



Regional Centre of Excellence in Biomedical Engineering and e-Health (CEBE)

**Design and Prototyping of a Real Time Condition
Monitoring System for Medical Equipment Maintenance
Management: Case study on Autoclave**

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A Dissertation Submitted to the Regional Centre of Excellence in Biomedical Engineering and e-Health (CEBE), University of Rwanda as partial fulfilment of the requirements for the Master's Degree in Biomedical Engineering.

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DECLARATION

I, Therese UWIRAGIYE, hereby declare that this dissertation entitled “Design and Prototyping of a Real Time Condition Monitoring System For Medical Equipment Maintenance management: Case study on autoclave” is my original work based on a simulation and prototype and has not been submitted for any other degree or professional qualification, except where work that has formed part of jointly-authored publications has been included.

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CERTIFICATE

This is to certify that the project entitled “**Design and Prototyping of a Real Time Condition Monitoring System For Medical Equipment Maintenance management: Case study on autoclave**” is a record of original work done by **Therese UWIARGIYE**.....

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ABSTRACT

Healthcare industry's key drivers are technological improvements, which have a significant impact on providing best patient care. In recent years, medical equipment used to support high-quality patient care has highly increased, however healthcare institutes have been facing a couple of unexpected troubles of medical equipment due to lack of proper preventive measures and maintenance on time leading to the use of equipment in improper condition and increased equipment downtime which can threaten people's lives and increase the maintenance cost. Therefore, to ensure that equipment is functioning on the required level of performance there is a need of a system that can detect early deviation in normal function of equipment to prevent failure or to detect a failure before it becomes worse beyond repair. In this research, a smart Healthcare technology management (HTM) approach was designed based on real time data acquisition, processing and notification of fault detection outcomes to ensure accurate and timely maintenance strategies. Demonstration of this study was achieved by analyzing medical autoclave's functionality from King Faisal, Ruhengeri referral hospital and Butaro district Hospitals. In this approach, IoT and sensor technology were utilized to monitor the condition of medical equipment, store collected data on the cloud and in case of abnormal condition, maintenance team received an alter through SMS, and the buzzer is used to alter operator of the machine. In addition, this system has a control relay, which will automatically shutdowns the pump when it is beyond the tolerance range to avoid increment in the fault severity. By reviewing maintenance records, features such as temperature, vibration and power consumption were selected as the parameters that reflect to the status of medical autoclave, with this approach traditional PM and CM maintenance were replaced by condition based maintenance decision making. As a result, maintenance based on condition of equipment strategy will assist in improving PM and CM mechanisms to reduce equipment downtime, unplanned shutdowns, maintenance cost and increase equipment reliability which leads to efficient lifecycle management of medical equipment and hence effective healthcare provision. This approach may be used on other equipment with the same characteristics to offer patients with relevant diagnoses. Moreover this system can be scalable and it is cost effective.

Keywords: Healthcare Technology Management (HTM), Medical equipment, Condition monitoring, fault detection, Maintenance, sensors and Internet of Things (IoT).

LIST OF ACRONYMS

ANN: Artificial Neural Network

CBM: Condition based maintenance

CEBE: Centre of excellence in biomedical engineering and e-health

CM: Corrective Maintenance

FMEA: Failure mode effect analysis

HAIs: Hospital-acquired infections

HTM: Health Technology Management

IoT: Internet of Things

GPRS: General Packet Radio Services

GSM: Global system for mobile communication

KFH: King Faisal hospital

LCD: Liquid crystal display

LED: Light Emitting Diode

MCU: Microcontroller Unit

MEMS: Micro-Electro-Mechanical Systems

MoH: Ministry of Health

PdM: Predictive Maintenance

PM: Preventive Maintenance

RUL: Remaining useful life

WHO: World Health Organization

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CHAPTER 1. GENERAL INTRODUCTION

1.1 Introduction

Health industry has been working to enhance its system in order to reduce hazards, increase operational efficiency, asset availability and reliability. The fourth industrial revolution catapulted the health sector in terms of offering healthcare services. Medical equipment is an essential tool of medical devices used for diagnosis, prevention and treatment of disease or for rehabilitation of patients, this equipment has a lifecycle that requires calibration, maintenance, training of users and decommissioning managed by clinical engineers [[1]. However, healthcare institutions have been facing a couple of unexpected troubles with medical equipment where equipment are not functioning on the required level of performance or they experience increased unplanned shutdowns and downtime due to the lack of proper preventive measures and maintenance strategy which is affecting the quality of care delivery as well as the life of equipment [2].

WHO declared that 25 to 50% of medical equipment in developing countries are out of order, raised challenges are the lack of effective maintenance and shortage of clinical engineers leading to mismanagement of medical equipment [3]. On the other hand, the Ministry of Health (MoH) in Rwanda has expressed concerns about poor equipment management in various evaluations and audit reports undertaken in different health facilities They stated “challenges in terms of equipment and infrastructure management have been observed” [4].

Medical equipment are increasing in number and complexity at rapid pace. In a hospital, the number of medical devices that need to be managed range from 1,000 for small hospitals to over 10,000 for large hospitals or medical centers[5].Complex equipment such as electromechanical equipment contains a variety of components that execute a set of functions. These components slowly degrade overtime before its complete failure, when these equipment are about to fail will results in the quality of product being degraded [6].

Patients and staff health may be affected through the microorganism present in the environment, this microorganism could enter the body in different way and cause infection. One way is through the use of instruments that are not properly sterilized, improper medical devices sterilization are the leading cause of hospital-acquired infections (HAIs) as consequence the

leading cause of socioeconomic burden and preventable diseases such as pandemic like COVID-19, virus such as HIV and can result in deaths, it is in that case hospitals are putting too much attention in sterilization process [7]. A medical autoclave is a complex equipment that uses high pressure steam to kill the germs present on instruments in process called sterilization. Autoclave has a sterilization chamber where instruments are placed and equipment such as steam generator and pump unit that produce required steam for sterilization. In developing countries 10% of hospitalized patients affected by HAIs, as compared to 7% in developed countries, the most common cause of these infections is the improper sterilization process of medical tools. To prevent hospital-acquired infection, it is essential to monitor autoclave functionality for ensuring proper sterilization [8].

Common used methods for medical equipment maintenance in Rwandan hospitals are preventive maintenance (PM) done regularly as per equipment manufacturer's recommendation[9] and corrective maintenance (CM) which is repair or replacement after failure has occurred. Internal structure of equipment such as pump can only be detected through their symptoms and their functionality can be affected by factors such as environment and usage rate which means that failures frequency may vary even on the same types of equipment and this can happen unexpectedly, therefore conventional PM and routine maintenance are sometimes counterproductive which makes them not suitable solutions [6]. To ensure efficient lifecycle of an equipment, it is critical that we plan for the resources needed for maintenance which requires both repair work and preventive maintenance to be arranged ahead of time [10].

Study by Khalaf [11] showed that PM has a significant effect on survival of equipment however he also revealed that it does not match with the failure frequency of equipment. In healthcare industry, maintenance based on conditions of equipment reduces equipment downtime from 14days to 4days, expand the lifetime of equipment by 20% and improve safety and quality by 14% [12]. Using condition monitoring tools can reduce the unplanned shutdown up to 50% as compared to run to fail strategy, reduces downtime and devices failure [13]. In addition, the use of IoT technology can assist in the generation of data; real time monitoring the health of the machine, controlling and maintenance decision for failure management and all can be done remotely [14].

This study proposes an innovative real time system for medical equipment condition monitoring. The system will monitor the most common potential failure signs such as temperature, vibration and power consumption of steam generators and pumps based on the best practices that will use sensing methods for data collection, microcontroller and IoT platform for data storage to enable remote access of data using the internet. In case of abnormality, the system will provide alert and notification to maintainers through GSM/GPRS module.

The main implication of this research is that it takes advantage of increased safety, availability and reliability, expand the life of equipment and reduce maintainer's effort, it also takes advantage of time and cost-saving, as well integration in advance fault detection and troubleshooting to improve quality of live. Innovation to this system is that without any modification on existing equipment data collected can reflect deviated temperature, vibration and power consumption on more than one component and moreover the component with specific fault can be located. System is compatible with already manufactured equipment, it is scalable and can be used with other equipment with the same characteristics.

1.2 Problem statement

A lack of a proper maintenance strategy can lead to poor equipment management and the lack of budget planning for maintenance as a result equipment not function properly, a lack of spares and equipment situation beyond repair [15]. Many healthcare facilities do not use a real-time automated system to monitor the safety of medical equipment. However, the program could assist medical practitioners in detecting any issue with medical equipment before using it in a hazardous environment [10]. Regular PM without full information on the equipment status lead into too frequent maintenance which results in parts being replaced when they are still usable or too infrequent maintenance which risks damaging equipment beyond repair[16]. The introduction of healthcare technology management that ensure equipment performance is on the required level should enhance the quality-of-service delivery [17], consequently this technology is not advanced from our local health sectors and hospitals. Maintenance management that is well-executed can result in significant cost savings, on the other hand poor medical equipment management results in equipment deterioration, financial loss [18] and premature expiration [19], increased downtime and unexpected shutdowns.

Medical devices, specifically medical equipment have gotten increasingly complex and sophisticated, and they are expected to work in harsh conditions. Healthcare institutions must ensure that vital medical equipment is safe, available and reliable, on the other hand there is a shortage of biomedical engineers when compared to the number of equipment utilized in hospitals. So there is a need for a smart solution to mitigate the issues.

1.3 Research Questions

1. What are the most common signs of potential failure on a medical autoclave?
2. Why is condition-based maintenance strategy not adoptable in Rwandan hospitals?
3. What should be considered in developing a user-friendly smart system to achieve efficient lifecycle management of medical equipment?

1.4 Objectives

1.4.1 General Objective

This study aims to design and prototype a real time condition monitoring system for managing the maintenance of medical equipment to ensure high performance of medical equipment and reduced maintenance cost for to support hospitals in the provision of high quality patient care.

1.4.2 Specific objectives

1. Event data collection on potential failures and maintenance actions for selection of equipment and potential key performance indicators and their impact on the system.
2. To review existing smart systems for medical condition monitoring.
3. Design and Simulation of a real time condition monitoring system.
4. System implementation and test the complete prototype in the laboratory.

1.5 Study Scope

This research was based on the use of IoT and sensor technology to detect medical equipment fault in advance through their shown symptoms and locates fault components. The temperature, vibration and the power consumption of the medical autoclave steam generator and pump were monitored. The scope of this study however did not include the prediction of the equipment to anticipate the remaining useful life (RUL) and the maintenance action to be taken.

1.6 Significance of the Study

Implementation of this system will contribute to the sustainable development goals of good health and well-being of the Rwandan population by providing information that assists clinical engineers in detecting issues with medical equipment to enhance the quality of service delivery, equipment reliability and reduced downtime.

The system will help hospital administrators and managers to redirect their attention to fit requirements and facilitate them in budget planning for maintenance: a road map to efficient lifecycle management of medical equipment. With effective maintenance strategy, resources will be redirected in the training of users and clinical engineers, in communication,

Data to be stored on the cloud can be used in the future research in predictive maintenance that estimate the remaining useful life hence to the next maintenance generation known as maintenance 4.0 which is the maintenance based on evidence.

Moreover, the proposed system may be used by major medical centers for equipment with the same characteristics to offer patients with relevant diagnoses. Additionally the system is scalable and is cost effective.

1.7 Organization

This chapter one introduced the research study, chapter two discusses the review of the related and identified the gaps. Chapter three presents the methodology and the system design applied in this research study and Chapter four presents the prototype simulation and implementation and lastly Chapter five outlines the conclusions, recommendations and future works.

1.8 Summary

This chapter presented an introduction to the study, from the problem statement it is evident that the current maintenance strategy have led to the degradation in equipment performance and unnecessary or counterproductive maintenance and thus the need for the study. On implementation of the system, the study will among other benefits contribute towards the attaining the sustainable development goals of good health and well-being of the population and reduced wastage of hospitals resources by providing real time information that assists clinical engineers in timely maintenance that reduce maintenance cost, downtime and unexpected shutdown and result in expanded equipment lifetime.

CHAPTER 2. LITERATURE REVIEW

This chapter discusses the overview of maintenance where the condition monitoring system is used as the main tool for fault detection, fault diagnosis and condition based maintenance. Moreover, industry 4.0 and internet of things (IoT) which enable smart systems was discussed and finally work related to the equipment condition monitoring and more specifically to the monitoring of autoclave condition was discussed to highlight the gap and needs.

2.1 Maintenance management in Healthcare and fourth industry

As medical equipment gets more advanced and plays a more important part in modern healthcare, maintenance and management difficulties become more important [18]. Poor maintenance, planning, and administration are the most common causes of medical equipment downtime. Clinical engineers must assess and enhance their management techniques on a regular basis to stay up with advancements in equipment technology and the growing expectations of health-care organizations [2]. Maintenance covers all range of activities that prevent the breakdown, reduce the failure occurrence, ensuring proper function and high productivity and extending the life of equipment to ensure the quality of service delivered. Maintenance management system incorporates three essential elements such as life cycle management, maintenance cycle management and spares parts cycle management all known as 3-cycle management. To ensure equipment life cycle management is achieved efficiently there is a need of condition monitoring of equipment to ensure effective maintenance decision, for maintenance cycle management requires to choose proper maintenance strategy which maintain hazard free equipment function and attain extended lifetime of equipment. It has been shown that 60% of devices failure are due to degeneration of consumable components and accessories, by ensuring on time spare ordering and proper procurement process we can avoid this consequences [20]. Figure 2.1 shows the three elements of maintenance management.

