A Smart Intravenous Glucose Monitoring and Insulin Infusion System for Continuous Patient Care

The Glucosystem

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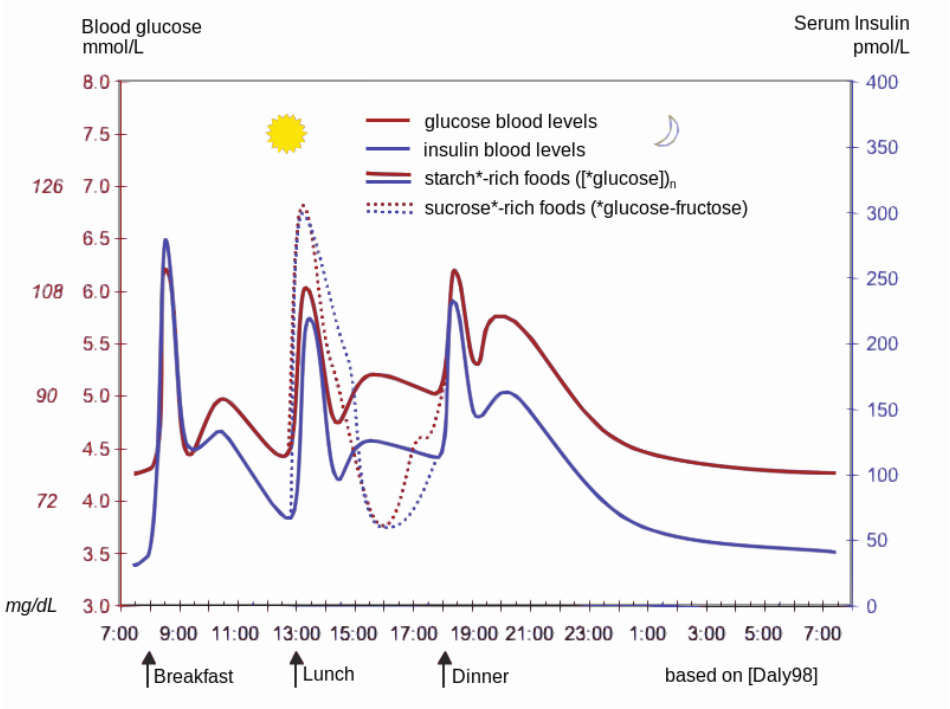
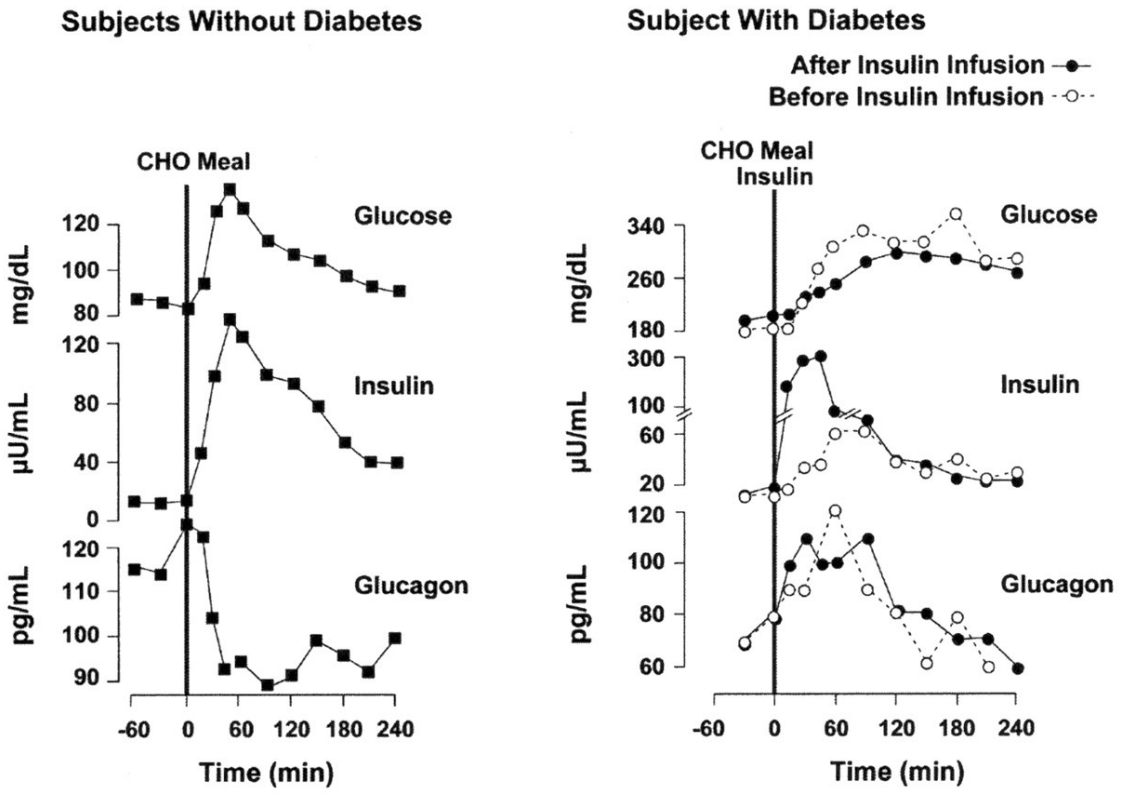
Background

