CYLCOMED

Device Integrity Check

RGB

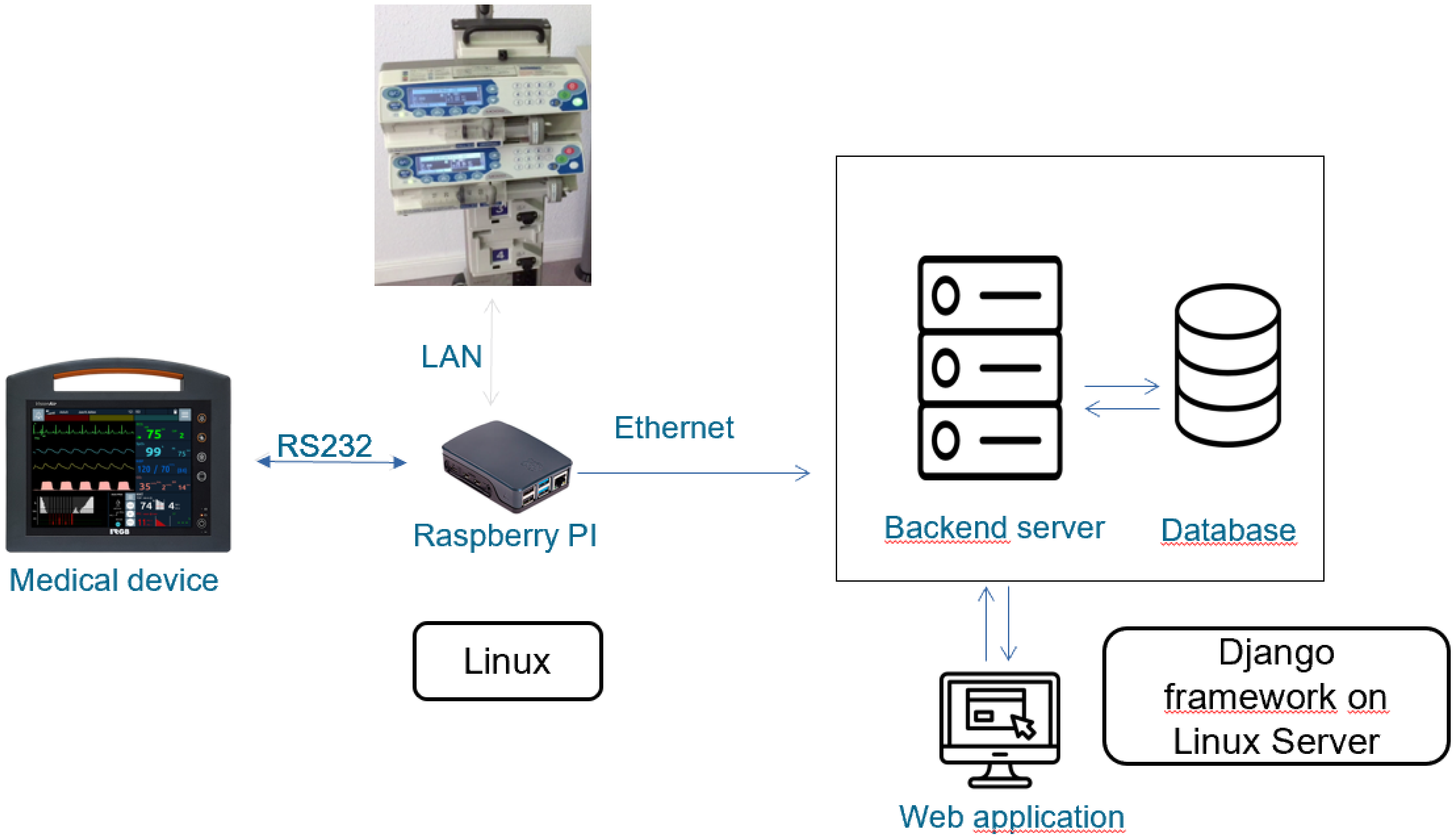
January 2025

Overview of Device Integrity Check Implementation

- The Device Integrity Check is a crucial component of the CYLCOMED toolbox, designed to ensure the reliability and security of connected medical devices (CMDs). This implementation focuses on maintaining the integrity of medical devices while facilitating secure updates and managing their lifecycle effectively. Its primary objective is to introduce cutting-edge cloud-native and service management solutions, with the overarching goal of automating the secure delivery of services both in the cloud and within the IoT/Edge layer, specifically tailored for medical solutions. It also incorporates a strategy to integrate security features into legacy medical devices by utilising a standard external Linux-based board that connects to the legacy device (Vision Air monitor) via a serial channel. This se
modifications in the legacy device.

