

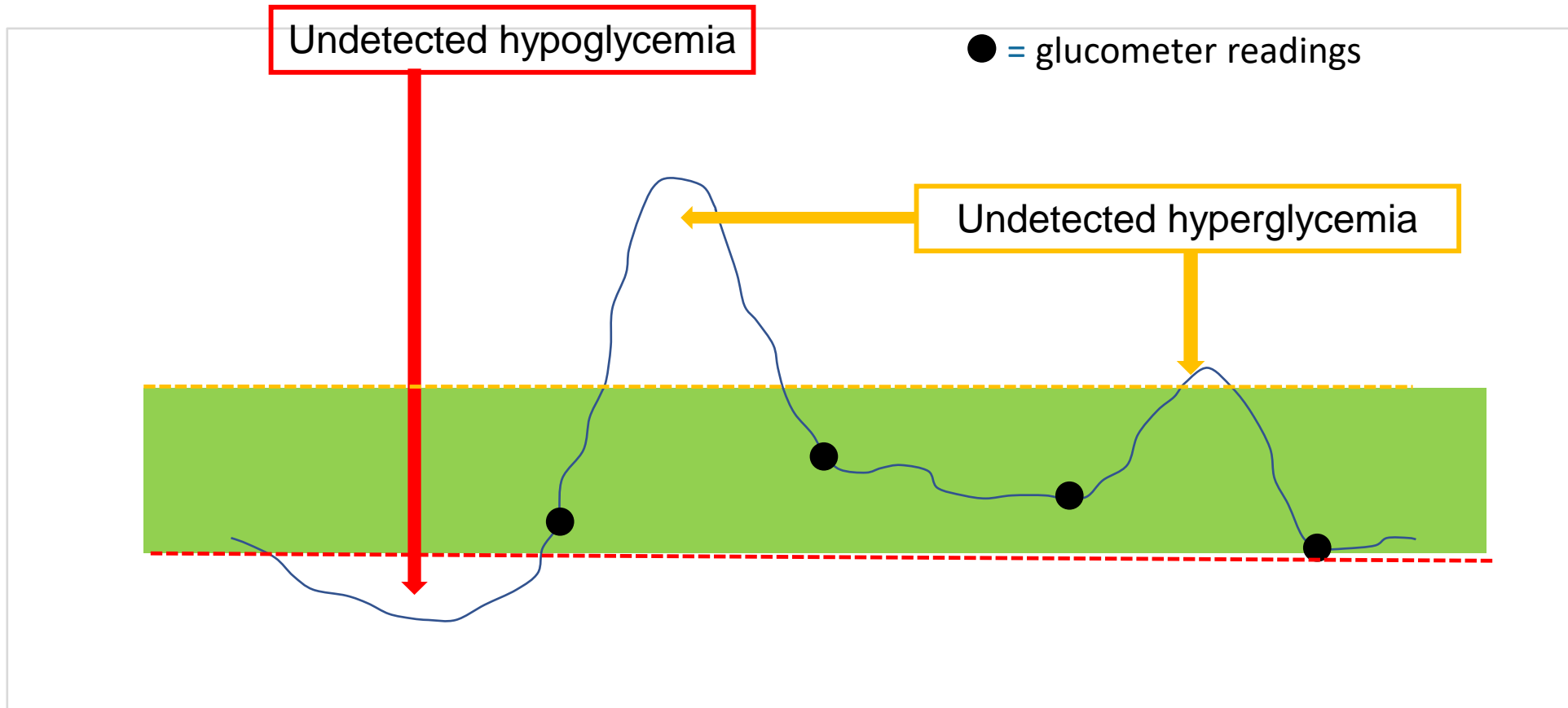
# CGM Facilitates Telehealth Services for Diabetes Management

Presented by Karen Earle, MD

Chief, Division of Endocrinology  
Medical Director, Center for Diabetes Services

California Pacific Medical Center

# BGM vs CGM



# 2020 ADA Standards of Care: Recommendations for Continuous Glucose Monitoring



rtCGM should be used continuously for maximal benefit.

isCGM should be scanned frequently throughout the day (minimum of once every 8 hours)

## CGM and T1D

- Real-time CGM (rtCGM) and intermittently scanned CGM (isCGM) are useful to lower A1C and/or reduce hypoglycemia in adults who are not meeting glycemic targets, have hypoglycemia episodes, and/or unawareness (**RT-CGM (A)**; **IS-CGM (C)**)
- rtCGM may be used to improve A1C levels and neonatal outcomes in pregnant women (**B**)
- Should be considered in all children and adolescents to improve glucose control regardless of insulin delivery method (**B**)

## CGM and T2D

- Useful tool, when used in conjunction with insulin therapy, to lower A1C and/or reduce hypoglycemia in adults with T2D who are not meeting glycemic targets (**B**)

# US and European Diabetes Associations Define Two CGM Categories



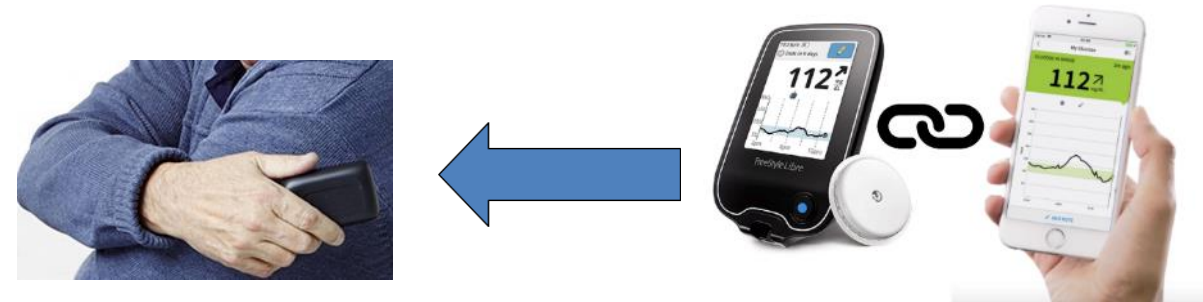
## Real-Time CGM (rtCGM)

- Sensor data transmitted continuously to a receiver or display device, which allows for glucose information to be provided to the wearer without any action



## Intermittently Scanned CGM (isCGM)

- Glucose results are available only when the sensor is scanned with a reading device
- Full 24-h data can be captured and downloaded if the sensor is scanned at least every 8 hours



# CGM Benefits

Regular Dexcom CGM use increases glucose awareness, helping to optimize diabetes management.<sup>1</sup> It has been shown to deliver the following benefits:

- Reduces both A1C and time spent in hypoglycemia (low glucose)<sup>1,2</sup>
- Decreases time in hyperglycemia (high glucose)<sup>1,2</sup>
- Increases time in range<sup>1</sup>
- Improves overall quality of life<sup>2</sup>

# FDA New iCGM Classification for the Dexcom G6 With Robust Standards for Performance and Accuracy

- New classification: Integrated Continuous Glucose Monitoring – Class II with Special Controls
- Benefits:
  - Streamlined premarket review process
  - Minimizes the FDA review time for new products
- Key criteria:
  - Performance and accuracy standards are robust and stringent
  - Can be used alone or integrated with digitally connected devices (eg, insulin pumps, insulin pens, AID systems for diabetes management)



AID = automated insulin dosing; FDA = US Food and Drug Administration; iCGM = integrated continuous glucose monitoring.  
FDA Authorizes First Fully Interoperable Continuous Glucose Monitoring System, Streamlines Review Pathway for Similar Devices. <https://www.fda.gov/news-events/press-announcements/fda-authorizes-first-fully-interoperable-continuous-glucose-monitoring-system-streamlines-review>. Accessed November 18, 2019.

**Dexcom**

# Dexcom G6 CGM System At-a-Glance

dexcomG6

- No fingersticks<sup>a</sup> ●
- No calibration required ●
- Urgent Low-Soon alert ●
- Overall MARD<sup>b</sup> of 9.0% ●
- Acetaminophen blocking<sup>a</sup> ●



- Custom alert schedules
- 10-day wear sensor
- Slimmer wearable profile
- Indicated for treatment decisions/dosing
- Simple, one-touch sensor insertion

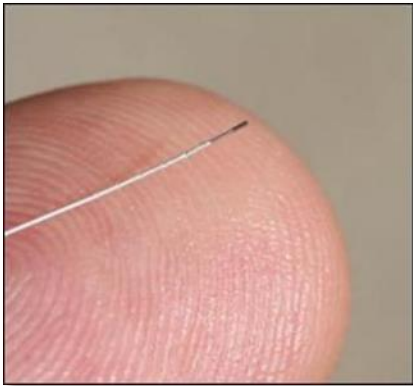
<sup>a</sup>If glucose alerts and readings from the G5 do not match symptoms or expectations or if dosage exceeds the recommended maximum dosage amount of 1000 mg of acetaminophen every 6 hours, a blood glucose meter should be used to make diabetes treatment decisions. <sup>b</sup>MARD is a statistical measure of accuracy, the lower the number, the better.

CGM = continuous glucose monitoring; MARD = mean absolute relative difference.

Dexcom G6 Continuous Glucose Monitoring System User Guide. <https://s3-us-west-2.amazonaws.com/dexcompdf/G6-CGM-Users-Guide.pdf>. Accessed November 18, 2019.

