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Dentistry — Intraoral camera

Médecine bucco-dentaire — Caméra intrabuccale

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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).

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 04, *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

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.

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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.

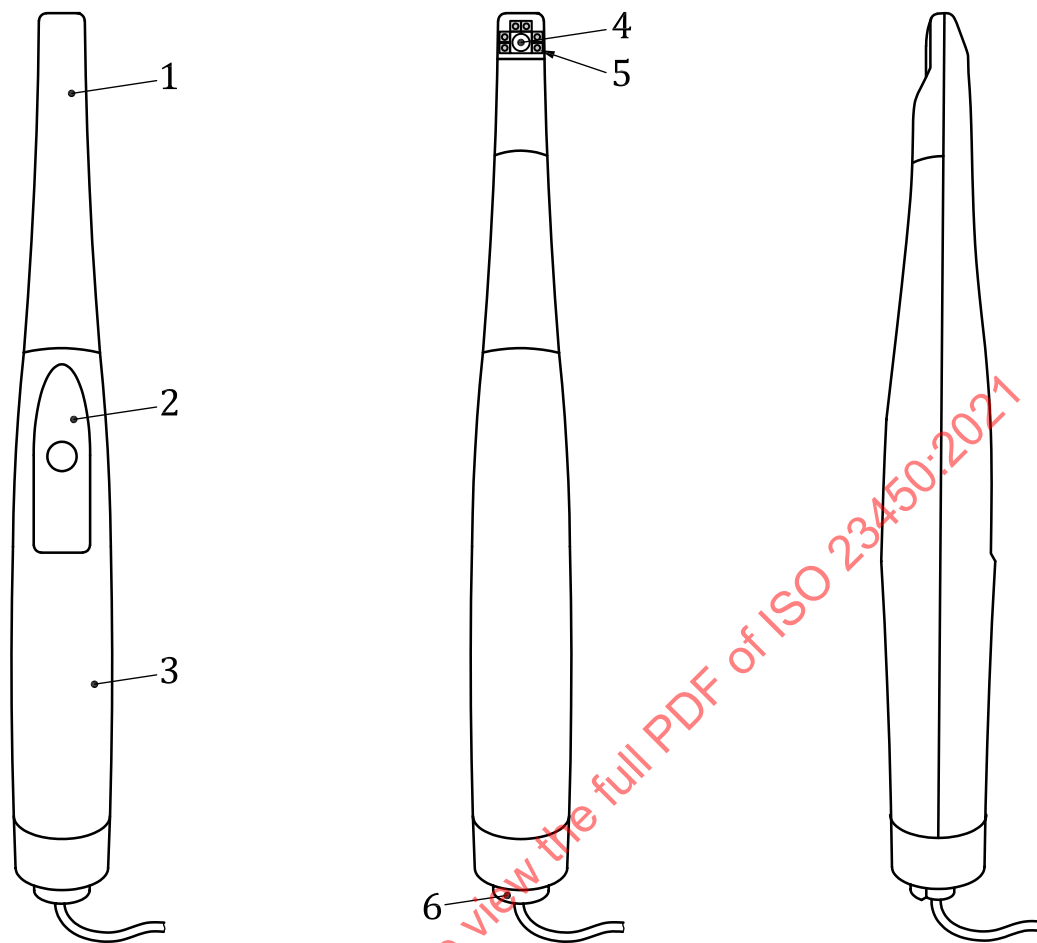
3.4

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

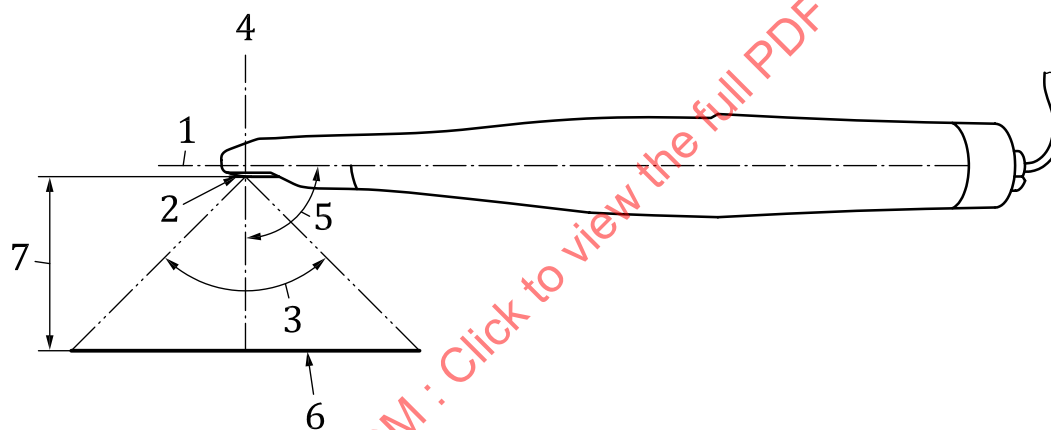
Note 1 to entry: See [Formula \(2\)](#) in [5.7.1](#) for the angular field of view.

