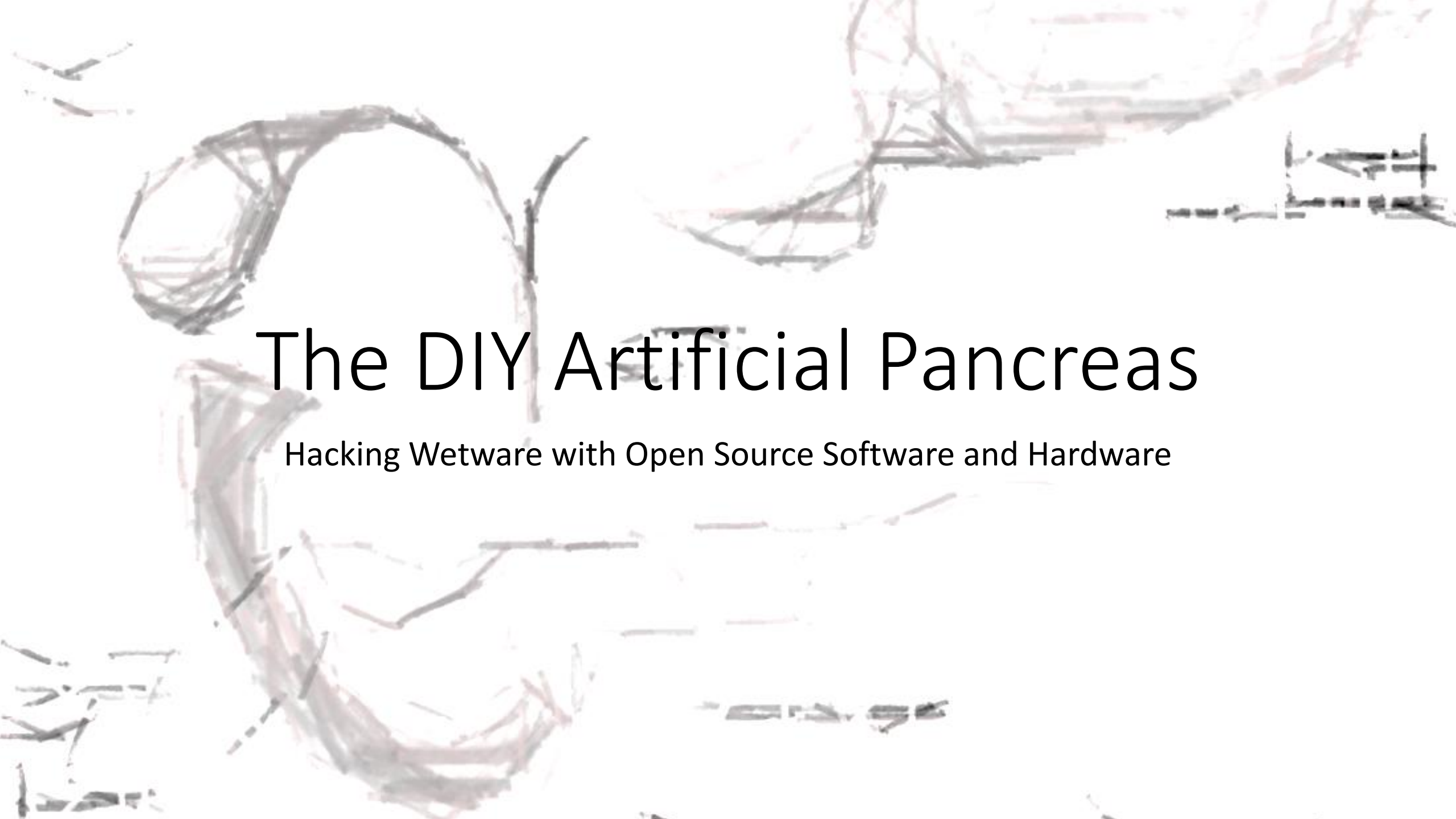

The DIY Artificial Pancreas

Hacking Wetware with Open Source Software and Hardware

Agenda

- `whoami`?
- Introduction to Diabetes
- Hardware
- Software and Safety
- Iterative Improvements
- Live Demo
- Results
- Exponential Growth
- Questions?

whoami?

- LAGORIO\Jay (jay@lagor.io)
- B.S. Computer Science, UMBC (2008)
- M. Eng. Electrical Engineering, NPS (2015)
- CISSP, various SANS certifications over the years
- Developer, IT Consultant, Private Investigator
  - Projects at UMBC as a student, many projects thereafter
  - Maryland-based Ambulance company
  - Other sectors, and myself

whoami?

- .NET Developer
  - Facebook API 1.0 library
  - Workflow management (PHP too!)
  - Craal
  - Lots of personal projects

Sugar

jay@lagor.io

Scott Hanselman has been trying to hack his diabetes through tech since he was 21.

Scott was diagnosed with diabetes at 21, and has been using technology to “hack” his health ever since.

“That’s the first thing every techie does once they’ve been diagnosed with diabetes,” says Scott. “They try to solve the problem with software or hardware.”

Agenda

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- **Introduction to Diabetes**
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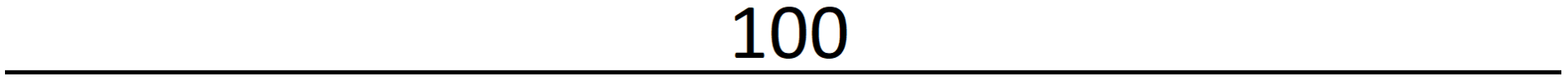
Introduction to Diabetes

- Diabetes affects nearly 200 million people worldwide and comes in two flavors
  - A deficiency in the pancreas to properly produce insulin (Type I), genetic
  - A deficiency in the body to absorb insulin (Type II)
- We've all heard the meme: There will be a cure in 5 years ™
- Insulin is a hormone required to sustain human life, so people with this disease must obtain it from another source
  - Long acting
  - Short acting

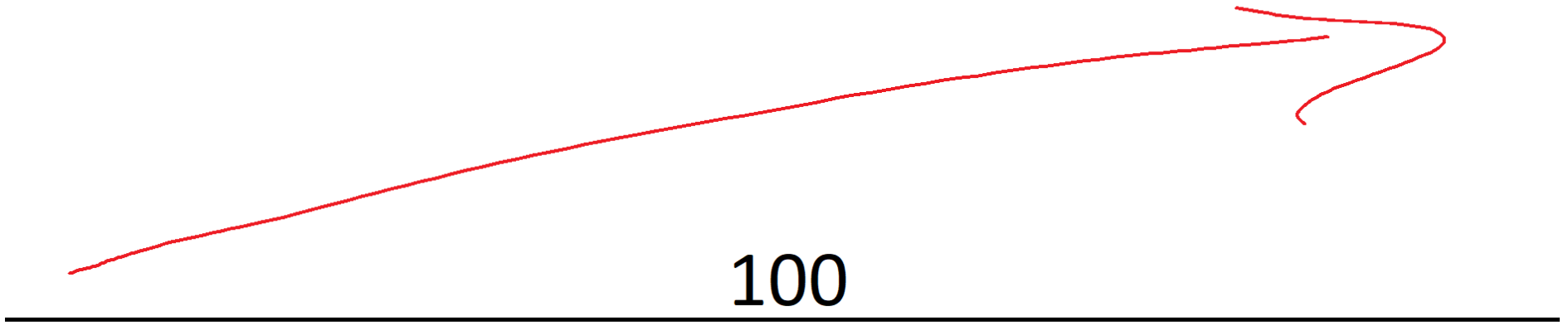
Introduction to Diabetes

- Administered according to a complex formula accounting for:
  - Carbohydrates
  - Physical activity
  - Sickness
  - Preexisting insulin levels
  - Adrenalin
  - Insulin Sensitivity
- Straddle a tenuous line between their blood sugar rising too high or dropping too low.

