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Aiding Self Administration of Insulin by Integration of Memory in Insulin Pens

Project Report

Course Code:	DS3001
Course Name:	Engineering Design – Including Design and Fabrication Project
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Introduction

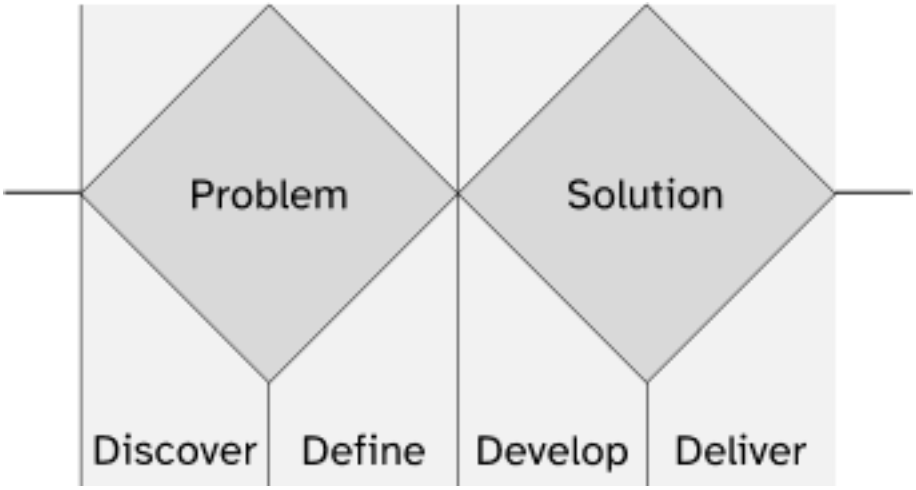
In today's world of rapid technological advancements, healthcare solutions must evolve to meet the growing needs of patients. Managing diabetes requires strict adherence to insulin schedules, yet keeping track of past injections and upcoming doses can be challenging. The risk of missed or incorrect doses highlights the need for a more efficient and user-friendly solution.

This challenge is particularly significant for older adults, who often struggle with remembering medical routines. Cognitive decline and the complexity of diabetes management can lead to inconsistencies in treatment, increasing health risks. A system that simplifies this process while ensuring critical information is easily accessible can greatly improve patient outcomes.

To address these concerns, our Smart Insulin Pen integrates technology with convenience. Designed with a built-in screen on the pen cap, it stores the last injection site, records previous dosage time, and provides reminders for the next dose. By offering a seamless tracking system, this innovation enhances safety, independence, and peace of mind—making diabetes management easier for all.

Methodology

We've used the double diamond process of design thinking during the design phase of our product. The process looked something like this:



Need Identification

For individuals managing diabetes, tracking insulin injections accurately is crucial to maintaining stable blood sugar levels. However, many struggle to remember their last injection time and site, leading to missed doses, overdosing, or repeated injections in the same area, which can cause medical complications like lipodystrophy. While some users manually record this information, methods like notebooks or phone notes are inefficient, prone to errors, and often forgotten.
We recognize the need for a smart and integrated tracking solution that eliminates reliance on manual record-keeping. Similar to glucometers and BP monitors, which provide digital tracking for better health management, insulin administration also requires seamless data recording, and timely reminders. This would not only enhance adherence to treatment but also ensure greater accuracy and ease of tracking insulin habits.
Our Smart Insulin Pen directly addresses these challenges with a built-in screen on the cap that stores the last injection time, site, and next dose reminder. By integrating tracking into the device itself, it eliminates manual errors, enhances safety and independence, and ensures a more efficient and reliable diabetes management experience.

User Study and Research

Our user research focused on the qualitative aspects to help us understand and empathize with the users. The quantitative data was taken from pre-existing studies.
Basic data was gathered on a wider scale to understand the full context of the subject at hand, the specific problem of interest was chosen at the end based on personal interest, problem quantum, practicality, and mentor suggestion.

Data to be Gathered

1. Existing products and their drawbacks.
2. Previous Innovations and ideas
3. Reasons for failure/success of previous innovations.
4. Amount of people affected.
5. Specific User Pain Points.
6. Type of product needed.
7. Area of intervention.
8. User Insights.
9. Are we qualified to solve the problem?

Research Methodology

1. Market study
2. Literature Review
3. Qualitative User study

Six participants between the ages 50 and 80 years were interviewed. Four of the participants were long-term insulin users, having used insulin for over a decade. Two participants required insulin temporarily due to surgical procedures.

