FINAL DRAFT International Standard

ISO/FDIS 18397

Dentistry — Powered scaler

Médecine bucco-dentaire — Instruments pour détartrage

ISO/TC **106**/SC **4**

Secretariat: **DIN**

Voting begins on:
2025-03-07

Voting terminates on:
2025-05-02

ISO/CEN PARALLEL PROCESSING

Reference number
ISO/FDIS 18397:2025(en)

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Published in Switzerland

Contents

Page

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 document 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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This document was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 4, *Dental instruments,* in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 55, *Dentistry,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 18397:2016), which has been technically revised.

The main changes are as follows:

— adaption of the part designations for the scaler tips;

— reducing the maximum frequency of the scaler tips for air-powered scaler handpieces;

— new specification on when to provide information on output power in the instructions for use;

— simplification of the description for the amplitude limit value.

Any feedback or questions on this document should be directed to the user’s national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

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

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 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 — Stationary dental units and dental patient chairs — Part 1: General requirements*

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

ISO 9687, *Dentistry — 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 information to be supplied by the manufacturer — Part 1: General requirements*

ISO 17664-1, *Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 1: Critical and semi-critical medical devices*

ISO 21531, *Dentistry — Graphical symbols for dental instruments*

IEC 60601-1:2005, *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, *Medical electrical equipment — Part 2-60: Particular requirements for the 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.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
powered scaler
scaler powered by air or electrical energy

3.2
scaler handpiece
powered handheld handpiece used to operate an oscillating *working part* (3.7)

3.3
air-powered scaler handpiece
scaler handpiece (3.2) powered by compressed air

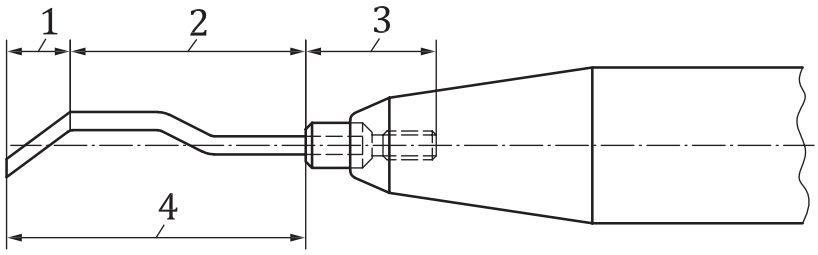
[SOURCE: ISO 14457:2017, 3.3 modified — The term “handpiece” was added to the term. The term “scaler” was added to the definition and “with an oscillating working part” was removed.]

3.4
electrical-powered scaler handpiece
scaler handpiece (3.2) powered by electrical energy

[SOURCE: ISO 14457:2017, 3.8 modified — The term “handpiece” was added to the term. The term “scaler” was added to the definition and “with an oscillating working part” was removed.]

3.5
operating area
area of the *working part* (3.7) for use as described by the manufacturer

3.6
scaler tip
fixed or interchangeable oscillating instrument used in a *scaler handpiece* (3.2) and consisting of a *shank* (3.9) and an *operative part* (3.10)



Key

1 working part
2 transmission part
3 shank
4 operative part

Figure 1 — Designation of parts for scaler tips

3.7
working part
distal end of an oscillating instrument intended for direct use in the oral cavity of the patient

Note 1 to entry: See Figure 1.

3.8
transmission part
part intended to transmit energy from the *shank* (3.9) to the *working part* (3.7)

Note 1 to entry: See Figure 1.

3.9
shank
part of an oscillating instrument connected to a *scaler handpiece* (3.2)

Note 1 to entry: See Figure 1.

3.10
operative part
part of a fixed or interchangeable instrument connected to a *scaler handpiece* (3.2)

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, when operated with the maximum power recommended by the manufacturer.

Table 1 — Frequency of scaler tips

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

5 Requirements and performance

5.1 General

The construction of handpieces shall be safe and provide reliable operation. These requirements shall conform to 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.

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

5.3 Drop test

The 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

The requirements, if applicable, shall be specified by the manufacturer and shall conform to ISO 7494-1.

Test in accordance with 7.3.

5.7 Energy for light source

The requirements of the light source, if applicable, shall be specified by the manufacturer and shall conform to ISO 7494-1.

Test in accordance with 7.3.

5.8 Air supply

Air-powered handpieces, if applicable, 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 1,013 25 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 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. they 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.