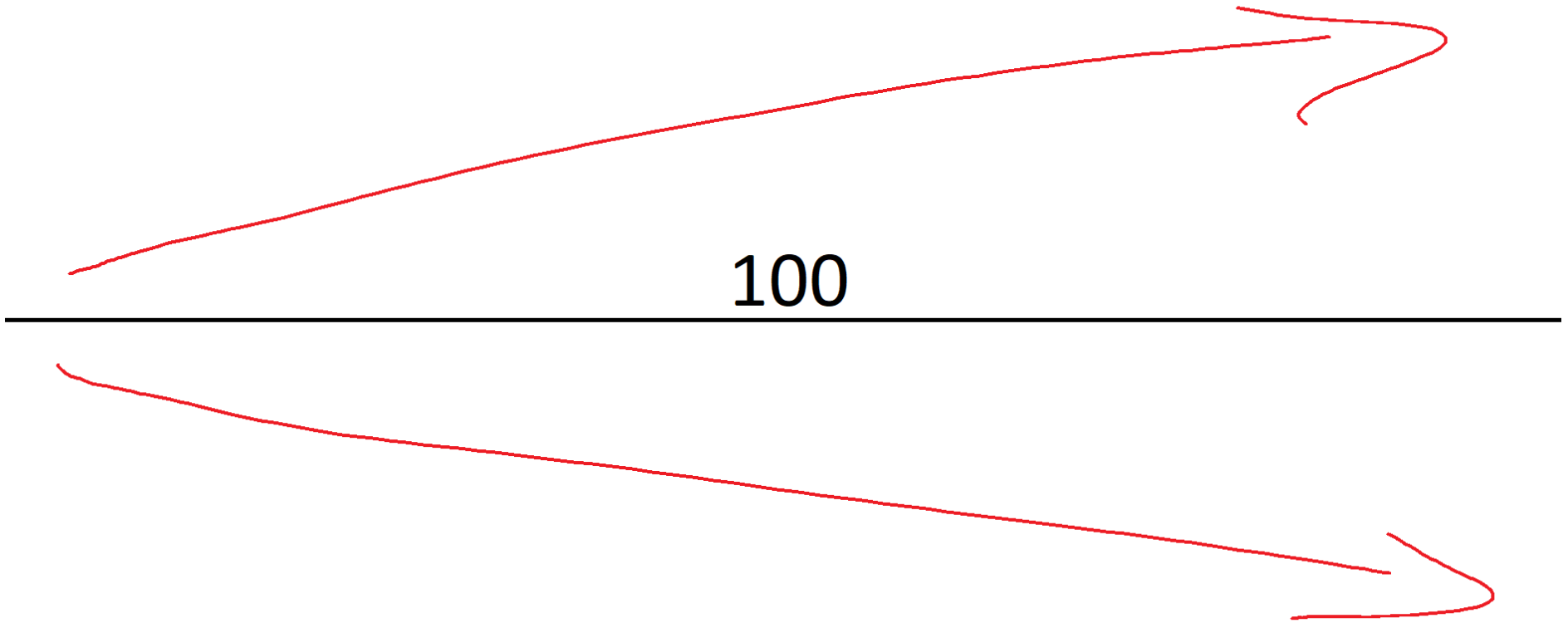
Introduction to Diabetes



Introduction to Diabetes



Introduction to Diabetes



Introduction to Diabetes

$$\frac{Carbohydrates + Sickness + Adrenalin}{Insulin + Exercise}$$

Introduction to Diabetes

$$\frac{Carbohydrates + Sickness + Adrenalin}{Insulin + Exercise}$$

- …ish
- You can’t measure all of these values
- You don’t know that the carbohydrates are going to hit your system at the same speed as the insulin, which could cause low blood sugar
- Sensitivity to insulin changes over time and is different in every person
- You have to maintain safety at night while you sleep – a 24/7 disease

Introduction to Diabetes

- How do you measure how well you're doing?
  - An A1c blood test measures a chemical related to your glucose levels over a period of about 3 months
  - In aggregate, it's a good approximation of how close your average blood sugar has been over that time
  - Blood sugar fluctuates during the day due to eating, so you have to maintain control because it affects your A1c
  - Blood sugar should not fluctuate wildly during sleep, so if you do well over night you get that measurement improvement "for free" since you're not eating while your range is maintained

Introduction to Diabetes

- Some technology exists to make it easier to maintain some form of control over blood sugar
  - Largely go toward easing the burden of monitoring and managing symptoms
  - None of these solutions take a decision-making role in management of the disease
- Injections: people used to give themselves multiple injections of different kinds of insulin per day
  - Use an insulin pump to both slowly dose background insulin throughout the day and to give themselves larger (but riskier!) doses required at meals
  - Worn for days at a time, eliminating multiple painful injections throughout the day and reducing a lot of medical waste

