भारतीय मानक
Indian Standard

IS 18775 : 2024
ISO 23450 : 2021

दंत चिकित्सा — इंट्राओरल कैमरा

Dentistry — Intraoral Camera

ICS 11.060.20

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Dentistry Sectional Committee, MHD 08

NATIONAL FOREWORD

This Indian Standard which is identical to ISO 23450 : 2021 'Dentistry — Intraoral camera' issued by the International Organization for Standardization (ISO) was adopted by the Bureau of Indian Standards on the recommendation of the Dentistry Sectional Committee and after approval of the Medical Equipment and Hospital Planning Division Council.

The text of ISO standard has been approved as suitable for publication as an Indian Standard without deviations. Certain conventions are, however, not identical to those used in Indian Standards. Attention is particularly drawn to the following:

a) Wherever the words 'International Standard' appear referring to this standard, they should be read as 'Indian Standard'; and

b) Comma (,) has been used as a decimal marker while in Indian Standards, the current practice is to use a point (.) as the decimal marker.

In this adopted standard, reference appears to certain International Standards for which Indian Standards also exist. The corresponding Indian Standards which are to be substituted in their respective places are listed below along with their degree of equivalence for the editions indicated:

International Standard	*Corresponding Indian Standard*	*Degree of Equivalence*
ISO 1942 Dentistry — Vocabulary	IS 17895 : 2023/ISO 1942 : 2020 Dentistry — Vocabulary	Identical
ISO 10993-1 Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process	IS 17932 (Part 1) : 2023 Biological evaluation of medical devices: Part 1 Evaluation and testing within a risk management process (ISO 10993-1 : 2018, MOD)	Modified
ISO 15223-1 Medical devices — Symbols to be used with medical device labels, labelling information to be supplied — Part 1: General requirements	IS 18105 (Part 1) : 2023/ISO 15223-1 : 2021 Medical devices — symbols to be used with information to be supplied by the manufacturer: Part 1 General requirements (*third revision*)	Identical
ISO 17664 Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 1: Critical and semi-critical medical devices	IS 18742 (Part 1) : 2024/ ISO 17664- 1 : 2021 Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices: Part 1 Critical and semi-critical medical devices	Identical

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Introduction

In the field of dentistry, intraoral cameras have been used in the oral cavity of patients for many years. The intraoral camera provides dentists with an aid which is able to significantly improve communication with the patient, facilitate documentation and raise the diagnostics to another qualitative level.

Technological advancement enables the continuous development of new and improved intraoral cameras, the handling of which is becoming easier and the possible applications of which are becoming more extensive.

These intraoral cameras are produced by the dental industry as high-quality medical devices under recognized quality management systems.

In order to maintain this high level of quality, this document describes the applicable technical product features.

This document refers to IEC 60601-1, the basic standard on safety of medical electrical equipment, by stating the respective clause numbers of IEC 60601-1 and IEC 80601-2-60.

Indian Standard

DENTISTRY — INTRAORAL CAMERA

1 Scope

This document specifies requirements and test methods for intraoral cameras used in dentistry on patients for pictorial representation of oral cavities in order to support diagnosis and facilitate patient information. It specifies requirements, test methods, instructions for use and marking.

This document is not applicable to:

a) powered polymerization activators for polymerization of dental materials;

b) exclusively extraoral camera equipment to prepare overviews or to record treatments;

c) dental microscopes for minimally invasive treatments;

d) medical endoscopes;

e) camera handpieces for tooth illumination (transillumination);

f) CAD or CAM scanner handpieces;

g) combinations of dental instruments with camera functions;

h) cameras for endodontic purposes;

i) devices for root canal inspection (endoscopic microcameras);

j) cameras for tool navigation;

k) cameras for determination of tooth colour.

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 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*

IEC 60601-1, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

IEC 60601-1-6, *Medical electrical equipment — Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability*

IEC 62366-1, *Medical devices — Part 1: Application of usability engineering to medical devices*

IEC 62471, *Photobiological safety of lamps and lamp systems*

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
intraoral camera
optical handpiece for use in the oral cavity of the patient to assist with diagnosis and facilitate patient information and treatment

3.2
patient side of intraoral camera
intraoral camera (3.1) part which is designed to be introduced into the oral cavity

Note 1 to entry: See Figure 1.

