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Dentistry — Multifunction handpieces

Médecine bucco-dentaire — Pièces à mains multifonctions

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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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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.

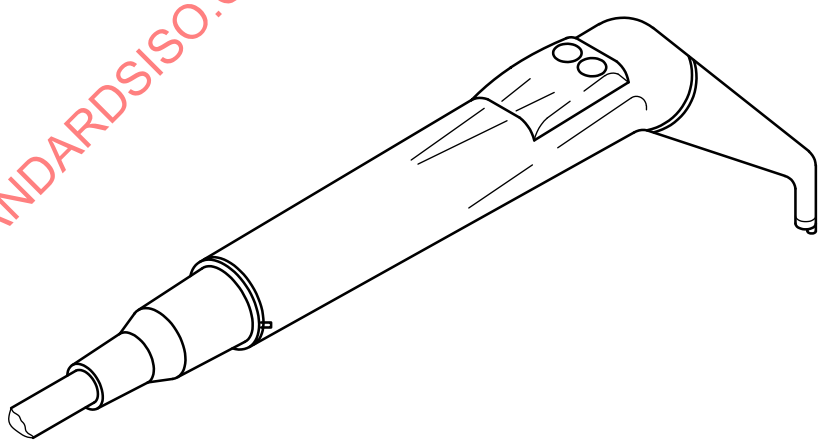


Figure 1 — Angled multifunction handpiece

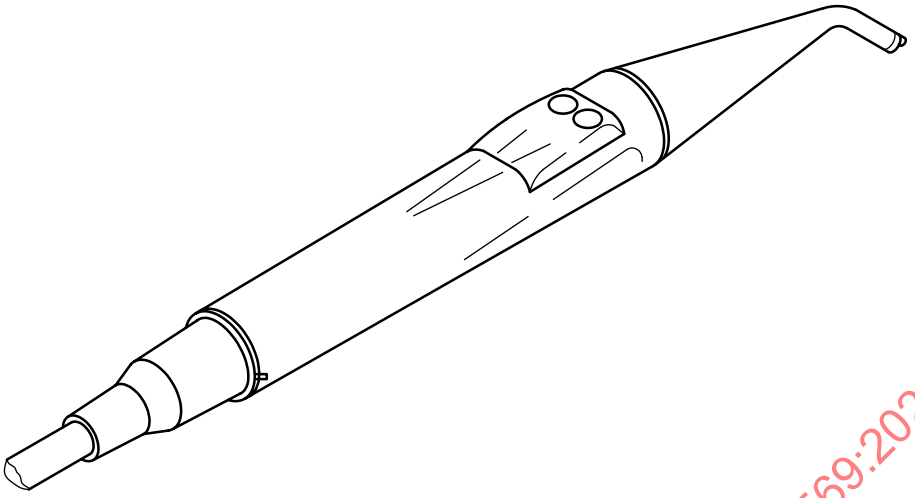


Figure 2 — Straight multifunction handpiece

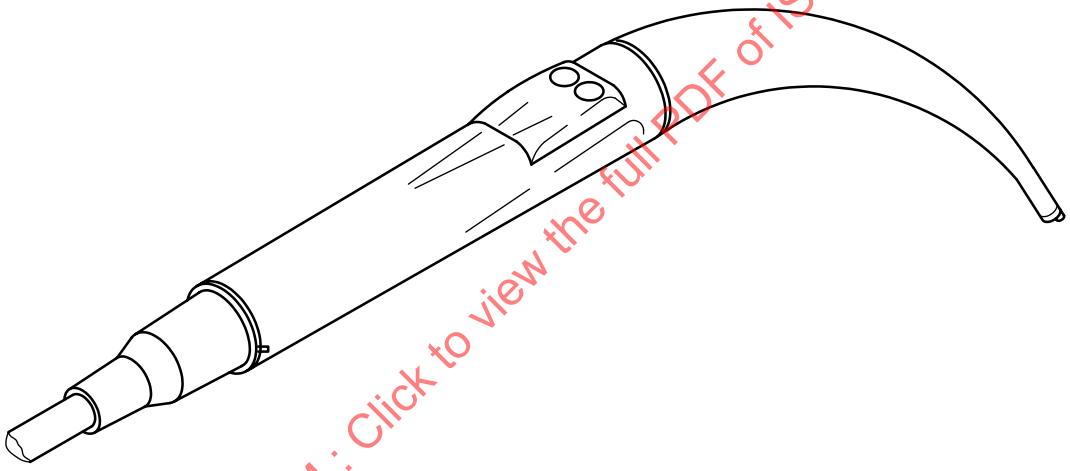


Figure 3 — Curved multifunction handpiece

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)].

Multifunction handpieces with a fluid heating and/or lighting function shall be powered by an electrical power supply as indicated by the manufacturer.

