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Dental handpieces — Air-powered scalers and scaler tips

Pièces à main dentaires — Instruments dentaires pour détartrage, actionnés par air comprimé, et parties actives de l'instrument pour détartrage

Reference number
ISO 15606:1999(E)

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 3.

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.

Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 15606 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 4, *Dental instruments*.

Introduction

This International Standard takes priority over IEC 60601-1:1988 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 60601-1:1988, the basic standard on safety of medical electrical equipment, wherever relevant, by stating the respective clause numbers of IEC 60601-1:1988.

Dental handpieces — Air-powered scalers and scaler tips

1 Scope

This International Standard specifies requirements and tests methods for dental air-powered scalers and scaler tips, operated by connection to dental units, for use on patients. It also contains specifications concerning manufacturers' instructions, marking and packaging.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

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

ISO 7000, *Graphical symbols for use on equipment — Index and synopsis.*

ISO 9168, *Dental handpieces — Hose connectors.*

ISO 9687, *Dental equipment — Graphical symbols.*

ISO 13402:1995, *Surgical and dental hand instruments — Determination of resistance against autoclaving, corrosion and thermal exposure.*

ISO/TR 15223, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.*

IEC 60601-1:1988, *Medical electrical equipment — Part 1: General requirements for safety.*

IEC 60651, *Sound level meters.*

3 Terms and definitions

For the purposes of this International Standard, the terms and definitions given in ISO 1942-3 and the following apply.

3.1
scaler tip
fixed or interchangeable dental instrument used in an air-powered scaler and consisting of a shaft and a working part for dental procedures of air scaling

4 Requirements and recommendations

4.1 General design

4.1.1 General

Dental air-powered scalers should be comfortable for the operator to use and easy to manipulate. The outside surface of the scaler should be easy to clean, and particular attention should be given to providing secure gripping surfaces for operator manipulation. In order to reduce glare, highly polished surfaces should be avoided.

Dental air-powered scalers normally comprise a handpiece into which scaler tips are interchangeably inserted.

Internal parts should be designed in such a way that either penetration of liquids or particles is impossible or the scalers are easy to clean.

Compliance with these requirements cannot be objectively assessed.

They are considered as fulfilled if all tests specified in clause 6 are passed. All tests described in this International Standard are type tests.

4.1.2 Materials

All materials used in the construction of dental air-powered scalers should be suitable for their intended use.

When tested in accordance with 6.10, dental air-powered scalers shall be resistant to cleaning, disinfecting and sterilizing procedures recommended by the manufacturer.

Compliance with these requirements cannot be objectively assessed.

They are considered as fulfilled if all tests specified in clause 6 are passed.

4.1.3 Construction and layout

The construction of dental air-powered scalers should provide for their safe and reliable operation. If field-repairable, the scalers should be capable of being easily disassembled and reassembled for maintenance and repair, utilizing either readily available tools or special tools supplied by the manufacturer.

Compliance with these requirements cannot be objectively assessed.

They are considered as fulfilled if all tests specified in clause 6 are passed.

4.1.4 Dimensions

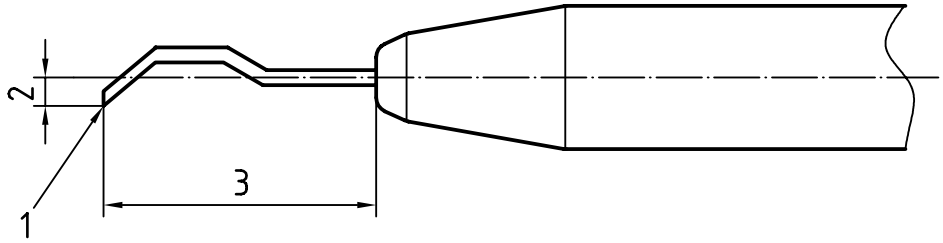
If the manufacturer includes the dimensions of the scaler tip in the operator's manual, they shall be the dimensions 2 and 3 named in Figure 1 and shall be expressed to an accuracy of ± 0,2 mm, using the nomenclature of Figure 1.

Testing shall be carried out by inspection and measurement in accordance with 6.2.

4.1.5 Handpiece connection

The configuration, dimensions and tolerances of hose connections shall be in accordance with ISO 9168.

Testing shall be carried out by inspection and measurement in accordance with 6.1.



Key

1 Scaler tip
2 Offset
3 Length

Figure 1 — Terminology for measuring dimensions

4.2 Scaler tip

4.2.1 Extraction force

When installed in accordance with the manufacturer's instructions, scaler tips shall withstand, without displacement, a minimum axial (extraction) force of 20 N.

Testing shall be carried out in accordance with 6.3.1.

4.2.2 Torque

When installed in accordance with the manufacturer's instructions, scaler tips shall withstand, without displacement, a minimum torque of 200 N · mm.

Testing shall be carried out in accordance with 6.3.2.

4.2.3 Insertion force

The insertion force required to fit scaler tips to the handpiece shall not exceed a force of 50 N and/or a torque of 700 N · mm.

Testing shall be carried out in accordance with 6.3.3.

