PEP: Hardware Emulation Platform for Physiological Closed-loop Control Systems

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Abstract. Physiological closed-loop control systems (PCLCS) provide reliable and efficient treatment in medical care, but it is crucial to ensure patient safety when examining the potential advantages. Traditional animal and clinical studies are resource-intensive and costly, making them impractical for evaluating PCLCS in every relevant clinical scenario. Therefore, computational or mathematical models have emerged as an alternative for assessing PCLCS. Hardware-in-the-loop testing platforms can provide a more efficient alternative to traditional animal and clinical studies. The platforms utilize computational or mathematical models to simulate PCLCS, providing a cost-effective and efficient approach that can minimize errors during the development process. Although various software simulation platforms can model specific physiological systems, there is a lack of hardware emulation platforms for PCLCS. In this demonstration, we present a novel *physiological emulation platform (PEP)* using a hardware-in-the-loop method developed to connect a computational model of the patient's physiology to the actual PCLC device hardware, enabling real-time testing of the device while incorporating the hardware components.

Keywords: hardware emulation, test platform, physiological closed-loop control systems (PCLCS)

1 Introduction and Motivation

Over the last few years, the quality and access to medical care have seen unprecedented improvements, stimulating a revived interest in clinical automation and pushing scientists to develop creative solutions in the domain of physiological closed-loop control systems (PCLCS). A wide variety of experts are striving to generate cutting-edge PCLC-based medical devices and setting up an integrated academic-commercial infrastructure to serve this quickly progressing domain. Given the potential advantages of PCLCS, such as reliable and efficient treatments and the ability to augment medical assistance, especially in emergencies, it becomes crucial to prioritize patient safety in evaluating these systems. The authors in [5] explored the security threats and attacks and the challenges associated with wearable and implantable medical devices (WIMDs) and closed-loop medical control systems.

Automated closed-loop insulin delivery, also known as the artificial pancreas system (APS), is a type of PCLCS that incorporates a continuous glucose sensor, insulin pump, and control algorithm to regulate insulin delivery based on real-time blood glucose values [3]. A well-functioning APS can provide numerous benefits to patients; however, a malfunctioning APS can lead to an overdose or underdose of insulin, putting the patient in danger. A study was conducted to investigate the safety and design requirements of the APS, focusing on both individual components and the system as a whole [1]. The US Food and Drug Administration (FDA) emphasizes the importance of ensuring the safety and reliability of PCLCS since malfunctioning medical devices can lead to severe injury or even death [2].