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 \(1\)](#).

$$r_1 = r_2 \frac{l_2}{l_1} \quad (1)$$

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

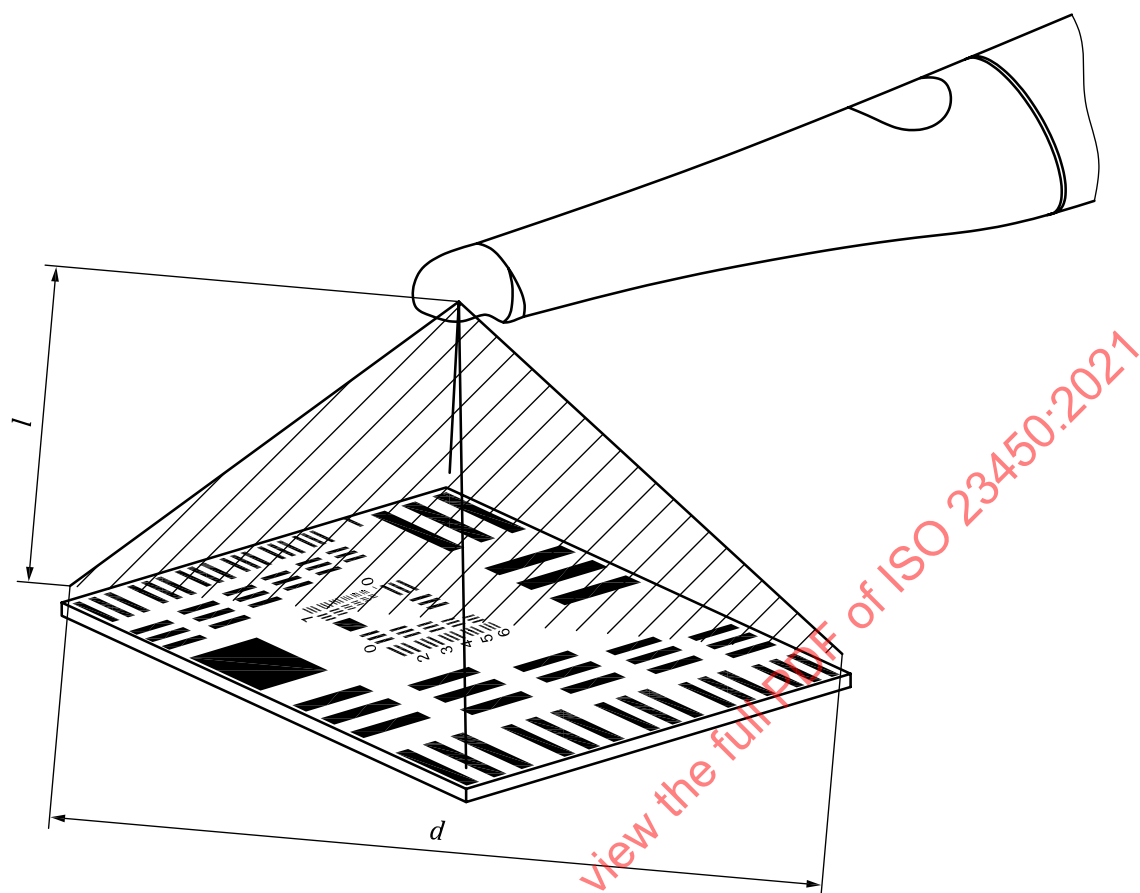
The angular field of view shall be specified in the technical description (see [Clause 9](#)). The angular field of view (β) is defined according to [Formula \(2\)](#) (see [Figure 3](#)):

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

where

d is the diagonal expansion of the object being displayed;

l is the working distance.



NOTE For an explanation 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 $\pm 3^\circ$.

