minimed

MiniMed Flex

System Technical Guide

Includes technology developed by dreamed diabetes ai

MiniMed Flex™

System Technical Guide

Contents

Pump and app

Continuous Glucose Monitoring

Suspend features

SmartGuard

Product specifications

Performance data

1

Introduction

1 Introduction

This system technical guide describes the technical aspects and performance data of the MiniMed Flex™ system with smart device connectivity. A mobile device or App Manager with the MiniMed™ app is connected to the MiniMed Flex pump with its consumables to control insulin delivery. A compatible sensor can be used for continuous glucose monitoring (CGM) and SmartGuard™ mode automatic insulin delivery adjustments.

Accessing user guides online

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

Using this guide

Use the table of contents at the beginning of 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 Flex 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

Description of the system

2 Description of the system

MiniMed Flex system components

The following items are the main components of the MiniMed Flex system:

- **MiniMed Flex pump** — The pump delivers insulin into your body through the infusion set, based on the settings provided by your healthcare professional. The pump also comes with a charger and charging cable.
- **MiniMed app** — The MiniMed app is your primary source of information about your therapy and for controlling insulin delivery.
- **Your compatible mobile device or the App Manager** — The MiniMed app can be installed on your own compatible Apple™* or Android™* mobile device, or you can use the App Manager, which comes with the app pre-installed. Your mobile device or App Manager connects to the pump through Bluetooth®* wireless connection.
- **Glucose sensors** — The MiniMed Flex system uses a compatible glucose sensor to measure glucose in the fluid under your skin and communicate with the pump through a Bluetooth wireless connection. The sensor provides sensor glucose (SG) values for use in the continuous glucose monitoring (CGM) system.
- **Infusion sets** — An infusion set connects to both the pump and your body. It carries the insulin as it is pushed out of the pump and delivered into the body.
- **Reservoirs** — The reservoir is filled with insulin and placed in the pump so that insulin can be delivered into your body through the infusion set.

Compatible devices and operating systems

The MiniMed app is compatible with many iOS™* and Android™* devices. To see if your device is compatible, visit https://www.medtronicdiabetes.com/customer-support/app-support/device-compatibility.

Consumables

The pump uses disposable, single-use MiniMed and Medtronic reservoirs and infusion sets for insulin delivery. Refer to https://www.diabetes.shop/ for the latest list of consumables.

- **Reservoirs** — If using a Medtronic Extended infusion set, use the Medtronic Extended reservoir MMT-342, 3.0 mL (300-unit). Otherwise, use the MiniMed reservoir MMT-332A, 3.0 mL (300-unit).
- **Infusion sets** — Contact a healthcare professional for help in choosing a Medtronic Diabetes infusion set. Change the infusion set per the duration of use in the infusion set user guide.

  The following table lists the compatible infusion sets. The MMT numbers may change if other compatible infusion sets become available.

Note the following regarding infusion sets:

- MiniMed Extended infusion sets are available in various pack sizes, each identified by a specific suffix such as A, AH, AJ, AG, and AK. All products refer to the MiniMed Extended infusion set only and are compatible with the MiniMed Flex pump system.
- Other infusion sets may end with the suffix AT, which also indicates a different pack size that is compatible with the MiniMed Flex pump system.

Type	MMT number
MiniMed Extended™ infusion set	MMT-431A, MMT-432A, MMT-441A, MMT-442A
MiniMed Quick-set™ infusion set	MMT-386A, MMT-387A, MMT-394A, MMT-396A, MMT-397A, MMT-398A, MMT-399A
MiniMed Mio™ Advance infusion set	MMT-213A, MMT-242A, MMT-243A, MMT-244A
MiniMed Sure-T™ infusion set	MMT-862A, MMT-864A, MMT-866A, MMT-874A, MMT-876A, MMT-884A, MMT-886A

Type	MMT number
MiniMed Silhouette™ infusion set	MMT-368A, MMT-377A, MMT-378A, MMT-381A, MMT-382A, MMT-383A, MMT-384A

Blood glucose meter

The MiniMed Flex system is compatible with any commercially available ISO 15197:2013 compliant blood glucose (BG) meters. Refer to the user guide that came with the blood glucose meter for all warnings, precautions, and instructions.

Note: A blood glucose meter is not provided by Medtronic as part of the MiniMed Flex system. An off-the-shelf commercially available ISO 15197:2013 compliant blood glucose (BG) meter is needed for use with the MiniMed Flex system.

Note: The MiniMed Flex pump does not connect wirelessly with a blood glucose meter. Blood glucose (BG) readings must be entered directly into the pump when they are requested by the system.

Additional items

The following items may be used with the MiniMed Flex system. Refer to https://www.diabetes.shop/ for the latest list of accessories.

- **Pump clip** — The pump clip attaches to a belt or waistband.
- **MiniMed Share app (MMT-6111 for Android or MMT-6112 for iOS)** — The app can be downloaded onto compatible mobile devices from the app store. Refer to the app user guide for setup and operation within the app. This optional app is available to care partners to view patient therapy data and to be notified of selected patient alerts. This app does not replace the real-time display of insulin pump data on the primary display device. All therapy decisions should be based on the primary display device. Refer to the local Medtronic Diabetes website for information about supported devices and operating systems.
- **Apple Watch™*** — The Apple Watch can be used as an optional, secondary display. Always refer to your MiniMed app screen prior to making treatment

decisions. The Apple Watch is not intended to replace the MiniMed app and guidance as directed by your healthcare professional. Your watch only communicates with your iPhone™*, not the pump or sensor. Additionally, there may be a brief delay before your watch app shows current information. Tap the data to refresh.

When using the Apple Watch as an optional, secondary display, make sure you understand how notifications and settings will behave when a watch is connected to your iPhone. Do not disable mirror alerts for the MiniMed app in the Apple Watch settings.

Do not use the Apple Watch if the screen or speakers are damaged.

- **App Manager** — The App Manager is a component available through Medtronic that comes with the MiniMed app pre-installed. The App Manager connects to the pump through Bluetooth wireless connection and can be used to control your pump instead of your personal mobile device. Unless otherwise stated, the term "mobile device" refers to your mobile device, or an App Manager.
- **Power adapter** — The power adapter plugs into a wall outlet and connects to the pump charger to power the pump. The MiniMed Flex pump should be used with a compatible IEC 62368-1 certified power adapter. Use the appropriate Medtronic power adapter listed in the following table:

Region	Manufacturer (Phihong Technology Co., Ltd.) part number	Medtronic part number
North America	AQ15A-050BW-H AQ15A-050B-H	ACC-807US

3

Indications and Contraindications

3 Indications and Contraindications

This chapter provides information about safe and intended use of the MiniMed Flex system.

Consult a healthcare professional before starting insulin pump therapy.

User safety

The MiniMed Flex pump system consists of the MiniMed Flex pump with SmartGuard technology and Predictive Low Glucose technology. Refer to the indications for use of SmartGuard technology and Predictive Low Glucose technology related to using those algorithms with the MiniMed Flex pump.

Indications for use

MiniMed Flex Pump

The MiniMed Flex pump is intended for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin.

The MiniMed Flex pump is able to reliably and securely communicate with compatible, digitally connected devices, including automated insulin dosing software, to receive, execute, and confirm commands from these devices.

The MiniMed Flex pump is indicated for use in persons 7 years of age and older.

The MiniMed Flex pump is intended for single patient use and requires a prescription.

Sensor

Refer to the sensor user guide for indications related to sensor use.

SmartGuard technology

SmartGuard technology is intended for use with compatible integrated continuous glucose monitors (iCGM), compatible Medtronic continuous glucose monitors (CGM), alternate controller enabled (ACE) pumps, and digitally connected devices to automatically adjust the delivery of basal insulin and to automatically deliver correction boluses based on sensor glucose (SG) values.

SmartGuard technology is intended for the management of type 1 diabetes mellitus in persons 7 years of age and older, and type 2 diabetes mellitus in persons 18 years of age and older requiring insulin.

SmartGuard technology is intended for single patient use and requires a prescription.

Predictive Low Glucose technology

Predictive Low Glucose technology is intended for use with compatible integrated continuous glucose monitors (iCGM), compatible Medtronic continuous glucose monitors (CGM), alternate controller enabled (ACE) pumps, and digitally connected devices to automatically suspend delivery of insulin when the sensor glucose (SG) value falls below or is predicted to fall below predefined threshold values.

Predictive Low Glucose technology suspends and resumes insulin delivery in Manual mode. Manual mode contains a bolus calculator that calculates an insulin dose based on user-entered data.

Predictive Low Glucose technology is intended for the management of type 1 diabetes mellitus in persons 7 years of age and older, and type 2 diabetes mellitus in persons 18 years of age and older requiring insulin.

Predictive Low Glucose technology is intended for single patient use and requires a prescription.

WARNING: Do not use the Suspend before low or Suspend on low features to prevent or treat low glucose. Always follow the instructions of a healthcare professional to treat low glucose. Using Suspend before low or Suspend on low features to prevent or treat low blood glucose (BG) may result in prolonged hypoglycemia.

Compatible digitally connected devices with SmartGuard technology and Predictive Low Glucose technology

The MiniMed Flex system includes the following technologies:

- SmartGuard technology, which is utilized by the SmartGuard feature. For more information, see *SmartGuard, page 93*.
- Predictive Low Glucose technology, which is utilized by the Suspend on low and Suspend before low features. For more information, see *Continuous Glucose Monitoring, page 77*.

Compatible ACE Pumps

The following ACE pump is compatible with SmartGuard technology and Predictive Low Glucose technology:

- MiniMed Flex pump (MMT-8062)

Compatible interoperable Medtronic CGMs

The following interoperable Medtronic CGMs are compatible with SmartGuard technology and Predictive Low Glucose technology:

- Simplera Sync™ sensor (MMT-5120)

Compatible system configurations

The following system configuration is compatible with SmartGuard technology and Predictive Low Glucose technology: MiniMed Flex system with Simplera Sync sensor.

Intended users

The MiniMed Flex system is intended for personal use by individuals to assist in the management of their diabetes, or for use by parents/caregivers who assist these individuals with diabetes management.

Contraindications

When using the Simplera Sync sensor, the MiniMed Flex system is contraindicated for use in persons under age 7.

Pump therapy is not recommended for people with a significant cognitive or physical impairment that affects their ability to safely operate the pump, including a lack of physical dexterity.

Pump therapy is not recommended for children who are not under the care of a parent or caregiver who is capable of safely operating the pump for the patient.

The reservoir is contraindicated for the infusion of blood or blood products.

Infusion sets are indicated for subcutaneous use only and not for intravenous (IV) Infusion.

Infusion sets are not indicated for the infusion of blood or blood products.

Insulin pump therapy is not recommended for persons who are unwilling or unable to perform BG meter readings.

Pump therapy is not recommended for people who are unwilling or unable to maintain contact with their healthcare professional.

Compatible insulins

The MiniMed Flex system has been studied with, and is intended for use with, the following compatible U-100 insulins:

- U-100 Admelog™*
- U-100 Humalog™*
- U-100 NovoLog™*
- U-100 Fiasp™*
- U-100 Lyumjev™*

Some insulin products are labeled for use in any pump that is compatible with the insulins listed above. To see if another insulin not listed above can be used, refer to section 2.2 of the prescribing information for that insulin product.

Fiasp and Lyumjev have a faster initial absorption than other rapid-acting U-100 insulins. Always consult your healthcare professional and refer to the insulin labeling before use.

Emergency kit

Keep an emergency kit available at all times and confirm that necessary supplies are available and not expired. Tell a family member or friend where to find the emergency kit.

When traveling, check blood glucose (BG) more frequently to accommodate for changes in activity levels and meal times.

Consult your healthcare professional on which of the following items to include in your emergency kit:

- Rapid-acting glucose
- Blood glucose (BG) testing supplies
- Urine or blood ketone monitoring supplies
- Extra infusion set and reservoir
- Pump charger and cable to connect to a power source
- Insulin syringe
- Short-acting insulin, long-acting insulin, or both (with dosage instructions from a healthcare professional)
- Adhesive dressing for your sensor
- Glucagon

4

Pump and app

4 Pump and app

This chapter provides information about starting the system, comparing the different operating modes, the use and care of your pump and app, and how to use Manual mode.

Starting the system

This section describes how to start using your MiniMed Flex system.

Your CareLink™ account

Whether using your own compatible mobile device or App Manager, you need to have a CareLink account to log in and manage your data. Your account authenticates the MiniMed app, secures the communication between the pump and app, and protects your data. When you open the MiniMed app for the first time, you are prompted to either log in or create a CareLink account before you can set up the MiniMed app.

You can manage your CareLink account by tapping the at the top of the MiniMed app Home screen.

Setting up the MiniMed app

After you log in to your CareLink account during startup, you are prompted to configure your MiniMed app settings. The app guides you through the settings. The table below shows the items that you are guided through to start using the MiniMed app.

Setup item	Details
App Settings, Security, and Simulator	

Setup item	Details
End-user license agreement	The MiniMed app user agreement authorizes the transmission of your personal health data for care.
Bluetooth & internet	The MiniMed app uses Bluetooth®* wireless connection to communicate between the system components, and internet connection to authenticate the app.
Screen lock (Android) Mobile device passcode (iOS)	Mobile devices require a security screen lock or passcode to prevent unauthorized access to your settings and data.
Notifications (Android) Notifications & Critical Alerts (iOS)	This setting is required to allow notifications and critical alerts.
Do not disturb	This setting is required to allow the app alerts to occur on your mobile device, even if Do not disturb is active.
Notification privacy	Provides an extra privacy option for notifications.
Important phone settings	Provides information about your mobile device features that allow you to limit app usage and manage accessibility. Make sure you are not using Digital Wellbeing or Accessibility features that could cause a disruption in your therapy.
Time difference	If the time zone setting on your mobile device is different from the time zone setting set on your pump, the system instructs you to confirm the difference, or to change the time zone settings to match.
Practice with MiniMed Simulator app	Once the app settings, security, and permissions have been set, tap here to open the Simulator app and begin practicing prior to training. The Simulator app is for demonstration purposes only, and does not connect to the pump.
Product Selection and Pairing	
Pair pump	Provides the steps to pair the pump to your mobile device.
Pair sensor	Provides the steps to insert and pair the sensor to the pump. If you skip this during setup, you cannot receive glucose alerts until a sensor is paired to the system.
Therapy Settings	
Basal settings	Set the Max basal rate and create a basal pattern for insulin delivery in Manual mode as instructed by your healthcare professional.

Setup item	Details
	If you skip this during setup, you must set this up later before starting insulin delivery in Manual mode or SmartGuard mode.
Bolus settings	Set the Bolus calculator settings provided by your healthcare professional. If you skip this during setup, Manual bolus in Manual mode is the only option for delivering a bolus, and SmartGuard mode cannot be activated until you enter these settings.
Glucose alerts	Set the glucose alerts and Suspend features settings provided by your healthcare professional. If you set these settings but do not pair a sensor, glucose alerts and Suspend features do not occur. If you pair a sensor and skip these settings, only default glucose alerts and suspend settings occur.

Verifying your identity

You are prompted to use the verification method that you set on your mobile device, such as pin, pattern, fingerprint, or face ID, when you perform certain actions in the MiniMed app, including the following:

- Deliver a bolus
- Save a max bolus
- Save an active basal pattern
- Save a max basal rate
- Start a temp basal

MiniMed app Home screen

The MiniMed app Home screen provides an overview of data received from the pump and sensor, status information, and alerts. Different icons and status information appear depending on the mode used for therapy and the status of the system.

The following diagram is an example of the Home screen in Manual mode using CGM. The information and alerts shown are examples and may not appear at the same time

when using the app for therapy. All icons that the Home screen displays are included in the table.

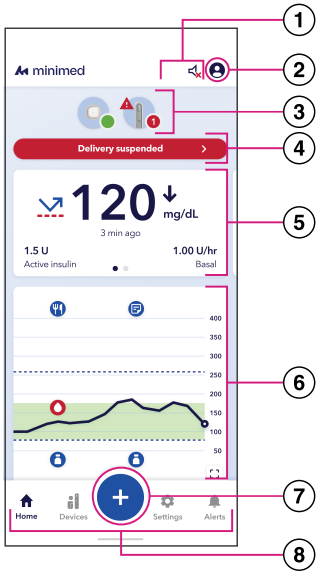


Image ID	Home screen section	Description
①	Top of the Home screen	The following system status icons may appear at the top of the Home screen. Tap the icon to view more details: — CareLink is logged out or lost connection — Alerts are disabled — Alerts are muted — The time zone in your Therapy time settings and your mobile device settings are different — SmartGuard mode is turned on but is not active
②	Profile menu	Tap the icon to view the following menus: Profile — View and edit your account information CareLink — Manage CareLink uploads and login Daily history — Review previously logged data and actions taken in the app Summary — Access and review your therapy and sensor data Help — Access contacts, diagnostic logs, and instruction guides

Image ID	Home screen section	Description
③	Device status	Tap the following device icons to view more details about the device status: Pump status Sensor status The following status icons may appear on the device icons. A number in the status icon indicates how many actions are needed: Green — No actions are needed at this time Yellow — An action is needed soon Red — An action is needed now Gray — No communication between devices Red triangle — An open alert requires an action now
④	Status and alerts banners	Banners displayed below the device icons show status information. Banners above the device icons show alerts that you have not responded to. Tap the banner for more information and follow the steps if needed.
⑤	Therapy status	View your glucose and therapy information. Swipe for details about your time in range. The most recent sensor glucose (SG) value is displayed. Dashes, "- - -," are displayed instead of a number if there is a sensor error or if no sensor data is available. The current active insulin based on delivered boluses and your active insulin time setting is displayed. The current basal rate from the active basal pattern in Manual mode is displayed. The following status icons may appear next to your glucose information: — SmartGuard mode is active. The timer in the Therapy status section indicates that you need to perform an action to stay in SmartGuard mode. — SmartGuard mode is active, but insulin delivery is suspended. — The suspend features based on your sensor glucose (SG) in Manual mode are active. This icon flashes to indicate that the suspend features suspended insulin delivery.

Image ID	Home screen section	Description
		— The suspend features based on your sensor glucose (SG) in Manual mode are temporarily unavailable. You can still manually suspend insulin delivery using Suspend all delivery if needed. — Active insulin was reset to zero. The following trend arrows indicate rising or falling sensor glucose (SG) rates and intensity: ↑ ↓ — Your sensor glucose (SG) is rising or falling at a rate of 20 to 40 mg/dL over the last 20 minutes, or 1 to 2 mg/dL/min. ↑↑ ↓↓ — Your sensor glucose (SG) is rising or falling at a rate of 40 to 60 mg/dL over the last 20 minutes, or 2 to 3 mg/dL/min. ↑↑↑ ↓↓↓ — Your sensor glucose (SG) is rising or falling at a rate of more than 60 mg/dL over the last 20 minutes, or more than 3 mg/dL/min.
⑥	Trend graph	View events and your glucose levels over time. Time is displayed on the bottom of the graph. Pinch or zoom the sensor graph to view from 1 hour to 24 hours. Swipe to view more historical information. The following event icons, bands, and bars may appear on or below the graph. Tap the icons and bars to view more information (not all have more information): — Bolus delivery — Carb entry — Blood glucose (BG) entry — Note entry — Time change event Green band — Glucose target range Yellow band — Insulin delivery was suspended by the suspend features in Manual mode Pink bars — Auto Basal delivery in SmartGuard mode Blue bars — Auto correction bolus delivery in SmartGuard mode Dark green bar — Temp target in SmartGuard mode
⑦	Therapy Action button	Tap the button to log an event or to access therapy actions such as delivering a bolus, setting a Temp basal, and suspending insulin delivery.
⑧	Menu bar	Tap the icon to access the following menus and screens:

Image ID	Home screen section	Description
		Home — View the Home screen Devices — View the status of your MiniMed Flex system devices Settings — Manage your MiniMed app settings Alerts — Respond to open alerts and view alerts history. A red dot on the Alerts icon indicates when there are one or more open alerts that have not been responded to.

The MiniMed Flex pump

Pump status signals

Press the oval Status button to check your alert and pump status. You can adjust your alert settings in the Alert and glucose settings menu.

Always refer to the MiniMed app when addressing an alert.

Pump status signal	Details
	• Red light — An action is needed immediately • Red light and a down arrow — There is a low glucose alert, and an action is needed immediately
	• Yellow light — An action is needed soon • Yellow light and a down arrow — There is a low glucose alert, and an action is needed soon
	• Green light that appears when the oval Status button is pressed — There is no alert condition requiring action at this time • Green light (steady light) — A bolus started • Green light that continuously pulses — The pump is charging
	• Blue light that continuously flashes — The pump is in pairing mode • Blue light (three short flashes) — The pump has lost communication with the app
	• No light appears when the oval Status button is pressed — The pump may have no power

Pump status signal	Details
Pump sounds	• Descending tone — There is a low glucose alert • Ascending tone — There is a high glucose alert • Non-ascending and non-descending tone — There is a system alert or other system condition
Pump vibration	• Once or in a pattern — There is an alert or other system condition

Charging the pump

When placed into the charger, the pump beeps, and the oval Status light, arrow and charger base lights blink white.

A green light on the pump flashes as the pump charges. When the pump is fully charged, the light stops flashing and remains green.

During use, the pump needs to be periodically charged. It takes approximately 30 minutes for a full charge, and a full charge usually lasts for one week.

Shutting down the pump

The pump shuts down when it is placed on the charger while the oval Status button is held down until the pump beeps twice and shows a steady blue light. Release the oval Status button and remove the pump from the charger. The pump icon in the app turns gray when the pump disconnects from the app. Remove the pump from the charger to store it.

If the oval Status button is released too soon, or if the pump is removed from the charger before the pump beeps twice, the pump does not power down. Perform the shutdown process again to complete shutting the pump down.

The pump turns on when it is placed on the charger. The pump light turns on and you are alerted when the pump has sufficient charge for use. The pump icon in the app turns green when a paired pump reconnects to the app.

The pump usually does not need to be re-paired after being shut down. If the pump does not reconnect to the app, the pump icon remains gray. Re-pair the pump if this happens.

The charger can be disconnected from power by unplugging the wall plug.

The charger can be disconnected from power by unplugging the power adapter. Make sure the power adapter is accessible to allow it to be disconnected from the power outlet.

Restarting the pump

Restart the pump by holding both the Status button and Action button on the pump down for 15 seconds until the pump beeps once and the light turns off.

The pump can be restarted to check for system errors. If there is an error, an alert occurs when the pump turns back on.

Alarm settings after power interruptions

If the pump loses power, the pump automatically restores the alarm settings that were active prior to the interruption. No user action is required.

Operating modes

Your pump operates in two different modes: Manual mode and SmartGuard mode.

When you first use your MiniMed Flex pump, it is in Manual mode.

Manual mode refers to a group of features that requires your input to deliver boluses for meals and to correct glucose levels. You may use Manual mode with or without CGM. When using CGM in Manual mode, you can see sensor glucose (SG) trends, receive low and high sensor glucose (SG) alerts, and suspend insulin delivery according to your settings.

While in Manual mode, Predictive Low Glucose features, including Suspend before low and Suspend on low, can be used as directed by your healthcare professional.

In Manual mode, the pump automatically delivers basal insulin based on settings that you input.

After a few days of use in Manual mode, and at the direction of your healthcare professional, you can use SmartGuard mode. When in SmartGuard mode, the pump automatically adjusts and delivers basal insulin and can also deliver automatic correction boluses to regulate glucose levels to a target sensor glucose (SG) value. You still need to enter a carb amount to deliver a bolus to cover carbs that you eat or drink.

The following tables compare the main characteristics of Manual mode without CGM, Manual mode with CGM, and SmartGuard mode. These modes are detailed further throughout this guide.

Table 1. Manual mode without CGM

Characteristic	Details
Bolus insulin delivery	• Bolus calculator in Manual mode – A bolus is calculated based on your bolus settings – A blood glucose (BG) meter reading is needed to calculate a correction for high glucose – A carb entry is needed to cover carbs that you eat or drink – The bolus amount can be adjusted – Your input is required to deliver the bolus • Manual bolus – You enter the units of insulin needed to cover carbs that you eat or drink or to correct high glucose – Your input is required to deliver the bolus
Basal insulin delivery	• Programmed basal pattern – The pump automatically delivers insulin based on basal delivery settings that you set – A Temp basal rate can be used to temporarily increase or decrease basal insulin delivery
Insulin suspension	• Suspend all delivery – Choose this option to stop all delivery of insulin
Glucose trend information	• Trend graph – The graph does not have a trend line showing sensor glucose (SG) information over time

Table 2. Manual mode with CGM

Characteristic	Details
Bolus insulin delivery	• The same as Manual mode without CGM
Basal insulin delivery	• The same as Manual mode without CGM
Insulin suspension	• Suspend all delivery – The same as Manual mode without CGM

Table 2. Manual mode with CGM (continued)

Characteristic	Details
	• Suspend before low and Suspend on low – Delivery is suspended automatically and you are alerted based on your settings
Glucose trend information	• Trend graph – The graph has a trend line showing sensor glucose (SG) information over time

Table 3. SmartGuard mode

Characteristic	Details
Bolus insulin delivery	• Bolus calculator in SmartGuard mode – A bolus is calculated by SmartGuard mode calculations that use your Carb ratio, Active insulin time, and Max bolus settings – Either a sensor glucose (SG) value or blood glucose (BG) meter reading can be used to calculate a correction for high glucose – A carb entry is needed to cover carbs that you eat or drink – The bolus amount cannot be adjusted – Your input is required to deliver the bolus • Auto correction – A bolus is automatically determined by SmartGuard mode, then delivered, to maximize time in range – The bolus is delivered without your input – The Auto correction setting must be turned on to use this feature
Basal insulin delivery	• Auto Basal – Basal insulin is automatically determined and adjusted by SmartGuard mode, then delivered, to target the glucose value you set (SmartGuard target) – Basal insulin is delivered without your input – A Temp target can be set when less insulin is needed, such as for exercise

Table 3. SmartGuard mode (continued)

Characteristic	Details
Insulin suspension	• Suspend all delivery – The same as Manual mode (with or without CGM)
Glucose trend information	• Trend graph – The same as Manual mode with CGM

Delivery settings

The following table describes whether each delivery setting impacts SmartGuard mode and Manual mode. Consult your healthcare professional before changing delivery settings.

Insulin setting	Impacts SmartGuard mode	Impacts Manual mode
Active insulin time	Yes	Yes
Basal pattern and basal rates	No	Yes
BG target	No	Yes
Bolus increments	Yes*	Yes
Carb ratio	Yes*	Yes
Dual Wave bolus / Square Wave bolus	No	Yes
Insulin sensitivity factor	No	Yes
Max basal	No	Yes
Max bolus	Yes*	Yes

*This setting impacts the Bolus calculator in SmartGuard mode. It does not impact Auto Basal or Auto correction.

Basal delivery in Manual mode

Basal insulin is the "background" insulin that the body needs throughout the day and night to maintain target blood glucose (BG) meter readings when food is not eaten. Basal insulin accounts for approximately one half of daily insulin requirements. The MiniMed Flex pump simulates a pancreas by delivering insulin continuously over 24 hours.

Basal rate

Basal rate is the specific amount of basal insulin that the pump continuously delivers each hour. While some people use one basal rate all day, others require different rates at different times of the day. Set your basal rates as directed by a healthcare professional.

