minimed

MiniMed Flex

Pump and App Instructions for Use

Includes technology developed by dreamed diabetes ai

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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.

WARNING: 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.

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.

System components

The MiniMed Flex system consists of the following devices:

- MiniMed Flex pump
- MiniMed™ app on a compatible mobile device
- Compatible CGM sensor
- Charger
- Charging cable

The system requires a prescription from a healthcare professional.

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 mode*, page 56.
- Predictive Low Glucose technology, which is utilized by the Suspend on low and Suspend before low features. For more information, refer to Continuous glucose monitoring in the System Technical guide located in the MiniMed app.

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 configurations are 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 blood glucose (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 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.

WARNING: Only use compatible U-100 insulin (Humalog, NovoLog, Admelog, Fiasp, or Lyumjev [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.

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.

- **Reservoirs** – Use a compatible reservoir manufactured or distributed by Medtronic Diabetes.
- **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.

Note: For infusion sets, MMT numbers that include the letter A are compatible with the pump system. MMT numbers that do not include the letter A are not compatible with the pump system.

For a list of compatible reservoirs, infusion sets, and MMT numbers, refer to the System Technical guide located in the MiniMed app or on the Global Patient Manuals Library website https://medtronic.com/manuals.

Additional items

The following items may be used with the MiniMed Flex system.

- Pump clip – The pump clip attaches to a belt or a waistband.
- MiniMed Share™ app for Android or iOS – The app can be downloaded onto compatible mobile devices. Refer to the MiniMed Share 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. Note: This product may be registered under one of the licensed names CareLink Connect or MiniMed Share in some countries.
- 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. Note: 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 device.

WARNING: Only use the power adapter provided by Medtronic. Using any other power adapter may not allow the pump to charge properly, leading to hyperglycemia.

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 your 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:

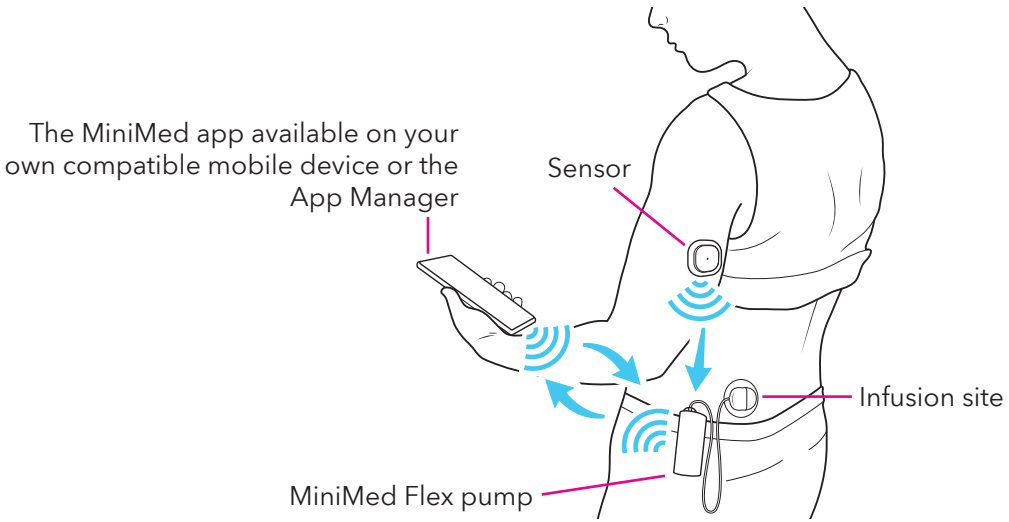
- Rapid-acting glucose
- Blood glucose (BG) testing supplies
- Urine or blood ketone monitoring supplies
- Extra infusion set and reservoir
- Pump charger and cable to connect to a power source
- Insulin syringe
- Short-acting insulin, long-acting insulin, or both (with dosage instructions from a healthcare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

- Adhesive dressing for your sensor
- Glucagon

System overview

Thank you for choosing the MiniMed Flex system.

The MiniMed app pairs with the MiniMed Flex pump to control your insulin delivery and monitor glucose levels. Important components of the system include the following:



Note: Additional components are required with the MiniMed Flex system. For additional information regarding your system and the other components, see the diagram on page 18.

For information on the warnings and precautions for this system, review the *Warnings and Precautions, Risks and Side Effects* section on page 80.

Daily life with your MiniMed Flex system

You can place the pump on or under your clothing to carry it throughout the day. For example, you may put it in a pocket or clip it to your waistband.

When sleeping, you can lay the pump beside you in the bed, place it in a pocket, or clip it to your sleepwear. Just be sure to keep it connected to you all night.

To shower or bathe, disconnect the tubing from your body at the infusion site.

Your pump is waterproof up to 8 feet (2.4 meters) for 1 hour and 45 minutes if you choose to stay connected while in water.

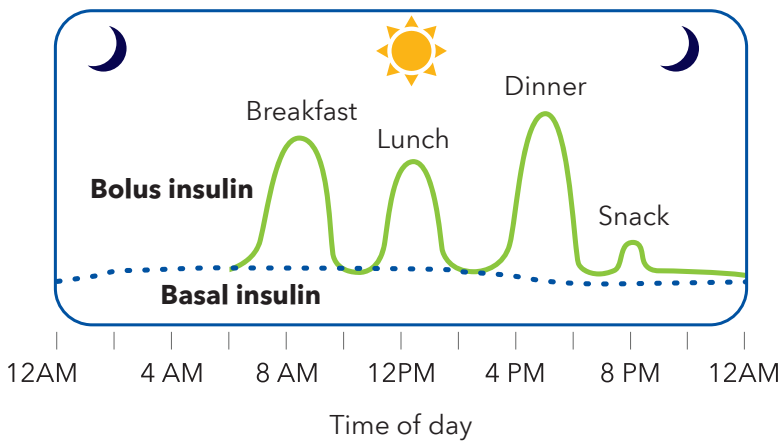
If you disconnect your pump from your body for swimming or activities, be sure to assess your sensor glucose (SG) levels and give a bolus if needed.

Basal and bolus insulin

The insulin in your pump is delivered as basal insulin and bolus insulin.

Basal insulin is small amounts of insulin delivered throughout the day and while you sleep.

Bolus insulin is delivered at the time that it is needed. A carb bolus is the insulin you deliver when you eat carbohydrates (carbs). If your glucose levels are high, a correction bolus can be delivered to help bring your glucose down to your target.



Differences between Manual mode and SmartGuard mode

Your MiniMed Flex system operates in two different modes: Manual mode and SmartGuard mode. Manual mode refers to a group of features that uses your programmed basal rate and requires blood glucose (BG) meter readings to correct glucose levels. SmartGuard mode uses meal information, sensor glucose (SG) values,

and SmartGuard target values to control basal insulin delivery and automatically deliver a correction bolus when glucose levels are high. Both modes require your input, such as entering carbs, to deliver a bolus for meals. When you first begin using the system you are in Manual mode. The system needs at least 48 hours of insulin delivery data before you can begin using SmartGuard mode. The 48 hours begins the first midnight after insulin delivery starts. The following table shows the differences between Manual mode and SmartGuard mode.

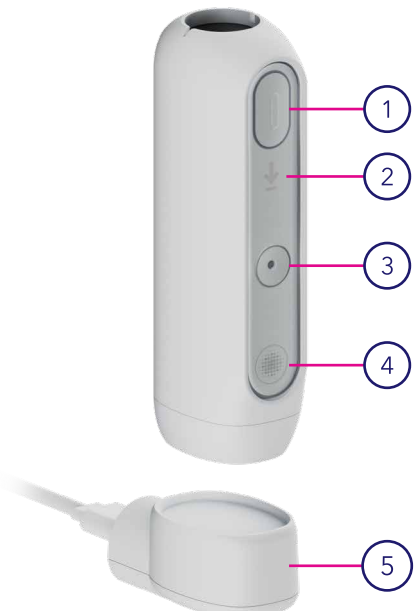
Manual mode	SmartGuard mode
You are in Manual mode when you first start using your pump.	Can be started after a few days of use in Manual mode, at the direction of your healthcare professional. Your system will be in Manual mode after a SmartGuard exit or if SmartGuard mode is not active.
Uses the basal rates you set for continuous insulin delivery during the day and night.	Automatically adjusts basal insulin delivery.
You must enter carbs in the app and deliver a bolus before eating.	You must enter carbs in the app and deliver a bolus before eating.
A blood glucose (BG) meter reading must be used when calculating a bolus.	A sensor glucose (SG) value can be used for bolus calculation if available.
If your glucose is high, you must enter a blood glucose (BG) meter reading to give a correction bolus.	Automatically gives auto corrections when a correction is needed.

