GlucoScreen: A Smartphone-based Readerless Glucose Test Strip for Prediabetes Screening

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Blood glucose measurement is commonly used to screen for and monitor diabetes, a chronic condition characterized by the inability to effectively modulate blood glucose that can lead to heart disease, vision loss, and kidney failure. Early detection of prediabetes can forestall or reverse more serious illness if healthy lifestyle adjustments or medical interventions are made in a timely manner. Current diabetes screening methods require visits to a healthcare facility and use of over-the-counter glucose-testing devices (glucometers), both of which are costly or inaccessible for many populations, reducing the chances of early disease detection. We therefore developed GlucoScreen, a readerless glucose test strip that enables affordable, single-use, at-home glucose testing, leveraging the user's touchscreen cellphone for reading and displaying results. By integrating minimal, low-cost electronics with commercially available blood glucose testing strips, the GlucoScreen prototype introduces a new type of low-cost, battery-free glucose testing tool that works with any smartphone, obviating the need to purchase a separate dedicated reader. Our key innovation is using the phone's capacitive touchscreen for the readout of the minimally modified commercially available glucose test strips. In an in vitro evaluation with artificial glucose solutions, we tested GlucoScreen with five different phones and compared the findings to two common glucometers, AccuChek and True Metrix. The mean absolute error (MAE) for our GlucoScreen prototype was 4.52 mg/dl (Accu-Chek test strips) and 3.7 mg/dl (True Metrix test strips), compared to 4.98 mg/dl and 5.44 mg/dl for the AccuChek glucometer and True Metrix glucometer, respectively. In a clinical investigation with 75 patients, GlucoScreen had a MAE of 10.47 mg/dl, while the AccuChek glucometer had a 9.88 mg/dl MAE. These results indicate that GlucoScreen's performance is comparable to that of commonly available over-the-counter blood glucose testing devices. With further development and validation, GlucoScreen has the potential to facilitate large-scale and lower cost diabetes screening. This work employs GlucoScreen's smartphone-based technology for glucose testing, but it could be extended to build other readerless electrochemical assays in the future.

CCS Concepts: • **Hardware → Sensor applications and deployments**; • **Human-centered computing → Ubiquitous and mobile computing systems and tools**; **Mobile phones**.

Additional Key Words and Phrases: diabetes, healthcare diagnostics, public health, rapid diagnostic testing, low-power, battery-free, smartphones, ubiquitous computing

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2474-9567/2023/3-ART30
https://doi.org/10.1145/3580855

ACM Reference Format:
Anandghan Waghmare, Farshid Salemi Parizi, Jason Hoffman, Yuntao Wang, Matthew Thompson, and Shwetak Patel. 2023. GlucoScreen: A Smartphone-based Readerless Glucose Test Strip for Prediabetes Screening. *Proc. ACM Interact. Mob. Wearable Ubiquitous Technol.* 7, 1, Article 30 (March 2023), 20 pages. https://doi.org/10.1145/3580855

1 INTRODUCTION

Diabetes mellitus (DM) is a chronic health condition that can lead to serious issues, including kidney failure, heart disease, and stroke, and its worldwide prevalence is rising. As of 2021, 537 million adults are living with diabetes [7]. This figure grew by 16% over the last two years and is expected to rise by a significant 46% to 783 million adults by 2045, outpacing population growth and leaving one of eight adults in need of treatment. In the US, 38% of all adults are estimated to have prediabetes[9], a condition in which blood sugar, while high, is not sufficiently elevated to be categorized as type 2 diabetes but that indicates the likelihood of developing diabetes in the future. However, only 19% of these at-risk prediabetes patients learned about their condition from a healthcare provider[9], leaving a concerning gap between disease risk state and awareness.

Accessible preventive screening for diabetes and prediabetes could aid in early detection and, with lifestyle modifications, potential reversal. Current screening approaches include blood sugar measurement using laboratory testing or point-of-care (POC) devices, called *portable glucose monitors* (PGMs), or *glucometers* [64]. These procedures, while effective, are costly [23] and can require access to extra devices or testing facilities [63]. As a result, many cases remain undiagnosed and untreated, motivating the need for an accessible, low-cost way to screen individuals likely to have prediabetic conditions.

The most common blood glucose testing device is a portable glucometer, a standalone device that interfaces with an electrochemically activated test strip to provide quick blood glucose readings. Glucometers work by analyzing a small blood sample, typically from the fingertip, placed on a test strip. The test strips they use cost less than a dollar each; however, the test strips sell in batches, and the device itself averages between $20-$80 [12]. The initial cost of purchasing the glucometer setup amortizes over time to become relatively affordable for routine device users, such as those already diagnosed with diabetes who are generally required to test their blood sugar daily. However, such amortization likely does not benefit screening use cases given that screening for at-risk individuals is recommended only every three years [3]. Preventive prediabetes screening is medically and financially prudent over the long term; therefore, lowering the cost and access barriers to screening for at-risk subjects is beneficial, especially in low- and middle-income nations [47].

To respond to the need for a cost-efficient, effective, and in-home prediabetes testing approach, we developed GlucoScreen, a *low-cost, battery-free, stand-alone glucose testing strip readable by any smartphone that measures blood glucose without the need for an external reader.* A smartphone app guides GlucoScreen users through steps needed to perform a fasting blood sugar or glucose tolerance self-test, both of which can indicate whether they have diabetes or prediabetes[84]. Such screening can help users make informed decisions about whether to follow up and seek in-person medical care from a clinician. At-home screening also lowers the barrier to action for getting screened, thereby increasing the likelihood of more people getting screened.

GlucoScreen uses a novel means of communication from the test strip to the phone: it electronically generates touch events from the test strip through the phone's capacitive touchscreen. This technique uses conventional glucose test strips enhanced with low-cost components. Once the smartphone processes the touchscreen events, they become available for immediate readout and storage locally or in an internet-connected health record. This communication method between test strip and phone consumes only 10 μW of power, orders of magnitude less than conventional low-power communication approaches, which can be easily harvested from the phones' flash. Our technique eliminates the need for batteries – which are common in other wireless communication methods, such as BLE (Bluetooth Low Energy), ZigBee, or ANT [29] – lowering costs and extending shelf life.

This research demonstrates and evaluates our touchscreen-based communication technique for blood sugar testing. Our new technique holds additional promise for building readerless assays for other electrochemical reaction-based tests, such as detecting heavy metals in water, detecting sodium in urine, and detecting malaria [66].

This paper makes the following contributions.

(1) We propose the design of a low-cost, low-power blood glucose test strip that enables diabetes prescreening using smartphones.
(2) We propose a hardware approach for an amperometric readout of a glucose test assay and encoding and communicating the reading to a smartphone via only its capacitive touchscreen.
(3) We present results from both benchtop and clinical experiments that evaluate our system. The benchtop study used multiple artificial glucose solutions, phones, and test strip brands to demonstrate that the proposed test strip works across phones and with various glucose concentrations. The clinical evaluation of 75 subjects demonstrates the accuracy of our approach with actual blood samples and compares our results to those achieved using current glucometers.

