Portable Sanitization Chamber

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Concept Generation and Selection

Document

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Table of Contents

Tables and Figures

1.0 INTRODUCTION

W.L. Gore is a company who designs products to the highest quality in their class. They are looking for a current portable sanitization device that will decrease the bioburden levels on select materials to a certain threshold. The concept generation consists of five different possible designs that meet both the client and engineering constraints. Certain concepts meet the needs of the client better than other concepts. The options for the different designs will be narrowed down based on the research done on the different concepts. The five concepts that will be looked into are UV lights, chemical sprays, infrared, lasers, and autoclaves.

1.1 BIOBURDEN LEVEL ANALYSIS AND KEY ASSUMPTIONS

For sanitization purposes, all processes will consider abiding by the USP 797 Compliance. This standard applies to sterility levels in clean facilities (e.g. Pharmaceutical and Lab clean rooms). Since sanitizing levels fall below the level of sterilization, a reasonable assumption is to hold sanitization processes to the risk classifications for sterilization. Therefore, in compliance with USP 797, the project at hand shall be designed to sanitize within ISO classification 8 (PathCon 2009) which dictates that quantities excessively over 100 colony forming units (CFU's) is deemed elevated.

To determine approximate expectations of log reduction, another assumption must be applied. Explicitly stated by W.L. Gore associates, sterilization tests will begin with 10^6 CFU's and expect to eliminate all contaminants, calculating a 6 log and then doubling for a 12 log reduction. For sanitizing purposes, testing with 10^6 CFU's would be excessive, so an assumption of 10^4 CFU's on any test sample may be more reasonable. To reduce this amount within ISO class 8, a calculated 2 log (and therefore a total 4 log reduction) would be necessary. For design expectations, a degree of 4 log reduction should be implemented.

2.0 CONCEPT DESIGN

There are many concepts for a sanitization device that can be used for this project. Based on the client requirements, five designs have been chosen to do further research to see which concept would best meet the clients' needs.

2.1 AUTOCLAVE

An autoclave is a device that uses steam to sterilize equipment and other objects. This kind of sterilization can be effectively achieved at a temperature above 100°C. This means that all bacteria, viruses, fungi, and spores are inactivated. However, prions, such as those associated with Creutzfeldt-Jakob disease, may not be destroyed by autoclaving at the typical 135 °C for three minutes or 121 °C for 15 minutes. Also, some organisms, such as the archaeon Geogemma barosii, can survive at temperatures above 121 °C. Water boils at 100°C at atmospheric pressure, but if pressure is raised, the temperature at which the water boils also increases. In an autoclave the water is boiled in a closed chamber, so we can easily increase the temperature to certain value by increasing the pressure.

Steam treatment is economically inefficient because of substantial energy requirements for production of the steam. Sanitation by steam should not be carried out on surfaces that do not meet the heat tolerant requirement. In addition, high temperature can cause scale deposition.

Table 1: Autoclave

Advantages	Disadvantages
More penetrative power than dry air	Economically inefficient
Readily available	Meet heat tolerant requirement
	Scale deposition

2.2 CHEMICAL PROCESSES AND FOGGING TECHNIQUES

One of the quickest and most efficient ways to sterilize is using chemicals. There are many chemicals that are used to sanitize/sterilize in both household and industrial applications. Many of these chemicals such as; bleach, ammonia, ethanol, hydrogen peroxide and others, can kill over 99% of bacteria when used in the correct concentrations. Anything that comes into direct contact with the chemical solutions will be effectively sterilized.

However, some chemicals have bad interactions with certain materials. Some alcohols, for instance can negatively affect plastics causing deterioration with repeat exposure. Further, paper and other materials cannot be sanitized by chemicals because they are not able to withstand being soaked by a liquid.

Fogging is one way of utilizing chemical disinfecting properties by heating the chemical into a dry fog. This cold steaming method allows the chemical to spread around an enclosed area, reaching every surface, without getting anything wet. The most commonly used chemical for fogging is hydrogen peroxide. Hydrogen peroxide is the safest chemical to use for fogging sanitization. Unlike bleach, which would create a possibly harmful vapor, or ethanol which would be highly flammable, hydrogen peroxide vapor is relatively safe.

