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Low-Cost Insulin Pump with Predictive-Based Mitigation of Hyperglycemia and Hypoglycemia

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Abstract

Equitable access to insulin pumps, the gold standard for diabetes management, remains elusive in low- and middle-income countries (LMICs). For example, in countries like Ethiopia, fewer than 1% of insulin-dependent patients access this technology, hindered by prohibitive pricing and regulatory complexities. The current study proposes a low-cost insulin pump integrating custom-made hardware design with predictive software algorithms. The proposed design features a micro control unit (MCU) within a threaded spindle-based mechanical framework, housed in a 3D-printed casing. A complete prototype using an Arduino microcontroller has been developed, and testing was conducted using a vision-based syringe displacement method. Novel contributions of this design include a Kalman filter algorithm for hypoglycemia prediction, Bluetooth-enabled Android app control, and automation software delivering personalized insulin doses. This design significantly lowers the total cost of production, with material costs alone reduced to USD $95, while achieving accuracy approaching that of commercial pumps (84.7% of basal doses within ±5%) and a 3.49% average infusion error. By leveraging custom PCB and mechanical designs, it bridges frugal engineering with clinical functionality, offering scalability potential through local manufacturing. Future steps involve conducting IEC-aligned safety testing and benchmarking against commercial pumps (e.g., Medtronic 640G) to validate real-world performance. This innovation demonstrates a pathway to democratize advanced diabetes care in LMICs, combining cost-effectiveness (projected retail price of USD $285– $475, assuming 3 to 5 times the bill of materials cost - BoM) with regulatory-compliant safety. It has the potential to reduce complications and improve outcomes in resource-constrained settings.

Keywords; *Insulin pump, Frugal engineering, Diabetes management, Kalman filter, 3D printing, Hypoglycemia prediction.*

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1. Introduction

Diabetes mellitus (DM) has evolved into one of the most pressing global health crises of the 21st century. As of 2024, approximately 588.7 million adults (20–79 years) live with diabetes worldwide, a figure projected to surge to 852.5 million by 2050.[1,2] This escalation is driven by urbanization, aging populations, sedentary lifestyles, and rising obesity rates, with low- and middle-income countries (LMICs) bearing the brunt of the epidemic. Alarmingly, 4 in 5 adults with diabetes reside in LMICs, where critical barriers like scarce insulin supplies, prohibitive costs, and limited medical technology severely hinder lifelong disease management.[3] In sub-Saharan Africa, where Ethiopia alone accounts for 2.6 million cases, over 50% of diabetes remains undiagnosed, and complications like retinopathy, cardiovascular disease, and kidney failure disproportionately burden vulnerable populations.[1,3,4]

Diabetes is primarily categorized as Type 1 (T1D) or Type 2 (T2D). T1D (5-10% of cases) stems from an inability to produce insulin, necessitating lifelong external injection. Alarmingly rising in under-resourced regions, childhood T1D faces critical gaps in specialist care, insulin access, and monitoring, resulting in tragically poor outcomes.[5,6] Despite its lower prevalence, T1D imposes a massive economic burden. T2D (>90% of cases) involves insulin deficiency or resistance. While initially manageable with lifestyle changes, an increasing proportion (projected 15% by 2030) will require insulin therapy, with 50-75% already dependent on basal insulin in some regions.

When blood glucose is improperly managed, diabetes can lead to serious macro- and micro-vascular complications, which burden health services and implicate in high medical, economic and social costs. In 2024, the estimated world diabetes-related health expenditure was $1.015 trillion, projected to reach about $ 1.043 trillion by 2050.[1]

This growing dependence on insulin coincides with forecasts of global shortages, highlighting the urgent need for scalable solutions to meet demand.[5–7] The management of insulin-dependent diabetes hinges on two primary approaches: conventional and intensive insulin therapy. Conventional therapy, involving twice-daily injections of premixed insulin, imposes rigid lifestyle constraints and often fails to maintain blood glucose levels within the optimal range (70–180 mg/dL), increasing risks of both hyper- and hypo-glycemia. In contrast, intensive insulin therapy enables dynamic dose adjustments aligned with real-time blood glucose levels, dietary intake, and physical activity. This approach is delivered via two methods: multiple daily injections (MDI) and continuous subcutaneous insulin infusion (CSII) using insulin pumps.[7–10] MDI combine rapid-acting insulin (administered pre-meal, dosed by carbohydrate intake) with long-acting basal insulin (1–2 daily injections) to maintain glycemic control between meals. While MDI offers flexibility compared to conventional therapy, it requires frequent self-monitoring and imposes a high cognitive burden, particularly in pediatric populations.[9,10] CSII, facilitated by wearable insulin pumps, represents the best and most convenient ways to deliver insulin. These devices mimic physiological insulin delivery through programmable basal rates (adjusted to circadian rhythms) and on-demand bolus dosing for meals or corrections. CSII is especially transformative for children with T1D, enabling micro-dosing (as low as

