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Dentistry - Intraoral camera (ISO 23450:2021)

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 07/21

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Dentistry - Intraoral camera (ISO 23450:2021)

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

Zahnheilkunde - Intraoralkamera (ISO 23450:2021)

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EN ISO 23450:2021 (E)

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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.

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Dentistry — Intraoral camera

Médecine bucco-dentaire — Caméra intrabuccale



Reference number
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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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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.

ISO 23450:2021(E)**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*

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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*

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