minimed

The MiniMed™ 780G system

School nurse guide

Medtronic

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Purpose & school orders

Purpose

This guide is intended to help school nurses with the basic operation of a student's MiniMed™ 780G 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.

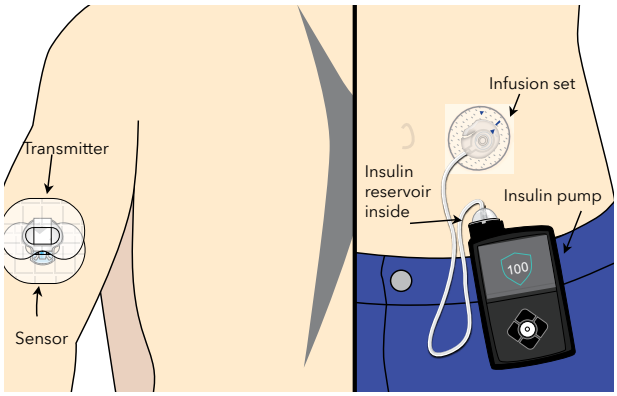
School orders with backup plan

Every student on the MiniMed™ 780G 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 with:
  - 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™ 780G system components



It's a good idea for every student on the MiniMed™ 780G system to have extra pump and sensor supplies, i.e. a spare, unused AA battery, an infusion set, serter, and reservoir so the student can change their own infusion set and/or sensor or change with the help of a caregiver or trained professional.

Understanding the MiniMed™ 780G system

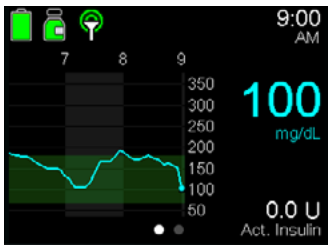
The MiniMed™ 780G system may be delivering insulin in one of two modes: **Manual Mode** and **SmartGuard™**.

Manual Mode is using the pump with or without a continuous glucose monitor (CGM) in a traditional way, like previous insulin pump systems from Medtronic.

SmartGuard™ technology: 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 SG reading. A student using SmartGuard™ technology may still occasionally be required to do a Blood Glucose (BG) check.

Home Screen in Manual Mode

Without CGM



With CGM

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 Wizard™ feature or with manual boluses as needed.
- May be used with or without CGM.

Home Screen in SmartGuard™ technology

SmartGuard™ technology shields

SmartGuard™ technology

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 SmartGuard™ Bolus feature.
- CGM is required.

SmartGuard™ technology

Important information about SmartGuard™ technology:

- Basal insulin and auto correction doses are delivered every 5 minutes, based on sensor glucose (SG).
- SmartGuard™ technology uses a sensor glucose target of 100 (default), 110, or 120 mg/dL as determined by the healthcare provider.
- A student can temporarily change the target to 150 mg/dL, like for times when less insulin is needed (i.e. exercise). Note: no auto corrections will be delivered when using a temp target.
- Carbs should be entered into the pump before meals.
- The Guardian™ 4 sensor does not require calibrations, or fingersticks when in SmartGuard™ technology.† If using the Guardian™ Sensor 3, BG checks are necessary at least every 12 hours to calibrate the sensor. Fingersticks should be used for dosing decisions.
- A student may receive an alert if the pump needs an action to be performed to stay in SmartGuard™ technology.

How to tell when the pump is in SmartGuard™ technology:

If you see the SmartGuard™ shield, the pump is in SmartGuard™ technology.

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

SmartGuard™ technology

When a student is wearing the MiniMed™ 780G system and SmartGuard™ technology is active, the student must still perform certain tasks:

1. **Bolus for carbs 15-20 minutes before eating.**

   When in SmartGuard™ technology, a student should bolus for carbs 15-20 minutes before each meal and snack. Giving insulin before a meal can help students avoid post-meal highs, which could lead to fewer alerts and improved glucose control.