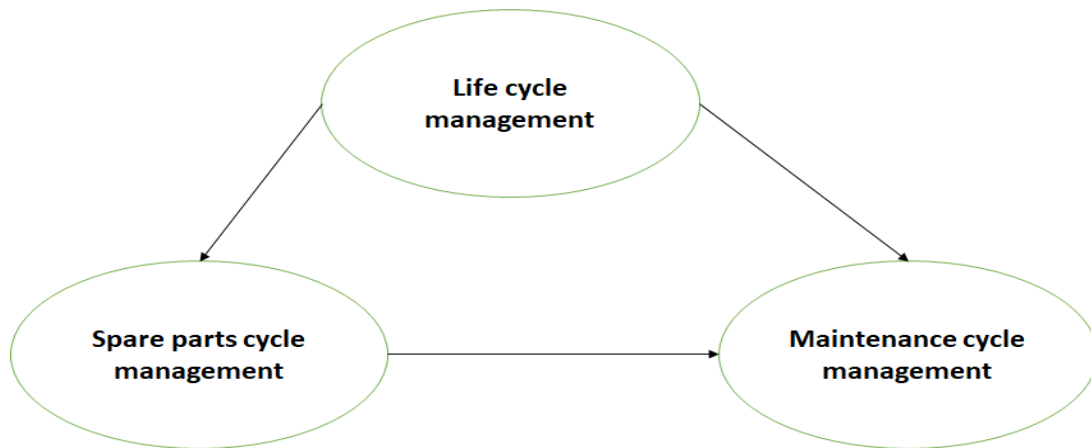


Figure 2. 1: Three element of maintenance management

With advance in technology and market need, rapid change in maintenance has been observed, maintenance that was reactive also known as corrective maintenance which is a repair or replacement done when equipment fail has changed to scheduled maintenance or time-based predictive maintenance, to condition based maintenance and currently to predictive maintenance also known as condition-based maintenance that anticipate the remaining useful life of equipment through the use of condition monitoring system. These changes are in order of complexity and efficiency and they are considered three maintenance policies, [12], [21]. Maintenance has a great effect on the lifecycle of equipment and on patient health. However, it can be concluded that preventive maintenance based on time as the most maintenance strategies implemented in healthcare organization reduces the failure occurrence but does not prevent breakdowns, also over maintenance can be lead to the equipment failure[22]. Figure 2.2 shows maintenance evolution.

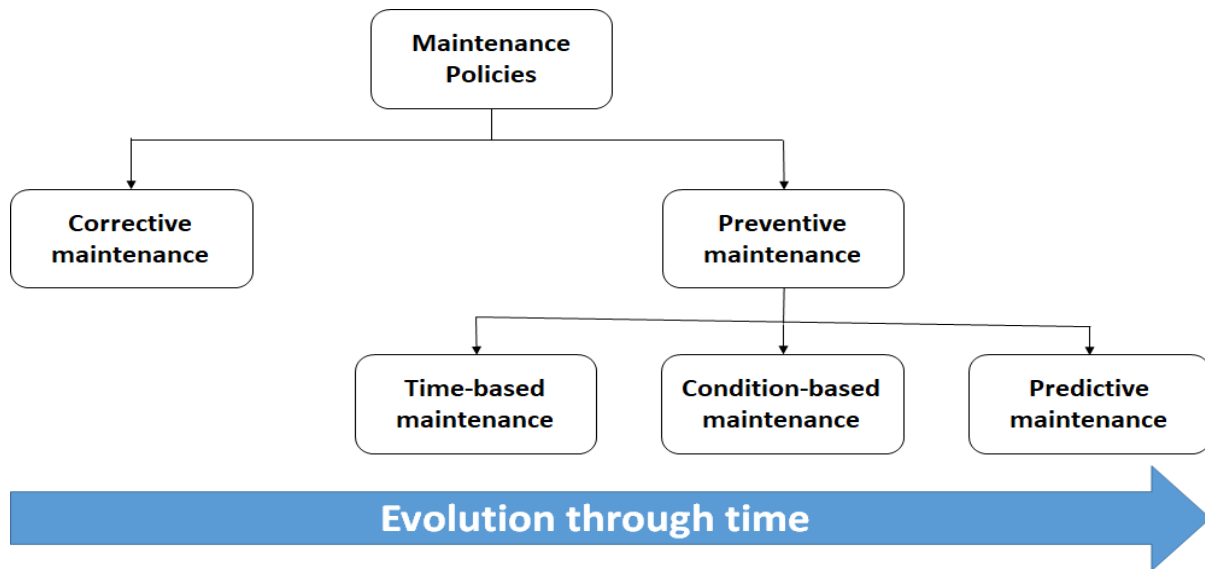


Figure 2. 2: Maintenance evolution

One use of industrial 4.0 technology is their application in Maintenance 4.0. Maintenance 4.0 refers to the next maintenance generation that enables manufacturing to remove unplanned downtime, reduce planned downtime, and improve people safety, extending useful life of an equipment that leads to manufacturing sustainability goals. Industrial 4.0 incorporates different technologies such as Internet of things, wireless sensor network and embedded technology. [23].

2.2 Medical equipment and critical components selection

In a hospital, the number of medical devices that need to be tracked and managed can range from 1,000 for small community hospitals to over 10,000 for large teaching hospitals, medical centers, and referral hospitals; their proper management is important [5].

Prognosis is defined as the process of determining equipment reliability through evaluation of its deviation or degradation from its intended operation condition, however due to the lack of sufficient data this method is facing challenges [24]. Different studies were conducted to generate data needed to define equipment deviation from its expected operation, work conducted by Wang et al. [25] provided a solution by generating digital twin data of an autoclave based on its geometry, physics, behavior and rules. However this method provides data in fault condition and still requires real data from equipment to detect system deviation to overcome these challenges continuous condition monitoring is needed [26].

Medical autoclave equipment is the equipment used for infection control in healthcare organization, the failure to its functionality or degradation to its performance can lead to the transmission of infection, hence the need for hospitals to ensure its proper function. Steam generator and pump unit are the two critical components of the autoclave machine considered in this study. Steam generator has water tank and heaters, heaters play a key role in sterilization process, heat is delivered to water through heaters in order to get high temperature/ saturated steam required (usually 121°C for 5minutes or 134°C for 3minutes) in autoclave chamber, when heater is used for longtime its resistance wire starts to increase, when wire resistance increase the overall thermal power of the component decrease which result in the decrease of the heating rate of autoclave and affect the overall temperature in sterilization chamber [25]. Another critical component of autoclave is a pump unit, the pump itself, motors, valves and other components compose a pump unit. In autoclave we have two types of centrifugal pumps, one called water pump used to supply water to steam generator and another called vacuum pump used to pull out the air from sterilization chamber to keep a vacuum condition inside the chamber, fail to this results in growth of micro-organism inside the chamber hence fail to sterilization process. For proper functionality, pump condition must be monitored, the most common known failure symptoms of this component are bearing failure, misalignment and other failures from motors and affect the normal working temperature and vibration of the pump and lead to pump deterioration and reduction in its life expectancy [27]. Factors influencing this failure include the, frequency of use, working environment(working voltage beyond designed voltage range) and the maintenance strategy used [28].

2.2.1 Factors associated with the failure of sterilization

In developing countries 10% of hospitalized patients affected by HAIs, as compared to 7% in developed countries, the most common cause of these infections is the improper sterilization process of medical tools. Autoclave the most used equipment for medical devices sterilization using high temperature saturated steam has shown high rate of failure in healthcare institutions in developing countries, which indicates high risk of transmitting communicable diseases through reusable medical devices [8]. Factors associated with sterilization failure include power failure, operation error, inadequate knowledge high frequency of sterilization per day, improper maintenance and equipment failure in general. Hence, the urgent need for autoclave performance monitoring as well as proper maintenance strategy to ensure proper functioning [29].

2.3 Condition monitoring and Fault diagnosis

This part gives the overview of the condition monitoring, fault detection and diagnosis and integration of an IoT technology to comply with advanced technology to optimize maintenance for quality improvement [30]. Figure 2.3 shows the schematic of a condition monitoring process.

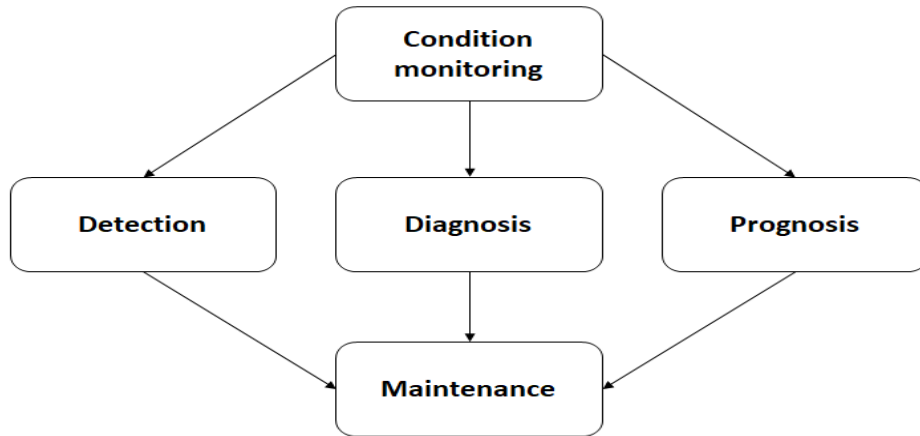


Figure 2. 3: Condition monitoring process

2.3.1 Fault detection and Diagnosis

Generally, malfunction of a system or equipment components happens that include hardware or software fault. The impact of it can run the entire range from easily fixed with minimal losses to catastrophic or beyond repair depending on different factors such as the costs of maintenance, downtime, condition and safety implications, and the impact on production and delivery of services. There are several common reasons equipment failure can happen. Understanding each one, and how to prevent them, is your first line of defense against the serious consequences of unplanned downtime. Fault diagnosis is the approach to identify asset status from its symptoms to identify the cause and effects that include acknowledgement of the presence of fault and identifying the location of fault. Fault diagnosis is normally used in health monitoring, fault detection and analysis during its lifetime [31]. On time and efficient treatment of malfunction result in downtime reduction, operational safety, and increased production are the top advantage of fault detection and diagnosis. To design a fault detection and diagnosis system requires prior knowledge on the structure and configuration of the system, data acquisition and signal processing, fault classification and maintenance decision actions which requires to undergo four stages of fault detection, fault identification, fault severity assessment, fault growth and

remaining useful life (RUL)[32]. Fault detection system needs to include sensors such as current, voltage, temperature, pressure, position, force, vibration and power consumption.

2.3.2 Internet of Things in Condition monitoring

Condition monitoring is the art of observing the state of the system and be able to act when it is necessary, this result in elimination of under and over preventive maintenance and unplanned down time of equipment which increase the performance of an asset as the specific advantage of condition monitoring. Condition monitoring is a tool of condition based maintenance, condition based maintenance is based on the real-time data to decision maintenance priority and action, this approach was introduced as motivation to address the issue of the time and industry resources wasted when following the time based maintenance recommended by manufacturers. Condition-based maintenance enables equipment degeneration identification before breakdown, which has an advantage of reducing breakdown in equipment and increasing its available resulting in quality improvement [33].

In IoT, smart system refers to the ability of a system to connect to the real world without intervention of human; it has sensors and connectivity for sharing information. Those systems works as a maintenance tool that facilitate monitoring, analysis and implementation in the maintenance process. Condition monitoring system considers data collection, data processing and decision-making. IoT support in sending collected data to enable remote and continuous monitoring, this provides the ability for continuous monitoring of equipment health status and thus reflect to the cost, performance and equipment's lifetime which will improve the quality of industry and patients' satisfaction levels[34].

Based on the IoT, The system monitors the coal equipment and take maintenance decision accordingly. The system is composed with sensor nodes to sense the change in temperature, pressure and detect the noise in the system, coal monitoring center was able to receive the collected data through wireless network or cable and stored on database after analysis, the stored data help the maintenance team in the evaluation and decision making for the maintenance action which would be possible without internet of things cloud based system [35].

2.3.3 Condition monitoring for maintenance decision

This part discusses the most recent works on condition monitoring that considered the current technology of condition monitoring tool that analyzed data collected from equipment functionality for deciding on optimal maintenance strategies as related to the study.

The most common tool of condition monitoring are vibration monitoring, temperature, current, pressure, acoustic emission, oil level monitoring.

Vibration analysis is the most common tool used to detect, identify and prevent the failure of the rotating machine; it assists in the indication of unwanted motion and dynamic stress exerted on the machine, which may result in the fatigue, energy loss, noise production and reduction in performance. Change in vibration are due to mechanical disturbances or electromagnetic forces from various source of an equipment such as engine and sound. It has been found that 90% of undesired vibration are due to misalignment and unbalance, other source of that vibration include wear and tear, looseness and ageing of the equipment parts. To avoid human loss, reduce risk of failure and improving quality control we need to control vibration of a rotating machine [33]. Detection of equipment motion in vibration monitoring is achieved through displacement, velocity and acceleration parameters. The sensitivity of sensors used for measuring these parameters varies with the frequency of the vibration. Velocity sensors are sensitive to later vibration and their frequency range varies from 10Hz to 1KHz, these sensors has large output signal, negligible maintenance and has strong anti-interference ability but they are prone to susceptible shock, relatively complex and large structure on the other hand accelerometer sensor has advantage of light weight, compactness, high frequency range, high sensitivity and resist damage due to shock and vibration [31].

