International Journal of Computer Information Systems and Industrial Management Applications
ISSN 2150-7988 Volume 18(20s) 2026 pp. 290-311
https://doi.org/10.70917/ijcisim-2026-5181
Article

Intelligent Medical Devices and Healthcare Management: Advances in Mechanical Engineering and Artificial Intelligence

Dr. G. Jagan Naik[1], Dr.Burla Srinivas[2],Dr. A. Vijendar[3],Jupaka Rajyalaxmi[4],Bhukya Madhu[5],Dr.Kontham Sridhar[6]

[1]Associate Professor,Department of CSE, CMR Institute of Technology-HYDERABAD-501401, gjnaik1106@gmail.com
[2]Associate Professor, Dept of CSE(AI &ML), CMR Institute of Technology, Kandlakoya, Medchal, Hyderabad -501401,Telangana, India. drburlasrinivas@gmail.com
[3]CMR Engineering College mgothu.vijendar@gmail.com
[4]Assistant professor,Dept of CSE,JNTUHUCEM,PANNUR,TELANGANA-505212,INDIA., rlaxmi2505@gmail.com
[5]Associate Professor, Department of CSE,Malla Reddy (MR) Deemed to be University, Hyderabad, Telangana, India -500100. madhu0525@gmail.com
[6]Associate Professor, Dept of CSE, Mother Theressa college of engineering and technology, Peddapally,pincode:505172 ,Telangana,India, sridharkontham@gmail.com

Abstract: The innovations in mechanical engineering, artificial intelligence, sensing, robotics, Internet of Things (IoT) and healthcare information systems are rapidly converging to revolutionize the design and management of modern medical devices. In a nutshell, the traditional medical devices have been transformed step by step from passive mechanical devices to intelligent cyber-physical devices that can sense physiological states, process multimodal information, assist the doctor in making clinical decisions, and adjust to the patient's needs. This review explores the latest developments of intelligent medical devices from an interdisciplinary point of view, focusing on mechanical design, artificial intelligence, machine learning, the digital twin, wearable systems, robotics, predictive maintenance, remote healthcare and healthcare management. The review brings together the contributions of mechanical engineering to provide reliable structures, actuation mechanisms, biomedical materials, ergonomic systems, microfluidic technologies, rehabilitation robots, and minimally invasive technologies, and explores how AI can support perception, prediction, personalization, anomaly detection, decision support and autonomous operation. Focus is paid to AI-based medical devices, digital-twin medical equipment management, AI-driven wearable systems, robotic healthcare technologies, and AI-driven medical equipment data-driven maintenance. Challenges with data quality, interoperability, cyber security, explainability, model drift, regulatory compliance, human factors, clinical validation are critically discussed. It is suggested to introduce a conceptual intelligent medical-device ecosystem comprising both physical devices and edge/cloud computing, AI analytics, digital twins, healthcare management platforms, and human oversight. The review recommends that future intelligent healthcare systems should shift from smart devices to trustworthy, interconnected, adaptive and patient-centric cyber-physical ecosystems. The research directions identified open up avenues for creating safer, more explainable, energy efficient, personalised, and clinically deployable intelligent medical technologies.
Keywords: Intelligent medical devices; artificial intelligence; machine learning; mechanical engineering; healthcare management; digital twins; medical robotics; wearable devices; IoT; predictive maintenance; clinical decision support

1. INTRODUCTION

The field of healthcare is undergoing a paradigm shift in technology that involves the merging of artificial intelligence (AI), cutting edge mechanical engineering, Internet of Things (IoT), robotics, cloud computing, sensors, additive manufacturing, and data analytics. Medical devices that had previously been mechanical or electronic devices with a given mechanical or electronic function are now increasingly becoming intelligent systems that can sense, communicate, learn and aid decision making. This shift is especially significant as healthcare systems evolve, demand real-time monitoring, individual care, early detection, optimized resource use, and enhanced handling of complex medical facilities. The creation of an intelligent medical device is an interdisciplinary issue. The physical shape, materials, mechanisms, actuation, fluidics, ergonomics, thermal management, structural reliability, and manufacturability of medical systems are delivered by mechanical engineering. Artificial intelligence brings computational power to explain what is being detected by the sensors, to identify patterns, recognize future states of the patient or device, detect anomalies, optimize operation of the device, and assist in clinical decision-making. This synergy results in a cyber-physical medical system in which the physical system and the computational intelligence are linked elements. The latest advancements are illustrative of the accelerating evolution of AI-powered medical devices. A study using public data conducted in 2024 found hundreds of FDA-approved medical devices that leverage AI/ML, and indicated that there has been a significant rise in approvals since 2018, with one area of particular interest being radiology [1]. This trend marks the shift from experimental algorithms for artificial intelligence to controlled medical technologies. But more rollouts mean greater demands for validation, transparency, cybersecurity, post-market tracking and human oversight. Another development that is significant is digital twin technology. A digital twin for a patient or a medical device, a physiological process or a healthcare operation can exist in a virtual world and continuously be updated with real-world data. However, recent reviews suggest that digital twins in healthcare could help in personalized medicine, treatment planning, remote monitoring, device design, hospital management and simulation [2–4]. However, the field is still in its infancy and important issues such as data quality, biological heterogeneity, interoperability, verification, validation, uncertainty, privacy and regulatory acceptance have yet to be addressed. Wearable sensors and remote monitoring are also becoming integral parts of intelligent medical devices more and more. Physiological Parameters like heart rate, blood oxygen saturation, temperature, motion, electrocardiography, electroencephalography, pressure and biochemical measurements can be taken continuously. These streams can be turned into clinically useful indicators using AI algorithms. It's a chance to shift the paradigm from simple monitoring to proactive and predictive care. Mechanical engineering is also a critical role in this transition. Reliable mechanical structures, miniaturized components, compliant mechanisms, soft robotics, microfluidic channels, precision actuators, biomedical implants, prostheses, rehabilitation devices, surgical robots, and ergonomic wearable structures are all essential for intelligent medical systems. Challenges in sensor placement, mechanical stability, vibration, and sterilization, as well as the interaction between humans and the device, are beyond the capabilities of any AI model. Thus, the focus of this review is the convergence of mechanical engineering and AI for creating intelligent medical devices and health care management. The review is based on five key questions:

