Diabetes Technology Update for 2018: New Pumps, Continuous glucose monitors and Insulin pens

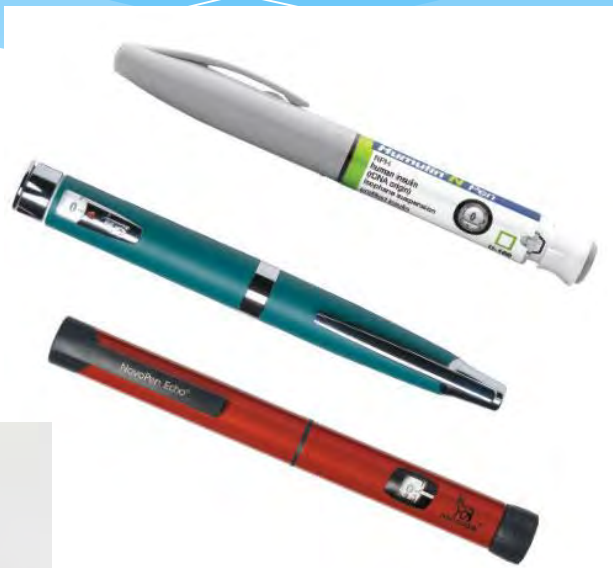
Kimberly Barnes RN, BSN

Diabetes Educator and Charge Nurse for the Vanderbilt Eskind Pediatric Diabetes Clinic

Objectives:

- Promote Understanding of existing and new technologies in the treatment and management of patients with diabetes including Insulin Pumps, Continuous Glucose Monitors, and insulin pens.
- Identify components of an insulin pump and how it works.
- Identify components of a Continuous Glucose Monitor and how it works
- Advantages and Disadvantages of insulin pump therapy
- What does the future hold?????

Times are changing!



Insulin Pumps

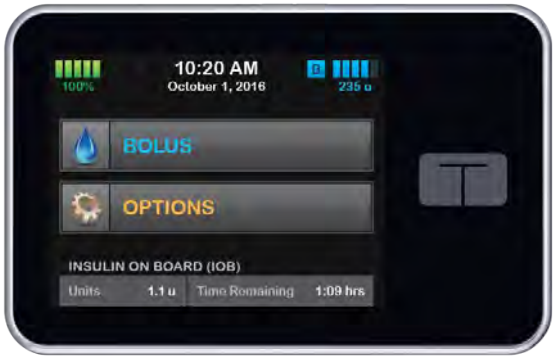
- The first insulin pump was developed in the late 1960's/early 1970s
- Little early excitement due to concerns from size, safety, efficacy and complications

Early Insulin Pumps

Insulin Pumps Available in the US Today

Components of Insulin Pump

- Insulin Pump



Components of an Insulin Pump

- Reservoir: Holds the insulin

Components of an Insulin Pump

- Infusion Set: What is inserted in the body and is changed every 2 to 3 days

Basics of Insulin Pump Therapy

- **Basal rate**
  - Continuous flow of insulin from pump to patient
  - This is background insulin
  - Controls blood glucose in a fasting state.
  - Different rates can be programmed throughout the day to deal with variable need
  - It mimics the steady and small amount of insulin secreted by pancreas throughout day and night
  - Very precise delivery

Basics of Insulin Pump Therapy

- **Bolus**
  - Insulin given at meals to "cover" food eaten and correct elevated blood glucose levels
  - **Insulin to Carb Ratio:** example) 1 unit of insulin taken for every 15 grams of carbs.
  - **Correction/Sensitivity**: amount of insulin given to correct for high blood glucose levels. Think of it as the sliding scale or correction
  - **Target Blood Glucose:** the blood glucose level you are aiming for
  - **Insulin Action/Active Insulin Time:** Affects the amount of correction that can be given and helps to prevent 'stacking' of correction boluses that can lead to lows. It will calculate how much active insulin is on board and not allow extra to be given. The usual setting is 2 to 4 hours.