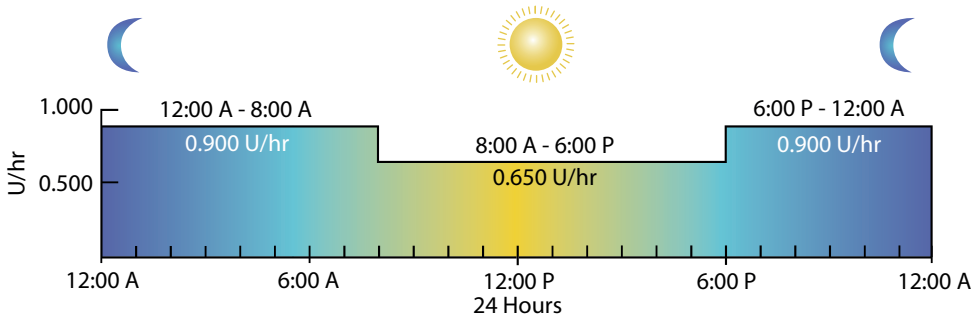
Basal rates are set in one or more basal patterns.

Basal rate settings apply to Manual mode only and do not affect how much insulin is delivered when using SmartGuard mode.

Basal pattern

The basal pattern determines the amount of basal insulin delivered throughout the day and night while in Manual mode. A basal pattern is made up of one to 48 basal rates that are set to cover a full 24-hour period. Because basal insulin needs can vary, two basal patterns can be set. Only one basal pattern can be active at a time.

The following example represents one basal pattern with three basal rates set for three different time periods.



Consult a healthcare professional to determine your basal pattern. A basal pattern must be manually entered into the app before the pump can deliver insulin.

Basal pattern settings apply to Manual mode only and do not affect how much insulin is delivered when using SmartGuard mode.

Max basal rate

The Max basal rate setting limits the maximum amount of basal insulin per hour that can be programmed. Consult a healthcare professional to personalize your Max basal rate setting.

It is not possible to set a basal rate or a Temp basal rate that would exceed the Max basal rate limit. After the basal patterns are set, the Max basal rate setting cannot be set lower than any existing basal rate.

If you require a Max basal rate higher than 6 units per hour, you are notified that a Max basal rate setting higher than 6 units per hour is outside of the typical range. A Max basal rate of 6 U/hr can allow basal delivery of up to 144 units per day in Manual mode. This amount of insulin may not be safe. Consult your healthcare professional to make sure your basal setting is appropriate for you.

The Max basal rate setting applies to Manual mode only and does not affect how much insulin SmartGuard mode delivers. When using SmartGuard mode, delivery limits are determined automatically.

Temp basal

The Temp basal feature is used to set and start a temporary basal rate that can be used immediately to manage blood glucose (BG) during short-term activities or conditions, such as during exercise.

The duration of the Temp basal can range from 30 minutes to 24 hours. When a Temp basal starts, basal delivery changes to the temporary basal rate for the set duration of time. After the Temp basal time is completed or canceled, the programmed basal pattern resumes. Temp basal rates can be defined using either a percentage of the current basal pattern or by setting a specific rate, as described in the following table.

Temp basal type	Description
Percent	• Percent delivers a percentage of the basal rates programmed in the active basal pattern for the duration of the Temp basal time. The Temp basal amount is rounded down to the next 0.05 U. The Temp basal amount is rounded to 0 U if the resulting amount set is too small to be delivered. • Temp basal rates can be set to deliver from 0% to 200% of the programmed basal rate.

Temp basal type	Description
	• The percentage used is based on the largest basal rate programmed during the Temp basal duration and is limited by the Max basal rate.
Rate	• Rate delivers a fixed basal insulin rate in units per hour for the duration of the Temp basal. • The amount set is limited by the Max basal rate.

Bolus delivery in Manual mode

A bolus is given for two reasons: to cover food that contains carbohydrates or to correct glucose levels that are above the target range. In Manual mode, a bolus can be delivered using either the Bolus calculator or Manual bolus option. Multiple types of bolus deliveries are available, including normal bolus, Square Wave™ bolus, and Dual Wave™ bolus. The bolus type depends on individual insulin needs as determined by your healthcare professional.

The following table describes how to deliver a bolus using the Bolus calculator or Manual bolus options in Manual mode.

Bolus option	Description
Bolus calculator	• Enter a blood glucose (BG) meter reading or the amount of carbs expected from a meal, or both. • The Bolus calculator calculates a bolus amount based on your insulin settings.
Manual bolus	• Calculate and manually enter the bolus amount.

Bolus types

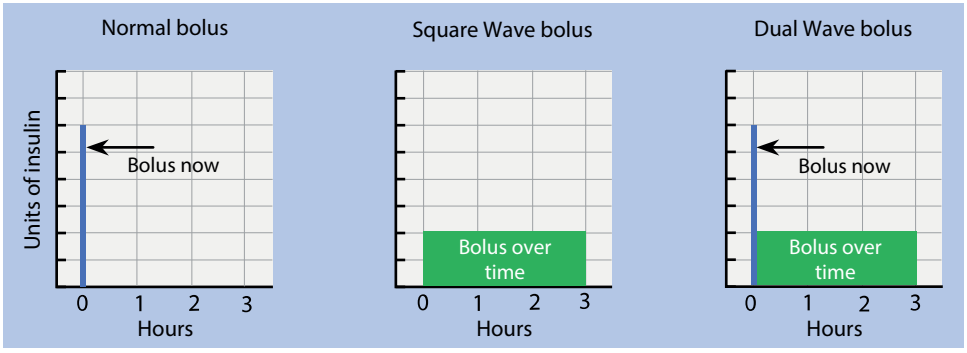
The following table provides general information about the available bolus types in Manual mode. The Square Wave bolus and Dual Wave bolus are called Extended bolus options in the Insulin settings menu.

Bolus type	Description	Details
Normal bolus	Provides a single immediate dose of insulin	This is the typical bolus type used to cover carb intake or to correct a high blood glucose (BG) meter reading
Square Wave	• Delivers a single bolus evenly over an extended period of	This bolus type can be used for the following reasons:

Bolus type	Description	Details
bolus	time, from 30 minutes up to 8 hours* • Insulin delivered over a period of time is more likely to be available when needed.	• When you have delayed food digestion due to gastroparesis or food intake that is high in fat • When you are snacking over an extended period of time • When a normal bolus drops blood glucose (BG) too rapidly
Dual Wave bolus	• Delivers a combination of an immediate normal bolus followed by a Square Wave bolus • Immediate and extended insulin needs are met by delivering a combination of a bolus delivered immediately and a bolus delivered over time	This bolus type can be used for the following reasons: • When food intake is high in carbs and fat, which may delay digestion • When an elevated blood glucose (BG) needs to be corrected before a meal, and a delayed bolus is needed for food that is absorbed slowly

* The maximum duration of time that a Square Wave bolus can be set is less than 8 hours when delivering 0.5 U of insulin or less.

The following example shows how the different bolus types work.



Note the following when using the different bolus types:

- The pump can deliver a normal bolus while a Square Wave bolus or the Square portion of a Dual Wave bolus is being delivered.

- When using the Bolus calculator, a Square Wave bolus is only available when giving a bolus to cover carbs alone. A Square Wave bolus is not available when there is a correction for a high blood glucose (BG) reading.
- A Square Wave bolus is not available when delivering less than 0.1 U of insulin.
- The start of a Square Wave bolus or Square portion of a Dual Wave bolus delivery does not occur immediately. Delivery is centered throughout the duration of time set.
- 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.

Stopping bolus delivery

Stopping a bolus in progress does not stop basal insulin delivery. Do not use the Suspend all delivery feature unless you want to stop both basal and bolus delivery.

Note the following when stopping bolus insulin delivery:

- When delivering a normal bolus during a Square Wave bolus or the Square portion of a Dual Wave bolus, both boluses are stopped.
- When a Dual Wave bolus is stopped during the Now portion, all bolus delivery is stopped including the Square portion.

Max bolus

The Max bolus setting limits the amount of insulin that can be programmed by the user for a single bolus. The pump prevents single bolus insulin deliveries that exceed the Max bolus amount. The Max bolus can be set from 0 to 25 units. Set the Max bolus as directed by a healthcare professional.

The Max bolus setting applies to boluses programmed by the user in Manual bolus, Bolus calculator in Manual mode, and Bolus calculator in SmartGuard mode. Auto correction limits are determined by SmartGuard mode.

Bolus calculator in Manual mode

The Bolus calculator in Manual mode uses blood glucose (BG) readings, carb amounts, and insulin settings to calculate a bolus of insulin. The Bolus calculator screen shows the most recent blood glucose (BG) reading if it is available to calculate a correction for high

glucose. If it is not available, the blood glucose (BG) appears as dashes, and you need to enter a new blood glucose (BG) meter reading if you want to include glucose information when calculating a bolus. Enter a carb amount if you want to deliver a bolus to cover carbs that you eat or drink.

When using the Bolus calculator in Manual mode, you can deliver a normal bolus, Square Wave bolus, or Dual Wave bolus.

Manual injections of insulin, given without using your pump, are not accounted for in the active insulin amount used in Bolus calculator calculations.

Note the following for using the Bolus calculator in Manual mode:

- Do not enter a sensor glucose (SG) value in the blood glucose (BG) field.
- Do not use a blood glucose (BG) meter reading that was taken more than 12 minutes ago. The reading and bolus calculations using the reading may no longer be accurate.
- The bolus amount is calculated to 0.0 U if you do not enter a blood glucose (BG) reading or carb entry.
- The calculated bolus amount can be manually adjusted.

Insulin settings

The Bolus calculator uses the Insulin settings to calculate a bolus amount. Set your Insulin settings as directed by a healthcare professional. Values for the Insulin settings in the following table must be set to calculate a bolus in the Bolus calculator.

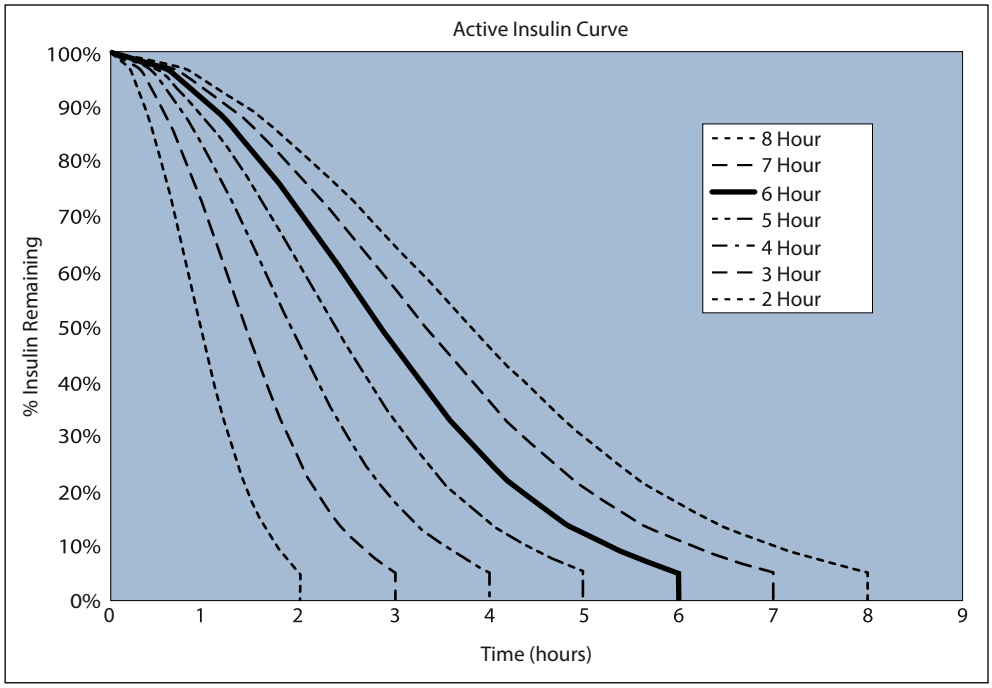
Insulin setting	Details
Active insulin time	• Active insulin is the bolus insulin that has been delivered by the pump and is still working to lower glucose levels. In the Bolus calculator and SmartGuard mode, the Active Insulin Time setting is used to calculate a correction bolus by subtracting the estimated active insulin from each bolus. In SmartGuard, auto correction boluses are delivered up to every 5 minutes. A shorter Active Insulin Time setting may result in more insulin being delivered in correction boluses. • A healthcare professional provides the personalized active insulin time based on historic glycemic control data for the individual user. When using SmartGuard, the recommended initial setting is

Insulin setting	Details
	an Active Insulin Time of 2-3 hours. The Active Insulin Time setting in the MiniMed Flex system is not necessarily reflective of the physiological insulin metabolism. Adjustments are not based on the pharmacokinetics and pharmacodynamics of the compatible insulin. The current active insulin amount appears on the Home screen and includes only the bolus insulin received.
BG target	• The high and low target values are the values that the Bolus calculator corrects to when calculating the correction portion of the total bolus in Manual mode. • High and low target values can be set to target a blood glucose (BG) range. The same value can be set for the high and low target values to target a single blood glucose (BG) reading instead of a range.
Carb ratio	• Carb ratio is the grams of carbs you eat or drink that are covered by 1 unit of insulin. • The Bolus calculator in Manual mode and SmartGuard mode uses the Carb ratio setting to calculate the carb estimate portion of the total bolus.
Insulin sensitivity factor	• Insulin sensitivity factor is the amount that your blood glucose (BG) is reduced per 1 unit of insulin. • The Bolus calculator in Manual mode uses the Insulin sensitivity factor setting to calculate the correction portion of the total bolus.

Active Insulin Curve graph

The Active Insulin Curve graph shows how the Active insulin time setting affects the active insulin amount that is subtracted from the correction portion of boluses over time. The percentage of insulin remaining changes at varying rates depending on the Active insulin time setting.

Active Insulin Curve Graph



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

Bolus calculator formulas

The Bolus calculator in Manual mode uses one of three formulas to estimate a bolus, depending on the current blood glucose (BG) reading.

The following formulas are used to calculate the total bolus estimate when the carb units are in grams:

1. Total bolus estimate = Carb estimate + Correction estimate - Active insulin

   If the current blood glucose (BG) reading is greater than the high BG Target value, and the correction for high glucose (correction estimate) is greater than the active insulin, then active insulin is subtracted from the correction estimate. This value is added to the carb estimate to get the total bolus estimate.

   The following formula is used by the Bolus calculator to calculate the total bolus estimate.

(carb estimate) (correction estimate)

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

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

2. Total bolus estimate = Carb estimate + Correction estimate

   If the current blood glucose (BG) is less than the low BG Target value, then the correction estimate is added to the carb estimate to get the total bolus estimate. Note that active insulin is not accounted for in the Bolus calculator calculation.

   The following formula is used by the Bolus calculator to calculate the total bolus estimate.

(carb estimate) (correction estimate)

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

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

3. Total bolus estimate = Carb estimate

   The total bolus estimate is based only on the carb estimate under the following conditions:

   - If the current blood glucose (BG) reading is higher than the high BG Target value, but the correction estimate is less than the active insulin
   - If the current blood glucose (BG) reading is within the high and low BG Target values
   - If no blood glucose (BG) reading is entered

The following figure shows the calculation used by the Bolus calculator to get the total bolus estimate.

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

Reservoir and infusion set

The app has options to change the reservoir only, the infusion set only, or both the reservoir and infusion set at the same time. Change the reservoir only if the reservoir runs out of insulin and neither the reservoir nor the infusion set has been used for the duration of use indicated for the infusion set. Change the infusion set as needed, and according to the duration of use indicated for the infusion set.

Refer to the infusion set user guide and the reservoir user guide for the duration of use indicated for each.

Do not begin the steps to replace the reservoir and infusion set until training has been received.

The following tables list the process steps the MiniMed app guides you through to change the reservoir and infusion set. Steps vary based on the types of consumables used and which consumables are changed. For example, not all infusion sets require a separate step to fill the cannula.

Table 4. Change reservoir and infusion set process

Process steps	Explanation
Remove infusion set	Remove the infusion set from your body.
Remove reservoir	Remove the reservoir and infusion set from your pump and rewind.
Fill new reservoir	Transfer insulin from a vial into a new reservoir.
Connect tubing to reservoir	Connect a new infusion set to the new reservoir.
Lock reservoir into pump	Place and secure the new reservoir in the pump and load.

Table 4. Change reservoir and infusion set process (continued)

Process steps	Explanation
Fill tubing	Fill the tubing with insulin.
Insert infusion set	Insert the infusion set into your body.
Fill cannula	Fill the inserted soft cannula with insulin.

Table 5. Change reservoir process

Process steps	Explanation
Disconnect infusion set	Disconnect the tubing from the cannula housing or set connector on your body.
Remove reservoir	Remove the reservoir from your pump, and remove the tubing from the used reservoir.
Fill new reservoir	Transfer insulin from a vial into a new reservoir.
Connect tubing to reservoir	Connect the existing tubing to the new reservoir.
Lock reservoir into pump	Place and secure the new reservoir in the pump.
Fill tubing	Fill the tubing with insulin.
Connect tubing	Connect the tubing to the cannula housing or set connector on your body.

Table 6. Change infusion set process

Process steps	Explanation
Remove infusion set	Remove the infusion set from your body.
Remove reservoir	Remove the reservoir from your pump and disconnect the used infusion set from the reservoir.
Connect tubing to reservoir	Connect a new infusion set to the existing reservoir.
Lock reservoir into pump	Place and secure the existing reservoir in the pump.
Fill tubing	Fill the tubing with insulin.
Insert infusion set	Insert the infusion set into your body.
Fill cannula	Fill the inserted soft cannula with insulin.

Table 7. Fill cannula process

Process steps	Explanation
Fill cannula	Fill the inserted soft cannula with insulin.

Setting up the reservoir and infusion set

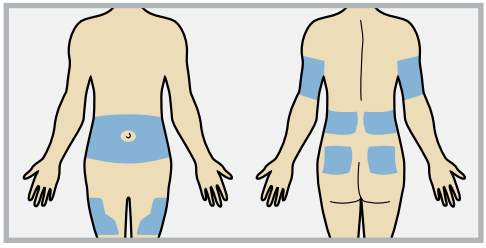
Consult a healthcare professional to determine the appropriate settings before insulin is used with the pump.

The following items are needed:

- MiniMed app
- MiniMed Flex pump
- Vial of rapid-acting U-100 insulin
- MiniMed or Medtronic reservoir
- MiniMed or Medtronic infusion set and its user guide
- Alcohol wipes

Approved insertion sites

Choose an insertion site from the shaded areas. Clean the insertion site with alcohol or other antiseptic as directed by a healthcare professional.



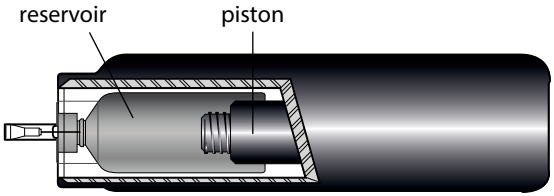
Rewinding the pump

Changing the reservoir or infusion set causes the pump to rewind.

When the pump rewinds, the piston in the reservoir compartment returns to its starting position and allows a new reservoir to be placed into the pump.

The piston is located in the reservoir compartment of the pump. It pushes insulin from the reservoir into the tubing.

The diagram below shows how the piston interacts with the reservoir in the pump.



General settings

Settings menus

The following table lists all the settings contained in the menus viewed from the ⚙ Settings icon on the MiniMed app Home screen.

Menu	Settings
Insulin settings	
Basal settings	Basal pattern and Max basal rate
Bolus settings	Carb ratio, Insulin sensitivity factor, BG target, Active insulin time, Max bolus, Bolus increments, and Extended bolus
Alert and glucose settings	
App volume and mute settings	Alert volume and mute and Mute timer
Pump sound and vibration settings	Pump sound, Pump vibration, and Lost communication
Low glucose settings	Set day and night, Day starts at, Night starts at, Max volume at night, Low limit, Alert before low, Alert on low, Fall alert, Fall rate, Suspend limit, Suspend before low, Alert for suspend before low, Suspend on low, and Snooze setting
High glucose settings	Set day and night, Day starts at, Night starts at, Max volume at night, High limit, Alert before high, Alert before high duration, Alert on high, Rise alert, Rise rate, and Snooze setting duration
System alerts settings	Low reservoir, Low pump battery – Battery remaining <10 hours, Low sensor life – Sensor life <24 hours, Low sensor life – Sensor life <12 hours, and Infusion set change reminder
SmartGuard settings	
SmartGuard settings	SmartGuard on, SmartGuard target, and Auto correction
App settings	
App settings	Therapy time

Therapy time setting

Your time zone setting in the app is used by the pump for insulin delivery. This setting is called Therapy time, and it is set to your mobile device's time zone by default.

When your mobile device updates to a different time zone (for example, when traveling or for daylight savings time), the app alerts you and provides the option to update your Therapy time to your current time zone. You can update your Therapy time at anytime from your App settings or by tapping on the Home screen.

Therapy time is used to log the timing of events in Daily History, the alerts History tab, and the Trend graph events. It is also used for the selectable time segments of Set day and night settings and Insulin settings, including basal insulin times. Inaccurate Therapy time may affect the accuracy of these logs and settings.

Consult your healthcare professional to determine if adjustments to your Therapy time are needed when your time zone changes.

Clearing the active insulin

Clearing the active insulin clears the SmartGuard mode therapy history and active insulin values that the pump has tracked. After the active insulin values are cleared, it sets the active insulin value to zero. Only clear the active insulin if instructed to by your healthcare professional.

Troubleshooting

Troubleshooting provides information about common MiniMed Flex pump and sensor issues, as well as possible resolutions.

Pump issues

The following table provides troubleshooting information for the insulin pump:

Issue	Resolution
The pump and app are not connected.	The pump icon in the app turns gray when the pump has disconnected from the app. Depending on your settings, the oval status light flashes three times in blue and the pump will sound, vibrate, or both every 30 minutes until the pump and mobile device are back in range. Move the mobile device closer to the pump to automatically reconnect the devices. The devices should be kept within 20 ft of each other to remain connected.

Issue	Resolution
	If this does not resolve the issue, try each of the following methods and re-opening the app: 1. Check if Bluetooth is turned off in the mobile device settings, and if it is off, turn it on. 2. If Bluetooth is turned on in the mobile device settings, turn it off. Wait 3 seconds, and then turn Bluetooth on. 3. Press the oval Status button to ensure that the pump has a sufficient charge, and that the pump is turned on. 4. Restart the mobile device. 5. If the issue persists for longer than 2 minutes after performing the above methods, then unpair the pump in the app and re-pair it. Refer to the Help screen in the app Profile menu for additional information on unpairing a connected pump and pairing a new device. If the issue persists, contact 24-Hour Technical Support for assistance.
The pump disconnects from the app due to pump battery life depletion.	The pump disconnects from the app ten minutes after the battery life has depleted. This means the pump has lost communication and a gray dot icon appears on the pump device status icon. The app alerts you that your pump battery needs to be charged. Place the pump on the charger until connection is restored to fully resolve the issue. If communication is not restored within 10 minutes, tap the gray pump device icon and follow the steps in the app.
The pump buttons are stuck.	Although it is rare, sometimes the pump buttons can get stuck. If this occurs, wait for the problem to correct itself. If a button on the pump has been pressed for more than 3 minutes, a Button error alert will occur. Press and release each button on the pump. If these steps do not correct the problem, contact 24-Hour Technical Support for assistance.
The oval Status light alternates red and yellow while on the charger.	The oval Status light alternates red and yellow when the pump is on the charger, but is operating with extremely low-power. The pump cannot communicate with the app, and does not make any beeps or vibrations. 1. Press and hold both round Action button and oval Status button for 15 seconds to restart the pump. 2. Leave the pump on the charger until fully recharged.
The oval Status light pulses in red	The oval Status light pulses in red when the pump is not properly charging (slowed or paused) because the pump or charger are too hot or too cold.

Issue	Resolution
while on the charger.	The pump cannot communicate with the app, and does not make any beeps or vibrations. Move your pump and charger to charging temperature range 41.0 °F to 93.2 °F (5.0 °C to 34.0 °C). Once the pump and charger are within the charging temperature range, pump begins charging and communicating with app.
The pump cannot communicate with the app, and the oval Status light flashes in red.	The pump cannot communicate with the app, and the oval Status light flashes in red. Your pump is not working properly because a critical pump error occurred, and insulin is suspended. Stop using your pump and remove the infusion set from your body. Check your blood glucose. Contact 24-Hour Technical Support. Insulin delivery is still required when the pump is removed. Consult a healthcare professional to determine an alternate method of insulin delivery while the pump is removed.

Sensor issues

Issue	Resolution
The system has lost connection with the sensor.	After 30 minutes without communication between the pump and sensor, the No SG values >30 minutes alert occurs. Follow the steps in the app or the steps below to try to resolve the issue. **Note:** If alerts are muted and a sensor alert occurs, the alert still appears on the screen. 1. Move the pump closer to the sensor. It can take up to 15 minutes for the pump and sensor to communicate again. 2. Move away from electronic devices, such as microwaves, Wi-Fi routers, and other smart devices or household appliances that may cause interference. Wait 15 minutes for the pump and sensor to communicate again. 3. Consider replacing sensor.

General warnings (pump and charger)

- Do not use the MiniMed Flex system until appropriate training has been received from a healthcare professional. Training is essential to ensure the safe use of the MiniMed Flex system.

- Do not use the pump in the presence of anesthetic mixtures that include oxidizing agents such as oxygen or nitrous oxide. Exposure to these conditions may damage the pump and result in serious injury.
- If insulin that was programmed into the pump was not the user's actual insulin delivery, clear active insulin and the total daily doses tracked by SmartGuard mode before using SmartGuard mode. Failure to do so may result in the delivery of too little or too much insulin, which can cause hyperglycemia or hypoglycemia. SmartGuard mode uses the recent delivery history on the pump to determine the insulin delivery amount.

  Consult your healthcare professional about using Clear Active Insulin to clear both active insulin and the total daily dose for SmartGuard mode.
- Always keep the charger and pump between 41 °F to 93 °F (5 °C to 34 °C) when charging. If the charger is too cold or too hot, it may not charge the pump properly, which may result in a delay in therapy, diabetic ketoacidosis, or hyperglycemia.
- Never expose the pump to temperatures below -4 °F (-20 °C) or above 122 °F (50 °C). Storing the pump in temperatures outside of this range can damage the pump.
- Do not use the pump if your paired mobile device is broken or if the screen is unreadable. If you cannot see or respond to alerts, you will not be able to control your pump, leading to hyperglycemia or hypoglycemia. Use alternate means of delivering insulin therapy until you can pair a replacement mobile device to the pump.
- Only clear active insulin if directed by your healthcare professional. Clearing active insulin without the advice of your healthcare professional, can lead to inaccurate bolus calculation, possibly leading to hypoglycemia.
- Do not rely on active insulin tracked in the pump when giving any bolus after active insulin has been reset to zero. Relying on the active insulin shown in the app can result in the infusion of too much insulin, which can cause hypoglycemia.
- After shutting down and restarting the pump, do not rely on active insulin tracked in the pump when making new Bolus calculator calculations. Turning off the pump clears active insulin. Inaccurate Bolus calculator calculations may result in inaccurate insulin delivery and serious injury.

