Diabetes Technologies Insulin Pump and Sensors

D. JAMES BAILEY, II, M.D., F.A.C.E
ENDOCRINOLOGY ASSOCIATES, INC.

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Diabetes Technologies – Glucose Sensors and Pumps

- 1. Discuss features of available professional and personal CGMs and insulin pumps.
- 2. List components of CGMs and insulin pumps
- 3. Describe appropriate candidates for insulin pump therapy
- 4. Describe inpatient considerations for insulin pump therapy and CGMs

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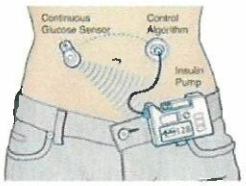
Diabetes Technology

- Diabetes technology is the term used to describe the hardware, devices and software that people with diabetes use to help self-manage their diabetes and improve quality of life.
- Advances in technology will continue to revolutionize and improve the way diabetes care is delivered.



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Diabetes Technology – Topics

This rapid change in the technology landscape can make it difficult and confusing for diabetes educators and providers to keep up to date.

Insulin delivery methods

- Insulin syringes, pens, disposable patch, pumps
- Setting and evaluating basal and bolus settings
- Inpatient management
- Traveling with technology

Continuous glucose monitoring

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Pump Candidates - People with diabetes who need insulin replacement

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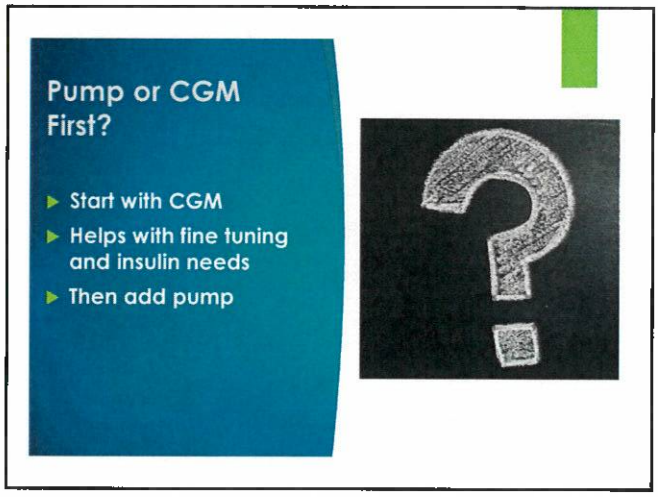
Pump or CGM First?
Start with CGM
Helps with fine tuning and insulin needs
Then add pump

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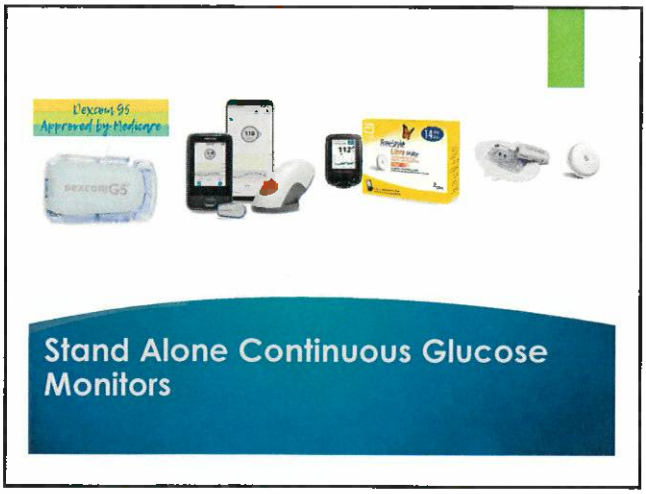
Dexcom G5
Approved by Medicare
Stand Alone Continuous Glucose Monitors