Advantages of Pump Therapy

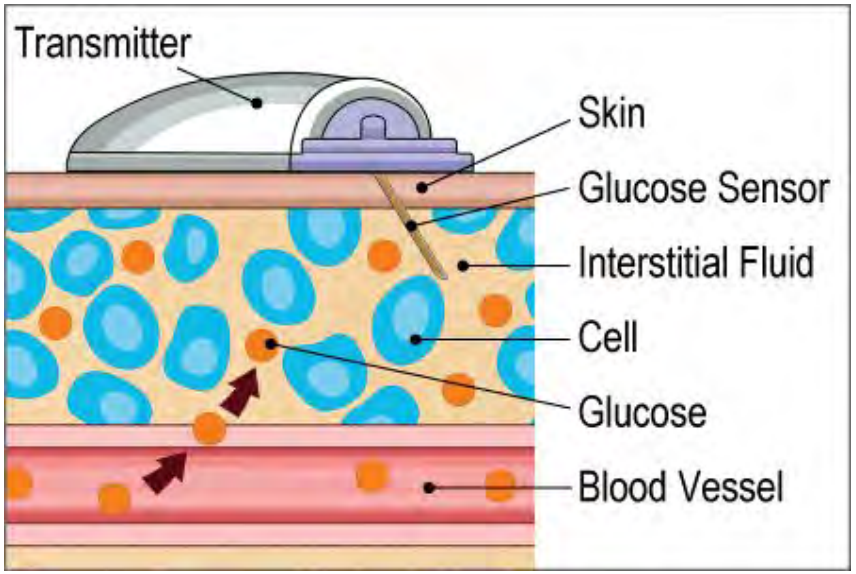
- Using an insulin pump means eliminating individual insulin injections: LESS SHOTS!
- Pumps deliver insulin more accurately and precisely than injections
- Ideal for athletes/exercise to decrease insulin delivery during an event or after through Temp Basal Rates
- Meal time doses can be delivered over a period of time instead of all at once—i.e. Extended boluses for high-fat/high carb meals
- Insulin pumps often improve A1C and glycemic control

Disadvantages of Pump Therapy

- Increased risk for Diabetic Ketoacidosis (DKA): Pump only delivers short acting insulin so there is a potential for rapid onset of significant hyperglycemia and DKA if insulin delivery is interrupted
- Risk for site infection
- Something is always attached to the person
- Cost (pump $4500-$8500+; yearly supplies ~ $1,500.) That does not include the cost of sensors.

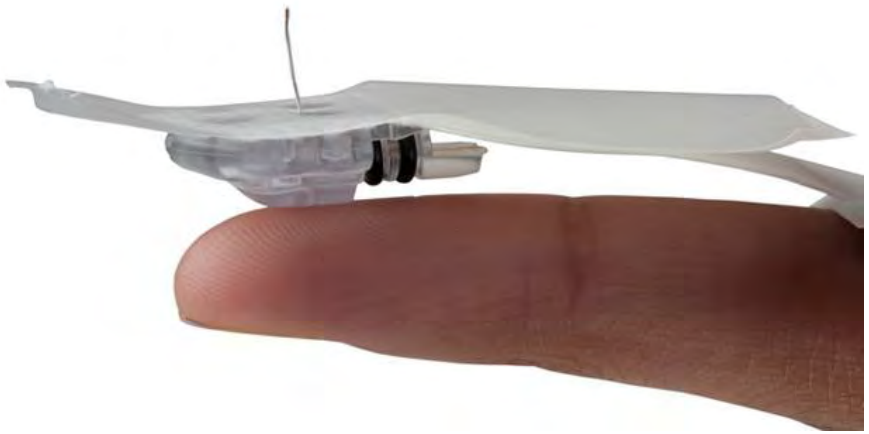
Continuous Glucose Monitoring System (CGM)

- Measures the Glucose in the body's interstitial fluid
- Not the same thing as a finger stick
- Interstitial Glucose levels lag behind blood glucose levels by 15-20 minutes.



Three Parts to a CGM: The Sensor

- Worn on the body, inserted with a needle and changed out every 7-10 days.
- The Sensor under the skin is the thickness of an eyelash.



Three Parts to a CGM: The Transmitter

- The Transmitter hooks into the sensor and sends all the glucose information to the receiver/monitor.
- This is the expensive part of the system and reused with each new sensor.

Three Parts to a CGM: The Receiver

- The Receiver has a screen where you can check your current glucose level, look at historical data, and get trends about whether the glucose is likely to go up or down and how fast.
- Can be a traditional receiver, a phone or an insulin pump.

Continuous Monitoring Systems: What makes them better than finger sticks?

- Throughout the day, the wearer can look down and see what their glucose value is within a 90% accuracy.
- Perhaps even more valuable than the immediate glucose level is the direction and speed at which glucose levels are heading.