3.3
resolving power
ability to distinguish between points or lines of an object which are close together in an image

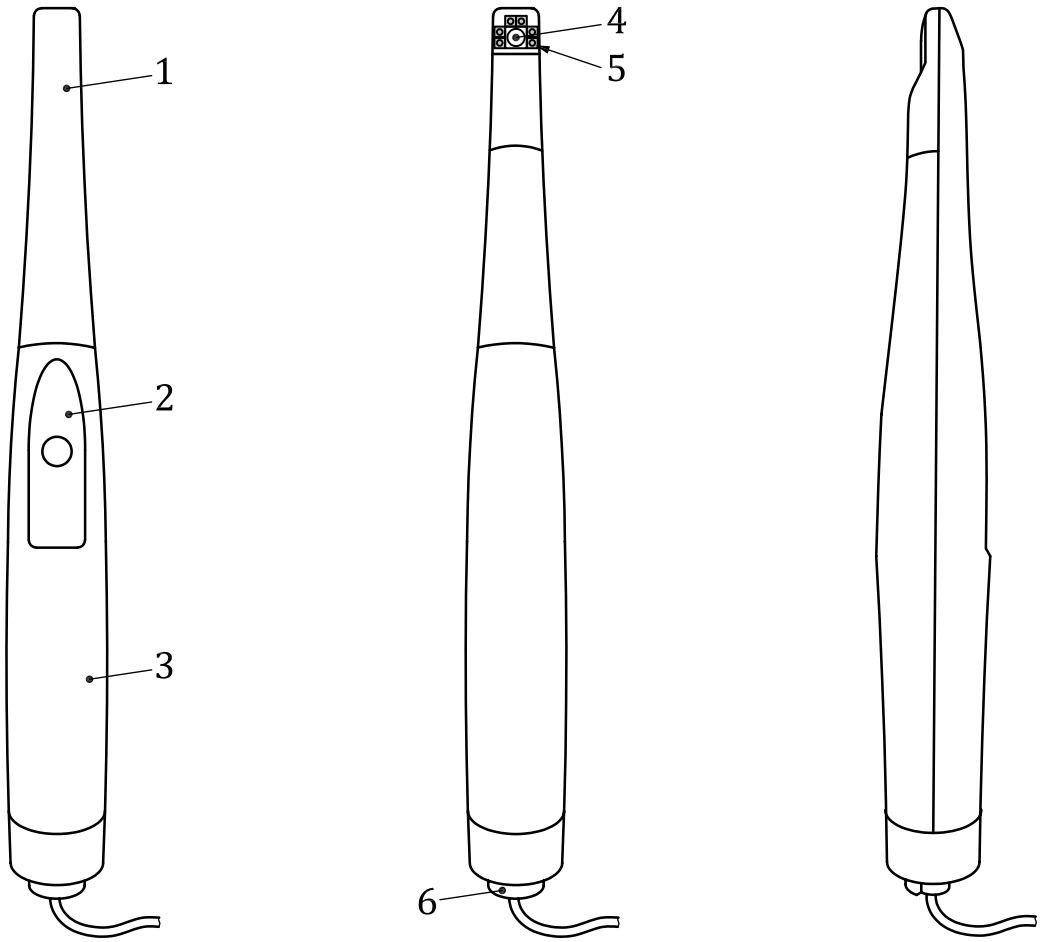
Note 1 to entry: The resolving power is defined as the line frequency in line pairs per millimetre (lp/mm), which is still resolved with a contrast transfer function of 20 %.

Note 2 to entry: A high resolving power means that the resolved distance is small.

Note 3 to entry: Unless otherwise specified, this term relates to distances perpendicular to the optical axis.

3.4
contrast transfer function
CTF
measurement describing the *resolving power* (3.3) by the number of equidistant black and white lines per millimetre which can still be resolved with a certain contrast (in per cent)

EXAMPLE 5 lp/mm = 5 line pairs per millimetre.



Key

1 head (patient side of intraoral camera)
2 operation part (operator side of intraoral camera)
3 hand-held part (operator side of intraoral camera)
4 viewing window (patient side of intraoral camera)
5 illumination part (patient side of intraoral camera)
6 interface (operator side of intraoral camera)

Figure 1 — Part designation of intraoral camera

3.5
dynamic range
ratio between the smallest and largest detectable light energy

Note 1 to entry: The dynamic range can be defined as a pure ratio (1:*n*) or in decibels [10 lg(*n*)].

Note 2 to entry: In a camera sensor, it is typically around 1:20 000. Since its signal is quantized during digital processing, however, the bit depth is the limiting factor. For example, a dynamic range of just 1:255 is achieved with 8 bits.

Note 3 to entry: The optics are another limiting factor.

3.6
signal-to-noise ratio
fluctuation overlaying the signal in proportion to the signal average value

Note 1 to entry: Standard deviation is noise.

