INTERNATIONAL STANDARD

ISO 18397

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Dentistry — Powered scaler

Médecine bucco-dentaire — Instruments pour le détartrage

Reference number
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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 106, *Dentistry*, Subcommittee SC 4, *Dental instruments*.

This first edition of ISO 18397 cancels and replaces ISO 15606:1999 and ISO 22374:2005, which have been technically revised.

Introduction

Dental scaler handpieces and scaler tips have been used in dental treatment procedures for many years.

As technical development has resulted in improved scaler handpieces and tips, this revised International Standard is necessary to ensure the level of safety and performance, both of the individual devices and in combination, is at an appropriate level.

Dentistry — Powered scaler

1 Scope

This International Standard specifies requirements and test methods for air-powered and electrical-powered scaler handpieces 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 documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. 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 5349-1, *Mechanical vibration — Measurement and evaluation of human exposure to hand-transmitted vibration — Part 1: General requirements*

ISO 5349-2, *Mechanical vibration — Measurement and evaluation of human exposure to hand-transmitted vibration — Part 2: Practical guidance for measurement at the workplace*

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

ISO 9168, *Dentistry — Hose connectors for air driven dental handpieces*

ISO 9687, *Dental equipment — Graphical symbols for dental equipment*

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 14457, *Dentistry — Handpieces and motors*

ISO 15223-1, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

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

ISO 21531, *Graphical symbols for dental instruments*

IEC 60601-1, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

IEC 60601-1-2, *Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral Standard: Electromagnetic disturbances — Requirements and tests*

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

IEC 62366-1, *Medical devices — Part 1: Application of usability engineering to medical devices*

IEC 80601-2-60:2012, *Medical electrical equipment — Part 2-60: Particular requirements for basic safety and essential performance of dental equipment*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 1942, ISO 14457 and the following apply.

3.1
powered scaler
scaler powered by air or electrical energy

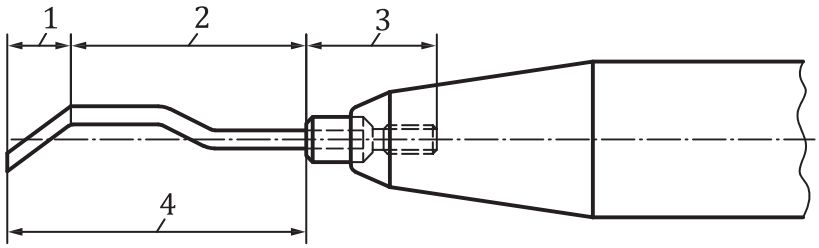
3.2
air-powered scaler
handpiece powered by pressurized air, with an oscillating working part

3.3
electrical-powered scaler
handpiece powered by electrical energy, with an oscillating working part

3.4
operating area of scaler tip
area of the working part for use as described by the manufacturer

3.5
scaler handpiece
powered handheld handpiece used to operate an oscillating or reciprocating working part

3.6
scaler tip
fixed or interchangeable instrument used in an air-powered or in an electrical-powered scaler handpiece and consisting of a shank and a working part



Key

1 working end
2 transmission part
3 shank
4 working part

Figure 1 — Designation of parts for scaler tips

3.7
transmission part
tool designed to transmit energy from the shank to the working end

Note 1 to entry: See Figure 1.

3.8
working end
distal end of an oscillating instrument intended for direct use in the oral cavity of the patient

Note 1 to entry: See Figure 1.

3.9
working part
part of a fixed or interchangeable instrument connected to a scaler handpiece

Note 1 to entry: See Figure 1.

3.10
shank
part of an oscillating instrument connected to a scaler handpiece

Note 1 to entry: See Figure 1.

4 Classification of scaler handpieces

Scaler handpieces are classified according to the frequency of the scaler tips into two types as given in Table 1.

Table 1 — Frequency of scaler tips

Type	Energy supply	Frequency
1	Air powered	4 000 Hz < frequency ≤ 40 000 Hz
2	Electrical powered	18 000 Hz < frequency ≤ 60 000 Hz

5 Requirements and performance

5.1 General

The construction of handpieces shall be safe and provide reliable operation. These requirements shall be compliant with IEC 62366-1.

If field-repairable, the handpieces shall be capable of being easily disassembled and reassembled for maintenance and repair utilizing either readily available tools or special tools supplied by the manufacturer.

