



MiniMed Flex™ system

School nurse guide

Table of contents

Purpose & school orders	2
MiniMed Flex system	3
Manual & SmartGuard™ mode	3
SmartGuard mode	4
Important information about SmartGuard	4
A student's responsibilities in SmartGuard	5
The MiniMed™ app	6
The Home screen	6
Key information	6
Device status	7
SmartGuard Bolus feature	8
How to deliver a bolus in SmartGuard	8
How to stop a bolus	8
Stopping and resuming insulin delivery	9
How to set a Temp target	10
How to log an event	11
How to deliver a bolus in Manual mode	11
Staying in SmartGuard	12
Checking last bolus	15
Safety Guidelines	16
Alerts	18
Charging the battery	19
Things to remember	20
Important safety information	21



When in doubt, call the student's parent or caregiver or MiniMed's 24-Hour Technical Support at 1-800-646-4633.

Purpose & school orders

Purpose

This guide is intended to help school nurses with the basic operation of a student's MiniMed Flex system. Please note that this booklet does not cover all aspects of insulin pump therapy and continuous glucose monitoring (CGM). It is written for healthcare professionals with some experience with this technology.

School orders with backup plan



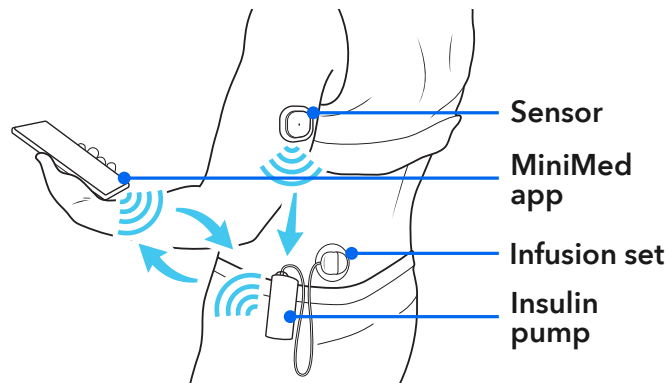
Every student on the MiniMed Flex system should have signed orders from the student's healthcare professional. They should include:

- Name of device with programmed settings. Note that the pump may be operating in one of two modes. See next page for more information.
- A backup plan if the pump is not able to be used to deliver insulin including:
 - Rapid-acting insulin pens or syringes, and doses for food and for correcting high blood glucose (BG).
 - Long-acting insulin pens or syringes, and dose if necessary for prolonged stays at school.



The responsibilities of the parent(s)/guardian(s), school nurse, and other school personnel should also be established.

The MiniMed Flex system components



It's a good idea for every student on the MiniMed Flex system to have extra pump and sensor supplies including:

- infusion sets
- reservoirs
- compatible sensor
- serter (if needed)
- insulin
- alcohol wipes

The MiniMed Flex pump does not use batteries, it is rechargeable. If needed, an extra charger can be ordered.

The MiniMed app acts as the pump's screen and controller. The app is used to deliver insulin, view sensor glucose levels, dismiss alerts, and interact with the system. The app will be on the student's phone or App manager, if they do not have a compatible phone.



Note: the MiniMed app, pump and sensor must remain within 20 feet (6 meters) of each other. Do not force close the app. Bluetooth should always be kept ON. The vibration setting should always be on.

Note: The MiniMed Flex system is compatible with the Instinct sensor, made by Abbott, and Simpler Sync sensor. Compatible sensors do not require calibrations, or fingerstick when in SmartGuard.[†]

2 [†] Fingersticks are required in Manual mode and to enter SmartGuard. If symptoms don't match alerts and readings, use a fingerstick. Refer to user guide. Pivotal trial participants spend average of > 93% in SmartGuard.

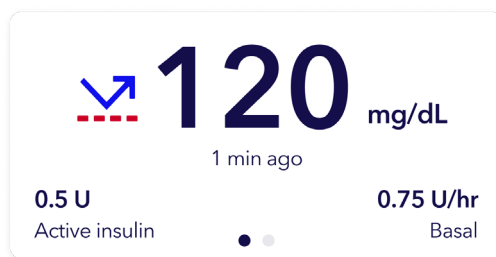
MiniMed Flex system

The MiniMed Flex system may be delivering insulin in one of two modes: **Manual mode** or **SmartGuard mode**.