- Do not rely solely on the sound or vibration notification when using the sound or vibrate options. These notifications may not occur as expected if the speaker or vibrator in the pump or App Manager malfunctions. A missed notification may result in the delivery of too much or too little insulin. Contact 24-Hour Technical Support with any concerns.
- You must have the volume set to an appropriate level to hear alerts. Setting the volume too low may result in missing alerts, leading to a delay in therapy or hyperglycemia.
- Always confirm that the infusion set tubing is disconnected from the body before doing the following steps:
  - while training to use the pump
  - placing the reservoir into the pump
  - rewinding the pump
  - loading the reservoir
  - filling the infusion set tubing

  Failing to disconnect the infusion set tubing from the body may result in an accidental infusion of insulin, and may cause hypoglycemia.
- Check the infusion set to confirm that no air bubbles are present in the tubing. Air in the tubing may result in inaccurate insulin delivery, and result in hyperglycemia.
- Do not insert an insulin-filled reservoir before rewinding the pump. Doing so may result in an accidental infusion of insulin, and may result in hypoglycemia.
- Do not use the MiniMed Flex pump or additional system devices next to other electrical equipment, which may cause interference. This includes mobile communication devices such as cell phones that are not paired with the MiniMed Flex system, GPS navigation systems, anti-theft systems, and any electrical equipment that has an output transmitter power greater than 1 W. The recommended separation distance between the insulin pump and common RF emitters is 12 in (30 cm). Other electrical equipment that may compromise normal system operation has been contraindicated.

- Only use compatible U-100 insulin (Humalog, NovoLog, Fiasp, Lyumjev, or Admelog, [for the approved age indication]) prescribed by a healthcare professional for use with an infusion pump. Use of any other drug or medication in the reservoir can cause serious injury.
- The safety of the MiniMed Flex system has not been studied in persons with impaired kidney function. Persons with kidney disease should consult a healthcare professional to determine if the potential benefits of pump therapy outweigh the risks.
- Monitor for diabetic retinopathy. During the beginning of insulin pump therapy, rapid improvement in glucose control and reduction in A1c may result in worsening of existing diabetic retinopathy. Use of the MiniMed Flex system has been associated with rapid improvement in glucose control. Monitor for diabetic retinopathy with retinal eye examinations and if necessary adequate treatment must be performed by a healthcare professional before beginning a treatment with the MiniMed Flex pump.
- The safety of the MiniMed Flex system has not been studied in pregnant women or in persons using other anti-hyperglycemic therapies that do not include insulin. Persons in these situations should consult a healthcare professional to determine if the potential benefits of pump therapy outweigh the risks.
- When the system is delivering a bolus, always tap the bolus delivery banner to stop bolus insulin delivery. Do not use the Suspend all delivery feature to stop bolus insulin. The Suspend all delivery feature stops both basal insulin and bolus insulin delivery. Failure to resume basal insulin delivery could result in too little insulin, which may cause hyperglycemia.
- The pump is intended to be used with a basal pattern. A basal pattern must be manually entered into the app before the pump can deliver insulin. Consult a healthcare professional to determine what basal pattern is needed.
- Confirm a basal pattern is entered. If a basal pattern is needed but not entered and saved, this could result in an under-delivery of basal insulin. Under-delivery of insulin can potentially cause severe hyperglycemia, which may lead to diabetic ketoacidosis.

- The user must have adequate vision and hearing to recognize all functions of the pump, including alerts, alarms, and reminders. Not recognizing an alert, alarm, or reminder could result in a hypoglycemic or hyperglycemic event.
- Use a stable internet connection throughout the entire software update process. Avoid the use of unsecure Wi-Fi™* networks or public Wi-Fi™* hotspots.
- Always monitor your glucose during air travel. Changes in air pressure that occur during flight takeoff and landing can cause over-delivery or under-delivery of insulin, which may result in hypoglycemia or hyperglycemia. Be ready to respond to alerts and symptoms. Talk with your healthcare professional to see if you need a different treatment plan in place.
- It is important to keep the location of your pump stable relative to your infusion site. Do not wear or place your pump more than 14 in (35.5 cm) above your infusion site. Doing so can cause an over-delivery of insulin, which may result in hypoglycemia.
- Only use the power adapter provided by Medtronic. Using any other power adapter may lead to damage to the pump, leading to delay in therapy, which may result in hyperglycemia.
- Always keep foreign material (such as metal, liquids, or dust) away from the charging points on the charger and on the pump. Foreign material on the charging points can overheat and prevent the pump from charging properly, which may result in burns when removing the material or low pump battery. Always inspect the charging points of the pump and charger to confirm that there is no foreign material.
- The pump and charger should be kept a minimum of 6 in (15 cm) away from any implanted device, such as pacemakers and defibrillators. The pump and charger contain magnets that may temporarily interfere with implanted devices. Exposure of an implanted device to the magnetic field may result in malfunction, leading to serious harm or death.

Exposure to magnetic fields and radiation (pump and charger)

- Do not expose the pump or charger to MRI equipment, diathermy devices, electrocautery devices, or other devices that generate strong magnetic fields (for

example, x-ray, CT scan, or other types of radiation). Strong magnetic fields can cause the system to malfunction, and result in serious injury. If the pump is exposed to a strong magnetic field, discontinue use and contact 24-Hour Technical Support for further assistance.

Magnetic fields, and direct contact with magnets, may affect the accurate functioning of the system which may lead to health risks such as hypoglycemia or hyperglycemia.

- Remove the pump and the App Manager or mobile device before entering a room with x-ray, MRI, diathermy, electrocautery devices, or CT scan equipment. The magnetic fields and radiation in the immediate vicinity of this equipment can make the devices nonfunctional or damage the part of the pump that regulates insulin delivery, possibly resulting in over-delivery and severe hypoglycemia.
- Do not expose the pump to a magnet, such as pump cases that have a magnetic clasp. Exposure to a magnet may interfere with the motor inside the pump. Damage to the motor can cause the device to malfunction, and result in serious injury.
- Do not send the pump or sensor through an x-ray scanning machine. The radiation can damage the pump components that regulate insulin delivery, and may result in over-delivery of insulin and hypoglycemia.

  All system components, including the pump and sensor, must be removed prior to being screened with an airport full-body scanner. To avoid system removal, request an alternative screening method, if necessary.
- The MiniMed Flex system is suitable for use in aircraft. When flying in an aircraft, it is important to keep the pump connected to the body and check glucose levels frequently. Check that the MiniMed app has maintained Bluetooth connection while in Airplane mode to ensure you receive alerts and notifications.
- If other devices that employ radio frequencies are in use, such as cell phones that are not paired with the MiniMed Flex system, cordless phones, walkie-talkies, and wireless networks, they may prevent communication between the sensor and the insulin pump. This interference does not cause any incorrect data to be sent and does not cause any harm to devices. Moving away from, or turning off, these other

devices may enable communication. Contact 24-Hour Technical Support if RF interference continues.

- Special Precautions regarding Electromagnetic Compatibility (EMC): This body-worn device is intended to be operated within a residential, domestic, public or work environment, where common levels of radiated "E" (V/m) or "H" fields (A/m) exist. Technologies that emit these fields include: cellular phones that are not paired with the MiniMed Flex system, wireless technology, electric can openers, microwaves, and induction ovens. The MiniMed Flex system 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 the operation of the MiniMed Flex system. If interference occurs, move away from the RF transmitter.
- The MiniMed Flex pump can generate, use, and radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. If the MiniMed Flex pump does cause interference to radio or television reception, try to correct the interference by one or more of the following measures:
  - Decrease the distance between the sensor and the insulin pump to 6 feet (1.8 meters) or less.
  - Decrease the distance between the App Manager or compatible mobile device and the insulin pump to 6 feet (1.8 meters) or less.
  - Increase the separation between the sensor and the device that is receiving/emitting interference.

Reservoir and infusion sets

For the most current warnings, see the user guides that were provided with reservoir and infusion set.

- Confirm that the infusion set selected on screen matches the infusion set you are using. Different infusion sets may have different instructions for insertion into the body. All procedures onscreen must be followed to change the reservoir and

infusion set. Using an incorrect infusion set or failing to follow all procedures may result in hypoglycemia or hyperglycemia.

- Always wash hands with soap and water before temporarily disconnecting the infusion set to prevent infection. Consult a healthcare professional for ways to compensate for missed insulin while the infusion set is disconnected to prevent hyperglycemia.
- Do not reuse the infusion set. Reuse of the infusion set may damage the cannula or needle, and lead to infection, site irritation, inaccurate insulin delivery, and diabetic ketoacidosis.
- Do not use an infusion set beyond the Use-by date, or if the package is opened or damaged, as sterility may be compromised or cause infection or hyperglycemia.
- If insulin, or any other liquid, gets inside the tubing connector, it can temporarily block the vents that allow the pump to properly fill the infusion set. This may result in the infusion of too little or too much insulin, and may result in hyperglycemia or hypoglycemia. If this occurs, start over with a new reservoir and infusion set.
- If a blood glucose (BG) reading is unexpectedly high during the infusion of insulin or if an occlusion alarm occurs, check the infusion set for clogs and leaks.

  If in doubt, change the infusion set in case the soft cannula is dislodged, crimped, or partially clogged. Consult a healthcare professional to create a plan for rapid insulin replacement in the event this occurs. Check blood glucose (BG) to confirm that the appropriate amount of insulin has been administered.
- Only use reservoir and infusion sets manufactured or distributed by Medtronic Diabetes. The pump has been tested to operate when used with compatible reservoirs and infusion sets. Medtronic Diabetes cannot guarantee appropriate operation if the pump is used with reservoirs or infusion sets offered by third parties. Use of incompatible reservoirs or infusion sets may lead to hyperglycemia, hypoglycemia, and diabetic ketoacidosis. Medtronic Diabetes is not responsible for any injury or pump malfunction that may occur in association with the use of incompatible components.
- Never leave the app on the Confirm fill amount screen. Insulin delivery is suspended while on the Confirm fill amount screen. Always confirm the fill amount

to avoid continued insulin delivery suspension. Prolonged suspension of insulin delivery may cause hyperglycemia.

Meter

For the most current warnings, see the user's manual that came with the meter.

General precautions (pump and charger)

Always consult the alert description shown in the MiniMed app before delivering treatment. Delivering treatment without reviewing the alert message may lead to incorrect treatment or hypoglycemia.

The pump does not notify the user of leaks in the infusion set or degradation of insulin. If blood glucose (BG) is too high, check the pump and the infusion set to confirm that the necessary amount of insulin is being delivered.

Do not use sharp objects to press the pump buttons. The use of sharp objects can damage the pump.

Check for adverse reactions where the pump comes into contact with skin. These reactions include redness, swelling, irritation, sensitization, rash, and other allergic reactions. Do not allow the pump to come into contact with skin wounds, as the pump materials have only been evaluated for safe contact with intact skin.

Never use organic solvents, such as lighter fluid, nail polish remover, or paint thinner to clean the MiniMed Flex pump. Never use lubricants with the pump. When the pump is being cleaned, be sure to keep the reservoir compartment dry and away from moisture. If organic solvents are used to clean the pump, they can cause the pump to malfunction and result in injury.

If the pump was dropped, hit, or damaged, monitor your glucose levels for the next 4 hours. Inspect the pump for cracks before exposing the pump to water. Water leakage can cause the pump to malfunction and result in injury.

The pump contains a battery. Disposal of the pump in any receptacle that could be exposed to extreme heat may cause the battery to ignite and result in serious injury. Always follow local laws and regulations for the disposal of medical devices.

Infusion sets and sites, sensor, and meter

Refer to the corresponding device user guide for all warnings, precautions, and instructions relating to the device. Failure to reference the corresponding device user guide can result in minor injury, or damage to the device.

Do not use the same infusion set insertion site for an extended period of time. This may cause the site to become overused. Rotate the infusion set insertion sites regularly.

Always change the infusion set as indicated by the infusion set user guide. Using the same infusion set for an extended period of time beyond its product labeling can cause infusion set occlusion or site infection.

Risks and side effects (pump)

Risks related to insulin administration and pump use

Risks related to insulin infusion and potential interruptions of insulin delivery include:

- Hypoglycemia
- Hyperglycemia
- Diabetic ketoacidosis
- Seizure
- Coma
- Death

Risks related to insulin pump infusion set

Risks related to insulin pump infusion set use include:

- Localized infection
- Skin irritation or redness
- Bruising
- Discomfort or pain
- Bleeding
- Irritation

- Rash
- Occlusions that may interrupt insulin delivery and lead to hyperglycemia and diabetic ketoacidosis

Follow the instructions in the provided user guides for the insertion and care of infusion sets. If an infusion site becomes irritated or inflamed, dispose of the infusion set in a sharps container, and select a different location to insert a new infusion set.

Risks related to the MiniMed Flex system

- Hypoglycemia
- Hyperglycemia
- Diabetic ketoacidosis
- Seizure
- Coma
- Death

General warnings (MiniMed app)

- If you are using Apple iOS 17 or higher, it is recommended to turn off the Assistive Access feature, if enabled. The Assistive Access feature of iOS may prevent the phone from properly opening, managing care partners or displaying onscreen instructions. Using the Assistive Access feature may result in over-delivery of insulin, which may lead to hypoglycemia.
- Keep the MiniMed app open at all times during therapy. Alerts do not display if the app is closed, causing a delay in therapy, possibly leading to hyperglycemia, hypoglycemia, or diabetic ketoacidosis.
- Do not rely on pump alerts, alarms, or reminders alone to check blood glucose (BG) levels. Set additional reminders on other compatible devices, such as a cell phone.

Cybersecurity

MiniMed Flex pump

The MiniMed Flex pump is designed with cybersecurity protections to keep data secure on the device and when communicating with the MiniMed app and compatible glucose sensors. These protections include encryption, integrity checks, and authentication checks. They are set in the factory and are ready to use when the insulin pump is received. The MiniMed Flex pump will detect security events and will inform the user when action is needed. Refer to the System Technical guide located in the MiniMed app for more information. The sensor uses Bluetooth®* Low Energy (BLE) communication to connect to compatible glucose sensors and MiniMed app. Refer to the sensor user guide for steps to ensure their security.

Medtronic will inform you when the pump reaches its end of life and end of support. Medtronic will inform you when a new version of software for the pump becomes available.

To keep the MiniMed Flex pump and data secure, follow the security guidelines provided.

- Perform pairing with MiniMed app and compatible glucose sensors in a private location.
- Do not leave the insulin pump or paired sensor unattended.
- Do not share the serial number or code of your insulin pump.
- Never use a pump that has a broken case or seal. Use of a pump with a broken seal or case may reduce cybersecurity protections for your therapy and data.
- Install updates for pump software when they become available from Medtronic.

MiniMed app

The MiniMed app has been designed with cybersecurity protections to help keep your data secure on your mobile device and when communicating with your devices and Medtronic. These protections include encryption, integrity checks, and authentication checks. The MiniMed app will detect security events and will inform the user when action is needed. Refer to the System Technical guide located in the MiniMed app for

more information. The MiniMed app uses Bluetooth Low Energy (BLE) to connect to MiniMed Flex pump.

To keep the MiniMed app and data secure, follow the security guidelines provided:

- Do not leave the mobile device unattended.
- Use caution when viewing or sharing data with others.
- Do not share your CareLink username and password with others.
- Enable a security lock on the mobile device. When the mobile device is not in use, lock it. Do not share your passcode or PIN with others.
- Keep your mobile device up to date with the latest security updates.
- Confirm version compatibility of the MiniMed app and operating system prior to updating your paired mobile device. Disable automatic operating system updates on your paired mobile device to avoid any unintentional updates that may prevent the app from operating, resulting in loss of alerts or therapy.
- Do not remove or interfere with the security features on your mobile device, such as Google Play Protect.
- Do not attempt to modify the operating system, jailbreak the device, root the device, or enable developer options. Any of these modifications may reduce the protection provided by your mobile device.
- Perform pairing with MiniMed Flex pump in a private location.
- Use only the official application store, such as the Apple App Store or the Google Play Store to get all mobile applications for the 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.

Uninstalling the app will remove all health and personal data stored by the MiniMed app from the mobile device.

Cybersecurity assistance

For questions or concerns about the cybersecurity of the MiniMed Flex pump or MiniMed app, refer to the System Technical guide located in the MiniMed app or visit www.minimed.com/security.

Reporting serious incidents

If a serious incident related to the device occurs, immediately report the incident to Medtronic and to the applicable competent authority with jurisdiction in their locale. Serious incidents may include death, temporary or permanent serious decline in health, or a serious public health threat. For healthcare professionals, immediately report any serious incident to the applicable competent authority.

5

Continuous Glucose Monitoring

5 Continuous Glucose Monitoring

Continuous glucose monitoring (CGM) uses a sensor to continuously measure the amount of glucose in interstitial fluid. It can be used to help identify sensor glucose (SG) trends.

CGM consists of the following items:

- Sensor glucose (SG) values that update every 5 minutes.
- Alerts that occur based on current and predicted high and low glucose levels.
- A graph (Trend graph) that shows glucose trends over time.
- Trend arrows that show the rate at which the most recent sensor glucose (SG) values rise or fall.

When CGM in Manual mode is active, the app alerts you when sensor glucose (SG) changes too rapidly and when it approaches or reaches values outside the glucose limits, based on your settings. The suspend features use sensor glucose (SG) values when CGM in Manual mode is active.

Because glucose is moving, blood glucose (BG) meter readings and sensor glucose (SG) values will be close, but will not always match. This difference is normal and should be expected. Sensor accuracy data can be found in *Performance data, page 133*.

CGM provides the following resources to keep you informed about your glucose:

- It tracks and displays sensor glucose (SG) values throughout the day and night.
- It shows the effects that diet, exercise, and medication can have on glucose levels.
- It provides alerts to help prevent high and low glucose levels.

Using CGM

CGM requires the following items to operate:

- MiniMed app
- MiniMed Flex pump
- Sensor alert settings provided by a healthcare professional
- Compatible sensor

Sensor glucose (SG) values are unavailable in the following situations:

- When a new sensor is started
- When an alert occurs notifying you that there is no sensor information available
- When the sensor requires a new blood glucose (BG) meter reading to be entered because the system was unable to use your last entry to update the sensor

Inserting the sensor

Refer to the user guide that came with your sensor for age range, insertion sites, and warm-up period.

Updating the sensor

Updating the sensor is the process of using a blood glucose (BG) meter reading to help the sensor glucose (SG) values more closely match the glucose measured in your blood.

Every blood glucose (BG) meter reading entered as a logged event or entered in the Bolus calculator is used to update the sensor. Do not enter a sensor glucose (SG) value in blood glucose (BG) fields in the app.

Use a blood glucose (BG) meter reading in the following circumstances:

- Anytime you enter a glucose entry into the app
- Anytime you deliver a bolus in Manual mode and you want to include a correction for high glucose in the calculation
- Anytime the system requests a blood glucose (BG) meter reading

General warnings (CGM)

Sensor

All system components, including the pump and the Simplera Sync sensor, must be removed prior to being screened with an airport full-body scanner. To avoid system removal, request an alternative screening method, if necessary.

For the most current warnings, see the user guide that came with the sensor.

- Read the entire sensor user guide before attempting to insert the Simplera Sync sensor. The inserter portion of the sensor does not work the same way as other Medtronic insertion devices. Failure to follow directions may result in improper insertion, pain, or injury.
- Do not use continuous glucose monitoring if hydroxyurea, also known as hydroxycarbamide, is taken. Hydroxyurea is used to treat certain diseases, such as cancer and sickle cell anemia. Hydroxyurea use results in higher sensor glucose values compared to blood glucose readings. Taking hydroxyurea while using continuous glucose monitoring can result in hypoglycemia caused by over-delivery of insulin, inaccurate or missed alarms and alerts, delay or loss of sensor-enabled insulin suspension, and substantially higher sensor glucose values in reports than actual blood glucose readings.

  Always check the label of any medication being taken to confirm if hydroxyurea or hydroxycarbamide is an active ingredient. If hydroxyurea is taken, consult a healthcare professional. Use additional blood glucose meter readings to verify glucose levels.
- Consult a healthcare professional if a medication that contains acetaminophen or paracetamol is taken while wearing the sensor. Medications that contain acetaminophen or paracetamol can falsely raise sensor glucose (SG) values. The level of inaccuracy depends on the amount of acetaminophen or paracetamol active in the body and can differ for each person. Falsely elevated sensor values can result in over-delivery of insulin, which can cause hypoglycemia. Medications that contain acetaminophen or paracetamol include, but are not limited to, cold medicines and fever reducers. Check the label of any medications being taken to see if acetaminophen or paracetamol is an active ingredient. Use additional blood glucose (BG) meter readings to confirm blood glucose (BG) levels.

- Do not expose the Simplera Sync sensor to MRI equipment, diathermy devices, electrocautery devices, or other devices that generate strong magnetic fields (for example, x-ray, CT scan, or other types of radiation).
- Remove the Simplera Sync sensor before entering a room with x-ray, MRI, diathermy, electrocautery, or CT scan equipment.
- Report any adverse reactions associated with the Simplera Sync sensor to 24-Hour Technical Support. Adverse reactions can cause serious injury.

General precautions (CGM)

Refer to the corresponding device user guide for all warnings, precautions, and instructions relating to the device. Failure to reference the corresponding device user guide can result in minor injury, or damage to the device.

Adverse reactions

Refer to the sensor user guide for adverse reactions related to sensor use. Failure to reference the sensor user guide may result in minor injury, or damage to the sensor.

Risks and side effects (CGM)

Risks related to sensor use

Do not use continuous glucose monitoring if hydroxyurea, also known as hydroxycarbamide, is taken. Hydroxyurea is used to treat certain diseases, such as cancer and sickle cell anemia. Hydroxyurea use results in higher sensor glucose readings compared to blood glucose readings. Taking hydroxyurea while using continuous glucose monitoring can result in hypoglycemia caused by over-delivery of insulin, inaccurate or missed alarms and alerts, delay or loss of sensor-enabled insulin suspension, and substantially higher sensor glucose readings in reports than actual blood glucose readings.

Always check the label of any medication being taken to confirm if hydroxyurea or hydroxycarbamide is an active ingredient. If hydroxyurea is taken, consult a healthcare professional. Use additional blood glucose meter readings to verify glucose levels.

Do not use sensor glucose (SG) values to make treatment decisions, including delivering a bolus, while the pump is in Manual mode. When the SmartGuard mode is

active and you are no longer in Manual mode, the pump uses a sensor glucose (SG) value, when available, to calculate a bolus amount. However, if your symptoms do not match the sensor glucose (SG) value, use a blood glucose (BG) meter to confirm the sensor glucose (SG) value. Failure to confirm glucose levels when your symptoms do not match the sensor glucose (SG) value can result in the infusion of too much or too little insulin, which may cause hypoglycemia or hyperglycemia.

6

Suspend features

6 Suspend features

When you are in Manual mode, Suspend features automatically suspend insulin when you are approaching, reach, or fall below the Suspend limit that you set. These suspend features, Suspend before low and Suspend on low, help to minimize hypoglycemia.

Note the following when selecting your suspend feature settings:

- You can set your Suspend limit from 55 mg/dL to 90 mg/dL.
- The Suspend before low feature is turned on by default, with a Suspend limit of 55 mg/dL.
- Suspend before low and Suspend on low cannot be on at the same time.
- If both Suspend before low and Suspend on low are turned off, your insulin delivery is automatically suspended if your glucose reaches or falls below 54 mg/dL.
- Different settings can be set for day and night.

Consult your healthcare professional before changing your Suspend features settings.

Whenever your insulin delivery is suspended, a Status banner appears on the Home screen. When a Suspend feature suspends insulin, the Suspend features icon flashes on the Home screen and the Trend graph shows a yellow band.

The Suspend features are used in Manual mode only. When SmartGuard mode is active, SmartGuard mode determines when to stop delivering insulin.

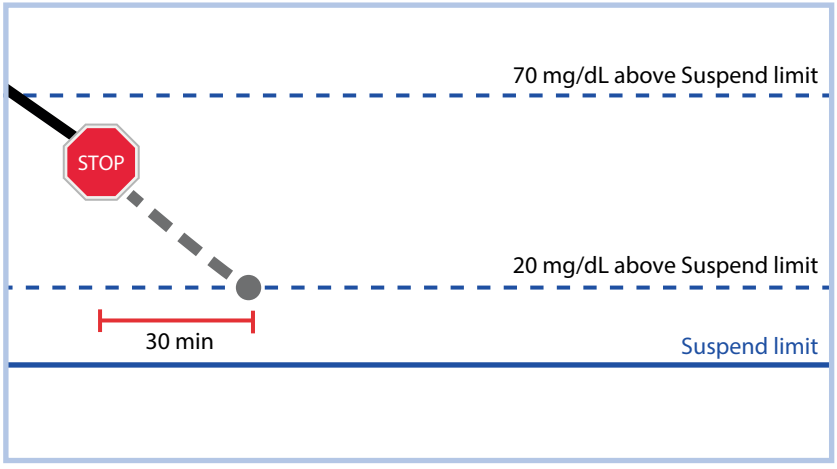
Suspend before low

You can use the Suspend before low feature to suspend insulin delivery before your sensor glucose (SG) value reaches your Suspend limit. Suspend before low suspends insulin delivery if your sensor glucose (SG) meets the following conditions:

- It is at or within 70 mg/dL above your Suspend limit.
- It is predicted to be at or below a level that is 20 mg/dL above your Suspend limit within approximately 30 minutes.

If you turn the Alert for Suspend before low feature on, you are alerted when your insulin delivery is suspended by the Suspend before low feature. Regardless of your settings, the system alerts you if your sensor glucose (SG) reaches your Suspend limit after your delivery has been suspended by the Suspend before low feature.

The following figure shows an example of insulin being suspended when the Suspend before low conditions are met.



Suspend on low

You can use the Suspend on low feature to suspend insulin delivery when your sensor glucose (SG) value reaches or falls below your Suspend limit. This feature can be used for situations when you cannot respond to a low glucose condition.

You are alerted if insulin delivery is suspended by the Suspend on low feature.

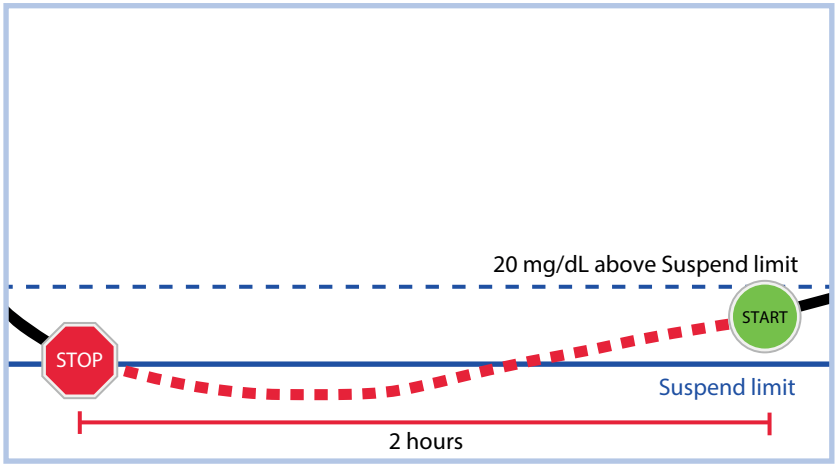
Resuming insulin delivery

If insulin is suspended due to a Suspend feature, basal insulin delivery automatically resumes under the following conditions:

- If insulin is suspended for a minimum of 30 min, and sensor glucose (SG) values are at least 20 mg/dL above the Suspend limit and expected to be more than 40 mg/dL above the Suspend limit within 30 min
- If insulin is suspended after the maximum 2-hour time limit

You are alerted if basal delivery resumes when maximum suspend time is reached. You can manually resume insulin delivery at any time.