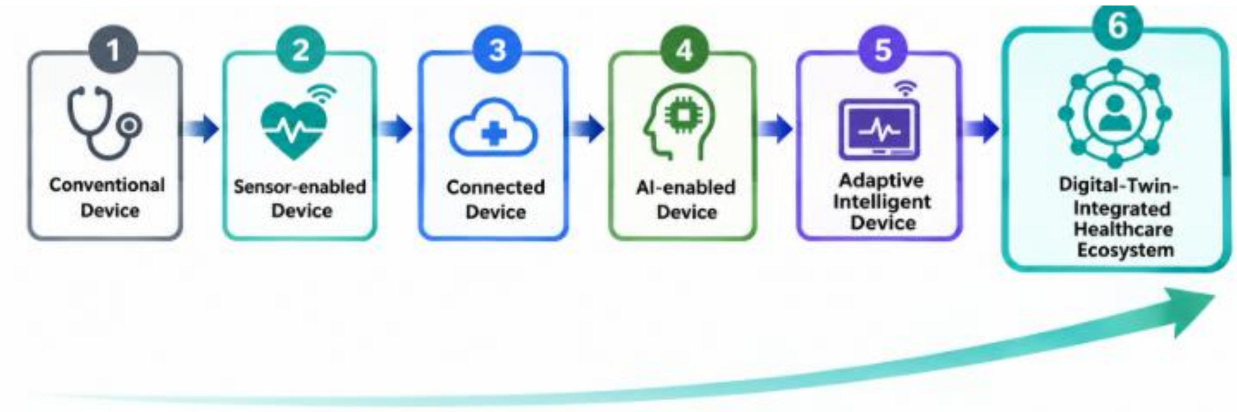
1. In what ways are mechanical engineers helping to make medical devices more intelligent?
2. How AI and machine learning are changing the game of sensing, diagnosis, prediction, control and management?
3. What roles do IoT, edge computing, cloud platforms, and digital twins play in connected medical systems?
4. What are the key technical, clinical, ethical, cybersecurity and regulatory issues?
5. How can future intelligent medical-device ecosystems be developed using a research architecture?

2. EVOLUTION OF MEDICAL DEVICES TOWARD INTELLIGENT HEALTHCARE SYSTEMS

2.1 From Conventional Devices to Cyber-Physical Medical Systems

In most cases a medical device will have a known function when it is conventional. They range from mechanical ventilators, infusion pumps, prosthetic limbs, surgical tools, wheelchairs, blood pressure monitors and diagnostic equipment. Such systems may be electronic controlled but they sometimes have limited operational intelligence. The next generation of devices combines sensors, processors, wireless communication and software. Such systems may gather physiological and/or mechanical data and pass it on to a local or remote computing system.

The evolution can be summarized as:



This progression changes the design philosophy. Engineers are not designing a physical product; they're designing a physical-digital product.

2.2 Intelligent Medical Devices as Cyber-Physical Systems

An intelligent medical device can be represented as five interconnected layers:

1. Physical/mechanical layer
2. Sensing and data-acquisition layer
3. Communication and computing layer
4. AI and decision layer
5. Healthcare management and human-interaction layer

The mechanical functionality is the function of the physical layer. States of patients or devices are measured by sensors. Communication infrastructure conveys information. The data is fed into AI models for analysis. Finally, the information generated is used by healthcare professionals or automated controllers.

Figure 1. Evolution of Intelligent Medical Devices

This evolution highlights the increasing importance of interoperability between mechanical and computational components.

3. ROLE OF MECHANICAL ENGINEERING IN INTELLIGENT MEDICAL DEVICES

3.1 Mechanical Design and Structural Reliability

The principles of mechanical engineering are the backbone of safe operation of medical devices. Medical devices face many complex loading, vibration, temperature, sterilization, fluid and direct human interaction requirements. Before actual production, the performance of the device can be assessed using finite element analysis (FEA), computational fluid dynamics (CFD), topology optimization, and computer-aided engineering. Such methods save the cost of prototyping and optimize the characteristics of weight, stiffness, strength, thermal and fluid flow. For instance, the rehabilitation robots need mechanical structures that can produce controlled forces while still ensuring safe interaction with the patients. Likewise, the mechanical properties of wearable devices need to be strong, yet flexible and comfortable.

3.2 Biomedical Materials and Additive Manufacturing

The design possibilities for medical devices has grown with the introduction of advanced materials. Use of polymers, ceramics, metals, hydrogels, composites, shape-memory materials and bio-compatible materials is possible depending on the medical needs. Patient-specific geometries can also be achieved by additive manufacturing. Three dimensional printing can now create a wide variety of "customized" prostheses, surgical guides, orthotic devices, anatomical models, and components with complex internal structures. In particular, the mobile combination of additive manufacturing and AI is worth noting. Geometric structure can be optimized by using AI to meet patient-specific needs, and mechanical simulation can analyze the optimized geometric structure.

3.3 Microfluidic and Lab-on-Chip Systems

Another significant area of mechanical engineering and healthcare where microfluidics comes into play is in devices for microsurgical operations. Very small amounts of biological fluids can be manipulated in miniaturized channels for diagnostic or biochemical analysis.

Intelligent microfluidic systems can be integrated with:

- Sample preparation
- Fluid transport
- Chemical sensing
- Optical detection
- Electronic sensing
- AI-based classification
- Wireless communication

The microchannel geometry, pressure management, fluid dynamics, packaging and manufacturability are provided by mechanical engineering, while AI will be used to analyze the patterns of the sensors to identify biochemical conditions.

3.4 Wearable and Soft Medical Devices

Mechanical structure must be both flexible and lightweight to be applied to wearable healthcare systems. Rigid electronics like traditional electronics cause discomfort when worn around the body for extended periods of time. Soft materials and flexible structures can enhance skin conformability, decrease mechanical interference. There are also opportunities for rehabilitation, prosthetics, assistive devices and human-machine interfaces in soft robotics. AI can adapt control strategies according to patient movement and physiological feedback.

3.5 Surgical and Rehabilitation Robotics

One of the most promising areas of AI and mechanical engineering is robotic medical systems. The mechanical aspects offer precise positioning and controlled movement, while AI can aid in perception, trajectory planning, tissue recognition, and adaptive control. Robotic exoskeletons can be used to help patients during rehabilitation based on their movements and forces measured. AI algorithms can predict patient intent and adaptively provide patient support. Medical robotics, however, has to be kept under strict safety constraints. Medical robots interact directly with fragile human beings, while the industrial robots are not directly subjected to human beings and are used in restricted environments. Mechanical fail-safe devices, multiple sensors, emergency stops, limiting forces and human monitoring must be retained as essential.

4. ARTIFICIAL INTELLIGENCE IN INTELLIGENT MEDICAL DEVICES

4.1 Machine Learning

Machine learning (ML) allows devices to learn the relationship between the data instead of depending only on manually configured rules. Abnormal physiological patterns may be classified, continuous variables may be estimated through regression models and deviations from normal behavior may be detected by anomaly-detection algorithms. Commonly used ML techniques are:

- Logistic regression
- Decision trees
- Random forests
- Support vector machines
- Gradient boosting
- XGBoost

- K-nearest neighbors
- Neural networks

When datasets are relatively small and features can be engineered from a physiological or a mechanical signal, traditional ML can be particularly useful.