3.7
vignetting
measure for the relative illumination in the field of view

3.8
distortion
deviation from the true image due to an optical system whereby the lateral magnification in the field of view varies with the distance from the optical axis

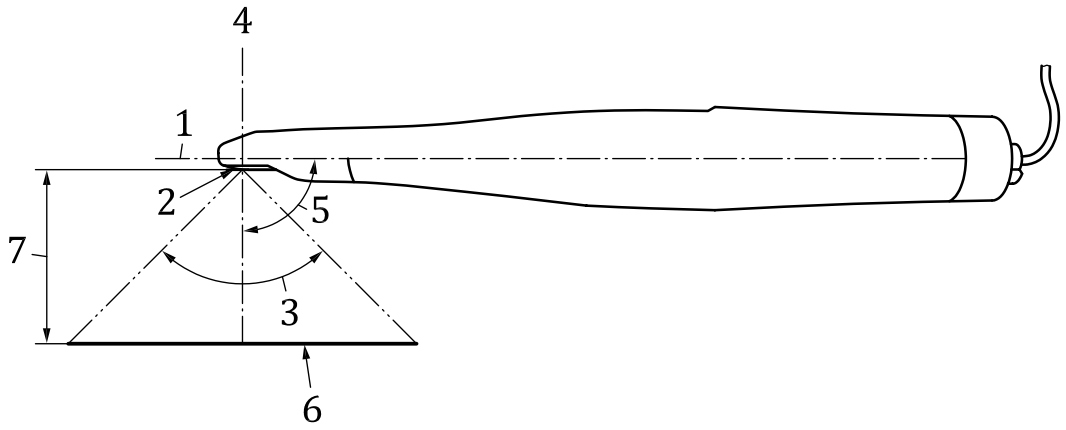
Note 1 to entry: The distortion is defined as a percentage of the image height.

3.9
angular field of view
angle under which an object appears at a given diagonal expansion and distance

Note 1 to entry: See Formula (2) in 5.7.1 for the angular field of view.

3.10
working distance
distance between the object and the outside of the light entrance window of the *intraoral camera* (3.1)

Note 1 to entry: See Figure 2.



Key
1 intraoral camera normal axis
2 distal window surface of intraoral camera
3 angular field of view (angular aperture)
4 central axis of field of view
5 direction of view (angle of the central axis)
6 field of view
7 working distance

Figure 2 — Optical definitions

3.11
direction of view
location of the centre of the object field relative to the normal axis of the *intraoral camera* (3.1) expressed as the angle (in degrees) between the normal axis of the intraoral camera and the central axis of the field of view

3.12
depth of field
range in which an object remains sharp, i.e. the range of distances in which the demand of the *resolving power* (3.3) is fulfilled without refocusing

3.13
image resolution
fineness of the image rasterization, i.e. the number of pixels of the entire transmission chain actually used for image transmission

3.14
latency
time delay of the data acquisition (sensor image) until the same data is displayed on the camera interface

3.15
fixed-focus
lenses or systems with a fixed distance setting

3.16
autofocus
lenses or systems with at least one active element for focusing

Note 1 to entry: Autofocusing can be activated manually or automatically.

3.17
focusing time
time from the start of the action to final focusing

3.18
pixel error
pixel in the image that is displayed incorrectly, constantly black or white

4 Classification

Intraoral cameras are classified according to their optical setup as follows:

a) fixed-focus cameras;

b) variable focus cameras

- manual
- autofocus.

5 Requirements

5.1 General

An intraoral camera is an electromedical device and shall be designed and manufactured so that its application jeopardizes neither the clinical condition and safety of the patient nor the health and safety of the operator or any third party.

The patient side of the intraoral camera is designed to be introduced into the oral cavity where all parts of the dental handpiece within 80 mm to the tip shall be considered as an applied part in accordance with IEC 60601-1.

For general requirements for the basic safety of intraoral cameras IEC 60601-1 and IEC 80601-2-60 shall apply.

5.2 Biocompatibility

Biological evaluation of intraoral cameras shall be made in accordance with ISO 10993-1 and applies to:

— the patient side of the intraoral camera and other parts of the intraoral camera which are expected to have direct or indirect contact with the patient body;

— the hygienic protective sleeves, if recommended or required by the manufacturer.

5.3 Usability

Usability evaluation and testing for intraoral cameras shall be carried out in accordance with IEC 62366-1.

All operating elements shall be arranged and designed so as to avoid accidental operation.

Symbols for operating elements, if appropriate, shall conform with ISO 9687 and ISO 15223-1.

5.4 Reprocessing

The manufacturer shall provide information on reprocessing for the intraoral camera in accordance with ISO 17664.

5.5 Protection from hazardous radiation

The illumination shall conform with the requirements for protection from hazardous radiation in IEC 62471.

5.6 Image quality

5.6.1 Resolving power

The resolving power of variable focus cameras shall be specified in the technical description.

Testing shall be carried out for the variable focus camera at a working distance of 10 mm (l_2) and for fixed-focus cameras at a working distance specified by the manufacturer.