Electrical requirements are only applicable to electrically powered handpieces and handpieces with light supply.

5.2 Materials

Materials used for parts of scaler handpieces or scaler tips that are likely to get in contact with the practitioner or the patient shall be biocompatible.

Test for biocompatibility shall be in accordance with ISO 10993-1.

5.3 Drop test

Test for scaler handpieces without tips shall be in accordance with IEC 60601-1.

NOTE In IEC 60601-1:2005, 15.3.4.1, the test procedure is stated.

5.4 Noise level

A-weighted sound pressure level by the scaler handpieces shall not exceed 80 dB(A).

Test in accordance with 7.11.

5.5 Surfaces

Particular attention should be given to providing secure gripping surfaces for operator manipulation under normal use conditions.

Test in accordance with IEC 62366-1.

In order to reduce glare, highly polished surfaces should be avoided.

5.6 Electrical power supply (if applicable)

The requirements shall be specified by the manufacturer and shall comply with ISO 7494-1.

Test in accordance with 7.3.

5.7 Energy for light source (if applicable)

The requirements of the light source shall be specified by the manufacturer and shall comply with ISO 7494-1.

Test in accordance with 7.3.

5.8 Air supply

Air-powered handpieces shall be operated by a pressurized air supply in accordance with the manufacturer's instructions. The necessary flow rate shall be <66 Nl/min in a pressure range of (300 ± 100) kPa [(3,0 ± 1,0) bar].

NOTE Nl/min indicates normal litres per minute, the amount of air that flows through a pipe calculated back to "normal" conditions [0 °C and 1 atm or 1, 0132 5 bar (1 bar = 0, 1 MPa = 0, 1 N/mm^2 = 105 N/m^2)].

Test in accordance with 7.4.

5.9 Supply of cooling liquid

If applicable, the amount of cooling liquid delivered to the operating area of the scaler tip shall be at minimum of 20 ml/min and shall not exceed 50 ml/min at the pressure specified by the manufacturer.

Test in accordance with 7.5.

5.10 Air and water pressure

Applicable scaler handpieces shall remain intact, i.e. shall not rupture or burst, when subjected to a pressure 50 % above the manufacturer's maximum recommended operating pressure.

Test in accordance with 7.6.

5.11 Temperature

5.11.1 Temperature rise of housing

IEC 80601-2-60 applies.

NOTE In IEC 80601-2–60:2012, 201.11.1.1, the requirement is stated.

Test in accordance with 7.12.

5.11.2 Temperature, excessive

IEC 80601-2-60 applies.

NOTE In IEC 80601-2–60:2012, 201.11.2.2, the requirement is stated.

Test in accordance with 7.13.

5.12 Vibrations

ISO 5349-1 and ISO 5349-2 apply.

5.13 Resistance to reprocessing

All scaler handpieces, and tips and parts of scaler handpieces, recommended for reprocessing shall withstand 250 reprocessing cycles as defined in the manufacturer's instructions without deterioration in performance or signs of corrosion both internally and externally. The reprocessing cycle for handpieces and their parts shall include the recommended methods of cleaning, disinfection and sterilization.

If the manufacturer states a lower number of permitted reprocessing cycles, then this number x1,5 shall be used in place of the 250 stated above.

This requirement is not applicable for single use scaler handpieces.

Single use handpieces or the disposable (non-reusable) parts of handpieces, tested in accordance with 7.14, 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.

Test in accordance with 7.14.

5.14 Leakage and/or ingress of water

IEC 60601-1 applies.

NOTE In IEC 60601:2005, 11.6, the requirement is stated.

5.15 Electromagnetic compatibility

IEC 60601-1-2 applies.

5.16 Operating controls

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.

By the use of operating controls, scaler handpieces and scaler tips shall be capable of changing power (e.g. amplitude, frequency,) as specified by the manufacturer. The controls shall be provided at the scaler handpiece itself or at the dental unit and or at the foot controller.

IEC 60601-1 applies.

NOTE In IEC 60601:2005, 15.1, the requirement is stated.

5.17 Usability

IEC 62366-1 applies.

5.18 Connection

5.18.1 General

Removable scaler handpieces shall be capable of being disconnected from hoses or from the device if handpiece has a fixed connection to hose, and maintenance equipment when applicable, and reconnected without any special tool.

