Specification of Requirements according to IEEE 830 Standard

IEEE Std. 830-1998
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App Design

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1. Introduction

1.1. Purpose

The purpose of this project is to develop a comprehensive system that optimizes and automates the scheduling of preventive maintenance for medical equipment, as well as the efficient management of associated diagnostics. The proposed solution aims to ensure the optimal operation of medical devices in strict compliance with current regulations, guaranteeing their safe and reliable performance.

Additionally, the system will incorporate the automated generation of certificates and reports, which will include the Unique Key for Health Establishments, thereby facilitating control and traceability of maintenance processes.

The platform will feature three user roles: technician, administrator, and client, each with differentiated access levels based on their responsibilities. Furthermore, a document management module called "Files" will be implemented to efficiently handle documents related to maintenance, reports, and certificates. This functionality will allow for document organization and the recording of key details, such as the user responsible for uploading, the date of inclusion, and the linkage to a specific maintenance task or piece of equipment.

1.2. System Scope

The system will enable users to manage and schedule preventive maintenance, handle diagnostics, and automatically generate reports and certificates. The solution will include a document management module called "Files" to record key maintenance details. There will be three types of users: technician, administrator, and client, each with different levels of access.

1.3. Definitions, Acronyms, and Abbreviations

Preventive Maintenance (PM): Scheduled activities designed to keep medical equipment functioning properly.

Report: A document summarizing maintenance details, observations, and technician inputs.

Certificate: A formal document verifying compliance with specific regulations and safety standards.

CLUES: Unique Code for Health Establishments.

1.4. References

IEEE Std 830-1998: IEEE Recommended Practice for Software Requirements Specifications.

FDA. (n.d.). 21 CFR Part 11 - Electronic Records; Electronic Signatures. U.S. Food and Drug Administration. Retrieved from https://www.fda.gov/regulatory-information/search-fda-guidance-documents/part-11-electronic-records-electronic-signatures-scope-and-application

Good Manufacturing Practices (GxP). (n.d.). Good Manufacturing Practices (GxP) Guidelines. U.S. Food and Drug Administration. Retrieved from https://www.fda.gov/drugs/pharmaceutical-quality-resources/current-good-manufacturing-practice-cgmp-regulations

2. General Description

2.1. Product Perspective

The system will be a web and mobile application focused on managing the maintenance of medical equipment. It will consist of interconnected modules for managing maintenance, diagnostics, documents, and users.

2.2. System Functions

- Automated planning of preventive maintenance.
- Management of medical equipment diagnostics.
- Generation of automated certificates and reports with CLUES.
- Document management module "Archives."
- User management with different access levels: technician, administrator, and client.
- "Scheduling" module for task organization by priority.
- Control of equipment history, including acquisition date.
- Detailed maintenance records, including replaced parts.
- Parts management with control over name, description, and available quantity.

2.3. User Characteristics

Technician: Responsible for recording maintenance tasks, diagnostics, and uploading documents.

Administrator: Oversees the system, manages users, and validates reports.

Client: Views the maintenance history and certificates related to their equipment.

2.4. Restrictions

- The system will depend on a stable internet connection for data synchronization.
- It is assumed that users have basic knowledge of using mobile applications.

3. Specific Requirements

3.1. Functional Requirements

FR1: The system will allow the registration, scheduling, and management of preventive maintenance.

FR2: Automatic generation of certificates and reports related to completed maintenance.

FR3: Document management through the "Archives" module.

FR4: Role-based access control (technician, administrator, client).

FR5: Registration and consultation of diagnostics associated with medical equipment.

FR6: Task organization by priority in the "Scheduling" module.

FR7: Control of equipment history, including acquisition dates and previous maintenance records.

FR8: Registration of parts replaced during maintenance.

FR9: Inventory management of parts, including name, description, and available quantity.

3.2. Non-Functional Requirements

NFR1: The application must be responsive and adapt to different screen sizes.

NFR2: Security in the management of sensitive data, including encryption of critical information.

NFR3: High availability and optimal performance in query operations and report generation.

NFR4: Compliance with accessibility standards for mobile applications.

3.3. Performance Requirements

PR1: Response Time

- The system must be capable of processing any request (such as queries, certificate generation, report generation, or data updates) within a maximum time of 2 seconds under normal load conditions.

PR2: Certificate and Report Generation Time

- The generation of certificates in PDF format, once maintenance is completed, must take a maximum of 5 seconds.

PR3: Scalability

- The system must be able to handle a minimum of 200 concurrent users (Clients, Technicians, and Administrators), maintaining the same level of performance.

3.4. Design Constraints

DC1: Development Technologies and Languages

- The system must be developed using React Native for the user interface and PHP for the backend.