The following figure shows an example of insulin delivery resuming when the maximum 2-hour time limit is reached after insulin is suspended by the Suspend on low feature.



Suspend features unavailability

After a Suspend feature suspends insulin, the Suspend features are not active for a temporary period of time to help prevent prolonged suspension of insulin delivery. During this time, the Home screen shows the Suspend feature icon with a red X to indicate that the Suspend features are unavailable.

If you have Suspend before low turned on, you are alerted when insulin is suspended.

Your response to the alert may impact the availability of the suspend features:

- Suspend before low
- Suspend on low
- Suspend limit reached
- Max suspend reached - Basal resumed
- CALL FOR EMERGENCY ASSISTANCE: I HAVE DIABETES

The table below shows the duration of time that the suspend feature is unavailable depending on how you respond.

Response to suspend feature and alert	Availability of suspend features
You manually resume basal insulin delivery before the max 2-hour suspend time is reached.	Unavailable for 30 minutes after basal insulin delivery resumes
You do not receive an alert, and basal insulin delivery automatically resumes.	Unavailable for 30 minutes after basal insulin delivery resumes
You respond to the alert within 30 minutes after basal insulin delivery automatically resumes.	Unavailable for the time remaining in the 30 minutes after basal insulin delivery resumes
You respond to the alert between 30 minutes and 4 hours from the time that basal insulin delivery automatically resumes.	Available
You do not respond to the alert in under 4 hours from the time that basal insulin delivery automatically resumes.	Unavailable for 4 hours after basal delivery automatically resumes

SmartGuard mode does not use the Suspend features to suspend insulin. If you exit SmartGuard mode, your Suspend before low and Suspend on low settings resume the way you set them.

General warnings (Predictive Low Glucose technology)

- Do not use the Bolus calculator to calculate a bolus for a period of time after giving a manual injection of insulin by syringe or pen. Manual injections are not accounted for in the active insulin amount. Using the Bolus calculator too soon after a manual injection may result in over-delivery of insulin and may cause

hypoglycemia. Consult a healthcare professional for how long to wait after a manual injection before using the Bolus calculator.

- The low sensor glucose (SG) alert functionality is distinct from the automated insulin dosing function of the MiniMed Flex system. When using the SmartGuard feature, the MiniMed Flex system has been shown to be safe and effective for its intended use in this population. However, do not rely solely on the use of the Low sensor glucose (SG) alarm, or the use of "Alert on Low" and "Alert before Low" when those alerts are set at or below 60 mg/dL. At these blood glucose (BG) levels, a low SG alarm or alert may not reflect the user's true blood glucose (BG), and you may not be notified. Do not ignore symptoms of low glucose. Always confirm sensor glucose (SG) values with a blood glucose (BG) meter, and treat according to the recommendation of a healthcare professional. Solely relying on these sensor glucose (SG) alerts and values for treatment decisions could result in missing severe hypoglycemia (low blood glucose (BG)) events.
- The safety of using the Suspend before low and Suspend on low features in patients who have no pump experience is not known. The Suspend before low and Suspend on low features should not be used if insulin pump settings have not been previously established. Insulin pump settings include basal rates, insulin to carb ratio, and insulin sensitivity factors. Consult a healthcare professional before using the Suspend before low or Suspend on low features.
- Do not use the Suspend before low or Suspend on low features to prevent or treat low glucose. Always follow the instructions of a healthcare professional to treat low glucose. Using Suspend before low or Suspend on low features to prevent or treat low blood glucose (BG) may result in prolonged hypoglycemia.
- Do not use the Suspend before Low or Suspend on Low features without first reading the information in this user guide and receiving training from a healthcare professional. The Suspend before Low and Suspend on Low features temporarily suspend insulin delivery for a maximum of 2 hours. Under some conditions of use, the pump can suspend insulin delivery again, resulting in under-delivery. Prolonged under-delivery of insulin may increase the risk of hyperglycemia and diabetic ketoacidosis. Always be aware of symptoms. If symptoms don't match sensor glucose (SG) readings, confirm sensor glucose (SG) with a blood glucose (BG) meter reading.

- Do not use continuous glucose monitoring if hydroxyurea, also known as hydroxycarbamide, is taken. Hydroxyurea is used to treat certain diseases, such as cancer and sickle cell anemia. Hydroxyurea use results in higher sensor glucose values compared to blood glucose readings. Taking hydroxyurea while using continuous glucose monitoring can result in hypoglycemia caused by over-delivery of insulin, inaccurate or missed alarms and alerts, delay or loss of sensor-enabled insulin suspension, and substantially higher sensor glucose values in reports than actual blood glucose readings.

  Always check the label of any medication being taken to confirm if hydroxyurea or hydroxycarbamide is an active ingredient. If hydroxyurea is taken, consult a healthcare professional. Use additional blood glucose meter readings to verify glucose levels.

- Consult a healthcare professional if a medication that contains acetaminophen or paracetamol is taken while wearing the sensor. Medications that contain acetaminophen or paracetamol can falsely raise sensor glucose (SG) values. The level of inaccuracy depends on the amount of acetaminophen or paracetamol active in the body and can differ for each person. Falsely elevated sensor values can result in over-delivery of insulin, which can cause hypoglycemia. Medications that contain acetaminophen or paracetamol include, but are not limited to, cold medicines and fever reducers. Check the label of any medications being taken to see if acetaminophen or paracetamol is an active ingredient. Use additional blood glucose (BG) meter readings to confirm blood glucose (BG) levels.

7

SmartGuard

7 SmartGuard

SmartGuard mode uses carb information, sensor glucose (SG) values, and target values to control insulin delivery. It also can automatically deliver a correction bolus to help correct a high sensor glucose (SG) value. The MiniMed Flex pump requires a minimum of eight units and a maximum of 250 units per day to operate using SmartGuard mode. Manual injections of insulin, given without using your pump, are not accounted for in the active insulin amount used in SmartGuard mode calculations.

SmartGuard mode is designed to maximize the amount of time that glucose stays in the range of 70 mg/dL to 180 mg/dL. SmartGuard mode uses targets and automated insulin delivery to maximize time in range. The following table describes targets used by SmartGuard mode.

Glucose target	Details
SmartGuard target	• The SmartGuard target may be set to 100 mg/dL (default value), 110 mg/dL or 120 mg/dL, which is used to determine basal insulin. Consult a healthcare professional to determine which SmartGuard target to use to maximize time in range. • Auto Basal uses the SmartGuard target when a Temp target is not active.
Auto correction target	• The target for Auto correction boluses is a fixed target of 120 mg/dL used to determine bolus insulin. • The Bolus calculator in SmartGuard mode uses the Auto correction target when Temp target is not active.

Glucose target	Details
Temp target	• The Temp target is a fixed target of 150 mg/dL used to determine basal insulin and bolus calculations for a duration of time set, from 30 minutes to 24 hours. • Auto Basal and the Bolus calculator in SmartGuard mode use this fixed target value when Temp target is active.

Basal insulin in SmartGuard mode

SmartGuard mode automatically calculates and delivers basal insulin doses based on sensor glucose (SG) information.

Auto Basal

When SmartGuard mode is active, basal insulin doses are calculated to the SmartGuard target using sensor glucose (SG) values. The pump automatically delivers the calculated basal insulin. The automatic calculation and delivery of basal insulin is called Auto Basal.

Bolus insulin in SmartGuard mode

You can set SmartGuard mode to automatically determine and deliver correction boluses based on sensor glucose (SG) information. SmartGuard mode also calculates boluses using glucose and carb information that you enter when you want to deliver a bolus.

Auto correction

The pump may deliver a bolus automatically when the SmartGuard feature determines it is needed for correction, to maximize the time in range, between 70 mg/dL and 180 mg/dL. Because this is an automated bolus, no action is required. The Home screen shows when an Auto Correction bolus occurs.

An Auto correction bolus may be delivered as frequently as every five minutes if SmartGuard mode determines it is necessary to maximize your time in range.

Note that Auto correction uses sensor glucose (SG) values to determine bolus amounts, and the accuracy of sensor glucose (SG) values can be lower than the accuracy of blood

glucose (BG) meter readings. Auto correction is defaulted on and may be turned off in the SmartGuard settings.

Note: When using SmartGuard mode, meal boluses are still required.

Bolus calculator

WARNING: When the SmartGuard mode is active, sensor glucose (SG) readings are used to calculate basal insulin delivery and correction boluses. Do not use sensor glucose readings to make treatment decisions while the pump is in Manual mode. Sensor glucose and blood glucose (BG) values may differ. Sensor performance may occasionally vary from sensor to sensor and in different situations for a sensor, such as on the first day of use.

A blood glucose meter reading is required in the following situations:

- Before a correction bolus is given in Manual mode.
- The sensor glucose reading is lower than expected.
- The sensor glucose reading is higher than expected.
- Suspected hypoglycemia or symptoms of hypoglycemia.
- Suspected hyperglycemia or symptoms of hyperglycemia.
- Suspected diabetic ketoacidosis or symptoms of diabetic ketoacidosis.

Use the Bolus calculator when you want to deliver a bolus in SmartGuard mode. The Bolus calculator in SmartGuard mode adjusts the calculated bolus based on the information you enter.

The carb amount that you enter is used with sensor information to calculate the bolus to cover carbs that you eat or drink.

When you want to include current glucose information to calculate a bolus, a sensor glucose (SG) value or a blood glucose (BG) meter reading can be used. Glucose entries

are used to calculate a correction, which is included in the SmartGuard adjustment portion of the total calculated bolus. Do not enter a sensor glucose (SG) value in the blood glucose (BG) field.

Because the sensor measures glucose in the interstitial fluid, and not the blood, sensor glucose (SG) values and blood glucose (BG) meter readings may not be the same.

Note the following for using the Bolus calculator in SmartGuard mode:

- Anytime you eat or drink carbs, use the Bolus calculator to deliver a bolus.
- If a blood glucose (BG) meter reading is required, the option to use sensor glucose (SG) is not available.
- If a sensor glucose (SG) value shows on the Home screen but is not available in the Bolus calculator, the system determined that the sensor glucose (SG) value is not optimal to use in the calculation.
- The calculated bolus amount cannot be manually adjusted.
- The Square Wave and Dual Wave features are not available.

No correction is recommended in the Bolus calculator in the following situations:

- If the blood glucose (BG) reading or sensor glucose (SG) value used by the Bolus calculator is less than 120 mg/dL
- If the correction is calculated to 0.0 U after the pump accounts for active insulin
- If SmartGuard mode estimates that the current basal delivery is sufficient

Bolus adjustments

SmartGuard mode may make an additional adjustment to a calculated bolus. These are called SmartGuard adjustments on the Bolus calculator screen. SmartGuard adjustments are automatically calculated by the system and cannot be edited. Carb entries are saved for future SmartGuard adjustment calculations.

SmartGuard adjustments are made according to the following table.

Condition	Bolus adjustment
SmartGuard mode predicts a risk of hypoglycemia after a meal.	Bolus adjusted down

Condition	Bolus adjustment
A correction is calculated as part of the bolus, and SmartGuard mode does not predict a risk of hypoglycemia after a meal (such as when there is high glucose and low active insulin).	Bolus adjusted up

If the bolus amount is adjusted down to 0.0 U, then no bolus is delivered and carb entries are saved for future bolus adjustment calculations.

Temp target

At times when less insulin is needed, such as during exercise, a temporary glucose target (Temp target) of 150 mg/dL can be set. Consult a healthcare professional before using a Temp target.

When active, the Temp target is used for basal delivery and for bolus calculations. Auto Basal and the Bolus calculator in SmartGuard mode use the Temp target to determine insulin doses.

The Auto correction feature is not active when a Temp target is active. Auto correction resumes after the Temp target duration is completed if the Auto correction setting is on in the SmartGuard settings.

Activating SmartGuard mode

Warm-up period

SmartGuard mode requires a 48-hour warm-up period before it is available for use. This warm-up period begins at midnight after the pump starts delivering insulin, and it does not require sensor use. During the warm-up period, the pump collects and processes data for use by SmartGuard mode.

A basal pattern must be programmed for use during the SmartGuard warm-up period and for instances when the pump is in Manual mode. During the warm-up period, the pump should also be used to give boluses.

Requirements to activate

SmartGuard mode is activated when all the checklist requirements that are listed in the SmartGuard settings menu are met. The SmartGuard setting can be turned on at any

time, but SmartGuard mode is not active if there are checklist items that are not ready or are incomplete.

The checklist items that are required to activate SmartGuard mode are as follows:

- An acceptable blood glucose (BG) meter reading is entered.
- A sensor is paired and ready for use.
- There is not a bolus delivery in progress.
- Insulin delivery is not suspended.
- A carb ratio is set in the Insulin settings.
- A basal pattern with at least one basal rate is set in the Insulin settings.
- There is not a 5-hour active insulin update in progress.
- There is not a 48-hour SmartGuard warm-up in progress.

SmartGuard checklist items are marked with the following icons to indicate if the requirement is met:

- — Requirement not met
- — Requirement met

Home screen display

When the pump is using SmartGuard mode, the Home screen displays a blue shield next to the current sensor glucose (SG) value. A basal pattern is not shown on the Home screen because basal patterns are only active when using Manual mode.

Auto Basal and Auto correction deliveries are shown below the Trend graph. When Temp target is in use, a green bar is shown on the Trend graph and a banner appears with a countdown timer.

Staying in SmartGuard mode

When the pump requires an action to stay in SmartGuard mode, it delivers insulin at a fixed basal rate for up to a maximum of 4 hours and does not deliver Auto correction boluses. The fixed basal rate is based on insulin delivery history and glucose history. It

is a rate estimated by SmartGuard mode to minimize the risk of hypoglycemia while sensor glucose (SG) values are unavailable.

When SmartGuard mode uses this fixed basal rate, a timer appears next to the SmartGuard icon on the Home screen showing the amount of time remaining before you exit SmartGuard mode. Check the SmartGuard checklist for requirements that need to be met to return to the Auto Basal function and continue using SmartGuard mode.

Maintaining sensor glucose (SG) function

You are alerted if there is a problem with your sensor glucose (SG) information that requires a blood glucose (BG) entry to stay in SmartGuard mode. Follow alert instructions to continue using SmartGuard mode. Because the system exits SmartGuard mode after 4 hours that no sensor glucose (SG) information is received from the sensor, make sure that warm-up for a new sensor is completed within that time when changing the sensor.

The following list describes alert conditions that require an action from you to ensure you are receiving sensor glucose (SG) values to continue using SmartGuard mode:

- SmartGuard mode reached the time limit for minimum delivery, which is either 3 or 6 hours. The time limit depends on individual conditions.
- SmartGuard mode reached the time limit for maximum delivery, which is 7 hours.
- The system detected that sensor glucose (SG) values may be lower than actual glucose values.
- No sensor glucose (SG) information has been received for at least 30 minutes.
- There was an error updating the sensor.

Exiting SmartGuard mode

You can exit SmartGuard mode at any time by turning the SmartGuard setting off. You are alerted anytime you exit SmartGuard mode.

The top of the Home screen shows a white shield with a red X if SmartGuard mode is turned on in the settings but is not active because a requirement is not met.

SmartGuard mode may stop functioning under the following conditions:

- The pump has been delivering basal insulin based on insulin delivery history and glucose history, not Auto Basal calculations, for 4 hours.
- All insulin delivery has been manually suspended and has not resumed for 4 hours.
- Sensor has been unpaired from the system for more than 4 hours.

Returning to SmartGuard mode

You can return to SmartGuard mode by turning the SmartGuard setting on and ensuring all requirements listed in the SmartGuard checklist are met. A new blood glucose (BG) meter reading is required if you want to use SmartGuard mode after exiting.

Additional warm-up and update

If the pump is turned off for more than two weeks or if the active insulin is manually cleared in the app, the system requires another 48-hour warm-up period before SmartGuard mode is available for use.

Active insulin information is valid until one of the following conditions occurs, which restarts the 5-hour update time required before SmartGuard mode is available:

- When a complete pump reset caused by a loss of power or a software error occurs that clears the active insulin.
- When the insulin is resumed after being manually suspended for 4 hours or longer.
- When the pump is shut off for less than two weeks and a memory error occurs.

When to use blood glucose (BG) in SmartGuard mode

The system may require that you enter a blood glucose (BG) meter reading to continue using SmartGuard mode.

Enter a blood glucose (BG) meter reading into the app in the following situations when using SmartGuard mode:

- When the system requests a blood glucose (BG) meter reading
- When you want to include a correction in the calculated bolus using the Bolus calculator, and a sensor glucose (SG) value is not available

- When you are using a medication that impacts glucose levels, such as acetaminophen or paracetamol
- When you are experiencing symptoms that do not match your sensor glucose (SG) value
- When you are unsure if your sensor glucose (SG) value is correct
- When your sensor glucose (SG) values are unavailable

Insulin suspension and SmartGuard mode

When SmartGuard mode is active, the Suspend before low and the Suspend on low features are not in use. SmartGuard mode determines when to stop delivering insulin. If you exit SmartGuard mode, your Suspend before low and Suspend on low features resume the way you set them.

You can manually suspend all insulin delivery at any time from the Therapy Action menu. The SmartGuard icon on the Home screen indicates that insulin delivery using SmartGuard mode is paused when you suspend insulin delivery. You are automatically exited from SmartGuard mode by the system after 4 hours that your insulin delivery is suspended.

General warnings (SmartGuard)

- Do not use the SmartGuard mode for people who require less than eight units or more than 250 units of total daily insulin per day. A total daily dose of at least eight units, but no more than 250 units, is required to use the SmartGuard mode.
- When the SmartGuard mode is active, sensor glucose (SG) readings are used to calculate basal insulin delivery and correction boluses. Do not use sensor glucose (SG) readings to make treatment decisions while the pump is in Manual mode. Sensor glucose (SG) and blood glucose (BG) values may differ. Sensor performance may occasionally vary from sensor to sensor and in different situations for a sensor, such as on the first day of use.

  A blood glucose (BG) meter reading is required in the following situations:

  – Before a correction bolus is given in Manual mode.

  – The sensor glucose (SG) reading is lower than expected.

  - The sensor glucose (SG) reading is higher than expected.
  - Suspected hypoglycemia or symptoms of hypoglycemia.
  - Suspected hyperglycemia or symptoms of hyperglycemia.
  - Suspected diabetic ketoacidosis or symptoms of diabetic ketoacidosis.
- Do not use the Bolus calculator or SmartGuard mode to calculate a bolus for a period of time after giving a manual injection of insulin by syringe or pen. Manual injections are not accounted for in the active insulin amount. Using the Bolus calculator or SmartGuard mode too soon after a manual injection may result in over-delivery of insulin and may cause hypoglycemia. Consult a healthcare professional for how long to wait after a manual injection before using the Bolus calculator or SmartGuard mode.
- If the pump has been used in the last 21 days to practice button pressing, or if insulin that was programmed into the pump was not the user's actual insulin delivery, clear active insulin and the total daily doses tracked by SmartGuard mode before using SmartGuard mode. Failure to do so may result in the delivery of too little or too much insulin, which can cause hyperglycemia or hypoglycemia. SmartGuard mode uses the recent delivery history on the pump to determine the insulin delivery amount.

  Consult your healthcare professional about using Clear Active Insulin to clear both active insulin and the total daily dose for SmartGuard mode.
- While the SmartGuard mode is active, if acetaminophen or paracetamol is taken, program a temp target for up to 8 hours, or the amount of time recommended by a healthcare professional. Use blood glucose (BG) values instead of sensor glucose (SG) readings to calculate a meal bolus or correction bolus for up to 8 hours, or the duration recommended by a healthcare professional, after taking acetaminophen or paracetamol.

8

Product specifications

8 Product specifications

Specifications and settings

Applied part

The pump, with its reservoir and infusion set, and the sensor are classified as type BF applied parts.

MiniMed Flex pump is IPX4 rated without consumables installed and IP28 rated with consumables installed.

The device without consumables ensures protection against 180 degree spray from vertical orientation at 10 L/min for 10 minutes. The device with consumables installed ensures protection at a submersion depth in water of 8 feet for 105 minutes.

Charger is IP22 rated. The device ensures protection against solid objects larger than 12.5 mm (e.g., a finger) and a drip rate of 3 mm/min.

Configurable settings

Table 8. Basal delivery

Item	Range	Increments	Default
Basal pattern rate	0 U/hr, 0.05 U/hr – Max basal rate	0.025 U/hr	N/A
Basal pattern rate duration	30 min – 24 hr	30 min	N/A
Basal pattern segment	1 – 48 segments totaling a 24-hour period; 1 – 2 patterns	1 hr for 0.05 – 0.075 U/hr and 30 min for 0.1 U/hr - Max basal	N/A

Table 8. Basal delivery (continued)

Item	Range	Increments	Default
		rate; 1 pattern may be active at a time	
Max basal rate	0 U/hr, 0.05 – 15 U/hr	0.025 U/hr	2 U/hr
Temp basal duration	30 min – 24 hr	15 min	30 min
Temp basal percentage	0% – 200%	10%	100%
Temp basal rate	0 U/hr, 0.05 U/hr – Max basal rate	0.025 U/hr	N/A

Table 9. Bolus delivery

Item	Range	Increments	Default
Active insulin time	2 – 8 hr	15 min	4 hr
Average Delivery speed	N/A	N/A	10 U/min
Bolus increments	0.01 U or 0.1 U	N/A	0.1 U
Carb ratio segment	1 – 8 segments totaling a 24-hour period	30 min	1 segment
Carb ratio value	1.0 g/U – 200 g/U	0.1 g/U for the range 1.0 – 9.9 g/U; 1.0 g/U for the range 10.0 – 200 g/U	N/A
Dual Wave bolus duration	30 min – 8 hr	30 min	N/A
Dual Wave bolus, Now portion	0 – 100% of the bolus (percent is calculated from the units entered)	Depends on the units entered	50% percent of the carb estimate portion of the total bolus, plus the remainder of the total bolus in the Bolus calculator; 50% of Manual bolus
Dual Wave bolus, Square portion	0 – 100% of the bolus (percent is calculated from the units entered)	Depends on the units entered	50% of the carb estimate portion of the total bolus in the Bolus calculator; 50% of the Manual bolus

Table 9. Bolus delivery (continued)

Item	Range	Increments	Default
BG target segment	1 – 8 segments totaling a 24-hour period	30 min	1 segment
BG target value	60 – 250 mg/dL	1 mg/dL	N/A
Insulin sensitivity factor segment	1 – 8 segments totaling a 24-hour period	30 min	1 segment
Insulin sensitivity factor value	5 mg/dL/U – 400 mg/dL/U	1 mg/dL/U	N/A
Manual bolus value	0.05 U – Max bolus or 0.1 U – Max bolus	0.01 U or 0.1 U	N/A
Max bolus value	0 U – 25.0 U	0.1 U	10 U
Square Wave bolus duration	30 min – 8 hr for 0.6 U or greater; from 30 min up to 7 hr for 0.5 U or less, depending on the units of insulin entered	30 min	N/A

Table 10. Glucose alerts and suspend

Item	Range	Increments	Default
Alert before high	5 – 30 min before High limit, or off	5 min if on; N/A if off	Off; 15 min if turned on
Alert before low	On or off	N/A	Off
Alert for suspend before low	On or off	N/A	Off
Alert on high	On or off	N/A	Off
Alert on low	On or off	N/A	Off
Fall alert	Falling at 1.0 – 3.0 mg/dL/min	1 mg/dL/min	Off; 3.0 mg/dL/min if turned on
High glucose alerts segment	1 (all-day) or 2 (day and night) totaling a 24-hour period	N/A for all-day; 1 min for day and night	1 segment
High limit	100 – 400 mg/dL	5 mg/dL	N/A
High glucose alerts snooze duration	10 min– 3 hr	5 min	2 hr

Table 10. Glucose alerts and suspend (continued)

Item	Range	Increments	Default
Low limit (Simplera Sync sensor)	65 – 90 mg/dL	5 mg/dL	N/A
Low glucose alerts segment (day and night)	1 (all-day) or 2 (day and night) totaling a 24-hour period	N/A for all-day; 1 min for day and night	1 segment
Low glucose alerts snooze duration	10 – 45 min	5 min	20 min
Max volume at night (low glucose and high glucose)	On or off	N/A	Off
Rise alert	Rising at 1.0 – 3.0 mg/dL/min	1 mg/dL/min	Off; 3.0 mg/dL/min if turned on
Suspend before low feature	On or off	N/A	On
Suspend limit	55 – 90 mg/dL	5 mg/dL	55 mg/dL
Suspend on low feature	On or off	N/A	Off

Table 11. SmartGuard settings

Item	Range	Increments	Default
Auto correction	On or off	N/A	On
SmartGuard target	100 – 120 mg/dL	10 mg/dL	100 mg/dL
Temp target duration	30 min – 24 hr	30 min	2 hr

Table 12. System alerts

Item	Range	Increments	Default
Lost pump communication	At 30 min or off	N/A	Off
Low pump battery (<10 hours)	Less than 10 hr life remaining or off	N/A	On
Low reservoir	5 – 50 U	5 U	20 U
Low sensor life (<12 hours)	Less than 12 hr of life remaining or off	N/A	Off

Table 12. System alerts (continued)

Item	Range	Increments	Default
Low sensor life (<24 hours)	Less than 24 hr of life remaining or off	N/A	Off
Set change	2 – 7 days or off	1 day	Off

MiniMed Flex Pump ACE Performance Characteristics

The MiniMed Flex 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 MiniMed.

Basal delivery

To assess basal delivery accuracy, 32 MiniMed Flex pumps were tested by delivering at minimum, intermediate, and max basal rates (0.05, 1.0, and 15 U/hr). Sixteen of the pumps were new, and 16 had been aged to simulate six months of shelf life and 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 their 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 the tables below.

Table 13. Minimum Basal Rate Delivery Performance (0.05 U/hr)

Basal Duration (Number of Units Delivered with 0.05 U/hr Setting)	1 hour (0.05 U)	6 hours (0.3 U)	12 hours (0.6 U)
Amount Delivered [min, max]	0.063 U [0.039 U, 0.093 U]	0.329 U [0.239 U, 0.393 U]	0.670 U [0.512 U, 0.775 U]

Table 14. Intermediate Basal Rate Delivery Performance (1.0 U/hr)

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]	0.94 U [0.86 U, 0.98 U]	5.84 U [5.41 U, 6.01 U]	11.75 U [11.55 U, 11.99 U]

Table 15. Maximum Basal Rate Delivery Performance (15.0 U/hr)

Basal Duration (Number of Units Delivered with 15.0 U/hr Setting)	1 hour (15 U)	6 hours (90 U)	12 hours (180 U)
Amount Delivered [min, max]	14.66 U [14.38 U, 14.77 U]	88.49 U [88.26 U, 88.72 U]	177.02 U [176.70 U, 177.43 U]

Bolus delivery

To assess bolus delivery accuracy, 32 MiniMed Flex pumps were tested by delivering consecutive minimum, intermediate, and max bolus volumes (0.05, 2.5, and 25 units). Sixteen of the pumps were new, and 16 had been aged to simulate six months of shelf life and 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 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. The table below shows average, minimum, and maximum bolus sizes observed. In addition, the tables in this section also show the number of boluses which were observed to be within the specified range for min bolus, intermediate bolus, and max bolus, respectively.

