Smart Artificial-Intelligence Based Self-Care-Device for Diabetic Patients

Saif K. Almulla, Omar Zaatar, Hamad S. Ahmed, Noor ul Misbah Khanum and Anwar Jarndal
Electrical Engineering Department, University of Sharjah
Sharjah, United Arab Emirates
ajarndal@sharjah.ac.ae

2022 Advances in Science and Engineering Technology International Conferences (ASET) | 978-1-6654-1801-0/22/$31.00 ©2022 IEEE | DOI: 10.1109/ASET53988.2022.9734874

Abstract— **The prevalence of diabetes has been consistently increasing over the past decades. While implementation of sensor-based systems for managing diabetes is on the rise, manual monitoring efforts are still required in case of abnormal fluctuations in the blood glucose levels due to lack of intelligent systems. This paper presents an incremental research work developed on top of a previous work to build a smart system. The proposed system helps in managing Type-1 diabetes using future predictions to avoid hypoglycemia or hyperglycemia. It presents a smart healthcare device for diabetic patients with the ability of intelligently controlling the insulin dosage each time during automatic injection to maintain normal blood glucose levels. The system consists of an insulin pump, a continuous glucose monitor (CGM), and a microprocessor unit which utilizes artificial intelligence (AI) based algorithms to predict future blood glucose levels to avoid serious conditions. The prediction feature used in the proposed system distinguishes it from other commercially available products. Furthermore, the proposed system monitors the blood glucose levels of the patient and notifies the patient in case of critical conditions. It can also send a summarized report to the healthcare center and provide the patient with a timeline of collected data and insulin dosages injected. The device was implemented and tested with very good results.**

Keywords—CGM; Automated insulin delivery; Diabetes; Machine Learning; Health Care Device; Artificial pancreas.

I. INTRODUCTION

Diabetes is a significant medical problem that is increasing at disturbing levels and is one of the fastest-growing global health emergencies in recent times. In 2019, there were 463 million diabetic patients, a future estimation of 578 million by 2030, and 700 million by 2045. Over four million people aged 20–79 years were estimated to die from diabetes-related causes in 2019 [1]. Diabetes is a severe chronic disease that impairs the body's capability to produce enough insulin or its inability to use the insulin it produces (cell resistant). Diabetes is mainly classified into two different types: Type-1 and Type-2. Type 1 diabetes, also known as juvenile diabetes, is the most chronic type where the pancreas fails to produce any insulin [2]. Type 1 diabetes occurs when the beta cells responsible for producing insulin are attacked and destroyed by the body's immune system. Type 2 diabetes, also known as non-insulin-dependent or adult-onset, results from insulin resistance [3]. Type-2 diabetes is caused due to insulin resistance, which is the incapability of the cells in the body to respond to insulin.

Type 1 diabetic patients are completely dependent on insulin doses to maintain glucose levels within range. Different factors are to be considered when controlling blood sugar as a diabetic patient. Coordinating food with medication is very important as a patient may be eating an insufficient amount of carbohydrates; while taking large doses of insulin and this accordingly could result in a drop in the level of the blood sugar (hypoglycemia). On the other hand, overeating carbohydrates with low insulin intake will lead to high blood sugar (hyperglycemia) [4]. Therefore, it is very important for the diabetic patients to keep track of their blood glucose levels and to inject proper dosage of insulin to avoid critical conditions.

New procedures for managing diabetes are essential tools for the patients. Different methods like insulin injections, insulin pens, insulin pumps and artificial pancreas system are being used by the patients to control diabetes [5] [6]. Although solutions based on technologies have emerged, manual effort is still required during abnormal fluctuations of blood glucose levels, which could be fatal if not addressed promptly. The artificial pancreas system regulates the blood glucose levels and aids in automatic injection of insulin doses in order to improve the quality of life for diabetic patients. The artificial pancreas systems are available in different types, which include open loop systems, fully automated and closed loop systems. The U.S Food and Drug Administration (FDA) approved artificial pancreas currently available is the Mini Med 770G by Medtronic launched in September 2020 [7].