2 RELATED WORK

We review three key areas that address crucial elements for building a low-cost readerless glucose monitoring system: glucose sensing approaches, phone-based biosensing interfaces, and capacitive touchscreen-based phone sensing. We analyze the most current technological advancements in these areas and critically assess technological gaps in developing an inexpensive readerless glucose monitoring system.

2.1 Glucose Sensing

Most common glucose bio-sensors are based on blood interactions with external enzymes to calculate blood glucose levels. The most common enzymes used are hexokinase, glucose oxidase (GOx), or glucose-1-dehydrogenase (GDH) [72, 93]. In many clinical laboratories, the hexokinase test is the standard method for detecting glucose with spectrophotometry [81]. Glucose biosensors for point-of-care glucose monitoring devices are usually based on the two enzyme families, GOx and GDH. GOx is easily accessible, inexpensive, and has relatively relaxed storage requirements, facilitating its application in non-laboratory settings [22, 41]; hence, it is considered the gold standard for glucose testing [34] and used in most commonly available self-monitoring blood glucose devices.

For commercial use, GOx-based assays are sold as glucose test strips with a dedicated test strip reader. Enzyme-based bio-sensors need a drop of blood for analysis, typically from a finger prick or a venous draw. They are available in two formats: those with a standalone test strip reader [14] and those that connect to a smartphone via Bluetooth or USB [15, 16]. The standalone devices display and may store results, while the smartphone-connected devices use an accompanying phone application to do so.

Among the non-invasive approaches for measuring blood glucose are optical, microwave, and electrochemical techniques. Optical methods include near-infrared (NIR) and mid-infrared (MIR) spectroscopy, optical polarimetry (OP), Raman spectroscopy, the fluorescence method, and optical coherence tomography (OCT). NIR/MIR use absorption spectroscopy by illuminating a body part with light and analyzing the reflection, which is correlated to blood glucose concentrations [20, 52]. OP leverages glucose as an optically active substance with stable optical rotation [71]; when a polarized beam of light hits a solution containing glucose solutes, glucose induces a certain rotation of the polarized plane of the incident light, and the rotation angle can be used to infer glucose concentration [60, 73]. Raman spectroscopy [39] laser-illuminates blood vessels and analyzes the scattered light, which is related to glucose concentrations [79]. Fluorescence-based approaches employ glucose-sensing molecules that increase or decrease fluorescence relative to a baseline depending on the ambient glucose concentration [51].

Finally, OCT uses low-coherence light with precise depth focusing ability to evaluate changes in microvasculature, which can be utilized to detect glucose [35].

Like optical methods, microwave-based technologies illuminate the skin with radio-frequency radiation and analyze the reflected signal. Blood glucose fluctuations impact blood and its underlying tissues' dielectric characteristics, affecting the reflected signal. Both optical and microwave technologies enable non-invasive, continuous monitoring with no bodily discomfort. However, they have a low correlation to actual blood glucose measurements and are impacted by skin tone, skin condition, and age [85].

Electrochemical methods use the correlation between biofluids (such as saliva [69, 92], tears [49, 56], sweat [65, 78], and interstitial fluid [27, 58]) and blood glucose concentration to indirectly measure blood glucose. However, their downsides include low sensitivity, delayed measurement results, and a calibration requirement[85].

Glucose is also measured using the colorimetric method, which provides a visual response proportional to the glucose concentration when a bodily fluid is introduced into the test assay. Some colorimetric tests are non-invasive and use bodily fluid such as saliva [37, 61] and sweat [40, 80], while others work with blood samples [32, 33, 88, 96]. However, colorimetric techniques are susceptible to interference from complex components found in clinical specimens, which affect their sensitivity and impose visual detection challenges due to variable color intensities [31].

2.2 Phone-Based Biosensing

Smartphones' pervasive availability and connectivity are altering the concept of mobile health and making them a suitable platform for biosensing. We describe below various recent approaches to smartphone-based biosensing systems.

Current research uses phone cameras in conjunction with an attachment to image standard cholesterol test strips to test cholesterol on the phone [68], to detect the influenza virus using fluorogenic-based assays [62], to quantify vitamin D levels [55], to detect and quantify allergen contamination in food products [28] and to identify various biomarkers in milk extracts [59]. [70] provided a method to display results of lateral-flow assays, such as those used to detect malaria and influenza, that uses no external accessories; other systems using cameras are sensitive to changes in ambient lighting, necessitating additional components, such as mobile phone-specific housing units and external illumination modules, to address these difficulties [74]. Such accessories impair the portability and adaptability of smartphone-based biosensors and the detection process.

[17, 24, 43] and [94] have respectively demonstrated methods to detect fluid viscosity and surface tension with smartphone sensors such as LiDAR, cameras, and accelerometers. These techniques detect the liquids' physical properties, which may correlate to their constituents. However, predicting blood glucose using viscosity is unreliable [18].

Some approaches proposed devices that display test assay results and communicate that information to the phone wirelessly over Bluetooth [36, 46, 50, 95] and NFC/RFID [21, 48, 91]. Other devices include USB dongles, which physically attach to the phone's USB port [19, 30, 54, 57, 86]. Bluetooth-enabled wireless devices, despite their portability, require complex components to connect to the phone; these need a battery, raising device cost. Though USB dongles and NFC-based solutions do not require batteries, they use sophisticated components such as microcontrollers to communicate over the USB or NFC protocol, which increases system cost.

Several proposed devices connect to the phone over its analog audio jack [67, 82, 83, 89]. This method enables battery-free operation with simple circuitry; however, phone manufacturers are currently phasing out analog audio ports in their latest smartphones. Therefore, a technological vacuum exists for a low-cost, low-power interface to connect biosensors to smartphones.

2.3 Capacitive Sensing on Smartphones

Modern capacitive touchscreens offer seamless multitouch input for phone interaction. Research is leveraging the touchscreen's capacitive sensor output to enable new applications, as well. [25, 45, 53, 76, 77, 87] investigated tangible widgets, such as sliders and knobs, that allow new forms of touchscreen input. [75] predict finger touch angle with the screen using raw-capacitance data to enable greater accuracy in pointing tasks. [38, 42] performs body imaging from capacitive touchscreen data to identify users. [90] extends capacitive sensing beyond the phone through conductive material for body posture recognition and to facilitate novel human-object interactions. These works demonstrate the enormous potential of capacitive touch sensing; this work describes how to employ capacitive sensing for low-power data communication with the phone.

3 GLUCOSCREEN

In response to a growing need for scalable and cost-efficient prediabetes screening to improve public health and the lack of a low-cost and effective glucose testing solution, we propose GlucoScreen.

