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Dentistry — Powered scalers

Médecine bucco-dentaire — Instruments pour détartrage

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Foreword

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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.

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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 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 scalers

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, *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*

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