INTERNATIONAL STANDARD

ISO 22374

First edition
2005-09-01

Dentistry — Dental handpieces — Electrical-powered scalers and scaler tips

Art dentaire — Pièces à main dentaires — Instruments pour détartrage électriques et parties actives des instruments pour détartrage

Reference number
ISO 22374:2005(E)

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Published in Switzerland

Contents

Page

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 2.

The main task of technical committees is to prepare International Standards. 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 document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 22374 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 4, *Dental instruments*.

Dentistry — Dental handpieces — Electrical-powered scalers and scaler tips

1 Scope

This International Standard specifies requirements and test methods for electrical-powered scalers and scaler tips, including piezo, ferrostrictive and magnetostrictive type ultrasonic scalers, operated as stand-alone items or connected to dental units, for use on patients. It also contains specifications on manufacturers' instructions, marking and packaging.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 1942, *Dentistry — Vocabulary*

ISO 7494-1, *Dentistry — Dental units — Part 1: General requirements and test methods*

ISO 9687, *Dental equipment — Graphical symbols*

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

ISO 17664, *Sterilization of medical devices — Information to be provided by the manufacturer for the processing of resterilizable medical devices*

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

IEC 61012, *Filters for the measurement of audible sound in the presence of ultrasound*

IEC 61672-1, *Electroacoustics — Sound level meters — Part 1: Specifications*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 1942 and the following apply.

3.1
electrical powered scaler
instrument with a oscillating scaler tip used in dental treatment consisting of a combination of a dental unit, a handpiece, the tubing connecting the handpiece to the dental unit, and an interchangeable scaler tip

NOTE The system also includes a connection to a supply of cooling liquid.

3.2
scaler insert system
interchangeable instrument used in an electrical-powered scaler and consisting of a working part and a transducer for dental scaling

3.3
scaler tip
fixed or interchangeable instrument used in an electrical-powered scaler and consisting of a shaft and a working part for dental procedures

3.4
operating area of the scaler tip
area for use, as described by the manufacturer for different scaler tips

4 Requirements

4.1 General design of handpiece connection

The configuration, dimensions and tolerances of hose connections, tested in accordance with 6.2, shall be in accordance with the manufacturer's instructions for use.

4.2 Scaler tip

4.2.1 Extraction force

When installed in accordance with the manufacturer's instructions for use, the scaler tip, tested in accordance with 6.3.1, shall withstand, without displacement, a minimum axial tension force of 20 N.

4.2.2 Torque (for screw-in-tips only)

The following requirement is only applicable for screw-in-tips.

When installed in accordance with the manufacturer's instructions, the scaler tip, tested in accordance with 6.3.2, shall withstand, without rotation displacement, a minimum torque of 200 N·mm.

4.2.3 Insertion of the scaler tip

The force required to insert and secure the scaler tip in the handpiece shall not exceed 30 N when tested in accordance with 6.3.3.

4.3 Performance

4.3.1 Frequency

When operated at the settings recommended by the manufacturer, the frequency of the scaler tip, tested in accordance with 6.4, shall be between 18 000 Hz and 60 000 Hz.

4.3.2 Amplitude, unloaded scaler tip

When operated at the maximum power recommended by the manufacturer, the maximum unloaded peak to peak excursion of the scaler tip, tested in accordance with 6.5, shall not exceed 200 µm.

4.3.3 Amplitude, loaded scaler tip

When operated with the maximum power recommended by the manufacturer, in a direction perpendicular to the plane of vibration (or to the vibration direction) and under a load of 1 N, the maximum amplitude of the working tip, tested in accordance with 6.6, shall not exceed 200 µm.

4.4 Supply of cooling liquid

When operated at the maximum power recommended by the manufacturer, the liquid cooling capability to the operating area of the scaler tip, tested in accordance with 6.7, shall be less than 50 ml/min.

4.5 Noise level

When operated at the maximum power recommended by the manufacturer, the A-weighted sound pressure value generated, tested in accordance with 6.8, shall not exceed 70 dB.

4.6 Resistance to sterilization

Electrically powered scaler handpieces and scaler tips shall be capable of withstanding a minimum of 250 sterilization cycles as defined in the manufacturer's instructions for use without deterioration in appearance or performance.

Single use handpieces or the disposable (non-reusable) parts of other handpieces, tested in accordance with 6.9, shall be supplied sterile or be capable of withstanding one sterilization cycle, as defined in the manufacturer's instructions, without deterioration in appearance or performance.

4.7 Energy for light source (if applicable)

The voltage of the light source in the handpiece, tested in accordance with 6.10, shall not exceed a nominal value of 25 V a.c. or 60 V d.c. 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.