Dexcom

# Dexcom G6 CGM System



## Sensor+Algorithm

- No calibration required
- 10-Day session duration
- Cannot restart sensor session
- Acetaminophen blocking
- Intended for use for ages 2 and older



## Applicator

- Less-painful, simple, push-button sensor applicator
- Tiny insertion needle (26Ga)



## Transmitter

- ~30% thinner
- Contoured, wearable
- 3-Month life
- 20-foot transmission range
- Built in BLE for direct transmission of CGM data to receiver and mobile device



## Receiver

- Touchscreen receiver
- NEW urgent low-soon alert
- Firmware upgradable
- Customizable alerts (settings and sounds)



Apps  

- Updated apps:
- New Dexcom G6 App
- Fully customizable alerts
- NEW urgent low-soon alert
- Upgradable CLARITY

Maintaining CGM performance that is safe for diabetes management decisions, with ZERO calibrations

BLE = Bluetooth low energy; CGM = continuous glucose monitoring.



# DiaMonD (T1D) Study: Dexcom rtCGM System vs SMBG in T1D

## Design

- Randomized, controlled 24-week trial in 158 adults (>25 y) with T1D (mean baseline A1C 8.6%)
- Primary endpoint: change in A1C from baseline to Week 24



### A1C Reduction

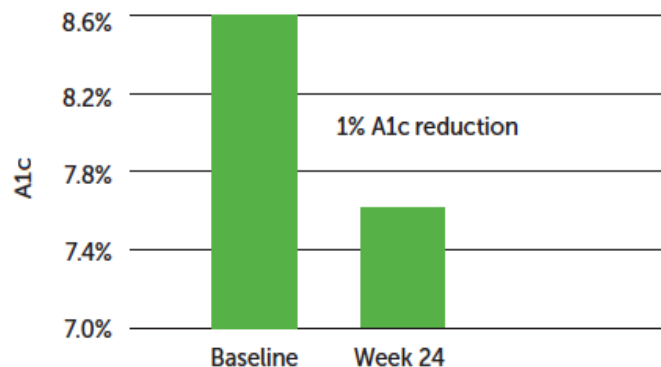
After 24 weeks, CGM users had a mean 1.0% A1C reduction from baseline (0.6% lower than SMBG;  $P < 0.001$ ).  
52% of patients had  $\geq 1\%$  A1C reduction.



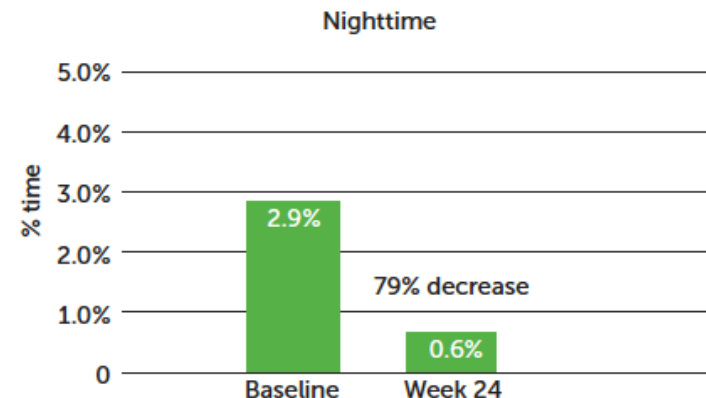
### Reduced Time in Nighttime Hypoglycemia (<60 mg/dL)

CGM group had 79% reduction in the median time spent in hypoglycemia at night.  
At Week 24, CGM users spent significantly less time in hypoglycemia vs SMBG users (0.6% vs 2.4%;  $P < 0.005$ ).

Significant A1c Reduction in MDI Patients with Dexcom CGM System



Dexcom CGM System Reduced Time Spent in Hypoglycemia (<60 mg/dL)



## RESULTS



**SIGNIFICANT A1c REDUCTIONS**  
regardless of patients' education level, math ability, and age

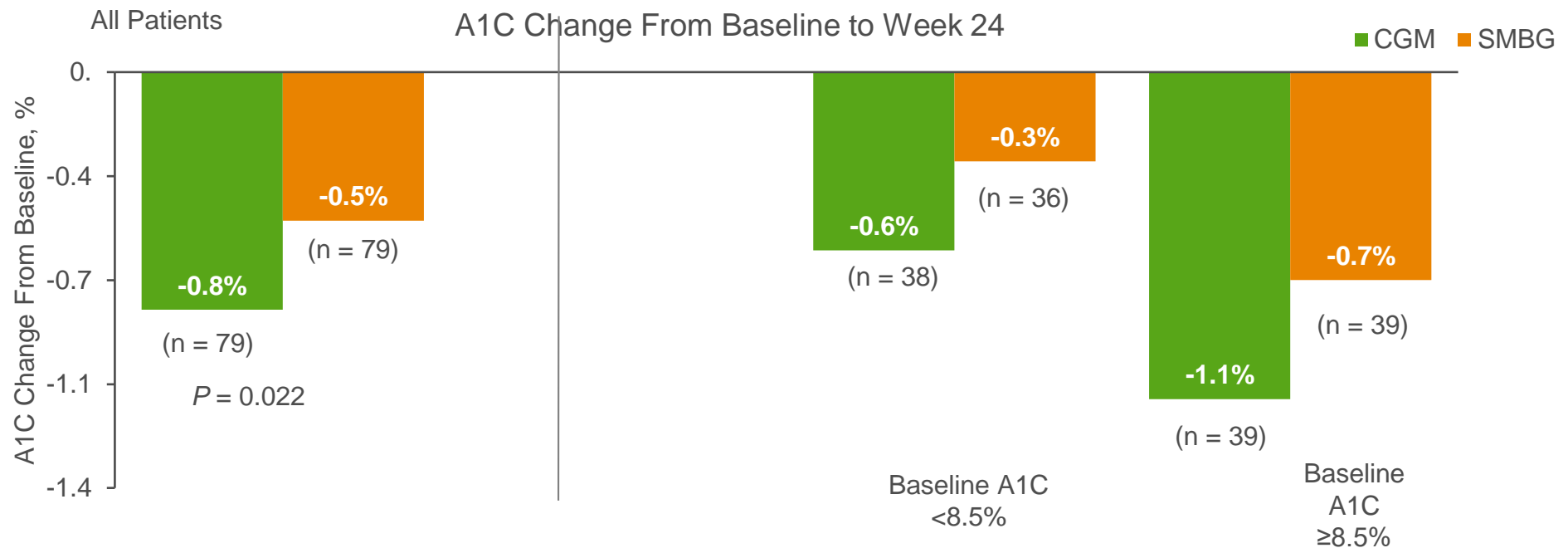


**HIGH RATE OF ADHERENCE**  
at week 24, 93% of patients were still using the Dexcom CGM System  $\geq 6$  days/week.

# DiaMonD (T2D) Study: Dexcom rtCGM System vs SMBG in T2D

## Design

- 24-Week RCT of 158 adults with T2D on MDI (mean baseline A1C 8.5% [7.5-9.9%])
- Primary endpoint: change in A1C from baseline to Week 24



