TR-008:2024(E)

Medical Device Administrative Control System (MDACS)

Artificial Intelligence Medical Devices (AI-MD)

Technical Reference: TR-008

中華人民共和國
香港特別行政區政府衞生署

Department of Health
The Government of the Hong Kong Special Administrative Region
The People's Republic of China

Revision History

Edition Number	Date of Revision	Summary of Revision	Reference Number
0	3 Jan 2024	• First issue of TR-008	TR-008:2024(E)

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1. Introduction

1.1 Background

1.1.1 Artificial Intelligence (AI) is a branch of computer science, statistics, and engineering that uses algorithms or models to perform tasks and exhibit behaviours including learning, making decisions and making predictions. Due to the advancement of technology and the global trend of medical device (MD) control, more updated elaboration is required on the control for AI application in MD so as to strike a balance between patient/consumer protection and facilitating innovation.

1.1.2 Machine Learning (ML), which is a subset of AI, refers to a set of algorithms and statistical models (e.g. Linear Regressions, Support Vector Machines, Random Forests) that allows machines to perform specific tasks without using explicit instructions.

1.1.3 When AI in the form of software is integrated with software in Medical Device (SiMD) or with software as MD (SaMD), it is known as “AI-MD”, and it may be called “ML-MD” and “AI/ML-MD”.

1.1.4 While the requirements on safety, quality and performance of MD have already been addressed by the Essential Principles of Safety and Performance of Medical Devices (EP) under the Medical Device Administrative Control System (MDACS), the advancement of AI application in MD may warrant more detailed description of listing requirements in this aspect.

1.1.5 This document aims to provide references on the listing requirements for AI-MD under MDACS from a technical perspective.

2. Scope

2.1 This document applies to all AI-MD that fall within the scope of the MDACS (please refer to the Guidance Notes GN-01 (Overview of the Medical Device Administrative Control System)).

3. Definitions and Abbreviations

3.1 **Artificial Intelligence (AI)** is a branch of computer science, statistics, and engineering that uses algorithms or models to perform tasks and exhibit behaviours including learning, making decisions and making predictions.

3.2 **Artificial Intelligence Medical Device (AI-MD)** is a medical device integrated with AI in the form of software.

3.3 **Continuous Learning Capability (CLC)** is the ability to change AI-MD’s behaviour after deployment.

3.4 **Machine Learning (ML)** refers to a set of algorithms and statistical models that allows machines to perform specific tasks without using explicit instructions.

3.5 Please refer to Guidance Notes GN-00 (Guidance Notes for Definitions and Abbreviations for Medical Device Administrative Control System) and Technical Reference TR-007 (Software Medical Devices and Cybersecurity) for the definitions and abbreviations of the terms that appear in this document.

4. Requirements for listing of AI-MD

4.1 The following information regarding AI-MD shall be properly recorded, maintained and made available upon request by Medical Device Division (MDD):

Categories	Requirements	Remarks
Dataset	Input data and features/attributes used to generate the corresponding output	This shall include the various input data and features/attributes selected for the AI-MD to generate the corresponding output result. This can be in the form of diagnostic images, patient's history, patient's physiological measurements, medication records, etc. In the event where pre-processing (e.g. signal pre-processing, image scaling) of data is required, the process should be clearly defined.
	Source, size and attribution of training, validation and test datasets	The source and size of training, validation and test dataset shall be defined. Information on labelling of datasets, curation, annotation or other steps shall be clearly presented. Description on dataset cleaning and missing data imputation shall also be defined.
AI Model	AI model selection	A description on the machine learning model (e.g. convolutional neural network) used in the AI-MD, including any base model, shall be defined.
Performance and Clinical Evaluation	Test protocol and report for verification and validation of the AI-MD	Based on the performance specification of the AI-MD, the test protocol and test report, as well as information on control measures to detect extremes/outliers, shall be defined.
	Performance of the AI-MD	Validation and verification test report(s) shall be provided to substantiate such performance claim (e.g. diagnostic sensitivity, diagnostic specificity, accuracy).
	Clinical Association between the AI-MD's output and clinical conditions(s)	Presence of a valid clinical association between the AI-MD's output and its targeted clinical condition shall be available.
Deployment	Device workflow including how the output result should be	The intended or recommended workflow during the deployment of the device shall be documented.

Categories	Requirements	Remarks
	used	
	Interval for training data update cycle	In cases where data is collected after the deployment of the AI-MD (fixed-version) and these datasets are used to re-train the subsequent models of the AI-MD, information on the interval for training data update cycle shall be defined. Any changes to the intended use, performance specifications, input data types, device workflow, degree of human intervention, choice of AI model, etc. shall be reported to MDD in accordance with Guidance Document GN-10 (Guidance Notes on Changes for Listed Medical Devices). Examples: i) Change in input data types: Addition of oxygen saturation readings as new input data type while Computed Tomography (CT) images and Electrocardiogram (ECG) signals are existing input data types of an AI-MD. ii) Change in degree of human intervention: Removal of the review of the AI-MD's output results by healthcare specialists from the workflow for deployment and use of the AI-MD.
	Software version and the procedure or plan implemented to trace the software version for subsequent iterations	For the purpose of traceability, the exact AI-MD version to be supplied in Hong Kong and description on how the version numbers are designated and traced shall be provided upon request.

