THE MINIMED™ 670G SYSTEM
GUIDE FOR SCHOOLS

ASCENSIA Diabetes Care

Medtronic

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Purpose

This guide is intended to help schools with the basic operation of a student's MiniMed™ 670G system. Please note that this booklet does not cover all aspects of insulin pump therapy and continuous glucose monitoring (CGM). It is written for people with some experience with this technology.

Individual Healthcare Plans

Every student on the MiniMed™ 670G system should have an Individual Healthcare Plan (IHP) from the student's healthcare professional. This 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 back up 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 parents/guardians and the school should also be established.

The MiniMed™ 670G System Components

It's a good idea for every student on the MiniMed™ 670G system to have extra pump supplies –

A spare unused AA battery

An infusion set, serter, reservoir and insulin if the student can change his own infusion set or change with the help of a caregiver or trained professional.

The MiniMed™ 670G system can be used in two different ways – **Manual Mode** and **Auto Mode.**

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

Auto Mode, a SmartGuard™ feature, automatically adjusts basal insulin every 5 minutes based on sensor glucose (SG) readings. A student using Auto Mode must still check BGs and calibrate (update) the sensor periodically, as well as bolus for carbs before meals.

HOME SCREEN IN MANUAL MODE

Manual Mode

Manual Mode with CGM

HOME SCREEN IN AUTO MODE

SmartGuard™ Auto Mode shields

Manual Mode

Using the pump in a traditional way,

- Basal rates are pre-programmed.
- Bolusing can be done with the Bolus Wizard™ feature or with manual boluses.
- May be used with or without CGM.

Auto Mode

Controlled by a SmartGuard™ algorithm that self-adjusts basal insulin based on sensor glucose readings.

- Basal insulin is automatically adjusted every 5 minutes.
- Bolusing before meals using the Bolus Wizard™ feature is necessary.
- CGM is required.

Important information about Auto Mode:

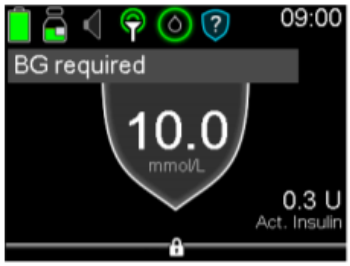
- Basal insulin is delivered based on SGs.
- Auto Mode uses a target of 6.7 mmol/L.
- A student can temporarily change the target to 8.3 mmol/L, like for exercise.
- Carbs must be entered into the pump before meals.
- BG checks are necessary to calibrate the sensor.
- When a student enters a BG over 8.3mmol/dL, Auto Mode may recommend a correction bolus.
- A student may receive a BG required alert if the pump needs a BG for Auto Mode.

How to tell when the MiniMed™ 670G system is in Auto Mode

If you see the SmartGuard™ shield, the pump is in Auto Mode, which includes Safe Basal.

Safe Basal

There are times in Auto Mode when basal insulin is being delivered according to *recent* insulin needs, but is not being adjusted based on SG readings. This is called **Safe Basal**, and when the pump is in Safe Basal, you will see the screen to the right.



Safe Basal activates, for example, if the pump and transmitter are not communicating, or a BG entered is very different from the SG. Very often, these situations will resolve themselves before the student is aware of it.

If the pump is in Safe Basal and there is something that can be done to resolve the issue, the pump will alert the student what to do, like check a BG.

A Student's Responsibilities in Auto Mode

When a student is wearing the MiniMed™ 670G system and Auto Mode is active, the student must still perform certain tasks:

1. Check BG and calibrate sensor
2. Bolus for carbs beforeeating
3. Respond to alarms and alerts

Check BG and calibrate sensor

Students should check their BGs prior to meals and calibrate their sensor. Calibrating the sensor is performing a fingerstick, and using that BG value to update the device. It is best to calibrate the sensor at least 3-4 times a day, before meals and at bedtime. So while at school, it is reasonable that a student might calibrate once before lunch and/or if the device asks for a calibration, or requests a BG.