3.1 Concept

The GlucoScreen prototype is a fully self-contained glucose testing strip designed for low-cost, single-use blood glucose testing, transmitting glucose measurements to a smartphone that requires no additional accessories such as a dedicated reader. To take a blood glucose reading, users simply stick the GlucoScreen prototype strip to their phone and apply a small drop of their blood to the tip. GlucoScreen calculates and displays glucose levels via a custom software application running on the phone. The blood required for testing can be drawn by a finger prick using a disposable lancet. Figure 1 shows the GlucoScreen prototype.

GlucoScreen measures blood glucose using a well-established method that is based on the oxidation of glucose by an enzyme (glucose oxidase), producing a secondary molecule (gluconic acid) that can be measured electrochemically [2] as a change in current flow. At present, our prototype strip performs the enzyme-based oxidation reaction using commercially available glucose test strips (i.e., Accu-Chek [6] and True Metrix [11]). The output of the oxidation reaction is measured using *amperometry* (i.e., the detection of ions in a solution based on electric current or changes in electric current) and communicated to the smartphone via simulated taps on the touchscreen. The GlucoScreen prototype includes all components required to perform an amphoteric glucose assay and send the data to a phone.

3.2 Low-Cost and Battery-Free Operation

To maintain a low price point, we designed the GlucoScreen strip to perform only the glucose detection reaction and leveraged the phone's resources for everything else. The strip only captures the output of the amphoteric glucose assay and sends it to the phone in real-time to process and display the results. The amperometry is performed using a custom low-power, three-electrode potentiostat on the strip, and its output is communicated to the phone via a novel communication channel—the phone's touchscreen. The strip communicates with the phone by periodically mimicking touch events on the phone's touchscreen, which the phone interprets as human touch events. The amperometry output is communicated by encoding the data in the timings of these touch events using pulse width modulation (PWM). A custom application running on the phone records and decodes the touch events.

The communication phase starts from the potentiostat. The potentiostat output is fed into a voltage controlled oscillator (VCO), which controls a cascode field effect transistor (FET) output stage; this stage simulates touch on the smartphone's touchscreen (details in Section 4). Compared to conventional low-power communication approaches – such as BLE, NFC, or ANT – our approach uses a smaller number of low-cost electrical components and requires four orders of magnitude less power [29], decreasing the strip's overall power requirements. The

GlucoScreen prototype strip uses only 20 μW of power for continuous operation, which is easily harvested from the phone's flash using a few photodiodes. This eliminates the need for batteries and USB components, reducing costs and extending shelf life.

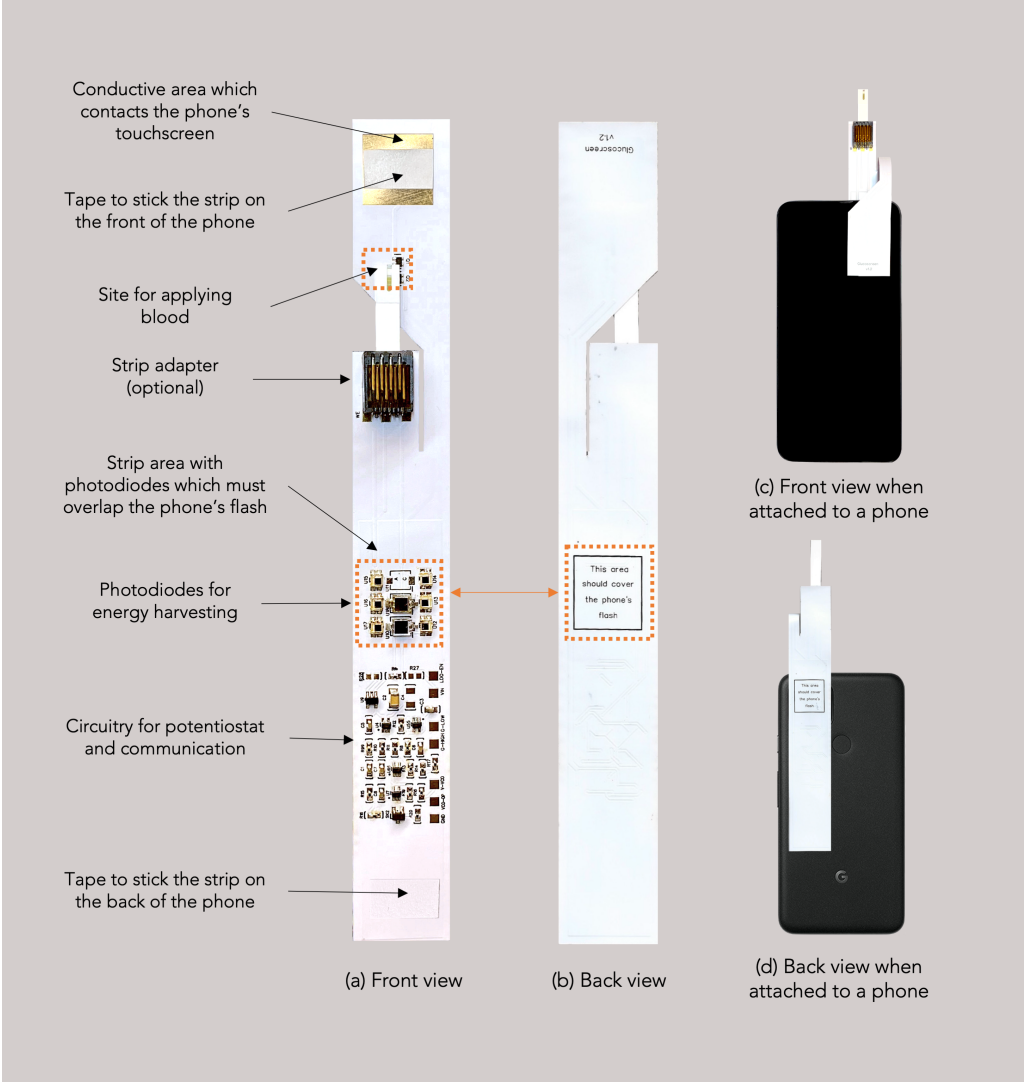


Fig. 1. GlucoScreen prototype. The GlucoScreen prototype contains circuitry that lets it conduct the response signal from commercially available electrochemical blood-glucose test strips directly to the capacitive touch sensor of any smartphone via pulse-width-modulated "touch events" interpretable by any phone with a capacitive touch screen. This is done via ultra low power energy harvesting from the phone's flash module, resulting in a novel, low-cost, self-contained blood-glucose test that obviates the need for an external reader.

