INTERNATIONAL STANDARD

ISO 23450

First edition
2021-03

Dentistry — Intraoral camera

Médecine bucco-dentaire — Caméra intrabuccale

Reference number
ISO 23450:2021(E)

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

Page

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.

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

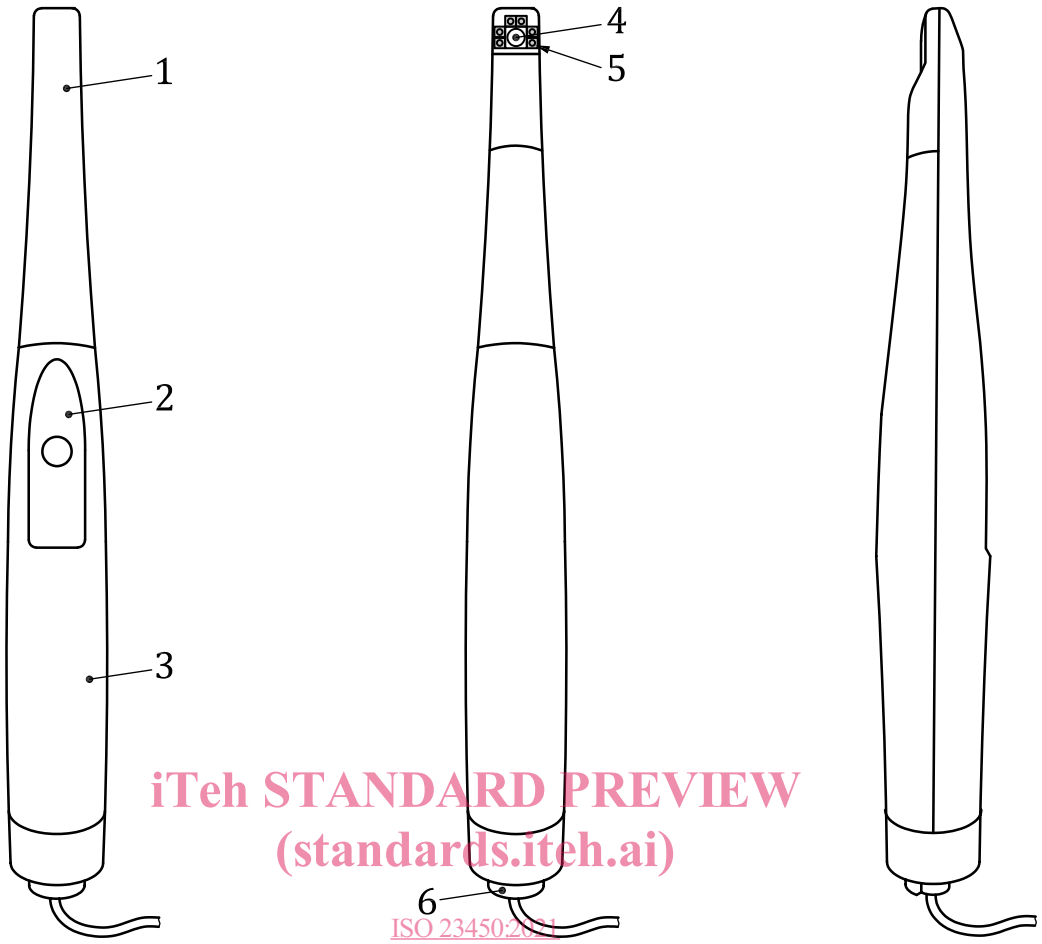
Note 1 to entry: The resolving power is defined as the line frequency in line pairs per millimetre (lp/mm), which is still resolved with a contrast transfer function of 20 %.

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

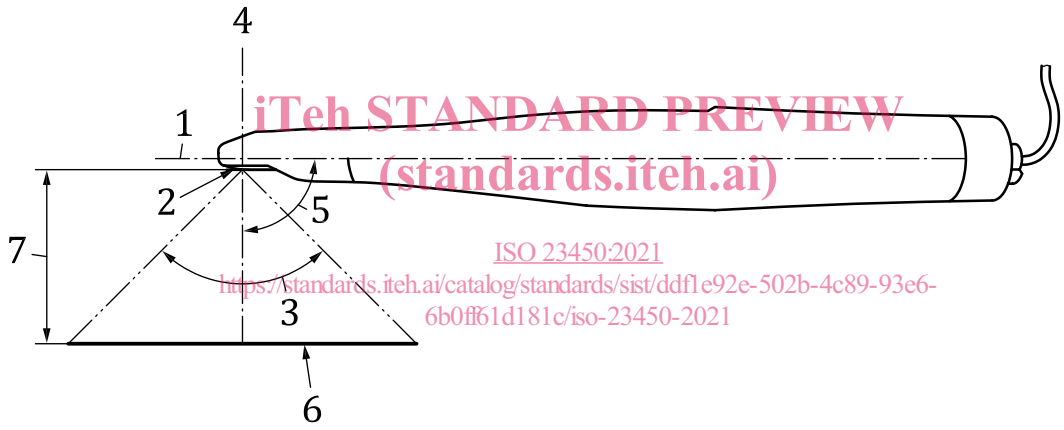
Note 1 to entry: The distortion is defined as a percentage of the image height.

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.