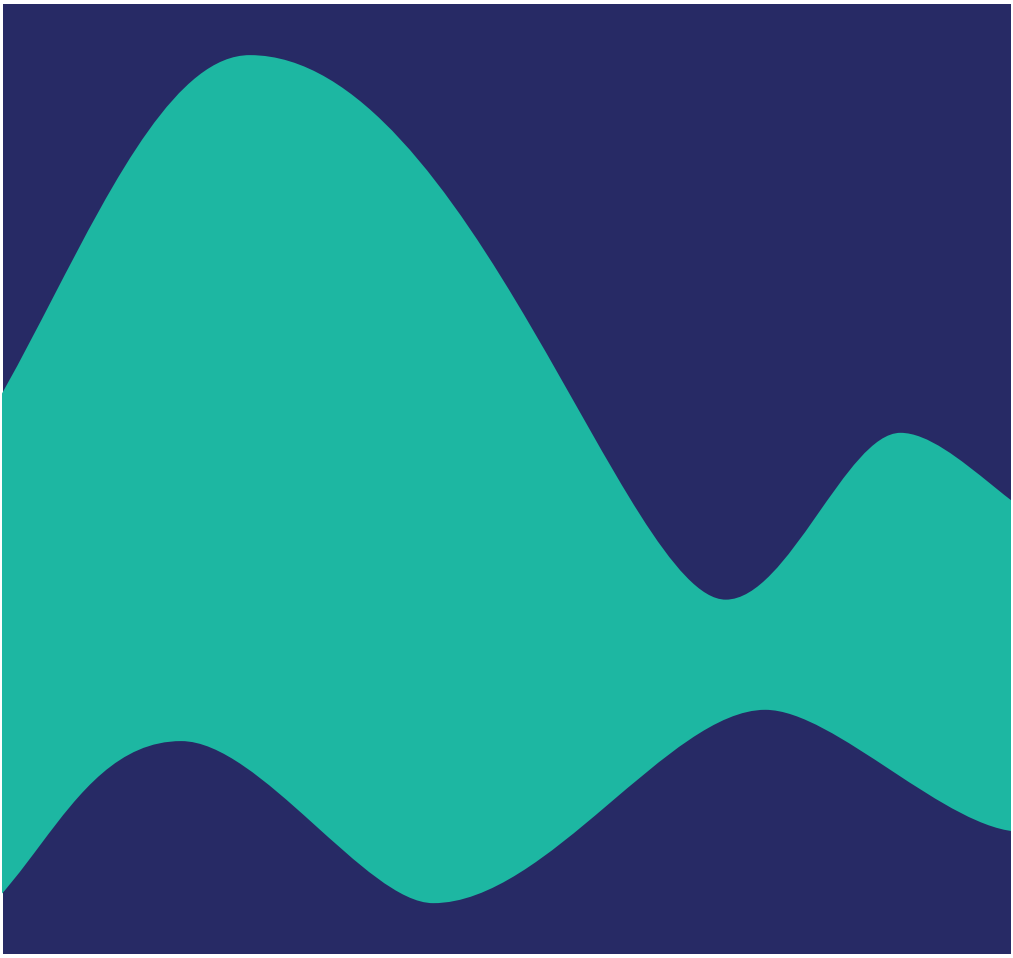
minimed

MiniMed Go

System Techincal Guide



Contents

MiniMed Go system technical guide

Introduction

This system technical guide describes the technical aspects of the MiniMed Go™ system. A mobile device with the MiniMed Go app is connected to the InPen smart insulin pen and a sensor.

Details about Intended use, Indications for use, contraindications, Intended clinical benefits, user safety warnings, and instructions about setting up the MiniMed Go app, refer to the MiniMed Go app user guide.