In [33], a vibration monitoring system for condition-based maintenance of a lathe machine was designed, the system has 4 vibration sensors that monitor vibration of lathe machine in 3-axis, collected data are transferred to computer via serial interface and displayed on LCD. The system has the capacity to switch off itself when the monitored vibration amplitude exceed the tolerable limit. This system has the novelty of enabling the use of machine only in the recommended limit, however the system evaluation is limited to the physical distance it is not taking the advantage of IoT technology for remote controlling.

Another IoT based smart vibration monitoring system for motors was developed [36], this system has three parts, sensing, processing and transmission parts. Sensing part which uses MEMS accelerometer for detecting change in vibration, in processing part microcontroller known as LPC1768 was used. The last part uses the ESP8266 Wi-Fi module for receiving data from the sensor to be transmitted through Wi-Fi. This smart system is light in weight, can transmit data and is based on low power consumption, however due to the limitation of internet in Rwanda as well in African settings, in case of emergency information such as urgent need of repair may be missed when the person in charge is in the area where internet is not enough or may be when he is out of internet bundle because the system is only based on Wi-Fi communication, therefore this system is not suitable use in Rwanda. The same scenario is applied [37], except that this work included an edge and fog computing layer for processing data before sending them to cloud via Thingspeak, this result minimizes the redundancy and amount of data being sent.

In [38], a generalized system for monitoring vibration of a rotating machine was designed, the design incorporate the use of Adxl335 tri-axial accelerometer for vibration measurement, the collected data are processed by Node MCU and transmitted on the Thingspeak via a ESP8266 Wi-Fi module and data from Thingspeak are analyzed using MATLAB. The system design did not consider any equipment structure and configuration, which differ from on equipment to another. Another system was designed for monitoring condition of an industrial motor[39]. system contains LM 135 temperature sensor which has operating temperature of +55°C to 150°C, adxl335 vibration sensor and ACS712 current sensor and use Arduino Uno for processing data and ESP8266 Wi-Fi module, however the system use Thingspeak as an IoT platform for data visualization, although Thingspeak is an open source it has the limitation of amount of data to be stored which can limit the needed information from the system.

To detect the deviation in normal functionality of an electric motor, current and voltage parameters were monitored and power consumption was calculated[40]. The design hardware was composed by ACS711 current sensor, reference transformer for voltage measurement, ARM NXP LPC1769 cortex-M3 processor for data processing, a 802.11.bg Wi-Fi module for data transmission and use 9V power supply as the power source for the system, Wi-Fi module

consume high power and is limited to the short covering area, also the use of battery requires additional money when battery life is expired.

2.3.4 Condition monitoring for medical autoclave

This part discusses the most recent works on an autoclave condition monitoring that are related to the study.

To ensure the steam quality in the sterilization process, some studies were done. The work of authors [41] monitored the performance of the autoclave machine, the system used 13 temperature sensors and 1 pressure sensor to collect temperature and pressure data in sterilization chamber during the process, those data were used to train the neural network, Artificial Neural Network (ANN) back projection algorithm was used to predict fault signs of autoclave based on the past and current information monitored by autoclave, to decide whether an autoclave is healthy or unhealthy, the output pressure values are compared with the real value of the machine at the time of process, when they match then it is concluded that the system is healthy otherwise the system is considered unhealthy. Developed systems considered an autoclave chamber for monitoring the sterilization process but did not consider autoclave components that produce the steam used in sterilization. The same research was done by Gonzalez-Palacio et al [42], study focused on the quality of the steam instead of the parts of the autoclave that produce that steam, except that to measure the quality of the steam thermodynamic is applied, sample in a container is taken through pipeline and use two resistance temperature detectors and one BME280 barometer pressure sensor to measure temperature and pressure respectively of the steam sample. Received data are processed by Raspberry Pi and transmitted on the cloud and to the monitor to be accessed remotely.

In the application of monitoring system for components health status, a real time monitoring system for motors was proposed [43], the system used piezoelectric sensor for vibration and thermistor for temperature to detect fault in induction motor, to process the sensed data in meaningful manner Waspmote IDE pro board was used. Received data were stored in local storage such as on SD card and on the cloud via cloud platform, which were accessed via the internet for further analysis. Furthermore, the system has the ability to send notification to the user when a deviation in normal operation is detected through the GPRS system. Operation cost will be increased due to the need to recharge the battery used to power the system, in a proposed work; 5V power supply will be used to reduce system operation cost.

Niyonambaza et al.[44] has developed a prediction maintenance structure that estimate the failure in autoclave's components such as pumps and steam generator using Long Short Term Memory Neural Network model that was trained using temperature data collected by NTC sensors mounted on these components, cloud for data storage and GSM module for alert in case of abnormality, this work has considered temperatures parameter as an indication of failure in autoclave's components. Another predictive structure for mechanical equipment was implement on the purpose to compare TinyLSTM and TinyModel from edge impulse[45], the system collected, temperature, vibration and the current of one component of sterilization equipment and send the collected data to virtual data base to be used in the calculation of remaining useful of that equipment. Their concluded that edge impulse is easy to develop and deployed.

2.4 Summary

To ensure the good condition of a medical autoclave machine, efforts have been put into developing a system that monitors the condition of medical autoclave based on the Internet of Things (IoT) technology. However as far as I know, there is no solution that focus on the critical components of autoclave as the parts that play a key role in controlling infection considering that more than one operation parameter can be the cause of failure on one component, for instance deviation in temperature or vibration of pump and as well considering the effect of more than one equipment for instance heater and pump in steam agent production and be able to enable the user to only use equipment in recommended condition by incorporating a control system that can ensure the use of equipment when it is required performance level . Ensuring that the results are shared using IoT platform and accessible through mobile phone to minimize the risk of missing important notification and being stacked by the poor access to the internet which is the case in Rwanda is an additional advantage of this study.

CHAPTER 3. RESEARCH METHODOLOGY

This chapter describes the selected methods and approaches used to conduct the study. This includes the steps undertaken to complete the study, the system design methodology and tools used in data collection, and prototyping of the proposed solution.

3.1 Research Process

3.1.1 System development methods

This research study was consisted by six main phases to be followed in order of complete this study. This software was selected based on their advantage of facilitating the developer to understand the requirement, evaluate the performance level and it is easy and fasten the process. In his approach the output of one step being the input in the next step. With this approach one step has to be completed before moving to the next step until the process is completed. Figure 3.1 shows the step of methodological approach used to develop a condition monitoring system.

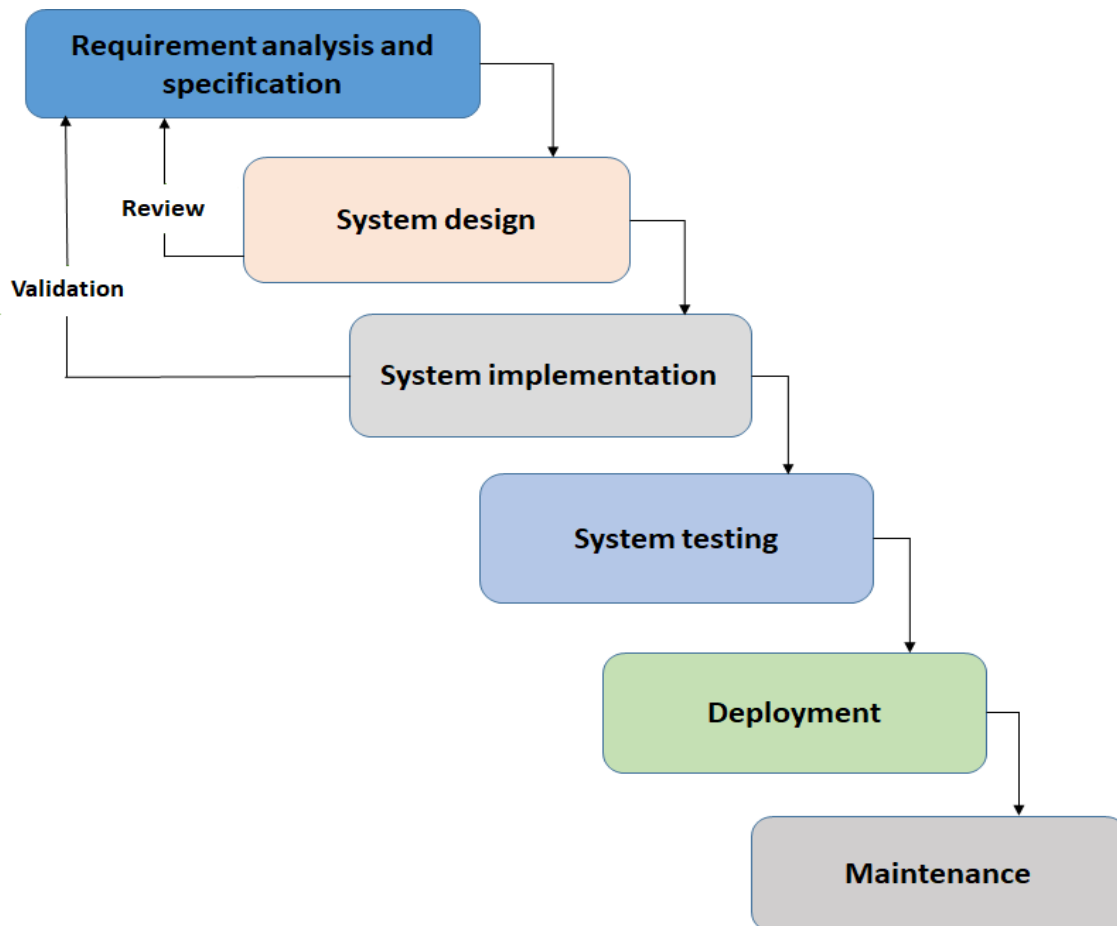


Figure 3. 1: Prototype model

Step 1: Requirement analysis and specification

This first step needs to understand the system functionality and what the user need out from the system to be developed and what the project team should consider to achieve the goal.

Step 2: Design and simulation

The researchers developed the system-level design including the system architecture, block diagram, use case diagram, simulation setup, and prototype design and dashboard for data visualization based on the information collected in the requirement stage, This consist of logic design that does not consider any hardware components and the physical design that consider hardware components.

Step 3: System implementation

In this stage the code to run and control the simulation and the prototype is written, this stage consider the requirement analysis, specification and the code application. This stage is started only once the design stage is reviewed and accepted considering the requirement.

Step 4: System Testing

After the system implementation, the next step is to test the system to ensure user requirements and criteria fulfillment. In our case, it incorporates prototype and dashboard testing.

Step 5: System Deployment

This stage consider installation of the developed system in the user environment. This will be done in the future.

Step 6: Maintenance

Maintenance stage ensure the proper functionality of the prototyped system and the defect fixation once it occur. This part will be considered in the future study.

3.1.2 Data collection

Given the interest in designing a real time system that can monitor the health of medical equipment to improve the quality of service delivered and extent the life of equipment, this study included three hospitals, King Faisal hospital (a teaching hospital), Ruhengeri Referral hospital and Butaro district hospital. The study employed a mixed methods approach.

A. Interview

A qualitative questionnaire was asked to hospital technicians and nurses at each of the participating hospitals. The researcher arranged the visit with each of the hospital technicians in advance. An introductory script and interview protocol was used to guide the discussion between

the interviewer and the interviewee. The interviewer sought verbal consent from the interviewee prior to the start of the interview and the interviews took 15 minutes to complete.

B. Observation

With observation data gathered by watching events, physical characteristics or behaviors in a natural setting.

C. Maintenance log review

In this step, a review on maintenance historical data and failure related information, a literature review which stand on previous research made for monitoring and main other technics for maintaining the safety of medical equipment and maintainers' expertise from King Faisal and Ruhengeri referral hospitals were used. Based on the information in the above sub step, equipment was selected based on the negative impact on the quality of service delivered and the impact on the business performance when equipment fail without warning this was achieved by considering equipment failure occurrence, usage, and equipment importance. Based on those criteria medical autoclave was selected as a case study and the assessment on the equipment health from its symptoms to determine the root cause and their effects on the functionality of the equipment and the action done by maintenance team to fix the defect.

D. Medical autoclave as a case study

After having determining the symptoms, root cause and their effect, we identify optimal maintenance strategy to be performed and the equipment physical performance condition parameters to be monitored. The selected parameter to be monitored was linked to the specific failure mode. At this stage, we considered condition-monitoring system as the effective tool for implementing condition based maintenance strategy and considered temperature, vibration and power consumption as the needed feature for early fault detection.

D. Data analysis

Content analysis was done based on the study objectives. Based on the maintenance log with the technicians expertise, answer from the interview and the review done on the existing system we came up with the main cause and effect of autoclave failure and the requirement to develop a flexible and affordable system that will ensure the proper functionality of autoclave.

3.2 Research Design Method

After getting required information of the needed system, component were selected and circuit was designed in proteus simulator, this part discusses the block diagram of the designed system,

the hardware components and the software tools, the flowchart, the functional and non-functional requirement used in the study.

3.2.1 System design

The system is composed by three layers, perception layer composed by sensing and processing parts, network layer that is in charge of transmitting collected data to the cloud and application layer where users access the system for report writing and decision making on maintenance optimization resources. Figure 3.3 shows the architecture of an IoT architecture used in the condition monitoring of medical equipment.