Bolus for carbs before eating

When in Auto Mode, a student must bolus for carbs before each meal and snack. Giving insulin before a meal can help students avoid post-meal high BGs, which could lead to fewer alerts and improved glucose control. Check the Individual Healthcare Plan for the ideal length of time to bolus pre-meal.

Respond to alarms and alerts

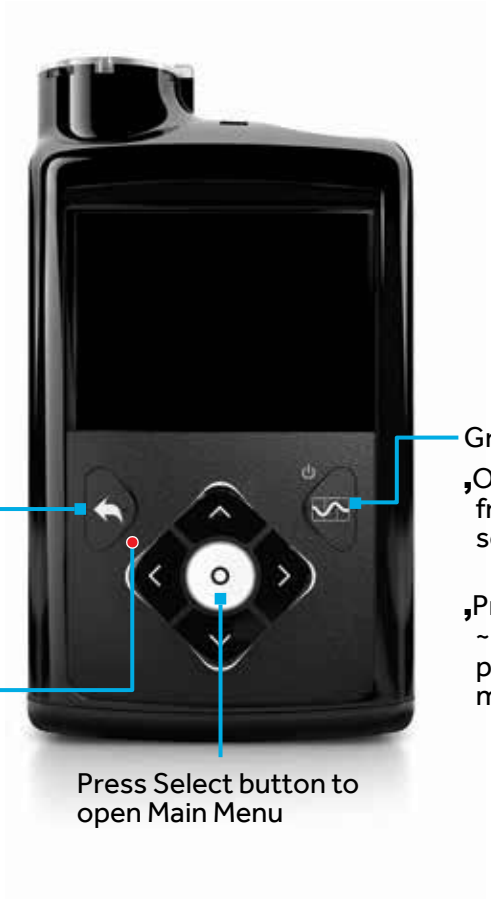
Students should respond promptly to all alarms and alerts to help spend more time in Auto Mode and avoid highs and lows, which could lead to more time spent in target range.

USING AUTO MODE

Sam's pump is in Auto Mode, and she would like to eat a meal. She knows that she should check her BG, calibrate the sensor and then enter carbs into the pump for the food she is certain she will eat.

Note: indicated for ages 7 and over.

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.

Unlocking the Pump

After the Backlight has been off for a few minutes, the pump goes into Sleep mode and the pump is locked.

To use the pump, press Select twice. You will see a screen like the one shown here. Press the arrow key that is highlighted to unlock the pump.

Locking the Pump

If you would like to lock the pump, simply press and hold the Graph button.

Using the CONTOUR®NEXT LINK 2.4 meter to enter a BG with or without carbs for food, calibrate the sensor, and deliver a bolus*

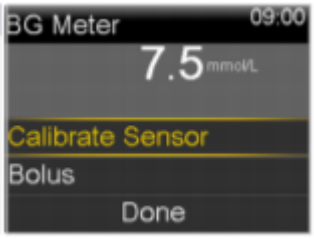
In Auto Mode
(with a linked meter)
1. Check BG
2. Calibrate sensor
3. Enter carbs and bolus

1. Check BG.

2. Select **Yes** to confirm the BG meter reading.

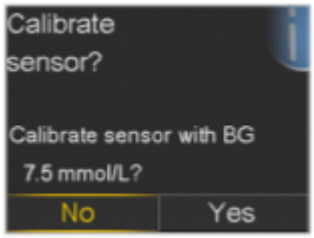
   If you do not believe the meter result is accurate, do not confirm now. Select **No**, wash hands, and recheck BG.

3. **Bolus** will be highlighted. If you want to calibrate with this BG, select **Calibrate Sensor.**



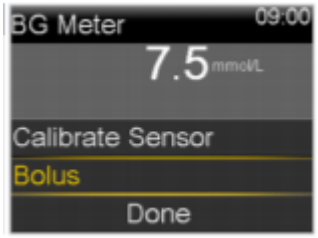
4. Select **Yes** to calibrate.

