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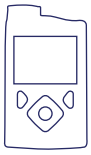

MiniMed 780G

System Technical Guide

Includes technology developed by dreamed diabetes ai

MiniMed™ 780G

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Introduction

1 Introduction

This system technical guide describes the technical aspects and performance data of the MiniMed™ 780G system.

Accessing user guides online

All user guides related to the MiniMed 780G system are available online. You can view or order printed copies by going to this website: https://manuals/.medtronic.com/manuals/.

This includes the following user guides:

- MiniMed 780G System User Guide
- Simplera Sync™ Sensor User Guide
- Guardian™ 4 Sensor User Guide

Using this guide

Use the table of contents at the beginning of the this guide and the index at the end of this guide to locate specific information.

Refer to the glossary for definitions of terms and acronyms used.

For instructions about setting up devices on the MiniMed 780G system, such as a sensor or infusion set, refer to the user guide for the related device.

Conventions

Convention	Definition
Caution	**CAUTION:** A caution informs of a potential hazard which, if not avoided, might result in minor or moderate injury, or damage to the equipment.
WARNING	**WARNING:** A warning informs of a potential safety hazard which, if not avoided, may result in serious injury or death. It may also describe potential serious adverse reactions.

2

MiniMed 780G pump specifications

2 MiniMed 780G pump specifications

Specifications and default settings

Alarm and alert escalation

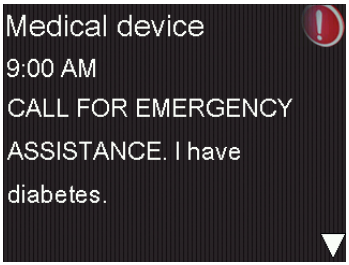
The following alerts may escalate to a siren if not cleared:

- Alert before high
- Alert before low
- Alert on high
- Alert on low
- Basal delivery resumed
- Calibration not accepted
- Change sensor
- Consider sensor change
- Enter BG now
- Failed BG check
- High SG
- Lost sensor signal
- Low SG XX mg/dL (SG is under 54 mg/dL)
- No calibration occurred
- Possible signal interference
- Rise Alert
- Sensor expired
- Sensor failed to pair with pump
- Sensor failed to start
- Sensor signal not found
- Sensor too hot
- Sensor too cold
- Sensor updating
- Very high basal setting
- Warm up not started

The MiniMed 780G insulin pump may generate a siren if the alert is not cleared within ten minutes. Before ten minutes, the pump beeps, vibrates, or both, depending on the sound and vibration settings.

Minutes	Sound	Vibration	Sound and vibration
0-5	Beep	Vibrate	Beep and vibrate
6-9	Beep and vibrate	Sound and vibrate	Beep and vibrate
10	Siren and vibrate	Siren and vibrate	Siren and vibrate

Note: The Medical device alarm plays a siren when this screen appears.



Altitude range

- Operating range: 10.2 psiA (70.33 kPa) to 15.4 psiA (106.18 kPa)
- Storage range: 7.2 psiA (49.64 kPa) to 15.4 psiA (106.18 kPa)

Backlight

Type	LED (Light-emitting Diode)
Time out	15 seconds (default), 30 seconds, one minute, three minutes
Time out when battery is low	15 seconds (default), 30 seconds

Basal delivery

The basal delivery specifications do not affect the amount of insulin delivered by SmartGuard™. These specifications relate to Manual mode only.

Delivery rate range	0 to 35 units per hour or the Max Basal Rate amount, whichever is lower. The default range is 0 to 10 U/hr.
Max Basal Rate default	2 units per hour
Basal patterns	Maximum of 8 patterns for Manual mode. Each pattern covers a 24-hour period and can have up to 48 rates. Rates are set in 30-minute increments.

Basal pattern names	Fixed names: Basal 1, Basal 2, Basal 3, Basal 4, Basal 5, Workday, Day Off, Sick Day
Increments	• 0.025 units per hour for basal amounts in the range 0 to 0.975 units • 0.05 units per hour for basal amounts in the range 1 to 9.95 units • 0.1 units per hour for basal amounts of 10 to 35 units

Bolus delivery

Bolus Speed options	• Standard: 1.5 units/minute • Quick: 15 units/minute
Bolus programming increments	• 0.025 units • 0.05 units • 0.1 units
Fluid delivered/stroke	• 0.25 µL (microliter) for 0.025 unit pump stroke • 0.5 µL for 0.05 unit pump stroke • 2.0 µL for 0.2 unit pump stroke

ACE Pump Performance Characteristics

The MiniMed 780G insulin pump delivers insulin in two ways: basal insulin delivery (continuous) and bolus insulin delivery. The following accuracy data was collected on both types of delivery in laboratory studies performed by Medtronic to demonstrate ACE (Alternative Controller Enabled) pump performance characteristics.

Basal delivery

To assess basal delivery accuracy, 32 MiniMed 780G pumps were tested by delivering at minimum, intermediate, and max basal rates (0.025, 1.0, and 35 U/hr). Sixteen of the pumps were new, and 16 had been aged to simulate four years of regular use. For both aged and unaged pumps, eight pumps were tested with new infusion sets and reservoirs, and eight with infusion sets and reservoirs that were aged to the duration of shelf life. Humalog placebo was used as a substitute for insulin. Humalog placebo was delivered into a container on a scale and the weight of the liquid at various time points was used to assess pumping accuracy.

The following tables report the typical basal performance (median) observed, along with the lowest and highest results observed for minimum, intermediate, and max basal rate settings for all pumps tested. For all basal rates, accuracy is reported from the time basal delivery started with no warm-up period. For each time period, the tables show the volume of insulin requested in the first row and the volume that was delivered as measured by the scale in the second row. Minimum basal, intermediate basal, and maximum basal results can be seen in *Table 1*, *Table 2*, and *Table 3*, respectively.

Table 1. Minimum Basal Rate Delivery Performance (0.025 U/hr)[i]

Basal Duration (Number of Units Delivered with 0.025 U/hr Setting)	1 hour (0.025 U)	6 hours (0.15 U)	12 hours (0.3 U)
Amount Delivered [min, max]	0.041 U [0.000 U, 0.094 U]	0.219 U [0.052 U, 0.364 U]	0.518 U [0.171 U, 0.695 U]

Table 2. Intermediate Basal Rate Delivery Performance (1.0 U/hr)[i]

Basal Duration (Number of Units Delivered with 1.0 U/hr Setting)	1 hour (1 U)	6 hours (6 U)	12 hours (12 U)
Amount Delivered [min, max]	0.89 U [0.81 U, 0.98 U]	5.81 U [5.62 U, 6.03 U]	11.79 U [11.46 U, 12.11 U]

Table 3. Maximum Basal Rate Delivery Performance (35.0 U/hr)[i]

Basal Duration (Number of Units Delivered with 35.0 U/hr Setting)	1 hour (35 U)	6 hours (210 U)
Amount Delivered [min, max]	33.21 U [31.53 U, 34.39 U]	205.33 U [203.31 U, 206.18 U]

Bolus delivery

To assess bolus delivery accuracy, 32 MiniMed 780G pumps were tested by delivering consecutive minimum, intermediate, and max bolus volumes (0.025, 2.5, and 25 units). Sixteen of the pumps were new, and 16 had been aged to simulate four years of regular use. For both aged and unaged pumps, eight pumps were tested with new infusion sets and reservoirs, and eight with infusion sets and reservoirs which underwent real time aging. Humalog placebo was used as a substitute for insulin for this testing. The Humalog placebo was pumped into a container on a scale, and the weight of the liquid at various time points was used to assess pumping accuracy.

Delivered bolus volumes were compared to the requested bolus volume delivery for minimum, intermediate, and maximum bolus volumes. *Table 4* below shows average, minimum, and maximum bolus sizes observed. In addition, *Table 5*, *Table 6*, and *Table 7* show the number of boluses which were observed to be within the specified range for min bolus, intermediate bolus, and max bolus, respectively.

Table 4. Summary of Bolus Delivery Performance (n=32 pumps)[i]

Individual Bolus Accuracy Performance	Target Bolus Size (U)	Mean Bolus Size (U)	Min Bolus Size (U)	Max Bolus Size (U)
Min Bolus Delivery Performance (n=800 boluses)	0.025	0.024	0.004	0.041
Intermediate Bolus Delivery Performance (n=800 boluses)	2.50	2.45	2.23	2.57
Max Bolus Delivery Performance (n=320 boluses)	25.00	24.58	24.20	24.89

Table 5. Min Bolus Delivery Performance (0.025U) (n=800 boluses)[i]

	Units of Insulin Delivered After a 0.025 U Bolus Request									
	<0.006 (<25%)	**0.006–0.019 (25–75%)**	**0.019–0.023 (75–90%)**	**0.023–0.024 (90–95%)**	**0.024–0.026 (95–105%)**	**0.026–0.028 (105–110%)**	**0.028–0.031 (110–125%)**	**0.031 –0.044 (125–175%)**	**0.044–0.063 (175–250%)**	**>0.063 (>250%)**
Number and Percent of Boluses within Range	2/800	116/800	179/800	72/800	133/800	111/800	106/800	81/800	0/800	0/800
	(0.3%)	(14.5%)	(22.4%)	(9.0%)	(16.6%)	(13.9%)	(13.3%)	(10.1%)	(0.0%)	(0.0%)

Table 6. Intermediate Bolus Delivery Performance (2.5U) (n=800 boluses)[i]

	Units of Insulin Delivered After a 2.5 U Bolus Request									
	<0.625 (<25%)	**0.625–1.875 (25–75%)**	**1.875–2.25 (75–90%)**	**2.25–2.375 (90–95%)**	**2.375–2.625 (95–105%)**	**2.625–2.75 (105–110%)**	**2.75–3.125 (110–125%)**	**3.125–4.375 (125–175%)**	**4.375–6.25 (175–250%)**	**>6.25 (>250%)**
Number and Percent of Boluses within Range	0/800	0/800	1/800	25/800	774/800	0/800	0/800	0/800	0/800	0/800
	(0.0%)	(0.0%)	(0.1%)	(3.1%)	(96.8%)	(0.0%)	(0.0%)	(0.0%)	(0.0%)	(0.0%)

Table 7. Max Bolus Delivery Performance (25U) (n=320 boluses)[i]

	Units of Insulin Delivered After a 2.5 U Bolus Request									
	<6.25 (<25%)	**6.25–18.75 (25–75%)**	**18.75–22.5 (75–90%)**	**22.5–23.75 (90–95%)**	**23.75–26.25 (95–105%)**	**26.25–27.5 (105–110%)**	**27.5–31.25 (110–125%)**	**31.25–43.75 (125–175%)**	**43.75–62.5 (175–250%)**	**>62.5 (>250%)**

Table 7. Max Bolus Delivery Performance (25U) (n=320 boluses)[i] (continued)

Units of Insulin Delivered After a 2.5 U Bolus Request										
Number and Percent of Boluses within Range	0/320 (0.0%)	0/320 (0.0%)	0/320 (0.0%)	0/320 (0.0%)	320/320 (100.0%)	0/320 (0.0%)	0/320 (0.0%)	0/320 (0.0%)	0/320 (0.0%)	0/320 (0.0%)

Occlusion detection

To assess occlusion detection activity, 32 MiniMed 780G pumps were tested by placing a hemostat clamp on the cannula of an infusion site (to simulate an occlusion) and then delivering either a 10-unit bolus tested at two different bolus speeds ("Quick" and "Standard" – *Table 8* lists out the values at which bolus is delivered at those respective speeds) or at three different basal rates denoted as "minimum", "intermediate", and "maximum" (0.025 units per hour, 1 unit per hour, and 35 units per hour, respectively). Upon start of each test leg, the time elapsed between start of delivery and when the occlusion alarm occurred via the 780G was recorded in *Table 9* below. Sixteen of the pumps were new, and 16 had been aged to simulate four years of regular use. For both aged and unaged pumps, eight pumps were tested with new infusion sets and reservoirs, and eight with infusion sets and reservoirs which underwent real time aging. Humalog placebo was used as a substitute for insulin for this testing.

Table 8. Bolus Duration for Standard and Quick Speeds

Characteristic	Value
Bolus – Standard Speed	1.5 units/min
Bolus – Quick Speed	15 units/min

Table 9. Time to Occlusion Alarm*[i]

Operating Rate	Typical	Maximum
Bolus (Standard Speed – 10 units)	1 minute, 42 seconds	2 minutes, 24 seconds
Bolus (Quick Speed – 10 units)	10 seconds	16 seconds
Basal (1 U/hr)	2 hours, 58 minutes	4 hours, 3 minutes
Basal (35 U/hr)	2 minutes, 30 seconds	4 minutes
Basal (0.025 U/hr)	174 hours, 53 minutes	199 hours
*The time to occlusion alarm is based on insulin volume not delivered. During an occlusion event, boluses of less than 3 units may not trigger an occlusion alarm if no basal insulin is being delivered. The bolus amount will reduce the time to occlusion depending on the Basal Rate.		

[i]Testing was completed with MiniMed Quick-set Infusion Sets (MMT-396A) and Medtronic Reservoir 3.0mL (MMT-332A).

Bolus Wizard feature in Manual mode default settings

Note: When using the SmartGuard feature, the Bolus Wizard feature is called the Bolus feature.

Item	Default	Limits	Maximum available segments	Increments
Carb units	grams	-	8	-
Insulin to carb ratio	None	1–200 g/U	8	0.1 g/U for 1–9.9 g/U; 1 g/U for ratios of 10 g/U to 200 g/U
Insulin Sensitivity Factor*	None	5–400 mg/dL	8	1 mg/dL
BG Target*	None	60–250 mg/dL	8	1 mg/dL
Active Insulin Time	4 hours	2 to 8 hours	1	15 minutes

*Applies to Manual mode only.

Bolus Wizard feature in Manual mode specifications

The Bolus Wizard feature uses four formulas to estimate a bolus, depending on the current BG reading. The following formulas apply only when the carb units are in grams.

1. If the current BG reading is higher than the High BG Target, the Bolus Wizard feature subtracts active insulin from the BG correction estimate, then adds this value to the food estimate to get the total bolus estimate. However, if the result of subtracting the active insulin amount from the BG correction estimate is a negative number (less than zero), the total bolus estimate is based only on the food estimate.

(food estimate) (correction estimate)

$$\text{total bolus estimate} = \frac{A}{B} + \frac{C - D}{E} - \text{active insulin}$$

where: A = food (grams)
B = carb ratio
C = current BG
D = High BG Target
E = insulin sensitivity

Food estimate:

Carb grams ÷ Carb ratio = Units of insulin

Correction estimate:

(Current BG - High BG Target) ÷ Insulin sensitivity - Active insulin = Units of insulin

Total bolus estimate:

Food estimate + Correction estimate = Units of insulin

2. If the current BG is less than the Low BG Target, the Bolus Wizard feature adds the BG correction estimate to the food estimate to get the total bolus estimate.

(food estimate) (correction estimate)

$$\text{total bolus estimate} = \frac{A}{B} + \frac{C - D}{E}$$

where: A = food (grams)
B = carb ratio
C = current BG
D = Low BG Target
E = insulin sensitivity

Food estimate:

Carb grams ÷ Carb ratio = Units of insulin

Correction estimate:

(Current BG - Low BG Target) ÷ Insulin sensitivity = Units of insulin

Total bolus estimate:

Food estimate + Correction estimate = Units of insulin

3. If the current BG reading is within the High or Low BG Target, the total bolus estimate is based only on the food estimate.

$$\text{total bolus estimate} = \text{(food estimate)} = \frac{\text{food (grams)}}{\text{carb ratio}}$$

Food estimate:

Carb grams ÷ Carb ratio = Units of insulin

> **Note:** When the current BG reading is below the Low BG Target, an active insulin amount is not considered in the Bolus Wizard feature calculations.

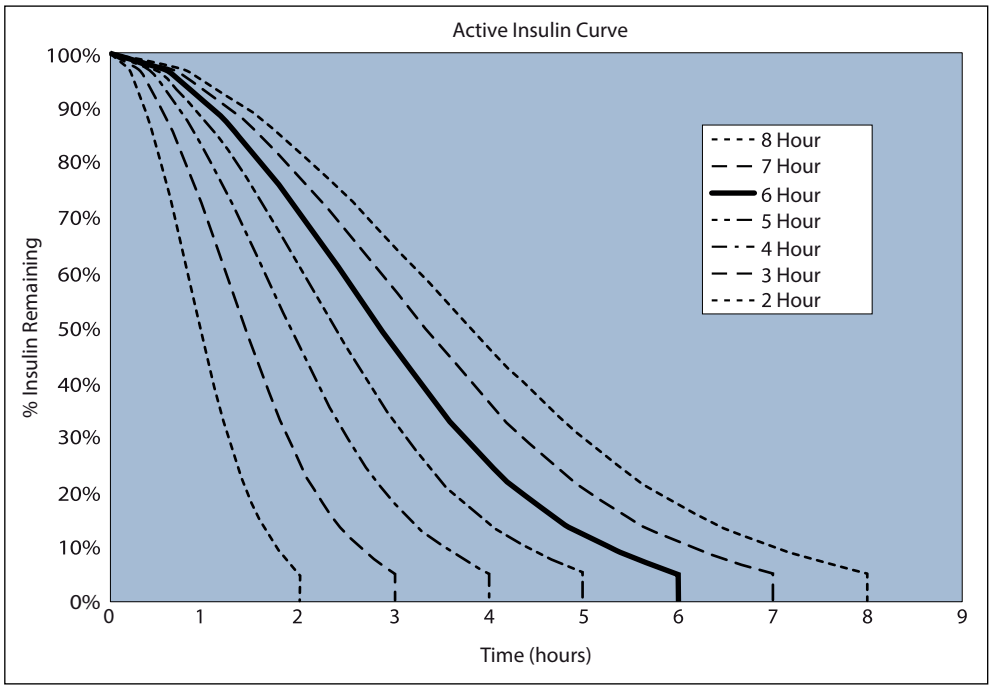
Total bolus estimate = Food estimate

4. If no BG reading is entered, the total bolus estimate is based only on the food estimate.

The following list includes additional conditions to consider when using the Bolus Wizard feature in Manual mode.

- If a Dual Wave bolus amount is less than the estimate due to the Max bolus limit or a change that is made, the Square portion of the bolus is reduced first.
- Active insulin is the bolus insulin that has been delivered by the pump and is still working to lower glucose levels. In the Bolus Wizard and SmartGuard Bolus feature, the Active Insulin Time setting is used to calculate a correction bolus by subtracting the estimated active insulin from each bolus. This is shown as Active Insulin, or Act. Insulin, on the Home screen, Bolus screen, Manual Bolus screen, Preset Bolus screen, and Daily History screen. This prevents over-infusion of insulin and reduces the risk of hypoglycemia.

- The Bolus Wizard feature may use the current BG reading, carb units, and active insulin to calculate the estimated bolus.
- The Active Insulin Curve graph shows how the Active Insulin Time setting affects the active insulin amount that is subtracted from correction boluses over time. The percentage of insulin remaining changes at varying rates depending on the Active Insulin Time setting.



Graph adapted from Mudaliar and colleagues, Diabetes Care, Volume 22, Number 9, Sept. 1999, page 1501.

Carb ratios

Maximum ratio settings	Range
8	1 to 200 g/U

Easy bolus feature

Use the Easy bolus feature to set up and deliver a normal bolus when the pump is in Sleep mode. This is done using ⋀ and with the help of sound and vibration cues.

