# MINIMED® 670G SYSTEM USER GUIDE



# Medtronic

# MiniMed® 670G SYSTEM USER GUIDE

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#### 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.

## Warranty

The expected life of the MiniMed insulin pump is a maximum of 4 years. Medtronic Diabetes warrants the MiniMed insulin pump against defects in materials and workmanship for a period of 4 years from the date of purchase.

During the warranty period, Medtronic Diabetes will, at its discretion, replace (with a new or recertified pump, at Medtronic Diabetes' discretion) any defective pump or motor, subject to the conditions and exclusions stated herein. In the event that a pump replaced, the warranty period will not be extended.

This warranty is valid only if the MiniMed insulin pump is used in accordance with the manufacturer's instructions. This warranty will not apply:

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

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

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

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

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Before you begin

# Before you begin

This user guide is designed to help you understand the operation of your MiniMed® 670G system with SmartGuard™ technology. In the MiniMed 670G system, SmartGuard technology can automatically adjust insulin delivery based on your sensor glucose values. Work closely with your healthcare professional when starting insulin pump therapy.

In this user guide, the term Auto Mode refers to the automatic control of insulin delivery. For more information, see *About Auto Mode, on page 229*. When your pump is not operating in Auto Mode, the term Manual Mode is used to describe its functions.

# Using this user guide

This user guide contains valuable information about using your new insulin pump. To help you find the information you need, you can use the table of contents at the beginning of the user guide and the index at the end of the user guide. There is also a glossary of terms, which starts on *page 351*.

The following table describes certain terms, conventions, and concepts used in this user guide.

Convention	What it means
Select	To activate a screen item, accept a value, or initiate an action.
Select and hold	To perform an action using your pump screen, press the Select button and hold until the action is complete.
Press	To push and then release a button.

Convention	What it means		
Press and hold	To push and keep pressure on a button.		
Bold text	To indicate screen items and buttons. For example, "Select <b>Next</b> to continue."		
X	To indicate a numeric value.		
Note	<b>Note:</b> A note provides helpful information.		

Caution



**Caution:** A caution notifies you of a potential hazard which, if not avoided, may result in minor or moderate injury or damage to the equipment.

WARNING



**WARNING:** A warning notifies you of a potential hazard which, if not avoided, could result in death or serious injury. It may also describe potential serious adverse reactions and safety hazards.

The MiniMed 670G System User Guide includes instructions on how to setup devices on your MiniMed 670G insulin pump. For additional instructions not included in the MiniMed 670G System User Guide, please refer to the instructions for the device.

Device	For instructions see	
Reservoir	Reservoir user guide	
Infusion Sets	Infusion set user guide	
Transmitter	Guardian® Link Transmitter User Guide	
Sensor	Guardian Sensor User Guide	
Meter	CONTOUR® NEXT LINK 2.4 meter user guide	

# **Acronyms and abbreviations**

The following table defines acronyms and abbreviations used in this guide.

Acronym and abbreviations	Definition
AST	alternative site testing
BG	blood glucose
CDC	Centers for Disease Control
CGM	continuous glucose monitoring
СТ	computed tomography
DKA	diabetic ketoacidosis
EMC	electromagnetic compatibility
ESD	electrostatic discharge
FCC	Federal Communications Commission
FDA	Food and Drug Administration
GPS	global positioning system
ISIG	interstitial signal
IV	intravenous
MRI	magnetic resonance imaging
NiMH	nickel-metal hydride
OTC	over the counter
RF	radio frequency
SG	sensor glucose
SN	serial number
TDD	total daily dose

# **Emergency kit**

Keep an emergency kit with you at all times to make sure that you always have necessary supplies. Tell a family member, co-worker, or friend where you keep your emergency kit.

It is important that you test your blood glucose (BG) more frequently while you are traveling. The routine hassle of travel, including stress, changes in time zones, schedules and activity levels, meal times and types of food, can all affect your diabetes control. Be extra attentive to monitoring your BG frequently, and be prepared to respond if needed.

Your emergency kit should include these items:

- Fast-acting glucose tablets.
- Blood glucose monitoring supplies.
- Urine or blood ketone monitoring supplies.
- Extra MiniMed infusion set and MiniMed reservoir.
- Extra new AA lithium or alkaline batteries, or fully charged NiMH batteries.
- Insulin syringe and fast-acting insulin (with dosage instructions from your healthcare professional).
- Wallet card (packaged with your pump accessories).
- Adhesive dressing.
- Glucagon emergency kit.



WARNING: Do not use the Bolus Wizard® to calculate a bolus for a period of time after giving a manual injection of insulin by syringe or pen. Manual injections are not accounted for in the active insulin amount. Therefore, the Bolus Wizard could prompt you to deliver more insulin than needed. Too much insulin can cause hypoglycemia. Consult with your healthcare professional for how long you need to wait after a manual injection of insulin before you can rely on the active insulin calculation of your Bolus Wizard.