Table 16. Summary of Bolus Delivery Performance (n=32 pumps)

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)	0.05	0.049	0.006	0.076

Table 16. Summary of Bolus Delivery Performance (n=32 pumps) (continued)

Individual Bolus Accuracy Performance	Target Bolus Size (U)	Mean Bolus Size (U)	Min Bolus Size (U)	Max Bolus Size (U)
Intermediate Bolus Delivery Performance (n=800 boluses)	2.50	2.45	2.12	2.80
Max Bolus Delivery Performance (n=320 boluses)	25.00	24.61	24.23	24.89

Table 17. Min Bolus Delivery Performance (0.05U) (n=800 boluses)

	Units of Insulin Delivered After a 0.05 U Bolus Request									
	<0.013 (<25%)	0.013–0.038 (25–75%)	0.038–0.045 (75–90%)	0.045–0.048 (90–95%)	0.048–0.053 (95–105%)	0.053–0.055 (105–110%)	0.055–0.063 (110–125%)	0.063–0.088 (125–175%)	0.088–0.125 (175–250%)	>0.125 (>250%)
Number and Percent of Boluses within Range	4/800	36/800	159/800	172/800	194/800	109/800	115/800	11/800	0/800	0/800
	(0.5%)	(4.5%)	(19.9%)	(21.5%)	(24.3%)	(13.6%)	(14.4%)	(1.4%)	(0.0%)	(0.0%)

Table 18. Intermediate Bolus Delivery Performance (2.5U) (n=800 boluses)

	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	8/800	44/800	742/800	4/800	2/800	0/800	0/800	0/800
	(0.0%)	(0.0%)	(1.0%)	(5.5%)	(92.8%)	(0.5%)	(0.3%)	(0.0%)	(0.0%)	(0.0%)

Table 19. Max Bolus Delivery Performance (25U) (n=320 boluses)

	Units of Insulin Delivered After a 25 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%)
Number and Percent of Boluses within Range	0/320	0/320	0/320	0/320	320/320	0/320	0/320	0/320	0/320	0/320
	(0.0%)	(0.0%)	(0.0%)	(0.0%)	(100.0%)	(0.0%)	(0.0%)	(0.0%)	(0.0%)	(0.0%)

Occlusion detection

To assess occlusion detection activity, 32 MiniMed Flex pumps were tested by placing a hemostat clamp on the end of the tubing (to simulate an occlusion) and then delivering either a 25-unit bolus or basal at three different rates denoted as "minimum", "intermediate", and "maximum" (0.05 units per hour, 1 unit per hour, and 15 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 MiniMed Flex was recorded in the table below. Sixteen of the pumps were new, and 16 had been aged to simulate six months of shelf life and 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 for this testing.

Table 20. Time to Occlusion Alarm

Operating Rate	Typical	Maximum
Bolus (25 U)	33 seconds	47 seconds
Basal (1 U/hr)	1 hour, 52 minutes	2 hours, 41 minutes
Basal (15 U/hr)	7 minutes	9 minutes
Basal (0.05 U/hr)	42 hours, 49 minutes	71 hours, 19 minutes

Delivery Accuracy per IEC 60601-2-24

- Insulin delivery error shall be less than or equal to 5% for a basal rate greater than or equal to 1 U/hr.

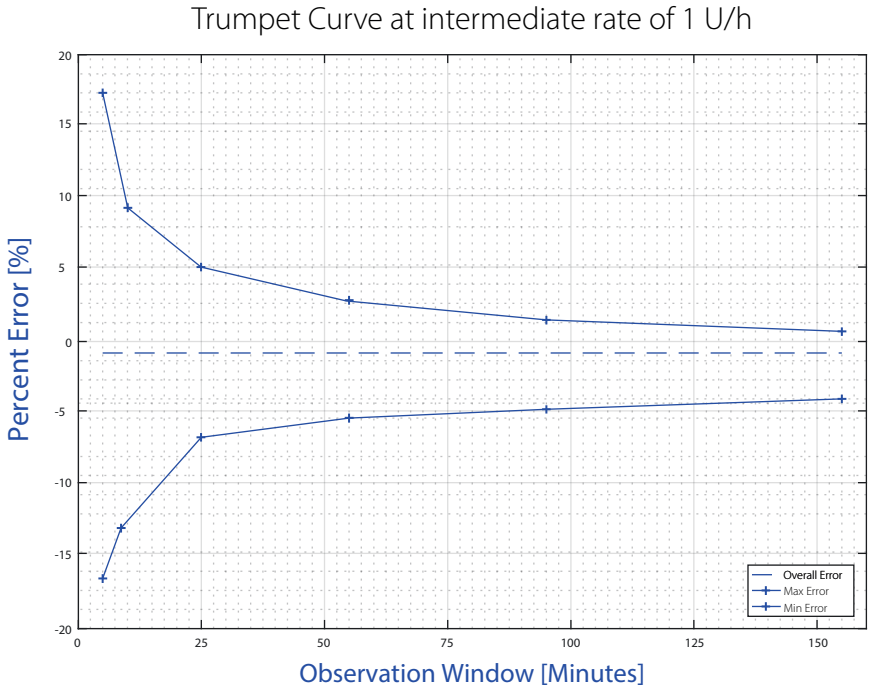
  Insulin delivery error shall be less than or equal to 0.05 U/hr for a basal rate less than 1 U/hr.

  Insulin delivery error shall be less than or equal to 5% for a bolus greater than or equal to 1 U.

  Insulin delivery error shall be less than or equal to 0.05 U for a bolus less than 1 U.

- During delivery, the maximum infusion pressure generated and the occlusion threshold pressure using a 3.0 mL reservoir does not exceed 19.13 psi (131.87 kPa). The average resulting bolus volume generated upon clearing the occlusion is 0.0097 mL (equivalent to 0.97 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.



This data is based on a sample size of 29 pumps tested.

Environmental conditions

The MiniMed Flex system is designed to withstand most conditions encountered in daily life. Details about environmental conditions, such as exposure to magnetic fields and radiation, waterproof capabilities, and extreme temperatures are contained in the warnings and precautions in this guide.

The following are the environmental condition ranges for pump operation:

- Temperature: 41 °F to 98.6 °F (5 °C to 37 °C)
- Humidity: 15% to 90% relative humidity
- Air pressure (altitude): 10.2 psiA to 15.4 psiA (700.0 hPa 1060.0 hPa)

Note: During use, the maximum surface temperature of the pump may reach up to 106.5 °F (41.4 °C). This is expected to be safe for most users for durations of more than 10 minutes.

The following are the environmental condition ranges for the pump and the charger while charging:

- Temperature: 41 °F to 93 °F (5 °C to 34 °C)
- Humidity: 15% to 90% relative humidity
- Air pressure (altitude): 10.2 psiA to 15.4 psiA (700.0 hPa 1060.0 hPa)

The following are the environmental condition ranges for the pump during transport (shipping):

- Temperature: -4 °F to 122 °F (-20 °C to 50 °C)
- Humidity: 25% to 90% relative humidity
- Air pressure (altitude): 8.6 psiA to 15.4 psi A (592.9 hPa to 1060.0 hPa)

The following are the environmental condition ranges for the charger during transport (shipping):

- Temperature: -4 °F to 122 °F (-20 °C to 50 °C)
- Humidity: 20% to 95% relative humidity
- Air pressure (altitude): 8.6 psiA to 15.4 psi A (592.9 hPa to 1060.0 hPa)

The following are the environmental condition ranges for pump storage:

- Temperature: 59 °F to 86 °F (15 °C to 30 °C)
- Humidity: 25% to 90% relative humidity
- Air pressure (altitude): 10.2 psiA to 15.4 psi A (700 hPa to 1060.0 hPa)

The following are the environmental condition ranges for charger storage:

- Temperature: 59 °F to 86 °F (15 °C to 30 °C)
- Humidity: 20% to 95% relative humidity
- Air pressure (altitude): 8.6 psiA to 15.4 psi A (592.9 hPa to 1060.0 hPa)

Essential performance

The system maintains the following functionalities to avoid under-infusion and over-infusion:

- Communicate with peripheral devices when in network
- Communicate notifications
- Communicate system status
- Deliver insulin accurately
- Detect occlusion
- Measure sensor glucose (SG) accurately
- Program insulin delivery
- Suspend insulin delivery

Expected service life

The overall expected service life for the MiniMed Flex pump and charger is four years when used in accordance with this guide. The shelf life for the insulin pump is six months; the shelf life for the charger is one year.

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

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

Filling the infusion set and cannula

- The cannula can be filled with 0.3, 0.5, 0.6, and 0.7 U.
- The average filling rate is 25 units per minute.
- When filling the tubing, a notification occurs at 23 U. A second notification occurs at 30 U 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.

Hard-coded limits

Table 21. Glucose alerts and suspend

Item	Limit
Alert before low	The sensor glucose (SG) value is predicted to be less than the Low limit in 30 min (when turned on in the settings).
Alert before high	The sensor glucose (SG) value is predicted to be greater than the High limit when the user-set Duration of time is reached (when turned on in the settings).
CALL FOR EMERGENCY ASSISTANCE: I HAVE DIABETES	After 10 min, if these alerts have not been acknowledged: • Suspend on low • Suspend limit reached • Max suspend reached - Basal resumed and sensor glucose (SG) is below the Suspend limit.
Suspend limit reached	Occurs when insulin is suspended by the Suspend before low feature (when turned on in the settings) and the current sensor glucose (SG) reaches the Suspend limit.
Prolonged high sensor glucose (SG)	The sensor glucose (SG) has been 250 mg/dL or greater for more than 3 hr.
Suspend before low	Occurs when both of the following conditions are met (when turned on in the settings and the feature is available): • The current sensor glucose (SG) value is at or within 70 mg/dL above the Suspend limit. • The sensor glucose (SG) value is predicted to be at or below a level that is 20 mg/dL above the Suspend limit within approximately 30 min.
Suspend on low	Occurs when either of the following conditions are met:

Table 21. Glucose alerts and suspend (continued)

Item	Limit
	• The sensor glucose value reaches or falls below 54 mg/dL when the Suspend on low and Suspend before low settings are turned off. • The Suspend on low feature is turned on and glucose reaches the Suspend limit.
Urgent low sensor glucose (SG)	The sensor glucose (SG) value is below 64 mg/dL.

Table 22. SmartGuard settings

Item	Limit
Auto correction target	120 mg/dL
Temp target	150 mg/dL (when enabled)

Table 23. System alerts

Item	Limit
Bolus not delivered	5 min
Button error	More than 3 min
Charge pump now	0% battery life
Delivery still suspended	More than 30 min
Delivery suspended (>30 minutes)	More than 30 min
Enter blood glucose (max delivery rate)	7 hr
Enter blood glucose (min delivery rate)	3 or 6 hr
Expired sensor	End of the 6-day + 24-hour grace period before there is no sensor life left
Low pump battery (< 1 hour)	Less than 1 hr
Suspend limit reached	User-set suspend limit when insulin was suspended by the Suspend before low feature
Low reservoir	User-set volume and less than 50% of the user-set volume
Max suspend reached - Basal resumed	2 hr
Mobile device battery low	20% battery life
No SG values >30 minutes	More than 30 min

Table 23. System alerts (continued)

Item	Limit
Reservoir empty	0 U
Resume delivery	Sufficient charge of 1 hr of battery life
Warm up has not started	30 min

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 1.88 units of missed insulin (bolus). This table shows occlusion detection for three different situations when using U-100 insulin.

Rate	Minimum time before alarm	Average time before alarm	Maximum time before alarm
Bolus delivery (10 U/min)	9 seconds	11 seconds	14 seconds
Basal delivery (1.0 U/hr)	1 hr, 18 min	1 hr, 57 min	2 hrs, 28 min
Basal delivery (0.05 U/hr)	28 hrs, 13 min	41 hrs, 43 min	54 hrs

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.

Program safety checks

There is a single fault condition that can occur where the pump may deliver a limited quantity of insulin without a delivery command from the system, which triggers an alert. The maximum infusion that can occur during this fault condition is 1 U of insulin before the pump detects the condition and suspends insulin delivery.

Pump dimensions

The pump dimensions in inches are no greater than 3.8 in length x 1.0 in width x 1.4 in depth.

The pump dimensions in centimeters are no greater than 9.7 cm length, 2.6 cm width, and 3.6 cm depth.

Pump preventative maintenance

The pump does not require preventative maintenance.

Pump weight

The mass of the insulin pump without consumables is 73 g.

Quality of service

Common consumer electronic devices that transmit the same frequency band used by the MiniMed Flex system transmitter may interrupt the transmission of glucose information. The MiniMed Flex system performs the following operations to prevent quality of service issues:

- The pump stores data locally in case the pump disconnects from the mobile device.
- The pump backfills data from the sensor in case the pump disconnects from the sensor.
- The pump resends data until all data is successfully transferred to the mobile device in case of radio interference.
- The pump maintains the data for a set amount of time after all data is successfully transferred to the mobile device.

To maintain consistent and reliable quality of service, adhere to the following:

- Keep the pump at a distance of 6 feet (1.8 meters) or less from the sensor.
- Keep the pump at a distance of 20 feet (6 meters) or less from the mobile device.

Sound frequency and decibels

The following table lists audible tones that the pump emits, and their corresponding frequencies and decibels. The frequencies in each tone are repeated in different patterns to create unique tones per alert type.

Associated alerts	Frequency (Hz)	dB (at 1 m)
High priority technical alerts • Charge pump now • Charge stopped • Delivery limit exceeded • Delivery still suspended • Delivery suspended (>30 minutes) • High pump temperature • Insulin flow blocked • Low pump temperature • No SG values > 30 minutes • Pump error occurred • Pump error - restart needed • Pump error - rewind pump and reload reservoir (both alerts) • Reservoir empty • Time settings error • Very high basal setting (high priority alert)	2616 then 2200	57.5 dBA
Medium priority technical alerts — non-suspend and non-resume delivery	2616 then 2200	66.4 dBA

Associated alerts	Frequency (Hz)	dB (at 1 m)
• Bolus stopped • Bolus not delivered • Low pump battery (<1 hour) • Low reservoir (medium priority alert) • Pump restarted - rewind required • Slow charging • SmartGuard exit • Warm up has not started		
Medium priority technical alerts — suspend and resume delivery • Delivery suspended >30 minutes (manually suspended insulin) • Pump is now cool • Pump is sufficiently charged	2919	66.4 dBA
High priority high glucose alerts • Prolonged high sensor glucose (SG)	2217, 2349, 2489, 2637, then 2793	57.5 dBA
Medium priority high glucose alerts • Alert on high	2217, 2349, 2489, 2637, then 2793	66.4 dBA
High priority low glucose alerts	2793, 2637, 2489, 2349, then 2217	57.5 dBA

Associated alerts	Frequency (Hz)	dB (at 1 m)
• CALL FOR EMERGENCY ASSISTANCE; I HAVE DIABETES • Low sensor glucose (SG) while suspended • Suspend on low • Urgent low sensor glucose (SG)		
Medium priority low glucose alerts • Alert on low	2793, 2637, 2489, 2349, then 2217	66.4 dBA
Lost communication message • Lost pump communication	2690	

System logs

Daily history logs up to 90 days of viewable information. The alert History tab on the Alerts screen logs up to 30 days of viewable information. When the log limit is reached, the oldest information is removed from the list when a new item is added.

Changes to therapy, such as manual suspend and resume, patient blood glucose (BG) input, and rate of insulin delivery are recorded to logs immediately. Sensor information such as sensor glucose (SG) value, interstitial signal (ISIG), and any closed loop algorithm updates are recorded every five minutes in nominal situations. The history record is sent from the pump to the app immediately.

The log is maintained when the system is powered down. In the event of a power loss, all log information is retained and immediately requested by the app once the pump is powered back on.

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 Flex 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.

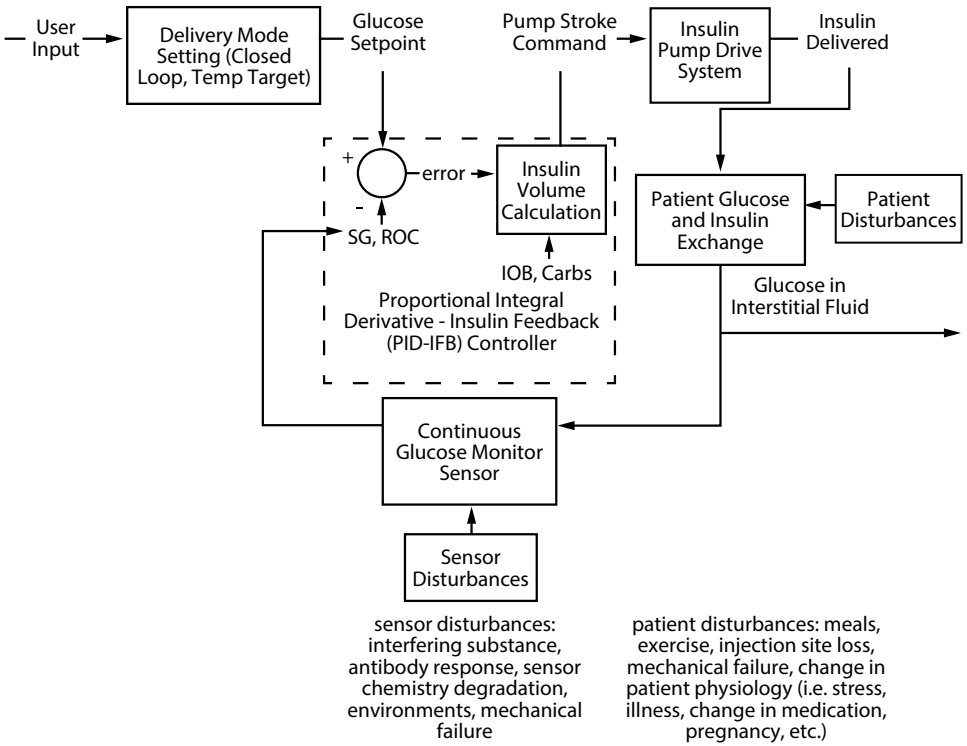
IEC 60601-1-2

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

IEC 60601-1-10: PCLCS

The MiniMed Flex 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 Flex system is intended for use in the electromagnetic environment specified below. Make sure that the MiniMed Flex system 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 Flex system 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 Flex system 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 Flex system is intended for use in the electromagnetic environment specified below. Make sure that the MiniMed Flex system 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 Flex system is intended for use in the electromagnetic environment specified below. The customer or user of the MiniMed Flex system 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 Flex system, including

Guidance and Manufacturer's Declaration — Electromagnetic Immunity			
	80% AM at 1 kHz	80% AM at 1 kHz	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 Flex pump communicates using smart device connectivity.

Item	Specification
Operating frequency, modulation type	2.4 GHz, GFSK
Effective radiated power (ERP)	1.98 mW (2.96 dBm)
Effective isotropic radiated power (EIRP)	3.24 mW (5.11 dBm)

For Wireless Power Transfer, the following specs apply:

Item	Specification
Operating frequency, modulation type	141 kHz, FSK
Output power	16.9 dBµA/m at 10 m

For the charger, the following specs apply:

Item	Specification
Operating frequency, modulation type	141 kHz, FSK
Output power	16.9 dBµA/m at 10 m

FCC notice

The pump and sensor comply 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.

Changes or modifications not expressly approved by Medtronic could void the user's authority to operate the equipment.

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.

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 shall be governed entirely by the terms and conditions of such license.

The source and object code, and applicable license for any Open Source Software can be obtained at the following site(s):

- LZ4–compression library: http://www.lz4.org
- QP Frame-work: http://www.state-machine.com
- ThreadX Operating System: https://github.com/eclipse-threadx/threadx
- Nordic nRF Connect SDK: https://www.nordicsemi.com/Products/Development-software/nRF-Connect-SDK
- WolfSSL: https://www.wolfssl.com/
- WolfSSL wolfBoot: https://github.com/wolfSSL/wolfBoot
- WolfSSL mdt-wolfBoot: https://code.medtronic.com/diabetes-software/third-party/wolf/mdt-wolfboot
- Protobuf-c: https://github.com/protobuf-c/protobuf-c
- CRC32 algorithm: https://web.mit.edu/freebsd/head/sys/libkern/crc32.c
- STMicroelectronics STM32Cube MX: https://www.st.com/en/development-tools/stm32cubemx

- STMicroelectronics
  STM32CubeU5: https://www.st.com/en/embedded-software/stm32cubeu5.html
- STMicroelectronics
  STM32CubeL0: https://www.st.com/en/embedded-software/stm32cubel0.html
- MCU-tool MCUboot: https://github.com/mcu-tools/mcuboot

Icon glossary

For a definition of the symbols displayed on the device and package labels, please see http://www.medtronicdiabetes.com/symbol-definitions.

9

Performance data

9 Performance data

MiniMed Flex system device performance

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

- SmartGuard technology, which is utilized by the SmartGuard feature.
- Predictive Low Glucose technology, which is utilized by the Suspend on low and Suspend before low features.

In addition to the iAGCs listed above, this MiniMed AID system comprises an alternate controller enabled (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 Flex 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 Flex 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 Flex 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 optional

---

[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.

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

The SmartGuard feature

Type 1 Diabetes Pivotal Clinical Study Overview

The SmartGuard feature with modifications (that controls insulin dosing in the MiniMed Flex 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 SmartGuard feature is equivalent between the Flex and 780G systems. 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.

---

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

A total of 250 subjects were enrolled, and 212 subjects completed the study.

The SmartGuard feature tested in this study of the MiniMed 780G system is equivalent to the SmartGuard feature in the MiniMed Flex system. The Flex system is compatible with the Simplera Sync sensor.

SmartGuard Performance: HbA1C and Time in Target Range

Table 24 shows the mean HbA1C from Baseline to the end of the 3-month study period. This data helps explain how using the 780G SmartGuard feature with the Auto correction feature enabled might affect a patient's HbA1C.

Table 24. Mean 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 25 reports the mean percentage of time spent in range (TIR, 70-180 mg/dL) in Stage 3 of the Study Period.

Table 25. 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 26 lists the device-related adverse events reported at screening, and during the run-in and study periods. Overall, 59 device-related 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 26. 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

Table 26. 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
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
Severe hyperglycemia	0	1	3	0	0	1
Total	**0**	**12**	**26**	**0**	**11**	**10**

Table 27 lists the study-period related adverse events. A total of 83 adverse events during the study period 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 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 27. Study Period Related Adverse Events

Category	Age 7–17 Years (N = 112)	Age 18–80 Years (N = 110)
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		

Table 27. Study Period Related Adverse Events (continued)

Category	Age 7–17 Years (N = 112)	Age 18–80 Years (N = 110)
Severe hypoglycemia	0	2
Severe hyperglycemia	8	1
Diabetic ketoacidosis (DKA)	0	1
None of the above	75	46
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 28* 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 28. 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 29 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 29* 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.

[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 29. 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)
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 30 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 30. 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 as 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). *Table 31* 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 31* 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 31. 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 as 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.
Note 3: For the 150 mg/dL set point (Temp Target), all the available periods of temp target were included in the analysis.

Figure 1 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

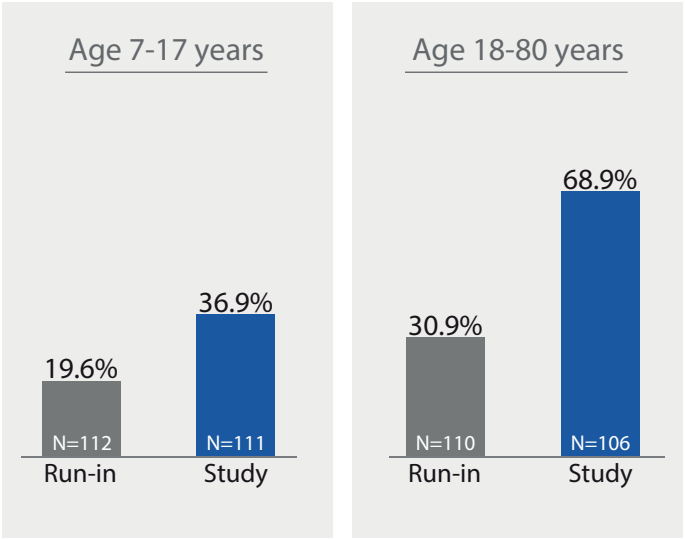


Table 32 shows the change in total daily dose of insulin (TDD) from the run-in period to study period stage 3, and the change in weight and BMI Z-score (for pediatrics) from baseline to the end of the study. Mean TDD increased for both pediatric and adult subjects. Mean weight increased slightly for pediatric subjects and remained unchanged for adult subjects. 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.

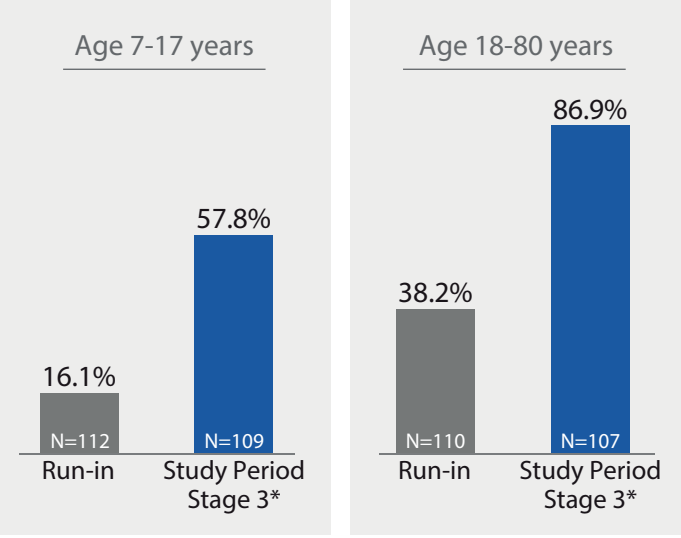
Table 32. Changes in Mean TDD and Weight

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 study period stage 3. 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.

SmartGuard with Fiasp Clinical Study Overview

The SmartGuard feature, without modifications, was studied in subjects with type 1 diabetes who used the ultra-rapid-acting insulin Fiasp (insulin aspart) with the MiniMed 780G pump, the Guardian 4 sensor and the Extended infusion set and reservoir at home for 3 months.[8] The SmartGuard feature is equivalent between the Flex and 780G systems. The study did not include a control group. The study included subjects from different clinics around the United States, Canada and Australia 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 Medtronic AID pump experience were

---

[8] Medtronic Inc., Clinical Study Report: Evaluation of the MiniMed™ 780G System in Type 1 Adult and Pediatric Subjects Utilizing Insulin Fiasp® (Insulin Aspart Injection).

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, either Humalog (insulin lispro injection) or NovoLog/NovoRapid™* (insulin aspart solution for injection).