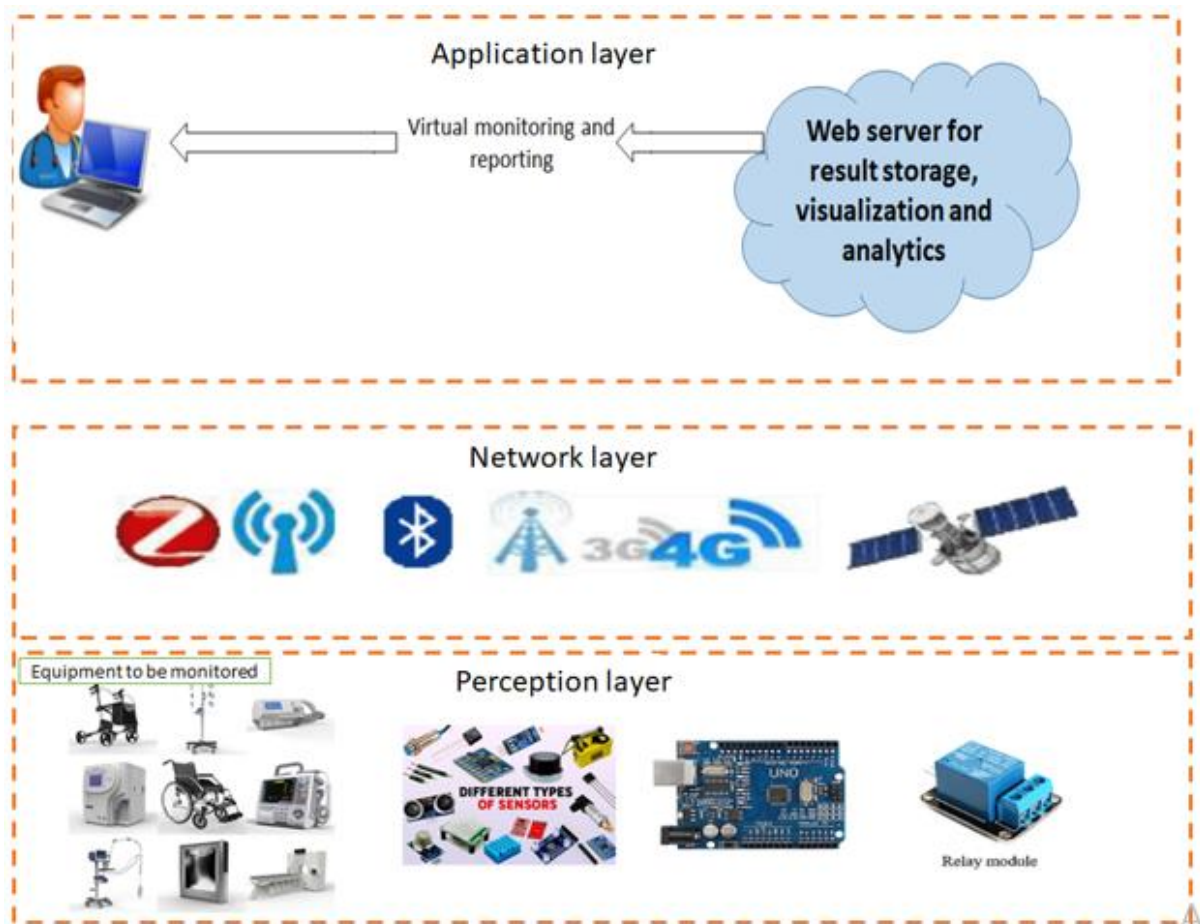


Figure 3. 2: System architecture

3.2.2 Embedded system block diagram

This system consists of two NTC thermistor sensors for detecting temperature, ADXL335 tri-axial accelerometer sensor for detecting vibration and ACS712 sensor for measuring current. The input parameters were processed by microcontroller and sent to the cloud via GSM/GPRS module for storage. Liquid crystal display (LCD) is used on the user side to monitor collected

parameters and the Relay for system self-switch off in case of non-tolerable working condition. The system is supplied by 5V power supply. Figure 3.4 shows the block diagram of the proposed solution.

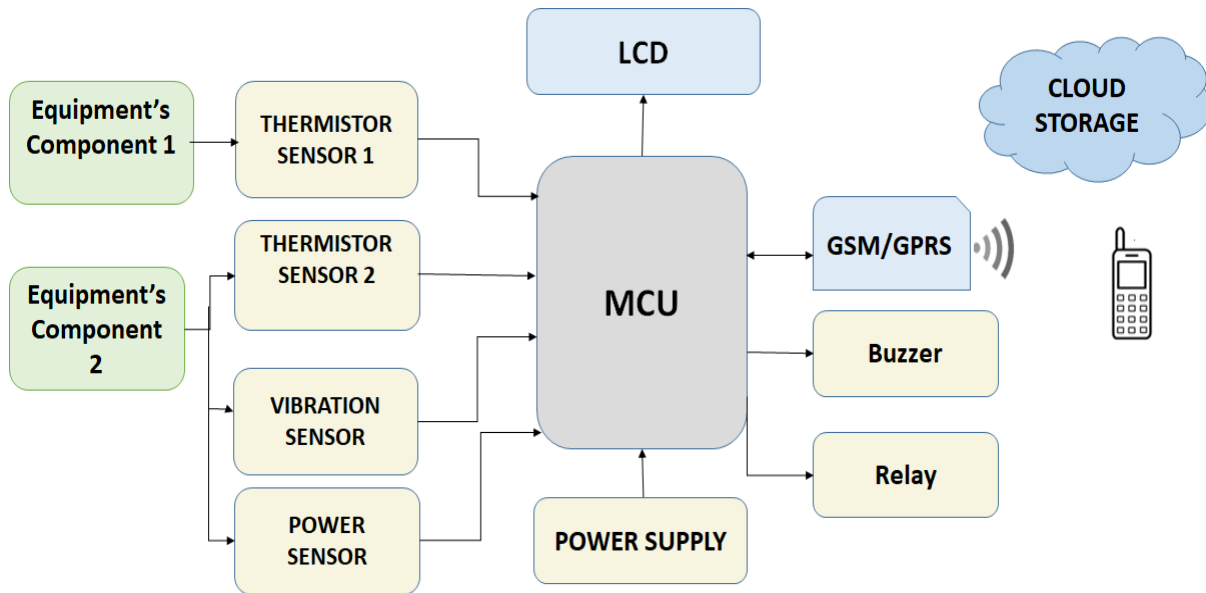


Figure 3. 3: System block diagram

3.2.3 Hardware components

A. Arduino Uno

The Arduino Uno is a microcontroller board based on the ATmega328. It has a total of 14 digital input/output pins among which 6 pins are analog input pins. It has a 16 MHz crystal oscillator, an USB connection, a power jack and a reset button. It operates on both 3.3v and 5v. It takes the advantage of being cheap, easily programmable, low power consumption, available and provide needed analog input pin[46]. Figure 3.5 shows the pin layout of Arduino Uno board.

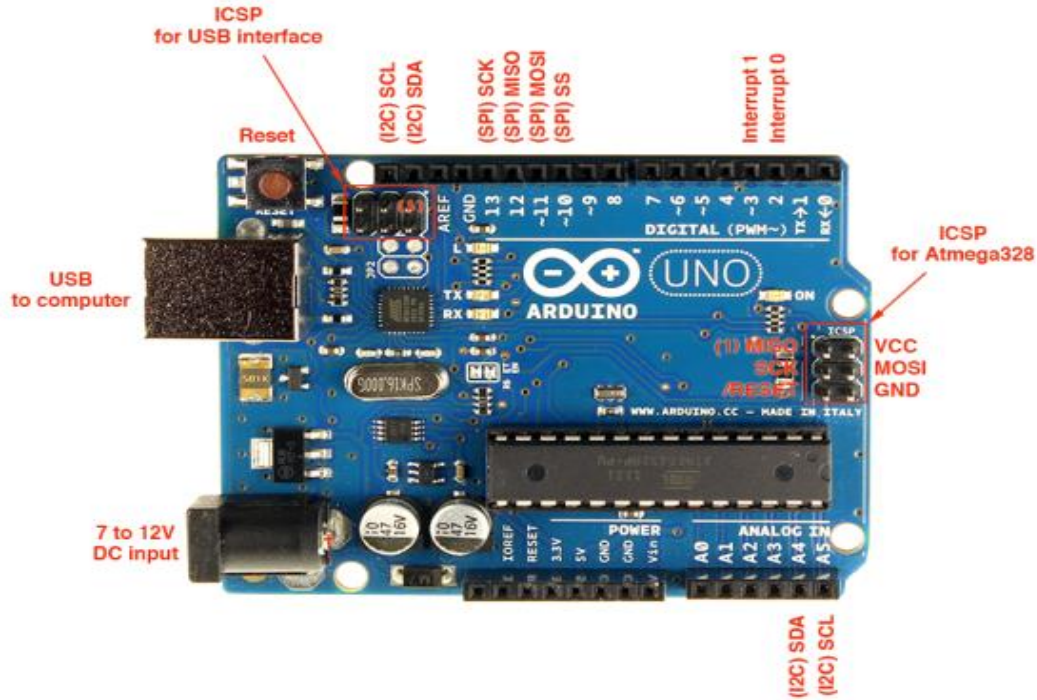


Figure 3. 4: Arduino Uno board pin layout

B. ADXL335 accelerometer sensor

The vibration sensor or accelerometer used is ADXL 335 which is a small, thin, low power and 3-axis accelerometer containing signal conditioned voltage outputs. It measures a full scale acceleration with a range of $\pm 3g$. It measures both static and dynamic accelerations. The dynamic acceleration resulting from motion, shock or vibrations is measured in here. Depending on the application different bandwidths can be selected for three axes. For x-axis and y-axis bandwidths range from 0.5Hz to 1600Hz and for z-axis it is from 0.5hz to 550Hz [47]. It gives three values for three axes that represents the motor vibrations. A powerful calibration technique is used to convert the analog units from ADXL335 to “m/s²” units. Figure 3.6 shows ADXL335 sensor pin layout.

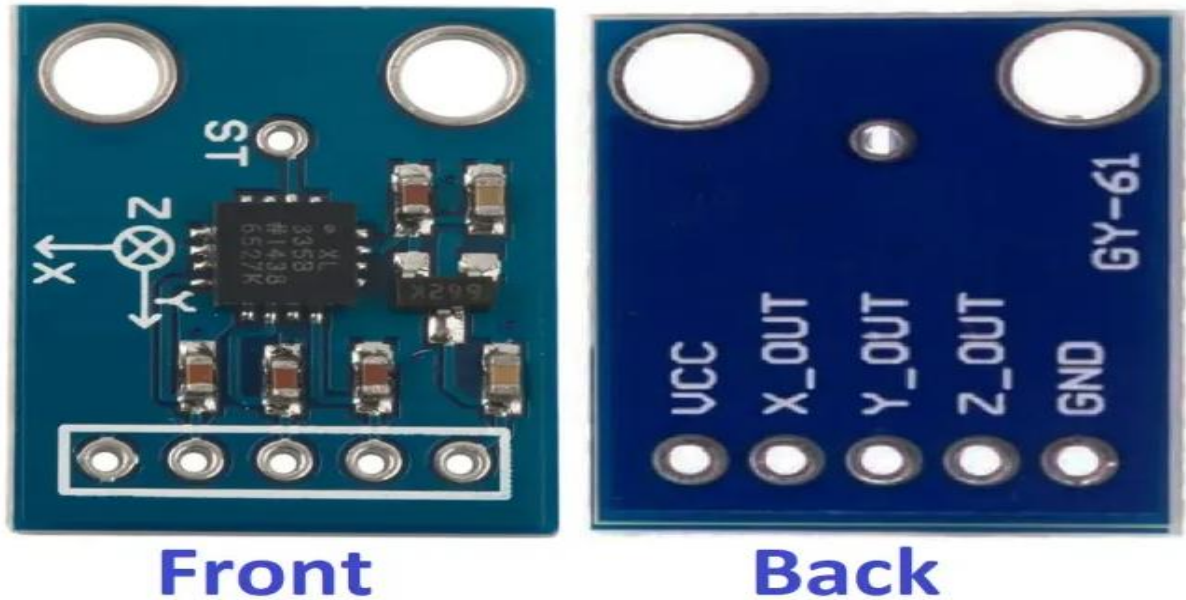


Figure 3. 5: ADXL335 tri-axial accelerometer

C. Temperature sensor

NTC (Negative Temperature Coefficient) thermistors are thermally sensitive semiconductor resistors which show a decrease in resistance as temperature increases. With 2%/K to 6%/K, the negative temperature coefficients of resistance are about ten times greater than those of metals and about five times greater than those of silicon temperature sensors. Changes in the resistance of the NTC thermistor can be brought about either externally by a change in ambient temperature or internally by self-heating resulting from a current flowing through the device[48]. Used NTC thermistor operate between $-40\text{ }^{\circ}\text{C}$ to $+300\text{ }^{\circ}\text{C}$. Figure 3.7 show the NTC temperature sensor.



Figure 3. 6: NTC thermistor

D. Current sensor

ACS712 sensor is a half effect linear based current sensor used to measure ACS712ELC 5A 20A 30A Amps. It works on the principle of Hall effect. It has an output sensitivity of 66 to 185 mV/A. The selection of this sensor was not only based on its economical but also on the precise solution for AC and DC current sensing[49]. Pin layout of this sensor is shown in Figure 3.8.