DC2: Compliance with Maintenance Standards

- The formats of the certificates and reports must comply with the requirements of the regulatory authorities in the biomedical maintenance field.

DC3: User Interface and Accessibility

- The interface must be responsive and properly adapt to mobile devices, tablets, and desktop screens.

DC4: Document Storage and Format

- All generated certificates and reports must be stored in PDF format.

  The system must ensure that the PDFs are properly formatted and readable in any standard viewer.

  The system must keep copies of all generated documents.

DC5: Third-Party Dependencies

- The use of third-party libraries or services that require expensive licenses or long-term dependencies should be minimized, unless necessary for compliance with regulations or security (e.g., libraries for PDF generation or email sending).

3.5. System Attributes:

- **Security:** Data protection through authentication and encryption.
- **Scalability:** Ability to increase infrastructure as needed.
- **Maintainability:** Modular and documented code to facilitate updates.

3.6. External Interface:

- REST API for integration with other hospital systems.
- Compatibility with QR code reading for equipment identification.
- Exporting reports in PDF and Excel formats.

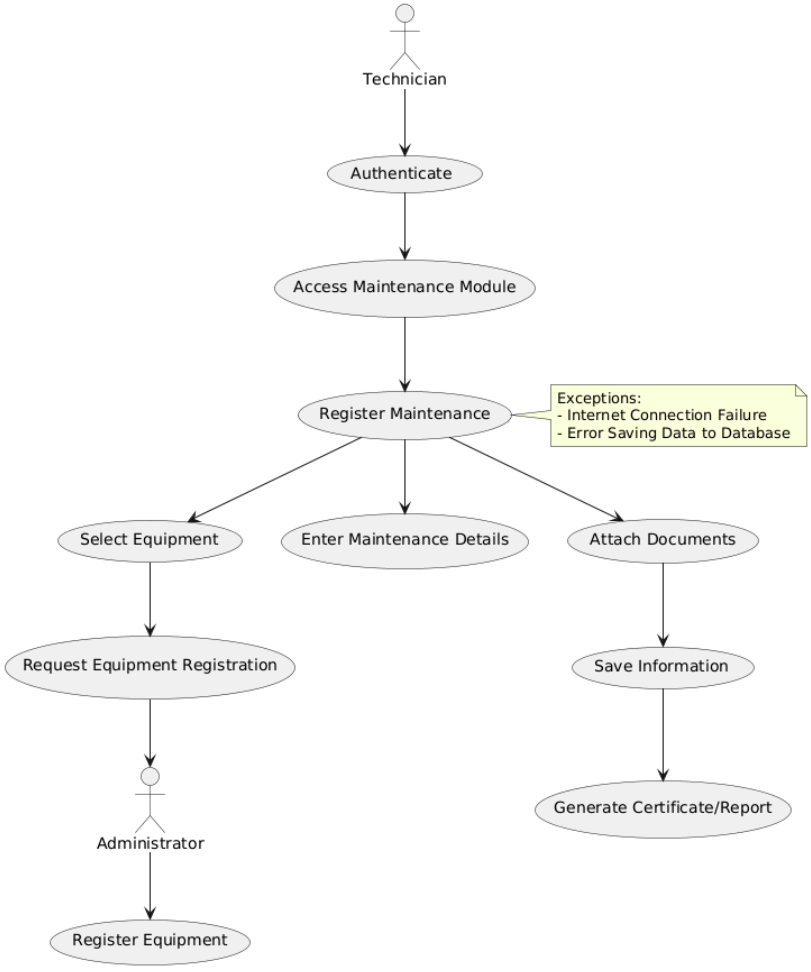
4. Appendices

4.1. UML: Use Cases

- **Use Case 1: Log Maintenance**

Name	Register Maintenance
Actors	Technician
Description	The technician registers the preventive or corrective maintenance of a medical device in the system.
Preconditions	● The technician must be authenticated in the system. ● The equipment must be registered in the database.
Main Flow	1. The technician accesses the maintenance module. 2. Selects the medical equipment to be registered. 3. Enters maintenance details (date, description, equipment status, replaced parts). 4. Attaches relevant documentation (if applicable). 5. Saves the information. 6. The system confirms successful registration.

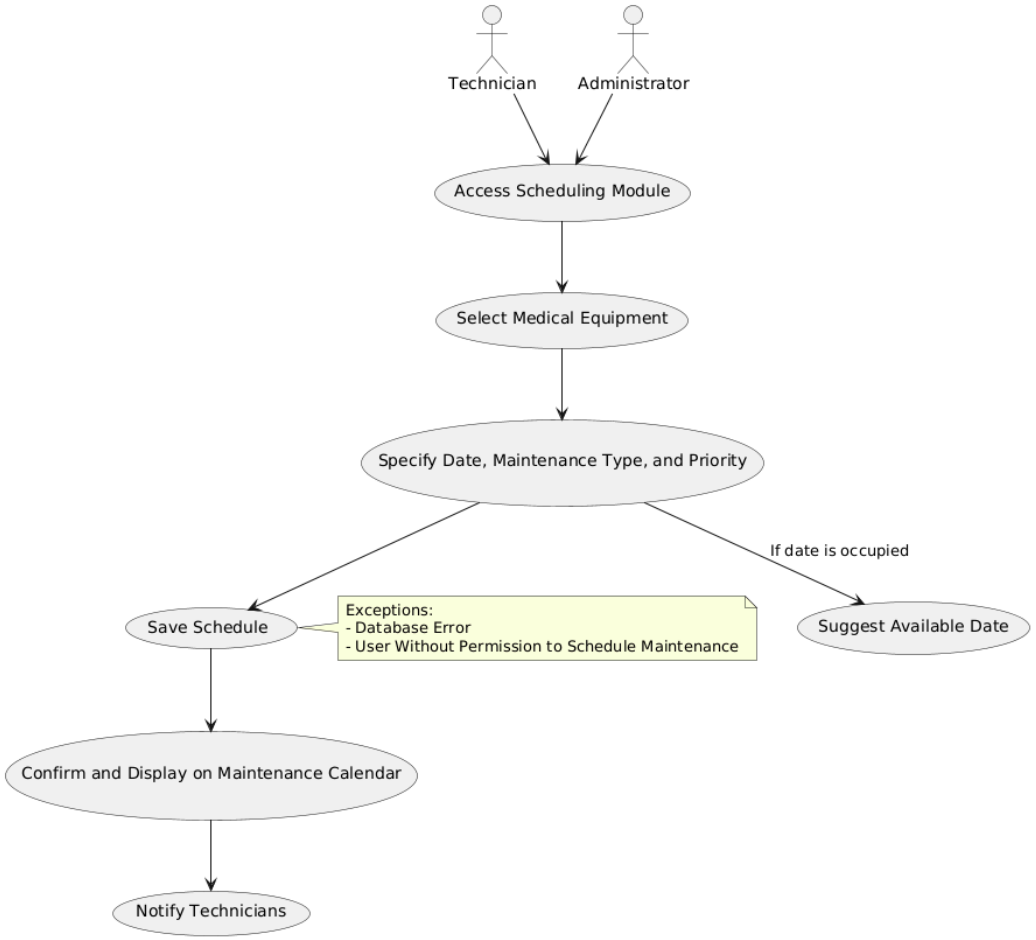
Alternative Flow	If the equipment is not registered, the technician must request its registration from the administrator.
postconditions	• The maintenance is recorded in the equipment's history. • A maintenance certificate or report is generated.



- **Use Case 2: Schedule Maintenance**

Name	Schedule Maintenance
Actors	Technician, Administrator
Description	Allows scheduling preventive maintenance for equipment based on priority.
Preconditions	● The equipment must be registered in the system. ● The user must be authenticated with the appropriate permissions.
Main Flow	1. The user accesses the scheduling module. 2. Selects the medical equipment to be scheduled. 3. Specifies the date, type of maintenance, and priority. 4. Saves the schedule. 5. The system confirms the scheduling and displays it on the maintenance calendar.
Alternative Flow	If the user selects an occupied date, the system suggests another available date.
postconditions	● The maintenance is recorded in the system.

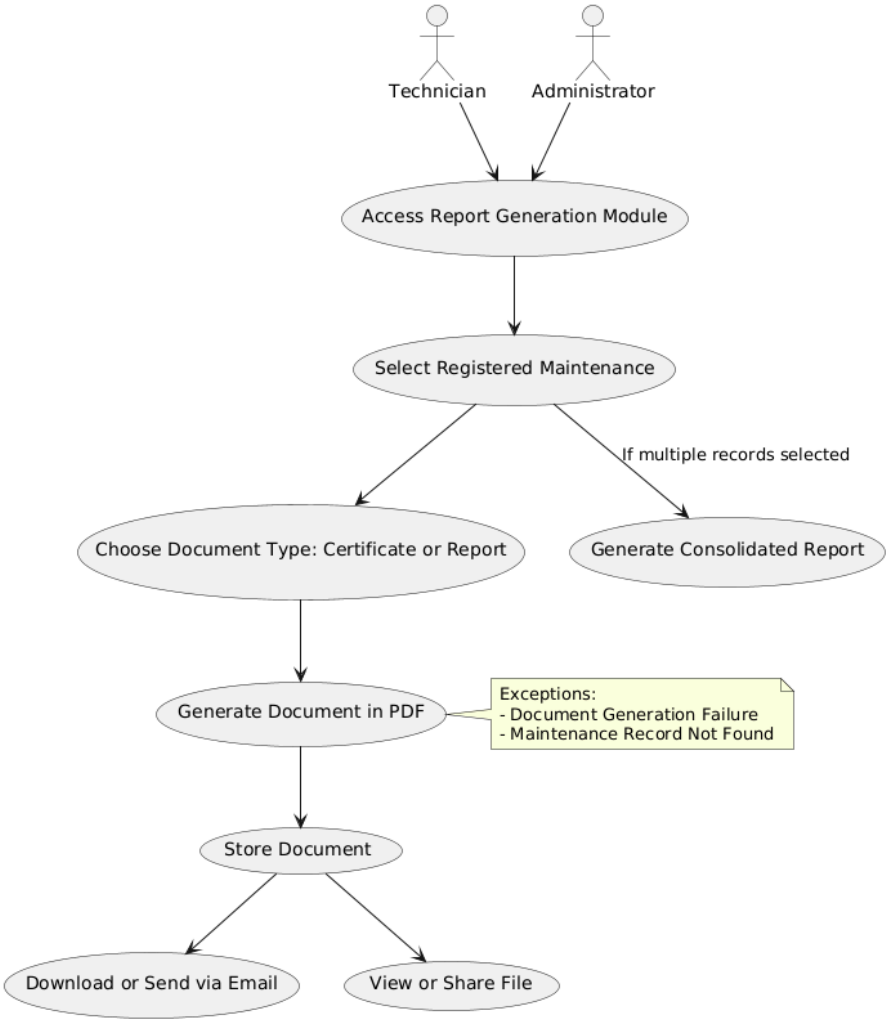
	• Technicians receive a notification of the new schedule.



- **Use Case 3: Generate Report/Certificate**

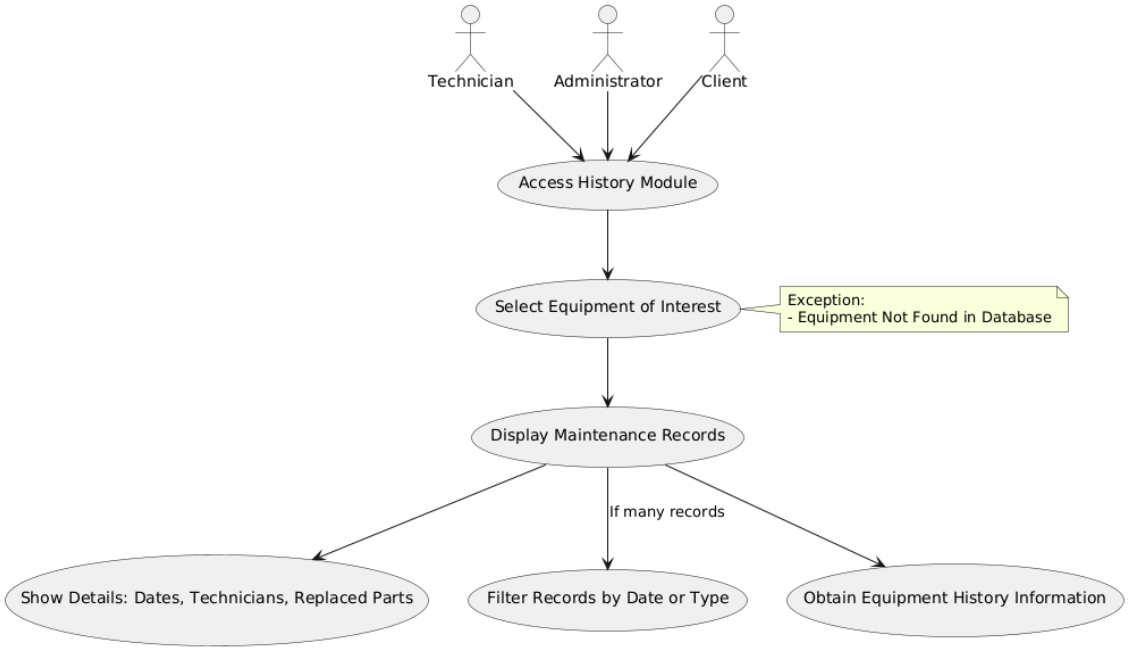
Name	Generate Report/Certificate
Actors	Technician, Administrator
Description	Allows the automatic generation of maintenance reports or certificates in PDF.
Preconditions	● There must be a registered maintenance record. ● The user must have technician or administrator permissions.
Main Flow	1. The user accesses the report generation module. 2. Selects a previously registered maintenance record. 3. Choose the document type (certificate or detailed report). 4. Generates the document in PDF format. 5. The system stores the document and allows it to be downloaded or sent via email.
Alternative Flow	If the user selects multiple maintenance records, a consolidated report is generated.

postconditions	• The document is stored in the database. • The user can view or share the file.

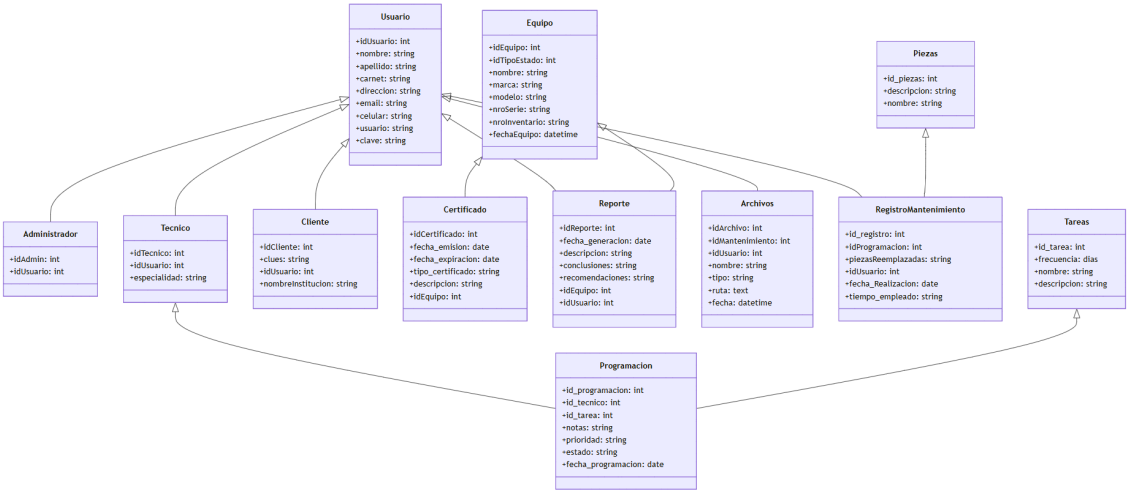


- **Use Case 4: View Equipment History**

Name	View Equipment History
Actors	Technician, Administrator, Client
Description	Allows viewing the previous maintenance activities performed on a medical device.
Preconditions	● The user must be authenticated. ● The equipment must be registered in the system.
Main Flow	1. The user accesses the history module. 2. Selects the equipment of interest. 3. The system displays previous maintenance records with details (dates, responsible technicians, replaced parts).
Alternative Flow	If the equipment has many records, the user can filter them by date or type of maintenance.
postconditions	The user obtains the equipment history information.

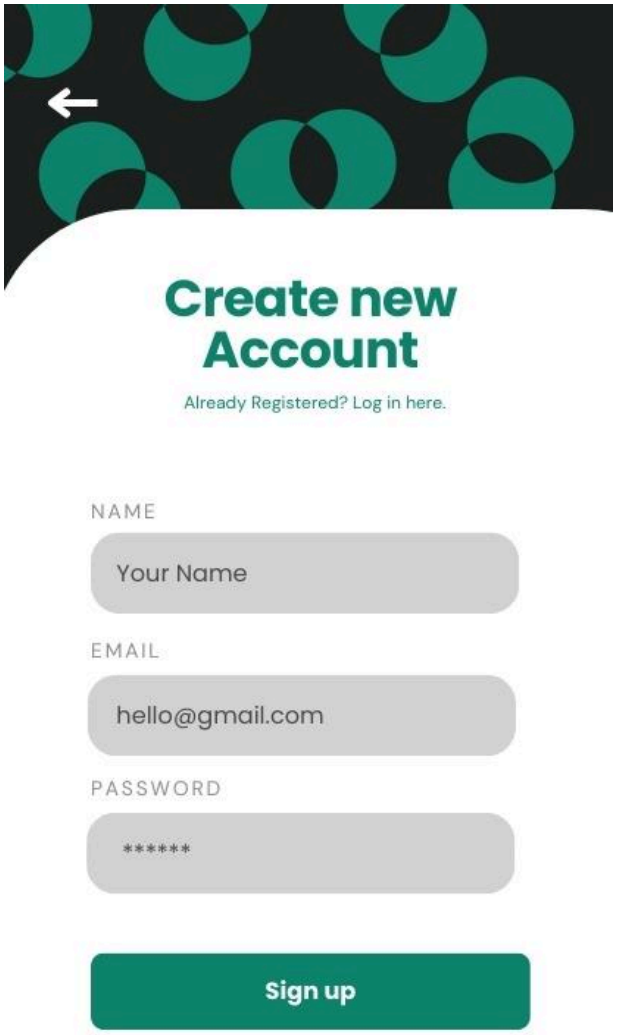

Technician
Administrator
Client
Access History Module
Select Equipment of Interest
Exception:
- Equipment Not Found in Database
Display Maintenance Records
If many records
Show Details: Dates, Technicians, Replaced Parts
Filter Records by Date or Type
Obtain Equipment History Information

- **Class Diagram**

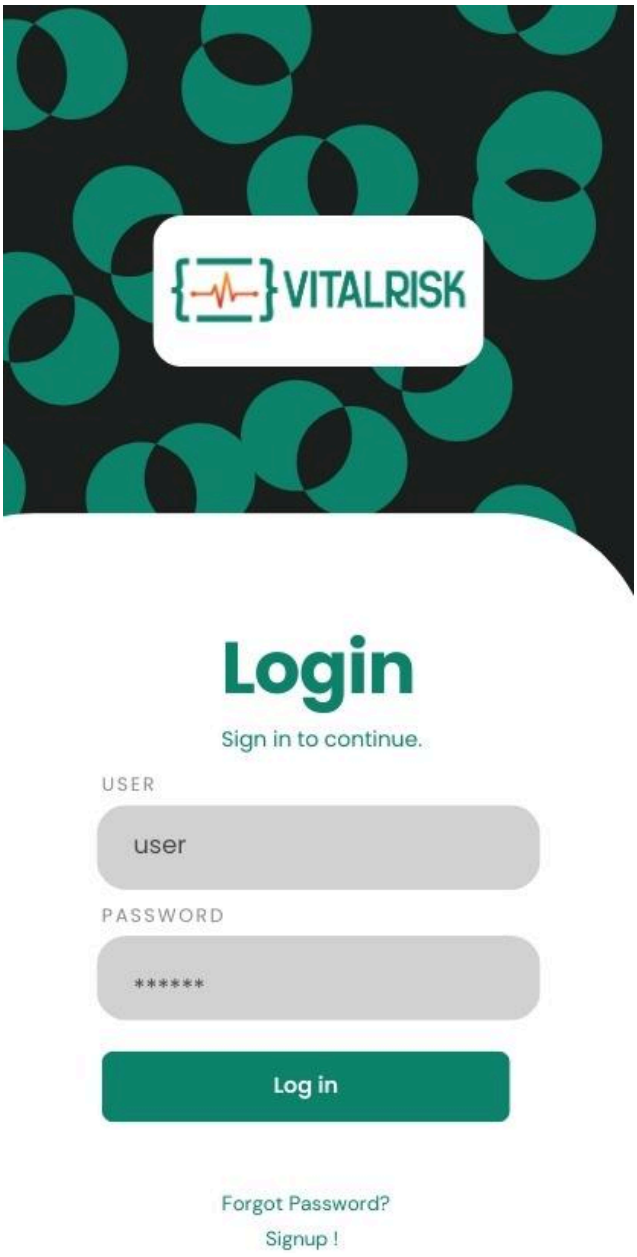


4.2. UI: User Interfaces

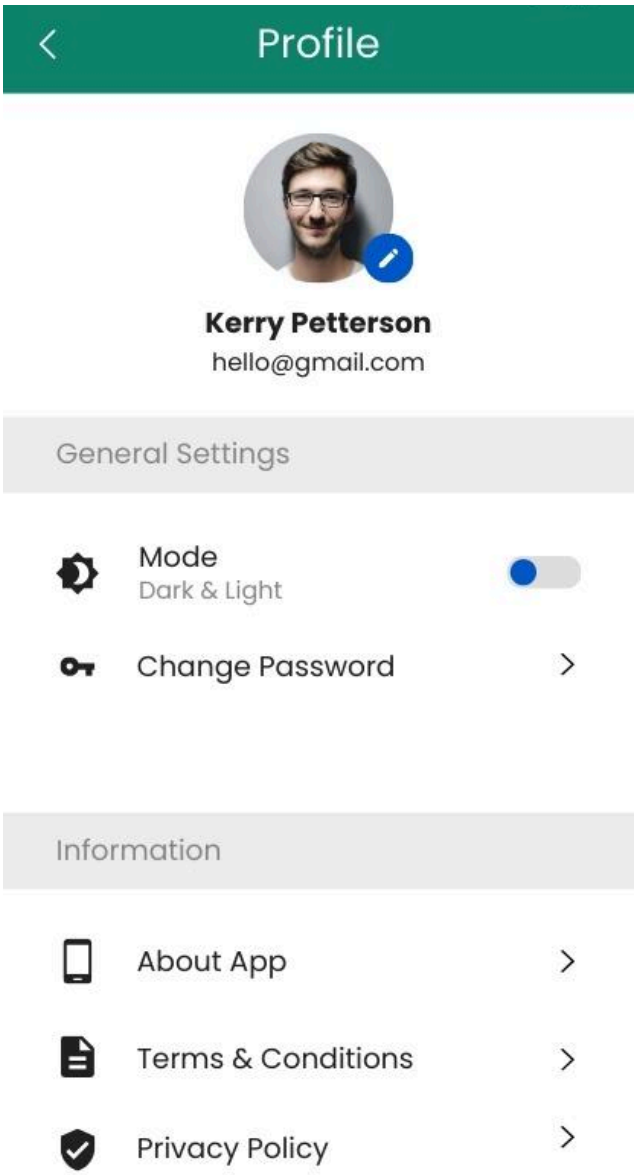
- **Registration**



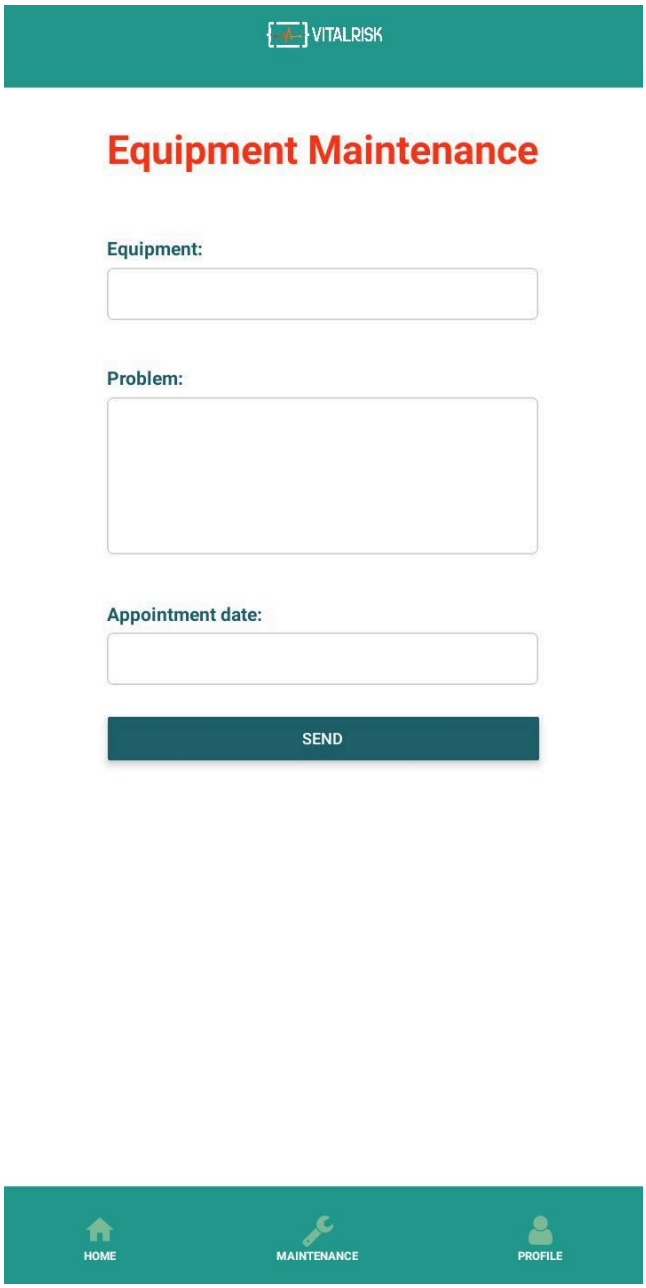
- **Login**


VITALRISK
Login
Sign in to continue.
USER
user
PASSWORD
******
Log in
Forgot Password?
Signup !