4.2 Deep Learning

Deep learning is increasingly used for complex medical data. CNNs are suitable for image-based analysis, RNNs and LSTMs are suitable for temporal signals, and the transformer architectures offer powerful sequence and multimodal learning capabilities.

Potential applications include:

- Medical-image analysis
- ECG interpretation
- EEG analysis
- Respiratory monitoring
- Activity recognition
- Skin-condition assessment
- Device fault detection
- Surgical-image interpretation

One of the major benefits of deep learning is the automatic feature learning. This normally needs more data and verification.

4.3 Explainable Artificial Intelligence

Physicians and health care professionals should know the rationale behind a system's recommendations. Interpretable evidence can be provided through methods of explainable AI (XAI), including: SHAP, LIME, feature attribution, saliency maps, and counterfactual explanations. Rather than providing just the information above: 87% is the risk of abnormal condition. an intelligent system could indicate: Abnormal heart-rate variation, trend in oxygen saturation and changes in respiratory rate were the major factors that drove the prediction. Explainability becomes crucial when the impact of AI decisions is on clinical health. Integrating Generative AI and Foundation Models.

4.4 Generative AI and Foundation Models

Healthcare management is encountering new opportunities with the advent of Generative AI. Large language models (LLMs) and multimodal foundation models (MMFMs) can combine clinical notes, sensor data, images, reports, and structured data.

Potential applications include:

- Clinical report generation
- Medical-device troubleshooting
- Patient communication
- Decision-support interfaces
- Knowledge retrieval

- Device maintenance assistance
- Multimodal medical-data interpretation

The use of generative AI, however, comes with its own set of challenges, including the potential for hallucination, lack of consistency, privacy issues, and unpredictable behavior. Thus, it is necessary to robustly validate and monitor its application in high-risk medical environments.

5. INTELLIGENT SENSING AND WEARABLE MEDICAL DEVICES

Wearable devices are one of the significant channels for continual monitoring of healthcare. Physiological signals can be collected from the sensors without the need to make frequent visits to the hospital.

Examples include:

Sensor	**Typical Measurement**	**Potential Application**
ECG	Electrical cardiac activity	Cardiac monitoring
PPG	Blood-volume changes	Heart rate, oxygen-related monitoring
Temperature	Body temperature	Fever monitoring
Accelerometer	Motion	Fall detection, rehabilitation
Gyroscope	Orientation	Movement analysis
EEG	Brain electrical activity	Neurological monitoring
Pressure sensor	Force/pressure	Gait and rehabilitation
Biochemical sensor	Biomarkers	Point-of-care monitoring

AI can combine these signals to create a multimodal representation of patient status.

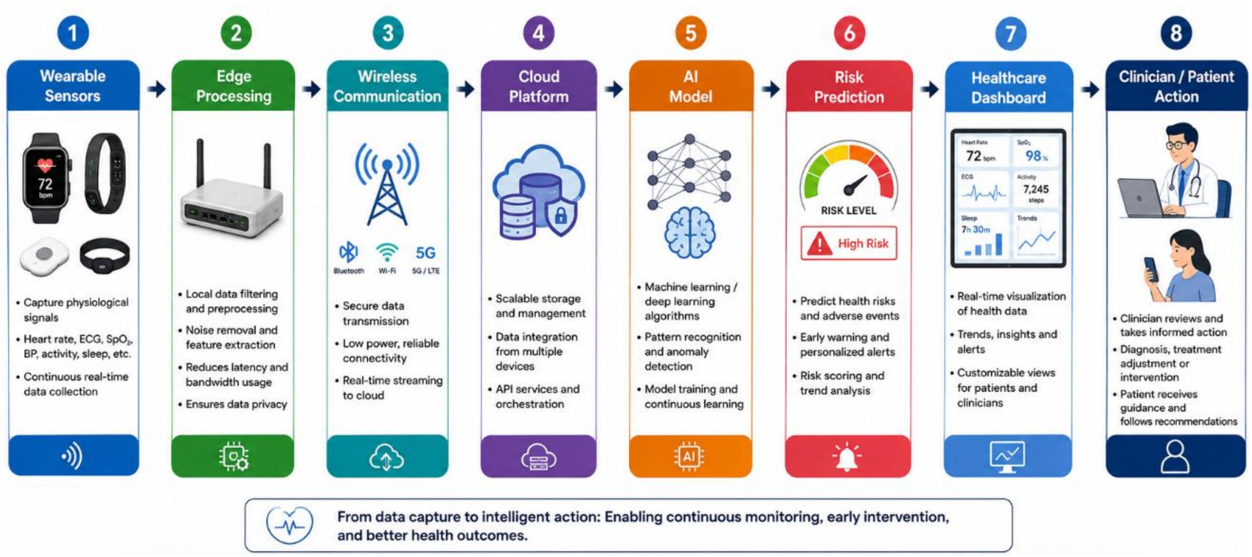


Figure 2. AI-Enabled Wearable Healthcare Architecture

The major research challenge is reliable operation outside laboratory environments. AI performance can be significantly impacted by motion artifacts, sensor displacement, environmental conditions, battery constraints and missing data.

6. EDGE AI, CLOUD COMPUTING AND IOT IN HEALTHCARE

6.1 Internet of Medical Things

Internet of Medical Things (IoMT): It is a network of all medical devices, sensors, healthcare systems, and computing systems. An IoMT ecosystem could include:

- Wearable devices
- Hospital equipment
- Patient monitors
- Smart beds
- Medical robots
- Diagnostic devices
- Mobile applications
- Cloud platforms

This can result in large amounts of data, which may necessitate data processing and communication that can be scaled up to meet the demands. This can generate significant amounts of data, leading to the need for scalable data processing and secure communication.

6.2 Edge AI

The benefits of cloud computing are significant resources, however, frequent data transfer of sensitive health information can introduce delays and privacy concerns. Edge AI solves this problem by running the data closer to the device.

Advantages include:

- Reduced latency
- Lower bandwidth consumption
- Faster responses
- Improved privacy
- Greater resilience during network interruption

Improved ability to manage network disruption events. Increased resilience during network disruption events.