0.025–0.05 IU) tailored to small body weights and unpredictable routines. Studies demonstrate CSII reduces hypoglycemic events by 30% and HbA1c levels by 1.5% compared to MDI, while significantly improving quality of life for patients and caregivers.[11–14]

However, global access to CSII remains starkly unequal. Commercial pumps, costing USD $4,500–$8,000 upfront with USD $400/month in consumables, are unaffordable for LMICs. This inequity perpetuates preventable complications: in sub-Saharan Africa, 53.6% of diabetes cases are undiagnosed, and premature mortality rates are 3×higher than in high-income countries due to delayed insulin dependence and limited glucose monitoring.[15–17]

In response to the urgent need for accessible insulin delivery systems in low-resource settings, the current study proposed a regulatory-compliant, low-cost insulin pump prototype designed to bridge the affordability gap while maintaining clinical precision. Guided by four strategic pillars (affordable hardware, smart algorithms, user-centric design, and regulatory compliance), this innovation targets scalability in markets in LMICs where many people live with diabetes and a few have access to advanced insulin infusion pumps.

2. Proposed Method

Commercial insulin infusion pumps operate according to well-established generic functional models. As demonstrated by Zhang et al.,[18] such models define critical system boundaries and enable preliminary hazard analysis for safety-critical medical devices. The insulin reservoir selection emerged as a critical driver: in the current study, we adopted the commercially available Lucheck 3mL syringe to minimize recurring costs. This standardized component directly influenced multiple hardware parameters, including pump casing dimensions, and PCB layout, due to its mechanical constraints. The Lucheck syringe's barrel diameter enables compact casing geometry while minimizing required drive torque. Future safety enhancements will explore prefilled biocompatible syringe integration to eliminate contamination risks during reservoir changes. The proposed work implements this modeling framework through two mechanical design iterations that maintain the essential operational paradigm while optimizing for low-resource settings. The first iteration (in vitro tested) combines a threaded spindle shaft with Arduino Uno control. The second iterates with a streamlined spindle mechanism, custom PCB, and dedicated battery management system using a micro controller unit (MCU), significantly reducing bulk. The designs come with advanced software features: a mathematical model enabling adaptive basal-bolus insulin dosing, and a real-time hypoglycemia prediction system using Kalman filter algorithm. Additionally, to create a more intuitive user interface, a Bluetooth-enabled Android app has been developed that complements the physical button controls for remote operation.[19]

The current work aligns with advances in intelligent insulin delivery, where Continuous Glucose Monitoring (CGM) integration enables predictive algorithms to mitigate glycemic extremes.[20] Studies demonstrate the efficacy of such systems: Buckingham et al. utilized glucose monitoring involving Kalman filter for noise reduction and as a result prevented 73% of nocturnal hypoglycemia events,[21] while MiniMed 640G real-world data showed wider acceptability of CGM by patients for

basal infusion suspension.[22] Also, the dual hypoglycemia/hyperglycemia minimization system proposed by Spaic et al. highlights the potential of closed-loop control for CGM.[23]

Infusion pumps are safety-critical systems demanding rigorous validation. The development process in the current study reflects this imperative: to date, core validation has focused on quantitative accuracy testing via in vitro measurement of syringe plunger displacement against programmed infusion rates following the methodology developed by Coskun et al.[24] While this methodology is inspired by IEC 60601-2-24 and confirms a prototype's foundational dosing precision, it does not yet constitute full compliance. Consequently, three critical safety requirements of the IEC 60601-2-24[25] standard remain unverified: (i) alarm system response times for occlusions, low battery, or system errors; (ii) dynamic flow rate accuracy under variable backpressure or temperature conditions; and (iii) fault detection protocols for scenarios like power interruption or motor failure. Formal validation of these safety-critical aspects is essential prior to clinical deployment but that is beyond the scope of the current study.

