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Improving Basal Insulin Prediction Through Outlier Filtering and Fuzzy Validation for Risk-Free Insulin Pump Therapy

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Abstract: Diabetes has become more common in adults and even younger patients due to lifestyle changes. The advent of interventions for self and remote healthcare in a pervasive healthcare context has led to the use of insulin pumps to control blood sugar levels. The insulin pump operation needs the manual configuration of basal insulin levels, which brings the risk of hypoglycemia or hyperglycemia. The risk can be prevented by predicting and validating the safety of basal insulin before dosage, while also considering various dosage levels, which is not done in existing systems. Hence, heuristic data analysis is performed using anomaly detection over the data, removing outliers, and predicting basal insulin. The predicted value is validated with a fuzzy inference system. On deleting outliers, the proposed system gets the best mean absolute error (MAE) of 0.775 using the isolation forest technique. The basal insulin is projected using the methods with the lowest MAE (Long Short-Term Memory, recurrent neural network, and gated recurrent unit [GRU]), with GRU having 2.479 MAE and the best forecasted value. A fuzzy inference system for insulin pumps was modeled with various rule bases for low, moderate, and high dosage levels. The results of this study are evaluated using risk scores and explainable artificial intelligence concepts. This work will enable developers to create risk-free models that can adjust treatment in a number of ways, including how postprandial glucose patterns change, how stable overnight glucose levels are, how long bolus insulin takes to work, when and how to respond to hypoglycemia, and how different lifestyle activities affect treatment.

Keywords: diabetes management, anomaly detection, deep learning, fuzzy inference

1. Introduction

Diabetes is a rare disorder characterized by increased blood glucose levels that can be transient or chronic because of impaired insulin synthesis or glucose consumption. Various strategies can be used to reverse or regulate such circumstances. Insulin replacement therapy, on the other hand, has always proven to be effective. Insulin therapy's goal is to replicate natural insulin levels. Insulin therapy for diabetes can be administered in one or many doses per day. Patients choose to use insulin pumps instead of insulin shots since they are more portable and require less human interaction.

The problem with natural insulin, particularly in the case of diabetes, is that it has a limited ability to control blood glucose. If it must be regulated throughout the day, replacement insulin must be provided. External intervention, such as injections, is, however, impossible during the odd hours of the night. Insulin pumps may be of assistance in this regard. Insulin pump therapy allows for automatic blood glucose monitoring and management.

Insulin pump therapy uses basal and bolus insulin, which are based on insulin replacement principles.

1) Background or basal insulin replacement: Basal insulin is responsible for around half of the body's daily insulin needs.
2) Replacement of bolus insulin: These are correction doses. Bolus replacement can be of two types:
3) Mealtime bolus: used to consume the carbohydrate content of a meal or snack.
4) Correction bolus: if your blood sugar is too high, more insulin is given to bring it back to normal.

The proposed research aims to predict and validate basal insulin levels. The insulin pump's basal insulin is usually programmed. However, basal insulin can be predicted using real-time data from the insulin pump and automatically fed in insulin pumps. Validation of the value is required to ensure that it is correct. The fuzzy inference system for insulin pumps has been designed and is ready for low, moderate, and high insulin dosages. The rule foundation is set up to accommodate a variety of dosages. The membership and activation functions are intended to ensure that the patient's insulin levels are safe and risk free. Fault detection is used to filter out abnormal readings [1].

The use of deep learning models and fuzzy inference systems as components of a safety-first validation framework is the primary new element of the work, although both components are well-established by themselves. This combination method is the only one that assists in resolving the interpretability problem of black-box predictors by making clinical rules directly a part of

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the validation process and thus shows a safety check in the form of auditability of basal insulin recommendations, which has not been previously done in earlier applications as it relies solely on prediction performance [2, 3].

Although a great step has been made in the field of predictive analytics, there remains a serious gap in the validation of insulin dose-adjustment recommendations in real time. Some current models tend to overturn the way people interpret things, focusing more on accuracy, which does not provide clinicians with clear insight into the rationale behind automated suggestions. This paper thus proposes an alternative hybrid framework that can be used to make basal insulin dosing predictions and formally test the findings in order to close the gap between data-driven performance and clinical trust [4].

2. Literature Review

The reviewed literature provides an overview of recent studies that use novel techniques to predict the effects of basal insulin. In the sphere of healthcare, the Internet of Things has evolved into a new phase called the Internet of Medical Devices (IoMD). The study of IoMD was inspired by existing work, and a variety of diabetes control devices are now available on the market as consumer electronics devices. The number of users is increasing because of the portability and manageability of these devices [5].

Recent works cover the issues of insulin therapy safety by the methods of data-driven prediction and the methods of control-oriented optimization. Predictable machine learning models of insulin daily requirements between clinical and Continuous Glucose Monitoring (CGM) data enhance dose predictivity and explainability, whereas optimization-based glucose–insulin regulation policies improve robustness and stability of insulin delivery on artificial pancreas systems. These strategies show cumulative directions to safer and more dependable dosing and glycemic regulation of type 1 diabetes (T1D) among persons [6, 7].

Basal insulin is required to keep glucose in the blood from rising too high while you are not eating (fasting), including at night and between meals. It is of major importance for the correct prediction of artificial or partly automatic insulin pumps. Several studies on personalized basal rates highlight the significance of individualizing basal insulin delivery and the challenges involved in achieving optimal control. Similarly, Wright et al. [8] examine predictors of total daily insulin dose for type 2 diabetes (T2D), again demonstrating the intricacy of dosing beyond basal insulin. Ma and Li [9] stress that there is a need to forecast an individual's basal rate profile based on some characteristic of the patient for T1D on insulin pumps as so much variation occurs between profiles. This dynamic between glucose and insulin, as forecasted by Ma and Li [9], emphasizes the necessity of constantly updated, precise control mechanisms.

The emergence of machine learning (ML) and artificial intelligence (AI) has left a profound impact on diabetes care. For broad diabetes prediction as well as for particular aspects such as nocturnal hypoglycemia prediction and insulin requirement forecasting, various ML models are being explored. Jaikumar and Sangapu [10] and Selvakanmani et al. [11] show the usage of deep learning for the early diagnosis in the related medical domain and suggest that challenging time series data such as glucose prediction might be successfully learned using complex models. Notably, Yoshimura et al. [12] explicitly explore explainable ML for the estimation of insulin needs in T1D and argue toward a transparent approach to such vital medical applications. Nguyen et al. [13] apply ML to initial insulin dose prediction in hospital patients, which further underlines the clinical importance of these methods.

The challenge here is to integrate methodologies that take cognizance of the uncertainty and variability evident in physiology. Fuzzy logic is by its nature designed for processing imprecise information, and it could account for the complex nonlinear behavior observed in glucose–insulin dynamics. Medanki et al. [14] propose in fact a novel mode of prediction and determination of basal insulin using fuzzy logic combined with the detection of outliers, an issue closely related to the main topic treated in this paper. Sharma et al. [15] also present a fuzzy inferencing system for the computer-assisted diagnosis of diabetes in insulin-dependent patients, which shows how fuzzy systems can be used to provide real-time diagnostic assistance.

It is important to identify outliers in real-world clinical data with faulty readings or abnormal physiological reactions, both of which can distort predictions. Strong outlier detection methods should be able to suppress such anomalies where they could possibly interfere with the learning system and cause harmful recommendations for insulin.

