



International
Standard

ISO 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*

**First edition
2025-04**

ISO 18374:2025

<https://standards.iteh.ai/catalog/standards/iso/fa262f2a-157c-4010-840e-dc4ed6fc213a/iso-18374-2025>

iTeh Standards
(<https://standards.itih.ai>)
Document Preview

ISO 18374:2025

<https://standards.itih.ai/catalog/standards/iso/fa262f2a-157c-4010-840e-dc4ed6fc213a/iso-18374-2025>



COPYRIGHT PROTECTED DOCUMENT

© ISO 2025

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

Page

Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
3.1 Artificial intelligence (AI) and its components	1
3.2 Machine learning techniques	2
3.3 Data processing and privacy	2
3.4 Data annotation and labelling	3
3.5 Dataset management	3
3.6 Assessment and evaluation	4
4 Abbreviated terms	4
5 General	4
6 Requirements	4
6.1 Data	4
6.1.1 Quantity, scope and handling of data	4
6.1.2 Quality control	5
6.1.3 Factors for the bias analysis	5
6.1.4 Input (training, testing and validation) data	5
6.1.5 Data validation	5
6.1.6 Data protection	5
6.1.7 Data protection control	5
6.2 Data annotation (labelling)	6
6.2.1 Annotation strategy	6
6.2.2 Annotation procedure	6
6.2.3 Competence	6
6.3 Data pre-processing	6
6.3.1 Pre-processing the data	6
6.3.2 Risks of data processing	6
6.4 Data post-processing	6
7 Test method	6
7.1 General	6
7.2 Data	7
7.2.1 Quantity and scope	7
7.2.2 Inclusion and exclusion criteria	7
7.2.3 Quality control	7
7.2.4 Factors for the bias analysis	7
7.2.5 Input data	8
7.2.6 Data validation	8
7.2.7 Data protection	9
7.2.8 Data protection control	9
7.3 Data annotation (labelling)	10
7.3.1 Annotation strategy	10
7.3.2 Annotation procedure	10
7.3.3 Competence	10
7.4 Data pre-processing	11
7.4.1 General	11
7.4.2 Risks of data processing	11
8 Test report	11
9 Electronic instructions for use	12
Bibliography	13

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).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents. ISO shall not be held responsible for identifying any or all such patent rights.

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*, 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 18374:2025

<https://standards.iteh.ai/catalog/standards/iso/fa262f2a-157c-4010-840e-dc4ed6fc213a/iso-18374-2025>