IEC 62366-1 applies.

5.18.2 Connections for air-powered scaler handpieces

The dimensions and tolerances of the hose connections for drive air, exhaust air, spray air, cooling water and fibre-optic light, as appropriate, shall be in accordance with ISO 9168.

Test in accordance with 7.7.

The configuration of the hose connections for drive air, exhaust air, spray air, cooling water and fibre-optic light, as appropriate, shall be in accordance with ISO 9168.

Test in accordance with 7.2.

In case the quick connection is provided by the quick connection coupler, the hose side connector of the coupler shall be in accordance with ISO 9168.

Test in accordance with 7.2.

5.18.3 Connector for electrical-powered scaler handpieces

The configuration of the hose connections shall be in accordance with the manufacturer's instruction for use.

Test in accordance with 7.2.

5.19 Scaler tip performance

5.19.1 Scaler tip connection

The type of the connection between the scaler tips and the scaler handpiece is given by the manufacturer.

Test in accordance with 7.2.

5.19.2 Extraction force (for non-screw tips only)

When installed in accordance with the manufacturer's instructions for use, the scaler tip, excluding the working parts shall withstand without displacement, a minimum axial tension force of 7 N.

Test in accordance with 7.8.1.

5.19.3 Holding 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 shall withstand, without rotation displacement, a minimum torque of 200 mN·m.

Test in accordance with 7.8.2.

5.19.4 Insertion force (for non-screw-tips only)

The force required to insert and secure the scaler tip in the scaler handpiece shall not exceed 50 N.

Test in accordance with 7.8.3.

5.19.5 Tightening torque (for screw-in-tips only)

The torque required to insert and secure the scaler tip in the scaler handpiece shall not exceed 1 200 mN·m.

Test in accordance with 7.8.4.

5.19.6 Stall effort

With the air-powered scaler handpiece 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.

Test in accordance with 7.8.5.

5.19.7 Power output, scaler tips

The manufacturer shall describe the output power of the scaler tips in the instructions for use.

Test in accordance with 7.8.6.

5.19.8 Breakage resistance

Scaler tips shall be resistant against breakage and withstand the loads applied within the intended use by the manufacturer.

Test in accordance with 7.8.7.

5.20 Frequency

When operated at the settings recommended by the manufacturer, the frequency of the scaler tip shall be in the frequency range as given in Table 1.

Test in accordance with 7.9.

5.21 Amplitude

When operated with the maximum power recommended by the manufacturer, in a direction perpendicular to the plane of vibration (or to the vibration direction), the maximum peak to peak excursion of the working tip shall not exceed 200 µm.

If the maximum peak to peak excursion of the working end exceeds 200 µm in any direction, the manufacturer's instruction shall include a corresponding warning.

Test in accordance with 7.10.

6 Sampling

At least one handpiece for each model series shall be evaluated for compliance with this International Standard.

7 Testing

7.1 General test conditions

All tests described in this International Standard are type tests.

7.2 Visual inspection

Visually inspect without magnification to determine compliance with the requirements.

7.3 Power supply — Electrical

The test methods given in IEC 60601-1 and IEC 80601-2-60 apply.

7.4 Air supply

7.4.1 Apparatus

7.4.1.1 Flowmeter, with an accuracy of 5 %, to measure the scaler handpiece supply air flowrate.

7.4.1.2 Pressure gauges, with an accuracy of 5 %, to measure the air supply pressure at the inlet of the scaler handpiece.

7.4.2 Procedure

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

7.5 Supply of cooling liquid

7.5.1 Apparatus

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

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

7.5.2 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.

7.6 Air and water pressure

7.6.1 Apparatus

7.6.1.1 Pressure gauge, capable of measuring the supply pressure to an accuracy of 5 % of the expected value.

7.6.2 Procedure

Operate the handpiece at 50 % above the recommended operating pressure for a period of 10 min.

Observe if the handpiece ruptures or bursts.

7.7 Measuring device for dimensions

Measuring device, such as a gauge or dial indicator with an accuracy of 0,01 mm for linear dimension and ±1 degree on angles. Measure and record the dimensions.

7.8 Scaler tips

7.8.1 Extraction force (for non-screw-tips only)

7.8.1.1 Apparatus

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

7.8.1.2 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 amplitude 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.

