

An Approach to Avoid Hypoglycemia: A Model for Mealtime Insulin Dose Calculation for Diabetic People

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 Hypoglycemia; Food Carbohydrate. Type: Research Article ∂ Open Access ☑ Open Access ☑ Peer Reviewed ☑ CC BY Datients has steadily increased over the past decades. Particularly Type 1 and Type 2 diabetics are required to use insulin therapy to maintain their BG levels. Technological advancements in the production of insulin pumps and monitoring devices have aided diabetics in maintaining a healthy lifestyle. A patient with Diabetes Mellitus (DM) requires insulin therapy with profound roots. Most diabetics require a minimum of two daily insulin injections, with dosage adjustments dependent on selfmonitoring of BG levels. Aim: However, it is frequently observed that determining insulin dose is a somewhat perplexing and not always appropriate task. When the incorrect insulin dose is administered, hypoglycemia, which is a BG level below 70 mg/dL, frequently occurs. This condition places the patient at significant risk and should 	Author Keywords	Abstract
Type: Research Article a Open Access b Open Access b Open Reviewed c Open Access c Open Ac		Background: It has been observed that the number of diabetes patients has steadily increased over the past decades. Particularly Type 1 and Type 2 diabetics are required to use insulin therapy to
Count Mealtime Insulin Dose) model for calculating the Mealtime Insulin Dose (MID) based on insulin sensitivity, insulin carbohydrate ratio, and automatic calculation of carbohydrate count based on food intake using the Indian Food Carbohydrate Lookup Table. Conclusion: Target Blood Glucose Monitoring value attained by injecting MID(FCCMID) value of insulin is very close to the desired target Blood Glucose Monitoring Value (between 80 mg/dL to 130 mg/dL), thereby preventing Hypoglycemia or Hyperglycemia. The	Type: Research Article Open Access Peer Reviewed	 Type 1 and Type 2 diabetics are required to use insulin therapy to maintain their BG levels. Technological advancements in the production of insulin pumps and monitoring devices have aided diabetics in maintaining a healthy lifestyle. A patient with Diabetes Mellitus (DM) requires insulin therapy with profound roots. Most diabetics require a minimum of two daily insulin injections, with dosage adjustments dependent on self-monitoring of BG levels. Aim: However, it is frequently observed that determining insulin dose is a somewhat perplexing and not always appropriate task. When the incorrect insulin dose is administered, hypoglycemia, which is a BG level below 70 mg/dL, frequently occurs. This condition places the patient at significant risk and should therefore not be ignored. Method: This paper proposes an FCCMID (Food Carbohydrate Count Mealtime Insulin Dose) model for calculating the Mealtime Insulin Dose (MID) based on insulin sensitivity, insulin carbohydrate ratio, and automatic calculation of carbohydrate Lookup Table. Conclusion: Target Blood Glucose Monitoring value attained by injecting MID(FCCMID) value of insulin is very close to the desired target Blood Glucose Monitoring Value (between 80 mg/dL to 130 mg/dL), thereby preventing Hypoglycemia or Hyperglycemia. The observed average target BG level is 110 mg/dL, which is very near

1. Introduction

Before each meal, insulin dependent diabetics must check their Blood Glucose (BG) levels. In Type 1 diabetics, the pancreas secretes significantly less insulin or does not function at all (Kousar 2019)(Katsarou et al. 2017)(Krzymien and Ladyzynski 2019). While in Type 2 diabetes the body cells are weak and they are not able to absorb insulin. If the appropriate insulin dose is not manually administered, the glucose level in the body will rise after each meal or it may result in drop in BG level too. Hypoglycemia or hyperglycemia can be the consequences of inappropriate insulin injection. There are a variety of devices available on the market for measuring blood glucose (in mg/dL), many of which involve pricking or injecting.

