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Part 2: Machine learning in artificial intelligence

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Foreword

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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.

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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*:

a) *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*.

b) 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.

c) *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*.

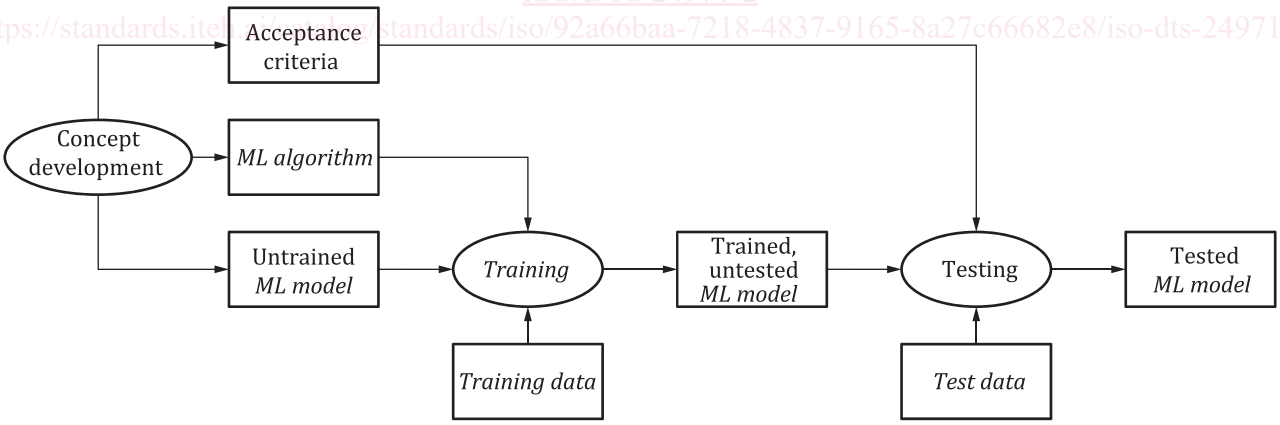

Figure 1 — Concept development, *training* and testing stages of the *ML model* and its relationship with the *ML algorithm*, the *training data* and the *test data*

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