Observations and User Insights

- Users encounter difficulties in consistently administering insulin due to various factors, such as forgetfulness, lack of seriousness, and context.
- Users skip insulin doses when they need to attend brief social functions.
- Users demand privacy when self-administering insulin and prefer not to face inquiries about it.
- Users typically adhere to the initial product they have used and resist change.

Users desire to self-administer insulin
independently, effortlessly and discreetly,
without apprehension of judgment, in any location.

Reasons for Missed Insulin Doses

- Forgetfulness – Busy schedules or memory issues.
- Lack of Awareness – Some patients do not understand the importance of timely insulin administration.
- Fear of Hypoglycaemia – Patients may skip doses to avoid low blood sugar.
- Technical Issues – Running out of insulin, malfunctioning pens, or difficulty administering injections.

In one study it was reported that 56.2% of adults missed at least one bolus insulin dose in the last month, another demonstrated that 21.4% missed at least one dose (insulin type not specified) in the last week, and a third study reported that 12% missed at least one bolus dose per day.

Effects of Missing an Insulin Dose:

- Hyperglycaemia (High Blood Sugar) – Leads to symptoms like thirst, fatigue, and frequent urination.
- Risk of Diabetic Ketoacidosis (DKA) – In Type 1 diabetes, prolonged high blood sugar can cause serious complications.
- Poor Long-Term Control – Increases the risk of heart disease, nerve damage, and kidney problems.
- Cognitive Impairment – High blood sugar can cause confusion, dizziness, and difficulty concentrating.

Lipohypertrophy

Repeated injections in the same area cause lipohypertrophy, which involves a lump of fatty tissue under your skin. The area may feel lumpy, firm or rubbery. The condition is common in people with diabetes, affecting as many as 64% of this population at some point.
Causes include Failing to rotate or change injection or infusion (pump) sites regularly. In addition to causing lumps, the condition can affect the way your body absorbs insulin. If you inject or infuse insulin into an area with lipohypertrophy, the insulin might be absorbed more slowly or quickly than expected.

Effects of Lipohypertrophy

- Diabetes-related ketoacidosis (DKA), a potentially life-threatening complication of diabetes.
- High blood sugar (hyperglycaemia).
- Low blood sugar (hypoglycaemia).
- Need for higher doses of insulin.
- Poor results on the glycosylated haemoglobin (A1c) test (high A1c level)

Market Study

Here are some products which follow a compact pen-based approach for insulin administration.

Insulin Pens

Insulin pens are widely used for diabetes management, offering a convenient and precise way to administer insulin compared to traditional syringes. They come in reusable and disposable forms, making them a popular choice among diabetic patients for their ease of use and portability.
However, they lack any built-in tracking features, making it difficult for users to remember their last dosage and injection site, increasing the risk of missed or duplicate doses. Additionally, they provide no reminders or dosage guidance, leading to potential errors in insulin administration. Without digital integration, users must separately record their insulin intake, which can be inconvenient and prone to inaccuracies.

INPENS

INPEN takes insulin management a step forward by integrating the insulin pen with a smartphone app. This smart system allows users to track their insulin doses in real time, receive reminders for upcoming injections, and monitor their insulin history effortlessly. Its connectivity with mobile devices ensures that users have instant access to their insulin data, enabling better decision-making and improved diabetes management.
However, one limitation of INPEN is its reliance on smartphone connectivity for optimal functionality. Users without a compatible device or those experiencing technical issues, such as app malfunctions or battery depletion, may face challenges in accessing their insulin data in real time. Additionally, the system may not be ideal for users who prefer a fully independent insulin pen without the need for digital integration.

Problem Definition

> *How Might We redesign Insulin Pens to remind users when to take insulin and encourage proper insulin administration behaviours, while also helping them remember the previous site of injection, without the use of external integrations.*

Develop Phase

Multiple ideations were made in the form of sketches and concepts to solve the problem at hand. SCAMPER method was used to combine and polish the ideas into one product that is functional and integrates with an insulin pen without disturbing its existing function.

Our Solution

The invention is a smart insulin pen equipped with a small screen on the pen cap's side. This screen displays essential information such as the last injected location, the time of the last dose, and the next scheduled dosage. By integrating digital tracking, the device helps users manage their insulin intake more effectively, reducing the risk of missed or incorrect doses. The smart pen enhances diabetes management by providing real-time information, improving adherence, and minimizing potential health complications.

