AbbVie Pump Automator
Engineering Science Capstone Design Project
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Abstract

AbbVie Biopharmaceutical Company manufactures and supplies drugs that are delivered by the CADD-Legacy 1400 infusion pump. To ensure the pump is functioning properly, in-house performance testing checks that infusion pump engineering standards are being met. These tests can be tedious when done manually. To simplify and speed up this testing process, the Pump Automator was built. Using actuators to press buttons and a camera to read the screen, the Pump Automator removes the need for a lab technician to manually perform tests, ultimately saving time and providing a more robust testing process.

Introduction

An infusion pump is a medical device used to deliver fluids, such as nutrients or drugs, to a patient in a controlled manner. Infusion pumps are used for critical care, emergency care, and long- and short-term disease maintenance. Infusion pumps are required to comply with relevant engineering standards to ensure they are safe and effective for patients. An internationally recognized standard for infusion pumps is IEC 60601-2-24:2012 which outlines the device's particular requirements for the basic safety and performance, such as how the infusion pump should respond to a blockage in its tubing.

Design Requirements

To test performance characteristics against engineering standards, the Pump Automator required three main functionalities that are controlled through a developed LabVIEW software:

1. **Button Actuation:** A hardware interface to press buttons on a pump while keeping the screen clear of obstructions.

2. **Optical Character Recognition:** Screen and character recognition capabilities to read information from the pump screen.

3. **Tubing Occlusion:** A hardware interface to block and unblock the tubing set automatically. By blocking the tubing, the Pump Automator can test that the infusion pump can detect and respond to the blockage.

Methods

The engineering design process can quickly become convoluted with many different features required in a final design. To streamline the construction of the Pump Automator, the FDA's model-based engineering design process was used. This process encourages engineers to break down a system into smaller subsystems. All subsystems are then outlined in a system diagram (Figure 1). Each subsystem has their own set of requirements that are defined in a Project Requirements Specification document. For example, the button actuation subsystem is required to receive a signal and press the appropriate button.
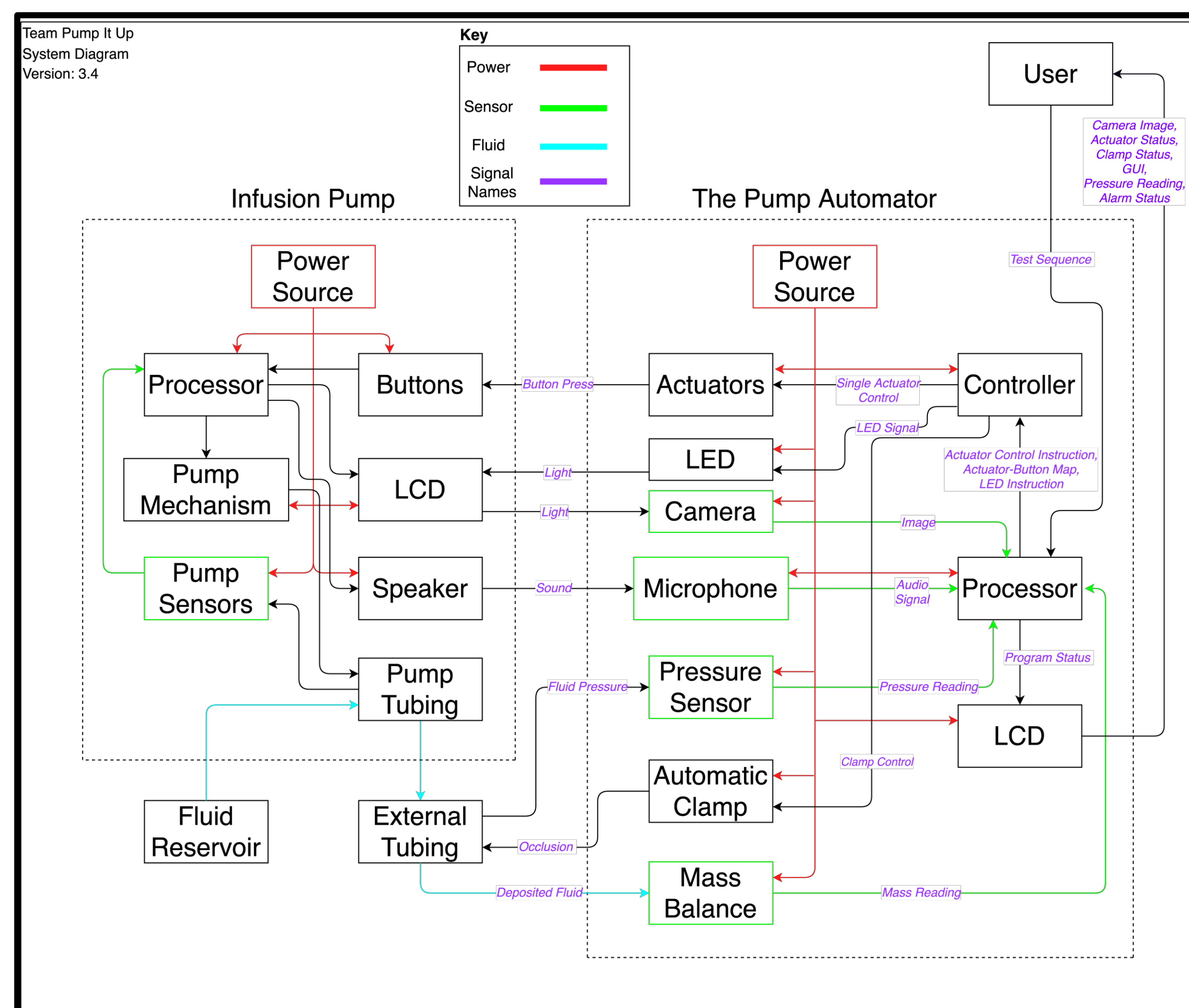

