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Dentistry - Powder jet handpieces and powders (ISO 20608:2018)

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

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**Dentistry - Powder jet handpieces and powders (ISO
20608:2018)**

Médecine bucco-dentaire - Poudres et pièces à main de
pulvérisation (ISO 20608:2018)

Zahnheilkunde - Pulverstrahl-Handstücke und Pulver
(ISO 20608:2018)

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EN ISO 20608:2018 (E)

Contents	Page
European foreword.....	3

European foreword

This document (EN ISO 20608:2018) has been prepared by Technical Committee ISO/TC 106 “Dentistry” in collaboration with Technical Committee CEN/TC 55 “Dentistry” the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by November 2018, and conflicting national standards shall be withdrawn at the latest by November 2018.

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INTERNATIONAL STANDARD

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Dentistry — Powder jet handpieces and powders

Médecine bucco-dentaire — Poudres et pièces à main de pulvérisation



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Contents

Page

Foreword	v
Introduction	vi
1 Scope	1
2 Normative references	1
3 Terms and definitions	2
4 Classification of handpieces	3
5 Requirements	3
5.1 Powder for powder jet handpieces	3
5.1.1 General	3
5.1.2 Biocompatibility	3
5.2 Powder jet handpieces	4
5.2.1 General	4
5.2.2 Biocompatibility of materials	4
5.2.3 Drop test	4
5.2.4 Noise level	4
5.2.5 Surfaces	4
5.2.6 Nozzle rotation	4
5.3 Air and water supply	4
5.3.1 Drive air	4
5.3.2 Spray water	5
5.4 Excessive air and water pressure	5
5.5 Temperature	5
5.5.1 Maximum temperature during normal use	5
5.5.2 Applied parts not intended to supply heat to a patient	5
5.6 Vibrations	5
5.7 Resistance to reprocessing	5
5.8 Leakage and/or ingress of water	5
5.9 Operating controls	6
5.10 Usability	6
5.11 Connection	6
5.11.1 General	6
5.11.2 Connections	6
5.12 Backflow preventer	6
5.13 Electrical safety	6
5.14 Test report	7
6 Sampling	7
7 Measurement and test methods	7
7.1 General test conditions	7
7.2 Visual inspection	7
7.2.1 Visual inspection of equipment	7
7.2.2 Visual inspection of documentation or test reports	7
7.3 Drive air	7
7.3.1 Apparatus	7
7.3.2 Procedure	7
7.4 Spray water	7
7.4.1 Apparatus	7
7.4.2 Procedure	8
7.5 Air and water pressure	8
7.5.1 Apparatus	8
7.5.2 Procedure	8
7.6 Connection	8
7.6.1 Apparatus	8

ISO 20608:2018(E)

	7.6.2	Procedure.....	8
7.7		Noise level.....	8
	7.7.1	Apparatus.....	8
	7.7.2	Test chamber.....	8
	7.7.3	Procedure.....	8
7.8		Maximum temperature during normal use.....	9
7.9		Applied parts not intended to supply heat to a patient.....	9
7.10		Resistance to reprocessing.....	9
7.11		Backflow preventer.....	9
8		Instructions for use, maintenance and service.....	10
	8.1	Powder jet handpieces.....	10
	8.2	Powder.....	11
9		Technical description.....	11
	9.1	Powder jet handpiece.....	11
	9.2	Powder.....	11
10		Marking and labelling.....	11
	10.1	General.....	11
	10.2	Powder jet handpieces.....	12
	10.3	Powders.....	12
11		Packaging.....	12
		Annex A (informative) Example of a test report.....	13

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 on 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 the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 4, *Dental instruments*.

ISO 20608:2018(E)**Introduction**

Powder jet handpieces have been used in applications and procedures in the field of dentistry for many years.

Technological developments continuously create better powder jet handpieces that are easier to handle, as well as the associated powders in use, for example for teeth cleaning. The correct combination of these elements is very important in order to achieve a good clinical performance

Dentistry — Powder jet handpieces and powders

1 Scope

This document specifies the general requirements, test methods, manufacturer's information, marking and packaging, independently of the design of the powder jet handpieces (see [Figure 1](#)).

This document applies to powder jet handpieces and their associated powders for use in the field of dentistry. They are used on patients to remove dental debris, discolourations and plaque and to clean and polish teeth where abrasion is a side effect.

It is also applicable to powder jet handpieces and their associated powders that are used in dentistry for air driven abrasion, e.g. minimally invasive cavity preparation, preparation of surfaces for adhesives and for the removal of cement residues where abrasion is part of the desired outcome.

This document is not applicable for the dental units that are employed to supply the powder jet handpieces.

This document is not applicable to dental prophylaxis handpieces (contra angles), or electrically driven plaque removers (scalers) or multifunctional handpieces (syringes).

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 — Dental units — Part 1: General requirements and test methods*

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 11014, *Safety data sheet for chemical products — Content and order of sections*

ISO 14971, *Medical devices — Application of risk management to medical devices*

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, *Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices*

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

ISO 20608:2018(E)

IEC 60601-1:2005+AMD1: 2012, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

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*

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