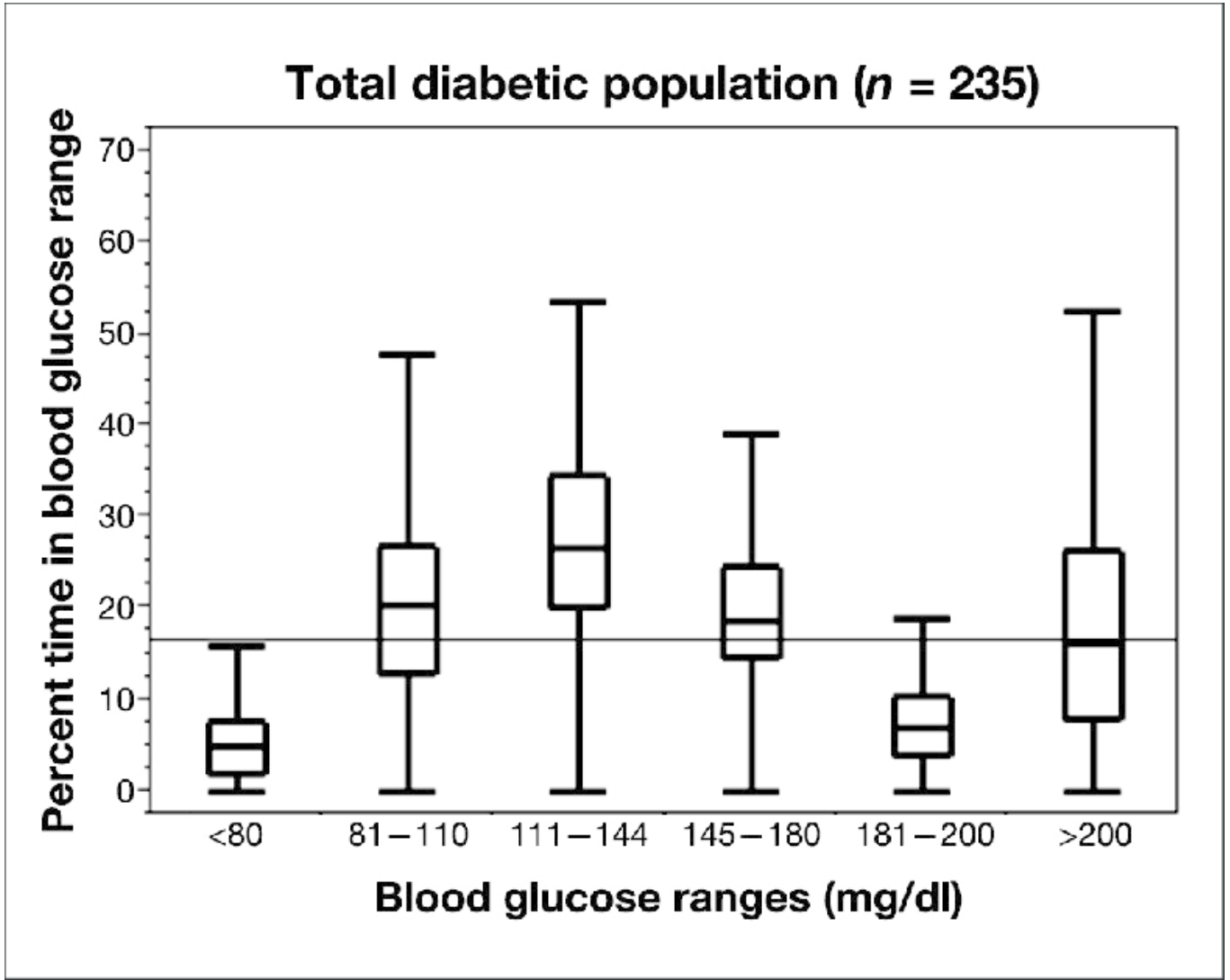
Introduction to Diabetes

- Blood Glucose Measurement: Most patients still must use some finger sticks to draw blood to check their blood sugar
  - A point-in-time measurement lacking real-world context like trend direction
- Continuous Glucose Monitor (CGM): Sensor that stays attached to you for days at a time
  - Takes a reading every five minutes, exposing trends
  - The CGM receiver alarms when readings venture outside of pre-set parameters
  - Wake the patient up at night to take needed action to raise or lower their blood sugar back to safe levels

Introduction to Diabetes

- No bedtime snacks, you don’t know what’s going to happen while you sleep
- You intentionally go to bed on the higher end of the scale, but not too high, because your glucose will be pushed down by the unthinking insulin pump and you don’t want to alarm or wake up too low
- Every meal, even meals you have often that are usually predictable, can become an hours long battle to get back to normal
- Rule of thumb: If you wake up too high there is no recovery to a good state during the day

Introduction to Diabetes



jay@lagor.io

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Hardware

It must be restated:

None of the FDA-certified components take action on behalf of the patient and a human is still required to be in the loop.

Hardware

- We need to develop a solution that:
  - Takes the data from the CGM
  - Processes it with what it already knows about our bodies and current state
  - Predicts future effects based on existing state, proposed changes, and medication calculations
  - And delivers a command to an insulin pump to do something other than deliver regular, unchanging background insulin.

Hardware

- This requires us to overcome four technical challenges:
  - We need a small, low-power and portable platform that the user can easily bring with them through their day to do all of this.
  - A visualization solution that allows us to monitor the system both historically and as it works in real-time is required to monitor the status of the solution.
  - We need to collect blood sugar readings from an FDA-certified CGM system.
  - We need to be able to query and control an FDA-certified insulin pump.

Hardware

- The Raspberry Pi, particularly the Pi Zero, and Intel Edison are ultra-portable platforms that make phenomenal solutions on which to run our code
- Each has built-in Bluetooth and Wi-Fi making it easy to connect them to known networks or tether them to a cell phone when not at home without needing extra attachments
- We can collect CGM data over Bluetooth without having to plug the manufacturer-provided receiver into the board, although that remains an option with USB OTG

Hardware

- Our CGM and platform problems solved, the Open Source hardware community stepped in and created two solutions to the pump problem.
  - The Explorer Board for the Intel Edison
  - Explorer HAT for the Raspberry Pi
- 900 MHz radios that while advertised as general-purpose ISM band radios communicate with the insulin pumps using the proprietary protocol
- Protocol reverse engineered by a community member over the course of several years: @bewestisdoing

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Software and Safety

- Our visualization software solution stack:
  - Node and Go
  - Mongo
  - Python and Bash
- Nightscout is a purpose-built visualization and web-based data warehousing platform built on Mongo and Node designed specifically for remotely monitoring the well-being of a diabetic, whether yourself or those under your care.

Software and Safety

- Each person builds their own Nightscout instance
  - Heroku or Azure, free tier plans
  - You can run it on private infrastructure if you have that option available to you
- Nightscout is good for point-in-time representation about things now
- Also useful it to give our solution some insight into our actions so it can make treatment decisions
- Serves as a great reporting tool that can be used to generate charts and reports to bring to routine medical appointments

Software and Safety

- The Open Artificial Pancreas System, or OpenAPS
- Node, Python, Go, and Bash suite of components that runs on Linux
- Designed to acquire CGM data, process it using an algorithm and deliver a dosage command to an insulin pump
  - More than 1,440 people are using this around the world
  - 13.7M person-hours of algorithm experience combined

Software and Safety

- A person can be expected to do the equation just several times per day
- OpenAPS processes data and can make dosing decisions every five minutes
  - That's 288 times per day
  - Including, most importantly, while the patient is sleeping
- Better decision making than the patient because even more can be taken into account
  - Insulin Absorption Modelling: Uses the manufacturer's equations to predict impact
  - Autotune: Tunes the algorithm to carbs and insulin over weeks
  - Autosens: Tunes the algorithm to your body over the last 24 hours
- Advance warnings: Tells you how much to eat as a correction to keep up

Software and Safety

- Can normally be expected to wake up at least once or twice every night to alarms requiring action
  - OpenAPS works to keep the patient in range without intervention
  - Sleep is one particular area of life that improves dramatically almost immediately
- A sleeping patient isn’t eating so it’s easy for the system to maintain them within range
- Good time in range, especially at night, improves A1c measurement without any work on their part as well

Software and Safety

Dr. Holly Witteman
@hwitteman

I slept so well. 100% in range. No buzzing, no alarms. If this keeps up, this is going to be life-changing. Thank you again to everyone in the #WeAreNotWaiting community who has generously worked to make this possible for others.