Figure 1. System Diagram.

Figure 2. 3D Model of Pump Automator.

Figure 3. Pump Automator.

Software

The software to control the subsystems is created in LabVIEW and communicates with the hardware through an Arduino microcontroller. Extra power is provided to the actuators through an Adafruit servo driver. The LabVIEW software utilizes the Message Handling Loop (MHL) architecture which allows asynchronous control of the different subsystems. The software can perform higher level instructions such as 'Turn On Pump' and 'Perform Occlusion Test'. These instructions are composed of a series of lower level instructions such as 'Press Enter Button', 'Wait For Screen Text' and 'Block Tubing'.

Button Actuation

Nine Actuonix actuators were used to press the nine buttons on the infusion pump. The actuators are housed in a 3D printed fixture that aligns them with the infusion pump buttons (Figure 2, 3). Each actuator has a 3D printed tip to provide a consistent button press.

Optical Character Recognition

Mounted within the 3D printed fixture is a near field high resolution camera that continuously captures an image of the pump screen (Figure 4). The image is fed through preprocessing to isolate the characters on screen. Finally, the characters are read by comparing them to previously recognized characters to find a match (Figure 5). The recognized characters are used by the software to help determine the Pump Automator's next action.

Figure 4. Acquired image of pump screen.

Figure 5. Read screen text from OCR.

Tubing Occlusion

A subsystem named the Automatic Clamp was created to handle blocking and unblocking of the tubing. A single Actuonix actuator is mounted within the Automatic Clamp fixture (Figure 3,5). The actuator uses a specialized 3D printed tip to fully block the tubing running through the fixture.