Manual mode is using the pump with or without a continuous glucose monitor (CGM) where insulin is delivered using pre-programmed basal rates.

SmartGuard mode: The system automatically adjusts basal insulin every 5 minutes based on sensor glucose (SG) readings. It also can automatically deliver a correction bolus, based on SG readings and trends, to help correct a high glucose. A student using SmartGuard may still occasionally be required to enter a blood glucose (BG).

Home screen in Manual mode



Manual mode

Using the pump with pre-programmed basal rates.

- Basal rates are pre-programmed for the pump to deliver.
- Meal doses/boluses can be calculated and delivered using the Bolus calculator feature or with manual boluses as needed.
- May be used with or without CGM.

Home screen in SmartGuard mode



SmartGuard mode

Using automated insulin delivery that self adjusts based on SG readings.

- Basal insulin is automatically adjusted every 5 minutes.
- May deliver a bolus automatically if the SmartGuard feature determines that a correction bolus is necessary.
- It is still recommended to bolus before meals using the Bolus calculator.
- CGM is required.

SmartGuard mode

SmartGuard shield

Sensor glucose

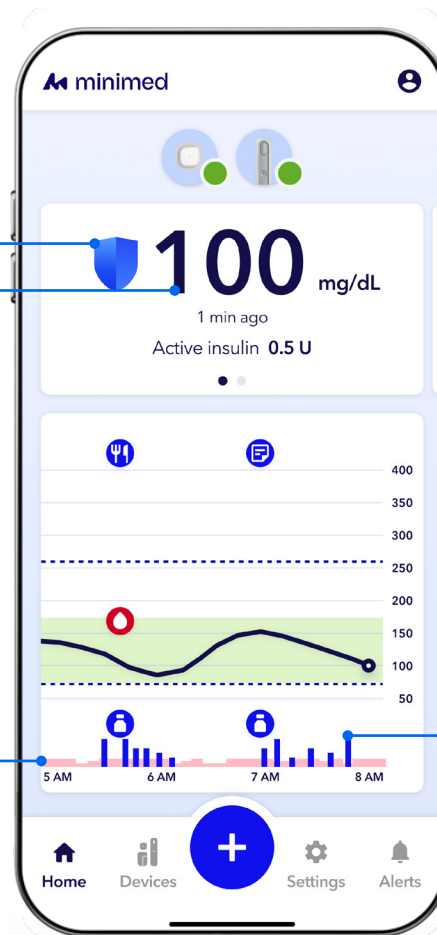
Auto basal

Auto basal uses SG readings to **increase, decrease or stop insulin** to bring SG levels to the SmartGuard target.

The system will correct to the programmed SmartGuard™ target.

The target can be set to:

- 100 mg/dL (default), 110 mg/dL, 120 mg/dL
- Temp Target: 150 mg/dL



If you see the SmartGuard shield  the pump is in SmartGuard mode.

Auto corrections

An **auto correction bolus** will be delivered based on the current SG, how fast the SG is rising and how much total insulin is active in the body

Auto correction uses SG readings and **can be delivered every five minutes** when:

- Maximum Auto Basal delivery is reached and
- SG is above 120 mg/dL



When a Temp Target is set, auto correction boluses are not delivered.



Manual mode basal rates and Max Basal settings do no impact insulin delivery in SmartGuard mode.

When a student is wearing the MiniMed Flex system and SmartGuard mode is active, the student must still perform certain tasks:

1. Bolus for carbs before eating.

Giving insulin before a meal can help students avoid post-meal highs, which could lead to fewer alerts and improved glucose control.



Caregiver assistance for bolus and carb entry:

Only enter and bolus for the carbs you're confident the child will eat. Try to give the bolus before the meal or snack when possible. Split boluses aren't recommended with this system.