A resolving power of at least 20 lp/mm (CTF) at a working distance of 10 mm shall be reached.

For fixed-focus cameras with a working distance other than 10 mm, the minimum resolving power shall be calculated according to Formula (1).

$$r_1 = r_2 \frac{l_2}{l_1} \tag{1}$$

where

r_1 is the minimum resolving power at working distance;

r_2 is the required resolving power at a working distance of 10 mm; 20 lp/mm;

l_1 is the actual working distance of the fixed-focus camera;

l_2 is a working distance of 10 mm.

Test according to 7.1.2.

5.6.2 Dynamic range

The dynamic range of the sensor image specified in this document shall be at least 1:10 or 10 dB.

5.6.3 Illumination

The intraoral camera shall have integrated illumination.

Verify by visual inspection.

5.6.4 Vignetting

The illumination shall decrease in intensity progressively and smoothly towards the pattern edge.

The drop of brightness from the middle to the edges shall be less than 50 %.

Test according to 7.1.3.

5.6.5 Distortion

The distortion (the maximum deviation from the reference image) at a working distance of 10 mm shall be less than ± 10 %.

Test according to 7.1.4.

5.7 Optical characteristics

5.7.1 Angular field of view

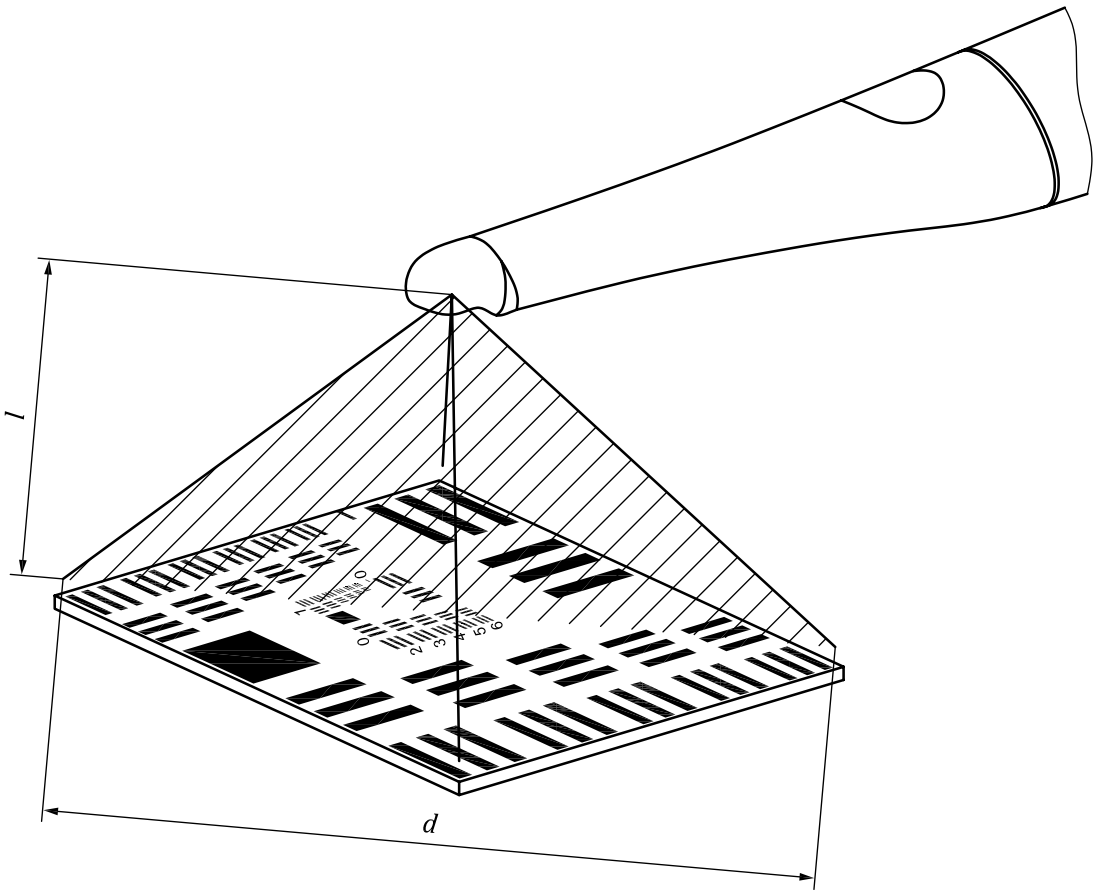
The angular field of view shall be specified in the technical description (see Clause 9). The angular field of view (β) is defined according to Formula (2) (see Figure 3):

$$\beta = 2 \arctan\left(\frac{d}{2l}\right) \tag{2}$$

where

d is the diagonal expansion of the object being displayed;

l is the working distance.



