Design and Development of Steam Sterilizer

A Master thesis

Presented in Partial Fulfillment of the Requirements for the Degree of

Master of Science in Biomedical Engineering

By

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Addis Ababa, Ethiopia, June 2023

Declaration

I, the undersigned, declare that this thesis is my original work. It has never been presented for a degree in any other institution and that all sources of materials used in it have been duly acknowledged.

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This MSc. thesis has been submitted for examination with my approval as an advisor.

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Dawit Assefa Haile, PhD

Certificate of Examination

This is to certify that the thesis prepared by Yemane Tesfay entitled "Designing a Steam Sterilizer" submitted in partial fulfillment of the requirements for the degree of Master of Science in Biomedical Engineering (Bioinstrumentation and Imaging) complies with the regulations of the University and meets the accepted standards concerning originality and quality.

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Acknowledgments

First and for most I thank the Almighty God who created me to create and who was and who is and who will be nearby me and guiding me through all aspects of my life. He made everything possible regardless of the challenges out there.

I would like to show gratitude to my honorable advisor, Dr. Dawit Assefa Haile (PhD), for his constructive advice and principled approach. He is positive and responsive whenever I need help at any time with any condition even at night time. Without his instrumental supports, this thesis could not have been done. God bless his future purposeful, indeed.

I am also grateful to Dr. Masreshaw Demelash (PhD) as well as Dr. Frehiwot Woldehanna (PhD). I am grateful to Dr. Mengistu Kifle (PhD) and Mr. Ashenafi Husseien (MSc) for sharing with me their expertise in steam sterilizer (autoclave) and encouraging me during all courses of the research. In addition, I thank Dr. Abdu Abagile (PhD), director-general of the national metrology institution of Ethiopia (NMIE) for his great support. Thank you, my friends, and colleagues, for all the care and support you have given me.

Last but not least, I would like to extend my sincere gratitude to my Family. I would also want to thank my loved ones, who have supported me throughout the entire process, both by keeping me harmonious and helping me putting pieces together. I will be grateful forever for your love.

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List of Abbreviations

AC	Alternating Current
Atm	Atmosphere
CFD	Computational Fuld Dynamic
DC	Direct Current
I2C	Inter-integrated Circuit
IC	Integrated Circuit
ISO	International Organization for Standard
LCD	Liquid Crystal Display
LED	Light Emitting Diode
MC	Microcontroller
MP	Microprocessor
PIC	Peripheral Interface Control
PLC	Programmable Logic Control
PPE	Personal Protective Equipment
PSI	Pounds per Square Inch
RTC	Real-time Clock
RTD	Resistance Temperature Detector
SAL	Sterilization Assurance Level
SPI	Serial Peripheral Interface
SSR	Solid State Relay
SSD	Sterile Service Department
WHO	World Health Organization

Abstract

According to the 2010 WHO infectious disease report, hundreds of millions of patients around the world are affected by healthcare-associated infections which cause extended clinic stays, long-term disability, massive additional costs, and unnecessary deaths. This folds higher in low-income countries but it is a global burden. To minimize the burden of these infections, cleaning, disinfection, and sterilization techniques have been applied. For a sterilization technique, different steam sterilizers are available in the market ranging from the simplest electro-mechanical portable systems to the complex microcontroller-based double-door floor fixed types. However, those steam sterilizers can't adjust environmental pressure for altitudinal changes that often fail to function properly under significant pressure variation. Countries like Ethiopia have great geographical diversity, known altitude ranges from the highest peak at Ras Dashen (4,620m) down to the Dallol Depression (-148m), which highly affect the performance of steam sterilizers. The main intent of this thesis study is to design a microcontroller-based smart steam sterilizer that adjusts itself to variable altitudes since steam sterilizers that work in all altitudes are vital for the healthcare system. The sterilizer also comes with a water electrical conductivity sensor to completely avoid the use of hard water integrated with a water level regulator to protect the heater when water runs out inside the chamber. Interfacing between the proposed smart pressure compensator, conductivity sensor with water level regulator of steam sterilizers is worked out in this study. The developed control system senses the environmental condition using BMP280 sensor to adjust itself based on the altitudinal changes as well as water electrical conductivity, water level, pressure, and temperature sensors. A formula is developed based on the altitude pressure compensation to solve the problem of altitudinal effect and for water quality and quantity measurement guided by a programmable microcontroller. The control system can adjust the pressure based on the altitudinal variations. The system offers better efficiency, precision and comes with great ease of use. The designed smart steam sterilizer is as effective as existing modern sterilizers with an added feature of blocking use of hard water. Meanwhile, further research might be needed to make the device more efficient, lower cost, durable, and safer.

Keywords: Steam sterilizer, Microcontroller, Water hardness, Water level regulator, Altitudinal variation, Temperature, Pressure sensor.

Chapter 1: Introduction

1.1. Background

In ancient times, demons and evil spirits were conceived to be the causal agent of serious diseases that could lead to infection or even death and witchcrafts and magic were used to drive them away. In around 3,000 BC, some ways were introduced that help to kill pathogenic microorganisms with fewer side effects to the human body tissues [1]. Resins and aromatics were widely employed by the Egyptians in embalming bodies even before they had written language. They became so skillful in the art of preserving a dead body that mummies of thousands of years old are still in good condition. The earliest Egyptians also have had a good experience in preventing infections using copper as a decontamination agent for injuries and water [2].

Moses was the first person to prescribe the process of removing impurities by fire. The fumes of burning chemicals were also used by the ancients to eliminating the odor and minimizing microorganisms which are causal agents for diseases. Treating with sulfur for preservation purposes was the first of the useful chemicals to be mentioned [2]. From 130 to 200 AD, the works of Galen from Greece and those of Hippocrates (the father of healing) were the established authority for medicine for many centuries [3]. At the middle age, in the period from 900 to 1500 AD, significant progress was made from the standpoint of remarkable contributions having a direct bearing on the development of the art of infection minimization.

These basic methods used by the Egyptians and Greeks were relatively efficient but not fully and likely considered revolutionary at the time. The interesting thing was, however, that none of the people implementing these practices had any idea of why heat and chemicals would reduce infection rate or prevent people from getting ill from drinking water. In 1683, Antonie van Leeuwenhoek invented and manufactured the microscope for the first time and demonstrated the existence of microorganisms, and in 1862, Louis Pasteur, French chemist and microbiologist published his findings on how germs cause disease "the germ theory of disease transmission" which he later used to develop the pasteurization process [3].

1.2. Infection in a Healthcare Facility

Infection is the process of invasion of the tissue by pathogenic organisms characterized by their multiplication in the body of the host to produce disease. Infectious diseases can happen because of pathogenic microorganisms such as viruses, bacteria, and larger organisms like parasites and fungi. Infectious diseases can be transmitted directly or indirectly from the diseased person to others and even to care givers. Infectious diseases can happen depending on the number of pathogenic microorganisms and the immunity or resistivity of the person [4] [5].

Healthcare associated infections (infections in healthcare settings) include surgical site, dental, Myocardial, and occupational infections between staffs. No institution/country can claim to have solved the problem of infections in a healthcare setting yet. Based on data from several countries, it can be estimated that each year, hundreds of millions of patients around the world are affected by healthcare associated infections [6]. The burden of infections around healthcare settings is several folds higher in low-income countries. Healthcare setting infections can cause extended hospital stays, semi/permanent disabilities, increased resistance of microorganisms to antimicrobials, monolithic additional costs, high costs for patients and their families, and at times deaths.

Figure 1-1 below presents the infection cycle showing the infection chain. Scientific methods need to be developed in order to break the chain to control the pathogenic microorganisms. Essential measures should be taken to help prevent and control this cycle of infection, including limiting or destroying sources, preventing, or breaking the routes of transmission, minimizing portals of entry, and protecting susceptible patients. If measures are not taken, patients and staffs may be exposed unnecessarily to pathogenic microorganisms (contagion). There is also now an international agreement for urgent action to break the infection chain or prevent and control the spread of antibiotic-resistant pathogenic micro-organisms [7]. This calls for an efficient infection prevention and control system to be deployed in healthcare center.

1.3. Infection Prevention and Control

Infection prevention and control is a technological approach and practical solution designed to break the infection chain or to prevent harm caused by infection for patients and health care workers. Listed below are some of the WHO guidelines to deal with infection control:

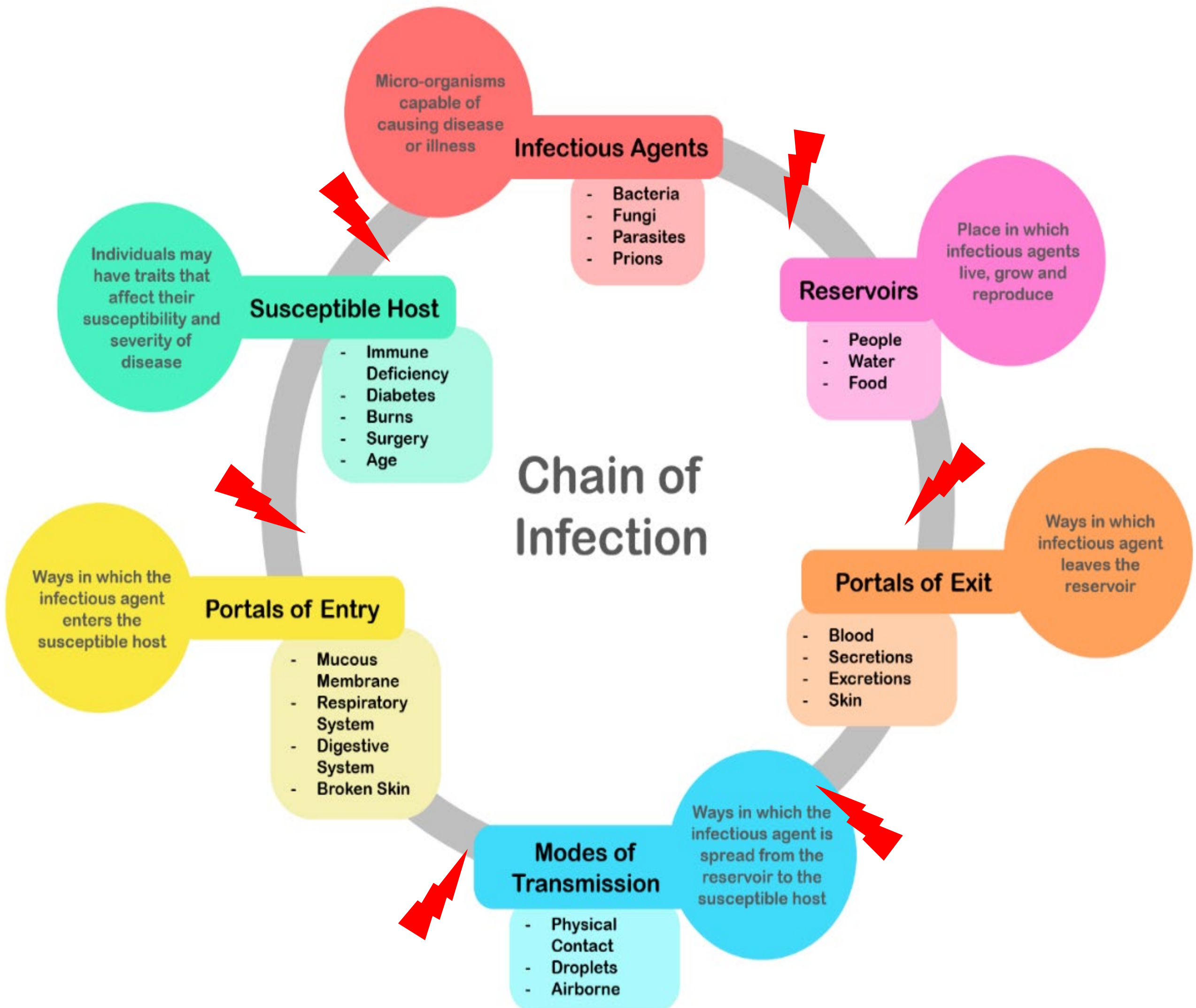


Figure 1-1: Infection cycle **[5]**.

i. International, national, and local evidence-based guidance for cleaning, disinfection, and sterilization processes for medical devices and equipment, including restrictions and risks for reprocessing single-use items. If guidance is not followed, there may be an increased risk of cross-infection for both patients and staff.

ii. Concepts of cleaning, disinfection, and sterilization.

iii. Classification for non-critical, semi-critical, and critical medical equipment:

iv. Standard methods for achieving effective sterilization:

a. Quality assurance: documentation and monitoring for cleaning, disinfection (including high-level disinfection), and sterilization processes;

b. Advantages and disadvantages of chemical agents used as a chemical sterilizer and/or high-level disinfectants, including the level of action of chemical germicides (low, intermediate, and high);

c. Components of sterilization validation:

- ✓ Types of sterilizers and methods of validation (for example, testing and monitoring of physical, chemical, and biological indicators for the monitoring of sterilizers);
- ✓ Recommended quality indicators to monitor the sterilization process and their interpretation.

d. Risk management in decontamination and sterilization processes;

e. Required air changes, negative pressure for decontamination, storage room and racks, temperature, and humidity ranges for each working area, etc.

v. Preparation and handling of used medical devices at the point of use.

vi. Storage, handling, and transportation of contaminated, clean, and/or sterile supplies and medical devices to SSD (internally or externally), including factors that affect the shelf life of sterile items [8].

In addition to the above guidelines of the WHO, hand washing is the most significant and effective infection control measure in healthcare settings. Proper hand washing can limit both cross-infection of microorganisms and contamination from blood borne pathogens. Besides, dressing (wearing) of personal protective equipment (PPE) is additional safety to protect oneself and the community from pathogenic microorganisms [9] [10].

1.4. Cleaning

Cleaning is a physical process that removes residue, visible contamination particles like dust, oil, and organic materials such as blood, secretions, excretions, and microorganisms from an instrument for further processing or intended use. Cleaning doesn’t necessarily defeat all micro-organisms. Cleaned instruments should be dried thoroughly to prevent them from rusting. Two types of cleaning could be used for medical instruments: hand cleaning and mechanical cleaning.

Hand cleaning is a very effective method for removing the dust of medical instruments using water, soap, alcohol, detergent, or other enzymatic solutions. It requires maximum direct contact with contaminated instruments because it is performed by hand. When one is cleaning contaminated medical instruments, he/she must wash hands before and after cleaning the device and wear a glove. On the other hand, in Mechanical cleaning/Ultrasonic cleaning, Ultrasonic energy creates billions of very small bubbles in a cleaning solvent that breaks down and produce high turbulence at the surface of instruments that dislodges the dirt. Mechanical clearing is the safest and most efficient way to clean sharp medical instruments. Cleaning of medical instruments should be carried out for eight to ten minutes and double the period if the medical instrument is in a cassette and per manufacturer's recommendations.

There are certain acceptance criteria measures used to validate if a cleaning procedure has been successful or not: visually clean and a minimum of 3-log micro-organisms reduction. The normal cleaning mechanism, however, can't clean mean particle residual limit levels below the following: Protein < 6.4μg/cm^2, Hemoglobin < 2.2μg/cm^2, Carbohydrate < 1.8μg/cm^2 and Endotoxin < 2.2μg/cm^2.

1.5. Disinfection

Disinfection is a procedure that kills all microorganisms except for bacterial spores from inanimate objects. This is generally accomplished using liquid chemicals or wet pasteurization. The efficiency of disinfection is affected by several factors, each of which may nullify or limit the efficaciousness of the process. Here are levels of disinfection based on their efficiency:

a. High-level: It must be killing all microorganisms, apart from bacterial spores.

b. Medium-level: deactivates mycobacterium tuberculosis, vegetative bacteria, most viruses, and fungi but doesn't necessarily destroy bacterial spores.

c. Low-level: removes bacteria, some viruses, and fungi but not necessarily highly resistive microorganisms like bacterial spores.

Chemical sterilant is a chemical applied to illuminate all types of microbial life, including fungal and bacterial spores. These same chemical germicides may also be part of the high-level disinfection process when used for shorter exposure periods.

Medical instruments could be classified into three based on their risk when we re-use.

a. *Critical Items:* Items assigned to the critical items categories are those with a high risk of contamination if the medical instrument is contaminated with any microorganism. If the critical medical instruments enter the body cavity, bloodstream, sterile tissue, the vascular system or generally if it penetrates soft tissue or bone, it must be sterile. This category includes surgical cardiac, implants, forceps, and needles. Most of the critical items should be sterilized by steam under pressure, if possible. If heat-labile, the object may be treated by a low-temperature sterilization process, or, if other methods are unsuitable like chemical sterilant [11].

b. *Semi-Critical:* Items assigned to the semi-critical items category are at medium probability of infection if the medical instrument is contaminated. These are medical instruments that come in contact with semi-critical surfaces of our body including oral mucosa, non-intact skin, liquid body substance and teeth. For medium-risk medical instruments, sterilization is mandatory. If serialization is not accessible, one should disinfect them with high-level disinfection with enough exposure time medical devices such as mouth mirror, explorer and amalgam condensers, air-water syringe, and dental hand-pieces.

c. *Non-Critical:* Items assigned to the non-critical category are at low risk of infection if the medical instrument is contaminated. Examples of non-critical items include BP apparatus, stethoscope, dental chair, and magnifier lenses. Such can be disinfected with intermediate or low-level disinfection or detergent and water washing.

The sterility of any medical device product is defined by the probability of a viable microorganism on the medical instrument surface after it has been sterilized or disinfected. Sterility assurance level disinfection must be greater than 10^{-3} SAL from 10^{-n} SAL pathogenic microorganisms [12].

1.6. Inspection and Function Test

Inspection, maintenance, and testing of a medical device must be carried out by suitably well trained and certified staff with the manufacturer, international and national standards, policies and guidelines. In practice, inspection and functionality-testing of surgical instruments should not be checked out by the same staff responsible for cleaning the devices. These staff members have the responsibility for ensuring the item is thoroughly cleaned and fit for reuse. The recording is performed for every stage including inspection and functionality testing. Inspection is checking visually for cleanliness and free of moisture to prevent from corrosion. All non-conforming devices that are dirty, wet, or stained should be rejected and returned to the wash area for manual cleaning. Functionality testing is part of the decontamination process where instruments are checked for full functionality. The procedure guarantees free and full movement of all parts, if joints do not stick and there are no overlaps.

1.7. Packaging

Packing is not always necessary for medical instruments before being sterilized. Some types of sterilizer machines like the gravitational air removing mechanism or non-vacuum sterilizer are affected by the packing material as it can affect steam penetration into the parts of the contaminated instrument. There are different types of packaging materials available in the market for different surgical instruments. The choice of type and size will depend on the item to be packaged [13] [14].

1.8. Sterilization

Sterilization effectively destroy or eliminate transmissible agents or harmful microorganisms (fungi, bacteria, viruses, and prions) from a surface, instrument or devices, foods, medications, or biomedical culture medium by alteration of the cell wall or cytoplasmic membrane, protein denaturing, and interference with nucleic acid. There are different types of sterilization methods:

- Physical method: exposure to extreme heat or freezing, desiccation, osmotic pressure, or radiation.
- Chemical method: a process of sterilization, disinfection or cleaning using chemical agents such as alcohols with OH, halogens, oxidizing agents, aldehydes, gaseous agents, anti-microbes, etc.
- Mechanical method (or filtration): these could be candle filters, asbestos disc filters, sintered glass filters, membrane filters, air filters and syringe filters.

Figure 1-2 presents a block diagram for different types of sterilization and disinfection techniques available for the control of pathogens. The sterility assurance levels using physical, chemical, and mechanical sterilization must be greater than 10^{-6} SAL from 10^{-n} SAL pathogenic microorganisms, i.e. existence of pathogenic microorganisms is 1 in 1,000,000 [12] [15].

1.9. Transportation of Decontaminated Medical Instruments

Often the central sterilization system is far from the health care center and hence the decontaminated instrument needs to be transported using some mechanism. The mechanism to transport medical instruments and equipment is determined by the type of device and the distance between the sterilization center and the user among other things. One must prevent contamination of staff when transporting contaminated instruments for sterilization. The transportation container must be waterproof, comfortable to decontamination, rigid, fully & securely closed and clearly labeled.

1.10. Storage of Sterile Instrument

Generally, the function of standard storage of sterilized instruments is to keep sterility or to prevent decontamination again. The storage area should be appropriately designed to prevent damage to packs, shelving should be easily cleaned, clean air must be flowing freely, the packages do not have direct contact with sunlight, dirt, and water [13].

1.11. Use of Sterilized Instruments

The use of the sterilized instruments is the responsibility of the user. Users have to make sure that the product has been subjected to an appropriately validated process and that every reasonable precaution has been taken to the products [13]. The responsibility for ensuring that safe and effective decontamination of devices has taken place falls on several healthcare workers depending on the setting in which they work. Note that all the above-mentioned stages of controlling pathogenic microorganisms need to be executed in accordance with the required international (such as that of the WHO) and local guidelines and policies.

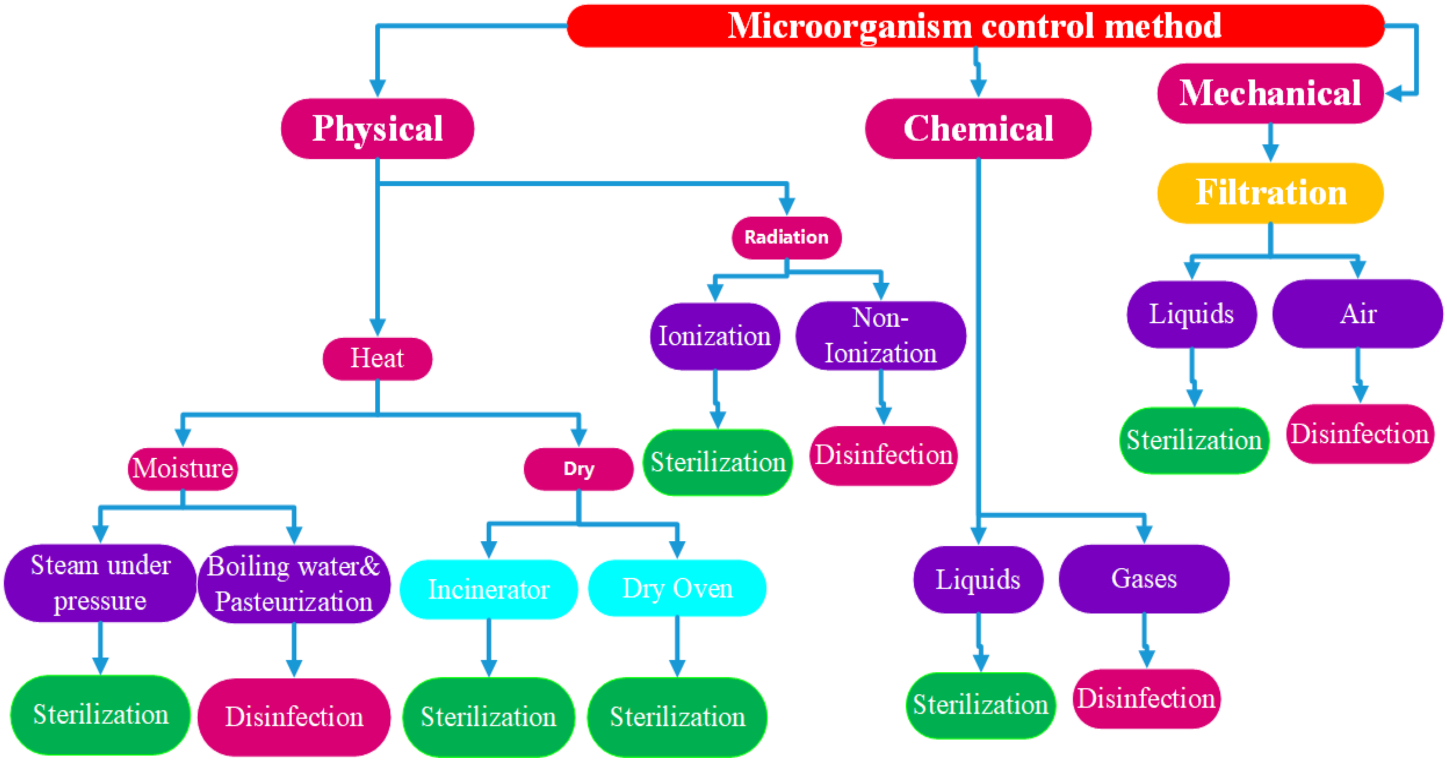


Figure 1-2: Summery of pathogenic microorganism controlling methods [16].

1.12. Steam Sterilization Machine

In 1680, Denis Papin, a British physicist born in French, invented the “Digester” or Sterilizer (pressure cooker). Pressure cookers function by creating a tight seal between the compartment and door lid. This seal traps the air inside the chamber as it gets heated. As the air gets heated, it expands and pressure increases. As pressure increases inside the chamber, the boiling temperature of the water inside increases by about 101352.9 pascal pressure above the standard atmospheric pressure (a typical pressure-cooker setting) boosts the water boiling temperature from its normal 100°C to about 121°C. The superheated steam trapped in the cooker circulates around the items inside quickly penetrating them, or in the case of food, quickly cooking it. Now is developed into a steam sterilizer under pressure (autoclave).

In 1876, Charles Chamberland, Louis Pasteur’s pupil, created and formulated the first digester or steam sterilizer under a pressure machine and he later reformed this machine into a medical or scientific instrument in 1879. He was the first to create the steam sterilizer under pressure or autoclave. He also invented a filter consisted of porcelain [16]. In the same year in 1876, John Tyndall, an English physicist, discovered heat-resistant bacteria. Based on this discovery, he later originated the method of fractional sterilization by non-continuous (intermittent) heating. In 1881, Robert Koch researched on steam and hot air disinfecting properties and this was the beginning of the science of disinfection and sterilization steam sterilizer. The first non-pressure flowing steam sterilizer instrument was devised at the time and sterilization by boiling was introduced.

In 1885, Ernst von Bergmann, a German physician first used steam sterilizer for the sterilization of surgical instruments. In the 1900s, Aesculap created rigid instrument containers, originally made of stainless steel, or chrome-plated containers for safe transport of sterile instruments manufactured in Germany. In the years from 1885 to 1900 the Germans contributed remarkable knowledge on the principle of steam sterilization technique.

In the 1930s and in the 1960s reusable textile filters and rubber gaskets were added to the sterilizer to ensure a proper seal between the chamber container and door lid and anodized aluminum was replaced with stainless steel to provide optimal heat retention and distribution in the sequential years [17].

Steam sterilization is the most effective, rigorous, and environmentally friendly method of all other sterilization techniques and is used in hospitals and health care service centers, research and laboratory centers, agricultural and higher educational institutions. Intuitively speaking, steam sterilization is the use of steam under pressure to deliver a particular temperature for an appropriate time to destroy all harmful pathogenic microorganisms. Sterilization occurs as the latent heat of condensation is transferred to the load causing it to heat rapidly. Steam is the most effective sterilant because of two reasons [17].

a. Steam is an extremely effective carrier of thermal energy, and
b. Any resistant, protective outer layer of the microorganisms can be softened by the steam, allowing coagulation of the sensitive inner proteins of the microorganism.

Steam sterilizer is available in the market ranging from the simple electromechanical pressure cooker with manual semi-automatic and full-automatic control to the latest very complex electronic and mechatronics controlling using programmable logic control and microcontroller-based system. The size ranges from small inside portable to large or fixed which is mounted on the floor. All however have to pass through performance test at absolute pressure or sea level (zero-meter geographical elevation). They often fail to compensate for pressure to function properly in high altitudes. These features might be available in the latest versions of steam sterilizers though there are other additional features that they still might lack. One of these issues is a water quality control mechanism.

1.13. Type of Steam Sterilizers

Steam sterilizer machines can be categorized in different aspects based on their application, controlling system, ambient air removing or air displacement mechanism, temperature range, chamber shape, loading type, and so on.