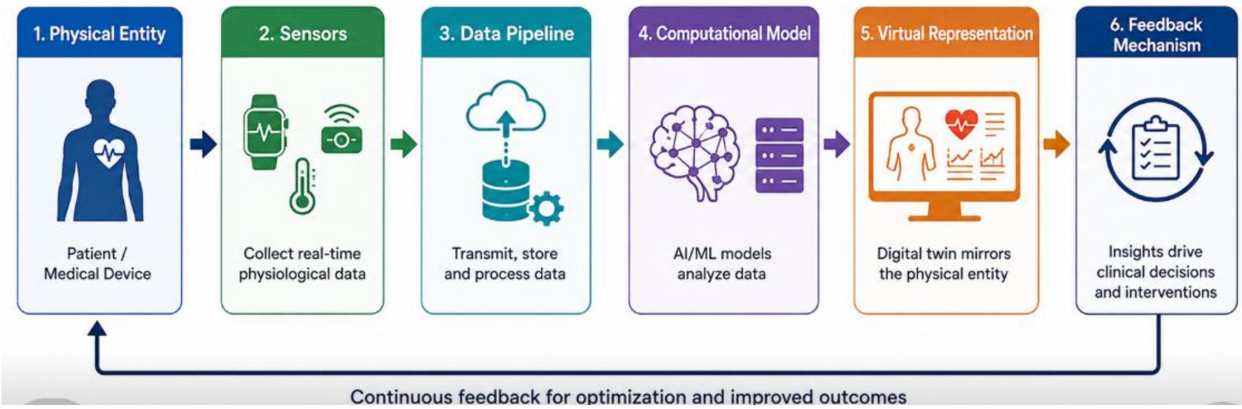
6.3 Cloud-Based Healthcare Management

Information from various devices and healthcare departments can be integrated into cloud platforms. This facilitates centralized dashboards, population-based analytics, equipment management, remote monitoring and clinical decision support. But the challenges of authentication, encryption, access control, auditability, data ownership and regulatory compliance must be overcome by cloud healthcare systems.

7. DIGITAL TWINS FOR INTELLIGENT MEDICAL DEVICES AND HEALTHCARE MANAGEMENT

Digital twins have become a key technology in linking physical systems with virtual systems. In healthcare, they can be patient or organs, medical devices, hospital processes, or even healthcare ecosystems [2–5].

A digital twin typically involves:



Recent reviews highlight the possible applications in Personalized Medicine, Clinical Decision Support, Treatment Planning, Remote Monitoring, Medical-Device Design, and Hospital Management [2-4].

7.1 Medical Device Digital Twins

A medical-device digital twin would be able to constantly track the physical device and make an estimate of how it's working on the inside. For example: Data from sensors is used to update a physical ventilator in the field via a digital twin, which then uses AI to generate a maintenance recommendation. The twin can be able to detect degradation before catastrophic failures happen.

7.2 Patient Digital Twins

Patient digital twins seek to characterise a patient's physiological condition based on multimodal data including medical imaging, laboratory data, clinical data, wearable sensors, and physiological data. Long-term vision is the simulation and prediction of personalized. The literature suggests that many systems so far presented as health-care DTs are not completely within the scope of strict DTs definitions that are characterized by personalization, dynamic updating, prediction and meaningful interaction with the physical counterpart [6]. This separation will be important for future studies.

7.3 Digital Twins for Healthcare Management

A digital twin can also be a representation of hospital operations.

Possible applications include:

- Patient-flow optimization
- Operating-room planning
- Medical-equipment utilization
- Energy optimization
- Staff allocation
- Emergency-department simulation
- Maintenance planning
- Infection-control simulation

This creates a bridge between medical engineering and industrial management.

8. AI-BASED PREDICTIVE MAINTENANCE OF MEDICAL EQUIPMENT

Failure of medical equipment can affect clinical services and pose a potential safety hazard. Typical maintenance approaches are enacted on a time basis. Predictive maintenance, on the other hand, takes equipment data to predict the probability of failure. Possible sensor inputs are:

- Vibration
- Temperature
- Motor current
- Pressure
- Acoustic signals
- Operating cycles
- Error logs
- Component age
- Maintenance history

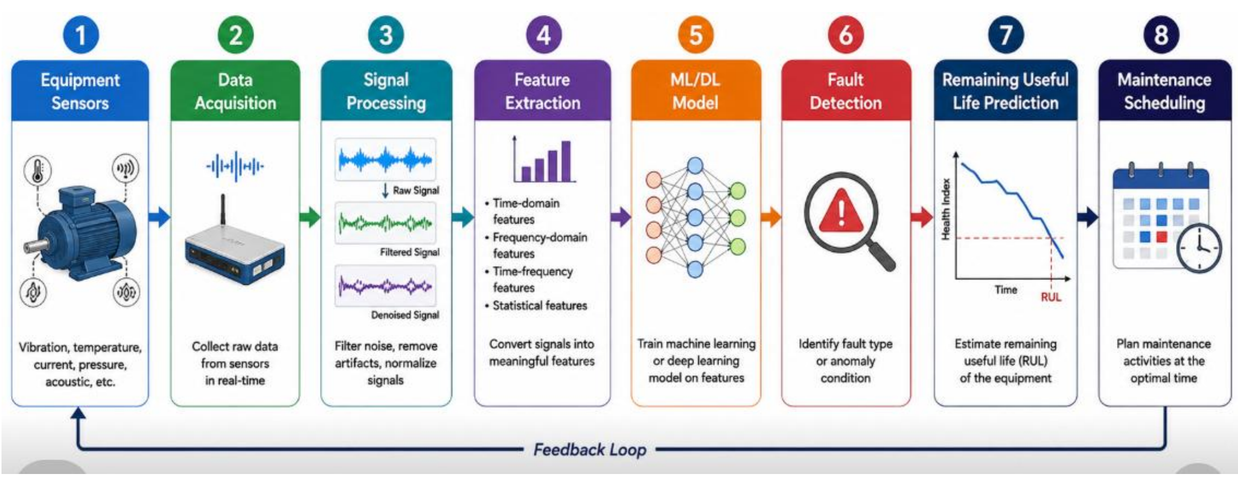
Machine learning can estimate:

Probability of failure

or

Remaining useful life (RUL).

Figure 3. AI-Based Predictive Maintenance Framework



This can help minimize unwanted maintenance and increase equipment availability. But for medical facilities, mandatory safety inspections should not be replaced by predictive maintenance. AI predictions should augment existing engineering and regulatory processes.

9. INTELLIGENT ROBOTICS IN HEALTHCARE

The medical robots involve surgical robots, rehabilitation robots, assistive robots, hospital logistics robots, robots prostheses, and exoskeletons.

9.1 Surgical Robotics

A surgical robot offers precision, stability and better control of instruments. AI can aid in image interpretation, navigation in surgery, tissue identification, and motion analysis. The closest the current near-term application of AI is to free hands-on surgery is to make decisions and sense perceptions.

9.2 Rehabilitation Robotics

Rehabilitation robot can measure the patient's movements and provide controlled assistance.

AI can estimate:

- Movement intention
- Muscle fatigue
- Gait quality
- Recovery progress
- Assistance requirements

The mechanical assistance can then be adjusted in an adaptive manner.