2. Respond to alerts.

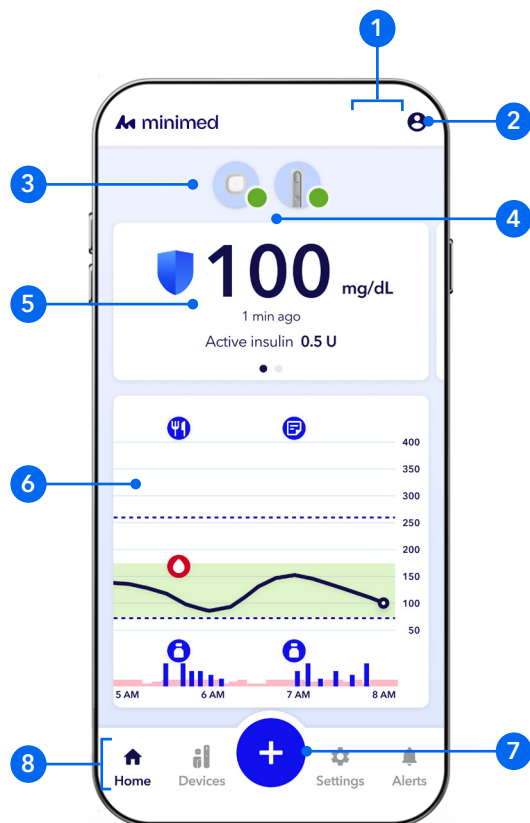
Students should respond promptly to all alerts to avoid highs and lows.

3. Check glucose trends.

Students should check their glucose trends while at school. It's reasonable a student may need to check a BG from time to time if requested by the system or symptoms do not match the SG reading.

The MiniMed app

The Home screen



- 1 Icons**
Icons may appear in this location. Tap the icon to see more details
- 2 Profile menu**
View information such as the Daily History, CareLink, and the Help menu
- 3 Device status**
View the status of paired devices and tap the device icon to see more information
- 4 Status banner**
A banner may appear here. Tap the banner for more information and follow steps if needed
- 5 Therapy status**
View your glucose and therapy information. Swipe left for Time in Range
- 6 Trend graph**
View the graph to see glucose levels over time. Tap on the icons for more information about events, such as insulin doses and carb entries
- 7 Therapy action button**
Access therapy actions such as the Bolus calculator, suspend delivery, or log an event
- 8 Menu bar**
Access device information, settings, and alert history

Verification required to:

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

Keep things connected:

The MiniMed app should **always be kept open** on the mobile device or App Manager.

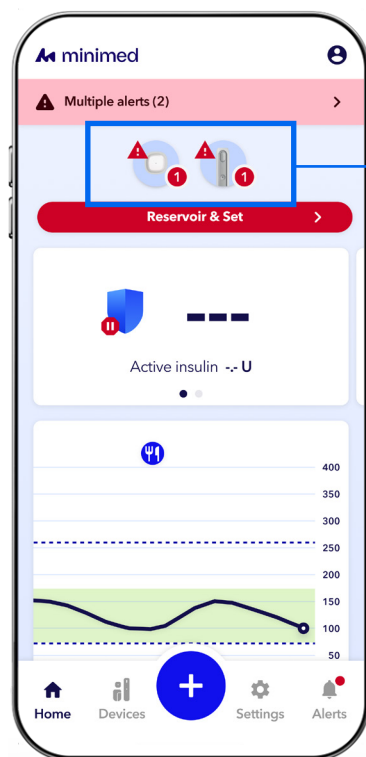
If the app is closed, SG values or notifications **will NOT be received**.

Keep the pump, sensor and mobile device within 20 feet of each other.

Bluetooth should always be kept ON.

Always keep mobile device's **vibration setting ON**.

Device status



Tap the sensor or pump device icon to view more details about the paired device status

The following colors may appear on the device icons. A number in the status icon indicates how many actions are needed.

- No action needed
- Action needed soon
- Action needed now
- No communication between devices
- ▲ An open alert requires an action now

SmartGuard Bolus feature

Bolus recommendations in SmartGuard mode

When should you bolus?

A bolus should be delivered **before** meals or snacks that contain carbohydrates

What if you forget?

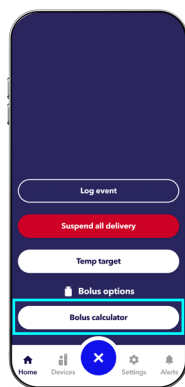
If you remember **within 30 minutes of the meal** or snack, **deliver a bolus for 50% (or half)** of the carbohydrates that the student ate

If it has been **over 30 minutes**, deliver a **correction bolus** if recommended by the system

