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Preface

The following Thesis is for the accomplishment of our master's program in Mechanical Engineering at Halmstad University. The study has been conducted by a group of two, Abdelrahman Alsallout and Khaja Khalid in collaboration with the company Getinge AB, Sweden. The work aimed at process evaluation and improvement of steam sterilizers testing process in Getinge. The project was helpful to gain more knowledge in mechanical production and thermal streams.

We would like to convey our heartfelt gratitude to Professor Aron Chibba, our supervisor, for the guidance, feedback, and support throughout the work.
We would like to appreciate Anna Runa and Per Ebers, the Getinge manager and technician, who consistently supported us and by sharing relevant data to conduct the investigation and to complete this thesis. A special thanks to our great families, for inculcating the importance of higher education, and their endless support for us.

Abstract

This thesis was conducted to analyze and investigate improvement methods for the testing process of steam sterilizers at Getinge AB.
Getinge is a leading MedTech multinational company based in Sweden. Steam sterilizer is one of their prominent products. A series of testing must be done before handing over the product to the customer, which mainly requires water and steam as consumable resources. The intention of this project is to find improvement methods or optimization techniques for the testing process and reduce the consumption of resources which would significantly impact the production lead time and cost. Upon the careful examination of the testing process it has been noticed that a significant amount of pure water with heat content has been wasted during the testing process, which could be recirculated/ reused, and the heat could be regenerated for useful purposes. The proposed optimization suggestions through this project are a thermally stratified tank which could handle cold and hot water as the testing process needs the supply of both. Majority of the faults during testing are identified in software implementation and a few in mechanical. A dummy testing is recommended to identify the faults in the implementation of the software without the need of consumable resources. A few methods to tackle mechanical faults are discussed further in this report. When implementing these optimization suggestions, it would drastically improve the testing process by reducing the consumption of resources like water, steam, natural gas, time, and labor.

Keywords: Steam sterilizer, Sterilizers, Getinge, Heat recovery, Optimization, Improvement, Testing process.

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1 Introduction

According to the World Health Organization, infections and diseases connected with healthcare are prominent side effects of medical treatment for patients. Everyone should receive quality medical care services to reduce premature mortality and disability, manage and prevent diseases. Surgery is a major room for the transmission of pathogenic organisms as the same surgical instruments have to be used for different patients (Ituna-Yudonago et al., 2021).

The process of destroying or deactivating all forms of life is called sterilization. Sterility is a phrase used to indicate the complete absence of all life forms in an environment, surface, object, or in an item that can be consumed such as food, medical, or pharmaceutical products. Thus, an object is said to be sterile when it is free from all forms of life. It is important to ensure sterility in certain categories of medical, pharmaceutical, and food industries. For example, Dentistry is the branch of medicine that deals with the mouth and teeth. Bacteria enter the human body most frequently through the mouth. As a result, every instrument should be thoroughly cleaned as diseases and infections can be transmitted by saliva. Hepatitis, herpes, and TB are only a few of them. Unfortunately, an infection excess can be fatal. Sterilization ensures that bacteria from one patient's mouth will not spread to another (Rutala, 2008).

Sterilization can be classified basically into two types: physical and chemical. The method selected depends upon the material to be sterilized. The classification is shown in the figure (1-1) (Oyawale, 2007).

The importance of suitable sterilization and disinfection procedures has been emphasized by various researchers documenting infection after improper decontamination of medical and patient-care equipment. Failing to execute proper sterilization leads to significant costs, patient diseases or even death. Since it is necessary to sterilize all the equipment, the hospital policies must ensure whether or not the procedure of disinfection took place (Rutala & Weber, 1999).

This project is focusing on the concept of optimization in the process of testing of the sterilization autoclave machines. The consumption of resources used in the process like water, steam and natural gas is to be optimized, where the objective is to find alternative solutions for the testing process to reduce the consumption of water, steam and natural gas to guarantee a sustainable procedure and usage of resources. Also, the aim is to optimize the testing process to reduce the number of cycles by understanding and analyzing the testing process failures, and what hinders the progress of the testing, and suggest solutions to them.

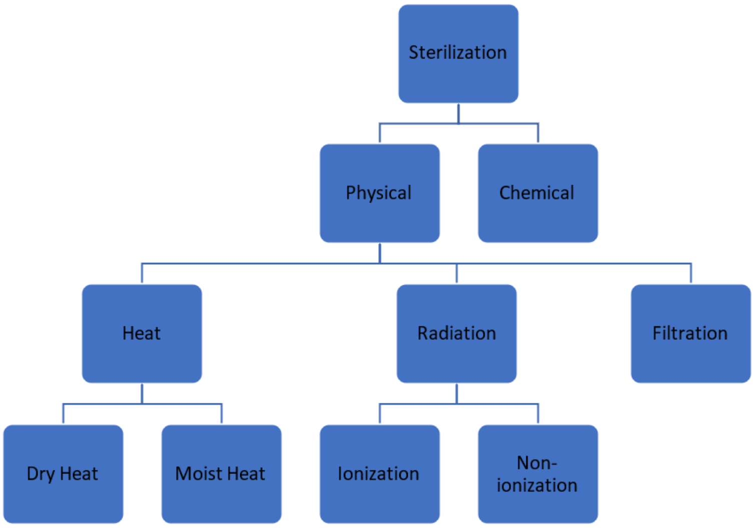

Figure 1-1: Types of Sterilization (Oyawale, 2007)

1.1 Background

Steam sterilization is one of the best and commonly used techniques as it has the advantages of low cost, short processing time and good sterilization capacity. The steam sterilization process is carried out with a device known as an autoclave. The term auto indicates automated, and the word clave denotes locking mechanism, and it is commonly known as automatic locking. The autoclave has been in use since the 1600s. Denis Papin, a French engineer, invented the steam pressure cooker in 1679. Louis Pasteur (1822–1895), a French biologist, contributed to the confirmation of the germ theory in the 1860s. Charles Chamberland, one of Pasteur's partners, invented the first pressure steam sterilizer, or modern autoclave, in 1876. In 1885, a German surgeon named Ernst von Bergmann became the first to use steam to sterilize surgical instruments. Currently steam sterilizers are widely used in the medical sector for sterilization of equipment (Ituna-Yudonago et al., 2021).

Getinge is a leading MedTech company in Sweden and the whole world, founded in 1904 in a small town of Getinge, Sweden. Getinge designed an autoclave steam sterilizer that will operate to decontaminate and sterilize medical equipment. For over a century, steam sterilizers have been used to sterilize equipment that can withstand the temperature and moisture inside the autoclave. Steam originates from water, which is readily available, non-toxic, and easier to control than other gasses (Dion & Parker, 2013).

There are six critical factors to the steam sterilization principles adapted from Dion and Parker (2013)

- Exposure time
- Temperature
- Moisture
- Direct steam contact
- Air removal
- Drying

The exposure time or sterilization is a critical factor since the organisms that live on the equipment will not die at the same time, some organisms are resistant to high temperature and moisture, thus requiring more time to sterilize. The time required to disinfect the equipment is inversely proportional to the temperature, if the temperature increases, time needed to sterilize the equipment will decrease, as shown in figure (1.2) (Dion & Parker, 2013).

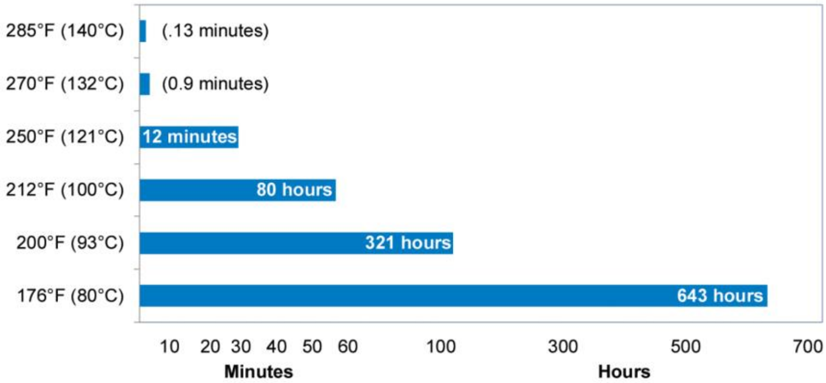

Figure 1-2: Sterilization time vs. temperature (Dion & Parker, 2013)

It is recommended to use saturated steam for sterilization, since moisture has the ability to coagulate and denature proteins, hence the importance of using saturated steam that has the maximum amount of moisture without any liquid present.

