

# Systematically Assessing the Security Risks of AI/ML-enabled Connected Healthcare Systems



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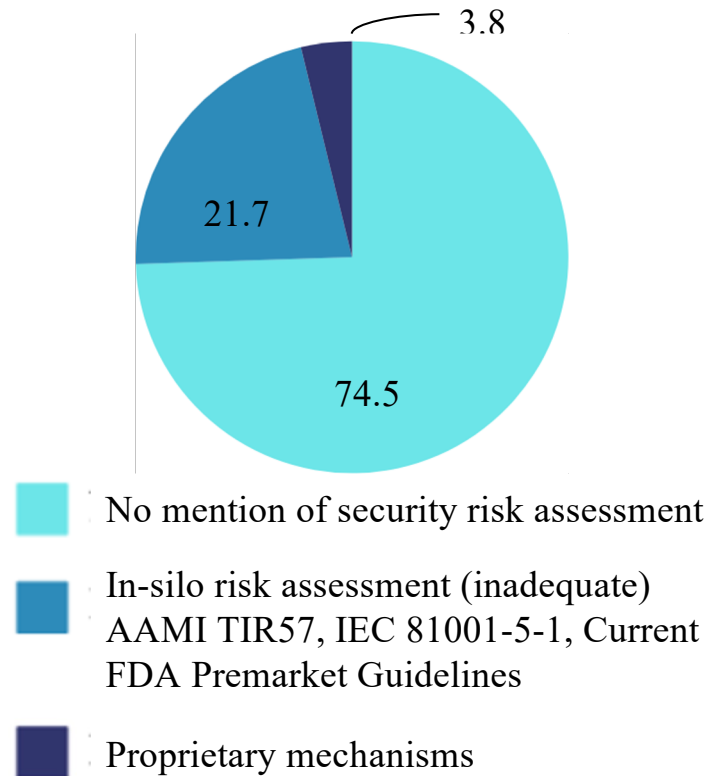
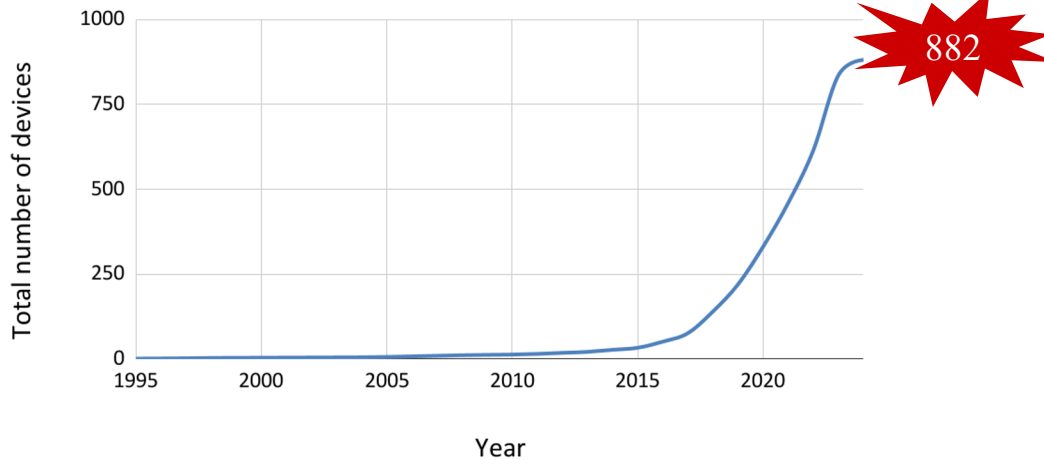


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# Why focus on security of ML-enabled medical devices?

