 Apparatus

- a) **Flowmeter**, with an accuracy of 5 %, to measure the spray air flowrate.
- b) **Pressure gauges**, with an accuracy of 5 %, to measure the air supply pressure at the inlet of the dental air-motor.

7.2.3.2 Procedure

Install the flowmeter at the dental air-motor connector and measure the spray air flowrate while operating the dental air-motor at the maximum recommended operating pressure. Air flow measurements shall be corrected to standard flowrates.

7.2.4 Motor air supply

7.2.4.1 Apparatus

- a) **Flowmeter**, with an accuracy of 5 %, to measure the motor cooling air flowrate.
- b) **Pressure gauges**, with an accuracy of 5 %, to measure the air supply pressure at the inlet of the dental air-motor.

7.2.4.2 Procedure

Install the flowmeter at the dental air-motor connector and measure the motor air supply flowrate while operating the dental air-motor at the maximum recommended operating pressure. Air flow measurements shall be corrected to standard flowrates.

7.2.5 Speed

7.2.5.1 Apparatus

- a) **Ungeared (1:1) dental handpiece**, in accordance with ISO 7785-2.
- b) **Non-contacting tachometer**, e.g. magnetic proximity gauge or photo-optic tachometer or spectrum analyzer with appropriate transducer, accurate to 5 %.

7.2.5.2 Procedure

Using the dental handpiece, operate the dental air-motor using the maximum recommended power supply and measure the speed in reciprocal minutes (revolutions per minute).

7.2.6 Stall torque

7.2.6.1 Apparatus

- a) **Dental handpiece**, in accordance with ISO 7785-2.
- b) **Non-contacting tachometer**, e.g. magnetic proximity gauge or photo-optic tachometer or spectrum analyzer with appropriate transducer, accurate to 5 %.
- c) **Torque watch or dynamometer**, capable of measuring the stall torque in newton centimetres with an accuracy of 10 %.

7.2.6.2 Procedure

Using the dental handpiece, operate the dental air-motor using the recommended power supply and measure the torque over the speed range.

7.2.7 Noise level

7.2.7.1 Apparatus

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

7.2.7.2 Test environment

The measurements shall be taken in a room with dimensions greater than 2,5 m x 2,5 m x 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 dB. There shall be no hard reflective surface within a 1 m envelope of the dental air-motor under test. Foam or non-reflective material may be used to reduce reflections from hard surfaces.

7.2.7.3 Procedure

Suspend the dental air-motor in the centre of the chamber by means of a non-rigid suspension system. Operate the dental air-motor at the maximum recommended unloaded speed. Using the sound level meter, measure the maximum A-weighted sound pressure level generated from the dental air-motor at a distance of 0,45 m from the motor centre.

7.2.8 Air pressure

7.2.8.1 Apparatus

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

7.2.8.2 Procedure

Operate the dental air-motor at 50 % above the recommended operating pressure for a period of 10 min. Observe if the air-motor ruptures or bursts.

7.3 Environmental conditions

7.3.1 Operation

The requirements given in IEC 601-1:1988, clause 10.2 apply.

7.3.2 Energy for light supply (if applicable)

7.3.2.1 Power supply

The dental air-motor shall be designed to operate from supply mains as described by the manufacturer.

The requirements given in IEC 601-1:1988, clause 19.1 c) apply.

Testing shall be carried out following instructions in accordance with 8.1 and using readily available measuring instruments.

7.3.2.2 Continuous leakage currents and patient auxiliary currents

Test the patient leakage current and the patient auxiliary current with the complete light system

- a) after the dental air-motor has been brought up to normal operating temperature in accordance with the requirements of IEC 601-1:1988, clause 7;
- b) after the moisture preconditioning treatment as described in IEC 601-1:1988, clause 4.10. The measurements shall be carried out with equipment located outside the humidity cabinet and shall commence 1 h after equipment has been taken out of this cabinet, and has been placed in an environment with a temperature less