1.1. Literature Review

The author described capillary blood glucose testing, venous or plasma blood sample testing, and continuous glucose monitoring. Blood is extracted from areas such as the fingertips or palms and applied to medicated strips, which are subsequently inserted into a battery-operated gadget that quantifies blood glucose levels. Whenever BGM is to be conducted, pricking must be executed, and the strips are costly. The plasma blood sample test is a conventional pathology method that involves obtaining a hypodermic blood sample and employing pathology procedures to determine the average blood glucose level during the preceding six months. This examination is referred to as the HBA1c.Miller, 2020

Continuous Glucose Monitoring involves pricking and attaching a sensor to body regions such as the arm, abdomen, or thigh, and rolling a reader to obtain a blood glucose reading(Richardson et al. 2024) (Nihaal Reddy, BS, Neha Verma, MD 2023). All of these techniques involve some form of prodding. Blood glucose monitoring is performed primarily to detect glucose levels. Blood glucose monitoring (BGM) devices primarily fall into two categories. Insulin Pumps and Rapid Glucose Monitoring Equipment.

1.2. Insulin Pumps (Miller 2020)

The insulin pump has two variants where in the first variant insulin pump is in the pocket and when required can be attached to inject insulin while in the second variant, the pump is attached to the body with a patch for injecting(Rimon et al. 2024). Through the use of a needle to introduce a cannula beneath the skin, an insulin pump delivers insulin to the body. Insulin can be constantly administered by the pump, administered when needed, or used to treat elevated blood glucose levels. You can use a band, belt, pouch, clip, or tape to wear the pump on your body. Inserting the cannula into the stomach, thigh, or buttocks is a common procedure. After applying the adhesive to your skin and filling the reservoir with insulin, you press a button to release the needle. Insulin pumps can increase blood glucose regulation, lower the risk of hypoglycemia, and give you more control over when you eat and exercise(Carić et al. 2024).

1.2.1.Flash glucose monitoring: (Miller 2020)(Liang et al. 2022; Krakauer et al. 2021; Mancini et al. 2018)

It is a two-component bundle consisting of a sensor that is affixed to the thigh or arm and a reader that measures the BG level. The sensor monitors BG levels throughout the day and displays readings whenever the reader is scrolled over. A device called flash glucose monitoring (FGM) is used to check diabetics' blood sugar levels. The finger prick test can be substituted with this method. By giving patients more information than finger pricks and assisting them in understanding how things like diet and exercise affect blood sugar, FGM can help people manage their diabetes. On the back of the arm, a sensor is placed beneath the skin. Every minute, the glucose sensor takes a reading, which it records every 15 minutes. The current glucose level, trends, and an 8-hour graph are displayed by a reader device that reads the sensor. Insulin dosages, food, exercise, and stress can all be tracked by patients using a log. In order to understand their blood sugar levels and modify their treatment, patients can collaborate with medical professionals.

1.3. Research Objective

In the proposed research, an attempt was made to determine the correct insulin dosage that will prevent hypoglycemia or hyperglycemia. It is a two-experiment procedure. The experiment proposes a model for calculating the required insulin dose based on the present BG level, dietary intake, and total daily dose. After receiving these three inputs, the model

calculates the insulin dose, and the diabetic injects the calculated dose. This experiment will determine the veracity and efficacy of the proposed FCCMID model.

The main contributions of this paper are

- Insulin dose calculation basics in section 1.4 to 1.9
- Proposing a state-of-art FCCMID model for insulin dose calculation which is explained in detail in section 2.1
- Results for FCCMID with its discussion in section 3.
- Proving the effectiveness of FCCMID in section 4.

To understand further experimentations few terms related to Diabetes Insulin Dose need to be understood. These terms are explained below.

1.4. Mealtime Insulin Dose (MID): (Miller 2020)(Maurizi et al. 2011)(Walsh, Roberts, and Bailey 2010)

Mealtime Insulin measure refers to the unit measure of insulin that must be injected prior to meals in order to maintain a normal BG level. Regardless of the method used for blood glucose monitoring, the primary concern is administering the correct amount of insulin. The insulin dose is measured in unit. The commonly used insulin is 500 units/ml of insulin. If the incorrect dose of insulin is administered, hypoglycemia, which is a BG level below 70 mg/dL, may result. Hypoglycemia is considered extremely dangerous because it can result in the abrupt failure of one or more organs. Hyperglycemia is also to be taken care of. But Hyperglycemia shows it's symptoms on prolonged hyperglycemia state. It means if Hyperglycemia continuous to be for days and months then complications may arise. Various methods have been proposed for calculating the mealtime insulin dose, also known as the bolus insulin dose. Within 15 to 20 minutes of injection, the bolus insulin begins to act swiftly. The precise duration depends on the substance and its brand. To calculate the MID value, multiple types of literature were proposed.