- Patient's blood glucose levels (shown in red) rises rapidly after meals.
- Typically, the basal glucose for patients with normal BMI hovers around 80 mg/dL
- For non-diabetic patients, a rise in blood glucose is immediately followed by a rise in insulin (shown in blue)
- In diabetic patients, the pancreas cannot sufficiently produce enough insulin following a rise in blood glucose
- Blood glucose remains high well after meals.
- Treatment for diabetes involves supplementing the patient with external insulin so that there is sufficient insulin to bring down glucose levels
- Too much insulin at one time can also be bad. It causes hypoglycemia (lower than normal blood glucose levels)

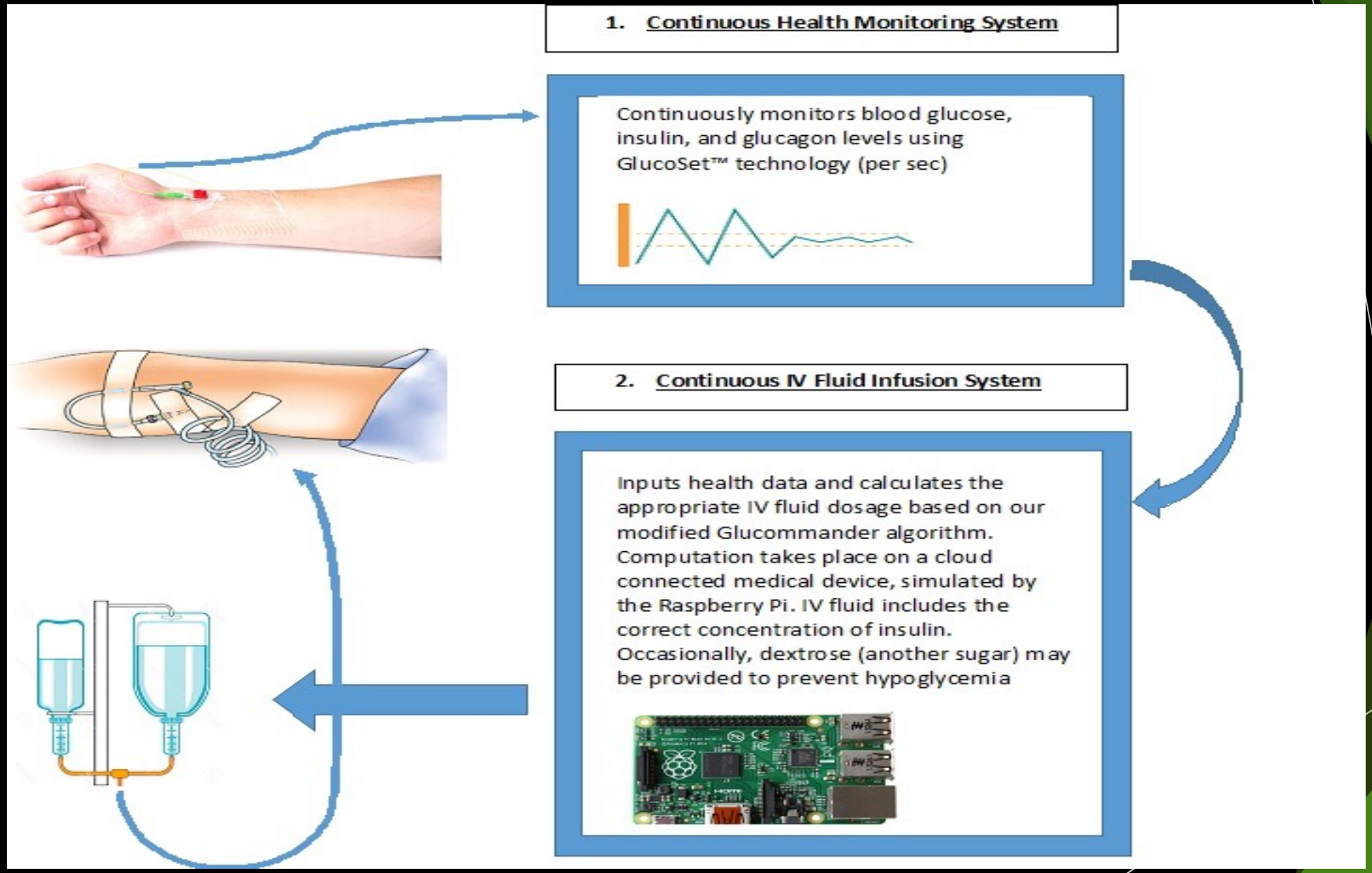


Background

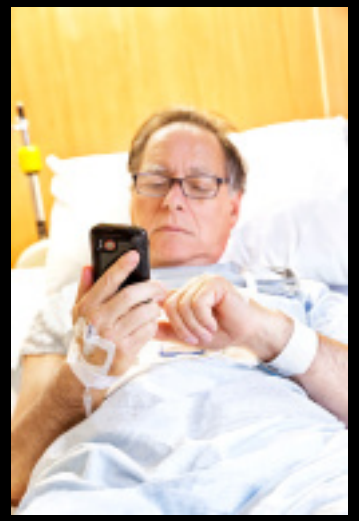

Subjects Without Diabetes
CHO Meal
Glucose
Insulin
Glucagon
mg/dL
μU/mL
pg/mL
120
100
80
120
80
40
0
120
110
100
90
-60
0
60
120
180
240
Time (min)
Subject With Diabetes
After Insulin Infusion
Before Insulin Infusion
CHO Meal
Insulin
Glucose
Insulin
Glucagon
mg/dL
μU/mL
pg/mL
340
260
180
300
100
60
20
120
100
80
60
-60
0
60
120
180
240
Time (min)

Components of the Glucosystem IV

- 1. Continuous IV Health Monitoring System
  - Monitors the patient's blood glucose, glucagon, and insulin levels every second
- 2. Continuous IV Fluid Infusion System
  - Supplies the right dosage of insulin concentration at every second through IV
  - Supplies dextrose (another sugar) if needed to prevent hypoglycemia