How to deliver a bolus in SmartGuard



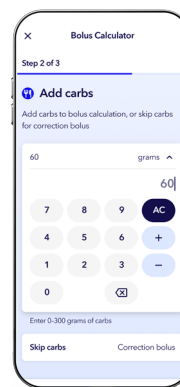
Tap the
**Therapy
Action Button**



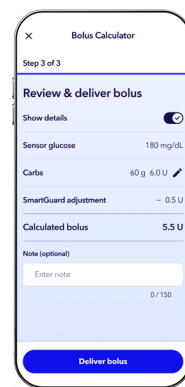
Tap **Bolus
calculator**



Select the
appropriate
glucose option
and tap **Next**



Enter carbs if
eating and tap
Next or tap
Skip carbs if
not eating

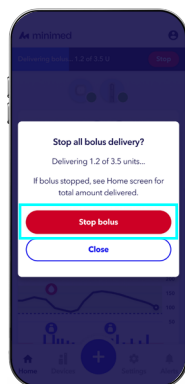


Tap **Deliver
bolus**

How to stop a bolus



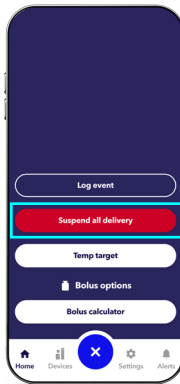
Tap **Stop**



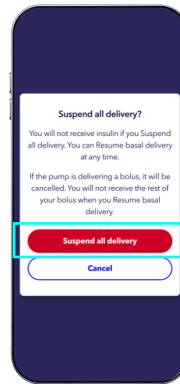
Tap **Stop bolus**

Stopping and resuming insulin delivery

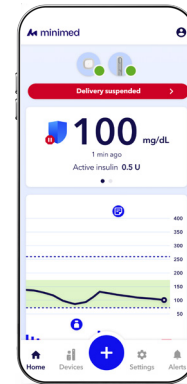
A student can use **Suspend All Delivery** if they need to stop all active basal and bolus insulin deliveries. While insulin delivery is suspended, the pump beeps, vibrates, or both depending on the audio settings. This occurs every 15 minutes to remind them that insulin is not being delivered.



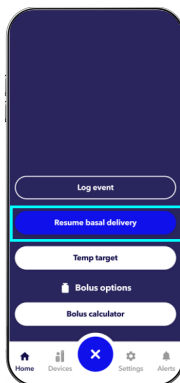
From the Therapy action menu, tap **Suspend all delivery**



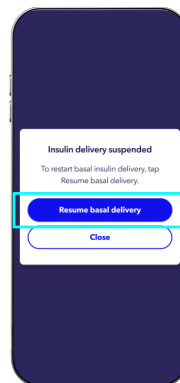
Tap **Suspend all delivery**



Delivery is suspended. To Resume, tap the **Therapy Action Button**



Tap **Resume basal delivery**



Tap **Resume basal delivery**



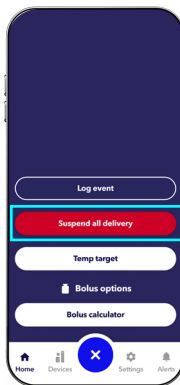
Basal delivery has resumed

How to set a Temp target

The SmartGuard™ targets are:

- 100 mg/dL
- 110 mg/dL
- 120 mg/dL

A student may want to temporarily change the SmartGuard™ mode target to 150 mg/dL for times less insulin is needed, like for physical activity.



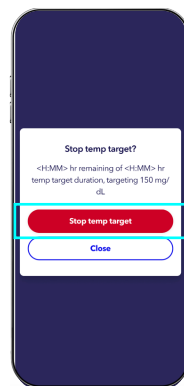
Tap **Temp target**



Enter duration and tap **Start temp target**



Darker green line indicates temp target



Temp target can be stopped early by tapping the Temp Target banner at the top of the Home screen and then tap **Stop temp target**

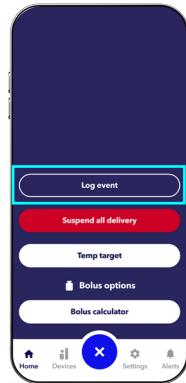


When Temp target is set, auto correction boluses are not delivered.

