2023

Whitepaper

Revolutionising Healthcare: Unleashing the Power of AI in Medical Devices

Summary

Introduction

Medical Device Software (MDSW) is a type of medical device which is standalone software or a software component incorporated into a medical device. MDSW generally needs to have an intended medical purpose and needs to process an input to provide an output. Artificial Intelligence has recently been incorporated into MDSW giving rise to the term Artificial Intelligence as a Medical Device (AIaMD).

Artificial intelligence (AI) is broadly defined as the science and engineering of making intelligent machines, especially intelligent computer programs. Machine Learning (ML) is an artificial intelligence technique that can be used to design and train software algorithms to learn from and act on data. Software developers can use ML to create an algorithm that is 'locked' so that its function does not change, or 'adaptive' so its behaviour can change over time based on new data.

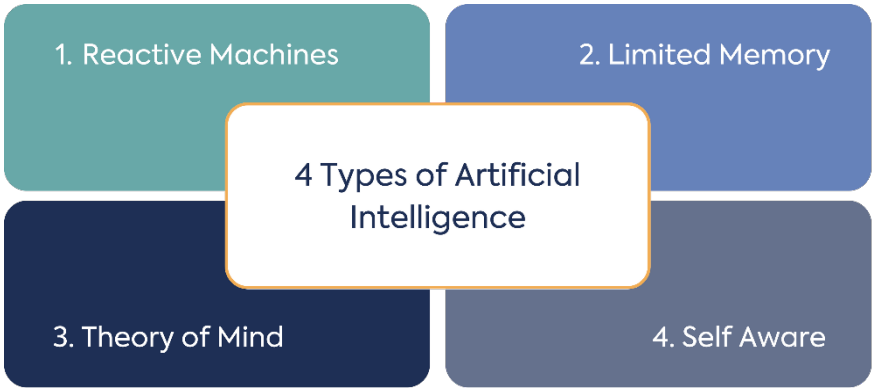
Significance of AI in Medical Devices

As populations get older, and human demand for efficiency continues to grow, the utilisation of AI and ML in medical technology will persist and expand exponentially. AI and ML enabled devices are already transforming the medical device industry by offering greater accuracy, streamlining administrative processes, and enabling personalised care. The US Food and Drug Administration (FDA) has recognised that AI or ML enabled devices have the potential 'to transform healthcare'.

As of October 2023, the FDA had included 692 AI/ML enabled medical devices to their list of cleared medical devices since 1995. In comparison to 2018, there was an 83% increase in FDA approvals in 2021 for AI and ML enabled medical devices. The year-on-year increase in 2020 compared to 2019 was 39%, but slowed in 2021 to 15% and in 2022 to 14%. This highlights the extensive history of development and widespread utilisation of these medical devices over the last few decades.

Key Concepts of AI

It is generally accepted that AI has the potential to revolutionise the field of medical devices, enhancing diagnostic accuracy, treatment planning, and patient care. AI can use different techniques, including models based on statistical analysis of data, expert systems that primarily rely on if-then statements, and machine learning. The key concepts allowing application of AI in medical devices are based around reactive AI and limited memory machines.



Reactive AI

Reactive AI is a form of AI programmed to provide a predictable output based on the input it receives. While reactive AI algorithms operate solely on present data without any memory of past experiences, they respond in the exact same way every time to identical situations. Reactive AI lacks the ability to learn from historical information, but excels in specific tasks due to consistency and data processing capabilities. Examples include IBM's Deep Blue (which defeated chess grandmaster Garry Kasparov), spam filters and facial recognition. Reactive AI is limited in its functionality because it is unable to learn from past data to inform future decisions. It also requires large sets of data to learn simple algorithms.

Limited Memory Machines

Limited memory-based AI can temporarily learn from data and store data from past experiences. As the name suggests, such AI has a short-term memory that allows it to use this stored data to make decisions and perform tasks. These models handle imperfect information and predict outcomes well in advance. In 2012, deep learning revolutionised AI by mimicking neural

connections in the brain. Deep learning neural networks, a subset of ML, consist of a digital input which is processed through multiple layers of connected 'neurons' to progressively detect features and provide an output. Deep learning models typically process image or speech inputs and made a significant improvement in image recognition applications such as in facial recognition systems.

Google's AlphaStar project demonstrated that AI could learn strategies by playing against itself in the real-time strategy game StarCraft II. Limited Memory AI is also commonly used in chatbots, virtual assistants and natural language processing. Limited memory AI cannot, however, retain this information permanently or use it to improve its future performance.

Future Directions

As AI continues to evolve, researchers aim for theory of mind and self-aware AI. Theory of mind AI describes machines that can attribute mental states to themselves and others to predict human behaviour and the motives of other entities, subsequently using this information to direct their actions.

