IEC PAS 63621

Edition 1.0 2026-03

PUBLICLY AVAILABLE SPECIFICATION

Artificial intelligence enabled medical devices - Data management

ICS 11.040; 11.020

ISBN 978-2-8327-1124-8

IEC PAS 63621:2026-03(en)

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Artificial intelligence enabled medical devices - Data management

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The text of this Publicly Available Specification is based on the following documents:

Draft	Report on voting
62/559/DPAS	62/579/RVDPAS

Full information on the voting for its approval can be found in the report on voting indicated in the above table.

The language used for the development of this is English.

This document was drafted in accordance with ISO/IEC Directives, Part 2, and developed in accordance with ISO/IEC Directives, Part 1 and ISO/IEC Directives, IEC Supplement, available at www.iec.ch/members_experts/refdocs . The main document types developed by IEC are described in greater detail at www.iec.ch/standardsdev/publications.

The committee has decided that the contents of this document will remain unchanged until the stability date indicated on the IEC website under webstore.iec.ch in the data related to the specific document. At this date, the document will be

– reconfirmed,
– withdrawn, or
– revised.

NOTE In accordance with ISO/IEC Directives, Part 1, IEC PASs are automatically withdrawn after 4 years.

INTRODUCTION

Ensuring the safety and effectiveness of a medical device that incorporates AI involves several steps. These steps include establishing data requirements, data planning and data acquisition, managing data throughout its life cycle, and demonstrating that the device meets its intended purpose without posing unacceptable risks.

This document outlines requirements for data management lifecycle cycle processes, detailing the activities and tasks essential for managing data used by medical devices incorporating AI. It specifies requirements for each stage of the data life cycle.

The data management process consists of a number of activities. These activities are shown in Figure 1 below.

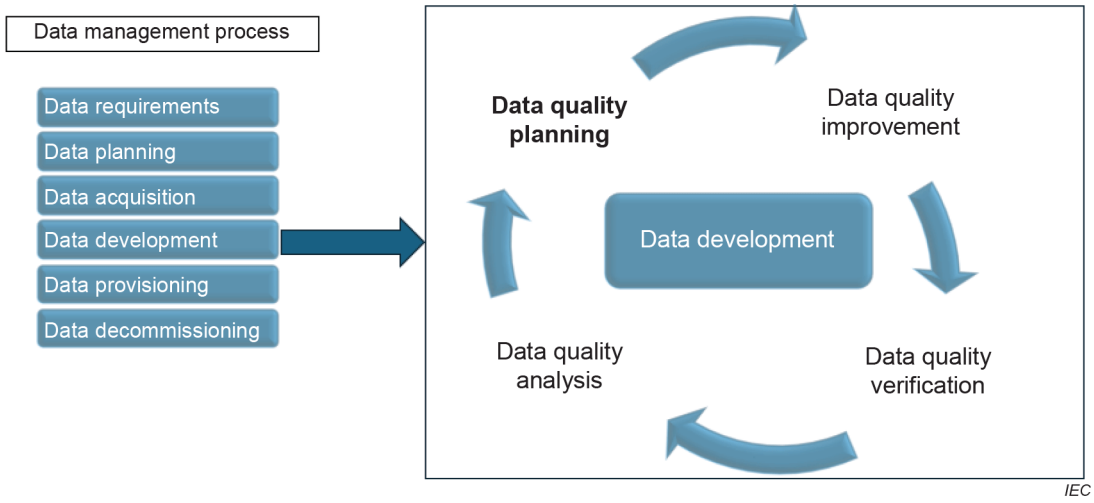

Figure 1 – Data management process

Data management process: Data management is a lifecycle activity that continues throughout the full device lifecycle. This includes adjustments to improve the data quality in case data characteristics no longer meet the requirements defined in data planning.

This document does not specify an organizational structure for the manufacturer or which part of the organization is to perform which process, activity, or task.

This document does not specify the name, format, or detailed content of the required documentation. While this document provides requirements about the documentation of tasks, it leaves the choice of how to organize and present this documentation up to the user.

Annex A provides further information about how the clauses of this document should be seen in relation to the quality management system.

This document assumes that the manufacturer has a quality management system in place which is appropriate for medical device development.

For the purposes of this document:

– "shall" means that conformance with a requirement is mandatory for conformance with this document;
– "should" means that conformance with a recommendation but is not mandatory for conformance with this document;

– "may" is used to describe a permissible way to achieve conformance with a requirement;
– "establish" means to define, document, and implement; and
– where this document uses the term "as appropriate" in conjunction with a required process, activity, task or output, the intention is that the manufacturer shall use the process, activity, task or output unless the manufacturer can document a justification for not so doing.

1 Scope

This document provides a framework for the data life cycle processes for management of data used to train, test or validate an AI model that is part of a medical device.

For data acquisition and management lifecycle the following considerations apply, amongst others: data suitability, data quality and integrity insurance, data privacy and security, data governance and documentation, data sampling and bias mitigation, data versioning and traceability, data storage and infrastructure, data access and sharing, and data labelling and annotation.

This document outlines the requirements for the data lifecycle, covering stages from planning and acquisition to usage and decommissioning. It emphasizes maintaining data quality, including aspects such as dataset classification, data annotations, traceability, metadata comprehensiveness, representativeness, and validity periods.

The scope is limited to the high-level process concepts applicable across medical specialties and device types and does not include specific requirements that can be covered by modality- or device-specific standards documents.

This document outlines the additional requirements for AI data management for data management, where an organization demonstrates its capability to manage data in accordance with applicable medical device guidance and standards. Organizations can be involved in one or more stages of the life-cycle, including design and development, production, storage and distribution, installation, or servicing and maintenance of a medical device that incorporates AI. This document can also be used by suppliers or external parties that provide data, including quality management system-related services to such organizations.

2 Normative references

There are no normative references in this document.

Bibliography

[1] ISO 13485:2016, *Medical devices — Quality management systems — Requirements for regulatory purposes*

[2] ISO/IEC 2382:2015, *Information technology — Vocabulary*

[3] ISO/IEC 22989:2022, *Information technology - Artificial intelligence - Artificial intelligence concepts and terminology*

[4] ISO 8000-2:2020, *Data quality — Part 2: Vocabulary*

[5] ISO/IEC 25012:2008, *Software engineering — Software product Quality Requirements and Evaluation (SQuaRE) — Data quality model*

[6] ISO/IEC Guide 63:2019, *Guide to the development and inclusion of aspects of safety in International Standards for medical devices*

[7] ISO/IEC 11179-1:2023, *Information technology — Metadata registries (MDR) — Part 1: Framework*

[8] ISO 9000:2015, *Quality management systems — Fundamentals and vocabulary*

[9] YY/T 1833.2:2022, *Artificial intelligence medical device - Quality requirements and evaluation - Part 2: General requirements for datasets*

[10] ISO/IEC 27559, *Information security, cybersecurity and privacy protection – Privacy enhancing data de-identification framework*

[11] ISO 8000-8:2015, *Data quality — Part 8: Information and data quality: Concepts and measuring*

[12] ISO/IEC TR 20547-2:2018, *Information technology — Big data reference architecture — Part 2: Use cases and derived requirements*

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