Dentistry - Artificial intelligence (AI) and augmented intelligence (AuI) based 2D radiograph analysis - Data generation, data annotation and data processing (ISO 18374:2025)

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NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 18374:2025 sisaldab Euroopa standardi EN ISO 18374:2025 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 18374:2025 consists of the English text of the European standard EN ISO 18374:2025.
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 07.05.2025.	Date of Availability of the European standard is 07.05.2025.
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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English Version

Dentistry - Artificial intelligence (AI) and augmented intelligence (AuI) based 2D radiograph analysis - Data generation, data annotation and data processing (ISO 18374:2025)

Médecine bucco-dentaire - Analyse des radiographies bidimensionnelles basée sur l'intelligence artificielle (IA) et l'intelligence augmentée (IAu) - Génération, annotation et traitement des données (ISO 18374:2025)

Zahnmedizin - Künstliche Intelligenz (KI) und erweiterte Intelligenz (AuI) für die Analyse von 2D-Röntgenbildern - Datengenerierung, Datenkommentierung und Datenverarbeitung (ISO 18374:2025)

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

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European foreword

This document (EN ISO 18374:2025) 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of an identical text or by endorsement, at the latest by November 2025, and conflicting national standards shall be withdrawn at the latest by November 2025.

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Endorsement notice

The text of ISO 18374:2025 has been approved by CEN as EN ISO 18374:2025 without any modification.

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Foreword

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This document was prepared by Technical Committee ISO/TC 106 *Dentistry*, 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

Artificial intelligence (AI) and augmented intelligence (AuI) systems have gained growing prominence in the field of dentistry. These systems enhance both clinical decision support (CDS) and administrative operations and improve the accessibility, quality and efficiency of dental care. These systems are designed to guide clinical decisions related to disease prevention, management and surgical interventions, so specific consideration is needed to differentiate between normal, pre-pathologic and pathologic radiographic findings and manage them appropriately. Regulation plays an important role in ensuring the safety of patients and users as well as in commercialisation and market acceptance.

AI and AuI systems regularly involve supervised and unsupervised machine learning (ML) and, specifically, deep learning, and can be used for computer vision. Machine learning involves training computing systems to look for patterns in data to build models. Deep learning utilizes the neural networks of computing systems to discover and analyse complicated patterns in large "big data" databases. Computer vision can involve the use of deep learning to recognize patterns in images or videos.

One focus of current efforts around AI and AuI in dentistry is dental radiograph analysis, in particular, the analysis of 2-D dental radiographs like panoramic, bitewing or periapical or cephalometric radiographs. For these use cases, AI and AuI provide diagnostic support, but also facilitate documentation (reporting) and communication. The focus on 2-D radiograph analysis is due to the following:

— in dentistry, operators produce a high volume of radiographic images;

— the accuracy of dental practitioners when interpreting these images is limited (e.g. the sensitivity for the detection of early caries lesion on radiographic images is <50 %)[14], high inter- and intra- practitioner variability with human operators (e.g. influence of the circumstances of the day, resources available at one location)[15];

— a systematic and comprehensive diagnosis and documentation of the diagnosis results is time-consuming.

AI- and AuI-based software applications regularly detect non-pathological and pathological structures on radiographic images (e.g. teeth, anatomical structures, restorations, caries lesions). The functionality, performance specifications and safety of AI- and AuI-based medical software applications, including those for 2D radiographic image analysis in dentistry, are significantly influenced by the underlying data. Data generation, annotation and pre-processing raise technological, methodical and ethical questions. They also raise questions about data protection, safety and the law. There is a need for appropriate mechanisms that ensure the performance, compatibility, safety and efficacy of AI- and AuI-based medical software applications. Domain-specific aspects and particularities of dental data, in particular radiographs, and clinical requirements to analyse these data are expected to be taken into account when regulating AI- and AuI-applications. For example:

— there are usually several images of the same patient in one data set, these images can stem from the same time point (cross-sectional) or different time points (longitudinal);

— there is severe clustering of pathologies and statistical units;

— there is a range of levels on which data can be analysed and results be reported, like image, tooth, site or pixel level.

This document adopts recommendations by the Focus Group on Artificial Intelligence for Health of the International Telecommunication Union and World Health Organization towards regulating data generation, annotation and processing around AI- and AuI-based medical applications.

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1 Scope

This document defines the requirements for developing and documenting the goals, limitations, target end users and target patient population for artificial intelligence (AI) and augmented intelligence (AuI) enabled 2D radiograph analysis software for dentistry applications. It outlines the requirements for appropriate training data, validation data, test data and annotation for the software to ensure that it achieves its intended goals, and is restricted to the aspects. This document does not cover the specific implementation details, and focuses on static (i.e. non-dynamic) AI/AuI.

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 27799, *Health informatics — Information security management in health using ISO/IEC 27002*

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 terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1 Artificial intelligence (AI) and its components

3.1.1
artificial intelligence
AI
branch of computer science devoted to developing data processing systems that perform functions normally associated with human intelligence, such as reasoning, learning, and self-improvement

[SOURCE: ISO/IEC/IEEE 24765:2017, 3.234]

3.1.2
augmented intelligence
AuI
<system> capability to acquire, process, create and apply knowledge, held in the form of a model, to conduct one or more given tasks that require the inclusion of human decision-making