2. **Respond to alarms and alerts.**

   Students should respond promptly to all alarms and alerts to avoid highs and lows, which could lead to more time spent in SmartGuard™ technology.

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. Occasional fingerstick testing of glucose levels may be required.

Important to know:

The MiniMed™ 780G system is a Bluetooth®-enabled device. This means that students are able to view their sensor glucose values and receive optional glucose alerts on a smartphone and Apple® Watch using the MiniMed™ Mobile app. This data can be shared remotely with parents or caregivers through the CareLink™ Connect app if the student's mobile device is connected to the internet. Care partners can also now follow up to 5 MiniMed™ Mobile app users.

The Basics | Buttons, unlocking & locking the pump

Pump buttons

Backlight

When you are not pressing buttons on the pump, you will notice that the backlight will soon turn off. The pump is still on; it is just saving battery life. You can simply press any button to make the screen reappear.

Using the pump in SmartGuard™ technology

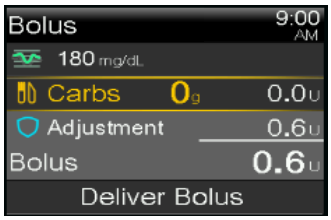
In SmartGuard™ technology

1. Enter carbs (if eating).
2. Deliver bolus 15-20 minutes before eating.

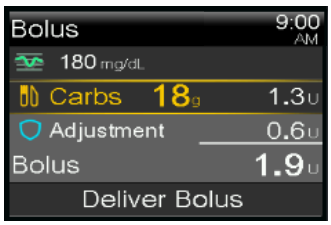
Delivering a bolus

1. From the home screen, press the **down** arrow for a shortcut to the Bolus screen.

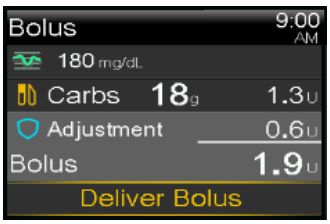
2. If you haven't entered a blood glucose (BG) into the pump in the past 12 minutes, the sensor glucose value (SG) will automatically populate on the screen and be used to bolus.



3. Select **Carbs** to enter carbs for food.
   If you are not eating carbs, go to the next step.



4. Review the bolus amount and select **Deliver Bolus** to give the bolus.



5. The Bolus Started message briefly appears, then the home screen appears, with a banner showing the bolus being delivered.

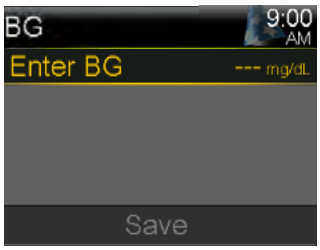
The same steps apply in Manual Mode. However, a BG is required when calculating a correction bolus using the Bolus Wizard™ feature.

Using the pump in SmartGuard™ technology

If needed, a blood glucose (BG) meter reading can be manually entered on the Bolus screen while using SmartGuard™ technology.

In SmartGuard™ technology (with an unlinked meter)
1. Check & enter BG
2. Enter carbs & bolus

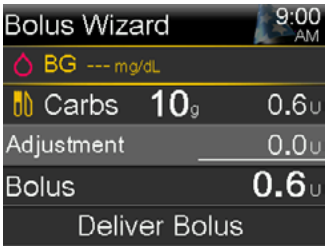
A BG value can be manually entered via the Blood Glucose menu or by using a compatible Accu-Chek® Guide Link Meter.



Send button
Press to send BG result immediately to the pump.

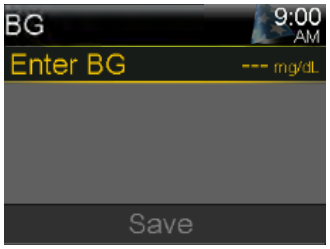
1. From the home screen, press the **down** arrow.