# WISDM: Wireless Innovation for Seniors With Diabetes Mellitus

Richard E Pratley

*AdventHealth Translational Research Institute for Metabolism and Diabetes*

*301 E Princeton Street*

*Orlando, FL 32804*

on behalf of the WISDM Study Group

# WISDM Study: Design<sup>1,2</sup>

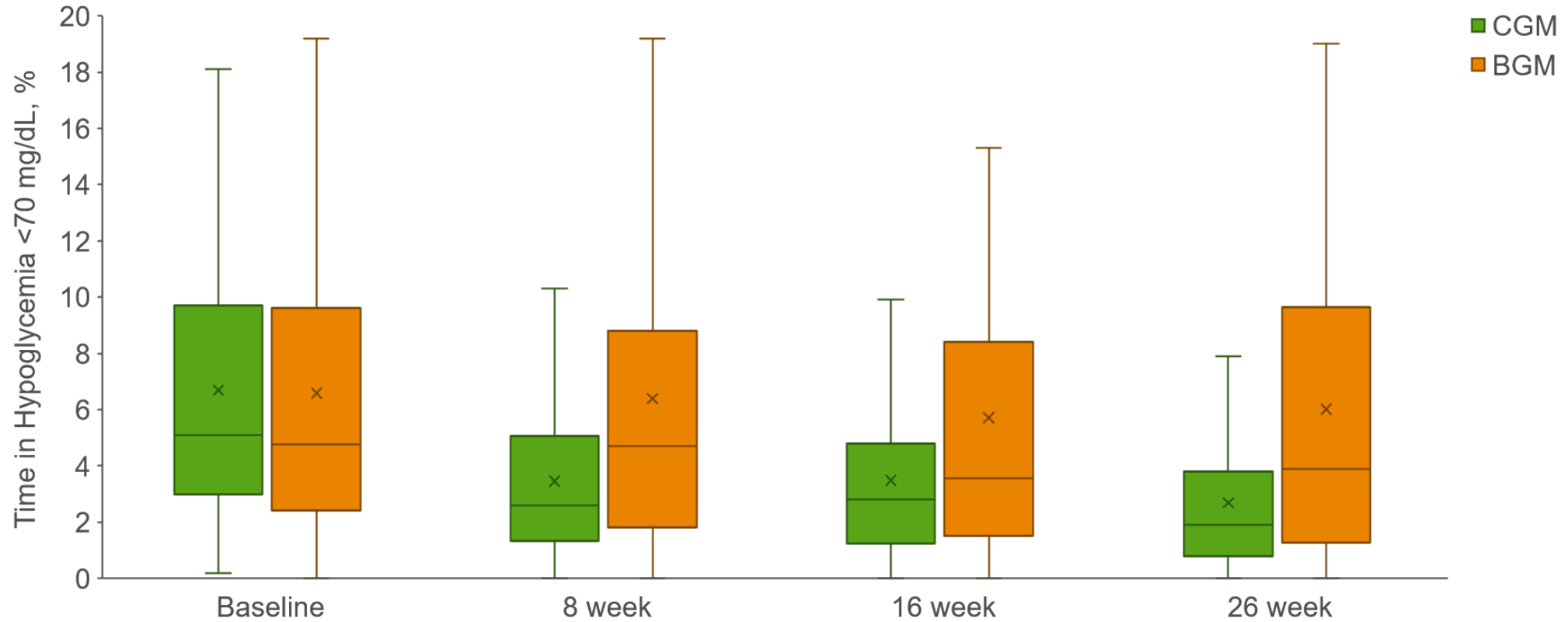
- 6-month, multicenter (22 sites), RCT
- Screening phase with masked CGM
  - Dexcom G4 Professional with 505 algorithm as in G5
- 203 participants randomly assigned (1:1) to
  - rtCGM using Dexcom G5 CGM (n = 103)
  - BGM with masked CGM (G4) at ~ 8, 16, 26 weeks (n = 100)

BGM = no intervention/usual care control group; CGM = continuous glucose monitoring; RCT = randomized controlled trial; rtCGM = real-time continuous glucose monitoring.

1. Pratley RE et al. Effect of continuous glucose monitoring on hypoglycemia in older adults with type 1 diabetes: A randomized clinical trial. *JAMA*. 2020;323(23):2397-2406. 2. NIH. Wireless Innovation for Seniors With Diabetes Mellitus (WISDM). <https://clinicaltrials.gov/ct2/show/NCT03240432>. Accessed November 19, 2010.

WISDM Study: Across Visits  
(Primary Outcome <70 mg/dL)

Adjusted Difference (pooled)  
-1.9% (-2.8%, -1.1%),  $P < 0.001$   
~27 min/d

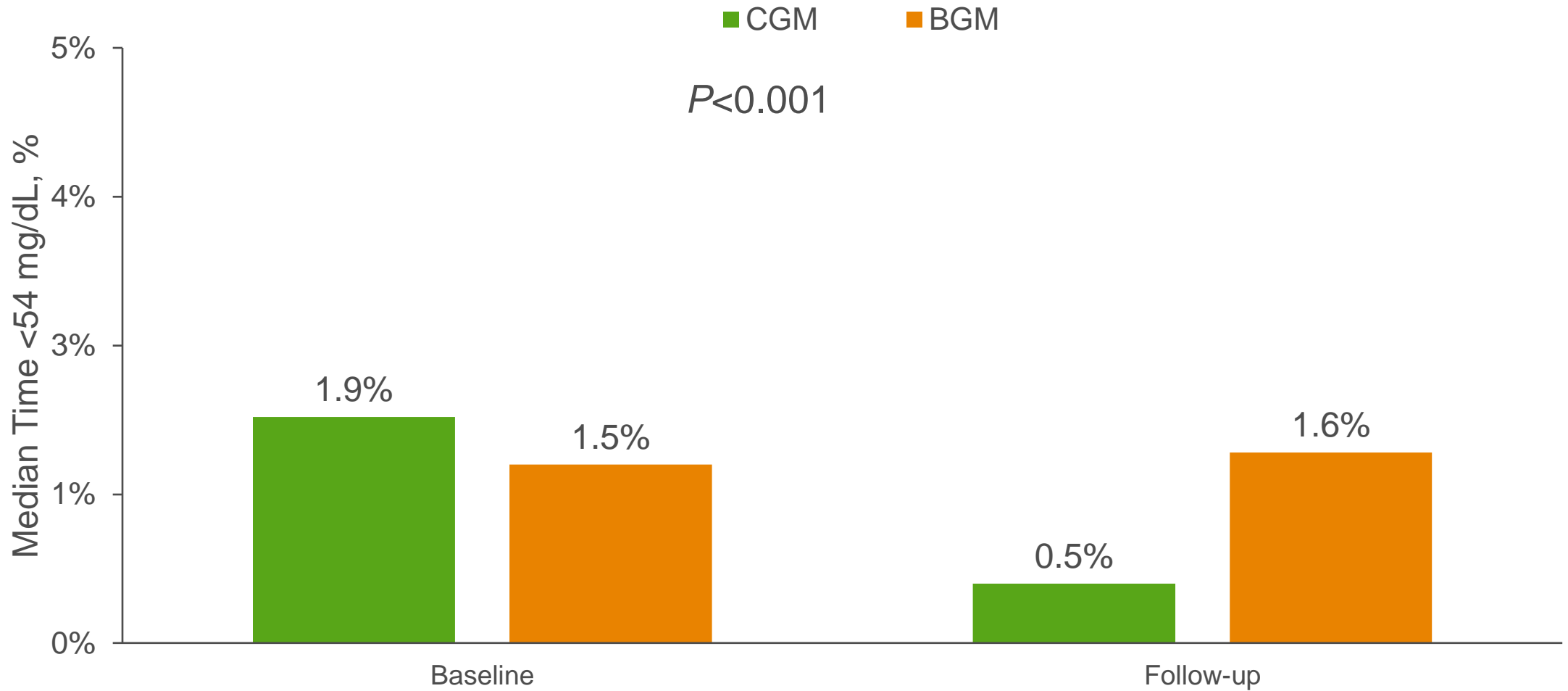


BGM = no intervention/usual care control group; CGM = continuous glucose monitoring.

1. Pratley RE et al. Effect of continuous glucose monitoring on hypoglycemia in older adults with type 1 diabetes: A randomized clinical trial. *JAMA*. 2020;323(23):2397-2406.

2. NIH. Wireless Innovation for Seniors With Diabetes Mellitus (WISDM). <https://clinicaltrials.gov/ct2/show/NCT03240432>. Accessed November 19, 2010.