After the run-in period, subjects were instructed to use the study devices with Fiasp insulin and 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, then adjusted towards 2-3 hours as considered best by the investigator for the individual subject (stage 1). Next, subjects were instructed 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 240 subjects were enrolled, and 215 subjects completed the study.

The SmartGuard feature tested in Phase 2 of this study of the updated MiniMed 780G system is equivalent to the SmartGuard feature in the MiniMed Flex system. The Flex system is compatible with the Simplera Sync sensor.

SmartGuard Performance: HbA1C and Time in Target Range

Table 33 shows the mean HbA1C from baseline to the end of the 3-month study period. This data helps explain how using the 780G SmartGuard feature and the Auto correction feature enabled with Fiasp insulin might affect a patient's HbA1C.

Table 33. Mean 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]	7.8 ± 0.9 (7.7) [107]	7.6 ± 0.8 (7.5) [104]	7.4 ± 0.8 (7.4) [116]	7.0 ± 0.7 (7.0) [114]

Table 34 reports the mean percentage of time spent in range (TIR, 70-180 mg/dL) in stage 3 of the Study Period.

Table 34. 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	106	65.7%	(63.5%, 67.9%)
18-80 Years	113	77.1%	(75.4%, 78.9%)

Safety

Table 35 lists the device-related adverse events reported at screening, and during the run-in and study periods. Overall, 39 device-related adverse events were reported. There were no reports of device-related unanticipated serious or non-serious adverse device effects during the study. For subjects ages 7-17 years, no severe hypoglycemia events and 1 diabetic ketoacidosis event was reported, but this was not device-related. For adult subjects, 1 severe hypoglycemia event was reported.

Table 35. Device-Related Adverse Events

Adverse Events	Age 7–17 Years (N = 115)			Age 18–80 Years (N = 125)		
	Screening period	Run-in period	Study period	Screening period	Run-in period	Study period
Discomfort/irritation with infusion set	0	2	8	0	0	1
Hyperglycemia	0	1	0	0	0	0
Infusion site infection	0	1	4	0	0	1
Ketonemia	0	0	1	0	0	0
Rash/contact dermatitis (infusion set related)	0	1	0	0	3	1
Rash/contact dermatitis (sensor/tape related)	0	0	2	0	0	3
Sensor site pain	0	2	0	0	0	0
Severe hyperglycemia	0	4	3	0	1	0
Total	**0**	**11**	**18**	**0**	**4**	**6**

Table 36 lists the study-period related adverse events. A total of 51 adverse events during the study period were reported from all investigational sites for 7–17-year-old study subjects enrolled in the study. There were no serious adverse events, no reports of severe hypoglycemia, 5 reports of severe hyperglycemia, 1 report of diabetic ketoacidosis, and no reports of unanticipated adverse device effects (UADEs).

A total of 37 adverse events during the study period were reported from all investigational sites for 18–80-year-old study subjects enrolled in the study. Out of 37 events, there were no serious adverse events, 1 report of severe hypoglycemia, no reports of severe hyperglycemia events, no reports of diabetic ketoacidosis, and no reports of unanticipated adverse device effects (UADEs).

Table 36. Study Period Related Adverse Events

Category	Age 7–17 Years (N = 107)	Age 18–80 Years (N = 116)
Total number of adverse events	51	37
Study Exit		
Led to study exit	0	1
Did not lead to study exit	51	36
Seriousness		
Serious adverse events (SAEs)	0	0
Death	0	0
Non-death	0	0
Non-serious adverse events	51	37
Diagnosis		
Severe hypoglycemia	0	1
Severe hyperglycemia	5	0
Diabetic ketoacidosis (DKA)	1	0
None of the above	45	36
Study procedure and device relatedness		
Related to study procedure only	0	0
Related to study device only	18	6
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)	18	6
Related to both study procedure and study device	0	0
Unanticipated adverse device effects (UADE) / Unanticipated serious adverse device effects (USADE)	0	0

Table 36. Study Period Related Adverse Events (continued)

Category	Age 7–17 Years (N = 107)	Age 18–80 Years (N = 116)
Unanticipated non-serious adverse device effects	0	0
Anticipated adverse device effects (ADEs)	0	0
Not related to study procedure or study device	33	31

SmartGuard Use

During the study period, subjects were instructed to use Fiasp insulin with the SmartGuard feature and Auto correction ON. *Table 37* presents the percentage of time that subjects spent using the sensor and the percentage of time spent using the SmartGuard feature. This information shows that the SmartGuard feature was ON greater than 87% of the time during the study period.

Table 37. Sensor and SmartGuard Usage (Percentage of Time), Overall Study Period

Category	Age 7-17 Years (N = 107)	Age 18-80 Years (N = 116)
Time spent using sensor	89.3%	94.1%
Time spent not using sensor	10.7%	5.9%
Time spent in SmartGuard	87.4%	95.1%
Time spent in Manual mode	12.6%	4.9%

SmartGuard Performance

Table 38 shows the mean percentage of SG values in specific glucose ranges during the run-in period and during stage 3 of the study period for all subjects using the 780G system with the Guardian 4 sensor and Fiasp insulin. 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.[9]

[9] 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.

The data in *Table 38* show that using Fiasp insulin with the SmartGuard feature and the Auto correction feature enabled kept SG values in range and reduced time above range. Specifically, adult subjects spent more time in the target range (TIR, 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 also spent more time in range (70–180 mg/dL) and less time in hyperglycemia (> 180 mg/dL) and less time in hypoglycemia (< 70 mg/dL) during stage 3 of the study period compared with the run-in period.

Table 38. 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 = 107)	Study Period Stage 3 (N = 106)	Run-in Period (N = 116)	Study Period Stage 3 (N = 113)
Low SG Value	< 54	0.6 ± 0.7 (0.4, 0.7)	0.3 ± 0.3 (0.3, 0.4)	0.5 ± 1.0 (0.3, 0.7)	0.3 ± 0.4 (0.2, 0.4)
	< 70	2.2 ± 2.0 (1.8, 2.6)	1.7 ± 1.3 (1.5, 1.9)	2.4 ± 2.9 (1.9, 3.0)	1.7 ± 1.3 (1.4, 1.9)
Target SG Value	70 – 140	31.2 ± 11.9 (28.9, 33.4)	43.0 ± 10.1 (41.1, 45.0)	41.5 ± 11.9 (39.3, 43.7)	51.4 ± 10.6 (49.5, 53.4)
	70 – 180	53.0 ± 14.5 (50.2, 55.7)	65.7 ± 11.3 (63.5, 67.9)	68.0 ± 12.2 (65.7, 70.2)	77.1 ± 9.6 (75.4, 78.9)
High SG Value	> 140	66.7 ± 12.8 (64.2, 69.1)	55.3 ± 10.6 (53.2, 57.3)	56.0 ± 12.9 (53.6, 58.4)	46.9 ± 11.0 (44.8, 48.9)
	> 180	44.9 ± 15.1 (42.0, 47.8)	32.6 ± 11.6 (30.3, 34.8)	29.6 ± 12.6 (27.2, 31.9)	21.2 ± 9.8 (19.3, 23.0)
	> 250	17.1 ± 10.5 (15.1, 19.1)	10.6 ± 7.7 (9.1, 12.0)	6.5 ± 5.6 (5.5, 7.6)	3.9 ± 3.7 (3.2, 4.6)
	> 350	2.4 ± 2.9 (1.9, 3.0)	1.7 ± 2.2 (1.3, 2.1)	0.4 ± 0.7 (0.2, 0.5)	0.2 ± 0.4 (0.2, 0.3)
Note: Values are presented as Mean ± SD (95% CI) except Number of subjects					

Table 39 shows the difference in mean sensor glucose from baseline to the end of the study period for all subjects using Fiasp insulin with the 780G pump and the Guardian 4 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 glucose range.

Table 39. 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 = 107)	Study Period Stage 3 (N = 106)	Difference between Run-in Period and Study Period Stage 3 (N = 106)	Run-in Period (N = 116)	Study Period Stage 3 (N = 113)	Difference between Run-in Period and Study Period Stage 3 (N = 113)
Mean Glucose Value	181.5 ± 25.2 (176.6,186.3)	163.4 ± 19.4 (159.7,167.1)	-18.1 ± 21.4 (-22.2, -14.0)	157.0 ± 18.0 (153.7, 160.3)	146.4 ± 13.7 (143.8, 148.9)	-9.9 ± 12.4 (-12.2, -7.6)

Table 39. Difference in Mean Sensor Glucose Values (mg/dL) between the Run-in Period and Study Period Stage 3 (continued)

Category	Age 7–17 Years			Age 18–80 Years		
	Run-in Period (N = 107)	Study Period Stage 3 (N = 106)	Difference between Run-in Period and Study Period Stage 3 (N = 106)	Run-in Period (N = 116)	Study Period Stage 3 (N = 113)	Difference between Run-in Period and Study Period Stage 3 (N = 113)
Note: Values are presented as Mean ± SD (95% CI) except Number of subjects.						

While using Fiasp insulin 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). *Table 40* 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 40* shows that using Fiasp insulin with the SmartGuard feature, the Auto correction feature enabled, and the 100 mg/dL target setpoint resulted in a lower mean SG value than when the features were used with Fiasp insulin at the 120 mg/dL target setpoint.

Table 40. 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 = 107)	Target Glucose (mg/dL)				Overall (N = 115)	Target Glucose (mg/L)			
		100 (N = 100)	110 (N = 5)	120 (N = 106)	150 (N = 21)		100 (N = 109)	110 (N = 2)	120 (N = 111)	150 (N = 34)
Mean Glucose Values During SmartGuard	161.0 ± 16.4 (157.9, 164.2)	158.7 ± 17.3 (155.2, 162.1)	160.3 ± 17.6 (138.5, 182.1)	164.3 ± 16.3 (161.2, 167.4)	167.9 ± 57.3 (141.8, 193.9)	148.4 ± 13.2 (146.0, 150.9)	145.1 ± 12.9 (142.7, 147.6)	158.6 ± 40.3 (-203.7, 520.9)	156.3 ± 14.3 (153.6, 159.0)	128.6 ± 31.1 (117.7, 139.4)
Note 1: Values are presented as 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. Note 3: For the 150 mg/dL set point (Temp Target), all the available periods of temp target were included in the analysis.										

Table 41 shows the change in total daily dose of insulin (TDD) from the run-in period to study period stage 3 and weight from baseline to the end of the study. TDD increased slightly in patients ages 7-17 years while no change was reported for patients ages 18-80 years. Mean weight in the pediatric subjects increased slightly and remained unchanged for adult subjects. This data helps explain how using the SmartGuard feature and the Auto correction feature with Fiasp insulin might affect a patient's TDD and weight.

Table 41. Changes in Mean TDD and Weight

Category	Age 7-17 Years		Age 18-80 Years	
TDD (U), Mean ± SD (Median)	**Run-in Period (N = 107)**	**Study Period Stage 3 (N = 106)**	**Run-in Period (N = 116)**	**Study Period Stage 3 (N = 114)**
	56.1 ± 21.0 (56.1)	61.7 ± 24.6 (59.0)	57.1± 35.2 (46.9)	57.6 ± 34.8 (48.1)
Weight (kg), Mean ± SD (Median)	**Baseline (N = 107)**	**End of Study (N = 104)**	**Baseline (N = 116)**	**End of Study (N = 114)**
	61.6 ±16.9 (61.3)	62.4 ± 16.8 (61.3)	86.2 ± 19.1 (87.2)	86.2 ± 19.7 (87.1)

Overall, the clinical study suggested that the 780G system was safe when used with Fiasp insulin, and subjects showed improvements in HbA1C (compared to baseline) and time in the target glucose range with use of the unmodified 780G pump and the Guardian 4 sensor. However, the study had the following limitations:

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). Additionally, subjects experienced two simultaneous changes between the run-in period and the study period: the SmartGuard feature modifications and an ultra-rapid-acting insulin. Since these changes occurred together, it is not possible to attribute the improvements to one specific change.

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

SmartGuard with Lyumjev Clinical Study Overview

The SmartGuard feature, without modifications, was studied in subjects with type 1 diabetes who used the ultra-rapid-acting insulin Lyumjev (insulin lispro-aabc) with the MiniMed 780G pump, the Guardian 4 sensor and the Extended infusion set and reservoir at home for 3 months.[10] The SmartGuard feature is equivalent between the Flex and 780G systems. The study did not include a control group. The study included subjects from different clinics around the United States 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, which means that the SmartGuard feature had to remain turned OFF. Subjects who had Medtronic 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, either Humalog™ (insulin lispro injection) or NovoLog® (insulin aspart solution for injection) and or Admelog.

After the run-in period, subjects were instructed to use the system with Lyumjev insulin and both the SmartGuard feature and the Auto correction feature turned ON during a 3-month long study period. During the first 3 weeks (also referred to as Stage 1), subjects were instructed to use the study pump set to the 120 mg/dL Auto basal target setpoint, with active insulin time set to 4 hours initially. However, the investigator was free to adjust towards a 2-3 hour active insulin time. For the next 3 weeks (also referred to as Stage 2), subjects were instructed to change the Auto basal target setpoint to 100 mg/dL, with active insulin time set to 2-3 hours. Again, the investigator was free to make adjustments to active insulin time, where needed. For the remaining 6 weeks of the study period (also referred to as Stage 3), until the end of their participation in the study, subjects were instructed to set the Auto basal target setpoint and active insulin time according to guidance given by the investigator. A total of 244 subjects were enrolled, and 198 subjects completed the study.

The SmartGuard feature tested in Phase 2 of this study of the updated MiniMed 780G system is equivalent to the SmartGuard feature in the MiniMed Flex system. The Flex system is compatible with the Simplera Sync sensor.

---

[10] Medtronic Inc., Clinical Study Report: CIP335 - Evaluation of the Advanced Hybrid Closed Loop (AHCL) System in Type 1 Adult and Pediatric Subjects Utilizing Lyumjev® insulin lispro-aabc.

SmartGuard Performance: HbA1C and Time in Target Range

Table 42 shows the mean HbA1C from Baseline to the end of the 3-month study period. This data helps explain how using the 780G SmartGuard feature with the Auto correction feature enabled might affect a patient's HbA1C.

Table 42. Mean 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]	7.6 ± 1.1 (7.6) [101]	7.5 ± 0.9 (7.5) [99]	7.4 ± 0.9 (7.3) [110]	6.9 ± 0.6 (6.9) [108]

Table 43 reports the mean percentage of time spent in the target range (TIR, 70–180 mg/dL) in Stage 3 of the Study Period.

Table 43. 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	98	68.6%	(66.6%, 70.7%)
18-80 Years	102	77.6%	(75.7%, 79.4%)

Safety

Table 44 lists the device-related adverse events reported at screening, and during the run-in and study periods. Overall, 61 device-related 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 device related severe hypoglycemia and no reports of unanticipated adverse device effects.

Table 44. Device-Related Adverse Events

Adverse Events	Age 7–17 Years (N = 120)			Age 18–80 Years (N = 124)		
	Screening period	Run-in period	Study period	Screening period	Run-in period	Study period
Arm cramping from sensor	0	0	0	0	0	1
Bleeding at sensor site	0	0	1	0	0	0
Discomfort/irritation with infusion set	0	0	1	0	0	0
Hyperglycemic episode	0	0	0	0	1	0
Infusion site bruising	0	0	0	0	0	1
Infusion site infection	0	1	1	0	0	0
Insulin infusion reaction	0	0	14	0	0	18
Prolonged hyperglycemia	0	0	1	0	0	0
Rash/contact dermatitis (infusion set related)	0	4	4	0	0	3
Rash/contact dermatitis (sensor/tape related)	0	0	0	0	0	2

Table 44. Device-Related Adverse Events (continued)

Adverse Events	Age 7–17 Years (N = 120)			Age 18–80 Years (N = 124)		
	Screening period	Run-in period	Study period	Screening period	Run-in period	Study period
Sensor site bruising	0	0	0	0	1	0
Sensor site infection	0	0	1	0	0	0
Sensor site irritation	0	0	2	0	1	0
Sensor site pain	0	1	0	0	0	0
Severe hyperglycemia	0	0	1	0	1	0
Total	**0**	**6**	**26**	**0**	**4**	**25**

Table 45 lists the study-period related adverse events. A total of 87 adverse events during the study period and no serious adverse events were reported from all investigational sites for 7–17-year-old study subjects enrolled in the study. There were no serious adverse events, no reports of severe hypoglycemia, 7 reports of severe hyperglycemia, no reports of diabetic ketoacidosis, and no reports of unanticipated adverse device effects (UADEs).

A total of 81 adverse events during the study period and no serious adverse events were reported from all investigational sites for 18–80-year-old study subjects enrolled in the study. Out of 81 events, there were no serious adverse events, no reports of hypoglycemia, 1 report of a hyperglycemia event, no reports of diabetic ketoacidosis events, and no reports of unanticipated adverse device effects (UADEs).

Table 45. Study Period Related Adverse Events

Category	Age 7–17 Years (N = 101)	Age 18–80 Years (N = 110)
Total number of adverse events	87	81
Study Exit		
Led to study exit	3	3
Did not lead to study exit	84	78
Seriousness		
Serious adverse events (SAEs)	0	0
Death	0	0
Non-death	0	0
Non-serious adverse events	87	81
Diagnosis		
Severe hypoglycemia	0	0
Severe hyperglycemia	7	1
Diabetic ketoacidosis (DKA)	0	0

Table 45. Study Period Related Adverse Events (continued)

Category	Age 7–17 Years (N = 101)	Age 18–80 Years (N = 110)
None of the above	80	80
Study procedure and device relatedness		
Related to study procedure only	0	0
Related to study device only	26	25
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	25
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	61	56

SmartGuard Use

During the study period, subjects were instructed to use Lyumjev with the SmartGuard feature and Auto correction ON. *Table 46* presents the percentage of time that subjects spent using the sensor and the percentage of time spent using the SmartGuard feature. This information shows that the SmartGuard feature was ON greater than 91% of the time during the study period.

Table 46. Sensor and SmartGuard Usage (Percentage of Time), Overall Study Period

Category	Age 7-17 Years	Age 18-80 Years
Time spent using sensor	92.8%	94.4%
Time spent not using sensor	7.2%	5.6%
Time spent in SmartGuard	91.4%	95.4%
Time spent in Manual mode	8.6%	4.6%

SmartGuard Performance

Table 47 shows the mean percentage of SG values in specific glucose ranges during the run-in period and during stage 3 of the study period for all subjects using the 780G system with the Guardian 4 sensor and Lyumjev insulin. 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.[11]

The data in *Table 47* show that using Lyumjev insulin with the SmartGuard feature and the Auto correction feature enabled 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 increasing time in hypoglycemia (<70 mg/dL) during stage 3 of the study period compared with the run-in period.

Table 47. 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 = 101)	Study Period Stage 3 (N = 98)	Run-in Period (N = 110)	Study Period Stage 3 (N = 102)
Low SG Value	<54	0.6 ± 0.8 (0.4, 0.8)	0.4 ± 0.5 (0.3, 0.5)	0.3 ± 0.5 (0.2, 0.4)	0.2 ± 0.3 (0.2, 0.3)
	<70	2.3 ± 2.2 (1.9, 2.7)	2.0 ± 1.8 (1.6, 2.3)	1.7 ± 1.8 (1.4, 2.1)	1.3 ± 1.1 (1.1, 1.5)
Target SG Value	70 – 140	30.1 ± 14.4 (27.3, 32.9)	46.1 ± 9.7 (44.2, 48.1)	39.5 ± 12.9 (37.1, 42.0)	51.1 ± 10.8 (49.0, 53.2)
	70 – 180	51.2 ± 17.2 (47.8, 54.6)	68.6 ± 10.3 (66.6, 70.7)	67.0 ± 13.6 (64.4, 69.6)	77.6 ± 9.6 (75.7, 79.4)

[11] 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 47. 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 = 101)	Study Period Stage 3 (N = 98)	Run-in Period (N = 110)	Study Period Stage 3 (N = 102)
High SG Value	> 140	67.6 ± 15.4 (64.6, 70.6)	51.9 ± 10.2 (49.8, 53.9)	58.8 ± 13.4 (56.2, 61.3)	47.7 ± 11.1 (45.5, 49.8)
	> 180	46.5 ± 18.0 (42.9, 50.0)	29.4 ± 10.5 (27.3, 31.5)	31.3 ± 13.7 (28.7, 33.9)	21.2 ± 9.7 (19.3, 23.1)
	> 250	18.3 ± 13.0 (15.7, 20.8)	9.1 ± 7.0 (7.7, 10.5)	7.1 ± 6.9 (5.8, 8.4)	3.8 ± 3.3 (3.1, 4.4)
	> 350	2.7 ± 3.6 (2.0, 3.4)	1.5 ± 2.3 (1.1, 2.0)	0.4 ± 1.1 (0.2, 0.6)	0.3 ± 0.7 (0.1, 0.4)
Note: Values are presented as Mean ± SD (95% CI) except Number of subjects					

Table 48 shows the difference in mean sensor glucose from run-in period to study period stage 3 for all subjects using Lyumjev insulin with the 780G pump and the Guardian 4 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 glucose range.

Table 48. 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 = 101)	Study Period Stage 3 (N = 98)	Difference between Run-in Period and Study Period Stage 3 (N = 98)	Run-in Period (N = 110)	Study Period Stage 3 (N = 102)	Difference between Run-in Period and Study Period Stage 3 (N = 102)
Mean Glucose Value	183.6 ± 30.2 (177.6,189.5)	158.3 ± 18.2 (154.6,161.9)	-26.0 ± 25.0 (-31.0, -21.0)	160.4 ± 19.3 (156.7, 164.0)	147.1 ± 13.4 (144.5, 149.8)	-13.5 ± 16.6 (-16.7, -10.2)
Note: Values are presented as Mean ± SD (95% CI) except Number of subjects.						

While using Lyumjev insulin during the study period, 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). *Table 49* 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 49* shows that using Lyumjev with the SmartGuard feature, the Auto correction feature enabled, and the 100 mg/dL target setpoint resulted in a lower mean SG value than when the features were used with Lyumjev at the 120 mg/dL target setpoint.

Table 49. Mean Sensor Glucose Values (mg/dL) during SmartGuard Use Stratified by Target Glucose Setpoint during the Study Period

	Age 7– 17 Years					Age 18–80 Years				
Category	Overall (N = 101)	Target Glucose (mg/dL)				Overall (N = 110)	Target Glucose (mg/L)			
		100 (N = 98)	110 (N = 6)	120 (N = 100)	150 (N = 25)		100 (N = 106)	110 (N = 4)	120 (N = 110)	150 (N = 34)
Mean Glucose Values During SmartGuard	157.3 ± 14.9 (154.3, 160.2)	155.6 ± 15.9 (152.4, 158.8)	151.6 ± 12.6 (138.4, 164.8)	160.8 ± 16.9 (157.4, 164.1)	147.8 ± 33.4 (134.0, 161.5)	148.7 ± 12.0 (146.5, 151.0)	146.4 ± 13.1 (143.9, 148.9)	153.0 ± 19.2 (122.4, 183.6)	154.4 ± 13.1 (151.9, 156.9)	134.1 ± 24.3 (125.6, 142.6)

Note 1: Values are presented as 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.
Note 3: For the 150 mg/dL set point (Temp Target), all the available periods of temp target were included in the analysis.

Table 50 shows the change in total daily dose of insulin (TDD) from the run-in period to study period stage 3, and weight from baseline to the end of the study. TDD for both adult and pediatric subjects increased. Mean weight for pediatric subjects increased slightly and remained unchanged for adult subjects. This data helps explain how using the SmartGuard feature with the Auto correction feature might affect a patient's TDD and weight.

Table 50. Changes in Mean TDD and Weight

Category	Age 7-17 Years		Age 18-80 Years	
TDD (U), Mean ± SD (Median)	**Run-in Period (N = 101)**	**Study Period Stage 3 (N = 98)**	**Run-in Period (N = 110)**	**Study Period Stage 3 (N = 102)**
	52.4 ± 23.0 (49.5)	57.5 ± 22.5 (55.1)	52.9 ± 26.8 (45.2)	57.2 ± 29.0 (48.4)
Weight (kg), Mean ± SD (Median)	**Baseline (N = 101)**	**End of Study (N = 100)**	**Baseline (N = 110)**	**End of Study (N = 108)**
	55.7 ±17.5 (55.6)	57.6 ± 17.1 (57.4)	87.0 ± 19.4 (83.9)	87.3 ± 19.4 (85.4)

Overall, the clinical study suggested that the 780G system was safe when used with Lyumjev insulin, and subjects showed improvements in HbA1C (compared to baseline) and time in the target glucose range with use of the unmodified 780G pump and the Guardian 4 Sensor. However, the study had the following limitations:

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). Additionally, subjects experienced two simultaneous changes between the run-in period and the study period: the SmartGuard feature modifications and an ultra-rapid-acting insulin. Since these changes occurred together, it is not possible to attribute the improvements to one specific change.

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

Type 2 Diabetes Pivotal Clinical Study Overview

The SmartGuard feature, with and without modifications, was studied in adult subjects with type 2 diabetes who wore the MiniMed 780G pump and the Extended infusion set and reservoir at home for 3 months.[12,13] The study was conducted in two phases. In Phase 1 of the study, the unmodified SmartGuard feature was studied with the Guardian 4 sensor, and the modified SmartGuard feature was studied with the Simplera Sync sensor in Phase 2. The SmartGuard feature studied in Phase 2 is equivalent between the Flex and 780G systems. The study did not include a control group. The study included subjects from different clinics around the US who were between 18 and 80 years old. Subjects had to have been diagnosed with insulin-requiring type 2 diabetes mellitus for at least two years. All subjects in the study also had to have been on a multiple daily injection (MDI) regimen (basal/bolus regimen with long-acting insulin and rapid-acting analogs) for at least 3 months prior to study, or on Continuous Subcutaneous Insulin Infusion (CSII) pump therapy with or without CGM, and had an HbA1C value of less than 10.0% at the time of screening.

Both study phases had a run-in (baseline) period and a study period. During run-in, subjects with no prior automated insulin delivery (AID) 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 study devices while using their own insulin.

---

[12] Medtronic Inc., CIP341 Clinical Study Report, In-Home Study with MiniMed Pump Automated Control in Type 2 - Evaluation of the AHCL System in Adults with Insulin-requiring Type 2 Diabetes – Phase 1

[13] Medtronic Inc., CIP341 Clinical Study Report, In-Home Study with MiniMed Pump Automated Control in Type 2 - Evaluation of the AHCL System in Adults with Insulin-requiring Type 2 Diabetes – Phase 2

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 (AIT) 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.

Subjects who participated in Phase 1 of the study underwent meal and exercise challenges during the run-in and study periods and had the opportunity to participate in a continued access period. Phase 1 subjects had the opportunity to transition into Phase 2 upon completion of the Phase 1 study period or during the continued access period. Subjects who transitioned from Phase 1 to Phase 2 of the study experienced a shortened run-in period in Phase 2 due to their previous exposure to MiniMed 780G system therapy during Phase 1. Phase 2 of the study did not include meal and exercise challenges or a continued access period. For Phase 1 of the study, a total of 165 subjects were enrolled, 89 subjects completed the study period, and 72 subjects transitioned to Phase 2. For Phase 2, a total of 481 subjects were enrolled, and 292 subjects completed the study period under Phase 2.