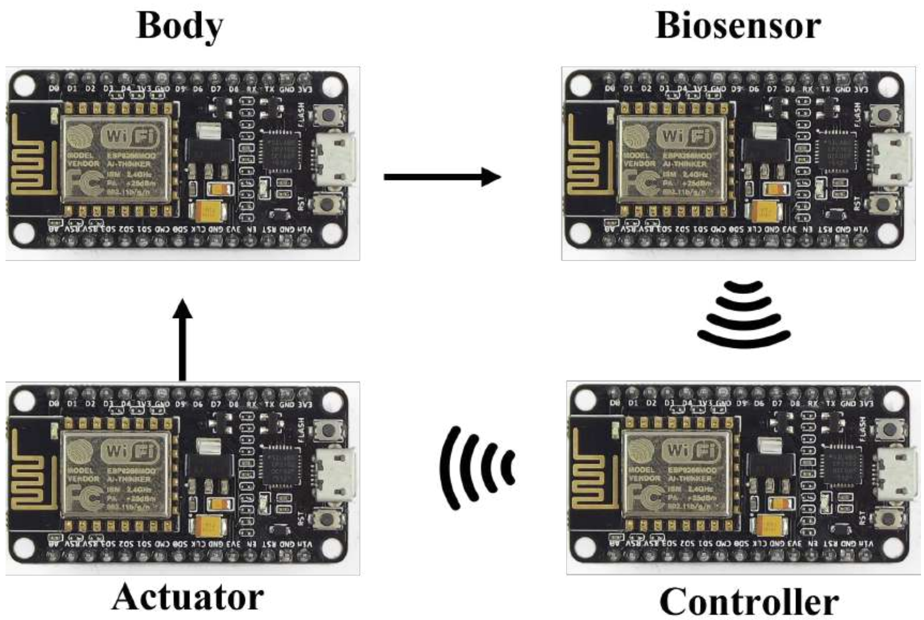

Fig. 1: Overview of our emulation platform showing the connectivity between the different hardware components.

Evaluating the functionality and safety of PCLCS in every relevant clinical scenario through animal and human trials is not practical due to the complexity of these systems and the potential for various disturbances to affect their operation. As a result, closed-loop systems in various engineering fields are typically designed through computational and mathematical modeling to increase efficiency, reduce costs, and avoid errors during the development process. This approach of evaluating PCLCS through a computational or mathematical model of the patient response can provide a complementary or alternative solution to traditional animal and clinical studies [2]. The development of hardware-in-the-loop testing platforms has been driven by the need for a more efficient alternative to costly and resource-intensive clinical trials. As a result, the focus has been on systems that impact the most vital organs, such as heart testbeds for the validation of pacemakers [4] and cardiovascular interventions [9], and robotic surgery testbeds for MRI-guided biopsy [7]. In recent years, there have been significant developments in the area of *in silico* trials for insulin control algorithms aimed at promoting research on APS [8]. Furthermore, the authors in [10] present a novel and open-source testbed for APS, which includes realistic controllers, simulations of a broad range of patient profiles, and a simulation of potential adverse events. Despite the presence of various software simulation platforms that can model certain physiological systems, there is currently a shortage of *hardware emulation platforms* for PCLCS. The creation of such a platform could provide a vast amount of data that can be further analyzed to enhance the safety and reliability of PCLCS. The overview of our emulation platform is shown in Figure 1, which displays the connectivity between the different hardware components.

In this research demonstration, we present a platform using a hardware-in-the-loop method that can connect a computational model of the patient's physiology to the actual PCLC device hardware, enabling real-time testing of the device while incorporating the hardware components. The main contributions are as follows:

1. We develop PEP, a novel *hardware emulation platform* comprised of all the major PCLCS components to serve as a reliable tool for testing and optimizing closed-loop medical control systems.
2. We simulate APS as a case study and demonstrate the emulator's effectiveness and functionality, which provides a comprehensive assessment of its ability to accurately mimic the physiological system's behavior.

2 Proposed Design

We developed a hardware emulation platform, PEP that consists of four modules: (1) body; (2) sensor; (3) controller; and (4) actuator. In this section, we will discuss the implementation details of each module, which collectively simulate an APS. Figure 2 illustrates the experimental setup of PEP, emphasizing the individual modules comprising the platform. The modules are based on the ESP8266 development kit, which features a 32-bit microprocessor using the Tensilica Diamond Standard 80 MHZ CPU. It has 17 GPIO pins and supports I2C, UART, and SPI buses. The ESP8266 also includes built-in wireless capabilities with a 2.4 GHz antenna, and deep sleep operating features, making it ideal for IoMT projects. The current system has the capability to emulate three distinct patient types: adult, adolescent, and child. Upon startup, the user can select the desired patient type from a menu screen displayed on an OLED I2C display. The patient data used for emulation is sourced from an average of 100 in silico adults, adolescents, and children, as detailed in [6]. It is worth noting that our system is flexible and can readily support other types of patients as needed.

2.1 Body

The body module replicates essential processes within the human body, such as blood glucose concentration. To generate glucose signals, a control algorithm based on glucose kinematics differential equations obtained from the UVA/PADOVA simulator [6] is employed. These signals are transmitted through a serial bus (UART) to and from the biosensor and controller module. A push-button is utilized as input through a dedicated receiving GPIO pin to mimic the effect of a meal. By modifying the biosignals based on inputs from the controller module, the platform emulates the dynamic behavior of an actual PCLCS.