7.8.2 Holding torque (for screw-in-tips only)

7.8.2.1 Apparatus

7.8.2.1.1 Torque watch or dynamometer, capable of measuring the torque in (mNm) to an accuracy of ±10 %.

7.8.2.2 Procedure

Install the scaler tip in the handpiece in accordance with the manufacturer's instructions. Operate the scaler handpiece at the recommended maximum liquid flow rate and maximum frequency amplitude 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 scaler handpiece.

7.8.3 Insertion force (for non-screw-tips only)

7.8.3.1 Apparatus

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

7.8.3.2 Procedure

Install the scaler tip in the scaler 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.

7.8.4 Tightening torque (for screw-in-tips only)

7.8.4.1 Apparatus

7.8.4.1.1 Torque watch or dynamometer, capable of measuring the torque in (mNm) to an accuracy of ±10 %.

7.8.4.2 Procedure

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

7.8.5 Stall effort

7.8.5.1 Apparatus

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

7.8.5.2 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 unloaded and stall the scaler tip through a force so that the movement of the end of the scaler tip becomes zero. Record the required force to stop the scaler tip in the handpiece.

7.8.6 Power output, scaler tips

7.8.6.1 Apparatus

7.8.6.1.1 Spring force gauge, with an accuracy of ±0,5 N, to measure the Fμ force for calculate the μ friction coefficient.

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

7.8.6.1.3 Flat, smooth glass surface, e.g. with the dimension of 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.

7.8.6.1.4 Microscope, with a magnification of at least 100-x and a calibrated eyepiece reticule or micrometer.

7.8.6.2 Procedure

For the determination of the friction coefficients, install the scaler tip in the handpiece in accordance with the manufacturer's instructions. Operate the scaler tip at the recommended maximum power without cooling liquid.

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

Measure the necessary force F_μ to move the working end on the glass surface and calculate $\mu = F_\mu/1$ N.

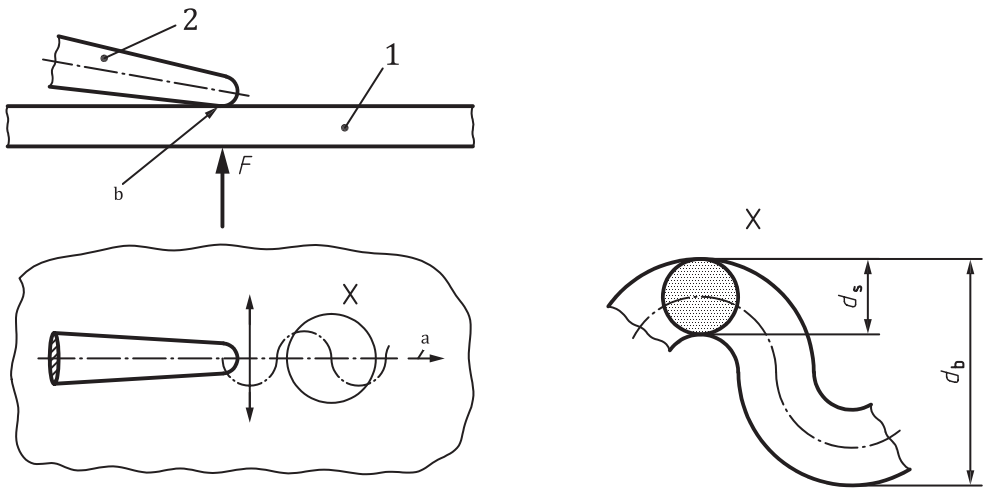
For measuring the peak to peak excursion install the scaler tip in the handpiece in accordance with the manufacturer's instructions. Operate the scaler tip at the recommended maximum power with and without cooling liquid.

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

Move the tip on the 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 in the moving direction for at least 40 mm.

Measure the amplitude of the track with and without power supply to the working tip and calculate the delivery power of the working tip as follows (see Figure 2).

NOTE The purpose of tracing without power supply is to obtain the tip width d_S.



Key

1 glass slide
2 working part of scaler tip
d_S tip width
d_b track width
a Moving direction.
b Scaler tip movement.

