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FACULTY OF APPLIED SCIENCES ANDTECHNOLOGY

**DEPARTMENT OF BIOMEDICAL SCIENCES AND ENGINEERING**

**AUTOMATED DIAGNOSTIC EQUIPMENT CALIBRATION MANAGEMENT SYSTEM**

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**TABLE OF CONTENTS**

[**CHAPTER 1.** **INTRODUCTION** 1](#_Toc182446348)

[**1.1** **BACKGROUND** 1](#_Toc182446349)

[**1.2** **PROBLEM STATEMENT** 2](#_Toc182446350)

[**1.3** **MAIN OBJECTIVE** 3](#_Toc182446351)

[**1.4** **SPECIFIC OBJECTIVES** 3](#_Toc182446352)

[**1.5** **SIGNIFICANCE OF THE PROJECT** 3](#_Toc182446353)

[**1.6** **RESEARCH QUESTIONS** 4](#_Toc182446354)

[**1.7** **SCOPE** 4](#_Toc182446355)

[**CHAPTER 2** : **LITERATURE REVIEW** 5](#_Toc182446356)

[**2.1** **INTRODUCTION** 5](#_Toc182446357)

[**2.2** **CALIBRATION TRACKING SYSTEM** 5](#_Toc182446358)

[**2.3** **STUDIES OF RESEARCH** 6](#_Toc182446359)

[**2.3.1** **Calibration Management System** 6](#_Toc182446360)

[**2.3.2** **Paper-based systems (Science direct)** 7](#_Toc182446361)

[**2.3.3** **In-house legacy systems (spreadsheets, databases, etc.)** 7](#_Toc182446362)

[**2.3.4** **Calibration module of a CMMS** 7](#_Toc182446363)

[**CHAPTER 3** 9](#_Toc182446364)

[**3.1** **METHODOLOGY** 9](#_Toc182446365)

[**3.1.1** **REQUIREMENTS GATHERING** 9](#_Toc182446366)

[**3.1.2** **TECHNOLOGY STACK SELECTION** 9](#_Toc182446367)

[**3.1.3** **SYSTEM DESIGN** 10](#_Toc182446368)

[**3.2** **WORK PLAN** 12](#_Toc182446369)

[**3.3** **BUDGET** 12](#_Toc182446370)

# **INTRODUCTION**

## **BACKGROUND**

Medical device calibration is a procedure for detecting and fixing the uncertainties in measurements and bringing them to an acceptable level.The calibration of medical devices is crucial to maintaining accuracy and reliability in healthcare settings[1]. Calibration ensures that devices provide consistent and reliable measurements. Accurate measurements are vital for patient safety, treatment effectiveness, and compliance with regulatory standards. One effective approach to managing medical device calibration is through digital solutions, such as a Calibration Equipment Management and Tracking System[1] This system automates key processes, providing reminders and notifications for upcoming calibrations, significantly reducing the risk of missed calibration events. By proactively managing calibration schedules, healthcare facilities can ensure that their equipment remains accurate and dependable.

 A key feature of such systems is the assignment of unique IDs to each asset, which streamlines asset management and tracking. This eliminates the challenges of manual data entry, ensuring that calibration activities are planned efficiently and reducing the chances of equipment misplacement. In addition, cloud-based storage allows for centralized documentation, simplifying the management of calibration records while providing secured access to important data. Through automation, this system prevents regulatory non-conformance by ensuring that calibration tasks are completed on time[1]. By tracking calibration schedules and automatically prompting responsible personnel, it helps healthcare organizations maintain a high level of operational efficiency, ultimately supporting the delivery of safe and effective patient care. This study aims to explore the benefits and importance of integrating such systems in medical device management, with a focus on improving accuracy and compliance in healthcare environments[1].