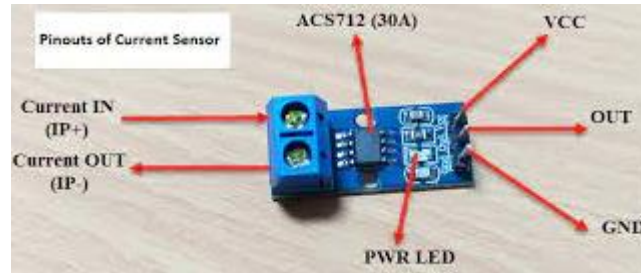


Figure 3. 7: ACS712 current sensor

E. Light Emitting Diode (LED)

A light-emitting diode is a semiconductor light source that emits light when current flows through it. Electrons in the semiconductor recombine with electron holes, releasing energy in the form of photons. Figure 3.9 show LED polarities.

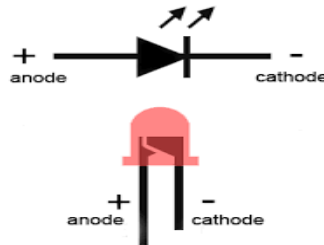


Figure 3. 8: Light emitting diode

F. RELAY Module

Relay is an electromechanical switch used as an automatic control system for closing and opening the circuits by receiving electrical signals from outside sources. It controls the opening and closing of the circuit contacts of an electronic circuit. It can detect overcurrent, overload, undercurrent, and reverse current to ensure the protection of an equipment. In this study it is used to ensure the autoclave is only working in recommended condition and switch it off once it is under critical condition. Figure 3.10 shows the relay module pin layout.

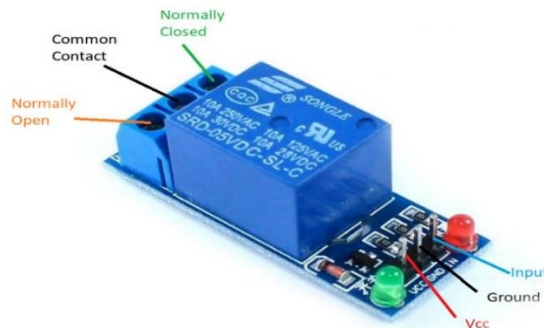


Figure 3. 9: Relay module

G. Liquid crystal display (LCD)

A 20x4 Liquid crystal display used in this study has four rows and enable twenty characters to be written per each row. This module uses HDD44780 (It is a controller used to display monochrome text displays) parallel interfacing. Liquid crystal display works on data and control signal. The existence of these signals can be identified through the on and off condition of RS pinout. Data can be read by pushing the Read/write pinout and it is has the input supply of 3V or 5V. Figure 3.11 shows the pin layout of an LCD display.

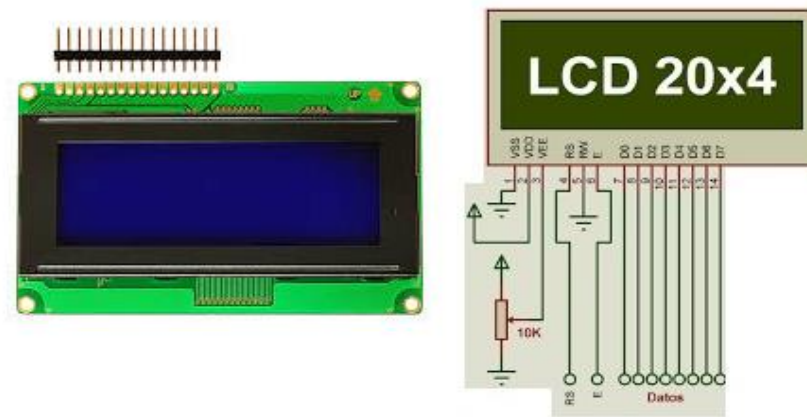


Figure 3. 10: 20x4 Liquid crystal display

H. GSM/GPRS Module

SIM800L GSM/GPRS module was used, it is preferred because it provisions Quad-band GSM/GPRS module which delivers 850/900/1800/1900MHz, it has the capability to transmit data, voice, and SMS through radio waves with low power consumption, transmit TTL output. It is compact in size and simple to use as plug and play in GSM Modem. It follows UART communication protocol to interface with microcontroller and all the activity of GSM modem is controlled by some AT (Attention) command. It requires a SIM card from a wireless carrier in order to operate as GSM module. This module has on-board LED indicators, when LED blinks every second it means that is connecting to a network, once it is connected it blinks once every three seconds. The SIM800L module requires voltage in range of 3.4 to 4.4 V[50]. Figure 3.12 shows the pin layout of SIM800L.

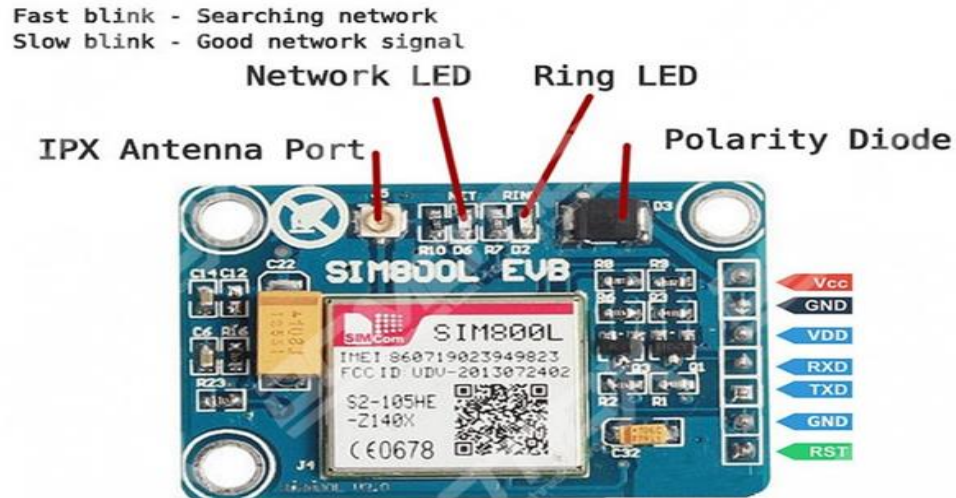


Figure 3. 11: The SIM800L GSM/GPRS module

3.2.4 Software tools

A. Proteus ISIS Circuit Simulator Software

This is a software simulator that assists in modeling real circuit designs interactively. It features a range of simulators for common microcontrollers and an interactive set of models for peripheral devices including LEDs and LCD screens, keypads, and more. Full microcontroller systems can be simulated and the software designed for them without physical prototype access. Models such as Atmega328, LED, LCD panel, switches, bowl, relays, resists, resistors and sources are used and tests have been verified by hardware performance.

B. Integrated Developed Environment

The IDE (Integrated Development Environment) is a software tool that allowed us to write the sketches for the Arduino board, in this study we use the C programming language.

3.2.5 System analysis

A. Functional requirement

The study goal is to deliver a high quality product that improve quality of lives. Functional requirements assists in directing the project team and include all function that must be incorporated for the user to achieve their goals.

In this study, the functional were as follows:

- The system should be able to sense temperature, vibration and the power consumed by the autoclave steam generator and unit pump.
- The system should enable remote and continuous monitoring

- The system should be able to send SMS in case of abnormality and switch off itself in case the recommended working condition is beyond the tolerable range.
- The maintenance team and administration should be able to view a dashboard with a variety of visualization tools of data stored in the cloud.
- The system should be powered by existing power source, use minimal power and need not to be recharged.

B. Non-functional requirement

Non-functional requirements are quality attributes that describe the ways the system should behave. They include the following:

- Availability: the system's functionality and services should be available for user.
- Reliability: The system should work as intended without failure for longtime.
- Scalability: The system must grow without negative influence on its performance.
- Power consumption: It should be in a position to consume as low power as possible.
- Performance: The system should ensure optimal level of performance
- Flexibility: The system should be easily modified
- Security: The system should be protected from unauthorized people
- Size: The system size should be small

3.2.6 System flow chart

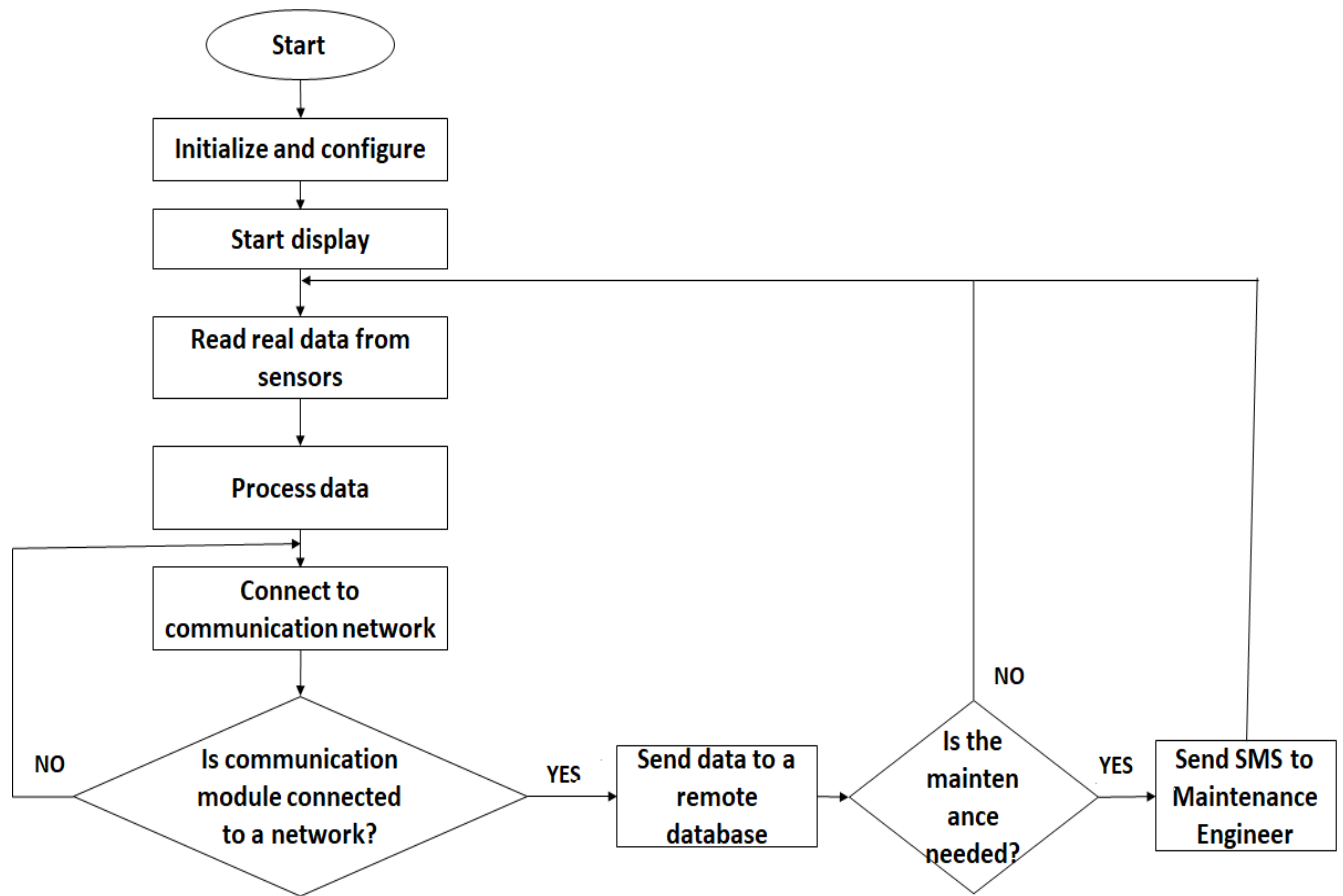


Figure 3. 12: System flow chart

3.2.7 Simulation design of the system

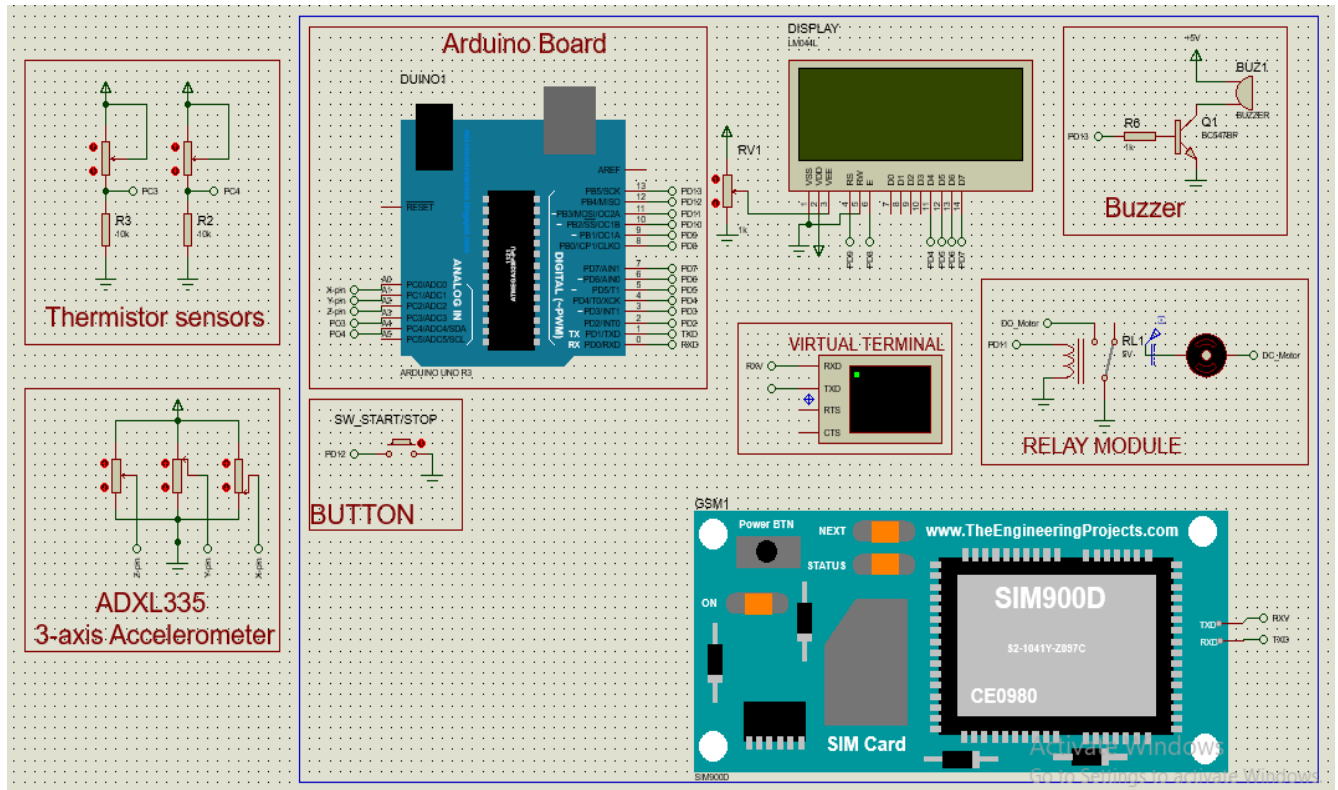


Figure 3. 13: Proteus design simulation layout

3.3 Summary

This part discussed the methodology approach used and the design and simulation part, we described the system architecture that is used in equipment condition monitoring, the logical design and physical design was demonstrated, the simulation part was used to test user requirement and system feasibility before doing prototyping, it assisted us in the modification of the system without spending any resources. Prototyping was build based and programmed based on the system flow chart. This part describe the system components and design which is the stage that lead us to the implementation stage.

