Continuous Glucose Monitoring & Insulin Pump Update

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MONUMENT HEALTH

Objectives

- By the end of the presentation, attendees will understand updates to continuous glucose monitoring therapy.

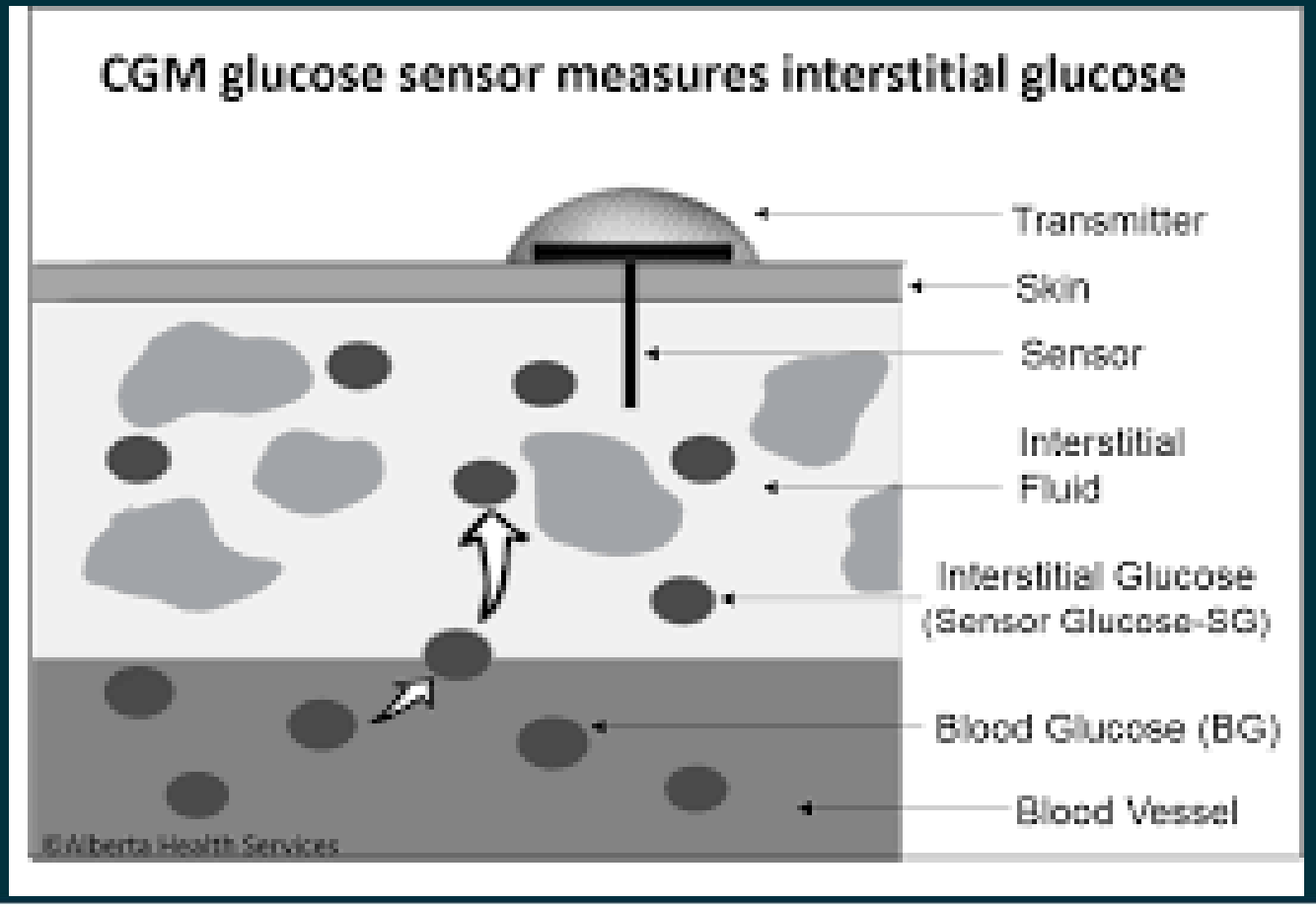
- By the end of the presentation, attendees will be familiar with new insulin pump options and features.

Conflicts

- No conflicts of interest to report

What is Continuous Glucose Monitoring?