NOTE For an explantion of dimensions *l* and *d* see Formula (2).

Figure 3 — Angular field of view

The angular field of view shall be set to capture all the molars in the oral cavity (image diagonal 15 mm).

At a working distance of 10 mm, the angular field of view specified by the manufacturer shall not deviate from that value by more than ± 3°.

Test according to 7.2.1.

5.7.2 Direction of view

The direction of view of the intraoral camera shall be 90° unless specified otherwise, in which case the deviation shall be specified in the technical description.

Verify by visual inspection.

5.7.3 Working range of the camera

For fixed-focus cameras, the working distance for which the intraoral camera is designed shall be specified in the technical description (see Clause 9).

For variable focus cameras, the minimum and maximum working distance for which the intraoral camera is designed shall be specified in the technical description (see Clause 9).

Verify the resolving power at the minimum working distance if it is in accordance with the manufacturer's specification.

Test according to 7.2.2.

5.7.4 Depth of field

The depth of field of an intraoral camera shall be at least 8 mm.

A depth of field of 8 mm should allow a sufficiently sharp display of a tooth from the chewing surface (occlusal surface) to the tooth neck (incisal surface).

A line frequency of 5 lp/mm shall be resolved within the depth of field range. The depth of field at a working distance of 10 mm shall be specified in the technical description (see Clause 9).

Test according to 7.2.3.

5.8 Performance characteristics

5.8.1 Image resolution

The image resolution shall be specified in pixels (width × height) in the technical description (see Clause 9).

5.8.2 Latency

The latency of the sensor shall not exceed 150 ms. Any higher latency times required shall be explicitly indicated in the technical description.

The perception limit of the human eye is about 200 ms. Therefore, this value should be lower.

Test according to 7.3.1.

5.8.3 Autofocus

The focusing time of an intraoral autofocus camera shall not exceed a maximum time of 1000 ms. Any higher focusing times required are to be explicitly indicated in the technical description.

Test according to 7.3.2.

5.8.4 Signal-to-noise ratio

The signal-to-noise ratio shall be specified in the technical description (see Clause 9).

Test according to 7.3.3.

5.8.5 Pixel error

Visible pixel errors within the of view shall not be permitted.

NOTE It is possible to perform pixel error correction in the image processing following the sensing.

Test according to 7.3.4.

5.8.6 Compression artefact formation

The requirements of the resolving power as defined in 5.6.1 shall be met without visual compression artefacts.

NOTE For examples of compression artefacts, see Annex A, Figure A.1.

Test according to 7.1.2.

5.8.7 Frame rate

The camera shall have a minimum rate of 20 frames per second.

The actual frame rate shall be specified in the technical description (see Clause 9).

5.9 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 include at least the following aspects:

— the name of the person performing the test;

— the name and the address of the testing laboratory;

— 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.

6 Sampling

A minimum of one intraoral camera from each series model shall be checked.

7 Measurement and test methods

7.1 Image quality

7.1.1 General

7.1.1.1 For fixed-focus cameras

Carry out all measurements at the working distance indicated in the product specification.

7.1.1.2 For variable focus cameras

Carry out all measurements at a working distance of 10 mm.

7.1.2 Resolving power and visual compression artefacts

Align the camera at the distance to be tested according to the resolution chart in Figure 5.

Verifiy the resolving power of the intraoral camera by visual assessment of the image of a test group (see Figure 4).

NOTE USAF 1951 is the resolution test chart defined by the United States Air Force.

Figure 4 — Test group according to USAF 1951

The black lines shall be clearly identifiable on the white background. Carry out the measurement on the axis and in the field of view. The complete test chart is shown in Figure 5.

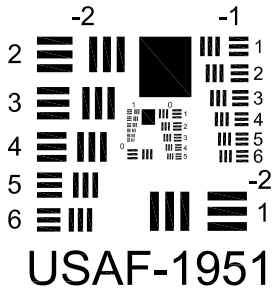


Figure 5 — Test chart according to USAF 1951

Determine the smallest test group, where the black lines can be clearly identified on the white background visually. Determine the resolving power according to Formula (3):

$$r = 2^{\{g+(e-1)/6\}} \tag{3}$$

where

r is the resolving power in line pair per millimetre, given as lp/mm;

g is the group (see Figure 4);

e is the element (see number in Figure 5).

NOTE A line pair conversion table is given in Annex B, Table B.1.