Sound mode range	0 to 20 increments or Max bolus limit, whichever comes first
Vibrate mode range	0 to 20 increments or Max bolus limit, whichever comes first
Default step size	0.1 unit
Adjustable step size	0.1 to 2 units per increment up to Max bolus limit

Environmental conditions

The MiniMed 780G system is designed to withstand most conditions encountered in daily life. For more details about environmental conditions, such as exposure to magnetic fields and radiation, waterproof capabilities, and extreme temperatures, see the MiniMed 780G System User Guide.

- Pump storage and transport temperature range without a AA battery is from -4 °F (-20 °C) to 122 °F (50 °C).
- Pump operating temperature range is from 41 °F (5 °C) to 98.6 °F (37 °C).
- Operating air pressure range is from 10.2 psi (700 hPa) to 15.4 psi (1060 hPa).
- Storage and transport air pressure range is from 7.2 psi (496.4 hPa) to 15.4 psi (1060 hPa).
- Relative humidity (RH) range during operation is from 20% to 90%.
- RH range during storage and transport is from 5% to 95%.

Essential performance

The pump will maintain the following functionalities to avoid under-infusion and over-infusion:

- Delivery accuracy
- Occlusion detection
- Empty reservoir detection
- Detection of power loss
- Pump therapy status–UI component: LCD
- Notification annunciation and display–UI components: piezo-electric speaker, LCD–applies to all features above

Expected service life

The overall expected service life for the MiniMed 780G insulin pump is four years when used in accordance with this guide.

If there are concerns that the insulin pump may be damaged, contact 24-Hour Technical Support.

For additional information, see the MiniMed 780G System User Guide.

For health-related questions or concerns, consult a healthcare professional.

Filling the infusion set and cannula

- The cannula can be filled from 0.025 units to 5.1 units, in increments of 0.025 units.
- The standard fill rate is 1.5 units per minute.

  The quick fill rate is 15 units per minute.
- When filling the tubing, a warning occurs at 30 units. A second warning occurs at 40 units indicating that the pump must be rewound.
- Insulin used to fill the infusion set is recorded in the Daily History. This insulin is NOT included in the Total Daily Delivery (TDD) totals on the Summary screen.

Sensor performance characteristics

For information about sensor performance characteristics, see the Performance Data document.

Insulin delivery default settings

Bolus settings

Item	Default setting	Limits	Increments
Bolus Wizard feature:	Off	-	-
Easy bolus feature:	Off	-	-
Easy bolus step size:	0.1 U	0.1 U to 2 U	-
Bolus increment:	0.10 U	0.025 U 0.05 U 0.10 U	-
Dual/Square bolus:	Off	-	-

Item	Default setting	Limits	Increments
Max bolus:	10 U	0 to 25 U (per single bolus)	-
Bolus BG Check Reminder:	Off	0:30 to 5:00	0:30

Basal settings for Manual mode

Item	Default setting	Limits	Increments
Max Basal Rate	2 U/hr	0–35 U/hr Default limit 10 U/hr	0.025 U for 0.025–0.975 U/hr 0.05 U for 1.00–9.95 U/hr 0.1 U for rates of 10.0 U/hr or more
Basal Rate	0.000 U/hr	0.000 U/hr to Max Basal Rate	0.025 U for 0.025–0.975 U/hr 0.05 U for 1.00–9.95 U/hr 0.1 U for rates of 10.0 U/hr or more
Temp Basal Type	Percent	Percent, Rate	N/A
Temp Basal Percent	100%	0–200%	5%
Temp Basal Rate	Current basal rate	0.0 U/hr to Max Basal Rate	0.025 U for 0.025–0.975 U/hr 0.05 U for 1.00–9.95 U/hr 0.1 U for rates of 10.0 U/hr or more

Low Reservoir reminder

The values are based on amount shown, not actual amount.

Alert range	Increment	Default value
The first reminder occurs at 5 to 50 units. The second reminder occurs at half of the remaining specified amount. The second reminder is automatic and cannot be changed.	1 unit	20 units

Max bolus

The Max bolus setting limits the amount of insulin that can be programmed by the user for a single bolus. This setting does not affect the amount of insulin SmartGuard automatically delivers.

Range	0 to 25 units
Default	10 units

Normal bolus

Range is 0.025 to 25 units of insulin, and limited by the Max bolus setting.

Percent temp basal

The default value is 100 percent of basal programming. For example, if six units of basal insulin are delivered per day, the default temp basal amount will be six units per day.

Range	0 to 200%
Default	100% of basal programming
Increment	5%

Program safety checks

A single fault condition causes the pump to suspend insulin delivery. Maximum infusion with a single fault condition is 0.2 units.

Pump dimensions

The pump dimensions in inches are no greater than 4.0 length x 2.3 width x 1.1 depth.

The pump dimensions in centimeters are no greater than 10.2 length x 5.8 width x 2.8 depth.

Pump memory

User settings and pump history are stored in pump memory. The pump keeps at least 35 days of history.

Pump performance characteristics

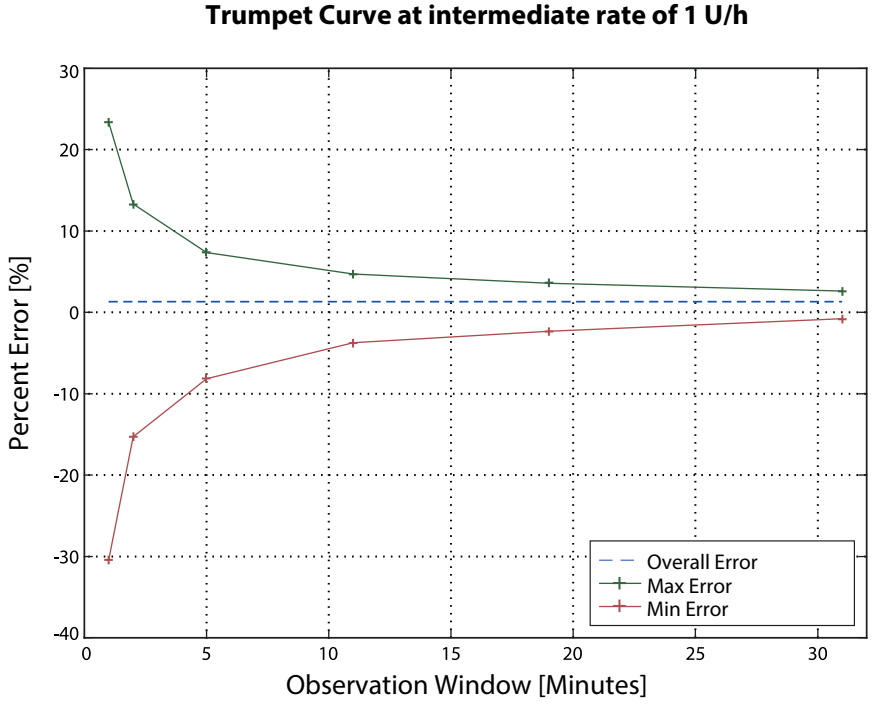
Delivery accuracy (tested per IEC 60601-2-24)

- For a basal rate of 1.0 U/hr, the delivery accuracy is ±5%.

  For a basal rate of 0.025 U/hr, the delivery accuracy is ±10%.

  Delivery accuracy for bolus volumes < 0.1 unit is ±20% and delivery accuracy for bolus volumes ≥ 0.1 unit is ±5%.

- All normal boluses are delivered within 16 minutes, 41 seconds ±3 seconds at Standard rate (25 units, at 1.5 units per minute), and within 1 minute, 41 seconds ±3 seconds at Quick rate (25 units, at 15 units per minute).
- During delivery, the maximum infusion pressure generated and the occlusion threshold pressure using a 3.0-mL reservoir does not exceed 13.15 psi (90.67 kPa). The average resulting bolus volume generated upon clearing the occlusion is 0.0112 mL (equivalent to 1.12 units of U-100 insulin).
- The following image is a representative delivery accuracy curve. The Trumpet Curve represents the maximum percentage change from the expected insulin dosage for a given time interval, known as the observation window, during the infusion of insulin. The upper curve corresponds to positive changes, and the lower curve corresponds to negative changes.



Infusion pressure

The maximum infusion pressure and occlusion pressure during the fill tubing process are 25 psi (172.4 kPa).

Occlusion detection

When occlusion is detected, the Insulin flow blocked alarm occurs. The occlusion alarm is triggered by an average of 2.98 units of missed insulin (standard bolus) or 2.45 units of missed insulin (quick bolus). This table shows occlusion detection for four different situations when using U-100 insulin.

Rate	Minimum time before alarm	Average time before alarm	Maximum time before alarm
bolus delivery (10 units at standard speed)	77 seconds	124 seconds	173 seconds
bolus delivery (10 units at quick speed)	10 seconds	13 seconds	20 seconds
basal delivery (1.0 U/hr)	2 hours 27 minutes	3 hours 21 minutes	4 hours 21 minutes
basal delivery (0.025 U/hr)	131 hours 5 minutes	181 hours 16 minutes	211 hours 30 minutes

Note: Certain factors, such as ambient temperature changes or the presence of air in the infusion set or the reservoir, can delay an occlusion alarm.

Sound frequency

The following table lists audible tones that the pump emits, and their corresponding frequencies:

Tone name	Frequency
Alarm	1655 Hz followed by 3310 Hz
Alternate Alarm	1850 Hz
Siren (escalated alarm)	1655 Hz, followed by 3310 Hz
Alert	934 Hz
High SG	1312 Hz, followed by 1410 Hz, 1500 Hz, 1619 Hz, 1722 Hz
Low SG	1722 Hz, 1619 Hz, 1500 Hz, 1410 Hz, 1312 Hz
Lost SG	1485 Hz, followed by 1395 Hz, 1320 Hz, 1395 Hz
Message tone	1655 Hz
Suspend message tone	2100 Hz, followed by 1800 Hz and 2100 Hz
Reminder tone	934 Hz

Tone name	Frequency
Fill tubing tone	1850 Hz
Bolus delivery cancellation tone	1485 Hz, followed by 1655 Hz and 1485 Hz
Loading complete tone	934 Hz
Reservoir loading in progress tone	1850 Hz
Easy bolus activation	1045 Hz
Easy bolus step 1 increment	1175 Hz
Easy bolus step 2 increment	1320 Hz
Easy bolus step 3 increment	1395 Hz
Easy bolus step 4 increment	1570 Hz
Easy bolus step 5 increment	1760 Hz

Pump weight

The mass of the insulin pump without battery and consumables is less than 117 grams.

Sensor default settings

High sensor settings			
Item	**Default setting**	**Limits**	**Increments**
High SG alert limit	250 mg/dL	100 to 400 mg/dL	5 mg/dL
High SG fixed alert	On (cannot be turned off)	250 mg/dL for 3 hours	-
Alert before high	Off	-	-
Alert on high	Off	-	-
Time before high	15 minutes	5 to 30 minutes	5 minutes
Rise Alert	Off	-	-
Rise Limit	Two up arrows	• 1 up arrow (1 mg/dL/min) • 2 up arrows (2 mg/dL/min) • 3 up arrows (3 mg/dL/min) • Custom limit (1.0 to 5.0 mg/dL/min)	
High Snooze	1 hour	5 minutes to 3 hours	5 minutes

Low sensor settings			
Item	**Default setting**	**Limits**	**Increments**
Low SG alert limit	60 mg/dL	50 to 90 mg/dL	5 mg/dL
Low SG alarm	On (cannot be turned off)	below 54 mg/dL	-
Suspend before low	Off	-	-
Suspend on low	Off	-	-
Alert before low	Off	-	-
Alert on low	Off	-	-
Low Snooze	20 minutes	5 minutes to 1 hour	5 minutes
Resume basal alert	Off	-	-

The SmartGuard feature settings			
Item	**Default setting**	**Limits**	**Increments**
SmartGuard	Off	-	-
Target	100 mg/dL	100 to 120 mg/dL	10 mg/dL
Auto Correction	On	120 mg/dL	-
Temp Target	Off	150 mg/dL	-
Temp Target Duration	2 hours	30 minutes to 24 hours	30 minutes

IEC 60601-1-2

Special EMC Precautions for Medical Electrical Equipment

1. Special Precautions regarding Electromagnetic Compatibility (EMC): This body worn device is intended to be operated within a reasonable residential, domestic, public or work environment, where common levels of radiated "E" (V/m) or "H" fields (A/m) exist; such as cellular phones that are not paired with the MiniMed 780G system, Wi-Fi™* networks, Bluetooth®* wireless technology, electric can openers, microwave and induction ovens. This device generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the provided instructions, may cause harmful interference to radio communications.
2. Portable and mobile RF communications equipment can affect Medical Electrical Equipment as well. If RF interference from a mobile or stationary RF

transmitter is encountered, move away from the RF transmitter that is causing the interference.

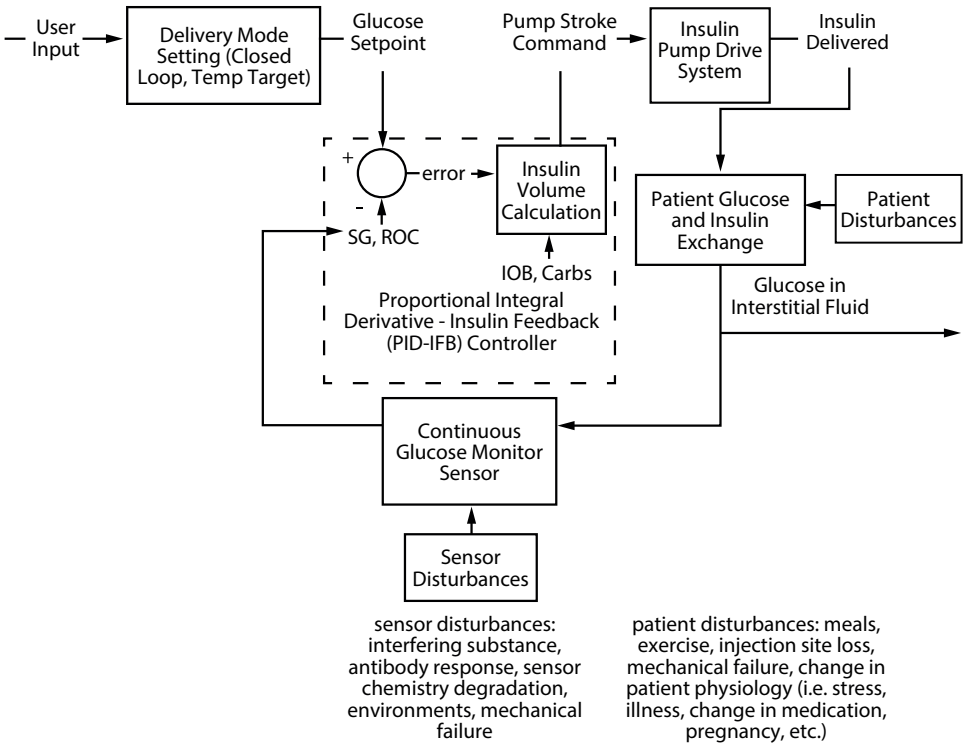
IEC 60601-1-2

The MiniMed 780G system should not be used adjacent to other electrical equipment. If adjacent use becomes necessary, the MiniMed 780G system should be observed to confirm normal system operation.

IEC 60601-1-10: PCLCS

The MiniMed 780G is a Physiological Closed-Loop Controlled system (PCLCS).

Auto Mode manages basal delivery using a closed loop control algorithm based on a Proportional Integral Derivative controller with insulin feedback (PID-IFB). The PID-IFB monitors the Rate Of Change (ROC) of sensor glucose (SG) and calculates the insulin volume using the Insulin On Board (IOB) and the reported Carbs. The closed loop controller uses continual feedback of SG values to calculate the insulin delivery rate for basal insulin control. The control algorithm is part of the pump application code. SG values are received by the pump via RF from the CGM sensor. This theory of operation is described in the following block diagram.



Guidance and manufacturer's declaration

Guidance and Manufacturer's Declaration - Electromagnetic Emissions		
The MiniMed 780G insulin pump is intended for use in the electromagnetic environment specified below. Make sure that the MiniMed 780G insulin pump is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment - Guidance**
RF emissions Test: 47 CFR Part 15, Subpart C Section 15.247/FCC Part 15 Subpart B Section 15.109	• 6 dB and 99% Bandwidths: Complies • Maximum Output Power: Complies • TX Spurious Emissions: Complies	The MiniMed 780G insulin pump must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.

Guidance and Manufacturer's Declaration - Electromagnetic Emissions		
	• Power Spectral Density: Complies • Radiated Emissions at Band Edge: Complies	
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not applicable	
RF emissions CISPR 11	Complies Group 1 Class B	The MiniMed 780G insulin pump is suitable for use in aircraft and in all establishments, including domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
RTCA DO 160G Radio Frequency Susceptibility (Radiated and Conducted) and Emission of Radio Frequency Energy	Complies	

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The MiniMed 780G insulin pump is intended for use in the electromagnetic environment specified below. Make sure that the MiniMed 780G insulin pump is used in such an environment.			
Immunity Test	**IEC 60601-1-2 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2, 4, 8, 15 kV air	±8 kV contact ±2, 4, 8, 15 kV air	For use in a typical domestic, commercial, or hospital environment.
Conducted disturbances induced by RF fields IEC 61000-4-6	3 V_{RMS} 150 kHz to 80 MHz 6 V_{RMS} ISM bands between 150 kHz to 80 MHz	Not applicable	Requirement does not apply to this battery powered device.
Electrical fast transient/burst IEC 61000-4-4	±2 kV 100 kHz repetition frequency	Not applicable	Requirement does not apply to this battery powered device.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
Surge IEC 61000-4-5	Line to Line: ±0.5 kV, ±1 kV Line to Ground: ±0.5 kV, ±1 kV, ±2 kV	Not applicable	Requirement does not apply to this battery powered device.
Voltage dips, short interruptions, and voltage variations on power supply lines IEC 61000-4-11	0% U_T; 0.5 cycle (at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315°) 0% U_T; 1 cycle (at 0°) 70% for 25/30 cycles (at 0°) 0% for 250/300 cycles	Not applicable	Requirement does not apply to this battery powered device.
Power frequency (50/60 Hz) electromagnetic field IEC 61000-4-8	30 A/m (continuous field at 60 seconds)	30 A/m 400 A/m per IEC 60601-2-24	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Proximity fields from RF wireless communications equipment IEC 61000-4-39	IEC 60601-1-2	IEC 60601-1-2	For use in a typical domestic, commercial, or hospital environment.
Note: U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The MiniMed 780G insulin pump is intended for use in the electromagnetic environment specified below. The customer or user of the MiniMed 780G insulin pump should assure that it is used in such an electromagnetic environment.			
Immunity Test	**IEC 60601-1-2 Test Level**	**Compliance Level**	**Electromagnetic Environment Guidance**
Radiated RF IEC 61000-4-3 EN 301 489-17	10 V/m 80 MHz to 2.7 GHz	10 V/m 80 MHz to 2.7 GHz	Portable and mobile RF communications equipment should be used no closer to any part of the MiniMed 780G insulin pump,

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
	80% AM at 1 kHz	80% AM at 1 kHz	including cables, than the recommended separation distance of 12 in (30 cm). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 

Wireless communication

The MiniMed 780G insulin pump communicates using smart device connectivity.

