INTERNATIONAL STANDARD

ISO 22569

First edition
2020-06

Dentistry — Multifunction handpieces

Médecine bucco-dentaire — Pièces à mains multifonctions

Reference number
ISO 22569:2020(E)

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
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 of 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 www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 4, *Dental instruments*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 55, *Dentistry*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

For many years, dental multifunction handpieces have been used in the field of dentistry to carry out treatment in the oral cavity of the patient.

Multifunction handpieces are connected to dental units and provide the user with water, air and spray for treatment purposes. Some multifunction handpieces provide also illumination of the situs.

Technological progress enables continual development of improved and new handpieces with simplified handling and extended range of applications.

These handpieces are produced by the dental industry as high-quality medical devices under application of quality management methods.

This document describes the applicable technical properties of products in order to maintain this high level of quality.

Dentistry — Multifunction handpieces

1 Scope

This document specifies requirements, test methods, instructions for use and marking for multifunction handpieces (colloquially called “syringes”) intended to be used in the oral cavity of the patient.

This document does not apply to dental handpieces and motors, intraoral cameras, dental polymerisation lamps, powered scalers, powder jet handpieces, prophy handpieces, suction cannulas and saliva ejectors.

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 7494-1, *Dentistry — Stationary dental units and dental patient chairs — Part 1: General requirements*

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 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 21530, *Dentistry — Materials used for dental equipment surfaces — Determination of resistance to chemical disinfectants*

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 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*

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:

— ISO Online browsing platform: available at https://www.iso.org/obp

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

3.1
multifunction handpiece
handpiece, which is supplied with air and water and transfers the water and air directly or as air water mixture (spray) in cold and/or warm state into the oral cavity of the patient

Note 1 to entry: Multifunction handpieces may be additionally equipped with a light function.

Note 2 to entry: Also used terms are multi-way syringe or multifunction syringe. A colloquial used term is "syringe".

3.2
cannula
forward, detachable part of the *multifunction handpiece* (3.1)

4 Classification

4.1 Shape

Multifunction handpieces are classified according to their geometry (as shown in Figure 1 to Figure 3) as follows:

— angled handpieces;

— straight handpieces;

— curved handpieces.

4.2 Number of functions

The number of transferable fluids such as air, water and spray as well as fluid heating is indicated with a numerical designation:

EXAMPLE 1 3-function handpiece: water, air, and spray.

EXAMPLE 2 6-function handpiece: water, air, spray, warm water, warm air, and warm spray.

In addition, the lighting equipment is also indicated if applicable.