Hydrogen peroxide vapor is currently being used by hospitals to sterilize entire rooms. The process takes around 15-30 minutes, with an additional 1-2 hour waiting time before the room can be safely occupied, depending on the size of the room. In hospitals a 7.5% hydrogen peroxide (H_2O_2) solution is used, higher H_2O_2 concentrations can corrode materials. The Environmental Protection Agency (EPA) has Vaporized Hydrogen Peroxide classified as a sterilant, defined by the EPA as eliminating all microbial life.

A small fog machine with a 7% H_2O_2 solution should create enough vaporized hydrogen peroxide to sanitize a small enclosed area. By building a box around the nozzle of the fog machine, this becomes a good design for a portable sanitization chamber. Additionally, the box would need a small filter to filter out the vapor that is being fogged through the box. This design should quickly and efficiently sanitize any object placed within the box. A sketch of a hydrogen vapor concept is provided in **Appendix A**.

Table 2: Chemical

Advantages	**Disadvantages**
Highly effective	Vapor cannot be inhaled
Fog sanitizes all exposed surfaces	Solution must be refilled regularly
Inexpensive	

2.3 ELECTRON-BEAM AND LASER BIOREDUCTION TECHNIQUES

Electron-beam is a device that uses particulate ionized rays to sterilize materials (Rao, 2009). The rays penetrate the objects and either destroy DNA strains or damages the DNA proteins beyond repair in small organisms.. The E-Beam is very convenient because there is no prep for the materials. All materials can be sterilized in their packaging avoiding any accidental contamination after sterilization. This would be one of the more ideal solutions if we were able to produce an electron-beam emitter on the small scale. One of the issues is that it is unclear what would have to be done to protect the user who would most likely be nearby.

Using lasers to reduce bioburdens have been used in some applications, specifically to sterilize dental instruments and oral surgical wounds. From our preliminary research, specific wavelengths are used for different tasks. One machine by Lutronic comes with different 'handpieces' that are easily exchanged to modify the wavelengths. These can be used to sterilize open wounds during surgery or to remove unwanted tattoos.

We have also found that some items that are space bound are sterilized by lasers. They use a laser with other sensory devices on the end of a robotic arm to scan the large items in a sterile environment.

Further research will be needed to find an ideal wavelength and power output to sanitize various products. Below in Table 3 is a summarized view of the pros and cons of E-Beam and laser methods that could be used for sanitization. Also, a sketch of how the laser system could potentially work is provided in **Appendix B**.

Table 3: Electron Beam

	Electron Beam	Laser
Pros	- sanitizes through items - very fast - does a large variety of materials - Zero prep is needed for materials	- relatively low power - quick - does various materials - Already used by dentists
Cons	-May not be able to produce on a small scale - Complicated control systems - Cost - Safety to the user	-May be cost prohibitive - Power requirements are different for various lasers/wavelengths - Doing large items may take too much time - only surface sanitized

2.4 INFRARED RADIATION

Many wavelengths within the light spectrum can be utilized in disinfection and sterilization processes. Infrared radiation (IR) falls on a longer wavelength, from 0.78µm - 1000µm, and exhibits high amounts of energy through heat transfer. The operating temperature for an IR system is a function of wavelength (C.E. Moss, pg. 86), which allows for intensity control when applying these processes for disinfection purposes. Some companies, like Heraeus, utilize carbon IR emitters to provide effective disinfection systems for the food service industry. These products expose baked goods, and the equipment used to handle foods, to temperatures up to 160°C for 10 – 30 seconds (Heraeus Noblelight). The effectiveness of an IR system under project requirements is listed in Table 4 below. In **Appendix C**, a sketch of a system that can hold an infrared system is provided.

Table 4: Infrared

Advantages	Disadvantages
low cycle time < 1 minute	not viable for heat-sensitive materials
compact size	costly

2.5 ULTRAVIOLET LIGHT

Ultraviolet light sanitation, also known as Ultraviolet Germicidal Irradiation (UVGI), is an effective and efficient way to sanitize a surface of an object. Since light is the only source of sanitization it is easy to produce. To properly sanitize a surface of an object there will only need to be one bulb that produces a wave length of about 240-280 nm but more bulbs can be used to increase effectiveness.[UV1] Also, since there are existing designs of the bulb it will be easy to design a chamber that suits the system. A possible chamber that can hold the UV lights is provided as a Sketch in **Appendix D**. Below is a table that outlines the advantages and disadvantages of using ultraviolet lights as a sanitization method [UV2,UV3].