Manual mode	SmartGuard mode
Alerts you of high and low glucose, and suspends insulin if needed based on the Alert and glucose settings you entered.	Alerts you of high and low glucose based on the Alert and glucose settings you entered. SmartGuard mode will suspend insulin when needed based on its own calculations.

When you see a note box with a shield icon in this document, the information included refers to SmartGuard mode.

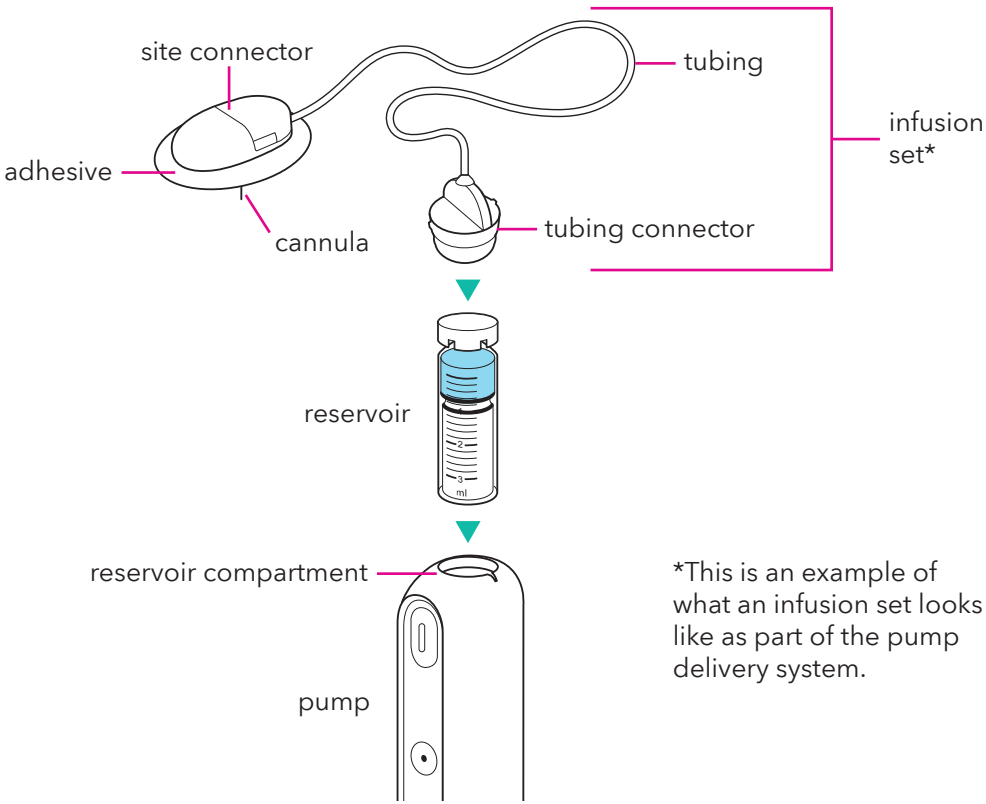
MiniMed Flex pump and delivery system

The MiniMed Flex pump delivers insulin into your body through an infusion set.



1. Status button: Press the oval-shaped button to check the alert status and color. This button is also used to show the pump charging status.
   For more information on pump status and alerts, see the *Pump status and alerts* section on page 44.
2. Low glucose alert arrow: The arrow lights up when a low glucose alert is occurring.
3. Action button: Press the round button to initiate pairing with the MiniMed app.
4. Speaker: The pump speaker is used for audio alerts.
5. Charger: The pump charger connects to a power source and charges the pump battery.

This diagram shows the parts of the pump delivery system, including the pump, reservoir, and an infusion set example.



*This is an example of what an infusion set looks like as part of the pump delivery system.

The pump delivers small doses of insulin. The smallest dose of insulin is 0.05 units. The piston inside the pump must be rewound each time a newly filled reservoir is inserted into the reservoir compartment.

Installing the MiniMed app and MiniMed Simulator app

Install the MiniMed app and the MiniMed Simulator app onto your own compatible mobile device. If you have received the App Manager, the apps are pre-installed. Do not use a damaged mobile device or App Manager with the MiniMed Flex system.

Refer to www.medtronicdiabetes.com or contact 24-Hour Technical Support at 1-800-646-4633 for information about supported devices and operating systems.

If you are using a compatible mobile device

1. Confirm your mobile device is connected to a stable Internet connection.
2. Search for the MiniMed app and MiniMed Simulator app on the Apple™* App Store™*, or the Google Play™* Store.
3. Install the MiniMed and MiniMed Simulator apps on your mobile device.

MiniMed app

MiniMed Simulator app

IMPORTANT: The MiniMed Simulator app is for demonstration purposes only, and does not connect to the pump. It is intended to demonstrate the user interface, and should not be used for therapy decisions. This simulator app should not be used as a substitute for the pump instructions for use and product training.

If you are using the App Manager

Refer to the App Manager Quick Reference Guide for instructions on how to turn on and set up the App Manager. The App Manager also serves as the primary display for patients when their health plan requires it. Once you have finished turning on your device and connecting it to Wi-Fi™*, continue with app setup on the next page.

The MiniMed app and MiniMed Simulator app come pre-installed on your App Manager.

MiniMed app

MiniMed Simulator app

How to begin using the MiniMed app

The MiniMed app is your primary source of information about your therapy and for controlling insulin delivery.

The MiniMed app guides you through the startup process. Read each screen and refer to this document for important information as you set up the app.

Tap the MiniMed app and get started.

MiniMed app: Use this app when you are entering your therapy settings and when you are ready to begin using your pump.

Signing in

Select your country and language, then log in with your existing username and password for your CareLink™ account. If you do not have a CareLink account set up, tap **Create an account** to create one and log in.

Note: Keep your login information so that you have it whenever needed.

Setting up your app

While setting up your MiniMed app, you will configure your app settings, security, and then practice with the MiniMed Simulator app. Follow the instructions in the app to complete these steps.

1 App Settings, Security, and Simulator app

Acknowledge the usage agreements and follow the steps to ensure your mobile device is set to work properly with the app, then tap **Practice with Simulator**.

Before training you can practice by using the MiniMed Simulator app. In the Simulator app you can explore and learn how to use the app features.

IMPORTANT: If you have not received training, STOP HERE and prepare for training using the checklist on the next page. Do not pair your pump or enter therapy settings at this time.

Being prepared for training

Before your training, make sure you have completed the following:

- ☐ Install apps: MiniMed app and the MiniMed Simulator app. (If you are using the App Manager, these apps are pre-installed.)
- ☐ In the MiniMed app, log in or create a CareLink account.
- ☐ Use the MiniMed Simulator app to learn more and practice using the app before your training.

Therapy settings will be entered during training. You can use the Simulator app to practice using the MiniMed app. The Simulator app is for demonstration purposes only, and does not connect to the pump.

You need the following items at your training. Your healthcare professional will let you know if you need to bring anything else:

- ☐ Your compatible mobile device or the App Manager.
- ☐ This Pump Instructions for Use
- ☐ MiniMed Flex pump and charger
- ☐ 1 box of reservoirs
- ☐ 1 box of infusion sets (and the inserter if one was provided)
- ☐ A vial of insulin prescribed for your pump
- ☐ Alcohol wipes
- ☐ 1 box of sensors

2 Product Selection and Pairing

Follow the instructions in the app to pair the pump with the MiniMed app. If you are starting the sensor at this time, you will also insert and pair your sensor.

Note: The mobile device and pump are connected through Bluetooth. Keep the mobile device within 3 feet (1 meter) of your pump throughout the pairing process. The pump only needs to be paired to the app once, while the sensor is disposable and needs to be paired each time.

3 Therapy Settings

Use the information provided by your healthcare professional and follow the instructions in the app to enter your therapy settings, including your basal and bolus settings, and glucose alert and suspend settings.