Operating frequency/Modulation type(s)	2.4 GHz band, GFSK
Effective radiated power (ERP)	1.48 mW (1.69 dBm)
Effective isotropic radiated power (EIRP)	2.42 mW (3.83 dBm)

FCC notice

This device complies with the United States Federal Communications Commission (FCC) and international standards for electromagnetic compatibility. This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation. These standards are designed to provide reasonable protection against excessive radio frequency interference, and to prevent undesirable operation of the devices from unwanted electromagnetic interference.

Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Decrease the distance between the transmitter and the insulin pump to 6 feet (1.8 meters) or less.
- Increase the separation between the transmitter and the device that is receiving/emitting interference.

IMPORTANT: Do not change or modify the internal RF transmitter or antenna unless expressly approved by Medtronic Diabetes. Doing so could interfere with your ability to operate the equipment.

Note: Harmful interference is defined by the FCC as follows. Any emission, radiation or induction that endangers the functioning of a radio navigation service or of other safety services or seriously degrades, obstructs or repeatedly interrupts a radio communications service operating in accordance with FCC rules.

Open Source Software disclosure

This document identifies the Open Source Software that may be separately called, executed, linked, affiliated, or otherwise utilized by this product.

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- LZ4–compression library (v1.9.1): http://www.lz4.org
- SWIG (v3.0.12): http://www.swig.org
- FNV-1 hash algorithm (v5.1): http://www.isthe.com/chongo/tech/comp/fnv/ and http://www.isthe.com/chongo/src/fnv/fnv64.c
- CRC32 algorithm: https://opensource.apple.com/source/xnu/xnu-792.13.8/bsd/libkern/crc32.c

3

MiniMed 780G system performance

3 MiniMed 780G system performance

Interoperable automated glycemic controller (iAGC) device performance

The MiniMed automated insulin delivery (AID) system includes the following interoperable automated glycemic controllers (iAGCs):

- SmartGuard Technology, also referred to as the Advanced Hybrid Closed Loop (AHCL) or the SmartGuard feature.
- Predictive Low Glucose Technology, also referred to as the Predictive Low Glucose Management (PLGM) feature and includes the Suspend on low and Suspend before low features.

In addition to the iAGCs listed above, the MiniMed AID system comprises an ACE pump, and either a compatible integrated continuous glucose monitor (iCGM) or interoperable Medtronic CGM. The iAGCs reside on the ACE pump, which receives inputs from the compatible CGM to facilitate AID system functionality.

The MiniMed AID system adjusts insulin delivery based on sensor glucose (SG) readings from the compatible CGM, while alleviating the complexity of trying to maintain glucose levels around meals. Clinical studies have shown that integrated insulin pump and CGM systems may provide better diabetes management, compared with multiple daily injections, or with a pump alone. Studies suggest that pump therapy, when

regulated by sensor information, can improve HbA1C levels significantly without increasing the risk of hypoglycemia.[1,2,3]

The MiniMed 780G system continues to use the SmartGuard feature, which is designed to keep patient blood sugar levels in range by automatically adjusting basal insulin dosage every five minutes, delivering more or less insulin when it predicts that SG values are trending too high or too low. The SmartGuard feature has been updated to adjust how auto correction boluses and daily user adaptations are calculated. The system continues to offer the following features:

1. **Adjustable glycemic target settings.** With the help of a healthcare provider, patients can program the device to one of three setpoints to target their ideal SG value (100, 110, or 120 mg/dL). The device uses the programmed setpoint as a reference to adjust the rate of insulin delivered, which helps maintain control according to patient needs.
2. **Automatic correction boluses.** Mealtimes can be stressful and require that patients calculate boluses prior to and after meals to avoid hyperglycemia. The SmartGuard feature also includes an Auto correction feature that can calculate and deliver correction boluses every five minutes if the patient underestimates the amount of carbs in a meal or if they accidentally forget to deliver a meal bolus prior to eating.

The MiniMed 780G system retains the Suspend on low and Suspend before low features that were introduced in prior MiniMed insulin pumps. These features temporarily stop insulin delivery when SG values reach a preset low target (Suspend on low) or are predicted to reach the preset low target within 15 or 30 minutes (Suspend before low). Insulin delivery also resumes when SG values return to a safe range. These

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[1] Bergenstal RM, Tamborlane WV, Ahmann A, et al. Effectiveness of sensor-augmented insulin-pump therapy in type 1 diabetes [STAR3 Study]. N Engl J Med.2010;363:311–320.

[2] Battelino T, Conget I, Olsen B, et al. The use and efficacy of continuous glucose monitoring in type 1 diabetes treated with insulin pump therapy [SWITCH study]. Diabetologia. 2012 Dec;55(12):3155-62. doi: 10.1007/s00125-012-2708-9. Epub 2012 Sept 11.

[3] Bergenstal RM, Klonoff DC, Bode BW, et al. Threshold-based insulin-pump interruption for reduction of hypoglycemia [ASPIRE in-home study]. N Engl J Med. 2013;369(3):224-232.

optional features are available when the pump is in Manual mode and function as a backup for the SmartGuard feature.

The SmartGuard feature

Clinical study overview

The SmartGuard feature with modifications (that controls insulin dosing in the MiniMed 780G system) was studied with subjects who wore the MiniMed 780G pump with the Simplera Sync sensor and the Extended infusion set and reservoir at home for 3 months.[4] The study did not include a control group. The study included subjects from different clinics around the US who were between 7 and 80 years old. Subjects had to have been diagnosed with type 1 diabetes mellitus for at least one year for subjects aged 7 to 13 years, and at least two years for subjects aged 14 to 80 years. All subjects in the study had to have used pump therapy for at least 6 months prior to screening and had an HbA1C value of less than 10.0% at the time of screening.

This study started with a run-in (baseline) period. During run-in, subjects with no prior automated insulin delivery (AID) pump experience were instructed to use the MiniMed 780G system with only the sensor augmented pump (SAP) function activated (i.e., SmartGuard feature turned OFF). Subjects with AID pump experience were instructed to use the MiniMed 780G system with the SmartGuard feature turned ON and the Auto correction feature turned OFF. The intent of the run-in period was to allow subjects to become familiar with the new study devices while using their own insulin.

After the run-in period, subjects were instructed to use the study devices with both the SmartGuard feature and the Auto correction feature turned ON during a study period comprising 3 stages. In the first two stages, subjects were instructed to use the study pump with the 120 mg/dL Auto basal target setpoint and active insulin time set to 4 hours (stage 1), then to change the pump settings to the 100 mg/dL setpoint and active insulin time set to 2-3 hours (stage 2). In stage 3, subjects were instructed to use the study pump with the Auto basal target setpoint and active insulin time set as considered best by the investigator for the individual subject. A total of 250 subjects were enrolled, and 212 subjects completed the study.

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[4] Medtronic Inc., Clinical Study Report: CIP337 Safety and Effectiveness Evaluation of the MiniMed 780G System Used in Combination with the DS5 CGM.

SmartGuard Performance: HbA1C and Time in Target Range

Table 1 shows the mean difference in HbA1C from Baseline to the end of the 3-month study. This data helps explain how using the 780G SmartGuard feature with the Auto correction feature enabled might affect a patient's HbA1C.

Table 10. HbA1C from Baseline to End of 3-month Study Period

Category	Age 7-17 Years		Age 18-80 Years	
	Baseline	End of Study	Baseline	End of Study
HbA1C (%) Mean ± SD (Median) [N]	7.7 ± 1.0 (7.8) [112]	7.3 ± 0.8 (7.2) [111]	7.4 ± 0.9 (7.3) [110]	6.7 ± 0.5 (6.7) [106]

Table 2 reports the mean percentage of time spent in range (TIR, 70-180 mg/dL) in Stage 3 of the Study Period.

Table 11. Mean Percentage of Time Spent in Range (70-180 mg/dL) in Study Period Stage 3

Subject Age	Number of Subjects	Mean	95% Confidence Interval
7-17 Years	109	71.4%	(69.5%, 73.3%)
18-80 Years	107	80.2%	(78.7%, 81.8%)

Safety

Table 3 lists the device-related adverse events reported at screening, and during the run-in and study periods. Overall, 59 adverse events were reported. For subjects ages 7–17 years, there were no reports of device-related severe hypoglycemia, unanticipated serious or non-serious adverse device effects during the study. For adult subjects, there were no reports of unanticipated adverse device effects. Two severe hypoglycemia events and 1 diabetic ketoacidosis event were reported for adult subjects but none of these were device-related.

Table 12. Device Related Adverse Events

Adverse Events	Age 7–17 Years (N = 125)			Age 18–80 Years (N = 125)		
	Screening period	Run-in period	Study period	Screening period	Run-in period	Study period
Bleeding at infusion site	0	0	1	0	0	0
Bleeding at sensor site	0	2	2	0	1	1
Discomfort/irritation with infusion set	0	2	1	0	6	5
Discomfort/irritation with sensor	0	3	2	0	1	1
Infusion site infection	0	4	15	0	0	0
Mild ketonemia	0	0	0	0	1	0
Rash/contact dermatitis (infusion set related)	0	0	1	0	2	2
Rash/contact dermatitis (sensor/tape related)	0	0	1	0	0	0

Table 12. Device Related Adverse Events (continued)

Adverse Events	Age 7–17 Years (N = 125)			Age 18–80 Years (N = 125)		
	Screening period	Run-in period	Study period	Screening period	Run-in period	Study period
Severe hyperglycemia	0	1	3	0	0	1
Total	**0**	**12**	**26**	**0**	**11**	**10**

Table 4 lists the study-period related adverse events. A total of 83 adverse events during the study period and one serious adverse event were reported from all investigational sites for 7–17-year-old study subjects enrolled in the study. There were 0 serious adverse events, no reports of severe hypoglycemia, 8 reports of severe hyperglycemia, no reports of diabetic ketoacidosis, and there were no reports of unanticipated adverse device effects (UADEs).

A total of 50 adverse events during the study period and three serious adverse events were reported from all investigational sites for 18–80-year-old study subjects enrolled in the study. Out of 50 events, there were 3 serious adverse events, 2 reports of hypoglycemia and 1 report of a hyperglycemia event. There was 1 report of a diabetic ketoacidosis event, and no reports of unanticipated adverse device effects (UADEs).

Table 13. Study Period Related Adverse Events

Category	**Age 7–17 Years (N = 112)**	**Age 18–80 Years (N = 110)**
	Study Period	**Study Period**
Total number of adverse events	83	50
Study Exit		
Led to study exit	0	1
Did not lead to study exit	83	49
Seriousness		
Serious adverse events (SAEs)	0	3
Death	0	0
Non-death	0	3
Non-serious adverse events	83	47
Diagnosis		
Severe hypoglycemia	0	2
Severe hyperglycemia	8	1
Diabetic ketoacidosis (DKA)	0	1
None of the above	75	46

Table 13. Study Period Related Adverse Events (continued)

Category	Age 7–17 Years (N = 112)	Age 18–80 Years (N = 110)
Study procedure and device relatedness		
Related to study procedure only	0	0
Related to study device only	26	10
Unanticipated adverse device effects (UADE) / Unanticipated serious adverse device effects (USADE)	0	0
Unanticipated non-serious adverse device effects	0	0
Anticipated adverse device effects (ADEs)	26	10
Related to both study procedure and study device	0	0
Unanticipated adverse device effects (UADE) / Unanticipated serious adverse device effects (USADE)	0	0
Unanticipated non-serious adverse device effects	0	0
Anticipated adverse device effects (ADEs)	0	0
Not related to study procedure or study device	57	40

SmartGuard Use

During the study period, subjects had access to the study device and were instructed to use SmartGuard with Auto correction ON. *Table 5* presents the percentage of time that subjects spent using the sensor and the percentage of time spent using the SmartGuard feature with the Auto correction feature turned ON during study period stage 3. This information shows that the SmartGuard feature was ON greater than 92% of the time during study period stage 3.

Table 14. Sensor and SmartGuard Usage (Percentage of Time) During Study Period, Stage 3

Category	Age 7-17 Years (N = 109)	Age 18-80 Years (N = 107)
Time spent using sensor	92.9%	95.8%
Time spent not using sensor	7.1%	4.2%
Time spent in SmartGuard	93.5%	96.6%
Time spent in Manual mode	6.5%	3.4%

SmartGuard Performance

Table 6 shows the mean percentage of SG values in specific glucose ranges during the run-in period and during stage 3 of the study period by all subjects using the 780G system with the Simplera Sync sensor. An international group of diabetes experts and the American Diabetes Association (ADA) consider patients in good control when patients are in the target glucose range of 70–180 mg/dL for more than 70% of the day.[5]

The data in *Table 6* show that using the SmartGuard feature with the Auto correction feature kept SG values in range and reduced time above range. Specifically, adult subjects spent more time in range (70–180 mg/dL) and less time in hypoglycemia (<70 mg/dL) and hyperglycemia (>180 mg/dL) during stage 3 of the study period compared with the run-in period. Pediatric subjects spent more time in range (70–180 mg/dL) and less time in hyperglycemia (>180 mg/dL) without significantly increasing time in hypoglycemia (<70 mg/dL) during stage 3 of the study period compared with the run-in period.

Table 15. Percentage of SG values in Different Ranges during the Run-in Period and Study Period Stage 3

Category	SG Range (mg/dL)	Age 7–17 Years		Age 18–80 Years	
		Run-in Period (N = 112)	Study Period Stage 3 (N = 109)	Run-in Period (N = 110)	Study Period Stage 3 (N = 107)
Low SG Value	<54	0.3 ± 0.6 (0.2, 0.4)	0.4 ± 0.3 (0.3, 0.4)	0.3 ± 0.5 (0.2, 0.4)	0.2 ± 0.4 (0.1, 0.3)
	<70	1.6 ± 1.7 (1.3, 1.9)	1.9 ± 1.4 (1.7, 2.2)	1.7 ± 1.9 (1.4, 2.1)	1.5 ± 1.4 (1.3, 1.8)

[5] Battelino T, Danne T, Bergenstal RM, et al. Clinical Targets for Continuous Glucose Monitoring Data Interpretation: Recommendations From the International Consensus on Time in Range. Diabetes Care. 2019 Aug; 42(8): 1593-1603. doi: 10.2337/ dci19-0028. Epub 2019 Jun 8.

Table 15. Percentage of SG values in Different Ranges during the Run-in Period and Study Period Stage 3 (continued)

Category	SG Range (mg/dL)	Age 7–17 Years		Age 18–80 Years	
		Run-in Period (N = 112)	Study Period Stage 3 (N = 109)	Run-in Period (N = 110)	Study Period Stage 3 (N = 107)
Target SG Value	70 – 140	32.1 ± 14.1 (29.5, 34.7)	49.2 ± 9.7 (47.4, 51.0)	39.2 ± 13.0 (36.8, 41.7)	56.1 ± 10.5 (54.1, 58.1)
	70 – 180	54.4 ± 15.7 (51.5, 57.3)	71.4 ± 9.9 (69.5, 73.3)	66.5 ± 12.6 (64.1, 68.8)	80.2 ± 8.1 (78.7, 81.8)
High SG Value	> 140	66.3 ± 14.7 (63.5, 69.0)	48.9 ± 10.0 (47.0, 50.8)	59.1 ± 13.9 (56.4, 61.7)	42.4 ± 11.0 (40.3, 44.5)
	> 180	44.0 ± 16.1 (41.0, 47.0)	26.7 ± 10.1 (24.7, 28.6)	31.8 ± 13.1 (29.4, 34.3)	18.2 ± 8.4 (16.6, 19.9)
	> 250	16.4 ± 11.1 (14.3, 18.5)	8.0 ± 6.6 (6.8, 9.3)	7.4 ± 6.1 (6.2, 8.5)	3.4 ± 3.0 (2.8, 4.0)
	> 350	2.4 ± 3.5 (1.8, 3.1)	1.3 ± 2.2 (0.9, 1.8)	0.4 ± 0.7 (0.3, 0.5)	0.3 ± 0.5 (0.2, 0.4)
Note: Values are presented as Mean ± SD (95% CI) except Number of subjects					

Table 7 shows the difference in mean sensor glucose from baseline to the end of the study period for all subjects using the 780G system with the Simplera Sync sensor. The data shows that, compared to the run-in period, the subjects' mean glucose levels during stage 3 of the study period were closer to the center of the target range.

Table 16. Difference in Mean Sensor Glucose Values (mg/dL) between the Run-in Period and Study Period Stage 3

Category	Age 7–17 Years			Age 18–80 Years		
	Run-in Period (N = 112)	Study Period Stage 3 (N = 109)	Difference between Run-in Period and Study Period Stage 3 (N = 109)	Run-in Period (N = 110)	Study Period Stage 3 (N = 107)	Difference between Run-in Period and Study Period Stage 3 (N = 107)
Mean Glucose Value	180.4 ± 27.1 (175.3, 185.4)	154.4 ± 17.6 (151.0, 157.7)	-26.2 ± 22.2 (-30.4, -22.0)	161.0 ± 18.7 (157.5, 164.5)	142.2 ± 12.8 (139.7,144.7)	-18.5 ± 14.0 (-21.2, -15.8)
Note: Values are presented by Mean ± SD (95% CI) except Number of subjects.						

During the study period, some subjects wore the study pump with the SmartGuard feature and the Auto correction feature turned ON, and with the target setpoint set to either 100 mg/dL, 110 mg/dL, 120 mg/dL, or 150 mg/dL (Temp Target) for at least an entire day. *Table 8* shows the mean sensor glucose (SG) value for each target setpoint option when that setpoint was used for the entire day during the overall study period. The data in *Table 8* shows that using the SmartGuard feature with the Auto correction feature and the 100 mg/dL target setpoint resulted in a lower mean SG value than when the features were used with the 120 mg/dL target setpoint.

Table 17. Mean Sensor Glucose Values (mg/dL) during SmartGuard Use Stratified by Target Glucose Setpoint during the Study Period

Category	Age 7– 17 Years					Age 18–80 Years				
	Overall (N = 112)	Target Glucose (mg/dL)				Overall (N = 109)	Target Glucose (mg/dL)			
		100 (N = 109)	110 (N = 12)	120 (N = 111)	150 (N = 52)		100 (N = 107)	110 (N = 5)	120 (N = 108)	150 (N = 48)
Mean Glucose Values During SmartGuard	153.6 ± 14.4 (150.9, 156.3)	151.9 ± 15.0 (149.1, 154.8)	149.5 ± 16.5 (139.0, 160.0)	157.8 ± 14.6 (155.1, 160.6)	157.3 ± 44.4 (145.0, 169.7)	143.8 ± 12.2 (141.4, 146.1)	141.0 ± 11.9 (138.7, 143.3)	139.8 ± 11.2 (125.9, 153.7)	150.5 ± 12.4 (148.1, 152.8)	137.5 ± 29.0 (129.1, 145.9)

Note 1: Values are presented by Mean ± SD (95% CI).

Note 2: Analysis of data was only performed when SmartGuard Glucose target was used the entire day (e.g., 100 mg/dL set point used for entire day versus 110 mg/dL set point used for entire day versus 120 mg/dL set point used for entire day). Any day with partial usage was excluded from this analysis.

Figure 1 below shows the percentage of subjects that had an HbA1C that was less than 7% during the run-in (baseline) and study periods. The ADA considers a HbA1C target of less than 7% appropriate for non-pregnant adults and many children.[6,7] *Figure 1* shows that a greater percentage of subjects had an HbA1C that was less than 7% at the end of the study than at baseline.

