

Improving the COP equipment to better comply with GMP standards

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1. Introduction

The project looks at improving the Clean-Out-Of-Place (COP) equipment at PCI Pharma services. PCI mainly manufactures highly potent drugs used for oncology treatment. Due to PCI pharma services being part of the pharmaceutical industry, which is a highly regulated sector, there was a need to comply with the standards set by Good Manufacturing Practice (GMP). This poster outlines the key areas of the process undertaken to meet the aim set for the project.

2. Aim

The main aim of the project is to improve the Clean-Out-Of-Place system. Targeting the following areas:

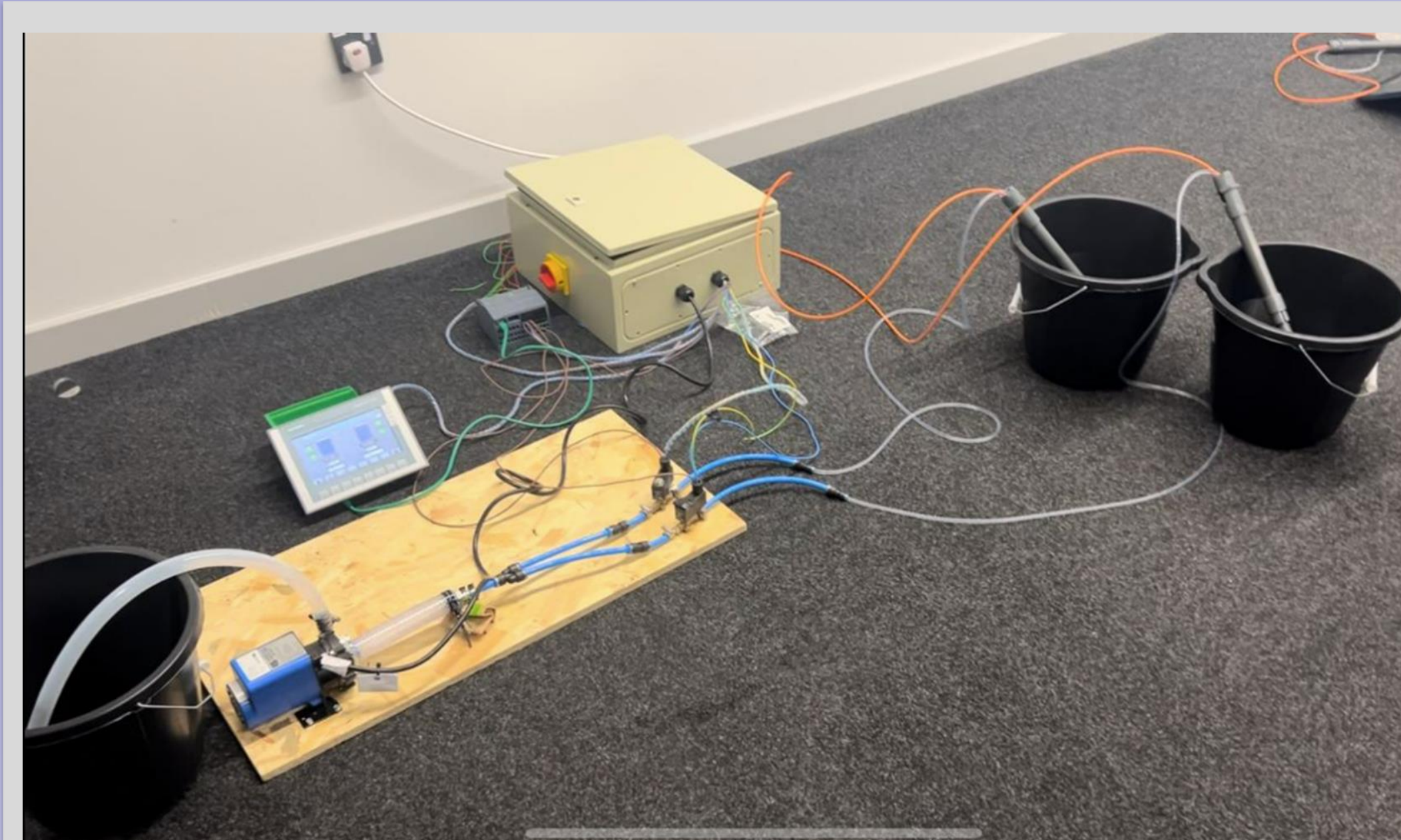
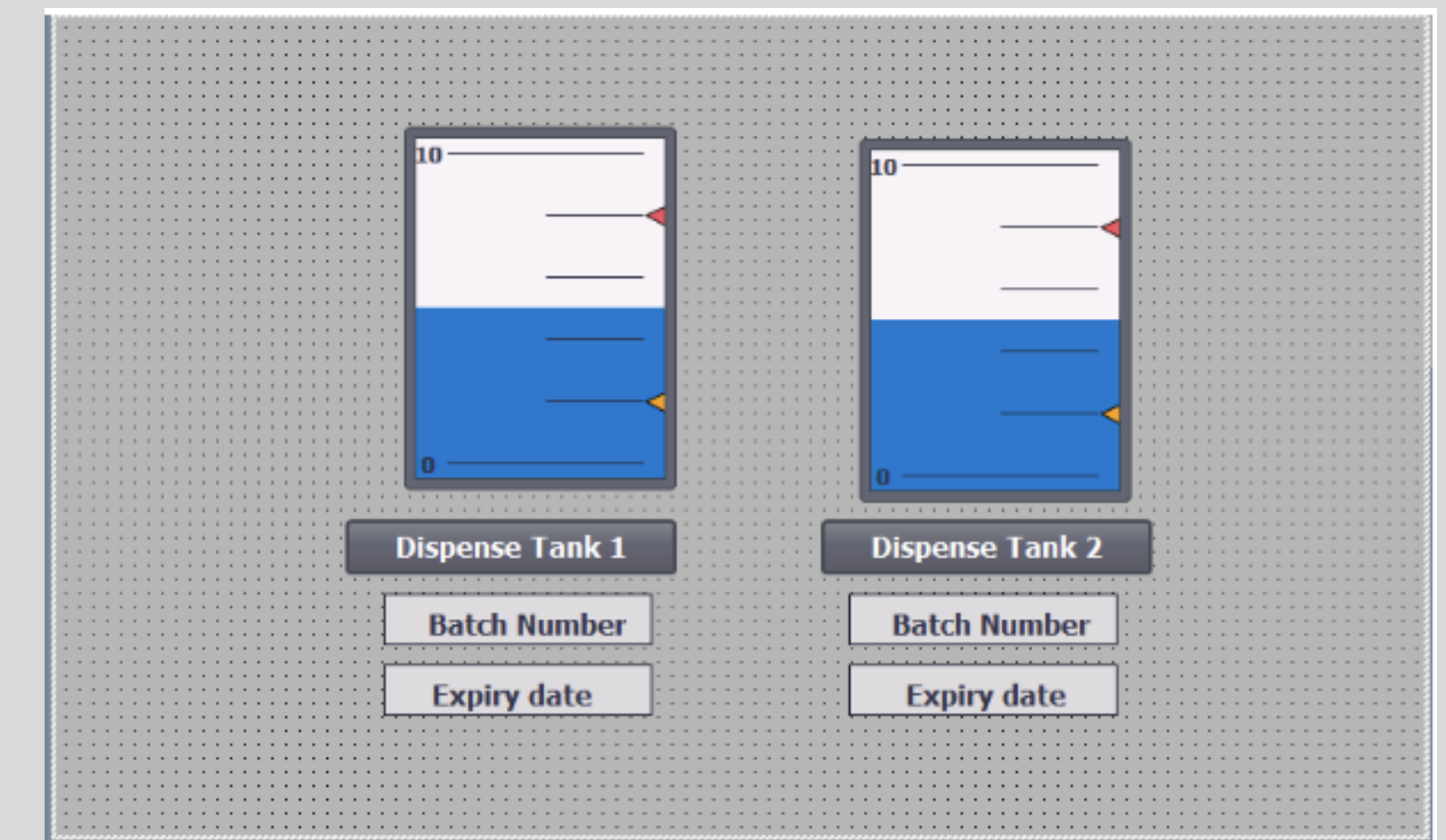
- Ease of use for the operator to run different detergent purging recipes.
- Reduce cross contamination between detergents.
- Make it easier for the operator to comply with GMP standards.
- Reduce the engineers' workload.

