W.L. Gore Portable Sanitization Chamber

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Problem Formulation and Project Plan

Document

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1.0 ABSTRACT

This document contains everything concerning the project formulation and the project plan. The project formulation consists of the client introduction, needs, goal, objectives, constraints, working environment, and quality function deployment (QFD). The client introduction will simply cover who our client is and what they stand for. Needs covers what our client is looking for in terms of the project. The goal is how the team will respond to the needs. Objectives describe the quantifiable expectations of performance. The constraints review the permissible conditions of design features. Working environment is simply where the product will be used and how it effects its surroundings. The QFD will summarize the client requirements with respect to engineering requirements. The project plan will be outlined as a set of tasks and summarized in a Gantt chart.

2.0 CLIENT INTRODUCTION

W. L. Gore design products to be the highest quality in their class and revolutionary in their effect. Associates address technical challenges with innovative, reliable solutions and the organization seeks growth by unleashing creativity and fostering teamwork. W.L. Gore create next-generation cable assemblies and components for the electronics industry, set the standard for outerwear comfort and protection, solve difficult industrial problems with innovative materials and technology, and Gore medical products work in harmony with the body's own tissues to restore normal body function.

3.0 NEEDS DESCRIPTION & GOAL

W.L. Gore needs a current portable sanitization device that will decrease the bioburden levels past a certain threshold. Many devices today are used for sterilization, but that is not always what is needed in the medical field. W.L. Gore is looking for a device that is safe for all users, portable, reduces the level of bioburdens on various instruments and materials, cost efficient, and finishes the process in a certain time limit. This device would mainly be used in the medical field or in certain industries where sanitization is needed on a regular basis.

The goal of the project is to develop a portable sanitization process that sanitizes bioburden amounts past acceptable levels.

4.0 OBJECTIVES

Descriptive requirements of the sanitizing device are provided by the W.L. Gore associates which can be broken down into project objectives. These objectives are derived from meetings and documents provided by the client. These objectives will show the main focuses of the project at hand.

Safety of the final design ties into the main focus: decreasing bioburden levels. These levels, along with the allowable exposure of certain substances that are deemed safe, will follow guidelines provided by the Occupational Safety and Health Administration (OSHA) [2]. Procedures and regulations for proper safety are quantified in their respective documentation, tabulated in concentration values.

The sanitization process requires an ability to function with a variety of objects and components of mixed materials and geometries. W.L. Gore provides examples of a tackle box (plastic), a notebook (sensitive), and hemostats (medical equipment). These examples emphasize a temperature range for heat sensitive materials and no impact for malleable material. The temperature range can be limited by annealing levels and melting points of materials which must remain below 70°C.

For the final product, the design must prove to be portable enough for the transportation of a single individual. The portability of the device in question can be defined as being able to fit through door frames and tight hallways while remaining under a weight threshold. Therefore, the maximum width shall be less than 3 feet and the maximum height less than 6 feet. Dimensions are estimated by comparing the common door sizes. The overall weight is limited by the average lifting of an individual and the weight limit allowable on free rotating wheels.

The expense of the product design follows the guidelines set by the budget provided. W.L. Gore is allowing a budget of $3,000 for research, presentation, and design prototyping. Estimations in need for research and presentations leave approximately $2,500 for the finalized design. This amount is more than affordable when compared to sterilization systems such as autoclaves, irradiation, and chemical processing (Ethylene Oxide).

Medical sanitizing requires a certain ease of use for the individuals running the device. Defining ease of use creates a criteria of characteristics as cycle time, process completion, and electrical comprehension. The cycle time must be kept within 60 minutes as this device will be sanitizing objects under immediate demand. To aid in process completion, the device should automatically end the process once sanitization is complete. All electrical components should be properly installed and allow for power through common wall outlets.

5.0 Constraints

In order to sanitize various materials with complex geometry, the sanitization chamber should comply with standard door sizes (limitation 3’x3’x6’). The total cycle time cannot exceed 60 minutes and cycle ends automatically. The ethylene oxide cannot be used as the source of the sanitization due to its harmful property to humans. To meet the portable requirement, the sanitization chamber should be transported and operated by one person easily.