WARNING: Do not use Auto Mode for a period of time after giving a manual injection of insulin by syringe or pen. Manual injections are not accounted for in Auto Mode. Therefore, Auto Mode could deliver too much insulin. Too much insulin may cause hypoglycemia. Consult with your healthcare professional for how long you need to wait after a manual injection of insulin before you resume Auto Mode.

For details on pump safety, see *User safety, on page 7*.

# **User safety**

### **Indications**

### 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, fourteen 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 Medtronic MiniMed 670G System consists of the following devices: MiniMed 670G Insulin Pump, the Guardian Link (3) Transmitter, the Guardian Sensor (3), One-press Serter, and the CONTOUR NEXT Link 2.4 Glucose Meter. The system requires a prescription.

The Guardian Sensor (3) is not intended to be used directly for making therapy adjustments, but rather to provide an indication of when a finger stick may be required. All therapy adjustments should be based on measurements obtained using a home glucose monitor and not on values provided by the Guardian Sensor (3).



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.



WARNING: Do not use the Suspend on low feature to prevent or treat low glucose. Always confirm your sensor glucose reading using your BG meter, and follow the instructions of your healthcare professional to treat low glucose. Using Suspend on low alone to prevent or treat low glucose may result in prolonged hypoglycemia.

### **Guardian Sensor (3)**

The Guardian Sensor (3) is intended for use with the MiniMed 670G system to continuously monitor glucose levels in persons with diabetes. It is intended to be used for detecting trends and tracking patterns in persons aged fourteen years and older, and to be used by the MiniMed 670G system to automatically adjust basal insulin levels. It is indicated for use as an adjunctive device to complement, not replace, information obtained from standard blood glucose monitoring devices. The sensor is intended for single use and requires a prescription. The Guardian Sensor (3) is indicated for 7 days of continuous use.

### **One-press Serter**

The serter is used as an aid for inserting the sensor. It is indicated for single-patient use and is not intended for multiple patient use.

### **Guardian Link (3) Transmitter**

The Guardian Link (3) Transmitter is intended for use with MiniMed 670G System. The Guardian Link (3) Transmitter powers the glucose sensor, collects and calculates sensor data, and wirelessly sends the data to the MiniMed 670G insulin pump. The Transmitter is intended for single-patient multi-use.

### **CONTOUR NEXT LINK 2.4 Glucose Meter**

The CONTOUR NEXT LINK 2.4 Wireless Blood Glucose Monitoring System is an over the counter (OTC) device utilized by persons with diabetes in home settings for the measurement of glucose in whole blood, and is for single patient use only and should not be shared. The CONTOUR NEXT LINK 2.4 wireless blood glucose monitoring system is indicated for use with fresh capillary whole blood samples drawn from the fingertip and palm only. The CONTOUR NEXT Test Strips are intended for self-testing by persons with diabetes for the quantitative measurement of glucose in whole blood samples from 20 to 600 mg/dL. The CONTOUR NEXT LINK 2.4 wireless blood glucose transmit glucose values to the MiniMed 670G insulin pump and facilitate transfer of information to Medtronic CareLink® Software through the use of radio frequency communication. The CONTOUR NEXT LINK 2.4 Wireless Blood Glucose Monitoring System is not intended for the diagnosis of, or screening for, diabetes mellitus. It is not intended for use on neonates.

### **Contraindications**

Pump therapy is not recommended for people whose vision or hearing does not allow recognition of pump signals and alarms.

Do not use the serter on products other than the Enlite sensor or Guardian Sensor (3). Medtronic cannot guarantee the safety or efficacy of this product if used with other products.

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

Infusion sets are indicated for subcutaneous use only and not for intravenous (IV) infusion or the infusion of blood or blood products.

Insulin pump therapy is not recommended for those who are unwilling to perform at least four blood glucose tests per day. As insulin pumps use rapid acting insulin only, BG testing is required to help identify rapid glycemic deterioration due to insulin infusion occlusion, infusion site problems, insulin stability issues, user error, or a combination of these.

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

### **Potential risks**

### Risks related to insulin pump infusion set

General risks related to insulin pump infusion set may include:

- Localized infection
- Skin irritation or redness
- Bruising
- Discomfort or pain
- Bleeding
- Irritation
- Rash
- Occlusions that can interrupt insulin delivery and lead to hyperglycemia or Diabetic Ketoacidosis

Patients should be instructed to follow the provided user guides for insertions and care of infusion sets. If an infusion site becomes irritated or inflamed, the infusion set should be removed and another placed in a new location.

