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Dental elevators —

Part 1:
General requirements

Élévateurs dentaires —

Partie 1: Exigences générales

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Contents

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 3.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

International Standard ISO 15087-1 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 4, *Dental instruments*.

ISO 15087 consists of the following parts, under the general title *Dental elevators*:

— *Part 1: General requirements*

— *Part 2: Warwick James elevators*

— *Part 3: Cryer elevators*

— *Part 4: Coupland elevators*

— *Part 5: Bein elevators*

— *Part 6: Flohr elevators*

Annexes A to D of this part of ISO 15087 are for information only.

Dental elevators —

Part 1:
General requirements

1 Scope

This part of ISO 15087 specifies the general material and performance requirements for dental elevators.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this part of ISO 15087. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this part of ISO 15087 are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 1942-3:1989, *Dental vocabulary — Part 3: Dental instruments.*

ISO 2592, *Petroleum products — Determination of flash and fire points — Cleveland open cup method.*

ISO 3104, *Petroleum products — Transparent and opaque liquids — Determination of kinematic viscosity and calculation of dynamic viscosity.*

ISO 6507-1:1997, *Metallic materials — Vickers hardness test — Part 1: Test method*.

ISO 7153-1:1991, *Surgical instruments — Metallic materials — Part 1: Stainless steel*.

ISO 13402, *Surgical and dental hand instruments — Determination of resistance against autoclaving, corrosion and thermal exposure*.

3 Terms and definitions

For the purposes of this part of ISO 15087, the terms and definitions given in ISO 1942-3 apply.

4 Classification

Dental elevators specified in all parts of ISO 15087 are classified according to the Vickers hardness of the working end into the following classes:

Class 1: 480 HV 1 to 600 HV 1

Class 2: 600 HV 1 to 720 HV 1

The manufacturer shall state the Vickers classification in the product documentation.

5 Material

5.1 Material of the working end

The working end shall be made of martensitic stainless steel of grade B, C, D or R complying with ISO 7153-1, or other materials providing the instrument made therefrom meets the requirements of clause 6.

5.2 Material of the handle

The material of the handle, selected at the discretion of the manufacturer, shall meet the requirements of clause 6.

6 Requirements

6.1 Maximum overall length

Unless otherwise specified in other parts of ISO 15087, the maximum overall length of dental elevators shall be 178 mm.

Annex A provides details of one method of measurement applicable to most types of dental elevators.

6.2 Vickers hardness of the working end

The Vickers hardness of the working end of the finished instrument, when tested in accordance with ISO 6507-1, shall be within the range of class 1 or class 2. The manufacturer shall state the appropriate hardness class for each instrument pattern or range of instruments in the product documentation.

Annex B provides details of a method of measurement for Vickers hardness.

6.3 Surface finish

6.3.1 All surfaces

All surfaces shall be visibly free from pores, crevices, grinding marks, residual scales, acid, grease and residual grinding and polishing materials, when inspected using normal vision.

6.3.2 Satin finish

Any satin finish shall be both uniform and smooth, and it shall reduce glare.

6.3.3 Mirror finish

Any mirror finish shall be ground to remove all surface imperfections and polished to remove grinding marks, resulting in a highly reflective surface.

6.4 Resistance against autoclaving

When tested in accordance with 7.2, the instrument shall exhibit no visible signs of alteration.

6.5 Resistance against corrosion

6.5.1 Working end

When tested for resistance to boiling water in accordance with 7.3, the working end shall exhibit no visible signs of corrosion.

6.5.2 Handle

When tested for resistance to boiling water in accordance with 7.3, the handle shall exhibit no visible signs of corrosion.

6.6 Resistance against thermal exposure

When tested for resistance against thermal exposure in accordance with 7.3, the instrument shall exhibit no visible signs of alteration.

6.7 Union between the working end and handle

The union between the working end and the handle of the instrument, previously tested in accordance with 6.3 to 6.6, shall not become loosened under tensile load when tested in accordance with 7.4.1 and under torque when tested in accordance with 7.4.2.

6.8 Hollow-handle leak test

When tested in accordance with 7.5.1 or 7.5.2, the instrument handle shall emit no bubbles which are a sign of leakage.