1.5. Total Daily Dose (TDD) (Miller 2020)(Maurizi et al. 2011)(Walsh, Roberts, and Bailey 2010)

The average daily dose of insulin needed by an individual is known as the total daily dose. This figure often corresponds to an individual's weight.

The general formula for calculating the TDD is,

Sometime it is observed that the TDD can show variations to value obtained from Eq. 1 because of age factor. After few months of trial and error this count of TDD can be obtained more accurately. For the initial value to be considered before starting trial and error, Eq. 1 can be used. The TDD varies from person to person depending on his/her body weight and age.

1.6. Insulin Carbohydrate Factor (ICF) (Miller 2020)(Maurizi et al. 2011)(Walsh, Roberts, and Bailey 2010)

The CarbF is the Insulin Carbohydrate Factor (ICF) which tells about the correlation between insulin dose and the meal intake carbohydrate consumed. Walsh and Roberts developed the "450 rule" to determine CIR in patients receiving MDI or CSII therapy. They calculated CIR by dividing 450 by the total daily dose (TDID) of insulin, based on their clinical experience.9. Nonetheless, insulin sensitivity is linked to both TDID and CIR.(Alcántara-Aragón et al. 2015)

Usually for calculating the ICF "450 Rule" of ICF is used.

1.7. Insulin Sensitivity Factor(ISF) (Miller 2020)(Maurizi et al. 2011)(Walsh, Roberts, and Bailey 2010)

The CorrF is also termed an Insulin Sensitivity Factor(ISF) which tells about how much blood glucose (mg/dL) is reduced per unit dose of insulin.(Maurizi et al. 2011; Eissa et al. 2020). To calculate the ISF either the "1500 rule" or "1800 rule" is used.

By using the "1500 rule", (Maurizi et al. 2011; Eissa et al. 2020)

By using the "1800 rule"

ISF=1800/TDD

For our implementation "1500 rule" is taken into consideration and thus Eq. 3 is used. (Erdo, Karadeniz, and De 2003). Using the TDD, ICF and ISF further two important calculations need to be done. One is calculating Mealtime Insulin Dose (MID) and Meal Carb Dose (MCD).

1.8. Premeal Insulin Dose(PID) (Miller 2020)(Maurizi et al. 2011)(Walsh, Roberts, and Bailey 2010)

Premeal Insulin Dose is the factor which depends on the current BG level and the Target BG level. The BGM can be obtained using any device from various Continuous glucose monitoring devices(CGM) or Flash Glucose Monitoring(FGM) devices. The discussion on CGM and FGM is done in section 2.1. The Target BGM for diabetic people is usually 100 mg/dL(Yun et al. 2019; Dean L 2004; Zahed et al. 2020). For person who is non-diabetic, it is 80 mg/dL which tells the BG level. According to American Diabetes Association the BGM level should be in the range of 80 mg/dL to 130 mg/dL. But for Diabetic people to avoid the possibility of lowering of blood sugar level, it is considered to be 100 mg/dL. *The TBGM in the ideal diabetic scenario is considered to be 100 mg/dL*. For our work too the TBGM is considered as 100 mg/dL.

(5)

(2)

(4)

1.9. Meal Carb Dose(MCD) (Miller 2020)(Maurizi et al. 2011)(Walsh, Roberts, and Bailey 2010)

Ρ

The meal carb dose required two main inputs, the approximate carbohydrate intake in mg and the ICF. The carbohydrate intake depends on the food which will be consumed. Food type and its quantity play important role.(Sterner Isaksson et al. 2024) For the Carb Count(CC), this is usually where mistake is done by the diabetic people or their family members.

Finally, from the PID and MCD the MID is calculated which is the ultimate goal. Once we get PID and MCD the final MID is calculated by,

MID=PID+MCD

The MID is the unit of insulin one should take before meals, to keep the target BG level at 100 mg/dL and ideally between 80 mg/dL to 130 mg/dL after consuming the meal.