Accessing user guides online

All user guides related to the MiniMed Go system are available online or through the app. You can view or order printed copies by going to this website: https://manuals.Medtronic.com/manuals. The following user guides are available on the website:

- MiniMed Go app user guide
- MiniMed Go system technical guide
- Simplera sensor user guide
- InPen smart insulin pen user guide

MiniMed Go app

System quality of service

The MiniMed Go system can use either Wi-Fi or cellular data to send data to the CareLink Connect app for remote monitoring, and to upload history to the CareLink Personal website. The system will use Wi-Fi to transmit data when a Wi-Fi connection is available, and cellular data if Wi-Fi is not available. Although all data sent by the system is encrypted, a secured Wi-Fi network is recommended.

A sensor connects to a compatible mobile device via a Bluetooth low energy technology network. The sensor sends glucose data and system-related alerts to the compatible mobile device, which verifies the integrity of received data after wireless transmission. The quality of the connection is in accordance with the Bluetooth Specification v4.2.

Data security

Sensors are designed to only accept radio frequency (RF) communications from a recognized and linked compatible mobile device. The sensor must be paired with the mobile device before the mobile device accepts information from the sensor.

The compatible mobile device ensures data security via proprietary means and data integrity using error checking processes, such as cyclic redundancy checks.

The MiniMed Go app has been designed with security features to help keep its data secure. However, there are important recommended steps to take to ensure the compatible mobile device used with the app is also secure:

- Do not leave the compatible mobile device unattended.
- Use caution when viewing or sharing data with others.
- Enable a security lock on the compatible mobile device. When the compatible mobile device is not in use, lock it in a way that requires the password to be entered in order to use it.
- Do not remove or interfere with the security features on the compatible mobile device.
- Do not attempt to modify the operating system, jailbreak, or root the device.

- Use only the official application store, such as the Apple App Store or the Google Play store to get all mobile applications used with the compatible mobile device.
- Do not click on links from email messages, web pages, or text messages received from an unknown or untrusted source.
- Avoid the use of unknown Wi-Fi networks or public Wi-Fi hotspots.
- Enable security protection on a home Wi-Fi network, such as the use of a password and encryption.

The app may send anonymous analytic data to Medtronic if permission has been granted in the setup of the app. This data is used to analyze crash logs and app performance. This access can be revoked or reinstated at any time in the CareLink screen of the app.

Open Source Software (OSS) disclosure

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

Such Open Source Software is licensed to users subject to the terms and conditions of the separate software license agreement for such Open Source Software.

Use of the Open Source Software by you shall be governed entirely by the terms and conditions of such license.

The source/object code and applicable license for the Open Source Software can be obtained at the following site: www.medtronicdiabetes.com/ossnotices.

Guidance and manufacturer's declaration

Guidance and Manufacturer's Declaration - Electromagnetic Emissions		
Emissions Test	**Compliance**	**Electromagnetic Environment - Guidance**
RF emissions CISPR 11	CISPR 11 Group 1, Class B	The transmitter uses RF energy only for system communications. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
Immunity Test	**IEC 60601-1-2 Test Level**	**IEC 60601-1-2 Compliance Level**	**Electromagnetic Environment Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	For use in a typical domestic, commercial, or hospital environment.
Power frequency magnetic field IEC 61000-4-8	30 A/m	30 A/m	For use in a typical domestic, commercial, or hospital environment.
Proximity magnetic fields IEC 61000-4-39, Table 11	IEC 60601-1-2, Table 11	IEC 60601-1-2, Table 11	For use in a typical domestic, commercial, or hospital environment.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
Immunity Test	**IEC 60601-1-2 Test Level**	**IEC 60601-1-2 Compliance Level**	**Electromagnetic Environment Guidance**
Proximity fields from RF wireless communications equipment	IEC 60601-1-2, Table 9	IEC 60601-1-2, Table 9	For use in a typical domestic, commercial, or hospital environment. Portable and mobile RF communications equipment should be used no closer to any part of the transmitter 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: 
Radiated RF electromagnetic fields IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz	10 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz	
Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption, and reflection from structures, objects and people.			