- Testing and validation: the implementation will undergo rigorous testing within a HiL and SiL testbench platform. This approach allows for the verification of the controller's performance in simulated environments before deployment in real-world settings.

- Communication with other components: the Device Integrity Check interacts with various components within the CYLCOMED ecosystem, including infusion Pump Controllers and Backend server/Web application. Notably, the focus lies on delivering key functionalities essential for optimising service delivery, ensuring security, and enhancing efficiency, such as ensure secure updates of services in the medical devices; reducing attack surface in the medical devices and cloud infrastructure; detecting misconfigurations and ensuring code and configuration integrity.



Architecture and Interoperability Strategy

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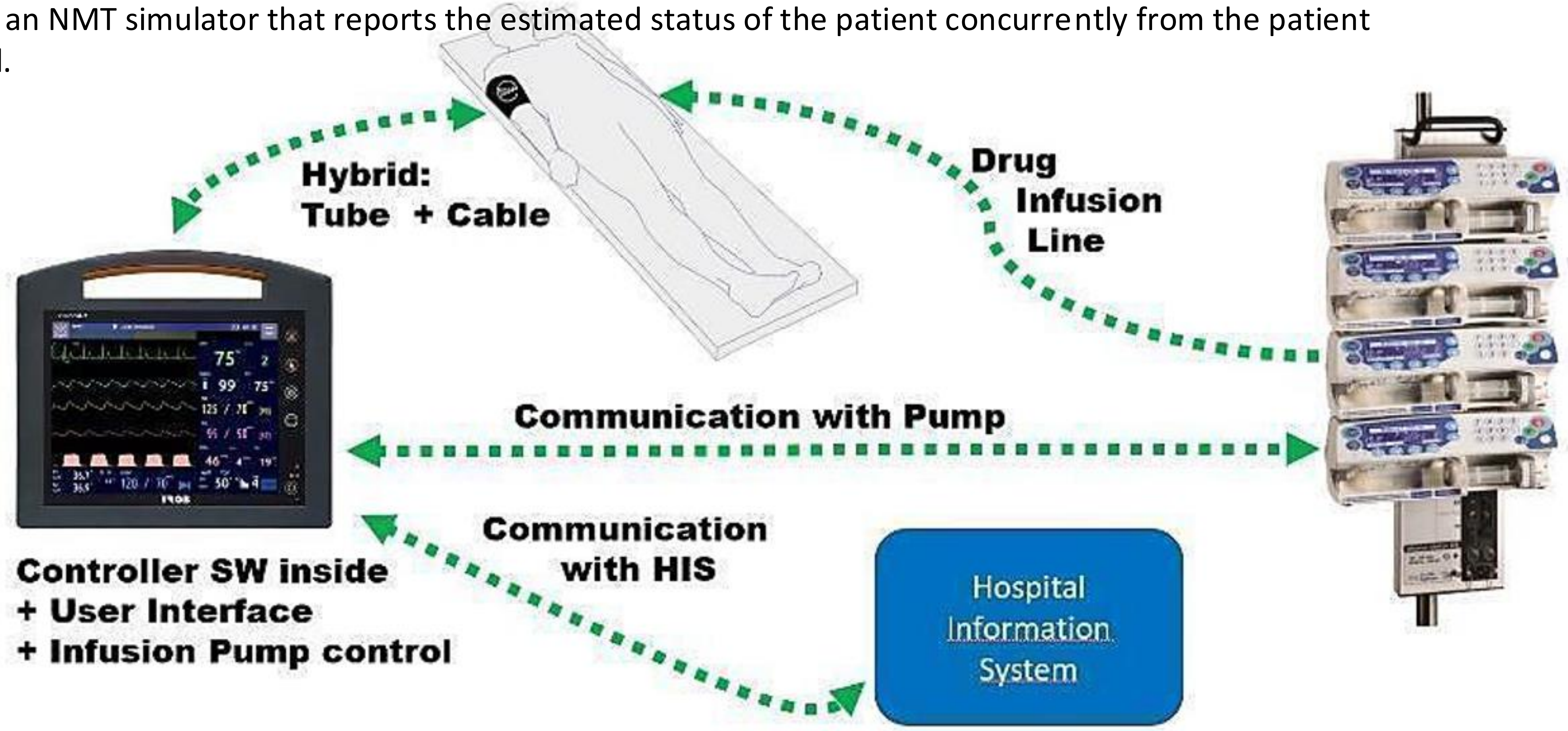
Overview of the System