1.10. Gap Identified

The Carbohydrate Count (CC) is the most difficult aspect of calculating MID. Typically, it is assumed to have a mean value, which is incorrect. It should be dependent on the diet of the diabetic individual(Guo et al. 2020)(Sami et al. 2017)(Forouhi et al. 2018). If a person consumes only rice and vegetables, their carbohydrate intake will differ from a person who consumes bread and vegetables. Furthermore, it depends on the quantity of food consumed. If the CC value is measured more precisely, the likelihood of a blood glucose drop or rise can be reduced. By inputting the food items and their respective quantities for a diabetic, the Carbohydrate dataset can serve as a reference to compute the carbohydrate count based on the selected food options. Should the automated model be integrated into the Flash Glucose Monitoring Device or the Continuous Glucose Monitoring Device, it will be considered a comprehensive diabetic care module. (Korbut et al. 2019)(Noaro et al. 2021)(Huckvale et al. 2015). Figure1 depicts the calculation for the aggregate Mealtime Insulin Dose.

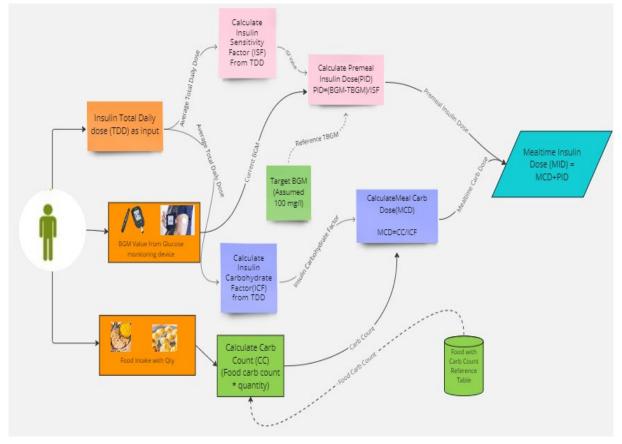


Figure 1: Mealtime Insulin Dose Calculation Process With its Requirements.

2. Materials and Methods

2.1. PROPOSED MODEL

After supplying all methods for calculating the MID, the challenge is to obtain a more accurate MID so that hypoglycemic or hyperglycemic states do not occur. Hypoglycemia is

(7)

characterized by a BG level of less than 70 mg/dL, whereas hyperglycemia is characterized by a BG level of more than 180 mg/dL. Care must be given of both conditions(Seaquist et al. 2013)(González-Vidal et al. 2024)(Umpierrez et al. 2024).

The difficulty here is calculating the amount of carbohydrates in the meal that will be consumed.

FCCMID (Food Carbohydrate Count Mealtime Insulin Dose) is therefore proposed as a paradigm.

In the supplied model, a lookup table with the approximate carbohydrate content of the majority of Indian culinary items is provided. The lookup table contains the food item's name, its quantity per unit, and its carbohydrate content. Table 1 provides an example of the same.

Indian Food Name	Measurement	Carbs (g)
Pulses-Sabji	1/4 Cup	12
Potato sabzi	1/2 Cup	15
Potato with green vegetable	1/2 Cup	12
Okra	½ Cup	13
Gram Flour without oil items	1/2 Cup	15
Gram flour oily items	½ cup	25
Steamed rice	½ cup	18
Roti	8 inch	15
Boiled Rice	1/3 Cup	15
Idli / Dosa	1 / 8 inch	15

Table 1: Indian Food Carbohydrate value dataset sample which gives details of the food item and its carbohydrate details for unit intake (Wagle and Director 2014).

The model FCCMID is an application that can be provided to diabetics where they need to give the following inputs,

- a. BGM current BG level(mg/dL)
- b. TDD Average total daily dose of insulin
- c. Food items to be consumed in a meal.

Based on the above three inputs given, the MID will be calculated.

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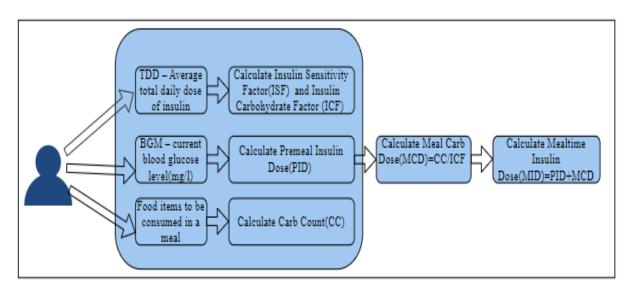


Figure 2: FCCMID Model Architecture

Figure 2 depicts the proposed FCCMID model's architecture. As TDD, BGM, and food items to be consumed, the diabetic's three primary inputs are TDD, BGM, and the food items to be consumed. The ISF, ICF, PID, and CC values are calculated based on these inputs, and the MCD is then calculated. Using the PID and MCD values, the Mealtime Insulin Dose (MID) is derived, which is simply the number of required insulin doses for the diabetic patient.