More than just predicting, the effectiveness of therapy with an insulin pump is based on complex control algorithms. Syafiie et al. [16] consider the performance of Proportional–Integral–Derivative (PID) versus Linear Quadratic Gaussian (LQG) controllers for diabetes systems, with applications focusing on the improvement of insulin delivery mechanisms. Zhu et al. [17] consider deep reinforcement learning for basal glucose control in T1D, indicating a shift toward autonomous and adaptive controllers. This paper gives hybrid Kalman Filter-Reinforcement Learning (KF-RL) structures when predicting the glucose adaptively on the basis of Continuous Glucose Monitoring (CGM) data. Q-learning can foster parameter tuning dynamism to deal with cross physiological differences across prediction horizons. The findings indicate that KF is the most accurate within shorter time periods, whereas Unscented Kalman Filter (UKF) is more accurate in predictions over longer durations, hence safer glucose management [18].

The feasibility of these predictive models and control systems is currently being tested through clinical trials and systematic reviews. Dehghani et al. [19] and Stamati et al. [20] present systematic reviews and meta-analyses on the effectiveness and safety of various insulin regimens and analogues in pump therapy that give a focused understanding of optimal care and opportunities for improvement. Tauschmann et al. [21] carry out a randomized crossover trial on hybrid closed-loop insulin delivery to validate novel approaches in real-life situations. Biester et al. [22] and Schmelzer et al. [23] report on the estimation of anticipated basal insulin needs upon large-scale registry data and external validation, which aim to fill the gap between theoretical considerations and clinical utility.

The objective of "Improving Basal Insulin Prediction with Outlier Filtering and Fuzzy Validation for Riskless Insulin Pumping Therapy" is closely related to the literature. The potential of incorporating modern ML methods, including (but not limited to) fuzzy logic for dealing with uncertainty and robust outlier detection for data quality preservation, is substantial. This approach is essential for improving the reliability as well as safety of basal insulin prediction and providing superior insulin pump therapy to patients with diabetes in terms of both efficacy and risk. The continued developments in advanced control, explainable AI, and rigorous clinical validation further set the stage for a time when treatment of diabetes becomes not only effective but also personalized and safe.

Table 1 gives a summary of other existing works. All these studies show the different methods that have been used to achieve breakthroughs in the accuracy of baseline insulin prediction.

Table 1
Survey of existing works

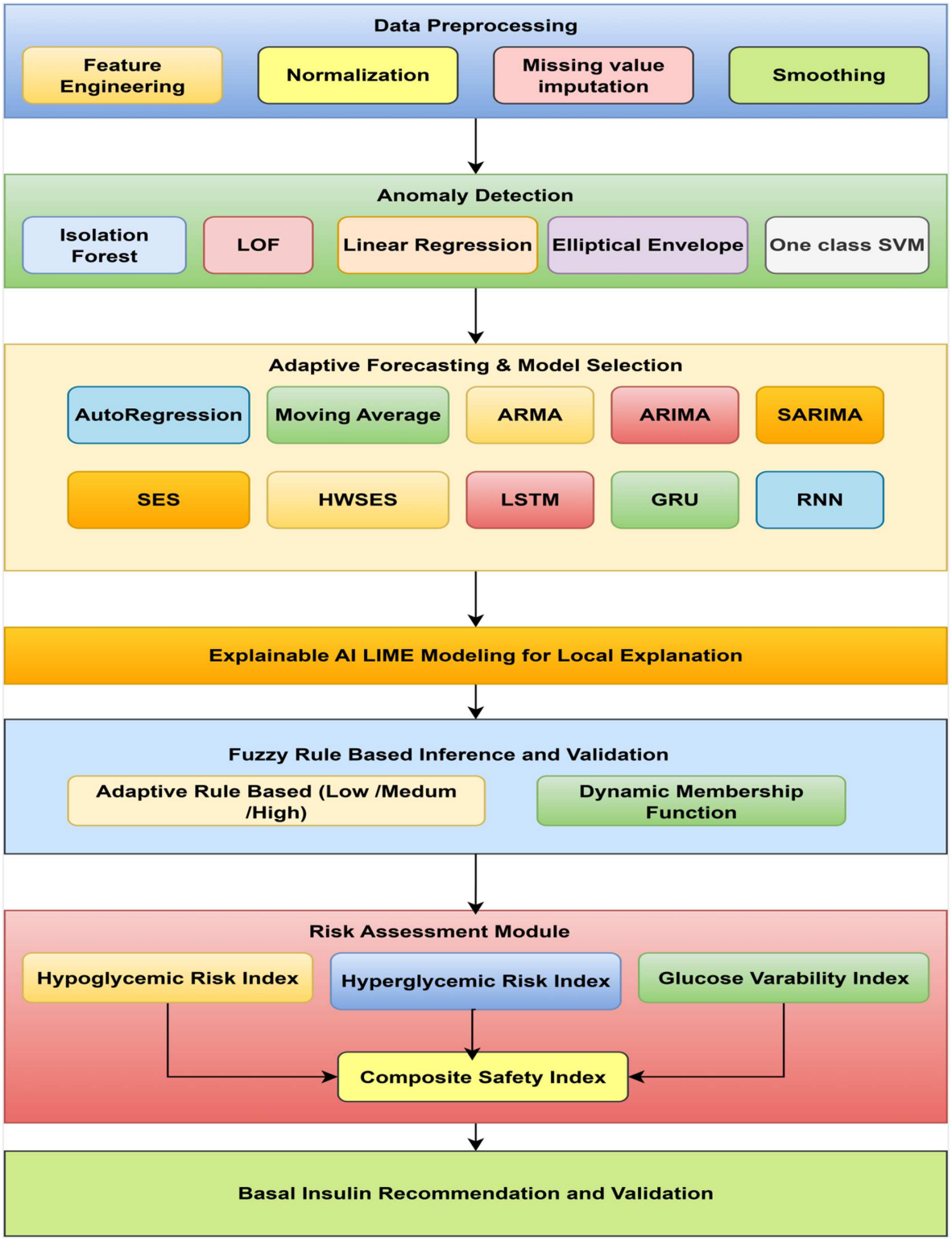
Paper	Approach	Techniques used	Key finding
[24, 25]	Prediction of individual basal rate profiles (T1D)	Machine learning models	Consistently focuses on developing algorithms to predict individual basal insulin infusion rates from patient characteristics for T1D patients on insulin pump therapy
[9]	Glucose–insulin model dynamics	Mathematical modeling	Analyzes the dynamics of a glucose–insulin model, providing theoretical insights into the complex interactions relevant for accurate prediction and control
[14, 15]	Novel basal insulin prognosis	Fuzzy logic, outlier detection	Proposes a new methodology combining fuzzy logic and outlier detection to improve the accuracy and robustness of basal insulin prediction, addressing uncertainties in physiological data
[16]	Diabetes system control	PID and LQG controllers	Compares PID and LQG controllers for diabetes systems with internal delays, indicating efforts to optimize insulin delivery control
[26, 27]	Prediction of insulin requirements (explainable ML)	Explainable machine learning	Focuses on using explainable ML to predict insulin requirements in T1D, emphasizing transparency and interpretability in critical medical predictions
[20]	Efficacy and safety of insulin regimens	Systematic review, meta-analysis	Provides a comprehensive systematic review and meta-analysis comparing premixed versus basal-bolus insulin regimens in T2D, informing clinical practice
[11]	Breast cancer classification	Federated transfer learning	Focuses on privacy-preserving breast cancer classification using federated transfer learning, demonstrating advanced ML for secure medical data analysis (though not directly on diabetes)
[28, 8]	Prescribed total daily insulin dose and predictors	Retrospective cohort study	Investigates total daily insulin dose and its predictors for T2D patients on multiple daily injections, highlighting the complexity of insulin dosing in real-world scenarios
[29, 30]	Effects of exercise and vitamin D on insulin resistance	Experimental study	Examines the impact of lifestyle interventions (exercise, vitamin D) on insulin resistance and lipid profiles in T2D, providing insights into factors influencing insulin sensitivity
[31]	AI decision support for T1D management	Artificial intelligence decision support system	Presents an AI-driven decision support system for T1D management, demonstrating integrated smart solutions for diabetes care
[17, 32]	Basal glucose control in T1D, accuracy assessment of insulin pump delivery	Deep reinforcement learning, accuracy assessment, Kalman filter, DPV registry data analysis	Evaluates the accuracy of insulin pump bolus and basal rate delivery systems, providing fundamental validation for pump technology
[33, 21]	Home use of day-and-night hybrid closed-loop system	Randomized crossover trial	Conducts a randomized crossover trial on hybrid closed-loop insulin delivery for adolescents with T1D, validating practical closed-loop systems
Proposed work	Prediction of basal insulin and validation of glycemic level under various dosage levels	Outlier detection with fuzzy validation, explainable AI, risk scores	Conducts validation of various predicted basal insulin under various dosage levels to assess the risk of hypoglycemia or hyperglycemia