1.13.1. Based on their Air Removing Mechanism

As the air inside the chamber is not good for sterilization, it has to be removed from the chamber steam sterilizer system. There are two type of air removing mechanisms (gravity air displacement and dynamic-air-removal or mechanical air dispense) in steam sterilizer machine.

a. *Gravity Displacement Sterilizers:* are available in various sizes for different applications based on the need. They are made of stainless steel, have a chamber with a door lid to load instruments, and can withstand recommended pressure and temperature. Steam is either generated inside the chamber at the bottom using water and temperature higher than 100℃ produced from the heater or pumped from outside or separate steam generator. As more and more steam enters the chamber, the cool air is forced out through the drain near the bottom of the chamber. Some sterilizers have a pool of water at the bottom, which is heated with electricity, kerosene/gas, and other sources of energy.

Once the cool air is removed, the steam will enter the chamber, triggering the thermally regulated valve to close. When the valve is closed, the steam continues to build up pressure until the operative temperature is reached. Typical ranges are 105°C (221°F) to 138°C (280.4°F) and pressure of 100 kilopascal to 250 kilopascal. The timer is then activated and timing begins. At the end of the cycle (typically 3 to 45 minutes, higher for unwrapped items than wrapped items), the relief valve is opened, which allows steam to escape. Usually steam passes through the water reservoir, where it condenses back to water and thus does not enter the room. After the pressure gauge returns to zero, the operator should open the door slightly and allow items inside to cool for about 30 minutes. If steam is still present, condensation of the moist air may wet the items or packs if they are placed on a cool or cold surface; wet packages or instruments can become easily contaminated.

Gravitational air removing mode steam sterilizers have an additional advantage over vacuum air removing mechanisms because of their lower cost and use in geographical areas of high humidity [18]. Gravity displacement sterilizers are not as effective on partially vented containers (stainless steel drums that hold instruments during sterilization, storage, transportation, and packaging). Gravity displacement sterilizers should be monitored for their effectiveness of the sterilization cycle on a routine basis as recommended by the manufacturer. The use of mechanical, physical, and biological indicators to monitor the cycle quality must be performed for each cycle [17] .

b. *Dynamic air removal sterilizers or mechanical air dispense sterilizers:* are like the gravity displacement sterilizers except that they have a vacuum pump system to remove the air in the chamber before the steam is pushed to the chamber. Typically, a series of alternating steam pressure injections and vacuum draws (called pulses) remove the air from the chamber. Negative chamber pressure allows steam to penetrate the load more quickly, resulting in more reliable sterilization and a shorter cycle time. Most pre-vacuum sterilizers are operated at the same temperature as gravity displacement sterilizers, but high-speed vacuum sterilizers operate at higher temperatures (138°C [280°F]) and pressure (193 kilopascals) and require shorter exposure time. It is very important to monitor the functioning of pre-vacuum sterilizers.

c. *Immediate-use Sterilizers (IUSs):* formally known as flash sterilizers, are small, table-top, pre-vacuum sterilizers, usually located in the operation room or adjacent areas. They are used to rapidly sterilize items that are urgently needed. Items are unwrapped and sterilized at a higher temperature (134°C [273°F]), therefore allowing for a shorter cycle time and hence rapid. The immediate use of the sterilizers should be reserved for urgent situations only, Eg: in the operation room.

Gravity displacement sterilizers are more commonly used in medium to small health care facilities. In most countries, high-speed vacuum and flash sterilizers are usually used in larger hospitals.

1.13.2. Based on Chamber Shape

Chamber is the main part or the heart of the steam sterilizer, which contains the sterilized instrument. The chamber wall must stand the operation pressure and temperature so the thickness of the stainless-steel sheet is greater than 3mm and more than 6mm for the door, according to the ISO 9001 standards. Most of the chamber shapes are two types: cylindrical or rectangular.

Cylindrical Shape: as its name indicates, the shape of the chamber is cylindrical. The shape of the chamber container affects the volume. If the steam sterilizer chamber shape is cylindrical, the volume is given by:

$$V = \pi * H * R^2 \quad \text{……………………………………………(2.1)}$$

where V is the volume of the cylinder, H is the height and R is the radius.

Rectangular Shape: is the other most common steam sterilizer chamber shape. The thickness of the wall and the door is the same as the cylindrical shape except for its shape. The volume is given by: $V=H*W$……………….……………………………(2.2)

where V is volume of the rectangular shape chamber, H is the height and W is the width.

1.13.3. Based on Their Application

Steam sterilizer machines can be used for different purposes: medical, industrial, laboratories, and research centers. Based on the application, those steam sterilizers have different requirements following the ISO standards.

Steam Sterilizer for Medical Use: this machine is like any other steam sterilizer except for its size and power consumption, especially when compared with an industrial steam sterilizer. The areas of applications include pharmaceutical, microbiology, medicine, body piercing, veterinary science, dentistry, podiatry, and metallurgy.

Steam Sterilizer for Industrial Use: this is also similar to other steam sterilizers except for its size, temperature range and power use. It may function electrically or it may use oil or gas in addition to the electrical power. Industrial sized steam sterilizers are used for leaching in the mineral processing industry where mineral ores undergo chemical treatment. In food processing industries, industrial steam sterilizer is used for food canning and frying.

1.13.4. Based on Loading Type

Based on the loading type, steam sterilizers can be categorized into front loading and top loading.

Front Loading Steam Sterilizer: if the contaminated medical instrument is loaded through the front door of the steam sterilizer machine chamber to decontaminate the instrument, we call it a front-loading steam sterilizer machine. The cylindrical or the rectangular shape of the chamber lay horizontally and the heater shape is also U, M, or zigzag rather than circular.

Top Loading Steam Sterilizer: This type of loading is through the top door of the machine. Top loading steam sterilizer is more advantageous over the front loading because it requires less floor space.

There is also single door and dual door steam sterilizer classification. Most of the time, single door is portable and the double door is fixed type or mounted with the room floor.

1.14. Steam Sterilizer Phases/Cycles

The phase or cycle of steam sterilizer is depending on the machine type or the mechanism of environmental air removal from the chamber, i.e., whether the machine is pre-vacuum air removing or gravitational air removing. The most common cycles for gravitational air dispense mechanisms are the heating cycle, sterilizing cycle, and cooling cycle. If the machine uses pre-vacuum air removing mechanism, it includes pre-heating, heating, sterilizing and drying cycles.

Pre-heating Cycle*:* is the conditioning of the system that includes the pre-vacuum air removal. The vacuum or the negative pressure is created by sucking the air from the chamber or pump the ambient air outside the chamber using the pump motor. This is performed by pumping the air and purging the steam and flushing several times. This helps to increase the flow of the steam in the chamber between the instruments easily.

Heating Cycle: is a common cycle for all steam sterilizer machines. Heating includes boiling the water and creating the steam until we get the desired temperature. After getting the desired temperature, it changes the cycle mode to the sterilization cycle. In this case, if the machine is at a high altitude and if doesn't properly adjust, the machine cannot get the set value. The water becomes steam early and the pressure is raised beyond the set value before the temperature gets to the set value. If the pressure is above the set value, the pressure control solenoid valve discharges the steam (or the pressure) to save the instrument and the temperature gets down.

The Sterilization Cycle: is the main stage to decontaminate or sterilize medical instruments. After fulfilling the desired temperature, the machine must maintain the temperature using different mechanisms until the desired time is completed. After accomplishing the mission, it changes the cycle mode to drying or cooling.

Drying or Cooling Cycle*:* this is the final stage cycle of the steam sterilizer machine system. If the machine uses pre-vacuum air removing mechanism, this would be a drying cycle accomplished by sucking the steam out of the bodily cavity to cool and dry the instruments. Else if the machine uses the gravitational air dispense mechanism, this would be cooling. In this case, the steam is exhausted through the steam exhaust solenoid valves.

1.15. Advantages and Disadvantages of Steam Sterilization

a. *Advantages:* Steam sterilization had better be used every time possible on all critical and semi-critical items that are heat and moisture unaffected because of the following reasons [19]:-

- ✓ Resourceful process
- ✓ Easy to control and safeguard
- ✓ Good diffusion of porous loads
- ✓ Faster than any other technique
- ✓ No contamination of the load
- ✓ Does not release pollution
- ✓ Reliable

b. *Disadvantages:* Steam sterilizers use water to get steam which can cause corrosion, scaling, and damage to equipment, especially for those which cannot resist high temperature (some plastics, Fiber optics, biological materials, and most polymers).

1.16. Common Problems of Steam Sterilizers

It is well known that it is highly recommended to use soft-water for steam generation purposes in a steam sterilizer. There are various methods of converting hard water to soft water such as distillation, reverse osmosis, and deionization. However, these methods bring additional operational costs, and as a result, hospitals often tend to ignore the recommendations and end up using hard water supply directly from the tap, and this leads to damage to the sterilization system specially the heater sensors, tubes, fittings, and valves.

Power fluctuation can burn the protective component of the AC and DC power supply unit and/or the entire control board. This problem is not only for steam sterilizer machines, it is common for all scientific, medical, and laboratory instruments especially in developing countries. In addition to power fluctuation, steam sterilizer machines can fail technically due to sensor faults like water level sensor and as a result the heater can burn out. Other technical component problems are door lock, gasket, filter chalk, or calcium accumulation (for those that use hard water) at the bottom of the chamber and that could decrease the heater efficiency, decrease the sensitivity of the temperature sensor, block water level sensor and could cause tube blockage.

Steam sterilization can be unsuccessful for several reasons, most commonly: improper calibration of the machine leading to temperature or pressure fluctuation, wrong cycle selection for the load materials or using a non-validated cycle, low-quality steam or vapor that is too high in water content or has been heated beyond the most efficient temperature for the steam sterilizer machine (generally 138° C), and improper packaging or positioning of materials to be sterilized [20].

1.17. Problem Statement

Steam sterilizer machine is an effective sterilization tool that uses high pressure with appropriate temperature for the appropriate time to destroy all pathogenic microorganisms. According to the EN ISO 17665-1, -2 and -3:2013 standards, most steam sterilizers have to go through a performance test carried out at sea level and some of the modern steam sterilizers work at a maximum of 2000 meters above sea level. The satirizers can be re-adjusted manually or automatically for altitudinal variations in order to satisfy the standard sterilization assurance level (SAL=10^{-6}). According to the ISO standards and manuals, since performance test is done at sea level, altitude has a significant impact on the performance of steam sterilizer. There are some modern steam sterilizers in the market which can consider the effect of the pressure difference. But they still need human involvement and temperature range to reset atmospheric pressure, and takes time to function properly.

If hard water is used to generate the steam, the minerals from the hard water are deposited on various parts of the steam sterilizer (such as the steam generator, heating element, pipes, valves, etc). Such mineral deposits can reduce the efficiency of the steam sterilizer (eg. the heating element will consume more energy). Through time, the mineral deposits will damage the various parts of the steam sterilizer, and lead to expensive repairs (eg. replacement of the damaged parts) as well as interruption of important clinical services such as surgery.

Therefore, this thesis is conducted to address the above mentioned gaps (water quality being the major one) and design and develop a smart steam sterilizer control board which can detect water quality and the altitude variation and adjust its pressure automatically with zero-time delay.

1.18. Research Justification

- A smart steam sterilizer that automatically adjusts itself when altitude changed to protect itself from environmental effects for sterilization;
- Applying modified PID temperature control to improve the sterilization processes and to solve power loss and protect from dulling sharp materials, wearing, and tiring of the sterilized medical instrument by over temperature and pressure;
- Introducing a water electrical conductivity sensor to check quality of the water to void use of hard-water (tap water) for steam generation because hard water contains high number of magnesium and calcium and other cations and anions which can disturb and damage the steam sterilizer of parts through time;
- Some of the passive and active components of the traditional steam sterilizer machines control board are to be replaced using a software-programmable microcontroller integrated circuit with a smaller number of jumper wires and passive components reducing the complexity;
- Designing linear high current source power supply 5V&12V DC with high amperes current;
- Prototyping a smart steam sterilizer control board is part of the scope of the project which might open opportunities for further research investigation in the future;
- The smart steam sterilizer control board can fit any gravitational steam sterilizer machine with little modification and training.

1.19. Objectives

1.19.1. General Objective

Design of a steam sterilizer integrated with self-adjust environmental pressure, modified PID temperature control, water quality sensor, and water level with auto-filling control systems.

1.19.2. Specific Objectives

- ✓ Design microcontroller-based smart steam sterilizer that adjust (does compensation) to altitude variations effect and comes with a PID temperature controller;
- ✓ Introduce a water electrical conductivity sensor to check quality of the water, to void use of hard water for steam generation and integrate with automatic water filling system by solenoid valve;
- ✓ Smart safety protectors for the machine itself and the operator from over-temperature, over-pressure, and electrical hazards including auto-door lock;
- ✓ Power supply with 5 & 12VDC supply with high ampere range is incorporated;
- ✓ Develop a smart control board for the steam sterilizer machine that can fit or be compatible with any steam sterilizer with little modification and training;
- ✓ Design and implement a graphic user interface to display the results in a colorful touch screen, and
- ✓ Investigate ways on how existing steam sterilizers could be interfaced with the developed system so that system upgrades could be performed.

1.20. Thesis Organization

The rest of the thesis has been organized into four chapters. Chapter two gives an overview of reviewed literatures on the International Organization for standardization (ISO) and national standard of steam sterilizer, service, and operational manuals of steam sterilizers history and current state of steam sterilization. Chapter three presents the materials and methods used in the current work to develop the smart steam sterilizer. Chapter four presents results and discussion while Chapter five includes research conclusions and possible future directions.

Chapter 2: Literature Review

This chapter presents reviews pertinent to existing steam sterilizers.

2.1. International Organization for Standardization Requirements of Steam Sterilizers

Standards are fundamental documents to design and producing anything especially for medical devices or machines. Standards regarding steam sterilizers are:

(2006) ISO 17665-1:2006(en) sterilization of health care products (Moist Heat) Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices, including saturated steam venting systems, saturated steam active air removal systems, air steam mixtures, water spray, and water immersion, among other things [21].

(2009) ISO/TS 17665-2:2009(en) sterilization of health care products (Moist Heat) Part 2: Guidance on the application of ISO 17665-1 [22].

(2013) ISO/TS 17665-3:2013(en) sterilization of health care products (Moist Heat) Part 3: Guidance on the designation of a medical device to a product family and processing category for steam sterilization [23].

(2018) ISO 25424:2018(en) sterilization of health care products (Low Temperature Steam): Requirements for development, validation, and routine control of a sterilization process for medical devices [24].

All these documents assume mean sea-level environmental condition (humidity, temperature, pressure). Based on these standards, there are steam sterilizer manufacturers of different models. All models have their own service and operational manuals (includes installation, servicing, preventive maintenance and corrective maintenance, error codes, etc…).

2.2. Overview of Steam Sterilizer Machine

Moses, Hippocrates, Lazzaro Spallanzani, Pasteur, Denis Papin and other scientists have all contributed a great deal to the science of sterilization. Building upon Denis Papin's work, Chamberland invented (1876 to 1880) the first steam sterilizer machine (Chamberland's Autoclave) in response to Pasteur's requirement for a sterilization technique that utilized temperatures higher than 100^{o}C. Von Bergmann of Berlin who was a pioneer for an aseptic method of surgery introduced a steam sterilizer machine into his clinic in 1885. In 1886, he realized from his experiences that steam only was not good enough to kill the microbial and steam must be under pressure to raise the temperature. Pressure steam sterilizers were later developed to kill resistant spores.

Many steam sterilizer technologies have evolved in the 21'st century. To mention few: R. J. Baez, DDS, MPH, and HFADI in 1998 introduced pressure cookers for sterilization of dental clinical instruments with same improvement or modifications [25]; Etheresia Pretorius and Zeno Apostolides in October 2002 carried out a validation approach for moist heat sterilization. The researchers tried to check the validation of moist heat sterilization of steam sterilizer using different methods like sterilization assurance level (SAL, 10^{-6}) [26]. Hoda Koushyar in 2007 investigated effects of variation in autoclave pressure, cure temperature, and vacuum application time on the porosity and mechanical properties of a carbon/epoxy composite [27]; Gregory Tao in 2012 proposed a low-cost autoclave for adoption in rural health posts of the developing world [28]. Again in 2012, Per Hamlin reported his studies on CFD analysis on the modeling of generation and distribution of steam in an autoclave [29]. F. A. Oyawale and A. E. Olaoye in 2007 presented the design and construction of an autoclave with a reduced size to reduce the mechanical cost [30].

Trabia, Sarah S. in 2012 showed the design and testing of a solar autoclave with broad spectrum of sterilization capabilities this is well present on the power sustainability especially for low resource settings or rural areas. There were also successful attempts for development of solar autoclaves to solve the power sustainability [31]. Similarly in spring 2013, Blake Lawrence, Eric Brettner, Yuchen Liu, Kyle Godwin, and Adam Compton presented a solar autoclave for use in rural areas [32]. This instrument had just little difference from the one presented by Sarah S.M. C. Juan Antonio Arízaga, Jorge de la Calleja, Roberto Hernández, and Antonio Benitez in February 2012 [33]. Another surface steam sterilization with penetration in narrow channels was also proposed and present on how tubular medical devices are difficult to get enough steam at the inner side [34]. Peter Stefanuto compared effectiveness of hospital central sterilization processing versus clinic-based sterilization protocols and he recommended central sterilization process to be more efficient and cost effective than clinical based sterilization protocol [35]. Wei Liang Lau in August 2015 carried out numerical modeling of heat and mass transfer in a steam-air sterilization process inside an industrial autoclave [36]. Sarina Arnold in 2015 researched a biofuel autoclave as a medical waste solution for the developing world as source of energy for the steam sterilization in addition of electrical energy [37]. Niamul M. Bari in September 2016 presented design, fabrication, and performance evaluation of continuously operating autoclave [38]. JPCM Van Doornmalen, Francesco Tessarolo and Klaas Kopinga in January 2014 showed that only pressure, temperature, and time are insufficient to monitor steam sterilization processes based on a case study; the researchers recommended additional factors (in addition to temperature, pressure, and time) to be considered [39].

As far as the literature reviews carried out in the current study are concerned, steam sterilizers that pressure adjust to altitudinal variations are new advancements in the technology. Also, the steam sterilizers deployed in the clinics (particularly those in the developing countries) have issues with regards to use of tap water. Use of distilled water to generate steam brings additional operational costs and people often use tap water instead, which in effect creates problems for the sterilizer machine. Hence there should be a mechanism that allows blocking use of hard water completely and developing such a controlling system. Due to use of hard water, the heater (which is the source of heat energy to generate steam) can easily be damaged, the sensors and tubes could be blocked, which in turn could decrease the efficiency of the machine. Including advanced PID temperature control helps to improve the temperature control mechanism and enhance the sterilization effectiveness. This calls for the design and development of a steam sterilizer control board by applying simpler design concepts and less costly materials particularly for use in low resource settings. In this regard, it is the intent of the current thesis work to introduce such a steam sterilization controlling system and test its efficiency. Five incidents could be mentioned here: five new and different steam sterilizers (autoclaves) were deployed in four places in Ethiopia: one it Debrezeit at the agricultural research center, two new steam sterilizer machines in Benishangul Gumuz Agriculture research Center, one in southern national state Duramie Agricultural Center and a fifth one at Haromaya University. The machines were plugged in successfully and started running but never reached their standard sterilization point and could not be active for some time. In the end, it was found out that altitudinal variations caused the machines not to run accurately.

Not all steam sterilizers deployed in Ethiopia have water level regulation systems in their chambers that could have an effect in easily damaging their heating element. Steam sterilizers are normally very expensive; their electrical systems and their plug-ins are often not compatible with the infrastructure of developing countries. Furthermore, their maintenance cost is high due to the complexity of their systems. The current thesis project intends to design and prototype a steam sterilizer control board with altitude, water level and water quality controller systems embedded.

Chapter 3: Materials and Methods

3.1. Pre-design

3.1.3. Effect of Altitude on Physical Parameters of Steam Sterilizer

As the steam is generated from boiling water using an electrical heater and the boiling point of the water is affected by the environmental conditions including pressure, humidity and temperature, the system is also affected by geographical location or altitude. As the altitude increases, the boiling temperature of water decreases.

3.1.4. Altitude and Boiling Point

The boiling point of a given substance particularly water is the temperature at which the vapor pressure of the liquid substance (water) is equal to the environmental atmospheric pressure at that specific altitude. In other words, to boil water, one must add enough heat energy to the water to force sufficient molecules into the vapor phase such that its vapor pressure is equal to the environmental atmospheric pressure at that geographical location or altitude. As the altitude gets increased, the pressure exerted by the atmosphere pushing down on the water surface decreases, and this allows the water to boil at lower temperatures. As the altitude decreases, the pressure exerted by the atmosphere pulling down to the water increases, as a result of which the water boils at higher temperature [40].

The steam inside the steam sterilizer chamber machine is created by boiling water using electrical heat energy (heater element), and the boiling point of water is affected by altitude so the system of the sterilizer machine is affected if it is operating out of sea-level especially at high altitude. Table 1 presents the relationship between boiling point of water and altitude while Figure 3-3 plots the boiling pint of water against altitudinal variations.

Table 3-1: Boiling point of water vs altitude [41]

Altitude (m)	Boiling point (°C)
-305	101.1
-229	100.8
-152	100.5
-76	100.3
0	100.0
76	99.7
152	99.5
229	99.2
305	98.9
381	98.6
457	98.4
533	98.1
610	97.8
686	97.6
762	97.3
838	97.1
914	96.8
991	96.5
1067	96.3
1143	96.0
1219	95.7
1295	95.5
1372	95.2
1448	94.9
1524	94.7
1600	94.4
1676	94.2
1753	93.9
1829	93.6
1905	93.4
1981	93.1
2057	92.9
2134	92.6
2210	92.4
2286	92.1
2362	91.8
2438	91.6
2515	91.3
2591	91.1
2667	90.8
2743	90.6
2819	90.3
2896	90.1
2972	89.8
3048	89.6
3124	89.3
3200	89.1
3277	88.8
3353	88.6
3429	88.3
3505	88.1
3581	87.8
3658	87.6
3734	87.3
3810	87.1
3886	86.8
3962	86.6
4037	86.4
4115	86.1
4191	85.9
4267	85.6
4343	85.4
4420	85.1
4496	84.9
4572	84.7
4648	84.4
4724	84.2
4801	83.9
4877	83.7
4953	83.5
5029	83.2
5105	83.0
5182	82.7
5258	82.5
5334	82.3
5410	82.0
5486	81.8
5563	81.6
5639	81.3
5715	81.1
5791	80.9
5867	80.6
5944	80.4
6020	80.2
6096	79.9
6172	79.7
6248	79.5
6325	79.3
6401	79.0
6477	78.8
6553	78.6
6629	78.3
6706	78.1
6782	77.9
6858	77.7
6934	77.4
7010	77.2
7087	77.0
7163	76.8
7239	76.5
7315	76.3
7391	76.1
7468	75.9
7544	75.6
7620	75.4
7696	75.2
7772	75.0
7849	74.8
7925	74.5
8001	74.3
8077	74.1
8153	73.9
8230	73.7
8306	73.5
8382	73.2
8458	73.0
8534	72.8
8611	72.6
8687	72.4
8763	72.2
8839	72.0
8916	71.7
8992	71.5
9068	71.3
9144	71.1

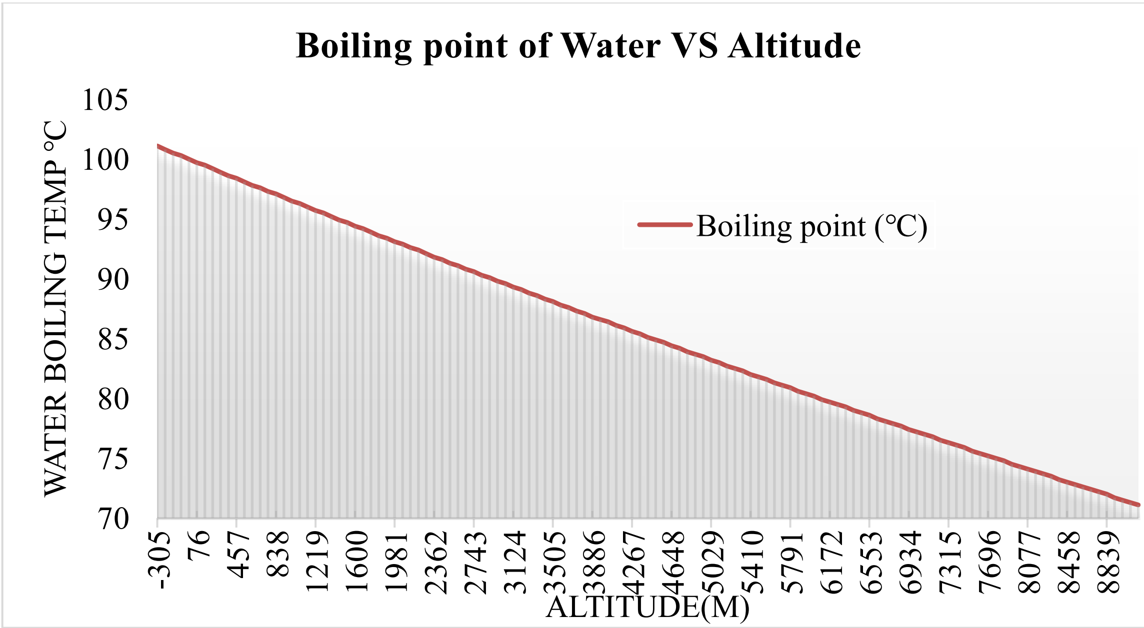


Figure 3-3: Boiling point of water vs altitude **[41]**.

3.1.5. Pressure and Temperature

In a closed vessel, pressure and temperature rise when the vessel is heated up. As the temperature gets 100℃ or the boiling point, water starts to change to steam. This steam creates pressure. As the pressure increases, the temperature also increases in the vessel. That means pressure and temperature have a direct relationship. At sea-level, ≤121℃ is equivalent to 1000 mbar pressure; in between121℃ & 134℃ temperature is 1500 mbar; ≥134℃ temperature is 2000 mbar pressure. In practice, most steam sterilizers have both pressure and temperature controlling system and a pressure and temperature gauge display.

3.1.6. Altitude vs Pressure

The atmospheric pressure normally changes with altitude. At mean sea level, it is 1013.25 mbar (absolute pressure) but it decreases as the altitude gets increased. That means altitude and pressure are inversely proportional to each other. That also means that at higher altitudes, water reaches its boiling point earlier. It boils at a temperature lower than 100°C. This altitudinal variation then affects the steam sterilizer system. When a pressure-control steam sterilizer at a high altitude reaches the 1000 mbar (gauge pressure) setting, it switches off the heater and opens the steam exhaust solenoid valve to regulate the pressure. However, the temperature has not reached 121°C and the instruments in the sterilizer cannot get sterile. We usually use the altitude effect pressure compensation table to adjust the pressure control setting manually and we must adjust the pressure limit to reach the needed sterilization temperature. If this is not possible, the sterilization time must be longer. When the steam sterilizer machine is far from sea-level by 1000 meters, then the absolute air pressure decreases by 100 mbar. Because of such changes in pressure, we often need to consider pressure compensation depending on the altitude. Table 3-2 displays the values of pressure compensation needed at different altitudes.

Table 3-2: Pressure compensation at 1000 and 2000 mbar **[42]**.

Altitude	Absolute air pressure	Temperature at 1 bar	Pressure compensation	Temperature at 2 bars	Pressure compensation
0 m	1000 mbar	121°C	+0.0 bar	134°C	+0.0 bar
1,000 m	900 mbar	118°C	+200 mbar	132°C	+100 mbar
2,000 m	800 mbar	117°C	+400 mbar	131°C	+200 mbar
3,000 m	700 mbar	115°C	+600 mbar	130°C	+300 mbar
4,000 m	600 mbar	114°C	+700 mbar	129°C	+400 mbar

3.1.7. Altitude and Time

As the altitude increase, the boiling point of water decreases so the water can boil early at less than 100^{O}C. When it comes to steam sterilizers, it becomes difficult to get the temperature above 100^{O}C without adjusting manually or automatically using altitude effect time compensation table from manual. When the pressure controller and the pressure solenoid valve cannot be adjusted on the steam sterilizer machine, we have to adjust the sterilization time according to the altitude effect time compensation manual, also been shown in Table 3-3 below.