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## **PROBLEM STATEMENT**

Delayed calibration or forgetting calibration schedules can result in inaccurate patient results, leading to improper treatments, jeopardizing patient safety, escalating healthcare costs, and, in the most severe cases, causing fatal outcomes. Errors in diagnostic equipment for example laboratory errors have a reported frequency of 0.012–0.6 % of all test results, which has a huge impact on diagnosis and patient management as 80–90 % of all diagnoses are made based on laboratory tests[2]. Laboratories as one of the departments that give directions for diagnosis have been at the forefront of efforts to enhance patient safety through a range of improvements such as increased automation of manual processes, the introduction of systematic internal quality control, and external quality assurance programs, thereby making pre- and post-analytical phases more vulnerable to laboratory errors. 11 Studies showed that 6.4% to 12% risk of inappropriate care and death occurs due to laboratory errors[3]. 12 Studies in the United States indicated that diagnostic errors occur in 5% of the outpatients and about half of the errors may cause severe harm to patients. This is supported by a study conducted in Malaysia with 3.6% errors[4]. A further study in Kabarole district in Uganda suggests that more than 200 people have received fake results from laboratories operating in Kabarole district [1] that is very risky to the patient safety.

In healthcare environments, the accuracy of medical devices is critical for patient safety and effective treatment. However, the manual management of device calibration schedules presents significant challenges. Many healthcare facilities still rely on traditional, labor- intensive processes to track and maintain calibration records, increasing the risk of human error, missed calibration events, and regulatory non-compliance. Missed or delayed calibration can result in inaccurate measurements, potentially compromising patient outcomes and leading to costly legal repercussions for healthcare providers. This study seeks to address these challenges by exploring the integration of a Calibration Equipment Management and Tracking System in healthcare settings especially for diagnostic equipment.

## **MAIN OBJECTIVE**

Development of a system that provides real-time monitoring of calibration statuses, alerts, and schedules for all critical Hospital diagnostic equipment.

## **SPECIFIC OBJECTIVES**

To design a centralized and secure database architecture for storing and managing equipment calibration data, schedules, and alerts, ensuring data integrity.

To write and develop the algorithms to automate calibration scheduling based on equipment usage patterns and send real-time alerts.

To validate system performance and reliability by conducting thorough testing across various operational scenarios, including real-time updates, alert notifications, and scheduling accuracy, to ensure high functionality and responsiveness.

## **SIGNIFICANCE OF THE PROJECT**

The system will enhance patient safety; Accurate and reliable results are important for patient care, and calibration monitoring systems will ensure the highest quality of results.

The system will ensure timely equipment calibration thus reducing the error rate that can lead to misdiagnosis.

The system will minimize equipment downtime by automating scheduling and providing real-time alerts reducing equipment failure.

The system will simplify calibration processes and reduce the administrators' burden on the staff thus improving efficiency.

## **RESEARCH QUESTIONS**

What is the most used diagnostic equipment that require frequent calibration?

How do biomedical engineers get to know that there is equipment due for calibration?

How do staff in-charge get to know that the equipment is due for calibration?

What are the essential elements required to create a database and write algorithms to interpret the database?

How can a system effectively prioritize and deliver real-time alerts for critical equipment calibration issues?

## **SCOPE**

**Physical scope.**

Our project will primarily focus on developing a comprehensive solution for calibrating, tracking, and managing the accuracy, reliability, and regulatory compliance of various diagnostic devices, ensuring optimal patient outcomes.

**Technological scope**

There will be the creation of a database using MYSQL workbench and it will also involve writing an algorithm to interpret the database using PYTHON software. Our project will leverage robust database and software technologies to build an efficient, automated system for managing diagnostic equipment calibration. This scope will encompass database design, implementation, and algorithm development to ensure smooth operation and data-driven decision making.

# : **LITERATURE REVIEW**

## **INTRODUCTION**

The deviation in output is not necessarily the fault of the device itself, nor can it represent the manufacturer’s incompetence. Most commonly, it results from continuous device usage, which over time affects its internal components, resulting in a deviation from the device standard measurement output[5]. The accuracy of the device has a great deal of importance, as it can seriously affect the diagnostic procedure and endanger patients’ life.

Common documentation includes:

* Calibration Plan, divided into monthly, quarterly, and yearly basis
* Calibration steps or a Standard Operating Procedure (SOP)
* Calibration Results Sheet indicating the actual results and tolerance limits

Calibration status is also indicated on the device, showing the calibration status, date of calibration, and next due date for calibration.

The Medical Device Industry is strictly regulated by regulatory bodies such as Food and Drug Administration (FDA) in the United States to make them compliant with the regulations. Additionally, standardization bodies such as the International Organization for Standardization (ISO) also provide standards for performing medical device calibration.

