syncroness™
complex problems inspired solutions

Dental Water Treatment System

• December 2015 - September 2016

Objectives

- Improve user interface
- Implement remote monitoring of system and filter performance
- Improve system up-time
- Reduce installation time and complexity
- Specify bill of materials compliant with Trade Agreements Act

Approach

- Use Model-Based Systems Engineering (MBSE)
- Accelerate software design and reduce risk with Agile process, virtual machines and breadboards
- Create feasibility prototypes
- Use a Python-based Graphical User Interface (GUI) toolkit

Results

- Designed and delivered two fully functional pilot units in nine months
- Added sophisticated monitoring and troubleshooting of system performance
- Reduced installation connections, external components, and installation time

"In working with Syncroness, their engineers operated at a high level of professionalism, responded quickly to our responses, and were always accessible."

~ Langston McDowell, Technical Director, Sterisil, Inc.

A Complete Product Development Partner

- Brainstorming and Concept Generation
- Feasibility Studies and System Architecture
- Detailed Product Design
- Prototyping
- Design for Manufacturing (DFM)
- Verification Testing
- Manufacturing Assembly and Test Equipment
- Sustaining Engineering

Complex Problem

The water that dentists use during procedures must be clean and not cause infection. Dental offices may have filtering for the water supplies; however, the water lines and tools can develop biofilm if not treated correctly and regularly. Sterisil develops dental waterline treatment products. Their filters remove particulates and dissolved solids, and treat for biologics.

Figure 1: CAD rendering of the G5 system

Sterisil's G4 has basic functionality to measure water quality and filter life using several separate off-the-shelf sensors but does not integrate the information gathered from individual sensors. This limits the G4's capabilities to perform system-level diagnostics. Additionally, the G4 does not automatically log sensor data, and the user interface consists only of several digital numeric displays with limited push-button inputs. Due to the cumbersome user interface and lack of long-term data trending, customers had difficulties troubleshooting common problems in the G4.

Sterisil asked Syncroness to design their next-generation G5 dental water purification system. Sterisil wanted the G5 system to have six stages to create three types of treated water: reverse osmosis (RO) water, autoclave / deionized (DI) water, and dental water used by dentists while treating patients. The system needed a National Sanitary Foundation/ANSI 55 Class A certified ultraviolet reactor to adequately remove biologics from supply water, making it safe for use even during a boil-alert. The final stage would be Sterisil's proprietary silver impregnated resin, which treats the outgoing dental water to remove acidity and provides stabilized silver to maintain and regenerate silver-based antimicrobial dental tubing.

The system had an aggressive cost target and needed to be compliant with the Trade Agreements Act (TAA), meaning all components must be manufactured or substantially transformed in an approved country.

Systems Engineering

Syncroness systems engineering created a product roadmap to help the customer determine which features to add into the new product. They worked to understand the intended use environment and external interfaces (context diagrams), mapped out how each type of user would interact with the system (use cases shown in Figure 2), and determined the implications of the product's regulations. These inputs were translated into the detailed requirements that guide the engineering team during development.

A patient safety-risk assessment allowed the team to incorporate risk mitigations early in the design. The team used the requirements to guide architecture and major component decisions, as well as to generate wireframe design for the GUI. Syncroness