2.1. Mathematical Modeling of Insulin Delivery

2.1.1. Physiological Basis & Clinical Foundation

In healthy individuals, pancreatic β-cells release basal insulin steadily to maintain stable blood glucose between meals. The proposed system replicates this via continuous subcutaneous infusion of rapid-acting insulin. Postprandial insulin surges (peaking at 30–50 minutes) are mimicked by pre-meal bolus doses delivered through the same wearable device. This dual-phase delivery framework personalizes therapy by synthesizing validated clinical guidelines, building upon Davidson et al.'s comparative analysis of basal-bolus protocols (AIM, Weight-Based, and 400/500 Rule systems) for enhanced robustness.[26–28]

2.1.2. Basal-Bolus Dosing Framework

This requires calculation of four parameters:

- Total Daily Insulin (TDI) = Average of prior daily dose (reduced by 25%) and half of body weight (kg)
- Carbohydrate-to-Insulin Ratio (CIR) = 450/TDI (g per insulin unit)

Note: The CIR is to be adjusted ±15% based on 2–3 days postprandial measurements.

- Insulin Sensitivity Factor (ISF) = 1,700/ TDI (mg/dL per insulin unit)
- Pre-meal correction (Correction dose) = (Current BG − Target BG) / ISF where BG refers to blood glucose

2.1.3. Adaptive Delivery Protocol

During therapy initiation (weeks 1–2), 8–10 daily glucose measurements are to be taken for possible personalized adjustments.

- Basal rate = 50% of TDI/24h

The basal rate (to be delivered at every hour for 24 hours) is to be adjusted according to the following two scenarios:

-*Nocturnal*: ±15% for sustained >30 mg/dL drift (12 AM–7 AM)

-*Daytime*: ±15% for rapid decline/increase (>60 mg/dL)

- Meal bolus = (Carbohydrate (g)/CIR) + Correction dose

2.2. Prediction-Based Attenuation Framework

2.2.1. Clinical Rationale for Predictive Features

Self-monitoring blood glucose (SMBG) provides limited snapshots (typically 3–4 daily measurements) of glycemic status, risking missed detection of acute fluctuations (Figure 1). CGM addresses this gap through near-continuous sampling (3-5 minutes interval), enabling comprehensive trend analysis. Integration with insulin pumps unlocks transformative safety potential; automated insulin attenuation prevents extremes while reducing user burden.[29]

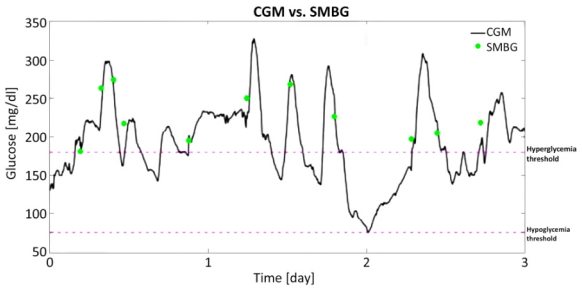

Figure 1. *Glycemic variability captured by SMBG (green diamonds) vs. CGM (black line) over 72 hours. SMBG's sparse sampling misses nocturnal hypoglycemia (02:00 on Day 2) and postprandial hyperglycemia (18:00 on Day 3).*

2.2.2. Kalman Filter Prediction Algorithm

The proposed system employs optimal estimation theory to forecast glucose trajectories, adopting a computationally efficient Kalman filter commonly used in aerospace systems. This algorithm dynamically updates two state variables every 5 minutes which are:

i. Real-time glucose concentration
ii. Rate-of-change (mg/dL/min)

Robustness is ensured through:

- **Input validation**: Rejecting physiologically implausible readings (> ±2 mg/dL/sec change).
- **Lag compensation**: Applying CGM-specific temporal offsets.
- **Signal gap mitigation**: Persisting predictions during <15-minute data losses.

2.2.1. Safety Intervention Protocol

Preemptive insulin modulation occurs for:

- **Hypoglycemia prevention**: Basal insulin pauses if predicted glucose is <70 mg/dL within 30 minutes, resuming only when forecasts stabilize at >140 mg/dL.
- **Hyperglycemia mitigation**: Users receive alerts for correction boluses at predicted glucose >180 mg/dL.