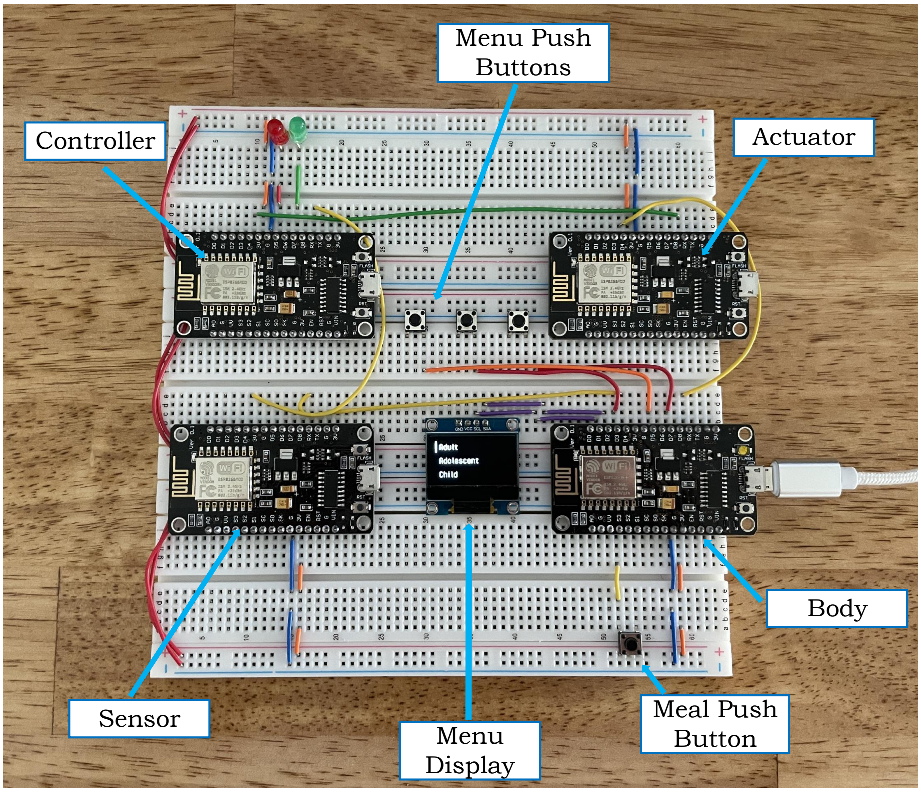

Fig. 2: Experimental setup of the proposed hardware emulation platform, *PEP*.

2.2 Sensor

The sensor module receives input data from the body module via a wired connection. The biosignals captured by the sensor module are then transmitted to the controller module through Wi-Fi, utilizing a client-server model with HTTP requests. This wireless transmission enables seamless communication between the modules, facilitating real-time data exchange. As a backup, the sensor is also connected to the controller via the UART bus, allowing for both wired and wireless testing methods.