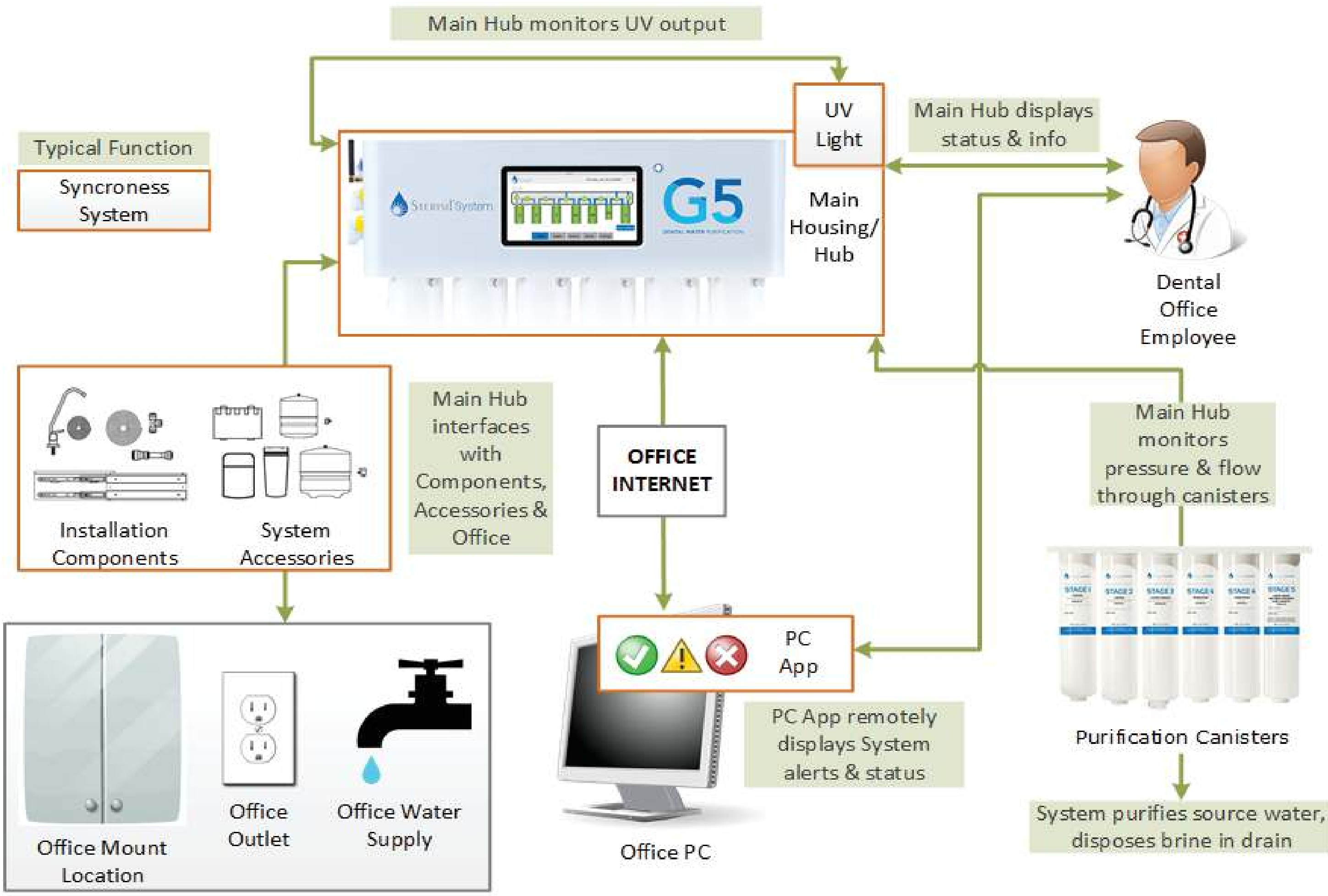

Figure 2: Simplified system use cases

created a custom industrial design for the GUI to best meet the needs of the system and intended user group. Feasibility prototypes, timed with the Agile development sprints, addressed the core functionality and challenging parts of the design, which reduced costly redesigns later in the project.

Mechanical Design

Syncroness designed the G5 system to fit into a standard sterilization cabinet, and designed an IP rated electrical box to protect electronics in the event of an internal or external water leak. The system design incorporated considerations for robustness in transport and long-term operation.

The G4 system had 20 components external to its housing. Syncroness mechanical engineers integrated 17 of the 20 external components into the inside of the G5 housing. They simplified the hydraulic and electrical routing, which reduced the number of installation connections from 30 to 14, and specified NSF-rated, food-grade materials for the drinking/dental water lines. The G5 system design also integrated new monitoring sensors for total dissolved solids (TDS), pressure, flow, and UV intensity. Syncroness developed and implemented a novel volume measurement

Figure 3: Prototype System during development shows hydraulic and electronics routing

