INTERNATIONAL STANDARD

**ISO 20608**

First edition
2018-04

# Dentistry — Powder jet handpieces and powders

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



Reference number
ISO 20608:2018(E)



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

Published in Switzerland

# Contents

Page

# 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 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*.

# 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*

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*

## 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:

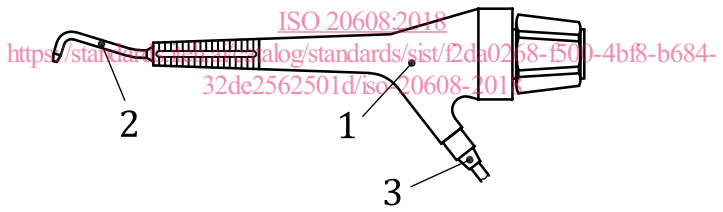
— IEC Electropedia: available at http://www.electropedia.org/

— ISO Online browsing platform: available at https://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 (e.g. table top control unit)






**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

**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 a powder jet handpiece

**3.4**
**spray water**
water that is used to suppress dust production and to wash away the powder

**3.5**
**dental unit**
device (stationary or non-stationary) through which electrical power and/or various fluids or gasses are supplied to at least one or more dental handpieces and devices

[SOURCE: IEC 80601-2-60:2012,201.3.206]

**3.6**
**dental handpiece**
handheld instrument used in dentistry for use in patient treatment and connected to the dental unit

[SOURCE: IEC 80601-2-60:2012,201.3.203]

## 4 Classification of handpieces

Powder jet handpieces are classified into two types according to their scope of application, as given in Table 1.

**Table 1 — Powder jet handpieces and powders according to scope of application**

| Number | Type | Common used powder substances |
|---|---|---|
| 1 | Cleaning powder jet handpiece | e.g. sodium hydrogen carbonate, sodium bicarbonate, calcium carbonate, glycine |
| 2 | Abrasion powder jet handpiece | e.g. corundum |



## 5 Requirements

### 5.1 Powder for powder jet handpieces

#### 5.1.1 General

The powders used in combination with powder jet handpieces shall ensure a safe and reliable operation and the efficacy of the system (powder and handpiece). The powders shall not present a hazard for the patient, the user or a third party when used in accordance with the manufacturer's instructions. To ensure this the manufacturer shall provide suitable protection measures against aspiration or ingestion of the powder where either would be hazardous to the patient.

IEC 62366-1 and ISO 14971 shall apply.

Test conformity in accordance with 7.2.2 and by examination of the instructions for use of the powder.

#### 5.1.2 Biocompatibility

Powders used for powder jet handpieces shall be evaluated for biocompatibility meeting the requirements of ISO 10993-1.

Test conformity in accordance with 7.2.2.

## 5.2 Powder jet handpieces

### 5.2.1 General

The design of the powder jet handpieces in combination with the powder shall ensure a safe and reliable operation. The use and handling of the powder jet handpiece in dental applications shall be easy and comfortable for the operator.

IEC 62366-1 and ISO 14971 shall apply.

Test conformity in accordance with 7.2.2.

If powder jet handpieces are intended for maintenance on site, they shall be easy to disassemble and assemble using either no tools, readily available tools, or special tools supplied by the manufacturer.

Test conformity in accordance with 7.2.1.

### 5.2.2 Biocompatibility of materials

Material tests for biocompatibility shall be in accordance with ISO 10993-1.

Test conformity in accordance with 7.2.2.

### 5.2.3 Drop test

IEC 60601-1:2005+AMD1: 2012, 15.3.4.1 shall apply.

Test conformity in accordance with 7.2.2.



### 5.2.4 Noise level



The A-weighted sound pressure level generated by the powder jet handpiece shall not exceed 80 dB(A).

Test in accordance with 7.7.

### 5.2.5 Surfaces

Particular attention should be given to provide secure gripping surfaces for operator manipulation under normal conditions of use.

IEC 62366-1 shall apply.

Test conformity in accordance with 7.2.2.

In order to reduce glare, highly polished surfaces should be avoided.

### 5.2.6 Nozzle rotation

To control the powder flow, the dental handpiece nozzle shall be rotatable.

Test in accordance with 7.2.1.

## 5.3 Air and water supply

### 5.3.1 Drive air

Powder jet handpieces, which can be connected to dental units meeting the requirements of ISO 7494-1 shall be operated by a pressurized air supply in accordance with the manufacturer's instructions. The

necessary air quantity (flow rate) shall be ≤40 Nl/min[1)] in a pressure range from 250 kPa (2,5 bar) up to the maximum recommended operating pressure.

Test in accordance with 7.3.

#### 5.3.2 Spray water

If applicable, powder jet handpieces, shall supply a water quantity to the operating area of the working part with a flow rate of ≥20 ml/min at 150 kPa (1,5 bar).

Test in accordance with 7.4.

### 5.4 Excessive air and water pressure

If applicable, powder jet handpieces shall remain functional, i.e. they shall not rupture or burst, when subjected to a pressure 50 % above the maximum recommended operating pressure.

Test in accordance with 7.5.

### 5.5 Temperature

#### 5.5.1 Maximum temperature during normal use

IEC 80601-2-60:2012, 201.11.1.1 shall apply.

Test in accordance with 7.8.



#### 5.5.2 Applied parts not intended to supply heat to a patient



IEC 80601-2-60:2012, 201.11.1.2.2 shall apply.

Test in accordance with 7.9.

### 5.6 Vibrations

ISO 5349-1 and ISO 5349-2 shall apply.

With justification it is possible to refrain from providing a test report according to ISO 5349-1 and ISO 5349-2.

Test conformity in accordance with 7.2.2.

### 5.7 Resistance to reprocessing

Powder jet handpieces shall withstand 250 reprocessing cycles as specified by the manufacturer without deterioration in performance. This entails that all other requirements in this document are met after the necessary reprocessing cycles have been completed.

If the manufacturer stipulates a lower number of permitted reprocessing cycles, then this number shall be used in place of the 250 cycles stated above.

Test in accordance with 7.10.

### 5.8 Leakage and/or ingress of water

IEC 60601-1:2005+AMD1: 2012, 11.6 shall apply.

---

1) Nl/min indicates normal litres per minute, the amount of air that flows through a pipe calculated back to "normal" conditions [0 °C and 1 atm or 1,013 25 bar (1 bar = 0,1 MPa = 0,1 $N/mm^2$ = $10^5$ $N/m^2$)].