- 3. Patient Control System
  - Mealtime Protocol
  - Disconnect IV Device
  - Request Medical Personnel
- 4. Medical Personnel Control System
  - Mealtime Protocol
  - Manage several patient data
  - Be notified of IV Fluid Refills
  - Attend to Patients


1. Continuous Health Monitoring System
Continuously monitors blood glucose, insulin, and glucagon levels using GlucoSet™ technology (per sec)
2. Continuous IV Fluid Infusion System
Inputs health data and calculates the appropriate IV fluid dosage based on our modified Glucommander algorithm. Computation takes place on a cloud connected medical device, simulated by the Raspberry Pi. IV fluid includes the correct concentration of insulin. Occasionally, dextrose (another sugar) may be provided to prevent hypoglycemia

3. Patient Control System



What Patients Control via their phones to Parse Cloud:

Time: 1300

Initialization: Patient enters Name, Age, Gender, Weight,

Food Request button: Available to patient from times 600-1000, 1200-1500, 1700-2000

IV Disconnect button: Patient presses this in order to stop IV infusion (i.e. when taking a bathroom break)

Request Medical Personnel button:

Parse Cloud sends Initialization, Food Request, IV Disconnect info to Raspberry Pi for computation/ processing

What the IV-Health Monitoring and Insulin Infusion System processes via Raspberry Pi:

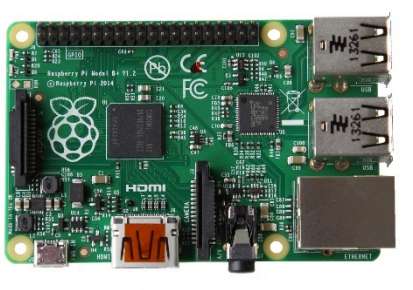
Runs Simulation Time (1 sec = 5 min)