**Growth in number of FDA-approved AI-powered medical devices**

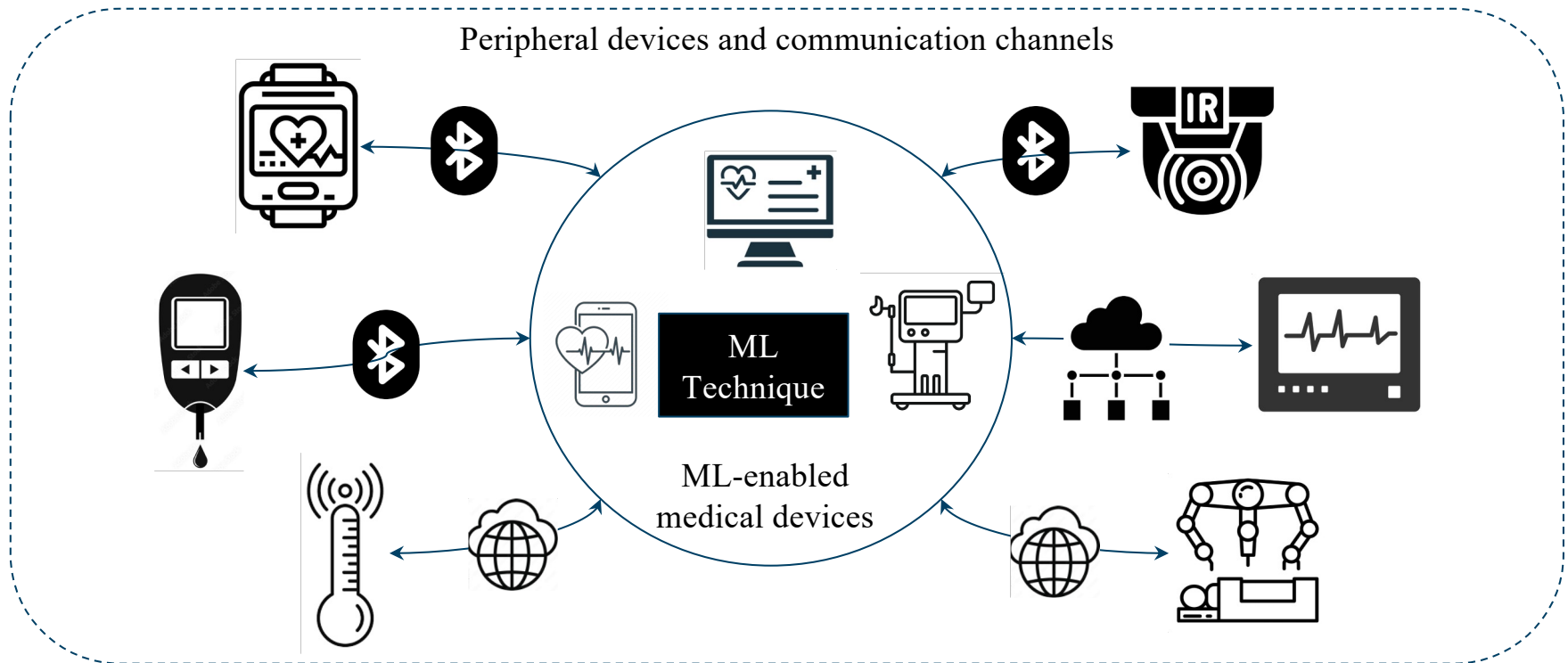


## Recent FDA guidelines

- Pre-market security assessment: Mandatory
- Design for Security with no implicit trust

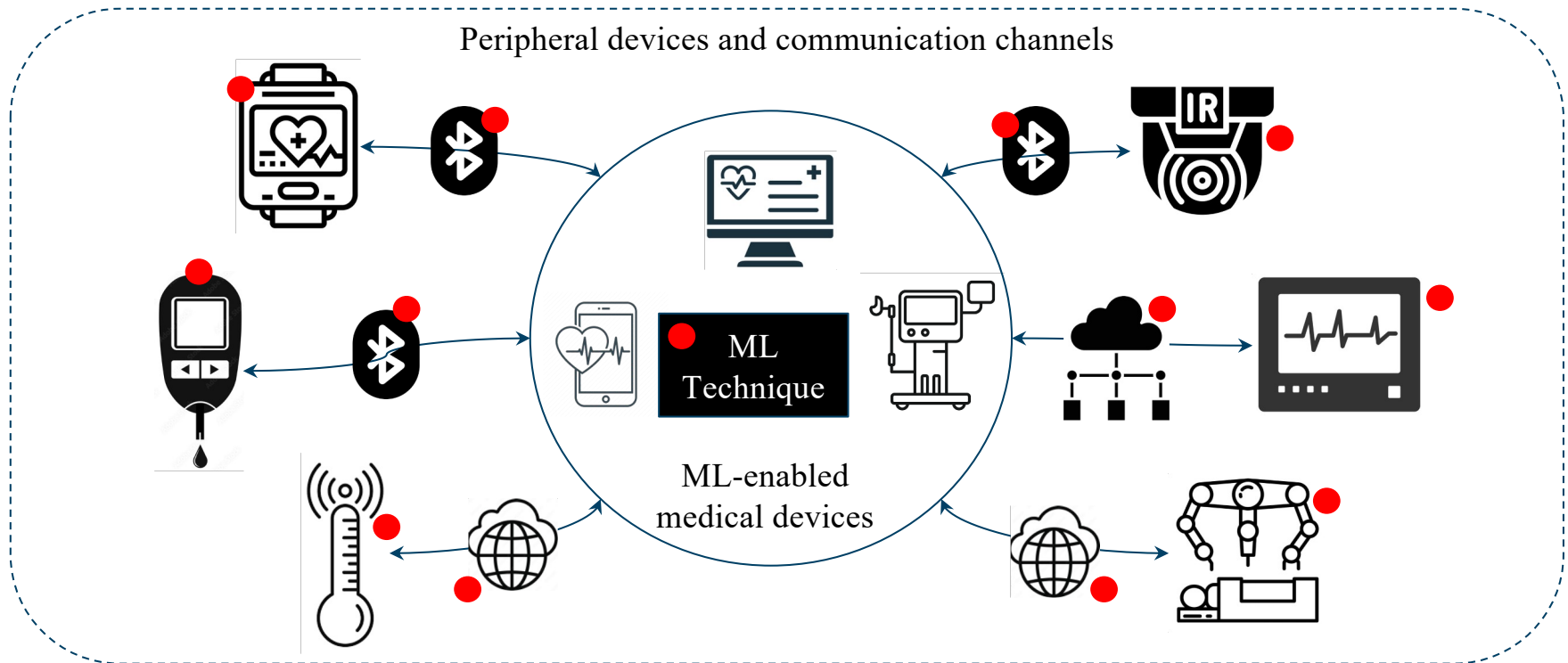
Source: <https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-aiml-enabled-medical-devices>, [Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions](#) by FDA