Table 5: UV Lights

Advantages	Disadvantages
Maximum kill potential occurs within 2- 15 minutes depending on virus or microorganism	Over exposure of UV rays will cause damage to humans
Can adjust light sensitivity to produce better results	Effectiveness of UV light lessens over time
Cost effective	May damage rubber, paper and plastic over time
Sanitize all surfaces	Must clean UV light bulbs regularly

3.0 Decision Matrix

The decision matrices are rated on a -1,0,1 scale with -1 meaning that the characteristic has a negative correlation, 0 meaning it is neutral, and 1 meaning that it has a positive correlation. The system with the highest total points is the design that would best satisfy the customer and engineering requirements. Both the UV lights and the chemical spray have the highest rating out of all of the designs. It is possible to use both of them in one system so that it is more diverse and can kill more bioburdens. This has many advantages and disadvantages. The chemical process might affect how well the UV lights work and may require more maintenance. But it can be designed to only do one process at once or both simultaneously. Combining these designs is within the budget and the dimension constraints given to us by the client.

Table 6: Weighting Characteristics

	Safety	Material	Maintience	Cycle Time	Cost	Power Required	Total + 1	
Safety		1	1	1	1	1	6	29%
Material	0		1	1	1	1	5	24%
Maintience	0	0		0	1	1	3	14%
Cycle Time	0	0	1		1	1	4	19%
Cost	0	0	0	0		1	2	10%
Power Required	0	0	0	0	0		1	5%

Table 7: Decision Matrix

	Safety	Material Compatibility	Maintenance	Cycle Time	Cost	Power Required	Total
Autoclave	0	-1	1	1	1	-1	0.14
Chemical Process	0	1	0	1	1	1	0.57
Lasers	1	1	1	0	-1	1	0.62
Infrared Radiation	0	-1	1	1	0	-1	0.05
UV Light	1	1	0	0	1	1	0.67
Weights	29%	24%	14%	19%	10%	5%	

4.0 CONCLUSION

There are many different chemicals that can be used to sanitize materials, but hydrogen peroxide is the best option when using a fog technique. With the fog technique, the chemical is heated to a dry fog and allows the chemical to spread around an enclosed area. This method is used to clean entire rooms and can take as little as 15 to 30 minutes to sanitize.

Gamma rays can also be used to sterilize or sanitize certain objects. Since gamma rays can penetrate the surface of objects, there is no need to wipe down the object before sanitization. It is easy to change out the wavelengths so it is easy to control how much to sanitize when needed.

Infrared radiation uses wavelengths to sanitize/sterilize objects. Since they are functions of wavelengths, they are easy to regulate how much is needed for certain uses. IR can exhibit how amounts of energy through heat, but that can potentially be harmful to some of the materials that will be disinfected.
Ultraviolet light sanitization can kill microorganisms within 2 to 15 minutes depending on the type of bacteria that is on the material. They are easily adjustable so they can run for different time lengths and be set to certain strength. They are less effective over time but are very cost effective.

Hot steam sanitization is similar to the fog technique used with chemicals except steam is used instead of fog. This means that more heat is used to sanitize objects. These are fairly inexpensive devices but are harmful to materials that cannot withstand these heats.

The highest rated design from the decision matrix was the chemical and UV lights. Each design has its own advantages, but they can both greatly benefit from each other when used in the same design.

References

[1] PathCon Laboratories, *The Microbial Bioburden of USP 797 Compliance*, 2009

[2] Sridhar Rao PN, *Sterilization and Disinfection*, 2009.

[3] C.E. Moss, R.J. Ellis, W.E. Murray and W.H. Parr, *Infrared Radiation*, 2013.