   Select **No** to not calibrate.



5. If you want to give a bolus, select **Bolus.**

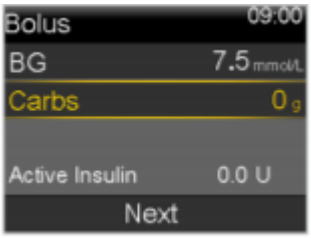
   If you do not want to give a bolus, press ⌄ and select **Done.**



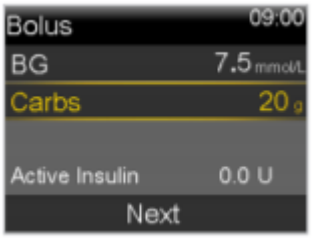
*Do not calibrate your CGM device or calculate a bolus using a blood glucose meter result taken from an Alternative Site (palm) or from a control solution test. It is not recommended to calibrate your CGM device when sensor or blood glucose values are changing rapidly e.g., following a meal or physical exercise.

6. Select **Carbs** to enter carbs for food.

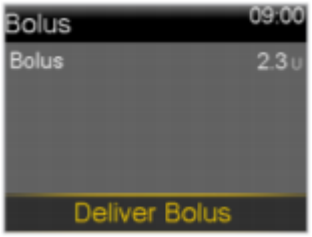
   If you are not eating carbs, go to the next step.



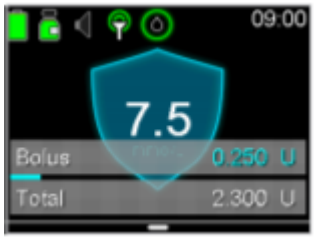
7. Select **Next** to review the calculated bolus amount.



8. Select **Deliver Bolus** to give the bolus.



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



USING THE PUMP IN AUTO MODE

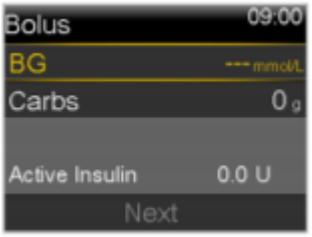
To manually enter a BG and carbs for food, deliver a bolus, and calibrate the sensor:

In Auto Mode (with an unlinked meter)
1. Check & enter BG
2. Enter carbs & bolus
3. Calibrate sensor

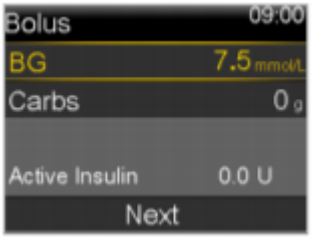
1. Press ○.

2. Select **Bolus.**

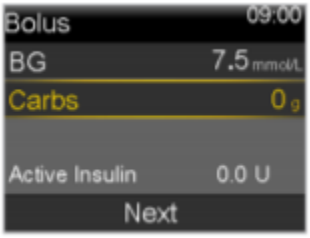
3. Select **BG.**



4. Press ^ or v to enter your BG reading, and press ○.

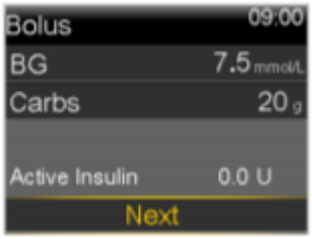


5. Select **Carbs.**



6. Press ^ or v to enter carbs for your food, and press O.

7. Select **Next.**



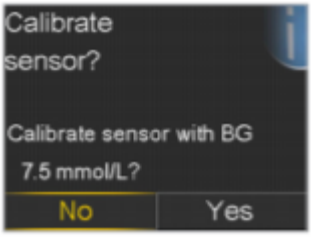
8. Review the calculated bolus amount.

