# Dentistry - Intraoral camera (ISO 23450:2021)

## EESTI STANDARDI EESSÕNA

## NATIONAL FOREWORD



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|---|---|
| See Eesti standard EVS-EN ISO 23450:2021 sisaldab Euroopa standardi EN ISO 23450:2021 ingliskeelset teksti. | This Estonian standard EVS-EN ISO 23450:2021 consists of the English text of the European standard EN ISO 23450:2021. |
| Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas. | This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation and Accreditation. |
| Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 14.04.2021. | Date of Availability of the European standard is 14.04.2021. |
| Standard on kättesaadav Eesti Standardimis- ja Akrediteerimiskeskusest. | The standard is available from the Estonian Centre for Standardisation and Accreditation. |

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

# EN ISO 23450

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English Version

# Dentistry - Intraoral camera (ISO 23450:2021)

Médecine bucco-dentaire - Caméra intrabuccale (ISO 23450:2021)

Zahnheilkunde - Intraoralkamera (ISO 23450:2021)

This European Standard was approved by CEN on 16 March 2021.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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Ref. No. EN ISO 23450:2021 E

## European foreword

This document (EN ISO 23450:2021) has been prepared by Technical Committee ISO/TC 106 "Dentistry" in collaboration with Technical Committee CEN/TC 55 “Dentistry” the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by October 2021, and conflicting national standards shall be withdrawn at the latest by October 2021.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

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## Endorsement notice

The text of ISO 23450:2021 has been approved by CEN as EN ISO 23450:2021 without any modification.

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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).

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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.