5.1 Working Environment

The portable sanitization chamber will be used to reduce bioburden to less than routine final bioburden level in the medical industry. The portable sanitization chamber will be used as an in line solution to reduce contamination during manufacturing, for sanitizing materials for entry into cleanrooms, or for entry into sterile hospital settings [1].

6.0 Quality Function Deployment (QFD) and House of Quality

The customer indicated that three main things were wanted in the product: safety, ease of use, and ability to clean various materials. The customer broke down ease of use where they wanted the device to have a short cycle time that ends automatically and that it can be easily transported by one person.

Using this criteria, a quality function deployment and house of quality were made. The team met together and rated the importance of each of the customer's wants and rated them on a scale of 1-5, five being the highest priority. W.L. Gore, while vague and not providing many wants, was adamant that most, if not all of these wants were important. They especially stressed safety, portability, and the ability to sanitize the sample materials without damage to them.

While the team is in early stages of research and brainstorming on what methods will be used to accomplish the goals of the project, a short list of engineering requirements were developed. These include:

- Size – The overall dimensions of the product. This must be manageable by one person while also being able to easily fit through standard doors. This is the cross sectional area.
- Weight – The weight of the device. This could lead to lower portability or higher cost.
- Cost to produce – Prototyping needs to fit within budget. It should be noted that W.L. Gore is known for not compromising a product due to cost.
- OSHA standards – standards set by the Occupational Safety and Health Administration. The device needs to meet the standards that apply to the design and process.
- Low operating temperature – This is required to be able to sanitize various materials which includes a polymer that has relatively low melting temperature.
- Cycle time – Client requested a low cycle time. The team noted that autoclaves can sterilize in 15-20 minutes and is looking for a similar time.
- Power source – This will become more important depending on the sanitization process chosen but the device will need a safe and reliable power source.
- Bioburden reduction – This is the main purpose of the device to reduce the bioburdens on the provided samples. This will be tested using a known amount of bioburdens and testing to see how much is left after one cycle.

The team discussed whether each of the customer requirements had a weak, medium, strong, or no correlation with the engineering requirements represented by 1, 3, 9, or 0 (blank) respectively. This creates a greater weight to for those that are strongly correlated.

Once this was done, the value was multiplied by the percent importance of the customer requirements and totaled for each engineering requirement. This leads the team to see that the most important thing is finding a process that will lower the bioburden levels. The next important requirements are the size and cycle time with the cost staying within budget.

Comparable processes or devices are the autoclave and a hydrogen peroxide vapor process. The autoclaves come in various sizes and are cheap. They sterilize in about 20 minutes but because of the steam process, they cannot be used due to potential damage to some of the items that

would need cleaning. The hydrogen peroxide process is very quick, about 6 seconds to sterilize water bottles, but it is prohibitively expensive and would be very difficult to scale down to a portable design.

The generated QFD matrix and House of Quality are in the appendix.

7.0 PROJECT PLANNING

Throughout the year, the Portable Sanitization Chamber project consists of 4 different categories: preliminary design, build prototype, test prototype, and final prototype. For the first semester, preliminary design will be the primary focus. This task is broken down into 5 subtasks: research, needs and specifications, concept generation, engineering analysis, and cost. The preliminary design will take approximately 13 weeks starting on September 11, 2013 through December 4, 2013. Listed below is the preliminary designs and their subtasks, explained in detail:

Task 1.0 ***Preliminary Design***

- **Task 1.1** ***Research***
  Contains all information that is gathered to help in the understanding of designing a portable sanitization chamber. This includes researching sanitization methods, existing designs, programming electrical systems, and the medical environment.

- **Task 1.2** ***Needs & Specifications***
  Gives a better understanding of what the client needs. Also, it will set general guidelines for future designing. This task includes client needs, objectives, and constraints.

- **Task 1.3** ***Concept Generation***
  Helps narrow down our understanding of what needs to be done. Concept generation includes brainstorming and a concept selection.

- **Task 1.4** ***Engineering Analysis***
  This task includes the complete design of the portable sanitization chamber. This includes any technical drawings, code, and system analysis. It is currently too early in the design process to list all possible engineering analysis.

- **Task 1.5** ***Cost***
  Contains the estimated cost of the portable sanitization chamber. After the engineering analysis we will have a better understanding of the cost.

