AI in Medical Devices
Benefits, Risks & Practical Considerations

JOHN CONNAH | SOFTWARE – TEAM LEAD

www.egtechnology.co.uk | johnconnah@egtechnology.co.uk

A practical and pragmatic discussion on AI in medical Devices

What is AI?

- Beyond the Hype – Benefits and Risks
- What is the difference between AI and ML

Implementing AI in Medical Devices

- Embedded AI platforms
- Running AI/ML Software on device

Legislation & regulation

- Risk based approach
- Legislation considerations

Conclusions

Q & A

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What is AI?

What is AI? | Beyond the hype

What is AI? | AI verses ML – What is the difference

Machine Learning – ML

- Learning Model is created using training data
- Learning model is fixed
- May need updating in field as more edge cases are discovered

Artificial Intelligence – AI

- Learning Model is created using training data
- Learning model is updated using the inputs presented to it
- Divergent models used in each device – how do we control / risk manage this adaptability
    - Do we reset the learning model or something smarter ?

What is AI? | Benefits

Advantages of AI and ML in Medicine:

- AI enables doctors and medical professionals to leverage immediate and precise data for critical clinical decision-making.
- Real-time analytics improve preventative steps, cost-savings, and patient wait times.
- AI automates tedious and meticulous tasks, enhancing efficiency.
  - Intelligent radiology technology for identifying visual markers and automated appointment scheduling.
- AI can efficiently diagnose diseases by analysing medical images, lab results, and patient history.
- It aids in drug discovery by identifying potential candidates and predicting their effectiveness.

What is AI? | Risks

Disadvantages of AI and ML in Medicine:

- It operates based on algorithms and data.
- AI systems can inherit biases from training data, leading to discriminatory outcomes – Green eyes!
- Storing and sharing sensitive patient data for AI analysis raises privacy and security risks.
- Regular updates, monitoring, and maintenance are necessary for optimal performance.
- Some healthcare professionals may be hesitant to trust AI-driven decisions.

In summary, while AI offers immense potential in medicine, it must be implemented thoughtfully, addressing ethical, social, and technical challenges

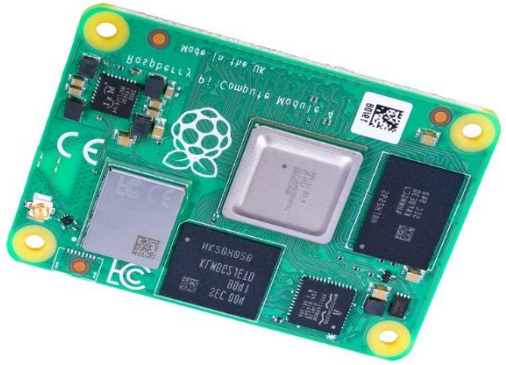
Implementing AI in Medical Devices

Implementing AI in Medical Devices | Embedded AI platforms

0.5 - 2 TOPS $1

4 TOPS $59

40 TOPS $350



Implementing AI in Medical Devices | Running AI/ML Software on device

NANOEDGE AI STUDIO

Legislation/regulation

Implementing AI in Medical Devices

All major healthcare regulators are looking at the medical/healthcare implications of AI/ML

EU Consultation: Artificial intelligence – ethical and legal requirements
FDA Action Plan: Artificial Intelligence and Machine Learning in Software as a Medical Device
GOV.UK *Good machine learning practice for medical device development guiding principles*

It may be some time until we have definitive, consistent guidance.

AI focus is likely to be on continued safety and efficacy throughout the product life

- The quality, size and scope of the initial training data
- Controlling in-market adaptations of the software as the system grows
- How to demonstrate safety and efficacy on an on-going basis

Until updated guidance is published remember:

- Follow good design, development and maintenance practices (state-of-the-art)
- Consider total product life-cycle implications
- Evaluate the risks!

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Conclusions

Issues to be resolved

- If the software is constantly evolving by itself, how can you make sure it is always adhering to the objective?
- Fixed model or a learning model – both have advantages/disadvantages
- ML - How often do you update the model?
- AI - If you let the software evolve automatically, how often should it be retrained?
- Risk that training sets should be representative of the intended patient population.
- Test datasets must be independent to training datasets – updated to match objective

Conclusions

- We need to plan the AI integration in the development
- Hardware and software are not a problem
- Need to monitor legislation so that device maintains best practice
- Identify and mitigate risks of AI – Not new/but additional area
- We need to take into account the maintenance and deployment in the field

Questions?

John Connah | eg technology Ltd

johnconnah@egtechnology.co.uk

www.egtechnology.co.uk

Please come and have a chat on the eg technology stand (40)

Farfield House, Albert Road, Stow-Cum-Quy, Cambridge, CB25 9AR

design@egtechnology.co.uk

www.egtechnology.co.uk

+44 (0) 1223 813184