INTERNATIONAL STANDARD

ISO 11498

First edition
1997-02-15

Dental handpieces — Dental low-voltage electrical motors

Pièces à main dentaires — Moteurs électriques dentaires à basse tension

Reference number
ISO 11498:1997(E)

Foreword

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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 11498 was prepared by Technical Committee ISO/TC 106, *Dentistry,* Subcommittee SC 4, *Dental instruments*.

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Printed in Switzerland

Dental handpieces – Dental low-voltage electrical motors

1 Scope

This International Standard specifies requirements and test methods for dental low-voltage electrical motors used in connection with dental handpieces for application on patients. It also contains specifications on manufacturer's instructions, packaging and marking. All tests described in this International Standard are type tests.

Dental low-voltage electrical motors are operated by dental units or as independent mobile devices. They are used for straight and geared angle handpieces.

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.

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

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, *Standard atmospheres for conditioning and/or testing — Specifications.*

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 4211:1979, *Furniture — Assessment of surface resistance to cold liquids.*

ISO 7494:1996, *Dental units.*

ISO 7785-2:1995, *Dental handpieces — Part 2: Straight and geared angle handpieces.*

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

IEC 601-1-2:1993, *Medical electrical equipment — Part 1: General requirements for safety — Part 2: Electromagnetic compatibility of medical electrical equipment and/or systems.*

IEC 651:1979, *Sound level meters.*

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 Range of free-running speed

Dental low-voltage electrical motors can be classified by their free-running speed range in accordance with table 1.

Table 1 — Classification of motor

Type	Speed range r/min
1	up to 20 000
2	4 000 to 40 000
3	4 000 to over 40 000

4.2 Type of protection against electric shock

Dental low voltage electrical motors are classified as Class II equipment, in which protection against electric shock does not rely on basic insulation only, but in which additional safety precautions such as double insulation or reinforced insulation are provided, there being no provision for protective earthing or reliance upon installation conditions.

4.3 Degree of protection against electric shock

Dental low-voltage electrical motors shall be grouped as either Type B or Type BF equipment (Type B equipment with an F-type isolated (floating) applied part).

4.4 Operating conditions

4.4.1 Intermittent operation

Dental low-voltage electrical motors are a type of dental equipment which is operated intermittently.

4.4.2 Environment

Dental low-voltage electrical motors shall not be used in the presence of a flammable anaesthetic gas mixed with air or with oxygen or nitrous oxide.

5 Requirements

5.1 General

5.1.1 Construction

The dental low-voltage electrical motor shall be constructed to provide safe and reliable operation and, if reparable on site, should be capable of being easily disassembled and reassembled for maintenance and repair, using readily available tools or those supplied by the manufacturer.

5.1.1.1 Mechanical strength

If not otherwise described by the manufacturer, the dental low-voltage electrical motor shall not incur damage such that its safety is no longer warranted as a result of a free fall from a height of 1 m onto a plain smooth ceramic floor surface.

Testing shall be carried out in accordance with 7.3.1 and, if applicable, IEC 601-1:1988, clause 21.5.

5.1.1.2 Surfaces, corners and edges

There shall be no uncovered rough surfaces, sharp corners or edges which may cause injury or damage.

Verification shall be carried out visually (7.3.1).

5.1.2 Power connection

The dental low-voltage electrical motor shall be capable of being easily disconnected from and reconnected to the power supply.

The service shall be supplied from a dental unit complying with ISO 7494.

Testing shall be carried out in accordance with 7.3.2.

5.1.3 Operating controls

5.1.3.1 General

Operating controls shall be designed and located to minimize unintentional activation.

Graphical symbols for operating controls and functions shall be in accordance with ISO 9687.

Verification shall be carried out visually (7.3.1)

5.1.3.2 Speed

The dental low-voltage electrical motor, or dental low-voltage electrical motor connected to a dental unit, shall be provided with operating controls to change the speed as described by the manufacturer.

Verification shall be carried out visually (7.3.1)

5.1.3.3 Direction of rotation

The dental low-voltage electrical motor, or dental low-voltage electrical motor connected to a dental unit, shall be provided with operator controls to allow clockwise and anticlockwise rotation as described by the manufacturer.