Table 3-3: Altitude and time relationship at 1000 mbar and 2000 mbar [43].

Altitude	Temperature at 1000 mbar	Sterilization Time	Temperature at 2000 mbar	Sterilization Time
0 m	121°C	20 min	134°C	3 min
500 m	120°C	25 min	133°C	10 min
1000 m	119°C	25 min	132°C	10 min
1500 m	118°C	30 min	132°C	10 min
2000 m	117°C	35 min	131°C	10 min
2500 m	116°C	40 min	131°C	10 min
3000 m	115°C	45 min	130°C	10 min
3500 m	114°C	50 min	129°C	10 min
4000 m	114°C	50 min	129C	10 min

3.1.8. Influence of Altitude on Disinfection and Sterilization

If the steam sterilizer machine or any disinfection system gets affected by the environment because of the altitudinal variation, it requires adjustment using the altitude effect compensation pressure table. Table 3-4 presents such un influence of altitude on disinfection and sterilization.

Table 3-4: Influence of altitude on disinfection and sterilization [43].

Altitude [m]	Atmospheric pressure [Bar_{abs}]	Pressure reduction [Bar]	Disinfection in boiling water: Temp [°C]	Disinfection in boiling water: Time [Min]	Sterilisation, Sea-level setting, 121°C/1 Bar_g: Temp [°C]	Sterilisation, Sea-level setting, 127°C/1.5 Bar_g: Temp [°C]	Sterilisation, Sea-level setting, 134°C/2 Bar_g: Temp [°C]
Sea level → 0	1.0	0.0	100	10	121	127	134
1,000	0.9	0.1	96	10	118	126	132
2,000	0.8	0.2	93	10	117	125	131
3,000	0.7	0.3	90	20	115	124	130
4,000	0.6	0.4	86	20	114	124	129
5,000	0.5	0.5	83	30	112	121	128
6,000	0.5	0.5	79	45	111	120	127
7,000	0.4	0.6	76	60	110	119	127

3.1.9. Geographical Elevation/Altitude of Ethiopia

Ethiopia is a land with great geographical diversity. The highest point is Ras Dashen, Semien found in the Amhara region at around 4,550 m (14,928 ft.) and the lowest point is Afar depression, found in the Afar region reaching -125 m (-410 ft.) below sea level. Major cities are found at different elevations. Figure 3-4 depicts altitudinal elevations of Ethiopia.

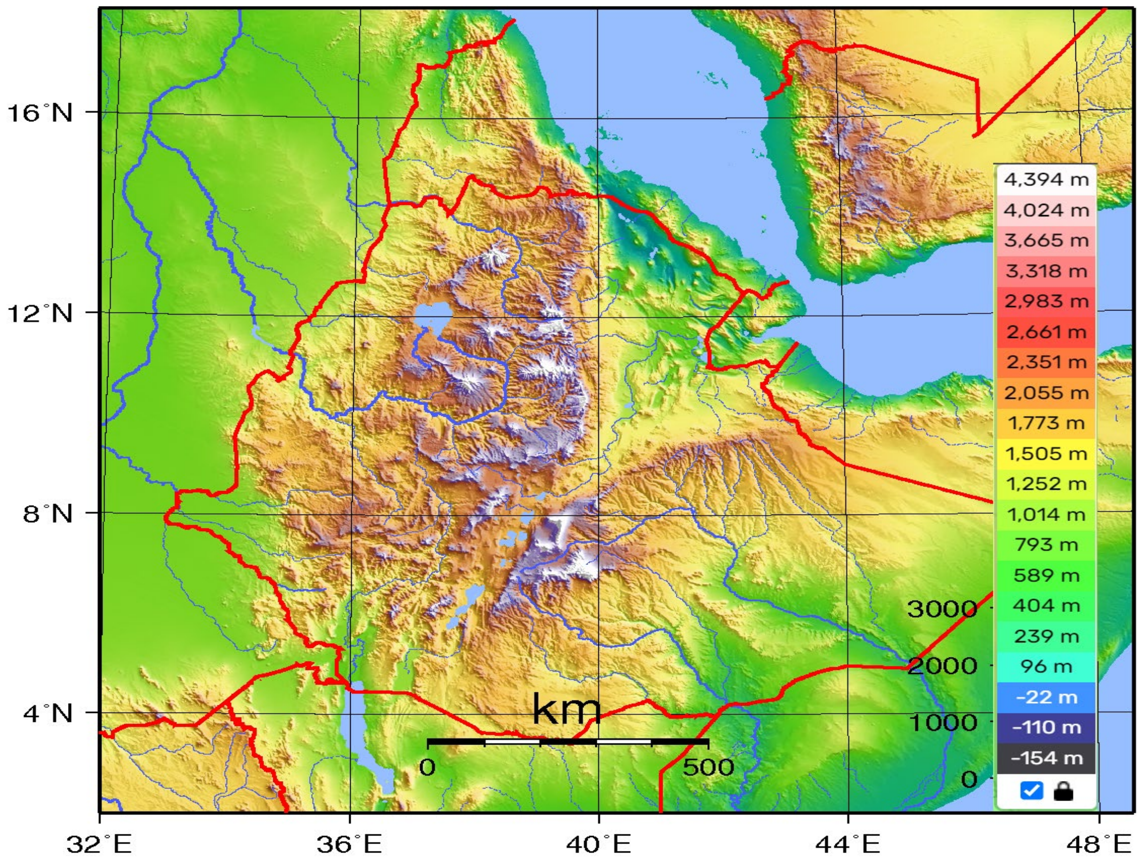


Figure 3-4: *Geographical altitudes of Ethiopia* **[44].**

If a new steam sterilization machine is installed in Addis Ababa, Ethiopia where the altitude reaches 2,355 meters above sea level, the machine would reach the 1000 mbar setting (121°C) already at 116°C. If the user of the machine would operate it at the normal 121°C temperature, the instrument inside would not be getting the 121°C temperature and hence cannot get sterile. In this case, either the Engineer must adjust the pressure control manually using the altitude effect pressure compensation table to 1400 mbar or, if this is not possible, the user must extend the sterilization time to 40 min. To adjust the pressure control manually or automatically, the altitude of geographical location/elevation must be measured by some means.

3.1.10. How to Measure Altitude

Altitude means the vertical position of a point or an object that is above the earth's surface above the sea level. The term altitude is often used in areas of aviation, military, physics research and many more. For example, the term altitude can be used to measure or to explain how high is flying objects like balloons, drones, and airplanes are above the mean sea level. There are different mechanisms to measure geographical location of elevation or altitudes like tide gauge data, satellite altimetry, gravity, crustal motion, GPS, sonic, and barometric.

In the current thesis research, altitude is measured using environmental pressure. When the altitude varies, the environmental pressure, humidity and temperature also vary. As it is not possible to measure it directly, the altitude is calculated based on the pressure read from the BMP/E sensor (085, 180 or 280) using the following formula:

$$Altitude = \left(44330 * \left(1 - (\frac{P}{P_0}\right)^{\frac{1}{5.255}}\right) = \left(44330 * \left(1 - (\frac{P}{P_0}\right)^{0.19}\right) \ldots\ldots\ldots\ldots 3.0$$

where P_0 = Atmospheric Pressure at sea level (in hpa) and P = Atmospheric Pressure at current location (in hpa) [45].

3.1.11. Water Quality

Water quality is a measure of the suitability of water for a particular use based on the selected physical, chemical, and biological characteristics according to the United States Geological Survey (USGS). Therefore, it's a measure of water quality condition. There are three parameters of water quality measurement [46]. These are:

1. ***Physical:*** are parameters which can check physicality like Colour of the water, Electrical conductivity, Taste, Odour, and Temperature.
2. ***Chemical:*** are parameters which can check chemical content of the water solution like Hardness, pH, alkalinity, Acidity and Chloride.
3. ***Biological:*** are parameters which can check existence of biological microorganisms inside the water like Algae, Bacteria, Protozoa, and Viruses.

Table 3-5 presents the parameters of water quality which should be checked.

Table 3-5: Parameters of water quality [46].

Physical	**Chemical**	**Biological**
Electrical conductivity (EC)	Hardness, pH, Alkalinity, Chloride	Algae
Temperature	Sulfate, Nitrogen, Fluoride, Acidity	Bacteria
Color	Chlorine residual, Copper, and zinc	Viruses
Taste and odor	Iron and manganese,	Protozoa
Solids	Biochemical oxygen demand (BOD)	
Turbidity	Chemical oxygen demand (COD)	
	Toxic inorganic substances	
	Toxic organic substances	
	Radioactive substances	
	Turbidity, Dissolved oxygen	

Most often, water is composed of chemicals and minerals. Water can be classified into hard water and soft water based on different type of minerals. Hard water contains large amount of minerals such as calcium, iron, and magnesium. On the other hand, soft water is a type of water that contains lower concentrations of minerals. It must be noted that determining the hardness or softness of water requires extensive testing. Based on the parameters listed in Table 3-6, water can be tested at the laboratories using different kits.

3.1.11.1. Water Electrical Conductivity (EC) Sensor

Electrical conductivity (EC) sensors are used to measure the conductivity of a water solution, which is a measure of its ability to conduct electricity. The conductivity of a solution is directly related to the concentration of ions in the solution. The term conductivity is derived from Ohm's law, E=I*R where E = Voltage which is the product of I = Current and R = Resistance [47]. When a voltage is connected across a conductor, a current will flow, which is dependent on the resistance of the conductivity of the solution. Conductivity is simply defined as the reciprocal of the Resistance of a solution between two electrodes. According to distinct measuring principles and methodologies, EC sensors can be separated into three: electrode-type conductivity (with two or four electrodes or poles, (reference electrode, a measuring electrode)), inductive conductivity

(Toroidal or electrodeless), and ultrasonic sensors [48]. The selected sensor in the current thesis work is electrode-type conductivity with two electrodes (reference electrode, a measuring electrode). This electrical conductivity sensor is more accurate, stable reading and easily accessible in the market. The reference electrode is used to provide a stable reference voltage for the measurement, while the measuring electrode is used to detect the current flowing through the solution. The electrodes are placed in the water solution being measured, and an electrical current is passed b/n the electrodes.

The conductivity of the water solution is determined based on the ions present or amount or concentration of Na, Ca, Cl, H, OH which are responsible for amount of current flow through the water solution. The SI unity of electrical conductivity is siemens per meter (S/m) and is calculated as $\sigma = L/(RA)$ where R = resistivity (which is reciprocal the conductance), L = length of the conductor and A = cross-section area [49]. The conductivity measurement can then be used to calculate the concentration of ions in the water solution using appropriate equations and conversion factors. In addition to the electrodes (reference electrode, a measuring electrode), conductivity sensor also typically includes temperature and other components to insure accurate and precise conductivity measurements. Electrical conductivity sensor can be used in water boiler, agriculture, Chemistry, Biology, environmental science, hydroponics, Freshwater systems to control the quantities of nutrients, salts or impurities in the water, chromatography, food production, cooling tower, fish farming, quality control, water conditioning, paper industries, TDS testing, Condensate and Steam quality protection, reverse osmosis, pools and spa, Pharmaceutical manufacturing processes, water salinity testing, waste water reverse osmosis (RO) treatment, concentration measurement and dilution control, hardness measurement in launder, desalination plant, boiler feed water and cooling tower water [50].

3.1.11.2. Electrical Conductivity (EC) and Total Dissolved Solids (TDS) Sensor

Based on the above specified sensor, total dissolved solids are derived or calculated from EC with constant factor. Based on the sensor result, EC or total dissolved solids water can be categorized into different water hardness levels. Table 3-6 shows the water category and hardness levels of the water based on the concentration of the minerals or total dissolved solids (TDS). Figure 3-5 displays the EC modeling, EC probe, and EC probe terminals.

Table 3-6: *Category of hardness water based on the electrical conductivity of the water* [51]

Water Type	**Conductivity (µS/cm)**	**TDS (ppm)**	**Hardness**
Total pure water	0.055	0.0352	Supper Ultra-Very Soft
Typical deionized water	0.1	0.064	Ultra-Very Soft
Distilled water	0.5 – 3.0	0.32 – 1.92	Very Soft
Reverse osmosis water	50 - 100	32 - 64	Soft
Domestic(tap) water	500 - 800	320 - 512	Moderate Hard
Potable water	1055 max	675.2 max	Hard
Sea water	56000	35840	Very Hard
Brackish water	100000	64000	Ultra Hard

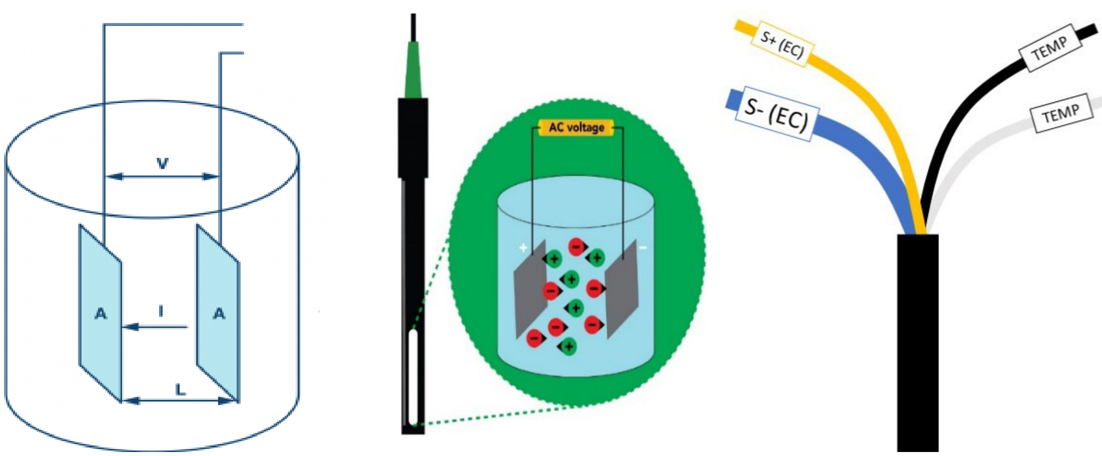


Figure 3-5: Electrical conductivity modeling (left), EC probe (middle) and EC probe terminals (right) **[52]**.

A. Hard Water

Water hardness is the measure of the capacity of water to react with soap, hard water requiring considerably more soap to produce lather. Hard water often produces a noticeable deposit of precipitate e.g., insoluble metals, soaps or salts. It's not caused by a single substance but by a variety of dissolved polyvalent metallic ions, predominantly calcium and magnesium cations, although other cations (e.g. aluminum, barium, iron, manganese, strontium, and zinc) also contribute. Hardness is most expressed as mg/liter of $CaCO_3$. Typical water $CaCO_3$ concentrations are [53]: 60mg/l is generally considered as soft; 60-120mg/l is moderately hard; 120-180mg/l is hard; and more than 180mg/l is very hard.

Although hardness is caused by cations, it may also be discussed in terms of carbonate (temporary) and non-carbonate (permanent) hardness. Calcium and magnesium, the two principal ions, are present in many sedimentary rocks, the most common being limestone and chalk. They are also common essential mineral constituents of food. A minor contribution to the total hardness of water is also made by other polyvalent ions, such as aluminum, barium, iron, manganese, strontium, and zinc [54]. Hard water is the number one reason for costly maintenance, avoidable repairs, and even contamination to steam sterilization systems. Figure 3-6 shows hard water containing concentrated Magnesium ion (Mg2+), Calcium ion (Ca2+) and Iron (Fe2+) and the grading levels of water hardness.

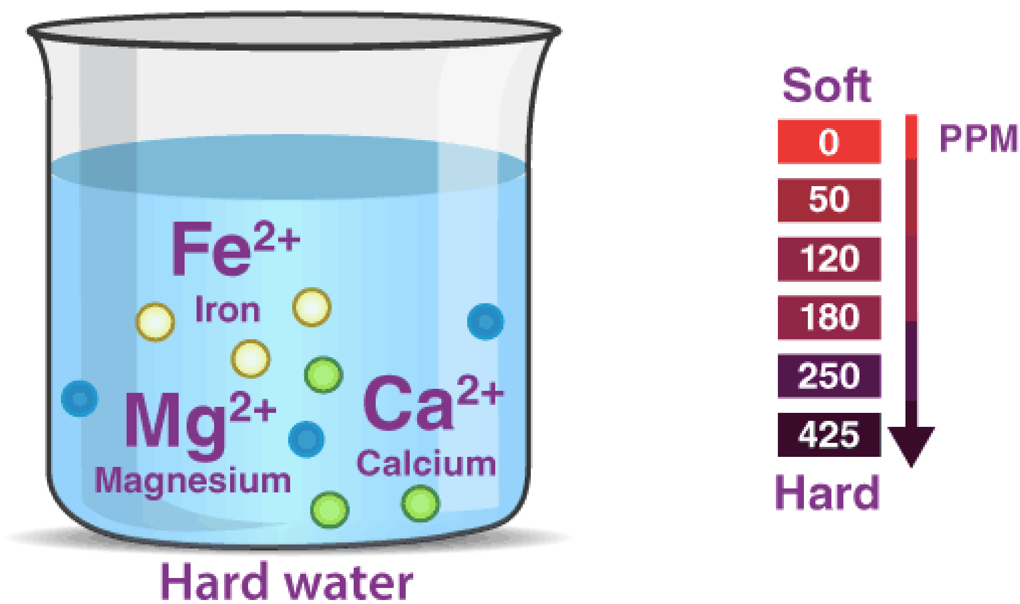


Figure 3-6: Hard water containing concentrated Mg2+, Ca2+ and Fe2+(left), and grading of water hardness (right) [55].

B. Soft-water

Soft water is defined as the type of water containing lower amount of minerals such as calcium and magnesium. The hardness of water is also known to measure the waters capacity to react with soup and form lather. Therefore, we can define soft water as the water that forms foam or lather. According to WHO, water containing $CaCO_3$ at concentration below 60 mg/l is soft water [53].

3.2. Materials

Steam sterilizer machines have three major modules/sections to control physical parametric quantities including temperature, pressure, time, and compensate for effect of environmental conditions. Those sections are input section, processor section and output section.

3.2.1. Input Section

The steam sterilizer machine considered in the current thesis work has an input module composed of a temperature sensor, pressure sensor, environmental condition sensor, water quality and level sensor, timekeeper, door close sensor, and keypad input from the TFT LCD touch screen display. The section also includes a micro controller-based analog to digital converter (ADC).

3.2.1.1. Chamber Pressure Sensor

Chamber pressure is a pressure that develops with the temperature and helps to create steam from water for sterilization inside a closed cylindrical or rectangular shape chamber. The chamber is prepared using a 3mm to 6mm thickness stainless steel containing chromium that makes it resistant to corrosion and hence do not contaminant the instruments during sterilization. Steam is generated inside the chamber to sterilize the medical instruments by the steam under pressure. Hence one has to measure the pressure inside the chamber to prevent overpressure scenarios which can burst out the chamber. For effective sterilization of a medical instrument, it might require up to 150^{O}C maximum temperature and equivalent pressure and this has to be monitored by a sensor. In the current thesis work, a 0~1000pascal High Temperature pressure sensor, a transducer to convert the pressure to electrical (current and voltage) energy and an ADC have been used before sending the digital output to the processer section. The pressure transducer converts physical or mechanical diaphragm change due to the pressure to electrical current and processes digitally using the ADC inside the microcontroller and displays the amount of pressure. The pressure sensor has additional features: compact, easy to install, high sealing performance, high quality hall effect sensor and RoHS compliant. Detail specifications of chamber pressure sensor are indicated in Table 3-7 while Figure. 3-7 presents a chamber pressure sensor.

Table 3-7: Pressure sensor specifications [56].

Working Voltage (VCC):	DC 5±0.5V
Working Current:	≤10mA (DC 5V)
Output Voltage (Vout):	DC 0.5~4.5V
P is Pressure	Vout = VCC x (0.75 x P + 0.1)
Working Pressure Rate Range:	0~1Mpa
Max. Pressure:	2.4Mpa
Destructive pressure:	3.0Mpa
Working Temperature:	-20～+ 105 ^{O}C
Storage Temperature:	-20～+ 105 ^{O}C
Measurement Accuracy:	±1.5%FS
Response Time:	≤2.0ms
Cycle Life:	1,000,000 pcs

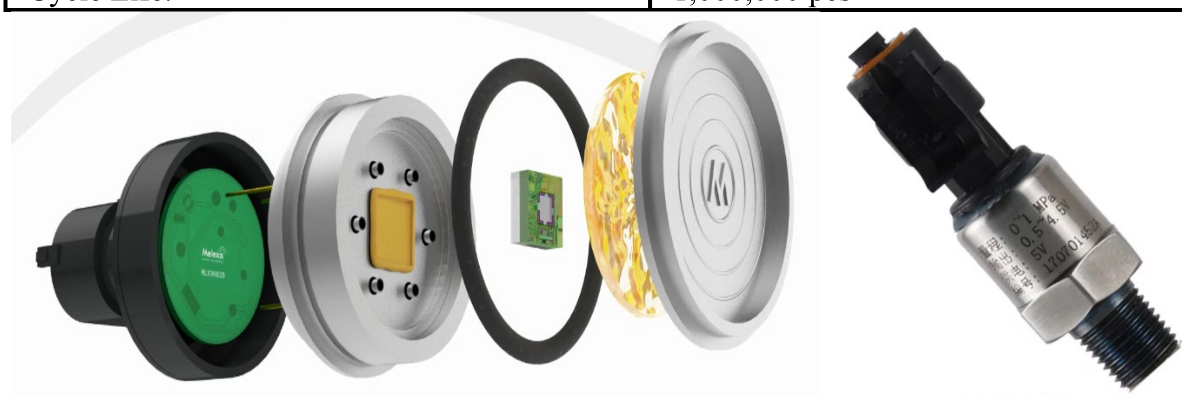


Figure 3-7: Chamber pressure sensor **[57]**.

3.2.1.2. Temperature Sensor

Temperature is one of the main physical parameters we get from the heater element to generate steam from the water to kill microorganisms demolishing their RNA. The PID temperature control and temperature sensor help as a feedback loop for control. In the current study, Pt100 thermocouple was selected because of its sensitivity, accuracy, affordability, ease of use and accessibility in the Ethiopian market as well as temperature-stable reading range. Pt100 temperature sensor is a K-type thermocouple junction with positive and negative polarity with two pin terminals.

The MAX6675 IC performs cold-junction compensation and digitizes signal from a type-K thermocouple junction and the sensor output to microcontroller (see also Figure 3-8). MAX6675 has an 8-pin surface-mounted package integral circuit IC (supply voltage = +5VDC, SO, SCK, CS, T-, T+, and GND pins) and designed to work in conjunction with an external digital electronics microcontroller or other intelligence in thermostatic, process-control or monitoring applications for industrial, domestic, and commercial appliances, HVAC, automotive industries, and others [58]. MAX6675 IC has an open sensor circuit detection future with an output voltage given by:

$$Vout = \left(\frac{41\mu V}{°C}\right) *(T_R - T_{AMB}) \quad \ldots\ldots(3.1)$$

where V_{out} is the thermocouple output voltage (µV), T_R is the temperature of the remote thermocouple junction (°C) and T_{AMB} is the ambient temperature (°C).

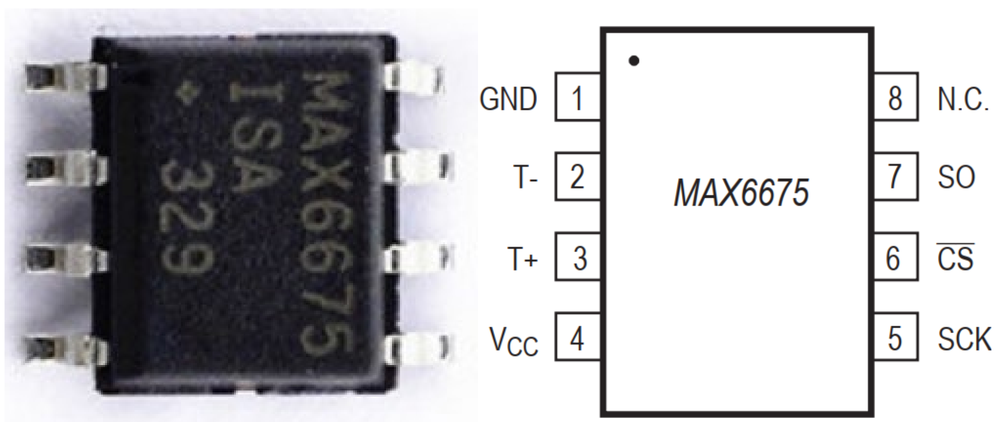


Figure 3-8: MAX6675 IC (left) & PIN of the IC (right) **[59].**

3.2.1.3. Environmental Condition Sensor

Digital BME/P280 is the latest and fast sensor that was upgraded from BME/P085 and BME/P180. Digital BME/P280 combined humidity, pressure, temperature, and proximate altitude sensors which are all physical parameters that affect a steam sterilizer. The sensor module is housed in an extremely compact metal-cover package. BMP/E is small, has vast applications in battery-driven low power consumption devices such as handsets, global positioning system (GPS) modules, and wall-mounted watches.

The BME/P280 achieves environmental humidity, temperature, pressure, and approximate altitude measurement (see also Figure 3-9). The GY-BME/P280 is better than BME/P80 and BME/P180 but not than BME/P680. The approximate altitude which is calculated from GY-BME/P280 environmental pressure sensor output is used for different applications including in environmental weather station or meteorological data, drone, robotic system, and mountain climbers.

The BMP offers both serial peripheral interface (SPI) protocol and inter integrated circuit (I2C) communication interfaces with the microcontroller and in the certain voltage ranges (1.71V_{DC} to 3.6 V_{DC} for the sensor supply V_{DD} and 1.2V_{DC} to 3.6V_{DC} for the interface supply V_{DD} Input-Output). When the sensor is disabled, current consumption drops to 0.1 μA. BME280 can be operated in three power modes: sleep mode, normal mode or forced mode [60].

Figure 3-9: GY-BMP/E280 combined humidity, pressure, temperature, proximate altitude sensor module front (left), back side (middle) and IC package (right) **[61].**

3.2.1.4. Timer

One of the physical parameters of steam sterilizers is time. It uses a timer for different cycles including pre-heating, heating, sterilization, cooling, drying, and total system time. DS1307 RTC is currently the best technology for the timer. The DS1307 is low-power battery package clock with 56 bytes of static random-access memory (SRAM). The clock/calendar provides year, month, date, hours, minutes, seconds, and milliseconds information. The DS1307 operates as a slave device on the inter integrated circuit (I2C) connection protocol bus and it has a power disconnect detector. When the supply power falls below the threshold battery voltage or CMOS battery, the device terminates access in progress and resets the device. When Vcc falls below CMOS battery, the device switches into a low current battery-backup mode. Upon power-up, the device switches from battery to Vcc when Vcc is greater than CMOS battery +0.2V and recognizes inputs when

VCC is greater than 1.25x CMOS battery. The crystal oscillator circuit of the DS1307 uses external 32.768 kHz frequency quartz and the oscillator circuit does not require any external resistors or capacitors to operate.

Clock and Calendars: The clock/time and calendar information is obtained by reading the appropriate register bytes and it is set/initialized by writing the appropriate register bytes. When the DS1307 RTC power is on for the first application to the device, the time and date registers are typically reset to 01/01/00 (MM/DD/YY) and 00:00:00 (HH: MM: SS). The DS1307 can be run in either in 12-hour or 24-hour mode.