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](#).

Verify 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](#).

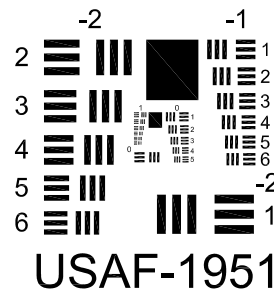


Figure 5 — Test chart according to USAF 1951

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 \(3\)](#):

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

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

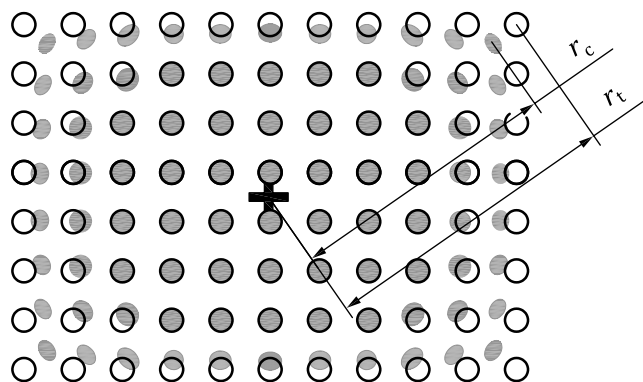
The vignetting is measured at a working distance of 10 mm as a drop of brightness in the field of view and shall be specified in per cent.

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 \(4\)](#).

$$d = \frac{(r_t - r_c)}{r_c} \cdot 100 \% \quad (4)$$

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.

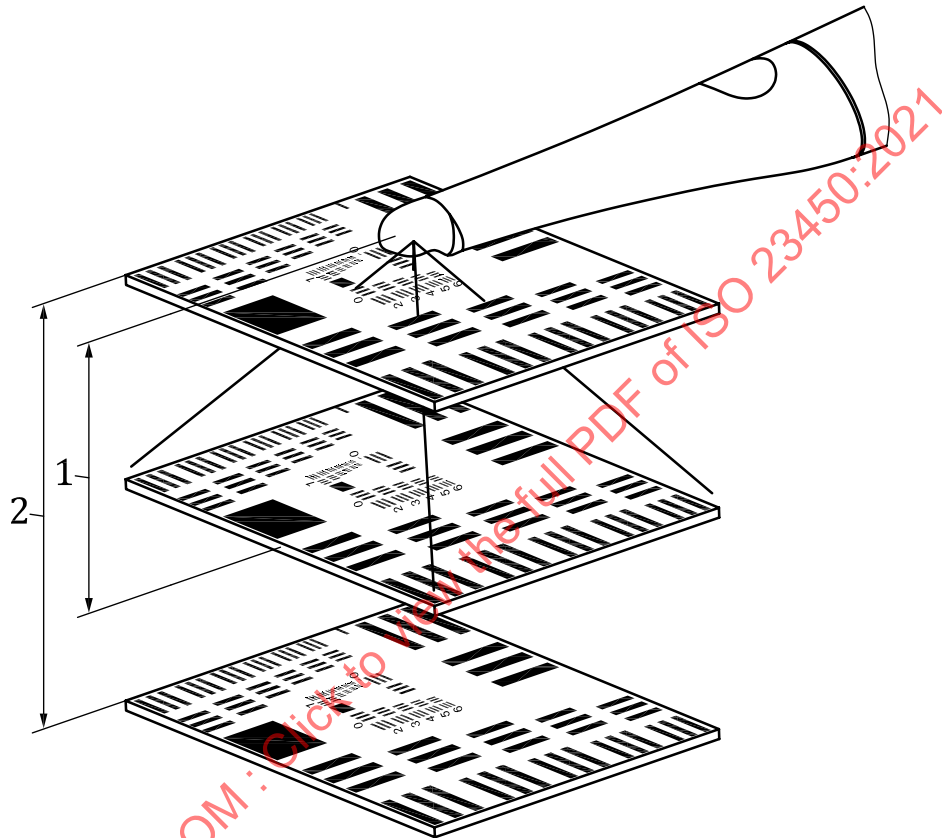
Align the intraoral camera to the resolution chart at a working distance of 10 mm and take test shots at additional working distances (without refocusing).

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 \(5\)](#).

$$\Delta = t_1 - t_2 \quad (5)$$

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 autofocus 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 \(6\)](#).

$$R_{SN} = \frac{P_S}{P_N} \quad (6)$$

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;