
Dentistry — Intra-oral mirrors

Médecine bucco-dentaire — Miroirs endobuccaux

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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.

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).

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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*.

This fourth edition cancels and replaces the third edition (ISO 9873:2017), of which it constitutes a minor revision. The main changes compared to the previous edition are as follows:

- recommendation for maximum length of intra-oral mirror has been reduced from 178 mm to 173 mm in [4.1.1](#);
- requirement for distortion has been added in [4.3.4](#);
- requirement for handle has been clarified in [4.5](#);
- resistance to reprocessing requirement has been clarified in [4.6](#);
- requirement for UDI code has been added in [Clause 6](#).

Introduction

This document specifies requirements for intra-oral viewing and retracting instruments which are in common use in dentistry.

However, it is well known that there are also other types of intra-oral mirrors in use which have different designs and/or are made of different materials. Amongst these other types are mirrors with a polished metal reflecting surface (as opposed to a coated glass surface).

Standardization of these other types can form the subject of future work.

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Dentistry — Intra-oral mirrors

1 Scope

This document specifies requirements and test methods for reusable intra-oral mirrors with a coated glass reflecting surface used for dental purposes in the oral cavity.

In addition, specific requirements for metallic casing and metallic handles are given.

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 263, *ISO inch screw threads — General plan and selection for screws, bolts and nuts — Diameter range 0,06 to 6 inch*

ISO 724, *ISO general-purpose metric screw threads — Basic dimensions*

ISO 965-1, *ISO general purpose metric screw threads — Tolerances — Part 1: Principles and basic data*

ISO 1942, *Dentistry — Vocabulary*

ISO 5864, *ISO inch screw threads — Allowances and tolerances*

ISO 17664, *Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices*

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

intra-oral mirror

mouth mirror

handheld dental instrument for intra-oral inspection or inspection and tissue retraction generally comprising the mirror head and the mirror handle

Note 1 to entry: See [Figure 1](#).

3.2

mirror head

assembly comprising a glass reflective surface, casing, packing (if present) and stem

3.3

stem

part of the intra-oral mirror connecting the reflecting surface to the handle

3.4 reflecting surface

layer applied to the mirror glass for the purpose of reflecting light

3.5 reflecting back surface

reflecting layer coated onto the back surface of the mirror glass so that the image can be observed through the glass

3.6 reflecting front surface

reflecting layer coated onto the front surface of the mirror glass so that the image can be observed with no intervening glass layer

3.7 plane mirror

intra-oral mirror whose reflective surface is flat

3.8 magnifying mirror

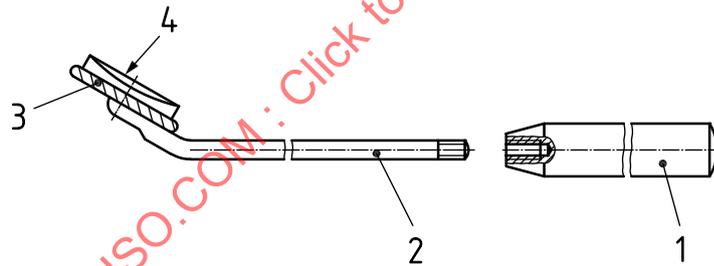
intra-oral mirror whose reflective surface is concave to produce an enlarged image of the object observed

3.9 viewing surface

surface of the mirror glass, excluding the bevel, not enclosed by the metal casing

3.10 distortion

image deformation due to optical defect(s)



Key

- 1 handle
- 2 stem
- 3 mirror head
- 4 reflecting surface

Figure 1 — Designation of intra-oral mirror parts

4 Requirements

4.1 Dimensions and designations

4.1.1 Overall length

The maximum overall length of an intra-oral mirror is at the manufacturer's discretion but it should be noted that there is a possibility that overall lengths in excess of 173 mm cause difficulty in containment within a sterilization cassette.

