

Introduction



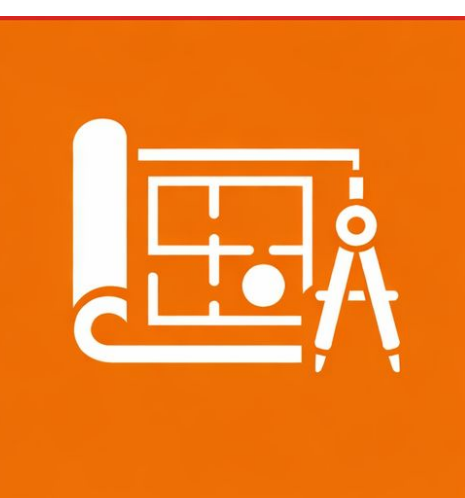
- **Modern medical devices are complex:** they're network- connected embedded systems that send and receive data over wireless and wired interfaces, via mobile applications, and to server- and serverless backends.



- Cybersecurity design defects and vulnerabilities in medical devices pose **life-threatening risks to patients**.



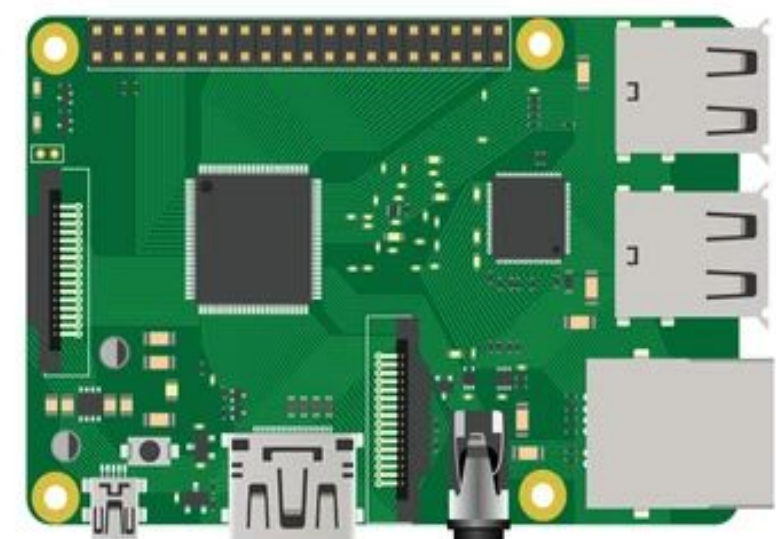
- Non-prescriptive regulatory cybersecurity expectations lead to varied practices that **hinder education and training**.



- We provide an **open-source platform** aligned with regulations to **standardize medical device cybersecurity education**.

Objective

- Device-to-cloud hardware, firmware, and software reproducible on open-source/commodity components and free-tier services.



- Quality system documentation, including design controls, design inputs, and design outputs.

#	Hazard	Hazardous Situation	Harm	Severity	Probability	Risk Control
PHA1	Battery failure	Device shuts down during critical monitoring	Loss of patient data; missed critical alerts	Serious	Occasional	Include battery health monitoring; provide low-power fallback mode
PHA2	Lack of encryption in transit	Data transmitted between the device/app and AWS is not encrypted	Interception of sensitive patient data by attackers	Critical	Occasional	Use TLS 1.3 for all communications; enforce HTTPS connections

Table 1: Quality system documentation example that defines patient harms.

Hands-On Platform Design

Our design supports a **real-world clinical application** with components typically found in **modern medical devices** to aid in diagnosis and treatment.