The key challenge in creating theory of mind AI is modelling human behaviour, mental states and preventing biases and shortcuts that may lead to an inaccurate outcome. Self-aware AI can understand and interact with thoughts, feelings and emotions of humans and other beings. This type of AI would mimic human-level consciousness and intelligence. The journey from reactive algorithms to sentient machines, currently the subject of science fiction and hopefully a technology realised in the future, could bring groundbreaking advancements in healthcare.

While AI enhances efficiency, and in some cases surpasses human capability due to its ability to store and analyse huge data sets, human expertise remains essential for compassionate patient care and ethical decision-making. Regulators have started to take steps to provide frameworks for the safe development and use of AI and ML enabled medical devices. However, evaluation and validation of AI such as theory of mind and self-aware AI is a challenge, owing to the difficulties in modelling the human-like behaviour required by such AI.

Current Applications

AI and ML incorporated into medical devices enhances their capabilities to analyse data, detect patterns, generate insights, and provide guidance and feedback to users. The most common therapeutic areas benefitting from AI/ML enabled technology are radiology, cardiovascular, haematology and neurology.

AI/ML enabled technology can roughly be classed into four applications: diagnosis and screening, prognosis, treatment support and data collection. Some of the current applications of AI in medical devices include:

Image Analysis

AI can help analyse medical images, such as X-rays, CT scans, MRI scans, ultrasound images, and microscopy images, to detect abnormalities, diagnose diseases, measure parameters, and guide interventions. An example of such a device is GE Healthcare's, Deep Learning Image Reconstruction. The device uses AI to produce cross-sectional images of the head and whole body by computer reconstruction of X-ray transmission data taken at different angles and planes. This device recreates better quality images from noisy and low-quality data.

Signal Processing

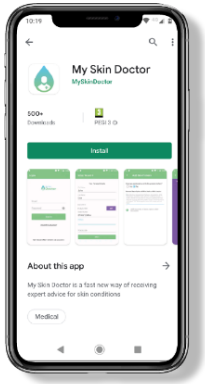
AI can help process signals from various sensors and devices, such as electrocardiograms (ECG), electroencephalograms (EEG), blood pressure monitors, pulse oximeters, and glucose meters, to extract features, identify patterns, and provide feedback. AliveCor's, KardiaMobile Single Lead ECG Device is a two-electrode device recording ECG to detect atrial fibrillation, bradycardia and tachycardia using AI. The device allows a user to capture a medical-grade ECG in 30 seconds and get an instant analysis on a smartphone.

Natural Language Processing

AI can help process natural language data from various sources, such as medical records, clinical notes, literature reviews, and patient feedback, to extract information, generate summaries, and provide insights.

Decision Support

AI can help provide decision support for clinicians and patients, such as recommending diagnosis, treatment options, drug dosages, and follow-up actions. MySkinDoctor is such a device allowing triage of a skin condition by sharing a photograph remotely via an app on a smartphone or tablet. Experienced consultant dermatologists subsequently provide a personalised care plan which includes a diagnosis, information about the condition and a treatment plan.



Personalised Medicine

AI can help tailor medical devices and procedures to individual patients' needs and preferences, such as customising implants, prosthetics, wearables, and drug delivery systems. Medtronic's UNID™ Adaptive Spine Intelligence (ASI) is one such software device using data science and data to design patient-specific spinal implants and related instruments. The software uses data aggregation of thousands of spinal procedures to create a pre-operative plan that optimises the sagittal alignment of the spine, provides intra-operative guidance and post-operative analysis to help surgeons execute the plan and evaluate the results.

Benefits and Challenges

The inclusion of AI in medical devices is transforming the capabilities of technology in the diagnosis, treatment, and prevention of medical conditions. The benefits of using AI in medical devices are vast and offer advantages over existing devices and human capabilities. These include:

- Improved accuracy and efficiency of diagnosis and prognosis, by analysing large amounts of data from various sources, such as medical records, images, sensors, and genomics.
- Enhanced personalisation and customisation of treatment and care, by tailoring interventions to the specific needs and preferences of each patient, based on their individual characteristics and history.
- Decrease burden on healthcare services and increased accessibility and affordability of health services, by enabling remote monitoring, telemedicine, and self-management of chronic conditions, as well as reducing costs and human errors.

AI also poses some challenges that need to be addressed, such as ethical, legal, and social implications, as well as technical and regulatory hurdles.