Direct steam contact with the surface is important for the sterilization process to proceed since it is needed to transfer the energy from the steam to the object. Prior to the steam sterilization, a series of vacuum pulses must be accomplished by vacuum pumps, because the air is the biggest deterrent of steam (Dion & Parker, 2013).

As a result of direct contact with the surface, condensate appears on the surface of the objects which must be dried before removing it from the sterilizer. Failure of drying the objects can result in recontamination while being removed from the sterilizer. Therefore prior to the extraction of the objects a vacuum pressure is recommended to make the condensate water boil and then removed from the chamber (Dion & Parker, 2013).

Getinge has taken an approach towards the optimization of the testing process and the consumption of resources they use, by offering the chance to work on this project where it aims and focuses on reducing the usage of water, steam and natural gas and to optimize the testing process taking place in testing the sterilizers before it is shipped out to the customers worldwide. A deep and wide research has taken place to find and analyze different solutions to get suitable solutions for the testing process to be more sustainable, and more time and cost effective

1.2 Aim of the study

The project aims to analyze and optimize the testing process of the steam sterilizers and the consumption of resources like water, electricity and steam that are used to test the steam sterilizers manufactured. Find the factors contributing to media consumption and hindering the testing process in order to propose improvement and optimization methods.

1.2.1 Problem definition

Testing of the sterilizing machines consumes a huge amount of time and resources like water, electricity, and steam which contributes to a major portion of the cost. Identifying the factors contributing to media consumption and optimizing the process to lower the cost and time utilized to test the products.

1.3 Limitations

Getinge produces a variety of autoclave sterilizers that are designed to work with different principles and processes. In this report to limit the research, a specific product was analyzed, Steam Sterilizers with the serial number GEV 91425 AR-2 and dimensions 0.9m x 1.4m x 2.5m. No standard measuring equipment or processes were available for measuring steam and electricity. Cost estimation will not be elaborated due to insufficient data and time constraints.

1.4 Individual responsibility and efforts during the project

A couple of site visits were done as a team to observe the processes closely and collect information from interviews and conversations with the employees. For identifying suitable substitutes for the existing process, articles and journals were referred individually and findings were discussed. Several brainstorming sessions were conducted to decide upon the best alternative out of it. Both project members contributed equally to this thesis. Thus, project report was prepared by dividing topics among the team members so that the workload gets distributed equally.

1.5 Study environment

The cycles, time, failure log, resource consumption data and the basic working model of the steam sterilizer have been gathered from the utility data sheets and documents provided by the company. The articles and literature required for the study have been collected using university library databases and google scholar. Several meetings or discussions were conducted in the project room in the university as well as via digital means.

2 Method

2.1 Alternative Methods

Several different methods can be used to find a solution to this problem. However, it is quite a difficult task to figure out the most suitable one. Different possible methods that can be used are discussed below.

According to Harrington and Voehl (2016) 5 Whys analysis is a problem-solving technique that involves determining the root cause of a problem. In principle, it's a straightforward process where a group of stakeholders who were involved in a failure is assembled, and one person asks, "What went wrong?". Repeat this question five times more in such a way that a why question is asked to the answer to previous question, until reached to the bottom of the problem. The 5 Whys analysis seeks to discover process flaws rather than human error. This method does not involve statistical tools or segmentation. The main drawback of this method is that it is completely dependent on the person, three different persons applying this technique may come up with 3 different answers.

DMAIC approach of Six sigma is another method which can be used for process improvement. The letter DMAIC stands for Define, Measure, Analyze, Improve and Control. Each step is discussed below in detail (Bisgaard et al., 2002).

Define: What issue would you wish to solve? The first step in the Six Sigma improvement process is to define. The project team writes a Project Charter, plots a high-level map of the process, and explains the process. They begin their journey of process understanding by conducting Process Walks and chatting to process participants (Bisgaard et al., 2002).

Measure: What is the current state of this process? What is the extent of the issue? Measurement is essential throughout the project's life cycle since it gives crucial indications of process health as well as pointers to where process difficulties are occurring. As the team gathers data, they concentrate on the process's lead time, or the quality customers receive as a result of the process. The team develops its measures and determines the current performance or baseline of the process before going on to the Analyze Phase (Bisgaard et al., 2002).

Analyze: What is the source of the issue? One of the most difficult tasks for teams is to avoid the impulse to jump to a solution before determining the underlying root causes of process problems. Without adequate analysis, teams may implement solutions that do not address the problem, wasting time, money, increasing variety, and potentially introducing new issues. Rather of executing solutions that don't solve the problem, teams should learn from their Process Walks, examine their charts and graphs, and utilize their observations to build and confirm theories about what's causing the problem they're attempting to solve. The goal of this phase is to test hypotheses before putting solutions in place (Bisgaard et al., 2002).

Improve: How will the team address the problem's root causes? It's time for the team to put strategies in place to address the root cause once they've figured out what's causing the issues. The team refines their countermeasure ideas, pilots process modifications, implements solutions, and finally collects data to demonstrate there is measurable improvement during the Improve Phase. A systematic improvement effort can result in inventive and elegant improvements that improve the baseline measure (Bisgaard et al., 2002).

Control: How do you keep the progress going? The team must endeavor to retain the gains and make it easy to update best practices now that changes have been implemented and the process problem has been resolved. The team creates a Monitoring Plan to track the success of the modified process and a Response Plan in case of a performance dip in the Control Phase. Once in place, the Process Owner keeps an eye on the current best technique and adjusts it as needed (Bisgaard et al., 2002).

2.2 Data collection methods

2.2.1 Interview

The interviews are a series of vocal exchanges in which the interviewer attempts to elicit information from the individual being interviewed. Interviews are the most common method for gathering data in research. Interviews do not require any prior statistical expertise, and interviewees are referred to as respondents, may be close by and ready to help. They are especially useful for figuring out the backstory to a participant's experiences. To learn more about a topic or further explore findings, researchers might follow a set of questions (Doody & Noonan, 2013).

In this project the individuals who are being interviewed are testers, who carry out testing operations in machines. A tester is assigned by the company to support the project. A list of questions has been created so as not to miss out any areas that we need more information. The people who have hands-on experience can supply more practical information that can be relied upon. The questions asked are included in the appendices.

2.2.2 Industrial visit

An industrial visit usually has one or more of the following goals. a) Opportunity to interact with industry experts and enhance learning b) to encourage collaboration between industry and educational institutions c) to enhance marketing d) for information sharing. The first two are relevant in this study. Industrial tours expose students to real-world industries, taking learning beyond the classroom and allowing them to gain insights, critical thinking skills, and practical as well as theoretical knowledge (Masturah M., et al 2010).

There are several procedures to be followed in conducting an industrial visit. The first step would be seeking approval from the company and the educational institution of the student. Then deciding upon the date and time depending upon the preference of the company. The prerequisite for entering the plant would be personal protective equipment such as safety helmet, jacket, earplug etc. Which depends upon the operation being carried out in the plant. PPEs are usually supplied by the company.

2.2.3 Literature Review

The aim of this project is to find a better alternative process or improvise the existing process, for that more information on the alternative processes currently existing or the studies going on in this area is gathered through different articles and journals. Databases such as ScienceDirect, Google Scholar, Elsevier, Emerald are used for gathering articles. Keywords used for literature search are “sterilization”, “steam sterilization”, “autoclave”, “steam sterilizer testing”. The initial filtering of articles was done by the heading and year of publication of the article. Then further filtering is done by scanning through the abstract and those articles which we found relevant are then analyzed in-depth and the possible alternative processes were noted down.

2.3 Chosen methodology for the project

The methodology that is used in this project is a combination of quantitative and qualitative. defined by Sogunru (2002) a quantitative methodology is the research of a problem based on theory testing consisting of variables measured with numbers. Since it is necessary to minimize the use of resources, numbers are important to complete the research and are dependent on it. The quantitative data that is needed will be provided by the company or measured on-site. The qualitative methodology is the research of understanding a human or social problem, based on building a picture formed with words based on information (Sogunru ,2002). Where it is important to use this method for the optimization process.

According to Kallet (2004) the methodology part in any paper should clarify the answers for two primary questions: How was the data collected or generated? How was it analyzed? Answering the first question, the data will be provided by Getinge as mentioned above and using the triangulation technique. triangulation as described by Briggs et al. (2021) is the process of integrating results from several approaches in order to conclude more reliable conclusions. In this report, collected data from Getinge and relevant articles or journals, interviews, and observations from site visits to the plant. All this information is used to build a better understanding of the testing process.