- Automatically tracks glucose data either continuously or intermittently depending on the device
- Measures an interstitial glucose & transmits data to receiver or phone that patient can view [1]



[2]

Benefits of CGM Therapy

- A1c does not always tell the whole story
- Elevated blood sugar readings & high A1c associated with increased risk of complications
- Glucose variability also associated with complications
- CGM helps “fill in the gaps of the story” to allow for tighter insulin titration & improved glycemic control
- Glucose alerts & ease of checking glucose gives patients & caregivers peace of mind
- Allows patients to see impact of food choices & exercise on blood sugar readings which can lead to healthier lifestyle changes

More Benefits of CGM Therapy

- Changed every 7-14 days
- Can be used with or without an insulin pump
- May alarm when glucose is too high or too low
- Data can be downloaded & reviewed by health care provider or family
- Empowers the patient with active knowledge

Drawbacks to CGM Therapy

- Alarm fatigue
- Discrepancy between CGM & finger stick glucose reading “lag time”
- Still important to confirm with finger stick blood glucose if symptoms do not match sensor glucose
- Allergies to adhesive, wearing a constant device
- Expense
- Acetaminophen, aspirin, or vitamin C interference

Ideal Patients for CGM

- Type 1 diabetics not meeting glycemic targets
- Patients on multiple daily insulin injections
- Frequent hypoglycemia & hypoglycemia unawareness
- Pregnant women with type 1 diabetes
- Patients requiring frequent glucose testing
- Patients on insulin who live alone
- Patients who struggle with dietary choices

Commonly used types of CGM at Monument Health

- Dexcom G6
- Freestyle Libre 2 and Libre 3
- Medtronic Guardian

Therapy Goals

- A1c 7.0%
- Time below 54 mg/dL (less than 1%)
- Time below 70 mg/dL (less than 4 %)
- Time in range (70-180 mg/dL), target greater than 70%
- Less stringent goals depending upon life expectancy, safety [3]