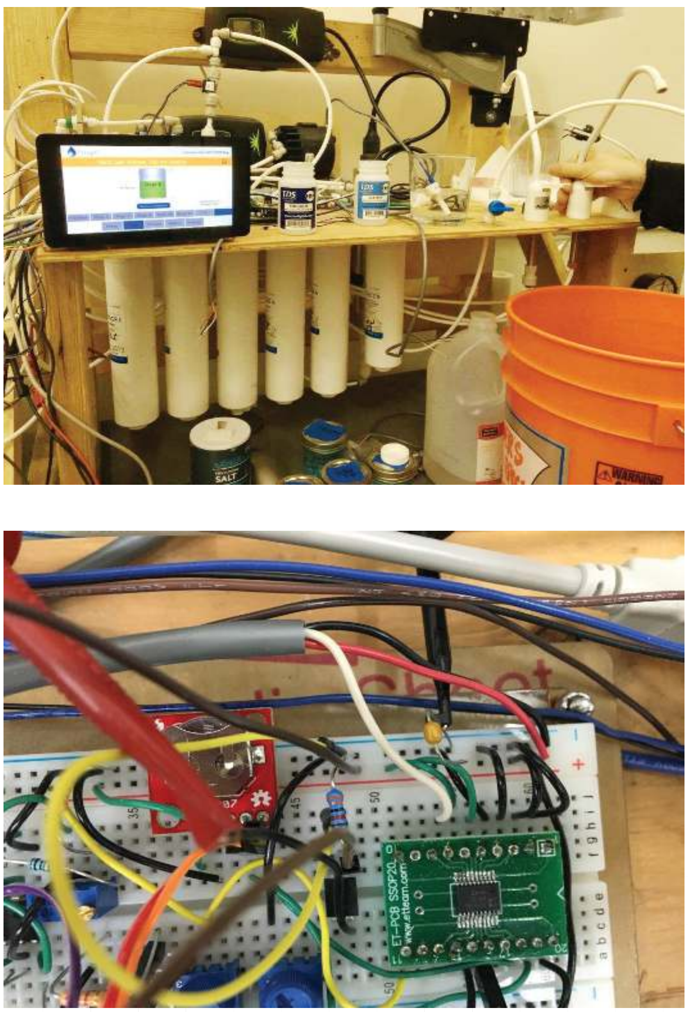

Figure 4a and 4b: Prototype used to test flow controls and demonstrate operation to Sterisil during development

system to accurately track the wide range of fluid flows required to measure filter expiration. Figure 3 shows the preliminary internal routing.

Embedded Systems Design

With a short development time frame and limited development budget, Syncroness implemented the electronics design around an off-the-shelf (OTS) Raspberry Pi Single Board Computer (SBC). The main electronic system components consisted of this SBC, an OTS touchscreen display, and a custom interface Printed Circuit Board Assembly (PCBA).

To facilitate software development and aid in feasibility studies, Syncroness created breadboard prototypes of key sub-circuits. This prototype setup is shown in Figures 4a and 4b. Iteratively adding onto this hardware prototype allowed software engineers to interface with the variety of sensors and debug any issues weeks prior to receiving PCBAs and assembling a production-equivalent unit.

The majority of the electrical effort in creating the Sterisil G5 assembly involved designing the custom interface PCBA. Key requirements of the PCBA included:

- Efficiently converting the 24VDC input supply down to the voltages required for the embedded circuitry
- Providing an interface for the Raspberry Pi to make analog voltage measurements from the pressure sensors
- Providing an isolated interface for the Raspberry Pi to make TDS measurements with temperature compensation
- Providing signal conditioning for multiple General

Purpose Inputs and Outputs (GPIO) for flow sensor measurement, solenoid control, and buzzer control
- Adding Wi-Fi and Ethernet network interface

Given the high rate of change of interfaces during requirements gathering, Syncroness designed the custom PCBA with spare inputs and outputs for future development. The majority of these spare interfaces were used by the end of the product design. Images of the PCBA can be seen in Figures 5a and 5b.