2. Select **BG.**

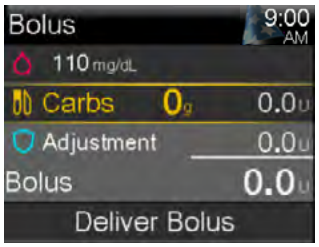


Using the pump in SmartGuard™ technology

3. Press ^ or v to enter your BG reading, and press **Save.**

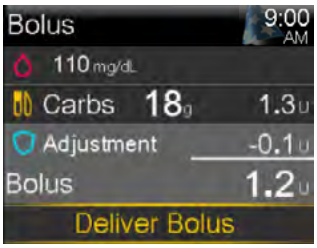


4. Select **Carbs.**



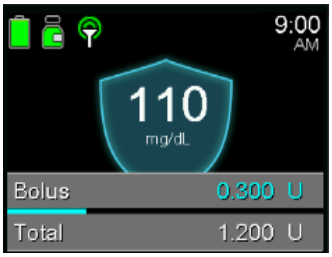
5. Press ^ or v to enter carbs for your food, and press ○.

6. Review the bolus amount and select **Deliver bolus** to give the bolus.



The Bolus Started message briefly appears.

The home screen appears showing the bolus being delivered.



Temp Target

The SmartGuard™ technology targets are:

100 mg/dL (default) 110 mg/dL 120 mg/dL

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

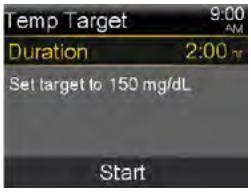
To set a Temp Target:

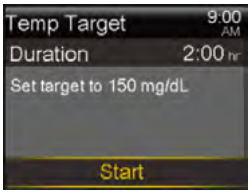
1. From the home screen, press the **Select**/circle button, and then select the **SmartGuard™** Shield.

2. Select **Temp Target** to turn the feature on.

3. Set the **Duration**, from 30 minutes to 24 hours, in 30-minute increments.

4. Select **Start**.





The screen shows a Temp Target Started message, and then changes to the home screen, where a banner shows the remaining Temp Target time.

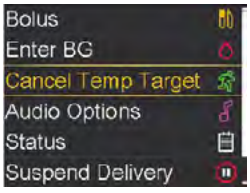
To cancel a Temp Target

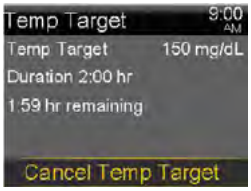
To return to the standard SmartGuard™ technology target of 120 mg/dL before the Temp Target duration expires, a student can cancel the Temp Target.

1. Press ○.

2. Select **Cancel Temp Target**.
   The Temp Target screen appears and shows the details of the temp target.

3. Select **Cancel Temp Target** to cancel the Temp Target.



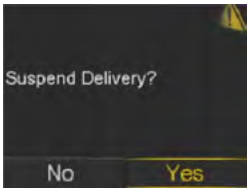


The Temp Target Ended message and duration of the Temp Target briefly appear. Then the home screen appears.

Stopping and resuming insulin delivery

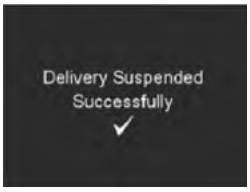
A student can use **Suspend All Delivery** pursuant to guidance from their HCP. While insulin delivery is suspended, the pump beeps, vibrates, or both depending on the audio settings. This occurs every 15 minutes to remind them that insulin is not being delivered. If the student has instruction from their HCP to suspend all delivery, the student should follow the steps below:

To suspend all delivery:



1. From the Home screen, press the **Up** arrow.

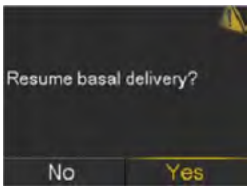
2. Select **Suspend all Delivery**. A confirmation message will appear.



3. To suspend, press the **Right** arrow and select **Yes**.
   A **Delivery Suspended Successfully** confirmation will appear.

4. After suspending delivery, the Home screen will show insulin delivery is suspended. The pump functions are limited until basal insulin delivery is resumed.