4.2 If the MD is also a software MD, please refer to Technical Reference TR-007 for the requirements.

4.3 The applicants shall refer to the following international standards or equivalent when listing AI-MD:

iii) ISO/IEC 22989 Information technology — Artificial intelligence — Artificial intelligence concepts and terminology

iv) ISO/IEC 23053 Framework for Artificial Intelligence (AI) Systems Using

Machine Learning (ML)

v) IEC 62304 Medical device software – Software life cycle processes

4.4 For AI-MD with CLC, complete information on the learning process including the process controls, verification, on-going model monitoring measures shall be clearly presented for review in the application for listing AI-MD. The following information in addition to those requirements described in Clause 4.1 shall be properly recorded, maintained and made available upon request by MDD:

4.4.1 Description on the process of continuous learning of the AI-MD during deployment.

4.4.2 Safety mechanism (can be built into the system) to detect anomalies and any inconsistencies in the output result and how these are mitigated. This can include process to detect and roll-back to the previous algorithm version which includes criteria by which the system is measured against (baseline).

4.4.3 During deployment, the AI-MD will learn from real world data. The source, datatype collected, data pre-processing steps and parameter extracted shall be defined to ensure there are no biasness in the process. The inclusion and exclusion criteria shall be listed and this shall be identical to the attributes of the original training dataset.

4.4.4 Process to ensure data integrity, reliability and validity of the new data set used for learning.

4.4.5 Software version controls shall be in place as the system has the potential for frequent updates and possibility for roll-back to the previous version in each of the deployment site.

4.5 Post Market Monitoring

4.5.1 Once AI-MD are deployed in the real-world environment, active monitoring, review and tuning are necessary. Manufacturers shall establish a process in collaboration with the Local Responsible Person (LRP), importers, distributors and users to ensure traceability and also implement mechanisms to monitor and review the performance of the AI-MD deployed in clinical setting. Such monitoring could be in the form of autonomous monitoring embedded in the system.

4.5.2 A robust system to ensure that the AI-MD especially those with continuous learning algorithms remain accurate and to prevent any concept drift shall be implemented. The manufacturer shall apply appropriate control measures based on the findings after deployment including submitting Change Applications to MDD and/or launching field safety corrective actions of the listed AI-MD. Please refer to Guidance Notes GN-10 for detailed requirements of Change Applications.

4.5.3 For all listed AI-MD, manufacturers shall monitor the real-world performance after deployment. Manufacturers also shall record, maintain and submit post-market reports to MDD upon request.

5. Other Requirements

5.1 Applicant shall also be aware of and follow, if appropriate, the relevant good practices, requirements or recommendations regarding AI application issued by the Office of the Government Chief Information Officer (OGCIO) of the Government of Hong Kong Special Administrative Region of the People's Republic of China.

6. Enquiries

6.1 Enquiries concerning this document and the MDACS should be directed to:

Medical Device Division,

Department of Health,

Telephone number: 3107 8484

Facsimile number: 3157 1286

Email address: mdd@dh.gov.hk

Website: www.mdd.gov.hk

7. References

7.1 Department of Health. Guidance Notes for Definitions and Abbreviations for Medical Device Administrative Control System. Guidance Notes GN-00.

7.2 Department of Health. Guidance Notes for Listing Class II/III/IV General Medical Devices. Guidance Notes GN-02.

7.3 Department of Health. Guidance Notes for Listing Class B, C and D In Vitro Diagnostic Medical Devices. Guidance Notes GN-06.

7.4 Department of Health. Guidance Notes for Changes of Listed Medical Devices. Guidance Notes GN-10

7.5 Department of Health. Classification of General Medical Devices. Technical Reference TR-003.

7.6 Department of Health. Classification of In Vitro Diagnostic (IVD) Medical Devices. Technical Reference TR-006.

7.7 Department of Health. Software Medical Devices and Cybersecurity. Technical Reference TR-007.

7.8 International Medical Device Regulators Form. Machine Learning-enabled Medical Devices: Key Terms and Definitions IMDRF/AIMD WG/N67. http://www.imdrf.org/ accessed on 22 November 2023.

7.9 Health Sciences Authority. Regulatory Guidelines for Software Medical Devices – A Life Cycle Approach. Rev. 2.0. 2022.04

7.10 Health Sciences Authority. Artificial Intelligence in Healthcare Guidelines (AIHGle).

2021.10

7.11 ISO/IEC 22989:2022 Information technology — Artificial intelligence — Artificial intelligence concepts and terminology

7.12 ISO/IEC 23053:2022 Framework for Artificial Intelligence (AI) Systems Using Machine Learning (ML)

7.13 Office of the Government Chief Information Officer. Ethical Artificial Intelligence Framework Version 1.3. 2023.08

7.14 Samuel, A. L. (1959). Some studies in machine learning using the game of checkers. IBM Journal of research and development, 3(3), 210-229.