FINAL DRAFT
Technical Report

ISO/IEC DTR 18988

Artificial intelligence — Application of AI technologies in health informatics

Intelligence artificielle — Application des technologies d'intelligence artificielle à l'informatique de santé

ISO/IEC JTC **1**/SC **42**

Secretariat: **ANSI**

Voting begins on:
2026-08-14

Voting terminates on:
2026-10-09

Member bodies are requested to consult relevant national interests in ISO/TC 215 before casting their ballot to the e-Balloting application.

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Reference number
ISO/IEC DTR 18988:2026(en)

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Published in Switzerland

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Foreword

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This document was prepared by Joint Technical Committee ISO/IEC JTC 1, Information technology, Subcommittee SC 42, *Artificial intelligence*.

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Introduction

This document is a landscape document which aims to describe certain key factors that can impact the use of AI-enabled health informatics in various clinical settings including in healthcare delivery organizations and home healthcare environments.

The document is written at a point in time and acknowledges that the use of large language models and agentic AI is undergoing rapid evolution in the way AI systems are being applied in many industries, including healthcare.

It is recognized that there is substantial existing and ongoing work on the development of standards for AI system use applicable across all industries and relevant references are included in the Bibliography.

The work programme of ISO/IEC JTC1 SC 42, *Artificial intelligence*, can be found at https://www.iso.org/committee/6794475/x/catalogue/p/0/u/1/w/0/d/0.

There is also a mature body of standards related to AI use in medical device software. The work programme of IEC TC 62 Medical equipment, software, and systems can be found at https://www.iec.ch/dyn/www/f?p=103:23:::::FSP_ORG_ID:1245.

The medical device sector is highly regulated and has stringent requirements for compliance. Health informatics has an important interface with medical devices that arises when the data from the device is used to inform clinical care.

This document is intended to help understand how some of the factors described can lend themselves to standardization and be seen as opportunities to complement the existing work of both ISO/IEC JTC1 SC42 and IEC TC 62.

The primary concern for healthcare is consideration of the extent to which standards adequately account for health informatics requirements. That outcome could be achieved by:

— developing any required healthcare specific documents,

— developing healthcare specific parts related to existing documents, or

— providing healthcare expertise and advice into the development and review of existing “horizontal” documents.

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Artificial intelligence — Application of AI technologies in health informatics

1 Scope

This document provides an overview of AI-enabled Health Informatics (AIHI). This document describes the properties, factors, available methods and processes relating to the use of AI in health informatics to effectively realize the potential benefits for healthcare use cases. This document identifies considerations for the use of AI systems in healthcare when developing AIHI-related standards, such as mapping and categorization, and points out some differences from horizontal cross-industry AI system standards.

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/IEC 22989, *Information technology — Artificial intelligence — Artificial intelligence concepts and terminology*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO/IEC 22989 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
ambient scribing product
tool that uses advanced speech technologies to automatically convert spoken words into text and other outputs, requiring minimal user intervention

Note 1 to entry: Ambient scribing products are designed to support clinical or patient documentation and workflows in healthcare.

3.2
generative AI system
generative artificial intelligence system, noun
GenAI system, noun
AI system based on techniques and models that aim to generate new content

Note 1 to entry: Examples of generated content can include text, audio, code, video, and image.

Note 2 to entry: Generated content encompasses new information or new ways to express pre-existing information. That pre-existing information can be drawn from the input, a dataset involved in building the model or an external repository.

[SOURCE: ISO/IEC 22989:2022/DAmd 1 [1], 3.1.38]

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3.3
health informatics
scientific discipline that is concerned with the cognitive, information processing and communication tasks of healthcare practice, education and research, including the information science and technology to support these tasks

[SOURCE: ISO/TR 18307:2001 [2], 3.73, modified — "healthcare" changed to "health".]

3.4
intended use
intended purpose, noun
use for which a product, process or service is intended according to the specifications, instructions and information provided by the manufacturer

Note 1 to entry: The intended medical indication, patient population, part of the body or type of tissue interacted with, user profile, use environment, and operating principle are typical elements of the intended use.

[SOURCE: ISO 14971:2019 [3], 3.6]

3.5
medical device
instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of:

— diagnosis, prevention, monitoring, treatment or alleviation of disease;

— diagnosis, monitoring, treatment, alleviation of or compensation for an injury;

— investigation, replacement, modification, or support of the anatomy or of a physiological process;

— supporting or sustaining life;

— control of conception;

— disinfection of medical devices;

— providing information by means of in vitro examination of specimens derived from the human body; and does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means

Note 1 to entry: Products which may be considered to be medical devices in some jurisdictions but not in others include:

— disinfection substances;

— aids for persons with disabilities;

— devices incorporating animal and/or human tissues;

— devices for in vitro fertilization or assisted reproduction technologies.

[SOURCE: ISO 13485:2016 [4], 3.11]

3.6
pseudonymization
pseudonymization particular type of de-identification that both removes the association with a data subject and adds an association between a particular set of characteristics relating to the data subject and one or more pseudonyms

[SOURCE: ISO 25237:2017 [5], 3.42]

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4 Abbreviated terms

AI	Artificial intelligence
AI-DSF	Artificial Intelligence-Enabled Device Software Functions
AAMI	Association for the Advancement of Medical Instrumentation
AIHI	AI-enabled health informatics
AIMD	Active implantable medical device
CHAI	Coalition for Health AI
CLS	Continuous learning system
EHR	Electronic health record
FFP	Fit for purpose
FG-AI4H	Focus Group on Artificial Intelligence for Health
GenAI	Generative AI
GI-AI4H	Global Initiative on Artificial Intelligence for Health
GMLP	Good machine learning practice
HIS	Hospital information system
HMT	Human machine teaming
IMDRF	International Medical Device Regulators Forum
LLM	Large language model
MSS	Management systen standard
NCD	Non-communicable disease
OECD	Organisation for Economic Co-operation and Development
PCCP	Predetermined Change Control Plan
RWD	Real-world data
SaMD	Software as a medical device

5 Current state of the health informatics ecosystem

5.1 Healthcare context

ISO TC 215 health informatics Task Force 5 has previously examined the challenges being faced by the healthcare system in the 21st Century (Application of AI Technologies in Health Informatics ISO/TC 215 AHG2 – Final Report March 1, 2021 [6]). These challenges are expected to continue shaping the ways in which AI is applied in health informatics to support managing and delivering healthcare.

Some of the challenges affect multiple industries (e.g. climate change) but the impact is different. Many are not controllable in the short term (e.g. changing population demographics) and possibly not even controllable

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