Basal and bolus settings

Enter your basal and bolus settings. You must set a basal pattern in order to begin using the system.

Basal settings: These settings control the amount of insulin you continuously receive throughout the day and night while in Manual mode.

Bolus settings: These settings determine the amount of insulin you give when eating carbohydrates or correcting glucose levels.

Glucose settings and alerts

Enter your alert and suspend settings. You can also customize settings for low and high glucose alerts, including turning on the Max volume at night feature.

Note: If you skip entering basal and bolus settings or glucose settings and alerts, you can enter and edit your settings after the app startup is complete. See *Insulin settings* on page 35 or *Glucose alerts* on page 53 for more information.

You've finished setting up your app!

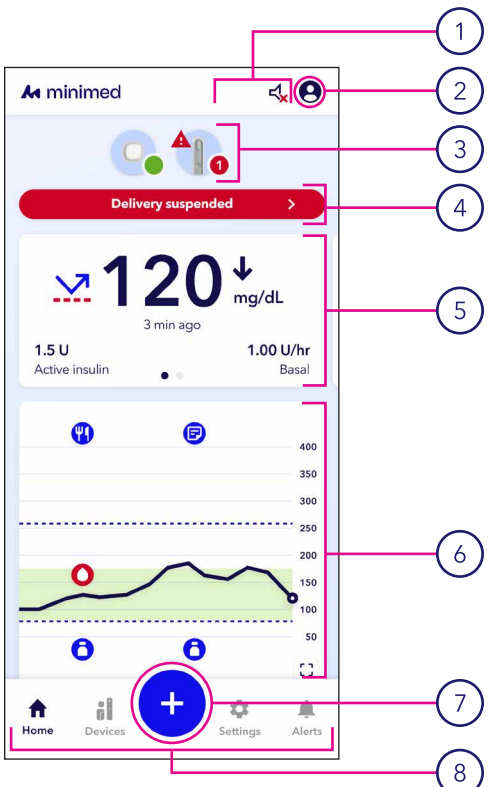
After completing the app startup, continue with one of the following options.

- Tap **Practice with Simulator** to practice therapy tasks.
- Tap **Use MiniMed** if you have received training and are ready to begin insulin pump therapy with the MiniMed Flex system.

Note: If you are not in the app, from your mobile device home screen, tap the MiniMed Simulator app or tap the MiniMed app.

Home screen

The MiniMed app Home screen provides an overview of data received from the pump and sensor. The information and alerts on this Home screen shown are examples and may not appear at the same time when using the app for therapy.



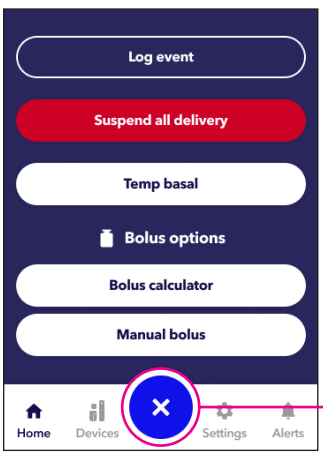
1. Icons: Icons may appear in this location. Tap any icon that appears here to view more details. You can find more information about icons in the Help menu in the app.
2. Profile menu: View a variety of information, such as Daily history, Summary of therapy data, and the Help menu, which includes Important phone settings.

   Daily history is where you can review previously logged data and actions taken within the app.
3. Device status: View the status of the paired devices and tap the device icon to see more information:

   - Green: No actions are needed at this time
   - Yellow: An action is needed soon
   - Red: An action is needed now
   - Gray: Communication between devices is lost and needs to be restored
4. Status banner: Tap the banner for information and follow the steps if needed.
5. Therapy status: View your glucose and therapy information, including the active insulin amount and current basal rate. Swipe for details about your time in range.
6. Trend graph: View the graph to see your glucose levels over time. Tap on the icons for more information about events, such as blood glucose (BG) meter readings and boluses. You can tap and scroll on the trend graph to view all information on the graph.
7. Therapy Action button: Access therapy actions such as the Bolus calculator and suspend delivery, or log an event.
8. Menu bar: Access your settings, device information, and alert history.

Therapy Action menu (Manual mode)

Tapping the Therapy Action button (+) opens a menu of actions you can perform, such as delivering a bolus or suspending insulin delivery. You can also tap **Log event** to enter a blood glucose (BG) meter reading or a note.



You can tap (×) to close the Therapy Action menu and return to the Home screen.

The list of actions you can perform is different depending on whether you are in Manual mode or SmartGuard mode. To learn more about SmartGuard mode, see the *SmartGuard mode* section on page 56.

Bolus options (Manual mode)

There are two Bolus options that can be accessed from the Therapy Action menu while in Manual mode:

- Bolus calculator
- Manual bolus

Instructions for using the Bolus calculator while in Manual mode are given in the next section.

Instructions for giving a Manual bolus are provided in the *Additional bolus options* section on page 49.

Bolus calculator (Manual mode)

The Bolus calculator uses your blood glucose (BG) meter reading and the amount of carbs you enter to calculate a bolus for you to deliver.

You can only use the Bolus calculator after you have entered your personalized therapy settings provided by your healthcare professional. If you skipped this step during setup, see *Settings menu* on page 35.

1. Tap + on the Home screen and select **Bolus calculator**.

2. Enter a glucose value as needed or skip if no correction is needed.

   - Tap **Enter blood glucose** and enter a blood glucose (BG) meter reading or tap **Skip glucose** if you only want to deliver a bolus based on the carbs you are eating. Tap **Next**.

- If you have recently entered a blood glucose (BG) meter reading, the blood glucose (BG) will automatically show on the screen. Tap **Use blood glucose** and tap **Next**.

3. Enter the amount of carbs you are eating, or tap **Skip carbs** if you are only delivering a bolus to correct high glucose. Tap **Next**.

4. Review the screen and tap **Deliver bolus** to send the bolus information to the pump to begin delivery.

Bolus delivery

When you start a bolus, the Home screen provides important information about the status of the bolus delivery.

1. Bolus delivery banner: Shows the progress of the bolus delivery.
2. Stop: Tap **Stop**, and then tap **Stop bolus** to stop a bolus delivery.
3. Active insulin: Shows insulin from boluses that are still active in your body and working to lower your glucose levels. When you have active insulin, your glucose levels may decrease as that insulin continues to work.
4. Carbs icon: Appears on the screen if you enter carbs into the Bolus calculator.
5. BG icon: Appears on the screen if you enter a blood glucose (BG).
6. Bolus icon: Appears on the graph when a bolus delivery is complete. Tap the bolus icon to see the bolus amount.

Stop a bolus delivery

You can stop a bolus delivery before it completes. This might happen if you entered an incorrect value in the Bolus calculator or if you need to delay your meal. The actual amount of insulin delivered is recorded as the bolus amount.

1. Tap **Stop** or anywhere on the bolus delivery banner at the top of the app Home screen.

2. Tap **Stop bolus** on the screen that appears. The amount of insulin that was delivered before the bolus was stopped appears in the bolus delivery banner and appears on the trend graph. Tap to see the amount of bolus insulin delivered before it was stopped or view Daily history in the Profile menu.

Suspend all insulin delivery

Suspending insulin delivery stops basal insulin as well as any bolus delivery in progress.

1. Tap + on the Home screen and select **Suspend all delivery**.

2. Tap **Suspend all delivery** on the screen that appears. Delivery suspended appears on the status banner.

Resume insulin delivery

Resuming insulin delivery will resume basal delivery. If a bolus was being delivered when delivery was suspended, it will not resume. If you disconnected your pump and infusion set after suspending insulin delivery, reconnect.

1. Tap **Delivery suspended** status banner at the top of the Home screen.

2. Tap **Resume basal delivery** on the screen that appears. Basal delivery resumed appears briefly on the Home screen.

Devices menu

Tap on the bottom of the Home screen to check the status of your device, pair a new device, change your sensor and infusion set, or view important information, such as the amount of insulin in the reservoir or the pump battery level.

Settings menu

Tap on the bottom of the Home screen to view and change your settings:

- Insulin settings: Enter basal and bolus settings, including basal patterns, carb ratios, and active insulin time.
- Alert and glucose settings: Set glucose alerts and suspend settings, or customize system alerts and audio settings.
- SmartGuard settings: Turn on SmartGuard, view the SmartGuard checklist, or change SmartGuard settings. For more information, see the *SmartGuard mode* section on page 56.
- App settings: Tap to set your therapy time zone.