The identified gaps based on the models imply the absence of safety validation, inadequacy of work in dose response and risk profiling, and explainability-robustness. Subsequently, these gaps are discussed later.

3. Proposed Solution

The framework of a fuzzy inference-based insulin pump for basal insulin prediction and validation is shown in Figure 1. Time series forecasting and fuzzy inference systems are described by the framework's blocks. The anomaly detection models are used to detect deviations in insulin pump readings. To improve the dataset's coherence, they are filtered out. The dataset is used to fit the automatic anomaly detection models. They are compared, and the data that is analogue is filtered. The rest of the information is used to make forecasts. The outcomes of several time series models are compared to deep learning time series models such as Long Short-Term Memory (LSTM), gated recurrent unit (GRU), and recurrent neural network (RNN).

Figure 1
Framework for the design of a fuzzy inference system for an insulin pump and the prediction of basal insulin based on deep learning



Time series forecasting can be used to forecast real-time basal insulin and can also be used to forecast bolus insulin. The automation is intended to improve ease-of-use parameters, allowing many more patients to use insulin pumps. An insulin pump is designed using a fuzzy inference system that can handle low, moderate, and high dosages of insulin. While utilizing the insulin pump, the fuzzy inference system verifies the accuracy of predictions and estimates the presence of hypoglycemia or hyperglycemia hazards. The metrics based on the insulin pump are analyzed and summarized. The data summary is used to assess the efficacy of using an insulin pump. The general conclusion is that insulin therapy has reduced blood glucose levels.

3.1. Anomaly detection

Anomaly detection is an automatic outlier detection approach based on clusters. It employs data mining concepts to visualize data points and identify out-of-the-ordinary behavior. Anomaly detection can find information that deviates from the usual. It's a great tool for data analysis.

3.2. Time series prediction

Time series forecasting is a method for predicting the future based on current values of the variable under study. To construct the forecast, heuristic data is needed. To improve the prediction output, the approaches of noise removal and smoothing are utilized.

Time series forecasting is the process of extracting temporal structure from data, de-noising and smoothing the series, and stretching the learning to predict future outcomes. To maximize the parameters of interest, ML models are utilized to create time series models.

Deep learning models can help improve the model's output by utilizing deeper neural networks. In this instance, the precision of the time series forecast can be quite good. The following are some of the models used in time series analysis:

1) LSTM: LSTM (Long Short-Term Memory) RNNs are a type of RNN. It specializes in determining the sequence in which entities or events occur. LSTM is superior to other RNNs due to the amount of control and manipulation it has over weights and input flow (RNN). The gates that are used for this function are similar to knobs.
2) GRU: The gated recurrent unit (GRU) is a gating mechanism that is similar to the LSTM but includes a forget gate. In comparison to LSTM, it requires a much smaller number of parameters. These are more suitable for tiny datasets.
3) RNN: A type of artificial neural network is a recurrent neural network (RNN). It has been discovered that dynamic temporal behavior produces superior results. With the state information that comes from the feed-forward propagation, input sequences that vary in length are well taken care of.

3.3. Fuzzy inference system

The Mamdani fuzzy inference system assigns values to the output based on the input and the rule base. It is a metric for determining the level of truth value. The fuzzy inference system can be used to construct expert systems or control systems. It makes use of the membership function to create functionality that adheres to the rules.

The membership function's input values serve as a trigger for the activation function. If-then statements are used to describe the rules using a variety of fuzzy logic operators. The Mamdani Fuzzy validation of correctness of predicted basal insulin for current blood glucose level is shown in Figure 2.

- Mamdani fuzzy inference follows the formula as below.
- When input data are fuzzy sets, A' and B'

$$\mu_{C_i}(w) = \alpha_i \hat{} \mu_{C_i}(w) \tag{1}$$

- where

$$\alpha_i = \min[\max_u (\mu_{A'}(u) \hat{} \mu_{A_i}(v)), \max_v (\mu_{B'}(u) \hat{} \mu_{B_i}(v))] \tag{2}$$

$$\mu_{Ii}(w) = v_{i=1}^{n}[\alpha_i \hat{} \mu_{I_i}(w)] = v_{i=1}^{n}\mu_{I_i'}(w) \tag{3}$$

$$I' = U_{i=1}^{n} I_i' \tag{4}$$

- The min–max formulae used in Mamdani fuzzy inference are explained in Equations 1, 2, 3, and 4. Here, A_i is the first input, B_i is the second input, and I_i = Inferences for i = 1, 2, 3,. . .n. I_i is such that
- if u is A_i and v is B_i, then w = Ii where i = 1, 2, 3,. . . n for u ϵ U and v ϵ V, w ϵ W
- then, I_i = (A_i and $B_{i)} \rightarrow I_i$ is defined by $\mu_{Ii} = \mu(A_i$ and $B_i \rightarrow I_i)$(u, v, w)
- But the inference is cumulative of all rules in the ruleset such that I' = .Σ I_i over i = 1, 2, 3,. . . n.