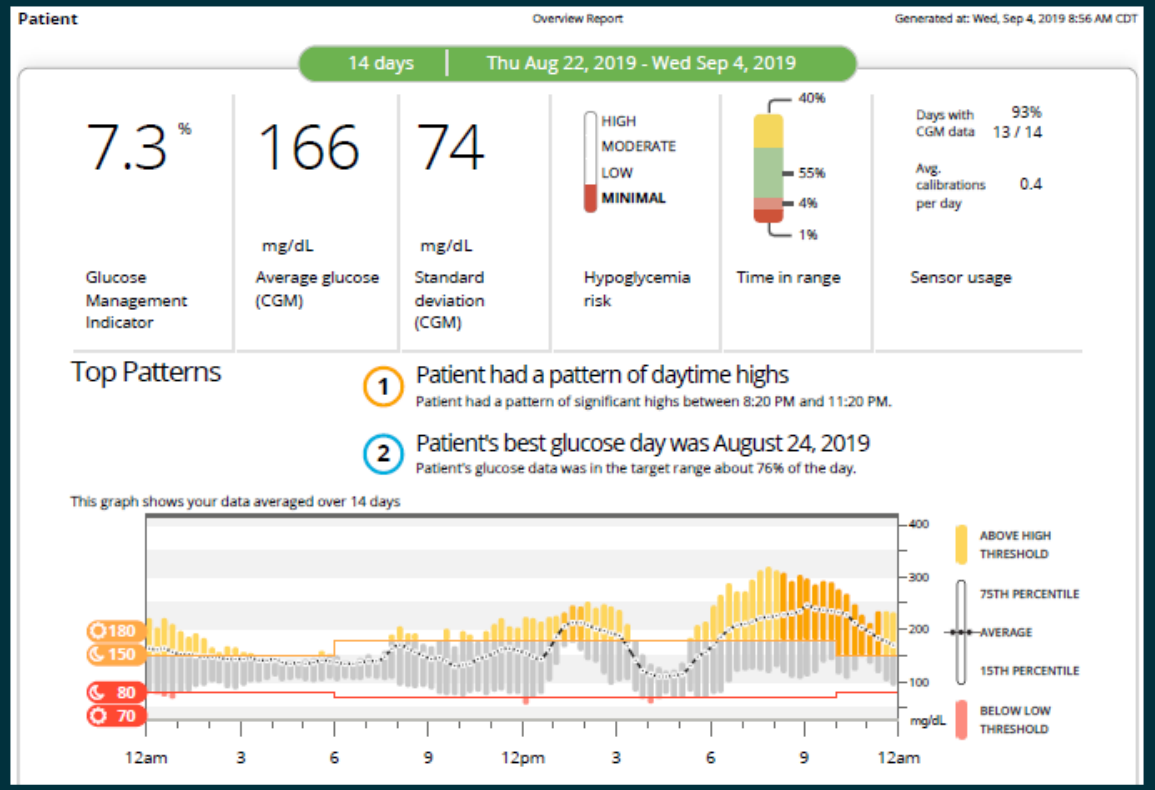
Dexcom G6

- No finger stick calibrations required
- New glucose reading every 5 minutes
- Requires 2 hour “warm up” time
- Data automatically transmits to receiver or Smartphone app
- Shareable data with up to 10 people
- Customizable alerts
- Sensors last 10 days, transmitter 3 months
- No interference with acetaminophen up to 1,000 mg every 6 hours
- Insurance and medicare coverage continues to improve
- Coordinates with T-slim insulin pump, “Control IQ”
- Dexcom G6 features an overall MARD of 9.0. [4]

Dexcom G6

[5]

Dexcom G6 example



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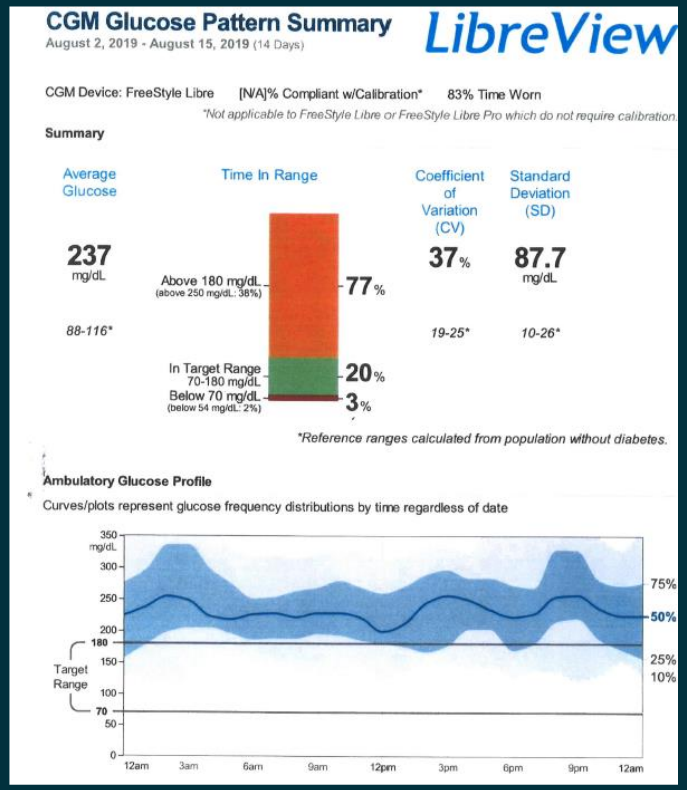
Freestyle Libre 2

[6]

Freestyle Libre 2

- Ability to alert patients to high & low glucose readings (still need to scan)
- iOS compatibility
- Android compatibility (not all phones)
- High levels of vitamin C can cause false readings
- Recommend double checking hypoglycemic readings with a fingerstick blood glucose
- Cost effective
- Overall MARD 9.2%[7]

Freestyle Libre



CGM Glucose Pattern Summary
August 2, 2019 - August 15, 2019 (14 Days)

LibreView

CGM Device: FreeStyle Libre [N/A]% Compliant w/Calibration* 83% Time Worn

*Not applicable to FreeStyle Libre or FreeStyle Libre Pro which do not require calibration.

Summary

Average Glucose	Time In Range	Coefficient of Variation (CV)	Standard Deviation (SD)
237 mg/dL	Above 180 mg/dL (above 250 mg/dL: 38%) 77%	37%	87.7 mg/dL
*88-116**	In Target Range 70-180 mg/dL 20%	*19-25**	*10-26**
	Below 70 mg/dL (below 54 mg/dL: 2%) 3%		

*Reference ranges calculated from population without diabetes.