The power supply shall be in accordance with ISO 7494-1, IEC 60601-1, and IEC 80601-2-60.

Multifunction handpieces shall be classified and marked according to IEC 60601-1 and IEC 80601-2-60.

5.15 Temperature

5.15.1 Water temperature

Multifunction handpieces with a water heating device shall limit the water discharge temperature to ≤ 43 °C.

Test in accordance with 7.9.1.

5.15.2 Air temperature

Multifunction handpieces with an air heating device shall limit the air discharge temperature to ≤ 43 °C.

Test in accordance with 7.9.2.

5.15.3 Spray temperature

Multifunction handpieces with a heating device for spray shall limit the spray discharge temperature to ≤ 43 °C.

Test in accordance with 7.9.3.

5.15.4 Temperature rise of the housing

IEC 60601-1 and IEC 80601-2-60 shall apply.

5.15.5 Temperature, excessive

IEC 60601-1 and IEC 80601-2-60 shall apply.

5.16 Backflow prevention

Multifunction handpieces shall prevent backflow of liquids into the supply lines for procedural water from the dental unit.

Test in accordance with 7.11.

5.17 Reprocessing

Any reusable parts shall be suitable for reprocessing using the agents and methods recommended by the manufacturer.

The manufacturer shall provide information on the reprocessing for the multifunction handpiece in accordance with ISO 17664.

5.18 Resistance to reprocessing

Multifunction handpieces and parts thereof shall withstand 250 reprocessing cycles as specified by the manufacturer without deterioration in performance and without deterioration of surfaces or labelling. All requirements in this document shall be met after the necessary reprocessing cycles have been completed.

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

Test in accordance with ISO 21530 and 7.12.

5.19 Operating controls

Operating controls of multifunction handpieces (e.g. for fluid type selection or fluid regulation) shall be designed and positioned such as to minimize hazard.

The air control should be marked "A" and the water control should be marked "W". When colour coding is used, the marking applied should be blue for air and green for water.

IEC 60601-1:2005/AMD1:2012, 15.1 shall apply.

Testing shall be carried out in accordance with IEC 60601-1.

5.20 Usability

Usability evaluation and testing shall be carried out following IEC 62366-1.

5.21 Connection and supply

This requirement applies for handpieces intended for the use with dental units which conform to ISO 7494-1.

Multifunction handpieces should be suitable for being disconnected from and reconnected to an instrument hose of a dental unit which conform to ISO 7494-1 without the use of any special tool.

Test in accordance with 7.2.

5.22 Test report

A test report shall be prepared to report the results of all applicable testing and inspection requirements specified in this document.

The test report shall at least include the following aspects:

— the standard used (including its year of publication);

— the method used (if the standard includes several);

— the result(s), including a reference to the clause which explains how the results were calculated;

— if present, any deviations from the procedure;

— if present, any unusual features observed;

— the date of the test.

An example for a test report template is given in Annex A.

6 Sampling

At least one representative handpiece for each model series shall be evaluated for compliance with this document.

7 Measurement and test methods

7.1 General test conditions

All tests described in this document are type tests.

7.2 Visual inspection

Conduct visual inspection at normal visual acuity without magnification.

7.3 Spray angle

7.3.1 Equipment

7.3.1.1 Camera

Take an image of the spray jet emitted from the multifunction handpiece.

7.3.1.2 Protractor

Measure the maximum angle of the spray jet.

7.3.2 Procedure

Operate the spray function of the multifunctional handpiece and capture the trajectory of the spray with the camera.

A background and illumination may be positioned so that the outline of the spray is better visible for capture by the camera.

Use the captured image to measure the spray angle at a distance of (3 ± 0,5) cm away from the outlet in the direction of the flow with the protractor.

If the spreading angle of the spray is not uniform, i.e. not emitted like a regular cone, the spray angle at maximum width shall be captured and measured. If the spray angle is influenced by the actuating path of the spray button the highest value for the spray angle shall be captured for measurement.

The measured spray angle shall be equal or below the value given in 5.11.

7.4 Handling

Rotate the cannula through 360° in relation to the handpiece.

Pull the cannula and the gripping sleeve off the multifunction handpiece while using suitable measuring instruments (e.g. spring balance), and record the forces required.

7.5 Air supply

7.5.1 Equipment

7.5.1.1 Flowmeter with a maximum permissible error of 5 % for measuring the air supply flow rate (air quantity).

7.5.1.2 Pressure gauge with a maximum permissible error of 5 % for measuring the air supply pressure at the inlet of the multifunction handpiece.

7.5.2 Procedure

Install the pressure gauge directly (i.e. not through the air hose) at the air connector of the multifunction handpiece and measure the air supply flow rate while operating the multifunction handpiece with air button fully pressed at the pressure given in 5.7. Correct air flow measurements to normal litres (Nl/min, standard flow rate).