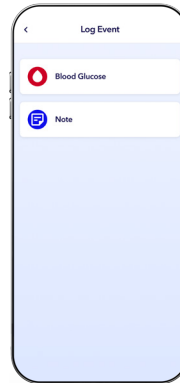
How to log an event



Tap the
**Therapy
Action Button**



Tap **Log event**



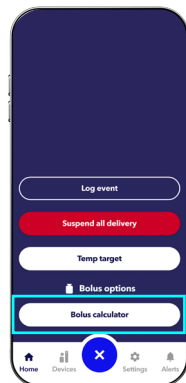
Tap the type of
event you would
like to log

You can add certain notes about a student's day under the Note event. Notes can be viewed by tapping the **Note icon** on the trend graph or by going into **Daily History** under the **Profile menu**.

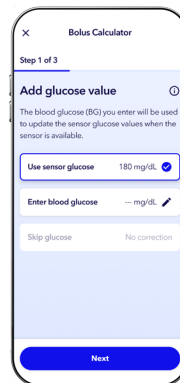
How to deliver a bolus in Manual mode



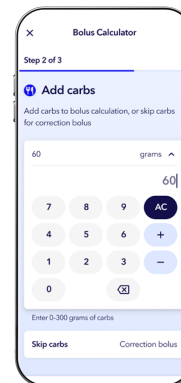
Tap the
**Therapy
Action Button**



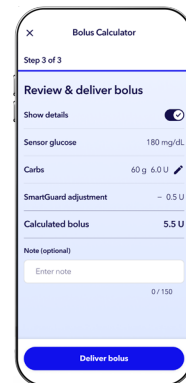
Tap **Bolus
Calculator**



Select the
appropriate
glucose option
and tap **Next**



Enter carbs if
eating and tap
Next or tap
Skip carbs if
not eating



Tap **Deliver
bolus**

Staying in SmartGuard



Action required

Time until exit

Suspend before low is active

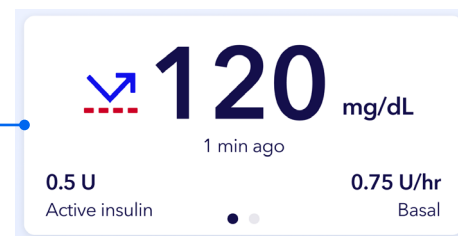
SmartGuard exits

Why do exits occur?

When the pump requires an action to stay in the SmartGuard feature, it delivers insulin at a fixed basal rate for a maximum of 4 hours.

The pump will provide a notification if any action is required, such as "Enter BG".

If there is an exit, the pump will go into Manual mode. In Manual mode, a student's pre-programmed Basal rates will start automatically. Also, a student can use the Bolus calculator to bolus for meals and corrections.

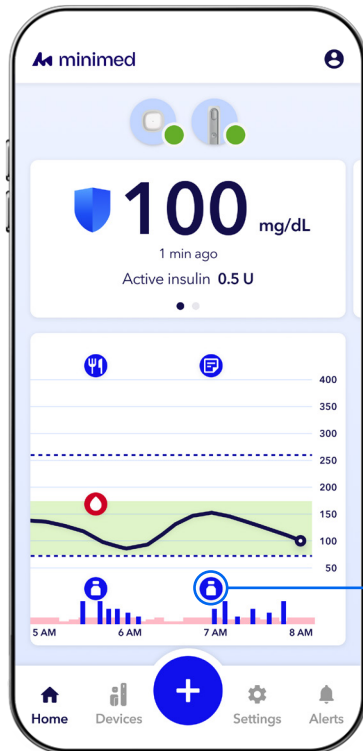


Suspend on low and **Suspend before low** will turn back on after a SmartGuard mode exit, if they were programmed to be on.

Checking last bolus

Checking last bolus and bolus history

Whether a student's pump is in SmartGuard or Manual mode, there may be times when you need to see the time or amount of the last bolus that was given. For example, you may want to check to make sure a student took a bolus at lunch or a parent may want to know the boluses their child gave throughout the day. You can see the last several boluses delivered on the Sensor graph. Just tap an icon to get more information.



Tapping the insulin icon will display the bolus time and amount, tap the notebook for even more details.

Safety Guidelines

Treating low glucose levels

How to treat mild/moderate lows

If glucose drops below 70 mg/dL:

- 1a. In SmartGuard, a student should consume 5-10 grams of fast-acting carbs (i.e., 2 oz juice or 2 glucose tabs).[†]
- 1b. In Manual mode, a student should consume 15 grams of fast-acting carbs (i.e., 4 oz. juice or 3-4 glucose tabs).
2. Monitor glucose in 15 minutes.
3. If glucose is still below 70 mg/dL, repeat steps 1 (a or b) & 2 every 15 minutes until glucose is within range.



