



SLOVENSKI STANDARD
oSIST prEN ISO 18397:2024
01-marec-2024

Nadomešča:
SIST EN ISO 18397:2016

Zobozdravstvo - Pripomočki za čiščenje (scaler) (ISO/DIS 18397:2024)

Dentistry - Powered scaler (ISO/DIS 18397:2024)

Zahnheilkunde - Angetriebener Scaler (ISO/DIS 18397:2024)

Médecine bucco-dentaire - Instruments pour détartrage (ISO/DIS 18397:2024)

Ta slovenski standard je istoveten z: prEN ISO 18397

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11.060.25 Zobotehnični instrumenti Dental instruments

oSIST prEN ISO 18397:2024

en,fr,de

DRAFT INTERNATIONAL STANDARD

ISO/DIS 18397

ISO/TC 106/SC 4

Secretariat: DIN

Voting begins on:
2024-01-26Voting terminates on:
2024-04-19

Dentistry — Powered scaler

Médecine bucco-dentaire — Instruments pour le détartrage

ICS: 11.060.25

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Published in Switzerland

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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.

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 of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

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

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

The main changes are as follows:

- adaptation of the part designations for the scaler tips,
- reducing the maximum frequency of the air powered scaler tips,
- new definition of when information on output power must be provided 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.

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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 document is necessary to ensure the level of safety and performance, both of the individual devices and in combination, is at an appropriate level.

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Dentistry — Powered scaler

1 Scope

This document specifies 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. 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*

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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 17664-1, *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, *Graphical symbols for dental instruments*

IEC 60601-1:2005+AMD1:2012+AMD2:2020, *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*

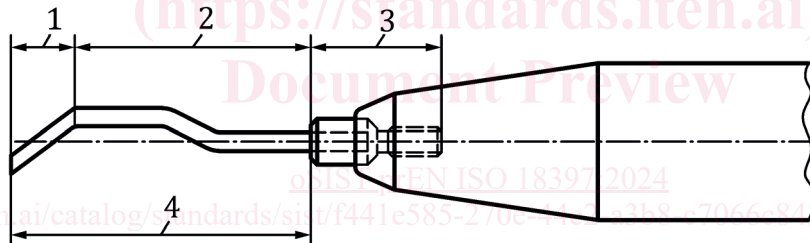
IEC 80601-2-60:2019, *Medical electrical equipment — Part 2-60: Particular requirements for basic safety and essential performance of dental equipment*

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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 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 an operative part



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
- 3.8 transmission part**
tool designed to transmit energy from the shank to the working part
- 3.9 shank**
part of an oscillating instrument connected to a scaler handpiece