Novelty

Our solution seamlessly integrates a smart insulin pen with a digital tracking system, offering both a tangible and digital means of managing insulin administration. It is user-friendly and bridges the gap between traditional record-keeping and modern digital organization. Additionally, our smart insulin pen uniquely integrates a location-storing feature, a first in the market, allowing users to track the exact site of their last injection, thereby improving accuracy and avoiding repetitive site usage.

Utility (advantages)

- Built-in Digital Tracking – Unlike traditional insulin pens that require manual logging or external apps, this device has a built-in screen displaying the last injection site, last dosage time, and next scheduled dose.
- Improved Patient Adherence – Users can easily check their dosage history, reducing missed or incorrect doses and improving glycaemic control.
- Compact and User-Friendly Design – The screen is integrated into the pen cap, making it convenient and easy to use without requiring additional devices or connectivity.
- No Dependence on External Devices – Unlike smart insulin pens that rely on Bluetooth or mobile apps, this pen provides real-time information without needing a smartphone or internet connection.

- Enhanced Safety and Accuracy – Reduces the risk of over-dosing or under-dosing by ensuring users have quick access to their insulin history.

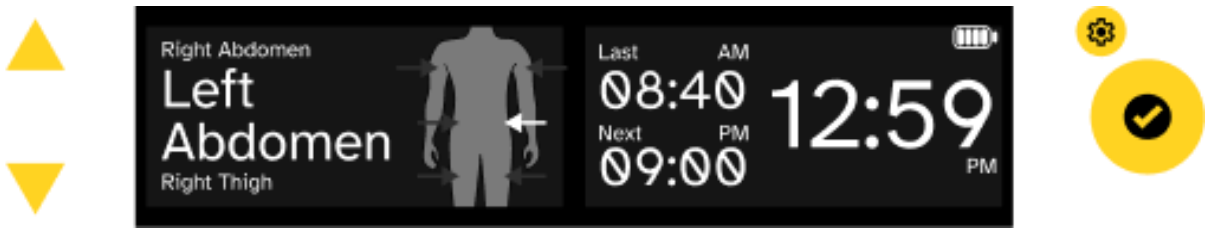
Application of Product

- Personal Diabetes Management – Helps individuals with diabetes track their insulin intake, ensuring proper dosage and adherence.
- Elderly and Forgetful Patients – Assists older adults and patients with memory issues by providing a clear record of their last injection and next dosage.
- Paediatric Diabetes Care – Supports parents and caregivers in monitoring insulin administration for children with diabetes.
- Hospitals and Clinics – Can be used by healthcare professionals to manage insulin administration for multiple patients, reducing errors in dosage tracking.
- Remote and Rural Healthcare – Beneficial for patients in areas with limited access to healthcare by offering an independent tracking system without requiring mobile apps or internet connectivity.
- Sports and Active Lifestyles – Supports athletes and active individuals with diabetes in maintaining proper insulin management without the need for additional tracking devices.

Completeness

Insulin pen design along with the UI of the screen is complete, with 3D modelling, circuitry and dimensioning.
Its circuit involves a Seeeduino Xiao rp2040 module with a rechargeable power source, buttons, an LCD screen, all mounted into the pen cap and assembled as shown in the TinkerCAD model.
The proposed smart insulin pen is a comprehensive and self-sufficient solution designed to enhance insulin management for diabetic patients. It effectively addresses common challenges such as missed doses, incorrect timing, and uncertainty about the last injection site.

User Interface



- Last Injection Tracking – Stores and displays the last injected location and time to prevent repetitive site usage.

- Next Dosage Reminder – Notifies users of their upcoming insulin administration time.

- User-Friendly Interface – Simple navigation using tactile buttons and a clear LCD display.

- Battery Indicator to inform user of the need to charge.
  Illustration for ease of identifying the location of injection site.

- Messages to show time of administering and positive feedback after the user is done with administration of the injection, to show the friendliness of the product.

User Journey Mapping

Normal State of Screen: Sleep mode to conserve battery

To Awaken Screen, Press any button

Screen Automatically Awakens at time of Next Dose and shows a message saying it's time for the next dose (it stays awake for an hour)

Once any button is pressed, the screen shows the Home Configuration, but now it's in "Input Mode"

(To force input mode before time, "Done" Button should be long pressed for 7 secs)

After entering input mode, the user can see the previous site, and administer insulin on a different site.

“Input Mode”
(Next time lower than Current time)

After Administration of Insulin, User has to input the Site of Administration into the device so that it remembers it for the next time. This can be done using the “Arrow” Buttons on the left side of the screen.