Ambulatory Glucose Profile

Curves/plots represent glucose frequency distributions by time regardless of date

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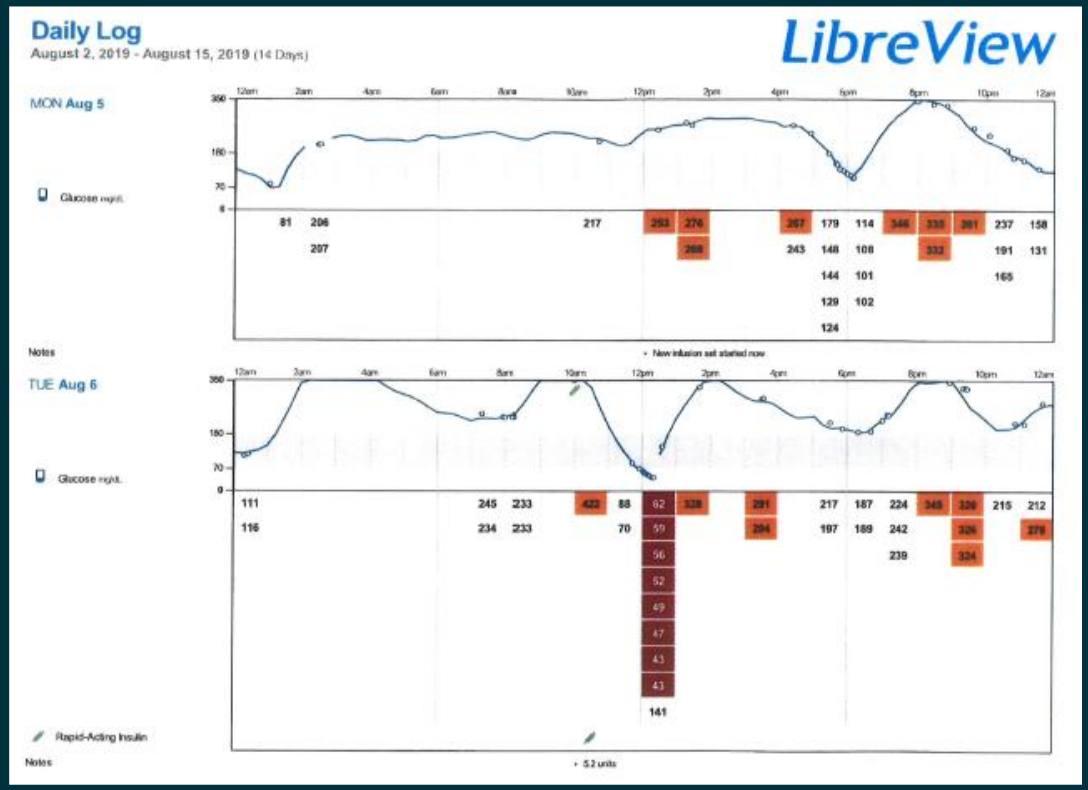
Freestyle Libre



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Freestyle Libre 3

- No need to scan
- New reading every minute
- 7.9% overall MARD
- No reader, so need to have compatible cell phone
- Only for commercial insurance patients
- Smaller than Libre 2
- Easier application, low cost

FreeStyle Libre 3 User's Manual.

Alva, Shridhara, Timothy Bailey, Ronald Brazg, Erwin S. Budiman, Kristin Castorino, Mark P. Christiansen, Gregory Forlenza, Mark Kipnes, David R. Liljenquist, and Hanqing Liu. "Accuracy of a 14-day factory-calibrated continuous glucose monitoring system with advanced algorithm in pediatric and adult population with diabetes." Journal of Diabetes Science and Technology 16, no. 1 (2022): 70-77.

Freestyle Libre 3

https://abbott.mediaroom.com/2020-09-28-Abbotts-FreeStyle-R-Libre-3-System-Receives-CE-Mark-Features-Worlds-Smallest-Thinnest-Sensor-with-Best-in-Class-Performance-at-the-Same-Low-Cost-for-People-with-Diabetes

Medtronic Guardian 3

- Requires at least 2 finger stick calibrations daily
- Lasts up to 7 days of wear
- Up to 2 hour “warm up” period
- Alerts to hypo & hyperglycemia
- Shareable data
- Smartphone compatibility
- Acetaminophen use can affect readings
- iOS and Android
- SUGAR.IQ diabetes assistant app [8]

Medtronic Guardian 3

- MARD 8.79% (arm) or 9.84% (3-4 calibrations/day)
- MARD 9.14% (arm) or 10.46% (2 calibrations/day)

[8]

Professional CGM

- Blinded or unblinded
- Covered by insurance (may need a prior-auth)
- Can choose to have interpretation done by endocrinology
- Helps detect trends in type 1 and type 2 diabetes, especially overnight trends and postprandial
- Investigate hypoglycemia

Insurance Coverage

- Can be costly
- Medicare previously required 3 times daily injections (requirements changing)
- Medicaid covers for type 1 or pregnancy (30 days of testing 4x/day)
- Commercial insurance coverage varies
- Other supporting data (hypoglycemia, third party intervention, ect.)