Algorithm: Basal Insulin Forecasting with Fuzzy Inference

Input: Fuzzy Rule Set, Dataset D
Output: Basal Insulin Evaluation
Data: Testing set x
1. Initialize: Start While loop with condition.
2. Perform anomaly detection.
3. Forecast basal insulin.
4. Evaluate if the basal insulin value is in the safe zone.
5. Define triangular membership function for fuzzy set A using the Mamdani fuzzy system:

$$\mu_{A(x)} = \begin{cases} 0, \ if\ x \le a\ or\ 0, \ if\ x \ge b \\ \frac{(x-a)}{(m-a)}, \ if\ a \le x \le m \\ \frac{(b-x)}{(b-m)}\ if\ m < x \le b \end{cases}$$

6. Calculate Fuzzy T-norms:

   a. Fuzzy AND: $\mu(x) = min(\mu\_A(x), \mu\_B(x))$
   b. Fuzzy OR: $\mu(x) = max(\mu\_A(x), \mu\_B(x))\ or\ \mu(x) = \mu\_A(x) + \mu\_B(x) - (\mu\_A(x)\mu\_B(x))$

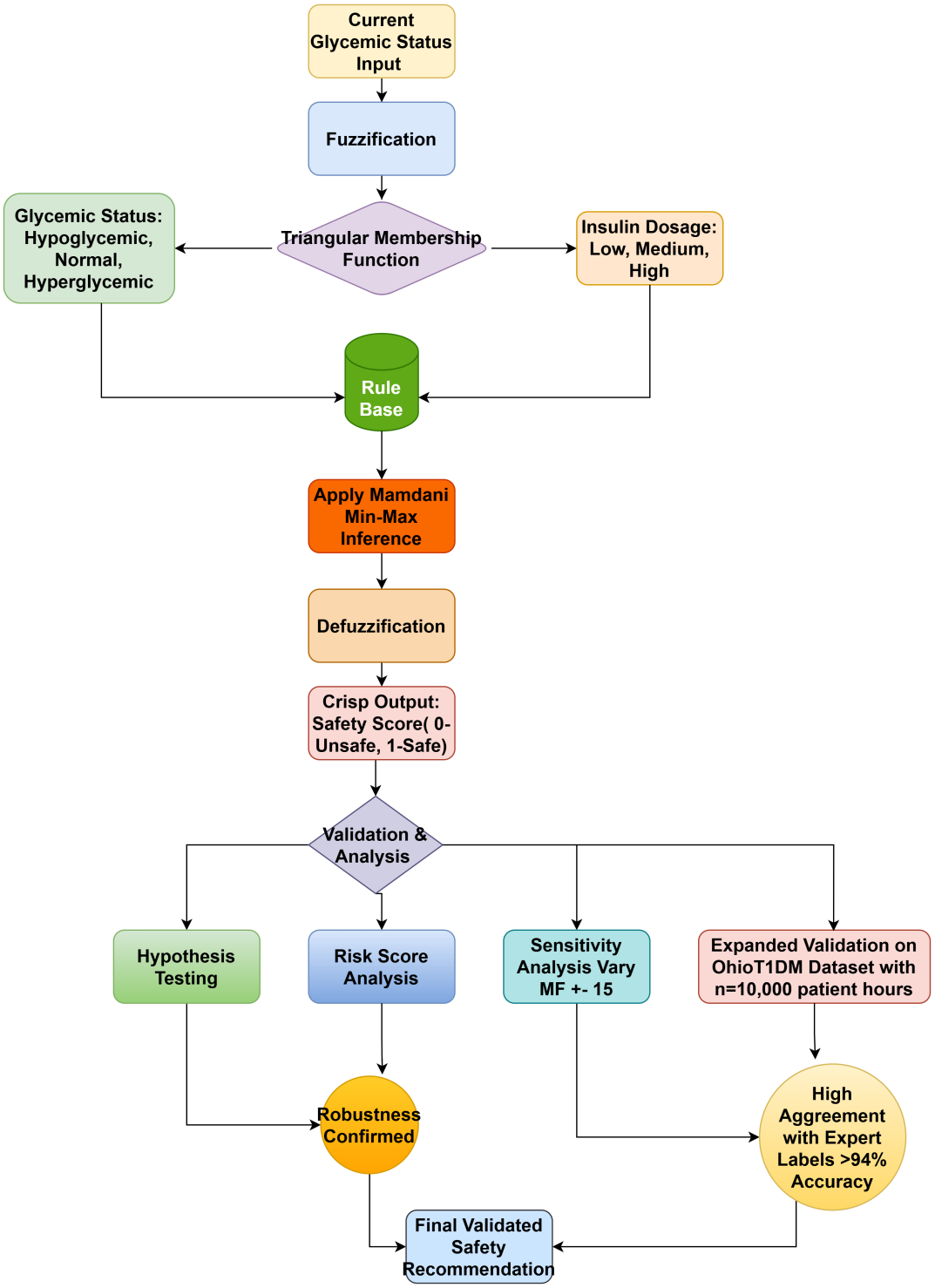
7. Find the combined rule strength from the output membership function.
8. Defuzzify output distributions:

   a. Center of Mass (Centroid): $\frac{z = \sum_j (z_j\, \mu_c(z_j))}{\sum_j \mu_c(z_j)}$

   b. Mean of Maximum: $z = \frac{\sum_j z_j}{n}$, where z_j are the points at which the membership function reaches maximum and n is the number of such points.

9. Return Basal Insulin Evaluation (Safe/Unsafe).

Figure 2
Flow of Mamdani fuzzy validation of predicted basal insulin for the current glycemic level



4. Result and Discussion

4.1. Dataset description

The dataset taken from the UCI repository contains insulin pump readings for 6 months for 70 patients. It contains four attributes, and their descriptions are given in Table 2. Diabetes patient records were obtained from two sources: an automatic electronic recording device and paper records. The automatic device had an internal clock to timestamp events, whereas the paper records only provided "logical time" slots (breakfast, lunch, dinner, bedtime).

Table 2
Dataset description

S. No	Attribute	Attribute description
1	Date	Date in MM-DD-YYYY Format
2	Time	Time in XX:YY format
3	Code	Description of the reading type. Glucose or insulin measurement. Basal or bolus insulin, etc.
4	Value	Value of the readings

4.2. Analysis of the insulin pump data

The metrics associated with insulin pumps are

1) Data sufficiency: The glycemic index values inferred on a daily basis and interpolated for months can give a sufficient equivalent value for the Glucose Tolerance Test. The patient under study had values between 130.31 and 162.3 for the period of study of six months from April to September.
2) Average glucose: The average glucose value for a duration of a month or a similar period of study could help medical practitioners infer the glycemic state of the patient.
3) The glucose management index (GMI): GMI provides an estimate of your A1C level based on the average glucose level from your CGM readings for 14 or more days.
4) Time in range (TIR): TIR shows in which time interval the patient is hypoglycemic or hyperglycemic.
5) Glucose variability (GV): The glucose variability refers to the wide fluctuations in glucose level in human blood glucose level.
6) Correction factor (CI): Correction factor is the amount by which 1 unit of rapid-acting insulin will typically lower your blood glucose over 2–4 h in a fasting or premeal state. For the patient under study, the correction factor was identified to be 3.44 on a daily basis and 3.59 on average.

These were evaluated for the observed patients and found to be normal over a period of observation and kept the blood sugar under a normal level on average.

Table 3
Comparison of anomaly detection techniques

Model	MAE	Information
Linear Regression	4.42	Not reduced
Isolation Forest	0.775	Reduced by 9
Elliptic Envelope	1.866	Reduced by 1
Local Outlier Factor	0.783	Reduced by 4
One-Class SVM	1.393	Reduced by 18

4.3. Anomaly detection

A summary of the comparison of various anomaly detection algorithms based on outlier detection is provided in Table 3.