2.2. Stepwise FCCMID

Once all the inputs are given by the diabetic person before consuming his/her meal, then the MID calculation steps are followed. Steps for calculating Mealtime Insulin Dose values using the FCCMID model are as given below,

Step 1: Taking Food intake as input

$$CC = \sum_{i=1}^{n} CCS * Q \tag{8}$$

Where,

n= Number of the item included in the meal

CC= Carb Count

CCS= Carb value of food item selected

Q= Qty of food items selected

Step 2: Taking TDD as input

Where, TDD=Total Daily Dose **Step 3:** Taking BGM as Input

Here TBGM is assumed to be 100 mg/dL

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Step 4:

$$MID_{FCCMID} = PID + MCD$$
(13)

Which is also equal to,

$$FCCMID = \frac{BGM - TBGM * TDD}{1500} + \frac{\sum_{i=1}^{n} CCS * Q * 450}{TDD}$$
(14)

Where

BGM-> Current BG level ,

TBGM - > Target BG level(Assumed to be 100 mg/dL)

TDD -> Total Daily Dose,

CCS -> Carb value of food item selected,

Q -> Qty of food item selected

2.2.1. Algorithm: FCCMID Algorithm

Algorithm 1:

Result: FCCMID Value (Insulin Dose units to be injected)

Input List: Total Daily Dose of an Individual (TDD), Current Blood Glucose Value(BGM), Food Intake with its Quantity(CCS as food selected, Q as respective quantity)

Assumption: Target Blood Glucose Value (TBGM) as 100 mg/dL

Steps:

Step 1: Start

Step 2: Accept the TDD, BGM and CCS with Respective Q from the diabetic person *Step 3:*

Calculate

$$CC = \sum_{i=1}^{n} CCS * Q$$

ICF=450/TDD
ISF=1500/ TDD

Step 4:

Calculate PID=(BGM-TBGM)/ISF MCD=CC/ICF

Step 5:

FCCMID= PID + MCD

Step 6:

Display "The insulin dose to be injected" as FCCMID

3. Result and Discussion

The FCCMID model was tested on 2,596 records obtained from diabetic individuals between the ages of 5 and 60. 42 different individuals with diabetes used the FCCMID model insulin dosage. The individual consumed different food at different times. They gave food item and its quantity as input to FCCMID. The FCCMID was calculated using the current BGM, TDD, and Food quantities as inputs. Once these inputs are given, the FCCMID will give insulin dose as the output which the diabetic need to inject. The Target BGM (TBGM obtained) was recorded one hour after the diabetic was injected with insulin. The obtained TBGM was then compared to the ideal target TBGM concentration of 100 mg/dL. Also it was found whether the result if the TBGM range between 80 mg/dL to 130 mg/dL, which is considered to be the ideal BGM level.

3.1. FCCMID Results

Table 2 shows the MID(FCCMID) value calculated using the FCCMID model.

TDD	Age	СС	BGM	ISF	ICR	PID	MCD	MID (FCCMID)
50	12	100	80	30	9	0	11	11
60	14	90	100	25	8	0	12	12
80	23	78	150	19	6	3	14	17
100	45	120	90	15	5	0	27	27
100	50	40	90	15	5	0	9	9
55	14	60	350	27	8	9	7	17
60	23	100	80	25	8	0	13	13
60	14	90	100	25	8	0	12	12
50	12	78	150	30	9	2	9	10
60	14	120	90	25	8	0	16	16
110	50	49	90	14	4	0	12	12
100	45	40	110	15	5	1	9	10

Table 2: FCCMID model applied to sample data

Based on the inputs given by the diabetic user the MID-FCCMID value is obtained as shown in Table 2.