Insulin settings

Here you enter your settings for basal and bolus insulin.

IMPORTANT: Consult your healthcare professional before entering or changing basal and bolus settings.

Basal settings

To access Basal settings, tap , tap **Insulin settings** and then tap **Basal** at the top of the screen. Any basal settings you entered during startup appear here. One active basal pattern must always be set. You can view and make changes to the basal pattern or set a Max basal rate here. You can also switch from one basal pattern to the other if you have

more than one set. The Max basal rate is the maximum amount of basal insulin that the pump can deliver per hour. Tap ⓘ to learn more about Basal settings.

Bolus settings

To access Bolus settings, tap ⚙, tap **Insulin settings** and then tap **Bolus** at the top of the screen. Any bolus settings you entered during startup appear here. There are additional bolus related delivery settings that your healthcare professional may ask you to edit including your Max bolus. A Max bolus is the maximum bolus amount that can be delivered in one single bolus. Tap ⓘ to learn more about the Bolus calculator settings.

Alert and glucose settings

These settings include Sound and vibration, Glucose alerts, and System alerts.

It is important to keep the volume set at an appropriate level so that you can hear alerts.

To access these settings, tap ⚙ at the bottom of the app Home screen and tap **Alert and glucose settings**.

Sound and vibration

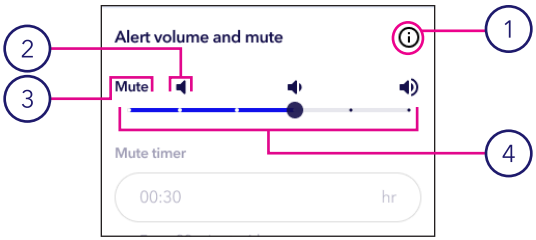
The Sound and vibration settings are as follows.

App volume and mute

The app sound and vibration settings are separate features from the pump sound and vibration settings.

To adjust the volume of app alerts, or mute all app alerts for a set period of time, tap **App volume and mute**.

You can use these controls on the App Volume and Mute screen:



1. Information icon: Tap ⓘ for more information about this screen.
2. No volume: Alerts are silent in the app, but begin to quietly sound, getting louder until they are addressed.
3. Mute: No alert sounds occur in the app for the duration of the set time. appears on the Home screen reminding you alerts are muted.
4. Alert volume: Controls the volume of the alerts that occur in the app.

Customizing the volume level of app alerts

1. Drag the slider or tap on the desired volume.
2. Tap **Save** to save the new volume.

Muting all app alerts for a set period of time

1. Drag the slider to the Mute position, or tap **Mute**.
2. Set the duration.

3. Review the mute settings and tap **Save**. appears on the app Home screen until the mute timer is stopped.

IMPORTANT: Make sure you keep your mobile device's vibration settings on to be informed of critical alerts. You will still receive alerts from the pump when the app volume is muted.

Stopping the mute timer

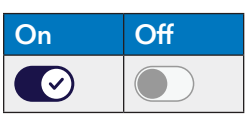
- From the App Volume and Mute screen: Tap **Stop mute timer** to stop the timer and update the alert volume.
- From the app Home screen: Tap and select **Stop mute timer**.

After the mute timer ends or is turned off, the app alert volume automatically returns to its previous volume.

Pump sound and vibration

Tap **Pump sound and vibration** to turn the pump sound and pump vibration on and off and set a Lost communication alert. You must have either the pump sound or the pump vibration turned on at all times.

1. Turn on either Pump sound or Pump vibration, or both.



2. Turn on Lost communication to be alerted on your pump when your pump and mobile device are not in range of each other. 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.

3. Review your settings and tap **Save**.

Glucose alerts

For more information on entering and changing glucose alert settings, see *Glucose alerts* on page 53.

System alerts

To set your System alerts, tap ⚙ at the bottom of the app Home screen and tap **Alert and glucose settings**. Under the System alerts section, you can set the following:

- Low reservoir: Set this alert to remind you when the reservoir is low on insulin.
- Low pump battery: Set this alert to remind you when the pump battery is low and the pump needs to be charged.
- Low sensor life: Set this alert to let you know your sensor needs to be replaced soon.
- Infusion set change: Set this alert to remind you when it's time to change your infusion set.

Viewing and responding to alerts

Alerts occur on both the MiniMed app and pump to notify you of situations that require your attention.

All alerts appear on the mobile device, but not all alerts occur on the pump.

IMPORTANT: The MiniMed Flex pump provides a limited amount of information. Always refer to the MiniMed app when an alert occurs.

For information on setting up your alerts, see *Alert and glucose settings* on page 36.

Tap at the bottom of the Home screen to see your open alerts and alert history. For additional information on alerts, tap on the Home screen and tap **Help**.

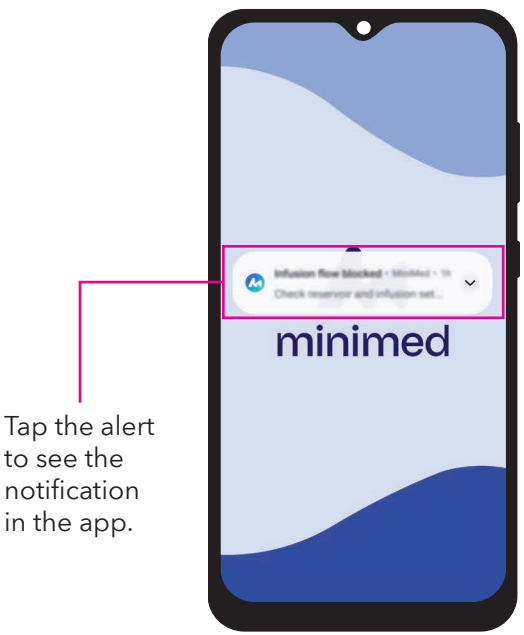
Alerts on your mobile device or the App Manager

Alerts appear on the mobile device lock screen and on the MiniMed app Home screen.

Alerts on the mobile device lock screen

Notifications received while your mobile device is locked will appear as a banner on the lock screen.

Note: To change the way notifications appear on your mobile device, refer to the *Important information* section on page 61.

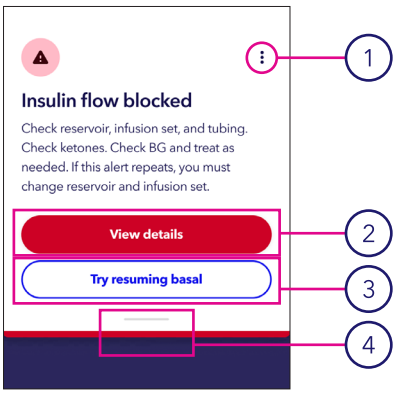


Tap the alert to see the notification in the app.

IMPORTANT: Do not force close the MiniMed app. Doing so prevents the alerts from occurring on the mobile device.

Example alert

After you tap the alert banner on the lock screen, the alert appears in the app as shown in this example alert screen.

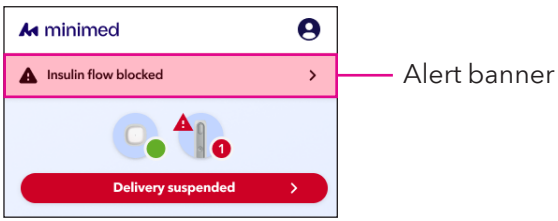


1. Tap ⋮ to see additional actions to address the alert.
2. Tap **View details** to view additional alert details.
3. An action to address the alert is displayed here.

   Certain alerts, such as glucose alerts, have the option to snooze. If a Snooze button is displayed, tap **Snooze** to silence the alert for the snooze time set. The alert will occur again after the snooze time if the condition still exits.
4. Swipe up or tap the blue area to view the app Home screen and trend graph.

Alerts on the MiniMed app Home screen

If you swipe up on the alert screen or if it is not addressed right away, the alert will appear at the top of the app Home screen.



Tap the alert banner to see details about the alert and take any necessary steps to address it.

Alerts on the pump

While all alerts occur in the app, the alerts that need attention will occur both in the app and on the pump. When an alert occurs on the pump, the pump status light flashes and the pump beeps or vibrates based on the settings in the app.