1:28 PM · Jul 23, 2019 · Twitter for iPhone

2 Retweets **30** Likes

Software and Safety

- While under development, users and maintainers have been building the plane while flying it.
- Safety is a critical factor in the way changes and features are implemented because it’s important that this doesn’t cause someone to be hospitalized
  - Several checks and double checks are made before making dosing decisions
  - Fallback behaviors are defined
  - Features that may impact the algorithm are scrutinized heavily

Software and Safety

- New failure modes are well defined:
  - OpenAPS is out of range of the source of glucose readings
  - OpenAPS is out of range of the insulin pump
  - A process running on the OpenAPS device dies and needs to be restarted
  - Power loss in one or more devices
- Commands are delivered so the pump reverts to normal, factory behavior when one of these failure modes occurs
- During sleep the manufacturer-provided CGM receiver can be used as a secondary safety system to sound an alarm if the blood sugar levels go out of a defined range

Software and Safety

- Normal care routines operate by making large drastic changes that can’t be undone in both carbohydrates and insulin intake
  - Eating 60g of carbohydrates? That might be 6.6U of insulin
- One indirect safety factor that was discovered through use of the system makes sense when thought to its logical conclusion:
  - Making very small changes every five minutes allows the system to self-correct after just five more minutes if the situation should suddenly change
  - Sudden rapid rise? Add more insulin
  - Sudden unexpected descent? Suspend delivery

Software and Safety

- Key during meals: don’t take the entire insulin dose at the beginning of a meal and hope the body doesn’t process the insulin faster than the carbohydrates
  - Taking the whole dose has a non-zero chance of causing low blood sugar
- OpenAPS mimics the pancreas’s normal function
  - Slowly doses insulin as the body processes carbohydrates, keeps the patient’s blood sugar from extremes
- Lesser amounts of insulin in a person’s system at any given time reduces the overall likelihood they experience blood sugar drop

Software and Safety

- This requires us to overcome four technical challenges:
  - We need a small, low-power and portable platform that the user can easily bring with them through their day to do all of this.
  - A visualization solution that allows us to monitor the system both historically and as it works in real-time is required to monitor the status of the solution.
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Software and Safety

- This requires us to overcome four technical challenges:
  - We need a small, low-power and portable platform that the user can easily bring with them through their day to do all of this.
  - A visualization solution that allows us to monitor the system both historically and as it works in real-time is required to monitor the status of the solution.
  - **We need to collect blood sugar readings from an FDA-certified CGM system.**
  - We need to be able to query and control an FDA-certified insulin pump.

Software and Safety

Software and Safety

- Older insulin pumps that have wireless connectivity allowed the manufacturer to use a proprietary protocol to communicate with the pump.
- Discovered and turned into a Black Hat talk in 2013 with an emphasis toward how this could be misused
- Manufacturers significantly limited how this functionality could be used on newer pumps.
- This wrinkle requires us to find and purchase older, used pumps and to use custom hardware and software.

Software and Safety

- Medtronic stopped manufacturing pumps that were remotely controllable, but did not recall the devices
- Older devices are already hard to acquire:
  - eBay
  - Craigslist
  - Mercari
  - MedWOW
- Price gouging galore: started at ~$300, skyrocketed to > ~$1000
- After the FDA warning about unapproved uses of medical devices, meaning CGM algorithms, another bomb drops

Software and Safety

CNN Health » Food | Fitness | Wellness | Parenting | Live Longer Live TV U.S. Edition +

Medtronic recalls MiniMed insulin pumps as FDA warns about hacking risk

By **Jacqueline Howard**, CNN

Updated 5:07 PM ET, Thu June 27, 2019

Software and Safety

```
512/712 (all firmware)
515/715 (all firmware)
522/722 (all firmware)
523/723 (with firmware 2.4A or lower)
554/754 (European Veo, with firmware 2.6A or lower; OR Canadian Veo with firmware 2.7A or lower)
```

As listed on the FDA's website, Medtronic is recalling the following insulin pumps:

- MiniMed 508 (with all software versions)
- MiniMed Paradigm 511 (with all software versions)
- MiniMed Paradigm 512/712 (with all software versions)
- MiniMed Paradigm 515/715 (with all software versions)
- MiniMed Paradigm 522/722 (with all software versions)
- MiniMed Paradigm 522K/722K (with all software versions)
- MiniMed Paradigm 523/723 (with software version 2.4A or lower)
- MiniMed Paradigm 523K/723K (with software version 2.4A or lower)
- MiniMed Paradigm 712E (with all software versions)
- MiniMed Paradigm Veo 554CM/754CM (with software version 2.7A or lower)
- MiniMed Paradigm Veo 554/754 (with software version 2.6A or lower)