[6] American Diabetes Association Professional Practice Committee; 6. Glycemic Goals and Hypoglycemia: Standards of Care in Diabetes—2025. Diabetes Care 2025; 48 (Supplement_1): S128-S145.

[7] American Diabetes Association Professional Practice Committee; 14. Children and Adolescents: Standards of Care in Diabetes—2025. Diabetes Care 2025; 48 (Supplement_1): S283-S305

Figure 1. Percentage of Patients with less than 7% HbA1C

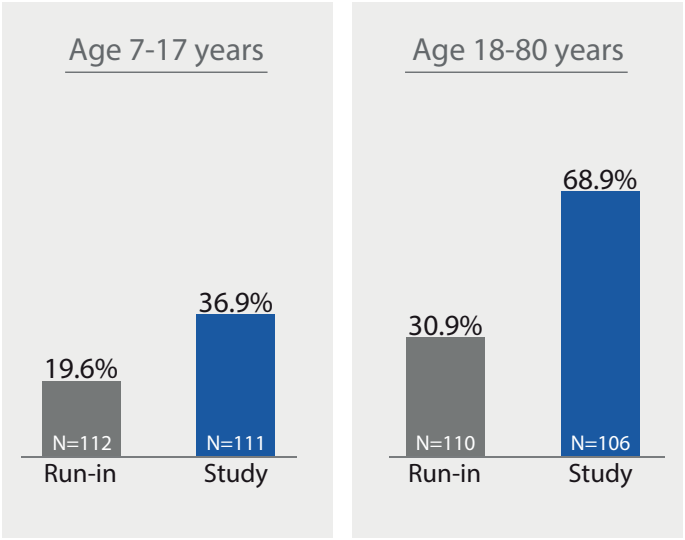


Table 9 shows the change in total daily dose of insulin (TDD) from the run-in period to study period stage 3, and the change in weight and BMI Z-score (for pediatrics) from baseline to the end of the study. Mean TDD increased for both pediatric and adult subjects. Mean weight increased slightly for pediatric subjects and remained unchanged for adults. In the pediatric population, 33 subjects gained more than 2.5 kg (5.5 lbs) in weight over the 3-month study period, and of these, 13 subjects gained 5 kg (11 lbs) or more. This data helps explain how using the SmartGuard feature with the Auto correction feature, childhood and pubertal growth, and elevated glucose levels may affect a patient's TDD and weight.

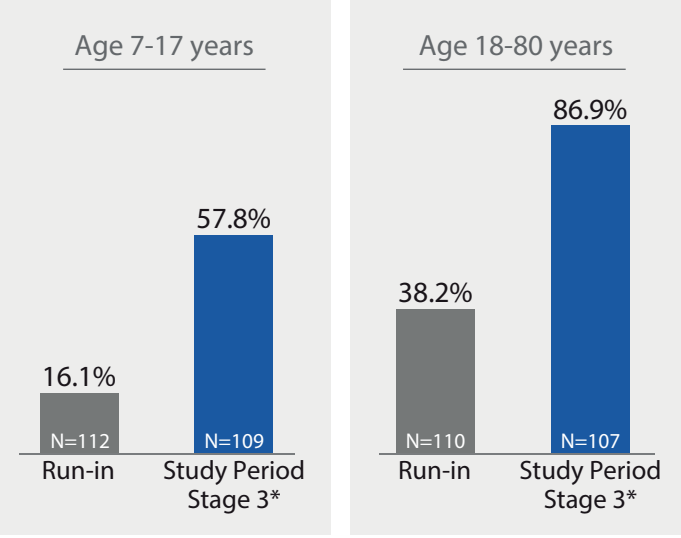
Table 18. Changes in Mean TDD and Weight

Category	Age 7-13 Years		Age 14-17 Years		Age 18-80 Years	
TDD (U), Mean ± SD (Median)	**Run-in Period (N = 57)**	**Study Period Stage 3 (N = 55)**	**Run-in Period (N = 55)**	**Study Period Stage 3 (N = 54)**	**Run-in Period (N = 110)**	**Study Period Stage 3 (N = 107)**
	43.2 ± 24.0 (35.7)	50.3 ± 29.7 (40.6)	64.3 ± 23.7 (59.0)	75.0 ± 29.3 (71.9)	54.7 ± 27.1 (50.9)	57.8 ± 28.0 (50.0)
Weight* (kg), Mean ± SD (Median)	**Baseline (N = 57)**	**End of Study (N = 56)**	**Baseline (N = 55)**	**End of Study (N = 55)**	**Baseline (N = 110)**	**End of Study (N = 108)**
	47.1 ± 17.9 (44.1)	49.0 ± 19.2 (45.8)	68.7 ± 14.0 (66.7)	70.3 ± 14.6 (68.9)	84.8 ± 19.5 (82.3)	84.8 ± 19.3 (82.0)
BMI Z-score*, Mean ± SD (Median)	**Baseline (N = 57)**	**End of Study (N = 56)**	**Baseline (N = 55)**	**End of Study (N = 55)**	–	–
	0.6 ± 1.0 (0.6)	0.7 ± 1.1 (0.7)	0.5 ± 1.0 (0.6)	0.6 ± 1.0 (0.8)	–	–
*Note: Weight and height were not collected in-clinic for some subjects.						

Figure 2 shows the percentage of subjects that spent more than 70% of time in range (70-180 mg/dL), which is considered good glucose control by diabetes experts and the ADA, during the run-in (baseline) and the different study periods. The system offers three SG target setpoint options that allow users to customize insulin delivery. For the study period, percentages are shown for subjects that used the SmartGuard feature with the Auto correction feature.

In both pediatric and adult patients, the percentage of subjects who spent more than 70% of time in range (70-180 mg/dL) when using the SmartGuard feature with the Auto correction feature increased in study period stage 3 from the run-in period. This data shows that most pediatric subjects and adult subjects using the SmartGuard feature with the Auto correction feature during study period stage 3 spent more than 70% time in range.

Figure 2. Percentage of Subjects who spent More than 70% of Time in Range (70-180 mg/dL)



*During this period, subjects were instructed to use the study device with the Auto basal target as well as Active insulin time (AIT) set to what is best for the individual subject, at the investigator's discretion. Note that 38% (41/109) of pediatric patients and

41% (44/107) of adult patients used the study device with the Auto Basal target with setpoint 100 mg/dL and AIT set to 2 hours during study period stage 3.

Overall, the clinical study suggested that the 780G system was safe, and subjects showed improvements in HbA1C (compared to baseline) and time in the target range with use of the updated 780G pump and the Simplera Sync sensor. However, the study had the following limitation:

It did not compare subjects who were using the SmartGuard feature and the Auto correction feature to those who were not on a system (control group). Instead, the study compared how subjects did before using the Auto correction feature (run in period -2 weeks) against results while using the Auto correction feature (study period -3 months).

Due to this limitation, the results of the study should be interpreted with caution and you should understand that your individual results may vary.

The Suspend before low feature

Clinical study overview (Ages 14-75 Years)

The Suspend before low feature was evaluated for safety in a multi-center, single-arm, in-clinic study of the MiniMed 640G System.[8] This feature is the same in the MiniMed 780G system. Study subjects included persons aged 14 to 75 years diagnosed with type 1 diabetes mellitus who were on pump therapy at the time of screening.

A total of 71 subjects were subjected to hypoglycemic induction, followed by an observation period. For hypoglycemic induction, the target was set to 65 mg/dL, using the rate of change basal increase algorithm. The Suspend before low feature was activated with the Low Limit setting for the Suspend before low feature ON set to 65 mg/dL, and the subject was observed with frequent sample testing (FST, or frequent blood sampling for glucose measurements) for a maximum of 19 hours. The observation period included the suspension period, the insulin resumption period, and if applicable, an insulin resuspension after basal insulin delivery resumed.

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[8] Buckingham BA, Bailey TS, Christiansen M, et al. Evaluation of a Predictive Low-Glucose Management System In-Clinic. Diabetes Technology and Therapeutics. 2017;19(5):288-292

Feature performance and safety

Of the 71 subjects with induced hypoglycemia, 69 inductions were successful, 27 subjects experienced a hypoglycemic event and 42 subjects did not. At 120 minutes after the start of the pump suspension events, the mean reference glucose value (measured using a Yellow Springs Instrument [YSI]) was 102 ± 34.6 mg/dL.

Five adverse events were reported during the study. Four adverse events were neither device nor procedure related. One adverse event was procedure related.

Data from this in-clinic study demonstrated that the Suspend before low feature is safe to use. Study success criteria, as defined in the protocol, were met (i.e. there were no device related serious adverse events, no diabetic ketoacidosis events related to the Suspend before low feature, and no unanticipated adverse device effects).

Clinical study overview (Ages 7-13 Years)

The Suspend before low feature was also evaluated in a study of the MiniMed 670G system that included subjects 7-13 years, diagnosed with type 1 diabetes mellitus.[9] This feature is the same in the MiniMed 780G system.

A total of 105 study subjects were observed overnight after exercise/activity while using the system with the Suspend before low feature activated. The Low Limit setting for the Suspend before low feature turned ON was set to 65 mg/dL and the subjects were observed with FST for a maximum of 12 hours.

Feature performance and safety

In 79.7% of cases, after activation of the Suspend before low feature, the threshold of ≤ 65 mg/dL was avoided. Mean glucose levels up to six hours after the suspend feature was activated remained below the starting glucose levels.

Data from this in-clinic evaluation demonstrated that the Suspend before low feature is safe to use in a pediatric population.

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[9] Forlenza G, Shulman D, Wood M, et al. Evaluation of the MiniMed™ 670G system predictive low glucose management feature in children. Diabetes Technology and Therapeutics. 2018;20:A19-A20.

4

Simplera Sync sensor performance

4 Simplera Sync sensor performance

Simplera Sync System Performance

Note: You should review the information in this section with your healthcare professional to understand the performance of the Simplera Sync system.

Clinical study overview

The performance of the Simplera Sync system was evaluated using data collected during a multi-center prospective clinical study.[10] The study included participants ages 7 to 80 years old. Within the 7 to 80 years age range, the study enrolled a total of 219 subjects previously diagnosed with type 1 or type 2 diabetes and 209 of these subjects completed the study. Subjects ages 18 years and older were instructed to wear a total of two sensors in the arm. Subjects ages 7 to 17 years old were instructed to wear a total of three sensors in the arm and buttock. For all subjects, the sensors were used to record raw sensor signals during the study and there was no real-time calculation of sensor glucose values.

Frequent sample testing (FST) was performed on four occasions for subjects 14 and older and on two occasions for subjects 7 to 13 years of age.

[10] 10976639DOC: CIP330 - Evaluation of Updated Continuous Glucose Monitoring (CGM) Form Factor in Adults, Adolescents and Pediatrics.

Reference blood (plasma) glucose values were obtained with a YSI Glucose Analyzer every 5-15 minutes for subjects 7 years and older. During each FST, subjects 14 years and older with an established insulin sensitivity ratio and insulin carbohydrate ratio underwent a hypoglycemic challenge or a hyperglycemic challenge.

Data collected during the study was post-processed after the study using the Simplera Sync system sensor algorithm to convert the raw sensor information to sensor glucose values every five minutes. For the accuracy information presented in the following sections, YSI reference values were paired with the closest sensor glucose reading within five minutes of the time of the reference value measurement.

Table 10 shows the overall accuracy of the Simplera Sync system when compared to the reference YSI Glucose Analyzer.

Sensor accuracy

Sensor accuracy was calculated for sensors compared to a YSI reference for subjects ages 7 years and older in the arm insertion site. Do not insert the sensor into any other location.

Table 19. Overall Accuracy Compared to YSI

Patient Population (Years)	Number of Subjects	Number of paired SG-YSI Points	Percent of SG within 20/20%* of YSI (95% lower bound)	Mean Absolute Relative Difference (%)
Adults (18+)	116	15405	90.7 (90.3)	10.2
Pediatrics (7-17)	89	8282	89.0 (88.4)	10.8
CGM readings are within 50-400 mg/dL, inclusive. *For 20% agreement, 20 mg/dL used when YSI < 70 mg/dL.				

In *Table 2* and *Table 3*, the agreement of the SG values to paired YSI values was assessed by calculating the percentage of SG values that were within 15%, 20%, and 40% of the paired YSI values. For SG readings less than 70 mg/dL, the absolute difference in mg/dL between the SG and paired YSI values was calculated.

Table 20. Overall accuracy of SG-YSI paired points within SG ranges; Adults, Arm

CGM Glucose Range (mg/dL)*	Number of Subjects	Number of paired CGM-YSI Points	Percent of SG within 15 mg/dL YSI	Percent of SG within 20 mg/dL YSI	Percent of SG within 40 mg/dL YSI	Percent of SG within 15% YSI	Percent of SG within 20% YSI	Percent of SG within 40% YSI	Bias (mg/dL)	MARD (%)
A) < 54	29	164	84.1	90.9	98.2				-7.8	14.6
B) 54-69	72	1609	90.1	94.7	98.2				-2.3	10.6
C) 70-180	116	9655				74.3	85.7	98.6	-1.6	11.0
D) 181-250	101	2593				85.6	94.8	99.6	-8.5	8.6
E) > 250	79	1384				89.8	96.7	100.0	-14.1	7.4
CGM readings are within 50-400 mg/dL, inclusive.										

Table 20. Overall accuracy of SG-YSI paired points within SG ranges; Adults, Arm (continued)

CGM Glucose Range (mg/dL)*	Number of Subjects	Number of paired CGM-YSI Points	Percent of SG within 15 mg/dL YSI	Percent of SG within 20 mg/dL YSI	Percent of SG within 40 mg/dL YSI	Percent of SG within 15% YSI	Percent of SG within 20% YSI	Percent of SG within 40% YSI	Bias (mg/dL)	MARD (%)
* For reference range < 70 mg/dL, agreement was based on 15/20/40 mg/dL.										

Table 21. Overall accuracy of SG-YSI paired points within SG ranges; Pediatrics*, Arm

CGM Glucose Range (mg/dL)**	Number of Subjects	Number of paired CGM-YSI	Percent of SG within 15 mg/dL YSI	Percent of SG within 20 mg/dL YSI	Percent of SG within 40 mg/dL YSI	Percent of SG within 15% YSI	Percent of SG within 20% YSI	Percent of SG within 40% YSI	Bias (mg/dL)	MARD (%)
A) < 54	22	91	90.1	97.8	100.0				-5.7	11.2
B) 54-69	49	941	94.0	97.3	99.8				-1.1	9.5
C) 70-180	88	4484				68.4	79.9	96.9	-4.4	12.8
D) 181-250	87	1547				83.3	92.5	99.3	-11.5	8.8
E) > 250	73	1219				91.3	97.0	100.0	-14.4	7.1
CGM readings are within 50-400 mg/dL, inclusive. * Data includes pediatric subjects 7–17 years of age. ** For reference range < 70 mg/dL, agreement was based on 15/20/40 mg/dL.										

Agreement when CGM reads "Below 50 mg/dL" or "Above 400 mg/dL"

The real-time CGM systems display glucose values between 50 mg/dL and 400 mg/dL. It displays "Below 50 mg/dL" when the SG value detected is below 50 mg/dL. It displays "Above 400 mg/dL" when the SG value detected is above 400 mg/dL. *Table 13* and *Table 14* illustrate the number and percentage of the paired YSI values in different BG levels when the CGM system displays "Below 50 mg/dL" (LOW) or "Above 400 mg/dL" (HIGH).

Table 22. The number and percentage of YSI values collected when CGM displays "Below 50" (LOW)

			YSI (mg/dL)					
CGM Display	**Population**	**CGM-YSI pairs**	**< 55**	**< 60**	**< 70**	**< 80**	**≥ 80**	**Total**
LOW	Adult (18+ YOs)	Cumulative, n	67	119	169	197	10	207
		Cumulative, %	32%	57%	82%	95%	5%	
	Pediatrics (7-17 YOs)	Cumulative, n	72	100	112	114	0	114
		Cumulative, %	63%	88%	98%	100%	0%	

Table 23. The number and percentage of YSI values collected when CGM displays "Above 400 mg/dL "(HIGH)

			YSI (mg/dL)					
CGM Display	**Population**	**CGM-YSI pairs**	**> 340**	**> 320**	**> 280**	**> 240**	**≤ 240**	**Total**
HIGH	Adult (18+ YOs)	Cumulative, n	14	14	14	14	0	14
		Cumulative, %	100%	100%	100%	100%	0%	
	Pediatrics (7-17 YOs)	Cumulative, n	9	9	9	9	0	9
		Cumulative, %	100%	100%	100%	100%	0%	

Concurrence of SG and YSI values

Table 15 and *Table 16* show, for each SG range, the percentage of concurring data points where the paired YSI values were in different blood glucose ranges.