4.1.2 Connection between the stem and handle, if applicable

4.1.2.1 One-piece design (not applicable)

This requirement is not applicable to intra-oral mirrors with a one-piece design.

4.1.2.2 Two-piece design (applicable)

4.1.2.2.1 Metric thread connection

The metric thread dimensions of the connection between the stem and handle shall be M 2,5 in accordance with ISO 724. The length of the thread engagement shall be as shown in [Figure 2](#).

The tolerances shall be in accordance with ISO 965-1 and shall be

- for the stem 6e,
- for the handle 6H.

4.1.2.2.2 Imperial thread connection

The imperial thread dimensions of the connection between the stem and handle shall be imperial thread No. 4-48 UNF, in accordance with ISO 263. The length of the thread engagement shall be as shown in [Figure 3](#).

The tolerances shall be in accordance with ISO 5864 and shall be

- for the stem 2A,
- for the handle 2B.

4.1.3 Dimensions of mirror casing and viewing surface

Intra-oral mirrors shall meet the dimensions given in [Figure 2](#), [Figure 3](#), and [Table 1](#).

4.1.4 Size designation of mirror head

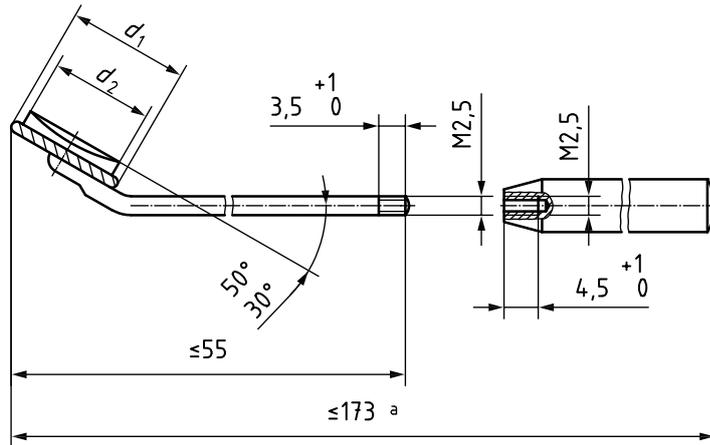
The mirror head size designations are based on the nominal diameter of the casing, d_1 , expressed in millimetres. Each subsequent size increases by 2 mm.

Table 1 — Mirror head and viewing surface

Dimensions in millimetres

Size designation	Nominal head diameter d_1	Nominal viewing surface d_2
00	12	$d_1 - 2,5$ mm max.
0	14	$d_1 - 2,5$ mm max.
1	16	$d_1 - 2,5$ mm max.
2	18	$d_1 - 2,5$ mm max.
3	19, 20	$d_1 - 2,5$ mm max.
4	21, 22	$d_1 - 2,5$ mm max.
5	24	$d_1 - 2,5$ mm max.
6	26	$d_1 - 3$ mm max.
7	28	$d_1 - 3$ mm max.
8	30	$d_1 - 3$ mm max.

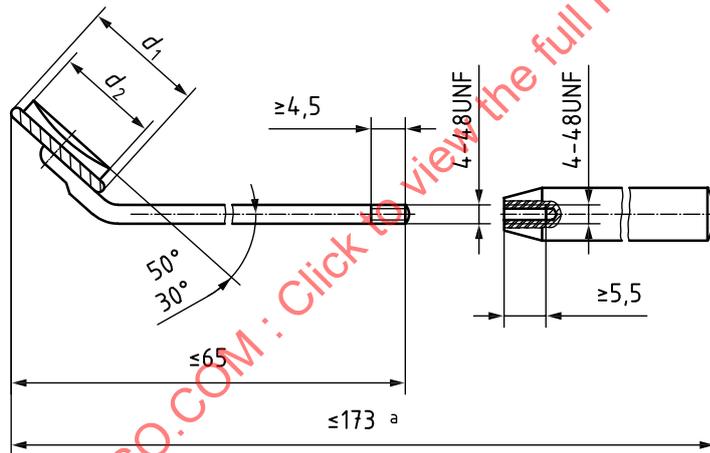
Dimensions in millimetres



a When assembled (recommended overall length).