Continuous Glucose Monitoring Systems

- The wearer can be alerted when they go above a preset high glucose level as well as a pre-set low glucose level.
- Advanced alerts can also be set to alert the wearer when they are dropping or rising at certain rates.
- We usually recommend just the High and Low Alerts. Typically our patients will not have their Advanced Alerts turned on as they tend to go off a lot and "drive kids crazy."

Continuous Glucose Monitoring Systems

- Key Point to Remember:

  The Systems being used today are accurate enough that they can replace finger sticks throughout the day and/ or insulin can be dosed off the readings.

Continuous Glucose Monitoring Systems on the Market

Dexcom G5 Sensor

- Worn for 7 days
- Provides real-time glucose readings every 5 minutes
- Patient can use a receiver or a phone to receive their data and alerts.
- If patient is using a phone as a receiver, up to 5 people can follow them on their phones and receive real-time glucose readings and alerts on their phones as well.

Dexcom G5 Sensor

- FDA approved system, for ages 2+, to replace finger sticks throughout the day:
  - If the wearer is calibrating the sensor, meaning entering a finger stick glucose into the sensor to update it, every 12 hours, the Dexcom Reading may be used in replace of a finger stick at other times throughout the day
  - We recommend calibrating each morning before breakfast and each evening before dinner. Bedtime calibrations are often done as well.

Dexcom G5 Sensor

- The FDA has approved the Dexcom Readings can also be used for treatment decisions.
  - The wearer can use the Dexcom reading to enter into their insulin pump for insulin dosing.
  - If not on an insulin pump, the reading can be used for determining sliding scale/correction insulin before meals.
  - The trend arrows can also be used to determine if less or more insulin is required before a meal or snack as well.
  - Can not use acetaminophen while wearing

Dexcom G6

FDA approved May 27, 2018

- No Fingerstick Calibrations: FDA approved to use and no fingersticks throughout the day.
- Water resistant, 10 day wear sensor
- Smaller Transmitter
- One button push inserter
- No contraindication to Tylenol.

Dexcom Sensor: Apps

Dexcom G5/G6 Mobile App

App on the child's phone to receive the real-time glucose data

Dexcom Clarity app

App on child's phone, Allows medical professionals and families to track and download data and reports

Dexcom Follow App

For the followers phone

Dexcom G5/G6 Sensor: Watch Integration

- The Dexcom G5 and G6 Mobile Apps support Apple Watch or Android Wear watches and can be used to discreetly view your glucose reading, trend arrow, and trend graph
- Phone must be carried when linked to watch. The Dexcom Transmitter must first be connected to phone and then the phone connects to the watch.

Dexcom G6 Sensor: Future Watch Integration

- The new **Apple watchOS 4** software upgrade will allow the Apple watch to be used as a receiver without a phone being nearby.
- The **Fitbit Ionic Smartwatch** will also begin integration with Dexcom CGM. Initially the sensor data will be relayed through an app on the wearer's phone. The goal is for eventual direct communication from the transmitter to the watch.
- **To date, none of these interfaces have been opened up yet.**

Dexcom in the Future

- Dexcom is sharing its technology with various insulin pump makers as they are developing their own closed loop systems (artificial pancreases).
- The FDA has just approved Dexcom G6 integration with the Tandem tSlim X2 pump know as Basal IQ which we will discuss more later.

FreeStyle Libre Flash Glucose Monitoring System

- Fully disposable system consists of a tiny insertable sensor and a patch about the size of a quarter worn on the arm for up to 10 days.
- The patch records glucose data every 15 minutes.
- Using a special reader, the wearer can scan the patch with NFC technology, checking their glucose as often as they want. A scan also gives eight hours of historical data and trend information.
- Eliminates the need for routine finger sticks and does not require finger stick calibration.

FreeStyle Libre Flash

- Receive glucose readings through clothing, making testing more convenient and discreet.
- Water-resistant, and can be worn in the shower and during swimming.
- Approved for ages 18 and above.
- No alerts or alarms based on glucose readings
- No data sharing at this time.

- Biggest Benefit Cost!

  With no insurance coverage:
  Reader is one time cost of $84
  Each Sensor is $43.