2.3. Prediction-Based Attenuation Framework

2.3.1. Power-Optimized System Design

To minimize MCU power consumption, our architecture strategically offloads computationally intensive tasks, including predictive algorithms (Kalman filter), insulin dosing calculations and data analytics, to a Bluetooth paired smartphone application. The MCU retains dedicated control over real-time hardware operations including stepper motor actuation, sensor interfacing, and basic alerts, while the App handles complex processing. This modular approach enhances energy efficiency, extends battery life, and enables seamless software updates through cloud connectivity.

2.3.2. MCU Software Implementation

The MCU firmware features four integrated modules: the *Main Controlle*r initializes peripherals (motor driver, LCD, Bluetooth, Real Time Clock - RTC), loads hardware parameters from flash memory (including the critical 786 motor steps per insulin unit conversion factor), and establishes Bluetooth synchronization for profile retrieval. The *Precision Motor Control* module converts insulin doses into stepper motor sequences at

0.00125 IU per step resolution while implementing voltage sequencing for displacement accuracy. Concurrently, the *Data Relay Interface* streams timestamped operational data (completed steps, reservoir levels) to the smartphone and receives real-time parameter updates (basal rates, carbohydrate-to-insulin ratios, insulin sensitivity factors). Finally, an *Emergency User Interface* provides LCD alerts for critical system events and physical buttons for essential functions including pause/ resume delivery and manual bolus triggering.

2.3.3. Smartphone Computational Modules

The companion application hosts five core subsystems: an *Algorithm Engine* executes the basal-bolus dosing model and a second *Algorithm Engine* executes a 30-minute Kalman filter prediction while dynamically adjusting therapy parameters based on glycemic trends. The *CGM Integration Hub* interfaces with commercial continuous glucose monitors to stream real-time data and trigger predictive safety interventions such as basal suspension when glucose is forecasted below 70 mg/dL. Complementing this, the *Clinical Data System* manages storage of therapy metrics and generates automated reports including ambulatory glucose profiles and hypoglycemia risk analyses for clinicians. The *Patient Interface* enables comprehensive profile configuration, remote therapy control, and push notifications for predicted events. Collectively, these modules leverage smartphone capabilities to perform calculations impractical for resource-constrained embedded systems.

2.3.4. Operational Workflow

System operation follows a defined sequence: during initialization, the MCU boots, connects via Bluetooth, and downloads user profiles. In the operational loop, the MCU continuously streams motor/sensor data to the smartphone, which computes dosing requirements and predictions before returning command instructions. For safety responses, when the smartphone detects impending hypoglycemia or hyperglycemia, it either commands immediate basal modulation through the MCU or issues correction alerts to the user interface.

2.3.5. Implementation Advantages

This architecture delivers significant benefits: power efficiency is enhanced in MCU computational load compared to standalone designs, while enabling complex algorithms previously infeasible on embedded platforms. The smartphone interface improves usability by replacing complex pump menus with intuitive touch controls, and allows future algorithm refinements, which are critical features for resource-constrained settings.

2.4. Prototype Design Evolution

2.4.1. First Iteration (Complete Prototype)

The initial prototype employs a syringe-based infusion mechanism with precise volumetric control, driven by a cost-optimized Arduino Uno microcontroller. This design prioritizes simplicity and affordability through integrated 3D-printed components (Figure 2). The infusion mechanism converts stepper motor rotation into linear plunger displacement via a threaded titanium spindle shaft (5×51mm) with steel ball bearings to minimize friction, actuating a disposable 3 mL Luecheck syringe reservoir. SOLIDWORKS-optimized polylactic acid enclosure (122×34×25mm) features a stabilized movement block for mechanical integrity. Control systems include an LCD interface with six-button

navigation for basal/bolus programming, Bluetooth-enabled Android connectivity, microSD data logging (hourly rates/boluses/ glucose), and DS3231RTC for timed delivery.

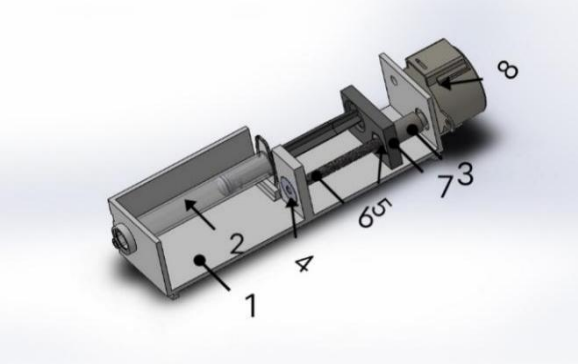

Figure 2. *First iteration design.*

Safety notifications employ RGB LED/ buzzer alerts for critical events. This iteration achieved core design goals: stepper motor precision (0.01 IU per revolution), material affordability, and open-source modularity using Fritzing for assembly. Table 1 summarizes a description of the materials used in the hardware design.