To resume basal insulin delivery:

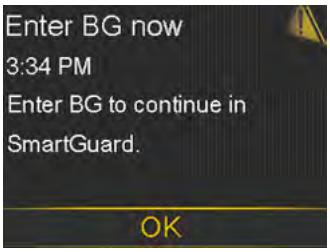


1. While insulin is suspended, from the Home screen press the **Up** arrow.

2. Select **Resume Basal**. A confirmation message appears.

3. To resume basal insulin, select **Yes**. A **Delivery Resumed Successfully** confirmation will appear.

SmartGuard™ technology exits

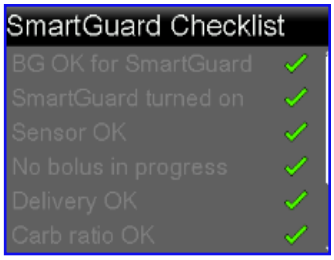


SmartGuard™ technology exits

Why do exits occur?

On average, system users are spending 95% of time in SmartGuard™ technology.[1] However, there are times when the pump will exit SmartGuard™ technology and return to Manual Mode for safety reasons.

What to do if there is an exit?



The SmartGuard Checklist screen (shown at right) helps you or a student determine why SmartGuard™ technology is not active. Go to the screen to see if there is something the student can do to activate SmartGuard™ technology, such as check a BG. Or you can go there from the home screen by selecting:

Menu > SmartGuard > SmartGuard Checklist

Manual Mode

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 Wizard™ feature to bolus for meals and corrections.

Note: Suspend on low and Suspend before low will turn back on after a SmartGuard™ technology exit, if they were programmed to be on.

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

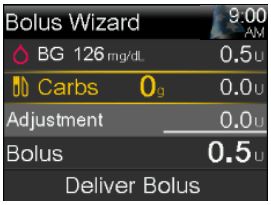
1. Data on file from CIP 321: Pivotal Trial (Age 14-75). N=152. 2020; 16 US sites.

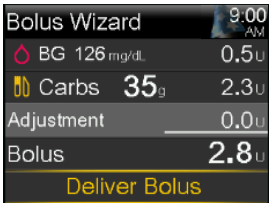
Using the pump in Manual Mode

How to use the Bolus Wizard™ feature in Manual Mode

Deliver correction and food bolus

1. Check BG.
2. From the home screen, press the **down** arrow.
3. If using a linked meter, the **BG** is on screen. If not, select **BG**.
4. Press ^ or v to enter BG and press O.
5. Select **Carbs**.
6. Press ^ to enter grams of carbs and press O.
7. Select **Deliver Bolus**.





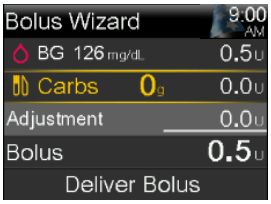
Deliver correction bolus – no food

1. Check BG.
2. From the home screen, press the **down** arrow.
3. If using a linked meter, the **BG** is on screen. If not, select **BG**.
4. Press ^ or v to enter BG and press O.
5. Press v and select **Next**.
6. Select **Deliver Bolus**.

Using the pump in Manual Mode

Deliver food bolus without a BG – no correction

1. From the home screen, press the **down** arrow.
2. Press ⌄ and select **Carbs**.
3. Press ⌃ to enter the amount of carbs you are eating and press ○.
4. Select **Next**.
5. Select **Deliver Bolus**.



For more information about using the MiniMed™ 780G system in Manual Mode, go to: **www.medtronicdiabetes.com/support**

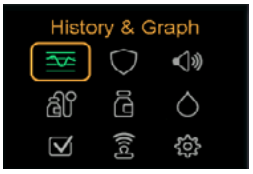
Checking last bolus

Checking last bolus and bolus history

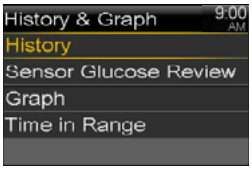
Whether a student's pump is in SmartGuard™ technology or Manual Mode, there may be times when you need to see the time or amount of the last bolus that was given. For example, you may want to check to make sure a student took a bolus at lunch or a parent may want to know the boluses their child gave throughout the day. You can see the last several boluses delivered in the **Daily History** screen. You can see the last bolus delivered in the **Quick Status** screen.