Treating severe low glucose levels

Glucagon can be given by injection or nasal spray to raise glucose levels if a student is unable to eat or drink to treat a low, or if they are unconscious.



Please note: As with all general diabetes safety guidelines, proper severe low glucose management should be discussed with a student's guardian at the beginning of the school year to ensure it is aligned with their specific healthcare provider protocol.

[†] SmartGuard mode delivers less insulin before and during lows, so students need less glucose when treating lows.

Managing high glucose levels

If glucose is high but lower than 250 mg/dL:

1. The student should take a correction bolus using their pump.
2. Recheck glucose in 1 hour:
 - If glucose is going down, they should continue to monitor until it's within normal range.
 - If glucose is the same or higher, they should:
 - Take a correction dose using a syringe or pen.
 - Change infusion site, infusion set, reservoir, and insulin.
 - Continue to check glucose every hour until it returns to target.

If glucose is higher than 250 mg/dL, check for ketones.

If ketone test is negative, the student should follow the steps as outlined above.

If the ketone test is positive, the student should:

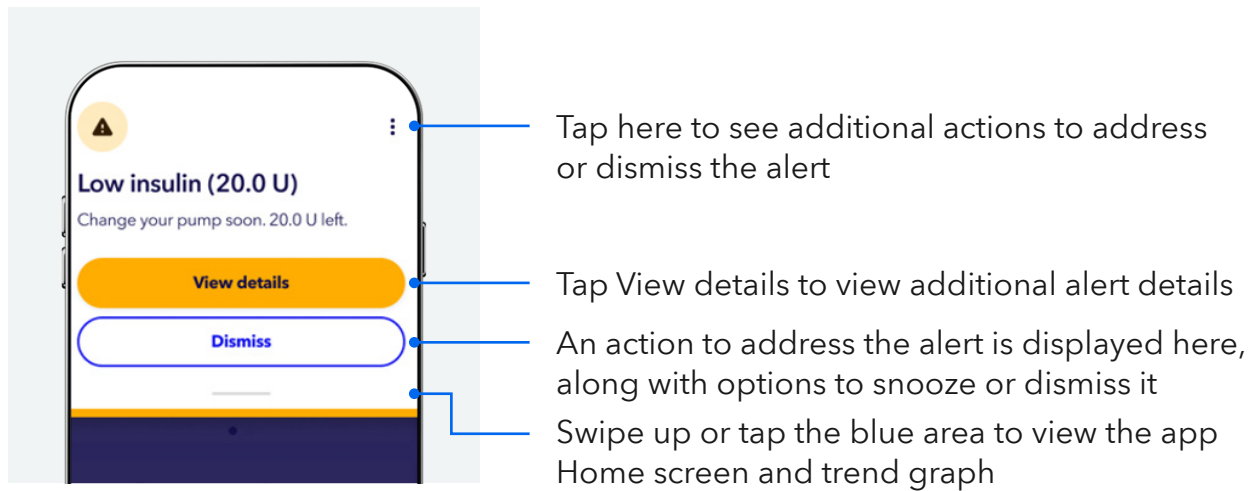
1. Take correction using a syringe or pen.
2. Change their infusion set, infusion site, reservoir, and insulin.
3. Call 1-800-646-4633 to troubleshoot the pump.
4. Monitor glucose every 1-2 hours, drink non-carbohydrate fluids, and deliver corrections as needed.



Please note: If the student's glucose continues to rise or if they have moderate to high ketones, nausea, vomiting, or difficulty breathing, notify their emergency contact and healthcare professional, and/or call 911.

Alerts

All alerts appear in the app



Some alerts, like glucose alerts, can be snoozed. If a Snooze button appears, tap Snooze to silence the alert for a set time. The alert will occur again after the snooze time if the condition persists.