IMPORTANT: Addressing an alert requires taking an action in the app. Taking an action to address an alert in the app clears it from the pump.

Pump status and alerts

Press the oval Status button on the pump to see the alert color or check the status of the pump.

Flashing red light – action needed immediately. The down arrow appears with the red light when an urgent low glucose condition occurs or when you have reached your suspend limit.

Flashing yellow light – action needed soon. The down arrow appears with the yellow light when Alert on low occurs.

Steady green light – no alert condition is requiring action at this time.

When audio is on, low glucose alerts will have a descending tone and high glucose alerts will have an ascending tone.

If no light appears on the pump after pressing the oval Status button, the pump may have no power. See *Charging your pump* on page 64 for more information.

A blue light on the pump signifies a Lost communication alert or means that the pump is in pairing mode.

Reservoir and infusion set

IMPORTANT: If this is your first time using the MiniMed Flex pump, do not begin these steps until you have received training.

IMPORTANT: If you skipped Therapy Settings during startup, make sure your basal and bolus settings are entered correctly before starting therapy. You must enter a basal pattern in order to set up your reservoir and infusion set. For more information on entering or changing basal and bolus settings, see *Insulin settings* on page 35.

Complete these steps when you are ready to fill a reservoir and connect the pump to your body for the first time.

1. Tap **Reservoir & Set** › on the Home screen.
2. Tap **Change reservoir & set**.
3. Tap to see the infusion set list and select the infusion set you are using. If your infusion set is not listed, select **Other** to get started.
4. Follow the instructions in the app to complete a reservoir and infusion set change.

After you begin using the pump, tap  on the Home screen to access reservoir and infusion set options.

- **Change reservoir & set** – Tap this when your reservoir is low on insulin and your infusion set is due to be changed.
- **Change reservoir** – Tap this when your reservoir is low on insulin, but the infusion set is not due to be changed yet.
- **Change infusion set** – Tap this when you need to change your infusion set but you still have insulin in your reservoir, for example, if your infusion set is pulled off.

Note: The pump icon on the Home screen displays a red or yellow status dot icon if an action such as changing your reservoir is needed.

Additional features in Manual mode

Additional basal options

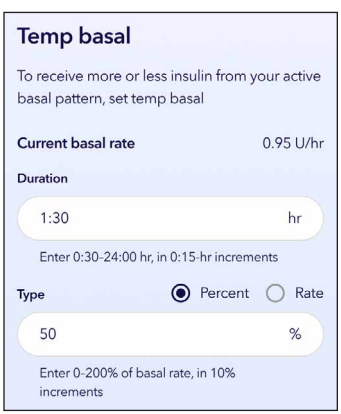
Temp basal

A temporary basal (temp basal) is used to increase or decrease your basal rate for a set duration of time.

Note: A temp basal can be used for activity or illness when the basal amount needs to temporarily change.

Start a temp basal

1. Tap + and tap **Temp basal**.
2. Enter the duration of time that the basal rate is adjusted.
3. Select the Type:
   Percent: Percent delivers a percentage of the basal rates programmed in the active basal pattern for the duration of the temp basal rate.
   Rate: Enter the units per hour that you want to be delivered.
4. After you have entered the settings, tap **Start temp basal**.



Temp Basal > appears on the Home screen with the time remaining.

Note: Features like the temporary basal rate allow you to minimize your risk of hypoglycemia during exercise.[1]

Stop a temp basal

When the temp basal time is complete, the pump returns to the programmed basal rate. You can stop the temp basal and return to your programmed basal rate sooner if needed.

1. Tap **Temp Basal** > on the Home screen to see time remaining and the amount being delivered.
2. Tap **Stop temp basal**.

Additional bolus options

There are additional bolus options when you are in Manual mode. For more information on the differences between Manual mode and SmartGuard mode, see *Differences between Manual mode and SmartGuard mode* on page 13.

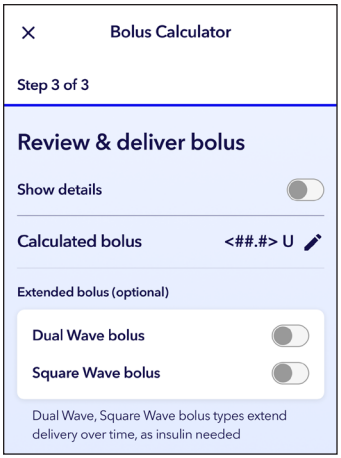
The following information describes the other bolus options that are available.

- Manual bolus: Tap + and select **Manual bolus** and enter the amount of bolus insulin units needed. Tap **Deliver bolus**.

[1] Chetty, Tarini, Shetty, Vinutha, Fournier, Paul A. et al., "Exercise management for young people with type 1 diabetes: A Structured Approach to the exercise consultation." Frontiers in Endocrinology, vol. 10, 14 June 2019, pp. 1–10, https://www.frontiersin.org/journals/endocrinology/articles/10.3389/fendo.2019.00326/full.

- Dual Wave™ and Square Wave™ bolus: Tap ⚙ at the bottom of the app Home screen, then tap **Insulin settings**. When the Insulin Settings menu appears, tap **Bolus**, then tap **Extended bolus**, and tap to turn on Dual Wave or Square Wave.

  The Dual Wave and Square Wave bolus options are available when using a Manual bolus or the Bolus calculator. Adjust the duration or bolus amount on the Review & deliver bolus screen.



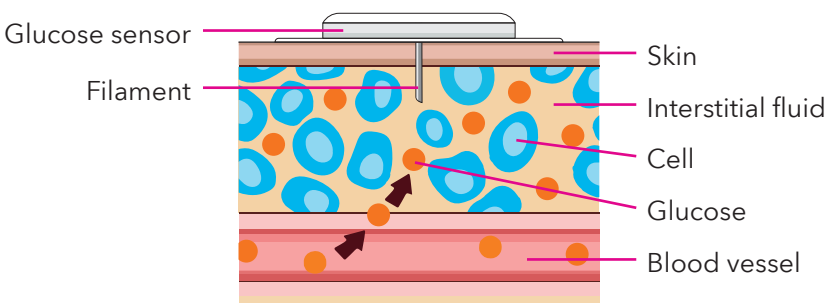
The Bolus calculator is the only bolus option when in SmartGuard mode. To learn more about SmartGuard mode, see the *SmartGuard mode* section on page 56.

Using the glucose sensor

Differences between blood glucose (BG) and sensor glucose (SG)

Your blood glucose (BG) meter measures glucose levels in your blood. The glucose sensor measures glucose in the fluid surrounding your cells, called interstitial fluid. Glucose travels between these two areas, most often from your blood into the interstitial fluid.

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 the MiniMed Flex System Technical guide.



When glucose levels are rising or falling quickly, expect larger differences between your blood glucose (BG) readings and sensor glucose (SG) values. Examples include:

- After meals or taking a bolus of insulin
- During exercise
- When trend arrows appear on your app screen

Note: Blood glucose (BG) meter reading entered as a logged event or entered in the Bolus calculator is used to update the sensor.

Using a blood glucose (BG) meter reading

It is important to check your blood glucose (BG) in specific situations, even if a sensor glucose (SG) is available.

Check your blood glucose (BG):

- When you are giving a bolus in Manual mode.
- When you aren't sure if your sensor glucose (SG) value is correct.
- When your symptoms don't match your sensor glucose (SG) value.
- When a sensor glucose (SG) value isn't available.
- When you have taken medications that may falsely raise your sensor glucose (SG) value, such as acetaminophen, also known as paracetamol.
- When you are using hydroxyurea or hydroxycarbamide, check with your healthcare professional.
- When the system requests a blood glucose (BG) reading.

IMPORTANT: When a glucose reading is entered into the app, it must be from a blood glucose (BG) meter. Blood glucose (BG) readings entered will be used to update the sensor.

Starting a new sensor

Tap at the bottom of the app Home screen, then tap **Pair new device**. Tap the listing for the new sensor, then tap **Continue** and follow the instructions.

Note: See your sensor user guide for information regarding daily sensor use.

Glucose alerts

To access Glucose alert settings, tap and tap **Alert and glucose settings**.

Any glucose alert settings you entered during startup appear here. You can view and make changes to low and high glucose alerts and suspend settings. You can also set different settings for day and night, and set a maximum volume for alerts at night. Enter these settings as directed by your healthcare professional.