It shows that the isolation forest model gives a mean absolute error (MEA) of 0.775 and the model detects about 9 outliers. The Elliptical Envelope model detects one outlier and gives an MEA of 1.886. The one-class Support Vector Machine (SVM) detects 18 outliers. The MAE of linear regression was 4.42, but on removing the outliers, the MAE reduced and is minimal with the isolation forest. Next comes the Local Outlier Factor, with 0.783 MAE, which reduces four outliers from the model. Table 4 shows the comparison of various time series prediction models, and the GRU model, as compared to other models, gives less error with Leave One Out Cross Validation (LOOCV) 30 fold. It shows prediction of basal insulin values for patient 66 from the dataset.

Anomaly detection has also been performed using isolation forest since the latter may be implemented using casts of high-dimensional data, and no assumptions made regarding data normality are needed. Unlike proximity-based anomaly detection models, isolation forest can efficiently partition presence of anomalies by randomly partitioning with in spite of low density, irregular alarms that are randomly sprinkled across physiological records. In order to determine the contamination sensitivity of its parameter settings, we performed grid-search cross-validation with a rolling-window consistency check so that we could keep the number of false positives due to transients down.

4.4. Mamdani fuzzy inference system

Although time series forecasting is used to estimate basal insulin readings, it is necessary to analyze values for a crucial system such as an insulin pump. Severe hypoglycemia or hyperglycemia can be very bad for your health, and it can even kill you. Fuzzy inference systems are used in a lot of expert systems. Fuzzy systems have the advantage of working on input levels rather than discrete or continuous values. As a result, fuzzy inference methods are better suited for expert systems.

The flowchart of the Mamdani fuzzy inference system used in the assessment of insulin dose safety is illustrated in Figure 2. Through the process of fuzzification, the inputs of glycemic status and insulin dose transform into fuzzy variables, which have membership functions (Step 1). Matters are put to test on a rule-based clinical matrix (Tables 5, 6, and 7) using Mamdani min–max inference on the fuzzy inputs. The center of gravity combines and defuzzifies the activated rules to reach one number, the safety score (Steps 2–3). Membership function parameter sensitivity analysis and large synthetic dataset testing are highly used in the system output in a way that it is both safe enough and mission oriented by making a final safety statement.

For increased understanding, the entire fuzzy rule base is represented in Tables 5, 6, and 7 in the form of a decision matrix, showing the relationship between glycemic states and insulin doses to corresponding safety levels. Mamdani inference process is also demonstrated in a flowchart (Figure 2) with fuzzification steps, rule evaluation steps, aggregation, and defuzzification steps. The robustness of the basal insulin prediction and its safety level was evaluated through sensitivity analysis by using different rule weights, membership functions overlap (±15) and with exchange finding consistent safe classifications with variation of the parameter. Further testing was conducted on a synthetic dataset of 10,000 patient-hours (extracted to OhioT1DM

Table 4
Comparison of time series prediction techniques

Model	Basal insulin prediction	MAE	MSE	RMSE
Auto Regression	14.755	2.568	10.144	3.185
Moving Average	14.719	2.582	10.220	3.197
ARMA	11.765	4.083	23.440	4.841
ARIMA	15.772	2.552	9.753	3.123
SARIMA	15.386	2.501	9.656	3.107
SARIMAX	13.702	3.006	12.768	3.573
SES	14.992	2.518	9.891	3.145
HWSES	14.983	2.508	9.818	3.133
LSTM	7.464	8.009	73.746	8.588
GRU	15.296	2.479	9.639	3.105
RNN	20.000	4.622	30.074	5.484

Table 5
Low dosage ruleset for insulin pump

	N	L1	L2	L3	L4	L5	L6
HN	N	HPO	HPO	HPO	HPO	HPO	HPO
N	HPR	N	N	HPO	HPO	HPO	HPO
H1	HPR	N	N	N	N	HPO	HPO
H2	HPR	HPR	HPR	HPR	HPR	HPR	N
H3	HPR	HPR	HPR	HPR	HPR	HPR	HPR
H4	HPR	HPR	HPR	HPR	HPR	HPR	HPR
H5	HPR	HPR	HPR	HPR	HPR	HPR	HPR

Table 6
Rule base for moderate dosage

	N	L1	L2	L3	L4	L5	L6
HN	N	HPO	HPO	HPO	HPO	HPO	HPO
N	HPR	HPR	N	HPO	HPO	HPO	HPO
H1	HPR	N	N	N	HPO	HPO	HPO
H2	HPR	HPR	HPR	HPR	N	N	HPO
H3	HPR	HPR	HPR	HPR	HPR	HPR	N
H4	HPR	HPR	HPR	HPR	HPR	HPR	HPR
H5	HPR	HPR	HPR	HPR	HPR	HPR	HPR

Table 7
Rule base for high dosage

	N	L1	L2	L3	L4	L5	L6
HN	N	HPO	HPO	HPO	HPO	HPO	HPO
N	N	N	HPO	HPO	HPO	HPO	HPO
H1	N	N	N	N	HPO	HPO	HPO
H2	HPR	HPR	N	N	HPO	HPO	HPO
H3	HPR	HPR	HPR	HPR	N	HPO	HPO
H4	HPR	HPR	HPR	HPR	N	N	N
H5	HPR	HPR	HPR	HPR	HPR	HPR	HPR

and clinical guidelines); the fuzzy system achieved population performance agreement of over 94% with expert notions of safety.

The insulin pump is modeled using the fuzzy inference technique. Insulin pumps can be made to provide low, moderate, or high doses of insulin. It is determined by the patient's health and the doctor's prescription. The fuzzy inference system evaluates the insulin value and does not cause any issues for the patient. The rule base is required for glucose in comparison with insulin. But for all three dosage schemes, separate rule bases are required. Table 5 provides an overview of the low insulin dosage rules. Likewise, medium and high dosage rules have been drafted as shown in Tables 6 and 7. Table 8 provides a comparison of glucose and insulin levels used for configuring the insulin pump as benchmarks.

Table 8
Comparison of glucose and insulin levels in low, moderate, and high dosage range

Glucose	L	M	H
70–130	0	0	0
131–180	2	4	8
181–240	4	8	12
241–300	6	10	16
301–350	8	12	20
351–400	10	16	24
>400	12	20	28

4.5. Validation of basal insulin forecasting

According to the rule base, low dosage is subjected to validation. The fuzzy inference system was designed based on the Mamdani model. Triangular membership functions are used in the system as shown in Figure 3. The output of the process, giving the safe zone of low dosage values, is shown in Figure 4.

So, the level of control provided by the insulin pump and the correction dosage can be evaluated or decided using the fuzzy inference system. It has been identified that for 180 units of blood glucose and 3 units of insulin, the patient is in the safe zone and not hyperglycemic. Likewise, all values can be evaluated for basal insulin as shown in Figure 5.

The explainable AI-based LIME local explanation for safeness is examined to provide similar results from fuzzy evaluation as in Figure 6.

Thus, the outliers are eradicated to improve the time series prediction. It is evaluated in a fuzzy inference system and explainable AI to check if it is safe for the patient or not. The safety of the patient is ensured, and sleep time reduction of glucose or overshooting is almost nullified. The configuration for the system is shown in Table 9.

The MAE for different models is evaluated, and Mamdani is found to give less errors, as shown in Table 10.