The aim of this work is to develop a smart system, which automatically delivers proper insulin dosage to the patient by predicting future glucose levels. The system will also be able to notify the user in case of any abnormal glucose levels and also send all collected data to both the user and the health care center. The main contribution of this work with respect to the previous work reported in [8] is to develop an intelligent system, which predicts future glucose levels to avoid hyperglycemia and hypoglycemia. The proposed system is more accurate and has better user-interface features as compared to the work done in [8].

This paper is organized into different sections with section II describes the system followed by the design of the artificial pancreas in section III. The testing methods and the obtained results are presented in Section IV. Finally, the paper is concluded in section V.

II. System Description

The proposed system consists of three main components which includes the insulin infusion pump, a continuous glucose monitoring (CGM) system and a processor unit that connects the CGM and the pump. The system is a closed loop system and mimics the function of pancreas in the body with respect to insulin delivery. The proposed system will regulate the blood glucose levels depending on current and historical measurements. These parameters will be used as inputs for a developed Artificial Intelligence (AI) based algorithm that will be discussed in the next sections. It will fix the insulin dosage and predicts any abnormal conditions. Moreover, this system will be linked to a mobile application that displays the glucose level statistics along with other additional features. The design criteria for this system is based on key factors like efficiency, safety, cost, ease of use and total power consumption.

As illustrated in Fig. 1, the device starts from the CGM sensor (Dexcom G5 [14]) taking the glucose levels measurements continuously for every five minutes and transmitting data to the microprocessor. The data of the glucose levels will be sent via Bluetooth version 5.0 to the Raspberry Pi 4 Model B microprocessor [9]. The Raspberry Pi 4 Model B will be programmed with an algorithm that uses AI to use the data received in order to calculate the required insulin dose and predict future glucose levels. After calculating, a command will be sent to the insulin pump (Medtronic MiniMed 722 [7]) to inject the correct dosage into the patient's body. The current and predicted glucose levels will be transmitted to the mobile application via Bluetooth version 5.0 as a reference for the user as illustrated in Fig.1. A report will be shared via the cloud (Firebase) with the healthcare facility for supervision by a specialist to track the patients' health condition. The system will be fitted on the patient; components are in close range connected via Bluetooth.

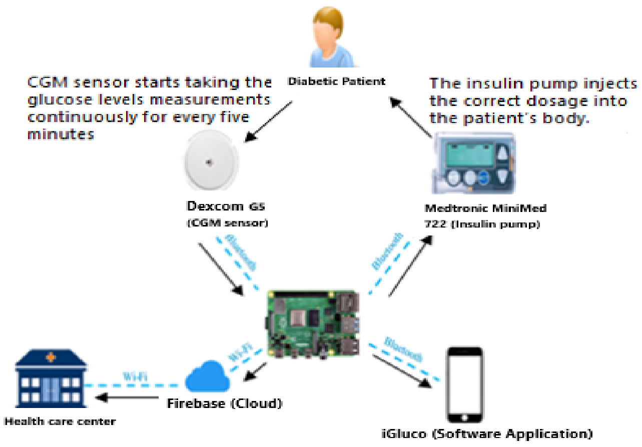

Fig.1: Proposed smart system for Diabetic patient.

The CGM sensors are classified into three main categories like Invasive (I), Non-Invasive (NI) and Minimal Invasive (MI). The mean-average-relative-measurement (MARD), which is a metric measurement to determine accuracy is used to test the efficiency, accuracy, and performance of glucose measurement devices. If the MARD percentage value is high, then the accuracy is very low [10]. The CGM sensor is attached to the body and is placed behind the skin and it is minimal invasive (MI) having a high accuracy with MARD of 9%. The main component of an artificial pancreas system is calculating the amount of insulin to be pumped in a Type 1 diabetes patient. The efficiency of the calculation method can be measured by comparing the percentage time, the glucose level of the patient spends below, on, and above the glucose target level. The less time spent below and above the target glucose level gives higher accuracy. An ideal method would not let the patient reach hypoglycemia nor hyperglycemia state.