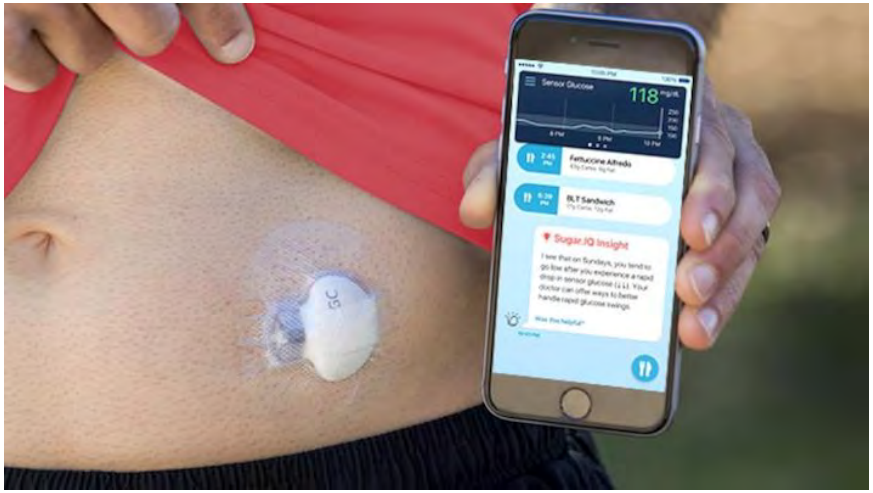
- Can be purchased at CVS, Kroger, Walgreens or Walmart

Medtronic Guardian Connect Continuous Glucose Monitor

- Stand alone sensor that utilizes the Guardian 3 sensor and transmitter
- Communicates with Guardian connect app on patient's mobile device (only Apple phones at this time)

Medtronic Guardian Connect

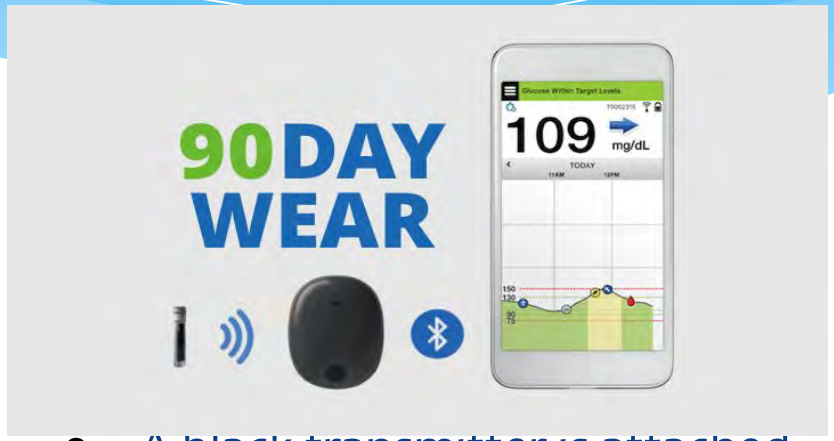
- Customizable low and high alerts
- Trend arrows and sensor graph
- Patient can log insulin, carbs, and exercise via app
- Caregiver Data-Sharing



- When used with Sugar.IQ™ diabetes assistant app, IBM Watson™ technology continually analyzes a patient's glucose and how they are reacting to food, insulin and other factors.
- Sugar.IQ™ provides pattern insights to patients via app for trends that are identified.

Eversense:

The first long-term continuous glucose monitor (CGM) that is implanted under the skin



- A tiny sensor, the shape of a rod and about the thickness of a Tylenol tab, is implanted under the skin in a 10 minute procedure in the doctor's office.
- 24 hour warm up period, but then is worn for 90 days.
- 2 Finger stick calibrations are required daily.
- Approved for ages 18 and above

- A black transmitter is attached with adhesive over the sensor and can be removed as often as needed for showering and sports.
- Transmitter must be charged daily for 10-15 minutes.

Eversense

- Transmitter on body will vibrate to alert wearer of highs and low.
- Along with the traditional Low, High and Rate of Change alerts, the Eversense can provide predictive alerts either via the on-body vibration feature or via the mobile app, which can give an audible alert or even flash a light to catch attention
- No receiver is needed, a smartphone (Android or Apple) is used as receiver

- Data-sharing capabilities with up to 10 people through the mobile app

Insulin Pumps on the market

Medtronic Insulin Pumps: MiniMed 670G System

Approved for ages 7 and older

- It is a Hybrid closed loop system
- Allows patient and Health Care provider to choose from increasing levels of automation that best fits their diabetes management needs
- New Guardian 3 Sensor, allows for 7 day wear
- Set Target of 120mg/dl

Medtronic Insulin Pumps: MiniMed 670G system

- It has the Smart Guard technology with the **Suspend before low feature**: avoids lows and rebound highs proactively by automatically stopping insulin 30 minutes before you reach your pre-selected low limits, then automatically restarts insulin when your levels recover, all without bothersome alerts.
- The **Auto Mode** option automatically adjusts your basal insulin delivery every 5 minutes based on your sugar levels to keep you in target range, all day and night.
- CONTOUR®NEXT LINK 2.4 meter links to pump provides remote set dose bolusing.