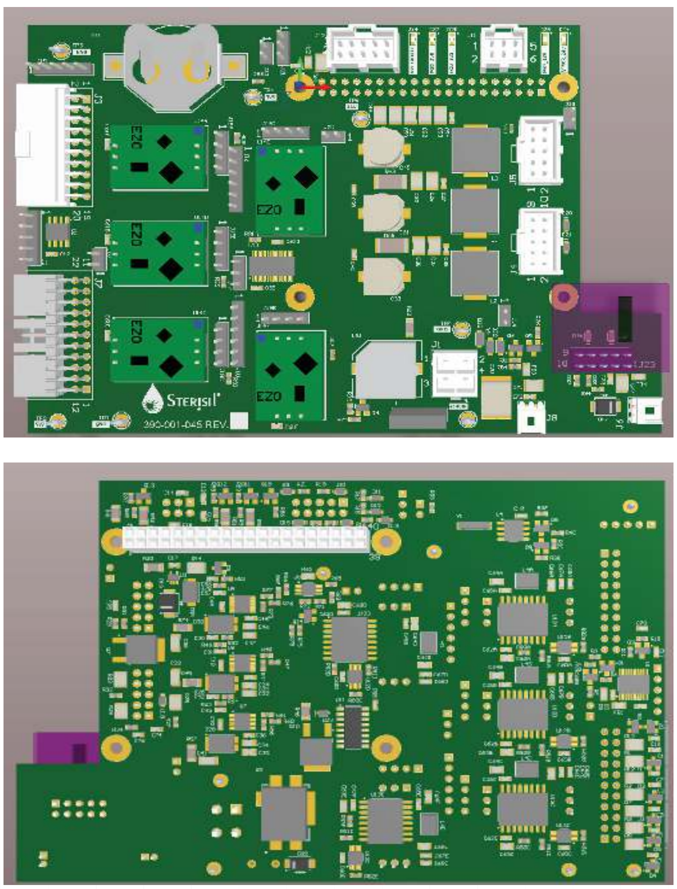

Figure 5a and 5b: CAD model of custom interface PCBA

Software

The software considerations for the G5 included secure and reliable network communication, flexibility of sensor components, system availability, and future growth and change. The software architecture is a layered structure that isolates GUI, sensor, or protocol changes from other elements of the system. The software is fundamentally event-driven but includes timer-driven polling of sensors and equipment status. Syncroness implemented a custom discovery protocol that allows PC applications to find Hubs on the local network, and an HTTP-based client/server protocol that provides standards-based network communication with easy paths to the implementation of monitoring from mobile or cloud applications.

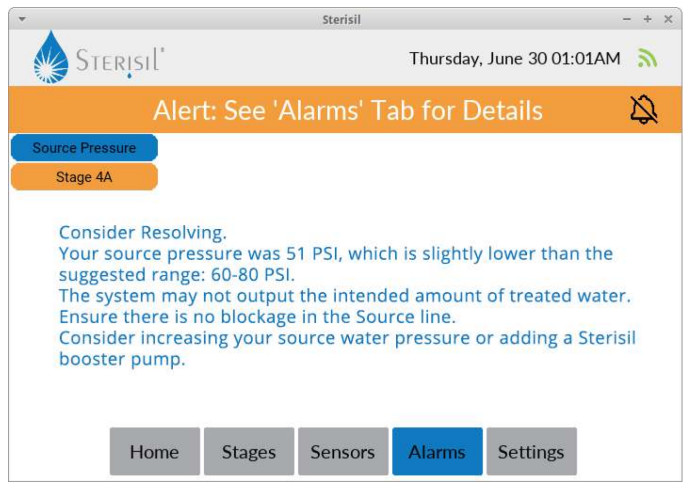

Figure 6: Example of alert screen on system GUI

A PC web application links with the G5 system on the network and relays alerts and alarms from sensors. The PC app is able to discover G5 Hub(s) connected on the local network. It then polls the Hub's status to display the system state, notify the remote user of alerts/alarms, and allow the user to remotely silence alerts without having to physically access the unit.

The touchscreen provides an improved user interface compared to the G4's digital displays and push-buttons. The touchscreen display provides the user

