WIRELESS REMOTE DISPLAY

FOR SAFETY CRITICAL THERAPY MANAGEMENT

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ABSTRACT

A team comprised of Loyola University Chicago Biomedical Engineering Capstone students, sponsored by Baxter Healthcare of Deerfield Illinois, created a system to limit clinicians' exposure via proximity or contact with hospital patients in the face of COVID-19. The team was assigned to implement a solution regarding infusion pump care. An infusion pump is a medical device that delivers fluids, such as nutrients and medications, into a patient's body in controlled amounts (FDA.gov). In order to maintain a clinician's safe separation from the bedside, the team developed a wireless remote display to control an infusion pump from a safe distance. The software-based solution allows data to be sent over Wi-Fi to a remote device. The team is currently performing Design Verification Testing (DVT) on the system to verify that one design requirement was met. The system is fully functional and provides clinicians the opportunity to provide care while keeping themselves and others safe from infection.

INTRODUCTION

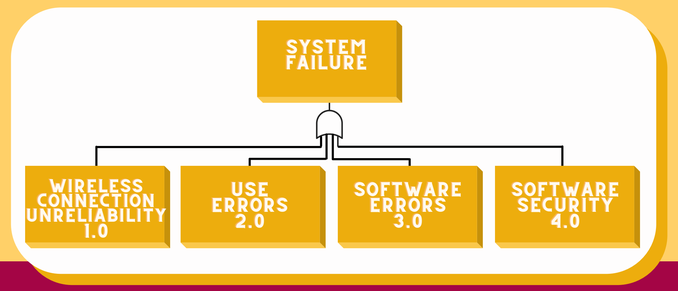
Increased emphasis on minimizing surface contamination and unnecessary close contact, during Covid-19, in the hospital setting has brought new infusion pump user needs to the forefront of product design. The ability to manage an infusion pump remotely without physically visiting the device could save time and increase safety in the hospital setting. To help address these unmet needs, Baxter asked the team to develop a wireless display for the infusion pumps that allows a user to operate the infusion pump's user interface remotely via an 802.11 Wi-Fi connection. The wireless display must account for the safety of the pump, per 60601-2-24, which calls for pumps to have no single-fault condition that can lead to harm. IEC 60601-1 defines single-fault Condition as a condition in which a single means for reducing a risk is defective, or a single abnormal condition is present. The reliability of the wireless connectivity has been fully considered in the design, with the assumption that if a failure occurs the user is not able to go to the physical pump to mitigate the failure.

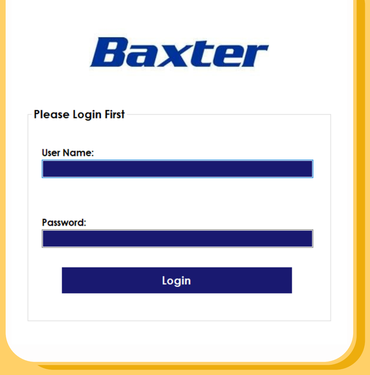
METHOD

The goal of this project is to devise a solution that allows one set of information to be transmitted wirelessly between two devices via a Wi-Fi connection: specifically, an infusion pump and a remote display. The scope of the project is to design a system that enables remote operability of this device. To define the scope, the team made decisions based on what shall not be included. In this case, system integration into the hospital environment is outside of the scope of the project. The only addition to the pump's functions will be remote operability. The team will not change or expand any other existing pump functionalities. Given the limited timeline of this project, the reasonable operability of the remote display to be completed by the end of the year includes the nurse's computer's transmission of the volume to be infused (VTBI) inputted by the user on the remote display and sent out as digital data from the Wi-Fi transceiver. The second half of the project involving two-way communication will not be implemented into the system, but only considered in the Risk Analysis.