Table 24. Overall concurrence of YSI values and SG readings using SG ranges; Adults, Arm

Percent of matched pairs in each YSI glucose range for each SG range (mg/dL)												
SG ranges (mg/dL)	Number of paired SG-YSI	YSI glucose ranges (mg/dL)										
		< 50	≥ 50–60	> 60–80	> 80–120	> 120–160	> 160–200	> 200–250	> 250–300	> 300–350	> 350–400	> 400
A) < 50	207	15.0% (31/207)	42.5% (88/207)	37.7% (78/207)	4.3% (9/207)	0.5% (1/207)	0.0% (0/207)	0.0% (0/207)	0.0% (0/207)	0.0% (0/207)	0.0% (0/207)	0.0% (0/207)
B) ≥ 50–60	684	5.8% (40/684)	43.4% (297/684)	47.1% (322/684)	2.3% (16/684)	1.3% (9/684)	0.0% (0/684)	0.0% (0/684)	0.0% (0/684)	0.0% (0/684)	0.0% (0/684)	0.0% (0/684)
C) > 60–80	2285	1.9% (44/2285)	15.6% (356/2285)	68.5% (1566/2285)	12.6% (288/2285)	1.3% (29/2285)	0.1% (2/2285)	0.0% (0/2285)	0.0% (0/2285)	0.0% (0/2285)	0.0% (0/2285)	0.0% (0/2285)
D) > 80–120	3693	0.1% (2/3693	0.9% (34/3693)	12.6% (465/3693)	68.8% (2542/3693)	16.9% (625/3693)	0.5% (19/3693)	0.1% (4/3693)	0.1% (2/3693)	0.0% (0/3693)	0.0% (0/3693)	0.0% (0/3693)
E) > 120–160	3532	0.0% (0/3532)	0.0% (0/3532)	0.1% (2/3532)	17.6% (622/3532)	66.3% (2342/3532)	15.3% (539/3532)	0.6% (22/3532)	0.1% (5/3532)	0.0% (0/3532)	0.0% (0/3532)	0.0% (0/3532)
F) > 160–200	2149	0.0% (0/2149)	0.0% (0/2149)	0.0% (0/2149)	0.3% (6/2149)	15.0% (323/2149)	59.7% (1282/2149)	24.2% (521/2149)	0.7% (14/2149)	0.1% (3/2149)	0.0% (0/2149)	0.0% (0/2149)
G > 200–250	1678	0.0% (0/1678)	0.0% (0/1678)	0.0% (0/1678)	0.0% (0/1678)	0.7% (11/1678)	12.5% (210/1678)	63.6% (1068/1678)	21.8% (366/1678)	1.1% (19/1678)	0.2% (4/1678)	0.0% (0/1678)
H) > 250–300	879	0.0% (0/879)	0.0% (0/879)	0.0% (0/879)	0.0% (0/879)	0.0% (0/879)	0.1% (1/879)	11.1% (98/879)	53.8% (473/879)	31.6% (278/879)	3.0% (26/879)	0.3% (3/879)
I) > 300–350	404	0.0% (0/404)	0.0% (0/404)	0.0% (0/404)	0.0% (0/404)	0.0% (0/404)	0.0% (0/404)	0.2% (1/404)	7.4% (30/404)	66.3% (268/404)	25.5% (103/404)	0.5% (2/404)
J) > 350–400	101	0.0% (0/101)	0.0% (0/101)	0.0% (0/101)	0.0% (0/101)	0.0% (0/101)	0.0% (0/101)	0.0% (0/101)	0.0% (0/101)	13.9% (14/101)	78.2% (79/101)	7.9% (8/101)
K) > 400	14	0.0% (0/14)	0.0% (0/14)	0.0% (0/14)	0.0% (0/14)	0.0% (0/14)	0.0% (0/14)	0.0% (0/14)	0.0% (0/14)	0.0% (0/14)	71.4% (10/14)	28.6% (4/14)

Table 25. Overall concurrence of YSI values and SG readings using SG ranges; Pediatrics*, Arm

Percent of matched pairs in each YSI glucose range for each SG range (mg/dL)												
SG ranges (mg/dL)	Number of paired SG-YSI	YSI glucose ranges										
		< 50	≥ 50–60	> 60–80	> 80–120	> 120–160	> 160–200	> 200–250	> 250–300	> 300–350	> 350–400	> 400
A) < 50	114	36.8%(42/114)	50.9% (58/114)	12.3% (14/114)	0.0% (0/114)	0.0% (0/114)	0.0% (0/114)	0.0% (0/114)	0.0% (0/114)	0.0% (0/114)	0.0% (0/114)	0.0% (0/114)
B) ≥ 50–60	388	7.0% (27/388)	49.0% (190/388)	42.3% (164/388)	1.8% (7/388)	0.0% (0/388)	0.0% (0/388)	0.0% (0/388)	0.0% (0/388)	0.0% (0/388)	0.0% (0/388)	0.0% (0/388)
C) > 60–80	1382	0.4% (5/1382)	15.6% (215/1382)	69.2% (957/1382)	14.1% (195/1382)	0.7% (9/1382)	0.0% (0/1382)	0.0% (0/1382)	0.1% (1/1382)	0.0% (0/1382)	0.0% (0/1382)	0.0% (0/1382)
D) > 80–120	1705	0.2% (3/1705)	0.9% (16/1705)	18.3% (312/1705)	60.5% (1031/1705)	17.8% (304/1705)	2.1% (36/1705)	0.0% (0/1705)	0.1% (1/1705)	0.1% (2/1705)	0.0% (0/1705)	0.0% (0/1705)

Table 25. Overall concurrence of YSI values and SG readings using SG ranges; Pediatrics*, Arm (continued)

Percent of matched pairs in each YSI glucose range for each SG range (mg/dL)												
SG ranges (mg/dL)	Number of paired SG-YSI	YSI glucose ranges										
		< 50	≥ 50–60	> 60–80	> 80–120	> 120–160	> 160–200	> 200–250	> 250–300	> 300–350	> 350–400	> 400
E) > 120–160	1398	0.0% (0/1398)	0.0% (0/1398)	0.4% (5/1398)	11.1% (155/1398)	62.7% (876/1398)	23.0% (322/1398)	2.2% (31/1398)	0.4% (6/1398)	0.1% (2/1398)	0.1% (1/1398)	0.0% (0/1398)
F) > 160–200	1170	0.0% (0/1170)	0.0% (0/1170)	0.0% (0/1170)	0.3% (4/1170)	13.3% (156/1170)	56.5% (661/1170)	27.4% (320/1170)	1.1% (13/1170)	0.9% (10/1170)	0.3% (4/1170)	0.2% (2/1170)
G) > 200–250	1020	0.0% (0/1020)	0.0% (0/1020)	0.0% (0/1020)	0.1% (1/1020)	0.7% (7/1020)	8.6% (88/1020)	62.8% (641/1020)	25.2% (257/1020)	2.5% (26/1020)	0.0% (0/1020)	0.0% (0/1020)
H) > 250–300	706	0.0% (0/706)	0.0% (0/706)	0.0% (0/706)	0.0% (0/706)	0.0% (0/706)	0.1% (1/706)	9.2% (65/706)	58.2% (411/706)	29.9% (211/706)	2.5% (18/706)	0.0% (0/706)
I) > 300–350	424	0.0% (0/424)	0.0% (0/424)	0.0% (0/424)	0.0% (0/424)	0.0% (0/424)	0.0% (0/424)	0.2% (1/424)	9.4% (40/424)	59.7% (253/424)	29.7% (126/424)	0.9% (4/424)
J) > 350–400	89	0.0% (0/89)	0.0% (0/89)	0.0% (0/89)	0.0% (0/89)	0.0% (0/89)	0.0% (0/89)	0.0% (0/89)	0.0% (0/89)	6.7% (6/89)	67.4% (60/89)	25.8% (23/89)
K) > 400	9	0.0% (0/9)	0.0% (0/9)	0.0% (0/9)	0.0% (0/9)	0.0% (0/9)	0.0% (0/9)	0.0% (0/9)	0.0% (0/9)	0.0% (0/9)	22.2% (2/9)	77.8% (7/9)
* Data includes pediatric subjects 7-17 years of age												

Trend accuracy

Table 26. Trend accuracy compared to YSI over time; Adults, Arm

	YSI (mg/dL/min)						
SG Rate Ranges (mg/dL/min)	No. of Paired Points SG-YSI	< -2	[-2,-1)	[-1, 0)	[0, 1]	(1, 2]	> 2
< -2	201	58.2% (117/201)	33.8% (68/201)	6.5% (13/201)	1.5% (3/201)	0.0% (0/201)	0.0% (0/201)
[-2,-1)	838	7.9% (66/838)	48.8% (409/838)	40.9% (343/838)	2.3% (19/838)	0.0% (0/838)	0.1% (1/838)
[-1, 0)	7350	0.2% (18/7350)	4.1% (301/7350)	75.9% (5581/7350)	19.1% (1407/7350)	0.5% (35/7350)	0.1% (8/7350)
[0, 1]	5484	0.1% (3/5484)	0.6% (33/5484)	22.9% (1257/5484)	68.5% (3757/5484)	7.6% (416/5484)	0.3% (18/5484)
(1, 2]	1156	0.0% (0/1156)	0.1% (1/1156)	2.5% (29/1156)	31.5% (364/1156)	56.5% (653/1156)	9.4% (109/1156)
> 2	350	0.0% (0/350)	0.0% (0/350)	0.6% (2/350)	4.6% (16/350)	36.0% (126/350)	58.9% (206/350)
CGM readings are within 50-400 mg/dL, inclusive.							

Table 27. Trend accuracy compared to YSI over time; Pediatrics**, Arm

	YSI (mg/dL/min)						
SG Rate Ranges (mg/dL/min)	No. of Paired Points SG-YSI	< -2	[-2,-1)	[-1, 0)	[0, 1]	(1, 2]	> 2
< -2	158	44.9% (71/158)	46.2% (73/158)	8.9% (14/158)	0.0% (0/158)	0.0% (0/158)	0.0% (0/158)
[-2,-1)	756	5.3% (40/756)	58.3% (441/756)	33.9% (256/756)	2.2% (17/756)	0.1% (1/756)	0.1% (1/756)
[-1, 0)	3507	0.5% (17/3507)	6.9% (243/3507)	74.5% (2612/3507)	17.5% (615/3507)	0.5% (19/3507)	0.0% (1/3507)
[0, 1]	2769	0.0% (1/2769)	1.0% (27/2769)	21.1% (584/2769)	69.2% (1915/2769)	7.9% (218/2769)	0.9% (24/2769)
(1, 2]	801	0.1% (1/801)	0.5% (4/801)	1.9% (15/801)	29.5% (236/801)	57.7% (462/801)	10.4% (83/801)
> 2	283	0.0% (0/283)	0.4% (1/283)	0.7% (2/283)	4.6% (13/283)	30.0% (85/283)	64.3% (182/283)
CGM readings are within 50-400 mg/dL, inclusive. ** Data includes pediatric subjects 7-17 years of age.							

Accuracy over time

The wear period was defined as: beginning (Elapsed day 1, 2), middle (Elapsed day 3, 4, 5), and end (Elapsed day 6, 7).

Table 28. Sensor Accuracy Compared to YSI Over Time; Adults, Arm

Wear Period**	Number of paired SG-YSI	Percent of SG within 15/15% of YSI (%)	Percent of SG within 20/20% of YSI (%)	Percent of SG within 40/40% of YSI (%)	Mean Absolute Relative Difference (%)
Beginning	4377	75.1	86.7	98.6	12
Middle	8207	82.4	92.5	99.7	9.5
End	2821	82.9	91.7	99.0	9.6

CGM readings are within 50-400 mg/dL, inclusive.
** For reference range < 70 mg/dL, agreement was based on 15/20/40 mg/dL.

Table 29. Sensor Accuracy Compared to YSI Over Time; Pediatrics*, Arm

Wear Period	Number of paired SG-YSI	Percent of SG within 15/15% of YSI (%)	Percent of SG within 20/20% of YSI (%)	Percent of SG within 40/40% of YSI (%)	Mean Absolute Relative Difference (%)
Beginning	2452	70.8	84.2	98.5	13.1
Middle	4337	82.4	91.5	98.8	9.7
End	1493	83.1	89.7	98.7	10.1

CGM readings are within 50-400 mg/dL, inclusive.
For reference range < 70 mg/dL, agreement was based on 15/20/40 mg/dL.
* Data includes pediatric subjects 7-17 years of age.

Reading capture rate

Table 30. Reading Capture Rate by Functional Wear Day; Adults, Arm

Functional Wear Day	Number of Sensors	Capture Rate* (%)
1	118	98.5
2	114	99.8
3	110	99.9
4	110	99.8
5	104	99.1
6	99	97.7
7	88	96.7

* The capture rate is based on the sensor's functional end time.

Table 31. Reading Capture Rate by Functional Wear Day; Pediatrics**, Arm

Functional Wear Day	Number of Sensors	Capture Rate* (%)
1	94	98.6
2	92	100
3	92	100
4	92	98.1
5	87	96.5
6	78	97.5
7	63	90.1

* The capture rate is based on the sensor's functional end time.
** Data includes pediatric subjects 7-17 years of age.

Precision

Precision of the system was evaluated by comparing the results from two separate sensors worn in the location on the same subject at the same time.

Table 32. Sensor precision

	Number of paired points	Percent Absolute Relative Difference (PARD)	Coefficient of variation (%CV)
7-17 YO Arm	9723	8.2	5.9
18+ YO Arm	36459	9.0	6.2

Sensor life

Sensors are designed to be worn for up to six days, followed by a grace period of 24 hours. Combining the six-day wear period with the 24-hour grace period allows for up to seven days of sensor usage. However, some sensors may not survive the full wear period for a variety of reasons. Please be prepared to replace the sensor during the grace period to ensure sensor glucose values continue to be monitored. To estimate how long a sensor will work, sensors were evaluated in a clinical study to determine how many days and hours of readings each sensor provided.

For the sensor life evaluation, sensors used by subjects in the study were censored from the survival analysis due to various reasons not related to the commercial device (e.g., subject dropped out of the study, subject accidentally removed sensors at the incorrect time, or software anomalies occurred that were only applicable to the investigational device and are resolved for the commercial device).

Adults

Among the 128 sensors evaluated, 11 sensors (8.6%) were censored from the survival analysis, 75.2% of the sensors lasted through the end of the entire six-day wear period, and 66.7% lasted through the end of the six-day wear period followed by a grace period of 24 hours.

Pediatrics

Among the 99 sensors evaluated, 8 sensors (8.1%) were censored from the survival analysis, 66.2% of the sensors lasted through the end of the entire six-day wear period,

and 47.5% lasted through the end of the six-day wear period followed by a grace period of 24 hours.

Safety

Device related adverse events were limited to pain or bruising at the sensor insertion site.

Alert performance

CGM enables a device to display SG readings, glucose trend arrows, glucose trend graphs, and SG alerts, for example, High and Low Sensor Glucose alerts, High and Low Predicted alerts, and Rise and Fall alerts for rate-of-change.

The high and low SG alerts (**Threshold alerts**) let the user know when the SG is at or above the high limit or at or below the low limit. Using only a high or low Threshold alert may reduce the number of false alerts, but does not provide a warning before reaching a high or low limit. The default alert thresholds are highlighted in gray below.

Predictive alerts notify users that their SG level may soon reach a high or low limit setting. Users may select how early they would like to be notified before their SG level reaches a high or low limit. The earliest warning is 60 minutes before reaching a high or low limit, but users can reduce the amount of warning down to 10 minutes. Users receive a Predictive alert when their SG level is predicted to reach their high or low limit in the Time Before High or Time Before Low setting they select. In general, the earlier the warning, the more time a user has to react to a potential high or low, but this also increases the potential for false alerts.

A predictive alert is simply an estimation of a future SG level compared to the high or low limit setting. If the predicted future SG value is at or above the high limit or is at or below the low limit, then a predictive alert is sounded even though the current SG level has not crossed the high or low limit. The predicted SG level is calculated using the current SG level, the derivative of current and previous SG readings (the trend or slope of the SG readings) and the Time Before High or Time Before Low duration the user selects.

The device always alerts the user with an Urgent Low glucose alert when the CGM reads that the user is at or below 63 mg/dL, regardless of the high/low threshold and/or predictive alerts that the user sets.

Glucose TRUE Alert Rate

The glucose true alert rate is the rate at which the blood glucose (BG) confirmed that the CGM alert was triggered correctly. For example:

- **True Threshold Hypoglycemic alert rate** is a measure of how often the CGM read that the user was at or below the low threshold and the user's BG was actually at or below that low threshold.
- **True Threshold Hyperglycemic alert rate** is a measure of how often the CGM read that the user was at or above the high threshold and the user's BG was actually at or above that high threshold.
- **True Predictive Hypoglycemic alert rate** is a measure of how often the CGM predicted that the user would reach or go below the low threshold and the user's BG was actually at or below that low threshold within 15 or 30 minutes.
- **True Predictive Hyperglycemic alert rate** is a measure of how often the CGM predicted that the user would reach or go above the high threshold and the user's BG was actually at or above that high threshold within 15 or 30 minutes.

The true alert rate is important because it is necessary that users be notified when their blood glucose is low (or high) so that they can correct the low (or high) blood glucose. A high true alert rate indicates that when the CGM says that their glucose values are, or will reach a specified threshold, the user's blood glucose is likely to be at or approaching that threshold.

For example, per the following table, the low glucose alerts would have correctly indicated that the user was at or below (i.e. threshold only), or predicted to reach or go below the threshold (i.e. predictive only) or both (threshold and predictive) 81.0%, 58.7%, or 66.7% of the time within 30 minutes (or 80.4%, 54.4% or 63.7% of the time within 15 minutes) when the user had BG values at or lower than 70 mg/dL for a sensor inserted in the adult arm.

Table 33. Glucose TRUE Alert Performance, Adults

	Threshold Only			Predictive Only			Threshold and Predictive		
Alert Type	**mg/dL**	**±30 Min**	**±15 Min**	**mg/dL**	**±30 Min**	**±15 Min**	**mg/dL**	**±30 Min**	**±15 Min**
Low glucose alert	**63**	73.7% (87/118)	72.9% (86/118)	**63**	53.3% (122/229)	48.5% (111/229)	**63**	60.2% (209/347)	56.8% (197/347)
	65	75.4% (101/134)	75.4% (101/134)	**65**	57.7% (138/239)	50.6% (121/239)	**65**	64.1% (239/373)	59.5% (222/373)
	70	81.0% (128/158)	80.4% (127/158)	**70**	58.7% (166/283)	54.4% (154/283)	**70**	66.7% (294/441)	63.7% (281/441)
	80	79.4% (177/223)	78.0% (174/223)	**80**	56.3% (206/366)	53.6% (196/366)	**80**	65.0% (383/589)	63.7% (370/589)
	90	75.9% (233/307)	75.9% (233/307)	**90**	61.7% (263/426)	56.3% (240/426)	**90**	67.7% (496/733)	64.5% (473/733)
High glucose alert	**300**	95.7% (90/94)	95.7% (90/94)	**300**	62.0% (129/208)	67.20% (119/208)	**300**	72.5% (219/302)	69.2% (209/302)
	250	90.1% (163/181)	89.5% (162/181)	**250**	57.7% (207/359)	55.2% (198/359)	**250**	68.5% (370/540)	66.7% (360/540)
	220	89.8% (246/274)	89.1% (244/274)	**220**	60.8% (296/487)	58.5% (285/487)	**220**	71.2% (542/761)	69.5% (529/761)
	180	88.5% (354/400)	88.3% (353/400)	**180**	63.0% (428/679)	60.5% (411/679)	**180**	72.5% (782/1079)	70.8% (764/1079)

Table 34. Glucose TRUE Alert Performance, Pediatrics

	Threshold Only			Predictive Only			Threshold and Predictive		
Alert Type	**(mg/dL)**	**±30 Min**	**±15 Min**	**(mg/dL)**	**±30 Min**	**±15 Min**	**(mg/dL)**	**±30 Min**	**±15 Min**
Low glucose alert	**63**	67.1% (57/85)	67.1% (57/85)	**63**	48.0% (82/171)	39.8% (68/171)	**63**	54.3% (139/256)	48.8% (125/256)
	65	73.3% (66/90)	72.2% (65/90)	**65**	49.2% (87/177)	42.9% (76/177)	**65**	57.3% (153/267)	52.8% (141/267)
	70	75.7% (81/107)	74.8% (80/107)	**70**	54.2% (109/201)	50.2% (101/201)	**70**	61.7% (190/308)	58.8% (181/308)
	80	71.9% (110/153)	71.2% (109/153)	**80**	55.7% (132/237)	52.7% (125/237)	**80**	62.1% (242/390)	60.0% (234/390)
	90	76.5% (137/179)	76.0% (136/179)	**90**	62.1% (164/264)	59.5% (157/264)	**90**	67.9% (301/443)	66.1% (293/443)
High glucose alert	**300**	89.7% (87/97)	89.7% (87/97)	**300**	57.2% (103/180)	55.0% (99/180)	**300**	68.6% (190/277)	67.1% (186/277)
	250	90.3% (149/165)	89.7% (148/165)	**250**	63.8% (185/290)	59.0% (171/290)	**250**	73.4% (334/455)	70.1% (319/455)
	220	93.9% (200/213)	93.4% (199/213)	**220**	68.6% (240/350)	65.4% (229/350)	**220**	78.2% (440/563)	76.0% (428/563)
	180	89.5% (263/294)	89.1% (262/294)	**180**	73.2% (303/414)	69.8% (289/414)	**180**	79.9% (566/708)	77.8% (551/708)

Glucose FALSE Alert Rate

The glucose false alert rate is the rate at which the BG did not confirm that the CGM alert was triggered correctly. For example:

- **False Threshold Hypoglycemic alert rate** is a measure of how often the CGM read that the user was at or below the low threshold, but the user's BG was actually above that low threshold.

