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Address: Medical Image and Signal Processing Research Center,

Isfahan University of Medical Sciences, Isfahan, Iran.

Email: jmss.mui@gmail.com AND jmss@mui.ac.ir

Tel: 0098 - 31 - 3792 - 3307

HTTP: jmssjournal.net



#### **Special Issue Invitation:**

In addition to regular paper submission to JMSS, we are happy to invite the authors to submit their papers to the following special issue:

**Special issue on** Al-Driven Development of Medical Devices: Evidence-Based Design and Clinical Efficacy Assessment

The integration of artificial intelligence (AI) into the design, development, and evaluation of medical devices has ushered in a new era of personalized and intelligent healthcare. With advancements in machine learning, deep learning, and real-time data analytics, medical devices can now provide dynamic support for diagnosis, monitoring, and therapeutic interventions. However, the translation of AI-based technologies into clinically effective medical devices requires rigorous evidence-based development and systematic clinical efficacy evaluation to ensure patient safety, reliability, and regulatory compliance. This special issue aims to explore the end-to-end pipeline of AI-enabled medical device innovation, from algorithm design and data integration to device prototyping, validation, and clinical deployment. Emphasis will be placed on clinical trial designs, real-world evidence (RWE), performance benchmarking, and health outcomes evaluation. Submissions that bridge the gap between computational innovation and clinical impact are especially welcome. As the demand for regulatory-grade AI medical devices continues to grow, so does the need for robust methodologies that can demonstrate clinical validity, utility, and cost-effectiveness. This special issue encourages contributions that provide insights into regulatory frameworks, humancenteredAI design, explainability, and multi-center validation of AI-driven devices across diverse clinical settings.

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#### Topics of inters:

- Potential topics include, but are not limited to:
- · Evidence-based frameworks for the development and validation of AI-powered medical
- · devices.
- · Real-world studies and clinical trials assessing clinical efficacy, safety, and usability of Alintegrated
- devices.
- Evaluation methodologies for AI algorithms embedded in diagnostic or therapeutic systems.
- Comparative studies between AI-enabled and conventional medical devices.
- Design and testing of wearable, implantable, or portable AI-assisted medical technologies.
- Human-AI interaction and clinical workflow integration of AI-powered devices.
- Regulatory considerations and approval pathways (e.g., FDA, CE) for AI medical
- technologies.
- Bias mitigation, fairness, and explainability in AI-driven medical device systems.
- Integration of multi-modal clinical data (e.g., imaging, biosignals, genomics) into intelligent
- device platforms.
- Economic evaluation and health technology assessments (HTA) of AI medical devices.

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#### **Guest Editors:**

Prof. Dr. Kelvin KL Wong,

PhD, FIEAust, FZaAS, SMIEEE

Department of Mechanical Engineering, University of Saskatchewan, Saskatoon, Canada.

E-mail: <a href="mailto:kelvin.wong@usask.ca">kelvin.wong@usask.ca</a>
Email: <a href="mailto:kelvin.wong@ieee.org">kelvin.wong@ieee.org</a>

Prof. Dr. Adrian David Cheok, PhD, AM FIET, FIEAust, FRSA

The Imagineering Institute, Lebuh Medini Utara Iskandar Puteri Johor, Malaysia.

**E-mail:** adrian@imagineeringinstitute.org

Prof. Dr. Dhanjoo N. Ghista

University 2020 Foundation, Northborough, MA, USA.

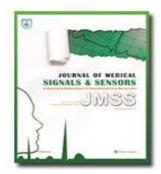
E-mail: d.ghista@gmail.com

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#### Important Dates:

✓ Submission deadline: March 31, 2026
✓ Author notification: May 31, 2026
✓ Revised papers due: June 30, 2026
✓ Final notification: July 30, 2026

✓ The Publication of the special issue will as per the policy of journal

The authors should register in <a href="https://review.jow.medknow.com/jmss">https://review.jow.medknow.com/jmss</a> to submit their work to JMSS. It's a self-explanatory and simple two-step process.

**NOTE:** Authors should mention in the cover letter which special issue their article is related to.