Table 1. *Material description.*

No	Component	Material	Dim (mm)	Description
1	Pump case	Polylactic acid	122*34*25	3D Printed
2	Insulin reservoir	Luecheck syringe	11*98	3ml Syringe
3	Connector	Polylactic acid	8*12	3D Printed
4	Ball bearings	Steel 440c	4*11	
5	Spindle nut	Titanium	7*M5	
6	Threaded spindle	Titanium	5*51	Micro-machined
7	Pusher block	Polylactic acid	30*20*5	3D Printed

2.4.2. Second Iteration

Building upon the first prototype, the next iteration focuses on enhanced durability, energy efficiency, and manufacturability for real-world deployment (see Figure 3). The redesigned motor system uses a GA12BY15-M455 stepper (5V DC) with 20:1 gearbox, validated for 800-day endurance, while configurable gear ratios (50:1 to 298:1) enable micro-dosing up to 5,960 steps/ revolution. An ATSAMD21G18A MCU replaces the Arduino, leveraging 38 GPIO pins, SPI buses, and low-power sleep modes to extend battery life, with 128MB flash memory for year-long data logging. Power management incorporates capacitor-backed RTC (70mF) for clock retention during battery changes. User interaction shifts to an LED array with three-button interrupt control, eliminating complex menus. This version advances key priorities: stress-tested mechanical durability, pocket-portable dimensions (95×60×25mm), and intuitive accessibility through simplified interfaces.

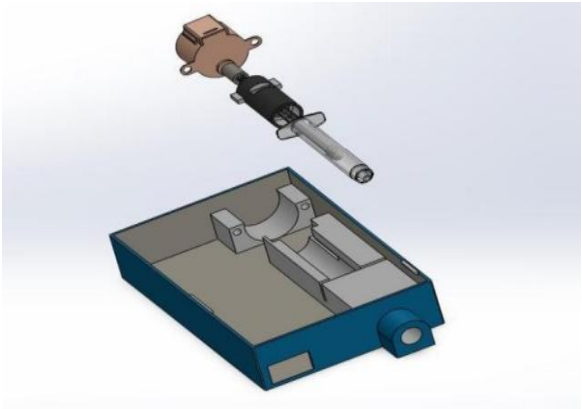

Figure 3. *Second iteration design.*

2.4.3. Design Progression Rationale

The first prototype validated core functionality through rapid prototyping with globally accessible components (Arduino, 3D printing), establishing foundational dosing accuracy. The second design transitions to optimized subsystems including specialized MCU, industrial-grade motor, and energy-aware architecture to address field deployment requirements in resource-constrained settings. This progression maintains core principles of precision and affordability while advancing toward regulatory compliance and clinical utility.

2.5. In Vitro Performance Test

2.5.1. Current Standards and Limitations

The most widely accepted method for evaluating insulin pump precision follows the IEC 60601-2-24 standard, the gravimetric technique, which measures flow accuracy by weighing insulin delivered through a standardized needle over time. However, accessibility of this specialized testing equipment is costly and rarely available outside advanced labs.[24] To address these challenges, we adapted a simplified approach focusing on tracking syringe plunger movement during insulin delivery using a camera. This approach introduces inherent limitations:

- Camera resolution constraints (smartphone: 12MP) limit minimum detectable displacement to ±0.1mm.
- Ambient light variability may cause marker detection errors during daytime testing.
- Measurement bias from parallax effects in non-orthogonal camera alignment.

2.5.2. Experimental Setup

All tests were conducted under controlled environmental conditions (23°C±1°C; 45-55%RH) with 24 replicates, 2-hour infusions at 5.0 IU, performed on 6 infusion samples (with a new syringe used for each sample) and 4 tests per sample. Each trial used:

Reference Markers: Two points were marked on the insulin pump prototype; one on the plunger's moving block and another on the device's sidewall.

Image Capture: A smartphone camera positioned laterally took photos every 5 minutes during 2-hour infusion tests.