3.3 Prototype and Usage

We built the GlucoScreen prototype using a newly designed flexible printed circuit board linked to an industry-standard microfluidic reaction chamber. The functional design of the GlucoScreen prototype bends over the phone's top edge to harvest energy from the phone's flash and communicate results via contact with the phone's touchscreen. Figure 2 shows the GlucoScreen installation process. For multi-phone compatibility, the physical form of the GlucoScreen strip is designed to fit and work with many phone models with differing screen sizes and flash positions on the back of the device. Our prototype uses double-sided tape adhesive, which adheres well to the phone and easily peels away with no damage or residue.

A user-friendly companion software application runs on the phone that walks users through the process of temporarily attaching the strip to the phone, drawing blood and applying it to the strip, and interpreting blood glucose readings. The application includes on-screen videos and illustrations that deliver step-by-step instructions to the user to improve ease-of-use and connectivity and ensure accurate results.

4 IMPLEMENTATION

4.1 Prototype Construction

We designed the strip prototype (19 cm x 2.7 cm) to be a flexible printed circuit using 0.23 mm thick polyimide as the base material. Circuit traces were laid out with copper of 55um thickness. A polymer-based solder mask was then used to cover both base material and traces. The remaining exposed copper was gold plated using the electroless nickel immersion gold (ENIG) process, and electrical components were attached to this circuit board with reflow soldering. A strip adapter was removed from the commodity devices and put on the prototype strip to simplify the replacement of used glucose strips. Separate adapters were used for the Accu-Chek and True Metrix glucose strips, and two prototype versions were created for the two glucose strip brands.

4.2 Circuit Design

The prototype strip consists of a three-electrode potentiostat designed with two operational amplifiers for amperometric glucose concentration measurement. The potentiostat holds the Accu-Chek and True Metrix glucose bio-sensor strips at a constant potential difference of 400mV. The current flow owing to the reaction that occurs after the introduction of glucose molecules is monitored as voltage output. The output gain of the potentiostat, i.e., the output voltage range, is set differently for Accu Chek and TrueMetrix to achieve optimal glucose detection sensitivity.

The potentiostat's output voltage is then fed into a VCO, constructed as a voltage integrator, followed by a Schmitt trigger. The VCO outputs voltage pulses, where the width of each pulse is proportional to the output voltage value from the potentiostat. These output pulses then drive a MOSFET setup, which simulates touch on the phone with a duration proportional to the input pulse widths. As a result, the period of touch on the phone is proportional to the potentiostat's output voltage.

The MOSFETs setup consists of two MOSFETs in a cascode configuration. It simulates touch on the phone by causing sufficient impedance change at the point of contact with the touchscreen for the phone to interpret it as a human touch: the MOSFETs provide a path for electrical charges generated by the touchscreen to flow to the prototype strip's ground. To do this effectively, the cascode configuration improves electrical isolation between the capacitive touchscreen and the strip circuitry. The prototype strip attached to the back of the phone also capacitively couples with the phone's ground, making it appear to be electrically larger than it is. This lets the strip simulate a larger impedance change, allowing the touch simulation to function properly.

Three parallel photodiodes power the entire circuit by harvesting the phone's flash energy. Six additional inexpensive photodiodes linked in series boost the output voltage to approximately 2.5V. We found that this method of voltage boosting was less expensive than using a voltage booster IC. A small capacitor bank filters the

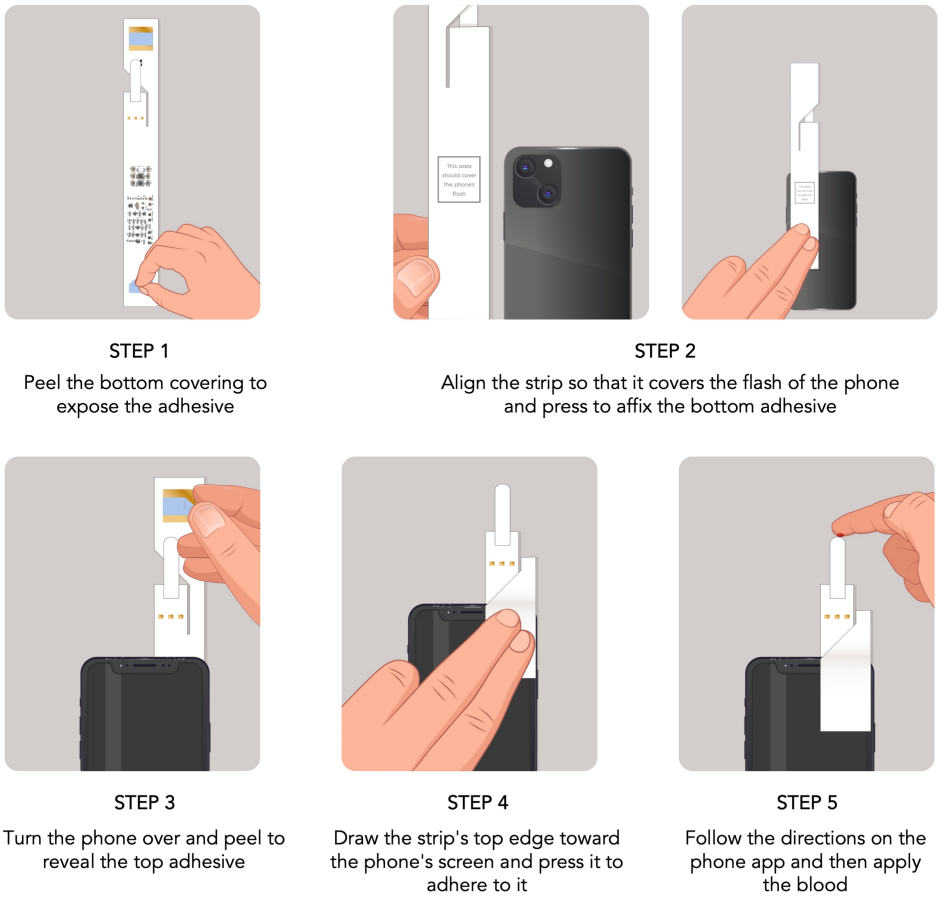


Fig. 2. Step-by-step instructions for attaching the GlucoScreen prototype to a smartphone. The GlucoScreen prototype strip temporarily attaches to the phone via two adhesive contacts on the front side of the strip. Users first align the designated spot on the prototype strip (as shown in Figure 1b) with the phone's flash. Then, they attach the strip to the back and front of the phone using the adhesive contacts. The strip features a long neck, which enables it to wrap around the phone and make adequate contact with the touchscreen.

output voltage and adapts for small power surges at the photodiode's output. Finally, we employ a low-dropout regulator (LDO) to maintain the output voltage at 1.8V. Figure A1 in section A (appendix) shows the schematic for the circuitry on the GlucoScreen strip.

4.3 Smartphone Applications

We developed three mobile applications: one for end users and two for data collection during the study. The user application guides users through the process of using GlucoScreen for glucose testing and includes a tutorial for first-time users; see the auxiliary material for app screenshots. The two data collection applications focus

on rapid data gathering with minimal user input; both share a common set of capabilities; they first ask for the experiment's name and then save the timing of the phone's touch up and touch down events to a file. These files can be retrieved from the phone for further processing.