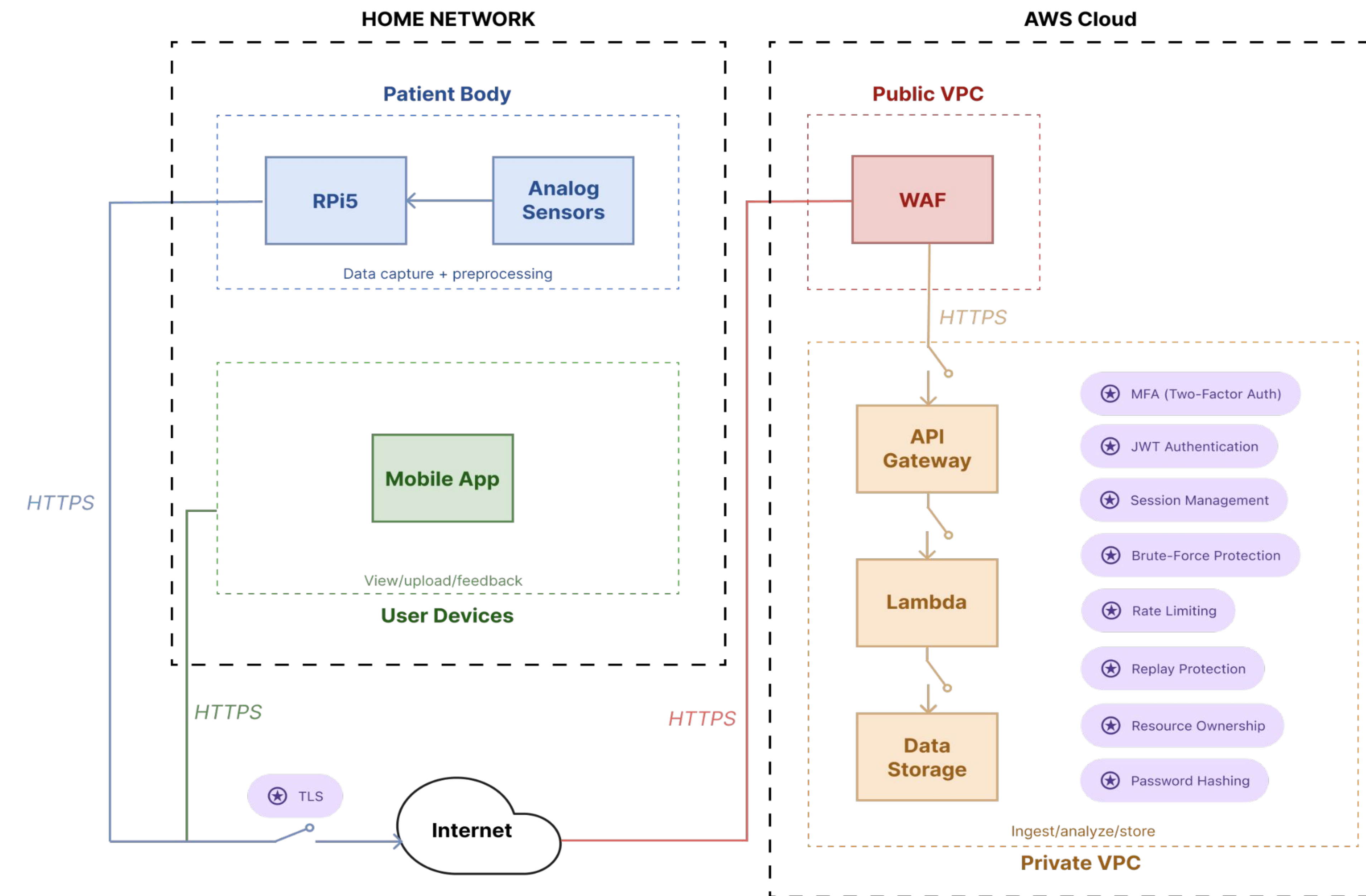