Figure 2 — Power output of scaler tips

Calculate the power output, P, by using the following formulae:

$$P(t) = F \cdot \mu \cdot \frac{\mathrm{d}s}{\mathrm{d}t} \tag{1}$$

where

F is applied vertical load, in Newton;

μ is the friction coefficient;

s is the distance;

t is the time.

with $s(t) = s_0 \sin \omega t$ (2)

$$\Rightarrow P(t) = F \cdot \mu \cdot s_0 \cdot \omega \cdot \cos\omega t \quad (3)$$

where

s_0 = $(d_b - d_s)/2$

d_s is the tip width;

d_b is the track width;

ω is the oscillation frequency.

$$P(t) = P_0 \cdot \cos\omega t \quad (4)$$

$$\text{with } P_0 = F \cdot \mu \cdot s_0 \cdot \omega \quad (5)$$

$$\Rightarrow P_{eff} = \frac{P_0}{\sqrt{2}} \quad (6)$$

With F = constant, μ = constant

$$\text{with } \omega = 2\pi \cdot f \quad (7)$$

$$P(t) \sim s_0 \cdot f \quad (8)$$

A calculation example for the power output is given in Annex A.

7.8.7 Breakage resistance

Apply a force of 1 N on the scaler tip, perpendicular to the sample under a 10° angle with the surface (sample to be defined, glass, metal or machinable ceramic). Move the tip in a direction parallel to the registered level and perpendicular to the vibration direction, for a certain period of time (1 min). The tips should not break (see Figure 2).

7.9 Frequency

7.9.1 Apparatus

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.

7.9.2 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 and record the frequency during all procedure.

7.10 Amplitude

7.10.1 Apparatus

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

7.10.1.2 Flat, smooth glass surface, e.g. with the dimension of 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.

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

7.10.2 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 in the direction of greatest amplitude. Record the measured peak to peak of the moving scaler tip.

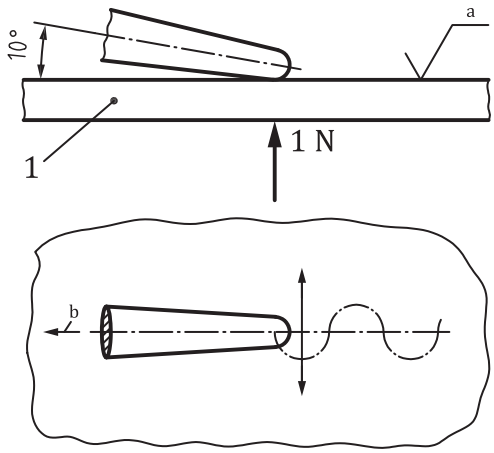
Press the handpiece laterally, i.e. vertically to the plane of vibration or vibration direction, with a load of 1 N on the coloured glass surface (registering plane). Only the end of the working tip may touch the glass top (see Figure 3).

NOTE 1 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.

NOTE 2 Alternate test methods can be used to measure amplitude at manufacturers discretion.

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 power supply to the working tip.



Key

1 glass

a Coloured.

b Moving direction.

Figure 3 — Amplitude and peak to peak of scaler under load

7.11 Noise level

7.11.1 Apparatus

7.11.1.1 Precision sound level meter, type 1 instrument as specified in IEC 61672-1.

7.11.1.2 Non-rigid suspension system.

7.11.2 Test conditions

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(A). The frequency range of the measurement shall be 20 Hz to 20,000 Hz. 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. Measure the noise for one minute.

7.11.3 Procedure

Install the scaler tip in the handpiece in accordance with the manufacturer's instructions. Suspend the handpiece in the centre of the chamber by means of a non-rigid suspension system. Operate the scaler handpiece at the maximum recommended air pressure, for air-powered handpieces, or the maximum recommended maximum power supply for electric scaler handpieces under unloaded conditions for at least 1 min. Using the sound level meter, measure the maximum A-weighted sound pressure value level generated from the scaler handpiece at a distance of 0,45 m from the head perpendicular to the long axis of the scaler handpiece. Do this measurement in the time range of 5 s + 5 s.

7.12 Temperature rise of housing

IEC 80601-2-60 applies.

NOTE In IEC 80601-2–60:2012, 201.11.1.3 bb), the requirement is stated.

7.13 Temperature, excessive

IEC 80601-2-60 applies.