CHAPTER 4. THE PROJECT RESULTS SIMULATION AND IMPLEMENTATION

This section discusses the experimental results and analysis of implementing condition-monitoring solution.

4.1 Data collection results

From the maintenance record, and information from the maintenance team, we have collected the most frequent failure and the action take to fix the issue as shown in the Table 4.1.

Table 4. 1: Maintenance log on the medical autoclave

Number	Failure	Cause of the failure	Action taken to fix the issue
1	Sterilization temperature out of range	Heaters fail	Replace heater
		Insufficient water or Pump fail	Fill the water in the tank or check the power supply
2	sterilization pressure out of range	Cavitation	Cleaning pump, lubrication
		No enough water	Filling water in the tank
3	Not able to pump water	Power fail	Check power supply
		Shaft misalignment	Alignment of the shaft
		Unknown	Pump replacement
4	Pump power out of range		Check power supply
5	High temperature Pump	lack of lubrication	put oil in the machine
6	Poor liquid flow	Misalignment, component loosing	Alignment and components tightening

4.2 Data analysis

4.2.1 Failure criticality analysis

After monitoring equipment for few weeks plus the record from maintenance and the information from maintenance team, based on the contents analysis we have found that the most failing parts of the autoclave machine are steam generator and unit pump consisting of the pump and the motor.

Based on the review done in the literature on the cause of the equipment failure, adding to the observation on the field, we found that some symptoms of failure are related to physical parameters that can be indicated using condition monitoring tool hence the decision for choosing to replace timely maintenance know as preventive maintenance and traditional corrective maintenance by condition based maintenance which can be achieved by mounting sensors that can collect physical parameters on the most failing components. In this study, we have also found that the most cause of failure are related to mechanical failure and electrical failure.

4.3 Needed feature for fault detection

Based on the nature of the failure and the components part that cause the whole machine failure, we found that physical parameters that can help us in the indication of the failure and their symptoms are temperature for the steam generator, temperature, vibration and power consumption for the pump[27]. Table 4.2 show the needed feature and fault detection.

Table 4. 2: Needed feature and defect to be detected.

Number	Needed feature	Defect to be detected
1	Temperature	Lack of lubrication
		Misalignment
		Corrosion
		Deviation in the flow normality
		Cavitation
2	Vibration	Misalignement
		Looseness
		Bearing and impeller fault
3	Power consumption	Current flow deviation
		Wear and tear

4.3.1 Availability of data

From the literature and experience shared by maintenance team, there is a need of automatic data collection from maintenance team for better decision making and to facilitate the researchers.

4.3.2 Equipment monitoring and control system

As far as I know, a system that monitor, control and send early warning to mitigate medical equipment failure issues caused by the lack of the system was not available and this would assists in early detection of fault and which improve the quality of lives. The reported cause of increased downtime and cost of maintenance include spare part issue, fault beyond repair and the delay in detecting the failure. This emphasize the need for our solution.

4.4 Simulation result

Figure 4.1 shows the simulation result in proteus software.

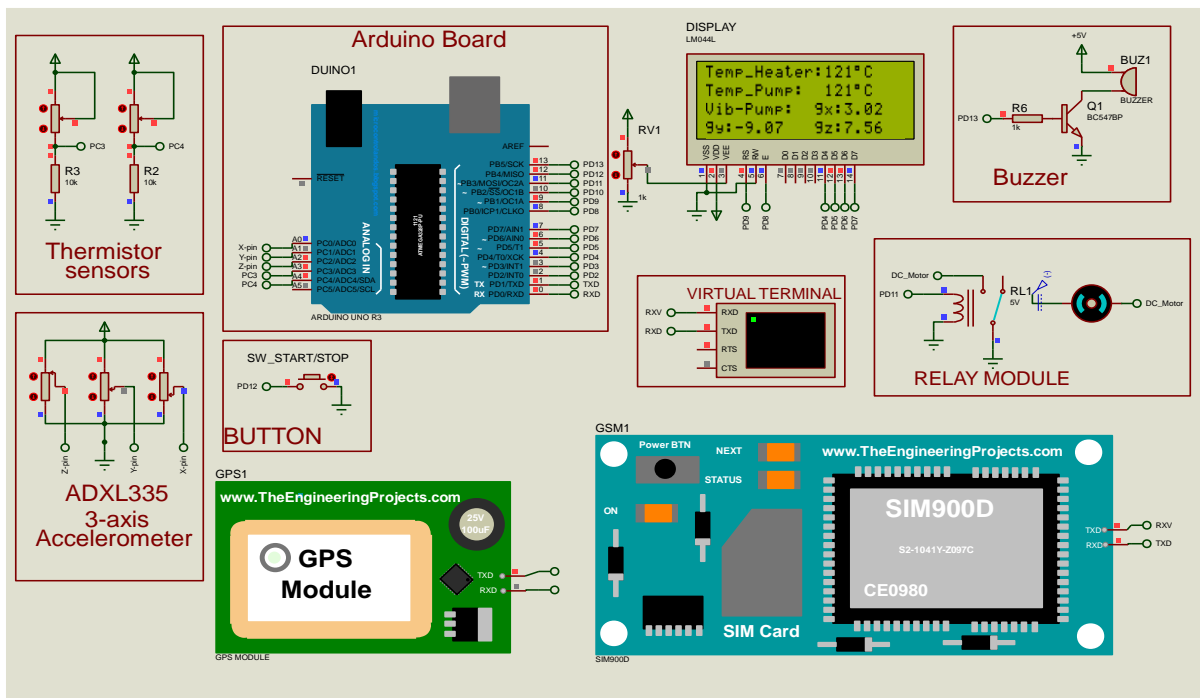


Figure 4. 1: Simulation results

4.5 Prototype result analysis

4.5.1 Prototype implementation

.Figure 4.2 shows the developed prototype and the connected components and the Figure 4.3 shows the system in the protecting box.

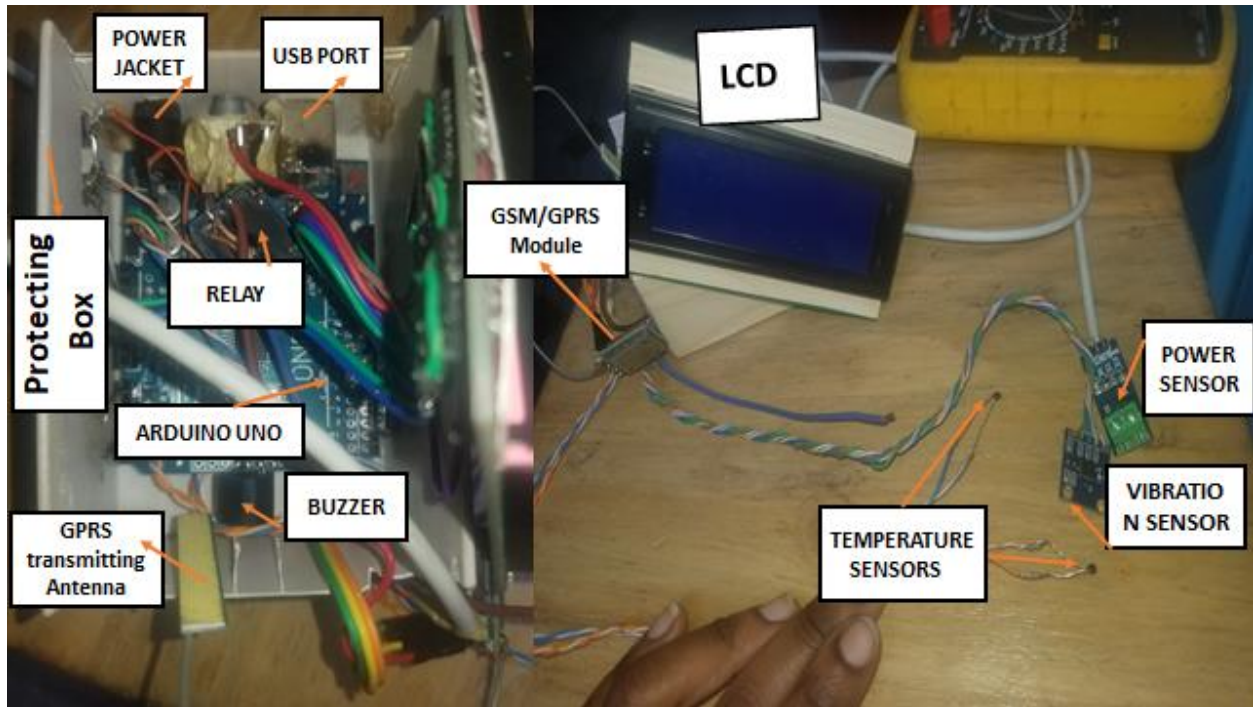


Figure 4. 2: The system prototype



Figure 4. 3: Packaged system

4.5.2 Sensor readings

The researchers were able to test the functionality of all sensors tested and were able to collect the needed data that formed inputs to the condition monitoring system. Figure 4.4 shows the LCD displaying the data collected by the sensors.



Figure 4. 4: System displaying sensor readings

4.5.3 Cloud platform for visualization

For remote monitoring, data saving and visualization, collected data were sent to a cloud platform. Figure 4.5-4.11 show the plots of the sample-collected data for power consumption; pump temperature, heater temperature and vibration readings for x-axis, y-axis and z-axis. Maintenance team are able to visualize this data and be able to make maintenance decision.