3. Objectives

- Assessment of current COP system
- Redesign hardware and software
- Produce a new procedure for operator
- Installation, validation and testing
- Implementation of new system

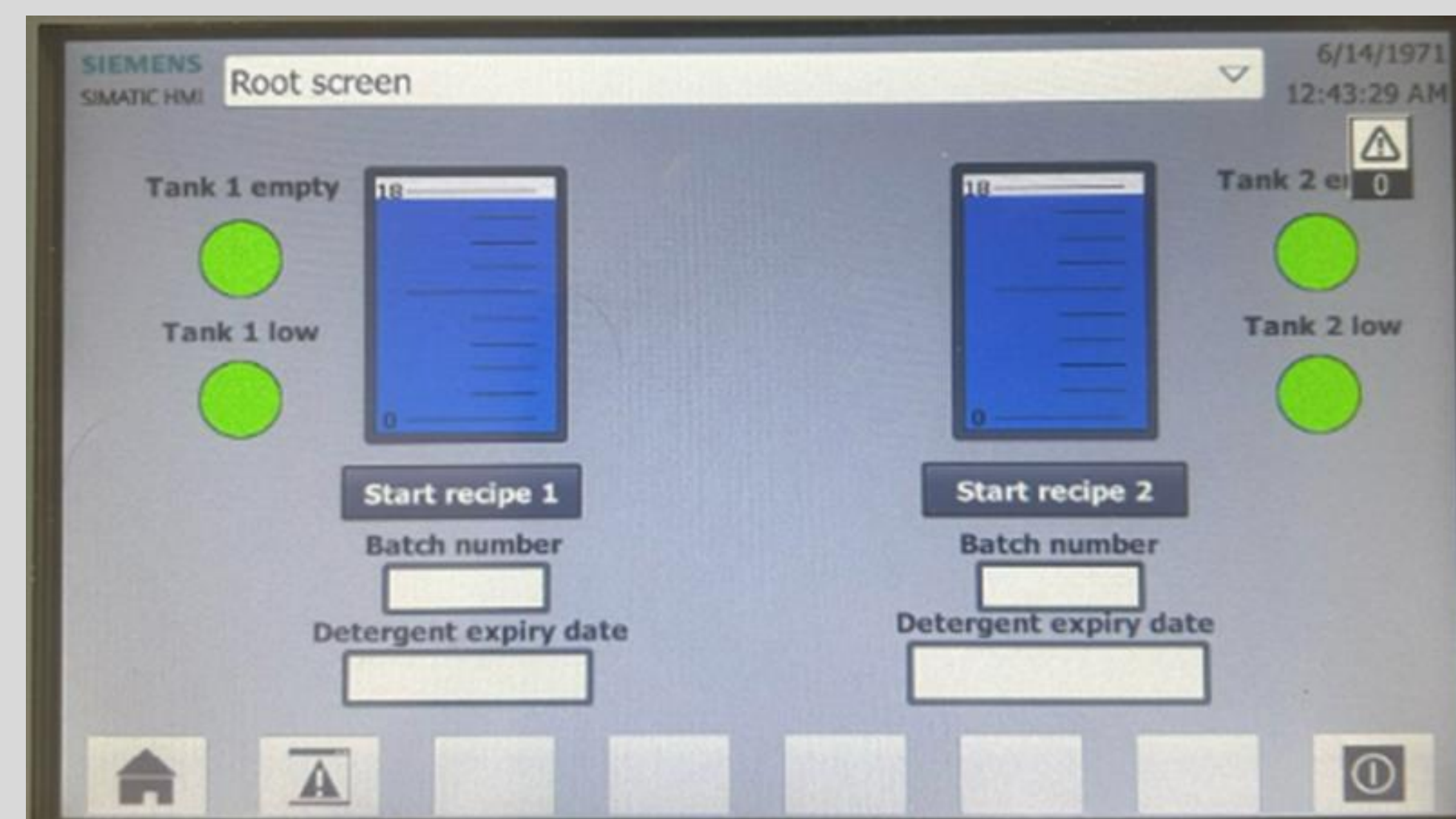
4. Simulation prototype

A simulation prototype was created at the early stages of the project to provide a concept of how the suggested improvements would be implemented on to the COP system. This was done using the tanks in Factory IO and Siemens TIA portal. The simulation displayed the new HMI screen showing where the GMP information would be presented and the level of detergent remaining in each jack. The prototype also showcased the ability to run different purging recipes from the same screen. When a recipe is selected on the HMI its respective tank lowered in Factory IO.



5. Proof-of-concept prototype

A proof-of-concept prototype was then created using hardware components such as a pump, suction lances and solenoids. An electrical panel was also built fitted with MCB's, a power supply and contactor. This would allow for the solenoids to open and the pump to start via the HMI and software program that was created using Siemens TIA portal. The new HMI allowed the operator to run different detergent recipes and input the required GMP information such as detergent batch number and expiry date. The new HMI also provided low and empty alarms for each detergent, giving the operator information on the remaining levels of detergent.



6. Conclusion

To conclude, the project was a success. The prototype worked as desired, delivering 720ml in 80 seconds. This was an acceptable volume set by the preventative maintenance work order. The prototypes provided PCI pharma services with a good understanding on how the suggested improvements would benefit the COP system and the targeted areas mentioned. There is still outstanding tasks due to time constraints, with the new system required to be installed on to the current equipment. A validation process is then necessary before full implementation.