7.6 Water supply

7.6.1 Equipment

7.6.1.1 Volume measuring vessel, with a maximum permissible error of 5 % for measuring the cooling water volume.

7.6.1.2 Pressure gauge, with a maximum permissible error of 5 % for measuring the water supply pressure at the inlet of the multifunction handpiece.

7.6.2 Procedure

For measuring the water flow rate, adjust the water supply pressure at the inlet of the multifunction handpiece to the pressure given in 5.8 and operate the handpiece with water button fully pressed for 1 min. Record the volume of the water collected.

7.7 Tightness

Remove the cannula from the multifunction handpiece and seal the water outlet opening. Operate the water control for at least 10 s. There shall be no water leakage.

7.8 Air and water pressure

7.8.1 Equipment

7.8.1.1 Pressure gauge, suitable for measuring the supply pressure with a maximum permissible error of 5 % of the expected value.

7.8.2 Procedure

Operate the multifunction handpiece at a pressure 50 % higher than the recommended operating pressure for 10 min.

Observe the multifunction handpiece for any signs of rupture or burst.

7.9 Temperature

7.9.1 Water temperature

Connect the multifunction handpiece, which is equipped with a water heating device, to the supply as indicated by the manufacturer. Measure the water discharge temperature at a distance of 10 mm from the discharge nozzle of the cannula at an ambient temperature of (23 ± 2) °C using a suitable temperature measurement device with a sensor in the water jet and record the measurement result.

7.9.2 Air temperature

Connect the multifunction handpiece, which is equipped with an air heating device, to the supply as indicated by the manufacturer. Measure the air discharge temperature at a distance of 10 mm from the

discharge nozzle of the cannula at an ambient temperature of (23 ± 2) °C using a suitable temperature measurement device with a sensor in the air jet and record the measurement result.

7.9.3 Spray temperature

Connect the multifunction handpiece, which is equipped with an air and/or a water heating device, to the supply as indicated by the manufacturer. Measure the spray discharge temperature at a distance of 10 mm from the discharge nozzle of the cannula at an ambient temperature of (23 ± 2) °C using a suitable temperature measurement device with a sensor in the spray jet and record the measurement result.

7.10 Air outlet

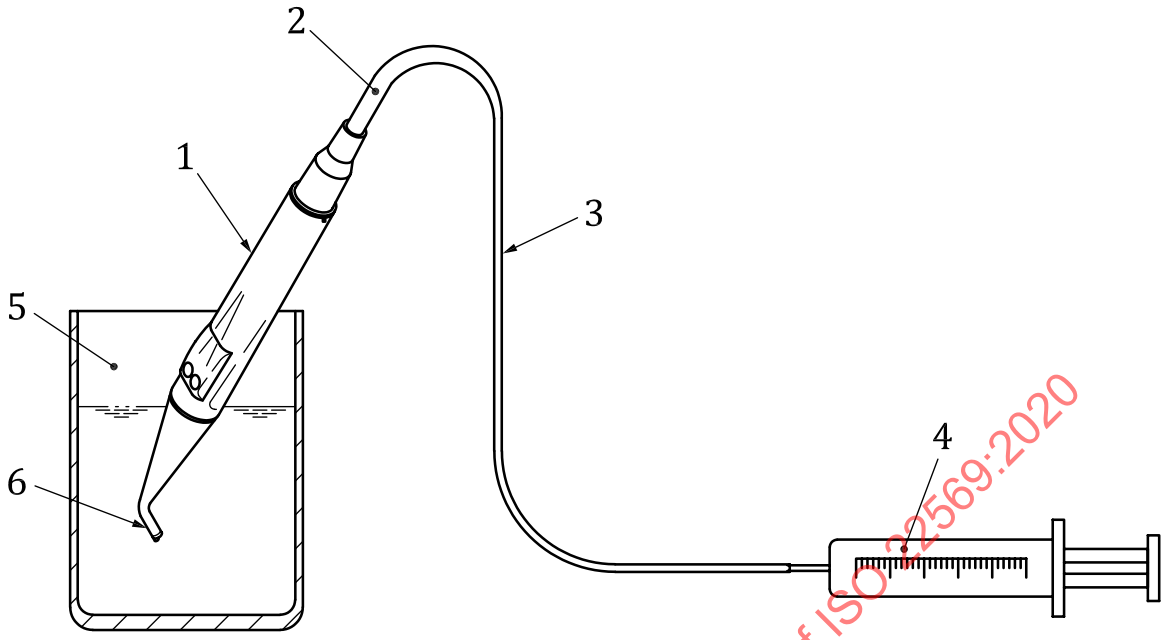
Connect the multifunction handpiece to the supply as indicated by the manufacturer.