Generates Basal Glucose and Insulin levels based on Patient's BMI Index determined by Age, Weight, and Gender

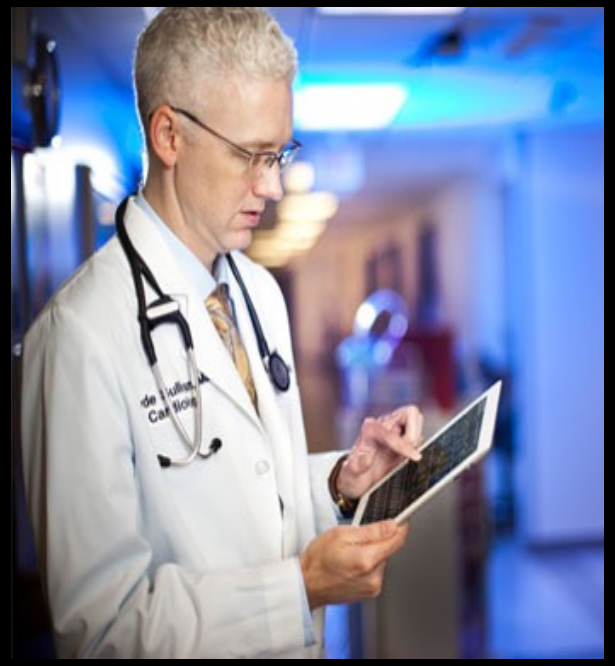
Elevates glucose levels after 'Accept Food Request' from Medical Personnel

Computes appropriate Total Insulin, glycogen, and glucose changes based on patient's diabetic severity

Relays information between patients and medical personnel via Parse Cloud



4. Medical Personnel Control System



What Medical Personnel Control via their Phones on Parse Cloud

Time: 1300

Important Notifications:

Please Refill Bob's Insulin

- **Insulin Refilled**

Bob requests medical personnel

- **Patient Served**

Sally has sent food request

- **Complete Food Request**

John has sent food request

- **Complete Food Request**

Select Patient Data:

- **Bob**
- **Sally**
- **John**

What Medical Personnel and Authorized Third Parties See via Parse Cloud:

Time: 1300

Patient Profile:
Bob
65/M/180 lbs
Diabetes: Severe

Last Meal: 1225
Blood Glucose: 300 mg/dl
Basal Insulin: 15 µU/mL
Total Insulin: 200 µU/mL
Infused Insulin: 180 µU/mL
Glucagon: 90 pg/mL
Insulin Fluid Left: 100 mL
Please Refill Bob's Insulin

Mealtime Protocol

- Typically, glucagon (produced when blood glucose is low) leads to hunger
- In our simulation, we have allowed patients to select ‘Food Request’ during set times of the day
- When patient clicks ‘Food Request’, patient’s blood glucose levels begin to decline from his or her basal glucose level (80 mg/dL)
- Medical Personnel must click ‘Accept Food Request’ (nurse has delivered food and oversaw patient eating)
- Otherwise, if patient’s blood glucose level drops to 70 mg/dL, patient becomes hypoglycemic. The Glucosystem automatically begins infusing patient with dextrose (a kind of sugar) to normalize blood glucose back

State of the Art: Insulin Infusion

- Current Methods of Taking Insulin
  - Insulin Needles/Syringes
  - Insulin Pumps
  - Intravenous Insulin
    - Non-Automated
      - Yale Protocol
        - The insulin dosage only changes when blood glucose levels outside of a given range
        - Requires nurses to monitor blood glucose levels at interval times (1-4 hours)
    - Automated
      - Glucommander Algorithm
        - Insulin dosage changed whenever measured glucose level changes
        - Still requires a nurse to monitor glucose levels at interval times (recommended 2 hour intervals)

YALE INSULIN INFUSION PROTOCOL

If BG ≥ 75 mg/dL:

STEP 1: Determine the CURRENT BG LEVEL - identifies a COLUMN in the table:

BG 75-99 mg/dL	BG 100-139 mg/dL	BG 140-199 mg/dL	BG ≥ 200 mg/dL

STEP 2: Determine the RATE OF CHANGE from the prior BG level - identifies a CELL in the table - Then move right for **INSTRUCTIONS:**

[Note: If the last BG was measured 2-4 hrs before the current BG, calculate the hourly rate of change. Example: If the BG at 2PM was 150 mg/dL and the BG at 4PM is now 120 mg/dL, the total change over 2 hours is -30 mg/dL; however, the hourly change is –30 mg/dL ÷ 2 hours = -15 mg/dL/hr.]