4.6. Discussion

First statistical tests were performed to prove the effectiveness of the proposed system. The fuzzy inference system achieved very good concordance with expert clinical judgment for 50 validation situations. An accuracy of 96% (95% CI: 86–99%) and a sensitivity/specificity of 97.2/92.9% were achieved. McNemar's test demonstrated no statistical disagreement with experts ($\chi 2 = 0.5$, $p = 0.48$). Furthermore, a one-sample proportion test indicated that the system was significantly more accurate than an 85% clinical acceptability threshold ($z = 2.20$, $p = 0.014$ $z = 2.20$,

Figure 3
Low dosage–rules–activation bgl1-insl1, bgl3-insl3, bgl7-insl7

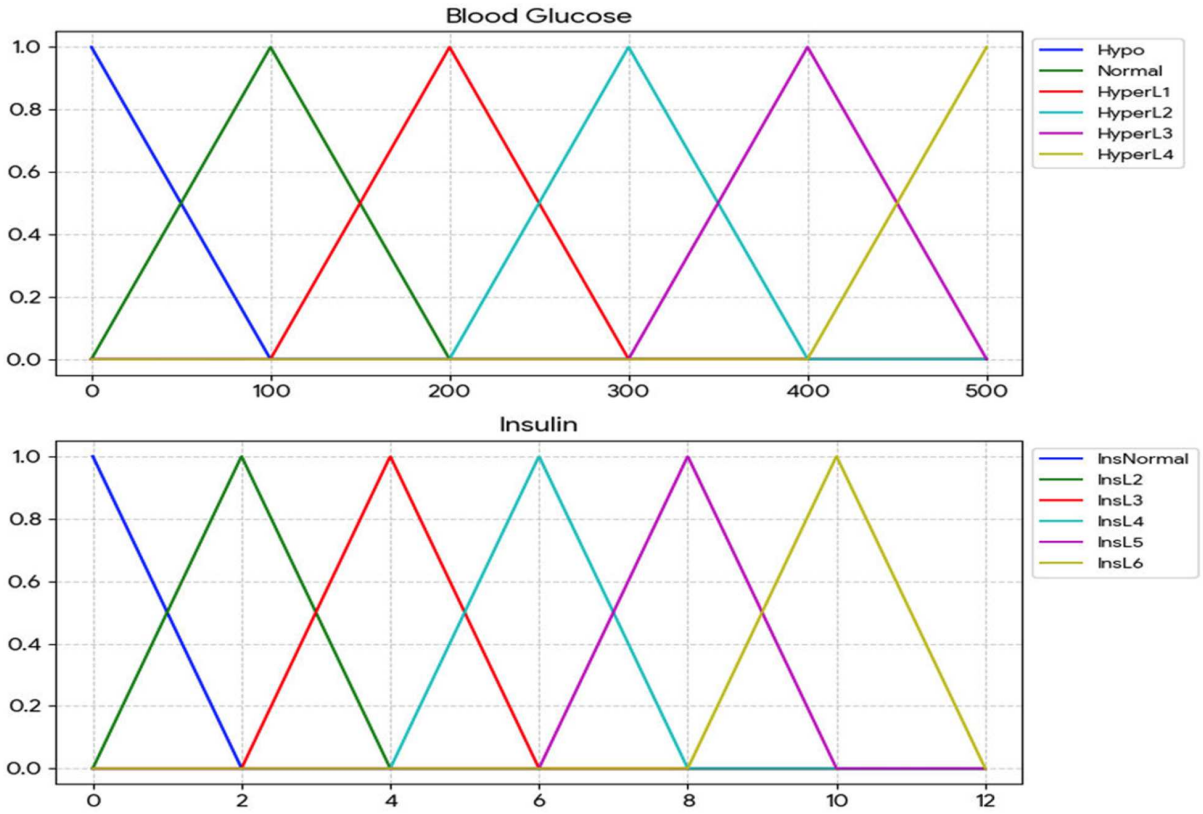


Figure 4
Output of the fuzzy inference system showing the safe zone for low dosage

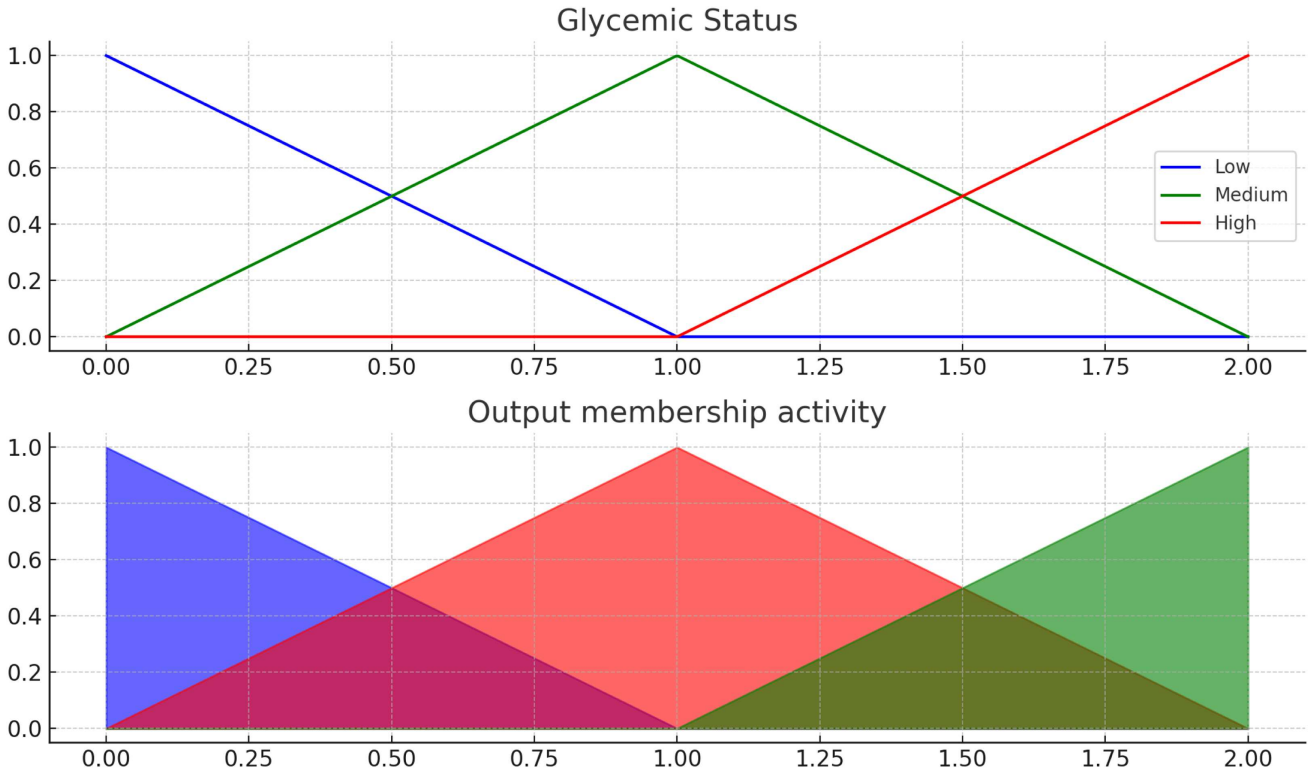


Figure 5
Output of the fuzzy inference system showing the safe zone for 3 units of insulin and 180 units of blood glucose