# Why is securing **ML-enabled** medical devices challenging?



**Highly interconnected multi-vendor setup**

# Why is securing **ML-enabled** medical devices challenging?

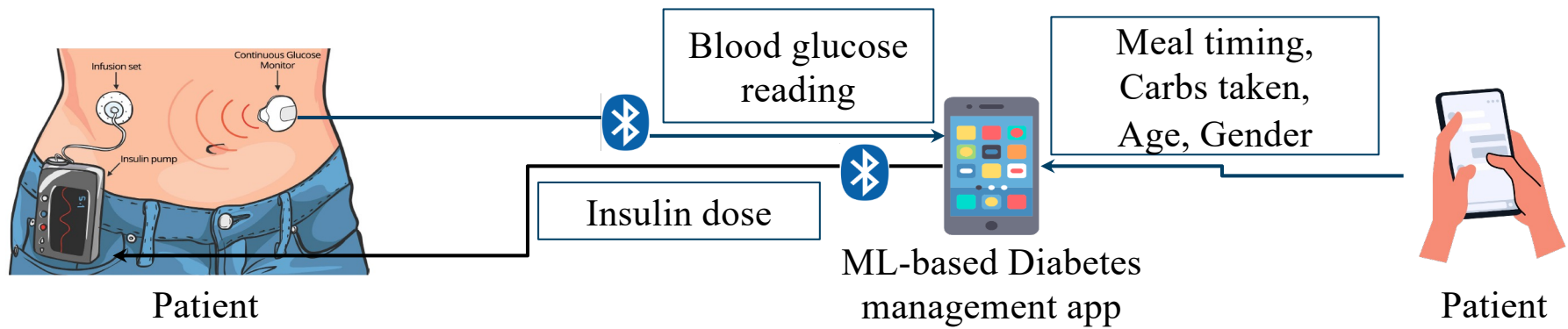


**Large number of attack points (attack surface) - Hard to foresee during design**

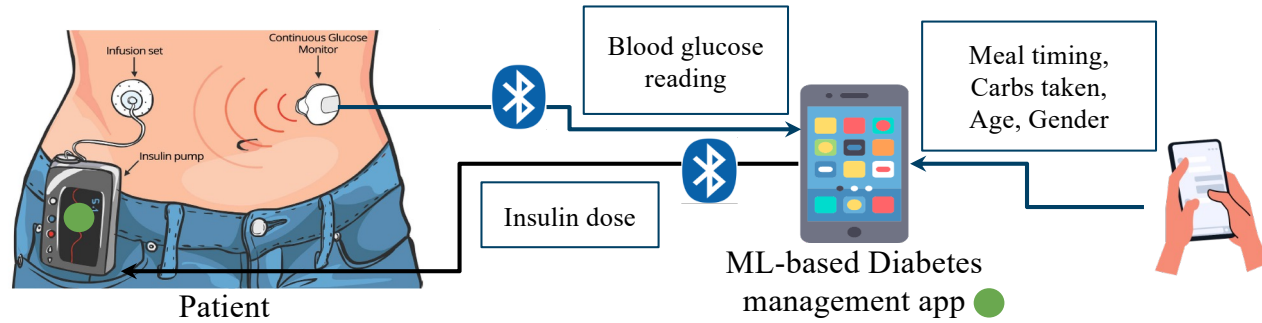
What can go wrong ?

A short story inspired by experiments

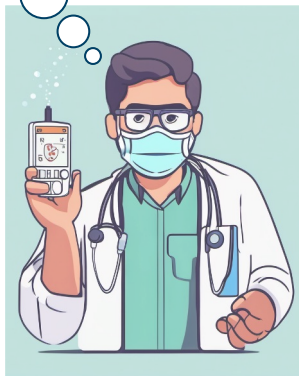
# ML-enabled Blood Glucose Management System (BGMS)



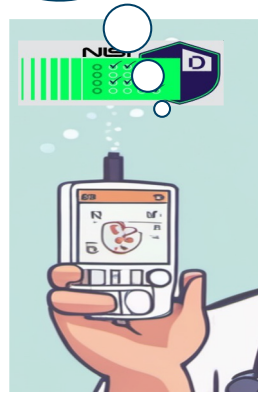
# ML-enabled Blood Glucose Management System (BGMS)



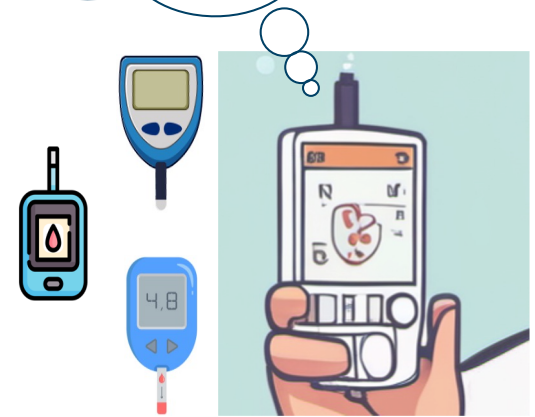
Here's the latest AI-powered insulin pump!