### Risks related to insulin administration and pump use

Due to the use of insulin, there is risk related to the infusion of insulin and the potential interruptions of insulin delivery. These general risks may include:

- Hypoglycemia
- Hyperglycemia
- Diabetic Ketoacidosis
- Seizure
- Coma
- Death

### Risks related to sensor use

### General risks related to sensor use may include:

- Skin irritation or other reactions
- Bruising
- Discomfort

- Redness
- Bleeding
- Pain
- Rash
- Infection
- Raised bump
- Appearance of a small "freckle-like" dot where needle was inserted
- Allergic reaction
- Fainting secondary to anxiety or fear of needle insertion
- Soreness or tenderness
- Swelling at insertion site
- Sensor fracture, breakage or damage
- Minimal blood splatter associated with sensor needle removal
- Residual redness associated with adhesive, tape, or both
- Scarring

### Specific risks related to sensor use

Taking medications with acetaminophen, including, but not limited to Tylenol®, fever reducers, or cold medicine, while wearing the sensor may falsely raise your sensor glucose readings. The level of inaccuracy depends on the amount of acetaminophen active in your body and may be different for each person. Always use BG meter readings to verify your glucose level before making therapy decisions, including when you could have acetaminophen active in your body. Avoid taking medications with acetaminophen while in Auto Mode. If acetaminophen is taken, use additional BG meter readings to verify your glucose levels, and consider exiting Auto Mode. Do not use these additional BG meter readings to calibrate the sensor. Always check the label of any medications to confirm whether acetaminophen is an active ingredient.

Sensor placement and insertion has been studied in the belly (abdomen) only and is not approved for other sites.

### Specific risks related to meter use

Some types of medication or chronic medical conditions may affect BG meter readings and cause you to get inaccurate results. The level of inaccuracy depends on the amount of certain substances that are active in your body and may be different for each person. If you have taken the following medications, do not use your BG meter readings to calibrate the sensor and exit Auto Mode.

- Ascorbic Acid (known as vitamin C) can interfere with your meter if you get vitamin C injections.
- Xylose: Do not use during or soon after xylose absorption testing. Xylose in the blood will cause an interference.

If you have the following conditions, always consult with your healthcare professional before using Auto Mode.

- Liver problems, such as cirrhosis or Gilberts Syndrome resulting in bilirubin levels greater than 54 mg/dL.
- Gout or chronic kidney disease resulting in uric acid levels greater than 59 mg/dL.

### Risks related to serter use

General risks with serter use may include skin infection around the area where the serter is used.

### Risks related to the MiniMed 670G insulin pump system

General risks related to the MiniMed 670G insulin pump system may include:

- Hypoglycemia
- Hyperglycemia
- Diabetic Ketoacidosis
- Seizure
- Coma
- Death

### Device performance: study description

The MiniMed 670G System can automatically increase or decrease insulin delivery when informed by continuous glucose monitoring (CGM) values; however, the user must still calculate and administer meal boluses. Previous clinical studies that did not involve the MiniMed 670G system have shown that other integrated insulin pump and CGM systems may provide better diabetes management, compared with multiple daily injections or with the pump alone. Some studies also suggest that when you pair pump therapy with the information provided by the sensor, it may significantly improve HbA1C levels without increasing the risk of hypoglycemia.<sup>1, 2, 3</sup>

The MiniMed 670G system also features SmartGuard technology with different types of diabetes management. There are two levels of SmartGuard technology:

- The first level of SmartGuard technology automatically suspends insulin when the sensor reaches a preset low limit or before the low limit is reached, referred to as Suspend on low and Suspend before low, respectively. When a Suspend on low event occurs, you can choose to continue to keep insulin suspended, or you can choose to resume insulin delivery. When a Suspend before low occurs, insulin delivery will automatically resume when the sensor glucose levels recover. The Suspend on low and Suspend before low features are optional features available when the system is in Manual Mode.
- The second level of SmartGuard technology automatically calculates insulin
  dose using CGM data, referred to as Auto Mode. The Auto Mode feature can
  automatically increase or decrease the amount of insulin delivered based on
  sensor values. Elevated sensor glucose readings result in increased delivery
  rates and decreased sensor glucose values result in decreased insulin delivery
  rates.

<sup>1</sup> Bergenstal RM, Tamborlane WV, Ahmann A, et al. Effectiveness of sensor-augmented insulin-pump therapy in type 1 diabetes [STAR3 Study]. N Engl J Med.2010;363:311–320.

<sup>2</sup> Battelino T, Conget I, Olsen B, et al. The use and efficacy of continuous glucose monitoring in type 1 diabetes treated with insulin pump therapy [SWITCH study]. Diabetologia. 2012 Dec;55(12):3155-62. doi: 10.1007/s00125-012-2708-9. Epub 2012 Sept 11.

<sup>3</sup> Bergenstal RM, Klonoff DC, Bode BW, et al. Threshold-based insulin-pump interruption for reduction of hypoglycemia [ASPIRE in-home study]. N Engl J Med. 2013;369(3):224-232.

During Auto Mode operation, the user must deliver meal boluses by entering the estimated amount of carbohydrates for meals at the time they are eaten. Failure to deliver meal boluses in association with meals during Auto Mode operation can result in significant post meal hyperglycemia.