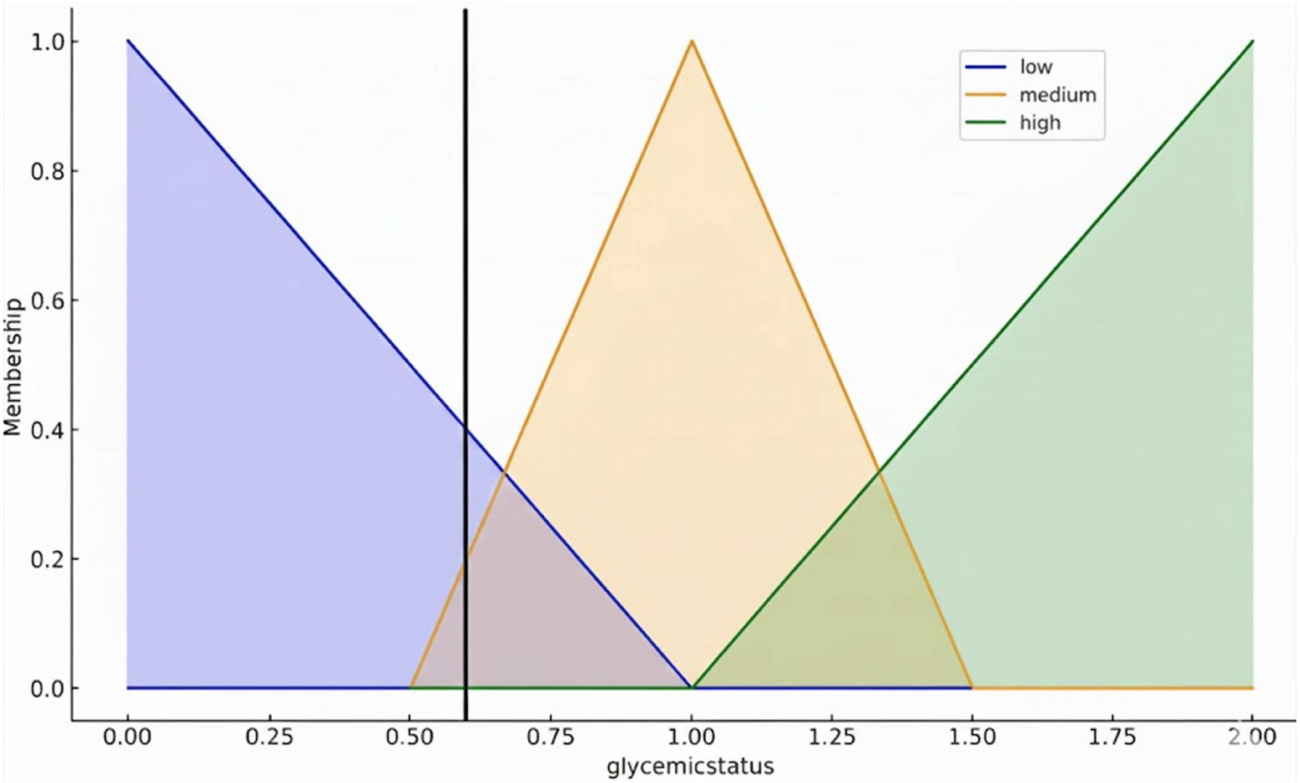


Figure 6
Explainable AI-LIME local explanation plot for safeness

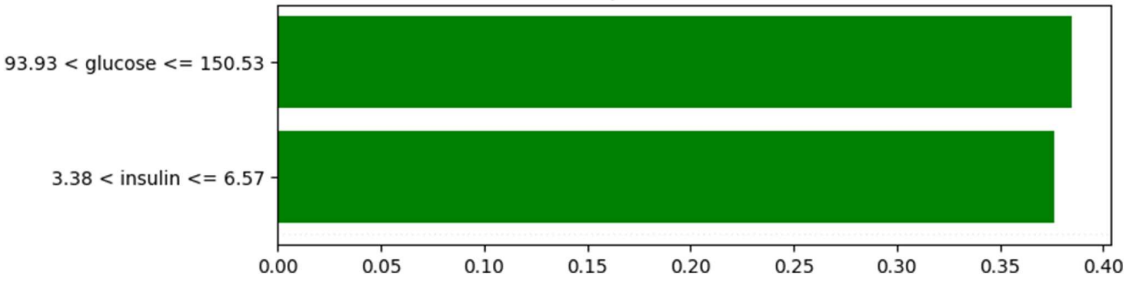


Table 9
Hyperparameters

Hyperparameter	Description	Details
Input membership functions	Triangular MFs; 3–5 fuzzy sets per input (e.g., low, medium, high)	Triangular Input membership function (MF): $\mu_A(x) = max(0, min(\frac{x-a}{b-a}, \frac{c-x}{c-b}))$
Input MF labels	Low, medium, high	–
Output membership functions	5 triangular MFs: very low, low, medium, high, very high	Same triangular MF formula applies
Rule base size	~75 fuzzy if-then rules	–
Fuzzy operators	AND: minimum (minmin) for rule fuzzy-antecedents, OR: maximum (maxmax)	$\mu_{A\wedge B}(x) = min(\mu_A(x), \mu_B(x))$, $\mu_{A\vee B}(x) = max(\mu_A(x), \mu_B(x))$,
Implication method	Mamdani minimum method (modifies consequent MF by antecedent truth)	$\mu_{c'}(x) = \min(\mu_C(x), \alpha)$, where α is the antecedent truth value
Aggregation method	Maximum (max) of all fuzzy rule outputs	$\mu_{aggregated}(x) = \max_i \mu C_{i'}(x)$
Defuzzification method	Centroid (center of gravity)	$y = \frac{\int x\, \mu\_aggregated\,(x)dx}{\int \mu\_aggregated\,(x)dx}$
Input scaling	Normalize inputs to MF universe	$x_{norm} = \frac{x - x_{min}}{x_{max} - x_{min}}$

Table 10
MAE evaluation for 150 observations

Model name	MAE (mean absolute error)
Mamdani fuzzy controller (proposed)	0.28
Genetic algorithm-optimized fuzzy	0.31
Interval type-2 fuzzy controller	0.33
Tsukeno fuzzy controller	0.35
Type-1 fuzzy controller	0.44

p = 0.014). These outcomes from the McNemar's test and one sample proportion test help to verify the strength of fuzzy system validations so that it is a very strong tool to check basal insulin dose safety.

The evaluation of the model was also mathematically performed with the study of risk factors from existing works [34–41]. The risk indices for hypoglycemia and hyperglycemia, glycemic variability index, and composite safety index are stated herein, which are evaluated as in Table 11, and the performance is shown to be risk free. Here, the variables are $\hat{g}_i$: deterministic point prediction of glucose; $\boldsymbol{\mu_i}$**:** mean predicted glucose (from probabilistic model); $\boldsymbol{\sigma_i}$**:** standard deviation of predicted glucose representing prediction uncertainty ($\boldsymbol{\sigma_i} > 0$); **L:** lower glucose threshold (hypoglycemia cutoff, typically 70 mg/dL); **U:** upper glucose threshold (hyperglycemia cutoff, typically 180 mg/dL); $\boldsymbol{i}$**:** index of time step, where I = 1,2,. . . ,N; $\boldsymbol{N}$**:** total number of time steps considered in evaluation; $\boldsymbol{\Delta t}$**:** time interval between two successive predictions (minutes); $\boldsymbol{\phi}(\cdot)$: standard normal cumulative distribution function; and $(\boldsymbol{x})^+$: positive part operator, max(x,0), ensuring non-negative values.

