



Realizing the Transformative Potential of AI & ML in Medical Devices

Executive Summary

Artificial intelligence (AI) and machine learning (ML) are emerging technologies that have the potential to substantially enhance medical devices and healthcare delivery. From improving disease diagnosis and treatment optimization to streamlining clinical workflows, these cutting-edge capabilities are poised to drive a new era of innovation.

Effectively harnessing AI/ML for medical devices will require overcoming technical and regulatory hurdles. Privacy, security, bias mitigation and proving real-world efficacy are just some of the challenges that must be addressed. However, with a strategic approach to exploring use cases, building a supportive data infrastructure, and carefully managing organizational change, medical device and healthcare delivery companies can lead the impactful transition to AI/ML enabled healthcare.

The AI/ML Opportunity in Medical Devices

AI is a system which can achieve desired goals through learning, reasoning and decision-making capabilities. Machine learning is the foundational technique that enables AI systems to learn directly from data without being explicitly programmed.

In healthcare, AI/ML can be applied across the entire patient journey. Some key value areas include:

Disease Diagnosis and Screening

- Augmenting radiologists, pathologists and other diagnosticians by analyzing medical images, genomic data and other complex datasets to detect abnormalities
- Prioritizing high-risk cases for expedited review
- Increasing diagnostic accuracy and consistency

Treatment Optimization

- Synthesizing diverse patient data to extract insights on optimal treatment protocols, medication efficacy and side effect management
- Predicting patient risk profiles and likely disease progression to guide preventative care
- Enabling precision medicine through sophisticated genotype-phenotype analysis

Clinical Workflow Streamlining

- Automating routine tasks like documentation, scheduling and medical coding
- Surfacing key insights from patient records to support clinical decision-making
- Providing clinical intelligence at the point of care through AI assistance

Remote Care Enablement

- Applying AI/ML models to wearable sensor data for home health monitoring
- Detecting adverse events and triggering interventions
- Enabling virtual triage and reducing unnecessary clinic visits

These potential use cases merely scratch the surface. Innovative leaders are finding novel ways to integrate AI/ML across the entire healthcare ecosystem, from drug discovery to optimized hospital operations to tech-enabled preventative wellness.



Barriers to AI/ML Adoption in Medical Devices

As promising as AI/ML may be, there are significant hurdles to clear before these technologies can be widely adopted in regulated medical devices and healthcare settings:

Data Scarcity and Quality

AI/ML models require large, high-quality datasets for effective training, which the healthcare industry has historically lacked due to data silos and inconsistent formats for patient records.

Accountability and Regulation

There are open questions around how to assign accountability for clinical decisions made by AI/ML systems. Emerging regulations are still evolving, presenting challenges for companies seeking to comply with requirements like algorithm transparency and reproducibility.

User Trust and Adoption

Among clinicians, nurses and other front-line staff, there is hesitancy to adopt technologies that could be perceived as replacing human expertise and judgment. AI/ML systems have to be implemented in ways that augment rather than replace existing workflows.

Bias and Fairness

If not carefully developed and tested, AI/ML models can reflect or amplify existing racial, gender, age and socioeconomic biases present in their training data. Adherence to AI ethics principles around fairness and non-discrimination will be critical to prevent adverse impacts.

Privacy and Security

Working with highly sensitive personal health data raises significant privacy and cybersecurity considerations that AI/ML platforms must be engineered to address through encryption, access controls, auditing and other protective measures.

Resourcing AI/ML Capabilities

Developing and deploying AI/ML solutions requires specialized skillsets - data scientists, machine learning engineers, AI ethicists - that are in short supply. Medical device and health care delivery companies may require partnering with third parties to secure needed talent.





Building the Foundation for AI/ML

While formidable, none of the adoption barriers for AI/ML in medical devices are insurmountable with proper strategy, resourcing and organizational commitment. *For device makers looking to get started, these preliminary steps can build the foundations for success:*

Identify High-Potential Use Cases

Conduct an objective assessment of where AI/ML can drive the greatest customer/patient impact and ROI. Start small with achievable pilots that can build organizational support. Use cases with strong existing data assets are ideal initial candidates.

Improve Data Readiness

Data readiness is critical for AI/ML, so invest in modernizing data infrastructure. Break down silos, improve data quality, automate data pipelines and explore synthetic data generation options to augment training datasets where needed.

Establish Governance Frameworks

Put guardrails in place early around algorithm testing, validation processes, model risk management, data governance and change management protocols. Doing so builds stakeholder trust and enables compliant / ethical AI/ML models.

Invest in Specialized Talent and Partners

Acquire the required AI/ML talent either by hiring dedicated data science teams or partnering with experienced AI development firms. Portfolio companies need a balance of internal and external expertise.

Embrace an AI-Centric Mindset

Significant organizational and cultural change is required to fully capitalize on AI/ML. Leadership must foster an AI-centric vision while equipping all functions - engineering, marketing, sales, support - to embrace an AI-enabled world.

Getting Started on the Journey

Artificial intelligence and machine learning have immense potential to make medical devices and healthcare delivery smarter, more personalized, and deliver better clinical outcomes - but only for companies bold enough to lay the technical and organizational groundwork.

Those who do will gain a powerful competitive advantage by pioneering AI-driven capabilities like autonomous diagnostics, highly precise and tailored treatment planning, and seamless data-driven patient experiences. Tomorrow's winners in medtech will be today's AI leaders. Now is the time to get started.

To learn more, contact Boston Engineering.



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About Boston Engineering

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