After the data is collected it is analyzed by identifying the factors that are contributing to the consumption of time and resources. Consequently, other alternative solutions to the problem were compared with the existing process in the plant, and results were found accordingly.

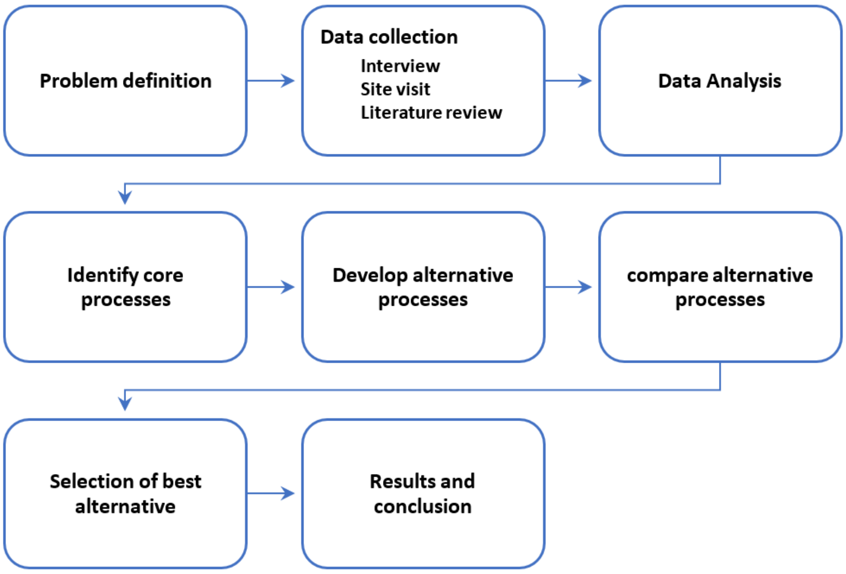

Figure 2-1:Methodology Scheme

2.3.1 Triangulation

Plenty of information was gathered during interviews with testers, observation on the site visit to the plant and data collection from different articles and journals in the literature review. Thus, making all this information add up to get a better understanding of this project would be a challenge. Therefore, the method of triangulation was used in order to connect the information gathered during all the three phases. Triangulation is the use of multiple forms of qualitative data or methods in an attempt to achieve a comprehensive view and understanding of the project (Denzin, 2012). After that, the data will be analyzed and acted upon to fulfill the goal of this project and to find and investigate alternate solutions.

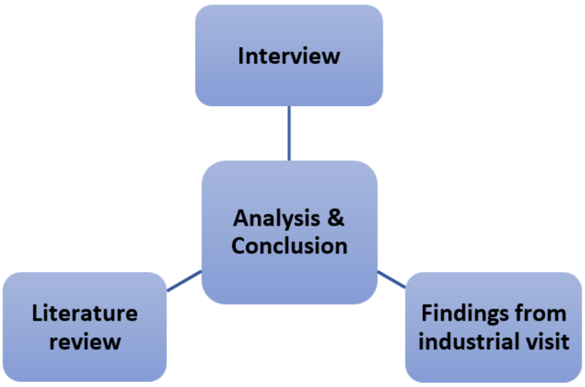

Figure 2-2: Triangulation

3 Theory

3.1 Summary of the literature study and state of art

This project aims at the optimization of the steam sterilizer testing process. Purpose of steam sterilizer, how a steam sterilizer works, resources for testing of steam sterilizers etc, are explained in the literature study. A huge amount of water has been wasted in each test cycle run on the machine. To optimize the consumption a few alternatives have been studied, one among them is running a dummy test and another one is heat regeneration and reusing of the water. Dummy testing means running the test without the consumable resources and ensuring that all the functions are intact or working properly. Once it is confirmed then the actual testing with the resources is initiated. Reusing of water involves the implementation of a closed circular path to the flow of water so that the water which has been wasted so far is fed to the system again.
According to the study conducted by Miró et al. (2016) approximately 10 GW h/y heat generated as a result of foundry operations has been left unutilized. It could have been recovered by transferring the heat energy to water and pumping it to a borehole thermal energy storage (BTES) in combination with a heat pump. It was estimated that 3800 MW h of surplus heat could be stored yearly in the BTES at 60–65^{o} C, which would result in 1500 t/y mitigation in carbon dioxide. Physical thermal energy storage is divided into two types: sensible thermal energy storage (STES) and latent thermal energy storage (LTES). STES saves thermal energy by variation of material temperature; concrete, water, metal etc. are examples whereas LTES stores energy with a phase change in materials; salts, paraffin, alcohols are examples of this category (Liu et al., 2020). A lot of research is being carried out in finding better alternatives for storing thermal energy. In this project, as water already has thermal energy in it, there is no confusion in material for storing energy. However, the method for storing energy is a bit of a challenging task as it needs to review the pros and cons of different alternatives.

Seasonal thermal energy storage (STES) holds great potential for storing summer heat for winter use. The use of seasonal thermal energy storage (STES) allows for the substitution of fossil fuel-based heat supply with alternative heat sources such as solar thermal energy, geothermal energy, and industrial waste heat. The thermal energy generated mostly from sustainable sources is captured and stored in the STES system for use in winter. The figure below shows the classification in STES technology. The development of various STES technologies has been extensively studied from a technical and economical perspective (Yang et al., 2021).

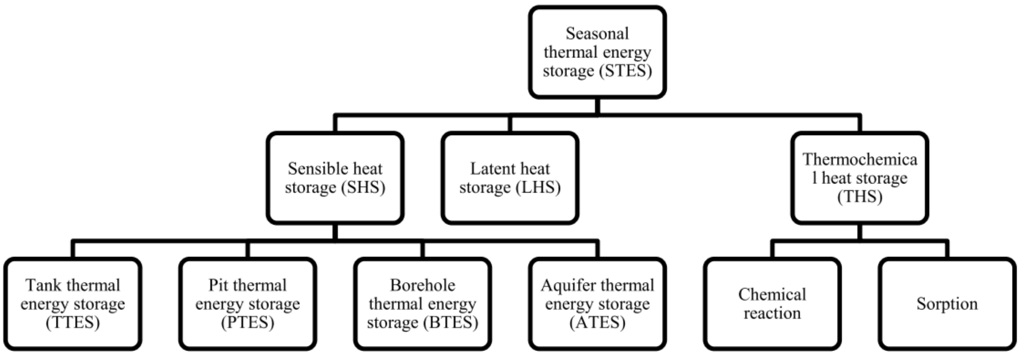

Figure 3-1: seasonal thermal energy storage technologies (Yang et al., 2021)

3.2 Function of steam sterilizers

Microorganisms are found everywhere where there is water. They are found in all living organisms including plants and animals. Some are necessary for day-to-day life while some others are harmful or even fatal. A germ or a pathogen is a microorganism that causes disease. Sterilization refers to the process that kills or deactivates all forms of life including the germs and pathogens. It is achieved with the help of sterilizers. Steam sterilizers can be used for sterilizing items which can withstand high temperature and pressure. Steam, the gaseous form of water, is non-toxic, readily available and easy to handle, which makes it one of the best alternatives among sterilizers (Dion & Parker, 2013).
According to Zhao et al. (2020) healthcare associated infections are affected by more than 19% of patients which results in long hospital stays and 30% higher mortality rate for critical patients. Aside from basic precautions and raising awareness, maintaining appropriate sanitation of invasive medical equipment is a vital step in overcoming this difficulty. Steam sterilization is the most successful and extensively used method for sterilizing medical equipment and materials, in which saturated steam condenses and rapidly releases its latent heat to destroy infectious agents at elevated temperatures and pressures.

All reusable essential devices that puncture soft tissue or bone and enter the circulatory system should be sterilized, according to the Centers for Disease Control and Prevention (CDC). High-speed handpieces and reusable equipment are also included in that guideline, even though they do not penetrate tissues. sterilization tries to break the chain of potential cross-infection between patients (Gurevich et al., 1996).

According to Ramesh (2020) it is an unavoidable factor in the food processing industry as it facilitates storage and distribution of food products at ambient temperatures with long shelf life by eliminating vegetative bacteria, yeasts, molds and spores. The 2 basic requirements expected from sterilization in the food processing industry are. Bacteria capable of creating food poisoning toxins, as well as microorganisms that cause food spoilage, must be absent from the processed product during its shelf life until it is consumed and as clostridium botulinum spores can grow in low-acid (pH >4.6) products during storage, they must be heat treated for at least 3 minutes at 121.1°C (an Fo value of 3) to obtain a 12-decimal reduction of the microbe.