The SmartGuard feature tested in Phase 2 of this study of the updated MiniMed 780G system with the Simplera Sync sensor is equivalent to the SmartGuard feature in the MiniMed Flex system. The Flex system is compatible with the Simplera Sync sensor.

SmartGuard Performance: HbA1C and Time in Target Range

Table 10 shows the mean HbA1C from Baseline to the end of the 3-month study period. This data helps explain how using the 780G SmartGuard feature with the Auto correction feature enabled might affect a patient's HbA1C.

Table 51. Mean HbA1C from Baseline to End of 3-month Study Period

Category	Phase 1		Phase 2 (Transition Subjects)		Phase 2 (Naïve Subjects)	
	Baseline	End of Study	Baseline[a]	End of Study	Baseline	End of Study
HbA1C (%) Mean ± SD (Median) [N]	7.9 ± 1.0 (7.9) [95]	7.2 ± 0.7 (7) [88]	7.1 ± 0.7 (6.9) [66]	6.8 ± 0.6 (6.7) [65]	7.7 ± 0.9 (7.7) [236]	6.9 ± 0.7 (6.9) [229]

[a] Baseline reflects data gathered at Phase 2 screening and is therefore not a true baseline.

Table 52 reports the mean percentage of time spent in target range (TIR, 70-180 mg/dL) in Stage 3 of the Study Period.

Table 52. Mean Percentage of Time Spent in Range (70-180 mg/dL) in Study Period Stage 3

Phase	Number of Subjects	Mean TIR[a]	95% Confidence Interval[a]
1	91	80.9%	(78.4%, 83.1%)
2	298	85.4%	(84.3%, 86.4%)

[a] Hodges-Lehmann method used to compute Mean TIR and 95% confidence interval.

Safety

Table 12 lists the device-related adverse events reported at screening, and during the run-in, study and continued access periods. For Phase 1, 144 adverse events were reported overall. There were 9 reports of device-related, anticipated, non-serious adverse device effects during Phase 1 of the study. One diabetic ketoacidosis (DKA) event was reported for an adult subject, but this was not device-related. For all subjects participating in Phase 2, 352 adverse events were reported overall. There were 63 reports of device-related, anticipated, non-serious adverse device effects during Phase 2 of the study. Two severe hypoglycemia events and 1 DKA event were reported for adult subjects but none of these were device-related.

Table 53. Device-Related Adverse Events

Adverse Events	Phase 1 (N = 165)[a]				Phase 2 (N = 481)[b]		
	Screening period	Run-in period	Study period	Continued Access period	Screening period	Run-in period	Study period
Abrasion	0	0	1	0	0	0	0
Bleeding at infusion site	0	0	0	0	0	1	0
Bleeding at sensor site	0	0	0	0	0	6	9
Bruising at sensor site	0	2	1	1	0	0	1
Discomfort/irritation with infusion set	0	1	0	0	0	11	11
Discomfort/irritation with insulin infusion	0	0	0	0	0	0	1
Discomfort/irritation with sensor	0	0	1	0	0	4	3
Excoriation	0	1	0	0	0	0	0
Infusion site bruising	0	0	0	0	0	1	1
Infusion site infection	0	0	0	0	0	1	1
Rash/contact dermatitis (infusion set related)	0	1	0	0	0	6	4
Rash/contact dermatitis (sensor/tape related)	0	0	0	0	0	1	0
Sensor site infection	0	0	0	0	0	1	0

Table 53. Device-Related Adverse Events (continued)

Adverse Events	Phase 1 (N = 165)[a]				Phase 2 (N = 481)[b]		
	Screening period	Run-in period	Study period	Continued Access period	Screening period	Run-in period	Study period
Total	0	5	3	1	0	32	31

[a] Adverse Events which occurred on the last date of Study Period participation and the first date of Continued Access Period participation were attributed to the Study Period. Adverse Events which occurred after the first date of Continued Access Period participation were attributed to the Continued Access Period.

[b] For subjects transitioning from Phase 1 to Phase 2, events occurring between Phase 2 screening date and the first date of Phase 2 Study Period participation contributed to the Phase 2 Run-in period.

Table 54 lists the study-period related adverse events. A total of 67 adverse events during the study period and four serious adverse events during the study period were reported from all investigational sites for phase 1 subjects enrolled in the study, while 216 total adverse events and 11 serious adverse events were reported for phase 2 during the study period. There were no reports of severe hypoglycemia or severe hyperglycemia, no reports of diabetic ketoacidosis, and there were no reports of unanticipated adverse device effects (UADEs) in phase 1 during the study period. There were 2 reports of severe hypoglycemia and 1 of severe hyperglycemia, no reports of diabetic ketoacidosis, and no reports of unanticipated adverse device effects (UADEs) in phase 2.

Table 54. Study Period Related Adverse Events

Category	Phase 1 (N=95)[a]	Phase 2 (N=302)
Total number of adverse events	67	216
Study Exit		
Led to study exit	1	2
Did not lead to study exit	66	214
Seriousness		
Serious adverse events (SAEs)	4	11
Death	0	1
Non-death	4	10
Non-serious adverse events	63	205
Diagnosis		
Severe hypoglycemia	0	2
Severe hyperglycemia	0	1
Diabetic ketoacidosis (DKA)	0	0

Table 54. Study Period Related Adverse Events (continued)

Category	Phase 1 (N=95)[a]	Phase 2 (N=302)
Hyperosmolar hyperglycemic state	0	0
None of the above	67	213
Study procedure and device relatedness		
Related to study procedure only	2	0
Related to study device only	3	31
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)	3	31
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	62	185

[a] Adverse Events which occurred on the last date of Study Period participation and the first date of Continued Access Period participation were attributed to the Study Period.

SmartGuard Use

During the study period, subjects had access to the study device and were instructed to use SmartGuard with Auto correction ON. *Table 55* 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 stage 3 of the study period. This information shows that the SmartGuard feature was ON greater than 91% during stage 3 of the study period for Phase 1 and greater than 92% during stage 3 of the study period for Phase 2.

Table 55. Sensor and SmartGuard Usage (Percentage of Time) During Study Period, Stage 3

Category	Phase 1	Phase 2
	Study Period Stage 3 (N = 91)	Study Period Stage 3 (N = 298)
Time spent using sensor	92.9%	94.5%
Time spent not using sensor	7.1%	5.5%
Time spent in SmartGuard	91.2%	92.8%
Time spent in Manual mode	8.8%	7.2%

SmartGuard Performance

Table 56 shows the mean percentage of SG values in specific glucose ranges during the run-in period (baseline) and during stage 3 of the study period by all subjects using the unmodified 780G pump with the Guardian 4 sensor in Phase 1 and by all transition and naïve subjects using the modified 780G pump with the Simplera Sync sensor in Phase 2. 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.[14]

The data in *Table 56* show that using the SmartGuard feature with the Auto correction feature kept SG values in the target range and reduced time above range for subjects with type 2 diabetes. Specifically, subjects spent more time in range (70–180 mg/dL) and less time in hyperglycemia (>180 mg/dL) during stage 3 of the study period compared with the run-in period for both study Phases 1 and 2 (both transition and naïve subjects).

[14] 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 56. Percentage of SG values in Different Ranges during the Run-in Period and Study Period Stage 3

Category	SG Range (mg/dL)	Phase 1		Phase 2 (Transition Subjects)		Phase 2 (Naïve Subjects)	
		Run-in Period (N = 95)	Study Period Stage 3 (N = 91)	Run-in Period[a] (N = 62)	Study Period Stage 3 (N = 66)	Run-in Period (N = 236)	Study Period Stage 3 (N = 232)
Low SG Value	<54	0.0 ± 0.1 (0.0, 0.1)	0.0 ± 0.1 (0.0, 0.1)	0.0 ± 0.1 (0.0, 0.1)	0.0 ± 0.0 (0.0, 0.0)	0.0 ± 0.1 (0.0, 0.0)	0.0 ± 0.1 (0.0, 0.0)
	<70	0.4 ± 0.7 (0.3, 0.6)	0.3 ± 0.4 (0.2, 0.4)	0.2 ± 0.5 (0.1, 0.4)	0.3 ± 0.3 (0.2, 0.3)	0.3 ± 0.5 (0.2, 0.4)	0.3 ± 0.4 (0.2, 0.4)
Target SG Value	70 – 140	41.5 ± 19.5 (37.6, 45.5)	50.9 ± 13.7 (48.1, 53.8)	49.0 ± 15.4 (45.1, 52.9)	56.5 ± 11.4 (53.7, 59.3)	45.3 ± 19.7 (42.8, 47.8)	58.1 ± 13.6 (56.4, 59.9)
	70 – 180	72.2 ± 17.1 (68.7, 75.7)	79.8 ± 11.4 (77.4, 82.2)	78.5 ± 14.0 (75.0, 82.1)	83.7 ± 8.9 (81.5, 85.9)	76.4 ± 15.9 (74.3, 78.4)	84.9 ± 9.7 (83.7, 86.2)
High SG Value	> 140	58.0 ± 19.7 (54.0, 62.0)	48.8 ± 13.7 (45.9, 51.6)	50.8 ± 15.4 (46.9, 54.7)	43.3 ± 11.4 (40.5, 46.1)	54.4 ± 19.8 (51.9, 56.9)	41.6 ± 13.6 (39.8, 43.3)
	> 180	27.3 ± 17.2 (23.8, 30.9)	19.9 ± 11.5 (17.5, 22.3)	21.2 ± 14.1 (17.6, 24.8)	16.0 ± 8.9 (13.8, 18.2)	23.4 ± 15.9 (21.3, 25.4)	14.8 ± 9.7 (13.5, 16.0)
	> 250	4.5 ± 5.7 (3.4, 5.7)	2.6 ± 3.8 (1.8, 3.4)	2.8 ± 4.3 (1.7, 3.9)	1.7 ± 2.1 (1.2, 2.2)	3.5 ± 5.2 (2.8, 4.1)	1.7 ± 2.5 (1.3, 2.0)
	> 350	0.2 ± 0.9 (0.0, 0.4)	0.1 ± 0.4 (0.0, 0.2)	0.1 ± 0.3 (-0.0, 0.2)	0.0 ± 0.1 (0.0, 0.1)	0.1 ± 0.4 (0.1, 0.2)	0.1 ± 0.2 (0.0, 0.1)
Note: Values are presented as Mean ± SD (95% CI) except Number of subjects							

[a] Baseline reflects data gathered at Phase 2 screening and is therefore not a true baseline.

Table 57 shows the difference in mean sensor glucose from run-in to study period stage 3 for all subjects using the unmodified 780G pump with the Guardian 4 sensor (Phase 1) and the modified 780G pump with the Simplera Sync sensor (Phase 2). 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 glucose range.

Table 57. Difference in Mean Glucose Value (mg/dL) between the Run-in Period and Study Period Stage 3

Category	Phase 1			Phase 2 (Transition Subjects)			Phase 2 (Naïve Subjects)		
	Run-in period (N =95)	Study Period Stage 3 (N = 91)	Difference between Run-in Period and Study Period Stage 3 (N = 91)	Run-in period[a] (N = 62)	Study Period Stage 3 (N = 66)	Difference between Run-in Period and Study Period Stage 3 (N = 62)	Run-in period (N = 236)	Study Period Stage 3 (N = 232)	Difference between Run-in Period and Study Period Stage 3 (N = 232)
Mean Glucose Value	157.1 ± 22.4 (152.5, 161.7)	147.5 ±15.2 (144.4, 150.7)	-9.1±18.3 (-12.9, -5.3)	149.8 ±17.6 (145.3, 154.2)	142.1 ±11.2 (139.4, 144.9)	-7.3 ±13.5 (-10.7, -3.9)	152.9 ±21.2 (150.2, 155.6)	140.7 ±13.3 (139.0, 142.4)	-12.3±19.5 (-14.9, -9.8)
Note: Values are presented as Mean ± SD (95% CI) except Number of subjects									

[a] Baseline reflects data gathered at Phase 2 screening and is therefore not a true baseline.

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). *Table 58* shows the mean sensor glucose (SG) value for each target setpoint option when that setpoint

was used during the overall study period. The data in *Table 58* 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 58. Mean Sensor Glucose Values (mg/dL) during SmartGuard Use Stratified by Target Glucose Setpoint during the Study Period

Phase 1					
Category	**Overall (N = 94)**	**Target Glucose (mg/dL)**			
		100 (N = 88)	**110 (N = 4)**	**120 (N = 94)**	**150 (N = 8)**
Mean Glucose Values During SmartGuard	150.6 ± 14.7 (147.6, 153.7)	146.7 ± 12.9 (144.0, 149.4)	151.7 ± 13.4 (130.4, 173.0)	155.6 ± 15.2 (152.4, 158.7)	179.0 ± 80.8 (111.4, 246.6)
Phase 2					
Category	**Overall (N = 302)**	**Target Glucose (mg/dL)**			
		100 (N = 291)	**110 (N = 12)**	**120 (N = 287)**	**150 (N = 25)**
Mean Glucose Values During SmartGuard	142.5 ± 11.1 (141.2, 143.7)	140.4 ± 11.2 (139.1, 141.7)	142.0 ± 11.3 (134.8, 149.1)	148.6 ± 14.9 (146.9, 150.3)	148.1 ± 38.7 (132.1, 164.1)
Note: Values are presented as Mean ± SD (95% CI).					

Figure 3 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.[15,16] *Figure 3* shows that a greater percentage of subjects had an HbA1C that was less than 7% at the end of the study than at baseline for Phase 1 and Phase 2.

[15] 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.

[16] 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 3. Percentage of Patients with less than 7% HbA1C

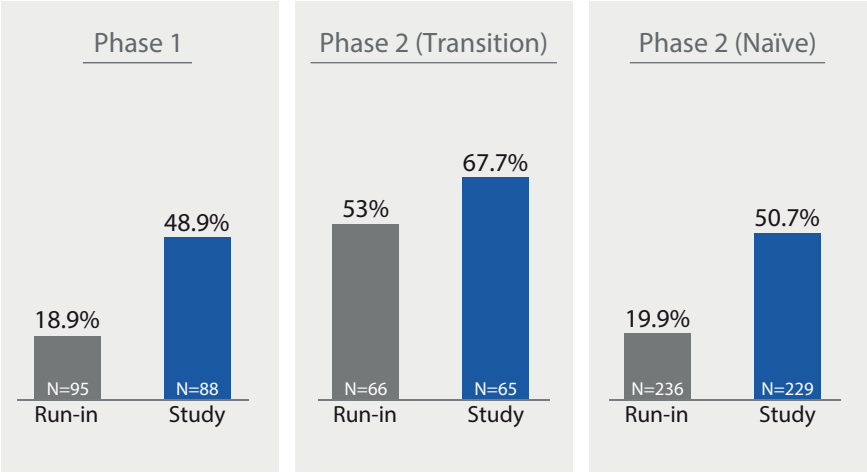


Table 59 shows the change in total daily dose of insulin (TDD) from the run-in period to study period stage 3, and the change in weight from baseline to the end of the study. The mean TDD increased for subjects in both phases of the study, and the mean weight increased slightly for Phase 1 and Phase 2 transition subjects but remained relatively unchanged for Phase 2 naïve subjects. This data helps explain how using the SmartGuard feature with the Auto correction feature might affect a patient's TDD and weight.

Table 59. Changes in Mean TDD and Weight

Category	Phase 1		Phase 2 (Transition Subjects)		Phase 2 (Naïve Subjects)	
TDD (U), Mean ± SD (Median)	**Run-in Period (N = 95)**	**Study Period Stage 3 (N = 91)**	**Run-in Period[a] (N = 63)**	**Study Period Stage 3 (N = 66)**	**Run-in Period (N = 236)**	**Study Period Stage 3 (N = 232)**
	77.4±38.5 (70.8)	91.8±49.3 (84)	93.9 ± 47.8 (88.3)	97.1 ± 42.9 (93.9)	61.0± 36.1 (55.5)	76.1± 44.1 (64.8)
Weight (kg), Mean ± SD (Median)	**Baseline (N = 95)**	**End of Study (N = 92)**	**Baseline[a] (N = 66)**	**End of Study (N = 65)**	**Baseline (N = 235)**	**End of Study (N = 229)**
	105.8 ±21.8 (103.1)	107.3 ±22.0 (105)	109.4 ± 24.1 (105.2)	110.3 ± 23.7 (104.8)	98.0 ± 22.8 (96.1)	98.4 ± 23.0 (96.1)
BMI (kg/m2) Mean ± SD (Median)	**Baseline (N = 95)**	**End of Study (N = 92)**	**Baseline[a] (N = 66)**	**End of Study (N = 65)**	**Baseline (N = 235)**	**End of Study (N = 229)**
	36.0 ± 7.4 (35.2)	36.4 ± 7.6 (35.6)	36.9 ± 8.5 (35.3)	37.2 ± 8.4 (35.1)	34.0 ± 7.3 (32.9)	34.2 ± 7.4 (33.1)

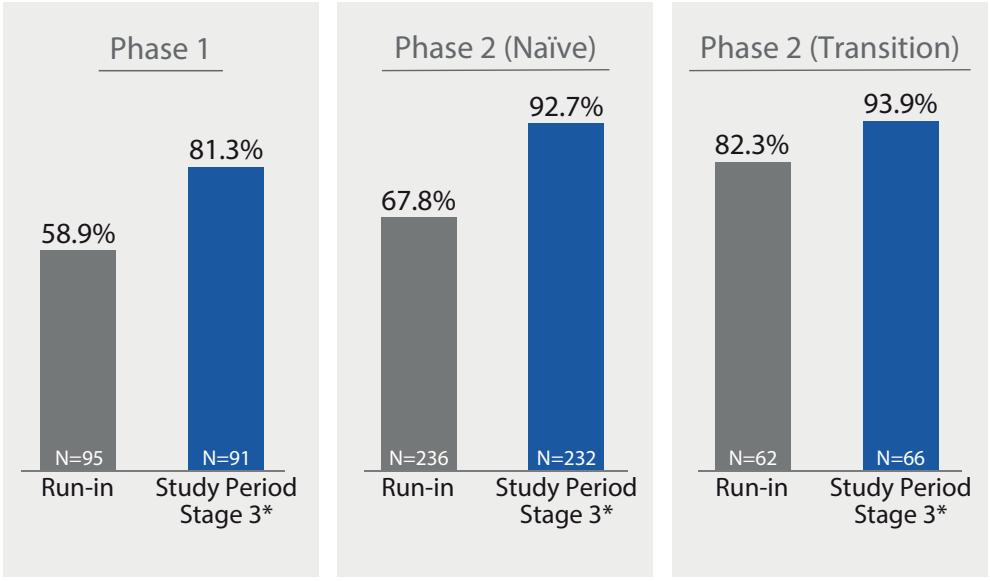
Note: Values are presented as Mean ± SD (Median) except Number of subjects
[a]Baseline reflects data gathered at Phase 2 screening and is therefore not a true baseline.

Figure 4 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 study period stage 3. 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.

For all phases, 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 a greater percentage of subjects using the SmartGuard feature with the Auto correction feature at the 100 mg/dL setpoint spent more time in range.

Figure 4. 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 14% (13/91) of Phase 1, 31% (72/232) of Phase 2 (Naïve) and 30% (20/66) of Phase 2 (Transition) 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 in adults with insulin-requiring type 2 diabetes, and subjects showed improvements in HbA1C (compared to baseline) and time in the target glucose range with use of the updated 780G pump and the Simplera Sync sensor. However, the study had the following limitations: 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 using manual mode or auto-mode (run in period -2 weeks) without Auto correction against results while using the Auto correction feature (study period -3 months).

Additionally, subjects experienced two simultaneous changes (SmartGuard feature modifications and a sensor change) between Phase 1 and Phase 2 of the study period. Since these changes occurred together, it is not possible to attribute the improvements to one specific change.

Due to these limitations, 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.[17] This feature is the same in the MiniMed Flex 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

[17] 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

observation period included the suspension period, the insulin resumption period, and if applicable, an insulin resuspension after basal insulin delivery resumed.

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.[18] This feature is the same in the MiniMed Flex 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.

---

[18] 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.

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

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.[19] 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.

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.

---

[19] 10976639DOC: CIP330 - Evaluation of Updated Continuous Glucose Monitoring (CGM) Form Factor in Adults, Adolescents and Pediatrics.

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 60. Overall Accuracy Compared to YSI

Patient Population (Years)	Number of Subjects	Number of paired SG-YSI Points	Percent of SG within 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 61* and *Table 62*, 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 61. 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.
* For reference range < 70 mg/dL, agreement was based on 15/20/40 mg/dL.

Table 62. 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 63* and *Table 64* 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 63. 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 64. 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 65 and *Table 66* show, for each SG range, the percentage of concurring data points where the paired YSI values were in different blood glucose ranges.

Table 65. 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)

Table 65. Overall concurrence of YSI values and SG readings using SG ranges; Adults, 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
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 66. 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)
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 67. Trend accuracy compared to YSI over time; Adults, Arm

SG Rate Ranges (mg/dL/min)	YSI (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 68. Trend accuracy compared to YSI over time; Pediatrics**, Arm

SG Rate Ranges (mg/dL/min)	YSI (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 69. 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 70. 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.

Table 70. Sensor Accuracy Compared to YSI Over Time; Pediatrics*, Arm (continued)

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 (%)
* Data includes pediatric subjects 7-17 years of age.					

Reading capture rate

Table 71. 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 72. 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 73. 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 74. Glucose TRUE 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**	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 75. Glucose TRUE 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**	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 76. Glucose FALSE 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**	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 77. 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 78. Glucose CORRECT DETECTION 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**	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 79. Glucose CORRECT DETECTION 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**	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)

Table 79. Glucose CORRECT DETECTION Alert Performance, Pediatrics (continued)

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
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 80. Glucose MISSED DETECTION 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**	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 81. Glucose MISSED Detection 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**	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)

Appendix A: Alerts

Appendix A: Alerts

Overview of alerts

The app generates alerts that notify you differently depending on when an action is required and what condition caused the alert. Always read and respond to alerts.

A red dot on the Alerts icon on the Home screen indicates that there are one or more open alerts. Tap to view the Open Alerts and History menus. If there is more than one alert, the alerts are listed by priority starting with the highest priority at the top.

The following table describes the icons that appear with alerts in the Alerts menu.

Priority alert icons	
	• High priority low glucose alerts • High priority system alerts • High priority suspend features alerts • Medium priority low glucose alert
	• High priority high glucose alert • Medium priority high glucose alert
	• Medium priority suspend features alert • Medium priority system alerts • Low priority low glucose alerts • Low priority high glucose alerts • Low priority system alerts

Priority alert icons	
	• Priority alerts that have been resolved or dismissed

Message icons	
	• Non-priority system alerts.
	• Non-priority system alerts that have been resolved or dismissed.

The following table describes the behaviors of notifications on your mobile device when an alert occurs in the MiniMed app.

Notifications on your mobile device	
Lock screen notification	• Occurs if push notifications are enabled in the mobile device settings. • The text that shows in the notification depends on your Notification privacy settings in the app.
Sound	• Occurs if sound is enabled in the mobile device settings and the App volume and mute settings in the app. • Alerts start at the volume you set in the App volume and mute settings in the app, and then get louder if not addressed.
Vibration	• Occurs if vibration is enabled in the mobile device settings.

High priority

High priority alerts warn you when there is a condition that requires you to respond to the alert immediately.

Alert behaviors	
App banners	• A temporary alert screen appears over the current app screen in view. • If the temporary alert screen is not addressed, it is replaced by a Home screen alert banner.
Pump light	• Flashes red. • The down arrow light also appears for low glucose alerts.
Pump sound and vibration	• Either one or both occur in a pattern based on your Pump sound and vibration settings in the app. • Both occur after 10 minutes if the alert condition is not resolved, even if one of the settings is turned off in the app.
Repeat	• Alert behaviors reoccur every 5 minutes until you respond to the alert or the condition resolves.

Note the following exceptions to the high priority alert behaviors:

- CALL FOR EMERGENCY ASSISTANCE: I HAVE DIABETES alert — The title of the alert displays on the lock screen, regardless of your privacy settings. Pump sound and pump vibration occur immediately, and the alert repeats every 2 minutes.
- Charge pump now alert — The pump sound and pump vibration occur immediately.
- The pump light color may vary if an alert occurs when the pump has low power while it is on the charger.
- Pump sound and pump vibration do not occur for alerts that do not have pump alert behaviors. These alerts are notated with an asterisk in the alerts list.
- High pump temperature while delivery is stopped — The pump sound and pump vibration occur immediately.
- Delivery suspended >30 minutes - The pump sound and pump vibration occur immediately.

Medium priority

Medium priority alerts warn you when there is a condition that requires you to respond to the alert soon.

Alert behaviors	
App banners	• A temporary alert screen appears over the current app screen in view. • If the temporary alert screen is not addressed, it is replaced by a Home screen alert banner.
Pump light	• Flashes yellow. • The down arrow light also appears for low glucose alerts.
Pump sound and vibration	• Either one or both occur based on your Pump sound and vibration settings in the app.
Repeat	• Alert behaviors reoccur every 15 minutes until you respond to the alert or the condition resolves.

Note the following exceptions to the medium priority alert behaviors:

- Alert on low alert – Repeats every 5 minutes until you respond to the alert.
- Alerts that do not have pump alert behaviors are notated with an asterisk in the alerts list.

Low priority

Low priority alerts warn you when there is a condition that requires you to respond to the alert.

Alert behaviors	
App banners	• A temporary alert screen appears over the current app screen in view. • If the temporary alert screen is not addressed, it is replaced by a Home screen alert banner.
Pump light	• Does not occur
Pump sound and vibration	• Does not occur.
Repeat	• Does not occur.

Note the following exception to the low priority alert behaviors:

- App closed. Tap to reopen the app. You will not receive SG values or notifications alert – This alert is a notification on the mobile device lock screen only and does not appear in the app.

Messages

Messages inform you about system conditions that are not critical.

Alert behaviors	
App banner	• A Home screen alert banner occurs.
Pump light	• Does not occur.
Pump sound and vibration	• Does not occur.
Repeat	• Does not occur.

Note the following exception to the messages behaviors:

- Lost pump communication alert – A blue pump light occurs. The pump sound or pump vibration, or both, also occur. The alert repeats every 30 minutes until you respond to the alert.

Alerts list

The following table lists the alerts that occur in the MiniMed app and an explanation of each alert, including how to resolve the alert condition. An asterisk (*) next to an alert title indicates there is no pump light, pump sound, or pump vibration for the alert.

Alert title	Explanation
Active insulin reset to zero* High priority 	An error caused the active insulin value on the pump and app to be reset to zero. Your active insulin may be greater than zero and correction boluses might be temporarily affected. Monitor your glucose during the time specified in the app.
Alert before high* Low priority 	Your sensor glucose (SG) is approaching the High limit you set. Monitor your glucose.
Alert before low* Low priority 	Your sensor glucose (SG) is approaching the Low limit you set. Monitor your glucose.