# WISDM Study: Time in Hypoglycemia <54 mg/dL

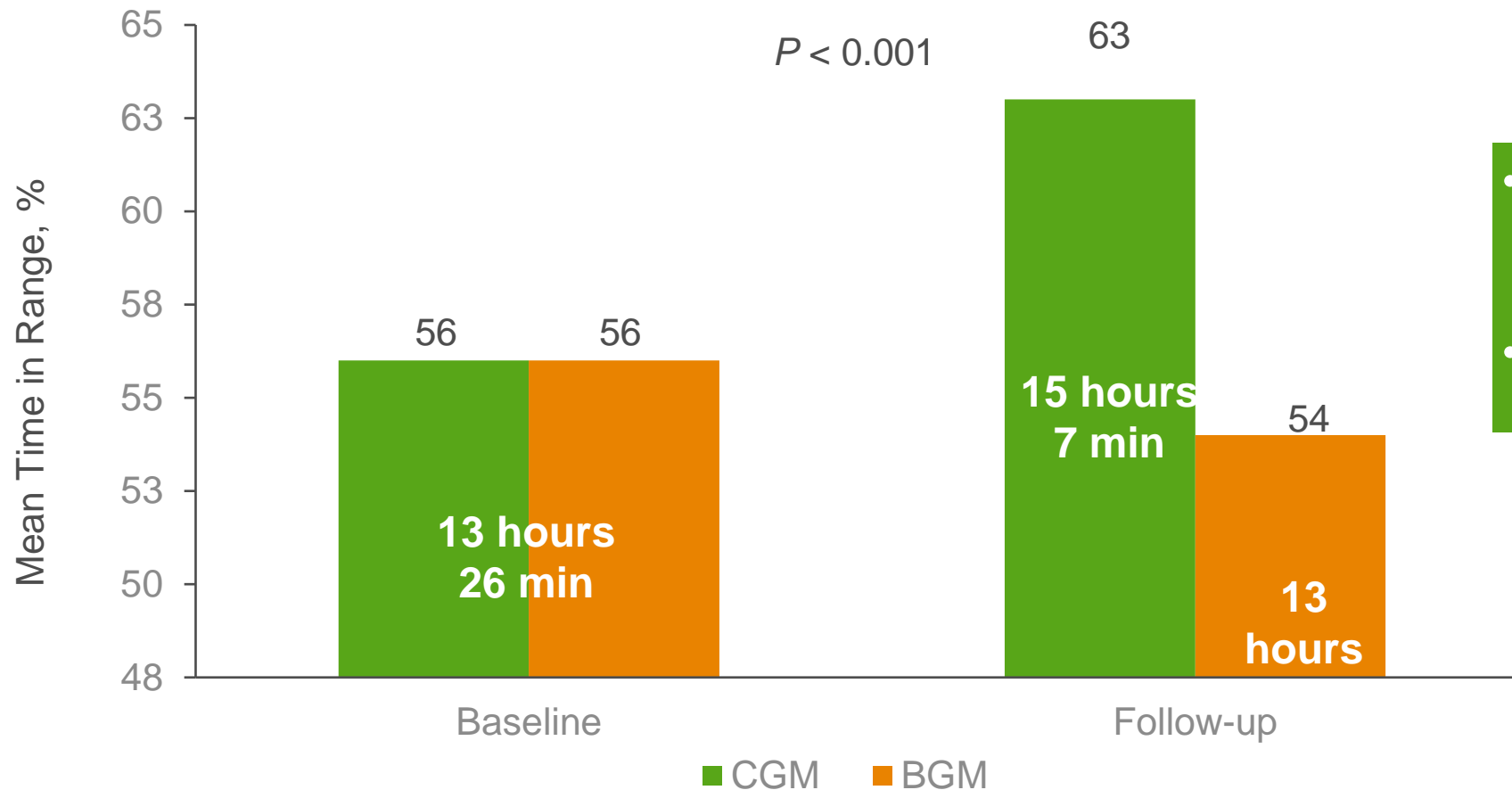


BGM = no intervention/usual care control group; CGM = continuous glucose monitoring.

1. Pratley RE et al. Effect of continuous glucose monitoring on hypoglycemia in older adults with type 1 diabetes: A randomized clinical trial. *JAMA*. 2020;323(23):2397-2406.

2. NIH. Wireless Innovation for Seniors With Diabetes Mellitus (WISDM). <https://clinicaltrials.gov/ct2/show/NCT03240432>. Accessed November 19, 2010.

# Secondary Outcome: Time in Range 70-180 mg/dL



- Mean A1C reduction of 0.3% ( $P < 0.001$ )
- Similar A1C reduction regardless of MDI or CSII

BGM = no intervention/usual care control group; CGM = continuous glucose monitoring; CSII = continuous subcutaneous insulin infusion; MDI = multiple daily injection.

Pratley RE et al. Effect of continuous glucose monitoring on hypoglycemia in older adults with type 1 diabetes: A randomized clinical trial. *JAMA*. 2020;323(23):2397-2406.

# Conclusions

- Use of rt-CGM significantly reduced the time in hypoglycemia AND the incidence of severe hypoglycemic events
- Use of rt-CGM in patients with T1D who were >60 years of age improved overall glucose control
- CSII and MDI had a similar 'treatment effect'
- Utilization of the CGM was quite high, with 83% of patients wearing the sensor  $\geq 6$  days/week

CSII = continuous subcutaneous insulin infusion; MDI = multiple daily injection; rtCGM = real-time continuous glucose monitoring; QOL = quality of life; T1D = type 1 diabetes.

Pratley RE et al. Effect of continuous glucose monitoring on hypoglycemia in older adults with type 1 diabetes: A randomized clinical trial. *JAMA*. 2020;323(23):2397-2406.

Pratley RE. Wireless innovations for seniors with diabetes mellitus: Primary results of the WISDM study. Presented at American Diabetes Association 79th Scientific Sessions. June 7-11, 2019, San Francisco, CA.



# Diabetes Management in the time of COVID-19

# Dexcom CLARITY

**Dexcom CLARITY has changed the way providers and patients access glucose data. Evaluate relevant glucose patterns and trends to help make diabetes management decisions from your clinic computer with Dexcom CLARITY.**


- One secure clinic account houses all patient data, accessible by all permitted staff
- Individual patient accounts collect CGM data history
- Range of interactive reports can be saved and printed
- Invite patients to share their CGM data for continuous data streaming and efficient appointments





# Patient List

Add new patient
Export all data

PATIENT NAME	DOB	PATIENT ID	LAST UPLOADED	DATA SHARING
Valkeamaki, Ville	30 Oct 1979	99867	18 Jun 2018	✔ On
Flick, P	27 Oct 1978	88643	6 Jul 2018	✔ On
S, Agnes	7 Oct 1994	22654	19 Oct 2018	✔ On
Bi, Ben	30 Aug 1986	16654	3 Jul 2018	✔ On
H., Verena	3 Jun 1988	10491	17 Jul 2018	✔ On <span style="float: right; font-size: 1.2em;">✕</span>

  
 Upload data

  
 Save or print report

  
 Go to interactive reports

🗑 Delete
 ✎ Edit
 📄 Export

Share data

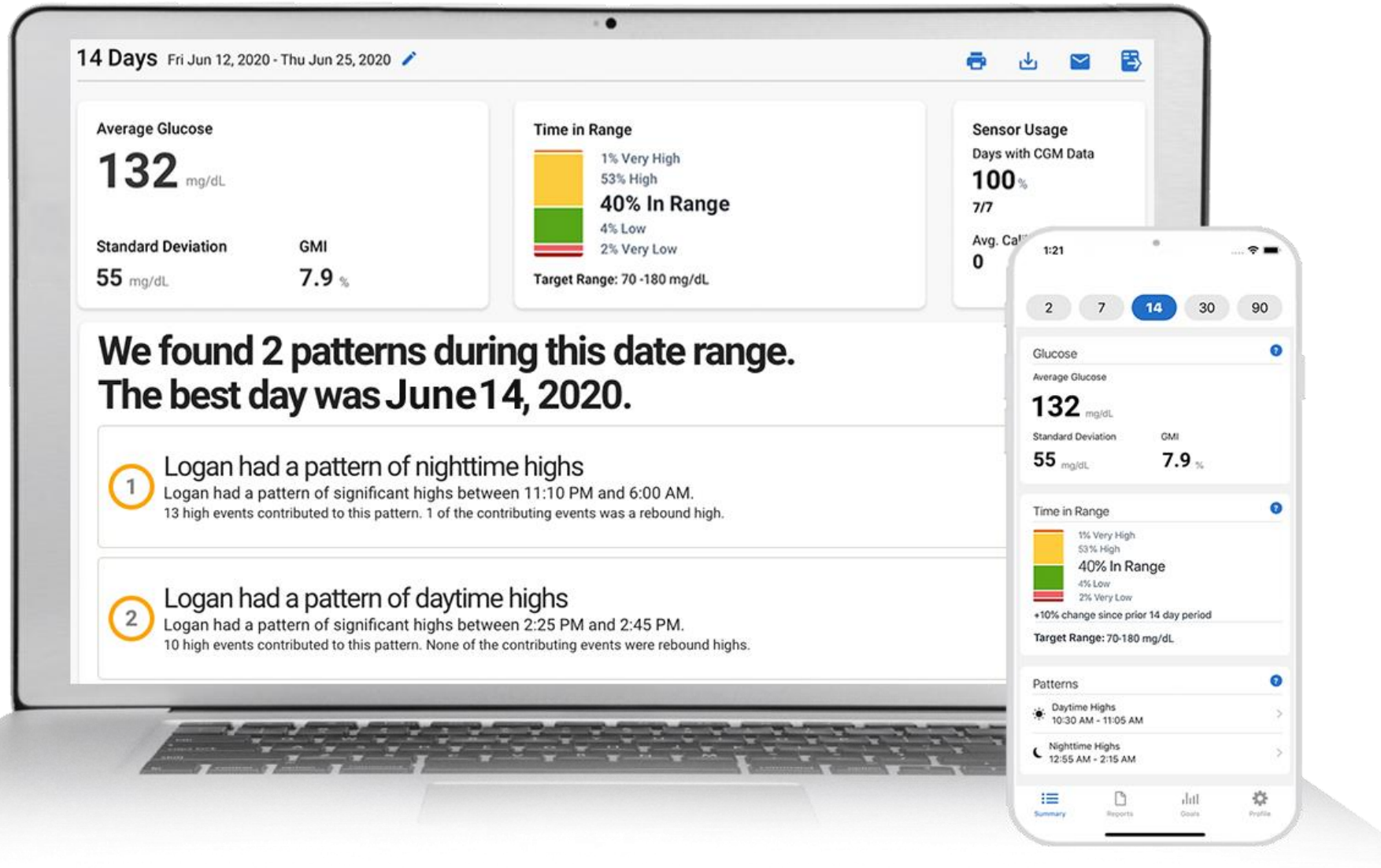
Collect CGM data history with the Patient List.

- Displays all patients entered into the clinic account.
- Clinic staff can be given access to this page.
- Upload receiver data directly to the patient's account.
- Save, print or export reports.
- View all reports interactively for more detailed data.
- Invite patients to authorize to share their data.