2.5.3. Distance Calculation

Images of the pump prototype were captured at 5-minutes intervals using a smartphone camera (16MP, 4608 × 3456-pixel resolution). Images were analyzed in MATLAB (Matlab 2020) to measure the distance between markers in pixels. A reference distance (4mm) was used to convert pixel counts to real-world measurements (centimeters). The real distance was then calculated as:

Distance = (Measured No. of Pixels × Reference Distance) / Reference No. of Pixels

2.5.4. Model Performance Evaluation

The model performance was evaluated in terms of multiple criteria. Figure 4 presents a snapshot showing the setup of the performance test.

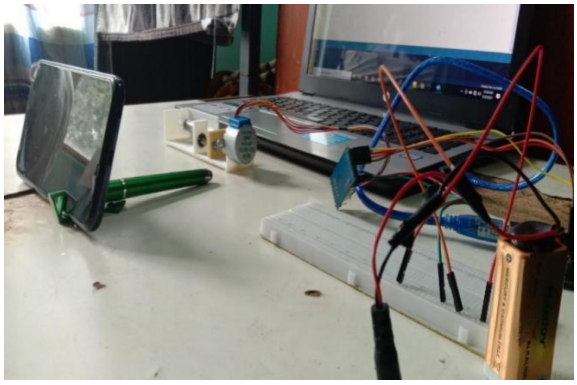

Figure 4. *A setup for the performance test.*

Target Dose*:* A 5.0 IU insulin dose was defined using a calibrated 3mL syringe and caliper.

Precision Thresholds*:* Deviations were categorized as ±5%, ±10%, or ±15% from the target dose.

Statistical Analysis: Results were benchmarked against literature data for commercial pumps, with statistical consistency evaluated across all 24 replicates.

3. Results

Figure 5 presents the developed insulin pump first complete prototype while Figure 6 shows a snapshot of the landing page of the developed App.

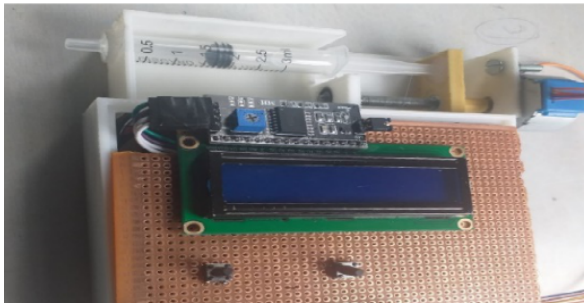

Figure 5. *First complete prototype.*

Figure 6. *The landing page of the developed App.*

3.1. Prototype Performance Test

3.1.1. Statistical Analysis

One-Way ANOVA test was performed to assess the precision of the syringe plunger displacement (cm) while the statistical parameters are presented in Table 2; SS is the sum of squares, df is the degrees of freedom and MS is the mean square. The between and within group df were 5 and 18 respectively. MS is the quadratic mean computed as SS/df. The F statistic is the ratio of the between and within group mean squares calculated to be 0.34. The resulting p value was computed to be 0.8825 showing there is statistically no significant difference between the groups being compared and hence precise plunger displacement measures by the proposed insulin pump design. The errors per each of the 6 groups is indicated as a scatter plot in Figure 7.

Table 2. *One-Way ANOVA test results.*

ANOVA Table

Source	SS	df	MS	F	Prob>F
Columns	0.29226	5	0.05845	0.34	0.8825
Error	3.10317	18	0.1724		
Total	3.39543	23			

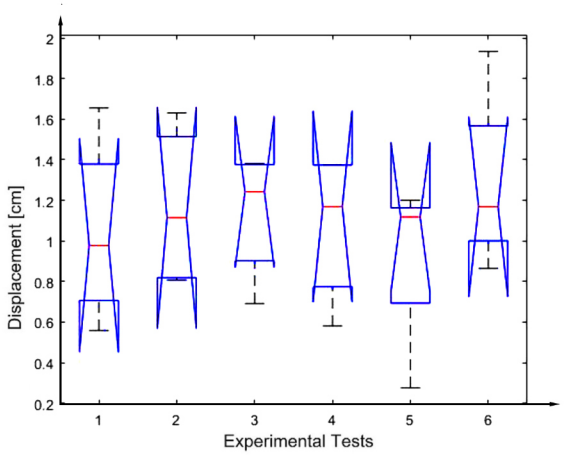

Figure 7. *Notched box plots of displacement across experimental tests.*

3.1.2. Accuracy Description

The overall accuracy of the proposed pump design was determined using the target dose and the average (over 24 replicates) of delivered doses obtained during the experimental trial. The average targeted distance (D_t) was measured to be 1.035mm while the actual measurement (D_m) was 1.0711mm which resulted in a small relative

percentage mean error of 3.49%. Around 12.5% of the measurements were under 5 IU, 62.5% were above while the remaining 25% measured exactly 5 IU, coinciding with the target dose (see also Table 3).