7.1.3 Vignetting

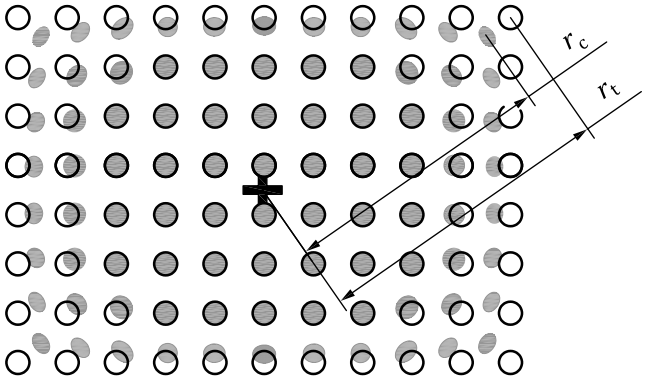
The vignetting is measured at a working distance of 10 mm as a drop of brightness in the field of view and shall be specified in per cent.

Align the intraoral camera at a working distance of 10 mm to a homogeneous white surface (or the specified working distance for fixed-focus cameras). Measure the brightness drop in the image from the centre to the image edge on the white surface at the specified working distance. Carry out the measurement with the camera's own irradiance without the influence of external light.

7.1.4 Distortion

Align the intraoral camera to a dot grid distortion target at a working distance of 10 mm (or specified working distance for fixed-focus cameras). The dot size of the target shall have a diameter of at least 0,5 mm. Ensure that the test chart fills the whole field of view of the intraoral camera.

NOTE Other distortion targets, such as concentric square targets, with equivalent resolution and thereby equivalent measurement results can also be used.



Key

r_c projected distance (camera);

r_t actual distance (test grid).

Figure 6 — Distortion test grid

Make a test shot of the distortion target and measure the distance r_c in the image with an adequate program, where r is the distance from the middle to the last fully displayed dot in one corner, see Figure 6. Next, calculate the distance r_t by counting the dots. The distortion ratio as a percentage is then given according to Formula (4).

$$d = \frac{(r_t - r_c)}{r_c} . 100\ \% \tag{4}$$

where

d is the distortion;

r_t is the actual distance (test grid);

r_c is the projected distance (camera).

If the distortion is non-symmetrical more than one measurement is necessary.

7.2 Optical characteristics

7.2.1 Angular field of view

Verify the angular field of view from the corresponding test shots.

7.2.2 Working range of the intraoral camera

For variable focus cameras, verify the minimum working distance defined by the manufacturer. 7.1.2 shall be applied for the test procedures and 5.6.1 shall be applied for calculating the minimum requirement of the resolving power.

NOTE The maximum working distance cannot be verified as it can be infinite.

7.2.3 Depth of field

Verify the depth of field on a resolution chart.

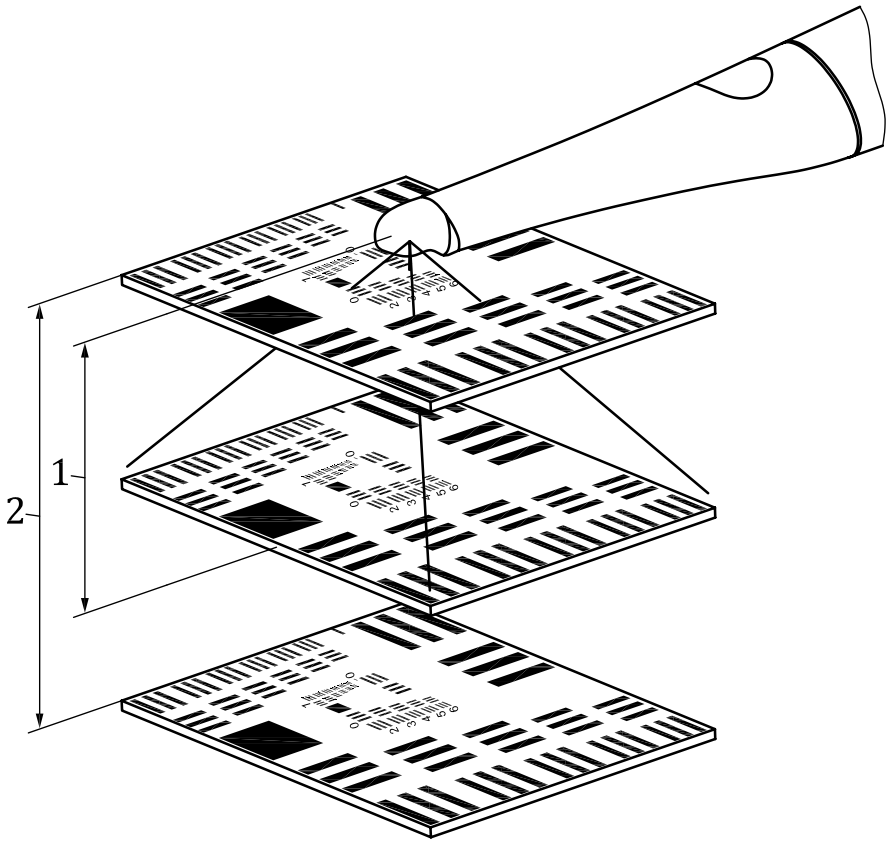
Align the intraoral camera to the resolution chart at a working distance of 10 mm and take test shots at additional working distances (without refocusing).