Since adjustments to insulin delivery rates when the system is in Auto Mode are based on sensor glucose readings, it is critical to monitor blood glucose values using a home glucose meter regardless of whether the system is operating in the Manual Mode or the Auto Mode. If these home glucose meter measurements indicate hypoglycemia or hyperglycemia, you must follow your physician's instruction for treating these conditions and you should not rely on the MiniMed 670G system to automatically restore your glucose levels to normal.

The SmartGuard technology contains two insulin delivery suspend options: Suspend on low, and Suspend before low. The Suspend on low was previously evaluated and is currently available on commercially available pumps (MiniMed 530G Pump and MiniMed 630G Pump).

The Suspend before low feature was evaluated for safety in a multi center, single arm, in-clinic study. Study subjects included persons aged 14-75 years diagnosed with type 1 diabetes mellitus who were on pump therapy at the time of screening. A total of 71 subjects were subjected to hypoglycemic induction, followed by an observation period. For hypoglycemic induction, the target was set to 65 mg/dL, using the rate of change basal increase algorithm. Suspend before low was activated with the Low Limit setting for Suspend before low ON set to 65 mg/dL, and the subject was observed with frequent sample testing (FST) for a maximum of 19 hours. The observation period included the suspension period, the insulin resumption period, and if applicable, an insulin re-suspension after insulin delivery resumed.

Five adverse events were reported during the study. Four adverse events were neither device nor procedure related. One adverse event was procedure related.

Data from this in-clinic study demonstrated that the Suspend before low feature is safe to use. Study success criteria, as defined in the protocol, were met (i.e. there were no device related serious adverse events, no diabetic ketoacidosis events related to the Suspend before low feature, and no unanticipated adverse device effects). The second level of SmartGuard technology was evaluated under a pivotal, single-arm, multi-center, home and hotel study in subjects with type 1 diabetes on

insulin pump therapy. Study subjects included persons aged 14-75 years diagnosed with type 1 diabetes mellitus for two years or more that had used pump therapy for more than 6 months prior to screening. Study subjects had an HbA1C value of less than 10.0% at the time of screening.

This study consisted of a 2-week run-in phase and a 3-month study phase. A total of 124 subjects used the MiniMed 670G System in Manual Mode only first, before transitioning to Auto Mode during the study phase. In addition to system use at home, the study phase included a 6-day/5-night hotel stay during which subjects underwent daytime and nighttime frequent sample testing for a total of approximately 24 hours. Subjects were allowed to eat as they normally would, and participated in a daily exercise/activity regimen for a minimum of 4 hours per day, spread throughout the day, during the hotel stay. Two of the 124 subjects did not participate in a hotel stay. One of these two subjects withdrew from the study.

The MiniMed 670G System was used for 12,389 patient days. No serious adverse events, diabetic ketoacidosis (DKA), or severe hypoglycemia were reported during the study. Compared to Manual Mode use during the run-in phase, use of the system was associated with a higher percentage of sensor glucose values within the range of 71 – 180 mg/dL and lower percentage of sensor glucose values in the low and high glucose ranges. A change in mean A1C from 7.4±0.91 (median 7.3) at the start of the study to 6.9±0.61 (6.8) at the end of the study was observed. This observation was associated with a modest increase in the mean total daily dose of insulin (47.5 baseline to 50.9) and mild increase in mean weight (76.9 baseline to 77.6).



**Caution:** Please note that since this study did not include a control group, no claims regarding effectiveness can be made. However, the study does support that the device is relatively safe for use.

Device related adverse events reported during the different phases of the pivotal trial are listed in the following table.

Table 1: Device Related Adverse Events					
Event Run-In Period Study Period					
Severe hyperglycemia	5	12			

Table 1: Device Related Adverse Events					
Event	Run-In Period	Study Period			
Hyperglycemia	0	6			
Skin irritation	3	0			
Irritation on sensor site	0	1			
Rash	0	1			

The following table shows the time spent per day in specific glucose ranges during the run-in and study phases by all subjects.

Table 2: Time Spent in Specific Glucose Ranges During the Run-In and **Study Phases by All Subjects Glucose Range** Run-In Phase Time in Glucose Study Phase Time in (mg/dL) Range Mean±SD Glucose Range Mean±SD < 50  $12.8 \text{ mins} \pm 14.5 \text{ mins}$  $7.7 \text{ mins} \pm 7.6 \text{ mins}$ < 6035.2 mins  $\pm$  31.2 mins  $19.9 \text{ mins} \pm 14.8 \text{ mins}$ < 70 1 hr 18.6 mins  $\pm$  55.3 mins  $42.9 \text{ mins} \pm 25.4 \text{ mins}$ 70 - 180 14 hrs 54.4 mins ± 3 hrs 1.4 16 hrs 2.2 mins ± 2 hrs 35.6 mins min > 180 6 hrs 2.1 mins ± 2 hrs 52.7 mins 5 hrs 20.7 mins ± 1 hr 46.9 mins > 250 1 hr 30.4 mins ± 1 hr 32.3 mins 1 hr 12.1 mins  $\pm$  52.6 mins > 300 29.6 mins ± 51.7 mins 21.1 mins ± 22.2 mins  $8.9 \text{ mins} \pm 20.7 \text{ mins}$  $6.1 \text{ mins} \pm 8.35 \text{ mins}$ > 350

The following table shows the ranges of changes in HbA1C observed in the study and indicates the number of subjects that demonstrated each type of change in HbA1C observed.