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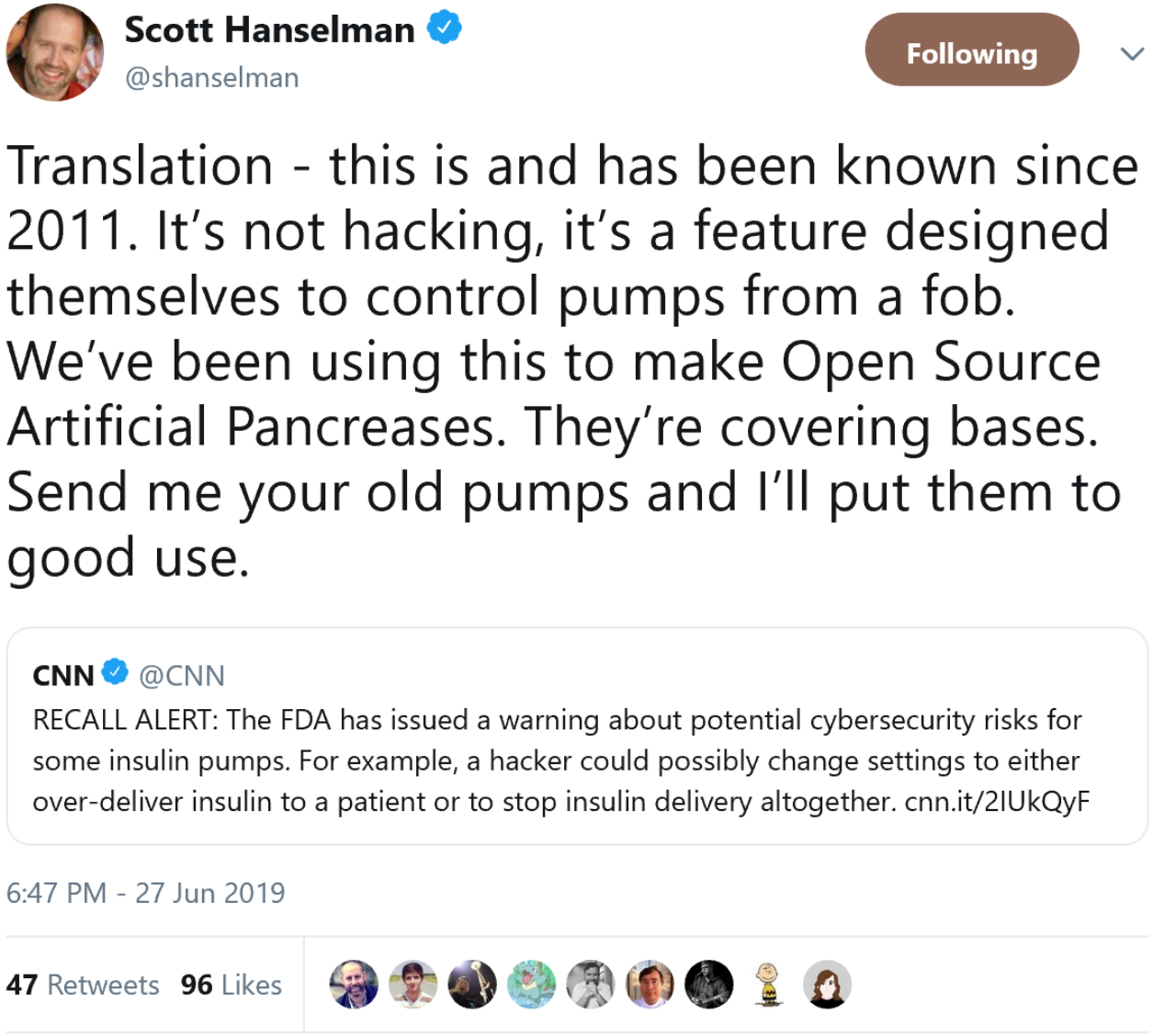
Software and Safety



Software and Safety

Weronika Burkot
@Blue_Sugar_Cube

Hackers Made an App That Kills to Prove a Point
wired.com/story/medtroni... #OpenAPS #Looping #T1D #type1diabetes #typeonediabetes #DIYpancreas #WeAreNotWaiting

Hackers Made an App That Kills to Prove a Point
Medtronic and the FDA left an insulin pump with a potentially deadly vulnerability on the market—until researchers who found the flaw showed how bad it could be.
wired.com

5:33 AM · Jul 18, 2019 · Twitter Web Client

TWO YEARS AGO, researchers Billy Rios and Jonathan Butts discovered disturbing vulnerabilities in Medtronic's popular MiniMed and MiniMed Paradigm insulin pump lines. An attacker could remotely target these pumps to withhold insulin from patients, or to trigger a potentially lethal overdose. And yet months of negotiations with Medtronic and regulators to implement a fix proved fruitless. So the researchers resorted to drastic measures. They built an Android app that could use the flaws to kill people.

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Iterative Improvements

- Several implementations built over the last three years
- Assemblies range in size
  - Large, requiring a shave kit bag modified to strap the components to the inside
  - Small, enough to fit unnoticed in a pant leg pocket.
- Each iteration and choice of component reduced the size, improved portability and battery life
  - Building the plane while flying it
- Contributed to OpenAPS projects adding improved compatibility with FDA-certified devices, reduced friction around installing the system

Iterative Improvements

- Implementation and improvement of an interactive setup script
- Maximum flexibility around connectivity
- The systems work without requiring a connection to the Internet when one isn’t available
- When Internet connectivity returns the device drops all of the data from the time it spent disconnected into Nightscout to aid in later analysis
- As long as it gets time when it starts up it doesn’t need to be connected to the Internet continuously

Iterative Improvements

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Iterative Improvements

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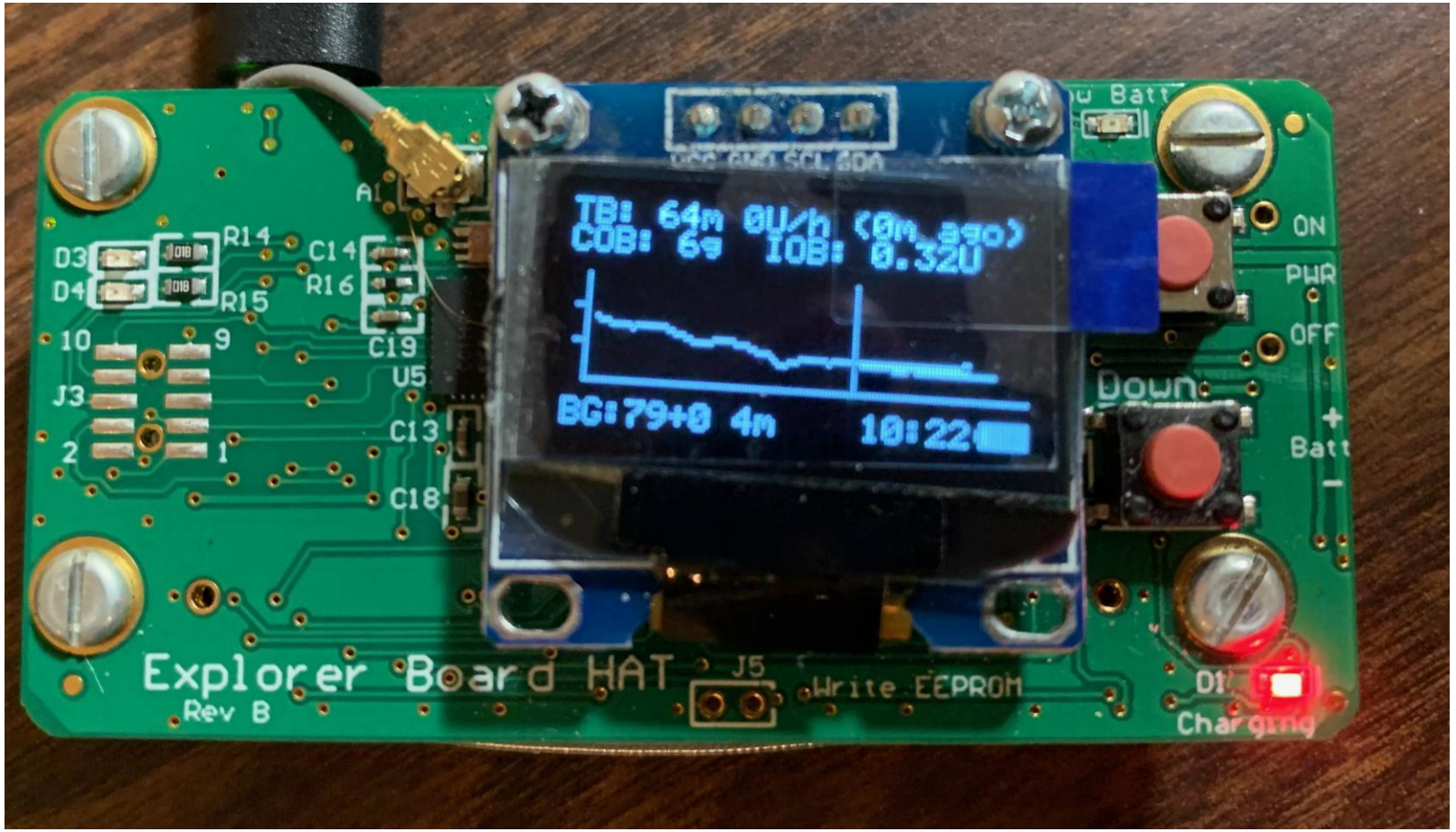
Iterative Improvements