Secondly, as mentioned above, regulatory bodies such as the FDA in the US have made it mandatory for manufacturers to perform routine calibration and maintain calibration records. Otherwise, the manufacturer is not granted accreditation and cannot start or continue its operations. The calibration must be regularly performed, and documentation maintained for presentation during a routine inspection[5].

## **CALIBRATION TRACKING SYSTEM**

Companies use calibration management systems to schedule equipment calibration and maintenance tasks. Equipment managers and technicians exchange and manage a substantial amount of calibration data. Manually logging data can quickly become overwhelming for everyone involved in the process. This is where a Calibration Tracking and Management equipment System can be a great resource. This system allows users to store all the calibration documents in a centralized system, in secured cloud-based storage and it tracks the documentation status and automatically prompts alerts to the responsible person to complete assignments. You can also create a calibration plan for the device, so you don’t need to inspect device by device to plan the device calibration. The system follows the calibration schedule and automatically alerts the responsible person when calibration is due for a particular device. This prevents you from missing the calibration for a specific device, as missed calibration can seriously cause regulatory [non-conformance](https://simplerqms.com/non-conformance/)[6]

## **STUDIES OF RESEARCH**

### **Calibration Management System**

Every process plant has some sort of system in place for managing instrument-calibration operations and data. Process measurement devices such as [temperature sensors](https://www.sciencedirect.com/topics/engineering/thermal-sensor), [pressure transducers](https://www.sciencedirect.com/topics/engineering/pressure-probe), and weighing instruments require regular calibration . However, different companies from a diverse range of industry sectors use very different methods of managing these calibrations. These methods differ greatly in terms of cost, quality, efficiency, and accuracy of data and their level of automation.

Documentation is a very important part of a calibration management process. ISO 9001:2000 and the FDA both state that calibration records must be maintained and that calibration must be carried out according to written and approved procedures. This means an instrument engineer can spend as much as 50% of his or her time on documentation and paperwork – time that could be better spent on other value-added activities. This paperwork typically involves making notes of calibration results in the field; and documenting and archiving calibration data. When it comes to the volume of documentation required, different industry sectors have different [requirements and regulations](https://www.sciencedirect.com/topics/engineering/requirements-and-regulation). Many hospitals rely on generic spreadsheets and/or databases for this, while others used a calibration module within an existing computerized maintenance management system (CMMS)[7].

### **Paper-based systems (Science direct)**

These systems typically involve handwritten documents. Typically, this might include engineers using pen and paper to record calibration results while out in the field. On returning to the office, these notes are then tidied up or transferred to another paper document, after which they are archived as paper documents. While using a manual, paper-based system requires little or no investment, it is very labor-intensive and means that historical trend analysis becomes very difficult to carry out. In addition, the calibration data is not easily accessible. The system is time consuming, soaks up a lot of resources and typing errors are commonplace. Dual effort and rekeying of calibration data are also significant costs here[8].

### **In-house legacy systems (spreadsheets, databases, etc.)**

Although certainly a step in the right direction, using an in-house legacy system to manage calibrations has its drawbacks. In these systems, calibration data is typically entered manually into a spreadsheet or database. The data is stored in electronic format, but the recording of calibration information is still time-consuming and typing errors are common. Also, the calibration process itself cannot be automated. For example, automatic alarms cannot be set up on instruments that are due for calibration[8].

### **Calibration module of a CMMS**

Many plants have already invested in a computerized maintenance management (CMM) system and so continue to use this for calibration management. Plant hierarchy and works orders can be stored in the CMM system, but the calibration cannot be automated because the system is not able to communicate with smart calibrators. Furthermore, CMM systems are not designed to manage calibrations and so often only provide the minimum calibration functionality, such as the scheduling of tasks and entry of calibration results. Although instrument data can be stored and managed efficiently in the plant’s database, the level of automation is still low. In addition, the CMM system may not meet the regulatory requirements (e.g., FDA) for managing calibration records.