The given formula in equation (1) estimates the insulin requirement needed by the body daily in the unit of insulin/day [11]. Basal and Bolus are two different types of insulin delivery. Basal is an insulin-type, vital to diabetic patients and it can be referred to background insulin for which it is mainly responsible for lowering the blood glucose levels in long-acting insulin action with providing a predictable amount of insulin dosage to prevent the secretion of glucose to the bloodstream from the liver throughout the day and night [12]. The patient's requirement of the Basal insulin dosage can be calculated using equation (2) [13]. Bolus insulin is a type of insulin that maintains blood glucose spikes after meals where its effect time is 2-4 hours each day. It is a rapid-acting insulin that performs quickly to the drop the blood sugar levels [12]. The Insulin-to-Carbohydrates (I:C) ratio has been used to prescribe to the patient's Bolus dosage. This ratio indicates the total grams of carbohydrates to be covered for a one unit of insulin. The total amount of Bolus insulin dosage can be calculated using factors like Carbohydrate Intake (CI), Current Measured Blood Glucose Level (CBG), Target Blood Glucose Level (TBG) and Remaining Body Insulin (RBI) as shown in equation (3).

$$TDI = Weight\ (in\ Kg) \times 0.55 \tag{1}$$

$$Basal\ Insulin\ Dosage = (40 - 50\%) \times TDI \tag{2}$$

$$Bolus\ Insulin\ Dosage = \frac{CI}{CR} + \frac{CBG - TBG}{CF} - RBI \tag{3}$$

III. Proposed System Desgin

In the proposed design, the Dexcom G5 CGM sensor is used, which is minimal invasive (MI) having high accuracy. It makes use of Bluetooth technology to receive and transmit data wirelessly with a range of 6 meters [14]. Another major factor for using Dexcom G5 is its availability in the U.A.E. The Medtronic MiniMed 722 insulin infusion pump was used in the system as it is compatible with the microprocessor. The chosen pump is an older version of Medtronic pumps that can be reprogrammed, feasible and will help reduce the cost of the system. The Raspberry Pi 4 Model B is used in the system as it is compatible with the other parts of the design. One of the important reasons for choosing Raspberry Pi 4 Model B is because it is built in the Bluetooth 5.0 technology, which will facilitate the communication between the CGM, pump and the designed application. This processor was also chosen for its processing speed of 1.5 GHz since a fast processing time is essential in our system design for real-time results in insulin calculation and future glucose levels prediction to avoid accidents. A storage unit is also accessible in the microprocessor for the CGM sensor data to be saved on. Fig. 2 shows the prototype of the smart health care device.

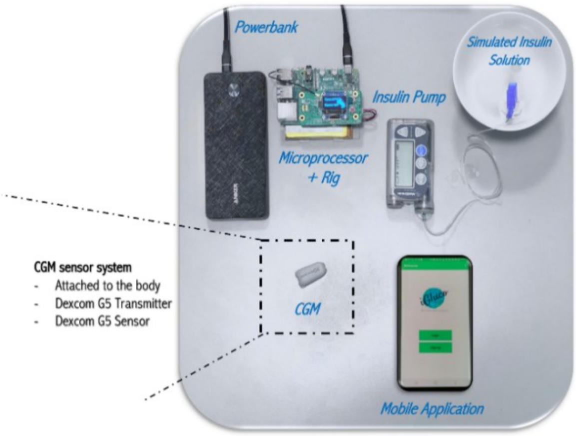

Fig.2: A prototype of the implemented system.

The microprocessor is being programmed using python language to operate the machine learning (ML) algorithm which aims to manage type 1 diabetes with the assistance of the CGM sensor by collecting data for ease of the future glucose level prediction. TensorFlow Lite library is used to build and train the ML model with Python as the programming language. The Machine Learning method used is the Long short-term memory (LSTM) architecture, which gives higher accuracy for our system of time-series based data. The Food and Drug Administration (FDA) approved UVA/Padova simulator is used because simulations from it reflect real-life testing scenarios and will help in saving time and money [15]. The simulator describes the glucose increase, and it reproduces the intra-day glucose variability, which is observed in clinical data and presents them in graphs, reports, and even raw data for each subject. In addition to glucose levels, other inputs can be considered in the simulation like carbohydrates intake, physical activity, and many other factors that affect the blood sugar levels.