Iterative Improvements



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Iterative Improvements

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Live Demo

- Show Nightscout

Live Demo

- Show loop log
- Show CGM log

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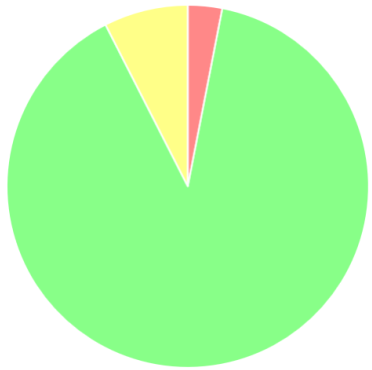
Glucose distribution (90 days total)

Range	% of Readings	# of Readings	Average	Median	Standard Deviation	A1c estimation*
Low (<80):	0.0%	0	N/A	N/A	N/A	
Normal:	69.4%	4820	150.4	152.0	17.7	
High (>=180):	30.6%	2127	200.8	197.0	16.7	
Overall:		6947	165.9	163.0	29.1	7.4%$_{DCCT}$ | 57$_{IFCC}$

Mean Total Daily Change	Time in fluctuation (>5 mg/dl/5m)	Time in rapid fluctuation (>10 mg/dl/5m)
748.43 mg/dl	10.0%	2.0%
Mean Hourly Change	**GVI**	**PGS**
31.18 mg/dl	1.19	60.08
Out of Range RMS		
14.82 mg/dl		

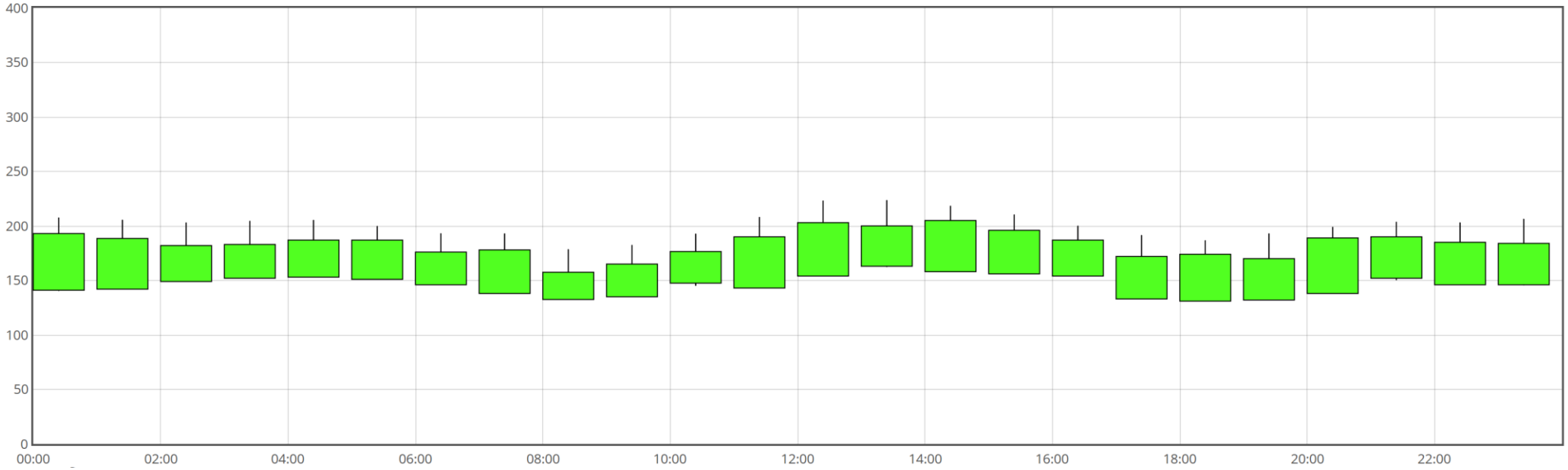
Glucose distribution (90 days total)

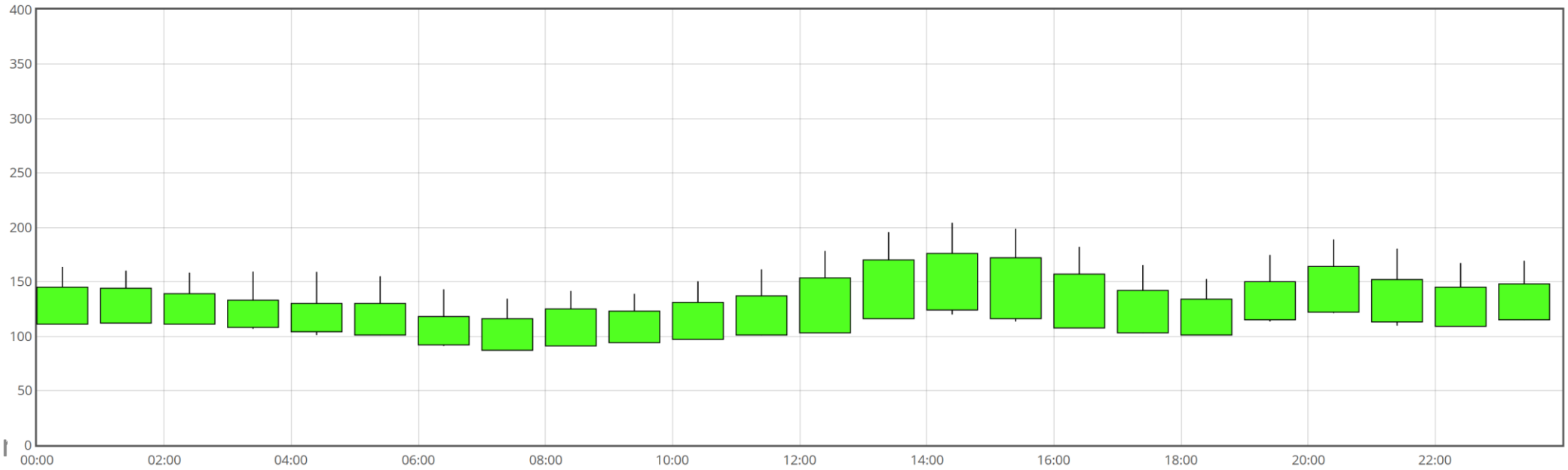


Range	% of Readings	# of Readings	Average	Median	Standard Deviation	A1c estimation*
Low (<80):	3.1%	1089	72.4	75.0	7.4	
Normal:	89.4%	31853	123.1	120.0	23.5	
High (>=180):	7.5%	2674	205.0	198.0	24.1	
Overall:		35616	127.7	122.0	33.2	6.1%$_{DCCT}$ | 43$_{IFCC}$