- **False Threshold Hyperglycemic alert rate** is a measure of how often the CGM read that the user was at or above the high threshold, but the user's BG was actually below that high threshold.
- **False Predictive Hypoglycemic alert rate** is a measure of how often the CGM predicted that the user would be at or below the low threshold, but the user's BG was actually above that low threshold within 15 or 30 minutes.
- **False Predictive Hyperglycemic alert rate** is a measure of how often the CGM predicted that the user would be at or above the high threshold, but the user's BG was actually below the high threshold within 15 or 30 minutes.

The false alert rate is important because it is necessary that users be correctly notified when their glucose is low or high so that they can correct the low or high glucose. A low false alert rate indicates that when the CGM says that their glucose values are, or will reach a specified threshold, the user's glucose is likely to be at or approaching that threshold. For example, per the following table, the high glucose threshold alerts would have incorrectly indicated that the user was at or above (i.e. threshold only), or predicted to reach or go above the threshold (i.e. predictive only), or both (threshold and predictive) for adult 11.5%, 37.0% or 27.5% of the time within 30 minutes (or 11.8%, 39.5%, or 29.2% of the time within 15 minutes) when the user had a BG at or greater than 180 mg/dL for a sensor inserted in the arm.

Table 35. Glucose FALSE Alert Performance, Adults

	Threshold Only			Predictive Only			Threshold and Predictive		
Alert Type	**mg/dL**	**±30 Min**	**±15 Min**	**mg/dL**	**±30 Min**	**±15 Min**	**mg/dL**	**±30 Min**	**±15 Min**
Low glucose alert	**63**	26.3% (31/118)	27.1% (32/118)	**63**	46.7% (107/229)	51.5% (118/229)	**63**	39.8% (138/347)	43.2% (150/347)
	65	24.6% (33/134)	24.6% (33/134)	**65**	42.3% (101/239)	49.4% (118/239)	**65**	35.9% (134/373)	40.5% (151/373)
	70	19.0% (30/158)	19.6% (31/158)	**70**	41.3% (117/283)	45.6% (129/283)	**70**	33.3% (147/441)	36.3% (160/441)
	80	20.6% (46/223)	22.0% (49/223)	**80**	43.7% (160/366)	46.4% (170/366)	**80**	35.0% (206/589)	37.2% (219/589)
	90	24.1% (74/307)	24.1% (74/307)	**90**	38.3% (163/426)	43.7% (186/426)	**90**	32.3% (237/733)	35.5% (260/733)
High glucose alert	**300**	4.3% (4/94)	4.3% (4/94)	**300**	38.0% (79/208)	42.8% (89/208)	**300**	27.5% (83/302)	30.8% (93/302)
	250	9.9% (18/181)	10.5% (19/181)	**250**	42.3% (152/359)	44.8% (161/359)	**250**	31.5% (170/540)	33.3% (180/540)
	220	10.2% (28/274)	10.9% (30/274)	**220**	39.2% (191/487)	41.5% (202/487)	**220**	28.8% (219/761)	30.5% (232/761)
	180	11.5% (46/400)	11.8% (47/400)	**180**	37.0% (251/679)	39.5% (268/679)	**180**	27.5% (297/1079)	29.2% (315/1079)

Table 36. Glucose FALSE Alert Performance, Pediatrics

Alert Type	Threshold Only			Predictive Only			Threshold and Predictive		
	mg/dL	±30 Min	±15 Min	mg/dL	±30 Min	±15 Min	mg/dL	±30 Min	±15 Min
Low glucose alert	**63**	32.9% (28/85)	32.9% (28/85)	**63**	52.0% (89/171)	60.2% (103/171)	**63**	45.7% (117/256)	51.2% (131/256)
	65	26.7% (24/90)	27.8% (25/90)	**65**	50.8% (90/177)	57.1% (101/177)	**65**	47.2% (126/267)	47.2% (126/267)
	70	24.3% (26/107)	25.2% (27/107)	**70**	45.8% (92/201)	49.8% (100/201)	**70**	38.3% (118/308)	41.2% (127/308)
	80	28.1% (43/153)	28.8% (44/153)	**80**	44.3% (105/237)	47.3% (112/237)	**80**	37.9% (148/390)	40.0% (234/390)
	90	23.5% (42/179)	24.0% (43/179)	**90**	37.9% (100/264)	40.5% (107/264)	**90**	32.1% (142/443)	33.9% (150/443)
High glucose alert	**300**	10.3% (10/97)	10.3% (10/97)	**300**	48.2% (77/180)	45.0% (81/180)	**300**	31.4% (87/277)	32.9% (91/277)
	250	9.7% (16/165)	10.3% (17/165)	**250**	36.2% (105/290)	41.0% (119/290)	**250**	26.6% (121/455)	29.9% (136/455)
	220	6.1% (13/213)	6.6% (14/213)	**220**	31.4% (110/350)	34.6% (121/350)	**220**	21.8% (123/563)	24.0% (135/563)
	180	10.5% (31/294)	10.9% (32/294)	**180**	26.8% (111/414)	30.2% (125/414)	**180**	20.1% (142/708)	22.2% (157/708)

Glucose Correct Detection Rate

Glucose Correct Detection Rate is the rate that the device alerted when it should have alerted. For example, the BG was at or below the hypoglycemic threshold, or at or above the hyperglycemic threshold, and the device sounded a threshold or predictive alert.

The correct detection rates are important because it is necessary that users be notified when their glucose is low or high so that they can correct the low or high glucose. A high glucose correct detection rate indicates that users can have confidence that they will be notified by the device if their glucose is low or high.

For example, per the following table, the threshold alert, the predictive alert, or both (threshold and predictive) for adults notified the user 90.2%, 98.4% or 98.6% of the time within 30 minutes (or 88.3%, 95.1% or 95.8% within 15 minutes) when the user had a BG at or greater than 70–180 mg/dL for a sensor inserted in the arm.

Table 37. Glucose CORRECT DETECTION Alert Performance, Adults

Alert Type	Threshold Only			Predictive Only			Threshold and Predictive		
	mg/dL	±30 Min	±15 Min	mg/dL	±30 Min	±15 Min	mg/dL	±30 Min	±15 Min
Low glucose alert	**63**	65.9% (89/135)	65.9% (89/135)	**63**	90.4% (122/135)	83.0% (112/135)	**63**	90.4% (122/135)	86.7% (117/135)
	65	72.0% (103/143)	70.6% (101/143)	**65**	91.6% (131/143)	85.3% (122/143)	**65**	91.6% (131/143)	87.4% (117/143)
	70	82.2% (125/152)	82.2% (125/152)	**70**	91.6% (131/152)	89.5% (122/152)	**70**	93.4% (142/152)	91.4% (139/152)
	80	86.8% (184/212)	84.9% (180/212)	**80**	93.9% (199/212)	91.0% (193/212)	**80**	94.3% (200/212)	91.0% (193/212)
	90	84.9% (242/285)	84.6% (241/285)	**90**	90.9% (259/285)	84.6% (241/285)	**90**	91.2% (260/285)	88.1% (251/285)
High glucose alert	**300**	74.6% (88/118)	73.7% (87/118)	**300**	94.9% (112/118)	89.0% (105/118)	**300**	94.9% (112/118)	89.8% (106/118)
	250	80.3% (163/203)	80.3% (163/203)	**250**	93.6% (190/203)	90.6% (184/203)	**250**	93.6% (190/203)	91.6% (186/203)
	220	85.9% (244/284)	85.6% (243/284)	**220**	95.8% (272/284)	93.3% (265/284)	**220**	96.1% (2734/284)	94.0% (267/284)
	180	90.2% (385/427)	88.3% (377/427)	**180**	98.4% (420/427)	95.1% (406/427)	**180**	98.6% (421/427)	95.8% (409/427)

Table 38. Glucose CORRECT DETECTION Alert Performance, Pediatrics

Alert Type	Threshold Only			Predictive Only			Threshold and Predictive		
	mg/dL	±30 Min	±15 Min	mg/dL	±30 Min	±15 Min	mg/dL	±30 Min	±15 Min
Low glucose alert	**63**	65.9% (56/85)	64.7% (55/85)	**63**	84.7% (72/85)	77.6% (66/85)	**63**	84.7% (72/85)	78.8% (67/85)
	65	71.9% (64/89)	70.8% (63/89)	**65**	91.0% (81/89)	80.2% (65/89)	**65**	91.0% (70/89)	83.1% (74/89)
	70	80.0% (80/100)	79.0% (79/100)	**70**	95.0% (95/100)	92.0% (92/100)	**70**	95.0% (9/100)	93.0% (93/100)
	80	92.0% (115/125)	91.2% (114/125)	**80**	97.6% (89/125)	96.0% (120/125)	**80**	97.6% (122/325)	96.8% (121/325)
	90	87.4% (139/159)	86.8% (138/159)	**90**	96.9% (154/159)	93.7% (149/159)	**90**	96.9% (154/159)	95.6% (152/159)
High glucose alert	**300**	82.1% (92/112)	81.3% (91/112)	**300**	89.3% (100/112)	84.8% (95/112)	**300**	90.2% (101/112)	88.4% (99/112)
	250	86.9% (159/183)	85.8% (157/183)	**250**	95.6% (175/183)	94.0% (172/183)	**250**	95.6% (175/183)	95.1% (174/183)
	220	90.7% (214/236)	89.8% (212/236)	**220**	96.6% (228/236)	94.9% (224/236)	**220**	96.6% (228/236)	95.3% (225/236)
	180	93.7% (282/301)	91.7% (276/301)	**180**	96.7% (291/301)	93.4% (281/301)	**180**	97.3% (293/301)	96.7% (291/301)

Glucose Missed Detection Rate

The Missed Detection Rate is the rate that the device did not alert when it should have. For example, the BG was at or below the hypoglycemic threshold, or at or above the hyperglycemic threshold, and the device did not sound a threshold or predictive alert.

Missed detection rates are important because it is necessary that users be notified when their glucose is low or high, so that they can correct the low or high glucose. A low missed detection rate indicates that users can have confidence that they will be notified by the device if their glucose is low or high.

For example, per the following table, the threshold alert, predictive alert, or both alerts (threshold and predictive) for adults did not sound 17.8%, 6.6% or 6.6% of the time within 30 minutes (or 17.8%, 10.5% or 8.6% within 15 minutes) when the user had a BG at or less than 70 mg/dL for a sensor inserted in the arm.

Table 39. Glucose MISSED DETECTION Performance, Adults

	Threshold Only			Predictive Only			Threshold and Predictive		
Alert Type	**mg/dL**	**±30 Min**	**±15 Min**	**mg/dL**	**±30 Min**	**±15 Min**	**mg/dL**	**±30 Min**	**±15 Min**
Low glucose alert	**63**	34.1% (46/135)	34.1% (46/135)	**63**	9.6% (13/135)	17.0% (23/135)	**63**	9.6% (13/135)	13.3% (18/135)
	65	28.0% (40/143)	29.4% (42/143)	**65**	8.4% (12/143)	14.7% (21/143)	**65**	8.4% (12/143)	12.6% (18/143)
	70	17.8% (27/152)	17.8% (27/152)	**70**	6.6% (10/152)	10.5% (16/152)	**70**	6.6% (10/152)	8.6% (13/152)
	80	13.2% (28/212)	15.1% (32/212)	**80**	6.1% (13/212)	9.0% (19/212)	**80**	5.7% (12/212)	9.0% (19/212)
	90	15.1% (43/285)	15.4% (44/285)	**90**	9.1% (26/285)	15.4% (44/285)	**90**	8.8% (25/285)	11.9% (34/285)
High glucose alert	**300**	25.4% (30/118)	26.3% (31/118)	**300**	5.1% (6/118)	11.0% (13/118)	**300**	5.1% (6/118)	10.2% (12/118)
	250	19.7% (40/203)	19.7% (40/203)	**250**	6.4% (13/203)	9.4% (19/203)	**250**	6.4% (13/203)	8.4% (17/203)
	220	14.1% (40/284)	14.4% (41/284)	**220**	4.2% (12/284)	6.7% (19/284)	**220**	3.9% (11/284)	6.0% (17/284)
	180	9.8% (42/427)	11.7% (42/427)	**180**	1.6% (7/427)	4.9% (21/427)	**180**	1.4% (5/427)	4.2% (18/427)

Table 40. Glucose MISSED Detection Performance, Pediatrics

	Threshold Only			Predictive Only			Threshold and Predictive		
Alert Type	**mg/dL**	**±30 Min**	**±15 Min**	**mg/dL**	**±30 Min**	**±15 Min**	**mg/dL**	**±30 Min**	**±15 Min**
Low glucose alert	**63**	34.1% (29/85)	35.3% (30/85)	**63**	15.3% (13/85)	22.4% (19/85)	**63**	15.3% (13/85)	21.2% (18/85)
	65	28.1% (25/89)	29.2% (26/89)	**65**	9.0% (8/89)	18.0% (16/89)	**65**	9.0% (8/89)	16.9% (15/89)
	70	20.0% (20/100)	21.0% (21/100)	**70**	5.0% (5/100)	8.0% (8/100)	**70**	5.0% (5/100)	7.0% (7/100)
	80	8.0% (10/125)	8.8% (11/125)	**80**	2.4% (3/125)	4.0% (5/125)	**80**	2.4% (3/125)	3.2% (4/125)
	90	12.6% (20/159)	13.2% (21/159)	**90**	3.1% (5/159)	6.3% (10/159)	**90**	3.1% (5/159)	4.4% (7/159)
High glucose alert	**300**	17.9% (20/112)	18.8% (21/112)	**300**	10.7% (12/112)	15.2% (17/112)	**300**	9.8% (11/112)	11.6% (13/112)
	250	13.1% (24/183)	14.2% (26/183)	**250**	4.4% (8/183)	6.0% (11/183)	**250**	4.4% (8/183)	4.9% (9/183)
	220	9.3% (22/236)	10.2% (24/236)	**220**	3.4% (8/236)	5.1% (12/236)	**220**	3.4% (8/236)	4.7% (11/236)
	180	6.3% (19/301)	8.3% (25/301)	**180**	3.3% (10/301)	6.6% (20/301)	**180**	2.7% (8/301)	3.3% (10/301)

5

Guardian 4 sensor performance

5 Guardian 4 sensor performance

Guardian 4 System Performance

Note: You should review the information in this section with your healthcare professional to understand the performance of the Simplera Sync system.

Clinical study overview

The performance of the Guardian 4 system was evaluated using data collected during a multi-center prospective clinical study.[11] The study included participants 7 to 80 years old. Within the 7 to 80 years age range, the study enrolled a total of 308 subjects previously diagnosed with type 1 or 2 diabetes and 267 of these subjects completed the study. Subjects ages 18 and older were instructed to wear a total of three sensors and transmitters in the abdomen and arm. Subjects ages 7 to 17 years old were instructed to wear a total of three sensors and transmitters in the arm and buttock. For all subjects, the transmitters were used to record raw sensor signals during the study and there was no real-time calculation of sensor glucose values.

Reference blood (plasma) glucose values were obtained with a Yellow Springs Instrument (YSI™*) Glucose Analyzer every 5-15 minutes for subjects 7 years and older. During each FST, subjects with an established insulin sensitivity ratio and insulin

[11] Medtronic Inc., Performance Evaluation of an Advanced Algorithm with CGM in Adults, Adolescents and Pediatrics 10838519DOC. September 2019.

carbohydrate ratio underwent a hypoglycemic challenge and a hyperglycemic challenge.

Frequent sample testing (FST) was performed on four occasions for subjects 14 years and older and on two occasions for subjects 7 to 13 years old.

Data collected during the study was post-processed after the study using the Simplera Sync system sensor algorithm to convert the raw sensor information to sensor glucose values every five minutes. For the accuracy information presented in the following sections, YSI™* reference values were paired with the closest sensor glucose reading within five minutes of the time of the reference value measurement.

Sensor accuracy

Sensor accuracy was calculated for sensors compared to a YSI™* reference for subjects 7 years and older, in the arm insertion site. Do not insert the sensor into any other location.

Table 41. Overall Accuracy Compared to YSI™*

Patient Population	Insertion Site	Number of Subjects	Number of paired SG-YSI™*	Percent of SG within 20/20% of YSI™*	Mean Absolute Relative Difference (%)
Adults (18+)	Arm	153	20612	88.3 (88.0)	10.6
Pediatrics (7-17)	Arm	107	7702	85.6 (85.0)	11.6
*CGM readings are within 50-400 mg/dL, inclusive, which are slightly truncated from GS3 (40-400 mg/dL). *For 20% agreement, 20 mg/dL used when YSI™* < 70 mg/dL.					

In *Table 42* through *Table 43*, the agreement of the SG values to paired YSI™* values was assessed by calculating the percentage of SG values that were within 15%, 20%, and 40% of the paired YSI™* values. For SG readings less than 70 mg/dL, the absolute difference in mg/dL between the SG and paired YSI™* values was calculated.

Table 42. Overall accuracy of SG-YSI™* paired points within SG ranges; Adults, Arm

CGM Glucose Range (mg/dL)	Number of Subjects	Number of paired CGM-YSI™*	Percent within 15 mg/dL YSI™*	Percent within 20 mg/dL YSI™*	Percent within 40 mg/dL YSI™*	Percent within 15% YSI™*	Percent within 20% YSI™*	Percent within 40% YSI™*	Bias (mg/dL)	MARD (%)
A) < 54	46	252	77.4	87.7	98.0				-9.3	14.9
B) 54-69	99	2204	91.0	95.9	99.7				-2.3	10.2
C) 70-180	153	12893				72.7	84.1	98.6	-4.9	11.3
D) 181-250	146	3857				81.6	91.1	99.7	-11.4	9.3
E) > 250	97	1406				86.5	94.5	99.9	-7.3	8.2
* For reference range < 70 mg/dL, agreement was based on 15/20/40 mg/dL. CGM readings are within 50-400 mg/dL, inclusive.										

Table 43. Overall accuracy of SG-YSI™* paired points within SG ranges; Pediatrics, Arm

CGM Glucose Range (mg/dL)	Number of Subjects	Number of paired CGM-YSI™*	Percent within 15 mg/dL YSI™*	Percent within 20 mg/dL YSI™*	Percent within 40 mg/dL YSI™*	Percent within 15% YSI™*	Percent within 20% YSI™*	Percent within 40% YSI™*	Bias (mg/dL)	MARD (%)
A) < 54	28	103	62.1	78.6	98.1				-13.0	19.4
B) 54-69	53	562	79.2	89.1	98.9				-6.3	12.9
C) 70-180	106	3967				64.6	79.2	98.4	-9.6	13.1
D) 181-250	103	1992				78.6	90.2	99.9	-14.1	9.9
E) > 250	77	1078				86.9	94.4	100.0	-8.0	8.3

* For reference range < 70 mg/dL, agreement was based on 15/20/40 mg/dL. CGM readings are within 50-400 mg/dL, inclusive.
* Includes pediatric subjects 7-17 years of age.

Agreement when CGM reads "Below 50 mg/dL" or "Above 400 mg/dL"

The real-time CGM systems display glucose values between 50 mg/dL and 400 mg/dL. It displays "Below 50 mg/dL" when the SG value detected is below 50 mg/dL. It displays "Above 400 mg/dL" when the SG value detected is above 400 mg/dL. *Table 44* and *Table 45* illustrate the number and percentage of the paired YSI™* values in different blood glucose levels when the CGM system displays "Below 50 mg/dL" (LOW) or "Above 400 mg/dL" (HIGH).