BG 75-99 mg/dL	BG 100-139 mg/dL	BG 140-199 mg/dL	BG ≥ 200 mg/dL	INSTRUCTIONS*
		BG ↑ by > 50 mg/dL/hr	BG ↑	↑ INFUSION by "2Δ"
	BG ↑ by > 25 mg/dL/hr	BG ↑ by 1-50 mg/dL/hr *OR* BG UNCHANGED	BG UNCHANGED *OR* BG ↓ by 1-25 mg/dL/hr	↑ INFUSION by "Δ"
BG ↑	BG ↑ by 1-25 mg/dL/hr, BG UNCHANGED, *OR* BG ↓ by 1-25 mg/dL/hr	BG ↓ by 1-50 mg/dL/hr	BG ↓ by 26-75 mg/dL/hr	NO INFUSION CHANGE
BG UNCHANGED *OR* BG ↓ by 1-25 mg/dL/hr	BG ↓ by 26-50 mg/dL/hr	BG ↓ by 51-75 mg/dL/hr	BG ↓ by 76-100 mg/dL/hr	↓ INFUSION by "Δ"
BG ↓ by > 25 mg/dL/hr *see below*†	BG ↓ by > 50 mg/dL/hr	BG ↓ by > 75 mg/dL/hr	BG ↓ by > 100 mg/dL/hr	HOLD x 30 min, then ↓ INFUSION by "2Δ"

†D/C INSULIN INFUSION; √BG q 30 min; when BG ≥ 100 mg/dL, restart infusion @75% of most recent rate.

*CHANGES IN INFUSION RATE ("Δ") are determined by the current rate:

Current Rate (U/hr)	Δ = Rate Change (U/hr)	2Δ = 2X Rate Change (U/hr)
< 3.0	0.5	1
3.0 - 6.0	1	2
6.5 - 9.5	1.5	3
10 - 14.5	2	4
15 - 19.5	3	6
20 - 24.5	4	8
≥ 25	≥ 5	10 *(consult MD)*

Original Glucommander Algorithm

- Based on a research article, *Glucommander: a computer-directed intravenous insulin system shown to be safe, simple, and effective in 120,618 h of operation*, by Davidson and Bode, who are now advisors at Glytec
- IV Insulin Infusion Rate (units of insulin/hour) = (Blood Glucose - 60) * multiplier
  - Initiate IV Insulin drip by applying current blood glucose and multiplier, 0.02, to the above formula
  - If the current blood glucose is greater than 110 and has not dropped at least 15% over the previous blood glucose, increase the multiplier by 0.01
  - If the current blood glucose is greater than 110 and has dropped at least 15% over the previous blood glucose, use the same multiplier
  - If the blood glucose is between 80 and 110, do not change the multiplier but continue adjusting the drip rate according to the formula
  - If the blood glucose is less than 80, refer to the hypoglycemia algorithm (not shown)