Medtronic Insulin Pumps: MiniMed 670G System

MiniMed 670G insulin pump modes and insulin delivery

	Manual Mode	Auto Mode Auto Basal delivery	Auto Mode Safe Basal delivery
Home screen display			

Medtronic Insulin Pumps: MiniMed 670G System

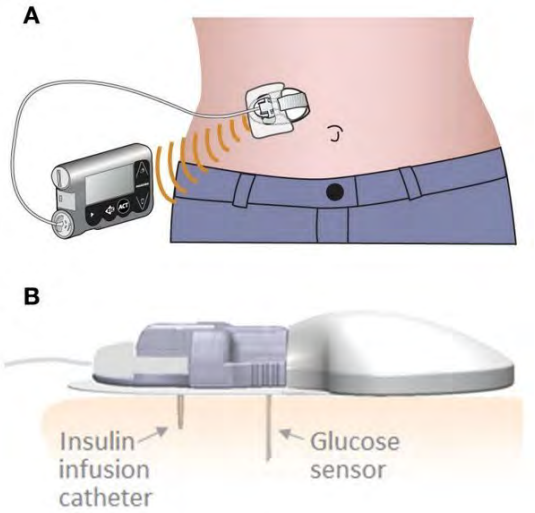
- The 670G is considered a "hybrid closed loop" system because it is not fully automated. The patient is still required to enter their finger stick glucose before meals and the total carbohydrates they will be eating throughout the day.
- It automatically adjusts basal insulin throughout the day based on the Guardian 3 sensor readings. It doesn't automatically give large correction boluses for elevated blood sugars.
- For example: If patient forgets to give insulin for a meal, they will still have elevated blood sugars. The basal rate will increase due to the elevation in blood sugars, but it won't automatically give a large correction bolus amount at one time.

Medtronic Insulin Pumps: Things to come

- Projected to hit the market in 2019/2020 is the next Medtronic Pump/Sensor combination that will allow for:
  - Target BG options of 100mg/ or 120mg/dl
  - Sensor glucose readings can be used in place of BG finger-sticks
  - Automatic correction boluses will be given in addition to increased basal for elevated glucose levels
  - SmartPhone App integration both for data viewing and pump control
  - Sugar IQ integration

Medtronic Insulin Pumps: Things to come

- Long term projects:
  - Disposable sensor with increased sensor wear up to 10-14 days and no calibrations
  - **Project Duo** Integrates Glucose Sensor, Insulin Infusion Into one device.



Insulet Insulin Pumps: Omnipod

- Only Tubeless insulin pump
- Waterproof
- Auto-Cannula insertion
- Approved for all ages: Pediatric through elderly

- PDM must be within 5 feet to communicate with Pod (for boluses)
- The Pod will deliver basal insulin 24 hours a day regardless of PDM location
- Personal Diabetes Manager (PDM) includes a Freestyle glucose meter
- 80 hour forced change-out (Pod can not be worn longer than 80 hours)

Insulet Insulin Pumps: Omnipod DASH

FDA Approved June 2018

- Replaces current PDM with "locked down" android phone
- CalorieKing® food library with carbohydrate content for up to 80,000 foods
- Optimized for use with the CONTOUR®NEXT ONE Blood Glucose Meter for wireless transfer of blood glucose readings to the DASH™PDM
- Limited market release of the DASH system has begun. Commercial Release of the DASH System is expected the early part of 2019.

Insulet Insulin Pumps: Omnipod DASH

- With Bluetooth® wireless technology in the Pod, the Omnipod DASH™ System will also feature a suite of mobile applications that will allow users quick and easy access to their PDM data on their smartphone and the ability to share therapy status information with up to 12 friends or family members.
  - Omnipod VIEW™ app lets parents and caregivers view PDM data on their smart-phones
  - Omnipod DISPLAY™ app offers PDM data on a user's smartphone and also has "Find my PDM" feature
  - Only available on Apple devices at this time
- OmniPod Dash will use different Pods than the current system but they are the same size as the current Pods.

Insulet Insulin Pump: Omnipod Future

omnipod®
HORIZON®
AUTOMATED GLUCOSE CONTROL

- Working on approval to use concentrated insulin in the pods to allow patients with higher total daily insulin needs to change out the pod every 3 days.