4.3 Performance

4.3.1 Frequency

The frequency of scaler tips shall be between 4 000 Hz and 40 000 Hz, when operated at the air flowrate and air pressure specified by the manufacturer.

Testing shall be carried out in accordance with 6.4.

4.3.2 Amplitude

The maximum amplitude of the scaler tip shall not normally exceed 200 µm, when operated at the air flowrate and air pressure as recommended by the manufacturer.

If the maximum amplitude of scaler tips exceeds 200 µm in any direction, the manufacturer’s instruction shall include a corresponding warning.

Testing shall be carried out in accordance with 6.5.

4.3.3 Stall effort

With the dental air-powered scaler operating at the manufacturer's specified air pressure and flowrate, the force applied to the scaler tip to stall vibration shall not exceed 10 N.

Testing shall be carried out in accordance with 6.6.

4.4 Water cooling

Air-powered scalers shall provide water-cooling capability to the operating area of the scaler tip at a minimum flowrate of 20 ml/min at 200 kPa (2,0 bar).

Testing shall be carried out in accordance with 6.7.

4.5 Air pressure

Air-powered scalers shall remain intact, i.e. they shall not rupture or burst, when subjected to an air pressure 50 % above the operating pressure specified by the manufacturer.

Testing shall be carried out in accordance with 6.8.

4.6 Noise level

The A-weighted sound pressure value generated by air-powered scalers shall not exceed 80 dBA.

NOTE It is recommended to reduce the the A-weighted noise level to 70 dBA.

Testing shall be carried out in accordance with 6.9.

4.7 Resistance to corrosion

Air-powered scalers 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 6.10.

Visual inspection shall be carried out in accordance with 6.1.

4.8 Resistance to sterilization

Air-powered scalers shall be capable of being subjected to a minimum of 250 cycles of the manufacturer's specified sterilizing procedure without any signs of deterioration or loss of performance.

Single-use scalers, or the disposable (non-reusable) parts of scalers, shall be supplied sterile or shall be capable of withstanding two cycles of sterilization in accordance with manufacturer's instructions.

Visual inspection shall be carried out to detect any signs of deterioration.

4.9 Energy for light supply (if applicable)

Scalers 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 main by a safety transformer or by a device with an equivalent separation.

Testing shall be carried out in accordance with 6.11.

5 Sampling

At least one scaler for each model series shall be tested for compliance with this International Standard.

6 Test methods

6.1 Visual inspection

Carry out visual inspection at normal visual acuity without magnification.

6.2 Dimensions

6.2.1 Apparatus

6.2.1.1 Measuring device, such as a gauge, dial indicator, etc. with an accuracy of 0,01 mm for measuring linear dimension.

6.2.2 Procedure

Fully insert the scaler tip in the handpiece. Measure and record the dimensions shown in Figure 1.

6.3 Scaler tip

6.3.1 Extraction

6.3.1.1 Apparatus

6.3.1.1.1 Spring force gauge with an accuracy of ± 0,5 N.

6.3.1.2 Procedure

Install the scaler tip in the handpiece in accordance with the manufacturer's instructions. Operate the handpiece at the recommended air flowrate, air pressure, maximum water flowrate and maximum frequency for at least 1 min. Adjust the force gauge to register the maximum force exerted. Apply the device and record the force required to extract the moving scaler tip.

6.3.2 Torque

6.3.2.1 Apparatus

6.3.2.1.1 Torque watch or dynamometer capable of measuring the torque in newton millimetres (N · mm) with an accuracy of ± 10 %.

6.3.2.2 Procedure

Install the scaler tip in the handpiece in accordance with the manufacturer's instructions. Operate the handpiece at the recommended air flowrate, air pressure, maximum water flowrate and maximum frequency for at least 1 min. Adjust the measuring device to register the maximum torque exerted. Apply the device and record the required torque to unlock the scaler tip from the air-powered scaler.

6.3.3 Insertion force

6.3.3.1 Apparatus

6.3.3.1.1 Spring force gauge with an accuracy of ± 0,5 N, and/or

6.3.3.1.2 Torque watch or dynamometer capable of measuring the torque in newton millimetres (N · mm) with an accuracy of ± 10 %.

6.3.3.2 Procedure

Install the scaler tip in the handpiece under application of the device in accordance with the manufacturer's instructions. Record the required force and/or torque to lock the scaler tip in the handpiece.

6.4 Frequency

6.4.1 Apparatus

6.4.1.1 Non-contacting vibrometer with an accuracy of ± 10 % of the measured value.

6.4.2 Procedure

Install the scaler tip in the handpiece in accordance with the manufacturer's instructions. Operate the handpiece at the recommended air flowrate, air pressure, maximum water flowrate and maximum frequency for at least 1 min without any applied load. The frequency of oscillation of the scaler tip shall be measured from the output of the vibrometer using either an electronic frequency counter or an oscilloscope with a calibrated timebase.

