



SLOVENSKI STANDARD
oSIST prEN ISO 20608:2017
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Zobozdravstvo - Ročni pripomočki in praški (ISO/DIS 20608:2017)

Dentistry - Powder jet handpieces and powders (ISO/DIS 20608:2017)

Zahnheilkunde - Luftbetriebene Pulverstrahlhandstücke und Pulver (ISO/DIS 20608:2017)

Médecine bucco-dentaire - Jet de poudre pour pièces à main (ISO/DIS 20608:2017)

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Dentistry — Powder jet handpieces and powders

Médecine bucco-dentaire — Jet de poudre pour pièces à main

ICS: 11.060.20

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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 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 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.

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

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ISO/DIS 20608:2017(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.

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Dentistry — Powder jet handpieces and powders

1 Scope

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 defines the general requirements, test methods, manufacturer's information, marking and packaging, independently of the design of the powder jet handpieces.

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, *Sterilization of medical devices — Information to be provided by the manufacturer for the processing of resterilizable medical devices*

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

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IEC 60601-1:2013-12, *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*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 1942 and the following apply.

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

- IEC Electropedia: available at <http://www.electropedia.org/>
- ISO Online browsing platform: available at <http://www.iso.org/obp>

3.1

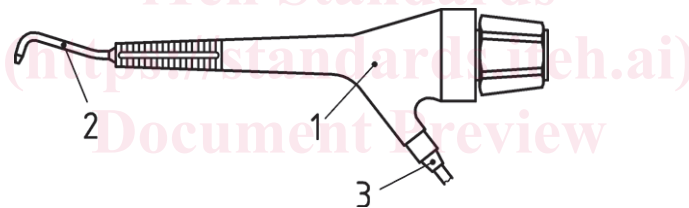
abrasion

removal of material using a powder by grinding, scouring or spraying

3.2

powder jet handpiece

dental handpiece designed to transfer powder to the patient, powered via a dental unit meeting the requirements of ISO 7494-1 or a dedicated dental unit according to the manufacturers discretion



Key

- 1 powder jet handpiece
- 2 handpiece nozzle
- 3 hose connector

Figure 1 — Powder jet handpiece

3.2.1

cleaning powder jet handpiece

dental handpiece designed to transfer powder to the patient for tooth cleaning and polishing

3.2.2

abrasion powder jet handpiece

dental handpiece designed to transfer powder to the patient for abrasive dental treatment, usually operated on a higher air pressure than a cleaning powder jet handpiece to achieve this

3.3

powder

dry material consisting of fine ground biocompatible substances intended for the cleaning, and polishing or abrasion of tooth surfaces in conjunction with an powder jet handpiece