Shortcomings of the Glucommander Algorithm

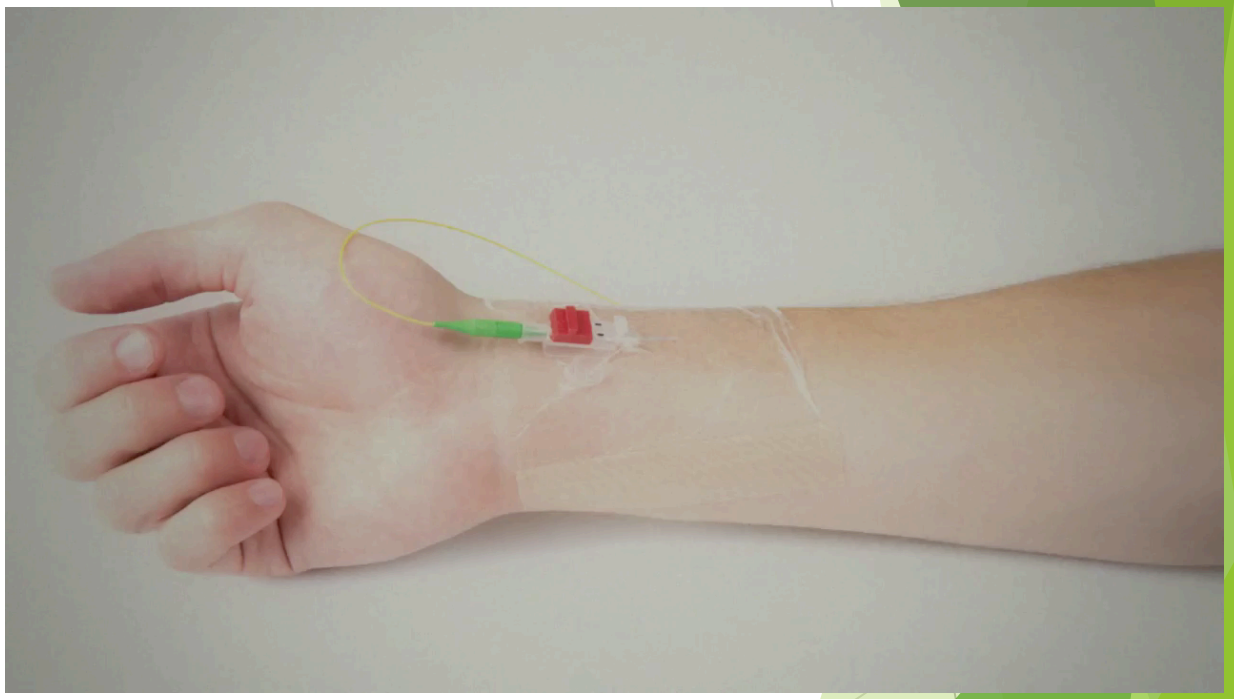
- The Glucommander does not work with patients taking meals. Instead the patient's blood glucose is solely a result of dextrose IV infusion
- While Glucommander's IV infusion is automatic, blood glucose measurements must still be taken and entered manually
- IV insulin dosages only change during the times when blood glucose measurements are taken (usually every 2 hours)

How Our Product, Glucosystem IV, Overcomes the Shortcomings

- Glucosystem IV is both meal-based (allowing patients to have meals, which lead to a spike in glucose) and meal-less (IV infusion of dextrose when patient is hypoglycemic)
- Glucosystem IV continuously (every second) takes in blood glucose measurements, instantly calculates the requisite insulin dosage, and continuously administers insulin

State of the Art: Continuous Glucose Monitoring

- Based on the input from the light traveling through an optical fiber toward a gel tip, the Glucoset™ sensor is able to calculate changes in blood glucose concentrations per second.
- This technology just came into market. Continuous Glucose Monitoring is a fairly recent phenomenon not yet utilized in IV Insulin Protocols!