Some of the challenges of AI in medical devices are:

- Ensuring safety and reliability of AI systems, by developing robust methods for testing, validation, verification, and certification, as well as addressing potential risks of bias, discrimination, and manipulation.
- Addressing generalisability and interpretation of data, executing AI updates, generating evidence, and post-market monitoring.
- Protecting privacy and security of personal data, by implementing appropriate measures for data governance, consent, encryption, anonymisation, and accountability, as well as respecting ethical principles and human rights.
- Addressing the digital divide – the uneven distribution of access to use of information and communication technologies.
- Fostering trust and acceptance of AI among users, by ensuring transparency, explainability, and interpretability of AI decisions and actions, as well as involving stakeholders in the design and evaluation of AI systems.

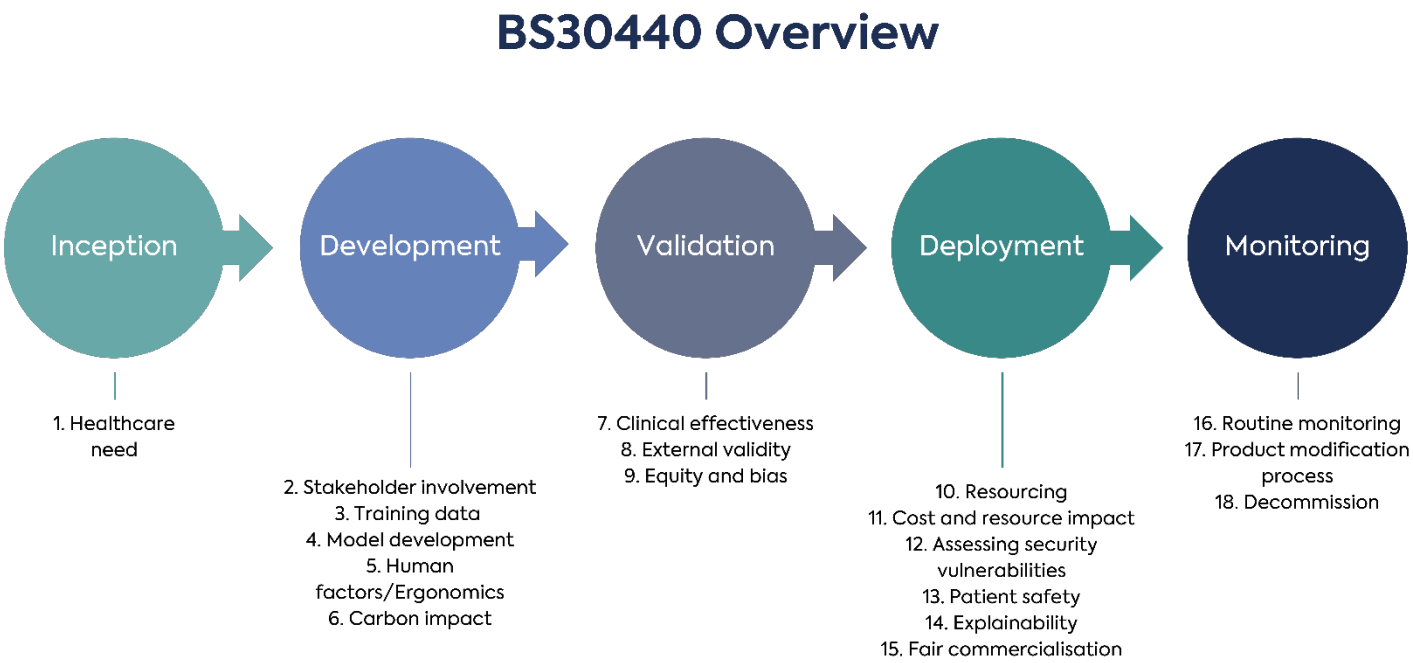
Regulatory Landscape

As the potential of AI and ML enabled medical devices shows incredible promise for efficiencies, progress is dependent upon the development of suitable standards and regulations specifically designed to assess the unique performance and safety issues associated with such technologies. Regulators around the world have recognised this need and are in the process of implementing regional frameworks.

The FDA released in January 2021 an Action Plan outlining the agency's proposed framework for the regulation and oversight of medical devices and software using AI technologies. The Action Plan presents a five-part proposition that the FDA intends to take to advance the agency's oversight of AI/ML-based Software as a Medical Device. The FDA has also more recently anticipated the creation of a framework for approving changes to devices with an AI component. The aim of this framework is to maintain regulatory oversight to allow for the iterative machine learning component of AI and ML enabled devices. The framework would include a 'predetermined change control plan' (PCCP) in premarket submissions which would detail the types of anticipated modifications and the associated methodology to implement those changes in a controlled manner whilst ensuring that risks to patients are managed. Manufacturers would be expected to commit to transparent and real-world performance monitoring of AI and ML based devices to ensure that a software product is appropriately monitored from the premarket development to post-market performance.