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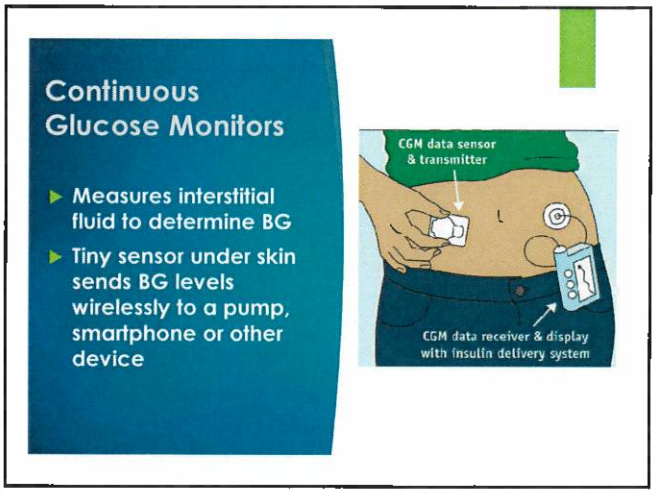
Continuous Glucose Monitors
Measures interstitial fluid to determine BG
Tiny sensor under skin sends BG levels wirelessly to a pump, smartphone or other device
CGM data sensor & transmitter
CGM data receiver & display with insulin delivery system

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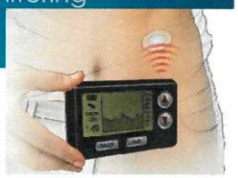
Continuous Glucose Monitoring (CGM)



- **CGM should be considered in children to adults**
- **Useful tool in those frequent hypoglycemia or hypoglycemia unawareness (alarm features)**
- **Measures percent of time in, above and below range**
- **Establishes glucose patterns**

CGM uses interstitial glucose – correlates with plasma glucose
Report glucose in
- Real time or
- Or intermittent scanning

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Benefits of CGM

Significant reductions in hypoglycemia Type 1	Type 2 less hypo too
• 38% reduction of overall hypo • 40% reduction of nighttime hypo	• 43% reduction overall hypo • 54% reduction in nighttime hypo

AADE Practice Paper; The Diabetes Educator Role in Continuous Glucose Monitoring, July 2018

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Professional CGM

- Person with diabetes is outfitted with CGM for 6-14 days
- Readings are collected every 1 to 5 minutes
- Retrospective data downloaded to review and make treatment adjustments – Diabetes educator familiar with software and downloading.
- Blinded CGM – user can't see results and therefore they don't alter behavior
- Unblinded – user sees glucose reading in real time on receiver and can take action

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Professional CGM

- Consider cost, disinfection issues
- Use to keep food and activity log
- Staff needs to know how to download and interpret data
- Evaluate insurance coverage first. After a minimum of 72 hours, bill using code 95250
- Interpretation of data can be done remotely using billing code 95921

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CGMs Professional

- Abbott Freestyle
  - LibrePro
- Equipment – sensor, reader
- 14 day wear, blinded
- 12 hr warm up, no calibration
- Disposable sensors
- MARD Accuracy 12.3%
- No alarms high/low

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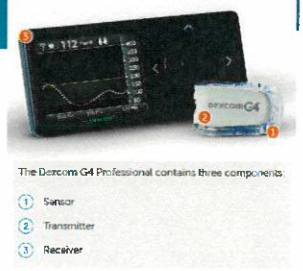
CGM Professional

- Dexcom
- Equipment – sensor, transmitter, receiver
- 7 day wear, blinded or not
- 2 hr warm-up, 2 calibrations per day
- Cleaned between uses
- Alarms customized by provider/ wearer



https://provider.dexcom.com/products/professional-cgm

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CGM Professional

- Medtronic
  - IPro2
- Equipment – sensor, transmitter, receiver
- Blinded
- 2 hr warm-up, 3-4 calibrations per day
- Cleaned between uses
- MARD Accuracy 11.05%
- No alarms

https://professional.medtronicdiabetes.com/ipro2-professional-cgm

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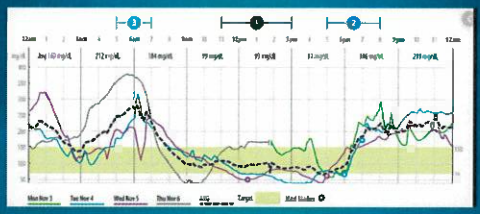
CGM Download



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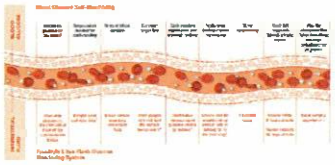
Personal CGM

- Benefits include less time in hypo /hyper glycemia
- A1c improvements
- Warning – rapid glucose changes
- Real time data
- 5-10 minute lag between BG and Interstitial Glucose (SG)