The controls shall be located on the dental low-voltage electrical motor itself or on the dental unit.

Verification shall be carried out visually (7.3.1)

5.1.4 Disinfection and cleaning

All accessible exterior parts of the dental low-voltage electrical motor shall be capable of undergoing surface disinfection and cleaning without causing deterioration of the motor's surface or markings, using agents recommended by the manufacturer.

Testing shall be carried out in accordance with 7.2.7.

5.1.5 Sterilizability

If applicable, the accessible exterior surfaces of the dental low-voltage electrical motor shall be sterilizable. Testing shall be carried out according to the manufacturer's instructions. The surfaces shall withstand a minimum of 250

cycles under the manufacturer's recommended sterilizing procedure without visible exterior signs of deterioration and no greater than 10 % reduction in motor shaft power.

NOTE — This test is not a test of service lifetime.

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

5.1.6 Temperature limits

5.1.6.1 Excessive temperatures

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

5.1.6.2 Temperature increase of housing

The temperature at the accessible exterior surfaces of the motor housing under no-load running conditions shall not exceed that of the ambient environment by more than 20 °C.

Testing shall be carried out in accordance with 7.2.8.

5.1.7 Corrosion resistance

The accessible exterior surfaces of the dental low-voltage electrical motor shall be corrosion-resistant as specified from the manufacturer, i.e. the materials used shall show no visible signs of corrosion after being subjected to autoclaving.

Testing shall be carried out in accordance with 7.2.9.

5.2 Operating requirements and recommendations

5.2.1 Spray water supply

If applicable, the dental low-voltage electrical motor shall supply equipment to transmit water to the dental handpiece (in accordance with ISO 7785-2). The equipment shall be capable of attaining a maximum water flowrate of a least 50 ml/min at 250 kPa (2,5 bar).

Testing shall be carried out in accordance with 7.3.3.

5.2.2 Spray air supply

If applicable, the dental low-voltage electrical motor shall supply equipment to transmit air to the 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.

Testing shall be carried out in accordance with 7.3.4.

5.2.3 Motor cooling air

If the dental low-voltage electrical motor is equipped with an air cooling system, the maximum air flowrate should be 40 l/min and the pressure range should be between 250 kPa to 500 kPa (2,5 bar to 5,0 bar).

The dental low-voltage electrical motor shall have an outlet connection for the motor air cooling.

Testing shall be carried out in accordance with 7.3.5.

5.2.4 Handpiece connector

The configuration, dimensions and tolerances of the dental handpiece connector to the dental low-voltage electrical motor should comply with ISO 3964.

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

5.2.5 Light supply

If the dental low-voltage electrical motor is equipped with a light supply system, this shall be described by the manufacturer.

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

5.2.6 Free-running speed

The free-running speed range of the dental low-voltage electrical motor shall be in accordance with the manufacturer's declaration, with a tolerance of ± 10 % for both clockwise and anticlockwise directions.

Testing shall be carried out in accordance with 7.3.6.

5.2.7 Rotation

The dental low-voltage electrical motor should be capable of clockwise and anticlockwise rotation as described by the manufacturer.

Verification shall be carried out visually (7.3.1).

5.2.8 Torque

The generated torque shall be more than 0,01 N·m for Types 1 and 2 motors; the generated torque shall be more than 0,02 N·m for Type 3.

Testing shall be carried out in accordance with 7.3.7.

5.2.9 Noise level

The A-weighted sound pressure value generated by the dental low-voltage electrical motor shall not exceed 75 dB.

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

Testing shall be carried out in accordance with 7.3.8.

5.3 Electrical requirements

5.3.1 Power input and supply voltage

The requirements given in IEC 601-1:1988, clause 7, apply.

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 7.4.1.2.

5.3.2 Single fault conditions

The requirements given in IEC 601-1:1988, clause 3.6. apply.

5.3.3 Protection against electric shock hazards

The requirements given in IEC 601-1:1988, clause 13 apply.

5.3.4 Requirements related to classification (see clause 4)

5.3.4.1 Class II equipment

The requirements given in IEC 601-1:1988, clause 14.2 apply.

