This is a preview - click here to buy the full publication

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)

This is a preview - click here to buy the full publication

CONTENTS

FOREWORD 4
INTRODUCTION 6
1 Scope 8
2 Normative references 8
3 Terms and definitions 8
4 Data management principles 11
5 Data management process 12
5.1 Data management process 12
5.2 Data development process 13
5.2.1 Data quality planning 13
5.2.2 Data quality improvement 13
5.2.3 Data quality verification 13
5.2.4 Data quality analysis 13
6 Data management 14
6.1 General 14
6.2 Data requirements 14
6.3 Data planning 15
6.4 Data acquisition 16
6.5 Data development 17
6.5.1 General 17
6.5.2 Data de-identification 18
6.5.3 Dataset composition 18
6.5.4 Data annotation 20
6.5.5 Data quality improvement 21
6.5.6 Data quality verification 22
6.5.7 Data quality analysis 23
6.6 Data provisioning 23
6.7 Data decommissioning 24
Annex A (informative) Explanation of data management techniques 25
A.1 Data quality improvement techniques 25
A.1.1 Cleaning 25
A.1.2 Data encoding 25
A.1.3 Data transformation 25
A.1.4 Data aggregation 26
A.1.5 Data normalization 26
A.1.6 Data standardization 26
A.1.7 Data imputation 26
A.1.8 Data augmentation 27
A.1.9 Data mining 28
A.2 Data quality verification 28
Annex B (informative) Data quality characteristics 30
B.1 Description of data quality characteristics 30
B.1.1 Integrity: Accuracy 30
B.1.2 Integrity: Completeness 30
B.1.3 Uniqueness 30
B.1.4 Consistency 30

This is a preview - click here to buy the full publication

B.1.5 Authenticity 30
B.1.6 Timeliness 30
B.1.7 Accessibility 30
B.1.8 Conformance 30
B.1.9 Confidentiality 31
B.1.10 Resource utilization 31
B.1.11 Precision 31
B.1.12 Traceability 31
B.1.13 Comprehensibility 31
B.1.14 Availability 31
B.1.15 Portability 31
B.1.16 Recoverability 31
B.1.17 Representativeness 31
B.2 Demonstration of data quality characteristics 32
B.2.1 Integrity: Accuracy 32
B.2.2 Integrity: Completeness 32
B.2.3 Uniqueness 32
B.2.4 Consistency 32
B.2.5 Authenticity 33
B.2.6 Timeliness 33
B.2.7 Accessibility 33
B.2.8 Conformance 33
B.2.9 Confidentiality 33
B.2.10 Resource utilization 33
B.2.11 Precision 33
B.2.12 Traceability 33
B.2.13 Comprehensibility 34
B.2.14 Availability 34
B.2.15 Portability 34
B.2.16 Recoverability 34
B.2.17 Representativeness 34
B.3 Evaluation of data characteristics 34
B.3.1 Accuracy 35
B.3.2 Completeness 35
B.3.3 Uniqueness 35
B.3.4 Consistency 35
B.3.5 Authenticity 35
B.3.6 Timeliness 35
B.3.7 Accessibility 36
B.3.8 Conformance 36
B.3.9 Confidentiality 36
B.3.10 Resource utilization 36
B.3.11 Precision 36
B.3.12 Traceability 36
B.3.13 Comprehensibility 36
B.3.14 Availability 36
B.3.15 Portability 36
B.3.16 Recoverability 36
B.3.17 Representativeness 36

This is a preview - click here to buy the full publication

B.3.18 Dataset risk analysis assessment 37
B.4 Evaluation of dataset description 37
Annex C (informative) Description of data screening and cleaning 38
Bibliography 39

Figure 1 – Data management process 6
Figure 2 – Data management process 12
Figure 3 – Data quality measures information for quality reports 22
Figure 4 – Data quality assessment in data development 23
Figure A.1 – Flow chart of dataset quality evaluation 29

Table B.1 – Classification and evaluation methods for data characteristics 35
Table C.1 – Examples for data screening 38
Table C.2 – Examples for data exclusion criteria 38

This is a preview - click here to buy the full publication

INTERNATIONAL ELECTROTECHNICAL COMMISSION

_____

Artificial intelligence enabled medical devices - Data management

FOREWORD

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.

2) The formal decisions or agreements of IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested IEC National Committees.

3) IEC Publications have the form of recommendations for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user.

4) In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible in their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter.

5) IEC itself does not provide any attestation of conformity. Independent certification bodies provide conformity assessment services and, in some areas, access to IEC marks of conformity. IEC is not responsible for any services carried out by independent certification bodies.

6) All users should ensure that they have the latest edition of this publication.

7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.

8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.

9) IEC draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). IEC 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, IEC 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 https://patents.iec.ch. IEC shall not be held responsible for identifying any or all such patent rights.

This is a preview - click here to buy the full publication

IEC PAS 63621 was prepared by IEC technical committee 62: Medical equipment, software, and systems. It is a Publicly Available Specification.

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.

This is a preview - click here to buy the full publication

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.

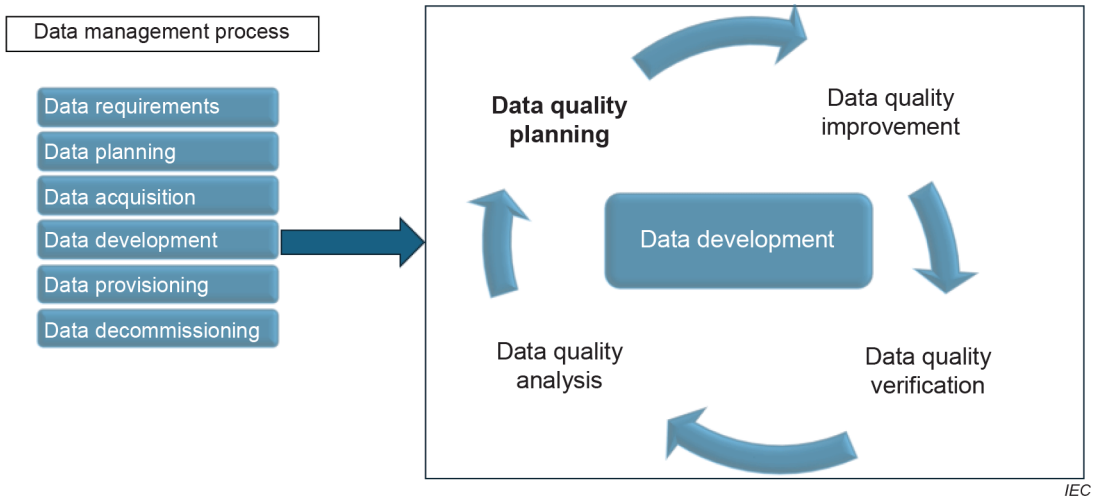

Figure 1 – Data management process

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;

This is a preview - click here to buy the full publication

- "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.

This is a preview - click here to buy the full publication

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.

This is a preview - click here to buy the full publication

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*

———————