3.3 Working principles of steam sterilizers

At Getinge, steam sterilizers work with different principles, the first type which will be explained is sterilizing with steam after the vacuum stage is done. In the beginning of the process, the chamber is loaded with the goods to be sterilized, and the door is closed, and a gasket will seal it properly using air pressure. Vacuum pump will start with pulses to drive out the air from the chamber, and after each pulse the chamber is fed with steam at a temperature between 121-134 degree Celsius. After the chamber pressure of 3 bar is reached, jackets around the chamber will be filled with steam to ensure the chamber temperature will be in the required range. The chamber will be filled with steam until it ramps up to a pressure of 3 bars, and will be held there for a specific amount of time depending on the load. When the sterilization stage is finished, all the steam is driven out of the chamber going through a vacuum pump equipped with a heat exchanger. Cold water will be also running in the heat exchanger in order to transform all the steam into water and dispose of the cooling water and the water that was generated from the steam after condensation right after. The chamber will be in vacuum after this stage, and will be held there for a specific amount of time, this happens to dispose of all the condensate water on the load to boil and make the load dry for extraction, a small vacuum pump will work to push back the gasket from the door to open it safely.

Not all the loads can handle the vacuum pressure or the pressure that is being held for the sterilization stage, thus a support pressure is needed. The main function of the support pressure is to prevent the load (which can be either plastic or glass bottles for instance) from collapsing or breaking due to the high-pressure difference between the inside and outside of the bottle. In this type of sterilizers, the vacuum pressure is skipped in the beginning, instead, the steam is directly added to the chamber while simultaneously removing the air from the chamber, the steam enters at the same temperature range as the previously explained type, 121-134 degree Celsius. In this type of autoclave, it is equipped with two fans inside the chamber that will stimulate the air mixture of air-steam inside the chamber, maximizing the efficiency and ensuring the dispersion of the mixture all over the chamber. Consequently, after reaching the required pressure inside the chamber, the sterilization stage starts, the temperature and pressure will be held for a specific time. Then after completion of the sterilization stage, the steam will go through openings inside the chamber that contain pipes with cold water running through it, in order to cool the steam and transform it to water. All the water condensate from the steam will be driven out through holes in the bottom of the chamber along with the cooling water in the pipes, into the drain to dispose the water into the lake. At the same time pressure normally drops but to even it out, compressed air is injected into the chamber, thus holding the pressure inside. After all the steam is out of the chamber, air slowly goes out of the chamber until the pressure reaches the normal atmospheric pressure, then a small vacuum pump will work to push back the gasket from the door to open it safely as depicted in the previous type.

Another type of steam sterilizers where it combines the two types above, it has the ability to perform vacuum stage and the ventilator type of sterilizers. All these products have a software to run all the stages; also known as cycles; automatically. It can be operated through a touch screen, where the program of sterilization can be chosen, and all the information and status during the process will be shown on the screen along with the temperature and pressure of multiple points in the autoclave. Sultana (2008) claims that steam in the autoclave will be pressurized to destroy microorganisms and bacteria. The sterilization in the autoclave embarks when the saturated steam at a high temperature fills the chamber. Moisture in the steam has a major impact on the ability of the steam to disinfect or coagulate proteins, thus it is important that steam is saturated where it has the maximum amount of liquid without the presence of liquid in that state (Dion & Parker, 2013).

3.4 Testing of steam sterilizers

Testing plan will be formulated per the consensus from a series of meetings with the client and Getinge. Apart from the testing cycles a hydrostatic testing is done at the beginning, which is a common test done on every single machine to ensure that the machine is leak proof. It is done by filling the chamber with water at a specific pressure. Water is used for testing instead of steam to reduce the risk if there is any leak in the machine.
Generally, 7 testing cycles were run in a machine. The cycles vary depending upon the machine and the requirement of the customer. The testing was controlled through the PLCs which is installed on the machine. Average duration of a cycle varies from 30 mins to 2 hours. On a medium sized machine each cycle consumes thousands of liters of water. The water consumption gets even higher on cold cycles.

3.4.1 Media consumption

Water: After sterilization the steam should be discharged. As per the regulations water should be discharged at a temperature of maximum 60 degrees Celsius. To cool down the steam and condense it into water below this temperature, either water will flow inside pipes that are inside the chamber lining or a heat exchanger working with cooling water is used, depending on the process. Each cycle consumes thousands of liters of cooling water. Water is also used for hydrostatic testing of the chamber. Water is supplied at 4 bar pressures in the facility and ground water is the source of water. A significant amount of water is being consumed in each cycle. One of the goals of this project is to find an alternative way to reduce the consumption or reuse the water being wasted.

Steam: Steam is used for sterilization as well as it is passed through jackets to isolate the chamber from the atmosphere to minimize the heat dissipation. Steam is supplied at a pressure of 2.8 bar in the facility. Approximately 250 kg of steam is used in each cycle. Majority of the machines are tested using steam produced from water purified using reverse osmosis. After each cycle the exhaust steam is cooled, condensed and the resulting water is discharged. Thus, the thermal energy in it is wasted. The next aim of this project is to identify a process or method to regenerate or reuse the thermal energy stored in the exhaust steam.

Natural Gas: Fossil fuels supply 87% of the energy used world wide, and the carbon dioxide emission from burning these fuels is the main reason for climate change (Cusick,ClimateWire, 2013). Thus, coal and oil that was burnt is replaced by natural gas, because natural gas emits around 30% less CO2 per kWh (Burnham et al., 2012).
In Getinge, the steam is produced in boilers that run on biobased natural gas that is actually certified as renewable, to make the process more sustainable. Cold water enters the boiler then it is transformed to steam which will be supplied to the plant for testing of steam sterilizers, or to heat the plant. Even though natural gas which Getinge uses is renewable, the aim is to optimize the consumption by reducing the amount of natural gas needed in the process of steam-generating. Hot water considered as waste from the steam sterilizers contains heat.

3.5 Peer comparison

Steam sterilizers are used widely around the globe, and many manufacturers produce them with different sizes and purposes. One of the steam sterilizers manufacturers is STERIS, it is an international company originating from the United States of America that specializes in decontamination, sterilizing and cleaning (Steris, 2022).
The steam sterilizer that is produced by AMSCO LSS large steam sterilizers, it works by removing the air from the chamber using vacuum and steam pulses. An alternate method to remove the air from the chamber is by gravity removal. Gravity removal is the process of removing air from the chamber by injecting steam into it. After that the steam will be sterilizing the load. Consequently, the drying phase can be accomplished by deep-vacuum, vacuum pulsing, or fast exhaust (Steris, 2022).

This process used by STERIS in their AMSCO LSS large steam sterilizers, is similar to the technology used in Getinge. On the contrary, Getinge produces a variety of capacities, from small to huge steam sterilizers, where there are different technologies used in different types of sterilizers (not only steam sterilizers).

3.6 Optimization of Testing Process

3.6.1 Heat Regeneration

The energy consumption around the world increases every year, and with this rising consumption rate, the fossil fuel consumption increases. Fossil fuel burning will increase the greenhouse emissions such as CO_2. This emission of greenhouse gasses is one of the main causes of climate change (Čehil et al., 2017).
Farahani et al. (2022) claims that to increase the efficiency of power plants, they can use the cogeneration to utilize the waste heat. The efficiency can increase from 50% to 70-90%. One of the biggest factors that directly contribute to the low efficiency of a cycle, either open or closed, is the lack of internal heat regenerative

heat exchanging, and there are many methods to recover heat energy instead of wasting it. “regeneration” refers to the internal heat exchange equipment or process, it works between two substances, one will be precooled and the other preheated (Qian et al., 2017). In this project, the water and steam which are circulating during the process of testing, is all cooled then wasted in a lake. Thus, the heat which is produced from the steam can be regenerated and be used to preheat coming water, in order to reduce the consumption of both water and steam, along with reducing the natural gas consumption, since it is going to preheat the water before going into the boiler.

Accumulation Tank with Thermal Stratification

Density of water changes with temperature. Water with the higher temperature will occupy the top layer and water with the lowest temperature would be in bottom layer as the density decreases when temperature increases. This type of arrangement in a tank is called thermally stratified tank. According to Han et al. (2009) energy storage can be significantly improved by thermal stratification. A study conducted by Ghaddar (1994) proves that energy efficiency of fully stratified water would be 6 to 20 % higher than that of fully mixed water tank. The article also stated that the average net energy efficiency of seasonal thermal energy storage can even increase up to 60%, by this method.