Settings Recommendations

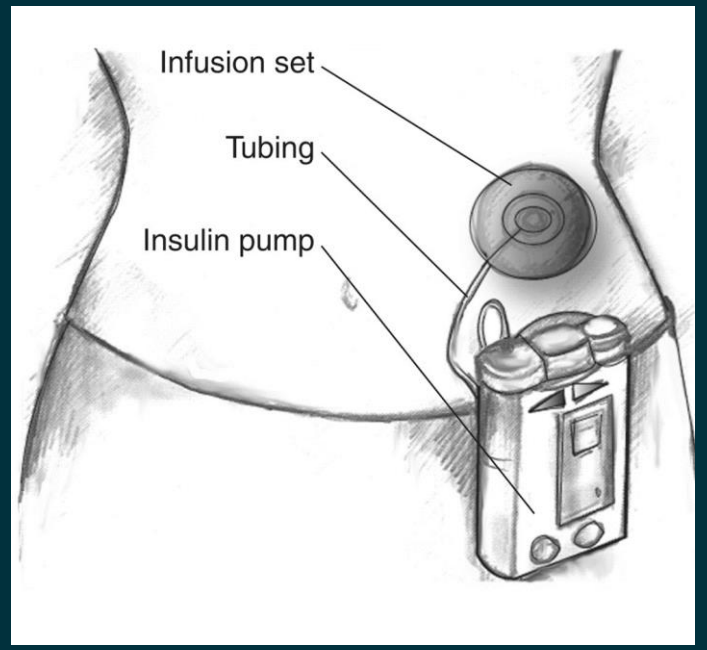
- Patient should choose alerts that will help them the most, but not be burdensome
- Low alert usually set at 70, repeat at 15 minutes
- High alert can start at 250, repeat at 1 hour

CGM programs to download data

- Programs vary, depending on device
- If cell phone compatible, easy to get reports
- Medtronic: Carelink
- Dexcom: Clarity
- Libre: LibreView

Insulin Pump Therapy

- Small device that administers insulin via small cannula in the sub-q tissue
  - Insulin stored in reservoir or pod
  - Cannula inserted via needle that is then removed
  - Infusion set or pods changed every 2-3 days



Insulin Pump Therapy

- Uses rapid-acting insulin
- Pump contains pre-set basal rates, carb ratios, insulin sensitivity factor, glucose target, & active insulin time
  - Basal rates deliver small amount of rapid-acting insulin every hour to replace need for long-acting insulin
  - Carb ratio determines how many units of insulin are needed for amount of carbs eaten
  - Insulin sensitivity = how many mg/dL 1 unit of insulin drops blood glucose to get to glucose target
  - Active insulin time = how long insulin stays active in body once administered

Benefits of Insulin Pump Therapy

- Minimizes number of injections
- Can allow for more precise delivery of insulin
- Can temporarily adjust or suspend insulin delivery
  - Helpful for exercise or change in activity
- Possibility of integrating with CGM
- Detailed reports

Drawbacks of Insulin Pump Therapy

- Skin infections
- Risk of DKA from pump malfunction or absorption issues
- Cost
- Feeling of being attached to a device

Ideal Patients for Pump Therapy

- Able to carb count
- Check blood glucose 4x/day or use a CGM
- Type 1 and type 2 diabetes
- Thorough understanding of disease state
- Pregnancy and requiring insulin