I2C Data Bus: The DS1307 has the I2C communication protocol additional feature. A DS1307 sends data onto the bus to transmit data and a microcontroller receives the data as a receiver. The microcontroller controls the communication between the DS1307 and the processer. The devices that are controlled by the microcontroller are referred to as slaves (DS1307 RTC). The bus must be controlled by a microcontroller that generates the SCL, controls the bus access, and generates the START and STOP conditions. The DS1307 operates as a slave on the I2C bus. Within the I2C bus specifications, a standard mode (100kHz clock rate) and a fast mode (400kHz clock rate) are defined and DS1307 operates in the standard mode (100kHz) only. DS1307 RTC integrated circuit package has an 8pin configuration [62]:

- ✓ X_1 and X_2: these two pins are connected with frequency or clock generator or oscillator 32.768 kHz frequency quartz.
- ✓ V_{BAT}: DS1307 gets power from CMOS battery through this pin while the main power is disconnected.
- ✓ *GND:* This is the common ground of all the circuit with IC.
- ✓ *SQW/OUT:* This is the square wave output pin generated by the oscillator quartz and modified by the module DS1307 IC.
- ✓ V_{CC}: this pin is the main power source (5.0V) acquired from the AC to DC power utility (not the CMOS battery).
- ✓ *SCL:* Serial clock input (SCL) is the clock input for the inter integrated circuit communication (I2C) protocol interface and is used to harmonize data movement on the serial interface.

- ✓ *SDA (Serial Data Input/Output):* SDA is the data input/output for the I2C serial interface. The SDA pin is open drain and requires an external pullup resistor. Figure 3-10 show the DS1307RTC used in the current study.

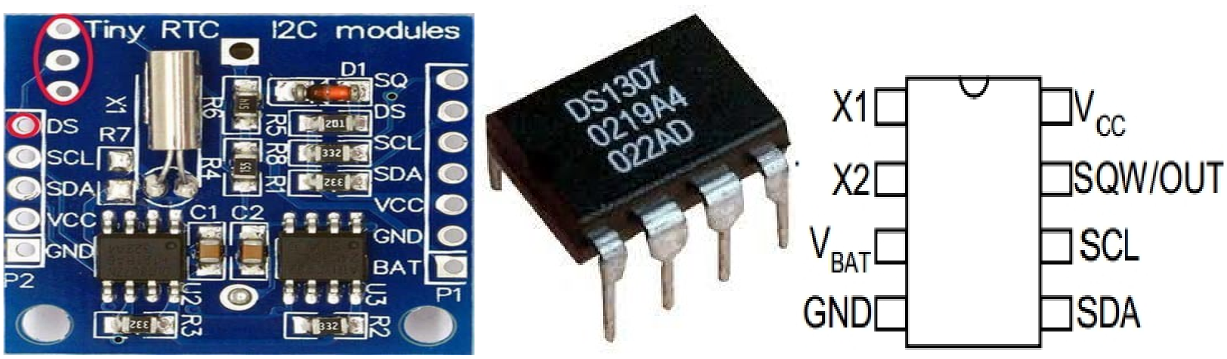


Figure 3-10: The DS1307 RTC module (left), DS1307 IC (middle) and DS1307IC pin description(right) [63].

3.2.1.5. Door Close Sensor

Steam sterilizer machine must be closed and locked properly to develop steam and pressure to raise the temperature above 100^{O}C, and the pressure more than the atmospheric pressure minimizing the risk of bursting of the steam sterilizer chamber which generates the steam by boiling the water using an electrical heater element. Currently, different types of technologies can check whether the door is closed or not including use of micro-switch, proximate sensor, photo sensor, pushbutton and optocoupler. In the current study, a micro-switch with optocoupler was used because of many reasons like ease of access on the market, ease of use, durability, affordability, and low power consumption. The only concern while picking the micro-switch is its physical size. Regarding its electrical characteristics, the signal is ground with low current. Figure 3-11 presents the micro-switch used in the current study.

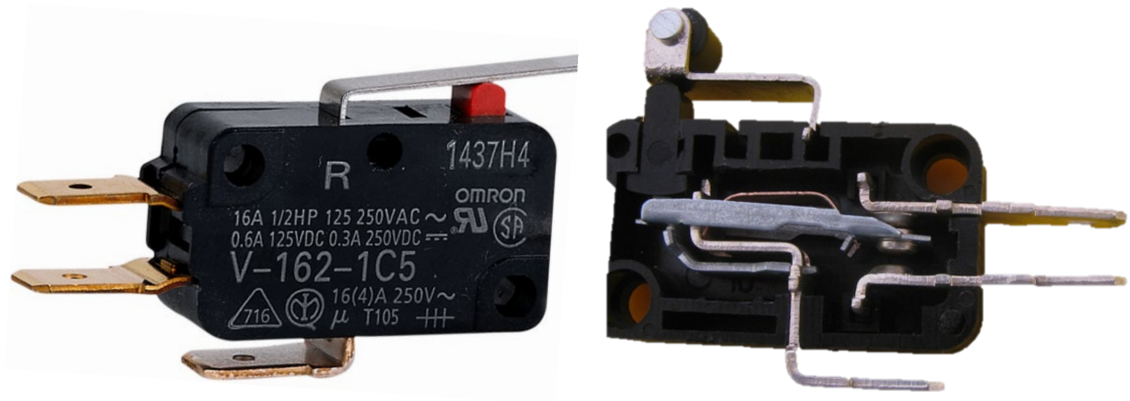


Figure 3-11: Micro-Switch(Bhatt)

*Photocoupler***:** A photo sensor or optocoupler is a latest technology. PC817, which is a general purpose photocoupler, is used in the current work which has an IRED optically coupled to a phototransistor and has 4pin double protection isolation DIP. The special application, PC817 optocoupler, is composed of mainly separation for microcontroller units (processer section), noise suppression in switching circuits, signal transmission between circuits of different potentials and impedances (see also Figure 3-12). The PC817 devices are used for designing in personal computers, office automation equipment, telecommunication equipment (terminal), test and measurement equipment, industrial control, audiovisual equipment, consumer electronics, transportation control and safety equipment (aircraft, trains, automobiles, etc.), traffic signals, gas leakage sensor breakers, alarm equipment and various safety devices [64]. Figure 3-12 presents the Optocoupler PC817X used in this study.

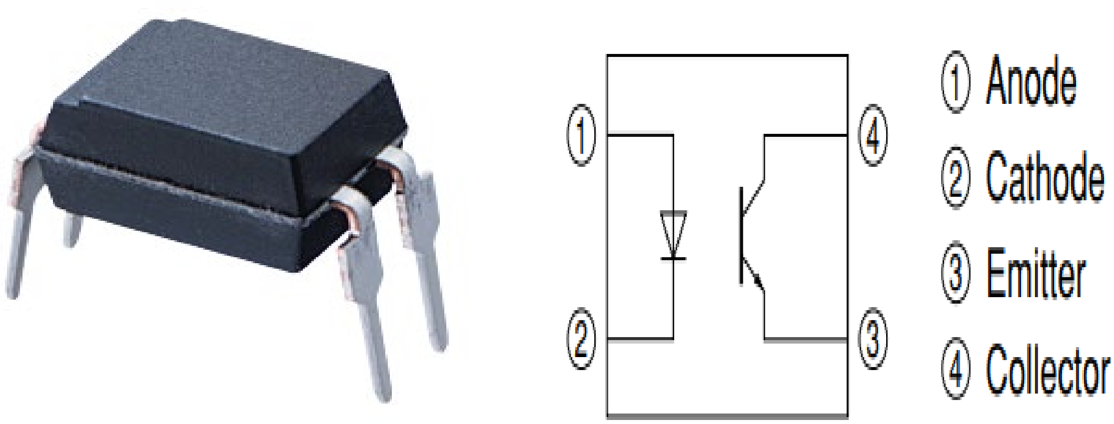


Figure 3-12: Optocoupler PC817X Series IC (Left) and PIN description (Right) **[65]**.

3.2.1.6. Water Quality Recommended for Steam Sterilization

There are two considerations for steam sterilizer water quality:

I. Water hardness: hard water causes harmful mineral scale to build up in the steam sterilizer chamber and tubes. When hard water is heated, Ca^{2+} ions react with bicarbonate (HCO_3) ions to form insoluble $CaCO_3$. Calcium carbonate and other minerals, such as lime, can build up quickly in steam sterilizer chamber. Over a relatively short period of time, the mineral scale form hard water will coat the heating elements, initially reducing their effectiveness and ultimately causing them to fail. Mineral scale will also affect the operation of water level sensors and the efficient operation of heater, sensors, tubes and valves.

II. Ultra-Pure water or pure water and deionized water are often available in research settings, but neither is suitable for use in a standard steam sterilizer for two reasons:
   - ✓ Extremely pure and deionized water are corrosive to the copper pipework and brass fitting inside steam sterilizer chamber.
   - ✓ Neither ultra-pure nor deionized water lacks the necessary conductivity for steam sterilizer sensors like water level sensor. There is a probe located at the bottom of the steam sterilizer chamber that uses conduction to sense whether or not there is enough pure water in the reservoir to run a cycle.

The recommended levels for water hardness and electrical conductivity are:

- Total hardness in terms of $CaCO_3$: < 50mg/L (50ppm)
- Conductivity: < 50 µS/cm [66]
- Distilled water or Tap Water + Deionized Water (3 to3.5liter + 50 to 100ml) [67].

Figure 3 13 shows as about water conductivity vs resistivity range with its water types.

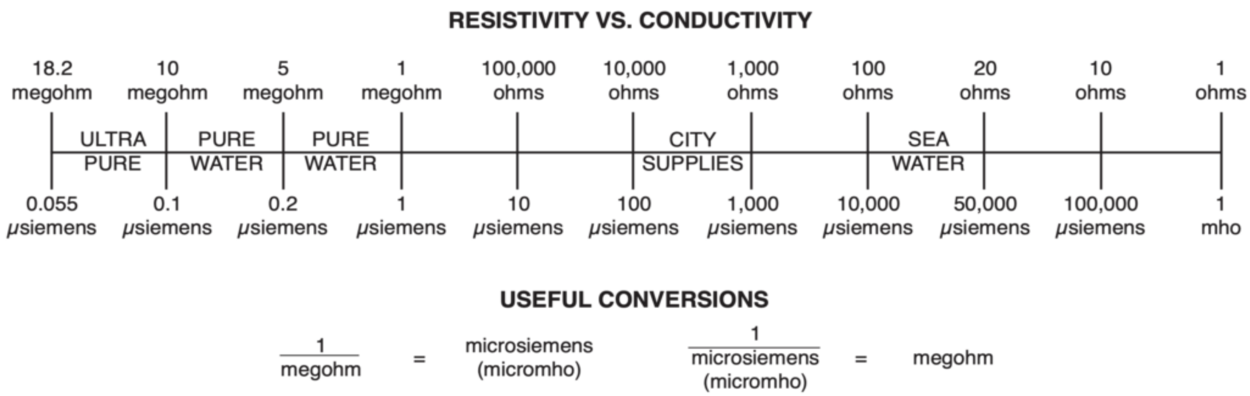


Figure 3-13: Water conductivity vs resistivity range **[68]**.

3.2.1.7. Specification of Electrical Conductivity (EC) Sensor for Steam Sterilizer

The EC sensor has two electrode measuring systems (one electrode for reference and the other for reading/detection). The body and the electrodes are of type stainless steel AISI 316L. The insulation is ceramic (or aluminum oxide); the connector has gold plated contacts with polyamide plug; the two Vario pins are made nickel-plated brass and have gold plated contacts.

The operating ranges (dynamic specifications) are:

- ✓ 0.0001 µS/cm to 1000mS/cm conductivity measuring range with 0.001 µS/cm to 1 mS/cm resolution; 0.01 mg/L to 1 g/L TDS; 0.00 to 1.0 psu Salinity; 0.00 to 1.0 MOhm/cm Resistivity; 0.001 to 1% Conductivity ash; 0°C to 250°C operating temperature, 0 to 40 bar operating pressure (bar gauge).

3.2.1.8. Water Level Sensor

As the steam sterilizer machine generates steam from boiling water using water immersed heater type, the water must be sensed carefully and precisely. If there is no water in the chamber, that means there is no steam and that scenario could trigger burnout of the heater element. The heater element is expensive and not easily accessible in the market due to shape and power rate. That simply means the water level should be sensed continuously and precisely and there are sensors that someone could use including ultrasonic sensors, capacitive water sensors and photosensors. In the current study, an Optocoupler with anti-corrosive chemical coated rod is selected due to its many benefits including ease of access, ease of use, durability, and affordability (see also Figure 3-14).

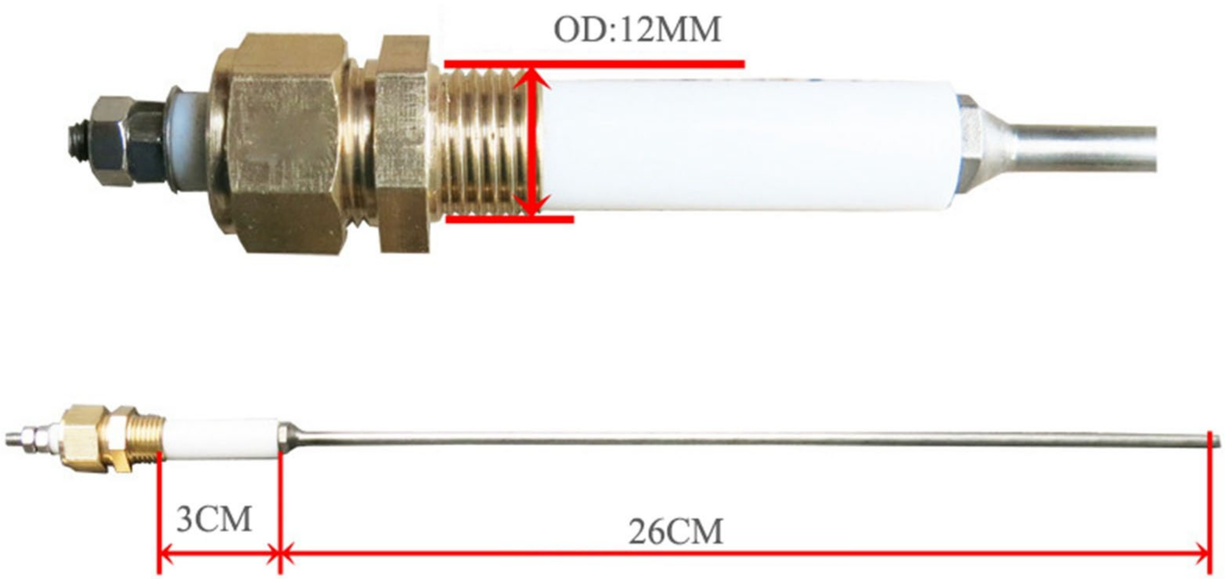


Figure 3-14: Water level sensor **[69]**.

3.2.2. Output Section

This section includes the whole output of the steam sterilizer machine actuators for acting, display, indicators (bulb, LED), sound or buzzer for alarming. The touch screen display, heater (electrical resistor) control high current TRIAC, solid-state relay (SSR), relay and contactors, pressure control solenoid valve, water inlet solenoid valve, and door lock linear solenoid valve are outputs controlled by the processor section according to the input section using some sort of codes and algorithm.

3.2.2.1. Touch Screen LCD Display

The display technology is the fastest growing for use in TV, smartphone, tablet, laptop screen, desktop monitor and display of any industrial, medical, and research laboratories. Touch screens are categorized into two: resistive and capacitive and they come in different screen sizes (1.8, 2.4, 3.2, 3.5, 4.0, 5.5, 6.0, 7.0, 8.0, 9.0, 10.0, 14, 17, 19, 21, 24, etc … inches). The criteria to select a touch screen LCD display are the size, data one wants to display, ease of use, accessibility in the market, affordability, and durability. Accordingly, in the current study, a ILI9486 TFT Shield LCD Module 480x320 multi-color display was selected.

The researcher tries to display what is inside the smart steam sterilizer including pressure, temperature, time, cycles/phase, states, warning/error messages and display environmental conditions which can affect the system of the steam sterilizer machine. The LCD TFT with ILI9486 driver IC Shield touch screen display has different features including 480×320 hardware resolution, better display, and resistive touch control. It is compatible with any version of microcontroller. Table 3-8 summarizes key parameters of the TFT ILI9486 touch screen display.

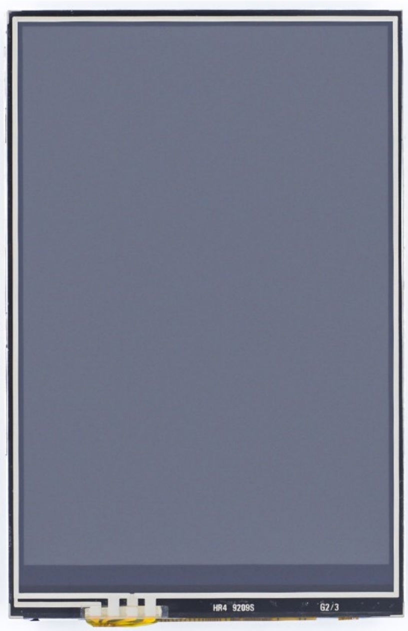
Table 3-7: Key parameters of 3.5" LCD TFT (ILI9486) touch screen display [70].

Name	Parameter
Display Color	RGB 65K color
SKU	MAR3501(have touch screen)/MAR3502(have no touch screen)
Type	TFT
Driver IC	ILI9486
Resolution	480*320 (Pixel)
Module Interface	8-bit parallel interface
Active Area	73.44*48.96(mm)
Module PCB Size	85.49*55.63(mm)
Operating Temperature	-20℃~70℃
Storage Temperature	-40℃~70℃
Operating Voltage	5V/3.3V
Power Consumption	TBD
Weight (Package containing)	44g(have touch screen)， 55g(have no touch screen)
Name	Parameter

The LCD touch screen display can be interfaced with any digital electronics microcontroller and microprocessor like 8051, PIC family, AVR, ARM, Arduino family and raspberry pi family. The pin description of the ILI9486 TFT Shield touch screen display with 480*320 hardware resolution is shown in Table 3-9 and Figure 3-15.

Table 3-8: Pin description of the ILI9486 TFT Shield touch screen display [70].

No	Pin Label	Pin Description
1	LCD_RST	LCD bus reset signal, low level reset
2	LCD_CS	LCD bus chip select signal, low level enables
3	LCD_RS	LCD bus command / data selection signal, low level: command, high level: data
4	LCD_WR	LCD bus write signal
5	LCD_RD	LCD bus read signal
6	GND	Power ground
7	5V	5V power input
8	3V3	3.3V power input, this pin can be disconnected
9	LCD_D0	LCD 8-bit data Bit0
10	LCD_D1	LCD 8-bit data Bit1
11	LCD_D2	LCD 8-bit data Bit2
12	LCD_D3	LCD 8-bit data Bit3
13	LCD_D4	LCD 8-bit data Bit4
14	LCD_D5	LCD 8-bit data Bit5
15	LCD_D6	LCD 8-bit data Bit6
16	LCD_D7	LCD 8-bit data Bit7
17	SD_SS	SD card SPI bus chip select signal, low level enables
18	SD_DI	SD card SPI bus MOSI signal
19	SD_DO	SD card SPI bus MISO signal
20	SD_SCK	SD card SPI bus clock signal



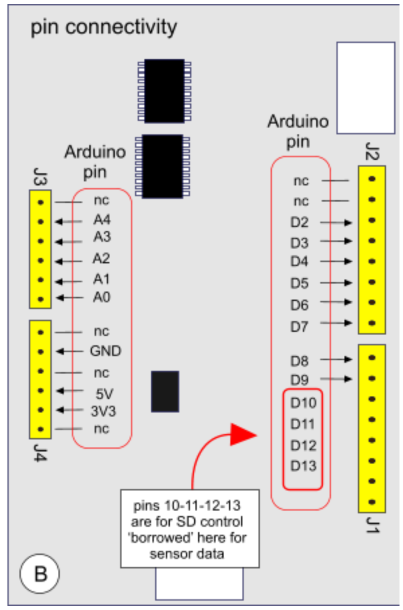


Figure 3-15: Front side (Left), and Back side physical pin (Right) a ILI9486 TFT Shield touch screen display **[71]**.

3.2.2.2. TRIode for Alternating Current (TRIAC)

TRIACs are bidirectional semiconductor devices designed to control ON/OFF. In the current research, TRIAC is used for controlling the heater (temperature control) with the help of modified PID and pulse modulation width. A TRIAC is packed with three terminals:

A. ***Gate Terminal***: used to trigger the TRIAC, meaning if it biases with minimum 1.4V and 10mA, it acts as a conductor or closes the circuit. If the gate voltage is less than 1.4V, it acts like open circuit not allowing current flow through the main terminal A1&A2.

B. ***Main Terminal 1 (A1)***: connected to the neutral or phase of alternative current or positive or negative direct current mains.

C. ***Main Terminal 2 (A2)***: connected to neutral or phase of alternative current or positive or negative direct current mains

TRIACs are computable with pulse modulation width (PMW) signals for fast switching high currents with big voltage. TRIACs have the capability to ON/OFF high currents (10A, 16A, 20A, 25A, 32A, 64A, 100A ... etc) and voltage loads (110, 250, 380 voltages). TRIACs can be used for different applications like AC light dimmers, temperature control, strobe lights, PID control, AC motor speed control, noise coupling circuits, AC/DC power control, for developing solid-state relay and controlling AC loads using a microcontroller [72].

3.2.2.3. Solid State Relay (SSR)

One of the aims of this research is to advance the steam sterilizer machine by adding more options to control the heater (temperature) using different mechanisms like TRIACs, solid-state relay (SSR), relay and contactors. The SSR is one of the options to control the electrical heater element. The SSR can switch high current with high voltage AC/DC without any moving materials (No spark and sound). SSRs are advanced switching technologies known for their speed, high frequency, durability, easy access at the market, ease of use and no electrical spark. SSR technologies can be used for applications in heating, lighting, motion control, and more. A SSR has four terminals: two of them are used to control by applying from 3 to 32V and the other two terminals are the main terminals which can switch depending on the model of the SSR. Figure 3-16 presents different types of SSRs.

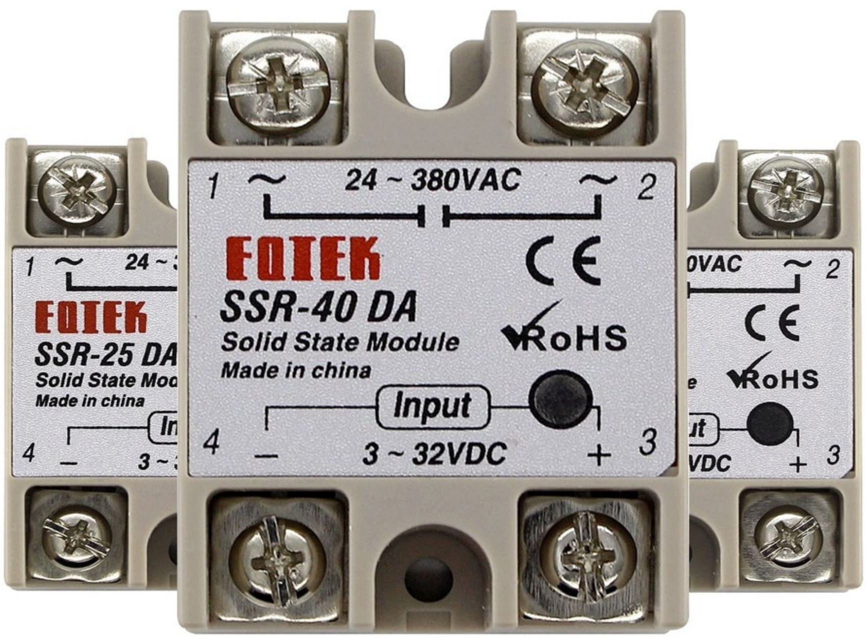


Figure 3-16: Different types of Solid-State Relays (SSR)(eBay).

3.2.2.4. Relay and Contactor

These are additional options for the design other than TRIACs and SSRs. Relays and contactors are electromechanical devices (see Figure 3-17) and old/traditional technologies with good switching applications using low signal voltage to control high current and voltage loads. Contactors and relays are ON/OFF by electrically magnetizing and demagnetizing the coil so one can control using different voltage levels. The most common voltages are 5, 12, 24, 32, 110, 220, 380 AC or DC while they can control up to thousands of current loads.

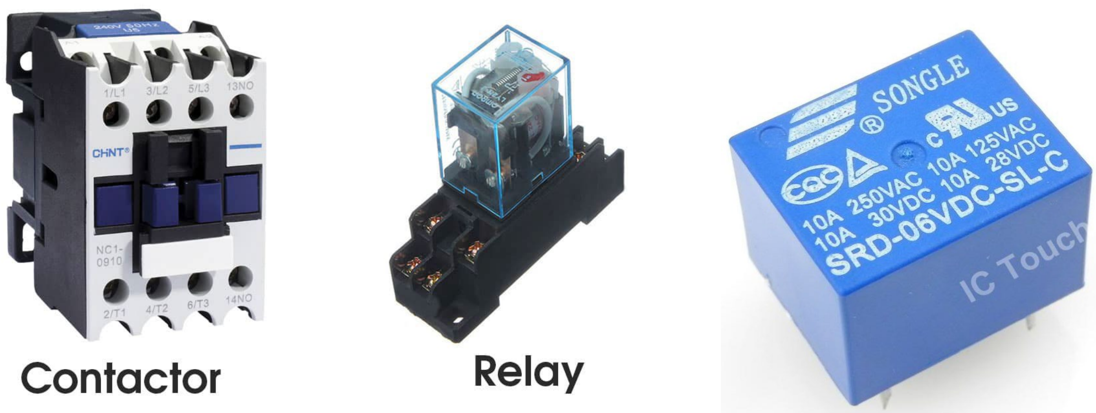


Figure 3-17: A contactor (left), E. M relay (middle) and an Electronics relay (right) **[73]**.

3.2.2.5. Heater

At the heart of the heater is electrical heating element. It is the main part no matter how big the heater is, no matter whether it's radiant heat, oil-filled, or fan-forced, somewhere inside is a heating element. The electric heating element is an electrical device. The heating element inside every electric heater is an electrical resistor, and works on the principle of Joule heating. During the heating process, electrical energy is converted to heat energy when the alternating current or direct current passes through the resistance wire alloy. There are different types of solid resistance wire (single strand wire) alloys.

All these alloys can get in the form of open coil, porcupine, ribbon, strip, serpentine, rod, plug or rack and we can use it for applications including space heating, cooking, water heating, and industrial processes. If the voltage and current are known, then the power can be calculated as: Power = Current*Voltage. As the voltage can be written as a product of current and resistance, then the power can also be written as: Power = $Voltage^2$/Resistance or Power = $Current^2$* Resistance.

Space heating is used to warm the interiors of buildings in different mechanisms including infrared radiant heaters, convection heaters, fan heaters, storage heating, domestic electrical under floor heating, lighting system and heat pumps. Heater elements are used with both small appliances (including space heaters, dress and hair dryers, hot guns, and heating pads including soldering and de-soldering) and large appliances (including freezers, refrigerators and dryers, industrial ovens and furnaces for heat treating, melting, holding, burn-off or powder coating, kilns, duct heaters room warmer for the medical appliance, incubators and steam sterilizers (boiling water)) [74]. In a steam sterilization machine, heater is used as a temperature source to generate steam by boiling the water. The heater is a water immersion type (see Figure 3-18). If it gets electrical energy without water, the heater cannot resist and it burns out. The heater is normally a use-and-throw type (not repairable).

Figure 3-18: U shape steam sterilizer heater **[57]**.

3.2.2.6. Pressure Control Valve

The pressure inside the chamber must be controlled to make it safe for both the user and the machine. There are different mechanisms to control the pressure inside the steam sterilizer chamber by coordinating the pressure control steam sterilizer solenoid valve and the pressure relief safety valve.

3.2.2.7. Pressure Control Solenoid Valve

Valves are mechanical devices used to regulate the flow and pressure of a container or chamber. Solenoid valves are electrically controlled valves consisting of an electrical solenoid and a mechanical valve body. When the coil is energized, it creates a magnetic field and this magnetic field act rotationally or linearly moving the mechanical plunger. The solenoid consists of an electrical coil and a movable ferromagnetic plunger. When an electric current passes through the coil wires, a magnetic field is created. This generates a magnetic field that exerts force to move the plunger to close or to open the valve.