99.9% accurate  
safe ✓  
secure ✓

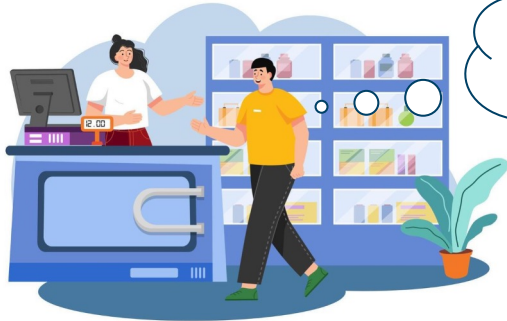


Compatible with many models of glucose meters



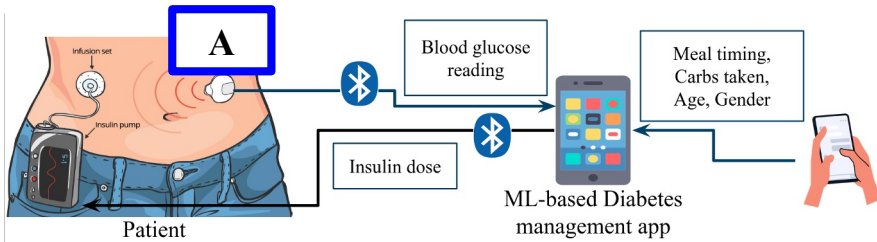
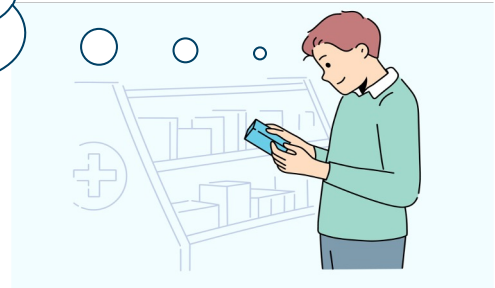


I want the new AI-powered insulin pump!

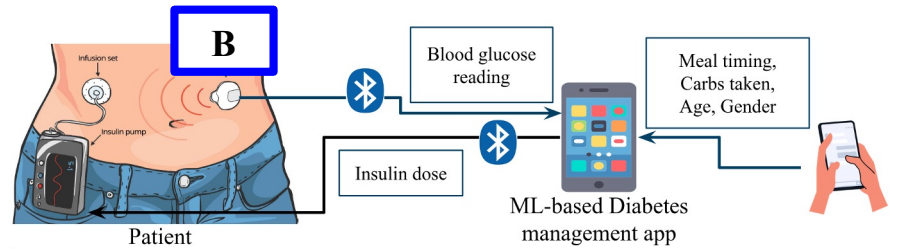


I'll get Glucose meter A

I'll buy Glucose meter B



Patient #1



Patient #2

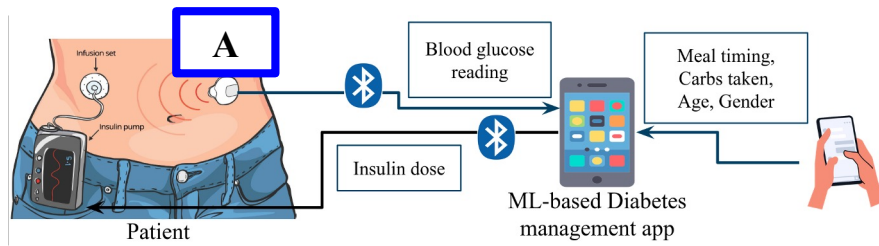


# Let's try evasion attack!

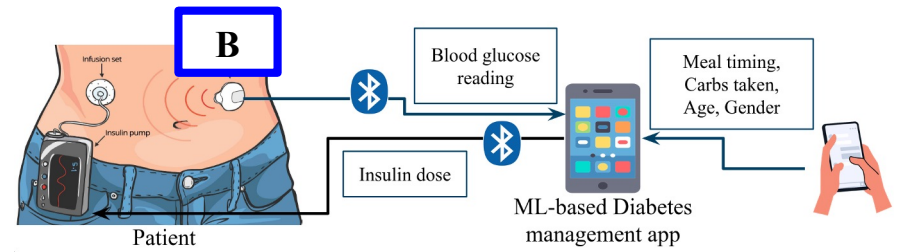


Let's make the app suggest a HIGH insulin dose when he DOESN'T need it

But how do I inject fake readings into the system?