4.6.1. Hypoglycemia risk index (HRI)

Probabilistic (with uncertainty)

$$p_i^{low} = \Phi\left(\frac{L - \mu_i}{\sigma_i}\right)$$

$$s_i^{low} = \Phi\left(\frac{L - \mu_i}{L}\right)$$

$$HRI = \frac{1}{N}\sum_{i=1}^{N} p_i^{low} s_i^{low}$$

Deterministic (severity–duration, Area under the curve (AUC) below)

$$HRI_{det} = \frac{1}{N}\sum\nolimits_{i=1}^{N}\left(\frac{L - \hat{g}_i}{L}\right)$$

Table 11
Evaluation of the proposed pipeline

Dosage level	HRI (hypoglycemia Risk)	HyRI (hyperglycemia risk)	GVI (glycemic variability)	CSI (composite safety index)	Proposed method outcome
Low	0.08 (low risk)	0.05 (very low risk)	0.10 (stable)	0.07 (safe)	Safe and stable
Medium	0.12 (low risk)	0.10 (low risk)	0.15 (moderately stable)	0.12 (safe)	Safe and optimal
High	0.18 (moderate risk)	0.14 (low risk)	0.20 (controlled variability)	0.17 (acceptable and safe)	Monitor, but safe

where $\boldsymbol{p_i^{low}}$**:** probability that glucose is below the hypoglycemia threshold L, $\boldsymbol{s_i^{low}}$**:** normalized severity of hypoglycemia, **HRI:** average hypoglycemia risk index across time steps, and $\boldsymbol{HRI_{det}}$**:** deterministic hypoglycemia index (AUC below L) using point predictions.

4.6.2. Hyperglycemia risk index (HyRI)

Probabilistic

$$p_i^{high} = 1 - \Phi\left(\frac{U - \mu_i}{\sigma_i}\right)$$

$$s_i^{high} = \left(\frac{\mu_i - U}{U}\right)$$

$$HyRI = \frac{1}{N}\sum_{i=1}^{N} p_i^{high} s_i^{high}$$

Deterministic (AUC below U)

$$HyRI_{det} = \frac{1}{N}\sum\nolimits_{i=1}^{N}\left(\frac{\hat{g}_i - U}{U}\right)$$

where $\boldsymbol{p_i^{high}}$**:** probability that glucose exceeds the hyperglycemia threshold U, $\boldsymbol{s_i^{high}}$**:** normalized severity of hyperglycemia, $\boldsymbol{H_yRI}$**:** average hyperglycemia risk index across time steps, and $\boldsymbol{HyRI_{det}}$**:** deterministic hyperglycemia index (AUC above U) using point predictions.

4.6.3. Glycemic variability index (GVI)

$$\bar{g} = \frac{1}{N}\sum_{i=1}^{N}\hat{g}_i$$

$$CV = \frac{\sqrt{\frac{1}{N}\sum\nolimits_{i=1}^{N}\left(\hat{g}_i - \bar{g}\right)^2}}{\bar{g}}$$

$$MASD = \frac{1}{N-1}\sum_{i=2}^{N}\frac{|\hat{g}_i - \widehat{g_{i-1}}|}{\bar{g}}$$

$$GV = \lambda\ x\ CV + (1-\lambda)\ MASD$$

where $\lambda\varepsilon\,[0,1]$ and $\boldsymbol{\bar{g}}$**:** mean of predicted glucose across all steps; **CV:** coefficient of variation of glucose (relative standard deviation); **MASD:** mean absolute successive difference, normalized by mean glucose; λ**:** weight parameter ($0 \le \lambda \le 10$) balancing CV and MASD; and **GV:** glycemic variability index combining CV and MASD.

4.6.4. Composite safety index (CSI)

Combine into a single score with interpretable weights

$$\alpha, \beta, \gamma \ge 0,\ \alpha + \beta + \gamma = 1:$$

$$CSI = \alpha\, HRI + \beta\, HyRI + \gamma\, GVI$$

where $\boldsymbol{\alpha}$**:** weight assigned to HRI, $\boldsymbol{\beta}$**:** weight assigned to HyRI, $\boldsymbol{\gamma}$**:** weight assigned to GVI, $\boldsymbol{\alpha + \beta + \gamma = 1}$**:** normalization constraint on weights, and **CSI:** composite index combining hypoglycemia, hyperglycemia, and variability risks into one score.

The comparison of all the aforementioned risk attributes is shown in Table 11. The risk scores evaluate the system to be safe too.

5. Conclusion

The primary contribution of the research work is a novel safety-validation architecture that synergizes data-driven prediction with rule-based reasoning. This design directly addresses clinical needs for both accuracy and interpretability, advancing beyond conventional single-model paradigms. The proposed system aims at avoiding any risks of using insulin pumps, which at times cause fainting or criticality of the patients due to acute hypo- or hyperglycemic conditions. It further aids in the estimation of TIR parameters. The use of an insulin pump reveals that hyperglycemia parameters fall in tandem with A1C improvements, with no effect on hypoglycemia. The users of the proposed system can obtain a clearer picture of whether their blood sugar is trending high or low with continuous glucose monitors, which provide blood sugar estimations every 5 minutes without the need for finger-prick tests. The prediction of basal insulin eliminates the need for manual keying. The results of this study's data analysis will enable developers to create models that better forecast the influence of meals and insulin on glucose levels, resulting in better blood sugar control and avoiding any risks because of prevalidation. Using this model, it is possible to adjust treatment in a number of ways, including how postprandial glucose patterns change, how stable overnight glucose levels are, how long bolus insulin takes to work, when and how to respond to hypoglycemia, and how different lifestyle activities affect treatment.

Recommendations

The finding revealed that the automatic setting of basal insulin may lead to hypoglycemia or hyperglycemia. Instead, validating the predicted basal insulin value from the proposed system to be within the safe zone before setting the value in the insulin pump will reduce the risk involved in using the insulin pump. In near future, the usage of automated, pervasive healthcare devices is likely to increase, hence the need for safety mechanisms for increased acceptance of the technology. The contribution of the research is focused on this section. Such technologies can be adopted by insulin pump manufacturers.

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Ethical Statement

The diabetes patient records used in this study were obtained from a publicly available and fully de-identified dataset (UCI Machine Learning Repository, https://archive.ics.uci.edu/dataset/34/diabetes). The dataset contains insulin pump readings for 70 patients over a 6-month period, including events recorded via automatic electronic devices and paper records. Therefore, ethical approval and informed consent were not required.

Conflicts of Interest

The authors declare that they have no conflicts of interest to this work.

Data Availability Statement

The data that support the findings of this study are openly available at https://archive.ics.uci.edu/dataset/34/diabetes. Further, for enhanced validation, the model was tested on https://webpages.charlotte.edu/rbunescu/data/ohiot1dm/OhioT1DM-dataset.html, which is available on request.

Author Contribution Statement

Jeyalakshmi Jeyabalan: Conceptualization, Methodology, Investigation, Writing – review & editing, Supervision, Project administration. **Karthikeyan Suresh:** Software, Validation, Formal analysis, Resources, Data curation, Writing – original draft, Visualization.

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