There are three types of solenoid valves:

i. *Normal open solenoid valve:* as its name indicates, this solenoid valve is open normally and if it gets electrical energy, it creates a magnet and the plunger moves and blocks the valve and changes its state from normal open to close or block the tunnel of the valve tube.
ii. *Normal close solenoid valve:* this is the opposite of the normally open solenoid valve. It is normally close if it gets energy and that opens the valve. This type of solenoid valve is used for the steam sterilizer machine because we want to release if the pressure is greater than the set value.
iii. *Bi-stable solenoid valve:* this is the combination of the normally closed and normally open valve. The working principle is to stay in their current position until power is applied. It is also known as a latching solenoid valve.

The coil of the solenoid valve can operate different types of voltages: DC (6V, 12V, 24V, 36V) and AC (24V, 36V, 110, 250V). A typical solenoid valve is shown in Figure 3-19.

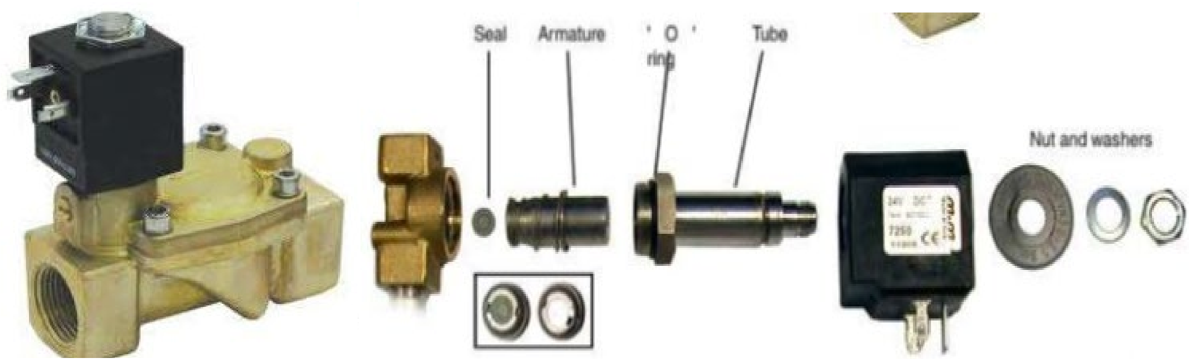


Figure 3-19: Solenoid valve device (left) and solenoid valve parts (right) **[75]**.

3.2.2.8. Safety Valve

A safety valve is mounted on the steam sterilizer chamber, which is crucial in cases where the electronics control of the steam sterilizer fails to perform its action or the pressure inside increases uncontrollably. The valve has a thin layer of rubber that bursts itself to release the pressure and to avoid the danger of explosion of the chamber machine and for user safety. Safety valve is set at the maximum capability of the chamber pressure.

3.2.2.9. Gauge

- ✓ *Pressure gauge:* A pressure gauge is installed into the steam sterilize chamber and is usually located in the front part of the machine to indicate the pressure created in the chamber during sterilization. The pressure gauge is essential to display and assure the safety of the steam sterilizer chamber and the working condition of the operation.
- ✓ *Temperature gauge:* Like the pressure gauge, the temperature gauge is also located in the front part of the steam sterilize chamber and it indicates the temperature created by the electrical heating element in the chamber during sterilization. The temperature gauge is essential to display and assure the safety of the steam sterilizer chamber and the working condition of the operation.
- ✓ *Pressure and Temperature gauge:* In this case, the same gauge can display pressure and temperature at the same time with the same device.

3.2.2.10. Water Inlet Valve

Steam is generated inside the chamber using the temperature of the heater element. So, water is essential to generate steam and for the safety of the heater element because the heater element is water immersed type. If water is not available inside the chamber, then the heater element burns out. So, to prevent the heater from burning, it needs automatic water feed, and the water inlet solenoid valve can perform this job. The water inlet solenoid valve has the same operation and characteristics as the pressure control steam exit solenoid valve so we can use it as a water inlet valve (see also Figure 3-20 or Figure 3-21).

Figure 3-20: Water inlet valve **[76]**.

3.2.2.11. Door Lock/Unlock

Steam sterilizer machines have auto-door lock mechanism for user safety. Commonly used door lock is a linear actuator push/pull solenoid electro-mechanical device (see also Fig. 3-21). A linear solenoid valve has electrical coil wined round a tubular with a ferromagnetic plunger that is free to move/slide IN/OUT of the body of the coil. Solenoids can lock or unlock doors and open/close valves and have electrical ON/OFF switches. Linear solenoids are designed as either a holding (continuously energized) or as a latching type (ON-OFF pulse) with the latching types being used in either energized or power-off applications and for proportional motion control where the plunger position is proportional to the power input that acts like a PID control which can contract in the form of a Pull-type that pulls to unlock or lock when energized, and the Push-type is the opposite of Pull-type.

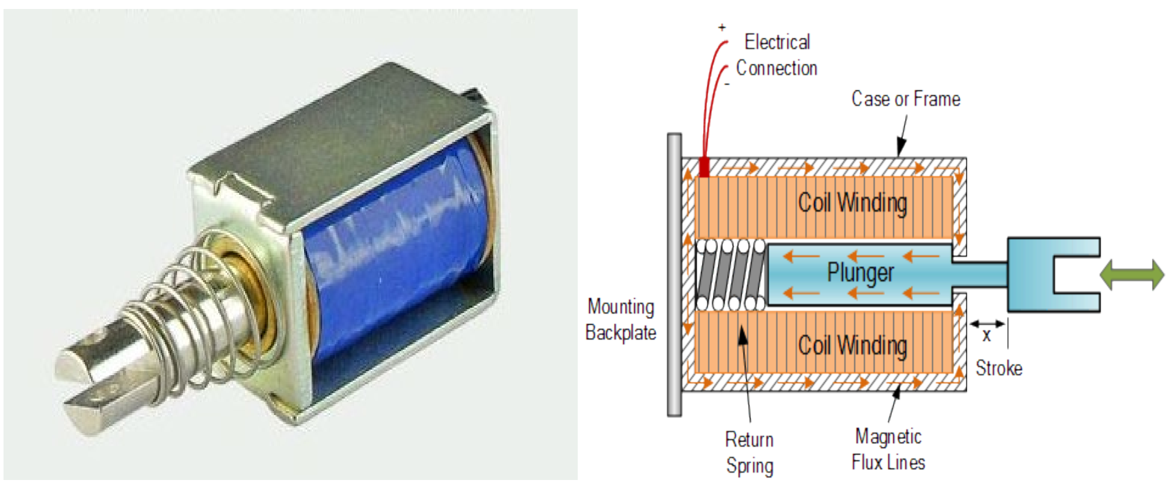


Figure 3-21: Linear actuator solenoid used for door lock/unlock **[77]**.

3.2.2.12. Warning

Buzzer Sound: A buzzer is an electronics component, small and efficient to get sound features at different frequencies. Piezo Electric Buzzer, speaker, it can be an active buzzer or passive buzzer for alarming circuits where the user must be alarmed about something, communication equipment, automobile electronics and portable equipment. It has compact size and low power consumption with different frequencies.

Indicator (Bulb or Light Emitting Diode - LED): Indicators are used to give attention to the machine. They can be LED or bulb lamps and emit light with different colors (Green, Yellow and

Red). Bulb lamp is an old technology and it is not efficient as it consumes electrical energy and it needs large space and wire to get power and cannot get different colors like LED. The color of the LED is determined by the energy band gap of the semiconductor. LED is the most recent/most up-to-date technology which can be used for different applications. It is used not only for indicators but also for illumination, display (out/in door). LED has two terminals: Anode which is the positive pin of the LED (the longer terminal) and Cathode which is the negative terminal of the LED (the shorter terminal). Table 3-10 presents different color LEDs and their voltage supplies.

Table 3-9: Forward voltage of different color LEDs [78].

LED Color	Supply Voltage
Red	1.63 ~ 2.03V
Yellow	2.10 ~ 2.18V
Orange	2.03 ~ 2.10V
Blue	2.48 ~ 3.7V
Green	1.9 ~ 4.0V
Violet	2.76 ~ 4.0V
UV	3.1 ~ 4.4V
White	3.2 ~ 3.6V

3.2.3. Processor Section

The processor section is the brain of the smart steam sterilizer machine. The main controller of the whole machine is the microcontroller which functions by taking input/s from the sensors. If we know the number of inputs, the number of pins it needs for the sensors, and the outputs, we could use IDE to develop effective and efficient code by integrating with the microcontroller. The hardware is also selected based on the number of pins, ISA, memory capacity, bus width, speed, effectiveness, communication protocols bus, power consumption, memory architecture, families, community, manufacturer, cost, other features, popular microcontrollers, easy access on market, etc.

3.2.3.1. Comparing of Microcontrollers Family

A comparison between the 8051, PIC, AVR, and ARM Microcontroller families was made and family and IC number selection was carried out based on Bus width, communication protocols, speed, memory, ISA, memory architecture, power consumption, families, manufacturer, cost (as compared to features it provides) and other features. To decide which microcontroller family and model number fits for the current work, the number of analogs and digital inputs, number of pins they need, number and type of outputs, digital pulse modulation width (PMW), type of communication that can fit the input sensors and actuators and TFT touch screen LCD display (like I2C and SPI) were checked. Also checked was whether the system can support additional features like USB, Bluetooth, WI-FI, and internet accessories. The IDE or debuggers and the programming language they support (Micro-C, C/C^{++}, C#, R, python, Java, Matlab) were also checked.

Table 3-11 presents specifications of the four microcontroller families in terms of all relevant features mentioned above. Accordingly, AVR and ARM were found fit to be used in the current study. Special additional features/characteristics are used to pick between AVR and ARM.

Table 3-11: Main difference between 8051, PIC, AVR, and ARM Microcontrollers [79]

	8051	PIC	AVR	ARM
Bus width	8-bit for standard core	8/16/32-bit	8/32-bit	Mostly 32-bit but also available in 64-bit
Communication protocols	UART, USART, SPI, I2C	PIC, UART, USART, LIN, CAN, Ethernet, SPI, I2S	UART, USART, SPI, I2C, (special purpose AVR support CAN, USB, Ethernet)	UART, USART, LIN, I2C, SPI, CAN, USB, Ethernet, I2S, DSP, SAI (serial audio interface), IrDA
Speed	12 Clock/instruction cycle	4 Clock/instruction cycle	1 clock/ instruction cycle	1 clock/instruction cycle
Memory	ROM, SRAM, FLASH	SRAM, FLASH	Flash, SRAM, EEPROM	Flash, SDRAM, EEPROM
ISA	CLSC	Some feature of RISC	RISC	RISC
Memory architecture	Von Neumann architecture	Harvard architecture	Modified	Modified Harvard architecture
Power consumption	Average	Low	Low	Low
Families	8051 variants	PIC16XX, PIC17XX, PIC18XX, PIC24XX, PIC32XX	Tiny, Atmega, Xmega	ARMv4,5,6,7 and series
Community	Vast	Very Good	Very Good	Vast
Manufacturer	NXP, Atmel, Silicon Labs, Dallas, Cyprus, Infineon, etc	Microchip Average	Atmel	Apple, Nvidia, Qualcomm, Samsung Electronics, TI, etc
Cost (as compared to features provide)	Very Low	Average	Average	Low
Other features	Known for its Standard	Cheap	Cheap, effective	High-speed operation Vast
Popular Microcontrollers	AT89C51, P89v51, etc.	PIC18fXX8, PIC16f88X, PIC32MXX	Atmega8, 16, 32, Arduino Community	LPC2148, ARM Cortex-M0 to ARM Cortex-M7, etc.

- ✓ **AVR Microcontroller**

This Microcontrollers family was created in 1996 by Atmel and acquired by Microchip Technology in 2016. Tiny-AVR, Mega-AVR, and Xmega-AVR are the families of AVR. AVR is not an acronym and does not stand for anything. The creators of the AVR gave no definitive answer as to what the term "AVR" stands for. However, it is commonly accepted that AVR stands for **A**lf and **V**egard's **R**ISC processor [80]. *Tiny-AVR* is in small size, has less memory, and is suitable for simple applications. *Mega-AVR* is the most popular AVR having a good amount of memory and a higher number of inbuilt peripherals which is suitable for moderate to complex applications. *XMega-AVR* is mainly for complex applications and requires huge program memory and high speed. Some application areas of AVR include home automation, touch screen, medical devices, automobiles, and defense.

- ✓ **Advanced RISC (Reduced Instructions Set Computer) Microcontroller (ARM)**

ARM Microcontroller was introduced by the Acron computer organization. It is the family of microcontrollers that is developed by different manufacturers including Apple, Nvidia, Motorola, Qualcomm, Samsung Electronics, ST Microelectronics and TI. ARM Cortex-A, ARM Cortex-R, and ARM Cortex-M are the most common ARM microcontroller family in an embedded system. Most industries prefer ARM since it consists of large features to implement products with an excellent appearance. This type of microcontroller is a cost-sensitive and high-performance device. It can be used in a wide range of applications such as sensors, automotive body systems, industrial instrument control systems, wireless networking, smart phones, tablets, and mobile devices. Table 3-12 summarizes comparison between AVR and ARM microcontrollers.

Table 3-12: Comparison between AVR and ARM Microcontroller families [81].

No.	AVR	ARM
1	AVR microcontroller refers to Advanced Virtual RISC (AVR).	ARM microcontroller refers to Advanced RISC Micro-controller (ARM).
2	It has a bus width of 8 bit or 32 bits.	It has a bus width of 32 bits and is available in 64 bits.
3	It uses ART, USART, SPI, I2C communication protocol.	It uses SPI, CAN, Ethernet, I2S, DSP, SAI, UART, USART communication protocols.
4	Its speed is 1 clock/instruction.	Its speed is also 1 clock/ instruction.
5	Its manufacturer is Atmel company.	Its manufacturer is Apple, Nvidia, Qualcomm, Samsung Electronics and TI, etc.
6	It uses Flash, SRAM, EEPROM memory.	It uses Flash, SDRAM, EEPROM.
7	Its family includes Tiny, ATMega, Xmega.	Its family includes ARMv4, 5, 6, 7, and series.
8	It is cheap and effective.	It provides high-speed operation.
9	Popular micro-controllers include Atmega8, Atmega16, Atmega32.	Popular micro-controllers include ARM Cortex-M0 to ARM Cortex-M7, LPC2148, etc.

Based on the comparison, IC number of ATMEGA2560P from the AVR microcontroller family and System on Chip Broadcom BCM2837 Central Processor Unit Cortex-A53 from the ARM microcontroller are compatible with the design utilized in the current study. Both of them are compatible but ATMega2560p is selected because the Chip Broadcom BCM2837 Central Processor Unit Cortex-A53 is little bit expansive. The integrated circuit (IC) has a big number of thin surface mount pins and to solder all these pins it needs a doable surface board and microscope to solder. To overcome such issues in the current study, the IC is used in the form of development board. The development board has additional applications like remove soldering. It is assumed a plug-in type developed board is easier to use.

✓ **ATMega2560P**

ATMEGA2560 from the AVR microcontroller is a better performance than all AVR families except ATSAM3X8E microcontroller IC. The ATMEGA2560P microchip IC comes with the following features:

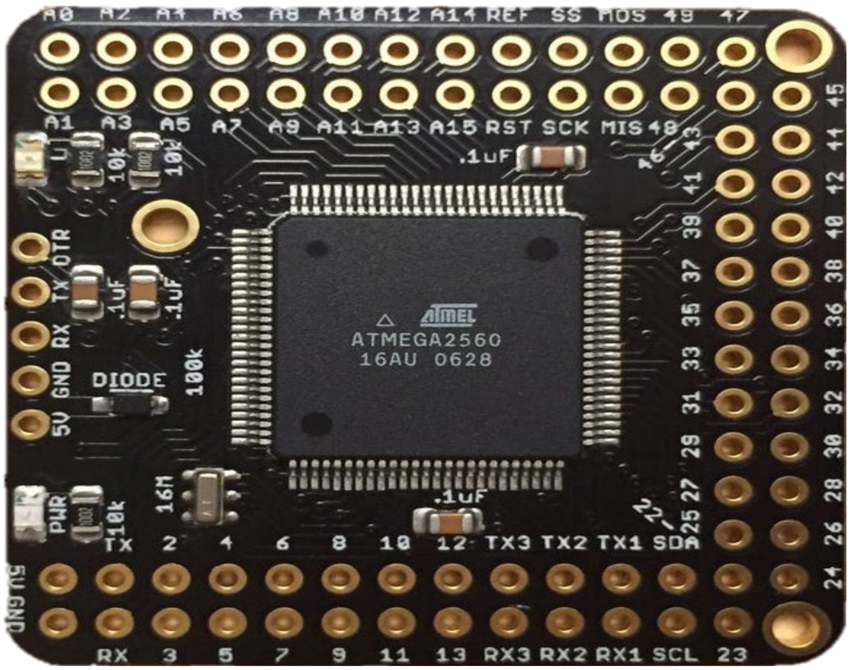
✓ Powered by Micro USB connector, or via the corresponding contact pin

- ✓ 800mA maximum output current from each GPIO.
- ✓ Has 5 and 3.3 voltage regulator IC; according to the document (datasheet) of the voltage regulator IC, it allows to use up to 16 Voltage input [82].

The main specifications and additional features of ATmega2560 mini pro are listed in Table 3-13. Figure 3-22 presents a snapshot of an ATMega2560 mini pro with its different components.

Table 3-13: Specifications of ATMEGA2560 mini pro **[83]**.

Microcontroller	**ATmega2560**
USB-TTL converter	CH340
Power Out	5V-800mA
Power IN	5V
Power IN. VIN/DC Jack	5V
Power Consumption	5V 220mA
Logic Level	5V
USB	Micro USB
Clock Frequency	16MHz
Operating Supply Voltage	5V
Digital I/O	54
Analog I/O	16
Memory Size	256kb
Data RAM Type/Size	8Kb
Data ROM Type/Size	4Kb
Interface Type	ISP
Operating temperature	−40C°/+85C°
Length x Width	38×54mm



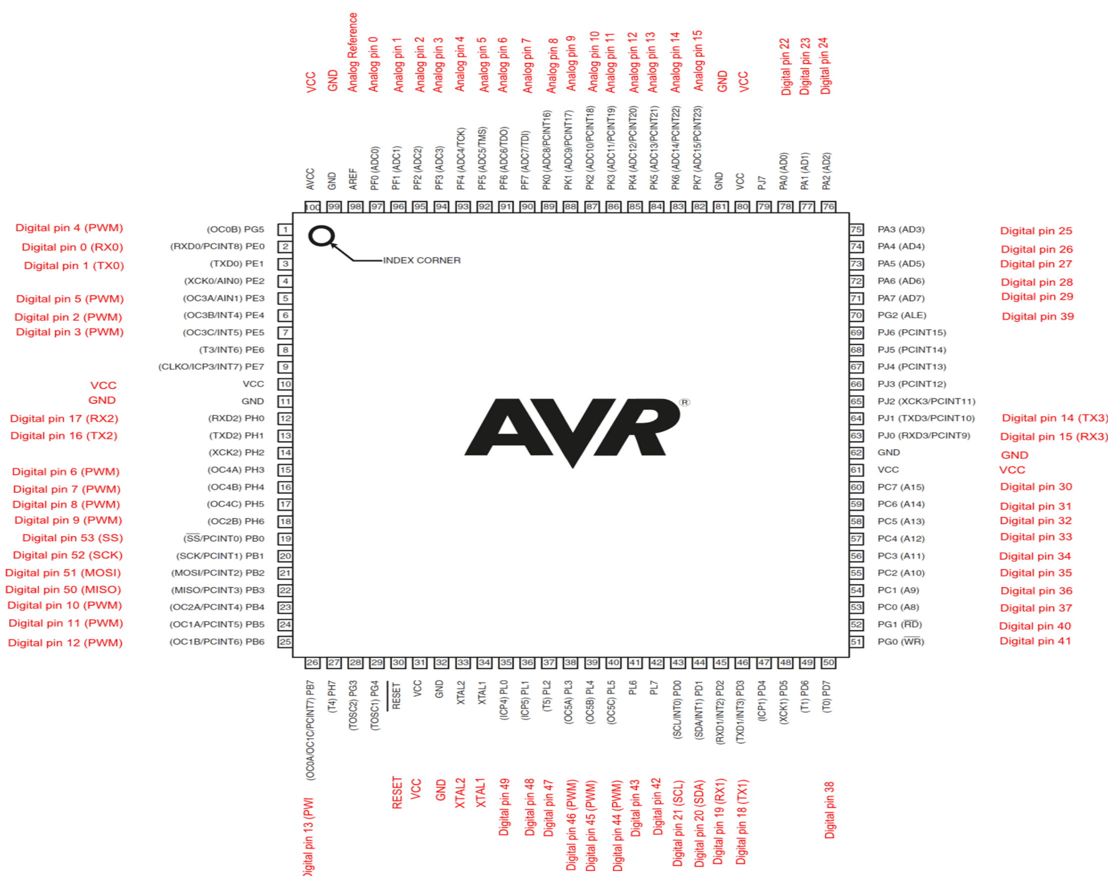


Figure 3-22: ATMega2560 microchip (upper) and pin description (lower) **[84]**.

3.3. Methods

The overall design of the smart steam sterilizer has an input section, processor section, and output section. Figure 3-23 presents the general block diagram of the input sensors, microcontroller (processor), output (actuator), and power supply section integration.

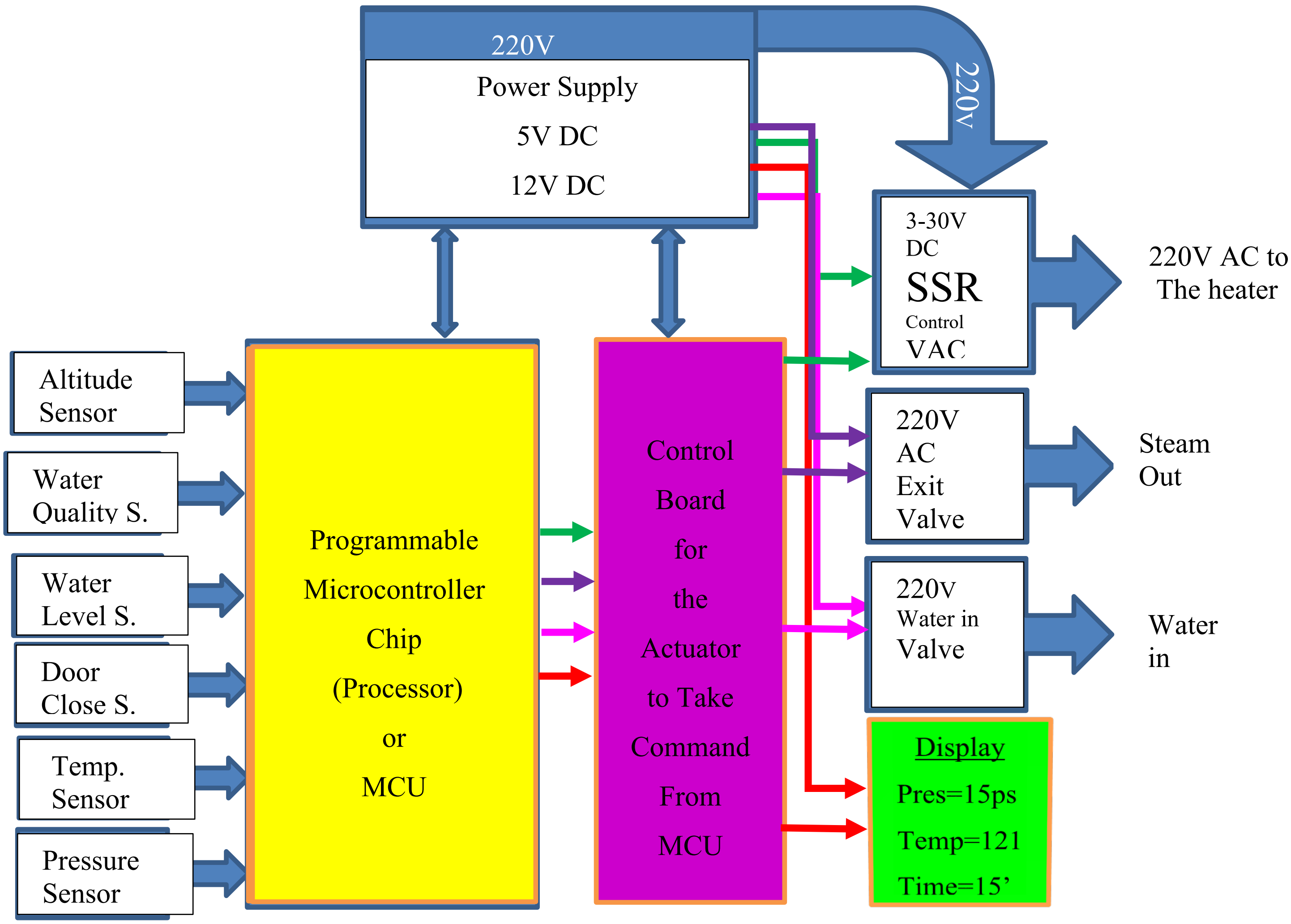


Figure 3-23: Block diagram of the Sensors, Processor and Actuator Integration

3.3.1. Flowchart

The flowcharts of the different input and output components of the design are presented below. ***Altitude Flowchart:*** Altitude has a significant effect on environmental conditions (humidity, pressure, and temperature) and hence on the boiling point of water and that affects the whole system of the steam sterilizer. To deal with this issue, we must adjust the machine manually using altitude effect pressure compensation manual. However, this method could be unnecessary if the process could be automated. The conversion requires a factor computed using the change in atmospheric pressure and change in pressure reduction. The values of the change in atmospheric pressure and that of the change in pressure reduction could be read from Table 4 in the previous Chapter.

$$Factor = \frac{\Delta Atmospheric\ Pressure\ due\ to\ \Delta altitude}{\Delta Pressure\ Reduction\ due\ to\ \Delta altitude} \quad \ldots\ldots(3.1)$$

According to Table 3-4, the factor can be calculated as $\frac{(0.9-1.0)}{(0.1-0.0)} = -1$

Now, the pressure compensation could be calculated as:

*Compensation pressure = (Factor*Atmospheric Pressure) + Standard Pressure Sea Level*

= Sea Level Pressure - Atmospheric Pressure ……………..……..(3.2)

Hence, the set pressure value is calculated as:

Set-value pressure = Compensation Pressure + Constant

= Standard Pressure Sea Level - Atmospheric Pressure + Constant.................(3.3)

where the *standard Pressure Sea Level or* mean Sea-level pressure =1013.25hpa [85], and Constant =1000hpa for ≤ 121℃, @1500hpa for <121℃ & 134℃> and @2000hpa for ≥ 134℃ For example, if the user set the temerature at 121℃, then the constant is 1000hpa and the set-value pressure is 1013.25hpa - Atmospheric pressure + 1000hpa = 2013.25hpa - Atmospheric Pressure. The complete flowchart for calculation of the compensation and effective pressure values to account for altitudinal effects is illustrated in Figure 3-24.