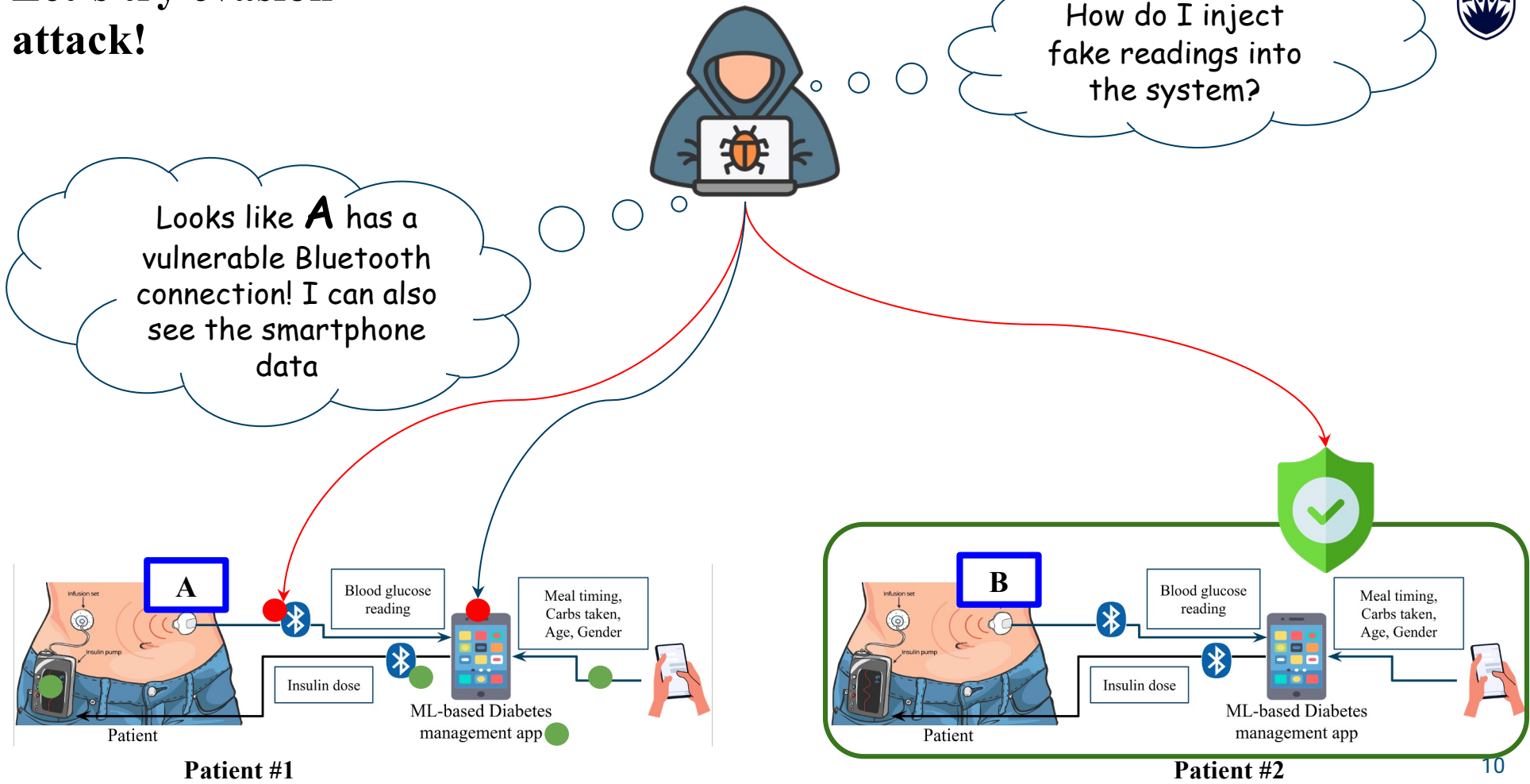


Patient #1

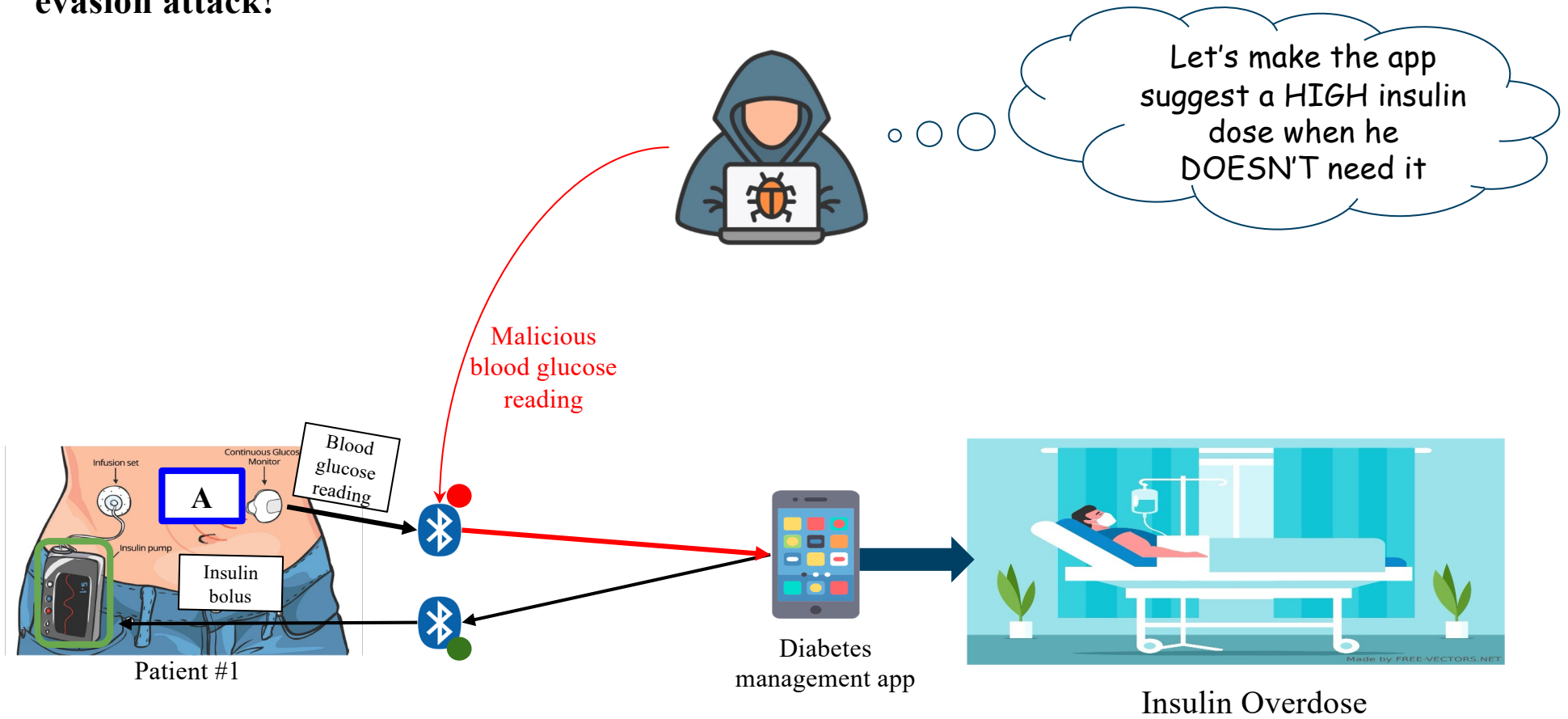


Patient #2

# Let's try evasion attack!

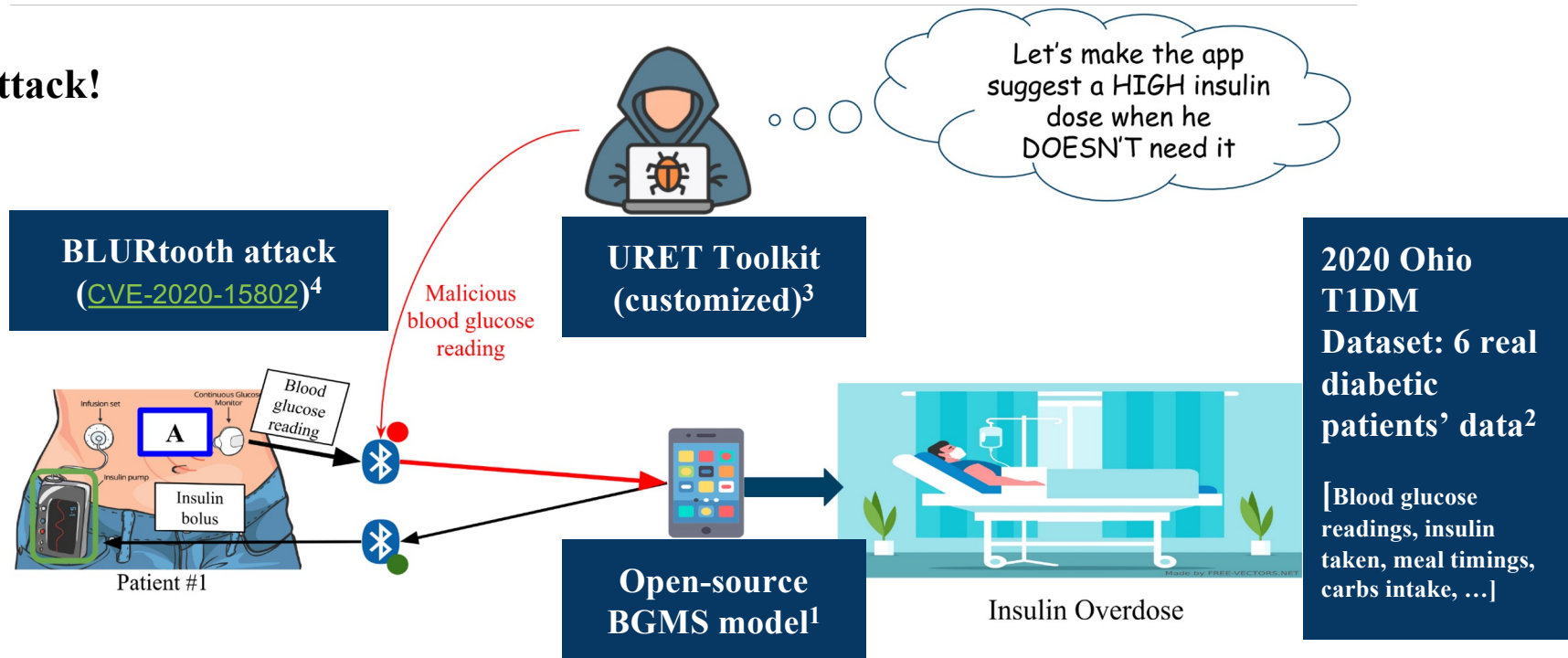


# Let's try evasion attack!



# Our Case Study

Let's try evasion attack!



<sup>1</sup> Harry Rubin-Falcone, Ian Fox, and Jenna Wiens. **Deep Residual Time-Series Forecasting: Application to Blood Glucose Prediction**. In KDH@ECAI, 2020.

<sup>2</sup> Cindy Marling and Razvan Bunescu. **The OhioT1DM dataset for blood glucose level prediction**. In CEUR workshop proceedings, NIH Public Access, 2020.

<sup>3</sup> Kevin Eykholt, Taesung Lee, Douglas Schales, Jiyong Jang, and Ian Molloy. **URET: Universal Robustness Evaluation Toolkit (for Evasion)**. In USENIX Security 2023

<sup>4</sup> Kasper Rasmussen. **BLURtooth: Exploiting Cross-Transport Key Derivation in Bluetooth Classic and Bluetooth Low Energy**. In AsiaCCS, 2022.

