



FINAL DRAFT Technical Specification

ISO/DTS 24971-2

Medical devices — Guidance on the application of ISO 14971 —

Part 2:

Machine learning in artificial intelligence

ISO/TC 210

Secretariat: **ANSI**

Voting begins on:
2025-08-28

Voting terminates on:
2025-11-20

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

[ISO/DTS 24971-2](https://standards.itech.ai/catalog/standards/iso/92a66baa-7218-4837-9165-8a27c66682e8/iso-dts-24971-2)

<https://standards.itech.ai/catalog/standards/iso/92a66baa-7218-4837-9165-8a27c66682e8/iso-dts-24971-2>

This draft is submitted to a parallel vote in ISO and in IEC.

ISO/CEN PARALLEL PROCESSING

RECIPIENTS OF THIS DRAFT ARE INVITED TO SUBMIT, WITH THEIR COMMENTS, NOTIFICATION OF ANY RELEVANT PATENT RIGHTS OF WHICH THEY ARE AWARE AND TO PROVIDE SUPPORTING DOCUMENTATION.

IN ADDITION TO THEIR EVALUATION AS BEING ACCEPTABLE FOR INDUSTRIAL, TECHNOLOGICAL, COMMERCIAL AND USER PURPOSES, DRAFT INTERNATIONAL STANDARDS MAY ON OCCASION HAVE TO BE CONSIDERED IN THE LIGHT OF THEIR POTENTIAL TO BECOME STANDARDS TO WHICH REFERENCE MAY BE MADE IN NATIONAL REGULATIONS.

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

ISO/DTS 24971-2

<https://standards.iteh.ai/catalog/standards/iso/92a66baa-7218-4837-9165-8a27c66682e8/iso-dts-24971-2>



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
4 General requirements for <i>risk management system</i>	3
4.1 <i>Risk management process</i>	3
4.2 Management responsibilities.....	4
4.3 Competence of personnel.....	4
4.4 <i>Risk management plan</i>	4
4.5 <i>Risk management file</i>	5
5 <i>Risk analysis</i>	5
5.1 <i>Risk analysis process</i>	5
5.2 <i>Intended use and reasonably foreseeable misuse</i>	5
5.3 Identification of characteristics related to <i>safety</i>	5
5.4 Identification of <i>hazards</i> and <i>hazardous situations</i>	6
5.5 <i>Risk estimation</i>	6
6 <i>Risk evaluation</i>	6
7 <i>Risk control</i>	6
7.1 <i>Risk control option analysis</i>	6
7.2 Implementation of <i>risk control</i> measures.....	7
7.3 <i>Residual risk</i> evaluation and subsequent steps.....	7
8 <i>Evaluation of overall residual risk</i>	8
8.1 General considerations for <i>MLMD</i>	8
8.2 Disclosure of significant <i>residual risks</i>	8
9 <i>Risk management review</i>	8
10 <i>Production and post-production activities</i>	9
10.1 General.....	9
10.2 Information collection.....	10
10.3 Information review.....	10
10.4 Actions.....	10
Annex A (informative) <i>Explanation of bias</i>	11
Annex B (informative) <i>Examples of hazards and hazardous situations</i>	14
Annex C (informative) <i>Identification of hazards and characteristics related to safety</i>	19
Annex D (informative) <i>Considerations for MLMD having a level of autonomy</i>	28
Bibliography.....	30

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 210, *Quality management and corresponding general aspects for products with a health purpose including medical devices*, in collaboration with Technical Committee IEC/TC 62, *Medical equipment, software, and systems*, Subcommittee SC 62A, *Common aspects of medical equipment, software, and systems*, and with the European Committee for Standardization (CEN) Technical Committee CEN/CLC/JTC 3, *Quality management and corresponding general aspects for medical devices*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

A list of all parts in the ISO 24971 series can be found on the ISO website.

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) is rapidly evolving and can bring advantages to healthcare. These advantages can be related to improved *benefits* for the patient, improved efficiencies in clinical workflows and improvement in the management of healthcare itself. However, the implementation of new technologies such as AI can also present new *risks* and can, for example, jeopardize patient *safety*, affect privacy and security, influence user actions, undermine trust in healthcare or adversely affect the management of healthcare.