Low alerts	High alerts
Alert before low You are approaching your low limit	Alert before high You are approaching your high limit
Alert on low You reached your low limit	Alert on high You reached your high limit
Fall alert Your glucose is falling fast	Rise alert Your glucose is rising fast

Suspend feature (Manual mode only)
Suspend before low Suspends insulin delivery when you are approaching your suspend limit. Insulin delivery will resume if glucose levels recover. You can choose to be alerted when this occurs.
Suspend on low Suspends insulin delivery when you have reached your suspend limit. Insulin delivery will resume when glucose levels recover or after 2 hours. You will always be alerted when this occurs.

- You will always receive an Urgent low alert when your sensor glucose (SG) is below 64 mg/dL.
- Insulin will always be suspended when your sensor glucose (SG) reaches or falls below 54 mg/dL, when the suspend features are off.
- If you snooze an alert, it will repeat after the snooze time if the alert condition still exists.
- Use the Max volume at night setting to help you hear High glucose or Low glucose alerts while you are sleeping. To use the Max volume at night setting, the Set day and night feature must be turned on.

Trend arrows and suspend feature icons

Therapy status


Icons	Descriptions
↑ or ↓	This means sensor glucose (SG) has been rising or falling at a rate of 20 to 40 mg/dL over the last 20 minutes, or 1 to 2 mg/dL per minute.
↑↑ or ↓↓	This means sensor glucose (SG) has been rising or falling at a rate of 40 to 60 mg/dL over the last 20 minutes, or 2 to 3 mg/dL per minute.
↑↑↑ or ↓↓↓	This means sensor glucose (SG) has been rising or falling at a rate of more than 60 mg/dL over the last 20 minutes, or more than 3 mg/dL per minute.
No arrows	If there are no arrows, sensor glucose (SG) is stable.
	This icon appears to let you know insulin delivery will be suspended based on your sensor glucose (SG) and suspend settings. The icon flashes when insulin delivery is suspended.
	This icon appears when the suspend feature based on your sensor glucose (SG) value is temporarily unavailable. You can still suspend insulin delivery using Suspend all delivery if needed.

SmartGuard mode

SmartGuard mode uses meal information, sensor glucose (SG), and SmartGuard target values to control basal insulin delivery. It can also automatically deliver an Auto correction bolus to maximize time in range. These can be delivered as frequently as every five minutes if SmartGuard mode determines a correction is necessary. The Auto correction feature uses a target of 120 mg/dL.

SmartGuard mode requires a minimum of 48 hours of insulin delivery data before it can begin. The 48 hours begins the first midnight after insulin delivery starts.

- Tap ⚙ at the bottom of the app Home screen and then tap **SmartGuard settings**. Here you can turn SmartGuard mode on and select the target setting provided by your healthcare professional. The default setting is 100 mg/dL, but 110 mg/dL or 120 mg/dL can also be used.

  Your insulin settings, including Carb ratio and Active insulin time, may need to be adjusted when using SmartGuard mode. Work with your healthcare professional to ensure your settings are correct.

- The SmartGuard checklist shows actions needed to enter SmartGuard mode, such as providing a blood glucose (BG) reading.

  When SmartGuard mode is active, the Home screen displays a blue shield. If SmartGuard mode is turned on but not active because the checklist items are not complete, appears at the top of the Home screen.

  Note: When in SmartGuard mode you must suspend insulin delivery whenever you disconnect the infusion set.

Medications that contain acetaminophen or paracetamol may falsely raise your sensor glucose (SG) value. These medications include, but are not limited to, cold medicines and fever reducers. If you have taken these medications while you are in SmartGuard mode, follow these steps:

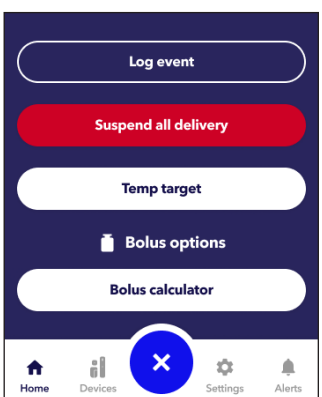
- Consult your healthcare professional.
- Program a Temp target for up to 8 hours, or the amount of time recommended by your healthcare professional. For information on temp targets, see *Using a temp target* on page 59.
- Use blood glucose (BG) meter readings instead of sensor glucose (SG) values when giving a bolus for up to 8 hours.

For additional information on taking a medication that contains acetaminophen or paracetamol, see the applicable warning on page 91.

Therapy Action menu (SmartGuard mode)

When you're in SmartGuard mode, the actions on your Therapy Action menu change.

You can suspend insulin delivery and stop a bolus in SmartGuard mode the same way you would in Manual mode. For more information see *Stop a bolus delivery* on page 33 and *Suspend all insulin delivery* on page 34.



Delivering a bolus in SmartGuard mode

The Bolus calculator is the only bolus option while you are in SmartGuard mode. A sensor glucose (SG) value may be available to calculate your bolus amount.

If you are taking certain medications that affect your sensor glucose (SG) you must use a blood glucose (BG) meter reading.

1. Tap + then tap **Bolus calculator**.

2. Select one of the following options to enter a glucose value, as needed and if available:

   - Tap **Use sensor glucose**, then tap **Next**.
   - Tap **Use blood glucose** if blood glucose (BG) was recently logged or tap **Enter blood glucose** to enter a blood glucose (BG) meter reading for your calculation. Then tap **Next**. If a blood glucose (BG) is recommended, you must use a blood glucose (BG) meter reading to correct the high glucose.
   - To give a bolus only for the carbs you are eating, tap **Skip glucose**, and then tap **Next**. If a glucose option is grayed out, then it is unavailable.

3. Enter the amount of carbs you are eating, or tap **Skip carbs** if you are only delivering a bolus to correct high glucose. Tap **Next**.

4. Review the screen and tap **Deliver bolus** to send the bolus information to the pump to begin delivery.

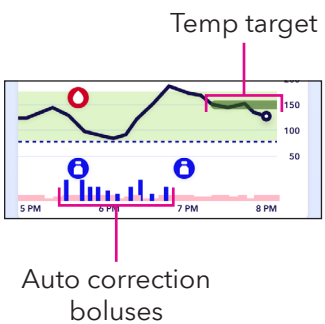
Using a temp target

A temporary target (temp target) can be set for times when less insulin is needed. SmartGuard mode uses a temp target of 150 mg/dL during this time. Auto correction boluses are not delivered when temp target is active.

1. Tap + and tap **Temp target**.

2. Enter the duration of time from 30 minutes to 24 hours. Tap **Start temp target**.

3. A banner appears on the Home screen indicating that the temp target is active.



To stop a temp target

When the temp target time is complete, the pump returns to normal delivery. You can stop the temp target and return to normal delivery sooner if needed.

1. Tap **Temp Target** > on the Home screen.

2. Tap **Stop temp target**.

Note: Features like temp target allow you to minimize your risk of hypoglycemia during exercise.[2]

Staying in SmartGuard mode

Sometimes an action is needed in SmartGuard mode.

In this example, a blood glucose (BG) reading must be entered within 4 hours to stay in SmartGuard mode.

1. Tap **Enter BG** on the Home screen.

2. Enter a current blood glucose (BG) reading and tap **Log blood glucose** to save.

If you do not enter a blood glucose (BG) reading within 4 hours, you will return to Manual mode until you enter a blood glucose (BG) reading and SmartGuard mode starts again. appears next to the profile icon on the Home screen.

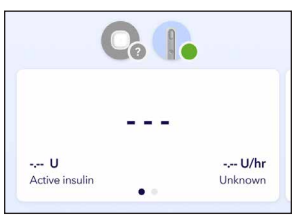
[2] O'Neal, David N., Zaharieva, Dessi P., Morrison, Dale et al. "Exercising safely with the MiniMed™ 780G automated insulin delivery system." Diabetes Technology & Therapeutics, vol. 26, no. S3, 5 Feb. 2024, pp. 84–96, https://liebertpub.com/doi/10.1089/dia.2023.0420.

Important information

When you are using the MiniMed Flex system, remember the following important steps.