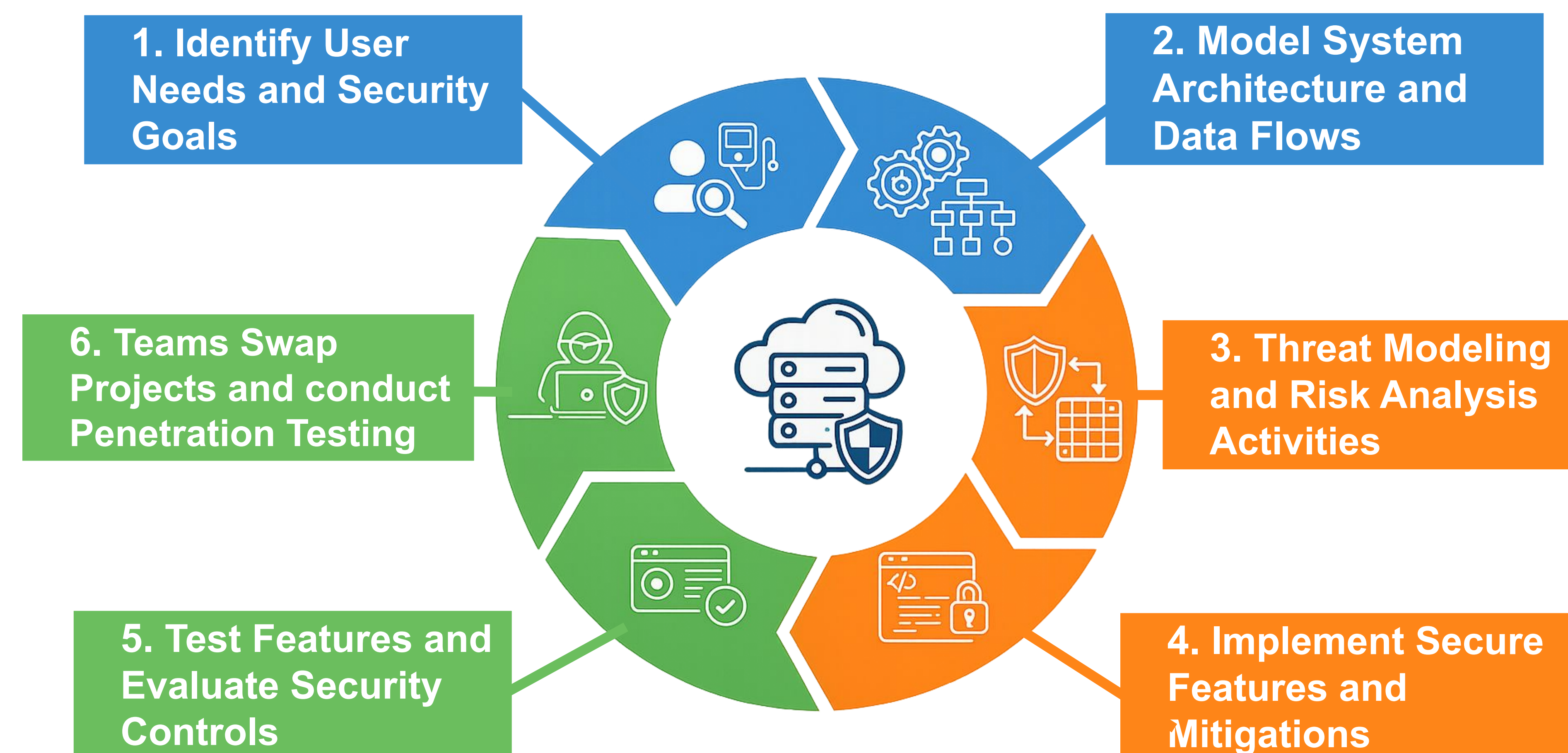