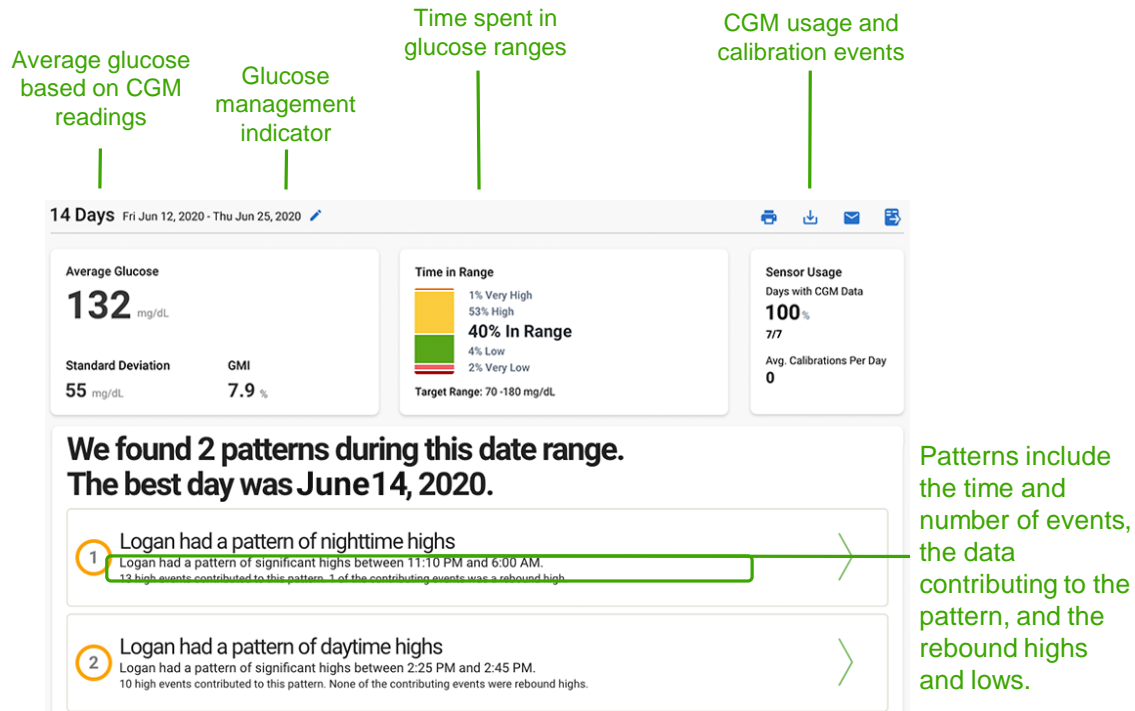
Dexcom CGM app data is uploaded automatically into the clinic account when:

1. Clinic has entered a patient in this list.
2. Sharing is authorized by the patient.

# Achieving Clinical Targets Utilizing Dexcom G6 and CLARITY



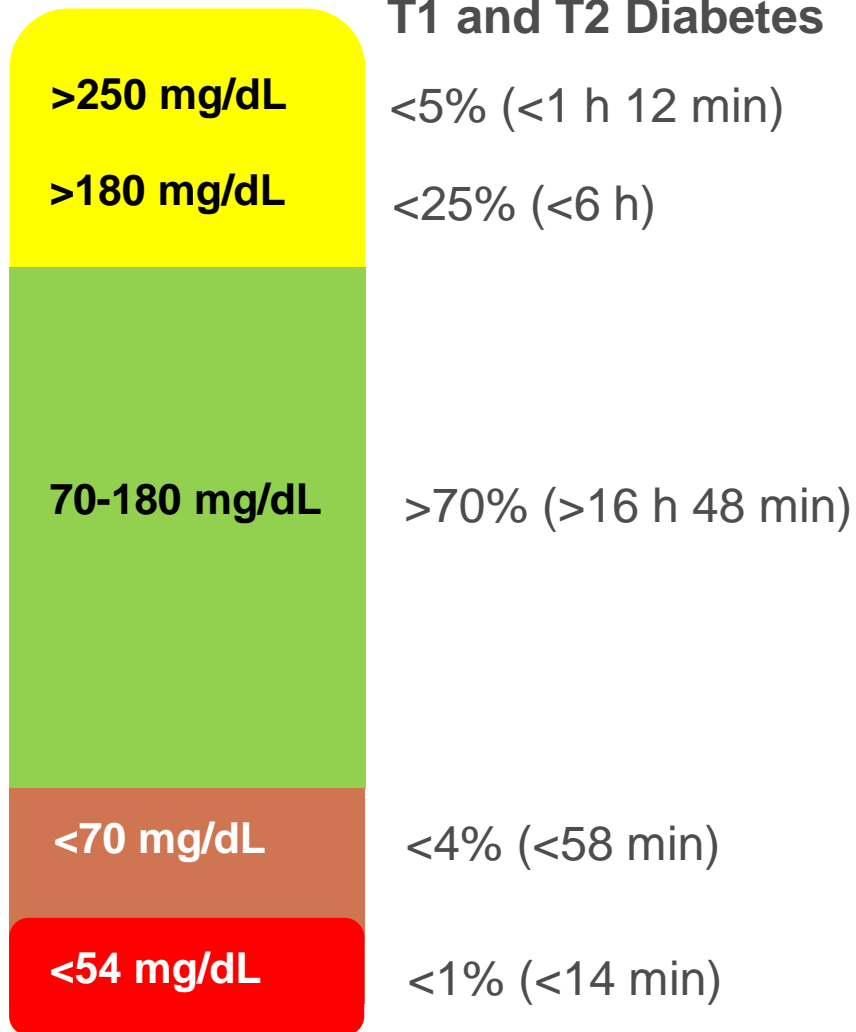
# Overview Report



The Overview report presents a summary of the most relevant clinical patterns.

- Focuses the discussion on areas contributing to hyperglycemia and hypoglycemia
- Provides data specific to the date range selected
- Summarizes the quality of glucose control via metrics
- Identifies daytime and nighttime patterns of highs and lows

# Correlation Between TIR and A1C



Time in Range (TIR), %	Average HbA1C, %
40	8.1
50	7.7
60	7.3
70	6.9
80	6.5

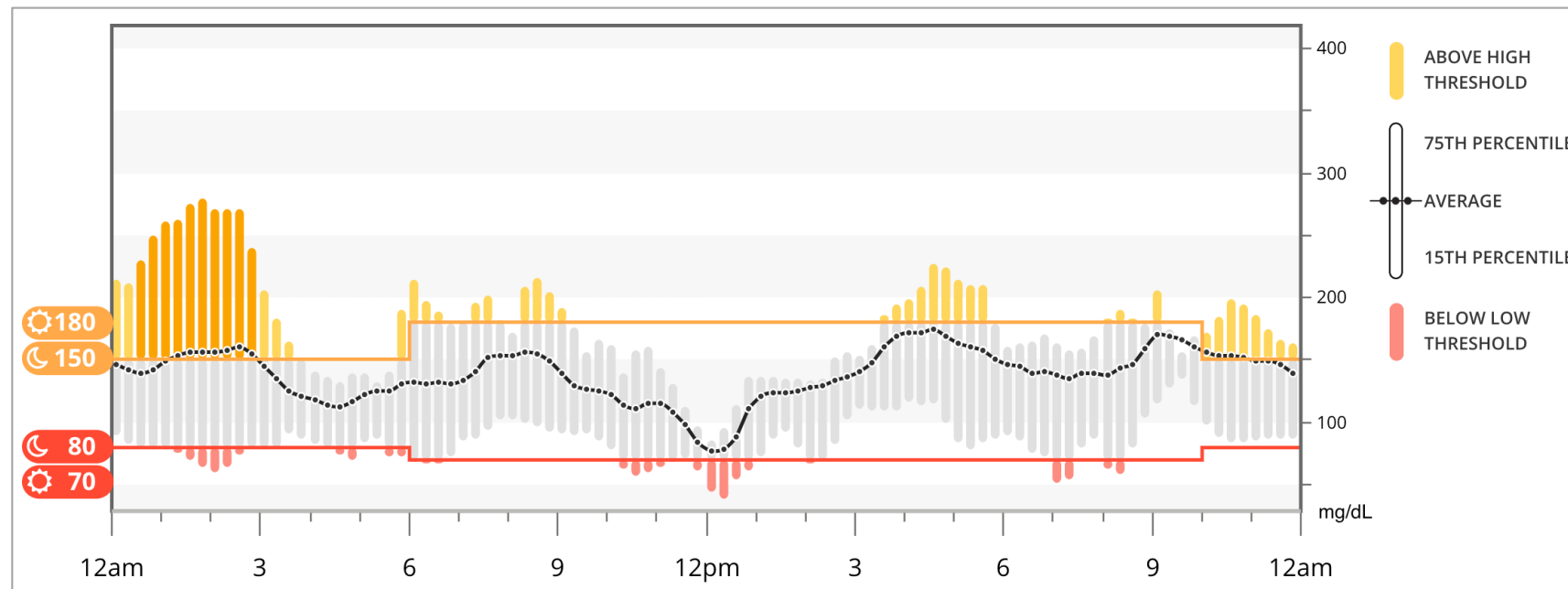
- ✓ TIR of 70% corresponds with an A1C of ~ 7%
- ✓ An increase in TIR of 10% corresponds to a decrease in A1C of ~0.5%