Dose calculator algorithm

There are four different formulas the dose calculator feature uses to estimate a bolus, depending on your current BG, and time since your last dose.

Glucose	**< 2 hours from last dose**	**≥ 2 hours from last dose**
Glucose > 180 mg/dL	Formula 1	Formula 1
Target glucose ≤ glucose ≤ 180 mg/dL	Formula 1	Formula 3
55 mg/dL < glucose < target glucose	Formula 2	Formula 3
No glucose entered	Formula 4	

1. If your current glucose is above 180 mg/dL, or between target glucose and 180 mg/dL within 2 hours of your last dose, the dose calculator feature subtracts active insulin from the correction estimate, then adds this to the food estimate to get the total bolus estimate. However, if the result of subtracting active insulin from correction estimate is a negative number (less than zero), the total bolus estimate is based only on the food estimate.

$$\text{TBE} = \underbrace{\frac{\text{C}}{\text{CR}}}_{\text{(food estimate)}} + \underbrace{\frac{\text{CG} - \text{TG}}{\text{ISF}}}_{\text{(correction estimate)}} - \text{AI}$$

Where:

TBE = Total Bolus Estimate

C = Carbs

CR = Carb Ratio

CG = Current Glucose

TG = Target Glucose

ISF = Insulin Sensitivity Factor

AI = Active Insulin

2. If your current glucose is less than your target glucose, and it has been less than 2 hours since your last dose, the food estimate is reduced by the correction estimate to get the total bolus estimate.

$$\text{TBE} = \underbrace{\frac{\text{C}}{\text{CR}}}_{\text{(food estimate)}} + \underbrace{\frac{\text{CG} - \text{TG}}{\text{ISF}}}_{\text{(correction estimate)}}$$

Note: When the current glucose is below the target glucose, and it has been less than 2 hours since your last dose, active insulin is not considered in the total bolus estimate.

Where:

TBE = Total Bolus Estimate

C = Carbs

CR = Carb Ratio

CG = Current Glucose

TG = Target Glucose

ISF = Insulin Sensitivity Factor

3. If it has been more than 2 hours since your last dose and your current glucose is > 55 mg/dL and ≤ 180 mg/dL, the dose calculator feature adds the correction estimate and subtracts active insulin from the food estimate to get the total bolus estimate. Note if glucose is below target glucose, the food estimate will be reduced by the correction estimate and active insulin.

$$\text{TBE} = \underbrace{\frac{\text{C}}{\text{CR}}}_{\text{(food estimate)}} + \underbrace{\frac{\text{CG} - \text{TG}}{\text{ISF}}}_{\text{(correction estimate)}} - \text{AI}$$

Where:
TBE = Total Bolus Estimate
C = Carbs
CR = Carb Ratio
CG = Current Glucose
TG = Target Glucose
ISF = Insulin Sensitivity Factor
AI = Active Insulin

4. If you do not enter a glucose, the total bolus estimate is based only on the food estimate.

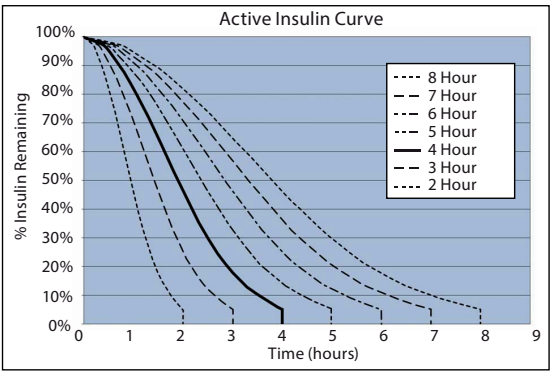
$$\text{TBE} = \underbrace{\frac{\text{C}}{\text{CR}}}_{\text{(food estimate)}}$$