Figure 5. Automatic Clamp Sketch

Conclusion

The final step in the model-based design processes involves a risk analysis in which subsystems are analyzed for risks such as software/hardware failure or injury to a user. These risks are then mitigated through design improvements. For example, the Pump Automator involves both water and electronics which poses a risk of electrical shock. To mitigate this risk, the tubing is fed to the mass balance which is surrounded by a shielding to lower the chance of liquid escaping the tubing. Lastly, the model-based design process involves a Design Verification Test (DVT) in which subsystems are verified. A DVT was performed on the Automatic Clamp subsystem using Simulink software to verify that the tubing is completely blocked. With the Risk Analysis and DVT completed, the Pump Automator is a proof of concept that the CADD-Legacy 1400 infusion pum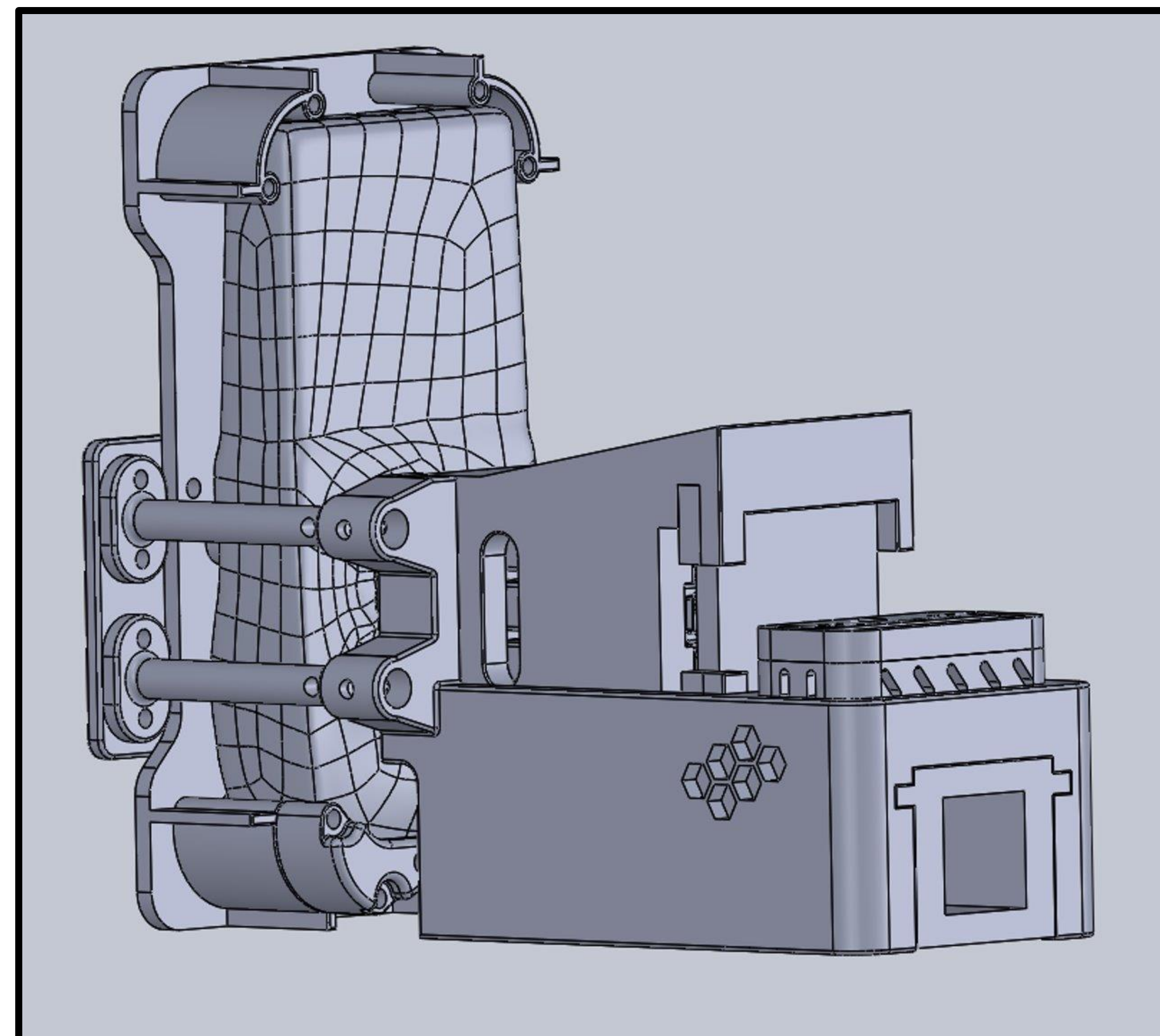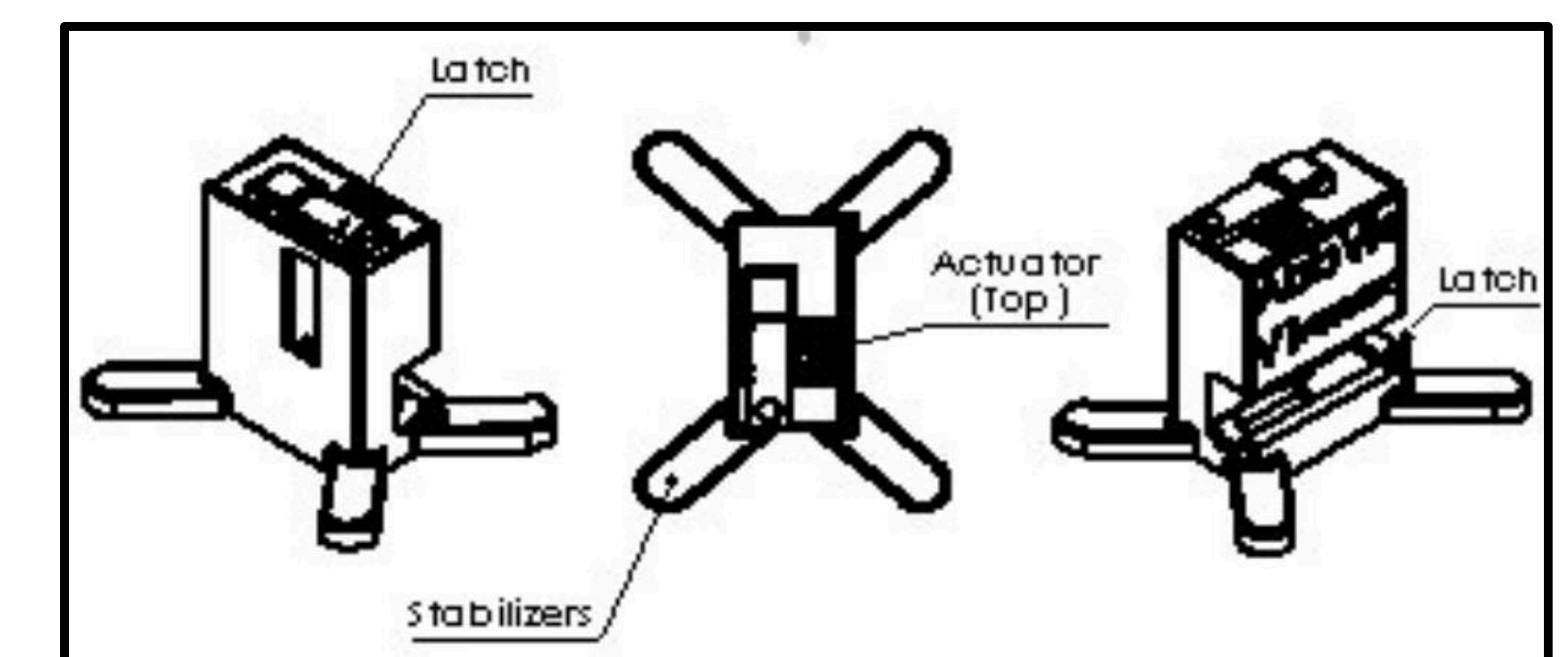p testing process can be automated.