9. Select **Deliver Bolus** to deliver the bolus.

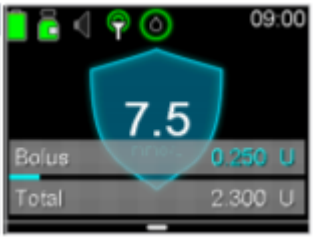
The message Bolus started briefly appears.

A message appears asking if you want to calibrate using the entered BG.

10. Select **Yes** to calibrate.
    Select **No** to not calibrate.

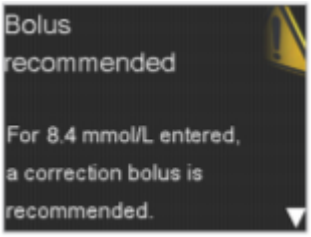


The Home screen appears showing the bolus being delivered.



Recommended Bolus

If a BG entered is greater than 8.3 mmol/L, Auto Mode may recommend a correction bolus. 1. Read the message on the first screen.



2. Press ⌄ to finish reading the message.

3. Select **Bolus.**

Auto Mode will calculate how much insulin to deliver.

A CORRECTION BOLUS IN AUTO MODE

Sam's pump is in Auto Mode. After lunch, Sam notices her SG levels are higher than normal, so Sam checks her BG. Auto Mode recommends a correction bolus for the high BG value, and Sam delivers the bolus. Sam feels safe knowing that Auto Mode estimates her correction bolus amount based on her glucose needs at that moment.

Bolusing for carbs without a BG entry

There may be times in Auto Mode when a student would like to eat a second helping of food or a snack without checking a BG.

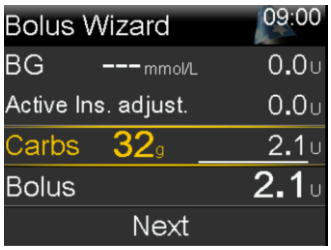
1. Press ○.

2. Select **Bolus.**

3. Press ∨ to **Carbs** and press ○.

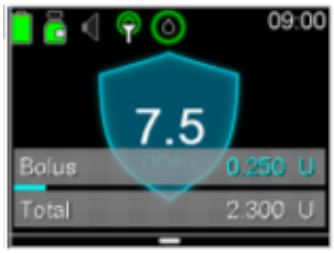
4. Press ∧ to enter the amount of carbs you are eating and press ○.

5. Select **Next.**



6. Select **Deliver Bolus.**

The Home screen appears showing the bolus being delivered.



Entering a BG

There may be times that Auto Mode requests a BG entry. You may check with a linked meter, or manually enter the BG.

If you are manually entering the BG:

1. Press ○ from the Home screen.

2. Select **Enter BG** and manually enter BG value.

3. Select **Save.**

To Enter a Temp Target

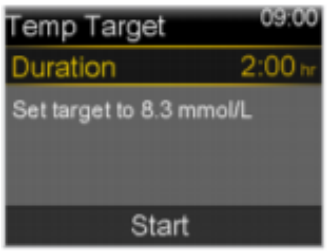
The standard Auto Mode target is 6.7 mmol/L, although a student may want to temporarily change the Auto Mode target to 8.3 mmol/L e.g. for physical activity.

1. Press ○.

2. Select **Temp Target.**

3. Press ∧ or ∨ to set the Temp Target duration and then press ○. The duration can be set in 30 minute increments. The default is 2 hours.

4. Select **Start.**



The message Temp Target Started briefly appears, then the Home screen appears with a banner showing the remaining Temp Target time.

To Cancel a Temp Target

Toreturn to the standard Auto Mode target of 120 mg/dL before the Temp Target duration expires, a student can cancel the Temp Target.

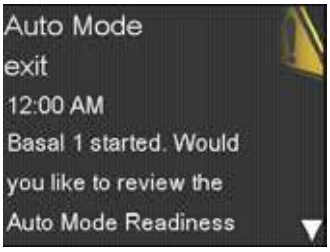
1. Press ○.