Critical alerts

Press the oval Status button on the pump to see the alert color



Flashing red light



Action is needed immediately

The down arrow appears with:

- Urgent low glucose alerts
- Suspend limit has been reached

Flashing yellow light



Action is needed soon

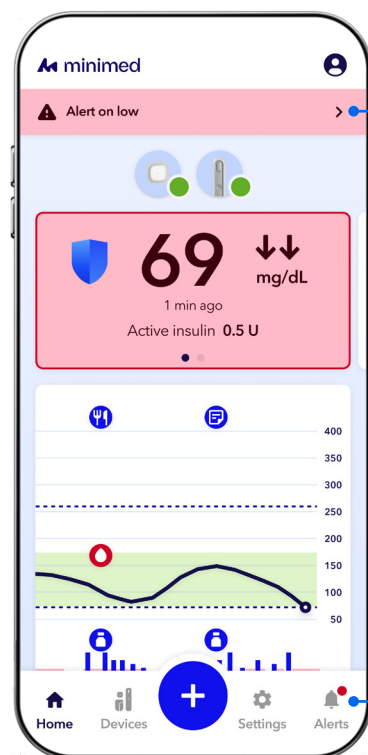
The down arrow appears with:

- Alert on Low



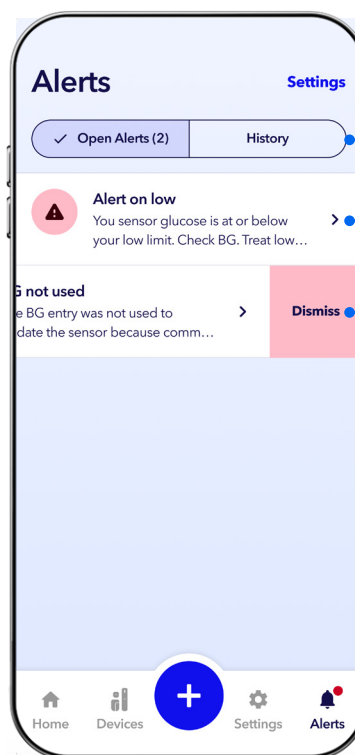
You must **navigate to the MiniMed app to take action**. Once addressed in the app the pump alert will be cleared.

Responding to alerts



Alert banner

A red dot on the Alerts icon indicates one or more open alerts



Tap history to view past alerts
Tap the alert to view more

Swipe and tap to Snooze or Dismiss

From the Home screen tap **Alerts**

Alerts will be listed by highest priority

Common alerts

Here are some common alerts that you might see on a student's pump in SmartGuard and/or Manual mode, and how to respond.

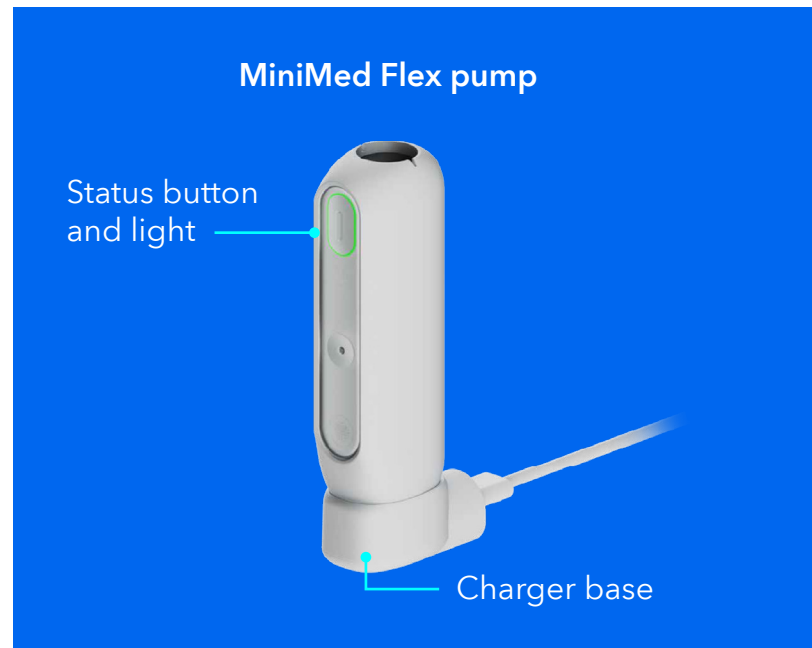
Alert	Reason	Steps to take
Very high basal setting	The pump sees that the current Manual mode basal insulin settings are programmed to deliver more insulin than they typically need.	Clear the alert. Contact the student's parent or caregiver so that they may consult with the student's healthcare professional.
Enter blood glucose	A BG is required to remain in SmartGuard.	Clear the alert. Enter a BG meter reading to return to auto basal. Follow instructions from a healthcare professional and continue to monitor BG.
No SG values > 30 minutes	Your SG values have been unavailable for more than 30 minutes.	Tap the Sensor icon for more information.
Lost pump communication	The mobile device lost Bluetooth connectivity with the pump. Sensor data and glucose alerts will not occur.	Make sure the mobile device is within range of the pump (within 20 feet), the mobile device Bluetooth is turned on and the pump is charged.
High pump temperature alert	The pump is too warm and the insulin in the pump can be damaged if it gets too hot.	Move the pump to a cooler place immediately. Resume insulin delivery when prompted by the app.
Low pump battery	The pump battery is becoming depleted, alert occurs at <10 hours and again at <1 hour.	Charge the pump to continue using the pump and sensor without interruption.
Low reservoir	Low reservoir.	Change reservoir when possible.
Insulin flow blocked	There is a block in the insulin flow and insulin is not being delivered.	Follow steps to troubleshoot issues, including calling 24-Hour Technical Support. Consider changing infusion set, reservoir, and insulin.