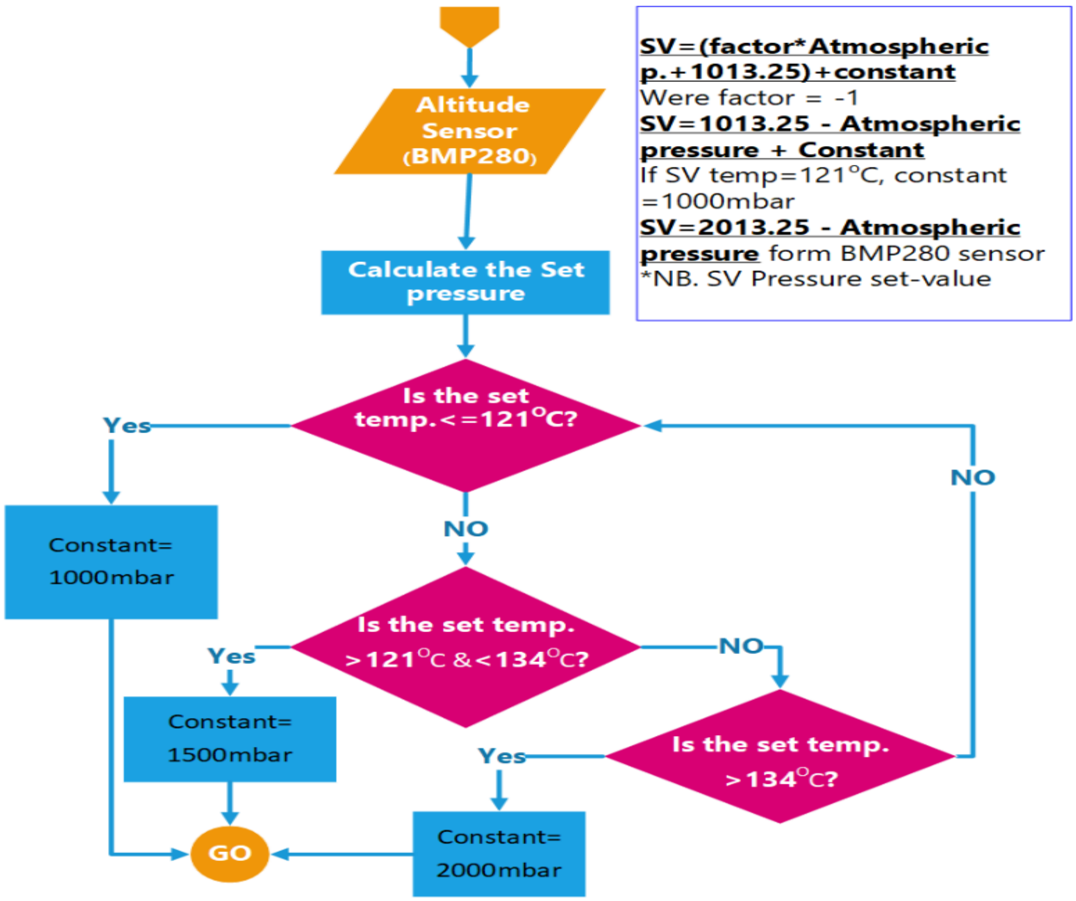


Figure 3-24: Flowchart for automatic pressure compensation to solve the altitude effect.

Door Close Check Flowchart: The steam sterilizer chamber must be closed to develop pressure and raise the temperature above 100ºc. Hence, the door is tightly closed with gasket and gasket maker to avoid possible leakages (see also Figure 3-25).

Water Level Check Flowchart: The water must be continuously monitored. In order to do effective sterilization, we need to generate steam inside the chamber. At the same time, the water level inside the chamber cannot drop below some level not to burn out the heater as we are using water immersed type. The complete flowchart for this process is depicted in Figure (3-26) and for both water level and water quality check Figure (3-28).

Water Quality Sensor Flowchart: quality of the water in steam sterilizer increases the efficiency and life of the machine and hence quality of the water should be checked. The quality of the water for steam sterilizer is recommended to be b/n 0.055µS/cm up to 50µS /cm or less than 100ppm. If the EC sensor reads below 55nS/cm, either it is a super ultra-pure water (so we need to add 50ml -100ml tap water for 3 – 3.5 liters of pure water) or there is no water at all (so a refill with pure water will be required). If the conductivity sensor reads above 50µS/cm it is hard water so we change it with 55nS/cm up to 50µS/cm pure water (see also Figure 3-27).

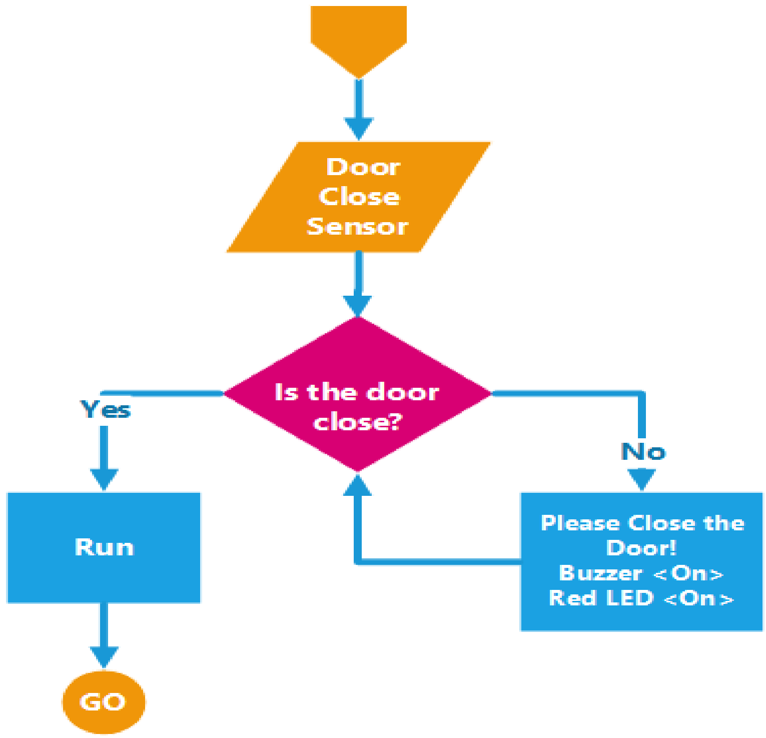


Figure 3-25: Flowchart for door close check.

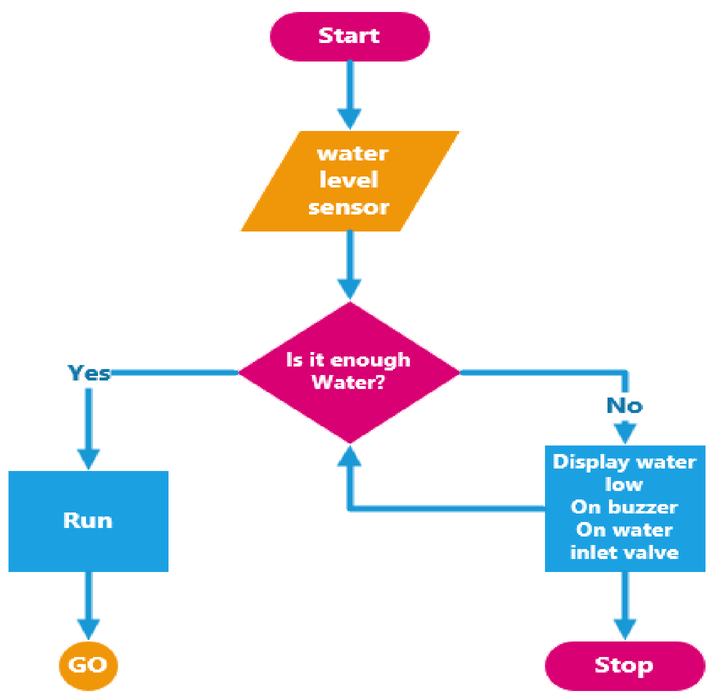


Figure 3-26: Flowchart for water level check.

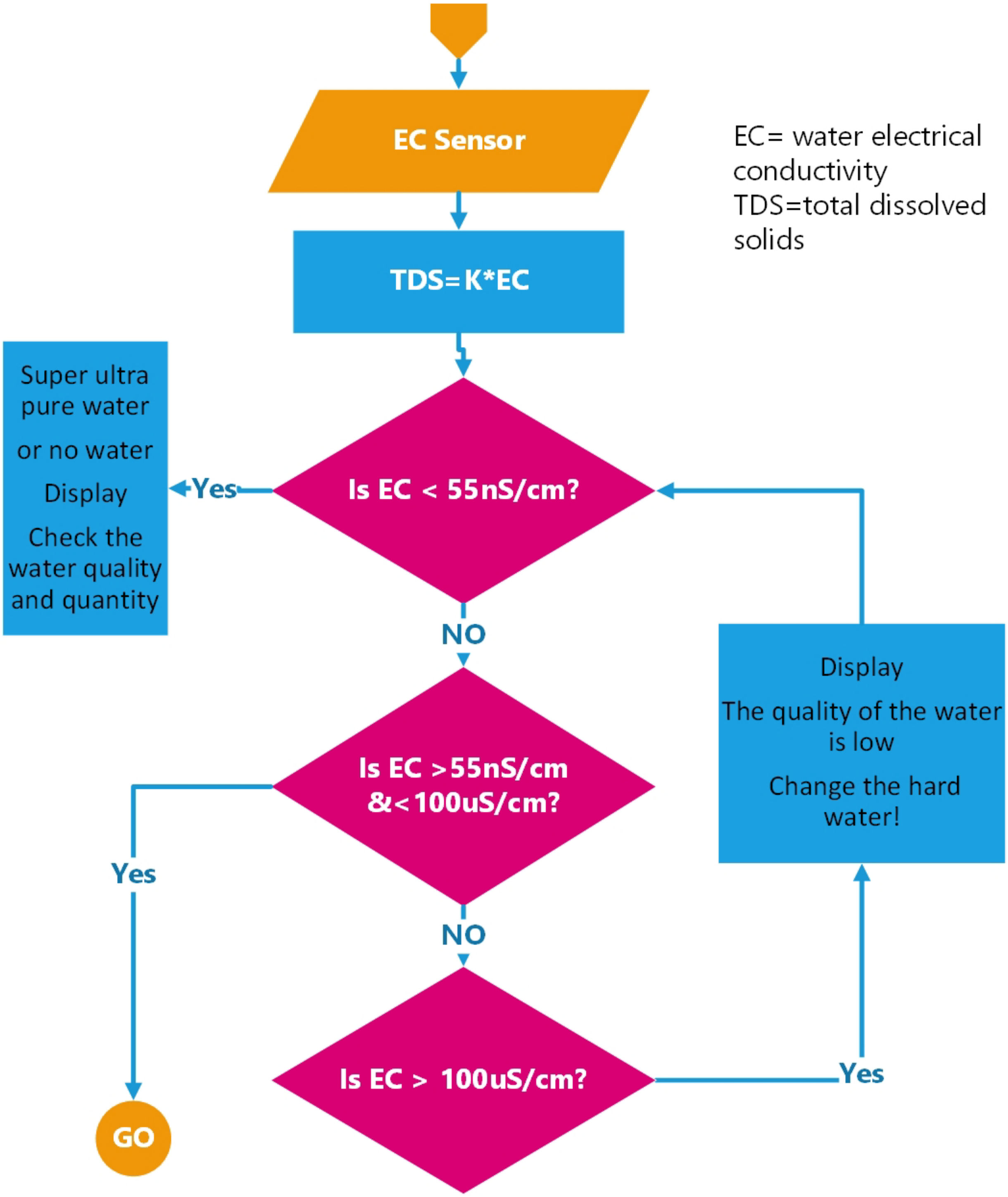


Figure 3-27: Flowchart for water quality control.

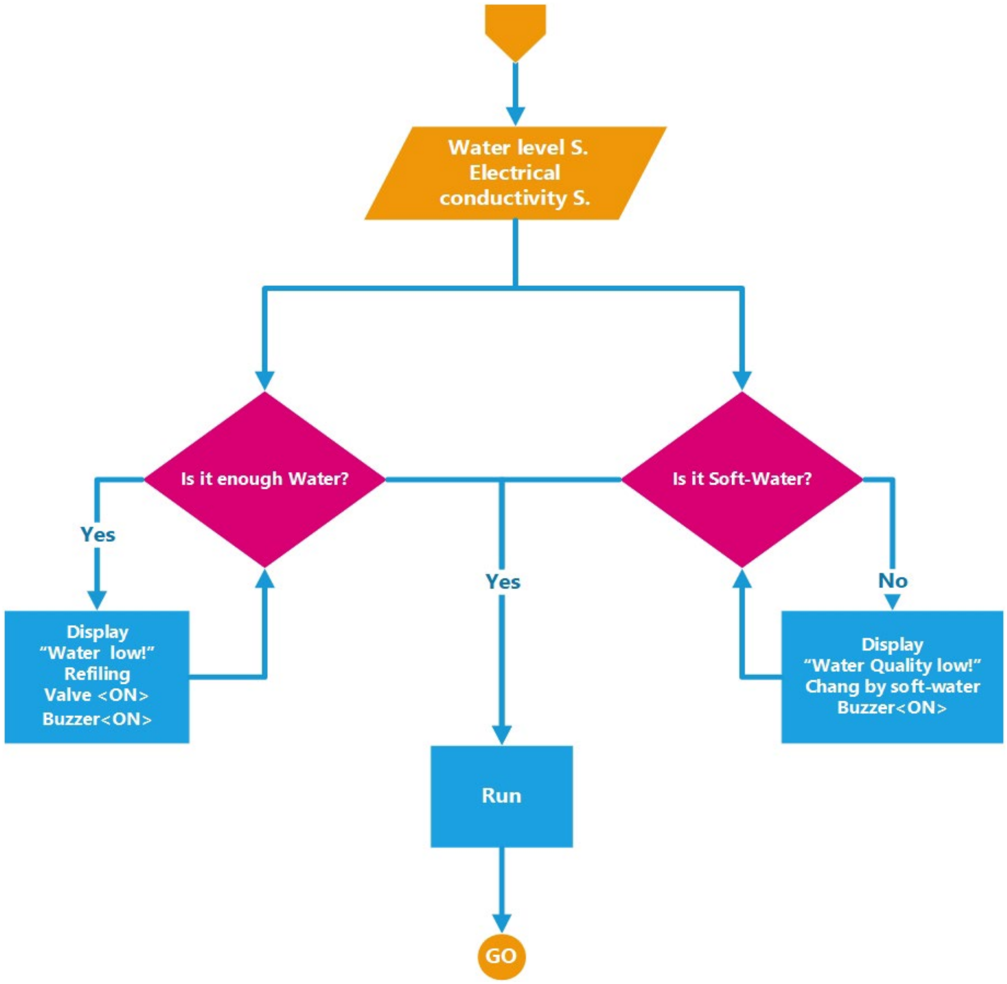


Figure 3-28: Flowchart for both water level and water quality check.

Temperature (PID) Control Flowchart: Temperature is one of the three physical quantities of steam sterilization. In the current work, a PID was utilized for temperature control and Figure 3-30 shows temperature control PID block diagram with the formula, and with anti-windup in Figure 3-31, and the flow chart in Figure 3-29 shows the controlling process.

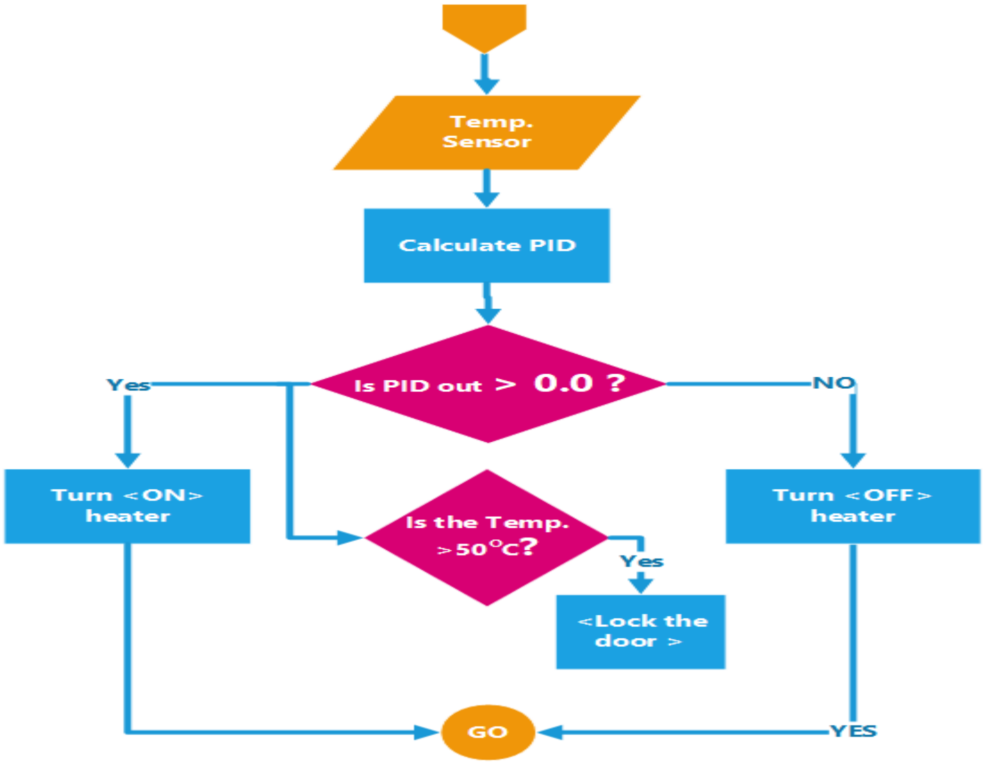


Figure 3-29: Temperature control flowchart.

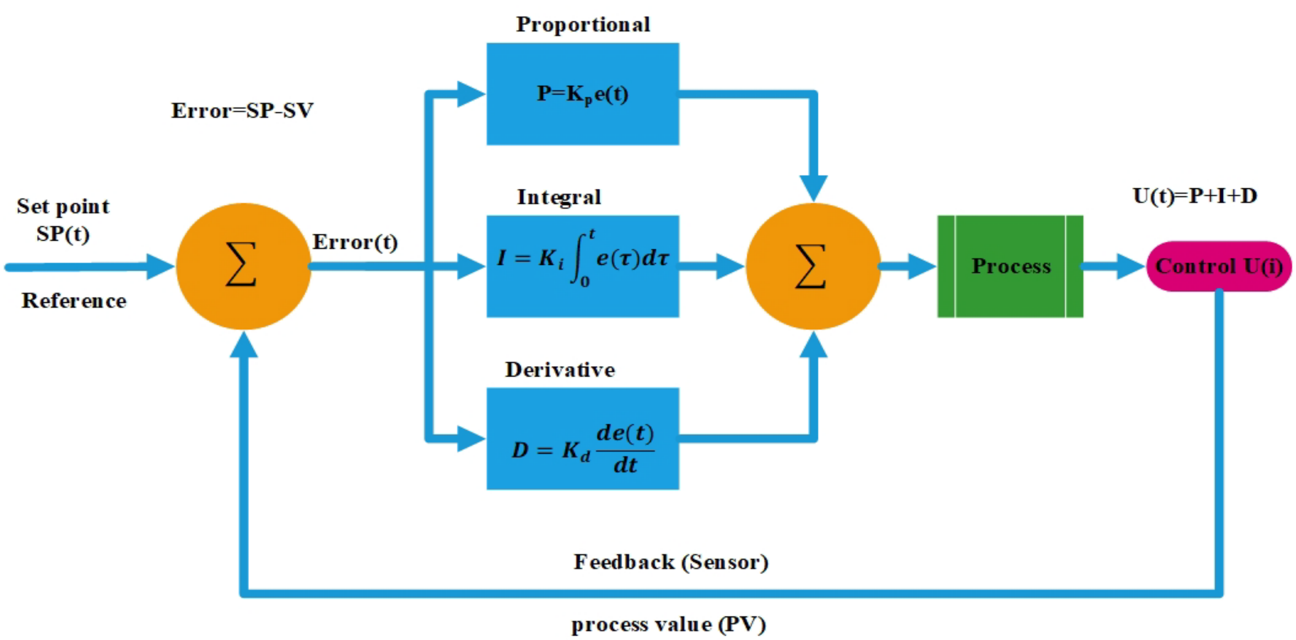


Figure 3-30: Block diagram of temperature control PID.

U(t) = P + I + D……………………………………………………..……………..3.4

$$U(t) = K_p e(t) + K_i \int_0^t e(\tau)dt + K_d \frac{de(t)}{dt}$$ ……………………….……..…………....3.5 [86]

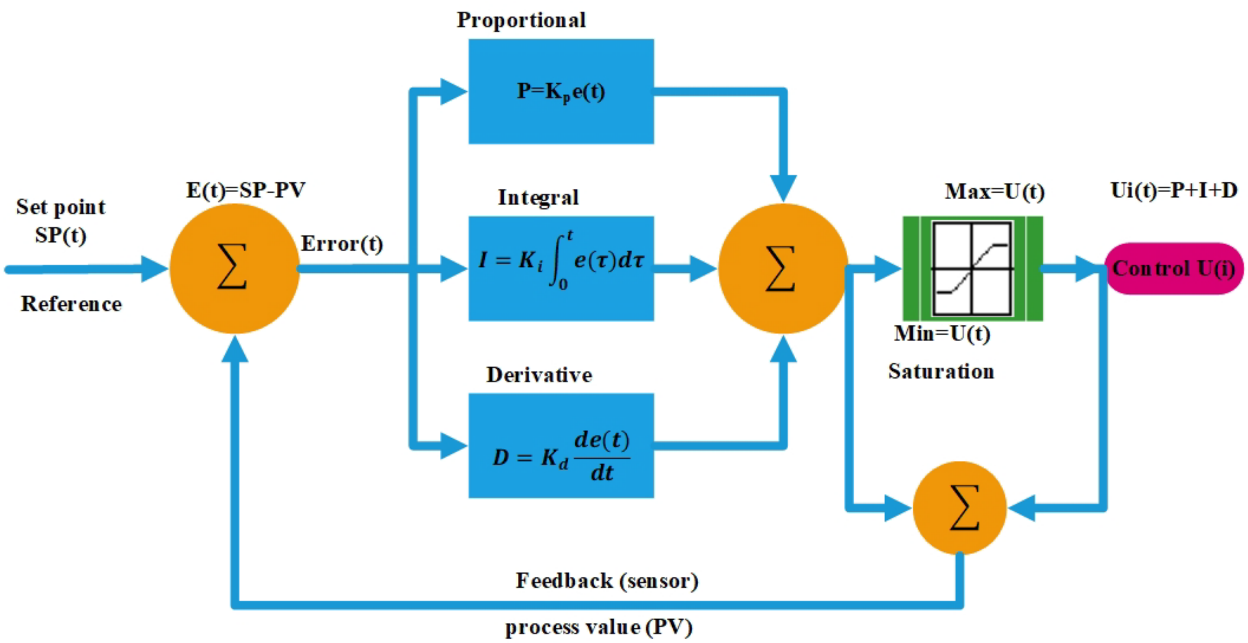


Figure 3-31: Block diagram of PID with anti-windup and formulas.

From this flow chart, the door lock command also gets from this. If the chamber temperature is greater than 50°C, the door of the chamber must be locked. 50°C is the maximum threshold for thermal damage to normal tissues (1st Degree Burn (minor burn)) [87].

Chamber Pressure Control Flowchart: Chamber pressure control applies pressure set-value (the pressure compensation formula) presented in this chapter and utilizes mainly pressure sensor and steam discharge solenoid valve. Figure 3-32 shows the chamber pressure flowchart.

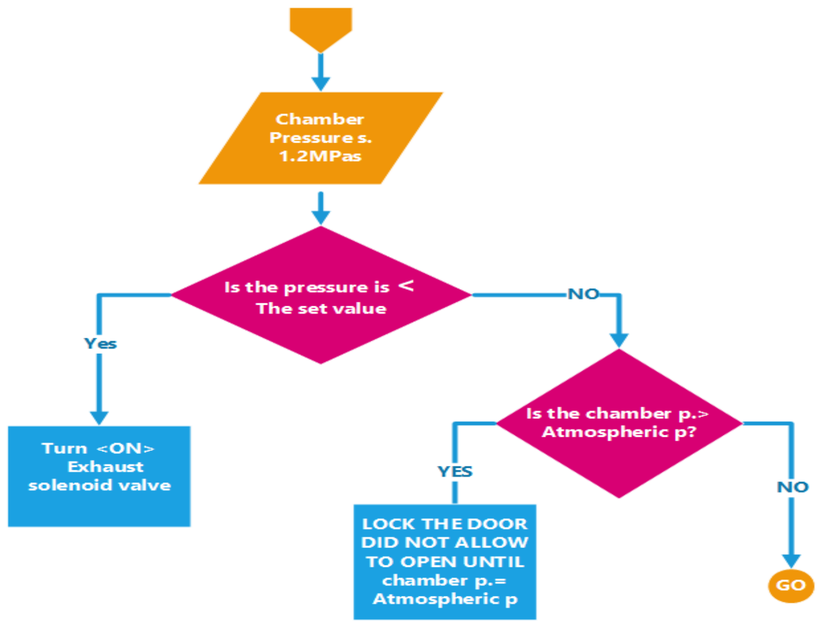


Figure 3-32: Pressure control flowchart.

Timer Flowchart: there are different cycles in the steam sterilizer system: pre-heating cycle, heating cycle, sterilization cycle, cooling cycle, and drying cycle, and total times during all these cycles is controlled using a timer flowchart. Drain and filling water also needs precise watchdog timer. Figure 3-33 shows total timer managing flowchart.

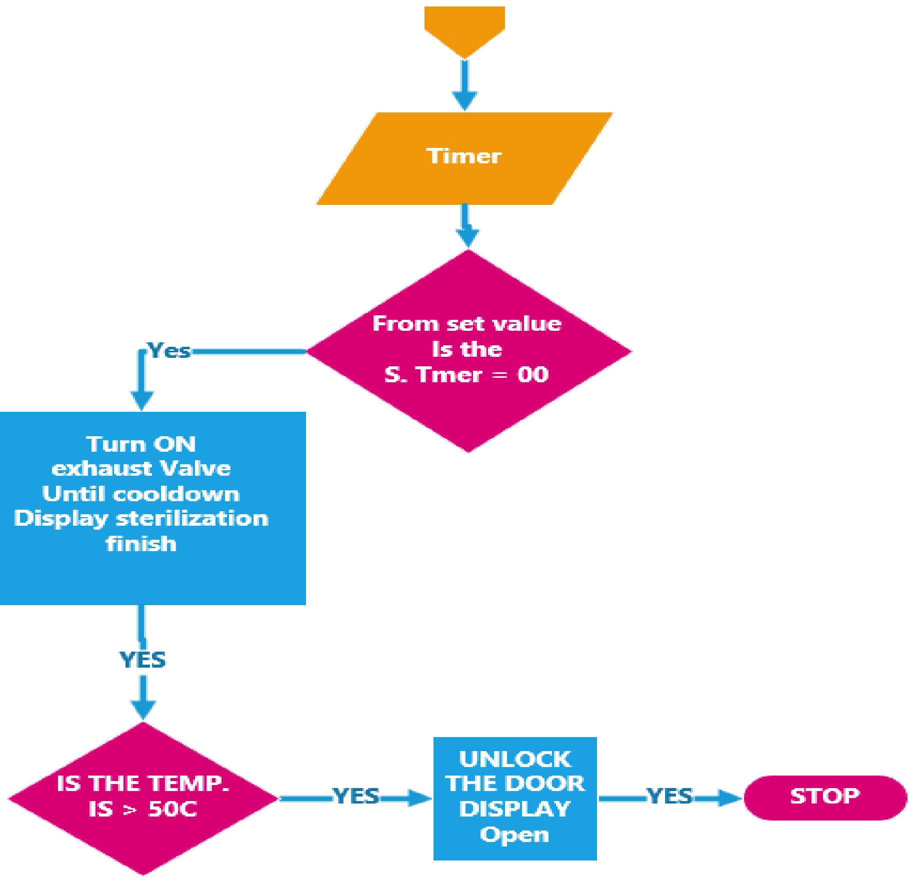


Figure 3-33: Timer flowchart.

3.3.2. Graphical User Interface (GUI)

The selected microcontroller for this research is AVR family ATmega2560-p microchip IC+ with a LCD ILI9486 driver IC Resistive Tin Film Touch screen which can display any graphical, symbolic or numeric data. The GUI is developed using C^{++} programming language and *MCUFRIEND_kbv.h*, *MCUFRIEND_GUI.h*, *Adafruit_GFX.h*, *TOUCHSCREEN.h* and *ONEWIRE.h* package libraries of C++. The GUI has options to select programming cycle, start/stop, open/close door, displaying option, main menu, setting, and other options. It can also display current outputs like temperature, pressure, time, environmental conditions (altitude, pressure, humidity, and temperature), states of the system, and error conditions. Figure 3-34 presents the main menu of the developed GUI.