Table 3. *Minimum, maximum and number of deviations of the proposed prototype, obtained by using displacement of syringe plunger at the bolus rate (5.0 IU).*

Infusion	Percentage	Bolus size of 5 IU
Under delivery	3 (12.5%)	4.56 (Min deviation)
Over deliverry	15 (62.5%)	0.43 (Max Deviation)

3.1.3 Single-Dose Accuracy

Figure 8 presents the measured single doses for all 24 experimental instances. Accordingly, 37.50% (equivalent to 9 measures) of the measured infusions were within ±5% of the target infusion while all 24 measurements were within 10% of the target infusion dose.

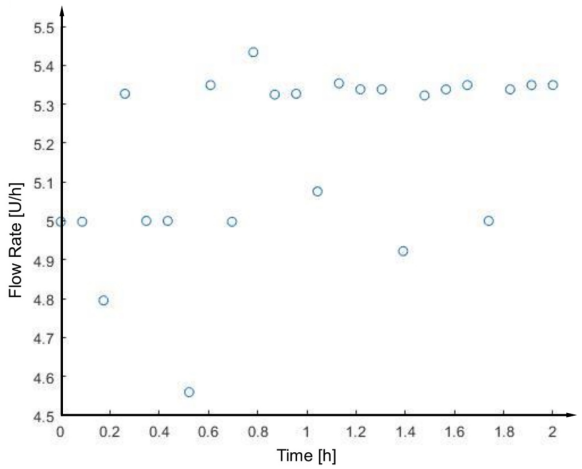

Figure 8. *Bolus rate accuracy over 2h window. Dots show single infusions at each time point (n = 24), the target rate is 5 IU.*

There are several commercially available insulin pump designs proposed previously and their performance reported by scholars[30–32]. The performance of the pump proposed in the current study has been compared with that of Freckman et al..[31] Table 4 summarizes the performance comparison between the two systems. Though the insulin pump system used by Freckman et al. was tested on 693 replicates (vs 24 for the proposed system), the overall result indicates the great promise the proposed frugal insulin pump design carries. Even at a clinically critical ±5% tolerance, the proposed design demonstrated acceptable dose delivery accuracy. At wider tolerances, it outperformed the design by Freckman et al., achieving 100% compliance. This result can be attributed in part to the extensive validation across a large sample range (n=693), which provided a more comprehensive assessment of performance. Notably, these results were derived from a simplified vision-based validation method, whereas Freckman et al. employed the rigorous IEC 60601-2-24 protocol as a gold standard [31].

Table 4. *Comparative performance of bolus infusions (5.0 IU).*

Maximum Accuracy Deviation	Proposed Design (n=24, 2-hours window)	Freckman et al. [31] (n=693, 1hour window)
±5%	37.5%	46.6%
±10%	100.0%	71.2%
±15%	100.0%	81.2%

4. Discussion

In LMICs, many individuals with diabetes rely on repeated insulin injections, which fail to mimic the body's natural, continuous insulin release. This approach increases risks of poor glycemic control, frequent hospitalizations, and hypoglycemia events. Insulin pumps, which deliver insulin continuously via subcutaneous catheters, align more closely with physiological secretion and have demonstrated improved HbA1c levels and reduced complications. Despite these benefits, pump adoption

remains low in resource-limited settings due to high costs of devices and consumables. The prototype proposed in the current study addresses this gap by prioritizing affordability while maintaining performance comparable to commercial systems.[28]