How can manufacturers foresee post-deployment security risks?

A systematic assessment of 20 FDA-approved devices



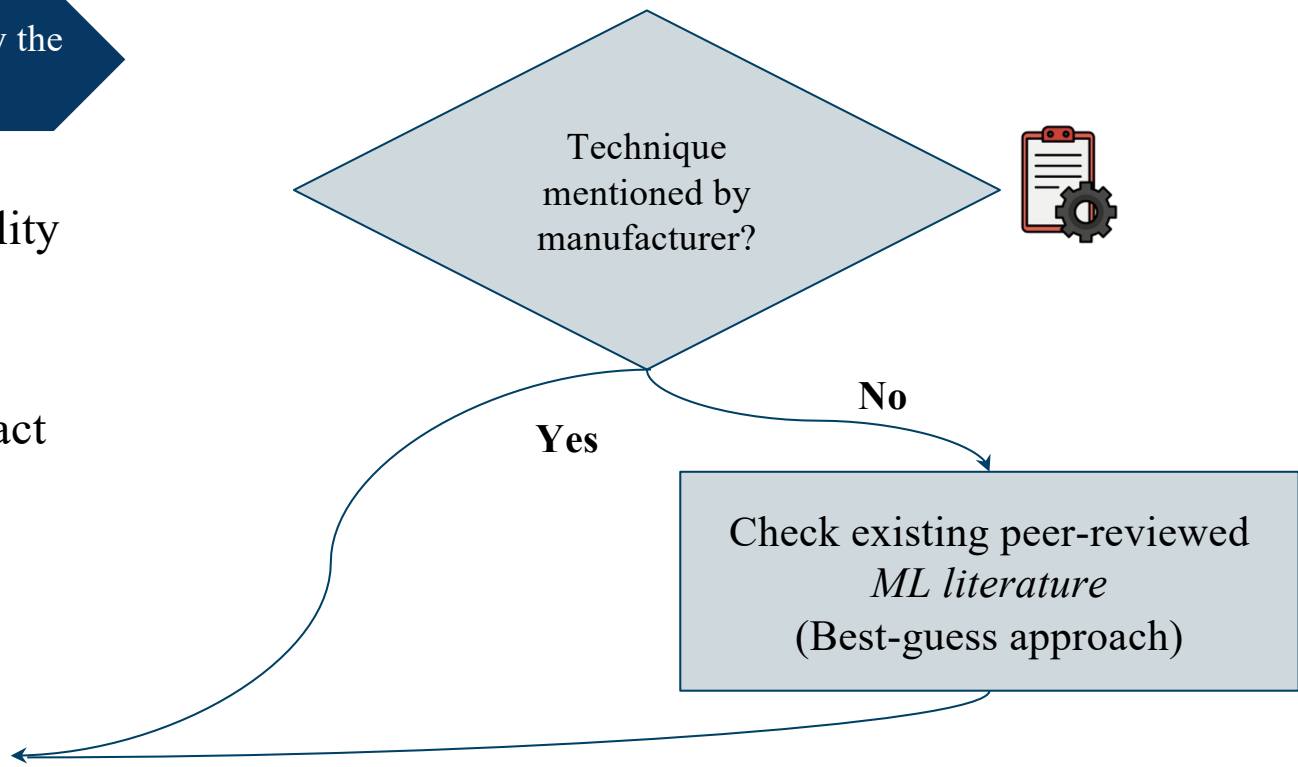
# Security Assessment Process



# Security Assessment Process

## 1. ML technique used by the device

- Device functionality
- ML engine  
mispredicts: Impact  
on patient?
- Input data types
- ML technique

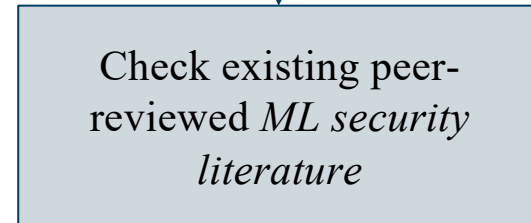


# Security Assessment Process



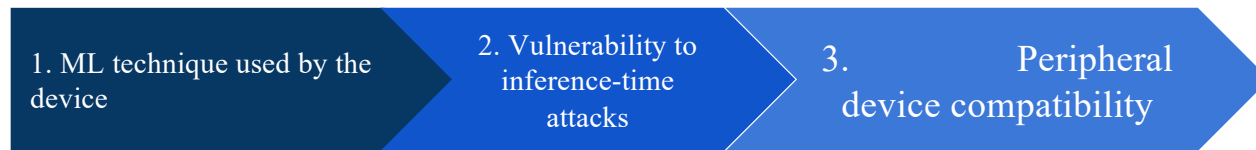
- Known attacks on ML technique
- Checks performed to detect malicious inputs? **No**, unless mentioned by manufacturer

ML technique in (1)