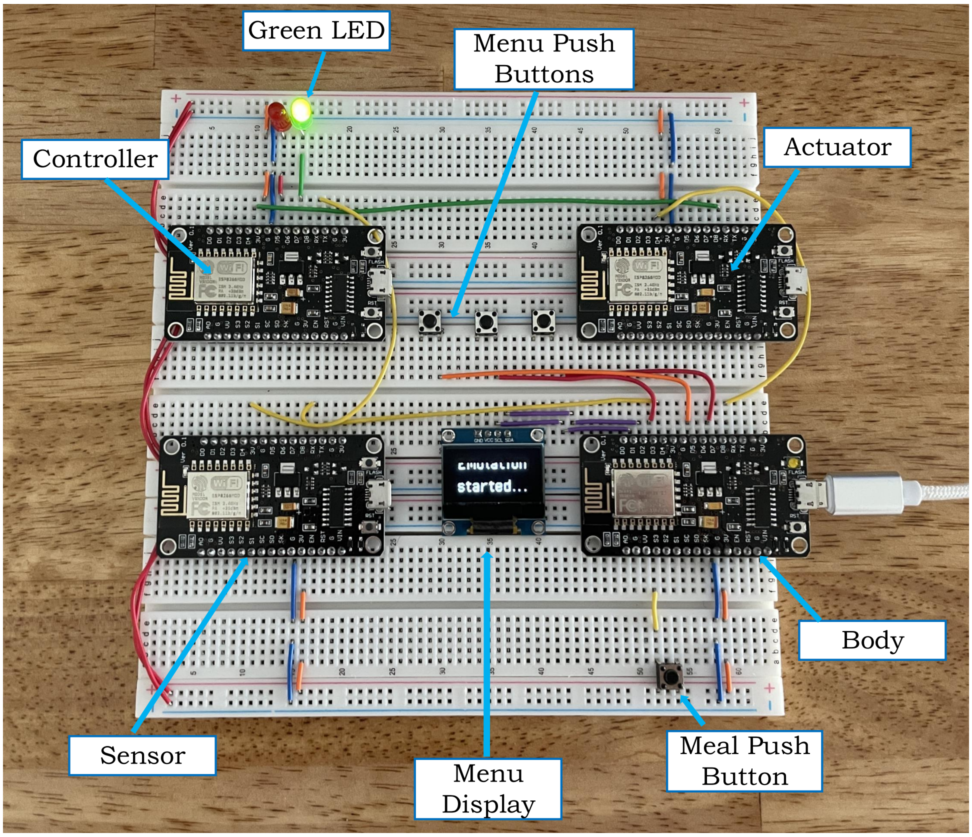

Fig. 3: PEP with a green led indicating a normal range of the measured glucose value.

2.3 Controller

Within the controller module, wireless input data is received from the sensor module. The controller module uses a control algorithm to calculate the appropriate therapy or treatment required. The calculations are based on the glucose kinematics differential equations. Once determined, the treatment amount is sent to the actuator module via Wi-Fi employing a client-server model with HTTP requests, or through a wired UART bus. The controller module also incorporates an alert system featuring green and red LEDs. These LEDs indicate normal and out-of-range glucose values, providing visual feedback to the user.

2.4 Actuator

The actuator module receives wireless input from the controller module and applies the necessary treatment to the body through wired connections. Based on the calculated treatment amount, the actuator module administers insulin or glucagon, aiming to maintain the physiological parameters within the desired range.