Carry out the measurement on the axis and in the field of view.

Verify the depth of field of the intraoral camera by visual assessment of the image of a test group (see Figure 7).

The black lines of test group +2/3 (5,04 lp/mm) shall be clearly identifiable on the white background.

The distance between the minimum and maximum distance (see Figure 7) where the defined test group of the resolution chart is clearly identifiable is the depth of field.



1 working distance of 10 mm

2 depth of field

Figure 7 — Depth of field

7.3 Performance characteristics

7.3.1 Latency

Verify the latency, Δ, using a digital PC clock with a resolution in milliseconds, using a PC specified by the manufacturer as the minimum requirement for the use of the intraoral camera. Visualize the PC clock with the intraoral camera on the same PC screen. Capture a screenshot to record both clocks. The latency shall be calculated according to Formula (5).

$$\Delta = t_1 - t_2 \tag{5}$$

where

Δ is latency;

t_1 is the time on the PC clock;

t_2 is the time on the intraoral camera clock.

7.3.2 Autofocus

Measure the time for autofocusing by capturing a video which records the focusing process triggered by the user (push of a button). Calculate the time by counting the frames it takes the image to reach exact focus.

7.3.3 Signal-to-noise ratio

Take a test shot of a homogeneous white surface. Select the exposure time in such a way that no overexposure or underexposure occurs.

For the evaluation, use a test box of 20 × 20 pixels approximately in the middle of the image. Calculate the mean value, P_S, and the standard deviation, P_N, of all pixels in the test box. The signal-to-noise ratio, R_{SN}, is calculated according to Formula (6).

$$R_{SN} = \frac{P_S}{P_N} \tag{6}$$

7.3.4 Pixel error

Align the intraoral camera at a working distance of 10 mm from a homogeneous white surface (or specified working distance for fixed-focus cameras) and take a test shot. Select the exposure time in such a way that no overexposure or underexposure occurs. Evaluate this image digitally. All pixels whose brightness value is less than a tenth of the average value are considered as defective.

Take another image and assess it with a darkened camera and illumination turned off. All pixels whose brightness value is more than 10 times the average value are considered to be defective.

8 Instructions for use, information on maintenance and servicing

Instructions for use and information on maintenance, safety and servicing shall be included with each intraoral camera.

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

a) name, trademark or both, and address of manufacturer or distributor;

b) model or type reference;

c) reprocessing instructions, if applicable, as specified in ISO 17664;

d) information as to whether maintenance can be carried out by the operator;

e) accessories and working tools, including use of hygienic protective sleeve, if applicable;

f) any other instructions for safe and effective use (e.g. power setting limitations) depending upon the specific model.

9 Technical description

In addition, the following information shall be provided by the manufacturer:

a) list of spare parts, which is intended for general use;

b) information on the potential repairs and maintenance work in the field, including a list of the required tools;

c) information on the following technical performance characteristics:

1) resolving power in lp/mm at a working distance of 10 mm;

2) signal-to-noise ratio in percentage or dB;

3) vignetting in percentage at a working distance of 10 mm;

4) distortion in percentage at a working distance of 10 mm;

5) angle of view;

6) direction of view, if it deviates from 90°;

7) working range in mm (from/to) as defined in 5.7.3;

8) depth of field in mm;

9) image resolution in pixels as defined in 5.8.1;

10) frame rate in Hz;

11) focus time in ms, if higher than 1000 ms;

12) working distance in mm, if fixed-focus camera.

10 Marking

10.1 General

Symbols used for controls and performance should be in accordance with ISO 9687 and ISO 15223-1 if applicable. If appropriate symbols are not found in ISO 9687 or ISO 15223-1, other symbols are permitted.

10.2 Intraoral camera

The marking on the intraoral camera shall include at least the following information:

a) name of manufacturer or trademark;

b) serial number or lot number;

c) model or type reference;

d) identification of the sterilizability, if applicable.

Accessories or their packaging shall be marked with model or type reference.

11 Labelling

If graphical symbols are used, they shall be in accordance with ISO 9687 and ISO 15223-1.

The packaging of the intraoral camera and its accessories shall be labelled as follows:

a) name of manufacturer or trademark;

b) serial number or lot number;

c) model or type reference;

d) identification of the sterilizability, if applicable;

e) for single-use items, the symbol for “Do not reuse”.