# Trends Report

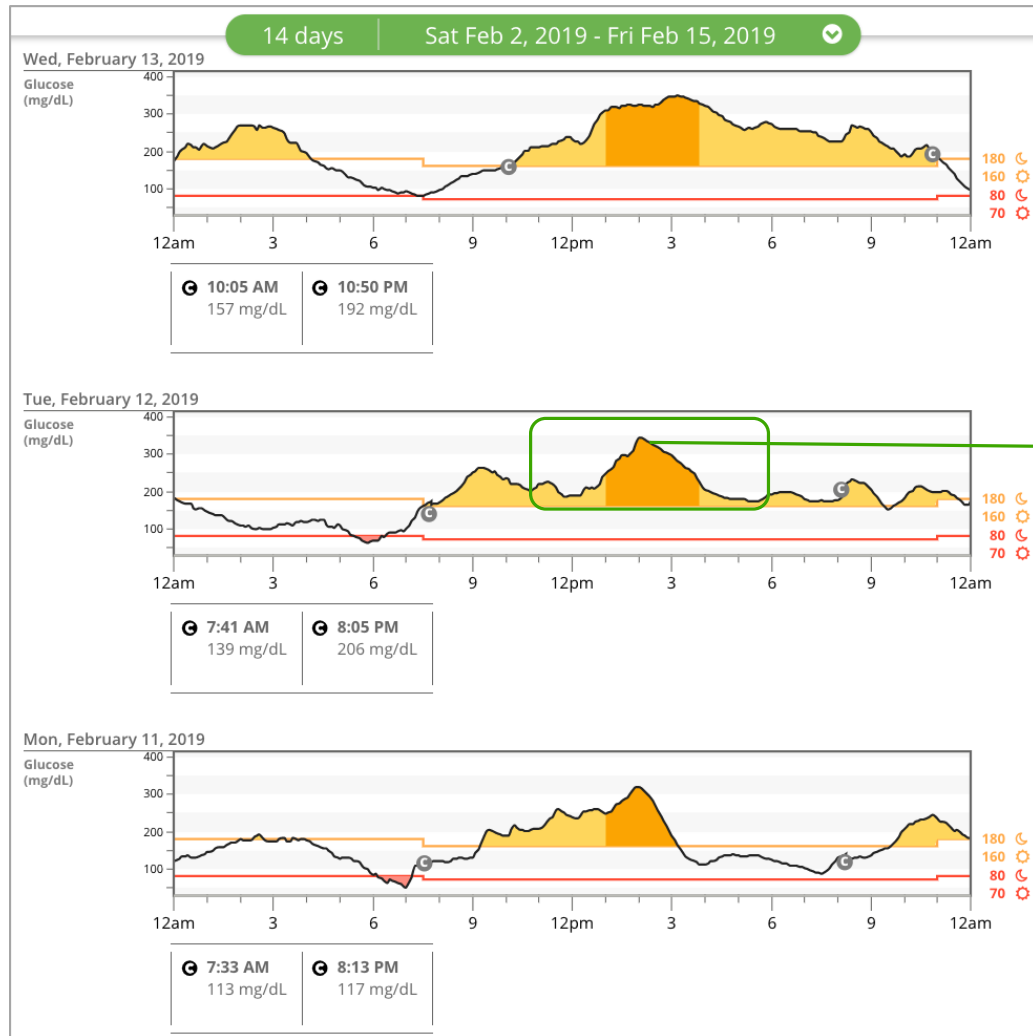
**Trends is a holistic visual representation of patterns. It helps prioritize clinical issues based on discussions with the patient.**

- Longer bars represent greater glycemic variability
- Clinically significant hypoglycemia patterns are red — the most significant are dark red
- Hyperglycemia patterns are yellow — the most significant are dark yellow
- Outlier data is removed to help focus on patterns, below the 15th percentile or above the 75th percentile

**A stepwise approach may help you identify patient challenges with hypo- and hyperglycemia.**



# Daily Report



- Every glucose reading is displayed in this report, including outliers
- Talk in-depth with patients about individual days and isolated events

CGM readings outside the target range are yellow for highs and red for lows. The darker the shade, the more intense the event.



# 2019 Continuous Glucose Monitoring (CGM) Coding Reference

Codes/Description	Medicare Physician Fee Schedule	Medicare Outpatient Diabetes Center	Private Payer (2018 Averages)	Relative Value Unit (RVU) Non-Facility*
<b>CGM Services</b>				
<b>CPT 95249 (Personal CGM - Startup/Training)</b>				
Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; patient-provided equipment, sensor placement, hook-up, calibration of monitor, patient training, and printout of recording.  <i>Bill only once during the time period that the patient owns the device.</i>	\$56.23	\$55.90 APC 5733	\$132	1.56
<b>CPT 95250 (Professional CGM)</b>				
Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; physician or other qualified health care professional (office) provided equipment, sensor placement, hook-up, calibration of monitor, patient training, removal of sensor, and printout of recording.  <i>Do not bill more than 1x/month.</i>	\$153.56	\$115.82 APC 5012	\$300	4.26
<b>CPT 95251 (CGM Interpretation)</b>				
Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; analysis, interpretation and report.  <i>Do not bill more than 1x/month</i>	\$36.41	Paid under physician fee schedule	\$89	1.01
<b>Evaluation and Management (E/M)</b>				
<b>CPT 99212-99215</b>				
For an established patient, office or outpatient visit. Appropriate code to be determined by the office.	\$45.78-\$147.79	\$115.82 APC 5012 G0463†	\$45-\$258	1.27-4.10

\*Non-facility is defined as office space. †Medicare outpatient clinic visits.

CGM = continuous glucose monitoring.

Dexcom. 2019 CGM Coding Reference. [https://dexcompdf.s3-us-west-2.amazonaws.com/HCP\\_Website/2019\\_CGM\\_Coding\\_Reference\\_LBL017757\\_REV001\\_\(1\)+\(1\).pdf](https://dexcompdf.s3-us-west-2.amazonaws.com/HCP_Website/2019_CGM_Coding_Reference_LBL017757_REV001_(1)+(1).pdf). Accessed November 25, 2019.

# CLARITY in Clinical Practice

Staff calls patient the day before video visit to talk with patient.

Staff helps patient walk through permission for our office to view Dexcom data on CLARITY Website.

Day of visit, staff clip the Overview report into medical record.

Full report added to media tab of Epic.

Physician can view data from CLARITY on the web or in patient chart.

# Type 2 Diabetes Case Study

# T2D Case

T2DM

58 y/o male

## Current meds:

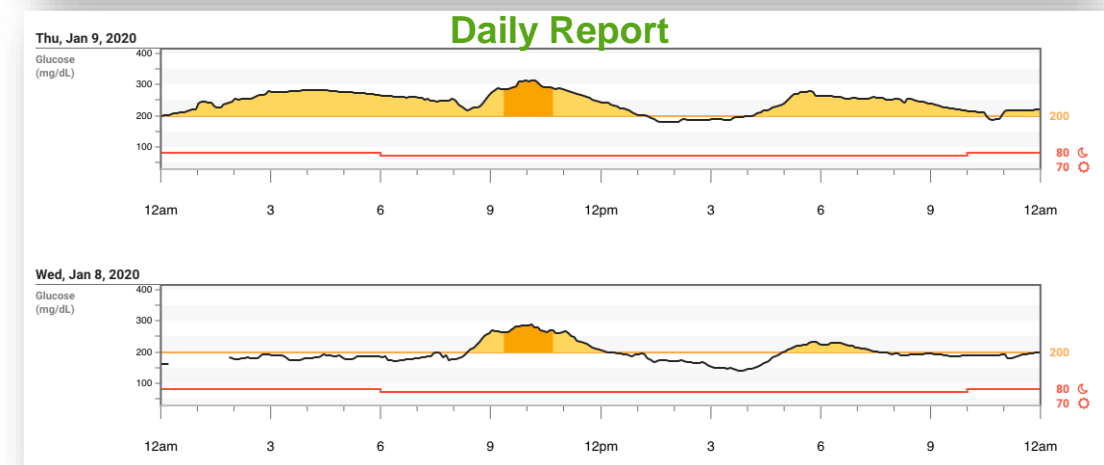
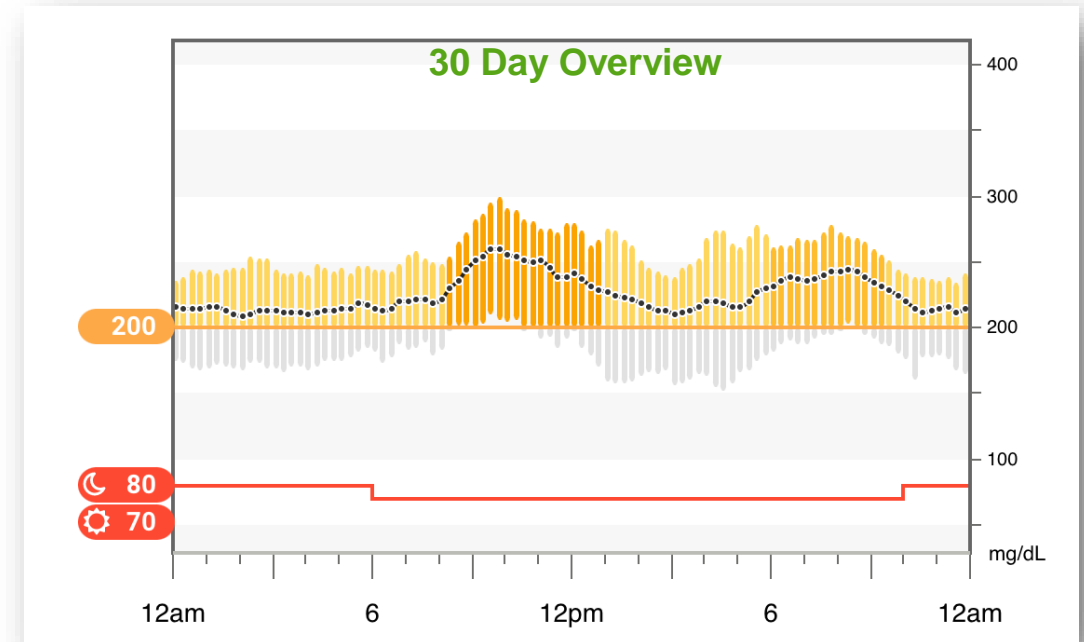
Metformin 2000 mg/day