- Implements a NMT (NeuroMuscular Transmission) infusion controller with RGB's NMTCUff monitoring system.
- Utilises electrical stimulation and response analysis of waveform expressions of vital signals, specifically through movement in the arm.
- Integration with NMT Simulator: the system employs an NMT simulator that reports the estimated status of the patient concurrently from the patient Pharmacokinetics/Pharmacodynamics (PK/PD) model.
- Control Algorithm: based on the information received from the NMT simulator, a control algorithm determines the appropriate new dose to be infused.
- User Interface and connectivity: The Vision Air multiparameter monitor serves as the user interface, providing connectivity means for seamless integration and monitoring. All this while enabling for remote updates the tools will ensure that delivered solutions are up-to-date with latest security patches and in the case of faulty configurations, these are not increasing the attack surface.



Data Security and Encryption Mechanisms

Secure Data Storage: encrypted data is securely stored on the backend server, with controlled access based on user roles and profiles.

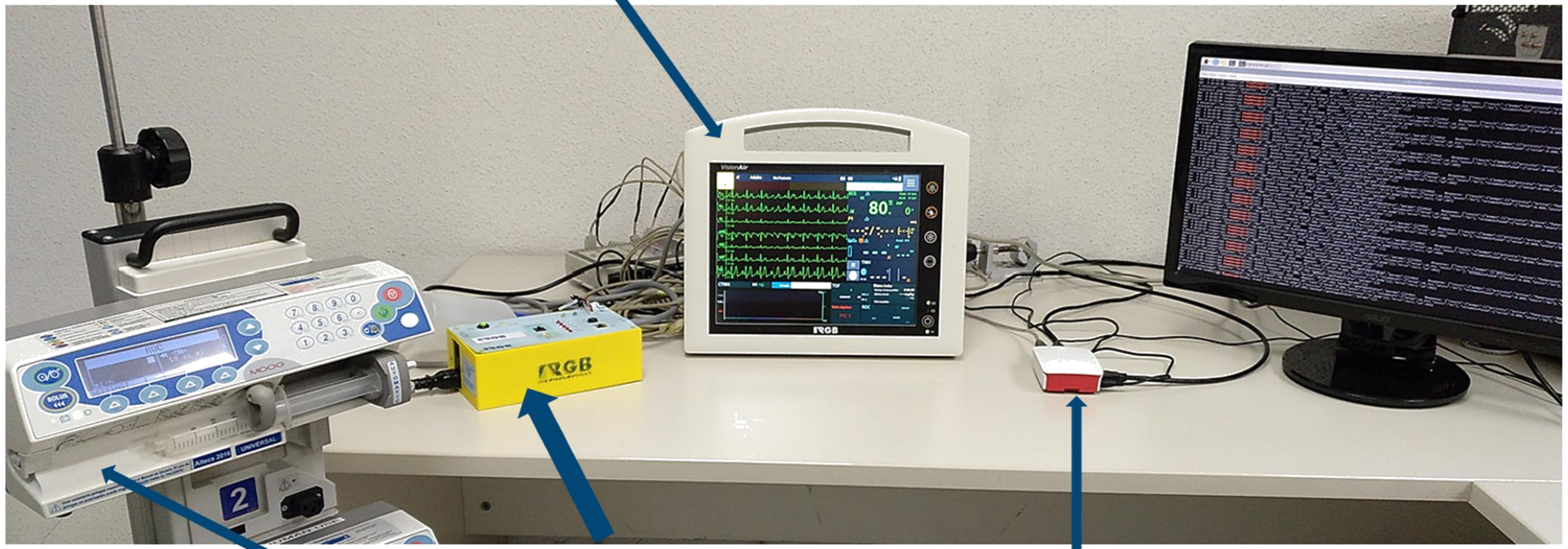
Current capabilities include: evaluation of encrypted data storage practices for enhanced security and implementation of access controls designed to protect sensitive patient information effectively.

Patient Simulation Testbench: The testbench includes a patient simulator that estimates the patient's evolution for a given infusion profile.

- A Raspberry Pi board is incorporated, which includes the controller software that converts the values received from the Raspberry Pi to the NMT effect and determines the new relaxant dose to infuse.

- The setup features patient model software specifically for the relaxant drug Rocuronium, enabling simulation functions where the vision interface shows an estimate of the patient's evolution based on the infusion profile.

- Controls the infusion pumps and integrates the CYLCOMED software for enhanced functionality.



THANK YOU FOR YOUR ATTENTION

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