As the UK transitions from the medical device EU Directives to the new UK Regulations, the impact of AI on healthcare has been recognised. The MHRA announced a Software and AI as a Medical Device Change Programme with the aim of addressing the challenges and opportunities of such products. The MHRA has acknowledged the need for a regulatory framework to support innovation and enable accelerated access to market for high risk and safe AIaMD, with a focus on evidence generation after deployment, proactive post-market monitoring and AIaMD model updates using change control plans.

Further to the development of a regulatory framework, a British Standard, BS 30440: Validation Framework for the Use of AI in Healthcare was published in July 2023. The standard provides a fully auditable standard for assessment of AI enabled healthcare products throughout the product lifecycle to ensure that they can demonstrate clinical benefit, offer sufficient levels of performance, can safely integrate into the healthcare environment and that they can deliver inclusive outcomes for all patients, users, and practitioners. Conformity with this standard can provide assurance of safety and performance to developers, healthcare providers and patients.



In 2021, the FDA, Health Canada, and MHRA jointly identified ten guiding principles to promote the development of safe, effective, and high-quality medical devices that use AI and ML. These principles are intended to form the basis for Good Machine Learning Practice (GMLP). Building on the ten guiding principles, in October 2023, five guiding principles have been developed to derive insights from health care data. These five principles outline how manufacturers of AI and ML enabled medical devices can create PCCPs that demonstrate which changes and updates to their devices would maintain safety and effectiveness without regulatory intervention across the UK, US

and Canada. The PCCPs will allow manufacturers of AI and ML enabled medical devices to reallocate resources to improve products, rather than undergoing frequent reassessments by regulators. Each regulator will have specific national guidance for manufacturers to follow. The MHRA intends to publish its guidance in 2024.

In the EU, the use of all AI, not only AI enabled medical devices, will be regulated by the AI Act. The AI Act was proposed in 2021 with final agreement on the Act expected to be reached by the end of the year. The AI Act aims to classify AI into categories of risk based on their application; unacceptable risk, high risk and limited risk. AI applications in the unacceptable risk category will be banned; such AI could include applications such as social scoring or biometric surveillance. The risk classification will drive the type of regulation required. AI and ML enabled medical devices would be classified into the 'high risk' category and will require assessment prior to being placed on the market and throughout their lifecycle.

The World Health Organisation (WHO) endorses six principles to guide the ethical use of AI for health, specifically to: protect autonomy, promote human well-being and safety, ensure transparency and explainability, foster responsibility and accountability, ensure inclusiveness and equity, and promote responsive and sustainable AI.

On a broader scale, the UK hosted the AI Safety Summit, a landmark event at Bletchley Park on 1st November 2023 to discuss the challenges and opportunities of AI. The summit gathered stakeholders from 28 nations including politicians, technology experts and academics resulting in the Bletchley Declaration. This agreement aims to seek collaboration on research of safety concerns around the world's most capable AI models. The UK and US governments also announced plans to establish their own AI safety institutes to test the safety of AI models before they are released to the public.

These new frameworks under development by various regulatory authorities demonstrate their dedication to guiding manufacturers to ensure the safe deployment of medical devices.

Future Trends

AI has the potential to transform medicine by enabling data-driven and high-performance healthcare. It can help doctors with tasks that require analysing large amounts of data, such as diagnosing diseases, detecting abnormalities, and monitoring vital signs. AI can also augment human intelligence by providing insights and recommendations that are based on robust and transparent algorithms.

However, AI is far from the hysteria that machines can replace human doctors. AI cannot take over complex and dynamic environments without human supervision. There are still many challenges and limitations, such as validation, debugging, audit, simulation, and ethical issues.

AI will be a powerful tool for clinicians in various domains of medicine with medical professionals employing some form of AI, for instance the use of deep learning for the interpretation of medical images, scans, slides, lesions, retinas, ECGs, and endoscopy; recognition of facial expressions and vital signs; use of natural language processing for interpretation of medical notes and triage.

Conclusion

The integration of AI in healthcare is a transformative movement, promising to enhance patient care, streamline medical processes, and unlock new possibilities in treatment and diagnosis. As we stand on the brink of this technological revolution, it is crucial to navigate its advancement with careful consideration for performance validation requirements, ethical standards, data security, and appropriate access to ensure that the benefits of AI are realised for all.

DLRC

Contact Us

UK: +44 (0)1462 372 472

EU: +49 (0)89 44489 311

US: +1 617 851 1438

hello@dlrcgroup.com

www.dlrcgroup.com

DLRC Regulatory Consultancy

2021