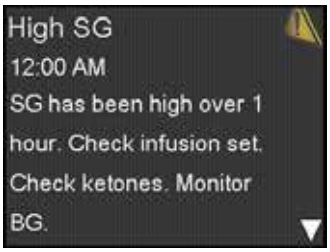
2. Select **Cancel Temp Target.**
   The Temp Target screen appears and shows the details of the temp target.

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.

Auto Mode Exits





Why do Auto Mode exits occur?

There are times when the pump will exit Auto Mode and return to Manual Mode for safety reasons.

There could be an alarm that needs attention. For example, a student could have a high SG (over 16.7 mmol/L) for more than 1 hour. The pump has exited to Manual Mode, and will need a BG to return to Auto Mode. This exit to Manual Mode allows a student time to troubleshoot the hyperglycemia and take action to resolve it, like give a correction bolus and monitor glucose levels.

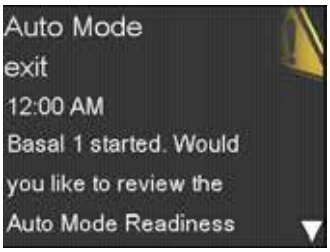
What to do if there is an Auto Mode exit?

The Auto Mode Readiness screen (shown at right) helps you or a student determine why Auto Mode is not active. Go to the screen to see if there is something the student can do to activate Auto Mode, such as check a BG. The pump may ask you if you would like to view the Auto Mode Readiness screen, or you can go there from the Home screen by selecting:

Menu > Status > Auto Mode Readiness

Manual Mode

If there is an Auto Mode 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.



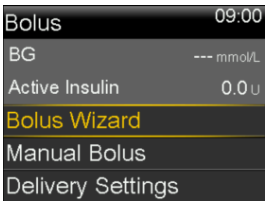
When in doubt, call the Medtronic 24-hour helpline for device-related questions, or the student's parent or guardian.

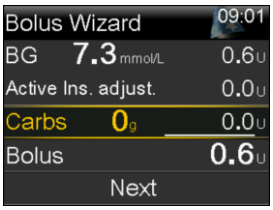
How to use the Bolus Wizard™ feature in Manual Mode

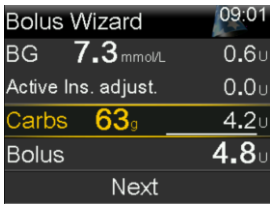
Deliver correction and food bolus

1. Check BG.
2. Press ○.
3. Select **Bolus.**
4. Select **Bolus Wizard.**

   If using a linked meter, the **BG** is on screen. If not, select **BG.**
5. Press ^ or v to enter BG and press ○.
6. Select **Carbs.**
7. Press ^ to enter grams of carbs and press ○.
8. Select **Next.**
9. Select **Deliver Bolus.**



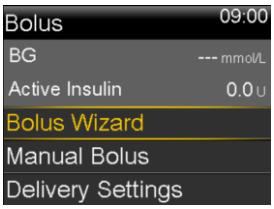




Deliver correction bolus—no food

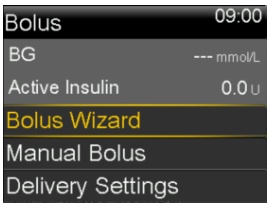
1. Check BG.
2. Press ○.
3. Select **Bolus.**
4. Select **Bolus Wizard.**

   If using a linked meter, the **BG** is on screen. If not, select **BG.**
5. Press ^ or v to enter BG and press ○.
6. Press v and select **Next.**
7. Select **Deliver Bolus.**

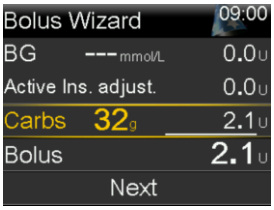


Deliver food bolus—no correction

1. Press ○.
2. Select **Bolus.**
3. Select **Bolus Wizard.**
4. Press ∨ and select **Carbs.**



5. Press ∧ to enter the amount of carbs you are eating and press ○.
6. Select **Next.**



7. Select **Deliver Bolus.**

For more information about using the MiniMed™ 670G in Manual Mode, go to: **https://www.medtronic-diabetes.co.uk** and click on **Support**