The Machine Learning model was built with training data based on a week. The model was tested by predicting glucose levels for the next 30 minutes every time. At the same time, the prediction only depended on data of the previous 6 hours. Five different types of LSTM models were built and the most accurate one with the best performance was chosen for the system. Data of 30 patients from UVA/Padova simulator is used to build the model. The data is divided into three categories based on the age group to build and test the model so that it suits everyone. Based on the age, ten patients each were selected from the children, adolescents and adults category. The dataset's parameters in the simulator are the patient's CGM glucose level readings, carbohydrate intake and patient's lifestyle. The patient's carbohydrates and lifestyle were randomized to consider most patients' cases in the model.

The collected data is classified into four parts. The first part is the training data set that will be used to build or train the model. Training data is the collected data of the last seven days. The second part is called the prediction data, which will be used to forecast. The prediction data will be based on the last 6 hours. The third part is the predicted data, which will be the model's output, which is the prediction of the next 30 minutes in the prediction horizon (PH). The last part is the testing data, which will be used to test the accuracy of the model. Preprocessing of the data was done to improve the model's accuracy. The process of Normalization was used to ensure the data is logically stored and also to eliminate unwanted and redundant data. The blood glucose readings ranging from 30 to 300 mg/dL approximately are used in the system.

After the collection of data from the UVA/Padova simulator, the data is trained and tested in order to develop the desired model. Firstly, the customized univariate time series refers to that the preprocessed data was split into various samples. Secondly, the input sequence was defined, which is the current glucose levels with a range of 1680 samples. Then, a selection of the number of time steps is defined for which the glucose level measurements lasts for 21,600 seconds (6 hours) on behalf of the data size of 72. The reading of the samples is every 5 minutes (300 seconds) and from this, the model is developed based on defined parameters and requirements in terms of neural networks and layers aiming for the optimum accuracy. Coding was done using Python to suit the system and the desired specifications precisely. Fig. 3 shows the flow chart representing the system's prediction methodology.

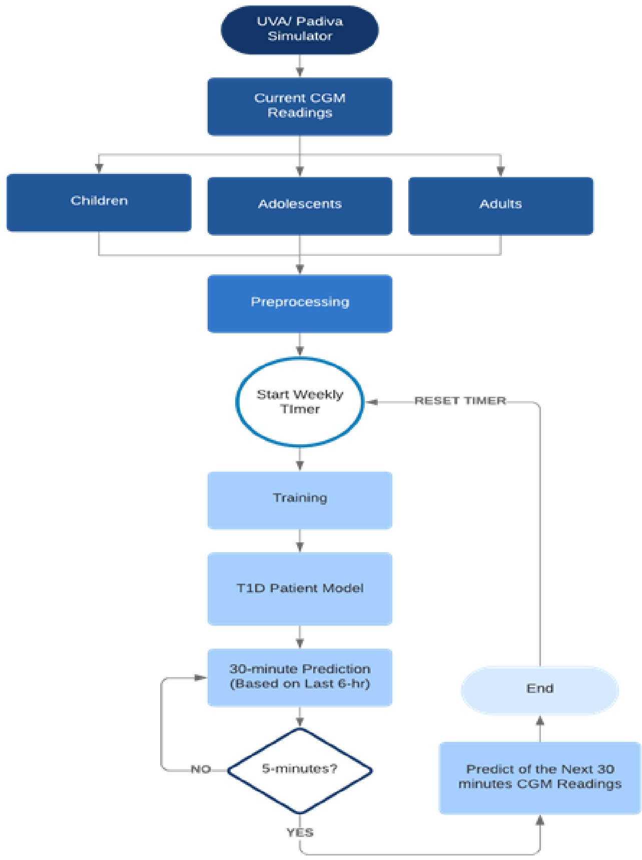

Fig.3: Flow chart showing the system's prediction methodology.

The Rectified linear unit (ReLU) math function was used to take a less period in training and running the model, which helped the system to perform better. ReLU is a commonly used activation function in Neural Networks (NN) that helps in overcoming the vanishing gradient problem, which significantly increases the model's performance [16]. The optimization algorithm called Adam was used in the model to update network weights iteratively based on training data. Adam stands for adaptive moment estimation, which is an extension to stochastic gradient descent that has been recently used widely in deep learning applications. Adam is a widely used NN algorithm due to its fast speed and accurate results [17].

