
Dentistry — Powered scaler

Médecine bucco-dentaire — Instruments pour le détartrage

Sample Document

get full document from standards.iteh.ai



Sample Document

get full document from standards.iteh.ai



COPYRIGHT PROTECTED DOCUMENT

© ISO 2016, Published in Switzerland

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

Contents

Page

Foreword	v
Introduction	vi
1 Scope	1
2 Normative references	1
3 Terms and definitions	2
4 Classification of scaler handpieces	3
5 Requirements and performance	3
5.1 General	3
5.2 Materials	3
5.3 Drop test	3
5.4 Noise level	3
5.5 Surfaces	4
5.6 Electrical power supply (if applicable)	4
5.7 Energy for light source (if applicable)	4
5.8 Air supply	4
5.9 Supply of cooling liquid	4
5.10 Air and water pressure	4
5.11 Temperature	4
5.11.1 Temperature rise of housing	4
5.11.2 Temperature, excessive	5
5.12 Vibrations	5
5.13 Resistance to reprocessing	5
5.14 Leakage and/or ingress of water	5
5.15 Electromagnetic compatibility	5
5.16 Operating controls	5
5.17 Usability	5
5.18 Connection	6
5.18.1 General	6
5.18.2 Connections for air-powered scaler handpieces	6
5.18.3 Connector for electrical-powered scaler handpieces	6
5.19 Scaler tip performance	6
5.19.1 Scaler tip connection	6
5.19.2 Extraction force (for non-screw tips only)	6
5.19.3 Holding torque (for screw-in-tips only)	6
5.19.4 Insertion force (for non-screw-tips only)	7
5.19.5 Tightening torque (for screw-in-tips only)	7
5.19.6 Stall effort	7
5.19.7 Power output, scaler tips	7
5.19.8 Breakage resistance	7
5.20 Frequency	7
5.21 Amplitude	7
6 Sampling	7
7 Testing	8
7.1 General test conditions	8
7.2 Visual inspection	8
7.3 Power supply — Electrical	8
7.4 Air supply	8
7.4.1 Apparatus	8
7.4.2 Procedure	8
7.5 Supply of cooling liquid	8
7.5.1 Apparatus	8
7.5.2 Procedure	8

7.6	Air and water pressure	8
7.6.1	Apparatus.....	8
7.6.2	Procedure.....	8
7.7	Measuring device for dimensions.....	9
7.8	Scaler tips	9
7.8.1	Extraction force (for non-screw-tips only).....	9
7.8.2	Holding torque (for screw-in-tips only)	9
7.8.3	Insertion force (for non-screw-tips only).....	9
7.8.4	Tightening torque (for screw-in-tips only)	9
7.8.5	Stall effort.....	10
7.8.6	Power output, scaler tips.....	10
7.8.7	Breakage resistance	12
7.9	Frequency.....	12
7.9.1	Apparatus.....	12
7.9.2	Procedure.....	12
7.10	Amplitude.....	12
7.10.1	Apparatus.....	12
7.10.2	Procedure.....	13
7.11	Noise level.....	13
7.11.1	Apparatus.....	13
7.11.2	Test conditions.....	14
7.11.3	Procedure.....	14
7.12	Temperature rise of housing.....	14
7.13	Temperature, excessive.....	14
7.14	Resistance to reprocessing.....	14
8	Instructions for use, maintenance and service.....	14
9	Technical description	15
10	Marking.....	15
10.1	General.....	15
10.2	Scaler handpieces.....	15
10.3	Scaler tips	16
11	Labelling.....	16
12	Packaging.....	16
Annex A (informative)	Calculation example for power output.....	17

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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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.

Sample Document

get full document from standards.iteh.ai

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*