Figure 2 — Intra-oral mirror with metric thread connection

Dimensions in millimetres



a When assembled (recommended overall length).

Figure 3 — Intra-oral mirror with imperial thread connection

4.1.5 Position of mirror head with respect to the stem

The mirror head shall be positioned such that the long axis of the stem bisects the casing to provide a symmetrical mount about the plane surface of the mirror glass/casing.

Test in accordance with 5.1.

4.2 Materials

4.2.1 Mirror glass

The mirror glass shall be made of polished glass free from visible defects such as waves, chips, scratches and other imperfections observable to the naked eye. Test in accordance with 5.1.

4.2.2 Mirror casing

4.2.2.1 Metallic mirror casing

The mirror casing shall be made of metal which is resistant to corrosion, e.g. stainless steel or a plated non-ferrous alloy.

Examples of suitable stainless steel or other metal alloys can be found in ISO 7153-1.

4.2.2.2 Plastic mirror casing

The material is left to the discretion of the manufacturer provided that it is in accordance with the requirements of this document.

4.2.3 Mirror handle

4.2.3.1 Metallic mirror handle

Mirror handles shall be made of metal which is resistant to corrosion, e.g. stainless steel or a plated non-ferrous alloy.

Examples of suitable stainless steel or other metal alloys can be found in ISO 7153-1.

4.2.3.2 Plastic mirror handles

The material for the plastic mirror handle is left to the discretion of the manufacturer provided that it is in accordance with the requirements of this document.

4.3 Mirror head

4.3.1 Casing of mirror head

The casing shall have a formed edge which shall be below the level of the viewing surface of the glass and shall be visibly free from burrs, flash or other irregularities. Test in accordance with [5.1](#).

4.3.2 Reflecting surfaces

The reflecting surfaces shall allow the image without deformation to be viewed through, or from, the whole of the viewing surface. Test in accordance with [5.1](#).

4.3.3 Nominal magnification

The nominal magnification of magnifying mirrors shall be between 2,8 M and 3,3 M .

Nominal magnification, M , is calculated using [Formula \(1\)](#):

$$M = \frac{250}{f} \quad (1)$$

where

f is the focal length, in millimetres;

250 is the least distance of distinct vision, in millimetres.

Test in accordance with [5.3](#).

4.3.4 Distortion

There shall be no observable distortion when the reflecting surface of the plane or magnifying mirror is tested in accordance with [5.4](#).

4.4 Casing/stem joint strength

The mirror casing/stem joint shall withstand the test load without any sign of weld failure. Distortion of the casing is not considered as a failure. Test in accordance with [5.5](#).

4.5 Handle

All external surfaces of the handle shall be visibly free from imperfections.

Test in accordance with [5.1](#).

4.6 Resistance to reprocessing

Intra-oral mirrors, including the handle, shall withstand 100 reprocessing cycles, as defined by the manufacturer's instructions in accordance with ISO 17664, without deformation or showing signs of corrosion. There shall be no visible damage to the reflective coating and there shall be no ingress of water.

The manufacturer shall specify if the mirror handle shall be disassembled from the head for the reprocessing cycle.

The manufacturer shall specify the maximum number of reprocessing cycles for both the mirror and the handle if this is less than 100 cycles. In this case this number shall be used for the test, in place of the 100 cycles.

Test in accordance with [5.2](#).

5 Measurement and test methods

5.1 Visual inspection

Conduct visual inspection at normal visual acuity without magnification.

5.2 Resistance to reprocessing

Submit the mouth mirror to 100 reprocessing cycles according to the manufacturer's instructions in accordance with ISO 17664. The reprocessing cycle shall include the manufacturer's recommended methods of cleaning, disinfection and sterilization, in accordance with ISO 17664.

