P3191

Type of Project: New IEEE Standard
Project Request Type: Initiation / New
PAR Request Date: 09 Jun 2022
PAR Approval Date: 21 Sep 2022
PAR Expiration Date: 31 Dec 2026
PAR Status: Active

1.1 Project Number: P3191
1.2 Type of Document: Recommended Practice
1.3 Life Cycle: Full Use

2.1 Project Title: Recommended Practice for Performance Monitoring of Machine Learning-enabled Medical Device in Clinical Use

3.1 Working Group: Machine learning-enabled medical device working group(EMB/Stds Com/MLMDWG)
3.1.1 Contact Information for Working Group Chair:
Name: Hao Wang
Email Address: drhw@foxmail.com
3.1.2 Contact Information for Working Group Vice Chair:
None
3.2 Society and Committee: IEEE Engineering in Medicine and Biology Society/Standards Committee(EMB/Stds Com)
3.2.1 Contact Information for Standards Committee Chair:
Name: Esteban Pino
Email Address: epino@ieee.org
3.2.2 Contact Information for Standards Committee Vice Chair:
Name: Hasan Al-Nashash
Email Address: hnashash@aus.edu
3.2.3 Contact Information for Standards Representative:
Name: Carole Carey
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4.1 Type of Ballot: Individual
4.2 Expected Date of submission of draft to the IEEE SA for Initial Standards Committee Ballot: Feb 2025
4.3 Projected Completion Date for Submittal to RevCom: Dec 2025

5.1 Approximate number of people expected to be actively involved in the development of this project: 50
5.2 Scope of proposed standard: The recommended practice describes a framework to monitor the performance of machine learning-enabled medical device (MLMD) in clinical use. The framework describes requirements, metrics, methods and procedures to implement performance monitoring.

5.3 Is the completion of this standard contingent upon the completion of another standard? No
5.4 Purpose: The purpose of this recommended practice is to define a framework that can be used by stakeholders to keep track of performance of MLMD in clinical use and provide information for post-market surveillance, technical vigilance and product changes.
5.5 Need for the Project: The MLMD industry is developing rapidly all over the world. Hundreds of products have been approved and applied in healthcare. Innovative and expanding use of machine learning techniques is met with rising public concern on its impact on product quality. For example, is the MLMD application as accurate and reliable in the real world as claimed by the manufacturer? Is there underlying algorithm discrimination for different groups of patients?
To protect the well-being of stakeholders and promote post-market regulation, it is important to understand how MLMD behaves in the clinical workflow and whether it continuously meets product expectations. A framework to monitor MLMD performance in clinical use is thus needed. Technical considerations include documentation, performance metrics, methodology, human-machine interaction, feedback collection and handling. Ethical consideration, such as algorithm fairness and transparency, also needs to be covered. The output of performance monitoring provides information for post-market surveillance, technical vigilance and product changes.

5.6 Stakeholders for the Standard: Regulators, manufacturers, clinical operators (for example, doctors, radiologists, nurses), patients, researchers, students.

6.1 Intellectual Property

6.1.1 Is the Standards Committee aware of any copyright permissions needed for this project?
No

6.1.2 Is the Standards Committee aware of possible registration activity related to this project?
No

7.1 Are there other standards or projects with a similar scope? No

7.2 Is it the intent to develop this document jointly with another organization? No

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8.1 Additional Explanatory Notes: