

# PROJECT REPORT

U R O - M O N I T O R

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April 29, 2025

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# Introduction

## Problem Statement

In Sri Lanka's healthcare system, especially in Intensive Care Units (ICUs) and during the management of critical dengue and immobile patients, urine output monitoring is still conducted manually. Nurses must physically visit each patient, observe urometer readings at eye level, and record data on paper typically every 30 minutes to two hours. This process is labor-intensive, time-consuming, and highly prone to human error, leading to inaccuracies in patient records and delays in detecting critical conditions like Acute Kidney Injury (AKI). While most vital signs such as heart rate, blood pressure, and oxygen saturation are continuously and electronically monitored, urine output a key indicator of kidney function remains analog and inefficient. This outdated approach not only increases the workload and stress of medical staff but also introduces risks to patient safety due to missed or incorrect data entries. Studies show that manual urine measurement contributes to errors in 30–40% of cases, potentially impacting timely diagnosis and treatment.

## Objectives

- Automate the monitoring of urine output using an IoT-based system to eliminate the need for manual measurements.
- Ensure real-time, accurate data collection using capacitive sensing technology and microcontroller-based processing.
- Minimize human error and enhance data integrity by integrating a centralized digital platform for storing and viewing patient data.
- Develop a nurse-friendly alert system (both digital and physical) to notify staff when a urometer is full or when anomalies are detected.
- Improve critical care decision-making by providing trend analysis and historical data for early detection of AKI and fluid management issues.
- Support healthcare digitalization goals in Sri Lanka by offering a scalable, affordable solution tailored to local hospital infrastructure.
- Design a hygienic and ergonomic device enclosure that is reusable and compatible with the widely used urometers in Sri Lanka.

## Scope

This project focuses on designing and prototyping URO-MONITOR, a smart extension to the conventional urometer that offers real-time, automated urine output monitoring. The system leverages capacitive liquid-level sensing via the FDC1004 IC, data processing through the ESP32 microcontroller, and wireless transmission using WiFi to a centralized database built on Firebase. A companion mobile/desktop app, developed using Flutter, allows medical personnel to remotely view urine volume data, receive alerts, and access patient history. The physical system consists of a reusable enclosure that securely holds the disposable urometer bag, ensuring accuracy and hygiene. While the initial prototype uses 3D printing, the design is optimized for mass production through plastic molding. The project aims to serve ICU and critical care units in Sri Lankan hospitals, with considerations for regulatory approval and scalability in other similar healthcare settings. The system will also be adaptable to multiple urometer models with minor calibration adjustments, thus enhancing compatibility and usability across institutions.

# Literature Review & Background Research

Urine output monitoring is a vital parameter in assessing renal function and fluid balance, particularly in critically ill patients. Despite the technological advancements in modern intensive care units (ICUs), this essential measurement is still commonly performed manually. Multiple studies have identified significant shortcomings in this approach. According to research published by the National Center for Biotechnology Information (NCBI), manual urine measurements in ICU settings are prone to 30–40% error rates, which can result in delayed interventions, misdiagnosis, or improper fluid management. This level of inaccuracy is especially concerning in high-risk environments like ICU wards, where timely data can mean the difference between recovery and complications.

Further evidence from the National Kidney Foundation reveals that Acute Kidney Injury (AKI) affects up to 20% of hospitalized patients and is responsible for nearly 50% of ICU mortality globally. Since urine output is one of the earliest indicators of AKI, continuous and accurate monitoring is critical for early detection and intervention. However, the reliance on manual recording makes it difficult to detect rapid physiological changes, potentially compromising patient outcomes.

In the context of tropical diseases like dengue fever—prevalent in Sri Lanka—urine output monitoring becomes even more critical. The World Health Organization (WHO) reports that timely and accurate fluid management can reduce severe dengue complications by up to 20%, highlighting the necessity for reliable monitoring systems, especially during dengue outbreaks in hospital settings.

The global healthcare industry is rapidly shifting toward automation and real-time data systems. Market research shows that the IoT in healthcare sector is expected to reach USD 188.2 billion by 2028, reflecting a growing demand for connected, intelligent medical devices. Despite this surge, many urimeters in current use—especially in Sri Lankan hospitals—remain either fully manual or partially digital without any smart integration. Our product aims to bridge this gap by introducing a cost-effective, IoT-integrated extension to existing urimeter systems, equipped with real-time alerts, data logging, and remote monitoring capabilities.

Together, these findings from academic research and global health organizations strongly support the development of an automated, intelligent urine monitoring solution. This literature-backed foundation not only confirms the validity of the problem but also highlights the innovation potential and local relevance of the URO-MONITOR system.

# Our Solution

## Introduction

Urine output monitoring is a critical parameter in evaluating the health status of patients, especially those admitted to ICUs, suffering from dengue fever, or who are unconscious and immobile. In Sri Lankan hospitals, this process is typically conducted using disposable urimeters that require nurses to physically check, record, and empty the urine collection chambers at frequent intervals. This repetitive task is both time-consuming and labor-intensive, significantly adding to the workload of already overburdened healthcare professionals. Furthermore, manual readings are vulnerable to errors, delays, and omissions, compromising timely medical decisions and potentially patient safety.

Despite widespread adoption of automated systems for monitoring vital signs such as heart rate and blood pressure, urine output—an equally important metric—remains largely dependent on outdated manual processes. In response to this challenge, we propose a smart, IoT-integrated urimeter designed specifically to meet the needs of Sri Lankan hospitals and elevate the standard of critical care monitoring.

## Overview of the Solution

Our proposed solution is a Smart Urometer System, an innovative device that automates the monitoring of urine output by integrating capacitive sensing technology with a microcontroller-based IoT platform. This system is designed to measure urine volume in real-time, transmit data via Wi-Fi, and alert medical personnel when the urometer needs to be emptied. It eliminates the need for constant manual readings, reduces human error, and ensures hygienic usage by preserving the disposable nature of the urometer.

The core of our system is a reusable, ergonomic, and cost-effective enclosure that fits around standard disposable urimeters without modifying or breaching their sealed structure. It uses capacitive sensors to detect the urine level inside the chamber without direct contact. This data is processed by an ESP32 microcontroller, which wirelessly transmits readings to a centralized server. The data is then accessible through a custom mobile/desktop app interface, allowing for remote and continuous monitoring by hospital staff.

An integrated alert system (both digital and physical) notifies nurses when the urine level reaches a predefined threshold, preventing overflows and ensuring prompt intervention. The system also maintains digital logs for each patient, enhancing traceability, reducing paperwork, and supporting long-term trend analysis—especially beneficial for detecting conditions like acute kidney injury (AKI).

## **Methodology**

The Smart Urometer operates on the principle of capacitive liquid level sensing, which measures changes in capacitance as the urine volume increases within the sealed chamber. The system consists of strategically placed capacitive sensor electrodes that detect variations in dielectric constant as the fluid level rises. These signals are interpreted by the ESP32 microcontroller, which calculates the urine volume based on the calibrated sensor readings.

The ESP32 then transmits this data via Wi-Fi to a cloud-based or local hospital server. A dedicated mobile and desktop app receives this data, presenting it in an intuitive, user-friendly interface for healthcare professionals. Real-time monitoring and historical data analysis are supported, allowing medical staff to track fluid output trends and detect early signs of complications.

Additionally, the system is equipped with an alert mechanism that includes an LED indicator, buzzer, and digital notifications through the app to inform staff when the urometer is full. This ensures timely waste disposal and uninterrupted monitoring. The entire assembly is designed to be non-invasive, easy to sterilize, and compatible with existing hospital infrastructure, making it an ideal solution for high-demand healthcare environments in Sri Lanka.

# Feasibility

The URO-MONITOR project is highly feasible from both a hardware and software perspective. It is built entirely using readily available components and mature, well-documented technologies, making it practical for both prototyping and large-scale deployment in healthcare environments.

## Component Availability and Hardware Feasibility

| Component        | Role in System                                    | Market Price         | Notes on Availability   | Justification on Suitability  |
|------------------|---|----------------------|---|---|
| FDC1004          | Capacitance-to-Digital Conversion for fluid level | ~1700LKR             | Used in prototyping and experimental applications   | High-resolution differential capacitance measurement; ideal for accurate and non-invasive liquid level sensing.   |
| ESP32            | Wi-Fi-enabled microcontroller                     | ~1500LKR             | Open-source and globally available  | Dual-core processor with integrated Wi-Fi & Bluetooth; supports OTA updates and remote monitoring, ideal for IoT medical devices.   |
| Copper Plates    | Sensor electrodes                                 | ~1500LKR for our use | Easily cut and shaped from copper sheet   | Excellent conductor and easily fabricated; ensures consistent capacitive response.  |
| Buzzer/LED       | Alert system                                      | ~150LKR              | Off-the-shelf, no customization needed  | Simple, reliable visual/audio alert for hospital environment without extra interfaces.  |
| PLA/ABS          | Enclosure material                                | ~1200LKR             | PLA for prototyping, Transition from PLA to injection-molded ABS (FDA compatible) for final use | PLA is biodegradable and quick for prototyping.<br>ABS is durable and suitable for sterilizable, long-term enclosures, reduces per-unit cost and proven in mass-produced medical IoT devices. |
| Ronsons Urometer | Disposable collection unit                        | ~2000LKR             | Already in hospital supply chains   | Ensures compatibility with current infrastructure, no new procurement process required.   |

## Technology Stack and Software Feasibility

| Layer          | Technology       | Justification  |
|----------------|------------------|--|
| Embedded Logic | Arduino on ESP32 | Enables rapid development and flexible firmware updates (via OTA), ensuring the device can evolve with clinical feedback and improve over time.                      |
| Connectivity   | Wi-Fi (ESP32)    | Facilitates real-time data transmission without GSM-related costs, ensuring immediate updates to caregivers and integration with hospital networks.                  |
| UI             | Flutter          | Delivers a consistent, intuitive interface across Android, iOS, and Web platforms, improving usability for diverse hospital staff with minimal training required.    |
| Backend        | Firebase         | Provides real-time data syncing, secure storage, and scalable infrastructure, supporting continuous patient monitoring and easy expansion across wards or hospitals. |

## The Ronsons Urometer



It is important to note that our design is based around the Ronson's urometer, which is the standard model used in the majority of hospitals in Sri Lanka, including Sri Jayawardenepura Hospital and the National Hospital of Sri Lanka (NHSL).

Our product is intended to function as an accessory to this commonly used urometer, enhancing its capabilities without replacing the base unit. As such, the cost of our product does not include the price of the Ronson's urometer itself. For hospitals or setups using different urometer models, our system can be easily adapted with minor mechanical or connector adjustments, ensuring broad compatibility across various clinical environments.

## Final price calculation for the initial prototype

|                               |         |
|-------------------------------|---------|
| ESP32 Microcontroller         | Rs 1500 |
| FDC1004 TI Chip               | Rs 1700 |
| Enclosure                     | Rs 1200 |
| Buzzer                        | Rs 150  |
| Wires and miscellaneous items | Rs 150  |
| Copper sheets                 | Rs 1500 |
| <hr/>                         | <hr/>   |
| Total                         | Rs 6200 |
| <hr/>                         | <hr/>   |

As it stands, the final price of the uro-monitor remains well under LKR 6,500, which is a strong achievement for a medical-oriented product.

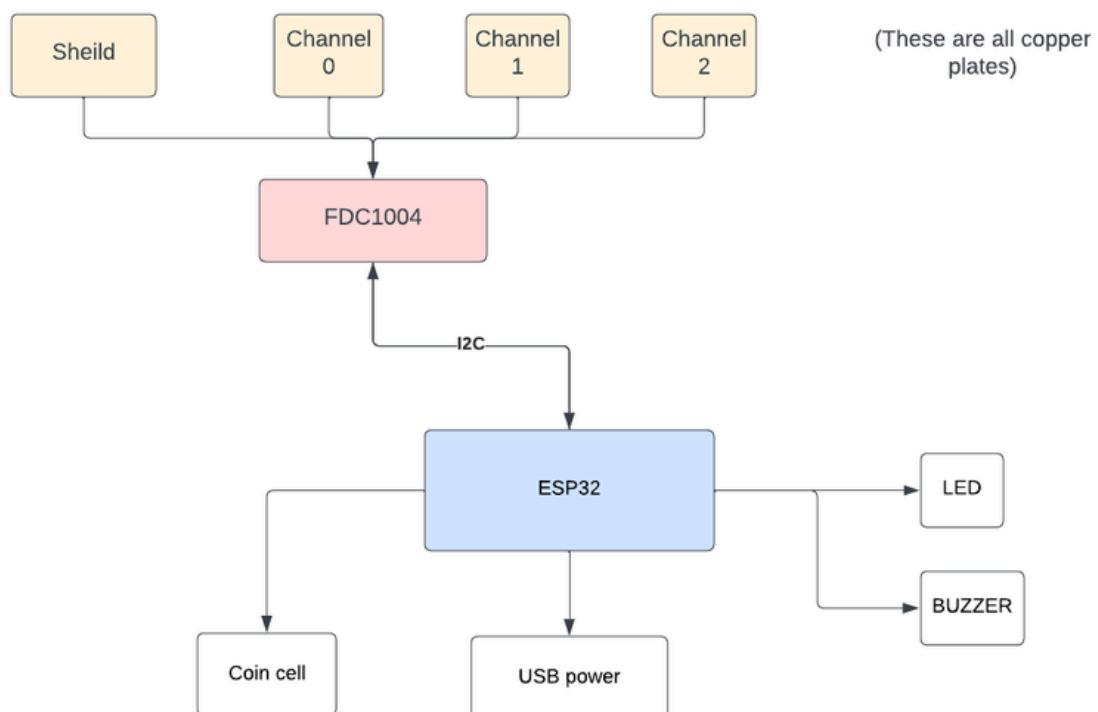
As development progresses, we plan to transition towards components that meet ISO and other relevant medical-grade standards, ensuring compliance with regulatory requirements. Even with these advancements, the overall cost is expected to remain very affordable, making the product accessible for widespread clinical and personal use. These considerations will be discussed further in the Regulations section of this document.

## **Manufacturing and Deployment Readiness**

- The system adopts a modular design where the reusable electronic enclosure pairs with a disposable urometer, ensuring hygiene while minimizing material waste.
- Its plug-and-play compatibility with existing Ronsons urometers allows seamless integration into current hospital workflows, requiring no extra staff training.
- The sterilizable electronics module extends device longevity and supports a more sustainable lifecycle.
- Quick deployment is possible with just a USB charger and Wi-Fi, enabling easy setup in standard medical environments.
- A flexible enclosure accommodates various urometer brands with minimal redesign, promoting scalable adoption across institutions.
- The current PLA prototype is ready for mass production via injection-molded ABS, a cost-effective and FDA-compliant material used in similar medical IoT devices.
- Overall, the design ensures a feasible, sustainable, and economical path from prototype to widespread hospital deployment.

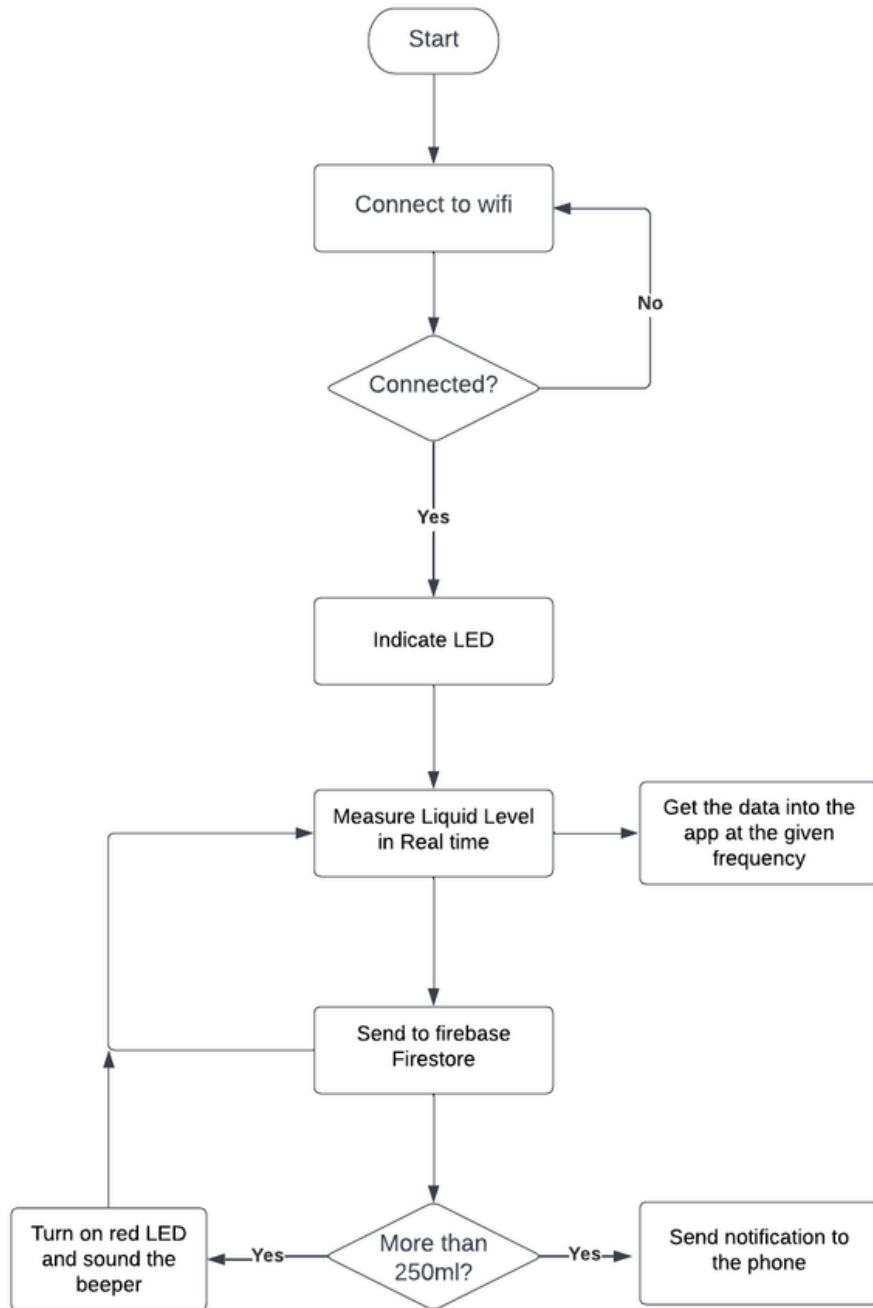
# Functionality

The functionality of our innovation is quite simple. The uro-monitor is designed to continuously measure the urine level in a urometer using a capacitive sensing system. The collected data is then transmitted to Firebase, enabling real-time cloud storage and access. Based on the doctor's specified interval—typically hourly or as medically required—the system calculates the urine output rate and delivers it directly to a connected mobile application. This allows for remote monitoring, timely intervention, and reduces the need for manual measurements in clinical settings.



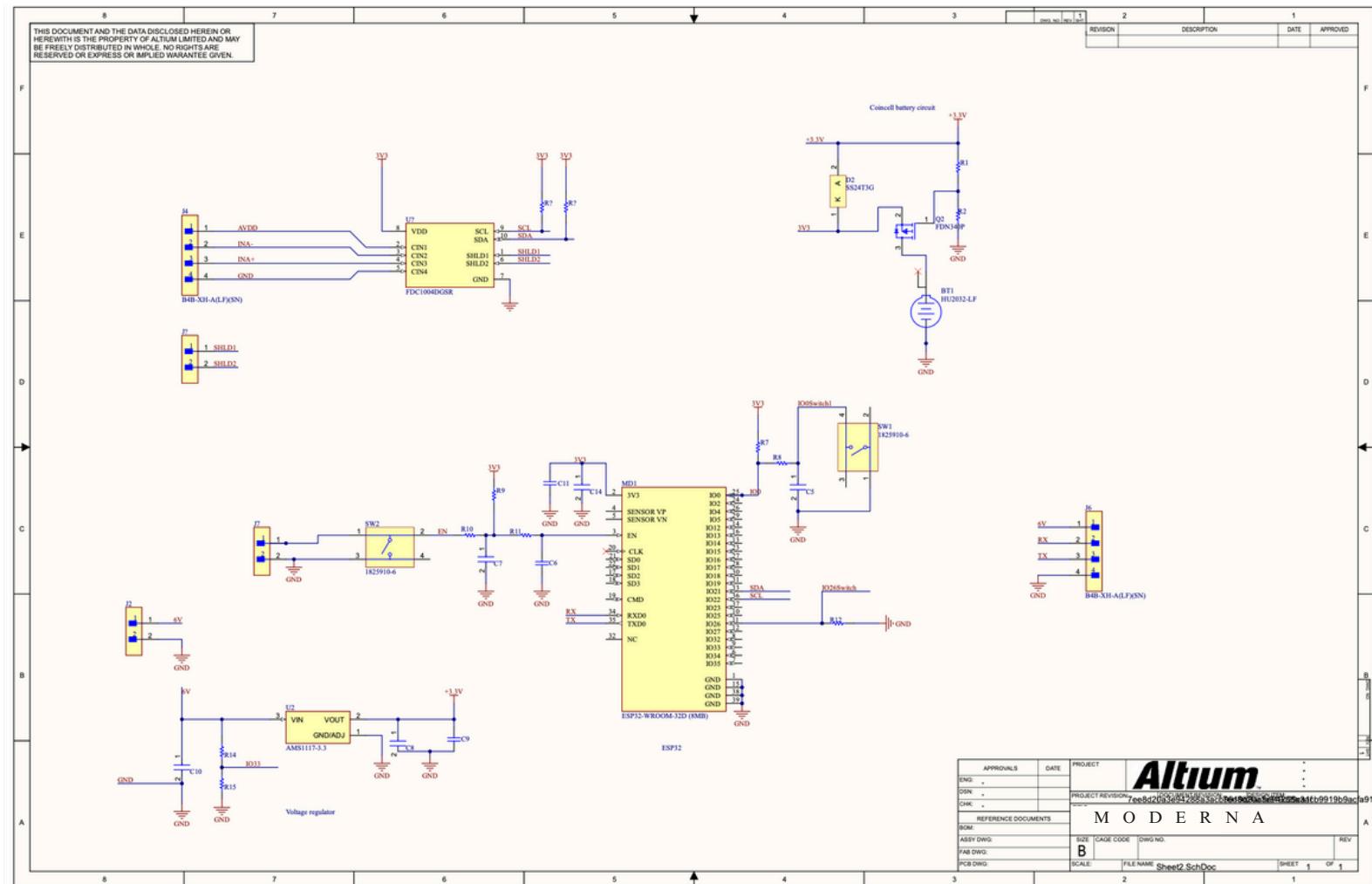
# Functionality

Here we have the simple hardware flow diagram of our product

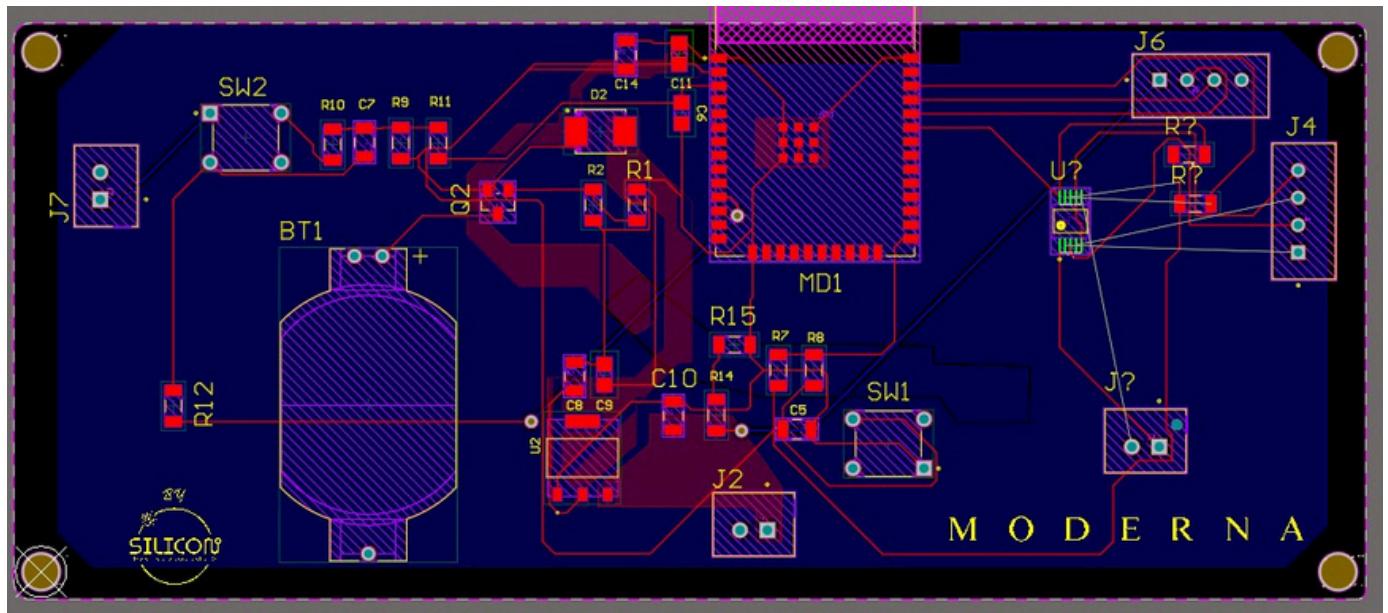


# Circuitry

## Schematic diagram



## PCB design



# Mobile Application

## Mobile App and Tech Stack

The mobile application was developed using the Flutter framework, which allows for cross-platform support on both Android and iOS. The backend is powered by Google Firebase, specifically using the Firebase Realtime Database to handle data storage and communication.

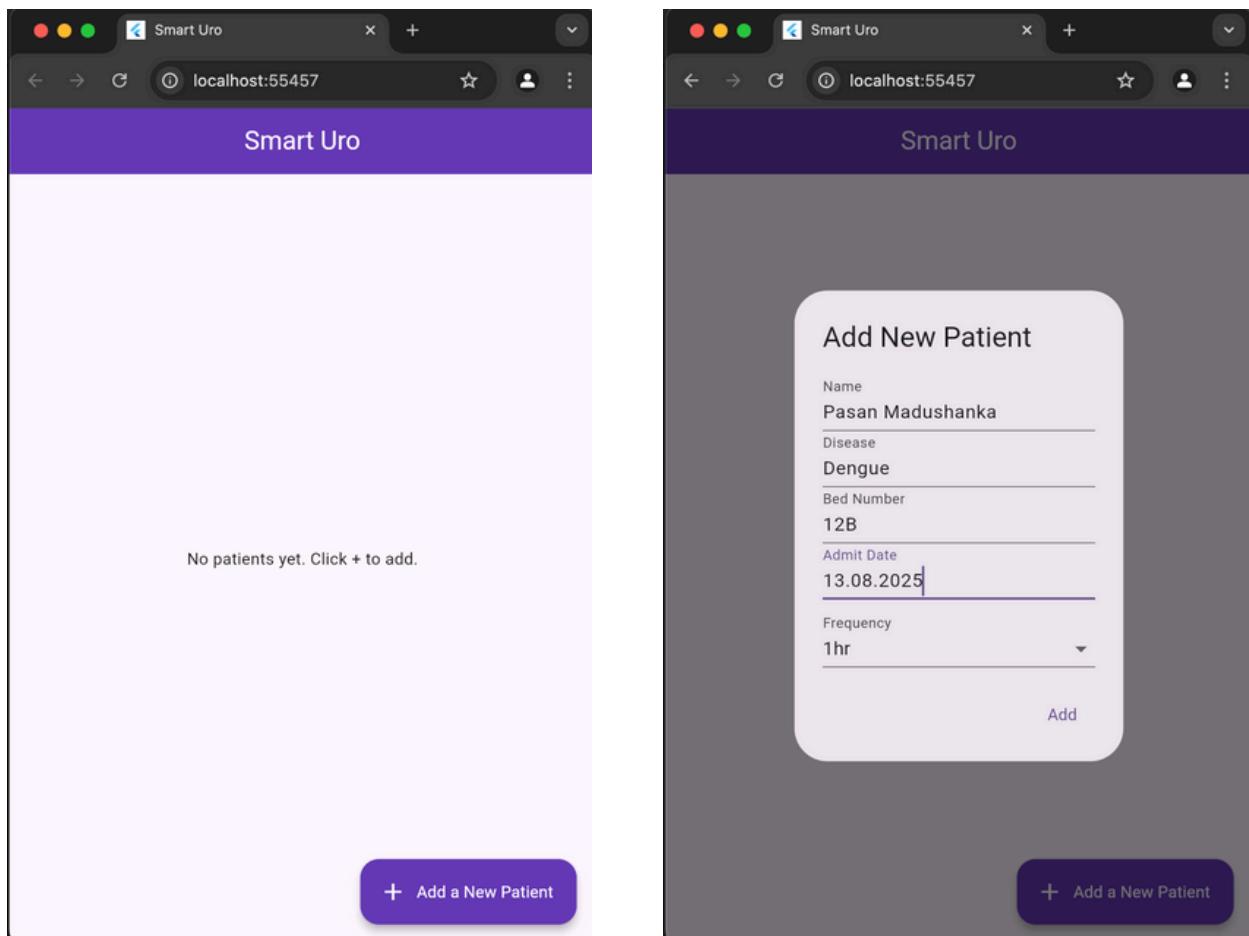
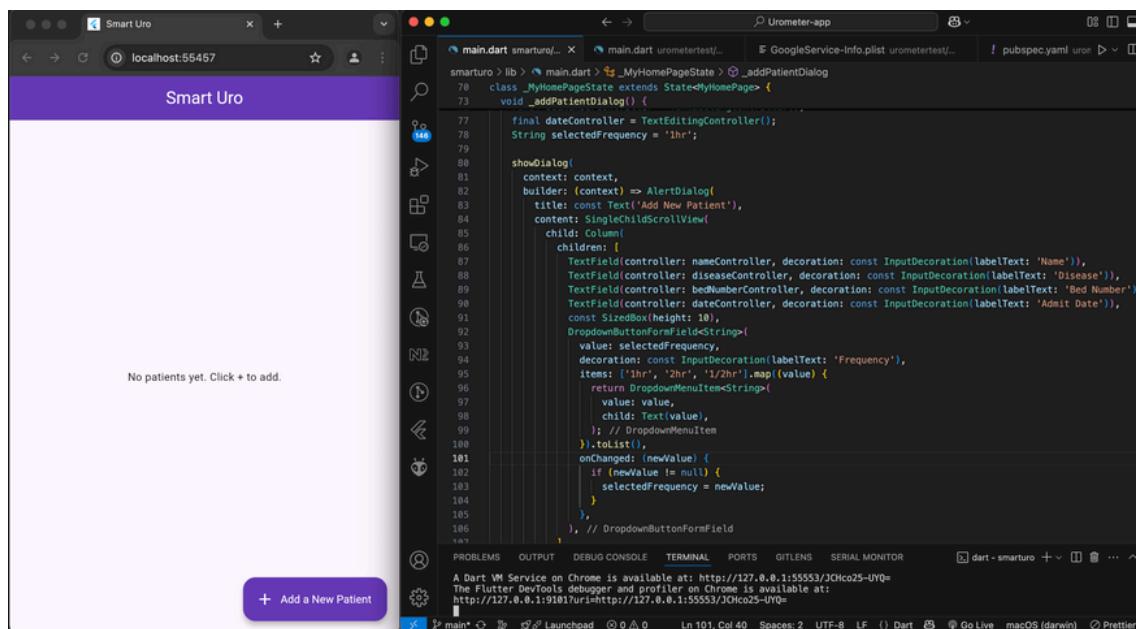
### Data Flow and Functionality

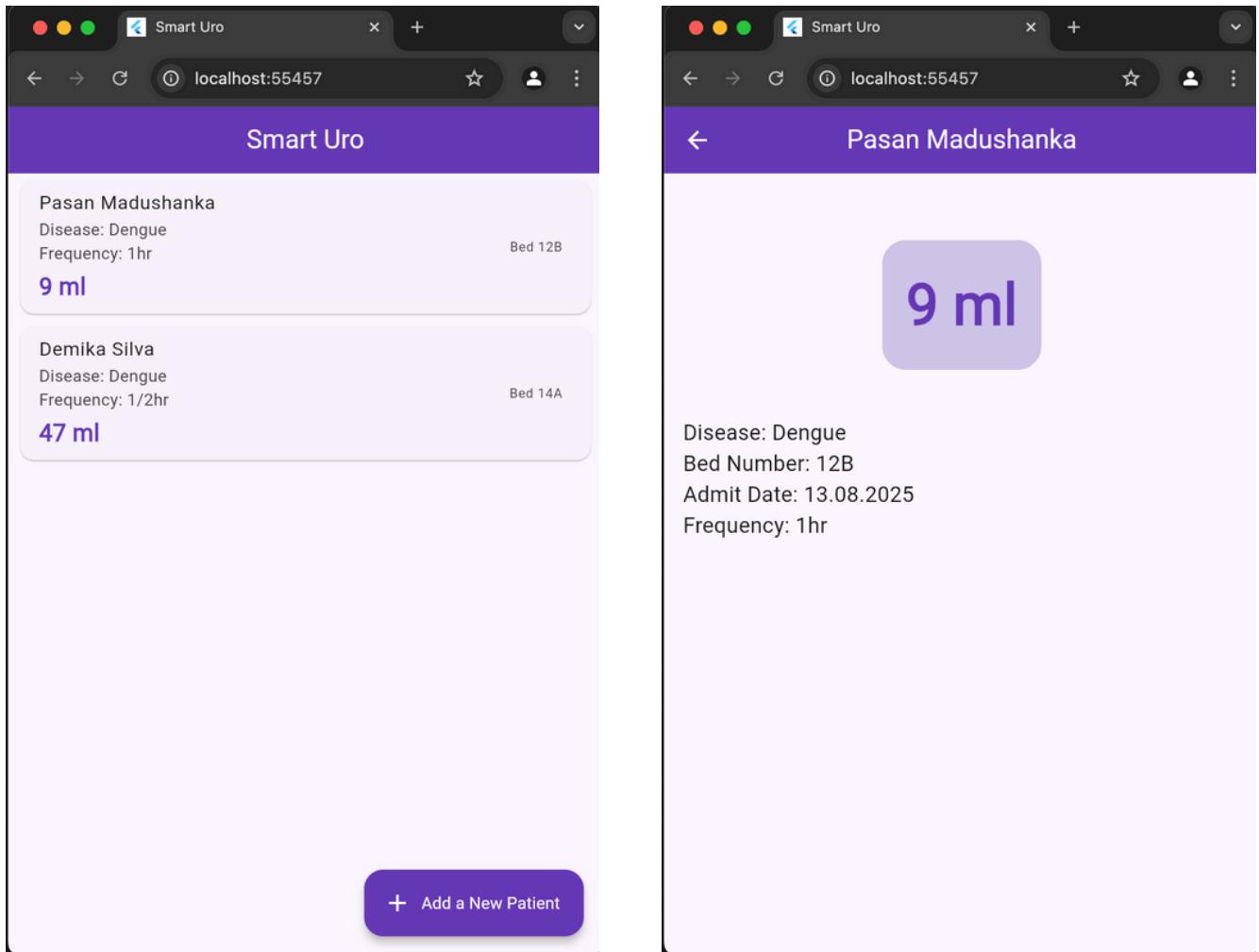
- The ESP32 microcontroller sends live urine level data to the Firebase Realtime Database via Wi-Fi.
- The mobile app retrieves this data based on the configured frequency, which can be set by the doctor or user (e.g., hourly, every 30 minutes).
- Once fetched, the app displays the historical and current readings in a clean, user-friendly interface.

This setup ensures real-time monitoring while maintaining simplicity, scalability, and low latency—ideal for both hospital and home-care use.



# Flutter App snapshots





## App Functionality Overview

The mobile app is designed to support multiple patients, making it suitable for hospital use. Users can:

- Add patients with details such as:
  - Name
  - Disease
  - Admission date
  - Bed number

Each patient is listed in a structured view. By clicking on a patient, the user is taken to a detailed view showing:

- Current fluid level
- Urine output history (future improvement)
- Graphs and trends over time based on reading frequency (future improvement)

This structure allows doctors and nurses to easily track and manage multiple patients' data from a single device, streamlining workflow and reducing manual logging.

Please note that the flutter application was opened in the chrome local host

# Simulation Results

Since this project involves live sensor readings, traditional simulation methods were not applicable. Instead, our focus was on hardware validation through real-world testing, which allowed us to assess the system's performance under realistic conditions.

A wide range of experiments were conducted to test every critical aspect of the sensing system:

1. Baseline testing before and after shielding to evaluate the impact of electrical noise.
2. Applying builtin shielding.
3. Testing with manual CAPDAC calibration to fine-tune sensitivity and dynamic range.
4. Implementation and assessment of a software low-pass filter to smoothen signal fluctuations.
5. All initial tests were done using a single channel of the capacitive sensor.
6. Further validation involved using three channels simultaneously to derive the final urine height more accurately.
7. An experiment was also conducted to examine the sensor's response to changing ion concentrations, which mimics realistic biological variations.

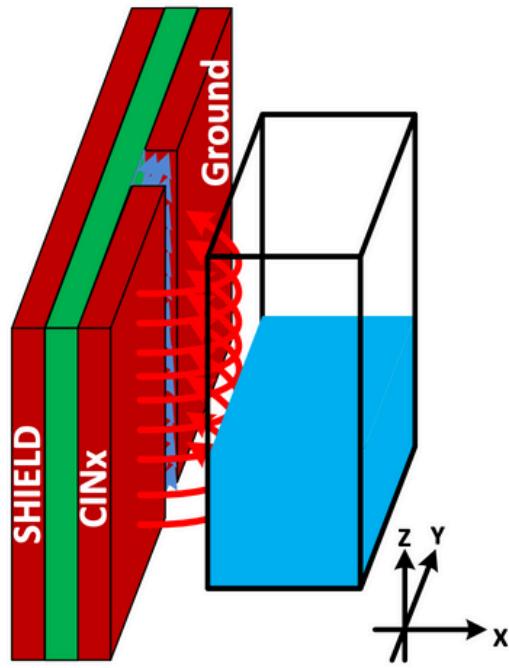
The results across all tests were very promising. Readings were mostly consistent and stable, indicating that the system is suitable for integration into a commercial product. I was genuinely pleased with the performance, especially given the low-cost components used.

It's important to emphasize that all experiments were conducted honestly, and the data presented reflect genuine, unaltered results from each stage of testing.

## 1. Baseline testing

Baseline testing was the first step in evaluating the raw performance of the capacitive sensing system without any shielding or filtering. The goal was to understand how the sensor behaved in its most unprotected state.

During these tests, it was observed that the readings were highly inconsistent. Even minor changes in the surrounding environment—such as hand movement nearby, slight shifts in wiring, or changes in humidity—caused significant fluctuations in the output. This made it clear that the system, in its baseline form, was extremely sensitive to noise and interference.



For the baseline testing, a simple parallel plate capacitive setup was used. One conductive plate was connected to Channel 0 of the FDC1004 capacitive sensor, and the opposing plate was connected to sensor ground (GND). The capacitance formed between these two plates—commonly referred to as the fringing capacitance—was the primary measurement of interest.

This setup aimed to directly measure the change in capacitance as urine levels changed between the plates. However, due to the lack of proper shielding and the use of unshielded jumper wires, the system suffered from high levels of parasitic capacitance. This included interference from:

- Ambient electric fields (e.g., human hands, nearby electronics)
- Capacitance between the wiring and nearby surfaces
- Crosstalk between adjacent wires

These factors caused the measured values to become unstable and unreliable, with even slight changes in the environment producing large fluctuations in the readings. The results clearly showed that without controlled wiring and electromagnetic shielding, the setup was not suitable for consistent measurements—paving the way for the improvements implemented in later stages.

## 2. After shielding

### What is the SHIELD?

The FDC1004 measures capacitance between CINn and ground. That means any capacitance to ground on signal path between the FDC1004 CINn pins and sensor is included in the FDC1004 conversion result. In some applications, the parasitic capacitance of the sensor connections can be larger than the capacitance of the sensor. If that parasitic capacitance is stable, the capacitance can be treated as a constant capacitive offset. However, the parasitic capacitance of the sensor connections can have significant variation due to environmental changes (such as mechanical movement, temperature shifts, humidity changes). These changes are seen as drift in the conversion result and can significantly compromise the system accuracy. To eliminate the CINn parasitic capacitance to ground, the FDC1004 SHLDx signals can be used for shielding the connection between the sensor and CINn.

### Results after shielding

Afterward, I added shielding to the setup and recorded the following values (shown in the table below). As you can see, there is good consistency between the empty and full capacitance readings, indicating stable and repeatable performance.

In this test, only one plate was used for sensing, but even with this simple setup, the results were promising. With proper shielding on both plates and refined wiring, the system's accuracy and reliability are expected to improve even further—making it highly suitable for real-world medical use.

| Empty(pF) | Full(pF) |
|-----------|----------|
| 9.5       | 27.1     |
| 9.9       | 27.2     |
| 9.96      | 27.5     |
| 9.94      | 27       |

### 3. Manual CAPDAC

The CAPDAC (Capacitance-to-Digital Auto-Calibration) feature in the FDC1004 allows offsetting of a fixed baseline capacitance so that the sensor can focus on detecting small changes within a specific range. Typically, a constant CAPDAC value is set in code based on the expected sensor offset.

However, in this project, I chose a more flexible approach: instead of hardcoding a constant CAPDAC value, I allowed it to be adjusted manually in the code during runtime. This helped in experimenting with different sensing setups and identifying the optimal range for each condition—especially when switching between empty and full states or testing with different fluid containers. It also gave better insight into how much baseline capacitance was being contributed by the environment or container material.

### 4. Software low pass filter

To further improve signal stability, I implemented a simple software-based low-pass filter in the code. This helped to smooth out short-term noise and fluctuations in the capacitance readings, especially those caused by minor hand movements or environmental disturbances.

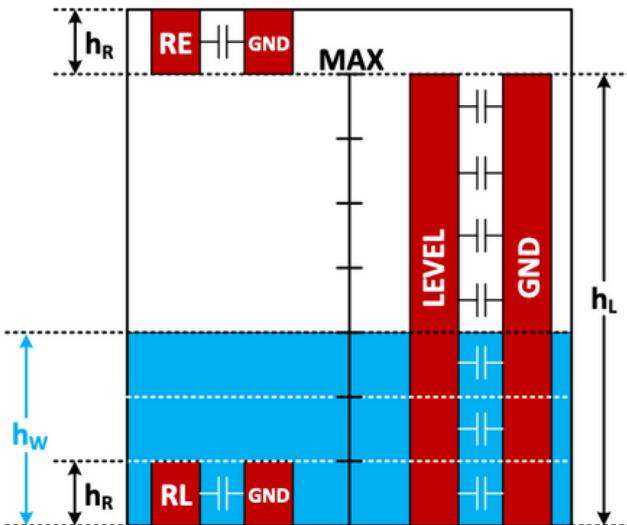
The filter worked by applying a weighted average to the incoming values, gradually adapting instead of reacting sharply to sudden changes. This made the output much cleaner and more usable, particularly when monitoring small variations in fluid level.

That said, the sampling rate and alpha value (the smoothing factor) still need to be fine-tuned. I have not yet conducted extensive testing to find the optimal values for these parameters, and doing so is a planned part of the next development phase.

```
float capacitance_pf = ((float)capacitance) / 1000.0;
filtered_capacitance[channel] = alpha * capacitance_pf + (1 - alpha) * filtered_capacitance[channel];
```

## 5. Height using 3 channels

To estimate urine height, I used three separate copper sensing channels positioned at different vertical levels. The height was calculated using the following equation:



Where:

$h_L$  = maximum height of the liquid  
 $h_w$  = height of liquid  
 $\epsilon_w$  = dielectric of liquid  
 $\epsilon_a$  = dielectric of air

To calculate the level of the liquid at any interval height,

$$\text{Level} = h_{RL} \frac{C_{\text{level}} - C_{\text{level}(0)}}{C_{RL} - C_{RE}}$$

These are the experimental values obtained. While there were some variations, the results were largely consistent and showed a clear correlation with fluid level changes.

In this method, I used the Conventional Liquid Level Sensing Approach, where capacitance from each channel was analyzed directly. However, it's important to note that a more advanced method—like the Out-of-Phase Technique—could offer even better accuracy and noise immunity, and this is something worth exploring in the future.

### Out of phase technique

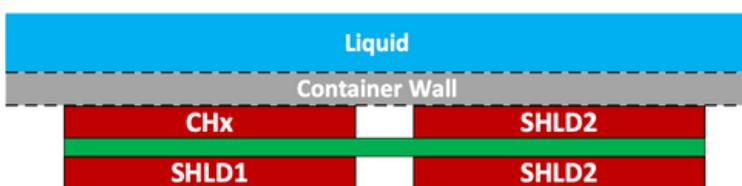


Figure 5. OoP Technique Sensor Layout for LEVEL and REF Sections

## Values recorded

Here are the experimental values I obtained for fluid levels at different volumes: 0 ml, 400 ml, 800 ml, and so on, up to 2000 ml. These values correspond to the readings taken from the three channels:

| 0ml     | 400ml  | 800ml  | 1200ml | 1600ml | 2000ml |
|---------|--------|--------|--------|--------|--------|
| 0.001cm | 8cm    | 16cm   | 28cm   | 38cm   | 41cm   |
| 0.12cm  | 8.7cm  | 16.5cm | 28.5cm | 38cm   | 42.9cm |
| -0.24cm | 9.7cm  | 19.8cm | 33.5cm | 44.3cm | 49.6cm |
| -0.28cm | 10cm   | 19.4cm | 31.8cm | 41.9cm | 46.1cm |
| -0.38cm | 10.1cm | 18cm   | 29.7cm | 38.6cm | 67.2cm |

## 6. Varying ion concentration levels

To simulate the effect of varying ion levels in urine, I conducted a simple test by adding increasing amounts of salt (NaCl) to water and mixing thoroughly. This allowed me to observe how changes in ion concentration affected the capacitance readings.

The goal was to evaluate whether the sensor system remains stable and reliable even with different urine compositions. The results showed minor variations, but overall the system handled the changes well—indicating that it could be suitable for real-world usage where urine properties can vary significantly from patient to patient.

| Tea spoons | Heigh(cm) |
|------------|-----------|
| 1          | 21.43     |
| 2          | 21.5      |
| 3          | 21.1      |
| 4          | 21.6      |



## Reasons for deviations and minor inconsistencies

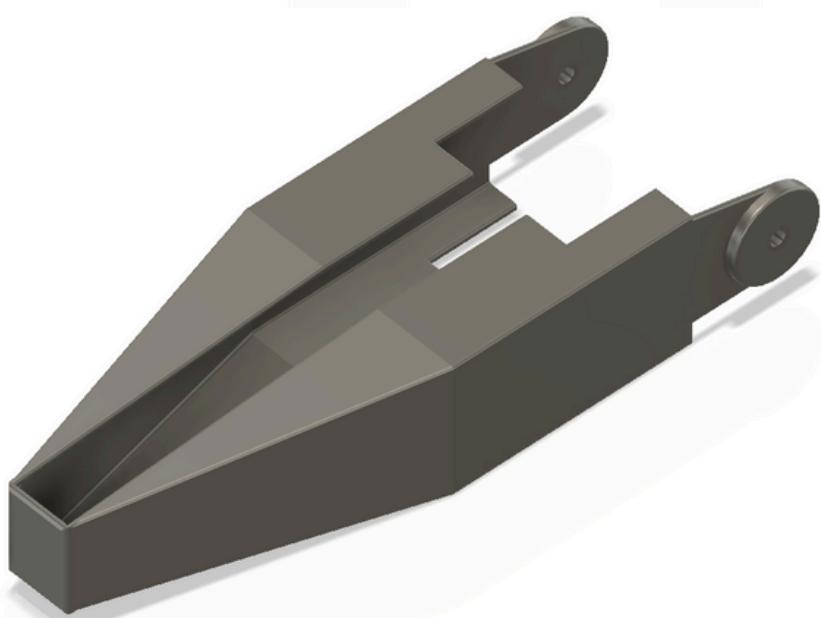
As seen in the experimental data, there are still some minor variations in the capacitance readings, even under controlled conditions. These deviations can be attributed to several factors:

- Incomplete shielding: While initial shielding was applied, further improvements are possible—especially around the sensor wires, which are still exposed and susceptible to interference.
- Parasitic capacitance from wires: The use of longer wires introduces parasitic capacitance, and even slight movements of the wires can lead to noticeable changes in readings.
- Human error during fluid level measurements: Minor inaccuracies in manually filling the container to specific volumes can also cause small reading discrepancies.

That said, these issues are expected to be eliminated in future iterations. The final version of the Smart Urometer will have the entire internal structure properly shielded, including the sensing electrodes and wiring. Additionally, by shifting to a custom PCB design, we'll reduce parasitic effects significantly and apply standard EMI shielding techniques—ensuring much more reliable and consistent measurements suitable for medical-grade performance.

# Design Files

Enclosure CAD



## Source Code

- Source Code Arduino. (just a part of the code)

```
31 WiFi.begin(ssid, password);
32 Serial.print("Connecting to WiFi");
33 while (WiFi.status() != WL_CONNECTED) {
34     delay(500); serial.print(".");
35 }
36 Serial.println("\nWiFi connected!");
37 }

38 void uploadVolumeToFirestore(float volume_ml) {
39     if (WiFi.status() != WL_CONNECTED) return;
40
41     String url = "https://firestore.googleapis.com/v1/projects/" + String(FIREBASE_PROJECT_ID) + "/databases/(default)/documents/volumeData/latest";
42     String payload = "{\"fields\": {\"volume_ml\": {\"doubleValue\": \"" + String(volume_ml, 2) + "\"}}}";
43
44     HTTPClient http;
45     http.begin(url);
46     http.addHeader("Content-Type", "application/json");
47     http.addHeader("Authorization", "Bearer " + String(FIREBASE_API_KEY)); // Optional if rules allow public write
48
49     int responseCode = http.PATCH(payload); // use PATCH to update a fixed document
50     if (responseCode > 0) {
51         Serial.print("Firestore update success: ");
52         Serial.println(responseCode);
53     } else {
54         Serial.print("Firestore update failed: ");
55         Serial.println(responseCode);
56     }
57     http.end();
58 }
59 }

60 void setup() {
61     Wire.begin(21, 22); // ESP32 I2C pins
62     Serial.begin(115200);
63     connectWifi();
64 }
65 }

66 void loop() {
67     int32_t raw_cap[3];
68
69     // Read capacitance in fF
70     raw_cap[0] = fdc.getCapacitance(0); delay(20);
71     raw_cap[1] = fdc.getCapacitance(1); delay(20);
72     raw_cap[2] = fdc.getCapacitance(2); delay(20);
73
74     // Apply filter and convert to pF
75     float cap_pf[3];
76     for (int i = 0; i < 3; i++) {
77         filtered_cap[i] = alpha * raw_cap[i] + (1.0 - alpha) * filtered_cap[i];
78         cap_pf[i] = filtered_cap[i] / 1000.0;
79     }
80
81     float Clevel = cap_pf[0];
82     float CRE    = cap_pf[1];
83     float CRL    = cap_pf[2];
84
85     float level = hRL * (Clevel - Clevel_0) / (CRL - CRE);
86     float volume_ml = (level - 14.5) * (2000.0 / (27.68 - 13.6)) + 80;
87
88     if (volume_ml < 0) volume_ml = 0;
89     if (volume_ml > 2000) volume_ml = 2000;
90
91     // Print to Serial
92     Serial.print("Level: ");
93     Serial.print(level, 3);
94     Serial.print(" cm\tVolume: ");
95     Serial.print(volume_ml, 0);
96     Serial.println(" mL");
97
98     uploadVolumeToFirestore(volume_ml);
99
100    delay(1000); // Adjust as needed
```

# Regulatory Aspects & Intellectual Property

## FDA

In preparation for potential commercialization, we conducted research into relevant regulatory pathways, particularly focusing on FDA classification. Our findings indicate that the URO-MONITOR system falls under the Class II medical device category according to FDA guidelines. This classification applies to devices that present moderate risk and typically require a Premarket Notification [510(k)] to demonstrate substantial equivalence to an existing legally marketed device.

During our research, we identified a few existing projects and products that incorporate some aspects similar to our concept such as electronic urine monitoring or remote data logging. However, none of them replicate the complete functionality, structure, and application scope of the URO-MONITOR. Our system uniquely integrates capacitive sensing, real-time IoT-based monitoring, digital alerting, and app-based remote access, all housed within a reusable, ergonomic enclosure compatible with standard disposable urometers.

| Product Classification   |  |
|--|--|
| <a href="#">FDA Home</a>   | <a href="#">Medical Devices</a>  |
| <a href="#">Databases</a>  |  |
| <a href="#">New Search</a>   | <a href="#">Back to Search Results</a>   |
| <b>Device</b>  | Urinometer, Electrical   |
| <b>Regulation Description</b>  | Urine flow or volume measuring system.   |
| <b>Regulation Medical Specialty</b>  | Gastroenterology/Urology   |
| <b>Review Panel</b>  | Gastroenterology/Urology   |
| <b>Product Code</b>  | EXS  |
| <b>Premarket Review</b>  | <a href="#">Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices (OHT3)</a><br><a href="#">Reproductive, Gynecology and Urology Devices (DHT3B)</a> |
| <b>Submission Type</b>   | 510(K) Exempt  |
| <b>Regulation Number</b>   | <a href="#">876.1800</a>   |
| <b>Device Class</b>  | 2  |
| <b>Total Product Life Cycle (TPLC)</b>   | <a href="#">TPLC Product Code Report</a>   |
| <b>GMP Exempt?</b>   | No   |
| <b>Summary Malfunction Reporting</b>   | Eligible   |
| <b>Note:</b> Class II devices  |  |
| the Food and Drug Administration (FDA) has also published a <a href="#">list of class II (special) controls</a> devices subject to certain limitations, that are exempt from premarket notification requirements under the Food and Drug Administration Modernization Act of 1997 (FDAMA) and the 21st Century Cures Act of 2016 (Cures Act). FDA believes that these exemptions will relieve manufacturers from the need to submit premarket notification submissions for these devices and will enable FDA to redirect the resources that would be spent on reviewing such submissions to more significant public health issues. FDA is taking this action in order to meet requirements of FDAMA and the Cures Act. |  |
| <b>Implanted Device?</b>   | No   |
| <b>Life-Sustain/Support Device?</b>  | No   |
| <b>Third Party Review</b>  | Not Third Party Eligible   |

A FDA approved product

However, URO-MONITOR integrates novel features such as real-time urine monitoring, capacitive sensing, wireless data transmission, and centralized digital alerting, which go beyond the functionality of traditional urometers currently on the market. Since no existing predicate device fully captures the combination of technologies and capabilities our product offers, a traditional 510(k) pathway is not applicable.

Therefore, we anticipate that the appropriate route would be the 510(k) De Novo pathway. This regulatory process is intended for first-of-its-kind, low- to moderate-risk devices and would allow the URO-MONITOR to be classified as a Class II device upon successful review. The De Novo process would recognize the unique innovation of our solution while establishing a new regulatory baseline for similar devices in the future.

The De Novo classification process is designed for first of a kind, low to moderate risk medical devices. To assess our eligibility, we examined the key De Novo criteria;

- No existing device classification or predicate on the market
- Low to moderate risk to patients
- General and special controls can assure safety and effectiveness
- The device is non-invasive and externally attached

Additionally, we explored the components required for a full De Novo application, including device description, risk analysis, performance validation, and proposed regulatory controls.

Although we have not yet initiated a formal submission, our research indicates that URO-MONITOR is a strong candidate for the De Novo process. We aim to proceed with the Pre-Submission and full De Novo filing in the future and are optimistic about receiving FDA clearance upon meeting all requirements.

In some cases, TI components may be promoted specifically to facilitate safety-related applications. With such components, TI's goal is to help enable customers to design and create their own end-product solutions that meet applicable functional safety standards and requirements. Nonetheless, such components are subject to these terms.

No TI components are authorized for use in FDA Class III (or similar life-critical medical equipment) unless authorized officers of the parties have executed a special agreement specifically governing such use.

Only those TI components which TI has specifically designated as military grade or "enhanced plastic" are designed and intended for use in military/aerospace applications or environments. Buyer acknowledges and agrees that any military or aerospace use of TI components which have **not** been so designated is solely at the Buyer's risk, and that Buyer is solely responsible for compliance with all legal and regulatory requirements in connection with such use.

TI has specifically designated certain components as meeting ISO/TS16949 requirements, mainly for automotive use. In any case of use of non-designated products, TI will not be responsible for any failure to meet ISO/TS16949.

FDC1004

Currently, our prototype utilizes the FDC1004 capacitance-to-digital converter (Texas Instruments) and the ESP32 microcontroller, which, while highly effective for development and testing, do not hold FDA or ISO 13485 medical-grade certifications. As part of our future regulatory compliance strategy, we recognize that using FDA-compliant or ISO-certified components is essential for De Novo approval and commercial deployment in clinical settings. Therefore, upon advancing toward production, we plan to source medically certified alternatives for both sensing and processing units that meet recognized standards for safety, reliability, and interoperability within medical environments. This proactive step ensures our design aligns with FDA expectations and improves the likelihood of successful clearance.

To align our URO-MONITOR system with future regulatory and medical-grade standards, we propose replacing the current capacitive sensing IC, the FDC1004 by Texas Instruments, with the AD7745 by Analog Devices in subsequent development phases. While the FDC1004 offers reliable picofarad-level resolution and shield-driven architecture ideal for prototyping, it lacks FDA or ISO certification. In contrast, the AD7745 is a 24-bit, high-resolution capacitance-to-digital converter known for its use in FDA-cleared and ISO 13485-compliant systems. It delivers superior noise immunity, temperature stability, and accuracy, all of which are essential for consistent performance in clinical environments. Furthermore, Analog Devices has an established reputation in the medical device industry, offering long-term availability, regulatory documentation, and application-specific support. By transitioning to the AD7745, we ensure not only improved sensing precision but also a clearer pathway toward regulatory compliance and clinical-grade reliability.



## 24-Bit Capacitance-to-Digital Converter with Temperature Sensor

**AD7745/AD7746**

### FEATURES

- Capacitance-to-digital converter**
- New standard in single chip solutions**
- Interfaces to single or differential floating sensors**
- Resolution down to 4 aF (that is, up to 21 ENOB)**
- Accuracy: 4 fF**
- Linearity: 0.01%**
- Common-mode (not changing) capacitance up to 17 pF**
- Full-scale (changing) capacitance range:  $\pm 4$  pF**
- Tolerant of parasitic capacitance to ground up to 60 pF**
- Update rate: 10 Hz to 90 Hz**
- Simultaneous 50 Hz and 60 Hz rejection at 16 Hz**
- Temperature sensor on-chip**
- Resolution:  $0.1^\circ\text{C}$ , accuracy:  $\pm 2^\circ\text{C}$**
- Voltage input channel**
- Internal clock oscillator**
- 2-wire serial interface ( $\text{I}^2\text{C}^*$ -compatible)**
- Power**
  - 2.7 V to 5.25 V single-supply operation**
  - 0.7 mA current consumption**
  - Operating temperature:  $-40^\circ\text{C}$  to  $+125^\circ\text{C}$**
  - 16-lead TSSOP package**

### APPLICATIONS

- Automotive, industrial, and medical systems for**
  - Pressure measurement**
  - Position sensing**
  - Level sensing**
  - Flowmeters**
  - Humidity sensing**
  - Impurity detection**

### GENERAL DESCRIPTION

The AD7745/AD7746 are a high resolution,  $\Sigma\Delta$  capacitance-to-digital converter (CDC). The capacitance to be measured is connected directly to the device inputs. The architecture features inherent high resolution (24-bit no missing codes, up to 21-bit effective resolution), high linearity ( $\pm 0.01\%$ ), and high accuracy ( $\pm 4$  fF factory calibrated). The AD7745/AD7746 capacitance input range is  $\pm 4$  pF (changing), while it can accept up to 17 pF common-mode capacitance (not changing), which can be balanced by a programmable on-chip, digital-to-capacitance converter (CAPDAC).

The AD7745 has one capacitance input channel, while the AD7746 has two channels. Each channel can be configured as single-ended or differential. The AD7745/AD7746 are designed for floating capacitive sensors. For capacitive sensors with one plate connected to ground, the AD7747 is recommended.

The parts have an on-chip temperature sensor with a resolution of  $0.1^\circ\text{C}$  and accuracy of  $\pm 2^\circ\text{C}$ . The on-chip voltage reference and the on-chip clock generator eliminate the need for any external components in capacitive sensor applications. The parts have a standard voltage input, which together with the differential reference input allows easy interface to an external temperature sensor, such as an RTD, thermistor, or diode.

The AD7745/AD7746 have a 2-wire,  $\text{I}^2\text{C}$ -compatible serial interface. Both parts can operate with a single power supply from 2.7 V to 5.25 V. They are specified over the automotive temperature range of  $-40^\circ\text{C}$  to  $+125^\circ\text{C}$  and are housed in a 16-lead TSSOP package.

## NMRA

In preparation for local commercialization, we have investigated the regulatory requirements outlined by the National Medicines Regulatory Authority (NMRA) of Sri Lanka, which governs the approval of medical devices in the country. Based on our analysis, the URO-MONITOR system a non-invasive, external urine monitoring device used in hospitals falls under the Class B medical device category due to its moderate risk profile.

This classification is supported by the fact that:

- The device does not enter the body and is non-invasive.
- It is used for monitoring purposes only, not for diagnosis or therapy.
- Its failure would not result in serious injury or immediate threat to life

To gain NMRA approval, we will comply with the following key requirements:

### Device Dossier Submission

We will compile a comprehensive device dossier that includes:

- A detailed device description with intended use and working principle (capacitive sensing).
- Engineering drawings and enclosure design data.
- Clinical evaluation and technical performance summaries (from bench testing and prototypes).
- A risk classification justification based on NMRA's risk-based rules.
- Detailed labeling and instructions for use (IFU), both in English and Sinhala.

### Quality Management System (QMS) and Manufacturing Assurance

While our current prototype is developed using 3D printing and open-source components (e.g., ESP32 and FDC1004), we understand that NMRA requires proof of a regulated manufacturing process. In our path to commercialization, we aim to:

- Transition to ISO 13485 compliant manufacturing.
- Source FDA/CE/NMRA certified components where possible (e.g., replacing FDC1004 with AD7745 or similar approved capacitive sensing ICs).
- Maintain traceability and quality control documentation through all stages of production

As of now, our key electronic components (FDC1004 and ESP32) are not FDA or ISO-certified.

NMRA approval typically depends on either:

- The overall device being certified in other countries (e.g., FDA/CE mark), or
- The use of approved, reliable components in a regulated system.

To address this, we plan to:

- Transition to an alternative capacitive sensor such as the AD7745, which offers similar functionality and has documented use in regulated environments.
- Incorporate medical-grade enclosures, power supply components, and shielding compliant with IEC 60601 standards for electrical safety in medical devices.
- Follow software lifecycle processes (IEC 62304) for our app/backend to ensure data security and safety.

Our app, developed in Flutter, and the Firebase-based backend are both subject to medical software validation. NMRA requires:

- Cybersecurity controls (encryption, authentication, secure APIs).
- Software risk analysis showing the app's role in patient safety.
- Clear data retention and access policies in compliance with local healthcare data standards.

We are designing our software architecture with these considerations in mind and will document our process using international software validation standards.

Based on our current design and development approach, we believe the URO-MONITOR system is highly feasible for NMRA approval, given that:

- It is low-to-moderate risk (Class B).
- It has a clear clinical purpose with a growing need in public healthcare (dengue, ICU use).
- We are committed to adapting our design to meet NMRA requirements, including sourcing compliant components and aligning with medical-grade standards.

Our roadmap includes converting our prototype into a scalable, compliant product that meets both local and international regulatory requirements a vital step toward making URO-MONITOR available in Sri Lankan hospitals and potentially across other regions.

# Intellectual Property (IP) Considerations

As part of our commercialization readiness, we have conducted a preliminary assessment of the Intellectual Property (IP) landscape related to non-invasive urine monitoring systems and capacitive sensing technologies.

## Freedom to Operate (FTO)

- We reviewed existing patents in the domain of capacitive liquid level sensing, digital urine output monitors, and microcontroller-integrated medical monitoring devices.
- Our approach using an external capacitive sensor (e.g., AD7745) to measure fluid level non-invasively, transmitting data via Wi-Fi, and displaying it through a custom app shows no direct infringement on existing patents according to initial public database searches (e.g., Google Patents, WIPO).
- However, we acknowledge that a full FTO analysis by a qualified patent attorney will be required before commercialization.

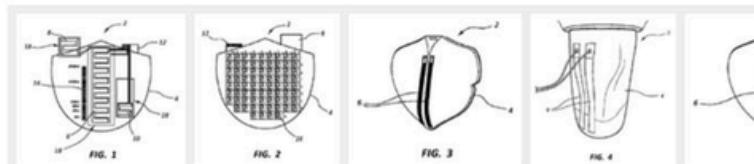
## Urine monitoring system and method

### Abstract

translated from Japanese

A fluid / **urine** monitoring device and / or system for monitoring fluid output including volume and flow is provided. One high resolution, low cost electronic **urine** monitoring device and system collects **urine** and includes a **capacitive sensor**. The capacitance of the capacitance **sensor** is correlated to the fluid content and can be used to identify **urine** volume and flow rate. Another high resolution, low cost flow meter is placed in line with the drain tubing and uses a **capacitive sensor** to measure fluid output without collecting fluid. Other low cost **urine** monitoring devices measure volume and flow using pressure or weight based measurement sensors. [Selection] Figure 1

### Images (29)



### Classifications

**A61B5/208** Sensing devices adapted to collect urine adapted to determine urine quantity, e.g. flow, volume

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JP2016520804A  
Japan

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Other languages: [Japanese](#)  
Inventor: ラモス, ルーベン, オグラディ, マイケル, チェン, フアンボア  
Current Assignee: CR Bard Inc

Worldwide applications  
2014 - [WO JP BR GA AU MX US CN](#)

Application JP2016502566A events [②](#)  
2014-03-17 • Application filed by CR Bard Inc  
2016-07-14 • Publication of JP2016520804A

Status [Pending](#)

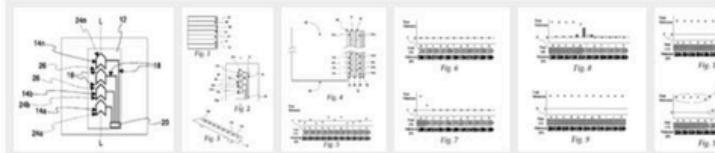
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## Capacitive continuous fluid level sensor

### Abstract

A fluid **level sensor** includes fluid sensing electrodes, reference electrodes, and a controller. The reference electrodes compensate for temperature fluctuations about the fluid electrodes. The controller determines fluid **level** based on the response of the fluid electrodes to the presence of the fluid in proximity thereto.

### Images (6)



### Classifications

■ **G01F23/268** Indicating or measuring liquid level or level of fluent solid material, e.g. indicating in terms of volume or indicating by means of an alarm by measuring physical variables, other than linear dimensions, pressure or weight, dependent on the level to be measured, e.g. by difference of heat transfer of steam or water by measuring variations of capacity or inductance of capacitors or inductors arising from the presence of liquid or fluent solid material in the electric or electromagnetic fields by measuring variations in capacitance of capacitors mounting arrangements of probes

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US10371555B2

United States

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Inventor: Randall PHILIPSON

Current Assignee: TouchSensor Technologies LLC

### Worldwide applications

2017 - CA WO US EP

### Application US15/655,444 events

2017-07-20 • Application filed by TouchSensor Technologies LLC

2017-07-20 • Priority to US15/655,444

2018-01-25 • Publication of US20180023993A1

2019-02-28 • Assigned to TOUCHSENSOR TECHNOLOGIES, LLC

2019-08-06 • Application granted

2019-08-06 • Publication of US10371555B2

2024-07-11 • Assigned to BANK OF AMERICA, N.A., AS ADMINISTRATIVE AGENT

## Patentability of URO-MONITOR

We believe the URO-MONITOR system qualifies as a novel and patentable invention based on the following:

- The specific enclosure design that adapts to multiple urometer models while ensuring accurate readings.
- The integration of capacitive sensing + regression-based volume mapping tailored for different container geometries.
- A custom alarm + cloud-based notification system that integrates hospital workflows and nurse alerts.

We are currently documenting the novelty and inventive step of our solution in preparation for a local patent application in Sri Lanka, with potential for filing a PCT (Patent Cooperation Treaty) application for broader protection.

## Future improvements

### 1. Battery Integration

Make the device wireless by adding a rechargeable battery, reducing dependency on external power.

### 2. Tilt Compensation

Add a gyroscope to detect and correct angle-related errors in capacitance readings.

### 3. Analytics Dashboard

Include real-time graphs showing urine output trends over time for better clinical insights.

### 4. Protected Copper Strips

Shield the capacitive sensors with a non-conductive coating to prevent interference and damage.

### 5. Local Alert System

Add LEDs or buzzers to give immediate alerts at the bedside when critical levels are reached.

### 6. Multi-Patient Monitoring

Enable multiple devices to report to a single dashboard for centralized ICU monitoring.

# References

- [1] H. R. Davies and M. J. Wilson, “Digital monitoring in critical care: Impact of automation on nursing workflow,” *Nature Biomedical Engineering*, vol. 6, no. 3, pp. 228–230, 2022.
- [2] A. Kashani et al., “Acute kidney injury risk assessment: From clinical trials to clinical practice,” *Critical Care*, vol. 21, no. 1, pp. 1–10, 2017.
- [3] World Health Organization, *Dengue: Guidelines for Diagnosis, Treatment, Prevention and Control*. Geneva: WHO, 2009. [Online]. Available: <https://www.who.int/publications/item/9789241547871>
- [4] P. S. Smith et al., “Evaluation of urine output charting errors in intensive care units,” *Journal of Intensive Care Medicine*, vol. 35, no. 4, pp. 381–387, 2020.
- [5] Verified Market Research, *IoT in Healthcare Market Size and Forecast*, 2023. [Online]. Available: <https://www.verifiedmarketresearch.com/product/iot-in-healthcare-market/>
- [6] Romsons International, “Urobag with measured volume chamber,” 2024. [Online]. Available: <https://romsons.com/products/urometer>
- [7] A. A. Omer and M. H. Al-Akhras, “Capacitive sensors for non-invasive biomedical monitoring,” *Sensors and Actuators A: Physical*, vol. 330, p. 112869, 2021.
- [8] U.S. Food and Drug Administration, *Design Control Guidance for Medical Device Manufacturers*, 1997. [Online]. Available: <https://www.fda.gov/media/116573/download>
- [9] International Organization for Standardization, *ISO 13485:2016 — Medical devices — Quality management systems — Requirements for regulatory purposes*, ISO, 2016.
- [10] National Medicines Regulatory Authority Sri Lanka, *Guidance for Registration of Medical Devices*, 2023. [Online]. Available: <https://www.nmra.gov.lk>