Table 3: Nu	Table 3: Number of Subjects with Change in HbA1C at Different Baselines						
HbA1C Change Range	Number of Su	Number of Subjects (% of Subjects) with Change in A1C					
Baseline A1C (%)	Decrease > 1%	Decrease 0 to 1%	No Change	Increase 0 to 1%	Increase > 1%		
5% ≤ A1C < 6%	0 (0.0%)	1 (0.8%)	0 (0.0%)	3 (2.4%)	0 (0.0%)		
6% ≤ A1C < 7%	1 (0.8%)	20 (16.1%)	5 (4.0%)	11 (8.9%)	0 (0.0%)		
7% ≤ A1C < 8%	8 (6.5%)	34 (27.4%)	1 (0.8%)	9 (7.3%)	0 (0.0%)		
8% ≤ A1C < 9%	11 (8.9%)	12 (9.7%)	1 (0.8%)	0 (0.0%)	0 (0.0%)		
9% ≤ A1C < 10%	6 (4.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		
Overall	26 (21.0%)	67 (54.0%)	7 (5.6%)	23 (18.5%)	0 (0.0%)		

The following table shows the number of subjects that spent a specific range of time per day in specific glucose ranges during the study phase.

Tabl	Table 4: Number of Subjects that Spent a Certain Time Range in Each Glucose Range During the Study Phase							
Time Range	Number of Subjects (% of Subjects) in the Glucose Range (mg/dL) Indicated							
	≤ 50	≤ 60	≤ 70	70 to 180	> 180	> 250	> 300	> 350
0 to 15 mins	105 (84.7%)	58 (46.8%)	12 (9.7%)	0 (0.0%)	0 (0.0%)	8 (6.5%)	66 (53.2%)	112 (90.3%)
15 to 30 mins	16 (12.9%)	43 (34.7%)	33 (26.6%)	0 (0.0%)	0 (0.0%)	16 (12.9%)	31 (25.0%)	6 (4.8%)

Table 4: Number of Subjects that Spent a Certain Time Range in Each Glucose Range During the Study Phase									
30 to 45 mins	3 (2.4%)	12 (9.7%)	29 (23.4%)	0 (0.0%)	0 (0.0%)	24 (19.4%)	12 (9.7%)	6 (4.8%)	
45 mins to 1 hr	0 (0.0%)	10 (8.1%)	25 (20.2%)	0 (0.0%)	0 (0.0%)	17 (13.7%)	6 (4.8%)	0 (0.0%)	
1 to 4 hr	0 (0.0%)	1 (0.8%)	25 (20.2%)	0 (0.0%)	34 (27.4%)	58 (46.8%)	9 (7.3%)	0 (0.0%)	
4 to 8 hr	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	83 (66.9%)	1 (0.8%)	0 (0.0%)	0 (0.0%)	
8 to 12 hr	0 (0.0%)	0 (0.0%)	0 (0.0%)	12 (9.7%)	7 (5.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	
12 to 16 hr	0 (0.0%)	0 (0.0%)	0 (0.0%)	38 (30.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	
16 to 20 hr	0 (0.0%)	0 (0.0%)	0 (0.0%)	70 (56.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	
20 to 24 hr	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (3.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	

The following table shows the average amount of time spent in Auto Mode per day.

Table 5: Time Spent in Auto Mode at Different Glucose Ranges during the Study Phase					
Glucose Range (mg/dL)	Study Phase Time in Glucose Range Mean±SD (95% CI)				
≤ 50	4.8 mins ± 4.6 mins				
	(4.0 mins, 5.6 mins)				
≤ 60	13.2 mins ± 10.1 mins				
	(11.4 mins, 15.0 mins)				

Table 5: Time Spent in Auto Mode at Different Glucose Ranges during the Study Phase		
Glucose Range (mg/dL)	Study Phase Time in Glucose Range Mean±SD (95% CI)	
≤ 70	29.9 mins ± 18.8 mins	
	(26.6 mins, 33.2 mins)	
70 to 180	13 hrs 50.3 mins ± 3 hrs 1.4 mins	
	(13 hrs 18.1 min, 14 hrs 22.5 mins)	
> 180	4 hrs 5.2 mins ± 1 hr 5.0 mins	
	(3 hrs 53.7 mins, 4 hrs, 16.8 mins)	
> 250	44.8 mins ± 24.9 mins	
	(40.4 mins, 49.2 mins)	
> 300	9.3 mins ± 7.6 mins	
	(8.0 mins, 10.7 mins)	
> 350	1.7 mins ± 2.0 mins	
	(1.3 mins, 2.0 mins)	
All	18 hrs 25.4 mins ± 2 hrs 44.4 mins	
	(17 hrs 56.2 mins, 18 hrs 54.7 mins)	

The pivotal clinical trial of the MiniMed 670G system suggested that the system was safe; however, this trial had a number of limitations which included the following:

- The study involved a relatively small number of patients.
- There was no control group for comparison purposes.
- The amount of time the system was used in the Manual Mode was much shorter than the time it was programmed to the Auto Mode. Additionally, for each subject, the study period lasted only three months.