TDD	Carb count	BGM	MID (FCCMID)	TBGM obtained	TBGM desired
50	100	80	11	110	100
60	90	100	12	114	100
80	78	150	17	97	100
100	120	90	27	99	100
100	40	90	9	103	100
55	60	350	17	126	100
60	100	80	13	95	100
60	90	100	12	101	100
50	78	150	10	115	100
60	120	90	16	120	100
110	49	90	12	110	100
100	40	110	10	104	100

Table 3: Target BG level obtained using FCCMID model (Sample 12 record)

Table 3 displays the target BGM (TBGM) obtained by injecting insulin with a MID (FCCMID) value that is very close to the intended target BGM (assumed to be 100 mg/dL). 100 mg/dL is considered to be the optimal BG level for diabetics. Also the TBGM calculated is in the range of 80 mg/dL and 130 mg/dL. In this case, neither Hypoglycemia nor Hyperglycemia describes the patient's condition.

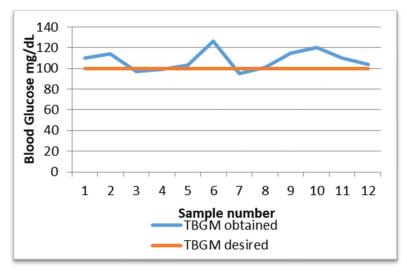


Figure 3: Comparison of TBGM obtained and TBGM desired

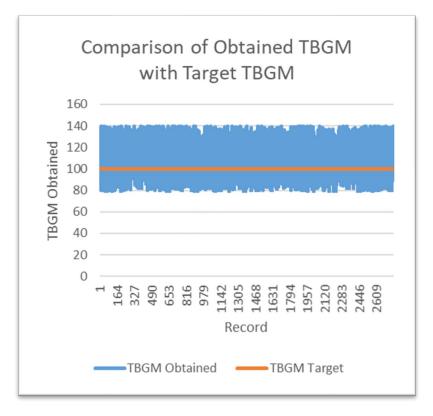


Figure 4: Comparison of TBGM obtained and TBGM desired for all 2596 records

Figure 3 and Figure 4 Shows the BG level values obtained 1 hour after injecting the insulin dose as per the FCCMID value calculated (Thomas Donnor, MD and Sudipa Sarkar, MD 2023). The most ideal BG level is 100 mg/dL which is taken as a reference value. The BG level after using FCCMID value insulin dose is also very close to the ideal target level.

The average TBGM obtained was 110 mg/dL which is very close to the desired TBGM.(Kahsay et al. 2019)

3.2. Discussion

The MID value derived by the FCCMID model is shown in Table 2. Using this paradigm, the diabetic does not need to be concerned with the number of insulin units to inject. The MID value is generated based on the present BG level, TDD, and carbohydrate count. The carbohydrate count is determined based on the food consumed and its quantity, which is input by the user. If the food to be consumed is known, then carb counting become easy by referring the food carb table. Care to be taken by individual that correct food item is selected with correct quantity given as input. If wrong inputs are given to FCCMID then it may lead to incorrect insulin dose value. This will ultimately lead to wrong TBGM value resulting in either hypoglycemia or hyperglycemia. Even if diabetic children submit these inputs, they will be able to calculate the injection dose of insulin. Table 3 displays the observed target BG level one hour after an insulin injection. These TBGM values are calculated for a given FCCMID insulin injection dose. The target TBGM is presumed to be 100 mg/dL, which is the optimal level for a diabetic individual, which satisfies the condition of TBGM to be in the range of 80 mg/dL to 130 mg/dL. Figures 3 and 4 demonstrate that the TBGM derived using the FCCMID model and the desired TBGM are extremely similar. The average glucose level determined from 2,596 samples is 110 mg/dL, which corresponds to an accuracy of nearly 90%. More it shows that the TBGM level is in the range of 80 mg/dL to 130 mg/dL, which is considered to be the ideal state.

4. Conclusions

The FCCMID model was applied for TBGM of 42 individuals for approximately 3 times a day for 6 months. The FCCMID calculated daily insulin dose has proven to give better results. Practically it is very difficult to maintain stable BG levels for diabetics, resulting often in hyperglycemic or hypoglycemic states because of the wrong mealtime insulin dose injected. This happens usually because the carbohydrate count based on food intake is just roughly calculated or assumed, which results in wrong insulin dose prediction. Thus, the FCCMID model if converted to an automatic mealtime insulin calculator device with an Indian food nutrition database, will prove to lead to a healthier life for diabetic patients. If this model is embedded along with existing blood glucose monitoring devices, then it will prove to be a boon to diabetic community. Thus, the FCCMID model if incorporated with the existing blood glucose injection.

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