Table 44. The number and percentage of YSI™* values collected when CGM displays "Below 50 mg/dL" (LOW)

				YSI™* (mg/dL)					
CGM Display	Population	Insertion Site	CGM-YSI™* pairs	<55	<60	<70	<80	≥80	Total
LOW	Adult	Arm	Cumulative, n	128	263	445	481	9	490
			Cumulative %	26%	54%	91%	98%	2%	
	Pediatrics	Arm	Cumulative, n	51	87	168	194	6	200
			Cumulative %	26%	44%	84%	97%	3%	

*Includes pediatric subjects 7-17 years of age.

Table 45. The number and percentage of YSI™* values collected when CGM displays "Above 400 mg/dL" (HIGH)

				YSI™* (mg/dL)					
CGM Display	Population	Insertion Site	CGM-YSI™* pairs	>340	>320	>280	>240	≤240	Total
HIGH	Adult	Arm	Cumulative, n	20	21	21	21	0	21
			Cumulative %	95%	100%	100%	100%	0%	
	Pediatrics	Arm	Cumulative, n	32	32	32	32	0	32
			Cumulative %	100%	100%	100%	100%	0%	

*Includes pediatric subjects 7-17 years of age.

Concurrence of SG and YSI™* values

Table 46 and *Table 47* show, for each SG range, the percentage of concurring data points where the paired YSI™* values were in different blood glucose ranges.

Table 46. Overall concurrence of YSI™* values and SG readings using SG ranges; Adults, Arm

Percent of matched pairs in each SMBG glucose range for each SG range (mg/dL)												
SG ranges (mg/dL)	Number of paired SG-YSI™*	YSI™* glucose ranges (mg/dL)										
		<50	≥50–60	>60–80	>80–120	>120–160	>160–200	>200–250	>250–300	>300–350	>350–400	>400
A) <50	490	6.7% (33/490)	47.6% (233/490)	43.9% (215/490)	1.8% (9/490)	0.0% (0/490)	0.0% (0/490)	0.0% (0/490)	0.0% (0/490)	0.0% (0/490)	0.0% (0/490)	0.0% (0/490)
B) ≥50–60	1036	7.0% (73/1036)	38.4% (398/1036)	50.8% (526/1036)	3.5% (36/1036)	0.1% (1/1036)	0.2% (2/1036)	0.0% (0/1036)	0.0% (0/1036)	0.0% (0/1036)	0.0% (0/1036)	0.0% (0/1036)
C) >60–80	2899	0.5% (15/2899)	17.8% (517/2899)	69.7% (2022/2899)	11.6% (335/2899)	0.2% (6/2899)	0.1% (4/2899)	0.0% (0/2899)	0.0% (0/2899)	0.0% (0/2899)	0.0% (0/2899)	0.0% (0/2899)
D) >80–120	4334	0.0% (2/4334)	0.7% (31/4334)	12.7% (552/4334)	63.0% (2730/4334)	22.5% (973/4334)	1.0% (43/4334)	0.1% (3/4334)	0.0% (0/4334)	0.0% (0/4334)	0.0% (0/4334)	0.0% (0/4334)
E) >120–160	5123	0.0% (0/5123)	0.0% (0/5123)	0.1% (6/5123)	11.8% (604/5123)	63.8% (3271/5123)	22.0% (1129/5123)	2.0% (105/5123)	0.2% (8/5123)	0.0% (0/5123)	0.0% (0/5123)	0.0% (0/5123)
F) >160–200	3337	0.0% (0/3337)	0.0% (0/3337)	0.0% (0/3337)	0.3% (10/3337)	13.4% (447/3337)	57.5% (1920/3337)	25.7% (856/3337)	2.8% (95/3337)	0.3% (9/3337)	0.0% (0/3337)	0.0% (0/3337)
G) >200–250	2477	0.0% (0/2477)	0.0% (0/2477)	0.0% (0/2477)	0.0% (0/2477)	0.3% (7/2477)	11.7% (291/2477)	61.1% (1514/2477)	23.8% (589/2477)	3.0% (74/2477)	0.1% (2/2477)	0.0% (0/2477)
H) >250–300	895	0.0% (0/895)	0.0% (0/895)	0.0% (0/895)	0.0% (0/895)	0.0% (0/895)	0.0% (0/895)	13.7% (123/895)	56.3% (504/895)	27.7% (248/895)	2.2% (20/895)	0.0% (0/895)
I) >300–350	390	0.0% (0/390)	0.0% (0/390)	0.0% (0/390)	0.0% (0/390)	0.0% (0/390)	0.0% (0/390)	1.0% (4/390)	25.4% (99/390)	55.4% (216/390)	16.7% (65/390)	1.5% (6/390)
J) >350–400	121	0.0% (0/121)	0.0% (0/121)	0.0% (0/121)	0.0% (0/121)	0.0% (0/121)	0.0% (0/121)	0.0% (0/121)	1.7% (2/121)	36.4% (44/121)	51.2% (62/121)	10.7% (13/121)
K) >400	21	0.0% (0/21)	0.0% (0/21)	0.0% (0/21)	0.0% (0/21)	0.0% (0/21)	0.0% (0/21)	0.0% (0/21)	0.0% (0/21)	4.8% (1/21)	52.4% (11/21)	42.9% (9/21)

Table 47. Overall concurrence of YSI™* values and SG readings using SG ranges; Pediatrics, Arm

Percent of matched pairs in each YSI™* glucose range for each SG range (mg/dL)												
SG Ranges (mg/dL)	Number of paired SG-YSI™*	YSI™* glucose ranges (mg/dL)										
		<50	≥50–60	>60–80	>80–120	>120–160	>160–200	>200–250	>250–300	>300–350	>350–400	>400
A) <50	200	11.5% (23/200)	32.5% (65/200)	53.0% (106/200)	2.5% (5/200)	0.5% (1/200)	0.0% (0/200)	0.0% (0/200)	0.0% (0/200)	0.0% (0/200)	0.0% (0/200)	0.0% (0/200)
B) ≥50–60	346	4.0% (14/346)	26.0% (90/346)	64.2% (222/346)	5.2% (18/346)	0.6% (2/346)	0.0% (0/346)	0.0% (0/346)	0.0% (0/346)	0.0% (0/346)	0.0% (0/346)	0.0% (0/346)
C) >60–80	692	0.7% (5/692)	13.4% (93/692)	61.6% (426/692)	23.6% (163/692)	0.7% (5/692)	0.0% (0/692)	0.0% (0/692)	0.0% (0/692)	0.0% (0/692)	0.0% (0/692)	0.0% (0/692)

Table 47. Overall concurrence of YSI™* values and SG readings using SG ranges; Pediatrics, Arm (continued)

Percent of matched pairs in each YSI™* glucose range for each SG range (mg/dL)												
SG Ranges (mg/dL)	Number of paired SG-YSI™*	YSI™* glucose ranges (mg/dL)										
		<50	≥50–60	>60–80	>80–120	>120–160	>160–200	>200–250	>250–300	>300–350	>350–400	>400
D) >80–120	1348	0.1% (1/1348)	1.2% (16/1348)	12.5% (168/1348)	57.0% (768/1348)	27.8% (375/1348)	1.4% (19/1348)	0.1% (1/1348)	0.0% (0/1348)	0.0% (0/1348)	0.0% (0/1348)	0.0% (0/1348)
E) >120–160	1529	0.0% (0/1529)	0.0% (0/1529)	0.1% (1/1529)	7.5% (114/1529)	58.3% (891/1529)	30.0% (458/1529)	3.4% (52/1529)	0.8% (12/1529)	0.1% (1/1529)	0.0% (0/1529)	0.0% (0/1529)
F) >160–200	1439	0.0% (0/1439)	0.0% (0/1439)	0.0% (0/1439)	0.1% (1/1439)	9.0% (129/1439)	51.4% (739/1439)	35.9% (516/1439)	3.3% (48/1439)	0.3% (5/1439)	0.0% (0/1439)	0.0% (0/1439)
G) >200–250	1270	0.0% (0/1270)	0.0% (0/1270)	0.0% (0/1270)	0.0% (0/1270)	0.2% (3/1270)	9.9% (126/1270)	59.4% (754/1270)	28.7% (364/1270)	1.8% (23/1270)	0.0% (0/1270)	0.0% (0/1270)
H) >250–300	695	0.0% (0/695)	0.0% (0/695)	0.0% (0/695)	0.0% (0/695)	0.0% (0/695)	0.1% (1/695)	13.1% (91/695)	58.6% (407/695)	25.8% (179/695)	2.4% (17/695)	0.0% (0/695)
I) >300–350	296	0.0% (0/296)	0.0% (0/296)	0.0% (0/296)	0.0% (0/296)	0.0% (0/296)	0.0% (0/296)	1.0% (3/296)	18.9% (56/296)	61.1% (181/296)	18.9% (56/296)	0.0% (0/296)
J) >350–400	87	0.0% (0/87)	0.0% (0/87)	0.0% (0/87)	0.0% (0/87)	0.0% (0/87)	0.0% (0/87)	0.0% (0/87)	5.7% (5/87)	24.1% (21/87)	60.9% (53/57)	9.2% (8/87)
K) >400	32	0.0% (0/32)	0.0% (0/32)	0.0% (0/32)	0.0% (0/32)	0.0% (0/32)	0.0% (0/32)	0.0% (0/32)	0.0% (0/32)	0.0% (0/32)	31.3% (10/32)	68.8% (22/32)

* Includes pediatric subjects 7-17 years of age.

Trend accuracy

Table 48. Trend accuracy compared to YSI™* over time; Adults, Arm

	YSI™* (mg/dL/min)						
SG Rate Ranges (mg/dL/min)	No. of Paired SG-YSI™*	<-2	[-2,-1)	[-1, 0)	[0, 1]	(1, 2]	>2
<-2	179	53.6% (96/179)	38.0% (68/179)	7.3% (13/179)	1.1% (2/179)	0.0% (0/179)	0.0% (0/179)
[-2,-1)	1036	5.2% (54/1036)	49.9% (517/1036)	42.3% (438/1036)	2.5% (26/1036)	0.1% (1/1036)	0.0% (0/1036)
[-1, 0)	10059	0.2% (17/10059)	4.0% (401/10059)	79.1% (7958/10059)	16.3% (1640/10059)	0.4% (37/10059)	0.1% (6/10059)
[0, 1]	7342	0.0% (3/7342)	0.5% (38/7342)	22.6% (1656/7342)	69.9% (5129/7342)	6.6% (487/7342)	0.4% (29/7342)
(1, 2]	1513	0.0% (0/1513)	0.3% (5/1513)	2.0% (31/1513)	29.5% (446/1513)	58.6% (886/1513)	9.6% (145/1513)
>2	461	0.0% (0/461)	0.0% (0/461)	0.4% (2/461)	4.3% (20/461)	37.5% (173/461)	57.7% (266/461)

CGM readings are within 50-400 mg/dL, inclusive.

Table 49. Trend accuracy compared to YSI™* over time; Pediatrics, Arm

	YSI™* (mg/dL/min)						
SG Rate Ranges (mg/dL/min)	No. of Paired SG-YSI™*	<-2	[-2,-1)	[-1, 0)	[0, 1]	(1, 2]	>2
<-2	196	50.5% (99/196)	41.3% (81/196)	7.1% (14/196)	1.0% (2/196)	0.0% (0/196)	0.0% (0/196)
[-2,-1)	742	6.2% (46/742)	53.6% (398/742)	36.7% (272/742)	2.7% (20/742)	0.7% (5/742)	0.1% (1/742)
[-1, 0)	3103	0.3% (9/3103)	6.5% (201/3103)	76.2% (2363/3103)	15.8% (490/3103)	1.0% (31/3103)	0.3% (9/3103)

Table 49. Trend accuracy compared to YSI™* over time; Pediatrics, Arm (continued)

SG Rate Ranges (mg/dL/min)	YSI™* (mg/dL/min)						
	No. of Paired SG-YSI™*	<-2	[-2,-1)	[-1, 0)	[0, 1]	(1, 2]	>2
[0, 1]	2450	0.0% (0/2450)	0.9% (23/2450)	21.1% (517/2450)	68.6% (1680/2450)	8.9% (218/2450)	0.4% (11/2450)
(1, 2]	851	0.0% (0/851)	0.1% (1/851)	3.1% (26/851)	32.2% (274/851)	55.9% (476/851)	8.7% (74/851)
>2	354	0.0% (0/354)	0.0% (0/354)	0.3% (1/354)	4.2% (15/354)	28.0% (99/354)	67.5% (239/354)

CGM readings are within 50-400 mg/dL, inclusive.
* Includes pediatric subjects 7-17 years of age.

Accuracy over time

Table 50. Sensor Accuracy Compared to YSI™* Over Time; Adults, Arm

Wear Period	Number of paired SG-YSI™*	Percent of SG within 15/15% of YSI™* (%)	Percent of SG within 20/20% of YSI™* (%)	Percent of SG within 40/40% of YSI™* (%)	Mean Absolute Relative Difference (%)
Beginning	5678	65.8	78.3	98.3	13.9
Early Middle	5504	80.9	91	99.7	10.0
Late Middle	5142	81	91.5	99.7	9.7
End	4288	87.5	94.4	99.7	8.3

CGM readings are within 50-400 mg/dL, inclusive.
* For reference range < 70 mg/dL, agreement was based on 15/20/40 mg/dL.

Table 51. Sensor Accuracy Compared to YSI™* Over Time; Pediatrics, Arm

Wear Period	Number of paired SG-YSI™*	Percent of SG within 15/15% of YSI™* (%)	Percent of SG within 20/20% of YSI™* (%)	Percent of SG within 40/40% of YSI™* (%)	Mean Absolute Relative Difference (%)
Beginning	3127	68.5	84.7	99.5	12.8
Early Middle	2546	74.4	85.5	98.9	11.5
Late Middle	1145	74.8	84.3	99.8	10.9
End	884	81.7	91	99.8	9.1

* Includes pediatric subjects 7-17 years of age. CGM readings are within 50-400 mg/dL, inclusive.
* For reference range < 70 mg/dL, agreement was based on 15/20/40 mg/dL.

Precision

Precision of the System was evaluated by comparing the results from two separate sensors worn in the location on the same subject at the same time.

Table 52. Sensor precision

	Number of paired points	Percent Absolute Relative Difference (PARD)	Coefficient of variation (%CV)
7-17 YO Arm	10386	9.48	6.5
18+ YO Arm	23549	9.08	6.5

Sensor Life

Adults (18-75 Years)

77.8% of sensors worn in the arm functioned more than six days and up to the full seven days of wear (144 to 168 hours). The median functional sensor life for sensors worn in the arm insertion site over the course of the study was 167.9 hours, with a mean functional life of 147.9 hours.

Pediatrics (7-17 Years)

61.7% of sensors worn in the arm functioned more than six days and up to the full seven days of wear (144 to 168 hours). The median functional sensor life for sensors worn in the arm insertion site over the course of the study was 163.7 hours, with a mean functional life of 138.9 hours.

Safety

There were no device-related or procedure-related serious adverse events, or unanticipated adverse device effects after seven days of use.

Alert performance

CGM enables a device to display SG readings, glucose trend arrows, glucose trend graphs, and SG alerts, for example, High and Low Sensor Glucose alerts, High and Low Predicted alerts, and Rise and Fall alerts for rate-of-change.

The high and low SG alerts (**Threshold alerts**) let the user know when the SG is at or above the high limit or at or below the low limit. Using only a high or low Threshold alert may reduce the number of false alerts, but does not provide a warning before reaching a high or low limit. The default alert thresholds are highlighted in gray below.

Predictive alerts notify users that their SG level may soon reach a high or low limit setting. Users may select how early they would like to be notified before their SG level reaches a high or low limit. The earliest warning is 60 minutes before reaching a high or low limit, but users can reduce the amount of warning down to 10 minutes. Users receive a Predictive alert when their SG level is predicted to reach their high or low limit in the Time Before High or Time Before Low setting they select. In general, the earlier the warning, the more time a user has to react to a potential high or low, but this also increases the potential for false alerts.

A predictive alert is simply an estimation of a future SG level compared to the high or low limit setting. If the predicted future SG value is above the high limit or below the low

limit, then a predictive alert is sounded even though the current SG level has not crossed the high or low limit. The predicted SG level is calculated using the current SG level, the derivative of current and previous SG readings (the trend or slope of the SG readings) and the Time Before High or Time Before Low duration the user selects.

The device always alerts the user with a Low SG alarm when the CGM reads that the user is at or below 64 mg/dL, regardless of the high/low threshold and/or predictive alerts that the user sets.

Glucose TRUE Alert Rate

The glucose true alert rate is the rate at which the blood glucose (BG) confirmed that the CGM alert was triggered correctly. For example:

- **True Threshold Hypoglycemic alert rate** is a measure of how often the CGM read that the user was at or below the low threshold and the user's BG was actually at or below that low threshold.
- **True Threshold Hyperglycemic alert rate** is a measure of how often the CGM read that the user was at or above the high threshold and the user's BG was actually at or above that high threshold.
- **True Predictive Hypoglycemic alert rate** is a measure of how often the CGM predicted that the user would reach or go below the low threshold and the user's BG was actually at or below that low threshold within 15 or 30 minutes.
- **True Predictive Hyperglycemic alert rate** is a measure of how often the CGM predicted that the user would reach or go above the high threshold and the user's BG was actually at or above that high threshold within 15 or 30 minutes.

The true alert rate is important because it is necessary that users be notified when their blood glucose is low (or high) so that they can correct the low (or high) blood glucose. A high true alert rate indicates that when the CGM says that their glucose values are, or will reach a specified threshold, the user's blood glucose is likely to be at or approaching that threshold.

For example, per the following table, the low glucose alerts would have correctly indicated that the user was below (i.e. threshold only), or predicted to reach below the threshold (i.e. predictive only) or both (predictive and threshold) 85.9%, 64.1%, or 72.4%

of the time within 30 minutes (or 85.9%, 60.3% or 70.1% of the time within 15 minutes) when the user had BG values lower than 70 mg/dL for a sensor inserted in the arm.

Table 53. Glucose TRUE Alert Performance, Adults

Glucose TRUE Alert Rate							
mg/dL	Insertion Site	Threshold Only		Predictive Only		Threshold and Predictive	
		30 min	15 min	30 min	15 min	30 min	15 min
50	Arm	27.3%	25.8%	28.3%	19.9%	28.0%	21.6%
60*	Arm	73.3%	71.9%	57.4%	53.0%	63.2%	59.9%
64	Arm	83.0%	82.4%	-	-	-	-
70	Arm	85.9%	85.9%	64.1%	60.3%	72.4%	70.1%
80	Arm	81.9%	80.8%	62.2%	58.9%	70.0%	67.6%
90	Arm	77.7%	77.4%	59.8%	57.0%	66.9%	65.1%
180	Arm	87.6%	87.2%	66.4%	64.0%	74.3%	72.7%
220	Arm	86.8%	86.8%	64.2%	62.1%	72.2%	70.9%
250	Arm	87.9%	87.0%	67.3%	62.0%	74.5%	70.8%
300	Arm	88.9%	88.9%	69.5%	65.5%	76.1%	73.5%

*The default alert threshold is highlighted in gray.