The user application was developed on the Android platform, and the data collection applications were designed for Android and iOS. Android applications, created in Java, are supported on the Android platform's API level 29; the iOS app, written in Objective-C, is compatible with iOS version 14.

4.4 Data Processing

Once a glucose test starts, the users' phone application begins to collect touchscreen data and beeps after a few seconds to tell the user to apply the glucose solution/blood to the test strip. After the beep, the app collects data for 60 more seconds.

To process the data from the glucose reading captured on the phone, GlucoScreen first decodes the signal. The data stored on the phone (i.e., the potentiostat's pulse width modulated output) is a series of pulses of varying widths, each of which represents a data point in the signal whose magnitude is proportional to the pulse width. The original signal is obtained by calculating all pulse widths and using them as amplitudes for every point. The acquired signal is then filtered using a Butterworth low-pass filter with a cutoff frequency of 3Hz. Next, the resultant signal is segmented to trim it from the time of glucose application to the strip until the data ends.

Based on an initial exploration, we discovered that signals acquired from our prototype share a distinctive shape: they are characterized by a sharp drop in signal magnitude followed by a prominent peak and a gradual decline proportional to the glucose concentration, as Figure 4 shows. The sudden drop represents the time at which the glucose solution/blood was introduced to the strip. We utilize this signature shape to crop the signal from glucose drop to data's end. We then used the resulting signal to predict the glucose concentration.

5 EVALUATION AND RESULTS

5.1 In Vitro Testing

To evaluate its accuracy, we conducted an in vitro study, testing GlucoScreen with nine different concentrations of artificial glucose solution in the clinically relevant range of 45-210 mg/dl (see Figure 3). This range is considered adequate for determining diabetes and prediabetes conditions [84]. To assess GlucoScreen's performance across various phones, we tested the concentrations using five different phones (four distinct models): Samsung A21, Google Pixel 5, iPhone 11, and two Motorola Moto G7 phones; we used two identical Moto G7 phones to compare performance across different devices of the same model. We selected these phones because they were among the most prevalent in the international market at the time of the study and covered both the popular Android and iOS operating systems.

For comparison, our study used the GlucoScreen prototype with two commercially available glucose strips, Accu-Chek and True Metrix. These brands are FDA-approved, widely available, and confirmed to be accurate[4, 44]. Figure 3 depicts the in vitro testing plan.

For calibration and validation, we prepared the artificial glucose solutions for in vitro testing using the control solutions provided by the AccuChek and True Metrix strip manufacturers. True Metrix offers three levels of control solution, while AccuChek provides two. We developed nine alternative solution concentrations for each AccuChek and True Metrix strip by mixing their respective control solutions in varying proportions.

We trained a linear regression model to estimate glucose concentration from the pre-processed study data, as shown in Figure 4. We explored other models for predicting glucose concentrations, such as random forest and support vector regressor. Given that all provided similar results, we chose linear regression because it does not overfit, letting us accurately predict glucose concentrations missing from the training data. For feature input to

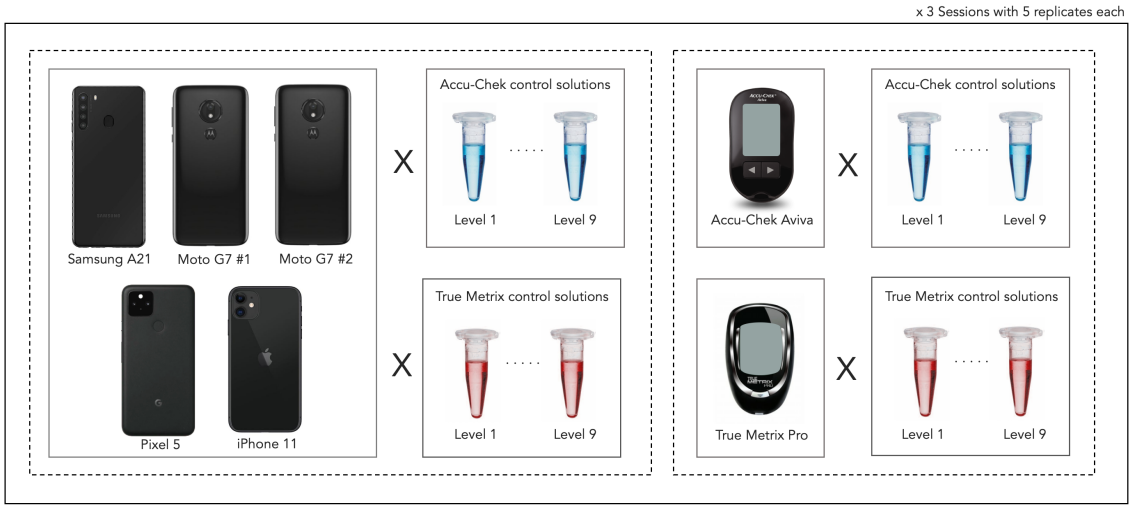
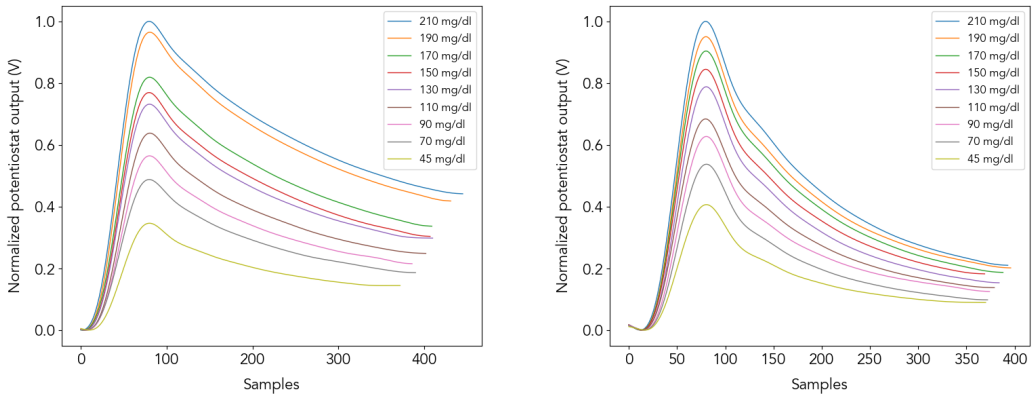


Fig. 3. In vitro test plan. We conducted three in vitro testing sessions for each of the five phone models. Every session included a total of five repetitions of each of nine distinct glucose solution levels: 45, 70, 90, 110, 130, 150, 170, 190, and 210 mg/dl. These sessions were performed using both commercially available (Accu-Chek and True Metrix) glucose test strips. Each test strip was tested with its own control solutions. In total, 1350 tests were conducted across all phones (5 phones * 3 sessions * 9 levels * 5 replicates * 2 test strip brands). Similar testing was conducted with commercial Accu-Chek and True Metrix glucometers and their respective strips and control solutions over three sessions, totaling 270 tests (2 test strip brands * 3 sessions * 9 levels * 5 replicates).

the model, we used 30 seconds of the decoded signal, starting from the time a glucose drop was applied to the test strip, divided it into ten equal segments, and summed individual segments to generate a ten-dimensional vector.