Charging the MiniMed Flex pump

- 1 Plug the charger base into an outlet.
- 2 Place the pump on the charging base.
- 3 A full charge will take about 30 minutes.
 - Flashing green light: pump is charging
 - Solid green light: pump is fully charged



A full charge lasts about one week (7+ days)



The MiniMed app controls the pump, so keeping the phone charged is essential.

Things to remember

- ✓ A student must bolus before meals and respond to alerts.
- ✓ Highs and lows can still occur, so make sure to have a plan in place on how to address them.
- ✓ Always have a backup plan in place.



Support your student on MiniMed systems



For any urgent technical questions, please call the **MiniMed 24-Hour Technical Support** at **1-800-646-4633**.



For additional information & support, go to minimed.com



MiniMed Simulator app: this app allows you to practice using the MiniMed app in a learning environment. Download it to get comfortable navigating the MiniMed app and performing essential everyday functions



MiniMed Share app: previously called the CareLink Connect app is for the Care Partner to view the students glucose, insulin and alert information

Other Helpful Resources:

American Diabetes Association – www.diabetes.org

Breakthrough T1D – <https://www.breakthrought1d.org/>

Important safety information

MINIMED FLEX™ SYSTEM WITH SMARTGUARD™ TECHNOLOGY WITH SIMPLERA SYNC™ SENSOR AND INSTINCT SENSOR

The MiniMed Flex™ system is intended for the continuous delivery of basal insulin at selectable rates, and the administration of insulin boluses at selectable rates for the management of type 1 diabetes mellitus in persons 7 years of age and older, and of type 2 diabetes mellitus in persons 18 years of age and older requiring insulin. The system is also intended to continuously monitor glucose values in the fluid under the skin.

The MiniMed Flex™ system includes SmartGuard™ technology, which can be programmed to automatically adjust insulin delivery based on continuous glucose monitoring (CGM) sensor glucose values and can suspend delivery of insulin when the SG value falls below or is predicted to fall below predefined threshold values. The system is intended for use with connected sensors, including the Simplera Sync™ sensor and integrated continuous glucose monitors, including the Instinct sensor, each of which has different wear-time, form factor, insertion site, and other distinguishing characteristics that relate to sensor performance. Consult the appropriate sensor user guide when using the system. Discuss treatment decisions with your HCP.

WARNING: Do not use the SmartGuard™ feature for people who require less than 8 units or more than 250 units of total daily insulin per day. A total daily dose of at least 8 units, but no more than 250 units, is required to operate in the SmartGuard™ feature.

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.

WARNING: Do not use SG values to make treatment decisions, including delivering a bolus, while the pump is in Manual Mode. When the SmartGuard™ feature is active and you are no longer in Manual Mode, the pump uses an SG value, when available, to calculate a bolus amount. However, if your symptoms do not match the SG value, use a blood glucose (BG) meter to confirm the SG value. Failure to confirm glucose levels when your symptoms do not match the SG value can result in the infusion of too much or too little insulin, which may cause hypoglycemia or hyperglycemia.

Pump therapy is not recommended for people whose vision or hearing does not allow for the recognition of pump signals, alerts, or alarms. 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. For complete details of the system, including user guides and important safety information such as indications, contraindications, warnings and precautions associated with system and its components, see <https://bit.ly/MiniMedRisks>.

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(24-Hour Technical Support for
Healthcare Professionals)



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