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Considerations

- CGM decreases need for BG Checks.
- But, following situations warrant a fingerstick:
  - Calibration or BG symbol appears on screen
  - Symptoms don't match CGM readings
  - If not FDA approved for insulin dosing
- Be on look our for alarm distress/burnout
- Not approved for
  - Pregnancy, dialysis, critically ill populations

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Abbott FreeStyle Libre Flash - Personal

Self insert sensor

Wave wand over to get reading

Wearable up to 14 days

LibreLink app shows user entered events, cloud based for sharing (up to 20 people can track) from iphone or android

Stores 90 days of data

FDA approved for insulin dosing

Medicare covers if take insulin 4xs a day

Interfering substances include salicylic acid, high dose vitamin C

https://www.freestylelibre.us

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Dexcom G-6

- **10 day wear**
- **No calibration**
- **1 step insertion**
- **Alerts for high /low**
- **FDA Approved to dose insulin**
- **No interfering substances**

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Medtronic Guardian

- Bluetooth connect Guardian Connect for IOS
- Sugar.IQ, mySugr app
- Wear for 7 days
- 2 hr warm up, 2 calibrations day
- Not FDA approved for insulin dosing
- CareLink software to share data and updated plan
- MARD 09.64%
- Alarms for high, low and predictive alerts

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Smart Pens Connect via bluetooth

InPen
https://www.companionmedical.com/InPenministered.

- smartphone app keeps track of insulin dose and time

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Clinical Indications for Insulin Pump

- Connected with medical team
- Not reaching targets in spite of Multiple Daily Injection (MDI) elevated A1c
- Nocturnal hypo
- Dawn phenomena
- Excessive glucose variability
- Irregular schedules (students shift workers)
- Monitors BG 4 times a day (or uses CGM)

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Clinical Indications for Insulin Pump

- Preconception planning and pregnancy
- Frequent hypo or hypo unawareness
- Extreme insulin sensitivity
- Needle aversion
- Gastroparesis, early neuropathy, nephropathy
- Renal transplantation

AADE Practice Paper 2018- Continuous Subcutaneous Insulin Infusion (CSII) Without and With Sensor Integration

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Insurance Coverage Issues

- Most carriers cover pumps
- Under terms of Durable Medical Equipment (DME) coverage
- Patch pump companies are covered under prescription plan
- Insurance requirements
  - Unable to normalize bg
  - Hypo or unawareness
  - Need for flexible insulin reg
  - Planning a pregnancy
- Some plans may not cover soon after dx

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Medicare Coverage

- Covers pumps for type 1 and insulin requiring type 2
- Serum C-peptide need to be <110% of lower limit of normal (if normal renal function) or positive beta cell antibodies
- Complete comprehensive DSMT
- Will cover supplies if using pump before enrolling
- Upgrades every 4-5 years

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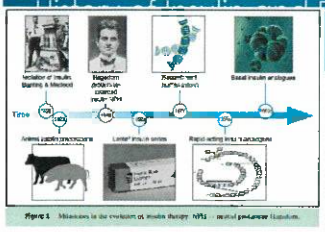
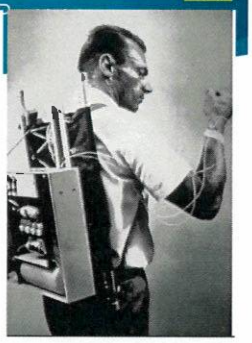
History of Insulin and P...



Evolution of Insulin: From Human to Analog. Joseph M. Tibaldi, MD American Journal of Medicine, 2014



1960s

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Traditional Pumps

Considerations

- Canula options
- Insertion device or manually
- Disconnect mechanism
- Tubing length

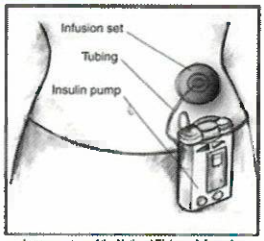

Image courtesy of the National Diabetes Information Clearinghouse, US Dept. of Health and Human Services

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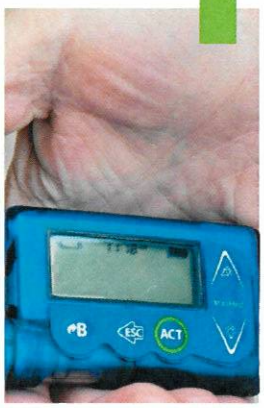
Common Pump Features