- DASH is an "interim step" to their full Pump+CGM closed loop system . Omnipod HORIZON will integrate with the Dexcom G6 CGM and has the possibility of bypassing a PDM and being controlled completely from a user's phone.
- Could also integrate with other CGMs such as Freestyle libre
- Date of approval for this is unknown. Expected Late 2019/Early 2020.

Tandem Insulin Pumps:

t:slim X2™ Insulin Pump

The only fully upgradeable insulin pump

Approved for ages 6 and older

Tandem Insulin Pumps:

- Color Screen
- Micro-delivery: Delivers insulin in the tiniest increments available
- Rechargeable battery
- USB connectivity: for convenient charging and fast data transfer speeds
- Watertight: up to 3 feet for 30 minutes

Tandem Insulin Pumps: t:slim x2

- Two-way Bluetooth radio allowing it to communicate with more than one external device at a time. (i.e. Phone, meter, CGM)
- Fully Upgradable Pump: Tandem Device Uploader is a tool for the remote update of Tandem insulin pump software, allowing users to update their pump from a personal computer as new features are approved by the FDA.

Tandem Insulin Pumps: t:slim x2 with Basal-IQ™

- Integrates with Dexcom G6
- Helps reduce the frequency and duration of low-glucose events by predicting glucose levels 30 minutes ahead and suspending insulin if they are expected to drop below 80 mg/dL
- Immediately resumes insulin delivery once glucose levels starts to rise

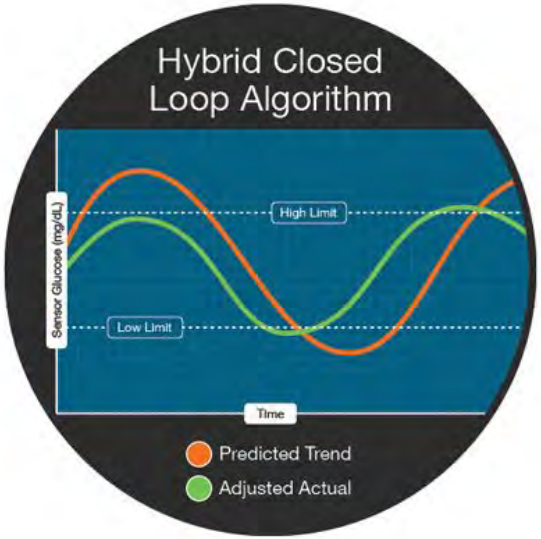
FDA approved June 21, 2018

Tandem Insulin Pumps: t:slim x2 with Basal-IQ™

- All in warranty t:slim X2 pump users will be able to download the Basal-IQ™ upgrade from a home computer for free through the end of 2018.
- To obtain upgrade you submit request online and are required to go through 45 minutes of online training before being sent instructions on how to download the Basal-IQ program to your pump.

Tandem Insulin Pumps: Future Upgrades Coming

Control IQ



TANDEM DIABETES CARE

dexcom

typezero

AUTOMATED INSULIN DELIVERY

Hybrid Closed Loop (HCL)

Tandem, Dexcom and TypeZero are working together on the integration of their technologies into the NIH-funded International Diabetes Closed Loop (IDCL) Trial. Tandem is working on development of an insulin pump that integrates the data from a Dexcom G6 sensor and TypeZero's inControl algorithm directly into the pump's touchscreen interface.

Timelines as of 7/30/2018:

- Pivotal data to be generated by ongoing IDCL Trial
- Launch goal: Summer 2019

Tandem Insulin Pumps: Future Upgrades Coming

- App coming before the end of the year to allow patients to view Pump Data and Dexcom G6 Data integrated on their phone.

Companion Medical

Smart Insulin Delivery

inpen®

InPen works exactly like a traditional insulin pen but has Bluetooth technology that connects to a smartphone app.

- Compatible with U100 Novolog and Humalog insulin

Inpen

- Dose calculation:

  Recommends insulin dose based on current BG, carbohydrates and active insulin time based on your personal settings
- Reminders and Alerts:

  Blood sugar checks/meals and reminders for insulin expiration
- Logbook and reports can be viewed for trend management

InPen

- Integrates with continuous glucose monitoring systems such as Dexcom G6 through Apple Health app.
- Cost:
  - Cash Price $549
  - Most commercial insurance $40 to $120 for pen
  - Pen is warrantied for 1 year.
  - No Medicaid coverage at this time.
  - Comes in Blue, Grey or Pink

Questions??????

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