Where:
TBE = Total Bolus Estimate
C = Carbs
CR = Carb Ratio

Following are some notes about the dose calculator:

- Total bolus estimates are rounded down to the nearest 0.5U.
- If glucose is ≤ 55 mg/dL, the dose calculator will recommend eating fast acting carbohydrates to raise glucose.
- If the total bolus estimate is negative and the calculator is in carb counting mode, the calculator will recommend eating X grams of carbohydrates as calculated by **carbs = –(total bolus estimate) * ICR.**
- The following Active Insulin Curve represents how long a bolus of insulin lowers your glucose after the bolus is given. The percentage of insulin remaining lowers at varying rates depending on how long the insulin is active in your body.[1]

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



Simplera sensor

Note: The patient should review the information in this section with a healthcare professional to understand the performance of the MiniMed Go system.

Exposure to magnetic fields and radiation

Do not expose the Simplera sensor to Magnetic Resonance Imaging (MRI) equipment, diathermy devices, or other devices that generate strong magnetic fields (for example, CT scan, or other types of radiation). Exposure to strong magnetic fields can cause the sensor to malfunction, result in serious injury, or be unsafe.

IEC 60601-1-2: 4th Edition; Special EMC Precautions for Medical Electrical Equipment

- 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, InPen, Simplera 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.
- Portable and mobile RF communications equipment can affect medical electrical equipment. If you encounter RF interference from a mobile or stationary RF transmitter, move away from the RF transmitter that is causing the interference.
- Be careful when using the Simplera sensor closer than 12 in (30 cm) to portable radio frequency (RF) equipment or electrical equipment. If the sensor must be used next to portable RF equipment or electrical equipment, observe the sensor to verify correct system operation. Degradation of the performance of the sensor could result.

Clinical study overview

The performance of the Simplera system was evaluated using data collected during a multi-center prospective clinical study. The study enrolled a total of 123 subjects ages 18-80 years previously diagnosed with type 1 or 2 diabetes, and 118 of these subjects completed the study. Subjects ages 18-80 years were instructed to wear a total of two sensors, in the arm. 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 value[2].

Frequent sample testing (FST) was performed on four occasions for subjects 18 and older.

During FST, reference blood (plasma) glucose values were obtained with a Yellow Springs Instrument (YSI™*) Glucose Analyzer every 5-15 minutes for subjects 18 and older. During each FST, subjects 18 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 system sensor algorithm to convert the raw sensor information to sensor glucose values every five minutes. For the accuracy information presented in the following section, 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 ages 18 and older.

Table 1. 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 % (95% lower bound)	Mean Absolute Relative Difference (%)
Adults (18+)	Arm	116	15405	90.7 (90.3)	10.2

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

**For 20% agreement, 20 mg/dL used when YSI <70 mg/dL.

In *Table 2*, 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 2. 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 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

For reference range < 70 mg/dL, agreement was based on 15/20/40 mg/dL.

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

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 3* and *Table 4* 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).

[2] https://clinicaltrials.gov/study/NCT04436822. Evaluation of Updated Continuous Monitoring (CGM) Form Factor in adults, Adolescents and Pediatrics. Updated June 2, 2023. Accessed August 16, 2024.

Table 3. 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	67	119	169	197	10	207
			Cumulative %	32%	57%	82%	95%	5%	

Table 4. 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	14	14	14	14	0	14
			Cumulative %	100%	100%	100%	100%	0%	

Concurrence of SG and YSI values

Table 5 shows, for each SG range, the percentage of concurring data points where the paired YSI values were in different blood glucose ranges.

Table 5. 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)

Trend Accuracy

Table 6. Trend accuracy compared to YSI over time; Adults, Arm

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**
< -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.

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 7. 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	9.6

For reference range < 70 mg/dL, agreement was based on 15/20/40 mg/dL.

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

Reading capture rate

Table 8. 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.		

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.