7 Test methods

7.1 Test sequence and cycles

Carry out one of the following testing alternatives in one continuous operation for five cycles:

a) autoclave test or

b) boiling water test and thermal exposure test.

After completing the test (7.2 or 7.3), rub the instrument vigorously with a cloth to remove blemishes.

NOTE Instruments with hollow handles, when subject to the combination of boiling water and thermal exposure tests, may rupture from the expansion of trapped moisture.

7.2 Autoclave test

Carry out the autoclave test as specified in ISO 13402.

7.3 Boiling water test and thermal exposure test

Carry out both the boiling water test and the thermal exposure test as specified in ISO 13402.

7.4 Test for union between working end and handle

7.4.1 Test under tensile load

Subject the union between the working end and the handle to a tensile force of 1000 N, applied in the direction parallel to the centreline of the handle, for a duration of at least 5 s.

Annex C describes a suitable test procedure.

7.4.2 Test under torque

Subject the union between the working end and the handle to a torque of 500 N · cm for a duration of at least 5 s.

Annex D describes a suitable test procedure.

7.5 Hollow-handle leak test

7.5.1 Heated oil test

7.5.1.1 Apparatus

7.5.1.1.1 Heat-resistant vessel.

7.5.1.1.2 Light oil, of minimum flash point 220 °C in accordance with ISO 2592 and nominal kinematic viscosity of 16,5 mm^2/s at 100 °C in accordance with ISO 3104.

7.5.1.2 Procedure

Put the light oil into the heat-resistant vessel.

Heat the oil to (180 ± 5) °C and then completely immerse the elevator handle in the oil for 2 min.

No air bubbles shall be emitted during this test.

7.5.2 Ultrasonic test

7.5.2.1 Apparatus

7.5.2.1.1 Ultrasonic cleaning apparatus.

7.5.2.1.2 Basket made of wire net.

7.5.2.2 Procedure

Align the dental elevators in a basket (7.5.2.1.2). Put the basket in an ultrasonic cleaning apparatus (7.5.2.1.1) filled with water at (40 ± 2) °C. Shake the basket carefully by hand and observe the appearance of the handles. If air bubbles immediately emerge from the handle surfaces, there are large-size pinholes in the handle.

Sink the basket slowly to the bottom, leave it for 3 min and observe again whether air bubbles emerge from the handle surfaces.

NOTE After a long time, air bubbles formed from air dissolved in water may adhere to the handle surfaces. Neglect them.

Subsequently put the basket in an ultrasonic cleaning apparatus under running water at (70 ± 2) °C for 5 min. The running water will remove any air bubbles adhering to the surface. If the emergence of such air bubbles is observed, there are very small size pinholes in the handle.

8 Marking

The instrument shall be indelibly marked with the following information:

a) manufacturer’s name or trade name;

b) pattern number or name;

c) lot number.

Annex A
(informative)

Measurement of dimensions

A.1 General

This method of measurement is applicable to most types of dental hand instrument and is based on the use of an optical projector. Dimensions are measured parallel, and at right angles, to the centreline of the instrument and are constructed from a datum point at its working end.

Although this is the preferred method, it is by no means the only technique available.

A.2 Apparatus

A.2.1 Optical projector (shadowgraph) fitted with a 10× magnifying lens and micrometer stage**.**

A.2.2 Glass specimen slide and plasticine, or

A.2.3 Mechanical holding device (e.g. light machine vice), or

A.2.4 V-block.

A.3 Procedure

A.3.1 Preparation for measurement

A.3.1.1 Support or hold the dental instrument using one of the devices in A.2.2, A.2.3 or A.2.4.

A.3.1.2 Place the supported instrument on the micrometer stage of the projector (A.2.1) and ensure that the following requirements are met:

a) the working end of the instrument projects beyond the holding device;

b) the instrument is securely held;

c) there is an unobstructed view of the working end.

A.3.1.3 Ensure that the dental instrument is parallel to the micrometer stage by focusing on, and traversing the length of, the handle. If the handle remains in focus over the traversed distance, then the instrument is ready for measurement.

If the handle does not remain in focus, repeat A.3.1.2 and A.3.1.3 until the handle remains in focus through the field of traverse.

A.3.1.4 Align the centreline of the dental instrument with the vertical or horizontal cross-wires on the projector screen.