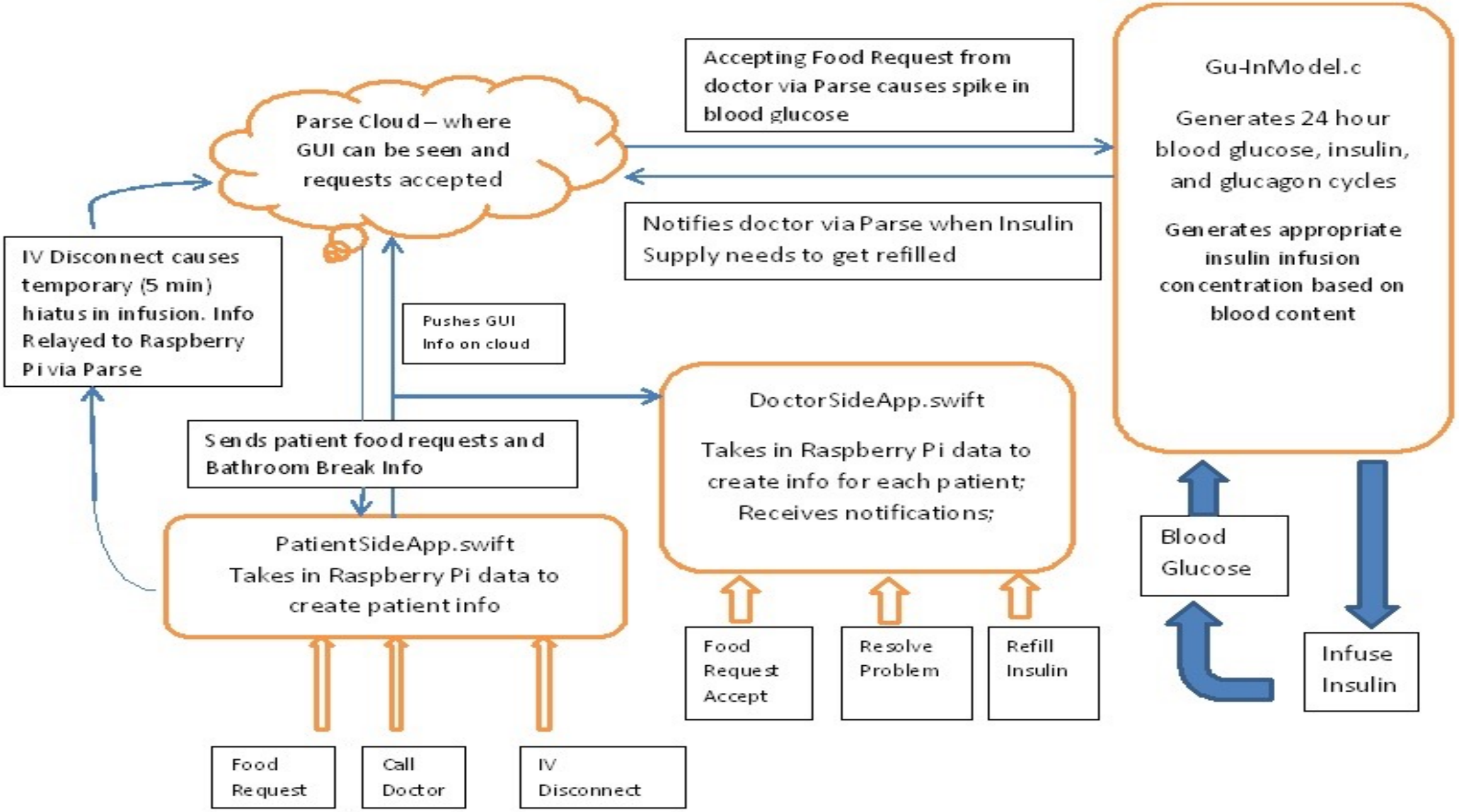


How the Glucosystem IV is Different

- In summary, our Smart IV Insulin Infusion System provides what Glucommander based devices were never able to provide, utilizes continuous glucose monitoring technology, and links patients, medical personnel, and authorized third parties through the Internet of Things:
  - It is based on ***continuously*** measured blood glucose levels from devices like Glucoset™
  - Taking in the blood glucose inputs, our device provides ***continuous*** insulin delivery based on a modified Glucommander algorithm.
  - This modified Glucommander algorithm is flexible enough so that patients can have meals or have carbohydrates intravenously infused to prevent hypoglycemia

Glucosystem's Value Add

	Insulin Syringes & Needles	Insulin Pumps & Patches	Yale IV Insulin Infusion Protocol	Glytec's Glucommander IV™	**The Glucosystem**
Delivers Insulin for Meal Time Usage	√	√	√		√
Protects Against Hypoglycemia (IV Infusion of dextrose)			√	√	√
Automated Insulin Delivery				√	√
Continuous Glucose Monitoring					√ Glucoset™
Continuous Insulin Delivery		√		√	√
IoT Based Connectivity Between Patient, Medical Personnel, Medical Device & Authorized Third Parties					√


Parse Cloud – where GUI can be seen and requests accepted
Accepting Food Request from doctor via Parse causes spike in blood glucose
Gu-InModel.c
Generates 24 hour blood glucose, insulin, and glucagon cycles
Generates appropriate insulin infusion concentration based on blood content
Notifies doctor via Parse when Insulin Supply needs to get refilled
IV Disconnect causes temporary (5 min) hiatus in infusion. Info Relayed to Raspberry Pi via Parse
Pushes GUI Info on cloud
DoctorSideApp.swift
Takes in Raspberry Pi data to create info for each patient; Receives notifications;
Sends patient food requests and Bathroom Break Info
PatientSideApp.swift
Takes in Raspberry Pi data to create patient info
Blood Glucose
Infuse Insulin
Food Request Accept
Resolve Problem
Refill Insulin
Food Request
Call Doctor
IV Disconnect

Latency

- We measure the latency by measuring the ping value from App to the Cloud.
- By using the query method , the App sends a request to the Cloud, and the Cloud responds instantly.
- Thus, by measuring the time interval between a request and response, we actually get the round-trip latency of the link, since we assume that it takes almost the same time for the message coming back as sending out, thus we can get the approximate one-way latency by dividing the ping value by 2.