Alert title	Explanation
Alert on high Medium priority 	Your sensor glucose (SG) is at or above the High limit you set. Check your blood glucose (BG) and treat your glucose as instructed by your healthcare professional.
Alert on low Medium priority 	Your sensor glucose (SG) is at or below the Low limit you set. Check your blood glucose (BG) and treat your glucose as instructed by your healthcare professional.
App closed. Tap to re-open the app. You will not receive SG values or notifications.* Low priority (No alert icon)	You are not getting sensor glucose (SG) information because the app closed. Bring the app to the foreground to continue getting sensor glucose (SG) values and glucose alerts.
BG not received* No priority 	The blood glucose (BG) reading you entered could not be used to update the sensor because your sensor lost Bluetooth connectivity with your pump. You may not be getting sensor glucose (SG) values or glucose alerts. Make sure your sensor and pump are close to your mobile device to update the sensor and continue getting sensor glucose (SG) values and glucose alerts. When your sensor reconnects, you are alerted if you need to enter a new blood glucose (BG) meter reading.
Blood glucose not accepted* Medium priority 	The blood glucose (BG) reading you entered could not be used to update the sensor. Monitor your blood glucose (BG). Consider waiting until you are prompted within 2 hours, then enter a new blood glucose (BG) meter reading to continue getting sensor glucose (SG) values and glucose alerts.
Blood glucose not accepted* Medium priority 	The blood glucose (BG) reading you entered could not be used to update the sensor. Wait at least 15 minutes, then enter a new blood glucose (BG) meter reading to continue getting sensor glucose (SG) values and glucose alerts.
Bluetooth off* No priority	Bluetooth is turned off in your mobile device settings. Bluetooth is used to deliver information between the app, pump, and sensor. Turn Bluetooth on in your mobile device settings to use the MiniMed Flex system.

Alert title	Explanation
	
Bolus not delivered Medium priority 	The Bolus calculator entry timed out and a bolus was not delivered. Return to the Bolus calculator and enter a value again to deliver a bolus as needed.
Bolus stopped Medium priority 	A pump error occurred and a bolus was stopped before it could be completed. You were delivering a normal bolus, a Dual Wave bolus, or a Square Wave bolus. Check Daily history for the amount of insulin delivered, then deliver the remaining bolus amount as needed.
Button error* Medium priority 	A button on your pump has been pressed for an unusually long time. Press and release each button on the pump to make sure buttons are not stuck.
CALL FOR EMERGENCY ASSISTANCE: I HAVE DIABETES High priority 	It has been 10 minutes and you have not responded to the Suspend on low alert or the Suspend limit reached alert. Your sensor glucose (SG) has been at or below your Suspend limit during this time and insulin delivery is still suspended. This alert also occurs 10 minutes after the Max suspend reached- Basal resumed alert if you have not responded. Immediately call for emergency assistance.
Change infusion set* Low priority 	You have reached the time that you selected to be reminded to change the infusion set. Change the infusion set, and change the reservoir if needed.
Change sensor* High priority 	Your current sensor is not working properly and cannot be used. Insert and pair a new sensor to continue getting sensor glucose (SG) values and glucose alerts.
Charge pump now High priority 	Your pump battery is depleted. Your pump cannot deliver insulin and sensor glucose (SG) values will soon be unavailable. Charge your pump until you are alerted that it has sufficient charge, then resume insulin delivery as prompted in the app. Continue charging your pump until it is fully charged.

Alert title	Explanation
Charge stopped High priority 	Charging has stopped because your pump temperature is too high. Try charging your pump in a cooler location.
Delivery limit exceeded High priority 	Your insulin delivery is suspended because your hourly insulin delivery limit was reached. Check your blood glucose (BG). Check your Daily history if you were delivering a bolus to see if insulin is still needed. Continue to monitor your glucose.
Delivery still suspended High priority 	Your insulin delivery has been suspended for more than 30 minutes. Insulin was suspended because your pump needs to finish installing an update. Complete the pump software update, then resume insulin delivery.
Delivery suspended > 30 minutes High priority 	Your insulin delivery has been suspended for more than 30 minutes. Insulin was suspended because of a pump-related alert. Tap the Pump icon for more information, then resume insulin delivery.
Delivery suspended > 30 minutes High priority 	Your insulin delivery has been suspended for more than 30 minutes. Insulin was suspended because either or both the reservoir and set were being changed, but the change was not completed. Some alerts cannot occur until the change is complete. Complete the reservoir and set change, then resume insulin delivery.
Delivery suspended > 30 minutes Medium priority 	Your insulin delivery has been suspended for more than 30 minutes. You manually suspended insulin. Resume insulin delivery as needed.
Enter blood glucose* Medium priority 	A blood glucose (BG) entry is needed to update sensor. Your last blood glucose (BG) entry was not accepted. Check and enter your blood glucose (BG) meter reading to continue getting sensor glucose (SG) values and glucose alerts.

Alert title	Explanation
Enter blood glucose* Low priority 	SmartGuard mode requires a blood glucose (BG) reading to update the sensor in order to begin or continue in SmartGuard mode. Enter your blood glucose (BG) meter reading to use SmartGuard mode.
Enter blood glucose* Low priority 	SmartGuard mode reached the time limit for the maximum delivery rate of 7 hours that is set by the system. To continue using SmartGuard mode, enter your blood glucose (BG) meter reading to update the sensor. Follow instructions from your healthcare professional to determine if you need to treat your glucose. Monitor your glucose.
Enter blood glucose* Low priority 	SmartGuard mode reached the time limit for the minimum delivery rate that is set by the system. Minimum delivery rate is either 3 hours or 6 hours, depending on individual conditions. To continue using SmartGuard mode, enter your blood glucose (BG) meter reading to update the sensor. Follow instructions from your healthcare professional to determine if you need to treat your glucose. Monitor your glucose.
Enter blood glucose* Low priority 	Your glucose may be lower than the sensor glucose (SG) value used by SmartGuard mode. To continue using SmartGuard mode, enter your blood glucose (BG) meter reading to update the sensor.
Expired sensor* Medium priority 	Your sensor reached the end of its useful life. Insert and pair a new sensor to continue getting sensor glucose (SG) values and glucose alerts.
Fall alert* Low priority 	Your sensor glucose (SG) is falling at or above the Fall rate you set. Check your blood glucose (BG) to determine if treatment is needed and continue to monitor your glucose.
Finish software update in the app* Medium priority 	You left the app while your pump was installing an update, and your pump can't deliver insulin until the update is complete. Return to the app to complete the pump software update, then resume insulin delivery. If you closed the app, all sensor glucose (SG) values and glucose alerts may not be available until you return to the app and the update is completed.

Alert title	Explanation
High pump temperature High priority 	The temperature of your pump is too high, and insulin is not being delivered. Your pump needs to be in a cooler location to prevent the insulin from getting too hot. Move your pump to a cooler location, then resume insulin delivery when prompted.
Insulin flow blocked High priority 	There is a block in the insulin flow, and insulin is not being delivered. Check your ketones and blood glucose (BG), and treat your glucose as needed. Check the tubing and infusion site for anything abnormal, and change the reservoir and infusion set as needed. You can try resuming basal insulin delivery, but if the alert repeats, you must change the reservoir and infusion set.
Lost pump communication No Priority 	Your mobile device lost Bluetooth connectivity with your pump and you are not getting sensor glucose (SG) values or glucose alerts. Make sure that Bluetooth is turned on in your mobile device settings and that your mobile device is not out of range from your pump. Make sure your pump is charged and is not shut down. If this does not solve the issue, follow the instructions in the app.
Low pump battery (<1 hour) Medium priority 	There is less than 1 hour of pump battery life remaining. Charge your pump now to continue using your pump and sensor without interruption.
Low pump battery (<10 hours)* Low priority 	There are less than 10 hours of use remaining before your pump battery is depleted. Charge your pump soon to continue using your pump without interruption.
Low pump temperature High priority 	The temperature of your pump is too low, and your pump is not charging. Your pump needs to be in a warmer location to charge and to prevent the insulin from getting too cold. Move your pump and charger to a warmer location, then continue charging your pump.
Low reservoir (<XX>X>U) Medium priority	The amount of insulin remaining in your pump reservoir is at half of the Low reservoir value you set. Change the reservoir soon.

Alert title	Explanation
	
Low reservoir (<XX>X>U)* Low priority 	The amount of insulin remaining in your pump reservoir reached the Low reservoir value you set. Change the reservoir soon.
Max suspend reached – Basal resumed High priority 	Your basal insulin delivery is resumed because the maximum 2-hour suspend time was reached. Check your blood glucose (BG) and treat your glucose as instructed by your healthcare professional.
Mobile device battery low* Low priority 	The battery is low on your mobile device. Recharge your mobile device to continue using the MiniMed Flex system without interruption.
No SG values > 30 minutes High priority 	Your sensor glucose (SG) values have been unavailable for more than 30 minutes since warmup. You are not getting sensor glucose (SG) values or glucose alerts. Tap the Sensor icon for more information.
No SG values > 30 minutes High priority 	Your sensor glucose (SG) values have been unavailable for more than 30 minutes. You are not getting sensor glucose (SG) values or glucose alerts. Tap the Sensor icon for more information.
Prolonged high sensor glucose High priority 	Your sensor glucose (SG) has been 250 mg/dL or higher for more than 3 hours. Check that your infusion set is functioning properly. Check your ketones and blood glucose (BG), and treat your glucose as instructed by your healthcare professional.
Pump error occurred High priority	An error occurred on your pump that has been resolved, but your pump is not delivering insulin. Resume insulin delivery.

Alert title	Explanation
	
Pump error - Restart needed High priority 	An error occurred on your pump that requires a restart, and your pump is not delivering insulin. Restart your pump. Afterward, rewind your pump, reinsert the reservoir in your pump, then resume insulin delivery.
Pump error - Rewind pump and load reservoir High priority 	An error occurred on your pump that has been resolved, but your pump is not delivering insulin. Rewind your pump, reinsert the reservoir in your pump, then resume insulin delivery. If it is time to replace the reservoir or replace the reservoir and infusion set, change the reservoir or the reservoir and infusion set when supplies are available. Disconnect the tubing from your body when prompted.
Pump error - Rewind pump and load reservoir High priority 	Your pump was exposed to a magnet or magnetic field that caused a pump error, and your pump is not delivering insulin. Move your pump away from the magnet or magnetic field. Afterward, rewind your pump, reinsert the reservoir in your pump, then resume insulin delivery. Monitor your glucose. If it is time to replace the reservoir or replace the reservoir and infusion set, change the reservoir or the reservoir and infusion set when supplies are available. Disconnect the tubing from your body when prompted.
Pump is now cool Medium priority 	Your pump was too hot, and now your pump is cool enough to deliver insulin. Resume insulin delivery as needed.
Pump is sufficiently charged Medium priority 	Your pump now has sufficient charge for use. Resume insulin delivery as needed. Your pump is not fully charged and needs to remain on the charger to finish charging completely.
Pump restarted - Rewind required Medium priority	A rewind is required because your pump restarted, and your pump is not delivering insulin. Rewind your pump, reinsert the reservoir, then resume insulin delivery as needed.

Alert title	Explanation
	
Reservoir empty High priority 	The reservoir is out of insulin and your pump is not delivering insulin. Change the reservoir to resume insulin delivery.
Rise alert* Low priority 	Your sensor glucose (SG) is rising at or above the Rise rate you set. Check your blood glucose (BG) to determine if treatment is needed and continue to monitor your glucose.
Sensor grace period ending soon* Low priority 	Your sensor is in the grace period. You will need to change your sensor within 12 hours.
Sensor grace period started* Low priority 	Your sensor is in the grace period. You will need to change your sensor within 24 hours.
Slow charging Medium priority 	Charging speed is slow because your pump temperature is higher than usual. You can keep charging your pump, but it will take longer than normal. Try charging your pump in a cooler location.
SmartGuard exit Medium priority 	You are no longer using SmartGuard mode. To return to SmartGuard mode, check the SmartGuard checklist for requirements that must be met. Tap requirements requiring an action and follow the onscreen instructions.
Suspended before low* Medium priority 	Your insulin delivery is suspended because your sensor glucose (SG) is approaching the Suspend limit you set. Monitor your glucose.
Suspend limit reached High priority	Your sensor glucose (SG) is at or below the Suspend limit you set and insulin delivery is still suspended. Your glucose continued

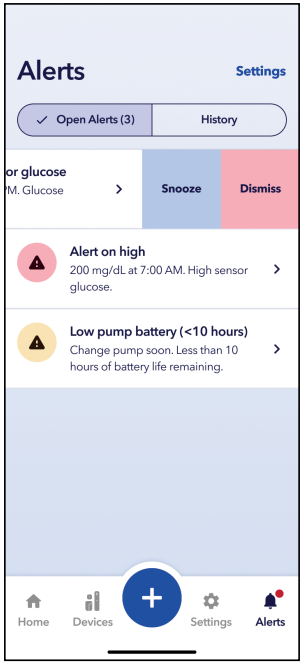
Alert title	Explanation
	to fall after delivery was suspended by the Suspend before low feature. Check your blood glucose (BG) and treat your glucose as instructed by your healthcare professional.
Suspend on low High priority 	Your insulin delivery is suspended because your sensor glucose (SG) is at or below the Suspend limit you set. Check your blood glucose (BG) and treat your glucose as instructed by your healthcare professional. Continue to monitor your glucose.
Time settings error High priority 	An error occurred with the time settings on your pump. Your pump is not delivering insulin and you are not getting sensor glucose (SG) values or glucose alerts. Follow the onscreen instructions in Learn more to fix your time settings and resume insulin delivery.
Time zone difference* Low priority 	Your Therapy time setting in the app is not the same as the time zone on your mobile device. Sync your Therapy time to your current time zone as directed by your healthcare professional.
Urgent low sensor glucose High priority 	Your sensor glucose (SG) is below 64 mg/dL. Check your blood glucose (BG) and treat your glucose as instructed by your healthcare professional.
Very high basal setting* Low priority 	The basal pattern that will be active when you exit SmartGuard mode may not be safe. It is set to deliver significantly more insulin than you typically need. Consult your healthcare professional about your basal settings in Manual mode.
Very high basal setting High priority 	Your active basal pattern may not be safe because it is delivering significantly more insulin than you typically need. You are using this basal pattern now because you are using Manual mode or because you exited SmartGuard mode. Check your glucose and consult your healthcare professional about your basal settings in Manual mode.
Warm up has not started Medium priority	A new sensor has not started the automatic 2-hour warm up required for use. Insert a new sensor if you have not inserted one, or if you inserted one more than 30 minutes ago.

Alert title	Explanation
⚠	

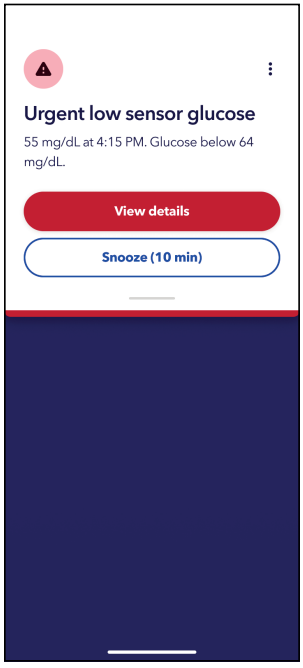
Responding to alerts

You respond to alerts by following instructions prompted by the app to resolve the condition, snoozing the alert, or dismissing the alert. Follow the alert instructions in the app to resolve the alert. Alerts move from the Open Alerts menu to the History menu when they are resolved or dismissed.

When you are unsure how to resolve an alert, or a system alert occurs frequently, contact 24-Hour Technical Support at +1-800-646-4633 for assistance. Write down error codes that appear on the alert screen, when displayed, to provide to 24-Hour Technical Support. Error codes can be accessed any time by tapping the alert in the Open Alerts menu or History menu.

Alert response options	
Screen	**Options**
	**Open Alerts menu** • Swipe on the alert to reveal the option to Dismiss. Snooze also appears if the alert can be snoozed. • Tap the alert to open the full alert details and all options available.

Alert response options



Temporary alert screen

Tap one of three options:

- The View details button that opens the full alert details and all options available.
- An action button to resolve, dismiss, or snooze the alert.
- The ⋮ menu that lists additional options available.

Home screen alert banner

Tap the banner to open one of two screens:

- The full alert details and all options available if there is only one open alert.
- The Open Alerts menu displaying all open alerts if there are multiple open alerts.

Snoozing alerts

When you snooze an alert, the alert repeats if the alert condition is still present after the duration of time that you set. The alert remains active in the Open Alerts menu. Alerts that can be snoozed are the glucose alerts in Alerts and glucose settings menu and the Very high basal setting alert.

Dismissing alerts

When you dismiss an alert, the alert is no longer open. Closed alerts move from the Open Alerts menu into the History menu, and the alert does not repeat.

The following alerts cannot be dismissed:

- Urgent low SG
- Prolonged high SG
- Delivery suspended > 30 minutes
- Delivery still suspended
- Button error
- Pump error occurred

Insulin suspension and alerts

Some alerts warn you that insulin delivery is stopped until manually resumed. A Status banner appears and remains on the Home screen even if the alert is dismissed or the alert condition is resolved. Use the Status banner to resume basal insulin delivery.

All alert conditions causing insulin suspension need to be resolved to resume insulin delivery. Consider using other insulin delivery methods as necessary if insulin delivery with your pump cannot be promptly resumed.

If insulin is suspended while the pump is delivering a bolus or filling the cannula, the bolus or cannula filling is cancelled. Check your Daily History to see the amount of bolus insulin that was delivered before suspension occurred. Deliver insulin if needed.

Glucose alerts

Sensor glucose (SG) values are used for glucose alerts. Optional glucose alerts are based on limits and rates that you set.

Alerts about your glucose show the sensor glucose (SG) value at the time of the alert. Different alert settings can be set for day and night, including Max volume at night.

High glucose alerts

The High limit and Rise rate in the High glucose settings are used to alert you when your sensor glucose (SG) is high or rising. Alerts based on these settings are optional.

Note the following when selecting High limit and Rise rate alert settings:

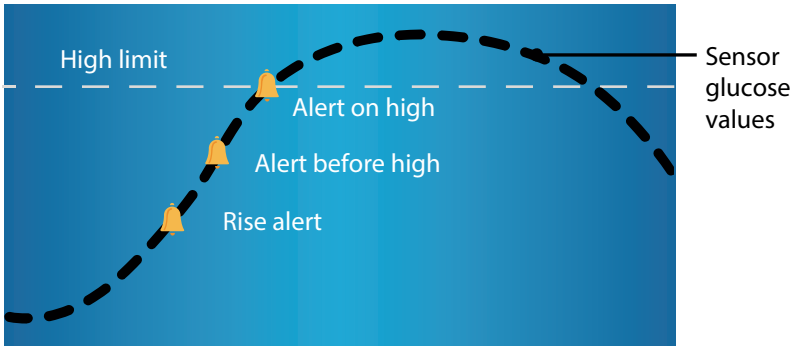
- The High limit can be set from 100 mg/dL to 400 mg/dL.
- The Rise rate can be set at 1 mg/dL/min, 2 mg/dL/min, or 3 mg/dL/min.
- You can snooze High limit alerts that occur, from 10 minutes to 3 hours.

A description of alerts that you can set based the High limit and Rise rate are described in the following table.

Alert	Description
Alert before high	• Alerts you when your sensor glucose (SG) is predicted to reach the High limit in the time duration you set, from 5 to 30 minutes • Raises your awareness of potential high sensor glucose (SG)
Alert on high	• Alerts you when your sensor glucose (SG) reaches or exceeds the High limit • Raises your awareness of current high sensor glucose (SG)
Rise alert	• Alerts you when your glucose is increasing at or more than the Rise rate you set • Raises your awareness that your sensor glucose (SG) is rising rapidly, such as after a meal or if a bolus is missed

You are always alerted if your sensor glucose (SG) is 250 mg/dL or greater for more than 3 hours, regardless of your settings.

The following graph shows the alerts that occur based on the High limit and Rise rate.



Low glucose alerts

The Low limit and the Fall rate in the Low glucose settings are used to alert you when your sensor glucose (SG) is low or falling. Alerts based on these settings are optional.

Note the following when selecting the Low limit and Fall rate alert settings:

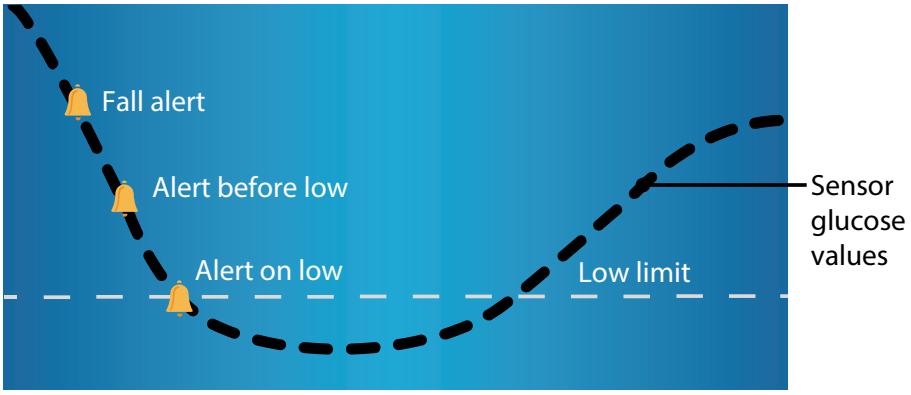
- The Low limit can be set from 65 mg/dL to 90 mg/dL.
- The Fall rate can be set at 1 mg/dL/min, 2 mg/dL/min, or 3 mg/dL/min.
- You can snooze Low limit alerts that occur, from 10 minutes to 45 minutes.

A description of alerts that you can set based on the Low limit and Fall rate are described in the following table.

Alert	Description
Alert before low	• Alerts you when your sensor glucose (SG) is predicted to reach the Low limit in 30 minutes • Raises your awareness of potential low sensor glucose (SG)
Alert on low	• Alerts you when your sensor glucose (SG) reaches or falls below the Low limit • Raises your awareness of current low sensor glucose (SG)
Fall alert	• Alerts you when your glucose is decreasing at or more than the Fall rate you set • Raises your awareness that your sensor glucose (SG) is falling rapidly, such as during exercise

You are always alerted if your sensor glucose (SG) is below 64 mg/dL, regardless of your settings. This threshold depends on the sensor that you use. Glucose detection and alert rate are less reliable below this threshold.

The following graph shows the alerts that occur based on the Low limit and Fall rate.



Suspend alerts

There are alerts that occur when your insulin is suspended due to the suspend features (Suspend before low and Suspend on low). These suspend features occur based on your Suspend limit and your sensor glucose (SG) value.

Note the following when selecting the suspend settings:

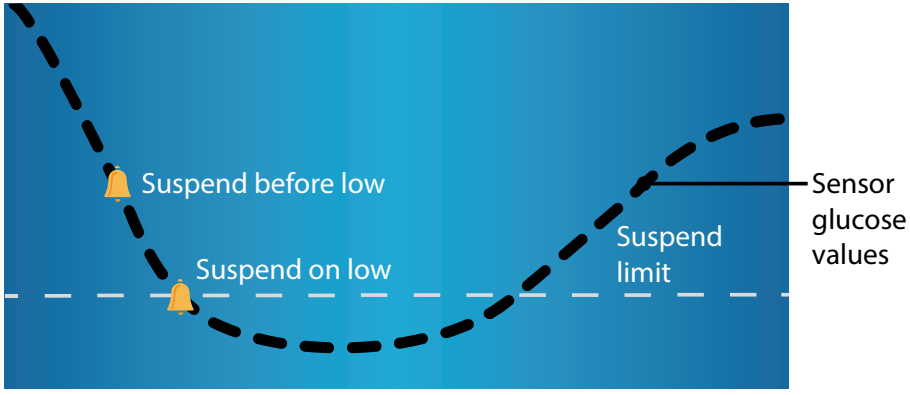
- The Suspend limit can be set from 55 mg/dL to 90 mg/dL.
- Suspend alerts cannot be snoozed.

Alert	Description
Suspend before low	• Alerts you when your insulin is suspended because your sensor glucose (SG) is predicted to reach the Suspend limit in 30 minutes • Raises your awareness that your insulin is suspended and of potential low sensor glucose (SG) • The alert can be turned on or off if you turn the Suspend before low feature on

Alert	Description
Suspend on low	• Alerts you when your insulin is suspended because your sensor glucose (SG) reaches or falls below the Suspend limit • Raises your awareness that your insulin is suspended and of current low sensor glucose (SG) • The alert automatically occurs when insulin is suspended due to the Suspend on low feature

If you do not turn either the Suspend before low or Suspend on low feature on, the system alerts you and suspends insulin if your sensor glucose (SG) reaches or falls below 54 mg/dL. You receive the CALL FOR EMERGENCY ASSISTANCE: I HAVE DIABETES alert after 10 minutes if you do not respond to an alert that occurs when you reach or fall below 54 mg/dL or your Suspend limit. You are always alerted if you reach or fall below your Suspend limit after your delivery is suspended by the Suspend before low feature.

The following graph shows the alerts that you can set to occur based on the Suspend limit.



Glossary

Glossary

ACE pump	An alternate controller enabled insulin pump is a device intended for the infusion of insulin into a patient. The ACE insulin pump may include basal and bolus drug delivery at set or variable rates.
active insulin	Active insulin is 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	A Bolus calculator setting used to indicate 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.
alternate controller enabled pump	see **ACE pump**.
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.

App Manager	The App Manager is a component available through Medtronic that comes with the MiniMed app pre-installed. The App Manager connects to the pump through Bluetooth®* wireless connection. Note: Unless otherwise stated, the term 'mobile device' refers to your mobile device, or an App Manager.
auto basal	The automatically adjusted basal insulin delivered in SmartGuard mode based on the current sensor glucose (SG) readings.
Auto correction	A correction bolus automatically delivered by the MiniMed Flex system to maximize time in range. Auto correction only occurs when using the SmartGuard 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 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 SmartGuard 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 BG levels due to carbohydrates, or to lower a high 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.
CareLink system software	CareLink 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.
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, 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.
high limit	The setting the insulin pump uses to determine when to alert for a high SG condition.
iCGM	The acronym for integrated continuous glucose monitor. See **CGM**.
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 BG is reduced by one unit of insulin. The insulin sensitivity factor is used to calculate correction bolus amounts.

Interoperability	The ability to communicate and exchange data with different systems.
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 SmartGuard 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 (BG) meter.
MiniMed Simulator app	An app which simulates the functions of the MiniMed app. The Simulator app is for demonstration purposes only, and does not connect to the pump.
mobile device	Your compatible device (such as a cell phone) where you install the MiniMed app. Your mobile device connects to the pump through Bluetooth®* wireless connection. Note: Unless otherwise stated, the term 'mobile device' refers to your mobile device, or an App Manager.
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.
Predictive Low Glucose technology	Software that allows an ACE pump to automatically suspend delivery of insulin when the sensor glucose (SG) value falls below (or is predicted to fall below) predefined threshold values.
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 (SG). For more information, see **sensor glucose (SG)**.
SmartGuard mode	An insulin delivery feature that automatically controls insulin delivery to regulate BG levels to a target SG value.
SmartGuard target	SmartGuard target is the setting to maximize time in range.
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 SmartGuard 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.

Index

Index

Medtronic

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

RF: M065019C001

℞ *Only*

M069910C001_4
2026-03-12

REF MMT-8062, MMT-8072, MMT-8098, MMT-8099

M069910C001

MiniMed Flex™