Our first investigation was conducted to determine the GlucoScreen's accuracy when analyzing a sample with unknown concentrations. We used cross-validation with one concentration left out; the model was trained on all remaining concentrations and then validated against the concentration that had been omitted. The MAE for GlucosScreen with Accu-Chek strips was 4.52 mg/dl across all concentrations, while the MAE for the Accu-Chek glucometer was 4.98 mg/dl. The MAE for GlucoScreen with True Metrix strips was 3.7 mg/dl across all concentrations, and it was 5.44 mg/dl for the True Metrix glucometer. GlucoScreen outperformed True Metrix glucometers, with a lower MAE at all concentrations. Accu-Chek strip results were mixed, with the Accu-Chek glucometer performing better in some instances. Figure 5 presents study results.

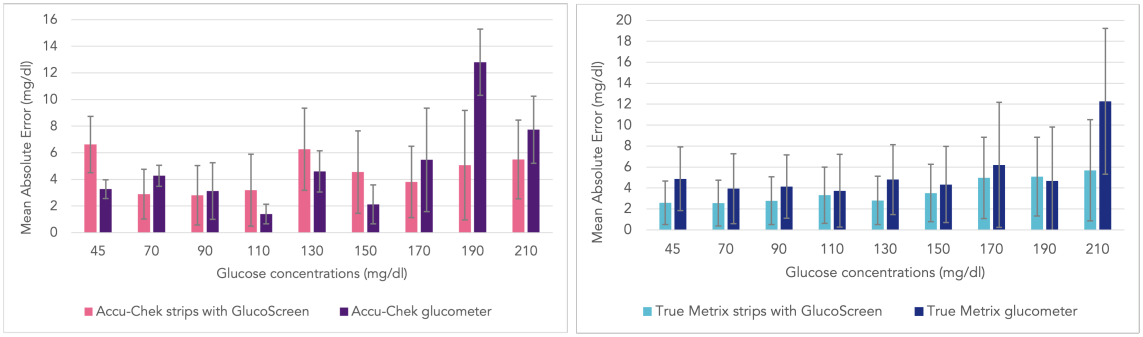
Our second investigation repeated cross-validation, this time withholding data from one phone and training a regression model on the data from the remaining phones. We then tested the model on the data from the excluded phone and repeated the procedure for each phone, one by one. The MAE (across all glucose concentrations) for each phone was found to be lower than the MAE for the matching glucometer, both for Accu-Chek and True Metrix strips. The iPhone 11 had the lowest MAE, 3.27 mg/dl, when using Accu-Chek strips, while the Moto G7 1 had the highest MAE, 4.41 mg/dl, when using True Metrix strips. The results showed a small difference in outcomes between the two Motorola phones (0.03 mg/dl with Accu-Chek strips and 0.01 mg/dl with True Metrix strips). All phones produced better results than the corresponding glucometers, indicating that GlucoScreen works with acceptable accuracy across phones. Figure 6 shows findings from our cross-phone investigation.



(a) Accu-Chek (b) True Metrix

Fig. 4. One repetition of data collected from a Google Pixel 5 phone during a single session for all glucose solution concentrations utilized in the in vitro testing. Figures (a) and (b) exhibit results from the GlucoScreen prototype with Accu-Chek and True Metrix test strips, respectively. The Y-axis represents amplitude on both graphs; the X-axis represents data samples. The plotted data is shown after pre-processing. Each curve depicts the response of the GlucoScreen prototype to a single solution; the lowest curve depicts the lowest concentration, while successively higher curves represent higher concentrations.

We used cross-validation for our final evaluation, omitting data from one session and constructing a linear regression model on the data from the other two sessions. In this evaluation, MAE values were lower than 0.5 mg/dl for all glucose concentrations for both Accu-Chek and True Metrix strips. Because the sessions were recorded on separate days using test strips from different lots, these results also establish that GlucoScreen functions consistently with data recorded on different days and across different test strip batches.



(a) Accu-Chek (b) True Metrix

Fig. 5. Outcomes of cross-validation when one glucose concentration is excluded from the training set of a regression model. The figure depicts the result at each concentration. For comparison, we present the MAE result from the corresponding glucometer (Accu-Chek and True Metrix) along with GlucoScreen's.

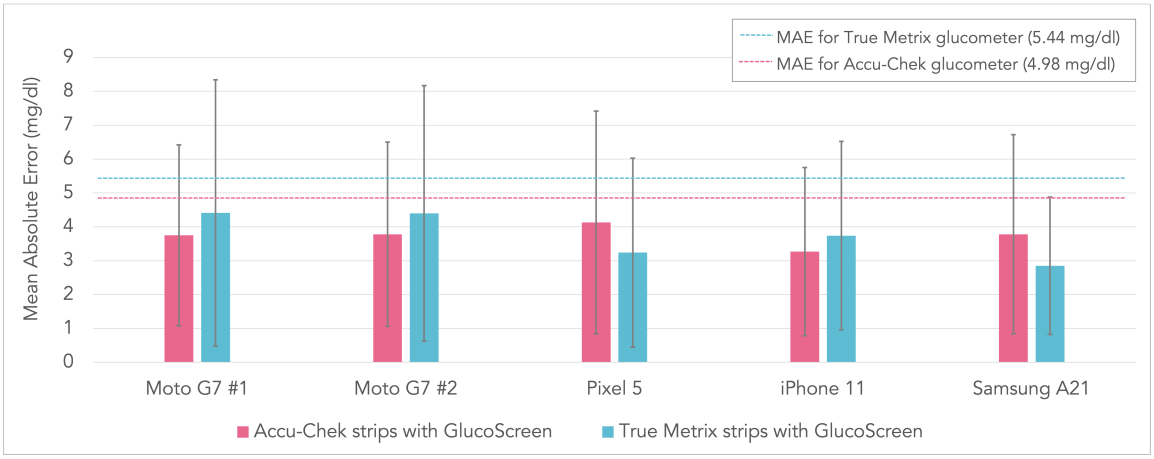


Fig. 6. Cross-validation study results when we excluded data from one phone and trained the model using data from the remaining phones. We show the GlucoScreen results side by side with Accu-Chek strips and True Metrix strips. The two dotted lines on the graph indicate the MAE for the Accu-Chek and True Metrix glucometers (across all glucose concentrations).