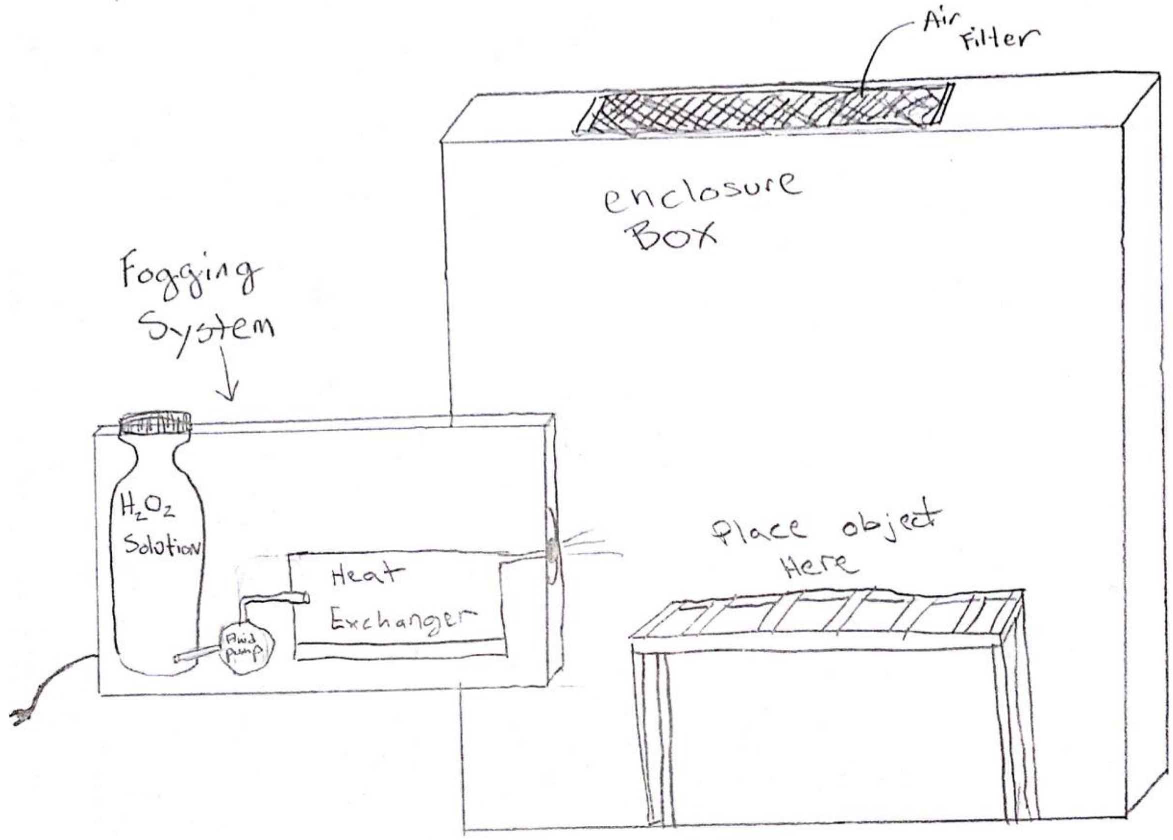
[4] Heraeus Noblelight LLC, *Infrared Heat for Disinfection in the Food Industry*, 2013.

[5] Rutala, W., Weber, D., *Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008*, Department of Health and Human Services, 2008

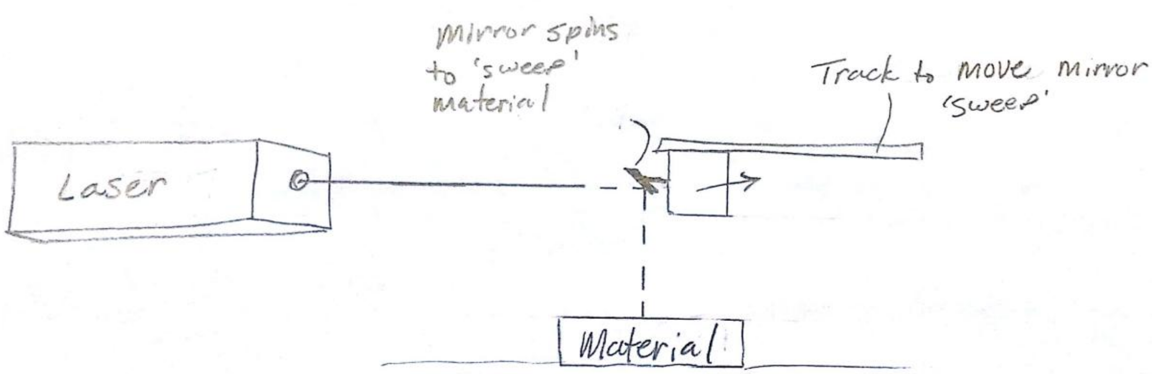
[6] Carlson, C., *The Use of UV Lights for Disinfection*. Arizona State University, From: https://cfo.asu.edu/node/2667