Insulin glargine 60 units/day

Insulin lispro 10 units bid with breakfast and supper

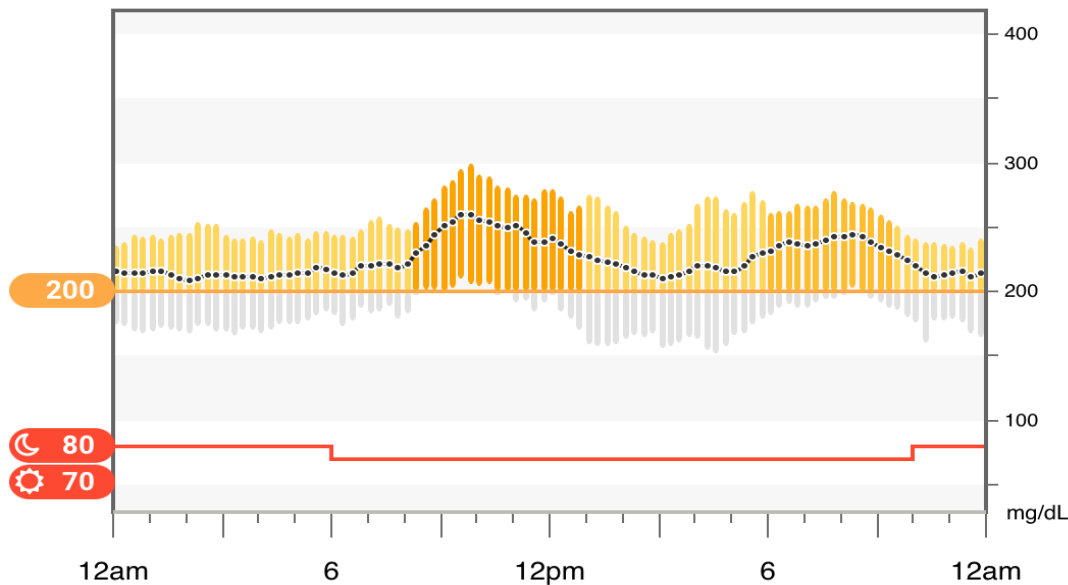
## Recommendations:

- u Add long-acting GLP1RA to lower fasting & post-prandial readings
- u Start Trulicity 0.75 mg weekly
- u Reduce lispro to 5 units at breakfast and supper

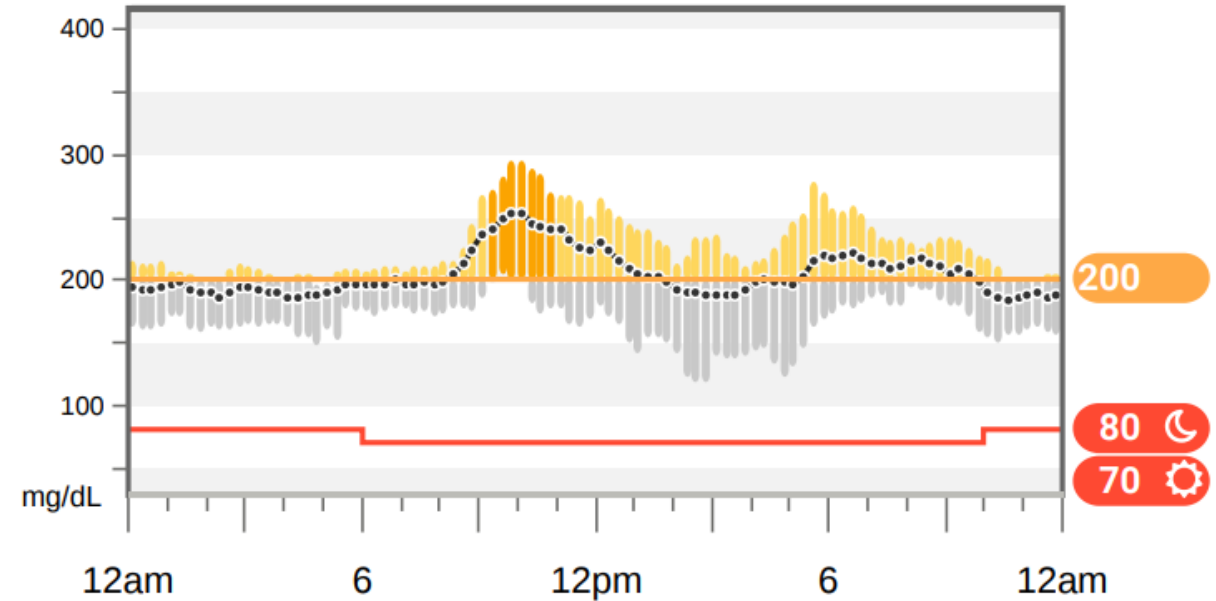


# T2D Case

BEFORE



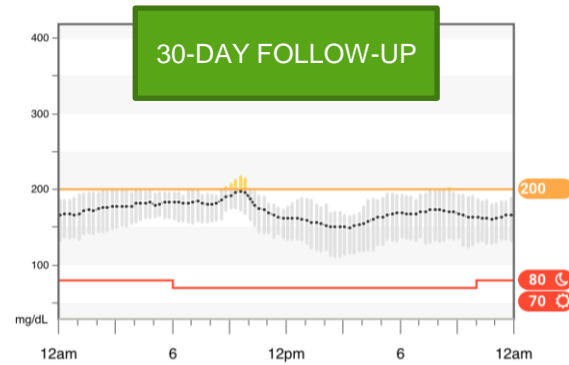
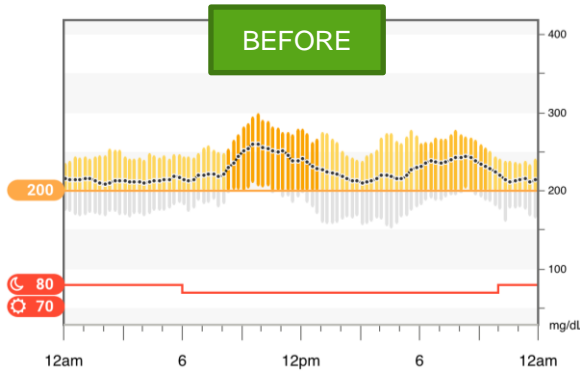
2 WEEK FOLLOW-UP



## Recommendations:

- Increase Trulicity to 1.5 mg weekly
- Stop supper insulin
- Reduce insulin glargine by 5 units per day if BG drops <90 mg/DI
- Return to clinic in 2 weeks

# T2D Case



Glucose Management Indicator	8.7 %						
Average glucose (CGM)	225 mg/dL						
Standard deviation (CGM)	47 mg/dL						
Hypoglycemia risk							
Time in range							
Sensor usage	<table border="0"> <tr> <td>Days with CGM data</td> <td>97%</td> </tr> <tr> <td></td> <td>29 / 30</td> </tr> <tr> <td>Avg. calibrations per day</td> <td>0.1</td> </tr> </table>	Days with CGM data	97%		29 / 30	Avg. calibrations per day	0.1
Days with CGM data	97%						
	29 / 30						
Avg. calibrations per day	0.1						

Glucose Management Indicator	↓ 7.4 %						
Average glucose (CGM)	↓ 171 mg/dL						
Standard deviation (CGM)	↓ 31 mg/dL						
Hypoglycemia risk							
Time in range							
Sensor usage	<table border="0"> <tr> <td>Days with CGM data</td> <td>100%</td> </tr> <tr> <td></td> <td>30 / 30</td> </tr> <tr> <td>Avg. calibrations per day</td> <td>0.2</td> </tr> </table>	Days with CGM data	100%		30 / 30	Avg. calibrations per day	0.2
Days with CGM data	100%						
	30 / 30						
Avg. calibrations per day	0.2						