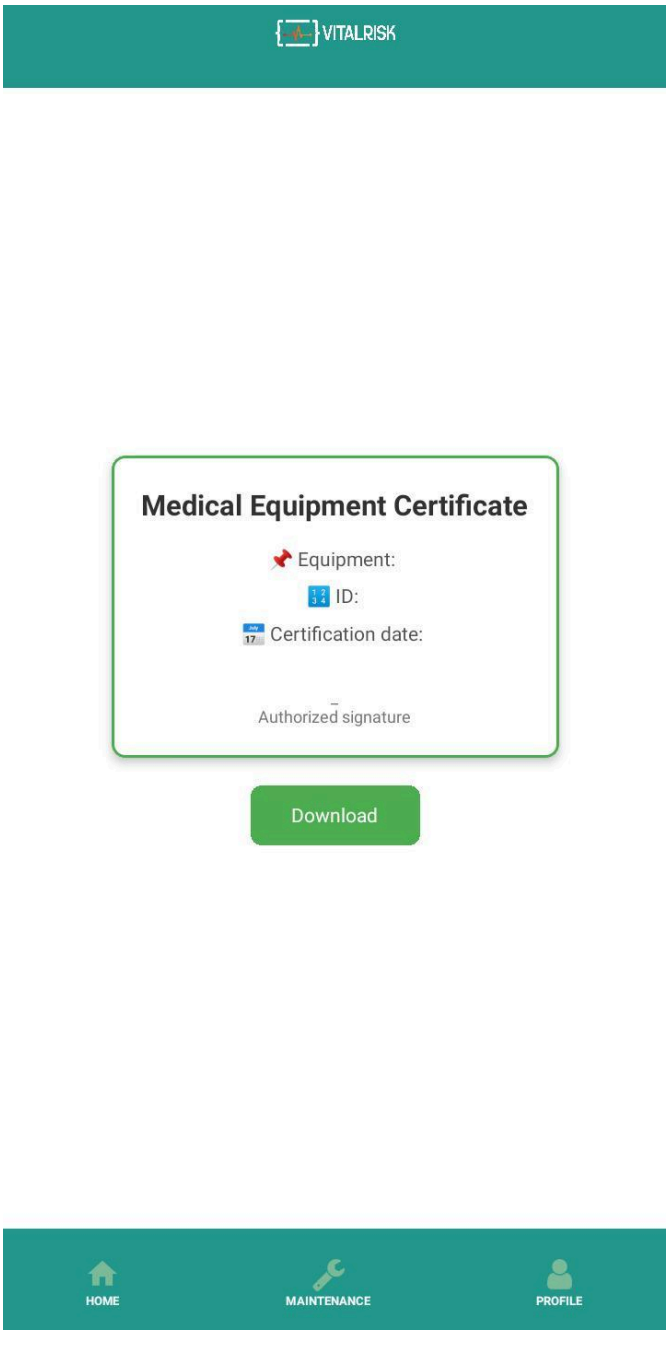
- **Profile**


Profile
Kerry Petterson
hello@gmail.com
General Settings
Mode
Dark & Light
Change Password
Information
About App
Terms & Conditions
Privacy Policy

- **Equipment management**



- **Medical Equipment Certification**



5. Other Requirements

Operating System: The project can run on operating systems such as **Windows**, **Linux**, or **macOS**, depending on the infrastructure of the clinic or hospital.

Communication Protocols: IoT sensors can be connected using standard communication protocols such as:

- **MQTT** for lightweight communication between IoT devices.
- **HTTP/HTTPS** for communication with backend servers.

Certification and Regulation: The software must comply with local health regulations such as **Good Manufacturing Practices (GxP)** and **21 CFR Part 11** from the FDA for electronic records management.

5.1. Hardware Requirements

Monitoring Sensors:
The following sensors will be required to capture data in medication storage rooms and medical equipment:

- **Temperature and humidity sensor**: Such as the **DHT22** or **SHT31**, to monitor environmental conditions in medication rooms and prevent alterations.
- **Motion sensor**: To detect unauthorized access to storage areas or unusual activity.
- **Vibration sensor**: To detect potential damage to medical equipment, especially those that may be moved or handled.

Microcontrollers/IoT Platform:
The data from the sensors can be collected and transmitted to the monitoring platform through microcontrollers such as:

- **ESP32** or **ESP8266**: These are perfect for IoT projects due to their integrated Wi-Fi connectivity.
- **Arduino**: Used for simpler integrations or initial prototypes.

Network and Communication:

- **Wi-Fi modem** or **Ethernet Network** to ensure continuous connectivity between IoT devices and the backend server.

LCD/OLED Display:
It is recommended to include displays such as **OLED 128x64** to show relevant sensor data locally in the monitoring areas.

Server and Storage:

- **Cloud server** (AWS, Google Cloud, or Azure) for storing and processing large volumes of data.
- **Local server** (if on-site storage is required) running an operating system such as **Linux** or **Windows Server**.
- **Backup storage**: It is recommended to have data backup systems in place, such as external hard drives or cloud storage.

Medical Equipment:

- **Measurement equipment** that requires remote monitoring (e.g., vital sign monitors, ventilators, etc.).
- **Certification of equipment** that must maintain a continuous record of the tests and maintenance performed on the medical equipment.