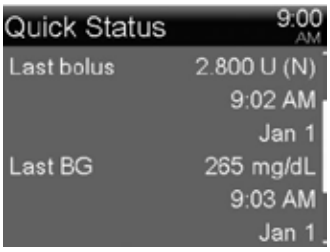
MANUAL MODE

Sam is taking steroids short-term for an illness, so Sam's doctor instructed Sam to use her pump in Manual Mode until she has finished the steroid course, and her insulin needs have returned to her typical daily doses. Sam feels good that she can still benefit from her insulin pump features and continuous glucose monitor.

Checking Last Bolus

Whether a student's pump is in Auto Mode 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. You can see the last bolus delivered in the **Quick Status** screen.

1. Press ○.
2. Press ∨ to **Status** and press ○.
3. Press ∨ to **Quick Status** and press ○.



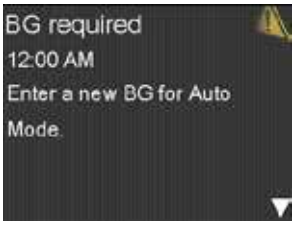
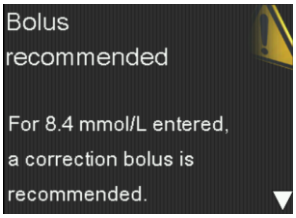
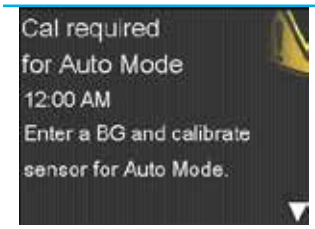
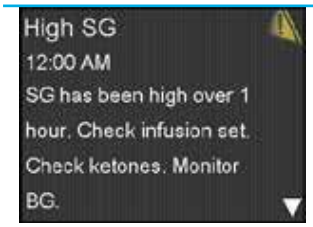
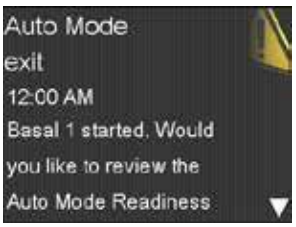
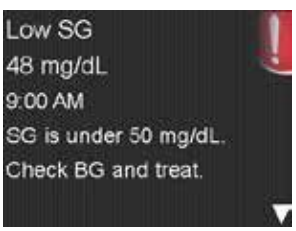
Checking Bolus History

You may also want to review the last several boluses that were delivered. For example, a parent might want to know the boluses their child gave throughout the day. You can see the last several boluses delivered in **Daily History**.

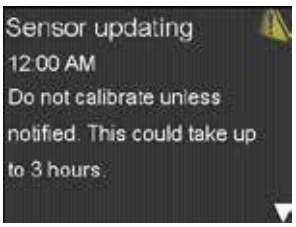
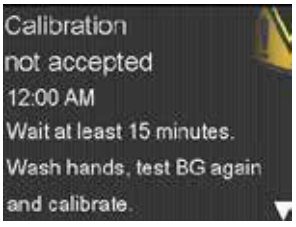
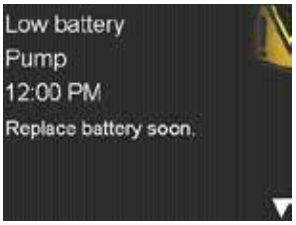
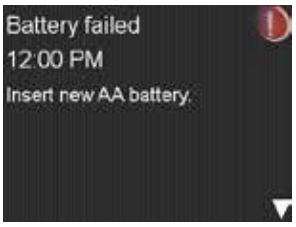
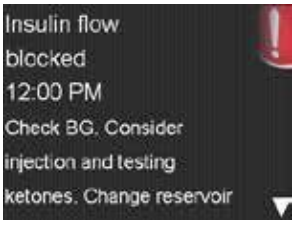
1. Press ○.
2. Press ∨ to **Options** and press ○.
3. Press ∨ to **History** and press ○.
4. Press ∨ to **Daily History** and press ○.
5. Press ○ on the day you would like to review.