	Number of paired points	Percent Absolute Relative Difference (PARD)	Coefficient of variation (%CV)
18+ YO Arm	36459	9	6.2

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.

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 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 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 BG is low or high so that they can correct the low or high BG. 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 BG 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 (predictive and threshold) 81.0%, 42.5%, or 53.3% of the time within 30 minutes (or 80.4%, 41.0% or 52.0% 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 arm.

Table 9. Glucose True Alert Rate, Adults

Glucose True Alert Rate							
		Threshold Only		Predictive Only		Threshold & Predictive	
Glucose (mg/dL)	Insertion Site	30 min	15 min	30 min	15 min	30 min	15 min
63	Arm	73.7%	72.9%	40.2%	36.0%	48.6%	45.2%
65	Arm	75.4%	75.4%	43.4%	39.6%	52.0%	49.2%
70	Arm	81.0%	80.4%	42.5%	41.0%	53.3%	52.0%
80	Arm	79.4%	78.0%	44.9%	41.8%	55.4%	52.8%
90	Arm	75.9%	75.9%	49.2%	46.1%	58.5%	56.4%
180	Arm	88.5%	88.3%	63.0%	60.5%	72.5%	70.8%
220	Arm	89.8%	89.1%	60.8%	58.5%	71.2%	69.5%
250	Arm	90.1%	89.5%	57.7%	55.2%	68.5%	66.7%
300	Arm	95.7%	95.7%	62.0%	57.2%	72.5%	69.2%

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 BG is low or high so that they can correct the low or high BG. 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 BG 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 BG at or greater than 180 mg/dL for a sensor inserted in the arm.

Table 10. Glucose False Alert Rate, Adults

Glucose False Alert Rate							
		Threshold Only		Predictive Only		Threshold & Predictive	
Glucose (mg/dL)	Insertion Site	30 min	15 min	30 min	15 min	30 min	15 min
63	Arm	26.3%	27.1%	59.8%	64.0%	51.4%	54.8%
65	Arm	24.6%	24.6%	56.6%	60.4%	48.0%	50.8%
70	Arm	19.0%	19.6%	57.5%	59.0%	46.7%	48.0%
80	Arm	20.6%	22.0%	55.1%	58.2%	44.6%	47.2%
90	Arm	24.1%	24.1%	50.8%	53.9%	41.5%	43.6%
180	Arm	11.5%	11.8%	37.0%	39.5%	27.5%	29.2%
220	Arm	10.2%	10.9%	39.2%	41.5%	28.8%	30.5%
250	Arm	9.9%	10.5%	42.3%	44.8%	31.5%	33.3%
300	Arm	4.3%	4.3%	38.0%	42.8%	27.5%	30.8%

Glucose correct detection alert rate

Glucose correct detection alert 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 an alert.

The correct detection rates are important because it is necessary that users be notified when their BG is low or high so that they can correct the low or high BG. A high glucose correct detection rate indicates that users can have confidence that they will be notified by the device if their BG 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 BG at or greater than 180 mg/dL in a sensor inserted in the arm.

Table 11. Glucose Correct Detection Alert Rate, Adults

Glucose Correct Detection Alert Rate							
		Threshold Only		Predictive Only		Threshold & Predictive	
Glucose (mg/dL)	Insertion Site	30 min	15 min	30 min	15 min	30 min	15 min
63	Arm	65.9%	65.9%	94.1%	90.4%	94.1%	91.1%
65	Arm	72.0%	70.6%	95.8%	93.0%	95.8%	93.7%
70	Arm	82.2%	82.2%	94.7%	92.1%	94.7%	92.8%
80	Arm	86.8%	84.9%	96.2%	93.4%	96.2%	93.9%
90	Arm	84.9%	84.6%	94.4%	90.2%	94.4%	91.9%
180	Arm	90.2%	88.3%	98.4%	95.1%	98.6%	95.8%
220	Arm	85.9%	85.6%	95.8%	93.3%	96.1%	94.0%
250	Arm	80.3%	80.3%	93.6%	90.6%	93.6%	91.6%
300	Arm	74.6%	73.7%	94.9%	89.0%	94.9%	89.8%