1. Press the **Select** button.

2. Choose the **History & Graph** icon.

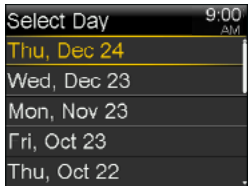


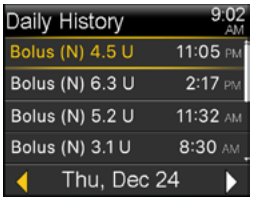
3. Go into **History**.



4. Select **Daily History**.

5. Select date you wish to review.





Safety Guidelines

Treating low glucose levels

How to treat mild/moderate lows

If glucose drops below 70 mg/dL:

1a. In SmartGuard™ technology, 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.

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.

† SmartGuard™ technology delivers less insulin before and during lows, so students need less glucose when treating lows.

Safety Guidelines

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 on the previous page.

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, option 1 to troubleshoot the pump.

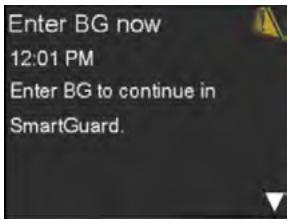
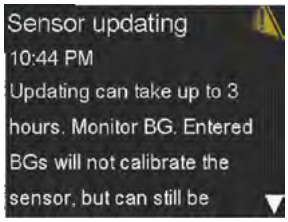
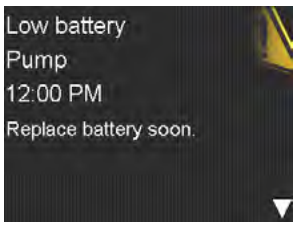
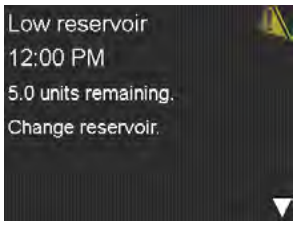
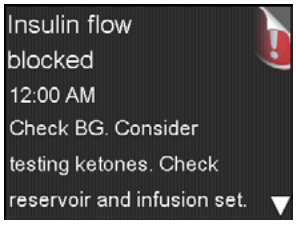
4. Monitor glucose every 1-2 hours, drink non-carbohydrate fluids, and deliver corrections as needed.

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.

Alarms & alerts

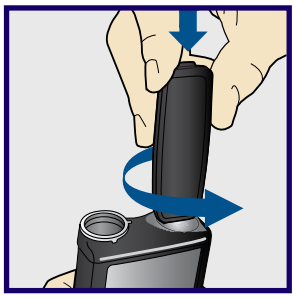
Here are some common alarms & alerts that you might see on a student's pump in SmartGuard™ technology and/or Manual Mode, and how to respond.

Read and address the alert, then clear it by pressing ✓ then ○

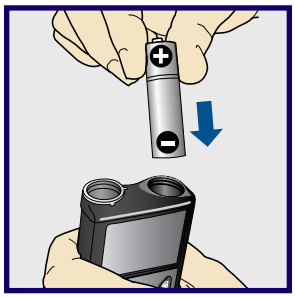
Alert	Reason	Steps to take
	A new BG is required to remain in SmartGuard™ technology.	Clear the alert. Enter a BG meter reading to return to auto basal. Follow instructions from a healthcare professional and continue to monitor BG.
	The SG reading is unavailable due to a temporary situation.	Clear the alert. Follow the instructions on the pump screen. The sensor does not need to be changed.
	Low battery.	Change battery when possible. See next page for how-to instructions.
	Low reservoir.	Change reservoir when possible.
	Insulin flow blocked.	Follow steps to troubleshoot issues, including calling 24-Hour Technical Support. Consider changing infusion set, reservoir, and insulin.