Here are some common alarms & alerts that you might see on a student's pump in Auto Mode 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 entry is required for Auto Mode.	Perform fingerstick and enter a new BG.
	Auto Mode recommends a correction bolus based on a BG that you have entered.	Consider delivering the recommended correction bolus.
	A calibration is required to keep your pump in Auto Mode.	Perform a fingerstick. Enter BG and calibrate your sensor.
 *Followed by* 	SG has been high for over one hour. This value is based on a set glucose threshold and length of time 16.7 mmol/L or higher for one hour; 13.9 mmol/L or higher for three hours.	**High SG** Check infusion set. Check ketones. Monitor BG. **Auto Mode Exit** Monitor BG and treat as necessary. Enter BG to continue in Auto Mode.
	SG is under 2.8 mmol/L.	Perform fingerstick and treat as needed. Monitor BG.

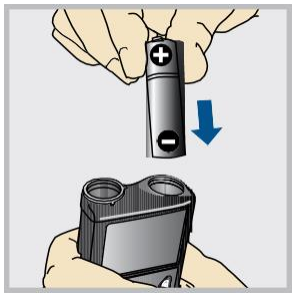
Read and address the alert, then clear it by pressing ⌄ then ○

Alert	Reason	Steps to take
	The sensor is updating	Do not calibrate unless notified. This could take up to 3 hours.
	Your system was unable to use the BG you entered to calibrate your sensor	In 15 minutes, your pump will prompt you to enter a new BG for calibration. Wash hands before checking.
	Low battery	Change battery when possible. See next page for how-to instructions.
	Failed battery test	Try again, or change battery and use new battery.
	Low Reservoir	Change reservoir when possible.
	Insulin Flow Blocked	Read message on screen to understand the alarm and choose the desired option.

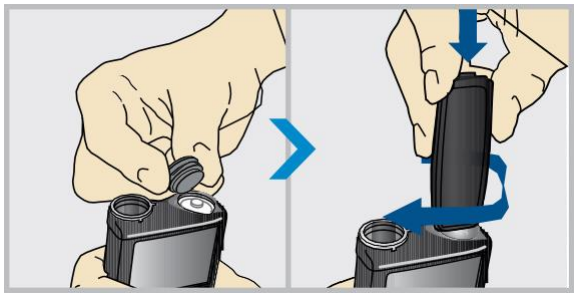
CHANGING THE BATTERY

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.)

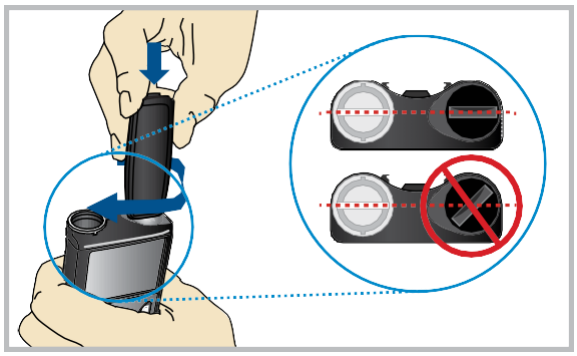


2. Insert battery with negative (flat) end going in first.



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 try to 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™ 670G system with SmartGuard™ technology can help keep your students' glucose levels in target range.* More time spent in target range may help your student live a healthier life and focus on learning!

Things to remember in Auto Mode:

- ✓ A student must check BGs and calibrate the sensor, 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 helpline** at **01932 205 167,**

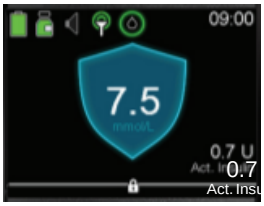
For additional information & support, go to **www.medtronic-diabetes.co.uk**

Other Helpful Resources:

Diabetes UK — **www.diabetes.org.uk**

JDRF (Juvenile Diabetes Research Foundation) — **www.jdrf.org**

*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 .