Due to these limitations, the results of the clinical trial must be interpreted with caution and you should understand that your individual results when using the MiniMed 670G system may be significantly different from those of the subjects who participated in the trial.

### **General warnings**

#### **Pump**

- Do not use the pump when a flammable anesthetic mixture with air, oxygen, or nitrous oxide is present. These environmental conditions can damage your pump and result in serious injury.
- Always use the fingertip for blood samples used for calibrating the sensor
  while in Auto Mode. The fingertip was the only site studied for use with Auto
  Mode. Do not use blood samples from the palm to calibrate the sensor as this
  site was not studied for use with Auto Mode and the performance of the
  system is not known.
- Do not make treatment decisions, such as determining your insulin dose for meals, using the 670G continuous glucose monitor (CGM) values, as they are not intended to be used to make such treatment decisions. The MiniMed 670G CGM does not replace a blood glucose meter. Always use the values from your blood glucose meter for treatment decisions. Blood glucose values may differ from sensor glucose values. Using the sensor glucose readings for treatment decisions could lead to high or low blood glucose.
- Never rely on the pump beeps or vibrations alone to navigate through the
  pump screens or menus. Always check your pump screen as you navigate.
  The pump beeps and vibrations are intended to notify you of a condition that
  may require attention. Relying on the pump beeps or vibrations alone to
  navigate can result in incorrect menu selection or settings.
- Do not use your pump if the screen appears broken or unreadable. In some instances, impact to the pump can damage the screen while the buttons continue to function. If the screen is broken or unreadable, do not press any buttons. Remove the pump and begin using your backup insulin plan per the direction of your healthcare professional. If the pump is accidentally programmed while the screen is broken or unreadable, this could result in high or low blood glucose levels. If your screen is damaged, contact the 24 Hour HelpLine to arrange for shipment of a replacement pump.

- Only use rapid acting U100 insulin (Humalog® and Novolog®) that has been
  prescribed by your healthcare professional for use with an infusion pump. Do
  not put any other drugs or medications inside your reservoir for use with this
  pump. Other drugs or medications are not intended for use with this pump.
  Use of other drugs or medications can cause serious injury.
- Always make sure the infusion set is disconnected from your body before you
  rewind your pump or fill the infusion set tubing. Never insert the reservoir into
  the pump while the tubing is connected to your body. Doing so could result
  in an accidental infusion of insulin.
- Do not insert the reservoir in the pump if you did not rewind your pump. Doing so could result in an accidental infusion of insulin.
- Do not use the MiniMed 670G insulin pump or additional system devices adjacent to other electrical equipment which may cause interference with the normal system operation. This includes mobile communication devices such as cell phones, GPS navigation systems, anti-theft systems, and any electrical equipment that has an output transmitter power greater than 1W. For more information about recommended separation distance guidelines between the insulin pump and common RF emitters, see *Guidance and manufacturer's declaration*, on page 335. The recommended separation distance between the insulin pump and common RF emitters is 12 inches. Other electrical equipment that may compromise normal system operation has been contraindicated. For more information, see *Exposure to magnetic fields and radiation*, on page 31.
- Do not unscrew or retighten the tubing connector on the reservoir while the infusion set is connected to your body. Doing so could result in an accidental infusion of insulin.
- Do not use standard Luer sets with the MiniMed 670G insulin pump. Luer sets are not compatible with the pump. MiniMed reservoirs and MiniMed infusion sets are specifically designed for use with the MiniMed 670G insulin pump.
- Do not change or modify your MiniMed reservoir or MiniMed infusion set unless expressly approved by Medtronic Diabetes. Modifying the devices can cause serious injury, interfere with your ability to operate the device, and void your warranty.