Inspect all surfaces of the instrument for any signs of corrosion or surface defects and inspect the reflective surface of the mirror for any loss of integrity.

NOTE Discolorations due to water stains are not signs of corrosion.

If the manufacturer specifies a maximum number of reprocessing cycles allowed, this specified number shall be used in place of the 100 cycles.

5.3 Determination of nominal magnification for magnifying mirrors

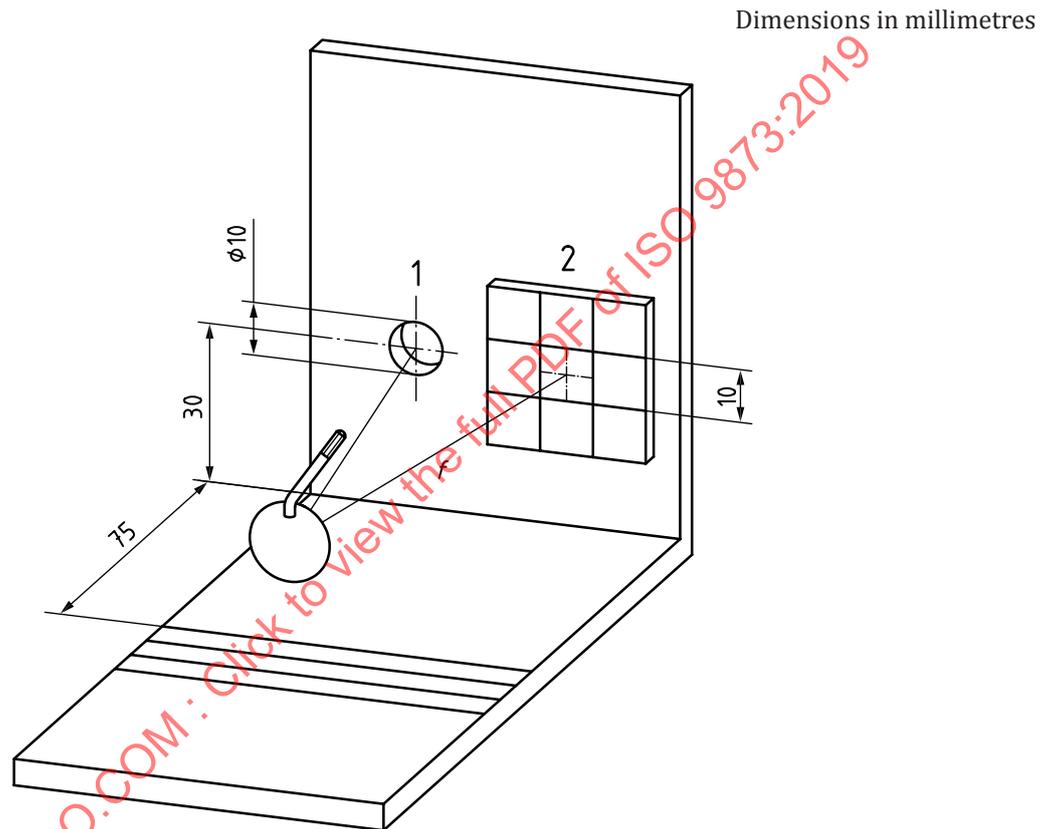
5.3.1 Apparatus

The apparatus for determination of nominal magnification is shown in [Figure 4](#).

The hole, key 1, which is 10 mm in diameter, has cross-wires positioned as shown and a light source situated immediately behind it. A white card, key 2, marked with squares as shown, is fixed close to the hole, so that the image of the cross-wires will be in the same horizontal plane as the cross-wires.

5.3.2 Procedure

Place the mirror (with or without the handle) as shown in [Figure 4](#) and move it forward or backward until the sharpest image is obtained in the centre square of the card. Measure the focal distance, f , to ± 1 mm, between the mirror and the card. Calculate the nominal magnification, M , in accordance with [4.3.3](#).