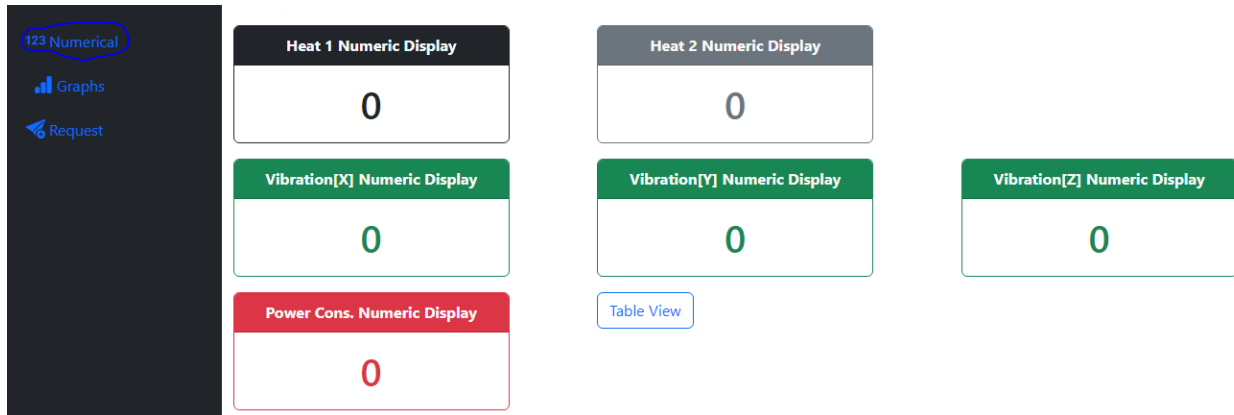


Figure 4. 5: System cloud dashboard

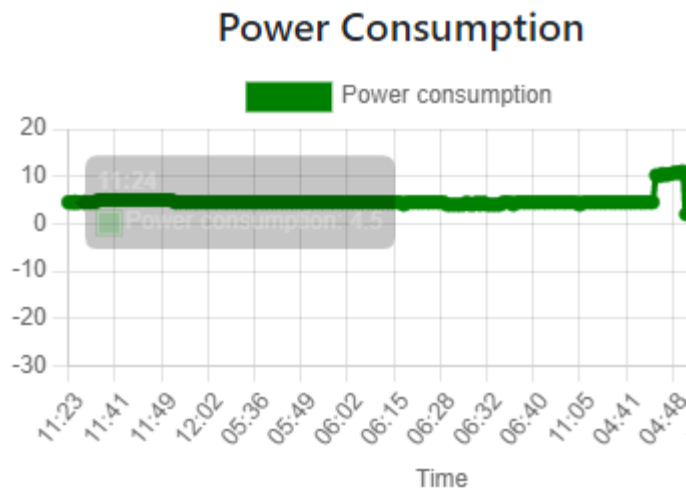


Figure 4. 6: Power consumption readings for the pump

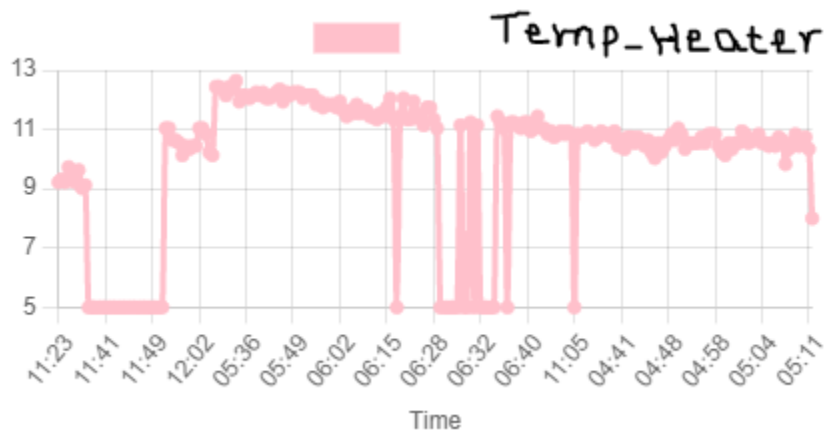


Figure 4. 7: Temperature readings for the heaters

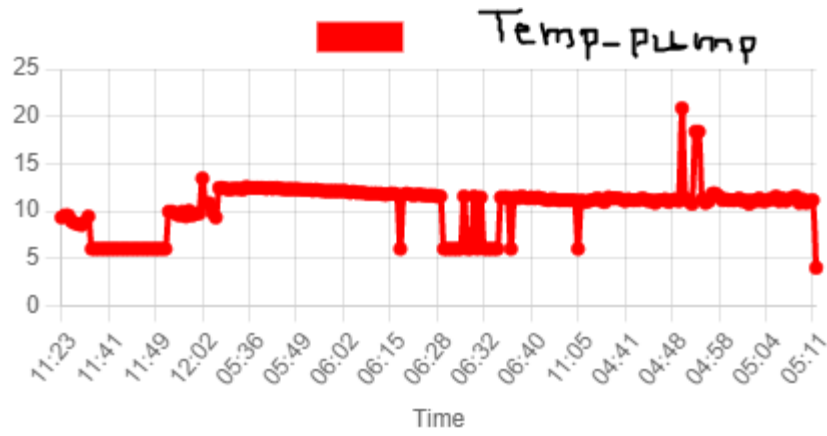


Figure 4. 8: Temperature readings for the pump

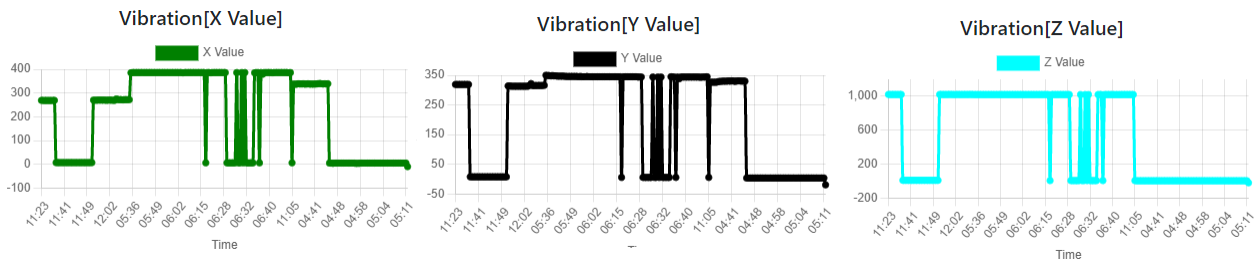


Figure 4. 9: Vibration in x, y and z-axis readings for the pump

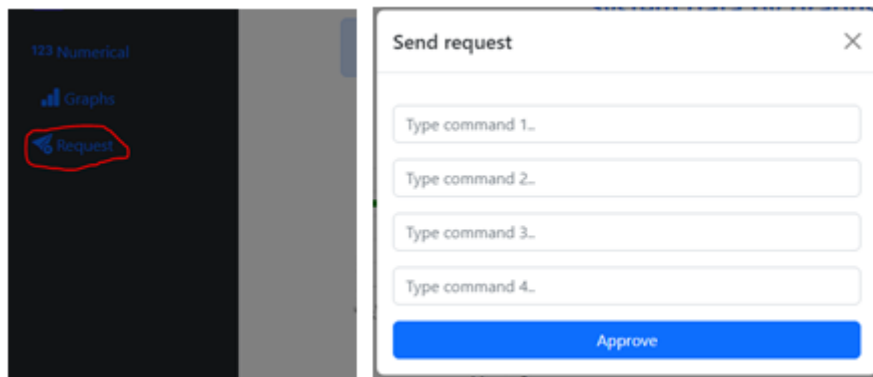


Figure 4. 10: Window for setting the thresholds value

192	0	10.54	11.24	5	4	4	09-01-2023 04:56:11
193	0	10.74	10.84	5	4	4	09-01-2023 04:56:35
194	0	10.54	11.04	4	4	4	09-01-2023 04:56:55
195	0	10.84	11.84	4	4	4	09-01-2023 04:57:18
196	0	10.84	11.84	4	4	4	09-01-2023 04:57:39
197	11	10.84	11.54	5	4	4	09-01-2023 04:58:01
198	11	10.44	11.14	5	4	4	09-01-2023 04:58:25
199	11	10.23	11.24	5	4	4	09-01-2023 04:58:47
200	11	10.13	11.14	5	4	4	09-01-2023 04:59:38
201	13.32	10.54	11.14	5	4	4	09-01-2023 05:00:23
202	11.47	10.34	11.14	5	4	4	09-01-2023 05:00:45
203	11.47	10.54	11.34	5	4	4	09-01-2023 05:01:08
204	11.47	10.54	11.04	5	4	4	09-01-2023 05:01:30
205	11.47	10.94	11.14	5	4	4	09-01-2023 05:01:52

Figure 4. 11: Sample data collected by the system

4.6 Financial benefit of the solution

Real-time condition monitoring system will result in the financial benefits include but not limited to

- Reduced downtime: Waiting time for fault detection and spare ordering will be reduced, when spare is not ordered as emergency the price decrease hence the total maintenance cost reduced.
- Reduced unplanned shutdowns which increase equipment availability hence production increase.
- Equipment lifetime will be extended which will reduce amount of resources spent on buying new equipment
- Time to record physical parameters periodically will be saved; hence, fewer maintenance employee will be needed while the health of equipment is monitored efficiently.

CHAPTER 5. CONCLUSION, RECOMMENDATION AND FUTURE WORK

5.1 Conclusion

In light of the increasing complexity of medical equipment technology, the importance of reducing unexpected downtime and increase equipment reliability, availability and financial concerns, medical equipment in clinics and hospitals requires a smart automated maintenance system based on IoT technology. This study proposes the use of real time condition monitoring system for effective management of medical equipment maintenance to ensure the best practice of high quality service delivery by reducing unexpected shutdown, downtime and ensure equipment performance on require level as well as the maintenance cost. This is took us from existing system solutions that do not consider equipment configuration and performance which differ from one equipment to another and do not include control part on the system. This system remove the limitation of distance, risky environment and ensure the real-time feedback for proper management of equipment. We collected maintenance logs of medical autoclave at King Faisal hospital as a case study for analysis. Based on the review done on maintenance logs and the failure analysis, without any modification on existing equipment, we build a system that can collect temperature, vibration and power consumption of the steam generator and pump components of this equipment to provide needed information that will assist in maintenance decisions. The system is scalable and can be used to other equipment with the same characteristics such as vitros immunoassay analyzer, centrifuges, generators... Generated data can also be used in medical equipment inventory, procurement in the selection of high quality equipment by considering history performance of certain model and as well as manufacturers. It is believed that with the deployment of condition monitoring systems in hospitals, maintenance will be improved and it will facilitate maintenance prioritization compared to the conventional use of time-based maintenance and run to fail techniques when equipment configuration and technical requirement is considered; however, this study does not include maintenance action that could be performed after detecting failures. From the study of medical equipment configuration we note that by the use of temperature, vibration and power consumption sensors, we can detect vital signs of equipment deterioration and plan maintenance a head of time while equipment is still used which reduces unexpected shutdowns, downtime and maintenance cost hence high quality of healthcare provision.

5.1.1 Nullifying the hypothesis

The hypothesis was that there is a positive relationship between condition monitoring system and equipment maintenance improvement and prioritization.

From our study findings, the system results shows that we can improve maintenance by reducing downtime and unexpected shutdown. Downtime includes the combination of waiting time and maintenance time. Waiting time include fault detection, fault localization, requesting spares from stores or purchasing them when not available store which all can be done while equipment is still in use when condition monitoring system is used. Also by avoiding unnecessary PM can reduce the shutdown of equipment, which extend the life of equipment and hence reduce maintenance cost. In addition, by knowing the state of equipment we can prioritize maintenance based on the one in emergency condition.

5.2 Recommendations

In this study have considered temperature, vibration and power consumption parameters for two components named steam generator and pump unit, however for reducing equipment failure which threaten patient's life more parameters such as pressure, noise level, lubricants need to be taken into consideration as well as other coupled devices. We recommend also the consideration of predictive maintenance system. Predictive maintenance helps in the anticipation of equipment remaining useful life and considered as advanced for maintenance decision. Inclusion of wireless option to the system is an additional advantage.

5.3 Future works

In this study, we have proposed a real-time condition monitoring system for optimal maintenance strategy; we built and tested a prototype of the proposed solution. The future works will involve implementation of the solution in the target environment for validation and do the multivariable correlation. Furthermore, in the future we will consider maintenance cost analysis based on the corrective or preventive maintenance and compare it to the cost when using condition-based maintenance.

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APPENDICES

Appendix 1: Notification of data collection approval from King Faisal Hospital IRB.



IRB Notification of Approval

Ref: KFH/2022/ 034/IRB

Date: December 23, 2022

Protocol Title: Design and Prototyping of Real Time Condition Monitoring system for medical equipment maintenance management

Principal Investigator:

Therese UWIRAGIYE

Email: ttchery77@gmail.com

Protocol Reference #: KFH/2022/ 034/IRB

Date of IRB Initial Review: December 13, 2022

Review Type: Expedited Review

IRB Review Decision: Approved

Date of Effectiveness: December 23, 2022

Date of Expiry: December 22nd, 2023

Dear Therese UWIRAGIYE,

King Faisal Hospital Rwanda's Institutional Review Board (KFH IRB) reviewed your protocol resubmission. This letter is to notify you that the KFH IRB approved your resubmission, and this approval is valid for one (1) year and then must be renewed according to the KFH IRB Standard Operating Procedures.

Please note the following considerations:

1. Please review the KFH IRB Standard Operating Procedures and ensure compliance with all requirements, including participant content, changes or amendments to the protocol, and reporting requirements.
2. All project materials, including signed consent forms, must be retained and are subject to review in case of a routine audit.
3. Notify the KFH Directorate of Research once data collection is completed.
4. The Principal Investigator is requested to submit a hard copy of his/her final manuscript to the Directorate of Research upon completion.
5. Principal Investigators must follow the appropriate study continuing review and closure procedures as indicated in the Standard Operating Procedures Manual.

Please contact us at irb@kfhkigali.com in case of any questions or clarifications.

Sincerely,

Dr. Jean Marie Vianney Dushimiyimana

Consultant ENT Surgeon

Chair, Institutional Review Board



Appendix 2: Notification of data collection approval at Ruhengeri Referral hospital IRB.

<p>REPUBLIC OF RWANDA</p>  <p>MINISTRY OF HEALTH</p>	<p>RUHENGARI REFERRAL HOSPITAL NR 4, RD 45 Po. Box: 57, MUSANZE Ruhengeri.Hospital@moh.gov.rw</p>	<p>Client centered Service Integrity Teamwork Innovation</p>
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Musanze, 21 OCT 2022

Ref. *Q88*...../RRH/DG/2022

Prof Celestin TWIZERE
Director of CEBE

Re: Your introduction for data collectors

Dear TWIZERE;

Reference is made to your letter dated on 22th September, introducing collectors and their respective projects:

We have the pleasure to inform you that they are allowed to conduct those research projects. However they're obliged to have all the required equipments for use and the final project report will be shared with Ruhengeri Referral Hospital.

Best regards,

Dr MUHIRE *Hilbert*
Director General of Ruhengeri Referral Hospital

Cc:

-Chair of Ethic committee

Appendix 3: Notification of data collection approval at CMHS IRB.



Appendix 4: Interview protocol

Introduction (to be read verbally to the hospital technicians and biomedical engineers - must seek confirmation them):

I, Therese UWIRAGIYE a master's student in Biomedical Engineering, Center of Excellence in Biomedical Engineering and e-Health (CEBE), University of Rwanda. I am conducting a researcher with a title "Design and prototyping of a real-time condition monitoring system for medical equipment maintenance management" I am trying to understand the role that biomedical equipment play for health care provision in your hospital and how their condition can be kept on required level of performance to ensure the best quality of service delivered. Condition monitoring is the art of observing the state of the system and be able to act when it is necessary.