- Do not rely on preset pump alarms or reminders alone to prompt you to check your blood glucose. This can cause you to forget to check your blood glucose. Set additional reminders on other devices, such as your cell phone.
- Do not change or modify the internal RF transmitter or antenna unless expressly approved by Medtronic Diabetes. Doing so could interfere with your ability to operate the equipment.
- Do not attempt to use the MiniLink® transmitter (MMT-7703), the Guardian® Link transmitter (MMT-7763), or the Guardian® Connect transmitter (MMT-7821) with the MiniMed 670G insulin pump. These transmitters do not communicate with this insulin pump.
- If other devices that employ radio frequencies are in use, such as cell phones, cordless phones, and wireless networks, they may prevent communication between the transmitter and the insulin pump. This interference does not cause any incorrect data to be sent and does not cause any harm to your devices. Moving away from, or turning off, these other devices may enable communication. If you continue to experience RF interference, please contact the 24 Hour HelpLine.
- Special Precautions regarding Electromagnetic Compatibility (EMC): This body worn device is intended to be operated within a reasonable residential, domestic, public or work environment, where common levels of radiated "E" (V/m) or "H" fields (A/m) exist; such as cellular phones, Wi-Fi®, Bluetooth®, electric can openers, microwave and induction ovens. This device generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the provided instructions, may cause harmful interference to radio communications.
- Portable and mobile RF communications equipment can affect Medical Electrical Equipment as well. If you encounter RF interference from a mobile or stationary RF transmitter, move away from the RF transmitter that is causing the interference.
- Do not rely on glucose sensor-enabled features when Airplane Mode is on because the pump does not receive sensor readings from the transmitter. Glucose sensor-enabled features include CGM, SmartGuard, and Auto Mode. When using Airplane Mode, always rely on your blood glucose (BG) values when making therapy decisions to avoid hypoglycemia or hyperglycemia.

- This device can generate, use, and radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. If the device does cause interference to radio or television reception, you are encouraged to try to correct the interference by one or more of the following measures:
  - Decrease the distance between the transmitter and the insulin pump to 6 feet (1.8 meters) or less.
  - Decrease the distance between the meter and the insulin pump to 6 feet (1.8 meters) or less.
  - Increase the separation between the transmitter and the device that is receiving/emitting interference.



**Note:** Harmful interference is defined by the FCC as follows. Any emission, radiation or induction that endangers the functioning of a radio navigation service or of other safety services or seriously degrades, obstructs or repeatedly interrupts a radio communications service operating in accordance with FCC rules.

- The safety of the MiniMed 670G system has not been studied in people with impaired kidney function. Please let your healthcare professional know if you have kidney disease so you and your healthcare professional can determine if the potential benefits of using the system outweigh the risks.
- The safety of the MiniMed 670G system has not been studied in pregnant women, people with type 2 diabetes, or in people using other antihyperglycemic therapies apart from insulin. Please let your healthcare professional know if any of these conditions apply to you so you and your healthcare professional can determine if the potential benefits of using the system outweigh the risks.
- The safety of using Auto Mode, Suspend before low, and Suspend on low in people who have no pump experience is not known. Auto Mode, Suspend before low, and Suspend on low should not be used if insulin pump settings have not been previously established. Insulin pump settings include basal

rates, insulin to carb ratio, or insulin sensitivity factors. Always discuss with your healthcare professional before using Auto Mode, Suspend before low, or Suspend on low.

#### Reservoir and infusion sets

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

- Only use rapid acting U100 insulin (Humalog® and Novolog®) that has been
  prescribed by your healthcare professional for use with an infusion pump. Do
  not put any other drugs or medications inside your reservoir for use with this
  pump. Other drugs or medications are not intended for use with this pump,
  and can result in serious injury.
- If insulin, or any liquid, gets inside the tubing connector, it can temporarily block the vents that allow the pump to properly prime the infusion set. This may result in the delivery of too little or too much insulin, which can cause hyperglycemia or hypoglycemia. If this occurs, start over with a new reservoir and infusion set.
- Do not reinsert the introducer needle into the infusion set. Reinsertion may cause tearing of the soft cannula, which may result in unpredictable medication flow.
- If infusing insulin, and your blood glucose level becomes unexplainably high, or an occlusion alarm occurs, check for clogs and/or leaks.
- If in doubt, change the infusion set because the soft cannula may be dislodged, crimped and/or partially clogged. Should any of these problems arise, make a plan with your healthcare professional for rapidly replacing insulin. Test your blood glucose level to make sure the problem is corrected.
- Reuse of the infusion set may cause damage to the cannula/needle and lead to infection, site irritation, and/or inaccurate medication delivery.
- Dispose of transfer guard safely in sharps container.
- Never prime the set or attempt to free a clogged line while the set is inserted. You may accidentally inject too much medication.
- Do not put disinfectants, perfumes, or deodorants on the infusion set as these may affect the integrity of the set.