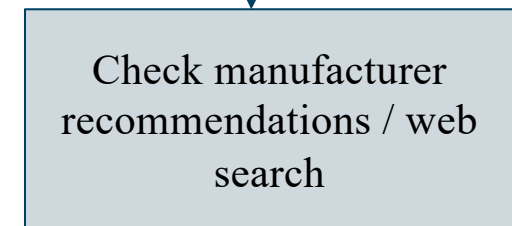


# Security Assessment Process



**Device description in (1)**

- Compatible peripheral devices and communication protocols



# Security Assessment Process



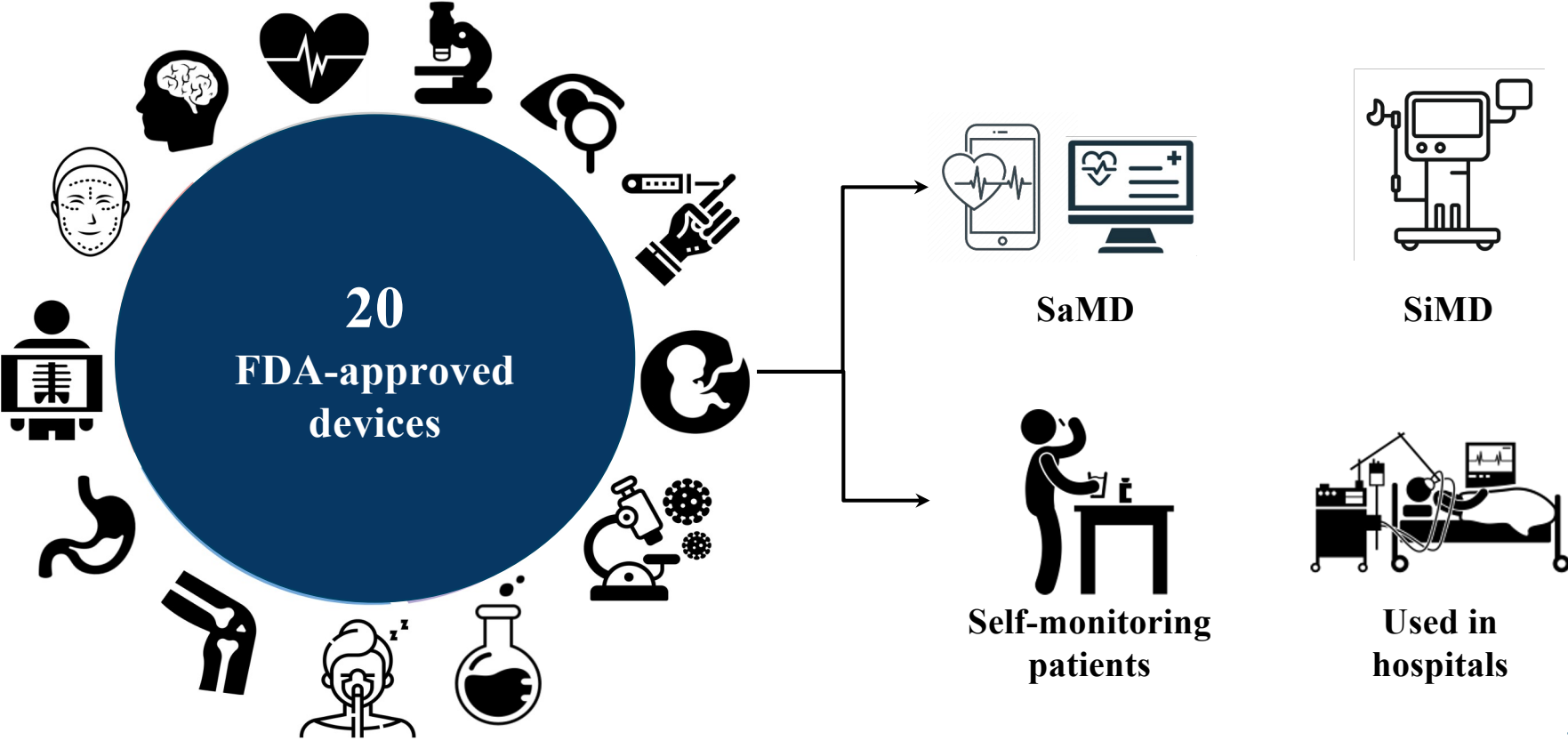
**Attack identified in (2),  
Peripheral devices identified in (3)**



Does any device / combination of devices have vulnerability that allows an attacker to execute the attack?

- Vulnerable devices and vulnerability descriptions
- Attacker position and capabilities

# Devices Assessed





## Interesting insights from the assessment

1. **Post-deployment attacks** : 16/20 devices vulnerable
2. **Attack Surface**: SaMD > SiMD
3. **Widespread Vulnerabilities** : Attack point - Core technology (e.g., IR cameras)
4. **Hard-to-detect attack paths**: e.g., IDx-DR software.
5. **Persistent Vulnerabilities**: Some won't be fixed by OEMs.



# Summary

- **ML-enabled medical applications:** Large, complex attack surface → Health risk
- **Our contribution:**
  - Systematic end-to-end security assessment process
  - Case study demonstration
- **Next steps:**
  - Automate assessment technique
  - Profile patients by security risk

**Systematically Assessing the Security Risks of AI/ML-enabled Connected Healthcare Systems**, *Mohammad ElNawawy, Mohammadreza Hallajiyani, Gargi Mitra, Shahrear Iqbal, and Karthik Pattabiraman*, IEEE/ACM international conference on Connected Health: Applications, Systems and Engineering Technologies (CHASE), 2024