Once done, User can press the “Done” Button on the right side. The “Done” Button, once pressed in “Input Mode”, resets the “Home Configuration” and lets the device exit Input Mode. The time at which the “Done” Button is pressed is set as the “Time of Previous Dose” and the site displayed on the screen when the “Done” Button is pressed is locked as “Previous Site of Injection”.

(Both the arrow keys can be pressed together for 3 seconds if the user accidentally locks the wrong location. This will force just the “Previous Site of Injection” field to enter input mode without disturbing the Time section)

The Site that was switched out is set on lockdown, and cannot be accessed for the next two doses. (Long press single arrow key to override) Users can stay on “Input mode” and scroll through the sites using the arrow keys to decide where to inject

The Screen flashes a positive feedback message after the “Done” button is clicked, before the Home Configuration gets reset for the next dose.

Back to Home Configuration after reset and updation

The Screen returns to sleep after a few minutes.

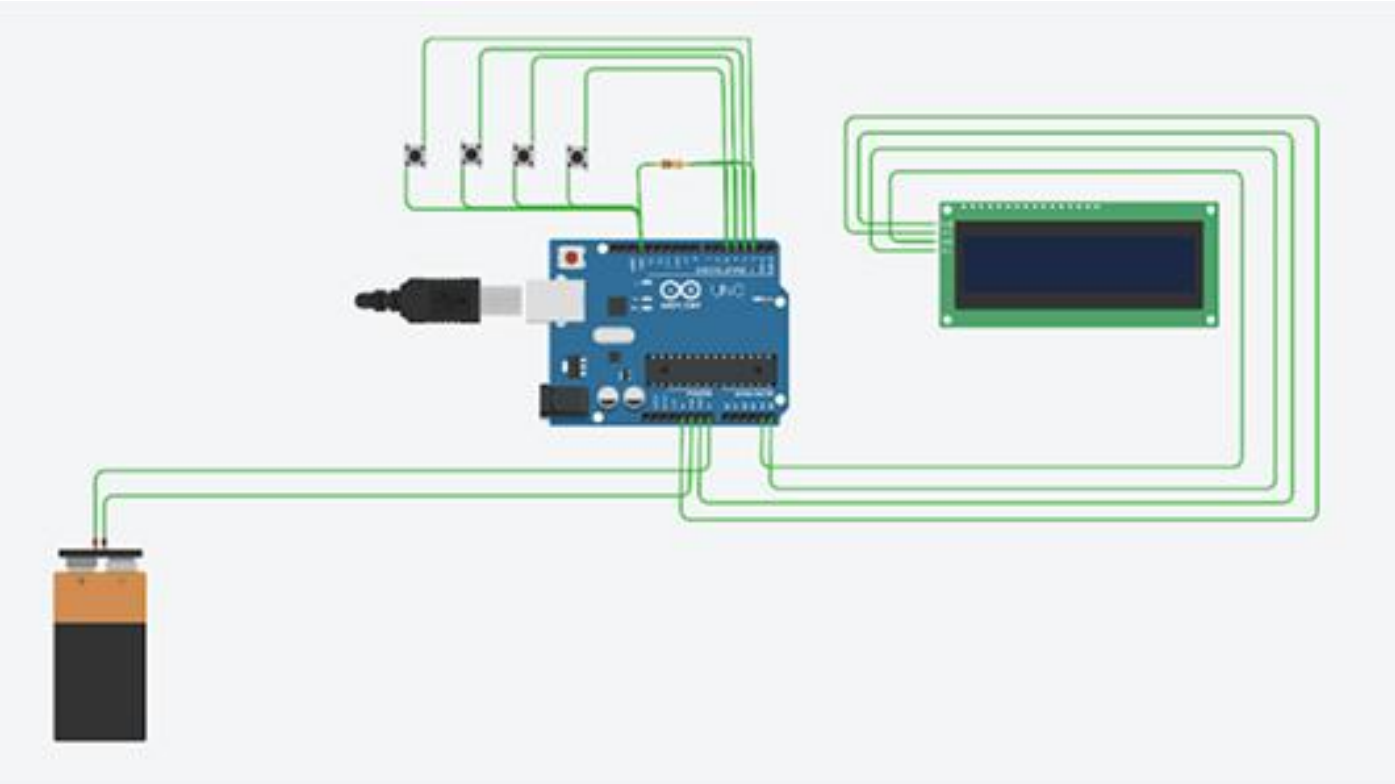
Setting Up the Device

The Set-Up Button and the Arrow keys can be used in combination to set up the Real Time Clock and the Dosage Times.

