



# FINAL DRAFT International Standard

## ISO/FDIS 18374

### Dentistry — Artificial intelligence (AI) and augmented intelligence (AuI) based 2D radiograph analysis — Data generation, data annotation and data processing

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

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CP 401 • Ch. de Blandonnet 8  
CH-1214 Vernier, Geneva  
Phone: +41 22 749 01 11  
Email: [copyright@iso.org](mailto:copyright@iso.org)  
Website: [www.iso.org](http://www.iso.org)

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## Foreword

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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](http://www.iso.org/directives)).

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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](http://www.iso.org/members.html).

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## Introduction

Artificial intelligence (AI) and augmented intelligence (Aul) 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 Aul 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 Aul 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 Aul 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 Aul-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 Aul-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 Aul-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 Aul-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 Aul-based medical applications.



# Dentistry — Artificial intelligence (AI) and augmented intelligence (AuI) based 2D radiograph analysis — Data generation, data annotation and data processing

## 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

### 3.1.3

#### **clinical decision support**

##### **CDS**

type of service that assists healthcare providers and patients in making collaborative medical decisions, which typically requires input of patient-specific clinical variables and provide patient-specific recommendations

[SOURCE: ISO/TS 22756:2020, 3.1, modified — The term “and patients” was added to “healthcare providers and patients” and “collaborative” was added to “collaborative medical decisions”.]

### 3.1.4

#### **AI model**

mathematical or computational representation of real-world systems that use *machine learning* (3.2.2) to create algorithms that enable *artificial intelligence* (3.1.1) system to make predictions and decisions based on learned patterns from data training

## **3.2 Machine learning techniques**

### 3.2.1

#### **algorithm**

set of rules or calculations applied to *test data* (3.5.5) that generate an interpretable or reportable result

[SOURCE: ISO 21474-1:2020, 3.2]

### 3.2.2

#### **machine learning**

##### **ML**

process of optimizing model parameters through computational techniques, such that the model's behaviour reflects the data or experience

[SOURCE: ISO/IEC 22989:2022, 3.3.5]

### 3.2.3

#### **supervised machine learning**

*machine learning* (3.2.2) that makes only use of *labelled data* (3.5.2) during training

[SOURCE: ISO/IEC 22989:2022, 3.3.12]

### 3.2.4

#### **unsupervised machine learning**

*machine learning* (3.2.2) that makes only use of unlabelled data during training

[SOURCE: ISO/IEC 22989:2022, 3.3.17]

### 3.2.5

#### **federated learning**

decentralized *machine learning* (3.2.2) model that enables collaborative distributed training while preserving data privacy

### 3.2.6

#### **secure aggregation**

combining sensitive data from multiple sources while preserving privacy and confidentiality

## **3.3 Data processing and privacy**

### 3.3.1

#### **de-identification**

general term for any process of reducing the association between a set of identifying data and the data subject

[SOURCE: ISO 25237:2017, 3.20]



## 3.3.2

**anonymization**

process by which personally identifiable information (PII) is irreversibly altered in such a way that a PII principal can no longer be identified directly or indirectly, either by the PII controller alone or in collaboration with any other party

[SOURCE: ISO/IEC 29100:2024, 3.2]

## 3.3.3

**pseudonymization**

sub-class of *de-identification* (3.3.1), which can be performed with or without the possibility of re-identifying the subject of the data/record content

Note 1 to entry: This term definition has been adapted from ISO 25237:2017, 3.42.

## 3.4 Data annotation and labelling

## 3.4.1

**annotate**

adding descriptive labels, tags, or metadata to data, enabling accurate *classification* (3.4.3) and other *artificial intelligence* (3.1.1) tasks during the training and evaluation of *AI model* (3.1.4)

## 3.4.2

**annotation**

labelling, markings or metadata added to data providing contextual relevance to the information and enabling the training, evaluation and understanding of the *AI model* (3.1.4)

## 3.4.3

**classification**

process by which an *artificial intelligence* (3.1.1) system categorizes or assigns data instances (objects or documents) into classes and subclasses in accordance with their characteristics

Note 1 to entry: This term definition has been adapted from ISO 10209:2022, 3.11.4.

## 3.5 Dataset management

## 3.5.1

**AI dataset**

structured or unstructured examples used by *machine learning* (3.2.2) models that contain features and corresponding labels necessary to facilitate accurate prediction or *classification* (3.4.3)

## 3.5.2

**labelled data**

*AI dataset* (3.5.1), that has been assigned a tag or identifier that represents the predefined category or class to enable *classification* (3.4.3) prediction or analysis by an *artificial intelligence* (3.1.1) system

## 3.5.3

**training dataset**

collection of annotated *AI datasets* (3.5.1) used to teach a *machine learning* (3.2.2) model to make accurate predictions or *classification* (3.4.3)

Note 1 to entry: In the context of this document, a training dataset typically consists of a collection of dental images.

## 3.5.4

**validation dataset**

independent dataset used to evaluate a candidate of a machine-learning model during training

[SOURCE: ISO/IEC TR 29119-11:2020, 3.1.86 modified]

### 3.5.5

#### **test dataset**

independent dataset used to provide an unbiased evaluation of the reliability and quantify the error rate of a machine-learning model

Note 1 to entry: This term definition has been adapted from ISO/IEC TR 29119-11:2020, 3.1.75.

### 3.5.5.1

#### **internal test dataset**

withheld subset of the *test dataset* (3.5.5) utilized to evaluate the predictive capabilities of an *AI model* (3.1.4)

### 3.5.5.2

#### **external test dataset**

independent *AI dataset* (3.5.1) distinct from the *training dataset* (3.5.3) or *validation dataset* (3.5.4) and *internal test dataset* (3.5.5.1) utilized to verify the generalizability of the predictive capabilities of an *AI model* (3.1.4)

## 3.6 Assessment and evaluation

### 3.6.1

#### **risk-based assessments**

systematic evaluation and analysis of potential risks associated with *AI model* (3.1.4)

### 3.6.2

#### **competence**

ability to apply scientifically and evidence-based knowledge and skills to achieve the intended results

[SOURCE: ISO 22000:2018, 3.4, modified — The term “scientifically and evidence-based” was added to “scientifically and evidence-based knowledge”.]

## 4 Abbreviated terms

The following symbols and abbreviated terms are used in this document:

AI artificial intelligence

Aug augmented intelligence

## 5 General

The user can refer to established management and life-cycle systems standards to develop AI-based medical software applications for 2D radiographic image analysis (e.g. IEC 62304).

The intended users and the application objective and the application context shall be defined.

NOTE The scope of medical devices depends on the regulatory authorities in each country.

## 6 Requirements

### 6.1 Data

#### 6.1.1 Quantity, scope and handling of data

The quantity and scope of the required radiographic image data sets shall be specified in accordance with evidence-based and clinically accepted methods as established by subject matter experts.

Test in accordance with 7.2.1.