4.8 Electrical power supply

This shall be as specified by the manufacturer and complying with ISO 7494-1.

5 Sampling

At least one handpiece or insert (scaler tip type) for each model series shall be tested for compliance with this International Standard.

6 Test methods

6.1 General

All tests described in this International Standard are type tests.

6.2 Visual inspection

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

6.3 Scaler tip

6.3.1 Extraction force

6.3.1.1 Apparatus

6.3.1.1.1 Force gauge, with an accuracy of ± 0,5 N, to measure the extraction force.

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 liquid flow rate and maximum frequency for at least 1 min and then switch off. Adjust the force gauge to register the maximum force exerted. Apply the device and record the required force to extract the moving scaler tip.

6.3.2 Torque (for screw-in-tips only)

6.3.2.1 Apparatus

6.3.2.1.1 Torque watch or dynamometer, capable of measuring the torque in (N·mm) to 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 maximum liquid flow rate and maximum frequency for at least 1 min and then switch off. 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 electrical-powered scaler.

6.3.3 Insertion of the scaler tip

6.3.3.1 Apparatus

6.3.3.1.1 Force gauge, with an accuracy of ± 0,5 N, to measure the insertion force.

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 to lock the scaler tip in the handpiece.

6.4 Frequency

6.4.1 Apparatus

6.4.1.1 A non-contacting frequency measurement device, with an electronic frequency counter or a calibrated time base and operating 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 scaler tip at the recommended maximum liquid flow rate and maximum power for at least 1 min without any applied load. Measure the frequency of the scaler tip at the operating area.

6.5 Amplitude, unloaded scaler tip

6.5.1 Apparatus

6.5.1.1 A non-contacting optical or electrical length measurement device, with an accuracy of ± 10 % of the measured value.

6.5.2 Procedure

Install the scaler tip in the handpiece in accordance with the manufacturer's instructions. Operate the handpiece at the maximum power recommended by the manufacturer with or without cooling liquid and without any applied load for 1 min. Measure the peak to peak distance of the scaler tip in the time range between 5 s and 10 s after using the scaler tip in all directions. Record the measured amplitude of the moving scaler tip.

6.6 Amplitude, loaded scaler tip

6.6.1 Apparatus

6.6.1.1 A non-contacting optical or electrical length measurement device, with an accuracy of ± 10 % of the measured value.

6.6.1.2 Flat, smooth glass surface, 50 mm × 50 mm, 2 mm thick with the top surface coloured.

NOTE The colouring may be achieved with the use of a permanent marker pen.

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

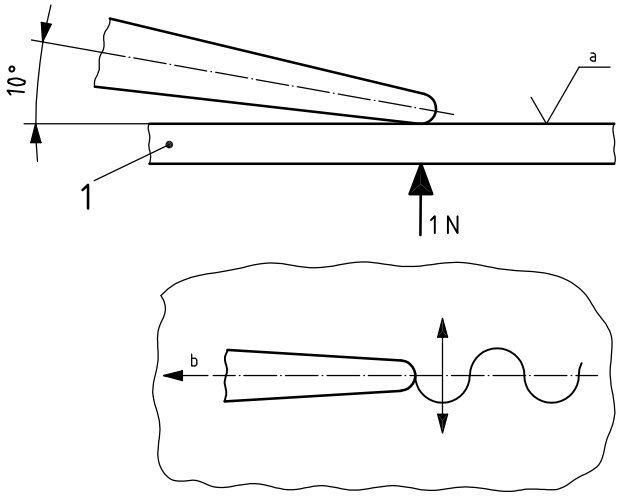
6.6.2 Procedure

Press the handpiece laterally, i.e. vertically to the plane of vibration or vibration direction, with a load of 1 N on the coloured glass surface (registering plane). Only the end of the working tip may touch the glass top. See Figure 1.

NOTE A deviation of the direction of maximum 10° (from 0° up to 10°) to the registering plane (glass top) is permitted in order to simplify the measurement.

Move the tip on the coloured glass surface or move the glass top under the tip in a direction parallel to the registering level and perpendicular to the vibration direction so that the track of the tip is recorded.

Measure the amplitude of the track with and without power supply to the working tip.



Key

1 glass

a Coloured.

b Moving direction.

Figure 1 — Amplitude of scaler tip with load

6.7 Supply of cooling liquid

6.7.1 Apparatus

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

6.7.1.2 **Pressure gauge**, with an accuracy of 5 %, to measure the liquid supply pressures to the handpiece inlet.

6.7.2 Procedure

Adjust the liquid supply pressure as recommended by the manufacturer and operate the handpiece for 1 min at maximum power. Observe the direction of the liquid to determine if it is properly directed to the operating area of the scaler tip. Record the volume of liquid collected.