5.3.4.2 Type B and BF

The requirements given in IEC 601-1:1988, clause 14.6 apply.

5.3.5 Enclosures and protective covers

The requirements given in IEC 601-1:1988, clause 16 apply.

5.3.6 Spillage, leakage and ingress of liquids

The requirements given in IEC 601-1:1988, clauses 44.3, 44.4 and 44.6, apply.

5.3.7 Protective earthing, functional earthing and potential equalization

The requirements given in IEC 601-1:1988, clause 18, items a) to g), apply.

5.3.8 Continuous leakage currents and patient auxiliary currents

The maximum allowable values shall be as specified in table 2.

Table 2 — Maximum allowable values of continuous leakage currents and patient auxiliary currents

Current path	Type BF	
	mA	
	NC [1]	SFC [2]
Patient leakage current	0,1	0,5
Patient leakage current (mains voltage on the applied part)	–	5

1) NC: Normal condition.
2) SFC: Single fault condition

Testing shall be carried out in accordance with 7.4.2.

5.3.9 Dielectric strength

The dental low-voltage electrical motor shall provide the dielectric strength to withstand the test voltage of 500 V applied between applied part and motor casing.

Testing shall be carried out in accordance with 7.4.3.

5.3.10 Interruption of power supply

The requirements given in IEC 601-1:1988, clauses 49.1 and 49.2, apply.

5.3.11 Abnormal operation and fault conditions

The requirements given in IEC 601-1:1988, clause 52, apply.

5.3.12 Components and general assembly

The requirements given in IEC 601-1:1988, clause 56.1, items b) and d), apply.

The requirements given in IEC 601-1:1988, clauses 56.3 to 56.10, apply.

The requirements given in IEC 601-1:1988, clause 56.11, item b) apply.

5.3.13 Construction and layout

The requirements given in IEC 601-1:1988, clause 59, apply.

5.3.14 Electromagnetic compatibility

The requirements given in IEC 601-1-2 apply.

6 Sampling

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

7 Testing

7.1 General

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. This applies specifically to the dielectric strength tests, which shall be made only on the manufacturer's premises or in independent test laboratories.

Since some of the tests described are destructive tests, the dental low-voltage electrical 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, it does not have to be tested for such a wider range.

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

7.2 Preliminary procedures

7.2.1 Ambient temperature, humidity, atmospheric pressure

After the dental low-voltage electrical motor being tested has been set up for normal use, carry out tests under operating conditions at

a) an ambient temperature within the range 21 °C to 35 °C;

b) a relative humidity within the range 45 % to 55 %;

c) an atmospheric pressure within the range 860 hPa to 1060 hPa (645 mmHg to 795 mmHg).

The dental low-voltage electrical motor shall be protected from other atmospheric conditions which might affect the validity of the tests (for example, draughts).

7.2.2 Other conditions

The requirements given in IEC 601-1:1988, clause 4.6, items a), b) and d), apply.

7.2.3 Supply and test voltages, type of current, nature of supply, frequency

The requirements given in IEC 601-1:1988, clause 4.7, apply.

7.2.4 Preconditioning

The requirements given in IEC 601-1:1988, clause 4.8, apply.

7.2.5 Repairs and modifications

The requirements given in IEC 601-1:1988, clause 4.9, apply.

7.2.6 Humidity preconditioning treatment

The requirements given in IEC 601-1:1988, clause 4.10, apply.

7.2.7 Disinfection and cleaning

A disinfection and cleaning test shall be carried out in accordance with ISO 4211. Disinfection and cleaning agents shall be applied for 24 h.

7.2.8 Temperature increase of housing

7.2.8.1 Apparatus

Electronic contact thermometer having an accuracy of ± 1 %.

7.2.8.2 Procedure

Operate the dental low-voltage electrical motor at maximum speed without load in accordance with the manufacturer's instructions. After 3 min, measure the temperature rise at the handpiece of the touchable surface of the dental low voltage electrical motor housing. Perform this test at (23 ± 2) °C ambient temperature in accordance with ISO 554.