Changing the battery

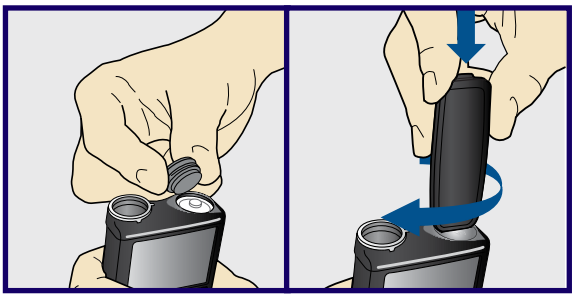
The pump is powered by a AA battery. A brand new Lithium, Alkaline, or fully-charged rechargeable battery can be used.



1. Unscrew the battery cap using the bottom edge of the belt clip. (Or use a thick coin.)

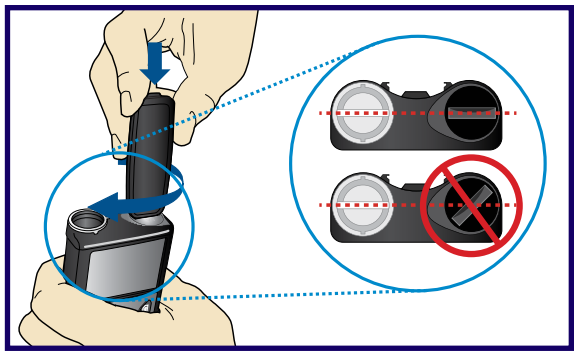


2. Insert battery with negative (flat) end going in first.



3. Place battery cap into the pump and use the edge of the belt clip to screw the cap back on.

Do not under-tighten or over-tighten the battery cap.
It should be aligned horizontally with the pump case as shown here.



Battery Alerts

- Low battery pump alert – 8-10 hours of battery life remains.
- Replace battery alert – 30 minutes of battery life remains.
- Replace battery now alarm – insulin delivery stopped due to low power.

Things to remember

The MiniMed™ 780G system with SmartGuard™ technology can help drive your students' glucose levels in target range.†[1] More time spent in target range may help your student live a healthier life and focus on learning!

Things to remember in SmartGuard™ technology:

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

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

For additional information & support, go to **www.medtronicdiabetes.com**

Other Helpful Resources:

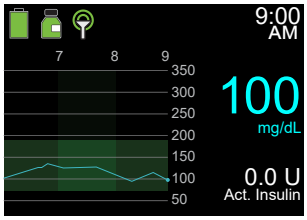
American Diabetes Association – **www.diabetes.org**

Breakthrough T1D – **https://www.breakthrought1d.org/**

† Refers to SmartGuard™ technology. Some user interaction required. Individual results may vary.

1 Bergenstal R, Garg S, Weinzimer S, et al. Saftey of a hybrid closed loop insulin delivery system in patients with type 1 diabetes. *JAMA*. 2016;316(13):1407-1408.

Appendix | MiniMed™ 780G pump modes

	Manual Mode	SmartGuard™ technology
Home screen display	 **Without CGM**  **With CGM**	
Availability	When SmartGuard™ technology is not active.	SmartGuard™ technology is active.
Basal	Uses the basal settings programmed into the pump.	Automatically adjusts basal insulin every 5 minutes depending on the SG value. May deliver a bolus automatically if the SmartGuard™ feature determines that a correction bolus is necessary.
Bolus	Uses the programmed Bolus Wizard™ settings to recommend a dose.	Should enter carbs into pump to get bolus recommendation.

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Important safety information

MiniMed™ 780G system with SmartGuard™ technology with Guardian™ sensor (3)

The MiniMed™ 780G system is intended for continuous delivery of basal insulin at selectable rates, and the administration of insulin boluses at selectable amounts for the management of type 1 diabetes mellitus in persons seven years of age and older requiring insulin as well as for the continuous monitoring and trending of glucose levels in the fluid under the skin. The MiniMed™ 780G System includes SmartGuard™ technology, which can be programmed to automatically adjust insulin delivery based on the 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 Medtronic MiniMed™ 780G System consists of the following devices: MiniMed™ 780G Insulin Pump, the Guardian™ Link (3) Transmitter, the Guardian™ Sensor (3), One-press serter, the Accu-Chek™ Guide Link blood glucose meter, and the Accu-Chek™ Guide Test Strips. The system requires a prescription from a healthcare professional.