NOTE In IEC 80601-2–60:2012, 201.11.1.3 bb), the requirement is stated.

7.14 Resistance to reprocessing

Carry out 250 reprocessing cycles as specified in the manufacturer's instructions.

If the manufacturer states a lower number of permitted reprocessing cycles then this number shall be used instead.

Inspect the surfaces in accordance with 7.2 for signs of rust, pitting or any other surface defects to assess the corrosion resistance.

All requirements of this International Standard shall be met subsequent to this test.

8 Instructions for use, maintenance and service

Each scaler handpiece 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 trademark and address of the manufacturer and/or his authorized representative;

b) model or type reference;

c) instructions for operating conditions (mode of operations, if applicable);

d) coupling identification for handpiece connection, for air powered scaler only;

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

f) recommended electrical power supply and rated electrical characteristics (e.g. voltage, frequency, fuse values) as given by the manufacturer, if applicable;

g) output power of the scaler tips;

h) statement as to whether the tool for changing the handpiece and scaler tips and working parts is sterilizable (if required), and by what methods;

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

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

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

l) statement as to whether the handpiece is field-repairable, if applicable;

m) recommended lubricating instructions, if applicable;

n) presence of light supply, if applicable;

o) accessories and working tools, if applicable;

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

q) recommended operating pressure of air and water, in SI units;

r) clear warnings and information concerning the reason(s) for exceeding the normal maximum peak to peak of 200 µm, if applicable;

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

t) release month and year or revision number of the instruction.

9 Technical description

In additional, the following information shall be provided by the manufacturer:

a) list of spare parts required in general use, if applicable;

b) schematic wiring diagrams, if applicable.

10 Marking

10.1 General

Graphical symbols used for marking of scaler handpieces and scaler tips shall be in accordance with ISO 9687, ISO 15223-1 and ISO 21531.

10.2 Scaler handpieces

Scaler handpieces shall have at least the following marking:

a) manufacturer’s name or trademark;

b) serial number or lot number;

c) model or type reference or catalogue number;

d) mark to indicate autoclave ability, if applicable;

e) for parts of single-use handpieces, if applicable  .

10.3 Scaler tips

Scaler tips or their packages shall have at least the following marking:

a) scaler tips and working parts shall be marked with a manufacturer's identification;

b) manufacturer's name or trademark;

c) serial number or lot number;

d) for parts of single-use handpieces, if applicable  ;

e) for parts if sold as sterile product, the packaging must specify the "use by" date on the packaging  .

11 Labelling

Graphical symbols used for labelling shall be in accordance with ISO 9687, ISO 15223-1 and ISO 21531.

The packaging of handpieces and working parts shall be labelled as follows:

a) manufacturer's name or trademark;

b) serial number or lot number;

c) model or type reference or catalogue number;

d) for single-use devices the symbol for "Do not reuse"  .

12 Packaging

Scaler handpieces and scaler tips shall be packaged for transportation at the discretion of the manufacturer in such a way that no damage may occur during anticipated transport conditions.

If several packages are supplied, they shall be marked on the outside to facilitate the assembly and installation.

Single use handpieces or the disposable (non-reusable) parts of other handpieces shall be packaged or wrapped individually by the manufacturer to maintain cleanliness.

Annex A
(informative)

Calculation example for power output

Symbol	Value	Remark
F	1 N	Measured
μ	0,6	Measured and calculated
f	30 000 Hz	Measured
s	100 µm	Measured

Condition	Remark
Cooling water	OFF

$$P(t) = F \cdot \mu \cdot s \cdot \omega \cdot \cos\omega t$$

$$P(t) = 1 \cdot 0{,}6 \cdot 100 \cdot 10^{-6} \cdot 2\pi \cdot 30\,000 \cdot \cos \omega t \quad \text{(A.1)}$$

$$\approx 11{,}3 \cdot \cos\omega t \quad \text{(A.2)}$$

$$P_{\text{eff}} = \frac{11{,}3}{\sqrt{2}} \approx 8{,}0 \text{ W} \quad \text{(A.3)}$$

where

F is applied vertical load in Newton;

μ is the friction coefficient;

f is the measured frequency in hertz;

s is the measured distance in micrometres;

P is the power output in watts;

ω is the oscillation frequency.

ICS 11.060.25

Price based on 17 pages