Mean Total Daily Change	Time in fluctuation (>5 mg/dl/5m)	Time in rapid fluctuation (>10 mg/dl/5m)
789.97 mg/dl	11.0%	3.0%
Mean Hourly Change	**GVI**	**PGS**
32.92 mg/dl	1.24	16.69
Out of Range RMS		
9.71 mg/dl		

Hourly stats





Results

Date	A1c	A1c Est
9/4/2008	16.5	
11/24/2008	6.2	
3/16/2009	7.0	
10/29/2009	7.1	
5/19/2010	6.9	
9/8/2010	6.9	
4/28/2011	7.1	
8/8/2011	7.2	
9/18/2012	6.6	
4/30/2013	6.9	
9/10/2013	7.1	
6/17/2014	7.3	
1/29/2015	6.6	
6/2/2015	6.7	
7/29/2015	7.2	
12/10/2015	7.5	
3/15/2016	7.3	
11/29/2016	6.7	6.5
8/8/2017	6.2	6.4
2/9/2018	6.2	6.4
1/22/2019	6.3	6.1

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Results

- Industry changes
  - Previously all integrated systems were monolithic systems

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MiniMed 530G MMG5NABI with Enlite 551 Purple

Add Your Review | **SKU:** MNMMG5NAPI | **Brand:** Medtronic Minimed

$ 7 800.00 USD & **FREE SHIPPING**

Quick Overview

- Automatically stops insulin delivery!
- Comfortable and accurate!
- Identify trends!

Results

- Industry changes
  - Previously all integrated systems were monolithic systems

Results

- Industry changes
  - Discrete CGM, pumps, and algorithms that all work without collective FDA approval
  - iCGM
    - Dexcom G6 is the first certified product

Results

- Industry changes
  - ACE (Alternate Controller Enabled)
    - An insulin pump, but works with an iCGM and iController
    - Tandem t:slim X2 is the first certified product

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Results

- Industry changes
  - iController
    - The algorithm, brings together iCGM and ACE to autopilot the plane for the patient
    - No certified products yet, but Tidepool is trying to get an FDA certified version of Loop, Tandem is attempting to push an integrated TypeZero product at the end of the year

Tidepool Loop, one year in: A development update

Christopher Snider on February 11, 2020

This post will cover everything about Tidepool Loop that we can cover, and there's a lot.

Results

Results

#WeAreNotWaiting

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- Questions?

Exponential Growth

- Everyone needs insulin, this is a biological fact
- Lack of the hormone is not a question of lifestyles, choices, or what the person could have done better
- This lightning strike could happen to anyone in this room
- People without it die, no question
  - Just like water
  - Just like air
- Most have it, some don’t: creates an economic opportunity

Exponential Growth

Your money or your life, kid

Exponential Growth

Insulin's High Cost Leads To Lethal Rationing

September 1, 2018 · 8:35 AM ET
Heard on Weekend Edition Saturday

BRAM SABLE-SMITH

"It shouldn't have happened," says Nicole Smith-Holt of Richfield, Minn., gazing at the death certificate of her son Alec Raeshawn Smith.

Bram Sable-Smith for NPR

Exponential Growth

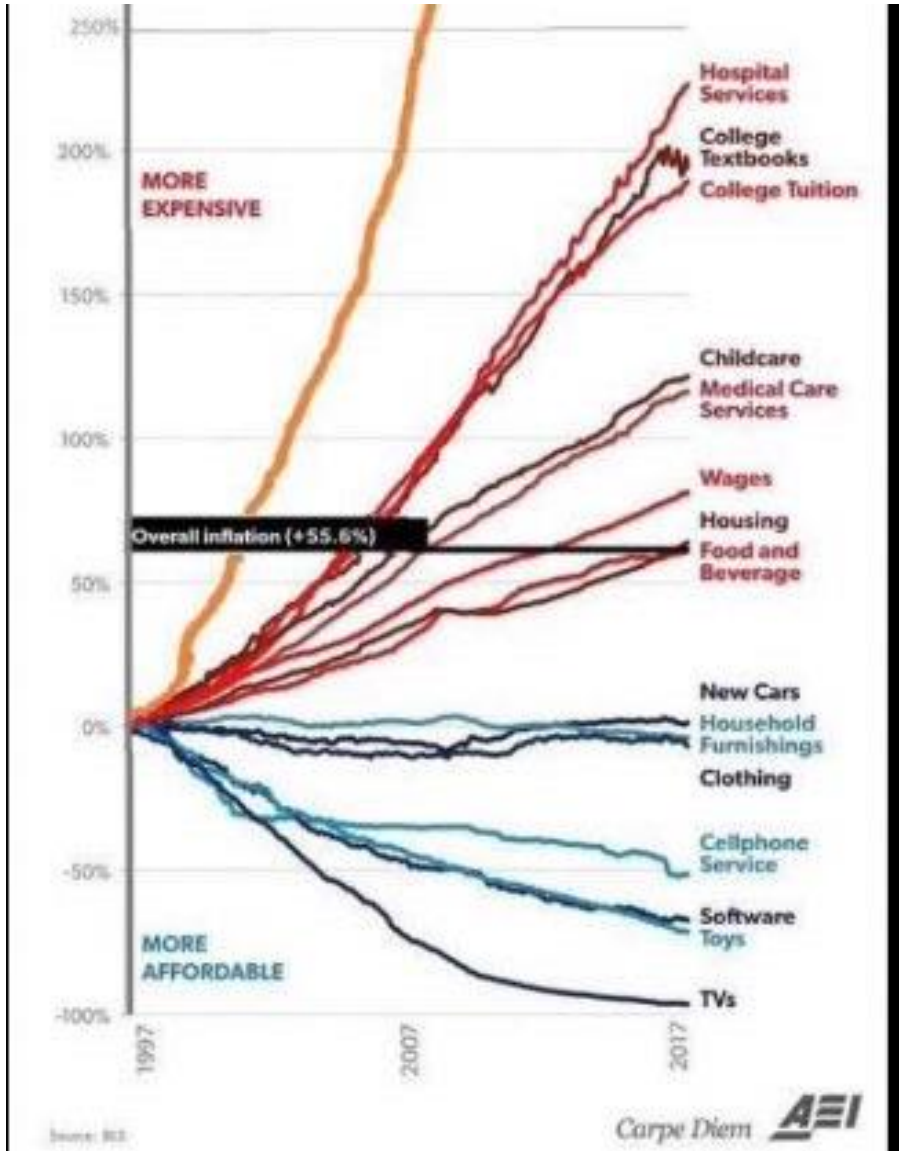
By ANNA WERNER / CBS NEWS / *April 10, 2019, 6:46 PM*