RISK ANALYSIS

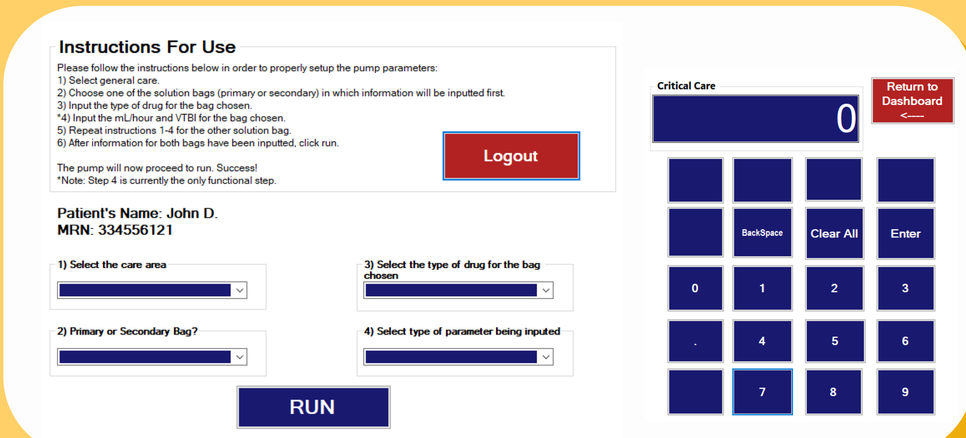
The objective of the project's software Risk Analysis is to identify and establish controls for potential hazards associated with the Wireless Remote Display for Safety Critical Therapy Management clinical release software. The focus of the analysis is to identify potential software failures that could lead to inappropriate or incorrect medication administration to the patient. The analysis highlights the identified hazards and risks for wireless two-way communication, as seen below in the general version of the team's Fault Tree Analysis (FTA).





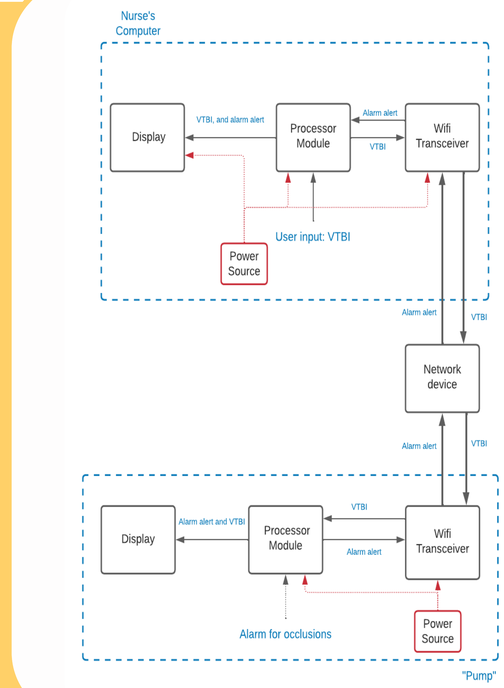
DESIGN REQUIREMENTS

The system to be designed involves its own specific process. The subsystems being discussed in the design requirement specification are as follows: (1) Nurse's Computer Display, (2) Nurse's Computer Processor Module, (3) Nurse'sComputer Wi-Fi Transceiver, (4) Network Device, (5) Pump Wi-Fi Transceiver, (6) Pump Processor Module, and (7) Pump Display. The team implemented the design requirements for the first half of the system (1-3). The second half of the system was forgone to focus on the complete system's Risk Analysis. The main requirement involved is the transmission of volume to be infused (VTBI) data, which is an essential infusion pump function. This data will be input, processed, and output from each subsystem in the Nurse's Computer. The team completed these functional subsystems: a display that shows the user's input, a processor module that sends the user's input to the computer's display and sends digital data to the Wi-Fi transceiver, and a Wi-Fi transceiver that can receive the digital data from the processor module and send it out wirelessly.



Pictured above are three forms: the Login, the Dashboard, and the Keypad. Each form has been coded and integrated to simulate a pump on the remote Nurse's computer.

SYSTEM DIAGRAM



RESULTS

The team has completed a functional infusion pump wireless remote that sends data over Wi-Fi. The team has demonstrated one-way communication within the system, but has provided the sponsor with a comprehensive Risk Analysis focusing on two-way communication over Wi-Fi in the hospital setting. Further, the team considered all significant risks of the system and implemented mitigations to the software that minimized all risks to an acceptable level. In addition to software mitigations, the team created a thorough User Manual and an Installation Qualification to lower the risk. Considering the functionality of the system and extensive Risk Management, the teamis successful in prototyping an original, safe Wireless Remote Display for Infusion Pumps.

RESOURCE: HTTPS://WWW.FDA.GOV/MEDICAL-DEVICES/GENERAL-HOSPITAL-DEVICES-AND-SUPPLIES/INFUSION-PUMPS