Software Validation Tool for Infusion Pumps
Engineering Science Capstone Design Project

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1 Abstract

AbbVie Biopharmaceutical Company manufactures and supplies drugs that are utilized by the Smiths Medical syringe pump. To ensure the syringe pump is working correctly, our senior capstone group has been tasked with developing a software validation tool. The software validation tool will ensure the syringe pump is providing the correct dose rate, loading dose, and bolus volume to the patient. The software tool will help to identify any faulty syringe pumps and help to maintain patient safety.

2 Introduction

Infusion pumps are a medical device used in the hospital setting and long-term care to provide a controlled delivery of fluids and medication. Infusion pumps are required to comply with relevant engineering standards to ensure they are safe and effective for patients. A new updated and recognized standard for infusion pumps is AAMI TIR 101:202 which outlines the devices particular requirements for the basic safety and performance.

3 Design Requirements

To test the accuracy of the software validation tool against engineering standards, three main calculation tests were focused on:

A. Bolus Volume: The amount of fluid and medication delivered during a set time.

$$\frac{mass_{final} - mass_{initial}\,[g]}{density\,[g/mL]}$$

B. Dose Rate: Strength of a treatment during a set time.

$$\sum \frac{\frac{mass_1\,[g] - mass_0[g]}{density\left[\frac{g}{mL}\right]} + \frac{mass_2[g] - mass_1[g]}{density\left[\frac{g}{mL}\right]}}{1\,hr} \ldots$$

C. Loading Dose: Initial higher dose or drug given at the beginning of treatment before dropping down to a maintenance dose.

$$\frac{mass_{at\,60\,min}\,[g] - mass_{at\,0\,min}[g]}{density\left[\frac{g}{mL}\right]}$$

4 Methodology

Figure 1 is associated with the software tool designed to analyze AbbVie pump data and consists of six subsystems: the GUI, Bolus Volume Calculations, Loading Dose Calculations, Dose Rate Calculations, Statistical Analysis, and the File Formatter/Exporter. The user inputs include the data files, specified accuracy test, acceptance criteria, syringe size, flow rate, density, and data file name. After the user inputs the necessary parameters, the data undergoes the specified calculation and statistical analysis. The results are displayed on the screen along with the percent error. The words “pass” and “fail” are accompanied by color respectively. The file formatter exports the calculated results.

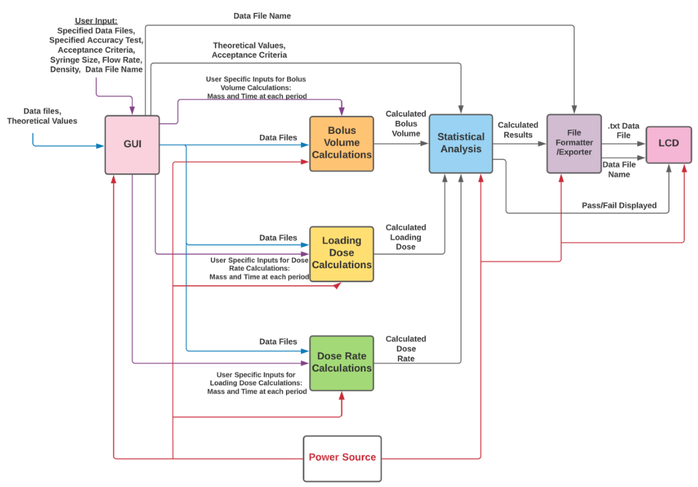

Figure 1: System Diagram

5 Results

To use our Software Tool, the user must first select the desired data file they would like to run and enter the data file name, syringe size, flow rate, density, and acceptance criteria. Second, the user must select which specific test they would like to run. After, the result of the percent error and either pass or fail will be displayed and saved to a .txt file.