The economic burden of diabetes complications, often exceeding pump costs over time, underscores the need for cost-effective solutions. Our preliminary analysis (carried out in selected hospitals in Ethiopia) revealed that hospitalization for acute complications like diabetic ketoacidosis (DKA) incur costs exceeding six months of cost of using an insulin pump, while chronic complication management (e.g., dialysis) results in costs that exceed multi-year expenses in using an insulin pump device. Studies also suggest that insulin pump-related expenses may be offset within three years by reducing acute complications and hospitalizations. Policymakers must therefore evaluate therapies holistically, considering long-term savings and quality-of-life improvements. The proposed frugal insulin pump prototype could expand access to advanced diabetes care in underserved regions.[5,33]

The proposed design integrates a hypoglycemia suspension feature, halting insulin delivery when glucose levels are predicted to drop below 70mg/dL, resuming only when levels stabilize above 140mg/dL. This autonomous function is critical for preventing nocturnal hypoglycemia. For hyperglycemia, the system alerts users to administer correction doses. To test this feature, we have used a virtual CGM data generator which mimics the real-time CGM and sends data to the insulin pump.

To mitigate dosing errors, a dedicated RTC timestamps insulin delivery and glucose readings, stored on an SD card. The RTC's backup battery ensures data retention during power loss, while alarms notify users of empty reservoirs or maintenance needs.

While the proposed design is still under further development, in its current state, the basal rate accuracy (tested under controlled in vitro conditions) aligns with values reported in previous literature for commercial insulin pumps. User manuals for FDA/CE-approved pumps typically specify basal rate errors $\leq \pm 5\%$ when tested per IEC 60601-2-24 protocols. Though no universal accuracy mandates exist, clinical consensus accepts $\leq 5\%$ mean deviation as optimal. In that sense, the 3.49% mean deviation by the proposed pump design clearly indicates its great potentials.[15,22,34] The simplified plunger-tracking approach introduced inherent error sources absent in microgravimetric IEC testing, primarily ambient light variability (causing marker contrast fluctuations), camera resolution constraints, and parallax distortion from non-orthogonal camera angles. These were systematically addressed through three countermeasures: i) testing in daylight illuminated light, ii) MATLAB-based perspective transforms corrected parallax using chessboard reference targets, and iii) Sobel edge detection enhanced marker boundary precision. Despite these mitigations, residual uncertainty remains, likely causing systematic underestimation of true performance relative to IEC-tested commercial pumps.

5. Conclusion and Future Works

This study demonstrated the successful development of a low-cost insulin pump prototype capable of precise, accurate, and repeatable insulin delivery. Through rigorous testing, the system achieved a performance that approaches that of commercial insulin pumps, as evidenced by controlled syringe-

plunger displacement measurements and consistent in-vitro results. The integration of hypoglycemia suspension, a critical safety feature, further enhances its potential to reduce risks for patients in resource-limited settings.

By prioritizing affordability and without compromising functionality, the proposed prototype addresses critical gaps in diabetes care particularly in LMICs, where high costs and limited access to advanced therapies remain barriers. Its design aligns with public health goals to reduce long-term complications and improve quality of life for individuals with diabetes. Future efforts will focus on clinical validation and scaling production to make this technology accessible to underserved populations globally.

While the proposed prototype demonstrates promising accuracy under controlled conditions, critical gaps still remain: it lacks essential safety features like occlusion detection and its durability remains unproven against real-world stressors such as impacts, moisture, or daily wear. Crucially, additions to address these gaps, whether hardware-based safety systems or robustness enhancements, may compromise current accuracy metrics.

Functionality enhancements will focus on three key advancements: First, rotary encoder integration will enable dynamic motor feedback control for delivery consistency. Second, machine learning algorithms will be developed for automated carbohydrate estimation from meal images. Third, subcutaneous infusion set compatibility must be established for end-to-end delivery. Most commercial insulin pumps come with integrated continuous glucose monitoring and inclusion of such in the proposed design might also be mandatory.

System validation requires progression from current vision-based assessment to formal IEC 60601-2-24 microgravimetric testing, addressing inherent limitations of plunger-displacement tracking (ambient light variability, parallax distortion). More rigorous comparative benchmarking against commercial pumps will further assess infusion consistency and alarm responsiveness.

Authors' Contributions

RM and SB designed the 3D-printed components and Android application interface. RM developed firmware architecture and electrical systems, while analyzing performance data. SB implemented the Bluetooth-integrated mobile app for patient interaction and participated in prototype testing. BG executed experimental validation protocols and conducted market research. All authors collaboratively wrote and revised the manuscript. DA supervised the research framework, technical development, and manuscript preparation.

Declaration of Interests

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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