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

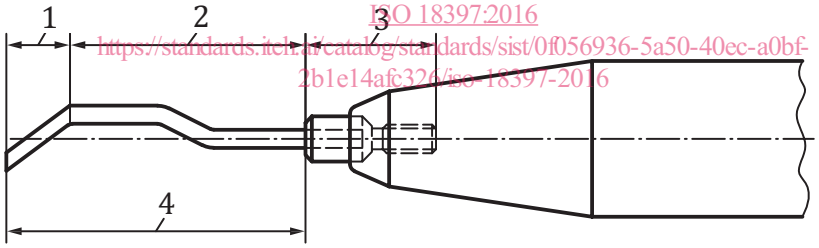
3.2
air-powered scaler
handpiece powered by pressurized air, with an oscillating working part

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.