The *safety* and effectiveness of AI in *medical devices* was explored in an AAMI-BSI document^[16], which identified three ways in which AI-based *medical devices* differed from “traditional” (non-AI) *medical devices*:

- Training.** These *medical devices* can process large amounts of data and learn from these data to improve their results. Thus, they can have positive effects on patient health within the scope of the *intended use* of the *medical device*.
- Level of autonomy.** These *medical devices* can have the ability to generate different treatment options, select the best option based on a trained model and execute the selected option (see for example IEC/TR 60601-4-1^[8]). These steps can be performed with reduced or even without direct user action, but only with human oversight.
- Explainability.** These *medical devices* often rely on complex algorithms and large datasets to generate output. However, the inherent opacity of these algorithms makes it challenging to interpret how specific conclusions or recommendations are derived. This can lead to difficulties in understanding their rationale, even by well-trained clinicians and other healthcare personnel, and certainly by individuals without specialist knowledge.

Many different AI-based technologies and algorithms exist today, including decision trees, genetic algorithms and deep learning-based technologies such as generative AI and neural networks. ISO/IEC 22989^[4] and ISO/IEC 23894^[6] provide general guidance on AI concepts, terminology and *risk management*, but they do not specifically address the application of AI to *medical devices*. It is noted that “*risk*” is defined in these documents as the effect of uncertainties on objectives (see also ISO 31000^[2]). This definition is useful for organizational or business *risk management*. The term “*risk*” used in the healthcare sector is different and is defined in ISO 14971:2019 as the combination of the probability of occurrence of *harm* and the *severity* of that *harm*.

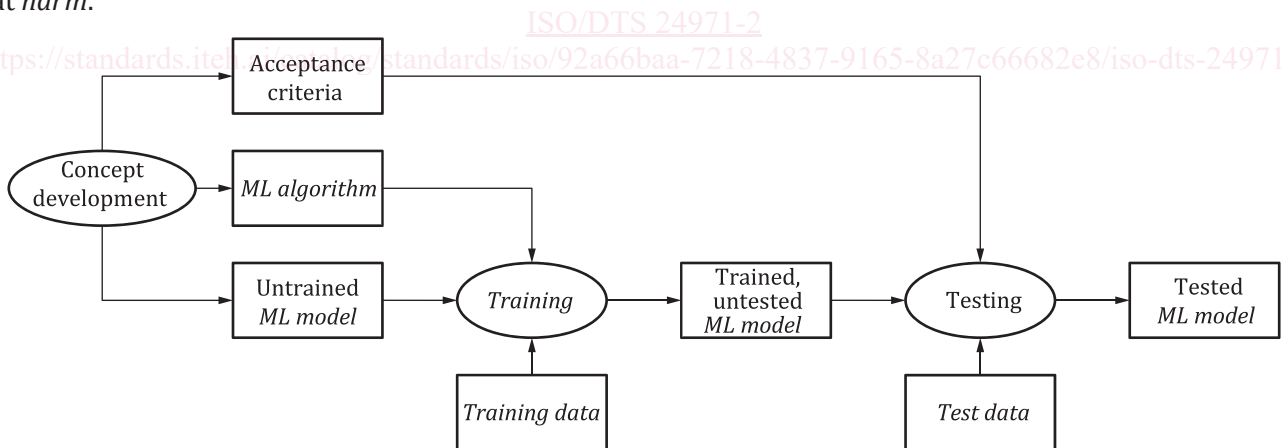


Figure 1 — Concept development, training and testing stages of the ML model and its relationship with the ML algorithm, the training data and the test data

This document focuses on *machine learning* (ML) techniques and is restricted to *ML-enabled medical devices* (MLMD). *Machine learning* is considered a subset of AI that involves an *ML model* and an *ML algorithm*. See [Figure 1](#). The *ML model* and the *ML algorithm* are the results of the concept development for a new MLMD, together with acceptance criteria for the eventual MLMD. It is important that the acceptance criteria are established at the start as part of concept development and not at the end of the MLMD development. After concept development, the *ML model* is trained by using an *ML algorithm* enabling it to learn patterns from *training data* without being explicitly programmed. Next, the trained *ML model* is applied to *test data* to