Annex A
(informative)

Examples of compression artefacts

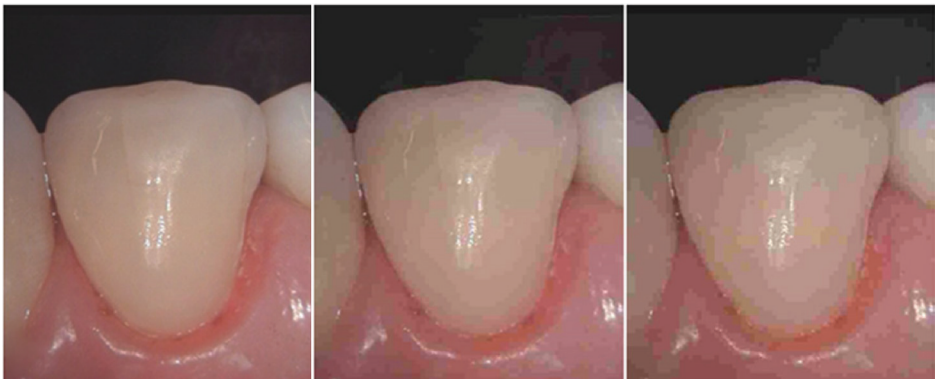


Figure A.1 — Example of blocking artefact

Annex B
(informative)

Line pairs conversion table

Table B.1 — Number of line pairs/mm in USAF resolving power test target 1951

Element	Group number											
	–2	**–1**	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**
1	0,250	0,500	1,00	2,00	4,00	8,00	16,00	32,0	64,0	128,0	256,0	512,0
2	0,281	0,561	1,12	2,24	4,49	8,98	17,96	35,9	71,8	143,7	287,4	574,7
3	0,315	0,630	1,26	2,52	5,04	10,08	20,16	40,3	80,6	161,3	322,5	645,1
4	0,354	0,707	1,41	2,83	5,66	11,31	22,63	45,3	90,5	181,0	362,0	724,1
5	0,397	0,794	1,59	3,17	6,35	12,70	25,40	50,8	101,6	203,2	406,4	812,7
6	0,445	0,891	1,78	3,56	7,13	14,25	28,51	57,0	114,0	228,1	456,1	912,3

NATIONAL ANNEX C

(*National Foreword*)

C-1 BIS Certification Marking

The product(s) conforming to the requirements of this standard may be certified as per the conformity assessment schemes under the provisions of the *Bureau of Indian Standards Act*, 2016 and the Rules and Regulations framed thereunder, and the product(s) may be marked with the Standard Mark.

(*Continued from second cover*)

International Standard	*Corresponding Indian Standard*	*Degree of Equivalence*
IEC 60601-1 Medical electrical equipment — Part 1: General requirements for basic safety and essential performance	IS 13450 (Part 1) : 2024 Medical electrical equipment: Part 1 General requirements for basic safety and essential performance (IEC 60601- 1 : 2020, MOD) (*third revision*)	Modified
IEC 60601-1-6 Medical electrical equipment — Part 1-6: General requirements for basic safety and essential performance — Collateral standard: Usability	IS 13450 (Part 1/Sec 6) : 2024 Medical electrical equipment: Part 1 General requirements for basic safety and essential performance, Section 6 Usability (IEC 60601-1-6 : 2020, MOD) (*first revision*)	Modified
IEC 62366-1 Medical devices — Part 1: Application of usability engineering to medical devices	IS 17922 (Part 1) : 2023/ IEC 62366- 1 : 2015 + AMD 1 : 2020 Medical devices: Part 1 Application of usability engineering (*first revision*)	Identical
IEC 62471 Photobiological safety of lamps and lamp systems	IS 16108 : 2012/IEC 62471 : 2006 Photobiological safety of lamps and lamp systems	Identical

The Committee has reviewed the provisions of the following International Standards referred in this adopted standard and has decided that they are acceptable for use in conjunction with this standard:

International Standard	*Title*
ISO 9687	Dentistry — Graphical symbols for dental equipment
IEC 80601-2-60	Medical electrical equipment — Part 2-60: Particular requirements for the basic safety and essential performance of dental equipment

This standard includes modification of cross reference from ISO 17664 to ISO 17664-1. Wherever reference to ISO 17664 occurs in the text, ISO 17664-1 has to be substituted.

This standard also makes a reference to the BIS Certification Marking of the product, details of which is given in National Annex C.

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated expressing the result of a test or analysis, shall be rounded off in accordance with IS 2 : 2022 ‘Rules for rounding off numerical values (*second revision*)’. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

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Review of Indian Standards

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Amendments Issued Since Publication

Amend No.	Date of Issue	Text Affected

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