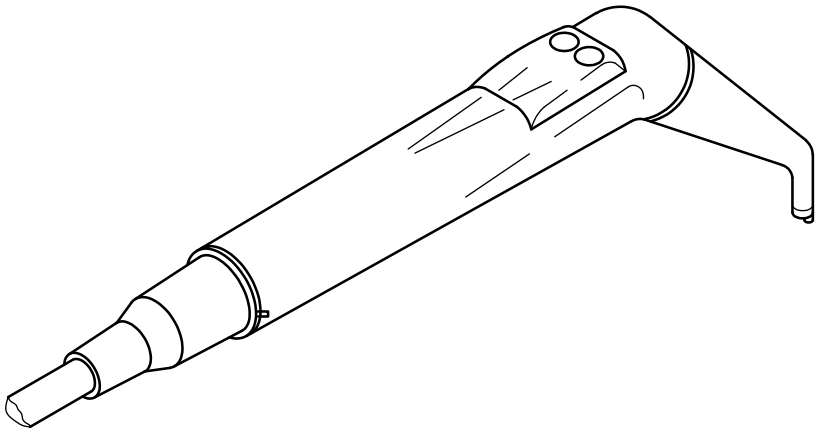

Figure 1 — Angled multifunction handpiece

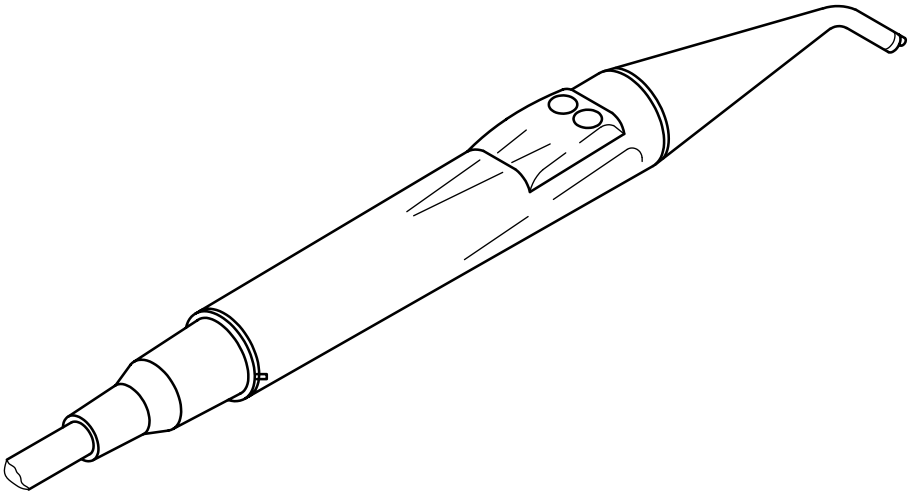

Figure 2 — Straight multifunction handpiece

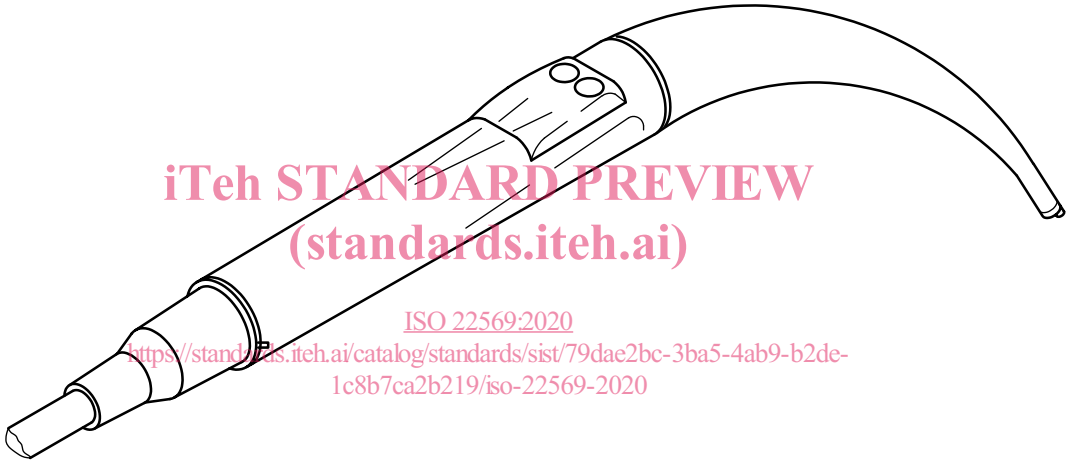

Figure 3 — Curved multifunction handpiece

4.3 Single use or reusable cannula

Cannula are classified by their capability to be reused as follows:

— single-use cannula;

— reusable cannula.

5 Requirements

5.1 General

The safe and reliable operation of multifunction handpieces shall be ensured by their design.

To meet this requirement, the handpiece shall be in accordance with the requirements specified in 5.2 to 5.22.

Multifunction handpieces should be suitable for continuous operation. IEC 60601-1:2005/AMD1:2012, 6.6 applies.

All pressure values given in the requirements are flow pressure values.

5.2 Handling

5.2.1 Rotation of cannula

The cannula of the multifunction handpiece used to control the discharged media shall be rotatable through 360°.

Test in accordance with 7.4.

5.2.2 Pull-off force of cannula

The pull-off force for removing the cannula and the grip sleeve of the multifunction handpiece shall be (30 ± 20) N.

This requirement only applies to handpieces intended for the use with dental units which conform to ISO 7494-1, and does not apply for handpieces with a lock system (e.g. push button or screw).

Test in accordance with 7.4.

5.3 Maintenance

If the multifunction handpieces are field-repairable according to the manufacturer's indications, they shall be easy to disassemble and reassemble for maintenance and repair. Either commonly used tools or special tools supplied by the manufacturer shall be used for this purpose.

IEC 62366-1 shall be followed.

5.4 Materials

Materials shall meet all requirements of this document. Choice of materials shall be at the discretion of the manufacturer.

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

5.5 Mechanical strength

IEC 60601-1:2005/AMD1:2012, 15.3.1 general shall apply.

IEC 60601-1:2005/AMD1:2012, 15.3.2 push test shall apply.

IEC 60601-1:2005/AMD1:2012, 15.3.3 impact test shall apply.

IEC 60601-1:2005/AMD1:2012, 15.3.4.1 drop test, hand-held ME equipment shall apply.

IEC 60601-1:2005/AMD1:2012, 15.3.6 mould stress relief test, if applicable, shall apply.

5.6 Surfaces

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

Test following the process described in IEC 62366-1.

To reduce glare, polished surfaces should be avoided.

5.7 Air supply

Multifunction handpieces shall be operated by an air supply as indicated by the manufacturer.

This requirement applies for handpieces intended for the use with dental units which conform to ISO 7494-1: multifunction handpieces shall be able to transfer an air quantity (flow rate) of no less than 10 Nl/min[1)] with a pressure at the discretion of the manufacturer to the treatment area.

Test in accordance with 7.5.

5.8 Water supply

Multifunction handpieces shall be operated by a water supply as indicated by the manufacturer.

Multifunction handpieces shall be able to transfer a water quantity (flow rate) of at least (50) ml/min with a pressure at the discretion of the manufacturer to the treatment area.

Test in accordance with 7.6.

5.9 Water outlet

The water shall be discharged in a focused jet in direction of the cannula without any dripping.

Test in accordance with 7.2.

5.10 Air outlet

The air discharged from the multifunction handpiece shall be dry.

Test in accordance with 7.10.

5.11 Spray outlet

The spray jet shall be discharged in an atomized condition with an angle of no more than 60° to a central axis normal to the plane of the spray outlet of the cannula.

Test in accordance with 7.3.

5.12 Tightness

During normal use, the housing of the multifunction handpiece shall not show any signs of water leakage.

Test in accordance with 7.7.

5.13 Air and water pressure

Multifunction handpieces shall remain functional and safe, i.e. they shall not rupture or burst, when subjected to a pressure 50 % higher than the maximal operating pressure recommended by the manufacturer.

Test in accordance with 7.8.

5.14 Electrical power supply

These requirements apply only to electrically powered multifunction handpieces.

Multifunction handpieces are connected to the dental unit and are therefore not intended for the direct connection to the mains supply.

---

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 = 105 N/m^2)].