Pressing the Set-Up Button for 3 secs enables setting up dosage hours. Long pressing it for 7 secs enables Real Time Clock set-up. The Arrow Buttons and Set-Up Button can be used to navigate through the different fields to set the times up. The Done button ends set-up mode and locks the settings.

The settings can also be carried out by connecting an external device through a USB-C cable. The interface for the same has not been designed by us, it'll remain as part of the future scope. Regardless, for easy customization, users can fill out the details of their go-to settings in the buyer's page, and all the setting up can be done by the provider.

Circuitry



The Seeeduino Xiao RP2040 module which includes the 4 push buttons can be connected with the LCD screen through connections as shown above.
The module can be coded using Arduino IDE to display the location details and the time details.
The circuit involves a push button to enter the details, 2 push buttons to navigate the interface and one push button to reset, display interface and Lipo 3.7V rechargeable battery.
The components in the TinkerCAD design above are to be substituted with the correct hardware components at the time of fabrication, the circuit connections however will remain the same.

Technical Specifications

1. Microcontroller
   Seeeduino Xiao RP2040 – A compact and powerful microcontroller based on the RP2040 chip. It features dual-core ARM Cortex-M0+ processors, making it efficient for real-time data processing and low-power applications.
2. Display Unit
   LCD Screen – A small, energy-efficient display mounted on the pen cap, providing real-time information such as the last injected location, previous dosage time, and next scheduled dosage.

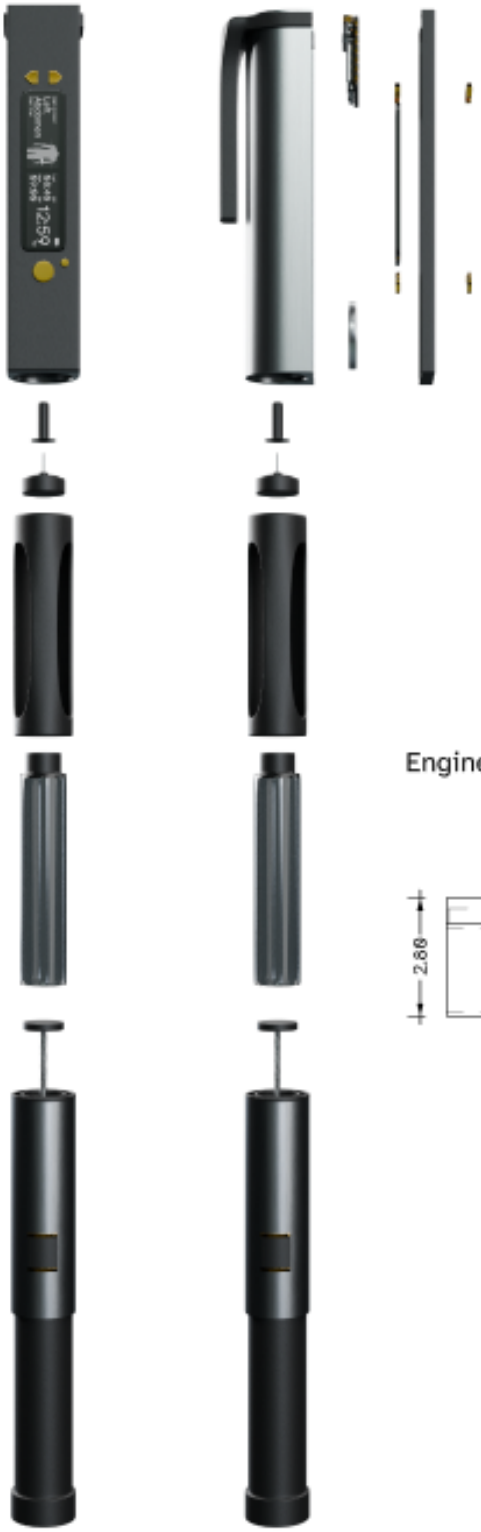
3. Input Controls
   Tactile Push Buttons – Used for user interaction, allowing patients to navigate through stored data and manually input required adjustments.
4. Sensors & Circuitry
   10KΩ Resistor – Used in the circuit for signal regulation and stable operation of electronic components.
   Jumper Wires – Essential for creating reliable connections between the microcontroller and other components.
5. Power Supply
   Rechargeable Battery Unit – Ensures long-lasting performance and portability, making the insulin pen convenient for everyday use.
6. Structural Design
   Plastic Printed Parts – Custom-designed and 3D-printed casing to house the electronic components securely while maintaining a sleek and ergonomic form factor.
   Aluminium Body - Custom-designed aluminium body to house the mounting mechanism and the dosage dial.