- We will focus specific questions on autoclaves.
- This interview may take up to one 15minutes of your time. We do not anticipate any risks or discomforts to you if you choose to participate. Your participation in this study will be kept confidential and will be de-identified from you.
- You can stop the interview at any point, and you do not have to answer every question.
- This research plan has been reviewed and approved by CMHS IRB. It also falls within the guidelines presented in the memorandum of understanding (MoU) held between the Regional Center of Excellence in Biomedical Engineering and E-health (CEBE) at the University of Rwanda and the Ministry of Health.
- I can also provide you with a written version of this information which I can read to you.
- Would you like to continue with the interview?

1. What is your job title/position? _____
 2. How many biomedical engineers do you have at your hospital? _____
 3. How many biomedical technicians do you have at your hospital? _____
 4. How many total biomedical devices does your hospital have? _____
 5. Do any of your hospital biomedical equipment rely on broadband internet?
 - Yes
 - No
 6. What are the major equipment which are wirelessly enabled at your hospital?
 - Autoclaves
 - CT machines
 - ECGs/EKGs
 - Patient monitors
 - Ultrasound machines
 - Other (specify): _____
-

7. What kind of broadband internet are used (select one or multiple)?
 - Satellite
 - Fiber optics
 - Mobile
 - Fixed Wireless
 - Cable
 - Other (specify):
8. How do you rate the stability of broadband internet for the provision of your services (where stability means the internet works as you need it to for the given percentage of the time)?
 - 0 - 10% stable
 - 10 - 25% stable
 - 25 - 50% stable
 - 50 - 75% stable
 - 70% - 90% stable
 - 90% + stable
9. How often is medical equipment retired/changed/rolled out?
 - I do not know
 - Never changed any equipment
 - When it reaches end of life
 - When we get new equipment for replacement
 - When equipment fails
 - Others (specify):
10. On average how long have you used the oldest medical equipment in the hospital?
 - 0 - 5 years
 - 5 - 10 years
 - 10 - 20 years
 - 20+ years
11. Have there been failures of medical equipment where the cause was not identified?
 - Yes
 - No
12. How is equipment introduced to the hospital?
 - Donated
 - Bought
 - Rented
 - Other (specify): _____
13. What is the average condition of the autoclave in your hospital?
 - Brand new
 - Old version _____
14. If the autoclave device is not currently working, why?
 - It's broken
 - Don't have trained staff who know how to use it
 - Don't need to use it
 - Too expensive to maintain and operate
 - Other (specify): _____

15. What is its operating voltage of an autoclave _____
16. What is its operating frequency of an autoclave? _____
17. What power does of an autoclave require _____
18. What is the operating rotational speed of the pump? _____
19. What types of maintenance performed on Autoclave?
- Preventive maintenance
 - Corrective maintenance
 - All above
 - Other (specify): _____
20. How many sterilization cycles per day?
- <10 cycles
 - 10-50 cycles
 - >50 cycles
21. What are the most common signs of failure on autoclave?
- Temperature deviation
 - Vibration deviation
 - Pressure deviation
 - Power failure
 - Others specify: _____
22. How much time do you spend on the maintenance of an autoclave _____
23. What percent increase in overall safety and quality improvement do you think device monitoring could provide?
- 0 - 10%
 - 10 - 25%
 - 25 - 50%
 - 50 - 75%
 - 75 - 90%
 - 90%+

Thank you for participating in this research.

Appendix 5: System codes

```
#include <LiquidCrystal.h>
#include <SoftwareSerial.h>
const int rs = 2, en = 3, d4 = 4, d5 = 5, d6 = 6, d7 = 7;
LiquidCrystal lcd(rs, en, d4, d5, d6, d7);

SoftwareSerial mySerial(9, 8);
SoftwareSerial gprsSerial(8, 9);
int ThermistorPin1 = A0;
int ThermistorPin2 = A1;
int Vo;
int Vo1;
float R1 = 10000;
float logR2, R2, T, Tc, Tf;
float logR21, R21, T1, Tc1, Tf1;
float c1 = 1.009249522e-03, c2 = 2.378405444e-04, c3 = 2.019202697e-07;
int xPin = A2;
int yPin = A5;
int zPin = A4;
int x = 0;
int y = 0;
int z = 0;
int buzzer = 11;
long prevMillissend = 0;
long sendInterval = 30000;
unsigned long duration;
unsigned long starttime;
unsigned long sampletime_ms = 200;
unsigned long lowpulseoccupancy = 0;
String fdbk = "";
int lim = 30;
const int Sensor_Pin = A3;
unsigned int Sensitivity = 185; // 185mV/A for 5A, 100 mV/A for 20A and 66mV/A for 30A
Module
float Vpp = 0; // peak-peak voltage
float Vrms = 0; // rms voltage
float Irms = 0; // rms current
float Supply_Voltage = 233.0; // reading from DMM
float Vcc = 5.0; // ADC reference voltage // voltage at 5V pin
float power = 0; // power in watt
float Wh = 0; // Energy in kWh
unsigned long last_time = 0;
unsigned long current_time = 0;
unsigned long interval = 100;
unsigned int calibration = 100; // V2 slider calibrates this
unsigned int pF = 85; // Power Factor default 95
```

```

float bill_amount = 0; // 30 day cost as present energy usage incl approx PF
unsigned int energyTariff = 8.0;
int ind = 10;
float pw1;
void setup() {
  lcd.begin(20, 4);
  lcd.setCursor(0, 0);
  lcd.print(" DETECTION OF HEAT");
  lcd.setCursor(0, 1);
  lcd.print("POWER AND VIBRATION");
  lcd.setCursor(4, 2);
  lcd.print("ANALYSIS");
  lcd.setCursor(1, 3);
  //initializing GPRS Connection
  lcd.print("Initialising.....");
  delay(1000);
  Serial.begin(115200);
  mySerial.begin(9600);
  gprsSerial.begin(9600);
  Serial.println("Initializing...");
  delay(1000);
  mySerial.println("AT");
  updateSerial();
  delay(500);

  pinMode(buzzer, OUTPUT);
  pinMode(ind, OUTPUT);
  pinMode(xPin, INPUT);
  pinMode(yPin, INPUT);

  gprsSerial.println("AT");
  delay(100);

  gprsSerial.println("AT+CPIN?");
  delay(100);

  gprsSerial.println("AT+CREG?");
  delay(100);

  gprsSerial.println("AT+CGATT?");
  delay(100);

  gprsSerial.println("AT+CIPSHUT");
  delay(100);

  gprsSerial.println("AT+CIPSTATUS");

```

```

delay(200);

gprsSerial.println("AT+CIPMUX=0");
delay(200);

ShowSerialData();

gprsSerial.println("AT+CSTT=\"internet.mtn\""); //start task and setting the APN,
delay(100);

ShowSerialData();

gprsSerial.println("AT+CIICR"); //bring up wireless connection
delay(300);

ShowSerialData();

gprsSerial.println("AT+CIFSR"); //get local IP adress
delay(200);

ShowSerialData();
}

void loop() {
  x = analogRead(xPin);
  x = x / 67.584;
  y = analogRead(yPin);
  y = y / 67.584;
  z = analogRead(A5);
  z = z / 67.584;
  int vib = (x + y) / 2;
  Vo = analogRead(ThermistorPin1);
  R2 = R1 * (1023.0 / (float)Vo - 1.0);
  logR2 = log(R2);
  T = (1.0 / (c1 + c2 * logR2 + c3 * logR2 * logR2 * logR2));
  Tc = T - 273.15;
  Tf = (Tc * 9.0) / 5.0 + 32.0;

  Vo1 = analogRead(ThermistorPin2);
  R21 = R1 * (1023.0 / (float)Vo1 - 1.0);
  logR21 = log(R21);
  T1 = (1.0 / (c1 + c2 * logR21 + c3 * logR21 * logR21 * logR21));
  Tc1 = T1 - 273.15;
  Tf1 = (Tc1 * 9.0) / 5.0 + 32.0;

  getACS712();
}

```

```

getVPP();

if(power <0){
  power =0;
}
if (Tc1 >= lim or Tc >= lim) {
  digitalWrite(buzzer, HIGH);
  digitalWrite(ind, HIGH);
  sms();
  delay(2000);

} else {
  digitalWrite(buzzer, LOW);
  digitalWrite(ind, LOW);
}
lcd.clear();
lcd.setCursor(0, 2);
lcd.print("Temp_heater:");
lcd.setCursor(12, 2);
lcd.print(Tc);
lcd.setCursor(17, 2);
lcd.print("\xDF""C");
lcd.setCursor(0, 1);
lcd.print("Temp_pump:");
lcd.setCursor(10, 1);
lcd.print(Tc1);
lcd.setCursor(15, 1);
lcd.print("\xDF""C");
lcd.setCursor(0, 0);
lcd.print("v=x: y: z: m/s2");
lcd.setCursor(4, 0);
lcd.print(x);
lcd.setCursor(8, 0);
lcd.print(y);
lcd.setCursor(12, 0);
lcd.print(z);
lcd.setCursor(0, 3);
lcd.print("Pump_power:" + String(power, 2) + "Wh");
delay(200);

pw1 =power;
if (millis() - prevMillissend > sendInterval) {
  // send();
  prevMillissend = millis();
}
send();

```

```

}
void sms() {
  mySerial.println("AT+CMGF=1"); // Configuring TEXT mode
  updateSerial();
  mySerial.println("AT+CMGS=\"+250780920819\""); //change ZZ with country code and
xxxxxxxxxxx with phone number to sms
  updateSerial();
  mySerial.print("Motor Heat is rising..."); //text content
  updateSerial();
  mySerial.write(26);
}
void updateSerial() {
  delay(500);
  while (Serial.available()) {
    mySerial.write(Serial.read()); //Forward what Serial received to Software Serial Port
  }
  while (mySerial.available()) {
    Serial.write(mySerial.read()); //Forward what Software Serial received to Serial Port
  }
}
void ShowSerialData() {
  while (gprsSerial.available() > 0) {
    Serial.write(gprsSerial.read());
    fdbk = gprsSerial.readString();

    if (fdbk.indexOf("command") >= 0) {
      Serial.print("Found threshold successfully= ");
      int index_line = fdbk.indexOf("command");
      index_line += 10;
      String threshold = fdbk.substring(index_line, index_line + 3);
      lim = threshold.toInt();
      Serial.println(lim);
      fdbk = "";
    }
  }
  // delay(500);
}
void send() {
  // lcd.clear();
  // lcd.setCursor(4, 0);
  // lcd.print("Sending data");
  // lcd.setCursor(8, 1);
  // lcd.print("to");
  // lcd.setCursor(5, 2);
  // lcd.print("Server.....");
  // x = analogRead(xPin);

```

```

// y = analogRead(yPin);
Tc1 = T1 - 273.15;
Tc = T - 273.15;
if (gprsSerial.available())
    Serial.write(gprsSerial.read());

gprsSerial.println("AT+CIPSPRT=0");
delay(2000);

ShowSerialData();

gprsSerial.println("AT+CIPSTART=\"TCP\", \"healthcereals.rw\", \"80\"); //start up the
connection
delay(3000);

ShowSerialData();

gprsSerial.println("AT+CIPSEND"); //begin send data to remote server
delay(2000);
ShowSerialData();

// String str = "GET
https://api.thingspeak.com/update?api_key=3O1OSEUQI959QC2E&field1=" + String(Tc) +
"&field2=" + String(Tc1) + "&field3=" + String(x) + "&field3=" + String(y) ;
String str = "GET http://healthcereals.rw/sion/sendData.php?power=" +
String(pw1)+"&heat=" + String(Tc) + "&heat2=" + String(Tc1) + "&vibx=" + String(x) +
"&viby=" + String(y) + "&vibz=" + String(z);
Serial.println(str);
gprsSerial.println(str); //begin send data to remote server

delay(3000);
ShowSerialData();

gprsSerial.println((char)26); //sending
delay(2000); //waitting for reply, important! the time is base on the condition of
internet
gprsSerial.println();

ShowSerialData();

gprsSerial.println("AT+CIPSHUT"); //close the connection
delay(1000);
ShowSerialData();
}
void getACS712() { // for AC
    Vpp = getVPP();

```

```

Vrms = (Vpp / 2.0) * 0.707;
Vrms = Vrms - (calibration / 10000.0); // calibrate to zero with slider
Irms = (Vrms * 1000) / Sensitivity;
if ((Irms > -0.015) && (Irms < 0.008)) { // remove low end chatter
  Irms = 0.0;
}
power = (Supply_Voltage * Irms) * (pF / 100.0);
last_time = current_time;
current_time = millis();
Wh = Wh + power * ((current_time - last_time) / 3600000.0); // calculating energy in Watt-
Hour
bill_amount = Wh * (energyTariff / 1000);
// if (power = -3.31) {
//   power = 0.000;
// }
Serial.print("Irms: ");
Serial.print(String(Irms, 3));
Serial.println(" A");
Serial.print("Power: ");
Serial.print(String(power, 3));
Serial.println(" W");
Serial.print(" Bill Amount: INR");
Serial.println(String(bill_amount, 2));
}
float getVPP()
{
  float result;
  int readValue;
  int maxValue = 0;
  int minValue = 1024;
  uint32_t start_time = millis();
  while ((millis() - start_time) < 950) //read every 0.95 Sec
  {
    readValue = analogRead(Sensor_Pin);
    if (readValue > maxValue)
    {
      maxValue = readValue;
    }
    if (readValue < minValue)
    {
      minValue = readValue;
    }
  }
  result = ((maxValue - minValue) * Vcc) / 1024.0;
  return result;
}

```