9.3 Assistive and Social Robots

Robots can assist the elderly age and patients with limited mobility. They can help remind, navigate, move things around, communicate and monitor. The engineering challenge is safe physical interaction. The core of AI challenge is the ability to comprehend human intent and behavior.

10. INTELLIGENT HEALTHCARE MANAGEMENT

Healthcare management is a process that is not limited to diagnosis and treatment. Beds, operating rooms, equipment, supplies, energy and people are all resources that must be managed in hospitals.

AI can support:

- Patient-flow prediction
- Bed allocation
- Appointment scheduling
- Staff scheduling
- Equipment utilization
- Inventory forecasting
- Emergency-resource allocation
- Hospital energy management
- Predictive maintenance
- Remote monitoring

For instance, a hospital digital twin can get real-time data from medical equipment connected to it, and forecast demand. Managers can then create alternative allocation strategies and test them out in simulation before making them a reality. This is a significant change: Device intelligence, departmental intelligence, hospital intelligence and healthcare-system intelligence.

11. SECURITY, PRIVACY AND TRUST

This growing networked connectivity of medical devices and devices is also accompanied by a corresponding rise in cybersecurity risk.

Threats may include:

- Unauthorized access
- Malware
- Data theft
- Device manipulation
- Ransomware
- Sensor spoofing
- Model poisoning
- Adversarial attacks
- Denial-of-service attacks

A medical device is susceptible to physical consequences from an attack. Thus, it is best to think about cyber security from pre-deployment, and not post-deployment.

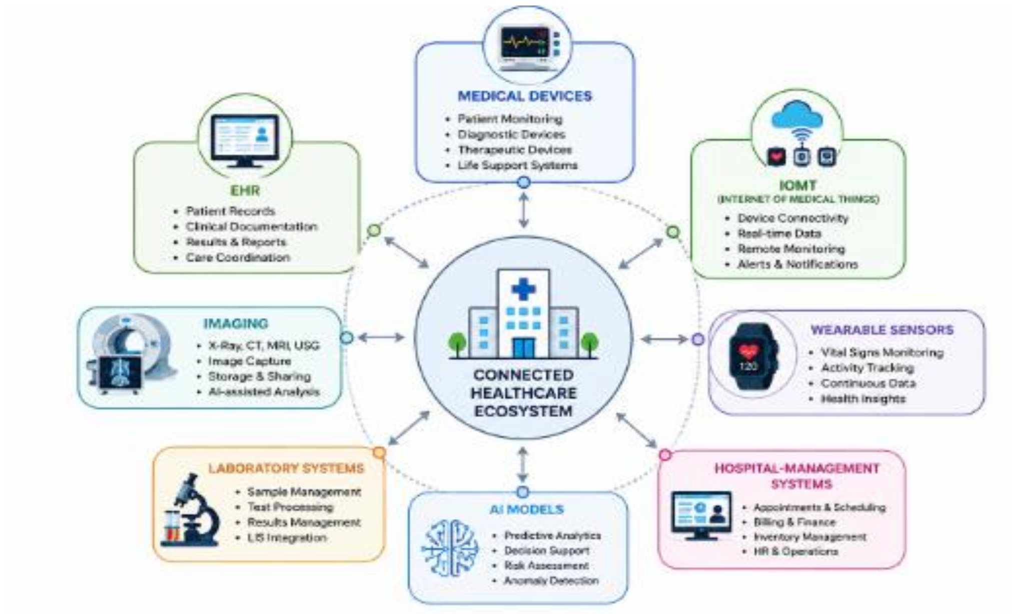
Potential safeguards include:

1. Strong authentication
2. Encryption
3. Role-based access control
4. Secure firmware
5. Device identity management
6. Network segmentation
7. Intrusion detection
8. Secure model updates
9. Audit logging
10. Continuous security monitoring

Anomaly detection is one way that AI can aid in cybersecurity. AI models can also be targets for attacks, though.

12. INTEROPERABILITY AND DATA INTEGRATION

Healthcare Data comes from a variety of (heterogeneous) sources. Medical devices can have various communication protocols, data formats, sampling rates, and metadata standards. It is thus vital that there is interoperability. Some of the necessary elements for an intelligent healthcare platform in the future are:



Technical interoperability is a prerequisite for FHIR and other healthcare interoperability standards to enable healthcare information exchange; however, technical interoperability is not enough.

13. REGULATORY AND ETHICAL CONSIDERATIONS

Medical devices powered by AI pose new regulatory hurdles, as software can change after the device is in use. Standard mechanical testing can be used for checking the performance of a conventional mechanical device against the stipulated performance requirements. An adaptive AI system could alter how it behaves in the face of changing distributions of data.

Important issues include:

- Algorithmic bias
- Dataset representativeness
- Model drift
- Explainability
- Clinical validation
- Human oversight
- Software updates
- Post-market surveillance
- Cybersecurity
- Patient consent
- Data privacy

In a recent review of FDA-cleared AI/ML medical devices in 2024, the authors also noted a fast expansion of the field and that there were gaps in clinical evidence, particularly regarding representativeness in terms of geography and demographics [1]. Regulatory landscape is continuing to change. In 2026, FDA has been studying new methods of assessing medical devices with adaptive and generative AI capabilities, demonstrating the challenges of using traditional medical-device assessment methods for adaptive- and generative-AI systems [7]. Thus, research in the future with intelligent medical devices needs to incorporate regulatory requirement into the research engineering design process.

14. HUMAN FACTORS AND EXPLAINABLE HEALTHCARE AI

Technological performance does not guarantee clinical usefulness. A medical device may work well with a high accuracy percentage, but lack classification if the healthcare personnel are not familiar or confident in it. Human-centered design should take into account:

- Usability
- Cognitive workload
- Alert fatigue
- Interpretability
- Accessibility
- Training requirements
- Workflow integration
- User confidence

Explanations of AI should thus be tailored to the decision context. For instance, a nurse watching patients might only need a short alert and trending view, whereas a biomedical engineer might require extensive details on the device. This means that explainability should not be considered as an algorithmic property only. This should be regarded as being a problem in human-computer interaction.

15. SUSTAINABILITY AND ENERGY EFFICIENCY

Sensors, edge processors, cloud systems, batteries, and electronic hardware are key components of intelligent healthcare systems that are becoming a growing necessity. Energy use is thus a key design factor.