Han et al. (2009) also explained that efficiency of solar water heaters can be significantly improved by thermal stratification as the lowest temperature layer water at the bottom of the tank is the inlet to the solar collector, high temperature gradient is created which results in high temperature flow. Figure below is the schematic representation of a typical solar water heater, which generally consists of heating loop, load loop and water tank with thermal stratification. The stratified tank is the central connection for the other loops. The heating loop consists of the solar collector, which generates the hot water. The load loop is the area where the energy is being utilized. It can be devices such as heat exchanger, air conditioner or in this project a boiler.

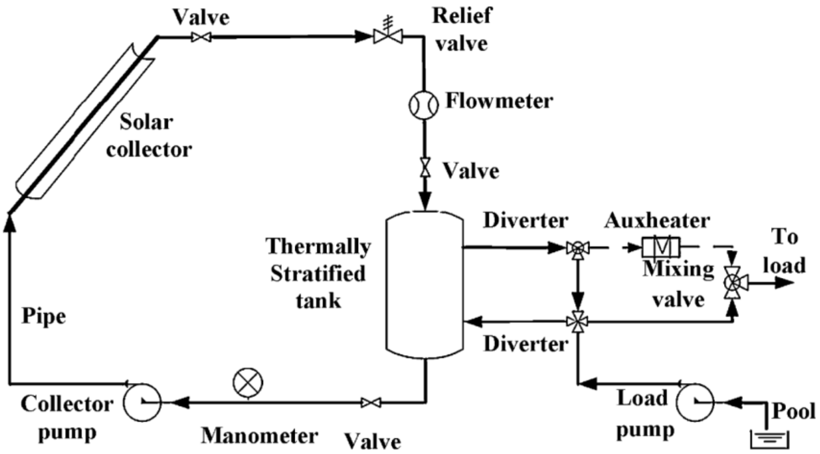

Figure 3-2: Solar water heater system Han et al. (2009)

Basically, stratified tanks are classified into 2 namely indirect and direct heating mode. Immersed tube or immersed coil, shell and tube, mantle heat exchangers are the sub classifications under indirect heating mode. It is a bit of a challenging task to sustain thermal stratification in a direct heat transfer storage tank.

A study of thermal stratification was conducted by Fan & Furbo (2012) on a tank of diameter .34m, height 1.68m and capacity of 152 l. In that study a tank was filled with water of 80^o C and with an ambient temperature of 23^o C. The tank is made of steel and insulated with mineral wool. The temperature variation for 24 hours was investigated experimentally and theoretically. The results show that moving to the bottom of the tank the temperature of water decreases gradually. The reason being the heat loss from the water near to the tank wall, the colder fluid flows down along the wall while the relatively higher temperature water at the middle of the tank moves upward thus bringing heat loss down to the bottom of the tank. After 1 hour of the experiment the temperature at the top of the tank was 79.3^o C while the bottom .3 m height if having a gradual temperature decrease from 79.3^o C to 74^o C. After 24 hours the water at the top has a temperature of 64.4^o C while the bottom 52.7^o C. which means thermal stratification builds further up.

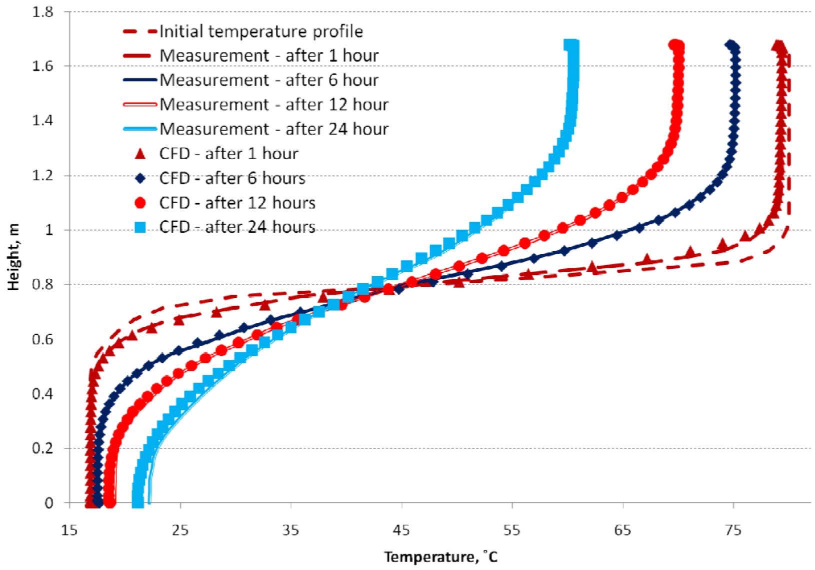

Figure 3-3: Theoretical and experimental temperature difference in the tank over time (Han et al., 2009)

Direct heat transfer

To avoid the turbulence caused by the direct heat transfer several measures are taken, such as adding porous mesh to slow the water flow, adding baffle plate at the inlet of the tank. Besides the above tank size, aspect ratio, inlet shape of diffuser system, baffle size and its shape to control flow parameters, velocity etc influence the thermal stratification.

According to study done by Han et al. (2009) stratification would improve significantly till aspect ratio of the length and wall thickness up to 3 and ratio of length of tank and inlet diameter up to 200. Also, performance can be enhanced by providing ports at different heights for inlet fluid with different temperatures.

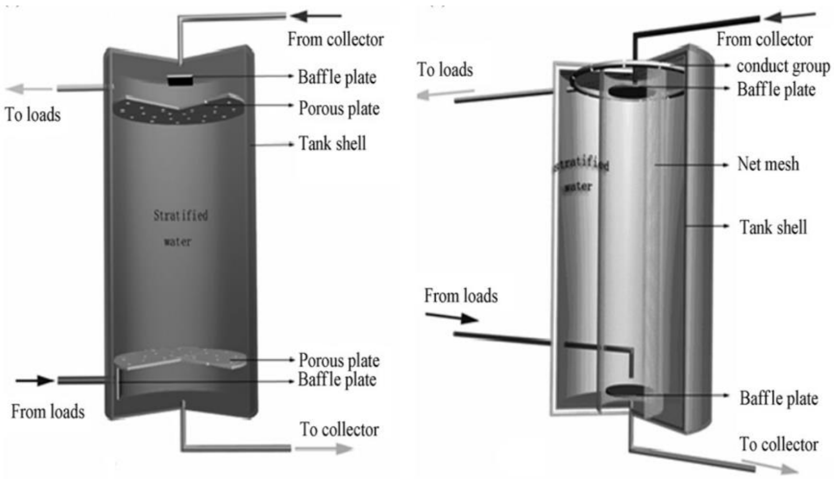

Figure 3-4:Thermal stratification: (a) porous structure applied within the tank and (b) baffle plate (Han et al., 2009)

Baffle plates can effectively decrease the turbulence and improve stratification. The study results shows that the obstacle (Baffle) with gap in the center can provide better stratification than those having gap near the tank wall. Also, the baffle with cone shape provides the best thermal stratification in the tank Han et al. (2009). Experimental investigation by Shyu et al. (1989) states that thermal diffusion in a tank has no significant effect in decay of thermal stratification. The article concludes that the heat lost to the ambient was the major contributor in decay of thermal stratification and it is mentioned that wall material has little effect in the formation of thermo-clines during charging and discharging.
According to the study conducted,

Hot water by direct steam injection

Direct steam injection is a highly efficient viable alternative to the traditional indirect heating. DSI system directly inject steam into cold water and heat it, unlike heat exchangers which transfer heat by conduction through metallic wall or tubes. The maximum efficiency a heat exchanger can provide is 75%, the reason being only latent heat is released to heat the water. However, direct steam injection systems utilizes both latent heat as well as the condensate heat, thereby it can provide 28% more efficiency than heat exchangers (Sutter, 2010).
In the case of traditional heat exchangers, a lot of energy is being wasted due to several reasons like, condensate returns to the boiler due to malfunctioning steam traps and auxiliary equipment, radiation from condensate return pipes, energy is lost when the condensate flashes as it is reduced to atmospheric pressure in the receiver tank. Also, Mineral deposits form on the wetted side of the metal conductor produce an insulating barrier, lowering overall efficiency. All these drawbacks of the heat exchangers can be limited significantly by using DSI system. 100% of the steam condenses as it heats the water with direct steam injection. Thereby the need of condensate return lines and associated energy losses can be avoided (Sutter, 2010). A typical DSI system is shown in the figure below.