Glucose missed detection alert rate

Glucose missed detection alert rate is the rate that the device did not alert 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 did not sound a threshold or predictive alert

Missed detection rates are important because it is necessary that users be notified when their BG is low or high, so that they can correct the low or high BG. A low missed detection rate indicates that users can have confidence that they will be notified by the device if their BG 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%, 5.3% or 5.3% of the time within 30 minutes (or 17.8%, 7.9% or 7.2% within 15 minutes) when the user had BG at or less than 70 mg/dL in a sensor inserted in the arm.

Table 12. Glucose Missed Detection Alert Rate, Adults

Glucose Missed Detection Alert Rate							
		Threshold Only		Predictive Only		Threshold & Predictive	
Glucose (mg/dL)	Insertion Site	30 min	15 min	30 min	15 min	30 min	15 min
63	Arm	34.1%	34.1%	5.9%	9.6%	5.9%	8.9%
65	Arm	28.0%	29.4%	4.2%	7.0%	4.2%	6.3%
70	Arm	17.8%	17.8%	5.3%	7.9%	5.3%	7.2%
80	Arm	13.2%	15.1%	3.8%	6.6%	3.8%	6.1%
90	Arm	15.1%	15.4%	5.6%	9.8%	5.6%	8.1%
180	Arm	9.8%	11.7%	1.6%	4.9%	1.4%	4.2%
220	Arm	14.1%	14.4%	4.2%	6.7%	3.9%	6.0%
250	Arm	19.7%	19.7%	6.4%	9.4%	6.4%	8.4%
300	Arm	25.4%	26.3%	5.1%	11.0%	5.1%	10.2%

Sensor life

Adults

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.

Among the 128 sensors evaluated, 11 sensors (8.6%) 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 that are only applicable to the investigational device but resolved for the commercial device). 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.

Safety

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

Specifications

Biocompatibility	Sensor: Complies with EN ISO 10993-1
Applied parts	Sensor
Operating conditions	Sensor temperature: 36 °F to 104 °F (2 °C to 40 °C) Sensor relative humidity: 15% to 95% with no condensation Sensor pressure: 10.2 psi to 15.4 psi (70.33 kPa to 106.17 kPa)
Storage conditions	Sensor temperature: 36 °F to 86 °F (2 °C to 30 °C) Sensor relative humidity: up to 95% with no condensation

	Sensor pressure: 10.2 psi to 15.4 psi (70.33 kPa to 106.17 kPa) **CAUTION:** Do not freeze the Simplera sensor, or store it in direct sunlight, extreme temperatures, or high humidity. These conditions may damage the device.
Sensor glucose measurement range	50 to 400 mg/dL
Duration of use	Up to six days of CGM followed by a grace period of 24 hours
Operating frequency	2.4 GHz band, Bluetooth wireless technology (version 4.2)
Effective radiated power (ERP)	1.53 mW (1.85 dBm)
Effective isotropic radiated power (EIRP)	2.51 mW (4.00 dBm)
Operating range	Minimum of 20 ft (6.09 m) line of sight in free-air
Sensor device approximate dimensions	2.366 x 2.366 x 2.919 in (6.009 x 6.009 x 7.414 cm)
Sensor device approximate weight	2.56 ounces (72.5 g)
Sensor approximate dimensions	1.128 x 1.128 x 0.188 in (2.865 x 2.865 x 0.477 cm)
Sensor approximate weight	0.16 ounces (4.6 g)

Medtronic

Medtronic MiniMed
18000 Devonshire Street
Northridge, CA 91325
USA
1 800 646 4633
+1 818 576 5555
www.medtronicdiabetes.com

℞ *Only*

M063493C002_1
2025-08-15