Potential approaches include:

- Low-power sensors
- Energy-efficient AI models
- Model compression
- Quantization
- Edge processing
- Energy harvesting
- Adaptive sampling
- Lightweight communication protocols

Moreover, medical device sustainability needs to take into account the full life cycle: Design – Manufacture – Deployment – Maintenance – Sterilisation – Re-use – Disposal. Digital technologies can assist in this lifecycle by forecasting equipment failures, optimizing maintenance and avoiding unnecessary equipment replacement. Recent research on the application of digital technologies in medical devices has focused on opportunities around digital twins, extended reality, manufacturing, sterilisation, supply chains, sustainability, and circularity [8]. The proposed Integrated Framework for Intelligent Medical Devices is shown below. By analyzing the analyzed technologies, the authors propose a five-layer intelligent medical-device framework.

16. PROPOSED INTEGRATED FRAMEWORK FOR INTELLIGENT MEDICAL DEVICES

Based on the reviewed technologies, this paper proposes a five-layer intelligent medical-device framework.

Layer 1: Physical and Mechanical Layer

Components:

- Mechanical structure
- Biomedical materials
- Actuators
- Microfluidics
- Robotics
- Wearable structures

Layer 2: Sensing Layer

Components:

- Physiological sensors
- Motion sensors
- Environmental sensors
- Device-condition sensors
- Imaging sensors

Layer 3: Connectivity and Computing Layer

Components:

- Embedded processors
- Edge AI
- IoT gateways
- Wireless communication
- Cloud infrastructure

Layer 4: Intelligence Layer

Components:

- ML
- Deep learning
- Transformer models
- Explainable AI
- Anomaly detection
- Predictive maintenance

- Digital twins

Layer 5: Healthcare Management Layer

Components:

- Clinical dashboard
- Decision support
- Patient monitoring
- Hospital management
- Maintenance planning
- Alerts
- Human oversight

Figure 4. Proposed Intelligent Medical Device Ecosystem

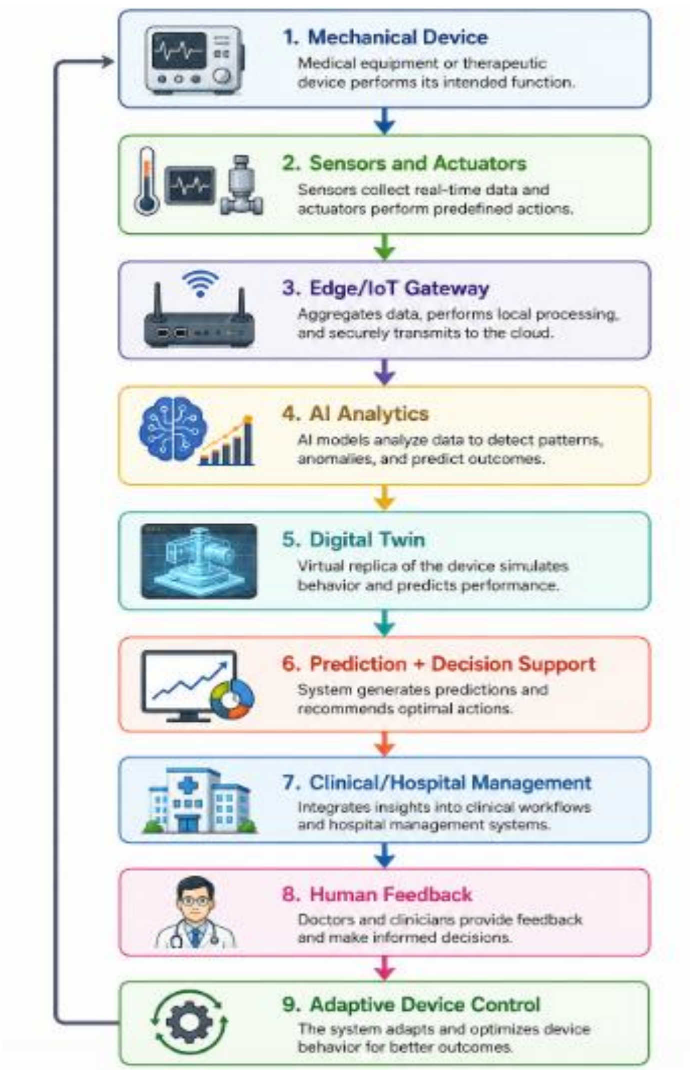


Figure 4. Proposed Intelligent Medical Device Ecosystem

The feedback loop is critical. Information should not just be transferred to the healthcare platform, but validated decisions should be able to transfer to the operation of the device.

17. COMPARATIVE ANALYSIS OF INTELLIGENT MEDICAL TECHNOLOGIES

Technology	Main Function	AI Contribution	Mechanical Engineering Contribution	Major Challenge
Wearable devices	Continuous monitoring	Pattern recognition and prediction	Flexible structures and ergonomics	Motion artifacts
Surgical robots	Precision intervention	Perception and decision support	Actuation and mechanical precision	Safety
Rehabilitation robots	Patient assistance	Adaptive control	Exoskeleton and mechanism design	Human-robot interaction
Microfluidic devices	Point-of-care testing	Signal interpretation	Fluid control and channel design	Miniaturization
Smart prostheses	Functional replacement	Intent recognition	Mechanical actuation	Personalization
Medical digital twins	Simulation/prediction	Predictive analytics	Device/system modeling	Validation
Predictive maintenance	Equipment reliability	Fault prediction	Mechanical condition monitoring	Data availability
IoMT systems	Connected healthcare	Multimodal analytics	Sensor integration	Cybersecurity
AI imaging devices	Diagnosis support	Image classification/segmentation	Imaging hardware	Explainability
Hospital digital twins	Operational optimization	Forecasting and simulation	Facility/system modeling	Interoperability

18. MAJOR RESEARCH GAPS

The literature shows some significant gaps in the research.

18.1 Lack of Fully Integrated Physical-Digital Systems

Numerous research projects have concentrated on either the mechanical device or the AI algorithm. Not many systems combine mechanical design, sensing, AI, digital twins, Cyber security and healthcare management onto a unified system architecture.

18.2 Limited Real-World Validation

What is good in the laboratory doesn't necessarily translate to what is good in the clinical environment. When it comes to real-world deployment, data is missing, demographics vary, and sensors can be imperfect, workflows limited, and devices vary.

18.3 Insufficient Explainability

There are many AI systems that are hard to interpret for clinicians and engineers. So, explainability needs to be built-in at design time.

18.4 Limited Digital-Twin Verification

While many healthcare systems have been studied, the rigorous verification, validation and uncertainty quantification are still not sufficiently discussed, as shown in [6].

18.5 Security-Performance Trade-Off

Security mechanisms can introduce computational overheads, latency and energy costs. Concurrently optimizing medical-device performance and security requires research.

18.6 Limited Multimodal Integration

Systems in the future will require to combine physiological, mechanical, environmental, imaging and contextual information.