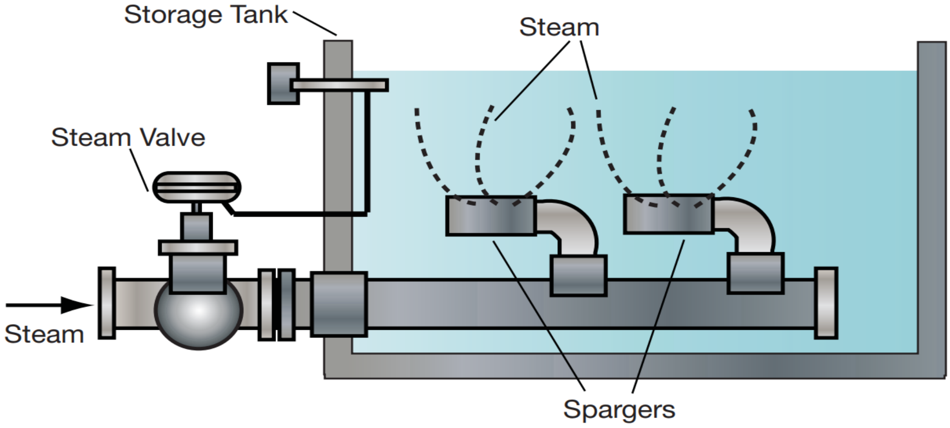

Figure 3-5: Direct steam injection (Sutter, 2010).

The main advantages of the system according to Sutter (2010) are

- High energy efficiency compared to heat exchangers
- Compactness: Even the most advanced DSI water heating systems are so small that they can be suspended from a wall or ceiling or put on a floor. This type of system can be used even there is a space constraint for storage tanks
- Temperature control: Very close temperature control can be attained at both variable and constant flow rates as the heat transfer is quick

3.6.2 Torque specification

Torque or the moment of force, as defined in physics is the tendency of a force to rotate a body which the force is applied to (Gregersen, 2017). Relatively, as a bolt is tightened, a tension between the bolt head and the top of the nut develops. This action will cause the bolt to stretch by a very small amount, like pulling a spring. When pulling a spring, the spring will try to return to its original shape, similarly, the bolt will act the same way as the spring as it tries to relieve the tension by returning to its original length. This will result in a force between the bolt head and the nut that will act as a compression or clamping force on the joint area. A demonstration is shown in the figure below (Smartbolt, 2022).

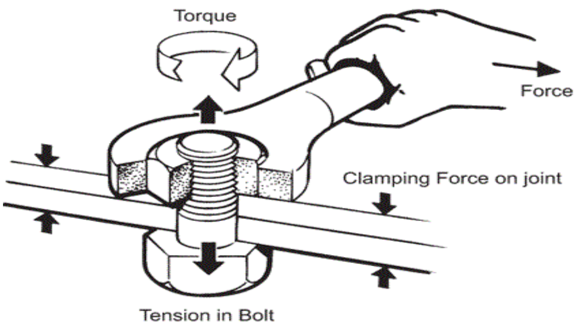

Figure 3-6: Torque and clamping force adapted from (Smartbolt, 2022)

When the bolt is not torque tightened, there is no clamping force or compression that will hold the joint together (Mínguez & Vogwell, 2006). In order to ensure a secure joint, a specific amount of torque force must be applied for a clamping force to develop, too much may cause the joint to warp or it could cause the bolt to break, and too little could cause a loose unsecured joint (Smartbolt, 2022).

The amount of required torque needed to hold the joint securely can be calculated by applying the equation below (Mínguez & Vogwell, 2006). Where the torque T is required to achieve an amount of preload F in a bolt, depending on the thread pitch, bolt diameter, and the friction coefficient between the nut and the bolt (Mínguez & Vogwell, 2006).

$$T=KFd \tag{3-1}$$

Where the thread coefficient is K, and d is the bolt diameter. The thread coefficient might be a value between 0.12 and 0.20, depending on many variables like the material or surface finish, tests show that the value can be calculated from the equation below (Mínguez & Vogwell, 2006).

$$F=5T/d \tag{3-2}$$

3.6.3 Testing

The usability of a product is determined by its set and combination of features, functionality, usefulness, and visual appeal. The product should be tailored to the function it is used in and should take in hand the characteristics of the operators or the people who are using it (Corrao et al., 2016).
Corrao et al. (2016) claims that the testing and analysis are being increasingly used by the medical community, for the development and improvement of medical devices. And this raises a question, what is testing?
Ahamed (2010) has a definition of testing as a set of activities that are planned ahead and conducted systematically. The main objective of the testing process is to find an error or failure in the product, either in a physical function or in the operating system by executing a program. The objective of testing is to figure out if the product meets the customer requirements or not.

3.6.4 Test plan

For performing any activity, planning must be done prior to the starting time. Similarly, testing commences with planning. The plan for testing is a general document for the entire project that will define the scope, approach, and the scheduling of the testing, as well as identifying the items to be tested for the entire process of testing, along with the personnel responsible for different activities of testing. The inputs for the testing plan are project plan and the requirements documents (Ahamed, 2010).
Ahamed (2010) claims that an ideal test plan contains the following parameters:

- Test unit specifications and details
- Features and functions to be tested

- Approach to testing process
- Test deliverables
- Scheduling
- Personnel allocating

3.6.5 Testability

The author Ahamed (2010) explains testability and defines it as the process of testing how adequately the particular set of tests will cover the product. The attributes of a good test as explained by the author Ahamed (2010) are:

- The test should have a high probability of finding an error or a failure. And the tester should have enough knowledge to understand and develop a mental picture of the failure possibilities.
- The test should not be redundant, since the testing time and resources are limited, it is of no importance at all to repeat the same test procedure as like the other, instead every test should have a different purpose.
- The test should be the best of its kind.
- The test should not be simple, neither complex. Although it is sometimes possible to combine a couple of tests into one test, the possibilities of this approach may mask error.

3.6.6 Verification and validation in medical equipment testing

Developing a medical equipment test includes verification and validation (V & V). Verification can be defined as the set of activities that ensure the product correctly implements a specific function. While validation is defined as the set of activities that ensure that the product has been built can be traced to what the customer requires (Campbell, 2021).
Verification: "Is the product built right?", Validation: "Are we building the right product?" The differences between the two concepts are given in some examples in the figure below (Campbell, 2021).

Table 3-1: Verification and validation (Campbell, 2021).

Verification	Validation
Checks whether requirements were met	Checks whether the product built meets the needs of the consumer
Finds issues early in the development cycle	Finds issues that the verification process can't identify
Tests sub-systems like software architecture, specifications, high-level design, and database design	Tests the actual product
Comes before validation	Comes later in the process
Involves static testing techniques	Involves dynamic testing techniques
An internal process that's used in development or production	An external process that seeks acceptance from users

3.6.7 Software testing methods

Software can never be free of bugs, no matter how hard they try to develop it. On average, well-written programs have one to three bugs every 100 statements. It is estimated that testing a software can take up to half the labor involved in the production of this software (Ahamed, 2010).

There are two main approaches to testing a software, which are white-box testing (structural) and black-box testing (functional). White-box t and black-box testing should be carried out together in order for the product to live up to the expectations of the customer on all the levels.

White-box testing is designing a test that will utilize every line of the code and making sure that it will be executed at least once. Very few white-box tests can be done without the modification of the actual program, changing the values to force the execution of different paths, or to generate inputs to test a particular function. White-box testing is a method to verify that the code is structured properly and has no hidden bugs (Ahamed, 2010).

Black-box testing checks whether an application functions as intended. This is done by comparing the actual functionality of a software and the intended functionality described in the specification documents. Black-box testing deals with the system as a black box, where it has no explicit use of the knowledge of the internal structure. However, it is designed to focus on testing the functional requirements. Some other names for it are functional, behavioral, opaque and closed box. In black-box testing the software is exercised over a full range of inputs and the outputs are observed to ensure its correctness. How it was achieved or what is happening inside "the box" does not matter in this method of testing.

This type of testing is inefficient by itself. Thus, a combination of the methods of testing would be the best practice of testing the software (Ahamed, 2010).

4 Results & Discussion

According to the research that have been carried out during this project, a number of four different optimization processes were developed and improved to be able to implement it in the process of testing of the sterilization machines in Getinge. The results were as follows in this section.