Key

- 1 hole
- 2 white card

Figure 4 — Apparatus for determination of nominal magnification

5.4 Distortion

5.4.1 Apparatus

The apparatus for the distortion test is shown in [Figure 5](#).

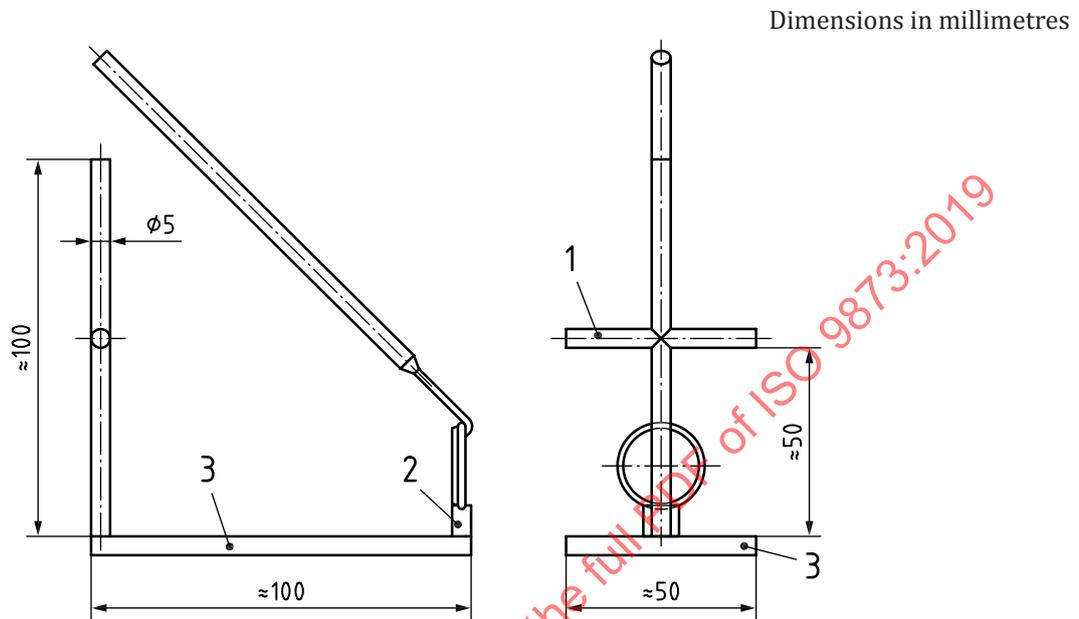
The apparatus consists of an upright rod of 5 mm in diameter with a horizontal crosspiece, key 1, at the midpoint. The mirror rest, key 2, has a groove into which the mirror head is placed.

5.4.2 Procedure

Screw the mirror head into the handle and place it in the mirror rest with the handle in the same vertical plane as the upright rod of the apparatus. View the reflecting surface from a position directly above the

upright rod and move the handle until the image of the intersection of the rod with the crosspiece is visible. Move the mirror vertically up and down, keeping it in line with the upright rod of the apparatus, and observe whether or not any distortion occurs in the image of the crosspiece and upright rod.

Repeat the exercise after placing a sheet of graph paper against the crosspiece of the apparatus. Once again, observe whether or not any distortion occurs in the image of the graph paper.



Key

- 1 crosspiece
- 2 mirror rest
- 3 baseplate

Figure 5 — Apparatus for distortion test

5.5 Casing/stem joint strength test

5.5.1 Apparatus

The clamping device for the mirror casing is shown in [Figure 6](#).

Keys 1 and 2 are two circular metal components shaped so that they fit the inside and outside contours respectively of the casing and stem assembly. Make the slot in component 1 (key 1) 3 mm wider than the stem at the point of union with the casing. The depth of the slot shall be sufficient to ensure that the mirror stem does not come into contact with the side of the slot during the test.

Key 3 is the mirror casing and stem assembly (without glass and packing).