18.7 Lack of Standardized Evaluation

There is no standardization in the evaluation. Standards are needed for:

- AI accuracy
- Clinical utility
- latency
- energy consumption
- reliability
- cybersecurity
- explainability
- usability
- mechanical performance

19. FUTURE RESEARCH DIRECTIONS

19.1 Multimodal AI

With the growing use of intelligent medical devices, the combination of multiple data modalities is becoming more common in the future. Physiological signals, picture, text, device data, and contextual information can be used together in the multimodal models.

19.2 Federated Learning

Federated learning can allow for multiple hospitals or devices to work together and train models without sharing raw patient information. This is especially important for healthcare as privacy constraints can hinder the collection of data at the central level.

19.3 Edge-Cloud Collaborative Intelligence

A hybrid approach can move latency-sensitive processing to the edge and scale large training models and perform long-term analytics in the cloud.

19.4 AI-Integrated Digital Twins

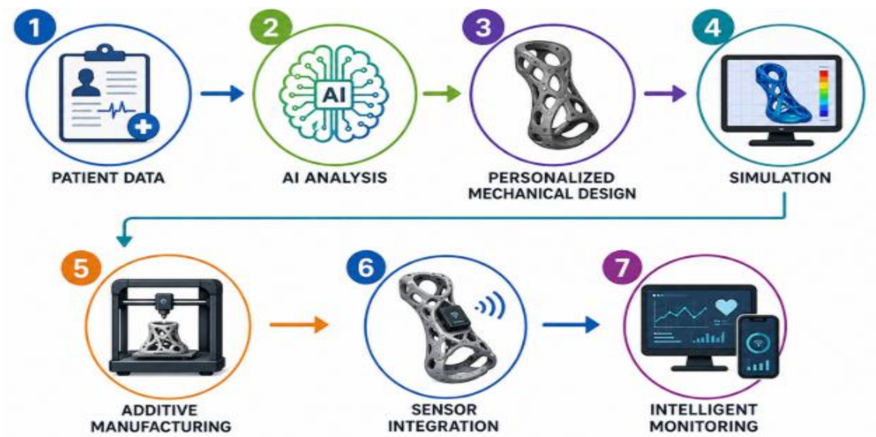
Digital twins can transform from visualization tools to predictive systems that can simulate device and patient response. AI combined with digital twins is expected to be a key research area for precision healthcare in the future [2–5].

19.5 Autonomous and Semi-Autonomous Medical Systems

There will be more and more systems capable of limited autonomous functions in the near future. But, gradually such autonomy should be introduced with proper safety conditions and human supervisions.

19.6 Personalized Medical Devices

Patient-specific medical devices can be realized with the help of AI and additive manufacturing. In the future, one possible work flow would consist of:



This will be a significant interdisciplinary research opportunity.

19.7 Generative AI for Medical Engineering

Generative AI has the potential to help engineers with the following:

- Device concept generation
- Design optimization
- Technical documentation
- Failure analysis
- Maintenance support
- Simulation scenario generation

But designs need to be routinely engineered before clinical use.

20. DISCUSSION

When mechanical engineering and AI converge, it's one thing that changes the notion of a medical device. A device is becoming more connected, intelligent and than just a physical product. Mechanical engineering is still very much relevant because healthcare is ultimately concerned with physical objects, materials, forces, fluids, movement and biological tissues. AI can't take the place of mechanically reliable, clinically safe devices. Instead, AI adds a computational intelligence layer capable of interpreting complex information and adapting system behavior.

In the same way, AI scientists must become familiar with the constraint of physical systems. These factors can directly impact AI performance, such as sensor noise, mechanical vibration, temperature, manufacturing tolerances, calibration errors, and human-device interaction. So comes an important principle:

How well an intelligent medical device performs depends on the interplay between mechanical durability, sensitivity of the sensors, computational intelligence, and clinical workflow.

Digital twins can offer a potentially powerful link in this domain. A digital twin can be associated with physical-device behavior and computational simulation and predictive analytics. The technology could also be used in healthcare to assist in patient care, medical-device lifecycle management, and hospital operations. Digital twins should not be seen as a visualisation tool, though. A good digital twin in healthcare needs to be personalized, dynamic, predictive, well-validated, and uncertain. Recent reviews have pointed out that the field of digital-twin healthcare is still in its infancy and that numerous digital twins that are said to exist do not currently meet all the strict definitions of a true digital twin [5,6]. Another central issue is trust. hat's not a fair measure of medical AI. A model may be poorly suitable for clinical use if it is accurate but not well calibrated, if external validation data is limited, or if the errors are not explained. Future research should thus report more than one aspect of performance. A comprehensive evaluation framework should include:

Also, the healthcare industry should go toward lifecycle-based intelligence. AI can not only assist in diagnosis during the treatment phase, but also be used to aid in the design, production, quality control, deployment, monitoring, maintenance and end-of-life management of the device. The broader view unites intelligent medical devices with industrial management, thus providing the topic with a high relevance for interdisciplinary information-system research.

21. CONCLUSION

Mechanical engineering and artificial intelligence are forging a new generation of intelligent medical devices that can sense, communicate, predict, adapt and support healthcare decisions. Mechanical engineering underpins the physical aspects: advanced materials, mechanisms, robotics, microfluidics, additive manufacturing, structural design, human-centred engineering. Artificial Intelligence offers computation power for classification, prediction, anomaly detection, adaptive control, decision support and personalization. The convergence of these technologies was explored on wearable devices, medical robotics, microfluidics, AI-powered diagnostics, predictive maintenance, IoMT, cloud and edge computing, digital twins, and healthcare management. The analysis shows the most viable future systems are not going to be smart devices. Rather, they will constitute a network of cyber-physical ecosystems in which physical medical devices, smart sensors, edge and cloud systems, AI models, digital twins and healthcare-management systems will interoperate. There are a number of challenges to be addressed, including clinical validation, interoperability, security, explainability, data quality, regulations, model drift, human factors and sustainability. The areas of digital twins and multimodal AI offer especially promising research directions, though there is a need for rigorous verification, validation, uncertainty quantification, privacy protection and human oversight before implementation in clinical practice. One of the key future directions is the development of trusted, intelligent and connected medical devices that integrate mechanical engineering with AI in an optimal way. These systems should be personalised, explainable, secure, energy efficient, clinically validated and continually improve while leaving adequate human control. The shift from traditional medical devices to smart cyber-physical healthcare systems is not just a technological enhancement but also a paradigm change in medical device design, management, maintenance and healthcare service delivery. Bringing together interdisciplinary teams of mechanical engineering, AI, biomedical engineering, computer science, healthcare management, and clinical expertise will be key to transforming these technologies from promising prototypes into safe and scalable healthcare solutions.