	Manual Mode		Auto Mode	Auto Mode- Safe Basal
Home screen display				
	Without CGM	With CGM		
Availability	When Auto Mode is not active		Auto Mode is active	Pump automatically transitions to Safe Basal when SGs are available
Basal	Uses the basal settings programmed into the pump		Automatically adjusts basal insulin every 5 minutes depending on the SG value	A fixed rate is delivered for a maximum of 90 minutes. If the cause doesn't resolve, then pump exits to Manual Mode
Bolus	Uses the programmed Bolus Wizard™ settings to recommend a dose		Must enter carbs into pump. Uses carb ratio to recommend a bolus. Auto Mode calculates and recommends a correction if BG >150 entered	Same as Auto Mode - Bolus

WARNING: (For MiniMed™ 670G System Users Ages 7-13): The low sensor glucose alert functionality is distinct from the automated insulin dosing function of the MiniMed™ 670G system.When used in Auto Mode, the MiniMed™ 670G 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 a low sensor glucose (SG) value for "Alert on Low" or "Alert before Low" for alerts set at 2.8 mmol/L and 3.3 mmol/L. A low sensor glucose alert may not reflect the user's true blood glucose at these levels or may not alert. Do not ignore symptoms of low glucose. Always confirm your sensor glucose readings with your blood glucose meter and treat according to the recommendations of your healthcare professional. Solely relying on these sensor glucose alerts and readings for treatment decisions could result in missing severe hypoglycemia (low blood glucose) events.

IMPORTANT SAFETY INFORMATION

MINIMED™ 670G SYSTEM

The Medtronic MiniMed™ 670G system is intended for continuous delivery of basal insulin (at user selectable rates) and administration of insulin boluses (in user 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™ 670G system includes SmartGuard technology, which can be programmed to automatically adjust delivery of basal insulin based on Continuous Glucose Monitor sensor glucose values and can suspend delivery of insulin when the sensor glucose value falls below or is predicted to fall below predefined threshold values. The system requires a prescription. The Guardian™ Sensor 3 glucose values are not intended to be used directly for making therapy adjustments, but rather to provide an indication of when a fingerstick may be required. A confirmatory finger stick test via the CONTOUR®NEXT LINK 2.4 blood glucose meter is required prior to making adjustments to diabetes therapy. All therapy adjustments should be based on measurements obtained using the CONTOUR®NEXT LINK 2 .4 blood glucose meter and not on values provided by the Guardian™ Sensor 3. Always check the pump display to ensure the glucose result shown agrees with the glucose results shown on the CONTOUR®NEXT LINK 2 .4 blood glucose meter.Do not calibrate your CGM device or calculate a bolus using a blood glucose meter result taken from an Alternative Site (palm) or from a control solution test. It is not recommended to calibrate your CGM device when sensor or blood glucose values are changing rapidly, e.g., following a meal or physical exercise. If a control solution test is out of range, please note that the result may be transmitted to your pump when in the "Always" send mode.

WARNING: Medtronic performed an evaluation of the MiniMed™ 670G system and determined that it may not be safe for use in children under the age of 7 because of the way that the system is designed and the daily insulin requirements. Therefore, this device should not be used in anyone under the age of 7 years old. This device should also not be used in patients who require less than a total daily insulin dose of 8 units per day because the device requires a minimum of 8 units per day to operate safely.

Pump therapy is not recommended for people whose vision or hearing does not allow recognition of pump signals and alarms. Pump therapy is not recommended for people who are unwilling or unable to maintain contact with their healthcare professional. The safety of the MiniMed™ 670G system has not been studied in pregnant women. 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 http://www .medtronicdiabetes .com/important-safety-information#minimed-670g and the appropriate user guide at http://www.medtronicdiabetes.com/download-library

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