5.2 Clinical Study

To evaluate performance in an environment that closely resembles real-world clinical use, we conducted a clinical study, directed by a phlebotomist, at a pathology department's blood collection facility in India. Patients who visited the facility for a blood glucose test were asked if they wanted to participate in this study. For those who consented (N=75 patients), a small volume of their blood sample collected for lab tests was used for this study. For a few patients (N=7), multiple blood samples were collected at different times of the day.

Blood samples were collected from a vein through venipuncture in the antecubital fossa. Every sample (N=85 samples) was run through the GlucoScreen prototype, and touchscreen data was recorded on the phone for further processing to calculate blood glucose levels. The prototype used Accu-Chek glucose test strips and was attached to an iPhone 11. For comparison, the blood glucose reading was obtained for the same blood sample using an Accu-Chek glucometer and a laboratory auto analyzer.

The clinical data collected did not have a uniform distribution over the glucose concentrations, which means that the data was not evenly distributed over the extreme glucose values in the dataset (71 mg/dl – 370 mg/dl). Figure 7 presents the glucose concentration distribution. Therefore, to generate uniform splits for cross-validation testing, we sorted the glucose samples into bins (N=28) and performed stratified splits (N=3) of the data. We validated that the splits represented the same distribution by running the Kolmogorov-Smirnov test on the data subsets and selecting only those with a p-value greater than 0.98 and a KS-value less than 0.1. We used a random forest regressor to perform cross-validation on three subsets;

For clinical testing, we divided into ten equal segments the decoded signal from the time of glucose drop application to the test strip. We calculated each segment's mean, standard deviation, sum, and median to form a 40-point vector (10x4). We used this vector as the feature input for the random forest regressor (number of estimators=50). The ground truth for the blood glucose level was the test result from the laboratory auto analyzer. The MAE for GlucoScreen with Accu-Chek strips was 10.47 mg/dl, and for the AccuChek glucometer it was 9.82 mg/dl. The standard deviation for GlucoScreen was 9.71 mg/dl, and for AccuChek it was 9.88 mg/dl. Figure 8 shows these results. The MAE for Leave One Out Cross Validation for GlucoScreen was 10.91 mg/dl.

The error in glucose concentration prediction with GlucoScreen is comparable to that of commodity glucometers. To screen for diabetes or prediabetes, however, a range of glucose concentrations far lower than GlucoScreen's resolution is required. For instance, a fasting blood sugar level of 99 mg/dL or less is considered normal, 100 to 125 mg/dL is considered prediabetes, and 126 mg/dL or above is considered diabetes [8]. Our results show that GlucoScreen accurately screens for diabetes and prediabetes.

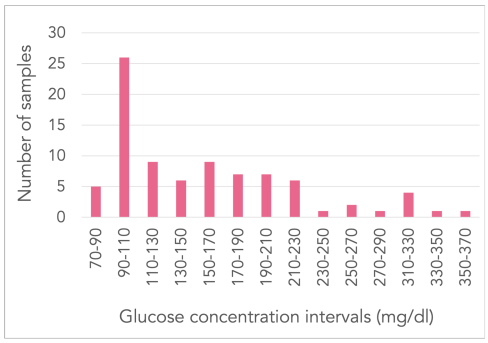


Fig. 7. The distribution of glucose sample concentrations in clinical trial data. We determined the glucose concentrations used to prepare this figure through laboratory examination of blood samples.

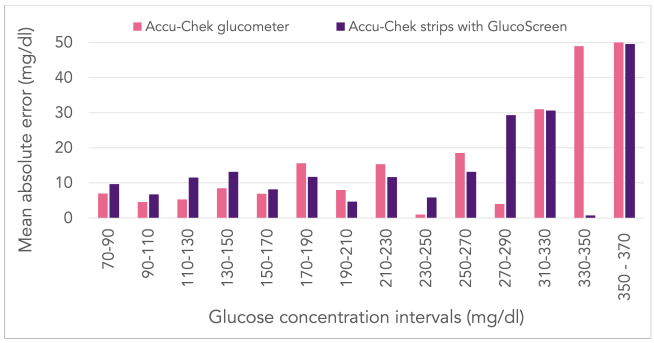


Fig. 8. Results derived from the cross-validation analysis of clinical study data. The results were binned into intervals of glucose concentration. The MAE values of GlucoScreen with AccuChek strips and the Accu-Chek glucometer are compared side by side.

6 DISCUSSION

Undetected and untreated prediabetes and diabetes are serious health conditions with life-threatening complications. With early detection and lifestyle changes, health outcomes can significantly improve. Current logistical and cost challenges of visiting healthcare venues or purchasing blood testing equipment for infrequent use reduce prescreening prevalence and therefore preemptive treatment. This ultimately increases downstream healthcare costs for treatment, motivating the development of our GlucoScreen prototype.

We designed GlucoScreen to be a low price point, easy-to-use and reliable in-home device that leverages ubiquitous technology, i.e., the smartphone and inexpensively modified test strips. Our key innovation is using the phone's capacitive touchscreen for data communication between the test strip and the phone, obviating the need for an external reader of low-cost test strips by leveraging devices that are already in many people's pockets. This technique is less expensive to deploy than USB, BLE, WiFi, or NFC based communication, which requires expensive and power-intensive ICs. Since most phones have capacitive touchscreens, our solution could work well for the large and growing population of smartphone owners.

We obtain the minuscule 20 μW of power needed to operate GlucoScreen from the phones' flash, eliminating the need for batteries or a USB connection to the phone. While an audio-port-based communication mechanism could also work with low-cost circuitry, phone manufacturers have been phasing out audio ports from their latest phones[10], making this approach unsustainable. Though we also considered using the phone's USB port for power, that technique would have demanded multiple versions of the test strip for different phones to accommodate the various USB types. However, photodiodes allow a single version to function on diverse phones for a similar price to the USB connector.

Our clinical evaluation MAE is more significant than it is for the benchtop study. One contributing factor is that testing with an artificial solution differs from testing with blood: unlike blood, the control solution does not include blood cells and interferents and is less viscous [5]. Consequently, the test strip response with blood

is noisier than the reaction with artificial glucose solutions. In addition, less training data were available for building the regression model in our clinical investigation than in the benchtop study. We posit that as more training data is acquired, the MAE for clinical testing will drop.

Though we conducted a clinical study to validate prototype accuracy, future work could conduct a usability study for general users to assess whether the population of smartphone users would adopt this testing option. In addition, a usability study could validate the accuracy of the prototype in terms of additional factors that non-expert users might face, such as comprehensibility of software-based instructions on the screen and clarity of instructions for supplying blood samples to the strip input.

We estimate that the cost of manufacturing a GlucoScreen strip at large scale (N = 10,000 units) would be around $2.8 per strip (see Table 1 for details). Though our prototype connects to a single glucose biosensor, the same strip could support multiple glucose biosensors for one-by-one application without requiring changes to the rest of the strip. Thus, a strip with two glucose testing sites would cost about $1.4 for each blood sugar test. The end result would be a cost for a prescreening test strip comparable to current test strips on the market today but with no external glucometer device, feasibly reducing the cost by over 90% for the initial screening test.