The mobile application is used as a graphical user interface to permit patients to track their health conditions and it is built on the MIT Inventor platform. The application was developed using Firebase and cloud was used to store the database. The purpose of the application is to display current CGM readings every five minutes (see Fig. 4), display historical data of the readings and an option to share the overall report with a specialist through email and to notify the user to take action in case of any abnormality. The dashboard of the application along with display of the current CGM readings is shown in Fig.4.

Fig.4: Insulin Delivery and Blood Glucose Monitoring Application.

IV. Testing and Results

The prototype was assembled and the system was tested to achieve better accuracy as compared to the work done in [8]. The results presented in Fig. 5, Fig. 6 and Fig. 7 show the comparison between actual and predicted glucose level readings over seven days. The figures present 1680 samples of glucose levels for all the three categories: children, adolescents and adults, respectively. As seen in the figures, the system has performed with high accuracy for all the three categories of the community.

Five different LSTM models were built, tested and their performances were compared by calculating the normalized mean square error (MSE) and root mean square error (RMSE). Table 1 shows the architecture for all the five built models. The Table also shows the number of neurons, number of layers, activation function, optimizer, number of epochs, and batch size for each model. The Stacked LSTM showed the best performance as shown in Table 2, with an MSE of 0.000915 and an RMSE of 0.03025.

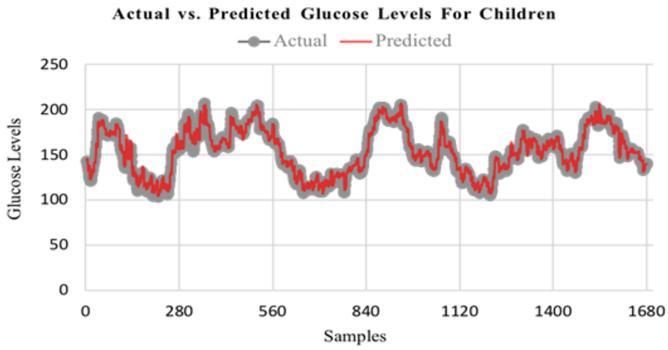

Fig.5: Actual vs. predicted glucose levels for children.