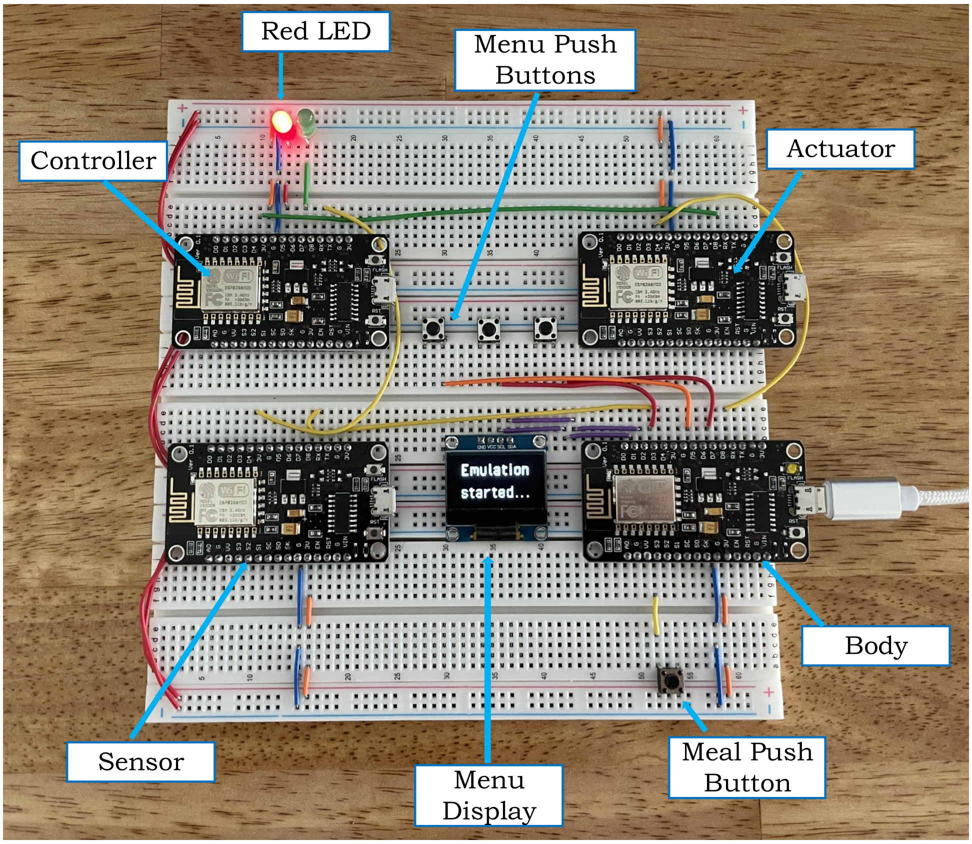

Fig. 4: PEP with a red LED indicating that the measured glucose value is out-of-range.

3 Experimental Results And Discussion

In this section, we present two figures that demonstrate the accuracy of PEP in indicating normal or out-of-range glucose values. Figure 3 shows a green LED, indicating that the measured glucose value is within the normal range. Figure 4 displays a red LED to highlight that the measured glucose value is outside the normal range, specifically, below 70 or above 180.

The PEP offers a versatile foundation for modeling various faults or attacks, considering the overall system and individual components. The sensor module can be configured through precise programming to replicate diverse issues, including sensor drift or defective acquisition circuits. Additionally, the controller within the PEP allows for the simulation of various faults or malicious attacks, such as denial of service (DoS) or communication prevention. By leveraging the capabilities of the PEP, the actuator can also be effectively modeled to mimic incorrect treatment scenarios, providing valuable insights into potential vulnerabilities or weaknesses in the medical system. This comprehensive fault and attack modeling capacity enables researchers and developers to conduct in-depth testing and assessment of the system's robustness and resilience against potential real-world challenges. Furthermore, the PEP's adaptability facilitates the examination of component-specific faults, enabling a granular analysis of individual modules within the medical system. Researchers can delve into the complex interplay between various components and evaluate the system's response to faults or attacks at different levels, paving the way for precise identification and resolution of weaknesses.

Overall, the PEP can be an indispensable tool for enhancing the security and reliability of closed-loop medical control systems, providing an invaluable testing platform for designing and reinforcing systems against potential faults and malicious intrusions. Its multifaceted capabilities can be utilized to optimize medical systems, ensuring their resilience and trustworthiness in real-world scenarios, ultimately contributing to safer and more efficient patient care.

4 Conclusion

In this research demonstration, we introduced the physiological emulation platform, PEP, a versatile hardware emulation platform capable of replicating the behavior of any physiological system. As a case study, we utilized PEP to simulate an Artificial Pancreas System (APS), showcasing its ability to effectively emulate the APS's functionality. By modeling various physiological responses and system components, PEP can serve as a valuable tool for assessing the security and reliability of PCLCS in different scenarios. Future work will involve expanding the platform to include modeling and evaluating different types of faults or attacks targeting individual system modules. This extension will enable comprehensive security analyses and help designers develop more robust and secure PCLCS in the evolving landscape of modern healthcare applications.

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