7.2.9 Corrosion resistance

7.2.9.1 Apparatus and material

a) Autoclave, capable of being operated at (136 ± 2) °C and 220 kPa (2,2 bar).

b) Distilled or deionized water, of grade 3 in accordance with ISO 3696.

7.2.9.2 Procedure

Subject the touchable surface to 10 autoclave cycles at (136 ± 2) °C.

Carry out the corrosion-resistance test in accordance with ISO 13402.

7.3 Operating requirements

7.3.1 Visual inspection

Visually inspect the motor at normal visual acuity without magnification.

7.3.2 Manual inspection

The disconnectability and reconnectability of the dental low-voltage electrical motor from the electrical supply shall be carried out by manual inspection.

7.3.3 Spray water supply

7.3.3.1 Apparatus

a) Volumetric measuring jar, to measure the volume of spray water with an accuracy of ± 5 %.

b) Pressure gauges, to measure with an accuracy of ± 5 % the pressure of the water supply to the inlet of the dental low-voltage electrical motor.

7.3.3.2 Procedure

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

7.3.4 Spray air supply

7.3.4.1 Apparatus

a) Flowmeter, to measure with an accuracy of ± 10 % the spray air flowrate.

b) Pressure gauges, to measure with an accuracy of ± 5 % the air supply pressure at the inlet of the dental low-voltage electrical motor.

7.3.4.2 Procedure

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

7.3.5 Motor cooling air

7.3.5.1 Apparatus

a) Flowmeter, to measure with an accuracy of ± 10 % the motor cooling air flowrate.

b) Pressure gauges, to measure with an accuracy of ± 5 % the air supply pressure at the inlet of the dental low voltage electrical motor.

7.3.5.2 Procedure

Install the flowmeter at the dental low-voltage electrical motor connector and measure the motor air cooling flowrate while operating the motor at the maximum recommended speed. Air flowrate measurements shall be corrected to standard flowrates.

7.3.6 Free-running speed

7.3.6.1 Apparatus

a) Ungeared (1:1) dental handpiece, in accordance with ISO 7785–2.

b) Noncontacting tachometer, e.g. magnetic proximity gauge or photooptic tachometer or spectrum analyser with appropriate transducer, accurate to ± 5 %.

7.3.6.2 Procedure

With the dental handpiece attached, operate the dental low-voltage electrical motor at the maximum and minimum of the rated power supply voltage range and measure the speed, in reciprocal minutes (revolutions per minute).

7.3.7 Torque

7.3.7.1 Apparatus

a) Dental handpiece, in accordance with ISO 7785–2.

b) Noncontacting tachometer, e.g. magnetic proximity gauge or photooptic tachometer or spectrum analyser with appropriate transducer, accurate to ± 5 %.

c) Torque watch or dynamometer, capable of measuring the torque in millinewton metres with an accuracy of ± 10 %.

7.3.7.2 Procedure

With the dental handpiece attached, operate the dental low-voltage electrical motor at the maximum and minimum of the rated power supply voltage range and measure the torque over the speed range.

Rotate the torque watch slowly and read the maximum value.

7.3.8 Noise level

7.3.8.1 Apparatus

a) Precision sound level meter, meeting the requirements for a type 1 instrument as specified in IEC 651.

b) Nonrigid suspension system.

7.3.8.2 Test environment

The measurements shall be taken in a room with dimensions greater than 2,5 m × 2,5 m × 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 low-voltage electrical motor under test. Foam or nonreflective material may be used to reduce reflections from hard surfaces.

7.3.8.3 Procedure

Suspend the dental low-voltage electrical motor under test in the centre of the chamber by means of a nonrigid suspension system. Operate the motor at the maximum and minimum rated unloaded speeds. Using the sound level meter, measure the maximum A-weighted sound pressure level value generated from the motor at a distance of 0,45 m from the motor centre.

7.4 Electrical requirements

7.4.1 Environmental conditions

7.4.1.1 Operation

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

7.4.1.2 Power supply

The dental low-voltage electrical 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, item c), apply.

Testing shall be carried out in accordance with 8.1, using readily available measuring instruments.