Limitations and Scope

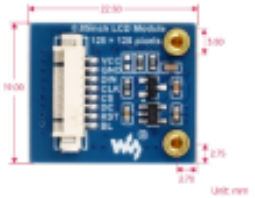
Our product does not allow for storage of tracked data over long periods of time. This could be enabled by integrating a memory storage component or cloud-based storage features. We could look into how to seamlessly integrate such features without complicating the device for the primary users.

The practicality of reminders could be improved through notifications on mobile phones, without complete reliability on smartphones for all functionality. Audio outputs from the device could be made more reliable somehow, we've stayed off of that for now due to the impracticality of anyone actually hearing the signals, when the pen is stored mostly inside refrigerators or medicine boxes.

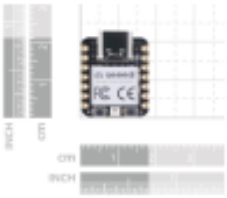
Detail Design



Screen 0.85 inch



Chip RP2040

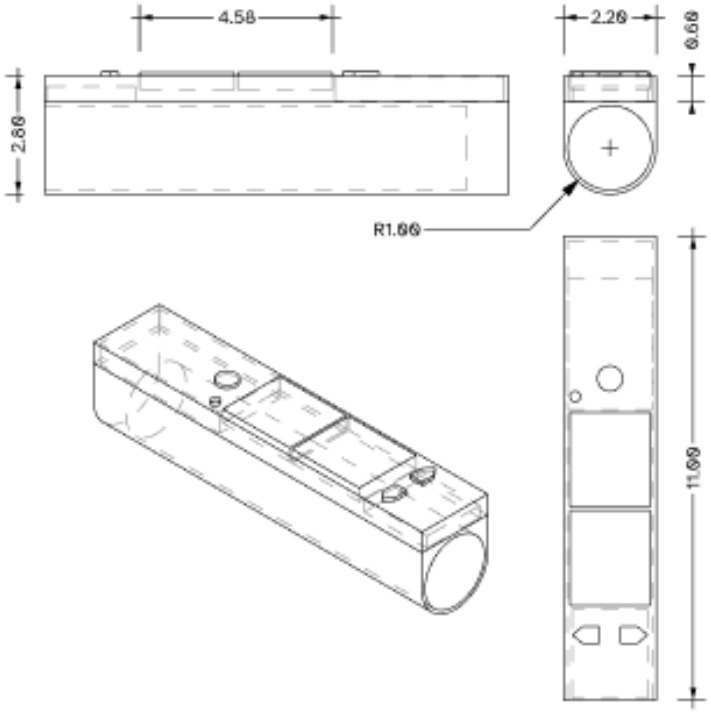


Battery

40 x 20 x 6 mm

Switches

Engineering Drawing (in cms)



Bill of Materials

S.No	Name	Justification	Quantity	Price	Amount	Link
1	Seeeduino Xiao RP2040	A compact and powerful microcontroller chosen for its incredibly small size.	2	476	952	robu.in
2	Waveshare 0.85inch LCD Display Module, IPS Panel, 128×128 Resolution, SPI Interface, 65K colours	Programmable screen. 128x128 chosen to accommodate all the required details to be shown to the user.	4	549	2,196	robu.in
3	Tactile buttons set of 10	Buttons for UI	2	53	106	robu.in
4	400 mAH rechargeable 3.7V LiPo Battery	Rechargeable battery because it needs to have a longer life.	2	177	354	robodo.in
5	Jumper wires (set of 40)	To connect the components in the circuit.	1	109	109	
6	VAKOOBA Aluminium Rod 30mm dia x 200mm length	To fabricate the main body	2	1,300	2600	Amazon
7	CNC Machine Handling Charges			600/hr	1200	
8	Orange ABS+ 1.75mm 3D Printing Filament 1kg-GREY	To fabricate parts	1	650	1300	robu.in
9	3D printing cost of full scale prototype		-	10/g	2000	-
10	Solder Wire 0.5mm 50g B Type 35% Tin content		1	229	229	robu.in
11	Soldron High-Quality 25 Watts/230Volts Soldering Iron		1	328	328	robu.in
12	Miscellaneous	(includes delivery charges, printing, sudden price hikes, etc.,)	-	5000	5000	
					16374	