## Medications at follow-up:

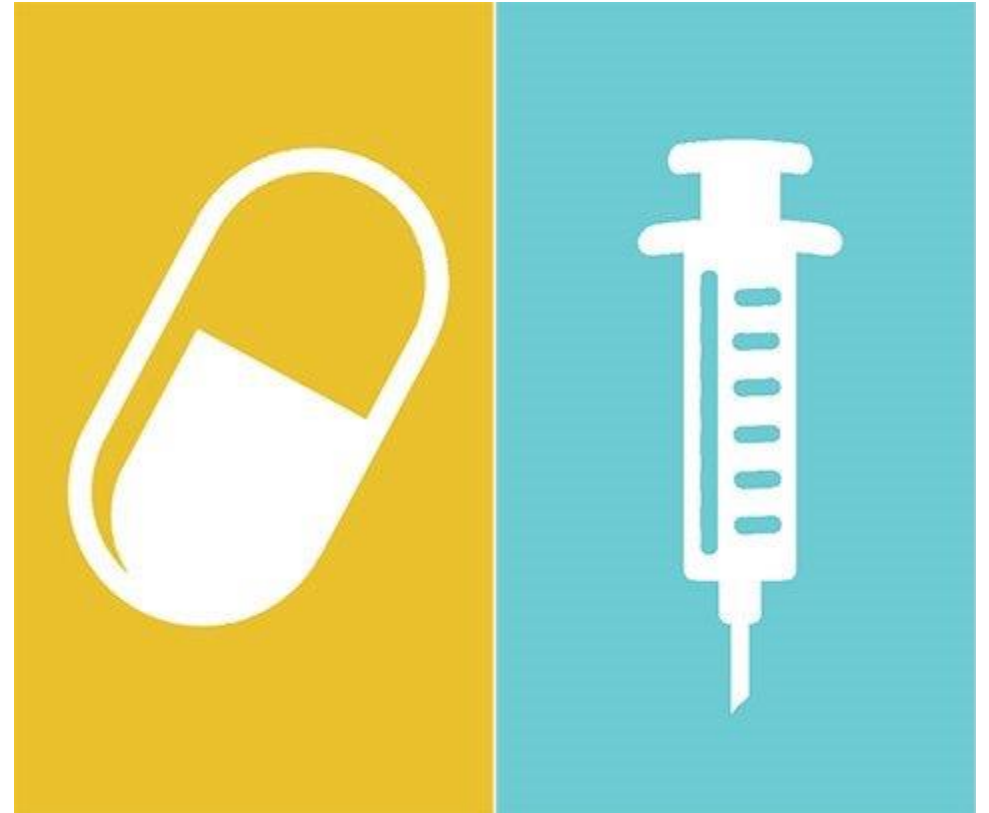
- Insulin glargine – 55 units
- Insulin lispro – 5 units with breakfast
- Trulicity – 1.5 mg weekly

## Recommendations:

- Continued dietary counseling – consider lower carb breakfast. Reduce insulin doses as able with more time on therapy

# Medication Effects

- Reduce fasting glucose: Metformin, basal insulin, long-acting GLP1ra, SGLT2, pioglitazone
- Reduce post-prandial glucose: Mealtime insulin, sulfonylurea, SGLT2i, GLP1ra, DPP4i
- Hypoglycemia caused by: Insulin and sulfonylurea



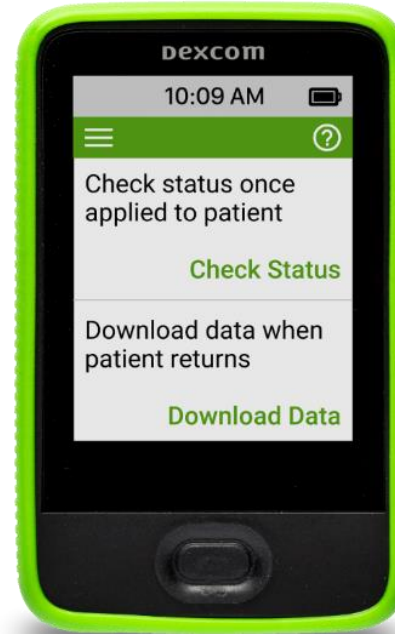
# G6 Professional

## Applicator and Sensor



- The sensor measures glucose levels just below the skin for up to 10 days
- Easily apply the sensor to your patient on either the abdomen or the abdomen and upper buttocks ages 2-17 y

## Reader



- Check system status after insertion
- Download sensor data to CLARITY after sensor session is over
- Stays in office, use on multiple patients

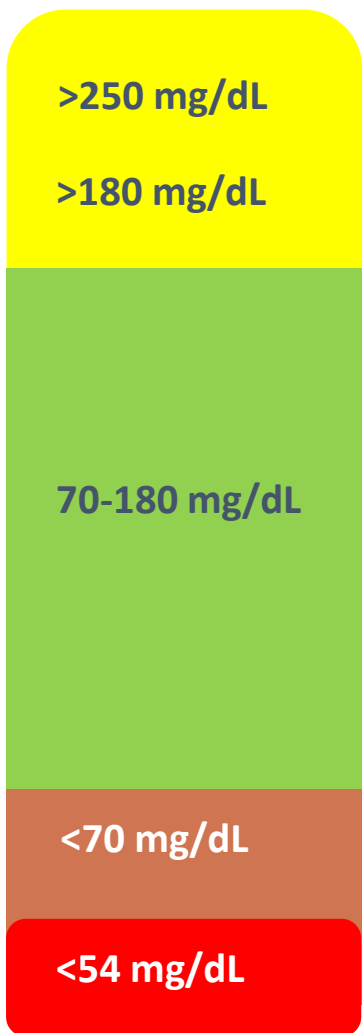
## Transmitter



- G6 Pro transmitter captures and stores data from the sensor
- After the sensor session, the patient returns the sensor and transmitter to office



# Dexcom CLARITY Pro Report Simplifies CGM Interpretation with TIR Metrics



## T1 and T2 Diabetes

<5% (<1 h 12 min)

<25% (<6 h)

>70% (>16 h 48 min)

<4% (<58 min)

<1% (<14 min)

Pro  
Session 1 |



### Glucose

Average Glucose

**158** mg/dL

Standard Deviation

**61** mg/dL

Coefficient Of Variation

**38%**

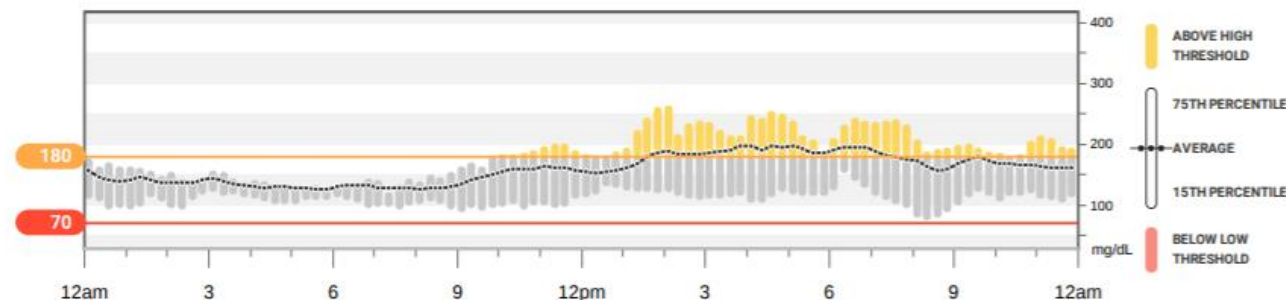
### Time in Range

8% Very High  
20% High  
**71% In Range**  
<1% Low  
0% Very Low  
Target Range: 70-180 mg/dL

### Sensor Usage

Days with CGM data  
**100%**  
10/10

### Pro Session Trends



### Patterns

**1** Patient's best glucose day was February 19, 2020  
Patient's glucose data was in the target range about 91% of the day.

Questions?

# Dexcom G6 Safety Statement

Failure to use the Dexcom G6 Continuous Glucose Monitoring System (G6) and its components according to the instructions for use provided with your device and available at <https://www.dexcom.com/safety-information> and to properly consider all indications, contraindications, warnings, precautions, and cautions in those instructions for use may result in you missing a severe hypoglycemia (low blood glucose) or hyperglycemia (high blood glucose) occurrence and/or making a treatment decision that may result in injury. If your glucose alerts and readings from the G6 do not match symptoms or expectations or you're taking over the recommended maximum dosage amount of 1000mg of acetaminophen every 6 hours, use a blood glucose meter to make diabetes treatment decisions. Seek medical advice and attention when appropriate, including for any medical emergency.

The web-based Dexcom CLARITY software is intended for use by both home users and healthcare professionals to assist people with diabetes and their healthcare professionals in the review, analysis, and evaluation of historical CGM data to support effective diabetes management. It is intended for use as an accessory to Dexcom CGM devices with data interface capabilities. Caution: The software does not provide any medical advice and should not be used for that purpose. Home users must consult a healthcare professional before making any medical interpretation and therapy adjustments from the information in the software. Caution: Healthcare professionals should use information in the software in conjunction with other clinical information available to them. Caution: Federal (US) law restricts this device to sale by or on the order of a licensed healthcare professional.

Dexcom, Dexcom G6, Dexcom Share, and Dexcom CLARITY are registered trademarks of Dexcom, Inc. in the United States and/or other countries.

Dexcom, Inc. | 6340 Sequence Drive | San Diego, CA 92121

Technical Support: 1-877-339-2664 | [www.dexcom.com](http://www.dexcom.com)

©2019 Dexcom, Inc. All rights reserved.

**Dexcom**