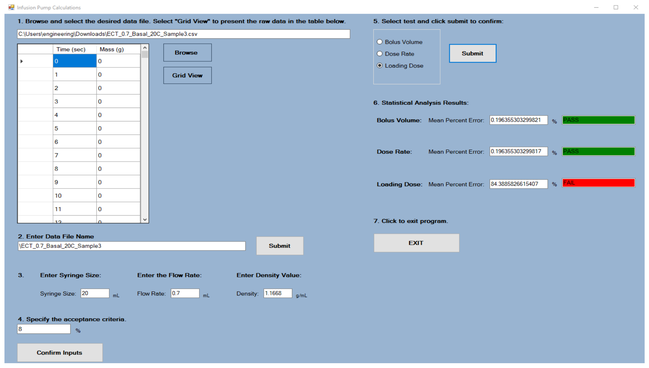

Figure 2: Software Tool User Interface

6 Risk Analysis

The risk analysis establishes controls for potential hazards associated with the software tool. A rating system for hazard determination was defined and applied to each identified risk. All identified potential hazards have been categorized under software with the major of hazards falling under user interface errors. Hazard analysis tables include the risk assessment as well as mitigation and verification protocol. The fault tree visually depicts the process leading to potential hazards.

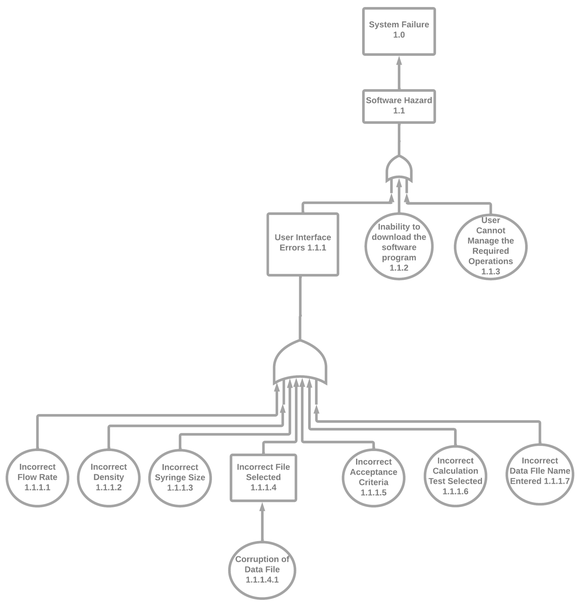

Figure 3: Fault Tree Analysis (FTA)

7 Discussion

The software tool will be used in an AbbVie research lab by a trained technician. This environment was taken into consideration when designing the user interface of the Software Tool. The implementation of the software will determine the accuracy of infusion pump systems. By ensuring that the behavior of the fluid delivery systems is in concordance with the acceptance criteria, the Sponsor will be able to identify errors more efficiently. Confirming the accuracy of the fluid delivery systems will ensure that patients receive the correct dose of medication as specified by the healthcare provider. If testing were not conducted using the software, errors could lead to injury and costly recalls. Implementation of the software can prevent recalls which will then reduce the resources needed to fix the faulty device, and it will reduce recall related costs (ex. transportation of the recalled products) for the manufacturer.

8 Conclusion

The software tool accurately calculates the percent error for bolus volume, dose rate, and loading dose utilizing test pump data provided by AbbVie. The functionality of the Software Tool is consistent with the initial requirements discussed with the Sponsor and meets all Engineering requirements. The final step in completing this project involved a model-based design control process called a Design Verification Test (DVT). The purpose of the DVT implemented for this project was to verify that the Software tool can perform the required functionality within an expected execution time. With the DVT completed, all necessary requirements have been implemented and verified. Lastly, for the future, the software tool will be able to analyze multiple pump data files and the user will be able to decide whether certain data files are acceptable. These additional implementations will maintain the same format that is currently functional for selecting the single data file and viewing test results.

9 Acknowledgements

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References

AAMI CDV-1 TIR101, *Fluid delivery performance testing for infusion pumps*. Infusion Device Committee, 20-Mar-2020.