4.1 Heat Regeneration

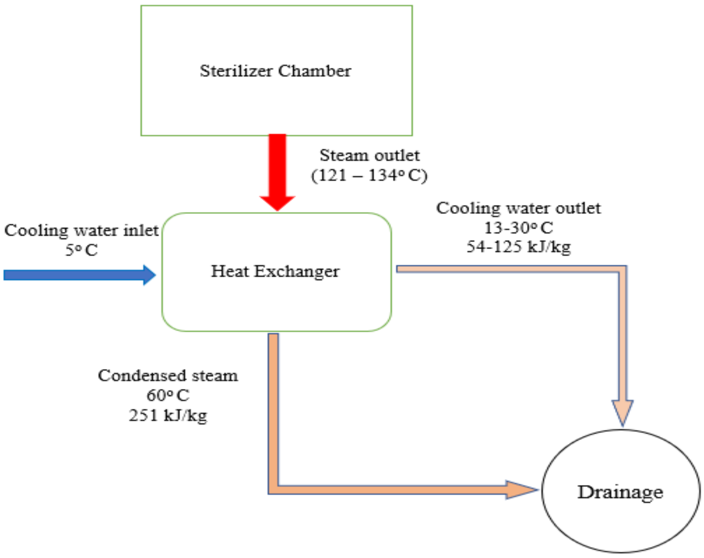

Figure 4-1: Current process flow

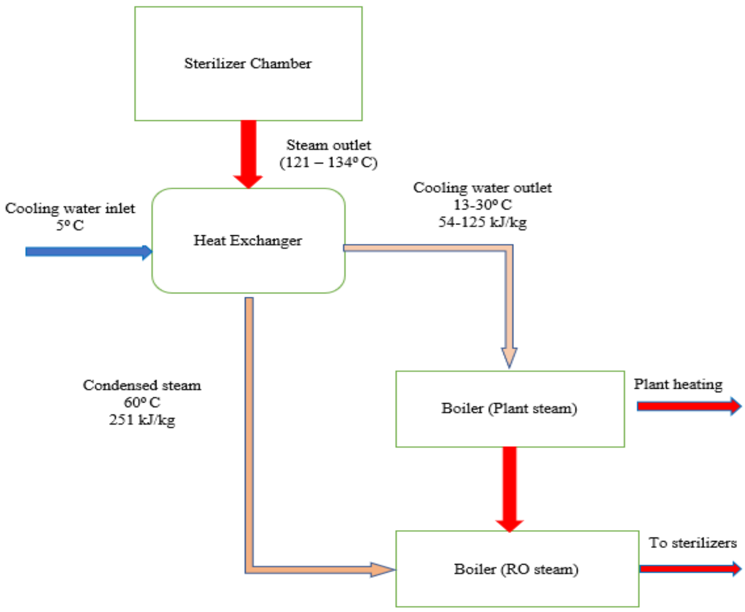

Figure 4-2: Suggested process flow

In Getinge, after the testing process is complete, all the water that is used in the process is discharged without energy recovery or reusing the water, as shown in figure (4-1). Thus, with heat regeneration all the water that is wasted can be recycled, which will reduce water consumption substantially. Also, the heat it contains can be recollected by redirecting the recycled water into the boiler. The figure above shows a simple diagram on how the water can be redirected and recycled.
After the testing process is done, the steam coming out of the sterilizing chamber will be cooled down and condensed in a heat exchanger that has cooling water running through it. All the water will be pumped into boilers for circulation.

According to the calculation, recycling the wastewater resulting from the testing cycles that also contains the heat content from the process, as shown in figure (4-2), can be useful in the sense that it can save energy, because the energy needed to heat up the water and transform it to steam will be less. The energy that will be recycled from the sterilizer's water waste can save 54-125 kJ for each kilogram of the cooling water, and 251 kJ for each kilogram of steam, in addition to the cost of water itself.

Also the energy that will be recycled from the circulating cooling water waste can save around 30 kJ for every kilogram of water used to cooldown and condense the steam resulting from the testing process in a heat exchanger.
Assuming that 1 kg of normal water enters at 5^{o} C to the boiler. And 1 kg of circulated water from the sterilization process either condensed from steam, or coming from the circulating water, enters the boiler, where it will be heated to create steam. Using the equation adapted from the author Menezes (2017).

$$Q=m*Cv*(Tf-Ti) \qquad (4\text{-}1)$$

The heat energy needed for the process of heating water to 100^{o} C can be calculated as follows:

- normal water to boil, 1 kg* 4182 Cv* (100^{o} C-5^{o} C)=397290 J = 397.3 kJ

- Circulated water to boil, Q=m*Cv*(Tf-Ti)= 1*4182*(100^{o} C-13^{o} C) =363.83
  (8.4%) less energy

- Steam water condensate to boil, 1 kg* 4182 Cv* (100^{o} C-60^{o} C)= 167.3 kJ +Vap.
  (57.8%) less energy

4.1.1 Heat Regeneration with solar collector and thermally stratified tank

The objective of this method is to add one more source of heat from solar rays which is renewable and green. A thermally stratified tank is used as the source of water to the boiler in the plant. The thermal stratified tank placed in this system impart two benefits to the system. The first one is It improves the thermal performance of the solar heating system. The lower inlet temperature to the solar collector will increase the thermal efficiency and operating hours of the solar collector (Andersen et al., 2007). The second benefit is high temperature water can be fed to the boiler by placing the outlet to the boiler properly. Based on the average temperature of water after testing the inlet to the stratified tank can be adjusted so as to place the water at the layer which is of nearest temperature range. Insulation can be provided around the tank to avoid excessive heat loss. The cooling water can be fed through a pipe from the bottom of the tank, where there is least temperature. To cool the water further a radiator system can be provided there by improving the cooling efficiency.

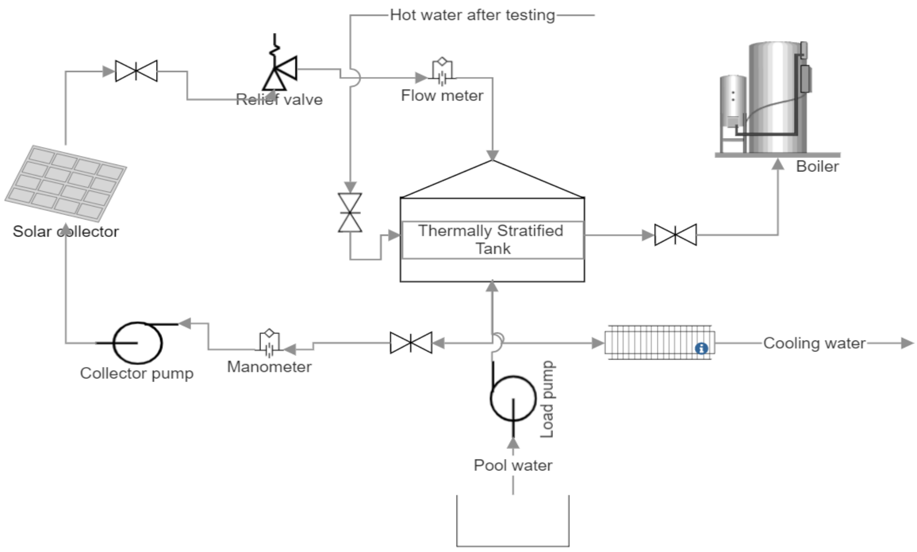

Figure 4-3: Heat Regeneration with solar collector

4.2 Process Faults

The number of cycles to be run on the machine is decided based on the agreement between the customer and Getinge. On an average there would be around 7 cycles per machine. If any of the cycle fails or didn't perform as per the expectations, then all the cycles should be run from beginning after identifying and resolving the issue. So, in effect the number of cycles running on the machine would be 4 to 6 times higher than the required number of cycles. It is not necessary that each cycle needs to run the complete duration. Instead, if a fault is identified or detected in the running of a cycle, the cycle is discontinued and take measures to resolve the issue. Mostly, the faults would be easy fixes like restarting the system would solve the issue. Another frequent fault was found in the program section. Mechanical faults were rare.

4.3 Torque Specification

During the testing procedure of the sterilizing machine GEV 91425 AR-2, several failures were detected which required maintenance and retesting to ensure the function of the machine, which means repeating the cycle. After looking at the failure log of the sterilizing machine GEV 91425 AR-2, there was indeed a failure that caused a leak in the fan gasket, and after investigating the root cause of the problem, it was found out that the bolts were not tightened properly to secure the joint.

In Getinge, the assembly line goes through this bolt tightening process, but there is no standard to specify the torque needed for the bolts, especially the ones that could lead to leakage if not properly tightened, which is exactly what happened in this case. As a preventive measure, it is recommended that the tightening torque would be specified as a standard for the assembly process. Also, proper tools should be provided, like torque wrenches, along with the proper guidance, training, and clear information about it.