Our present prototype uses a polymer substrate. However, we intend to make phone-based diagnostics like GlucoScreen more eco-friendly and sustainable. Modern glucose test strips contain paper substrates, and we anticipate that the necessary electronic components for GlucoScreen can be affixed directly to that substrate. As a result, the electronic components could be collected for further use after performing a blood test, and the test strip could be recycled. In addition, contemporary glucose test strips employ conductive traces that connect the biochemical reagents to the inputs of the glucometer device. These traces could be redesigned into a PCB circuit layout to which components may be attached. This approach would be more cost-effective for strip manufacturers embracing this technology since they could repurpose an existing assembly line process. Additionally, printable organic photodiodes could replace the currently used photodiodes; the former are environmentally friendly and could further reduce test strip pricing [26].

Table 1. GlucoScreen prototype component cost for large quantities (N=10,000 units). Electrical component pricing was obtained from Octapart.com [13] for 10,000 units each. Glucose strip manufacturing cost estimates were obtained from [1].

Part number	Price per unit ($)	Quantity	Total Price
BPW34FS	0.308	3	0.924
PD15-22C/TR8	0.091	6	0.546
3SK294	0.115	2	0.23
2N7002	0.012	1	0.012
TLV521	0.134	4	0.536
S1313	0.097	1	0.097
Passive components	-	-	<0.01
Glucose Test Strip	0.15	1	0.15
			Total price = $2.813

7 CONCLUSION

We present a new glucose testing strip, GlucoScreen, that communicates directly with a smartphone and enables self-administered blood glucose testing. In in vitro and clinical studies, GlucoScreen performed comparably to commercially available glucose testing systems. The ability to do self-administered glucose testing at a low cost and at home can promote needed large-scale screening. Preventing or delaying the onset of prediabetes and

diabetes and their related severe complications can yield long-term advantages for personal health and reduce the burden on healthcare resources.

ACKNOWLEDGEMENTS

We offer our gratitude to all those who participated in our study. Special thanks to Dr. Shailesh Pitale for his invaluable guidance and support in conducting the clinical study at Dew Medicare and Trinity Hospital (India). We also extend our appreciation to Dr. Farah Khan from the UW Diabetes Institute for her insightful feedback on the project, Dr. Vikram Iyer for his valuable input on the manuscript, Sandy Kaplan for proofreading the paper draft and Bo Liu for his contributions to developing the phone applications. Lastly, we appreciate the incisive comments and suggestions provided by all reviewers.

The study was approved by the University of Washington Institutional Review Board (IRB) under protocol IDs STUDY00012705 and STUDY00010388 and funded by the Bill and Melinda Gates Foundation and the University of Washington Gift Funds.

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A APPENDIX

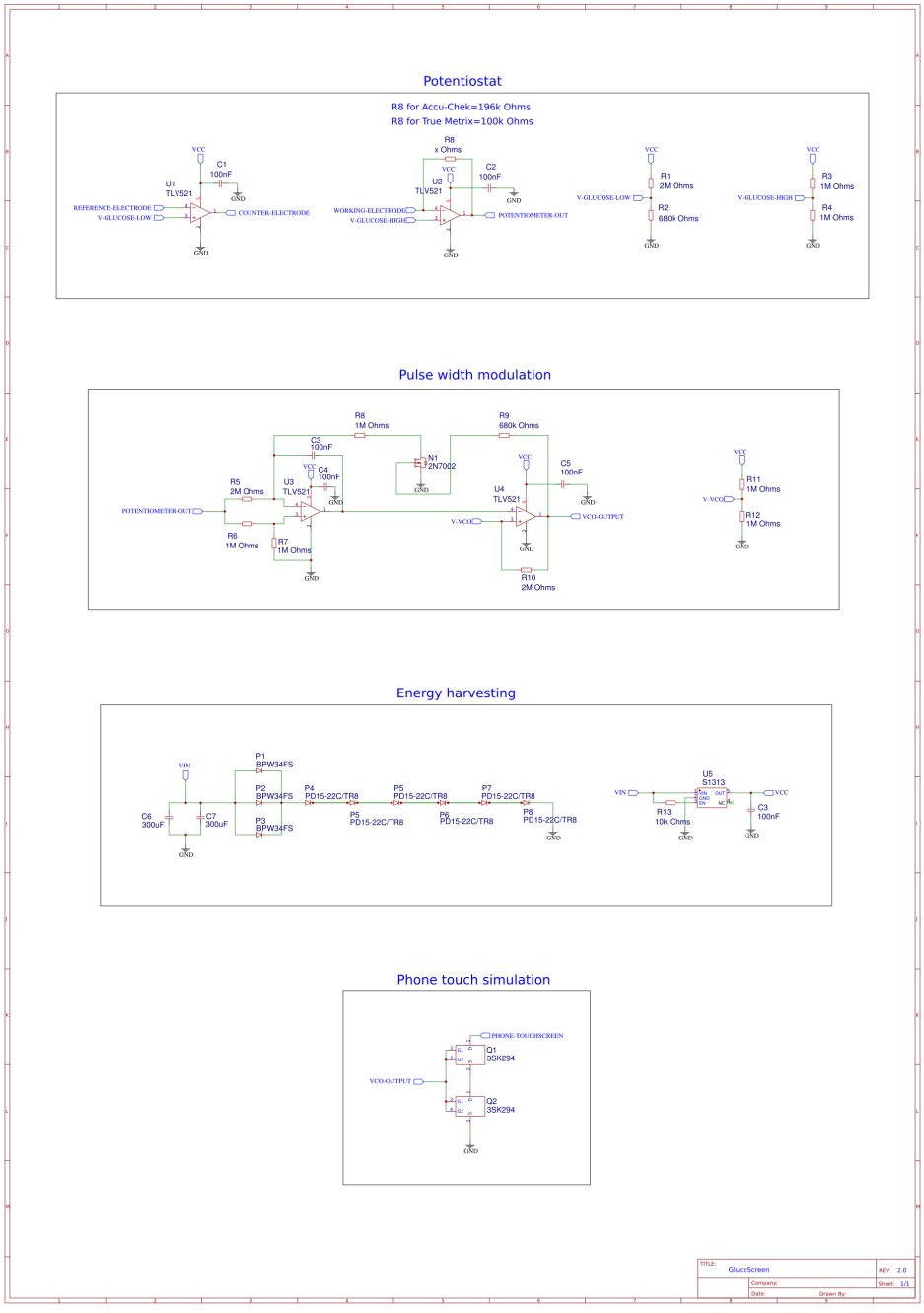

Fig. A1. Schematic for GlucoScreen prototype circuitry.