Medtronic 770G

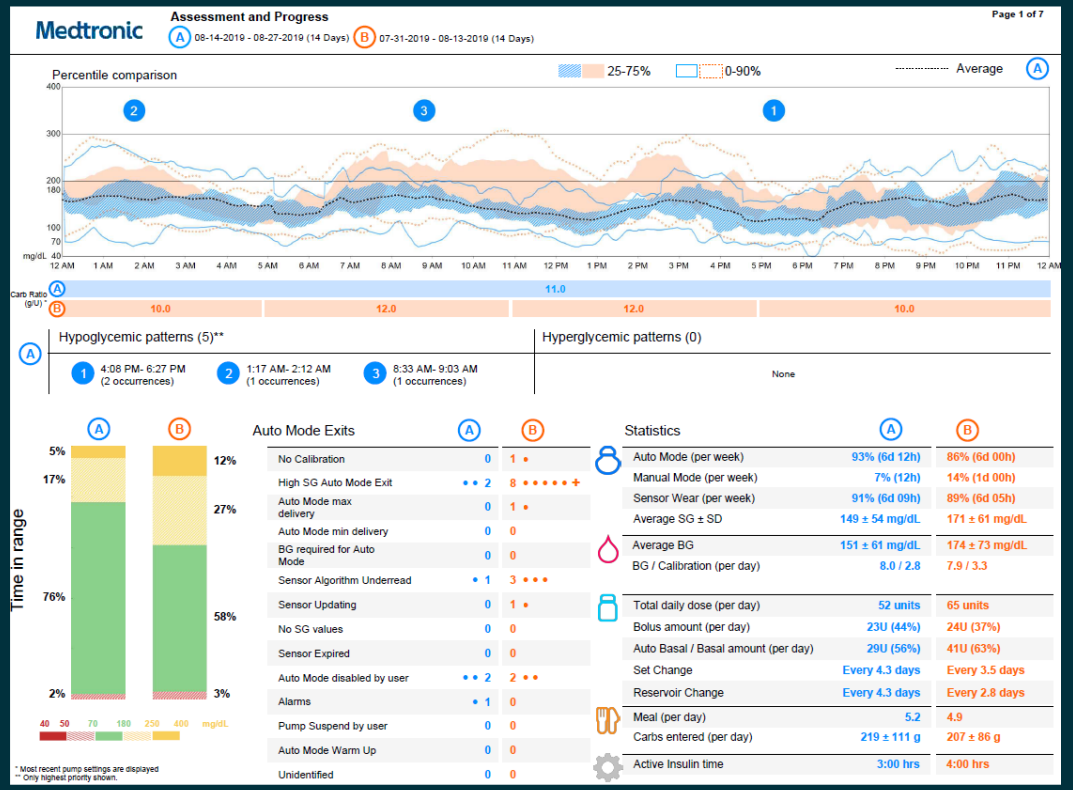
- SmartGuard™ tech. Increases or decreases insulin delivery, every five minutes per the CGM readings
  - Can predict hypoglycemia and hyperglycemia in advance.

- Bluetooth connectivity allows for automatic upload of data to Carelink [9]

Medtronic 770G

[9]

Auto Mode



Medtronic

Assessment and Progress

Page 1 of 7

A 08-14-2019 - 08-27-2019 (14 Days) B 07-31-2019 - 08-13-2019 (14 Days)

Percentile comparison

25-75% 0-90% Average A

mg/dL

12 AM 1 AM 2 AM 3 AM 4 AM 5 AM 6 AM 7 AM 8 AM 9 AM 10 AM 11 AM 12 PM 1 PM 2 PM 3 PM 4 PM 5 PM 6 PM 7 PM 8 PM 9 PM 10 PM 11 PM 12 AM

Carb Ratio (g/U)*

A 11.0

B 10.0 12.0 12.0 10.0

Hypoglycemic patterns (5)**

1 4:08 PM- 6:27 PM (2 occurrences)

2 1:17 AM- 2:12 AM (1 occurrences)

3 8:33 AM- 9:03 AM (1 occurrences)

Hyperglycemic patterns (0)

None

Time in range

A: 5% 17% 76% 2%

B: 12% 27% 58% 3%

40 50 70 180 250 400 mg/dL

* Most recent pump settings are displayed
** Only highest priority shown.

Auto Mode Exits	A	B
No Calibration	0	1 •
High SG Auto Mode Exit	• • 2	8 • • • • • +
Auto Mode max delivery	0	1 •
Auto Mode min delivery	0	0
BG required for Auto Mode	0	0
Sensor Algorithm Underread	• 1	3 • • •
Sensor Updating	0	1 •
No SG values	0	0
Sensor Expired	0	0
Auto Mode disabled by user	• • 2	2 • •
Alarms	• 1	0
Pump Suspend by user	0	0
Auto Mode Warm Up	0	0
Unidentified	0	0

Statistics	A	B
Auto Mode (per week)	93% (6d 12h)	86% (6d 00h)
Manual Mode (per week)	7% (12h)	14% (1d 00h)
Sensor Wear (per week)	91% (6d 09h)	89% (6d 05h)
Average SG ± SD	149 ± 54 mg/dL	171 ± 61 mg/dL
Average BG	151 ± 61 mg/dL	174 ± 73 mg/dL
BG / Calibration (per day)	8.0 / 2.8	7.9 / 3.3
Total daily dose (per day)	52 units	65 units
Bolus amount (per day)	23U (44%)	24U (37%)
Auto Basal / Basal amount (per day)	29U (56%)	41U (63%)
Set Change	Every 4.3 days	Every 3.5 days
Reservoir Change	Every 4.3 days	Every 2.8 days
Meal (per day)	5.2	4.9
Carbs entered (per day)	219 ± 111 g	207 ± 86 g
Active Insulin time	3:00 hrs	4:00 hrs