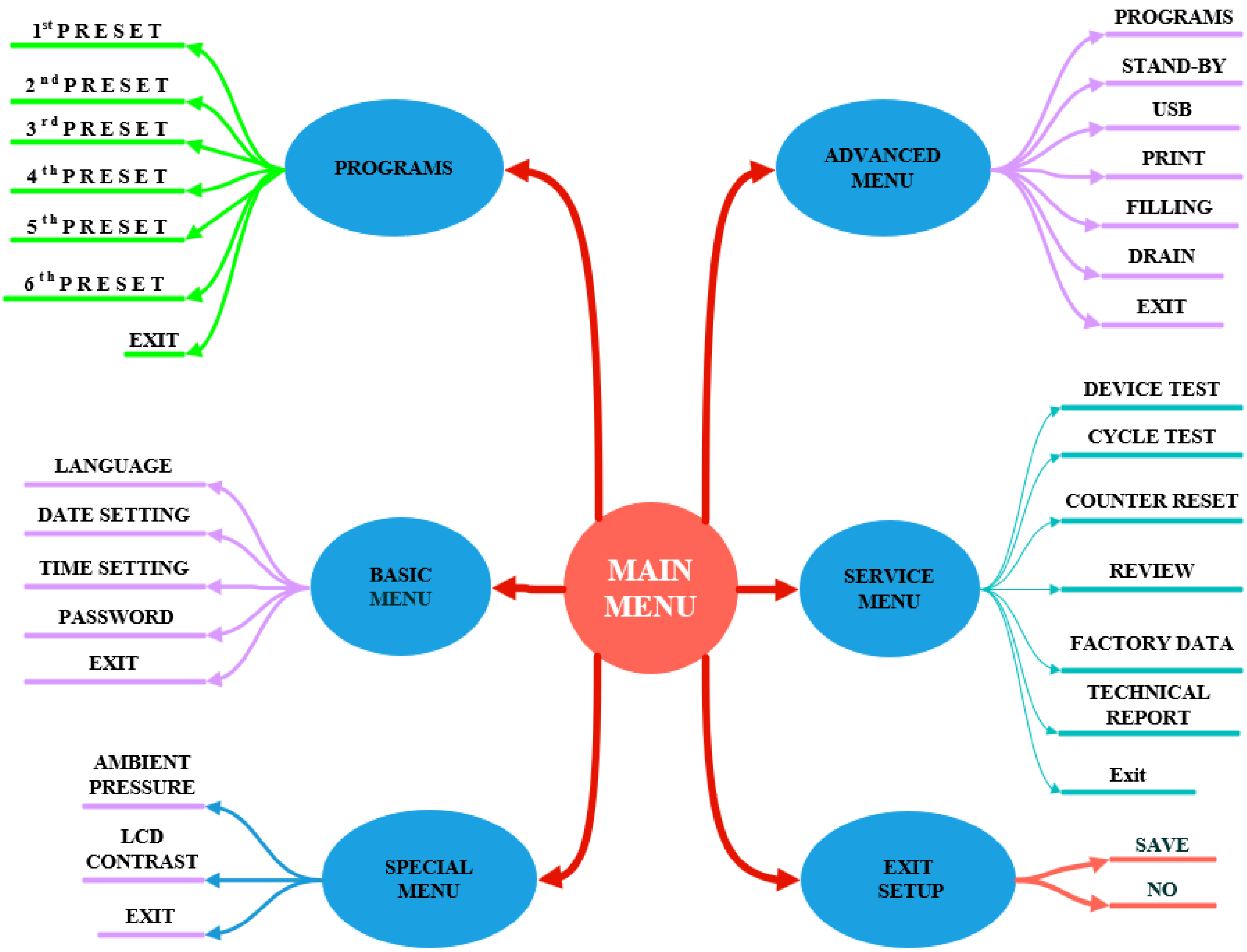


Figure 3-34: Main menu of smart steam sterilizer GUI chart.

The smart steam sterilizer has six (6) sub-menus under the main menu: *Programs, Basic and Advanced Menu, Special Menu, Service Menu,* and *Exit Menu (BACK)*. Some of these sub menus are further discussed subsequently below.

Advanced Menu: this menu includes sub-menus including programs (sterilization cycles based on the instrument under consideration), temperature, time and the like. Different options could also be set here: stand-by, USB, filling/drain, print or exit options. Figure 3-35 displays the advanced menu option chart.

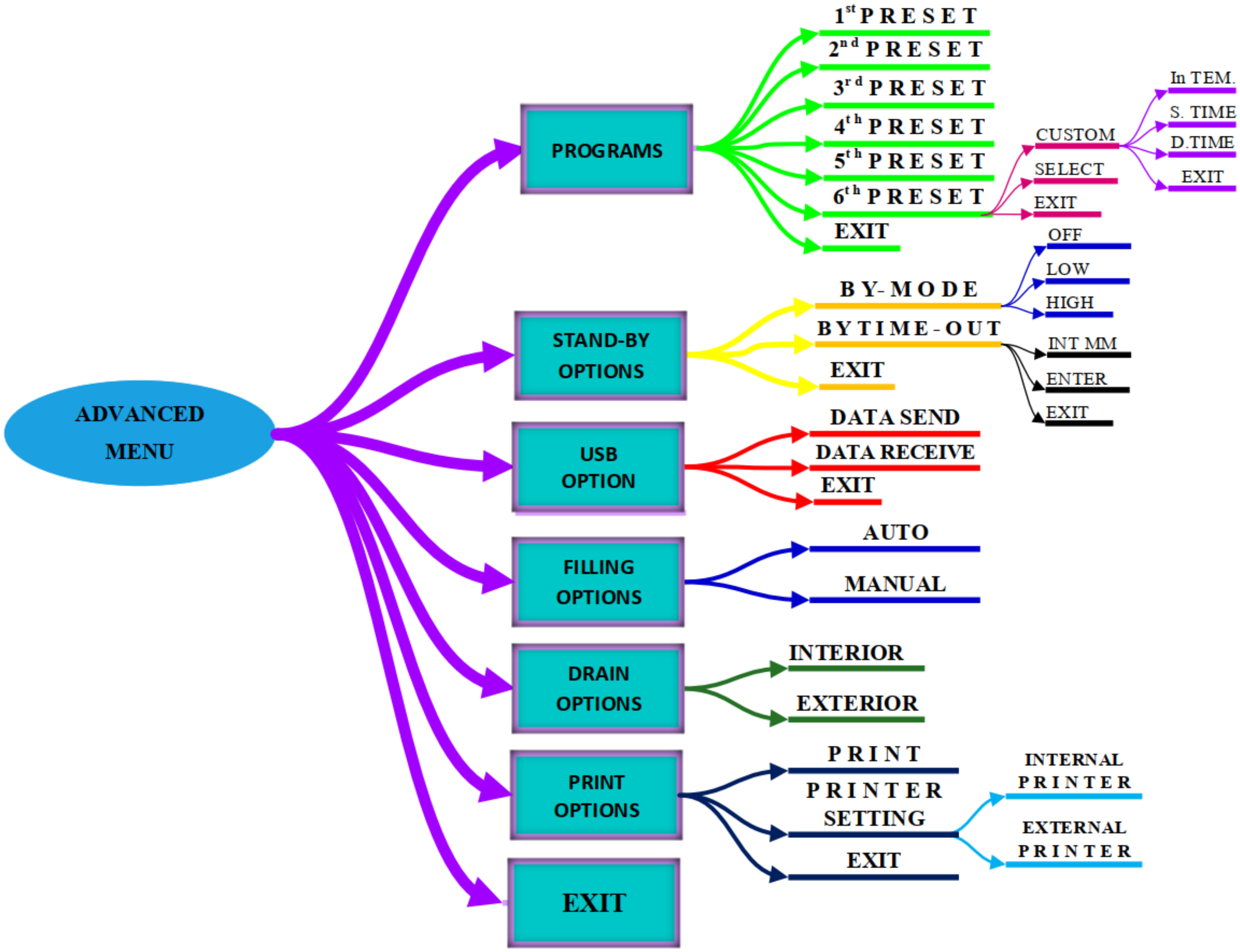


Figure 3-35: Advance menu option chart.

Basic Sub-Menu: this sub-menu includes language setting, date or calendar setting, time setting, password and exit options. The prototype that came out of the current research was made to operate in Amharic and English languages. In principle, one can create the basic sub-menu so that it operates in different local (such as Amharic, Afan Oromo, Tigrigna, etc) and international (such as English, German, Spanish etc) languages. Figure 3-36 shows the different options in the basic sub-menu.

Figure3-36: Basic sub-menu options.

Service Sub-Menu: this includes device test, cycle test, counter reset, technical report & error, and factory reset options (see also Figure 3-37).

Special Menu: with this sub-menu environmental conditions and TFT display contrast are included (see also Figure 3-38).

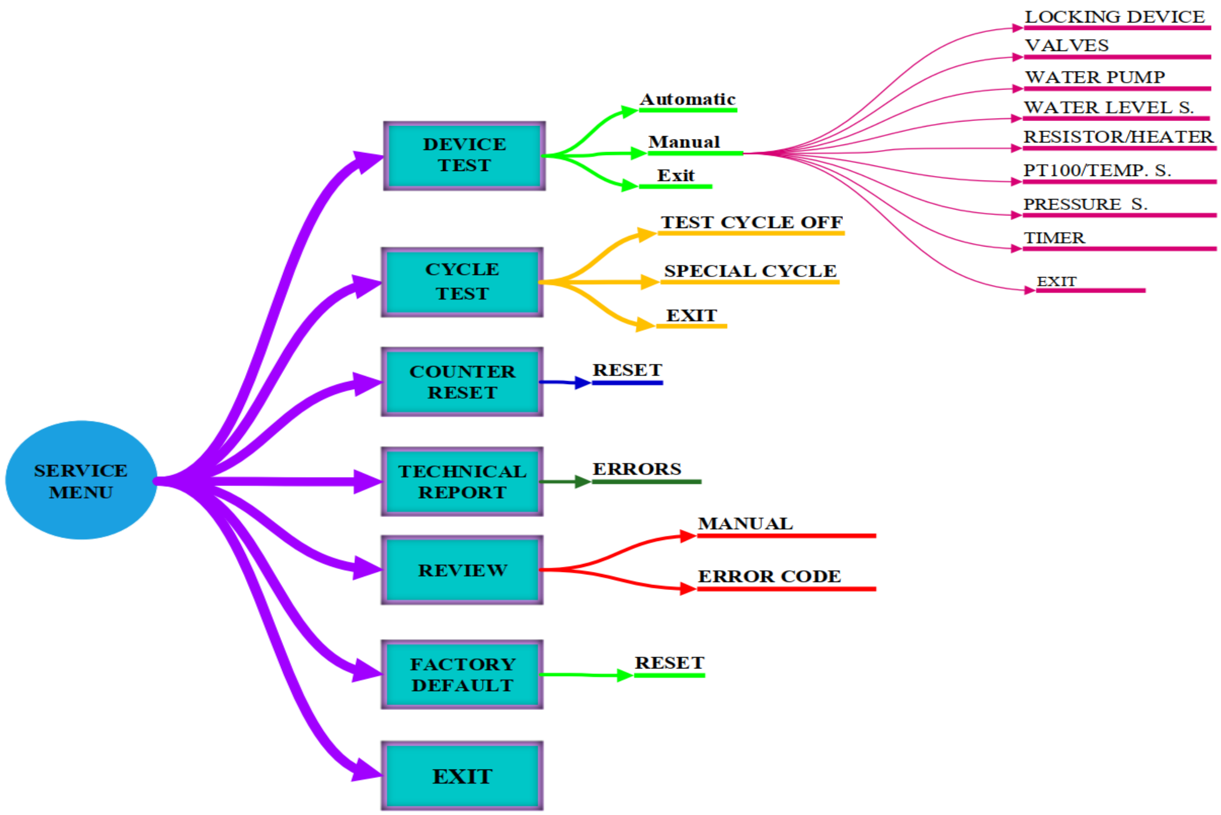


Figure 3-37: Service sub-menu option.

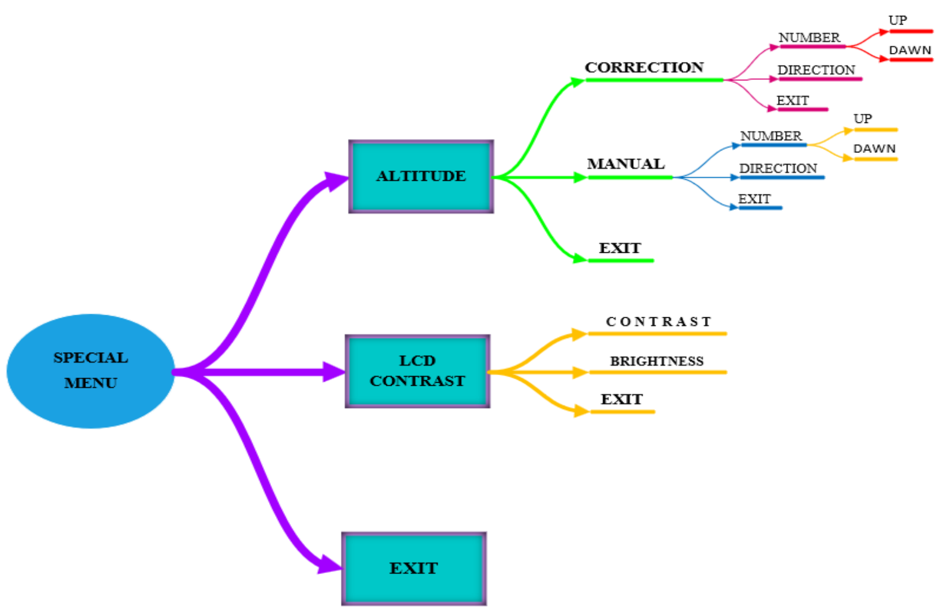


Figure 3-38: Special menu option.

Chapter 4: Results and Discussion

4.1. Result

This chapter presents key findings in this thesis with regards to the design of the proposed smart steam sterilizer that can function at all altitudes and comprising of a PID based temperature control as well as a water level controlling system.

4.1.1. Control Board Design

The control board was developed according to the block diagram and flowcharts described in the methodology section presented in the previous chapter. The control board is the main brain of the smart steam sterilizer machine. Following the ISO standards and service/operational manuals, the basic operations involved in the proposed steam sterilizer are heating, sterilization, and cooling, in that order. Before these operations are executed though, the machine checks if the water in the chamber is enough or not and if the door is closed or not.

Water quality: as we know all steam sterilizers need water to generate steam and the quality of the water must be high to increase the life of the machine and to increase the efficiency of the machine. Based on the design, the electrical conductivity of the water must be less than 50µS/cm. If the water quality is greater than 50µS/cm, the heater doesn't start (see Figure 4-39).

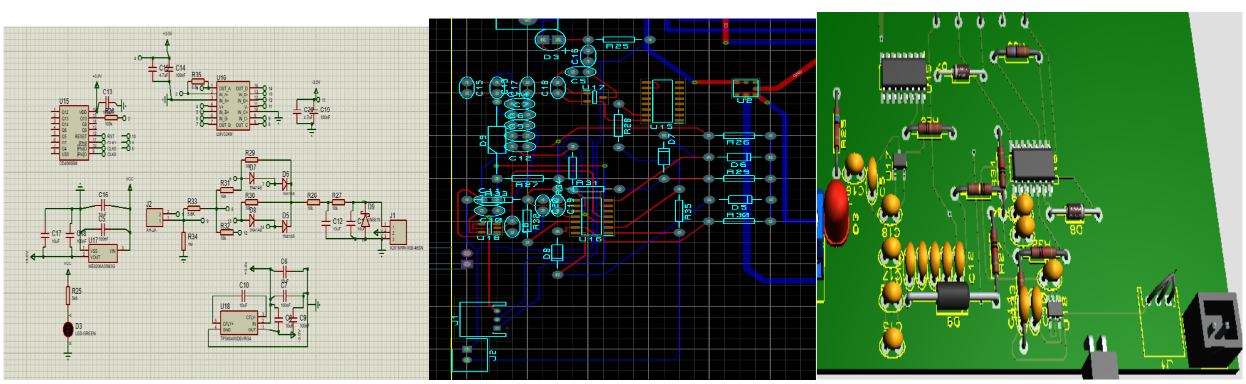


Figure 4-39: The water quality controlling unit: circuit diagram (left), PCB print (middle), and 3D views (right).

Water Level*:* To check if the water level in the chamber is adequate or not, a stainless-steel rod with plastic insulator was used inside the chamber to sense the water level with the help of an optocoupler PC817 and the microcontroller (see Figure 4-40).

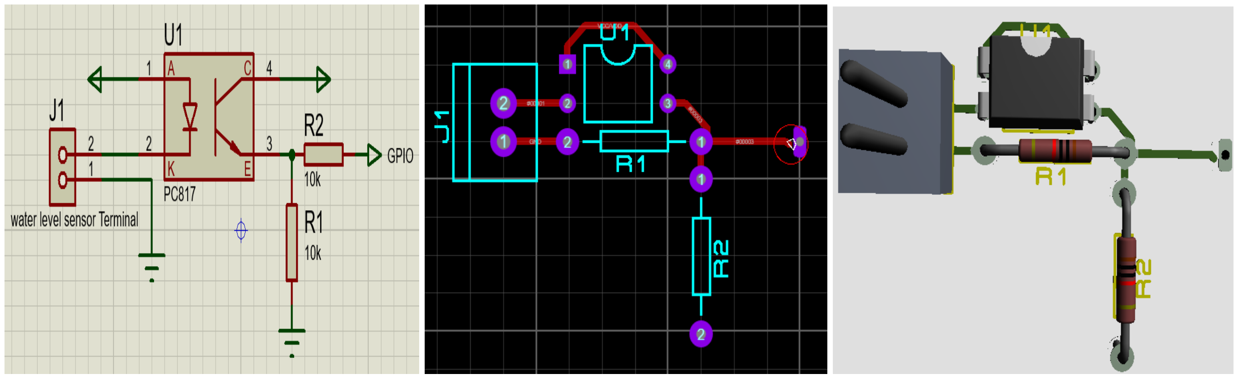


Figure 4-40: The water level controlling unit: circuit diagram (left), PCB print (middle), and 3D views (right).

Door Close: To check whether or not the chamber door is tightly closed before operation, a micro-switch is used to function with an optocoupler PC817 guided by the microcontroller (see Figure 4-41). If the door is not tightly closed, the steam can leak from the chamber, which could in turn limit the pressure inside from rising to the required level. If the pressure is not rising, the temperature cannot get to the desired point (above 100^{O}C).

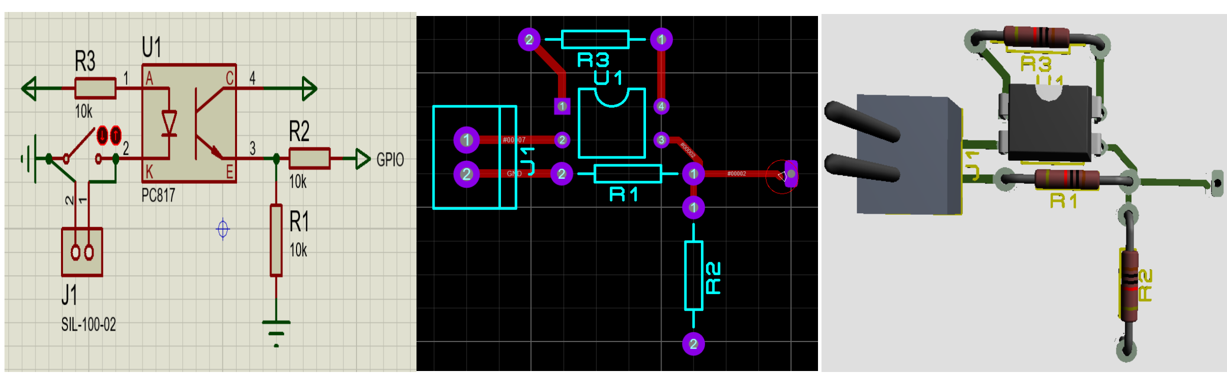


Figure 3-41: The door close controlling unit: circuit diagram (left), PCB print (middle), and 3D views (right).

Chamber Temperature: The next one is the chamber temperature controlling system. To read and control the chamber temperature of the smart steam sterilizer machine, a PT100 thermocouple temperature sensor with A MAX6675 ADC was used to convert the analogue temperature to digital and send to the microcontroller using SPI communication protocol. Once the microcontroller gets the digital read of the temperature, it compares with the user temperature setting (set-point). If the actual read is less than the set valve, the so called PID error is high and the heater is set to ON mode through the MOC3063 TRIAC Driver Optocoupler and the TRIAC switching mechanism (one could also use SSR, Contractor or Relay as a switching mechanism).

The PID is taking care of the temperature inside the chamber in coordination with the PT100 temperature sensor as feedback and the heater element as an output cooperate with actuators like Triac. Figure 4-42 shows the temperature control mechanism.

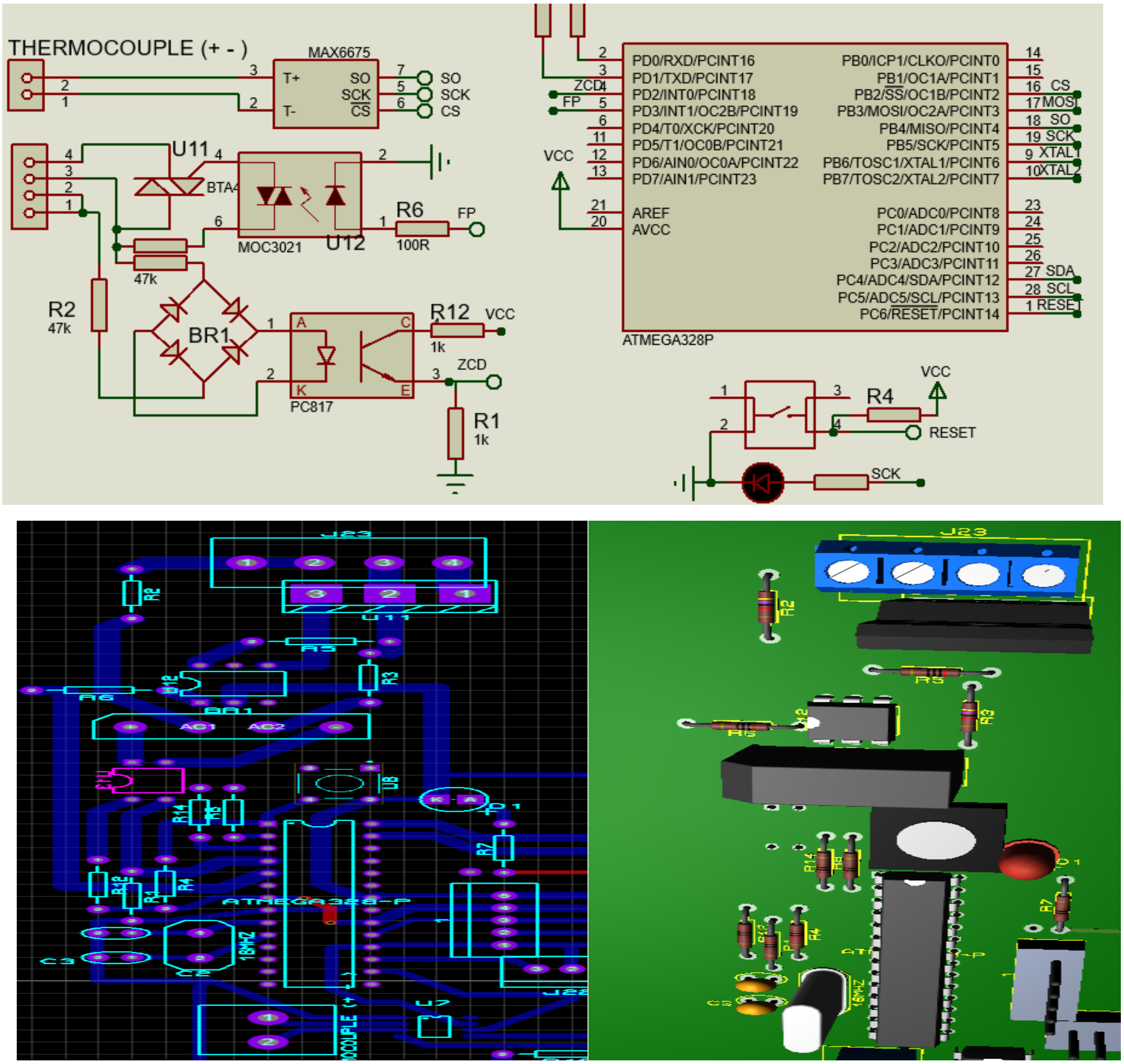


Figure 4-42: The temperature controlling unit: circuit diagram (upper), PCB print (left) 3D views (right)) (lower).

Environmental Factors*:* As explained in the previous chapter, environmental factors affect the process of steam sterilizers that include the environmental humidity, pressure, and temperature and those must be monitored. These environmental conditions are measured using the GY-BME/P280 sensor. Once the data is transferred to the microcontroller using the I2C communication protocol, the microcontroller calculates the altitude effect pressure compensation using the developed formula described in the previous chapter. Figure 4-43 shows the environmental condition sensor unit.

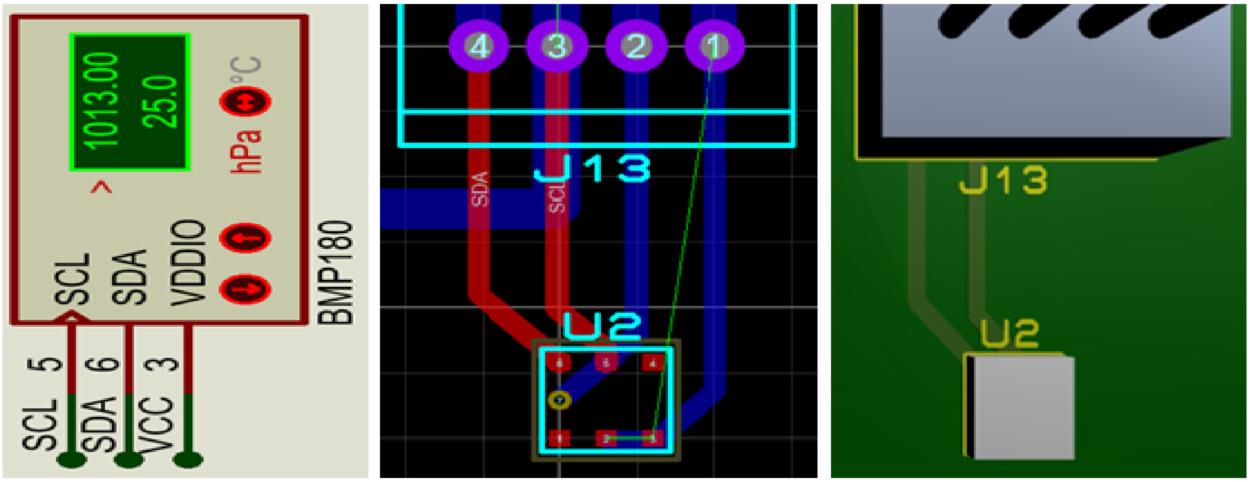


Figure 4-43: Environmental conditions sensor unit: circuit diagram (left), PCB print version (middle), and 3D view (right).

Chamber Pressure: The pressure inside the chamber is sensed using a 1.2Mpascal High Temperature pressure sensor and ones the data is captured by from the sensor, the microcontroller processes the data. If the pressure value is greater than the set value, then the microcontroller gives a command to the actuator (steam exhaust valve) to open through the PC817 optocoupler and 5V DC relay to energize the solenoid coil to open the steam exhaust valve. Through this mechanism, the pressure controlling unit controls/stabilizes the chamber pressure.

Timer: The heating time, sterilization time, cooling time or cycle, as well as the total sterilization time are mandatory information required for effective sterilization. In the current work, a DS1307 real-time clock (RTC) timer IC is used as it is the latest technology. DS1307 RTC counts milliseconds, seconds, minutes, hours, days, months, and years. It is also used as a watchdog to alarm users to service the machine. Figure 4-44 present timer control unit.