- Variable basal delivery
- Immediate or prolonged bolus delivery
- At least 4 yr warranty
- Temporary basal adjustment
- Bolus calculation feature
- Memory with record
- Downloadable
- Warning for low battery, low insulin & occlusion
- Safety mechanism to prevent accidental delivery
- 24 hour support, full training, 30 day guarantee



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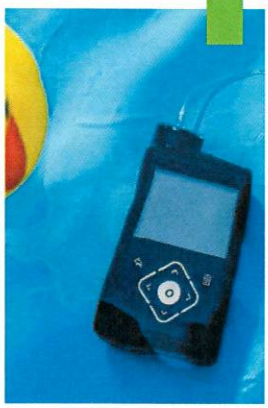
Pumps and Water

- Pumps are water tight
  - Patch pump
  - Infusion devices and tubing
  - Linked CGM
- Some are semi-water tight
  - For submersion, disconnect first
- Non-watertight
  - Remote programmers / linked meters
  - Can get waterproof pouches



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Poll Question 1

Which of the following is true regarding insulin pump therapy?

- Users don't have to monitor as often
- Approved for those 18 and older
- Associated with less hypoglycemia
- Deceases risk of weight gain

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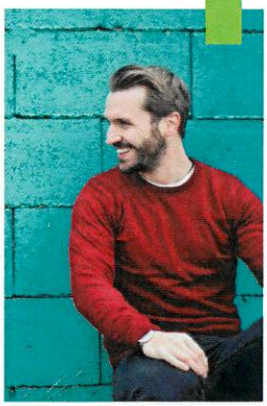
Advantages of Pump therapy

- A1c improvement
- Less glucose variability
- Reduction in duration and frequency of severe of hypo
- 50% drop in severe hypoglycemia
- Quality of life improves
- Precise can deliver .05, .025, or .01 units



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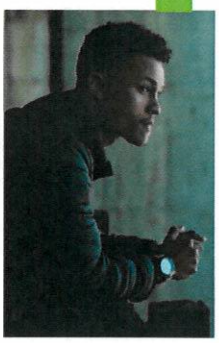
Realistic Expectations

- Tool not a cure
- Still need to check BG
- More freedom, but still can't graze
- Blood sugars will be in target more frequently, but not perfect
- Connected to a device



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Insulin Pump Barriers

- Standard pump cost
  - Getting started cost $5,000 -$7,000 for pump (avg $6,000)
  - Supplies 1-2 thousand dollars a year (200 a month)
- Patch/disposable pump
  - Approx $1000 up-front
  - Approx $400 / month for disposable supplies
- Other costs, extra test strips, cgm sensors, transmitters, accessories
- Weight gain
  - Easier to eat spontaneously
- Changes infusion set and tubing 5-10 mins
- More provider time
- Persistence and careful monitoring –no long acting insulin

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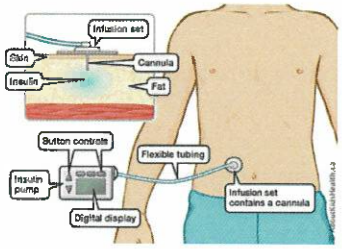
Insulin Pump Components

- User interface (buttons/screens)
- Insulin cartridge/reservoir
- Tubing (non-patch pumps)
- Infusion device infuses insulin below skin
- Integrated meter (some)
- Integrated CGM (some) display data on pump screen



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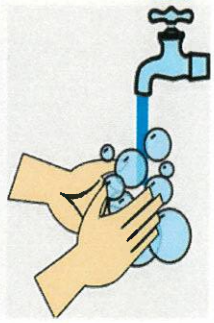
Infusion Device and Pump Preparation

- Clean with soap and water
  - If at risk infection, Hibiclens, Phisohex, Betadine
- Allow to dry
- Insertion devices
  - Manual or device aided
  - 1 time or multiple use
    - Helpful for young children, needle phobias
- Fill cartridge with insulin
- Prime tubing
- Connect to infusion device – make sure secure



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Canula Options

Flexible Plastic/teflon

- Needs introducer needle
- "More comfortable"
- Safer for those involved in contact sports
- Some have allergy

Steel

- Manual insertion
- Simple to insert
- Less likely to crimp or occlude
- Nickel allergy can be a problem