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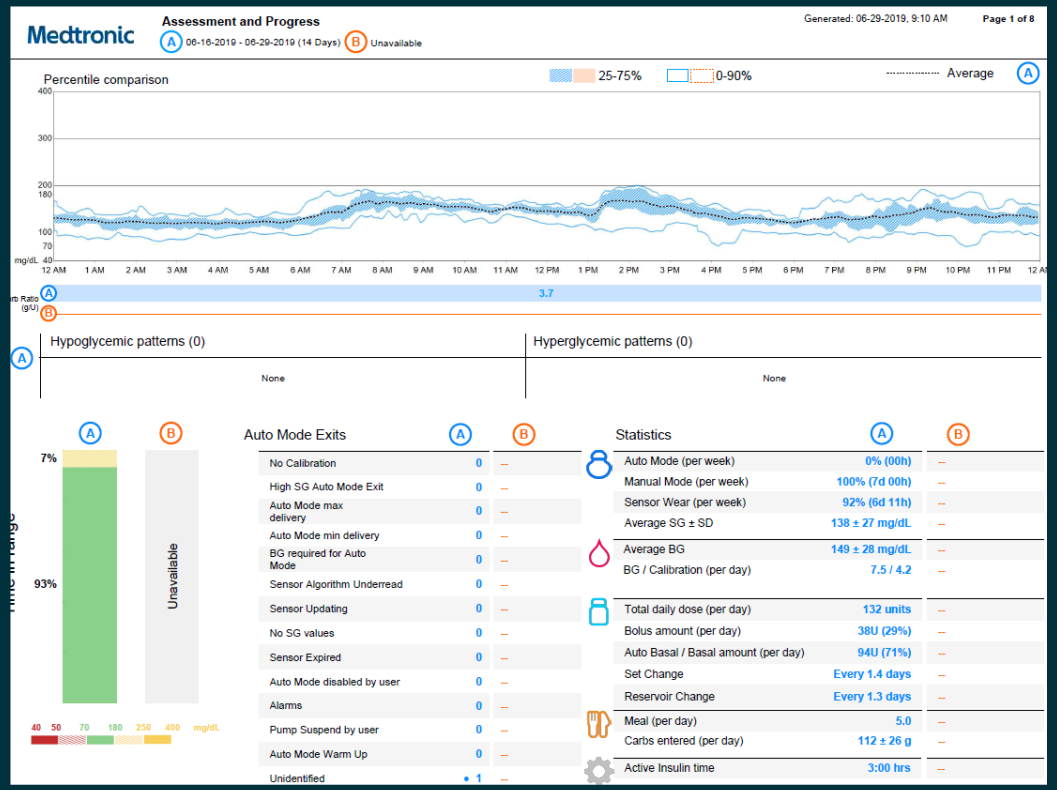
Auto Mode