Conduct the following test and, if applicable, repeat with fluid heating device.

Operate the water control at least twice to its maximum and release. Then, operate the air control at least twice to its maximum and release. Hold the discharge nozzle of the cannula at a height of 20 mm to 40 mm over a mirror and push the air control button to its maximum while rotating the nozzle at least three times through 180°. Record as a failure if visible signs of moisture are present.

7.11 Backflow prevention

Connect the water inlet of the multifunction handpiece to a 10 ml disposable syringe using a suitable length of transparent hose of (100 ± 2) mm. Dip the tip of the such prepared multifunction handpiece into a water-filled graduated beaker with a volume greater than 250 ml and draw up the syringe plunger (see Figure 4). There shall be no visible signs of water in the drawn disposable syringe caused by the vacuum created.



Key

1 multifunction handpiece
2 water inlet
3 hose
4 disposable syringe
5 graduated beaker
6 handpiece tip

Figure 4 — Apparatus for backflow prevention test

7.12 Resistance to reprocessing

Carry out 250 reprocessing cycles according to the reprocessing instructions given by the manufacturer in the instructions for use.

If the manufacturer recommends a maximum of less than 250 in the instructions, this maximum figure shall be used.

Inspect the surfaces in accordance with 7.2 for signs of rust or any surface defects to assess the corrosion resistance.

All requirements of this document shall be met subsequent for this test.

For accelerated testing, it is permissible to carry out the required sub steps of reprocessing in a block-by-block manner. For example, blocks of 10 times thermal disinfection followed by blocks of 10 times sterilization until the 250 reprocessing cycles are reached.

8 Instructions for use, maintenance and servicing

Each multifunction handpiece shall be supplied with instructions for use and information on maintenance, care, safety and servicing.

This information may be made available in electronic form or in print. If the information is provided only in electronic form, the manufacturer shall indicate this by means of a pictogram and describe where it is available.

NOTE The availability of this information is subject to national regulations.

Instructions shall include at least the following information applicable to each type:

a) name and/or trademark and address of manufacturer or distributor;

b) model or type designation;

c) scope of application of the multifunction handpieces and, if applicable, their accessories;

d) identification of the coupling (connection) for the multifunction handpiece connector;

e) recommended operating pressures for air and water;

f) quantities of air in litres per minute (l/min) and water in millilitres per minute (ml/min) at the specified operating pressures;

g) recommended spray supply, operating pressure and operating air flow rate, if applicable;

h) statement as to whether the tool for changing the handpiece and working parts can be reprocessed (if required) and by which procedures;

i) reprocessing instructions (cleaning, disinfection, sterilization), if applicable, as specified in ISO 17664;

j) statement as to whether the handpiece is field-repairable;

k) information indicating how the user is to check the safety and reliability, including the checking frequencies;

l) recommended care instructions;

m) accessories and working tools, if applicable;

n) any other instructions for safe and effective use (e.g. power setting limitations, liquid flow limitations) subject to the specific model;

o) information on environmentally friendly disposal.

9 Technical description

Additionally, the following information shall be provided by the manufacturer:

a) list of spare parts intended for general use;

b) repair instructions, if applicable.

10 Marking

10.1 General

If graphical symbols are applicable for product marking, they should be in accordance with ISO 9687, ISO 15223-1 and/or ISO 21531.

10.2 Multifunction handpieces

Multifunction handpieces shall be marked with at least the following:

a) manufacturer's name or trademark;

b) serial or lot number;

c) model or type designation.

Working parts or their packaging shall be marked with a production code.

11 Labelling

Graphical symbols used for labelling shall be in accordance with ISO 9687, ISO 15223-1 and/or ISO 21531.

The packaging of multifunction handpieces and working parts shall be labelled as follows:

a) manufacturer's name or trademark;

b) serial or lot number;

c) model or type designation (e.g. catalogue number);

d) for single-use devices, the symbol for “Do not re-use”.

12 Packaging

Multifunction handpieces shall be packaged for transportation at the discretion of the manufacturer in such a way that no damage can occur under the anticipated transport conditions.

Single-use handpieces or disposable (non-reusable) parts of handpieces shall be packaged or wrapped individually by the manufacturer in order to maintain cleanliness.

Annex A
(informative)

Example of a test report

Test report no.:	
Product:	
Name and address of the applicant/client:	
Name and address of the manufacturer:	
Name and address of the factory:	
Brand (if any):	
Model/Type ref.:	
Rating and principal characteristics:	
A sample of the product was tested and found to be in conformity with the international standard:	ISO 22569:2020
Additional information (if necessary):	
Information about modifications:	
This test report is issued by:	
Address:	
Date:	
Test by: (name + signature)	
Approved by: (name + signature)	