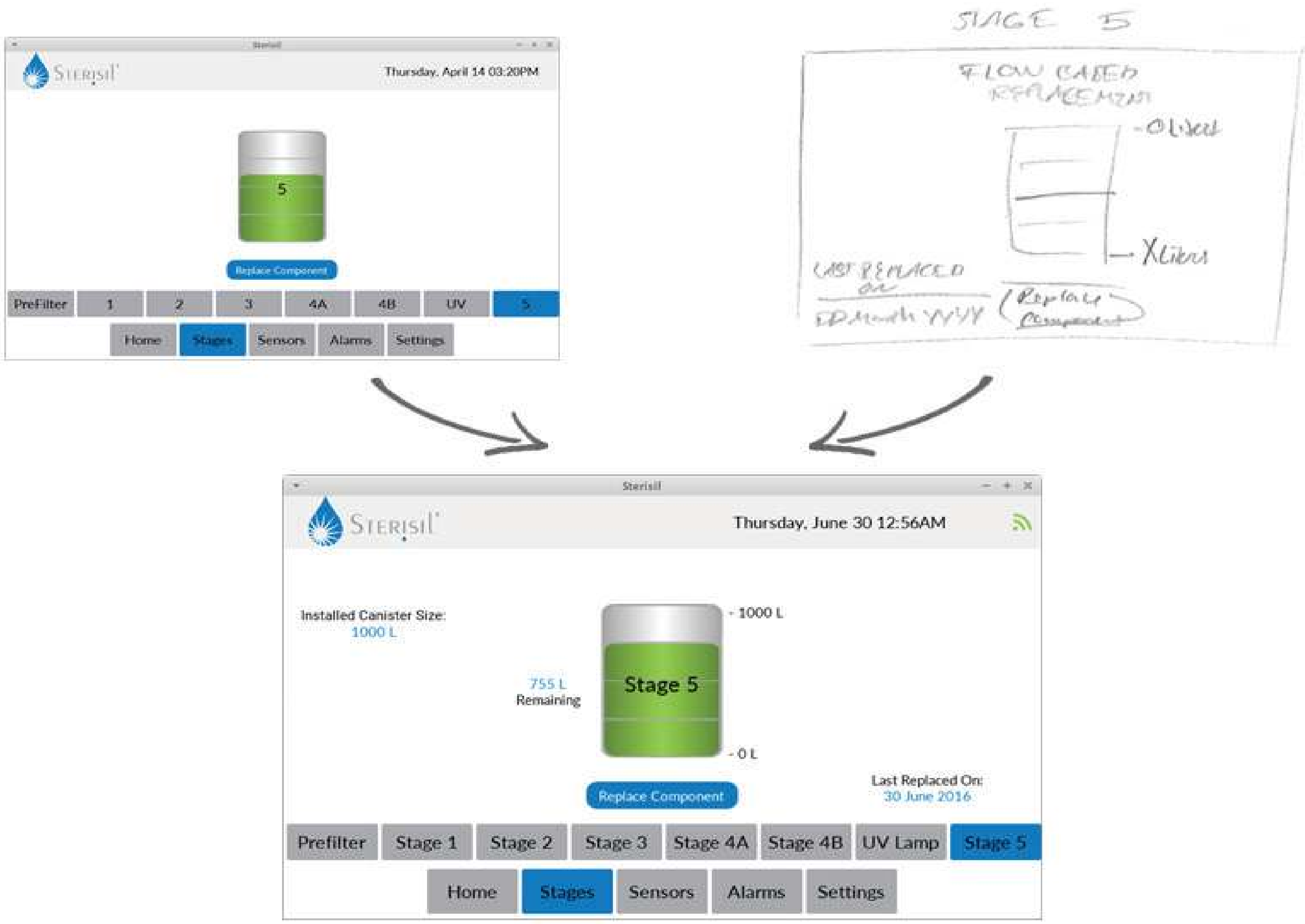

Figure 7: Example of interative design of system GUI

with visuals and information that allow them to easily see the current status of the system, identify the cause of an alert or alarm, and troubleshoot the problem. Alerts include reminders to order or replace expired canisters, critical for maintaining effectively treated dental water.

The initial ideas for user interface were converted from pencil sketches, to screen mockups, and eventually to final implementations, using an iterative, agile approach shown in Figure 7. Implementing in Python using the Kivy GUI toolkit allowed the development team to rapidly implement the application and then iterate it based on feedback from Sterisil.

Syncroness' Solution

The new G5, a modernized, intelligent water treatment system, will allow Sterisil to better serve customers by monitoring system diagnostics in real time. Syncroness engineers considered installation and manufacturing of the G5 system concentrating on reliability, minimizing the possibility for user error, and making the system easier to install and troubleshoot.

Syncroness' system engineering, using a phased development approach, helped Sterisil to define the use cases and organize the requirements early in the development process. Risks were identified early so that feasibility prototyping would prove out the challenging aspects of the design, reducing costly changes late in the development cycle.

The electrical engineers chose the Raspberry Pi single-board computer and touch screen as a platform, allowing a rapid hardware development cycle. They designed a custom interface board to connect the Raspberry Pi to the G5 sensor suite, with flexibility for adding additional sensors, which prevented costly redesign late in the project.

The software development team developed a Python-based GUI for the touchscreen, allowing for rapid application development and iteration. The .NET-based remote PC application was developed concurrently with the G5 software, allowing frequent integration testing.

Deliverables to Syncroness' Customer

- Two fully functional pilot units.
- All of the information required to build production units in nine months.
- Groundwork for both TAA- and NSF-compliance.
- Detailed hardware and software documentation, allowing Sterisil's engineers to understand the design and make future changes, if necessary.
- Transition planning with Sterisil engineers to bring the design to manufacturing.

About Syncroness

For more than 18 years, Syncroness has provided inspired solutions to highly complex business and technical problems. The company has a strong portfolio of clients in the medical device, aerospace, and industrial equipment industries. By providing a full complement of engineering services aligned to the entire product lifecycle, Syncroness enables companies to accelerate product development and drive more predictability and productivity into their businesses. Working with Syncroness, companies gain the critical insights necessary to develop products that make a difference and create a better world.

About Sterisil

Sterisil offers a full lineup of the only dental water line treatment and disinfection products with a registered EPA quantified claim of approximately less than or equal to 10 CFU/ml of HPC bacteria. Fifty times lower than the CDC and ADA registered limits! Sterisil's product line includes, Shock tablets, daily maintenance tablets, 1 year Sterisil Straws, Sterisil Cartridges for bottle-less municipal dental operatory units and finally, the turnkey Sterisil System.

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