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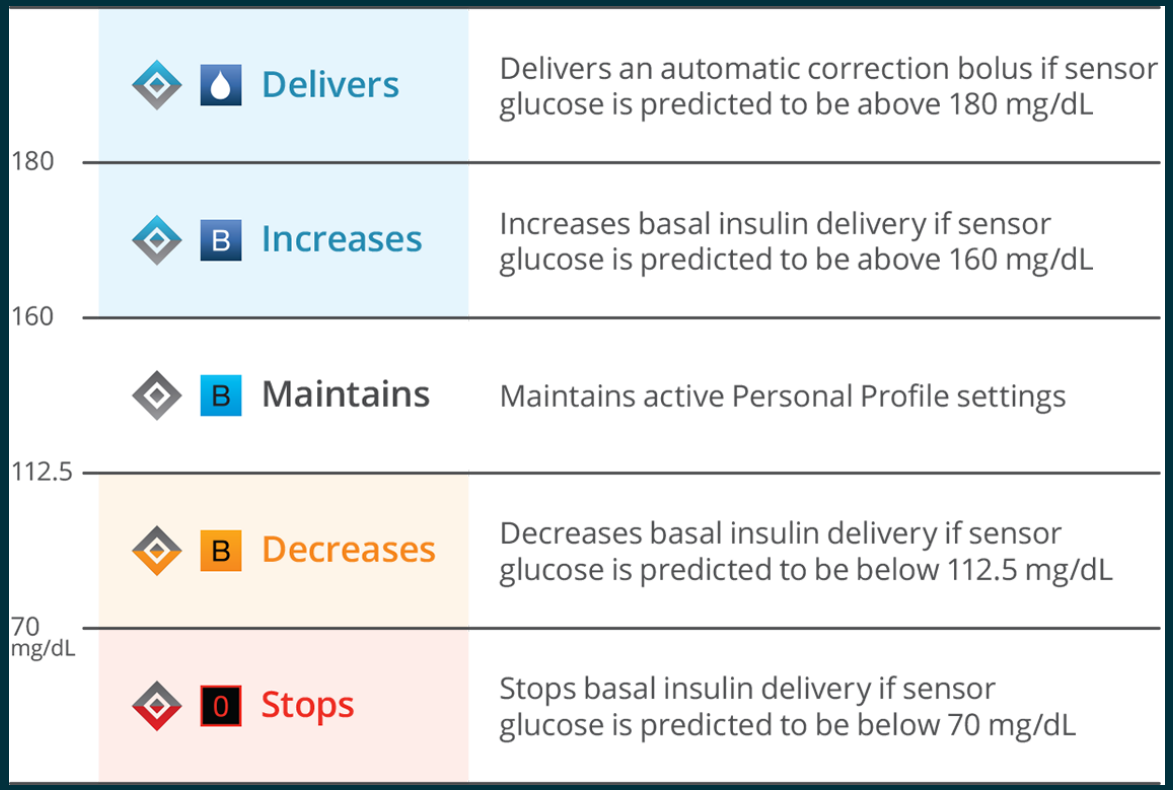
Tandem T-slim

- Color touchscreen
- Able to update via software download
- Charges via micro USB port
- Integrated with Dexcom G6 with data displayed on pump screen
- T-connect app allows for daily data upload and monitoring
- Mobile app now available to manage pump

[10]

Tandem T-slim



[10]

Tandem T-slim

t:slim X2™
Insulin Pump

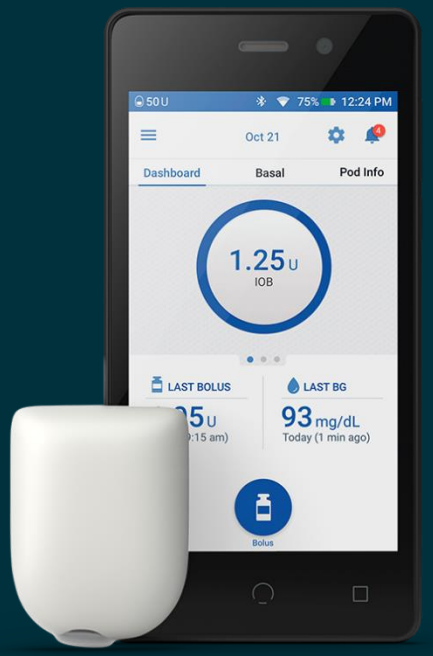
[10]

Omnipod

- Tubeless pump
  - Delivers insulin via pod instead of infusion set
  - Pod changed at least every 3 days
  - Good for very active people
- Use PDM to manage settings & deliver boluses
  - DASH system is touchscreen
- Some smartphone integration with compatible devices

[11]

Omnipod


50 U
75%
12:24 PM
Oct 21
Dashboard
Basal
Pod Info
1.25 U
IOB
LAST BOLUS
LAST BG
93 mg/dL
Today (1 min ago)
Bolus

[11]

Omnipod 5

- Automated mode integrated with Dexcom G6
- Compatible with certain cell phones
- Customizable glucose target
- System increases, decreases, or pauses insulin delivery every 5 minutes

https://www.omnipod.com/what-is-omnipod/omnipod-5

Insurance Coverage

- Some insurances require meeting with a diabetes educator
- Type 1 diabetes covered well (cost varies)
- Type 2 diabetes if on MDI
- Medicare:
  - Generally does not cover type 2 diabetes
  - Requires fasting c-peptide & glucose
  - Requires office visit every 3 months

Importance

- TIR 70% = A1c of 7.0%
- TIR 50% = A1c of 8.0%
- Every 10% increase in TIR = A1c decrease by 0.5%
- CGM use in pregnancy demonstrated a 13-percentage point increase in TIR (43% to 56%) 70-140 mg/dL
- Hazard rate for retinopathy progression increased by 64% for each 10% reduction in TIR
- Hazard rate for microalbuminuria development increased by 40% for each 10% reduction in TIR

(Battelino et al., 2019)

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Questions?