6.8 Noise level

6.8.1 Apparatus

6.8.1.1 **Sound level meter**, meeting requirements for a type 1 instrument as specified in IEC 61672-1.

6.8.1.2 **Non-rigid suspension system**.

6.8.1.3 **Filters,** as specified in IEC 61012, for scaler handpieces used in ultrasound mode.

6.8.2 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 55 dB. There shall be no hard reflective surface within a 1 m envelope of the handpiece under test. Foam or non-reflective material may be used to reduce reflections from hard surfaces.

6.8.3 Procedure

Suspend the handpiece in the centre of the chamber by means of a non-rigid suspension system. Operate the unloaded handpiece at the maximum recommended power supply.

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 tip.

6.9 Resistance to sterilization

Subject the test pieces to 250 sterilization cycles using the parameters defined by the manufacturer in the instructions for use.

After the final sterilization cycle, inspect the sterilized items, by visual inspection, in accordance with 6.2. There shall be no visible signs of deterioration.

Submit the sterilized items to the test procedures for the requirements 4.2, 4.3, 4.4, 4.5 and 4.7. All requirements shall be met.

6.10 Energy for light supply (if applicable)

6.10.1 Power supply

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

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

6.10.2 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 handpiece has been brought up 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, 4.10. Carry out the measurements with equipment located outside the humidity cabinet commencing 1 h after the equipment has been taken out of this cabinet, and placed in an environment with a temperature less than or equal to the temperature of the humidity cabinet. During testing, determine first those measurements which do not energize equipment.

IEC 60601-1:1988, 19.4 applies.

6.10.3 Dielectric strength and creepage distances and air clearances

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

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

b) immediately after the moisture preconditioning treatment (as described in IEC 60601-1:1988, 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, 44.7).

Initially apply 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, 20.4 and 57.10 d) apply.

7 Instructions for use, maintenance and service

Each electrical-powered scaler system shall be accompanied by documents containing instructions for use, maintenance, lubrication, safety and servicing.

Instructions for use shall include at least the following information:

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

b) model or type reference (e.g. piezo or ferrostrictive or magnetostrictive; frequency range);

c) coupling identification (connection to the handpiece as recommended by the manufacturer);

d) recommended electrical power supply as given by the manufacturer;

e) nominal consumption of liquid or other solutions as recommended by the manufacturer in millilitres per minutes (ml/min) at a given power;

f) statement as to whether the tool for changing the handpiece and scaler tip is sterilizable (if required) and by what methods;

g) recommended and validated decontamination procedures as specified in ISO 17664;

h) reprocessing instructions (cleaning, disinfecting, sterilizing) if applicable, as specified in ISO 17664;

i) for sterilizable handpieces and single-use handpieces supplied in a non-sterile condition, the recommended sterilizing instructions, if applicable, as specified in ISO 17664;

j) statement as to whether the handpiece is field-repairable;

k) recommended light-supply, if applicable;

l) accessories and working tools, if applicable;

m) statement of regular maintenance required to keep the handpiece in good working order, and a statement of the frequency required for this maintenance;

n) any other instructions for safe and effective use (e.g. power setting limitations, liquid flow limitations) depending upon the specific model or type of tip or handpiece.

8 Marking

Scaler handpieces shall be marked as follows:

a) manufacturer's name or trademark;

b) serial number or lot number;

c) model or type reference (e.g. catalogue number);

d) mark to indicate autoclaveability, if applicable;

e) only for single-use handpiece: the symbol for “Do not reuse”.

Scaler tips shall be marked with a manufacturer's code.

Graphical symbols for marking shall be in accordance with ISO 9687 and/or ISO 15223.

9 Labelling

The packaging of scaler handpieces and scaler tips shall be labelled as follows:

a) manufacturer's name or trademark;

b) serial number or lot number;

c) model or type reference (e.g. catalogue number);

d) only for scaler tips: mark to indicate autoclaveability, if applicable;

e) for single-use devices the symbol for “Do not reuse”.

Graphical symbols for marking shall be in accordance with ISO 9687 and/or ISO 15223.

10 Packaging

Scaler handpieces and scaler tips shall be packed for transportation in such a way that no damage to the product may occur during anticipated transport conditions.

Annex A
(informative)

Performance and general design

A.1 General

Electrical powered scalers should be comfortable for the operator to use and easy to manipulate. The outside surface of the electrical powered 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.

A.2 Materials

All materials used in the construction of electrical powered scalers should be suitable for their intended use and be unaffected by the decontamination and sterilizsation processes recommended by the manufacturer.

A.3 Construction and layout

The construction of electrical powered scalers should provide for their safe and reliable operation. If field-repairable, the electrical powered 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.

ICS 11.060.25

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