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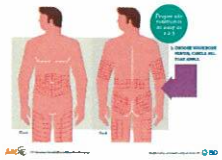
When to Change Pump Infusion Set

- Change infusion set every 48 hours
- Or if site irritation or blockage
- Make sure to rotate within area to prevent lipodystrophy
- Stay 1 -2 inch inch away from previous site. Keep old infusion set on to help determine next site
- Use a grid pattern to maximize space in site



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Omnipod with PDM/Tubeless

Pod is small, device Freestyle meter built into hand held programmer

- Pod holds up to 200 units. Includes small flexible cannula
- Communicates wirelessly with the Personal Diabetes Manager
- Wirelessly manages insulin delivery based on programmed settings.
- Built in FreeStyle BG meter
- Data can by uploaded to Insulet Provided Glooko
- Data can be viewed by up to 12 people

- Dash holds 200 units - can be connected to smartphone
- Use Contour Next BG machine

https://www.myomnipod.com/Omnipod-system

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Patch Pump - Omnipod

Benefits

- No tubing
- Automated infusion set insertion
- Lower upfront cost
- Smaller, more discreet
- No siphon or disconnecting
- Change site every 2-3 days

Considerations

- Can't disconnect
- Bigger skin patch
- Less canula choice
- If trouble applying insulin device, insulin lost.
- Higher disposable supply cost than traditional.

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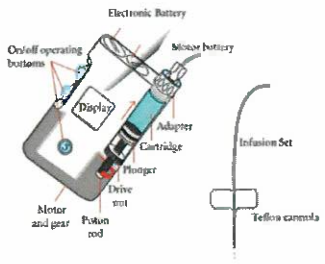
Insulin pump

- Battery powered
- Worn externally
- Beeper sized
- Infuses insulin
- Programmable by the user



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Insulin pumps

- Sensor augmented pumps
- Medtronic 670 G

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Automated Insulin Delivery

- Automated insulin delivery systems may be considered in children 7 years or older and adults to improve BG
- Consists of 3 components
  - Insulin pump
  - Continuous glucose monitor
  - Algorithm that determines insulin delivery
- These systems, insulin delivery can be suspended, increased or decreased.
- Currently, a hybrid closed loop (HCL) is approved which calculates basal rate, but requires users to bolus for meals and snacks
- Future – truly automated closed loop system

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Medtronic 670G insulin pump

Contour Next Link 2.4 meter

Guardian Sensor 3 – Change every 7 days

SmartGuard™ features:

AUTO MODE[1]

- Automatically adjusts your basal (background) insulin every five minutes based on your CGM readings.[1,2]
- Helps keep your sugar levels in your target range for fewer lows and highs — day and night.[1,2,3]

See how Auto Mode works

SUSPEND BEFORE LOW[1]

- Stops insulin up to 30 minutes before reaching your preset low limits.
- Automatically restarts insulin when your levels recover without bothersome alerts.[2]
- Helps you avoid lows and rebound highs.[1]

See how Suspend Before Low works

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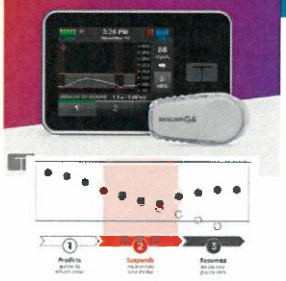
Tandem t:slim X2™ w/DexcomG6 CGM

FDA APPROVED!

Basal-IQ® Technology



- Zero fingersticks
- 10-day sensor wear
- Simple auto-applicator
- Acetaminophen blocking (up to 1000mg every 6 hours)
- View data on smart devices
- Share data with up to 10 followers.
- Upload updates

https://www.tandemdiabetes.com

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Insulin for Pumps

Rapid Insulin

- Analogs preferred
- U-200 Lispro can be used off label
- Regular can be used, but has delayed peak
- U-500 off label, harder to manage postprandials

FDA Approval

- Lispro in pump 3 days
- Aspart 6 days
- Glulisine up to 2 days, pregnancy category C
- All have similar efficacy, consider cost

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Pump variables to consider

- How much insulin does it hold?
- CGM results displays on pump screen
- Reminder options
- Remote on glucose meter, device, apps, smart phones
- Ease of data download and readability
- How does it look, feel, clip features
- Alarms and other features

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