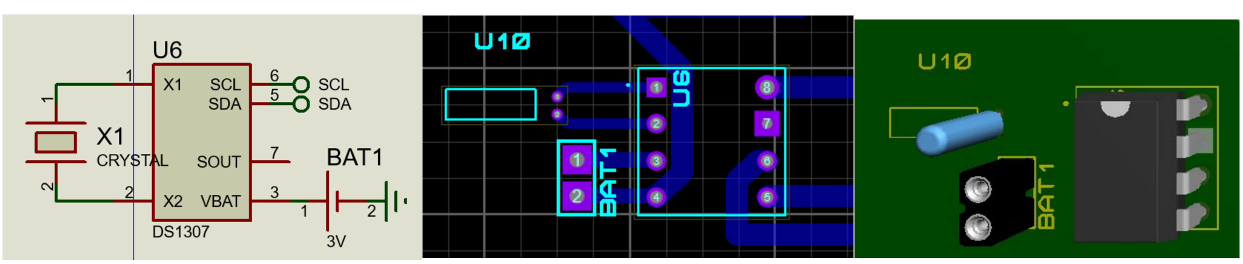


Figure 4-44: Time controlling unit: circuit diagram (left), PCB print version (middle), and 3D view (right).

4.1.2. Power Supply Design

There are two types of DC power supplies: linear and switching mode power supply. Linear mode power supply is the easiest and the simplest to design. However, it comes with high heat loss, large size, and low efficiency compared to switching mode power supply (SMPS). As we are designing only the control unit of the steam steriliser, which normally needs low current, the effect of heat loss, size and efficiency is assume to be not significant. Hence, in the current thesis work, we go for the easy and simple design option using the linear power supply type making it a low cost alternative. The main blocks of a linear power supply are step down transformer, rectification diode for AC to pulsating DC conversion, a capacitor for smoothing the pulsating DC and a regulator. Step-down transformer is an inductive electronic component that has primary and secondary coils with iron core. As its name implies, the application of this device is to step-down the 220V line AC voltage to 6V, 9V, 12V, 24V, etc AC voltages. In the current work, the transformer was used to step-down the 220 AC voltage to 6V, and 12 V AC voltages. There are three ways to use the rectification diode for AC to pulsating DC conversion. One is half wave rectification that uses one 1N4007 (or other general-purpose power rectifier diode) and only rectifies the positive wave (or the sine wave) above the baseline and it is less efficient. The other type, full wave rectification, is more efficient than the half-wave rectifier and uses two general-purpose power rectifier diodes (1N4007) and rectifies the two signs (the positive wave and the negative wave). The third type, bridge rectification, is the most efficient type of rectifier and uses four general purpose power rectifier diodes. We can also get a bridge rectifier in the form of an IC with different shapes: circular, square or rectangular shape and 4 pins with AC (phase), AC (neutral), and DC (+) and DC (-). Bridge rectifiers allow current outputs that range from small amps to high (as high as hundreds of amps).

Smoothing the pulsating DC helps to increase the efficiency of the DC output and to make it zero frequency which is performed using a polarized capacitor. The purpose of this filter capacitor is to smooth the current or to increase the output current.

The regulator helps to regulate the output to the load voltage and to get the needed constant voltage. One can use different types of regulators: Zener diode for low power, 78XX for medium positive power, and 79XX for medium negative power consumption electronic devices. For high current power supply, we have to add additional current regulator transistors together with the voltage regulator. Two popular high current transistors are 2N3055 Bipolar silicon NPN and

NTF3055 MOSFET. In the current work, we need 5V and 12V voltage and minimum current of 2500mA and a current booster was needed. For that purpose, a 2N3055 Bipolar silicon transistor was used to boost the current output.

Figure 4-45 presents a schematic of the linear power supply used in the current work while Figure 4-46 displays the PCB version including the component side, the soldering side as well the 3D view of the component side.

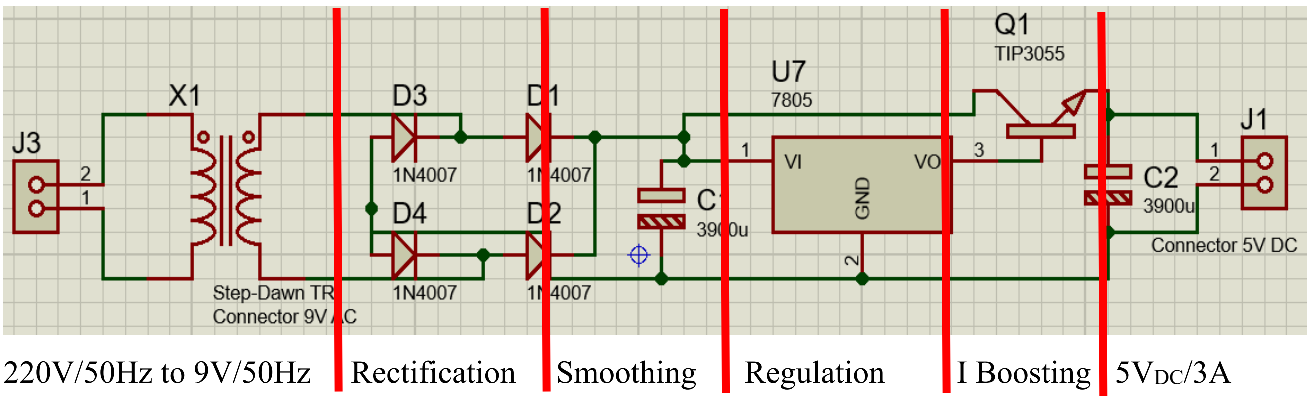


Figure 4-45: Schematic diagram of the power supply.

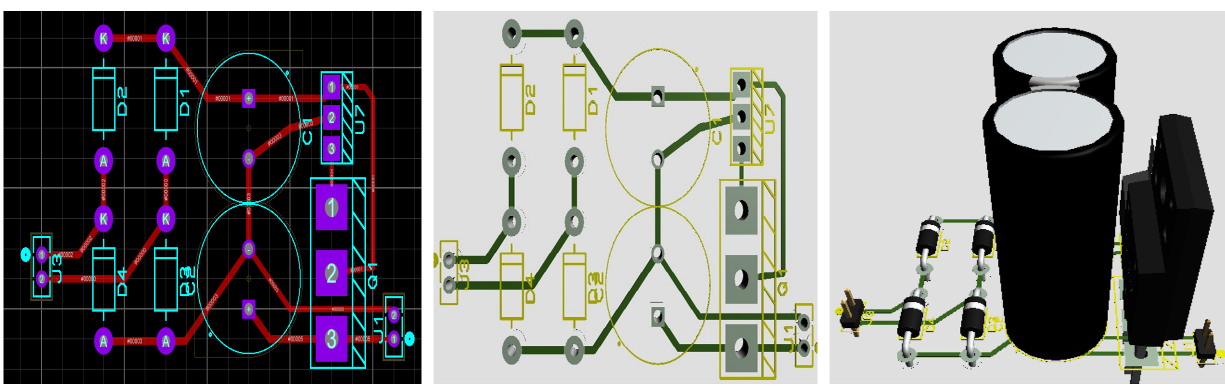


Figure 4-46: PCB of the power supply component side (left), soldering side (middle) and a 3D view of the component side (right).

4.1.3. Microcontroller (CPU)

The microcontroller is the brain of the smart steam sterilizer machine control board. The microcontroller gets inputs from different sensors and users via the GUI. It gets information from the different sensors and users, processes it using the algorithm embedded in it, and gives the command to the output.

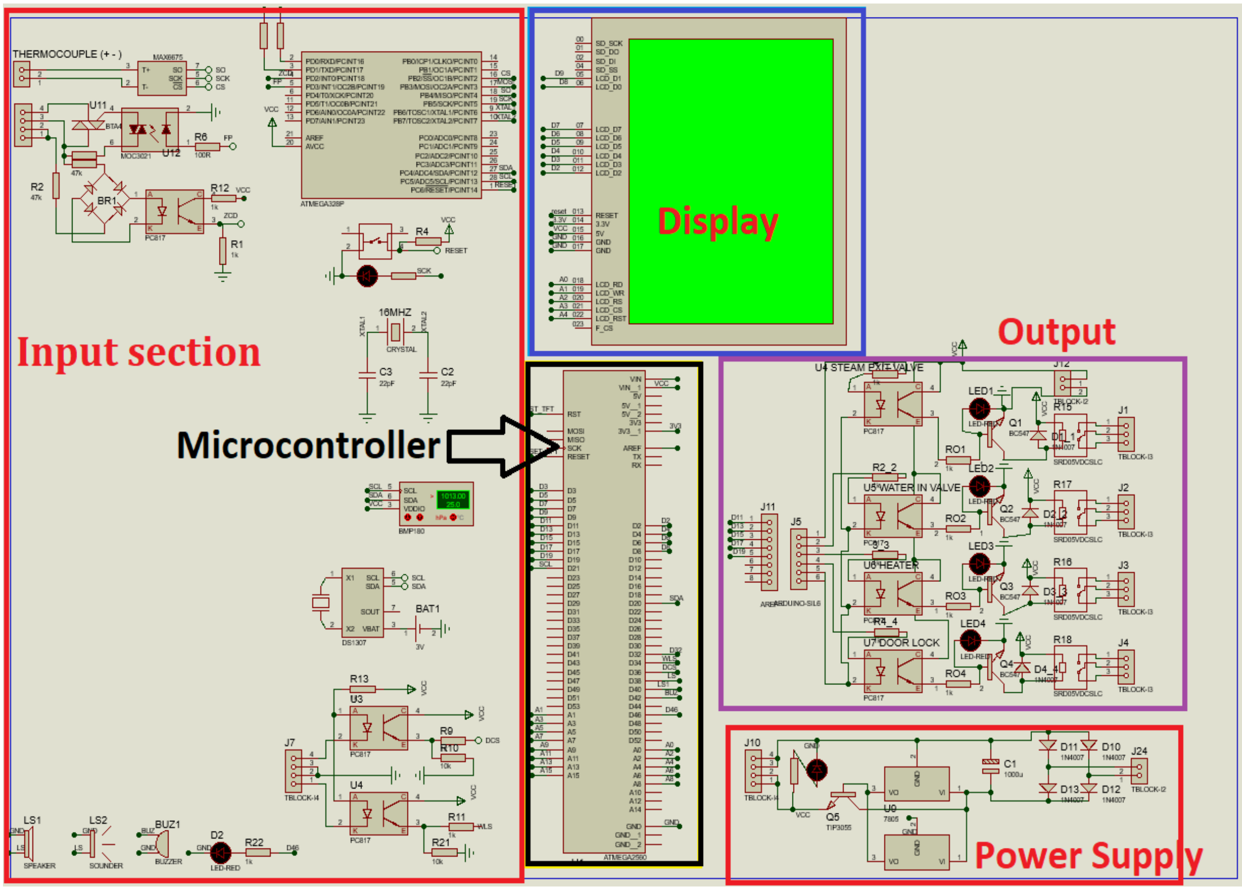


Figure 4-47*: Complete schematic diagram of the smart steam sterilizer system control unit.*

The output commands are used to control the actuators to control the physical parameters and cycles of the smart steam sterilizer machine. The microcontroller also triggers display of the output that could be in the form of an image, graph, alpha-numerical, or symbolically. The microcontroller also gives warnings to get the attention of the user. A complete schematic of the control system of the proposed smart sterilizer machine is shown in Figure 4-47. It includes four sections: input, processing, output and the power supply section. The complete PCB design is shown in Figure 4-48 where both the component side as well as the soldering side are displayed. The equivalent 3D views of the component side and soldering side are presented in Figure 4-49 and Figure 4-50.

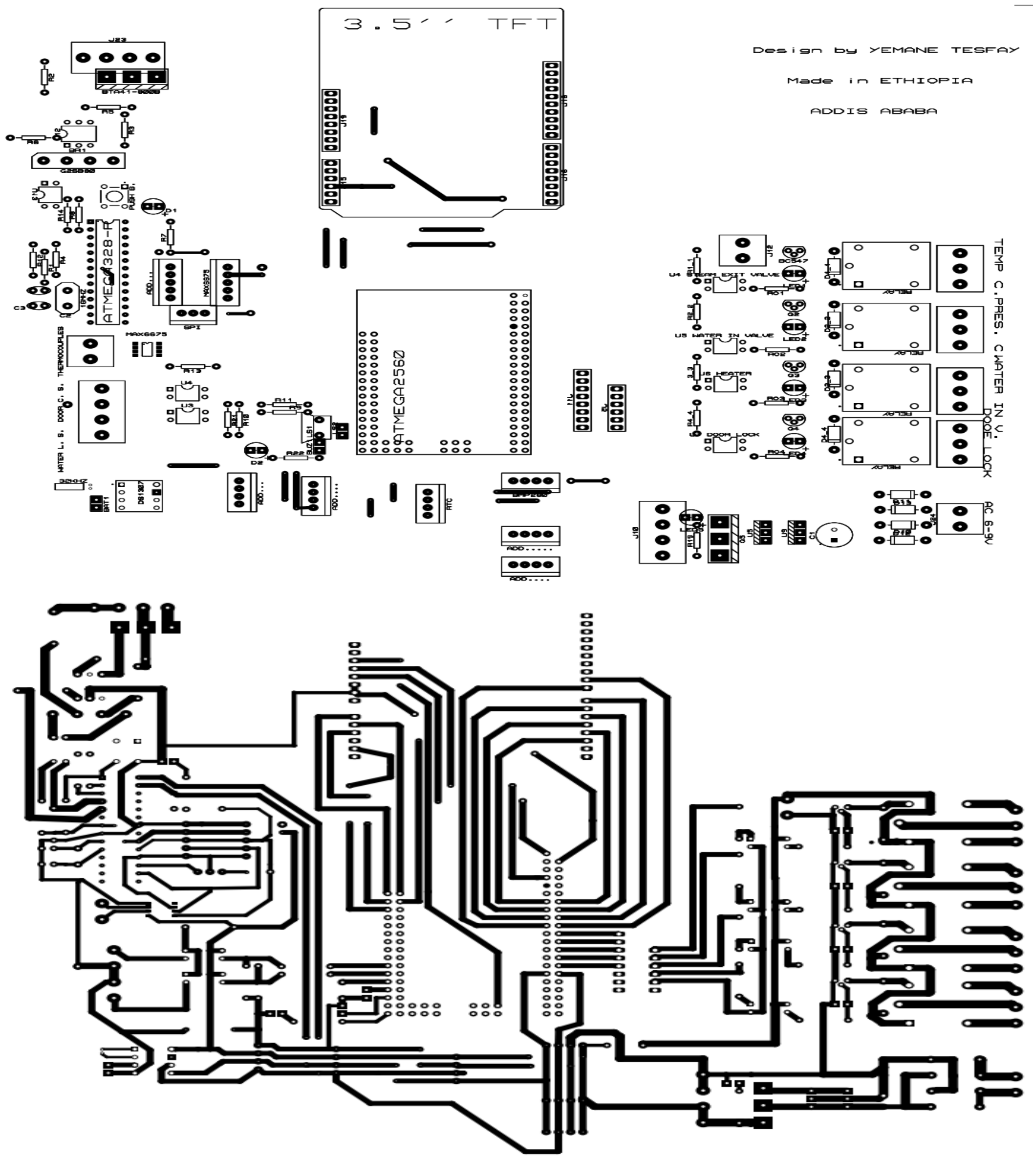


Figure 4-48: Complete PCB design of the smart steam sterilizer control unit: component side (top) and soldering side (bottom).

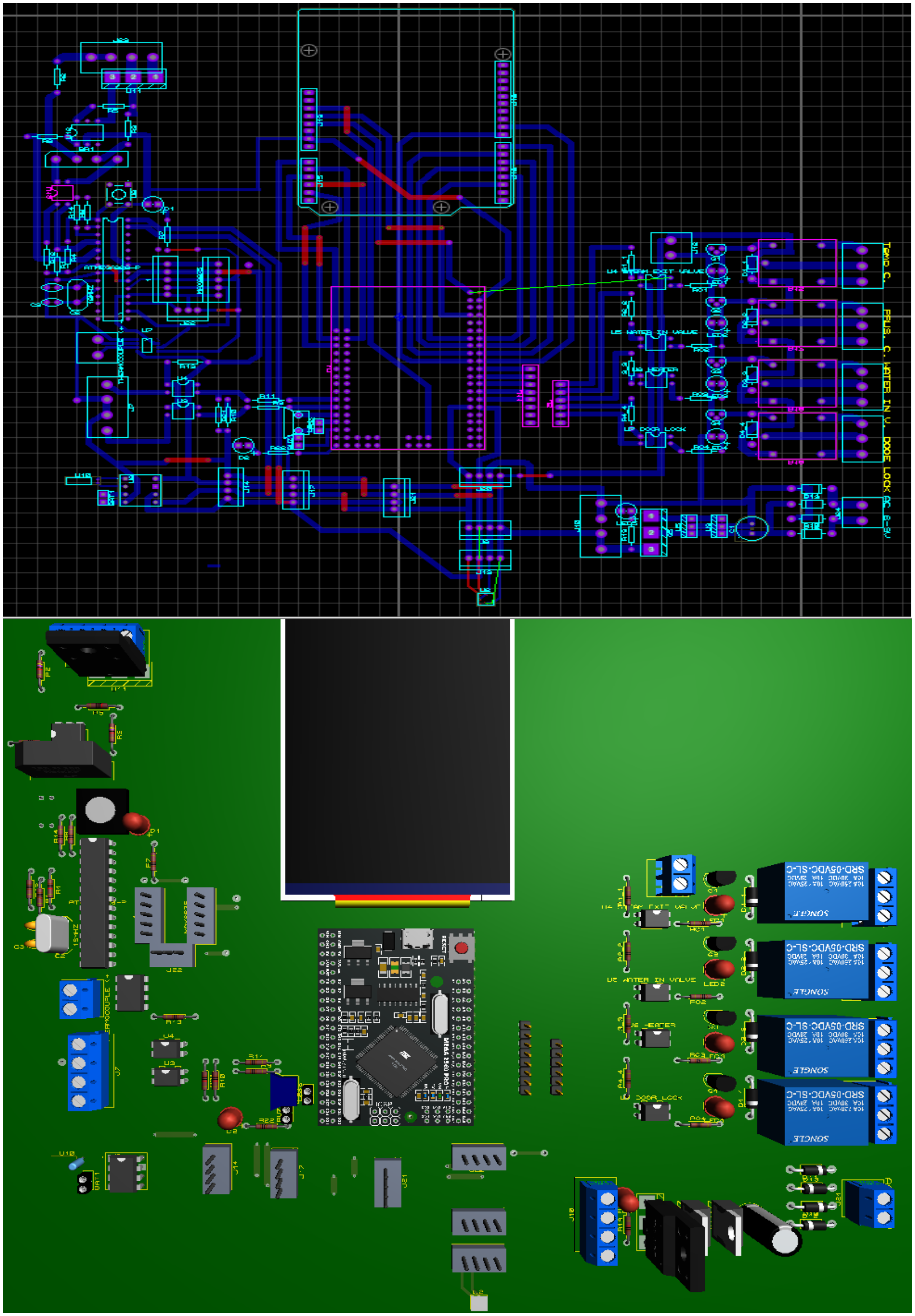


Figure 4-49: Control board of the smart steam sterilizer system: PCB layout (top) and 3D view (bottom).

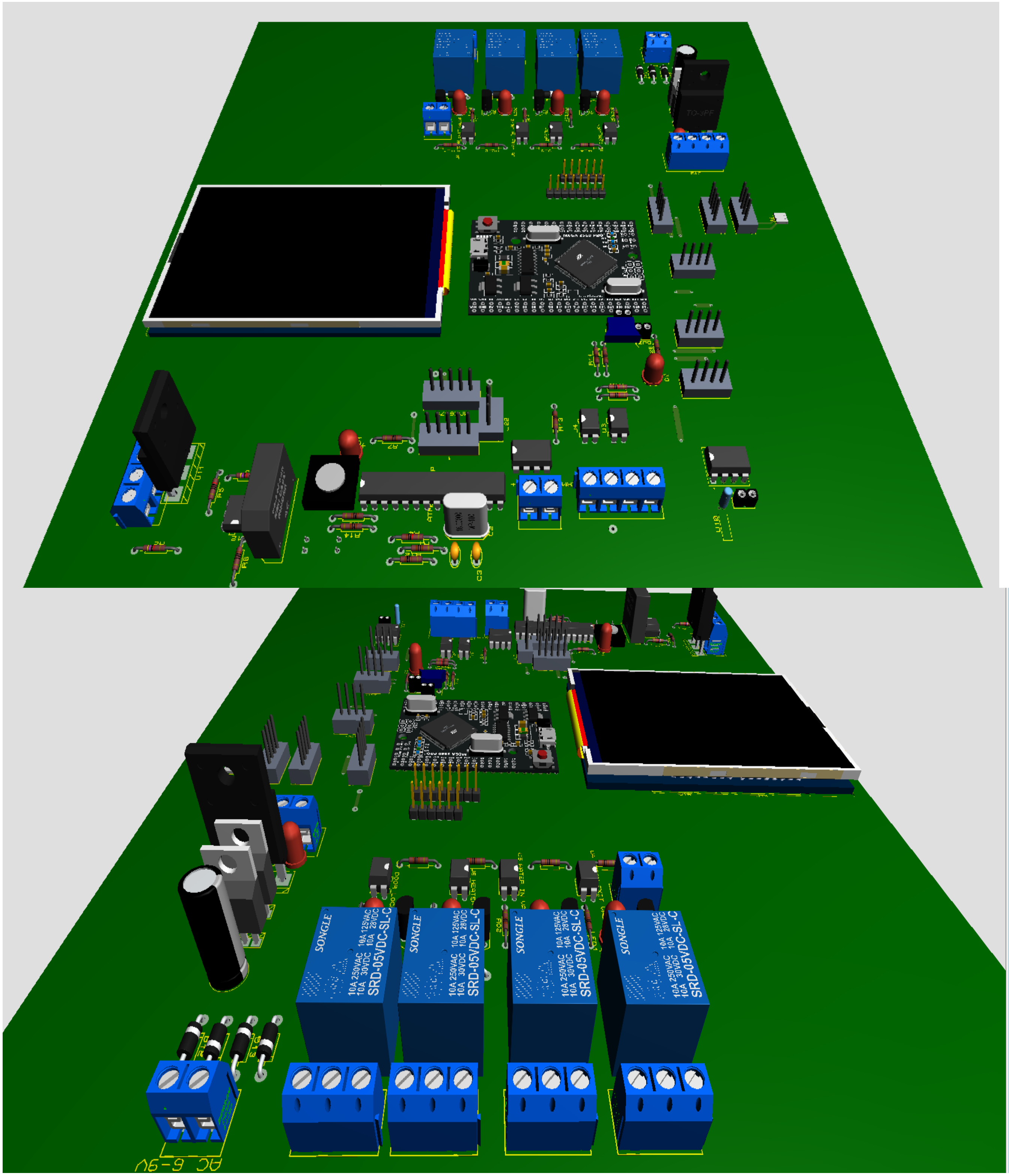


Figure 4-50: 3D view of the complete PCB design of the smart steam sterilizer control unit: front view (left) and rear view (right).

Testing and Calibration: The sterilizer is assumed to be calibrated at room temperature and sea levels. Standard calibration and testing procedures should be utilized to check the efficacy of the sterilization system.

4.2. Discussion

In countries like Ethiopia, where there is a diverse altitudinal landscape, medical devices should be designed in such a way that they can operate in different altitudes and conditions. The proposed steam sterilizer is designed in a way that it can operate in any altitude, and the heater ceases to run if the water source is hard water (EC > 50µS/cm). Instantaneous checking the water level inside the chamber allows better lifespan of the heating element there by reducing the total maintenance and operational cost. Cost reduction in low resource settings is preferred for an effective health care delivery system. In that sense, the proposed steam sterilizer would have a multiplicative effect. In order to achieve all those objectives of the study, keeping in mind that methods (block-diagram, flowchart, circuit diagram, PCB-print, assembly, and formula) have been developed.

4.2.1. Water Quality and Quantity of the Steam Sterilizer

As the steam generates from water, checking the water quality and quantity is mandatory to save the heater and the entire sterilization machine. Once getting the data of water quality and quantity from the electrical conductivity sensor, the water level sensor checks for the different scenarios. If the reading of the EC sensor is < 55nS/cm, the water quality is super ultra-pure or it is a no water scenario inside the chamber. If the reading is > 50µS/cm, the water is assumed hard and the heater should shut off by itself. If the sensor reading is in between 55nS/cm and 50µS/cm, the heater will be ON and the system is now running. The impression of introducing the water electrical conductivity sensor for the sterilizing system is well-thought-out.

4.2.2. Pressure Compensation (for Altitude Variations Effect)

One of the major aims of the study was reimbursement the pressure to set appropriate pressure with respect to the geographical location (Altitude) to minimize the environmental condition effect for the steam sterilization system, with appropriate temperature and time use for a proper sterilization (to meet SAL=10^{-6}). Ones getting environmental data from the

GY-BME/P280 air pressure, humidity, and temperature sensor module, the system smartly locates the altitude of the machine and solve the effect of environmental condition using the develop formula. This study demonstrated two basic functions with a typical sensor: one is to compensate the pressure in relation to the altitude and the other is to feed room temperature for the PID in order to set the minimum values of anti-windup. The idea of introducing the GY-BME/P280 environmental sensor for the sterilizing system was considered as a novel approach.

4.2.3. Temperature/Heater Control

The other objective of the study was to modify the existing controlling mechanism of the temperature (electrical heating element) with little modified minimum set value temperature (anti-windup) of the PID that gets the data from GY-BME/P280 to increase efficiency of the temperature control mechanism. There was no clear mechanism when the PID temperature control was used in previous studies. In the current study, the minimum set value of anti-windup of the PID is obtained via the GY-BME/P280 sensor. This gives more sense because of the use of proper power and protection of overheating of the sterilized medical devices due to the excellence of the PID (real minimum set value for the anti-windup).

4.2.4. Water Level Sensing

The third major objective of the study was controlling the amount of water inside the chamber to protect the electrical heating element from burnout by covering it with water (automatically re-filling if the heater is not covered with water). The results in the current study showed that if the water gets dropped, the power immediately gets cut off to save the heating element showing how robust the approach is compared to other traditional methods utilized in the area.

4.2.5. Additional Components

In addition of the above listed results, the study incorporated linear power supply (5V and $12V_{DC}$), door close micro-switch, solenoid valve (for water inlet, steam exhaust, water drainage and door lock). All these components can resist high heat, are corrosion free, environmental friendly and non-toxic.

Chapter 5: Conclusions and Future Directions

5.1. Conclusions

In this thesis work, the problem and effects of altitudinal variations on steam sterilizer machine are dealt with using the developed pressure compensation formula integrated with the system that allows auto-adjusting the pressure. The introduction of a modified proportional integral derivative (PID) based temperature control is meant to increase the efficiency of the system. Additionally, the water level sensor with auto water refill capability using a solenoid valve protects the electrical heating element from burnout. Most importantly the design addresses the level of water quality inside the steam steriliser for the wellbeing of the heater and the entire sterilization machine. In principle, the controlling board designed in the current thesis work can be integrated into any given steam sterilizer with little modification and setting re-adjustments.

5.2. Future Directions

Steam sterilizer machines have several other problems in addition to the problems mentioned in the current work. One is the limescale problem. Limescale is the hard off-white chalky (calcium carbonate $CaCO_3$) deposit found in hot water boilers (steam sterilizer machine chamber) which often damages the heating element and blocks the temperature and water level sensors as well as the tubes, and valves. Figure 5-51 presents a typical appearance a damaged heating element because of such deposition.

Figure 5-51*: Effect of chalky ($CaCO_3$) deposit on the heating element and tubes* [102].

Different options could be considered here to work around this issue: use of water softener, reverse osmosis, use of deionized water, use of distilled water, to mention few. Some of these methods are more expensive options than the others while some may not give adequate results. In this regard, a more effective and affordable solution could be sought. Nano technology based method, for example, could be one excellent candidate to work around the issue. Such is beyond the scope of the current study and its applicability would require much further studies.

A way to interface the proposed system with existing steam sterilizers shall be considered and total cost analysis shall be carried out. It is also expected the study will initiate more research to be carried out in the future with regards to sterilization technologies particularly for use in low resource settings.

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