



SLOVENSKI STANDARD
oSIST prEN ISO 18374:2024
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Zobozdravstvo - Analiza 2D rentgenskih posnetkov na podlagi umetne inteligence (AI) in razširjene inteligence (Aul) - Ustvarjanje podatkov, anotacija podatkov in obdelava podatkov (ISO/DIS 18374:2024)

Dentistry - Artificial intelligence (AI) and augmented intelligence (Aul) based 2D radiograph analysis - Data generation, data annotation and data processing (ISO/DIS 18374:2024)

Zahnmedizin - Künstliche Intelligenz (KI) und erweiterte Intelligenz (Aul) für die Analyse von 2D-Röntgenbildern - Datengenerierung, Datenkommentierung und Datenverarbeitung (ISO/DIS 18374:2024)

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/DIS 18374:2024)

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

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Introduction

Artificial intelligence (AI) and Augmented intelligence (AuI) systems have gained growing prominence in the field of dentistry, enhancing both clinical decision support (CDS) and administrative operations and improving the accessibility, quality, and efficiency of dental care. Since these systems are designed to guide clinical decisions related to disease prevention, management, and surgical interventions, 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 the commercialisation and market acceptance.

AI and AuI systems regularly involve supervised and unsupervised machine learning 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 neural networks of computing systems to discover and analyze 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 fact that

1. in dentistry, a high volume of radiographic images is produced;
2. the accuracy of dental practitioners when interpreting these images is limited (for instance, the sensitivity for the detection of early caries lesion on radiographic images is <50 %, ^[16] high inter- and intra- practitioner variability with human operators (given circumstances of the day/resources available at one location ^[17]); and
3. 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 (teeth, anatomical structures, restorations, caries lesions, etc.) on radiographic images. The functionality, performance specifications and safety of AI- and AuI-based medical software applications, including those for 2-D radiographic image analysis in dentistry, are significantly influenced by the underlying data. Data generation, data annotation and data pre-processing raise technological, methodical, ethical, data protection, safety and regulatory questions and 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, shall be taken into account when regulating AI- and AuI-applications accordingly (for instance, 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 are a range of levels on which data can be analysed and results be reported, like image, tooth, site or pixel level etc.).

This document adopts recommendations by the ITU/WHO Focus Group AI for Health (FGAI4Health) towards regulating data generation, annotation and processing around AI- and AuI-based medical applications.