For both Android™* mobile device users and iOS™* mobile device users:

- Keep the pump and mobile device charged.
- Keep Bluetooth enabled on the mobile device.
- The sensor sends values to the pump using Bluetooth.
  - Keep the pump and sensor within 20 feet (6 meters) of each other, making sure there are no barriers between them. If the sensor icon is gray, the sensor and pump are not communicating. Try decreasing the distance between the pump and sensor to 6 feet (1.8 meters) or less. Sensor values are unknown and glucose alerts are not occurring on the pump or app.
  - A No sensor glucose (SG) values alert occurs if the sensor and pump do not communicate for more than 30 minutes.



- The pump sends pump and sensor information to the mobile device using Bluetooth. Keep the mobile device and pump within 20 feet (6 meters) of each other, making sure there are no barriers between them.
  - If the pump icon is gray , the pump and mobile device are not communicating. Try decreasing the distance between the pump and mobile device to 6 feet (1.8 meters) or less. The pump may be receiving sensor values, but they are not being sent to the app. There are no alerts in the app, however depending on your settings, the Lost communication alert referenced in the *Pump sound and vibration* section on page 38, may occur after 30 minutes of no communication.

IMPORTANT: Insulin therapy continues as intended on the pump even when the app and pump are not communicating. Critical alerts are still communicated through the pump when the pump is not communicating with the app. Please reconnect the app and the pump to get details on alerts that appear on the pump.

- To help ensure you are always notified of alerts:
  - Keep your mobile device's vibration settings turned on.
  - Do not force close the MiniMed app.
  - To change your Notification and privacy settings set during app startup, tap and tap **Help** then **Notification Privacy**.
  - Tap **Help**, and then tap **Important phone settings** to understand how these settings can affect your mobile device's ability to use or receive alerts from the MiniMed app.

– Disable automatic operating system updates and confirm compatibility before updating the operating system on your mobile device to avoid updates to incompatible software that may cause loss of alerts or ability to use the app.

For Android mobile device users:

- Turn Bluetooth on when Airplane mode is active.
- Keep Battery optimization turned off to prevent your mobile device from shutting down the MiniMed app.
- Do not turn off Notifications or Do Not Disturb Permission in your mobile device settings.
- If you use Digital Wellbeing on your mobile device, do not set an app timer for the MiniMed app.

For iOS mobile device users:

- Make sure Bluetooth is on after turning on Airplane mode.
- Do not turn off Notifications or Critical Alerts in your mobile device settings.
- If you use Screen Time, add the MiniMed app to the Always Allowed apps.
- If using iOS 17 or greater, do not use Assistive Access. Assistive Access may prevent the MiniMed app from pairing with the pump or displaying alerts.

Charging your pump

To charge your pump, first connect the charging cable to the pump charger. Align the front of the pump with the front of the charger and place the pump on the charger, as shown.

- 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. It takes approximately 30 minutes for a full charge, and a full charge will last at least 7 days.

You may want to charge your pump every few days with the Medtronic supplied charger to ensure the battery is always charged. You can choose to stay connected or disconnect the pump from your body while charging.

WARNING: 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.

For more help

- While in the MiniMed app, tap at the top of the Home screen then tap **Help**.
- Contact 24-Hour Technical Support at 1-800-646-4633.
- For information on mobile app or smart device compatibility, visit https://www.medtronicdiabetes.com/customer-support/app-support/device-compatibility.

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

Device care and maintenance

This chapter provides information about maintaining the components of the MiniMed Flex system.

Updating your pump software

You can wirelessly update your pump using the MiniMed app. When an update is available for the pump software, Medtronic sends you a notification.

CAUTION: Use a stable internet connection throughout the entire software update process. Avoid the use of unsecure Wi-Fi networks or public Wi-Fi hotspots.

Preparing to download and install the pump software update

Before downloading and installing the pump software update, note the following guidelines:

- Downloading and installing the update requires Bluetooth and a stable internet connection.
- Keep the mobile device and the MiniMed Flex pump next to each other while updating.
- Make sure your mobile device is fully charged for downloading and installing the update.
- Do not force close the app while downloading or installing the update.
- While downloading the update, you may continue using your app, mobile device, and pump as normal.
- Downloading the update can take several minutes to complete, depending on your internet access speed.

- Check to see that Sync to CareLink is turned on in the MiniMed settings from the Profile menu on the Home screen. If it is not turned on, then tap **Upload now** in the CareLink menu before starting the update to ensure the pump data is saved.
- Installing the pump software update can take up to 20 minutes to complete. Insulin delivery will be suspended and alerts such as sensor glucose (SG) alerts and sensor glucose (SG) values will be unavailable during this time.
- Do not press the pump buttons while installing the update.
- If a manual insulin injection is needed during the update, it will not be accounted for in the active insulin amount. Consult a healthcare professional for how long to wait after a manual injection before using the Bolus calculator.

Downloading and installing the pump software update

Follow these steps to download and install the pump software update:

1. At the top of the Home screen, tap the pump icon.

   The pump menu opens.

2. Tap **Details**, then tap **Info** to see detailed information about your pump.
3. Tap **Check for updates**.

   The system begins checking for available updates for pump software.

4. Follow the onscreen instructions to download and install the pump software update.

Unpairing a pump

If you need to remove your pump from the MiniMed Flex system, use the unpairing steps. Once unpaired, you no longer have access to sensor glucose (SG) data.

Note:

- Once you have unpaired the pump, you no longer have access to pump or sensor glucose (SG) data. If you are no longer using the pump refer to the *Shutting down the pump* section on page 72.
- If a bolus delivery is in progress, you must allow the delivery to finish before unpairing the current pump.
- When you unpair your pump, you will continue to receive insulin unless you remove the infusion set from your body.
- Do not remove the reservoir while the pump is still in use.
- You must disconnect the pump from the Bluetooth wireless connection on your mobile device during the unpairing process.

To unpair the pump:

1. On the Home screen, tap .

   The Devices tab opens.

2. Select the pump.

   The menu for that pump opens.

3. Tap **Unpair pump**.

   Follow the onscreen instructions to complete the unpairing process.

Pair a new device

To pair a new device in the app:

1. From the Home screen, tap .

   The Devices tab opens.

2. Tap **Pair new device**, and then follow the onscreen instructions.

Replacing the mobile device or App Manager used with your MiniMed Flex system

If you are replacing your mobile device or App Manager used with the MiniMed Flex system, follow these steps.

1. Download the app and install it on your replacement mobile device. If you are using a replacement App Manager the app comes pre-installed.

   Once installed, open the app.

2. Sign in to CareLink, then tap **Continue**.

3. Follow instructions on screen to configure app settings, security, and permissions.

4. When the screen displays Product Selection and Pairing, tap **Next**.

5. Pair your replacement mobile device or App Manager with your existing MiniMed Flex pump. When complete, tap **Continue**.

6. Because the system is pairing an existing pump to a new mobile device or App Manager, the system begins the process of transferring your data.

7. When finished, the system displays the message Transfer successful. Tap **Continue**.

> **Note:** If the time zone setting of the new mobile device or App Manager is different from the time zone setting stored in the existing pump, the system instructs you to confirm the difference, or to change the time zone settings to match.

Pump maintenance

Clean and inspect the pump and charger between uses. If there are concerns that the pump or charger may be damaged contact 24-Hour Technical Support.

Cleaning the pump and charger

Prepare the following supplies to clean the pump and charger:

- clean soft cloths
- mixture of water and mild soap
- clean water
- 70% alcohol

CAUTION: 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.

To clean the pump:

1. Dampen a clean soft cloth with water mixed with a mild soap.
2. Use the cloth to wipe the outside of the pump while keeping the inside of the reservoir compartment dry.
3. Dampen a clean soft cloth with water and wipe the pump to remove any soap residue.
4. Dry the pump with a clean soft cloth.
5. Dampen a clean soft cloth with 70% alcohol and wipe the pump.

To clean the charger:

1. Unplug the charger.
2. Wipe the charger with a clean dry cloth.

Shutting down the pump

The pump should be shut down if you plan to store your pump for an extended period of time.

WARNING: 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.

To shut down the pump:

1. Place the pump on the charger.
2. Hold the oval Status button until the pump beeps twice and the Status button light shows a steady blue light.

   Note: The pump does not fully shut down until it beeps twice. If you remove the pump from the charger before the pump has shut down, the pump will restart.