6.5 Amplitude

6.5.1 Apparatus

6.5.1.1 Measuring device such as gauge, dial indicator, etc. with an accuracy of 0,01 mm.

6.5.1.2 Microscope, with a magnification of at least 100× and a calibrated eyepiece reticule or micrometer.

6.5.2 Procedure

Install the scaler tip in the handpiece in accordance with the manufacturer's instructions. The microscope shall be focused on the working end of the scaler tip. Operate the handpiece at the recommended air flowrate, air pressure, without water cooling and maximum frequency for at least 1 min without any applied load. The maximum amplitude in all directions shall be measured by means of the apparatus given in 6.5.1.

6.6 Stall force

6.6.1 Apparatus

6.6.1.1 Force gauge with an accuracy of ± 0,5 N.

6.6.2 Procedure

Install the scaler tip in the handpiece in accordance with the manufacturer's instructions. Operate the handpiece with the recommended air flowrate, air pressure and frequency for at least 1 min and stall the scaler tip through a force so that the movement of the end of the scaler tip becomes zero. Record the force required to stop the scaler tip.

6.7 Supply of cooling water

6.7.1 Apparatus

6.7.1.1 **Volumetric measuring jar** with an accuracy of 5 %, to measure the volume of cooling water.

6.7.1.2 **Pressure gauge** with an accuracy of 5 %, to measure the water supply pressure at the scaler inlet.

6.7.2 Procedure

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

6.8 Air pressure

6.8.1 Apparatus

6.8.1.1 **Pressure gauge** capable of measuring the air supply pressure to an accuracy of 5 % of the measured value.

6.8.2 Procedure

Operate the scaler at 50 % above the recommended operating pressure for a period of 10 min and record any signs of failure.

6.9 Noise level

6.9.1 Apparatus

6.9.1.1 **Precision sound level meter,** meeting the requirements for a type 1 instrument as specified in IEC 60651.

6.9.1.2 **Non-rigid suspension system**.

6.9.2 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 scaler under test. Foam or non-reflective material may be used to reduce reflections from hard surfaces.

6.9.3 Procedure

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

6.10 Resistance to corrosion

Subject the test pieces to 10 cycles of the autoclave test specified in ISO 13402:1995, clause 3.

6.11 Energy for light supply (if applicable)

6.11.1 Power supply

The scaler shall be designed to operate from supply mains as described by the manufacturer.

IEC 60601-1:1988, subclause 19.1 c) applies.

6.11.2 Continuous leakage currents and patient auxiliary currents

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

a) after the scaler has been brought to normal operating temperature in accordance with the requirements of IEC 60601-1:1988, clause 7;

b) after the moisture-preconditioning treatment as described in IEC 60601-1:1988, subclause 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 than or equal to the temperature of the humidity cabinet. During testing, those measurements which do not energize equipment shall be made first.

IEC 60601-1:1988, subclause 19.4 applies.

6.11.3 Dielectric strength and creepage distances and air clearances

Apply the test voltage of 500 V to the insulation parts of the complete handpiece system as described in IEC 60601-1:1988, subclause 20.2 but without testing B-d during 1 min and according to table V of IEC 60601-1:1988:

a) immediately after warming up to operating temperature and switching off the equipment and

b) immediately after the moisture-preconditioning treatment (as described in IEC 60601-1:1988, subclause 4.10) with the equipment de-energized during the test and kept in the humidity cabinet, and after the first required sterilization procedure with the equipment de-energized (see IEC 60601-1:1988, subclause 44.7).

Apply initially not more than half the prescribed voltage, then raise it over a period of 10 s to the full value, and maintain for 1 min.

IEC 60601-1:1988, subclauses 20.4 and 57.10 d) apply.

7 Instructions for use, maintenance and service

Each air-powered scaler shall be accompanied by documents containing instructions for operation, operator maintenance, lubrication, safety and servicing.

Instructions shall include at least the following information:

a) name and/or trade mark and address of manufacturer or distributor;

b) type;

c) coupling identification;

d) specified operating pressures of air and water, in kilopascals (kPa), as given by the manufacturer;

e) consumption of air, in litres per minute (l/min), and water, in millilitres per minute (ml/min), at the specified operating pressures;

f) clear warnings and information concerning the reason(s) for exceeding the normal maximum amplitude of 200 µm, where this is applicable;

g) statement as to whether the tool for changing the scaler and scaler tip is sterilizable, and by what methods;

h) specified cleaning and/or, if applicable, disinfecting agent;

i) for resterilizable scalers and single-use scalers supplied non-sterile, the specified sterilizing instructions;

j) statement as to whether the scaler is field-reparable;

k) specified light-supply, if applicable;

l) accessories and working tools, if applicable;

m) statement of regular maintenance required to maintain the scaler in good working order when the scaler is to be subject to repeated steam sterilization, and a statement of the frequency required for this maintenance.

Testing shall be carried out in accordance with 6.1.

8 Marking

Scalers shall be marked as follows:

a) manufacturer's name or trade mark;

b) serial number;

c) model or type reference;

d) mark to indicate autoclavability, if applicable;

e) for single-use scaler, the symbol  (see ISO 7000 – 1051 and ISO/TR 15223).

Graphical symbols used for marking shall be in accordance with ISO 9687.

9 Packaging

Scalers should be packed for transportation in such a way that no damage to the product may occur during anticipated transport conditions.

ICS 11.060.20

Price based on 9 pages