Below is an organized representation of each task, shown in the Figure 1. There are two critical paths for the first semester of the project. The first critical path is that concept generation cannot begin until research is finished. Also, the second critical path is that the

engineering analysis cannot start until the concept design has been selected. Tasks 3 through 4 will not be discussed during this semester.

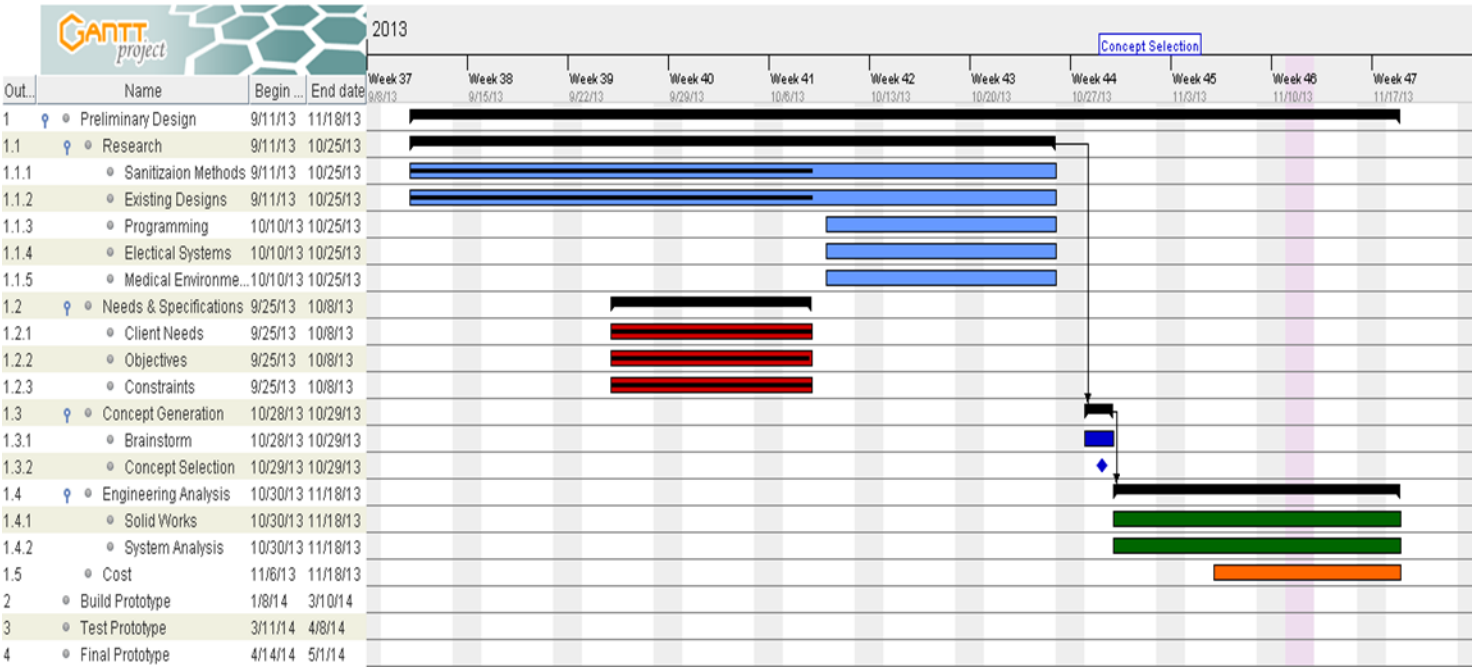

Figure 1: Gantt Chart

8.0 Conclusion

W.L. Gore is an international company making advances in a variety of fields such as; biomedical products, filters and fabrics, polymers, and more. A contract with W.L. Gore has been accepted to design and build a portable sanitization process that sanitizes bioburden amounts past acceptable levels. The final design must meet the objectives of being portable, safe, cost under $3,000 (unless additional cost has been cleared with the client), and efficiently reduce bioburden levels on three different objects in a timely matter. These objects are a hemostat, a tackle box, and a lab notebook.

The client, W. L. Gore, left many of the design constraints open-ended, so that the constraints can be determined along the design process. Current constraints include; complying with medical and industry standards, meeting OSHA standards, and the use of ethylene oxide is prohibited. Additional constrains include a size limitation of 3X3X6 feet and a 60 minute run time.