"People are dying": Diabetics rationing insulin amid rising drug prices

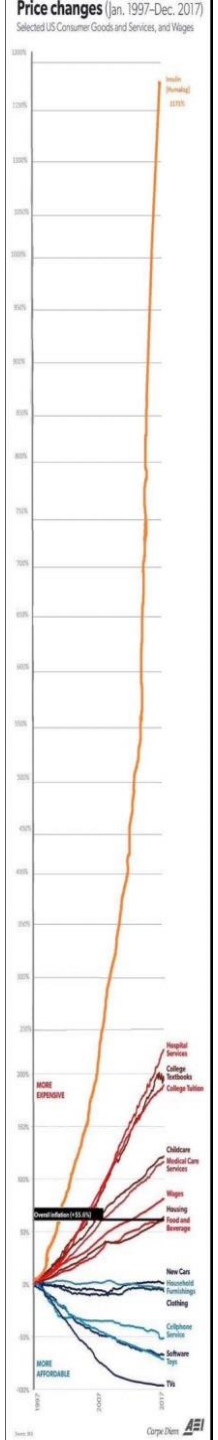
Share / Tweet / Reddit / Flipboard / Email

Exponential Growth

Exponential Growth

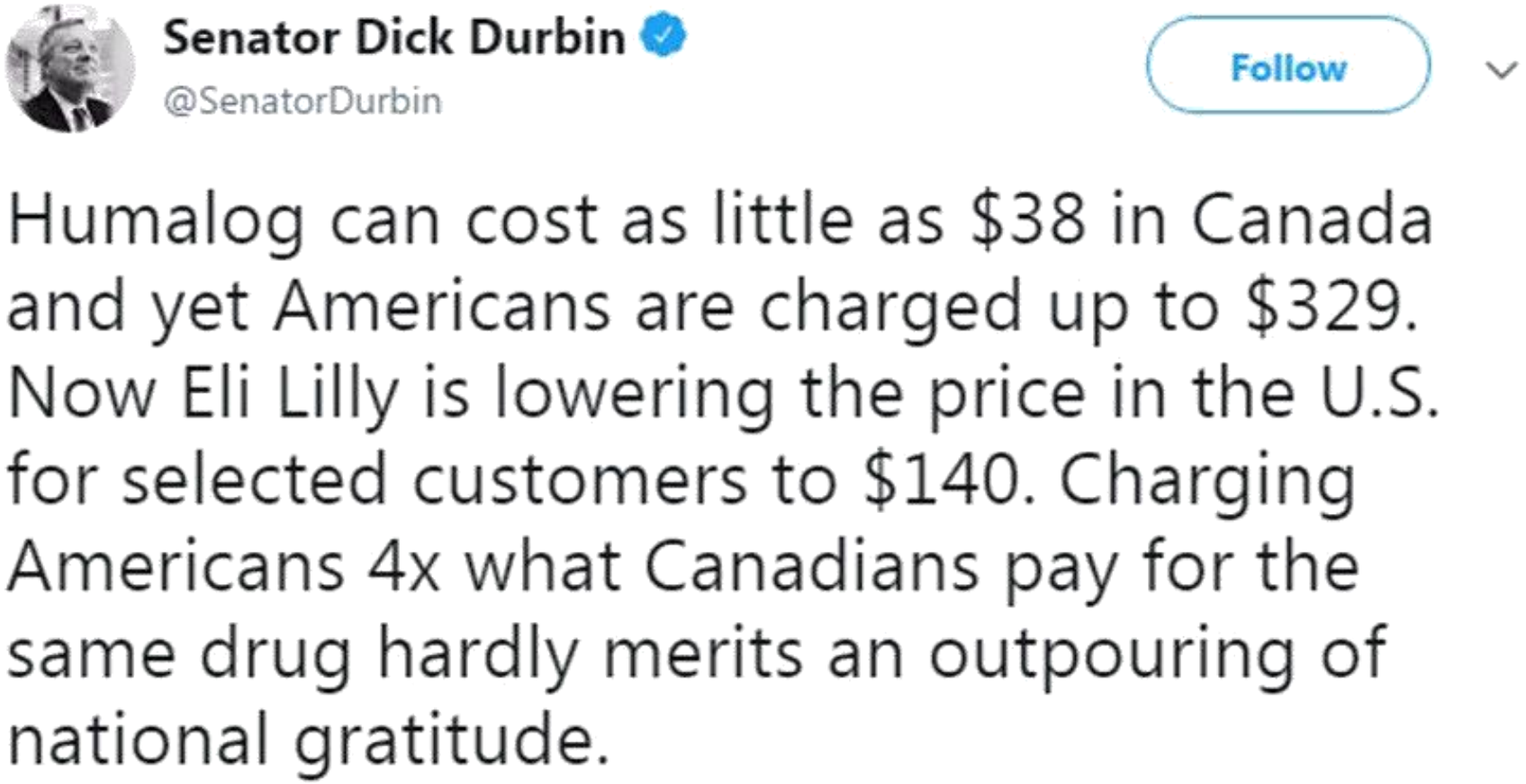


Exponential Growth



jay@lagor.io

Exponential Growth



Acknowledgements

- Ben West (@bewestisdoing)
- Dana M. Lewis (@danamlewis) and Scott Leibrand (@scottleibrand)
- Scott Hanselman (@shanselman)
- Xdrip-js (@thebookins, @efidoman, @ecc1, @mhaeberli, @pietergit, @cluckj, @jpcunningh)
- Milo (@sulkaharo)
- Nightscout (@WeAreNotWaiting, @sulkaharo, @PieterGit, @jasoncalabrese)
- T Schlussel, Andrew & B Holt, Danielle & A Crawley, Eric & B Lustik, Michael & Wade, Charles & Ft Uyehara, Catherine. (2011). Effect of Diabetes Mellitus on Outcomes of Hyperglycemia in a Mixed Medical Surgical Intensive Care Unit. Journal of diabetes science and technology. 5. 731-40. 10.1177/193229681100500328.
- Dr. L.

Agenda

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- Introduction to Diabetes
- Hardware
- Software and Safety
- Iterative Improvements
- Live Demo
- Results
- Exponential Growth
- Questions?

Questions?

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