

AI-based software has the potential to improve the EU health care industry

Product Watch: Artificial Intelligence-based software as a medical device

Artificial Intelligence (AI)

based software refers to computer programmes that have the capacity to perform operations analogous to learning and decisionmaking in humans. This type of software can accomplish specific tasks by processing large amounts of data, recognising patterns and mimicking biological intelligence. AI and machine learning (ML) technologies differ from other software as a medical device in the sense that they have the potential to adapt as more real-world data become available and optimise device performance in real-time to continuously improve healthcare for patients.

Al as a medical device	Function in healthcare	AI technology
 Al image analysis of computed tomography (CT) scans Orthopaedic planning software Skin disease detection AI Al detecting diabetic retinopathy 	Radiology Diagnosis Cardiac imaging analysis	Image recognition based on machine and deep learing models
 Al in monitoring electrocardiogram (ECG) or electroencephalography signals Medical devices for predictive analytics 	Monitoring of diseases Early warning system	Big data analysis, machine learning, deep learning algorithm, neural networks
• Al enhanced wearables • Glucose monitors equipped with Al	Health monitoring	Computer vision, gesture recognition, natural language processing
Medical robotic devices enhanced with AI Personal robotic assistant	Surgery Prescription dispensing Sterilisation Elderly care	Robotics, natural language processing, speech, face recognition, machine learning neural networks

Applications of Artificial Intelligence and Machine Learning-based Software as a Medical Device (SaMD)

Due to its versatility, Artificial Intelligence/Machine Learning-based Software as a Medical Device can be found in all segments of the health value chain

The greatest potential of AI software is currently identified in the R&D and patient care delivery stages, which are also the highest value-added activities along the healthcare value chain.



For more information, read the full Product Watch on Artificial Intelligence-based software as a medical device here: https://ati.ec.europa.eu/reports/product-watch/artificial-intelligence-based-software-medical-device

Challenges





Difficulties to access data and data governance

The barriers to systems interoperability No reimbursement of medicine and device expenses

Low user acceptance of AI





Integration of solution in clinal workflow

The EU has a range of opportunities to unlock the potential in this area for the benefit of its citizens



About the Advanced Technologies for Industry (ATI) project

The ATI project – funded by the European Commission – supports the **implementation** of Europe's new growth strategy with a systematic monitoring of technological trends and reliable, up-to-date data on advanced technologies.



The **Product Watch** analyses novel products that are based on advanced technologies for the development of goods and services - enhancing their overall commercial and social value. It supports cluster organisations and S3 partnerships, providing intelligence on innovation areas where European regions could team up and invest together.

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