Figure 1: Hands-On Platform architecture diagram.

Class Pilot: Activities



We use Structured Worksheets to **turn abstract FDA requirements** into **engineering tasks** that mirror the real-world regulatory lifecycle.

Class Pilot: Parkinson's Disease Monitoring

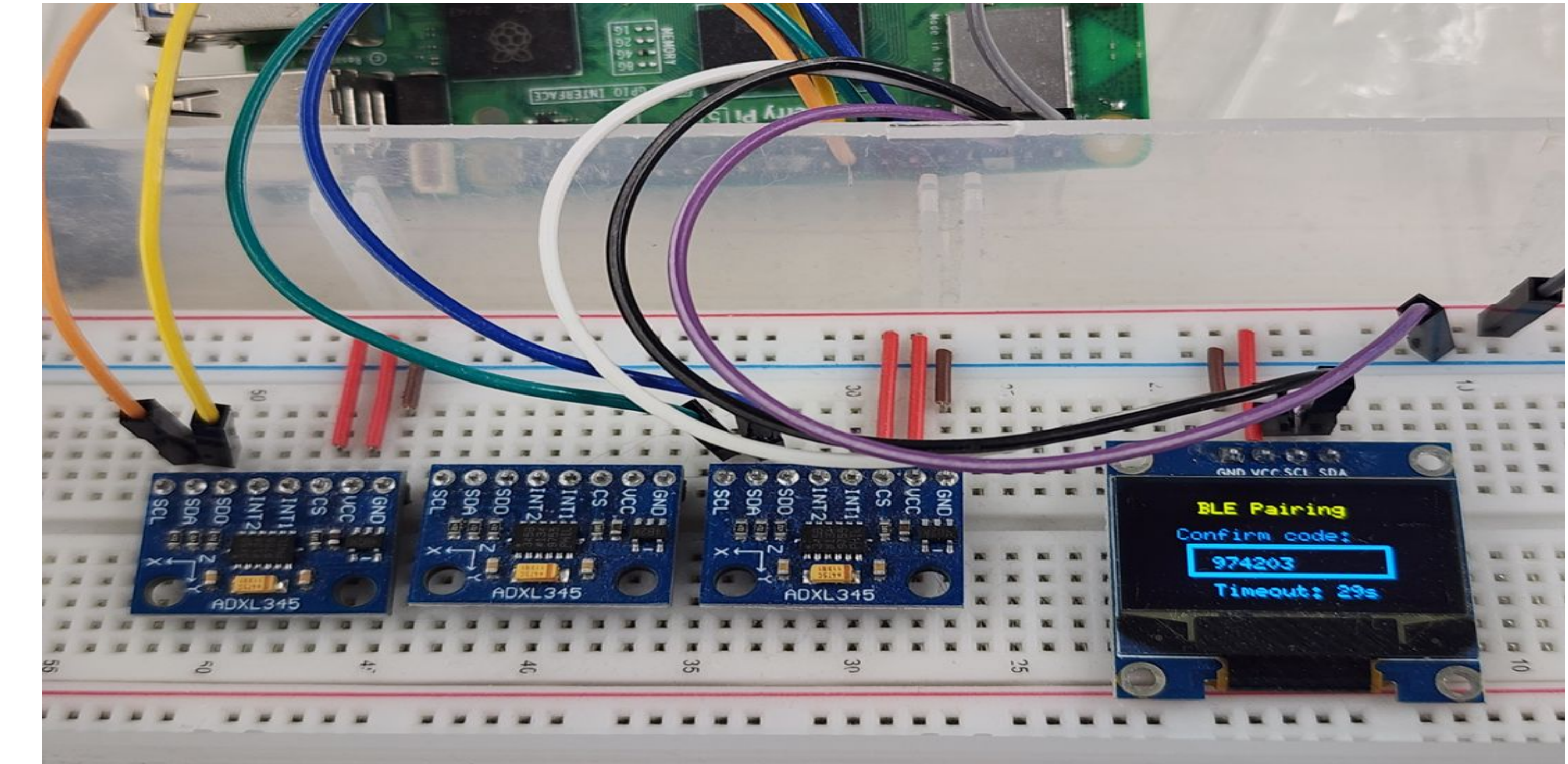


Figure 2: Medical Device for Parkinson's Treatment Monitoring

- Piloted in a course project focused on a **Parkinson's treatment monitoring medical device** scenario.
- Students applied **security by design** principles within a realistic, regulated development context.