The Guardian™ Sensor (3) is intended for use with the MiniMed™ 780G system and the Guardian™ Link (3) transmitter to monitor glucose levels for the management of diabetes. The sensor is intended for single use and requires a prescription. The Guardian™ (3) sensor is indicated for seven days of continuous use.

The Guardian™ Sensor (3) is not intended to be used directly to make therapy adjustment while the MiniMed™ 780G system is operating in manual mode. All therapy adjustments in manual mode should be based on measurements obtained using a blood glucose meter and not on values provided by the Guardian™ Sensor (3). The Guardian™ Sensor (3) is indicated for abdomen and buttock insertion for users ages 7-13 years, and abdomen and arm insertion for user ages 14 years and older.

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™ 780G system until appropriate training has been received from a healthcare professional. Training is essential to ensure the safe use of the MiniMed™ 780G 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 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™ 780G system has not been studied in pregnant women, persons with type 2 diabetes, or in persons using other anti-hyperglycemic therapies that do not include insulin. For complete details of the system, including product and important safety information such as indications, contraindications, warnings and precautions associated with the system and its components, please consult **https://www.medtronicdiabetes.com/important-safety-information#minimed-780g** and the appropriate user guide at **https://www.medtronicdiabetes.com/download-library**.

Important safety information

MiniMed™ 780G system with SmartGuard™ technology with Guardian™ 4 sensor

The MiniMed™ 780G system is intended for continuous delivery of basal insulin at selectable rates, and the administration of insulin boluses at selectable amounts for the management of type 1 diabetes mellitus in persons seven years of age and older requiring insulin as well as for the continuous monitoring and trending of glucose levels in the fluid under the skin. The MiniMed™ 780G System includes SmartGuard™ technology, which can be programmed to automatically adjust insulin delivery based on the 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 Medtronic MiniMed™ 780G System consists of the following devices: MiniMed™ 780G Insulin Pump, the Guardian™ 4 Transmitter, the Guardian™ 4 Sensor, One-press serter, the Accu-Chek™ Guide Link blood glucose meter, and the Accu-Chek™ Guide Test Strips. The system requires a prescription from a healthcare professional.

The Guardian™ 4 Sensor is intended for use with the MiniMed™ 780G system and the Guardian™ 4 transmitter to monitor glucose levels for the management of diabetes. The sensor is intended for single use and requires a prescription. The Guardian™ 4 sensor is indicated for **up to** seven days of continuous use.

The Guardian™ 4 sensor is not intended to be used directly to make therapy adjustments while the MiniMed™ 780G system is operating in manual mode. All therapy adjustments in manual mode should be based on measurements obtained using a blood glucose meter and not on values provided by the Guardian™ 4 sensor. The Guardian™ 4 sensor has been studied and is approved for use in patients ages 7 years and older and in the arm insertion site only. Do not use the Guardian™ 4 sensor in the abdomen or other body sites including the buttocks, due to unknown or different performance that could result in hypoglycemia or hyperglycemia.

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™ 780G system until appropriate training has been received from a healthcare professional. Training is essential to ensure the safe use of the MiniMed™ 780G 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 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™ 780G system has not been studied in pregnant women, persons with type 2 diabetes, or in persons using other anti-hyperglycemic therapies that do not include insulin. For complete details of the system, including product and important safety information such as indications, contraindications, warnings and precautions associated with system and its components, please consult **https://www.medtronicdiabetes.com/important-safety-information#minimed-780g** and the appropriate user guide at **https://www.medtronicdiabetes.com/download-library**.

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Medtronic