3. Release the oval Status button and remove the pump from the charger. The pump icon in the app turns gray when the pump has disconnected from the app and the pump buttons will no longer light up. The pump has been turned off. The pump can now be stored.

CAUTION: 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.

To use the pump after it has been shut down:

1. Place the pump on the charger.

2. Remove the pump from the charger for use when the oval Status button light turns on and the app shows that the pump has sufficient charge.

Note: The pump normally does not need to be re-paired after being turned off. In the app, a paired pump icon turns green when the pump reconnects. If the pump does not reconnect to the app within 10 minutes and the pump icon remains gray, see the *Troubleshooting* section on page 74.

Pump disposal

The pump contains a battery. Disposal of the battery 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.

Component disposal

For information on the disposal of the components used with the MiniMed Flex system, including reservoir, infusion set, and sensor, refer to the corresponding instructions for use.

Troubleshooting

This chapter 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 feet (6 meters) of each other to remain connected. 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.

Issue	Resolution
	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.

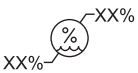
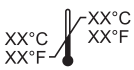
Issue	Resolution
The oval Status light alternates red and yellow while on the charger.	The oval Status light alternates red and yellow when the pump is on the charger, but is operating with extremely low-power. The pump cannot communicate with the app, and does not make any beeps or vibrations. 1. Press 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 while on the charger.	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. 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 (BG). 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 on the pump screen 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.

Icon table

	Consult instructions for use
	Caution: consult instructions for use for important warnings or precautions not found on the label
	Magnetic Resonance (MR) Unsafe
	Single patient multiple use
	Bluetooth® wireless technology or Bluetooth® enabled
	Manufacturer
	Country of manufacture (and Date of manufacture when a date appears beside)
	Do not dispose of this product in unsorted municipal waste stream
	Type BF applied part
	Use-by date
	Fragile, handle with care

	Keep dry
	Humidity limits
	Temperature limits
MD	Medical device
SN	Serial Number
UDI	Unique Device Identifier
REF	Catalogue number
LOT	Batch code
$\mathrm{R_x}$ *Only*	Requires prescription in the USA
(1x)	One per container/package
FCC ID	Complies with United States regulations for RF devices
IPX8	Protected against the effects of continuous immersion in water
RF	Identification number for global radio frequency certification

Warnings and Precautions, Risks and Side Effects

This section lists all warnings and precautions for safe use of the MiniMed Flex system. This section also lists all risks and side effects of using the MiniMed Flex system. Read all warnings, precautions, risks, and side effects before using the system to deliver insulin.

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 (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 (SG) values compared to blood glucose (BG) 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 (SG) values in reports than actual blood glucose (BG) 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 (BG) 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 readings 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 (SG) values compared to blood glucose (BG) 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 (SG) values in reports than actual blood glucose (BG) 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 (BG) 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 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.

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) values are used to calculate basal insulin delivery and correction boluses. Do not use sensor glucose (SG) values to make treatment decisions while the pump is in Manual mode. Sensor glucose (SG) values and blood glucose (BG) readings 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) value is lower than expected.
  – The sensor glucose (SG) value 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) readings instead of sensor glucose (SG) values 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.

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 Simplera Sync 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) values, 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 (SG) values compared to blood glucose (BG) 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 (SG) values in reports than actual blood glucose (BG) 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 (BG) 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 readings 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.

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 the 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.

Airport information

Airport security

Because travel rules are subject to change, it is advisable to check with the Transportation Safety Administration (TSA) before traveling. TSA information is found at https://www.tsa.gov/travel/tsa-cares or by calling 1-866-289-9673.

- The pump must not go through the x-ray machine that is used for carry-on or checked luggage.
- The full-body scanner is also a form of x-ray.
- Remove the insulin pump and disconnect the infusion set at the insertion site before going through the full-body scanner. If continuous glucose monitoring (CGM) is used, remove the sensor before the scan.
- To avoid removing the devices, request an alternative screening process that does not use x-ray.
- The insulin pump, infusion set, reservoir, and CGM system can withstand exposure to airport metal detectors used at airport security checkpoints.

In flight

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.

Pump warranty information

Medtronic MiniMed, Inc. (or such other legal entity as may be referred to as manufacturer on the labeling of this device "Medtronic MiniMed") warrants the Medtronic MiniMed insulin pump to the purchaser of the product against defects in material and workmanship for a period of four (4) years from the date of purchase.

During the warranty period, Medtronic MiniMed will replace or repair, at its discretion, any defective pump, subject to the conditions and exclusions stated herein. This warranty applies only to new devices. In the event a pump is replaced, the warranty period will not be extended past its original expiration date.

This warranty is valid only if the Medtronic MiniMed insulin pump is used in accordance with the manufacturer's instructions. Without limitation, this warranty will not apply:

- If damage results from changes or modifications made to the pump by the user, or third persons, after the date of purchase.
- If damage results from use of non-Medtronic reservoirs and/or infusion sets.
- If damage results from service or repairs performed by any person or entity other than the manufacturer.
- If damage results from a Force Majeure or other event beyond the control of the manufacturer.
- If damage results from negligence or improper use, including but not limited to: improper storage, submersion in water beyond manufacturer's waterproof instructions,

defective or improper batteries, or physical abuse such as dropping the pump, a hard impact, or otherwise.

- If damage results from use of the device in a manner other than according to the manufacturer's product labeling, instructions for use, or regulatory notifications.

This warranty shall be personal to the original purchaser. Any sale, rental or other transfer or use of the product covered by this warranty to or by a user other than the original purchaser shall cause this warranty to immediately terminate. This warranty does not apply to batteries, infusion sets, reservoirs, and other accessories.

The remedies provided for in this warranty are the exclusive remedies available for any breach hereof. Neither Medtronic MiniMed nor its suppliers or distributors shall be liable for any incidental, consequential, or special damage of any nature, or kind caused by or arising out of a defect in the product.

All other warranties, expressed or implied, are excluded, including the warranties of merchantability and fitness for a particular purpose.

FCC notice

The MiniMed Flex pump complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

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

Index

Medical Emergency Card

I wear a required medical device prescribed by my physician.

minimed

In an emergency, please contact
Physician name:
Phone number:

Emergency contact:
Phone number:

I have diabetes

If my behavior is peculiar, if I appear intoxicated, or if I am unconscious, it may be a result of severe low blood sugar.

I am not intoxicated
Call for medical assistance

If I am awake and able to swallow, give me a source of sugar (for example: juice, candy, or non-diet soft drink). Do not try to give me food or drink if I am unconscious.

Healthcare professionals

I wear an insulin pump.

- The pump delivers compatible insulin at a constant rate and is managed through an app on a mobile device.
- To stop insulin delivery, remove the infusion set at the end of the tubing where it is connected to the body.
- Follow the instructions on the mobile device lock screen.
- If the pump is sounding an alarm, it can only be silenced through the app. Contact 24-Hour Technical Support for further assistance.

Airport Information

Airport security

- Because travel rules are subject to change, it is advisable to check with the Transportation Safety Administration (TSA) before traveling. TSA information is found at https://www.tsa.gov/travel/tsa-cares or by calling 1-866-289-9673.
- The pump **must not** go through the x-ray machine that is used for carry-on or checked luggage.
- The full-body scanner is also a form of x-ray. Remove the insulin pump and disconnect the infusion set at the insertion site before going through the full-body scanner. If continuous glucose monitoring (CGM) is used, remove the sensor before the scan.
- To avoid removing the devices, request an alternative screening process that does not use x-ray.
- The insulin pump, infusion set, reservoir, and sensor can withstand exposure to airport metal detectors used at airport security checkpoints.

In flight

The MiniMed Flex™ insulin pump system is suitable for use in aircraft. Check that the MiniMed app maintains Bluetooth®* connection while in Airplane mode to receive alerts and notifications.

When flying in an aircraft, it is important to keep the pump connected to the body and monitor glucose levels. Changes in air pressure that occur during flight takeoff and landing can cause over-delivery or under-delivery of insulin. Be ready to respond to alerts and symptoms. Talk with your healthcare professional to see if you need a different treatment plan in place.

Patient information
Name:
Address:
Country:
Phone number (include country code):

Medical device information
Medical device type:
Device serial number:

Medtronic

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