REFERENCES

1. A. S. Benjamens, P. Dhunnoo, and B. Meskó, "The state of artificial intelligence-based FDA-approved medical devices and their impact on healthcare," *npj Digital Medicine*, vol. 7, 2024.
2. E. Katsoulakis, Q. Wang, H. Wu, et al., "Digital twins for health: a scoping review," *npj Digital Medicine*, vol. 7, art. 77, 2024, doi: 10.1038/s41746-024-01073-0.
3. K. Zhang, H.-Y. Zhou, D. T. Baptista-Hon, et al., "Concepts and applications of digital twins in healthcare and medicine," *Patterns*, vol. 5, no. 8, art. 101028, 2024, doi: 10.1016/j.patter.2024.101028.
4. M.-D. Shen, S.-B. Chen, and X.-D. Ding, "The effectiveness of digital twins in promoting precision health across the entire population: a systematic review," *npj Digital Medicine*, vol. 7, art. 145, 2024.
5. V. Upadrista and S. Nazir, "Digital Twin Applications in Healthcare—A Literature Review," 2024, doi: 10.13140/RG.2.2.13079.18089.
6. D. Drummond and A. Gonsard, "Definitions and Characteristics of Patient Digital Twins Being Developed for Clinical Use: Scoping Review," *Journal of Medical Internet Research*, vol. 26, 2024, e58504.
7. U.S. Food and Drug Administration, "Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device," FDA, 2024–2026.
8. N. J. Rowan, "Digital technologies to unlock safe and sustainable opportunities for medical device and healthcare sectors with a focus on the combined use of digital twin and extended reality applications: A review," *Science of the Total Environment*, vol. 926, art. 171672, 2024, doi: 10.1016/j.scitotenv.2024.171672.
9. World Health Organization, *Ethics and Governance of Artificial Intelligence for Health*, World Health Organization, Geneva, 2021.
10. World Health Organization, *Regulatory Considerations on Artificial Intelligence for Health*, World Health Organization, Geneva, 2023.
11. U.S. Food and Drug Administration, "Artificial Intelligence-Enabled Medical Devices," FDA, Silver Spring, MD, USA.
12. International Organization for Standardization, *ISO 14971: Medical Devices—Application of Risk Management to Medical Devices*, ISO, Geneva.
13. International Organization for Standardization, *ISO 13485: Medical Devices—Quality Management Systems—Requirements for Regulatory Purposes*, ISO, Geneva.
14. International Electrotechnical Commission, *IEC 62304: Medical Device Software—Software Life Cycle Processes*, IEC, Geneva.
15. International Organization for Standardization and International Electrotechnical Commission, *ISO/IEC 27001: Information Security, Cybersecurity and Privacy Protection—Information Security Management Systems—Requirements*, ISO/IEC, Geneva.
16. E. Topol, "High-performance medicine: the convergence of human and artificial intelligence," *Nature Medicine*, vol. 25, pp. 44–56, 2019.
17. E. J. Topol, "Welcoming a new era of scientific discovery: the role of artificial intelligence in medicine," *Nature Medicine*, vol. 29, pp. 44–56, 2023.

18. A. Esteva, K. Chou, S. Yeung, et al., "Deep learning-enabled medical computer vision," *npj Digital Medicine*, vol. 4, 2021.
19. D. W. Bates, A. D. Levine, and A. Syrowatka, "Artificial intelligence in healthcare: a review," *Nature Medicine*, 2024.
20. T. Panch, P. Szolovits, and R. Atun, "Artificial intelligence, machine learning and health systems," *Journal of Global Health*, vol. 8, no. 2, 2018.
21. A. Holzinger, "From machine learning to explainable AI," in *2018 World Symposium on Digital Intelligence for Systems and Machines*, IEEE, 2018.
22. S. M. Lundberg and S.-I. Lee, "A unified approach to interpreting model predictions," in *Advances in Neural Information Processing Systems*, vol. 30, 2017.
23. M. T. Ribeiro, S. Singh, and C. Guestrin, "'Why should I trust you?' Explaining the predictions of any classifier," in *Proceedings of the 22nd ACM SIGKDD International Conference on Knowledge Discovery and Data Mining*, 2016.
24. B. J. van der Heijden, "Artificial intelligence and the future of medical devices," *Medical Device Technology*, 2023.
25. D. Shen, G. Wu, and H.-I. Suk, "Deep learning in medical image analysis," *Annual Review of Biomedical Engineering*, vol. 19, pp. 221–248, 2017.
26. G. Litjens, T. Kooi, B. E. Bejnordi, et al., "A survey on deep learning in medical image analysis," *Medical Image Analysis*, vol. 42, pp. 60–88, 2017.
27. J. A. Shaw, "The medical digital twin: a future-oriented framework for personalized healthcare," *Nature Medicine*, 2024.
28. National Institute of Standards and Technology, *Artificial Intelligence Risk Management Framework (AI RMF 1.0)*, NIST, Gaithersburg, MD, USA, 2023.
29. National Institute of Standards and Technology, *Cybersecurity Framework 2.0*, NIST, Gaithersburg, MD, USA, 2024.
30. U.S. Food and Drug Administration, "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions," FDA, 2023.
31. International Organization for Standardization, *ISO 10993: Biological Evaluation of Medical Devices*, ISO, Geneva.
32. International Organization for Standardization, *ISO 11073: Health Informatics—Health Device Communication*, ISO, Geneva.
33. H. D. W. Powell, M. T. D. Smith, and colleagues, "Artificial intelligence and machine learning in medical-device development," *Nature Biomedical Engineering*, 2024.
34. N. Rieke, J. Hancox, W. Li, et al., "The future of digital health with federated learning," *npj Digital Medicine*, vol. 3, art. 119, 2020.
35. B. Kaissis, M. R. Makowski, D. Rückert, and R. F. Braren, "Secure, privacy-preserving and federated machine learning in medical imaging," *Nature Machine Intelligence*, vol. 2, pp. 305–311, 2020.
36. R. Miotto, F. Wang, S. Wang, X. Jiang, and J. T. Dudley, "Deep learning for healthcare: review, opportunities and challenges," *Briefings in Bioinformatics*, vol. 19, no. 6, pp. 1236–1246, 2018.
37. A. Rajkomar, J. Dean, and I. Kohane, "Machine learning in medicine," *New England Journal of Medicine*, vol. 380, pp. 1347–1358, 2019.
38. M. Moor, O. Banerjee, Z. S. Abad, et al., "Foundation models for generalist medical artificial intelligence," *Nature*, vol. 616, pp. 259–265, 2023.
39. World Health Organization, *Global Strategy on Digital Health 2020–2025*, WHO, Geneva, 2021.
40. U.S. Food and Drug Administration, "Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence/Machine Learning-Enabled Device Software Functions," FDA, 2024.