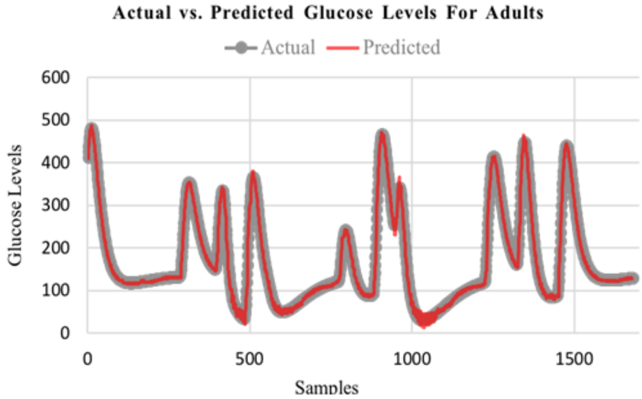

Fig.6: Actual vs. predicted glucose levels for adolescents

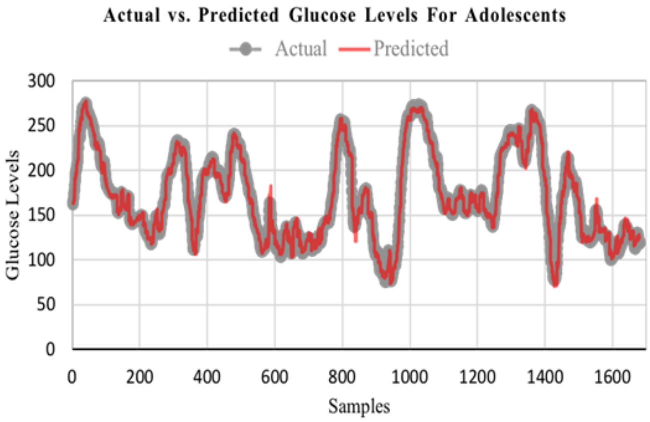

Fig.7: Actual vs. predicted glucose levels for adults

The overall cost of the proposed system accounts to around 1647.88 USD which is much less as compared to the commercially available systems (approximately 8000 USD). The total power consumption of the system is very low. The insulin pump consumes 1.3 Watt/h, and it uses an AAA replaceable battery that will last between 7 to 10 days. Also, infusion sets need to be changed every six days. The sensor does not have to be charged as it must be replaced every 14 days. Lastly, the raspberry pi consumes 3 Amperes and 5 Volts, which is equivalent to 15 Watts based on the worst-case scenario. However, the consumption of the raspberry pi for the system will not exceed 1 Ampere and 5 Volts, which is equal to 5 Watts since the power bank will power the raspberry pi and it has a 10000-mAh capacity. Thus, our system will be able to manage the mobile application as it includes a powerful processor, that is the raspberry pi which will last for around 10 hours, making it reliable and portable for the patient.

Table I. Architecture of all five LSTM models

Factors/ Model	Stacked LSTM	Vanilla LSTM	Bidirectional LSTM	CNN LSTM	Convolutional LSTM
MSE	9.15e-4	9.15e-4	9.15e-4	9.2e-4	9.15e-4
RMSE	0.03025	0.03025	0.03025	0.03025	0.03025
Number of Neurons	6	8	8	-	-
Number of Layers	2	1	1	-	-
Activation Function	ReLU	ReLU	ReLU	ReLU	ReLU
Optimizer	adam	adam	adam	adam	adam
Number of Epochs	150	150	150	150	150
Batch Size	12	12	12	12	12

Table II. Stacked LSTM model with MSE and RMSE

	CHILDREN		**ADOLESCENTS**		**ADULTS**	
Patients	**MSE**	**RMSE**	**MSE**	**RMSE**	**MSE**	**RMSE**
P1	**4e-4**	**212e-4**	**6e-4**	**26e-3**	**1e-3**	**328e-4**
P2	**15e-4**	**396e-4**	**8e-4**	**29e-3**	**15e-4**	**386e-4**
P3	**4e-4**	**223e-4**	**5e-4**	**23e-3**	**9e-4**	**309e-4**
P4	**15e-4**	**396e-4**	**6e-4**	**25e-3**	**7e-4**	**269e-4**
P5	**6e-4**	**261e-4**	**9e-4**	**30e-3**	**11e-4**	**331e-4**
P6	**6e-4**	**253e-4**	**8e-4**	**29e-3**	**6e-4**	**259e-4**
P7	**13e-4**	**360e-4**	**4e-4**	**21e-3**	**17e-4**	**415e-4**
P8	**9e-4**	**303e-4**	**8e-4**	**28e-3**	**16e-4**	**405e-4**
P9	**7e-4**	**266e-4**	**4e-4**	**2e-2**	**8e-4**	**283e-4**
P10	**5e-4**	**227e-4**	**6e-4**	**25e-3**	**1e-4**	**139e-4**
Average (Normalized)	**8e-4**	**29e-3**	**6e-4**	**26e-3**	**1e-3**	**312e-4**
Average (not normalized)	**129.227**	**11.161**	**89.203**	**9.323**	**80.442**	**8.878**

V. CONCLUSION

In this work, a smart and portable health care device for diabetic patients was presented. The system uses an insulin pump, a contiuous glucose monitoring (CGM) system and a microprocessor. Development of an AI algorithm for predicting future glucose levels to avoid hyperglycemia and hypoglycemia was done, which distinguishes the proposed system from other commercially available products. The system also showed efficiency in terms of reliability and speed of the communication link between the CGM, the pump and the patient as compared to the work done in [8]. A software application was developed, which shows the glucose levels to the user every 5 minutes. The application also sends notification to the user in case of critical condition and also allows the user to share a detailed report with the Healthcare center.

ACKNOWLEDGMENT

The authors gratefully acknowledge the support from the University of Sharjah, Sharjah, United Arab Emirates.

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