The preliminary design for the portable sanitization chamber will take about 13 weeks and be completed by December 4, 2013. Included in the preliminary design are; research, needs and specifications, concept generation, engineering analysis, and cost. After the preliminary design has been completed, there are three more categories of tasks to be completed. These tasks

include building the prototype, testing the prototype, and then building the final prototype. A Gantt chart was put together in order to effectively break down the time frames for each step of the design process.

REFERNCES

[1] W.L. Gore, *Portable Sanitization Chamber for Medical Manufacturing Use*, 2013.

[2] Occupational Safety and Health Administration, General Industry 29 CFR 1910: Hazardous and Toxic Substances, U. S. Department of Labor, Subpart Z. from url:https://www.osha.gov/SLTC/hazardoustoxicsubstances/index.html

Appendix

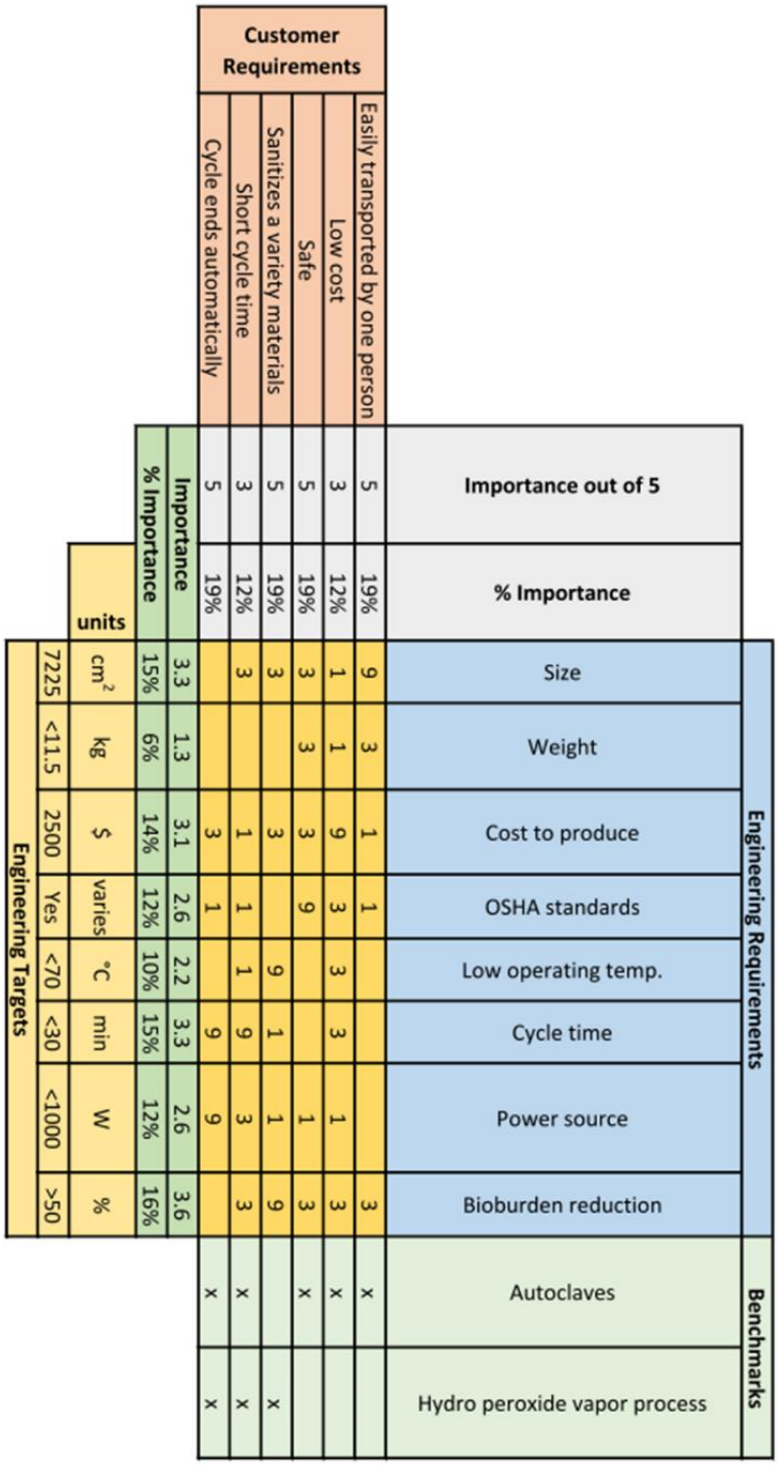

Figure 2: QFD

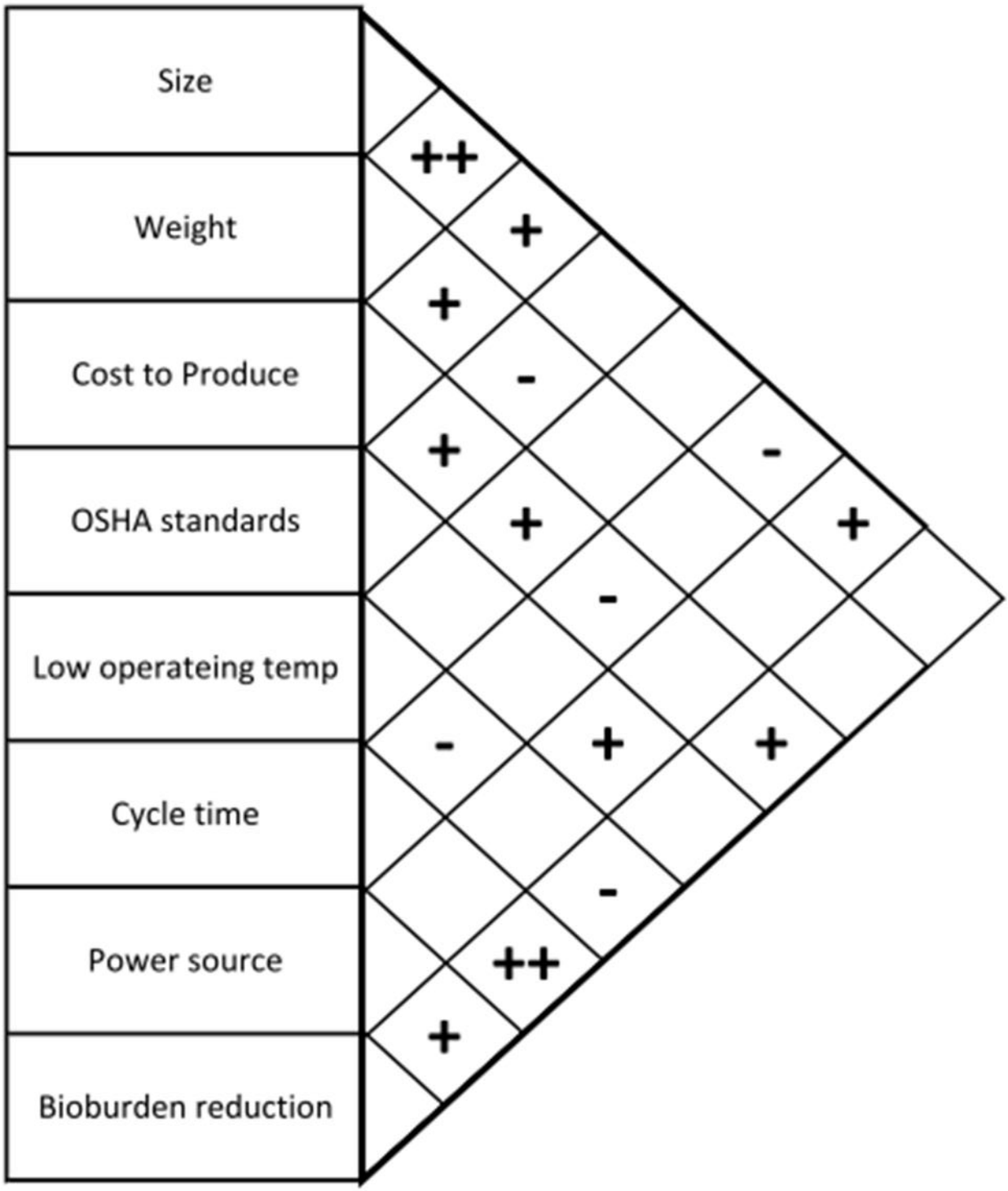

Figure 3: House of Quality