From our review of the past calibration management systems, several gaps and limitations stand out. Paper-based systems are time-consuming, labor-intensive, and prone to human error, making data retrieval and trend analysis difficult. In-house legacy systems, like spreadsheets and databases, also suffer from inefficiency due to manual data entry and lack automation for scheduling and alerts. Calibration modules within CMMS focus more on general maintenance and often provide only minimal calibration functionality. To improve upon these gaps, our system will offer complete automatic storage and retrieval of data within the databases, enabling real-time data logging during calibration with easy access for retrieval and historical analysis., automated alerts for calibration schedules and a user-friendly interface with customizable dashboards. It would also ensure regulatory compliance and mobile app support for on-site data entry and tracking[9].

In summary, hospitals can benefit from implementing specialist calibration management software. Compared to traditional, paper-based systems, in-house built legacy calibration systems or calibration modules with CMM systems, using dedicated calibration management software results in improved quality, increased productivity, and reduced costs of the entire calibration process. Despite these benefits, only one quarter of companies who need to manage instrument calibrations actually use software designed for that purpose.

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## **METHODOLOGY**

### **REQUIREMENTS GATHERING**

We shall engage with stakeholders, including engineers, compliance officers, and end-users, to collect and document functional and non-functional requirements for the system.

We shall Identify specific regulatory standards that the system must comply with and any unique needs of the organization.

### **TECHNOLOGY STACK SELECTION**

**Programming Languages:**

We will use Python, for backend development, which offers robust libraries for data handling and processing, and JavaScript for frontend development to enable dynamic user interfaces.

**Frameworks:**

We shall use Django, which provides a high-level framework with built-in features for security frameworks to facilitate rapid development. For the backend, we shall use and database management. For the frontend. We shall use react because of its ability to create interactive user interfaces and manage application state effectively.

**Cloud Services:**

We shall use cloud services like AWS for hosting our application and storing data. These platforms offer scalability, security, and flexibility for managing application resources.

**Database Management System:**

We shall use MySQL because of its wide adoption and community support.

### **SYSTEM DESIGN**

**Specific objective 1**

**Database Design:**

We shall develop a robust database schema to support the management of instruments and users. This schema will ensure efficient storage, retrieval, and manipulation of data.

Our design shall accommodate features such as maintaining log history for each instrument and user action, allowing for easy tracking of changes over time.

**Specific objective 2**

**User Interface Design:**

We shall develop wireframes and prototypes for the graphical user interface (GUI) to create a user-friendly experience. These prototypes should demonstrate how users will navigate through the system, ensuring ease of use and intuitive access to features.

The dashboard will serve as the central hub of the system, providing a clear overview of all functionalities available to the user based on their privileges. This includes visual indicators for upcoming recalibrations, notifications for necessary approvals, and quick access buttons for frequently used features such as instrument management and reporting.

We shall focus on accessibility and responsiveness to ensure the application is usable across various devices, including desktops, tablets, and smartphones.

**Development**

Backend Development:

We shall Implement APIs for data handling, enabling CRUD (Create, Read, Update, Delete) operations for calibration records. This will allow the system to manage data effectively and ensure that it can respond to user requests in real-time.

Develop the logic for scheduling reminders and compliance checks, ensuring that users receive timely notifications about upcoming calibrations and necessary actions.

Frontend Development:

Create the user interface based on the designs, ensuring responsiveness and usability. The interface should be intuitive, allowing users to navigate the system with ease.

**Specific objective 3**

**Testing**

We shall conduct unit testing, integration testing, and user acceptance testing to ensure all components function correctly and meet user expectations.

Test for security vulnerabilities, ensuring that all communications are SSL-secured with SHA-2 and 2048-bit encryption.

**Deployment**

We shall deploy our Calibration Management System on AWS to ensure it is accessible across devices (computers, laptops, tablets). We shall configure our system for automatic storage and retrieval of data within the databases, enabling real-time logging and easy access to historical records.

## **WORK PLAN**

## **BUDGET**

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| ITEM | DESCRIPTION | ESTIMATED COST |
| Stakeholder engagement | Interviews, surveys and gathering information  Transportation costs | Free  50,000 shillings |
| Technology stack | Cost of software tools and cloud services |  |
| Data services | Cost of data to use during the research period | 100,000 shillings |
| 1.Django  2. React | Backend framework for development  Frontend framework for user interface | Free  Free |
| MySQL | Database Management system | Free |
| 3.Amazon Cloud Services | Hosting, storage and computer resources | 52,800 shillings per month |
| TOTAL |  | 202,800shillings |

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