[7]*Ultraviolet Disinfection: Crucial Link in the Sterilization Chain*. Terra Universal Inc. From: http://www.terrauniversal.com/images/tools/catalog/uvc_germicidal_irradiation_082510135200.pdf

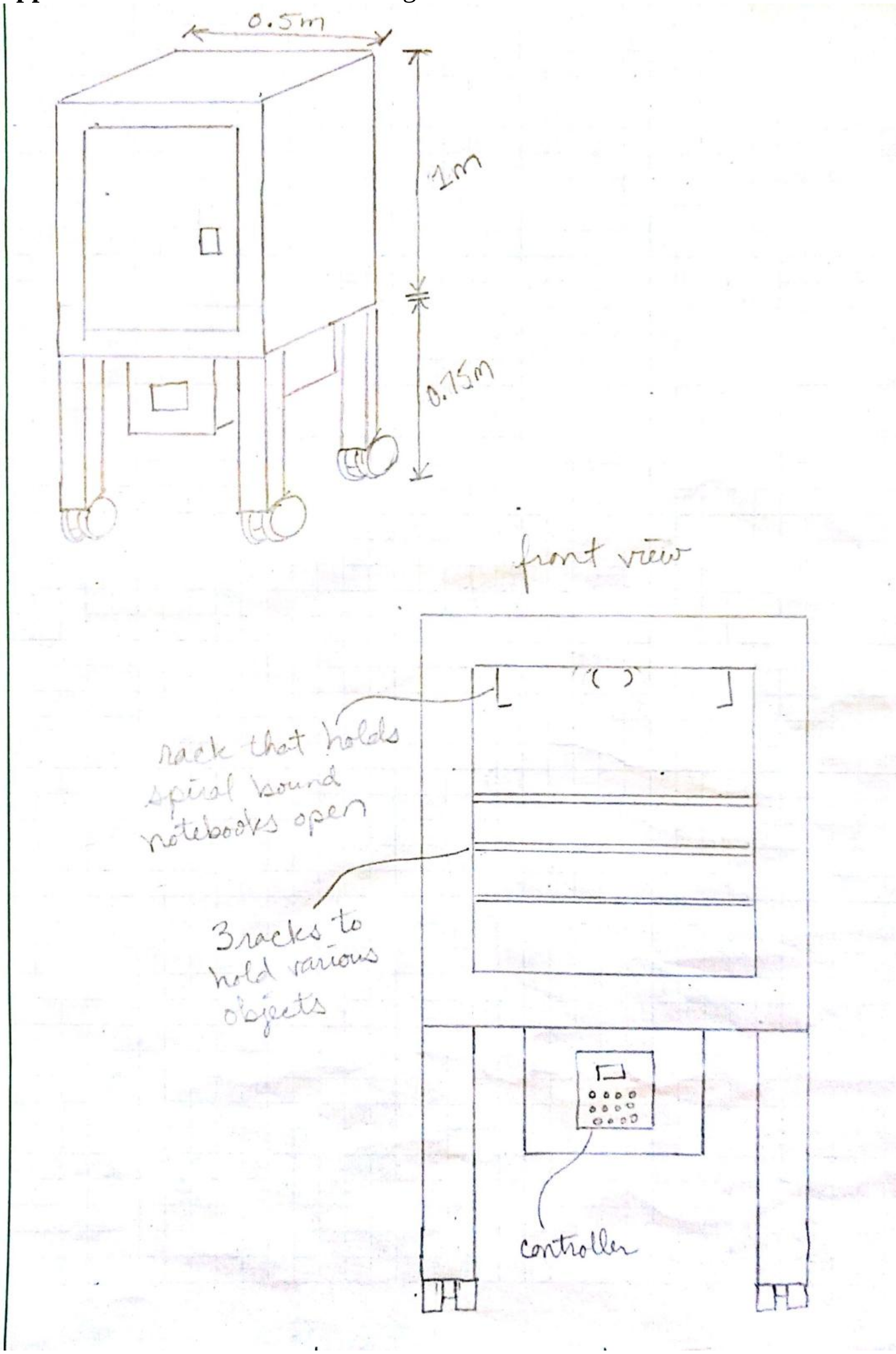
Appendix A: Chemical Process



Appendix B: Laser sanitation process



Appendix C: Infrared radiation design



Appendix D: UV Light design