4.4 Dummy Testing

In Getinge, the testing process starts after the assembly. The first stage of testing is the electrical testing, where the electrical boards and grounding are tested if it functions properly. The second stage is the leakage test, where the machine is fully filled with water. If any leakage is detected in this stage, then the maintenance is done on spot. The third stage is the cycles test, where depending on customer requirements for the number and type of cycles to be tested, the machine is tested for functionality. Any failure or error either a mechanical or programming error that is detected in this stage is fixed, then the cycle is run again. Consuming more time and resources.

After analyzing a failure log on the sterilizing machine with the serial number GEV 91425 AR-2. The expected number of cycles to be tested are 7, consequently, the average number of cycles that were run in the testing process is approximately 40 due to failures. Most of the failures that happened in the testing process were in the software implementation and the rest are mechanical failures, as shown in the figure below.

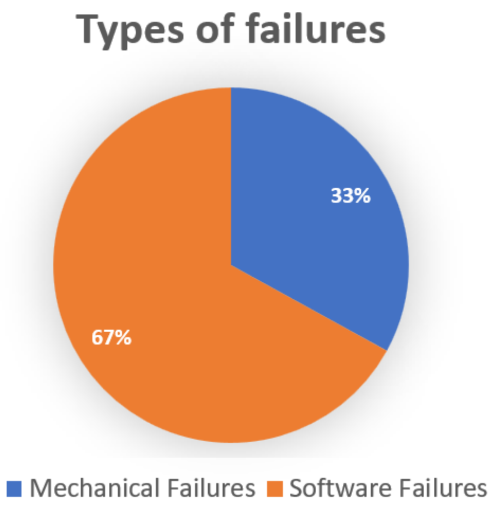

Figure 4-4: Types of failures

A possible solution for this is adding an extra stage between the second and third stage, as shown in the figure below. This extra stage would be the combination of a white and black-box test. The stage will include a modification of the program or the code in the testing process, made to run the machine without the use of any resources, and made to run every function and every line of the code.

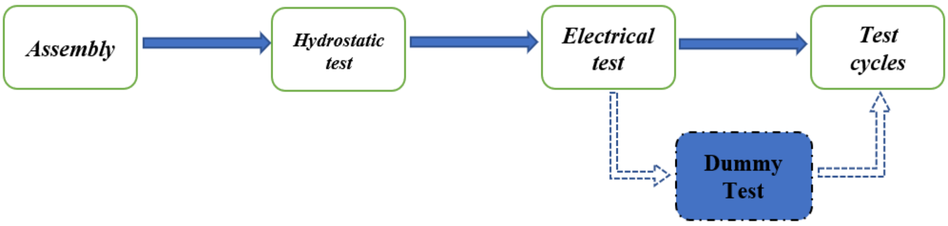

Figure 4-5: Suggested stages

The implementation of this stage in the testing process will offer many advantages that will contribute to the process of testing as a whole.

- Reduction of the media resources used in testing
- Early detection of failures, which will save time and money
- Reducing the number of cycles to be run again in the next stage, since the failures that could occur in the next stage can be avoided
- Cost reduction
- Reduce manpower requirement

4.5 Overall results – sum up

Four optimization methods were found as an overall result of the research. Heat regeneration, through water recycling and accumulation chamber, where it will benefit the whole testing process by reducing the consumption of water and regenerating the heat energy wasted in the exhaust water. Torque specification to be predetermined and utilized in the assembly process, that will ensure proper tightening torque at the bolted joints. Thus, reducing the possible failures due to loose bolts in the testing process. The final optimization method was dummy testing, this will benefit by reducing the time and number of cycles needed to complete the testing process. The following table is the sum up of the optimization method, suggested action, and possible benefits.

Table 4-1: Overall results

Optimization method	Suggested actions	Benefits
Water Recycling and Accumulation Tank	To implement one of the two process suggestion.	Drastically reduce the water consumption, and it will regenerate heat energy in the water.
Torque Specification	To be implemented in the assembly process	Reducing the risk of failures due to insufficient tightening torque
Dummy testing	To be implemented as an extra stage before the cycles testing	Drastically reducing the time and resources consumption due to failures.

5. Conclusion

In conclusion, testing of the steam sterilizers in Getinge consumes a significant amount of time and resources, like water, steam, natural gas, and labor.
This thesis focuses on analyzing and optimizing the testing process of the steam sterilizers in Getinge. Four alternative optimization processes were developed and analyzed to be integrated and implemented into the process viz., Water Recycling, Torque Specification, Accumulation Chamber, and Dummy Testing. It is quite difficult to rank these processes due to the lack of cost and savings estimation but could be done in future studies. Moreover, by implementing these processes in the testing process, it will significantly reduce the amount of time and resources needed to complete the testing process and validate the machine for delivery to the customer, depending on the machine and the failures that could be found during testing. That will significantly improve the process and make it more pragmatic.

5.1 Recommendation to future activities

After this thesis, cost estimation can be done for all the alternative optimization processes, including the initial cost, running cost, and the break even time to determine how long the process must run in order to cut down cost.
Accessing more data/information and exploring more machine types will ensure more accurate results for the development of the processes.
The size of the stratified chamber to accommodate the required water, including the material selection of chamber and thermal isolation should be determined. The results must be simulated using CAD and CFD to validate the information as the experiment done by Fan & Furbo (2012) proves that the CFD is in agreement with the actual values.

In the future, research can be conducted to further develop the alternative optimization processes, while involving more teams from different backgrounds, Automation, Engineering, Technical, Management etc., the research will produce far more promising results in optimizing the testing process that will benefit the company on various levels.

6. Critical Review

In general, the goal of this thesis is to optimize the testing process that is handled in Getinge Sterilization and to minimize the environmental impact from media consumption in the process. Every stage in the process has been analyzed, to check what different aspects hinder the progression of the process of testing. Research has been carried out to find alternative solutions to optimize the process. As a result of the research, four optimization suggestions were found. Heat regeneration suggestion through water recycling and accumulation chamber, where it was beneficial to reduce the consumption of the water and to regenerate the heat energy wasted in the exhaust water. Torque specification, in order to reduce the failures due to loose bolts. And finally, Dummy testing, to reduce the time and number of cycles needed to complete the testing process. The first two suggestions are alternative, while the remaining two can be implemented simultaneously. When implementing these processes, the company will benefit financially in the long run and the process of testing will be more sustainable.

The research that was carried out was enough to point out optimization processes, but the research could have been done better if more information were given, with no confidentiality restrictions. The research can be in a wider range, for several types of products, to get more accurate and efficient results. Also, with cost analysis to improve the research. Software is not a part of our expertise, therefore in the future involving specialized personnel to cover the need of the software knowledge is a merit and will enhance the result.

The methodology of the research was a combination of quantitative and qualitative methods, which positively impacted the results of the research. The involved personnel form both the university and the company, had the right knowledge to support our research. Also, the literature used in reference was quite relevant to our topic to a certain point, which allowed us to combine the different findings and sum up certain conclusions that are more accurately relevant to our research.

6.1 Standards and Ethics

In this project utmost care has been taken not to include any confidential information of the company in this report. The proposed models in this project are in full compliance with the Swedish rules and regulations. Getinge is moving aligned with Sweden's policy on sustainability and this project will support the same.

6.2 Environment

One of the aims of the project itself is to make the process more sustainable. The problem has been identified as the overconsumption of resources, primarily water. As per the suggested process, a closed loop for the flow of water has been made which will reduce the consumption significantly. Also, the heat carried by the water which has been wasted before is put into use as per this model. The sustainable source of energy, sunlight has been considered and put in the loop which will reduce the consumption of natural gas to a great extent and make the process more ecofriendly and sustainable. The dummy testing process which helps in early fault detection without the actual testing reduces the number of test cycles with the consumable resources and makes it even better.

6.3 Health, Safety and Society

The proposed models do not incur any additional health or safety hazards to the operator or anyone if the standard operating procedure existing currently is followed as the product is EU certified. The company has been following best safe practices and recommends using appropriate PPE's. We have strictly followed the safe practices during industrial visits. Care had been taken not to intervene with any staff in the company during their busy hours.

6.4 Economy

Even though it is an important aspect of the project, due to time constraints it is not included in the scope of the project. Return on investment, break even time and risk assessment are three important aspects which should be considered before the project implementation. It has been included in the recommended future activities. Even though it consumes a bit of initial cost it is expected that within a short duration it could break even and give returns.

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