Table 54. Glucose TRUE Alert Performance, Pediatrics (7-17 Years of Age)

Glucose TRUE Alert Rate							
mg/dL	Insertion Site	Threshold Only		Predictive Only		Threshold and Predictive	
		30 min	15 min	30 min	15 min	30 min	15 min
50	Arm	23.8%	23.8%	13.3%	9.2%	16.4%	13.6%
60*	Arm	52.8%	52.8%	34.3%	32.9%	40.6%	39.6%
64	Arm	59.2%	59.2%	-	-	-	-
70	Arm	63.0%	63.0%	44.6%	40.8%	51.1%	48.6%
80	Arm	69.1%	69.1%	50.0%	44.5%	57.1%	53.6%
90	Arm	74.4%	72.2%	56.3%	51.7%	63.6%	60.0%
180	Arm	92.2%	92.2%	82.7%	78.3%	86.8%	84.3%
220	Arm	91.3%	90.2%	77.3%	74.0%	83.0%	80.5%
250	Arm	88.4%	88.4%	70.7%	68.4%	77.4%	75.9%
300	Arm	85.2%	85.2%	60.5%	59.9%	68.9%	68.5%

* The default alert threshold is highlighted in gray.

* Includes pediatric subjects 7-17 years of age.

Glucose FALSE Alert Rate

The glucose false alert rate is the rate at which the BG did not confirm that the CGM alert was triggered correctly. For example:

- **False Threshold Hypoglycemic alert rate** is a measure of how often the CGM read that the user was at or below the low threshold, but the user's BG was actually above that low threshold.

- **False Threshold Hyperglycemic alert rate** is a measure of how often the CGM read that the user was at or above the high threshold, but the user's BG was actually below that high threshold.
- **False Predictive Hypoglycemic alert rate** is a measure of how often the CGM predicted that the user would be at or below the low threshold, but the user's BG was actually above that low threshold within 15 or 30 minutes.
- **False Predictive Hyperglycemic alert rate** is a measure of how often the CGM predicted that the user would be at or above the high threshold, but the user's BG was actually below the high threshold within 15 or 30 minutes.

The false alert rate is important because it is necessary that users be correctly notified when their glucose is low or high so that they can correct the low or high glucose. A low false alert rate indicates that when the CGM says that their glucose values are, or will reach a specified threshold, the user's glucose is likely to be at or approaching that threshold.

For example, per the following table, the high glucose threshold alerts would have incorrectly indicated that the user was above (i.e. threshold only), or predicted to reach above the threshold (i.e. predictive only), or both (threshold and predictive) for adult 12.4%, 33.6% or 25.7% of the time within 30 minutes (or 12.8%, 36.0%, or 27.3% of the time within 15 minutes) when the user had BG less than 180 mg/dL for a sensor inserted in the arm.

Table 55. Glucose FALSE Alert Performance, Adults

Glucose FALSE Alert Rate							
mg/dL	Insertion Site	Threshold Only		Predictive Only		Threshold and Predictive	
		30 min	15 min	30 min	15 min	30 min	15 min
50	Arm	72.7%	74.2%	71.7%	80.1%	72.0%	78.4%
60*	Arm	26.7%	28.1%	42.6%	47.0%	36.8%	40.1%
64	Arm	17.0%	17.6%	-	-	-	-
70	Arm	14.1%	14.1%	35.9%	39.7%	27.6%	29.9%
80	Arm	18.1%	19.2%	37.8%	41.1%	30.0%	32.4%
90	Arm	22.3%	22.6%	40.2%	43.0%	33.1%	34.9%
180	Arm	12.4%	12.8%	33.6%	36.0%	25.7%	27.3%
220	Arm	13.2%	13.2%	35.8%	37.9%	27.8%	29.1%
250	Arm	12.1%	13.0%	32.7%	38.0%	25.5%	29.2%
300	Arm	11.1%	11.1%	30.5%	34.5%	23.9%	26.5%

*The default alert threshold is highlighted in gray.

Table 56. Glucose FALSE Alert Performance, Pediatrics (7-17 Years of Age)

Glucose FALSE Alert Rate							
mg/dL	Insertion Site	Threshold Only		Predictive Only		Threshold and Predictive	
		30 min	15 min	30 min	15 min	30 min	15 min
50	Arm	76.2%	76.2%	86.7%	90.8%	83.6%	86.4%
60*	Arm	47.2%	47.2%	65.7%	67.1%	59.4%	60.4%
64	Arm	40.8%	40.8%	-	-	-	-
70	Arm	37.0%	37.0%	55.4%	59.2%	48.9%	51.4%
80	Arm	30.9%	30.9%	50.0%	55.5%	42.9%	46.4%
90	Arm	25.6%	27.8%	43.7%	48.3%	36.4%	40.0%
180	Arm	7.8%	7.8%	17.3%	21.7%	13.2%	15.7%
220	Arm	8.7%	9.8%	22.7%	26.0%	17.0%	19.5%
250	Arm	11.6%	11.6%	29.3%	31.6%	22.6%	24.1%
300	Arm	14.8%	14.8%	39.5%	40.1%	31.1%	31.5%

* The default alert threshold is highlighted in gray.

* Includes pediatric subjects 7-17 years of age.

Glucose Correct Detection Rate

Glucose Correct Detection Rate is the rate that the device alerted when it should have alerted. For example, the BG was at or below the hypoglycemic threshold, or at or above the hyperglycemic threshold, and the device sounded a threshold or predictive alert.

The correct detection rates are important because it is necessary that users be notified when their glucose is low or high so that they can correct the low or high glucose. A high glucose correct detection rate indicates that users can have confidence that they will be notified by the device if their glucose is low or high.

For example, per the following table, the threshold alert, the predictive alert, or both (threshold and predictive) for adults notified the user 83.0%, 94.2% or 94.4% of the time within 30 minutes (or 81.8%, 90.4% or 91.3% within 15 minutes) when the user had BG less than 180 mg/dL in a sensor inserted in the arm.

Table 57. Glucose CORRECT DETECTION Alert Performance, Adults

Glucose CORRECT DETECTION Alert Rate							
mg/dL	Insertion Site	Threshold Only		Predictive Only		Threshold and Predictive	
		30 min	15 min	30 min	15 min	30 min	15 min
50	Arm	37.5%	35.4%	89.6%	72.9%	89.6%	79.2%
60*	Arm	65.1%	64.0%	86.0%	83.7%	86.6%	84.3%
64	Arm	75.5%	75.0%	-	-	-	-
70	Arm	87.3%	86.8%	94.8%	93.4%	95.3%	94.3%
80	Arm	84.2%	83.1%	91.4%	86.8%	91.4%	88.7%
90	Arm	87.3%	86.3%	93.3%	90.2%	93.7%	91.7%
180	Arm	83.0%	81.8%	94.2%	90.4%	94.4%	91.3%
220	Arm	79.4%	78.3%	92.4%	90.6%	92.7%	90.9%

Table 57. Glucose CORRECT DETECTION Alert Performance, Adults (continued)

Glucose CORRECT DETECTION Alert Rate							
		Threshold Only		Predictive Only		Threshold and Predictive	
mg/dL	Insertion Site	30 min	15 min	30 min	15 min	30 min	15 min
250	Arm	72.5%	71.1%	88.3%	85.3%	88.3%	86.1%
300	Arm	62.3%	60.1%	83.3%	80.4%	83.3%	80.4%

*The default alert threshold is highlighted in gray.

Table 58. Glucose CORRECT DETECTION Alert Performance, Pediatrics (7-17 Years of Age)

Glucose CORRECT DETECTION Rate							
mg/dL	Insertion Site	Threshold Only		Predictive Only		Threshold and Predictive	
		30 min	15 min	30 min	15 min	30 min	15 min
50	Arm	66.7%	66.7%	86.7%	60.0%	86.7%	73.3%
60*	Arm	64.6%	64.6%	80.0%	75.4%	80.0%	76.9%
64	Arm	74.6%	74.6%	-	-	-	-
70	Arm	83.3%	81.0%	92.9%	86.9%	92.9%	91.7%
80	Arm	86.6%	85.7%	97.3%	89.3%	97.3%	92.9%
90	Arm	89.9%	87.9%	97.3%	89.9%	98.0%	93.3%
180	Arm	90.3%	89.0%	96.2%	91.3%	96.9%	94.1%
220	Arm	88.0%	84.9%	95.9%	92.1%	96.2%	94.5%
250	Arm	77.1%	74.8%	91.6%	85.0%	91.6%	87.4%
300	Arm	72.2%	72.2%	93.8%	88.7%	93.8%	89.7%

* The default alert threshold is highlighted in gray.

* Includes pediatric subjects 7-17 years of age.

Glucose Missed Detection Rate

The Missed Detection Rate is the rate that the device did not alert when it should have. For example, the BG was at or below the hypoglycemic threshold, or at or above the hyperglycemic threshold, and the device did not sound a threshold or predictive alert.

Missed detection rates are important because it is necessary that users be notified when their glucose is low or high, so that they can correct the low or high glucose. A low missed detection rate indicates that users can have confidence that they will be notified by the device if their glucose is low or high.

For example, per the following table, the threshold alert, predictive alert, or both alerts (threshold and predictive) for adults did not sound 12.7%, 5.2% or 4.7% of the time within 30 minutes (or 13.2%, 6.6% or 5.7% within 15 minutes) when the user had BG less than 70 mg/dL in a sensor inserted in the arm.

Table 59. Glucose MISSED Detection Performance, Adults

Glucose Missed Detection Rate							
mg/dL	Insertion Site	Threshold Only		Predictive Only		Threshold and Predictive	
		30 min	15 min	30 min	15 min	30 min	15 min
50	Arm	62.5%	64.6%	10.4%	27.1%	10.4%	20.8%
60*	Arm	34.9%	36.0%	14.0%	16.3%	13.4%	15.7%
64	Arm	24.5%	25.0%	-	-	-	-
70	Arm	12.7%	13.2%	5.2%	6.6%	4.7%	5.7%
80	Arm	15.8%	16.9%	8.6%	13.2%	8.6%	11.3%
90	Arm	12.7%	13.7%	6.7%	9.8%	6.3%	8.3%
180	Arm	17.0%	18.2%	5.8%	9.6%	5.6%	8.7%
220	Arm	20.6%	21.7%	7.6%	9.4%	7.3%	9.1%
250	Arm	27.5%	28.9%	11.7%	14.7%	11.7%	13.9%
300	Arm	37.7%	39.9%	16.7%	19.6%	16.7%	19.6%

*The default alert threshold is highlighted in gray.

Table 60. Glucose MISSED Detection Performance, Pediatrics (7-17 Years of Age)

Glucose MISSED Detection Rate							
mg/dL	Insertion Site	Threshold Only		Predictive Only		Threshold and Predictive	
		30 min	15 min	30 min	15 min	30 min	15 min
50	Arm	33.3%	33.3%	13.3%	40.0%	13.3%	26.7%
60*	Arm	35.4%	35.4%	20.0%	24.6%	20.0%	23.1%
64	Arm	25.4%	25.4%	-	-	-	-
70	Arm	16.7%	19.0%	7.1%	13.1%	7.1%	8.3%
80	Arm	13.4%	14.3%	2.7%	10.7%	2.7%	7.1%
90	Arm	10.1%	12.1%	2.7%	10.1%	2.0%	6.7%
180	Arm	9.7%	11.0%	3.8%	8.7%	3.1%	5.9%
220	Arm	12.0%	15.1%	4.1%	7.9%	3.8%	5.5%
250	Arm	22.9%	25.2%	8.4%	15.0%	8.4%	12.6%
300	Arm	27.8%	27.8%	6.2%	11.3%	6.2%	10.3%

* The default alert threshold is highlighted in gray.

* Includes pediatric subjects 7-17 years of age.

Glossary

Glossary

active insulin	Bolus insulin delivered by the insulin pump that continues to lower blood glucose (BG) levels. Active insulin is not necessarily reflective of the pharmacokinetics and pharmacodynamics of compatible insulins.
active insulin time	Length of time that bolus insulin is tracked as active insulin.
alert	An audible beep or vibration with a message to inform of a situation that may require attention.
alert before low	An alert that occurs when the low SG value is being approached.
alert history	A feature that displays a list of recent alerts.
alert limits	The settings that determine when low and high SG alerts are triggered.
alert on low	An alert that occurs when the SG value reaches or falls below the low limit.
applied part	Applied parts make physical contact with the user to perform their function. Applied parts adhering to the BF classification provide a high degree of protection against electric shock.
auto basal	The automatically adjusted basal insulin delivered in Model 6 mode based on the current sensor glucose (SG) values.
Auto correction	A correction bolus automatically delivered by the MiniMed 780G system to maximize time in range. Auto correction only occurs when using the Model 6 mode.
basal insulin	Insulin that is delivered by the insulin pump to meet insulin needs between meals and during sleep.
basal pattern	A set of one or more basal rates that covers a 24-hour period.
basal rate	The setting for the amount of continuous basal insulin to be delivered per hour.

BG	The acronym for blood glucose. For more information, see **blood glucose (BG)**.
BG target	The high and low blood glucose (BG) readings used for BG correction when using the Bolus calculator in Manual mode.
blood glucose (BG)	Glucose that is present in the blood, commonly measured by a blood glucose (BG) meter.
blood glucose (BG) meter	A device that measures glucose levels in the blood.
Bluetooth radio	A wireless technology standard by which the pump communicates with your paired mobile device and the CGM sensor.
Bolus calculator	The Bolus calculator is used to calculate a bolus amount in Manual mode and Model 6 mode, using your glucose value and the entered carbs, if necessary. Bolus calculator settings include Carb ratio, Insulin sensitivity factor, BG target, and Active insulin time.
Bolus increment	The Bolus increment setting determines the precision of bolus calculation or a manual bolus entry.
bolus insulin	Insulin used to cover an expected rise in blood glucose (BG) levels due to carbohydrates, or to lower a high blood glucose (BG) reading down to the BG target range.
cannula	Short, thin, and flexible tube placed in the tissue below the skin. Insulin is delivered through the cannula into the body.
carb bolus	A dose of insulin given to cover an expected rise in glucose levels from carbohydrates.
carb ratio	The number of grams of carbohydrates covered by one unit of insulin. The carb ratio is used to calculate bolus amounts.
CGM	The acronym for continuous glucose monitoring. For more information, see **continuous glucose monitoring (CGM)**.
continuous glucose monitoring (CGM)	A monitoring tool that uses a glucose sensor placed below the skin to continuously measure the amount of glucose in the interstitial fluid.

correction bolus	Insulin used to lower a high blood glucose (BG) reading or sensor glucose (SG) value down to a target value.
CT scan	The acronym for computed tomography scan.
daily history	Details of the events entered or actions performed using the insulin pump.
delivery limit	Your delivery limit is based on the Max bolus and Max basal settings.
diabetic ketoacidosis	A serious condition that occurs when insulin levels are low, blood glucose (BG) levels are elevated, and the body uses fat for energy. This process produces ketones, which upset the acid-base balance in the body, leading to a potentially life-threatening situation.
Dual Wave bolus	A type of bolus that provides a dose of insulin delivered as a combination of a normal bolus followed by a Square Wave bolus.
EMC	The acronym for electromagnetic compatibility.
ESD	The acronym for electrostatic discharge.
Extended bolus	Bolus delivery can be extended over time, using Dual Wave and Square bolus types.
fall alert	An alert that occurs if the sensor glucose (SG) value is falling rapidly.
FCC	The acronym for the Federal Communications Commission.
FDA	The acronym for the Food and Drug Administration.
GPS	The acronym for global positioning system.
Guardian 4 MiniMed 780G Simulator app	An app which simulates the functions of the Guardian 4 MiniMed 780G app. The Simulator app is for demonstration purposes only, and does not connect to the pump.
high limit	The setting the insulin pump uses to determine when to alert for a high sensor glucose (SG) condition.

infusion set	Tubing that connects to the reservoir on one end, and has a needle or cannula on the other end, that is inserted into the body. Insulin travels from the insulin pump through the infusion set into the body.
Infusion set change reminder	A user-defined reminder to change the infusion set.
infusion site	The location on the body where the infusion set is inserted.
insulin sensitivity factor	The amount that blood glucose (BG) is reduced by one unit of insulin. The insulin sensitivity factor is used to calculate correction bolus amounts.
interstitial fluid	The fluid that surrounds the cells in the body.
IV	The acronym for intravenous.
low limit	The setting the insulin pump uses to determine when to alert for a low sensor glucose (SG) condition.
Manual bolus	A feature to manually enter and deliver a dose of insulin.
Manual mode	Manual mode refers to system functions that are used when the Model 6 mode is not active.
Max basal rate	The maximum amount of basal insulin that can be delivered per hour.
Max bolus	The maximum bolus amount that can be programmed by the user in one dose.
meter	A term for any blood glucose meter.
MiniMed 780G system software	MiniMed 780G system software is a diabetes therapy management software for healthcare professionals and people living with diabetes. This software uses data from insulin pumps and sensors to show trends and patterns, and give insights about glycemic control.

mobile device	Your compatible device (such as a cell phone) where you install the Guardian 4 MiniMed 780G app. Your mobile device connects to the pump through Bluetooth® wireless connection.
Model 6 mode	An insulin delivery feature that automatically controls insulin delivery to regulate blood glucose (BG) levels to a target sensor glucose (SG) value.
Model 6 target	Model 6 target is the setting to maximize time in range.
MRI	The acronym for magnetic resonance imaging.
normal bolus	A type of bolus that provides an entire dose of insulin immediately.
notifications	All notifications are designed to get attention and convey different types of information. They include alarms, alerts, reminders, and messages.
occlusion	A blockage or crimp of the cannula or tubing that prevents proper insulin flow.
piston	The part of the insulin pump that engages the reservoir and moves insulin through the tubing.
reminder	A type of notification to help remember an action.
reservoir	The small container that is filled with insulin and inserted into the insulin pump.
rewind	A feature that returns the piston to its start position to place a new reservoir into the insulin pump.
RF	The acronym for radio frequency.
rise alert	An alert that occurs if the sensor glucose (SG) value is rising rapidly.
sensitivity	For more information, see **insulin sensitivity factor**.
sensor (glucose sensor)	The small part of the CGM system that is inserted just below the skin to measure glucose levels in the interstitial fluid.

sensor glucose (SG)	Glucose that is present in the interstitial fluid and is measured by a glucose sensor.
SG	The acronym for sensor glucose. For more information, see **sensor glucose (SG)**.
SN	The acronym for serial number.
Square Wave bolus	A bolus delivered evenly over the specified time period.
suspend	Suspend settings are used to stop insulin delivery due to low glucose values. Suspend settings include Suspend limit, Suspend before low, and Suspend on low.
Suspend all delivery	A feature that stops all insulin delivery until it is resumed. Only the basal insulin restarts when delivery is resumed.
Suspend before low	A feature that suspends insulin delivery when the sensor predicts the sensor glucose (SG) value is approaching the Suspend limit.
Suspend limit	The Suspend limit setting is a user-defined glucose setting used when automatically suspending insulin delivery.
Suspend on low	A feature that suspends insulin delivery when the sensor glucose (SG) value reaches or falls below the Suspend limit.
TDD	The acronym for Total daily dose.
temp basal (temporary basal)	A feature that temporarily increases or decreases the current basal rate for the specified duration of time.
Temp target	Temp target is used when in Model 6 mode for times when less insulin is needed (such as during exercise).
transfer guard	The plastic piece that comes attached to the reservoir. It is used to connect the reservoir to the insulin vial while the reservoir fills with insulin.

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