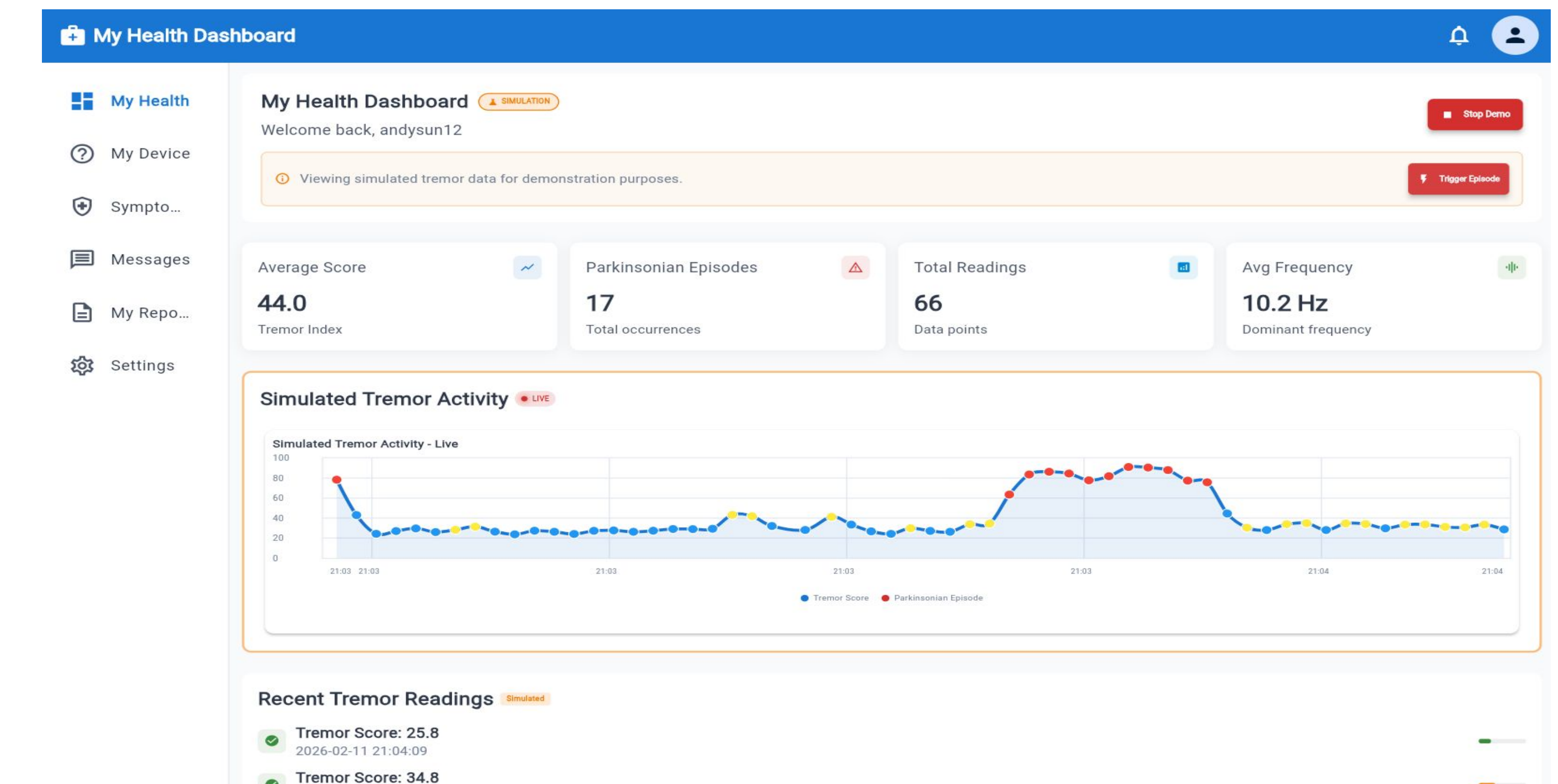


Figure 3: Patient Dashboard for Parkinson's Treatment Monitoring

Discussion

- What is the *educational value* of a hands-on platform for students learning medical device cybersecurity and patient safety?
- Can development and regulatory simulation *validate* educational efficacy?

Contact Us

Our goal is to extend our platform to students and the medical device community. Please use this **QR Code** to *contact us* or *learn more* about our platform.