- Dispose of the infusion set and introducer needle safely, in a sharps container, after a single use. Do not clean or re-sterilize.
- Store infusion sets in a cool, dry place. Do not leave infusion sets in direct sunlight or inside a vehicle.
- Only use reservoir and infusion sets manufactured or distributed by Medtronic Diabetes. The pump has undergone extensive testing to confirm appropriate operation when used with compatible reservoirs and infusion sets manufactured or distributed by Medtronic Diabetes. We cannot guarantee appropriate operation if the pump is used with reservoirs or infusion sets offered by third parties. We are not responsible for any injury or malfunctioning of the pump that may occur in association with such use.
- Use aseptic techniques when temporarily disconnecting the set and consult your healthcare provider on how to compensate for missed medication when disconnected.
- If infusing insulin, carefully monitor your blood glucose levels when disconnected and after reconnecting.
- Reservoir and transfer guard are sterile, non-pyrogenic, and for single use only.
- Do not clean or re-sterilize. Reuse of the reservoir may lead to insulin degradation, infection, inaccurate medication delivery, and/or leaks which may cause damage to the pump.
- Inaccurate medication delivery, infection and/or site irritation may result from improper insertion and maintenance of the infusion site.
- If using this infusion set for the first time, do the first set-up in the presence of your healthcare professional.
- Do not leave air in the infusion set. Prime completely.
- Replace the infusion set every 48 to 72 hours according to Centers for Disease Control guidelines, or per your healthcare professional's instructions.
- If infusing insulin, do not change the infusion set just before bedtime unless you can check your blood glucose 1 to 3 hours after insertion.
- Do not use if package has been opened or damaged.
- Ensure sterility by checking that the sterile paper and tamper-proof seal are not damaged .

- This device is sterile and non-pyrogenic unless the package has been opened or damaged. Do not use if the package has been opened or damaged. Do not use the infusion set if the tubing connector needle has been damaged.
- Do not use the infusion set for more than 3 days. Insulin is not labeled for more than three days when it is used in an infusion set. If insulin is used in the infusion set for more than three days, it may increase the risk of set occlusions and cause problems with insulin absorption, which may lead to severe hyperglycemia and DKA.
- Before insertion, clean the insertion site with isopropyl alcohol.
- Check frequently to make sure the soft cannula remains firmly in place as you may not feel pain if it pulls out. The soft cannula must always be completely inserted to receive the full amount of medication.
- Release the tubing with caution as a hard pull of the tubing can result in damage to the infusion set/introducer needle. Ensure that the infusion set is properly in place when the tubing is fully released.
- If the infusion site becomes inflamed, replace the set, and use a new site until the first site has healed. Replace the infusion set if the tape becomes loose, or if the soft cannula becomes fully or partially dislodged from the skin.
- Failure to remove trapped air from reservoir may result in inaccurate delivery of medication
- Never point a loaded insertion device towards the body part, where insertion is not desired.
- Remove the needle guard before inserting the infusion set.

#### Sensor and serter

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

- Keep the sensor away from children. This product contains small parts and may pose a choking hazard.
- Keep the serter away from children. This product contains small parts and may pose a choking hazard.

- A retractable needle is attached to the sensor and minimal blood splatter may occur. If you are a healthcare professional or caregiver, wrap sterile gauze around the sensor to minimize contact with blood. Keep as much distance as possible between you and the patient when removing the needle.
- Do not attempt to remove the sensor yourself if you suspect that the sensor is broken. While there is no evidence of a sensor breaking in a patient's body, sensor breakage can result in serious injury. Contact your healthcare professional for assistance in removing the sensor.
- Always inspect the packaging for damage prior to use. Sensors are sterile and non-pyrogenic, unless the package has been opened or damaged. Do not use the sensor if the sterile package has been opened or damaged. Use of an unsterile sensor can cause site infection.
- If bleeding continues, causes excessive pain or discomfort, or is significantly visible in the plastic base of the sensor, do the following:
  - a. Remove the sensor and continue to apply steady pressure until the bleeding stops. Discard the sensor in a sharps container .
  - b. Check the site for redness, bleeding, irritation, pain, tenderness, or inflammation. Treat based on instructions from your healthcare professional.
  - c. Insert a new sensor in a different location.
- The One-press serter (MMT-7512) does not work the same as other Medtronic insertion devices. Failure to follow directions or using a different serter may result in improper insertion, pain, or injury.
- Keep the needle housing within sight at all times to avoid an accidental needlestick or puncture.
- Taking medications with acetaminophen while wearing the sensor may falsely raise your sensor glucose readings. The level of inaccuracy depends on the amount of acetaminophen active in your body and may be different for each person.
- Make sure the sensor is securely placed in the serter to avoid improper insertion, pain, or minor injury.
- Watch for bleeding at the insertion site (under, around, or on top of the sensor). If bleeding occurs, do the following:

- a. Apply steady pressure, using sterile gauze or a clean cloth placed on top of the sensor, for up to three minutes. The use of unsterile gauze can cause site infection.
- b. If bleeding stops, connect the transmitter (or recorder) to the sensor. If bleeding does not stop, do not connect the transmitter to the sensor because blood can get into the transmitter connector, and could damage the device.
- The sensor is designed to work with Guardian Link (3) transmitter only. It is not interchangeable with transmitters and recorders that are not compatible with the sensor. Connecting your sensor to a transmitter or recorder that is not approved for use with the sensor may cause damage to the components or inaccurate sensor glucose values.
- It is not known how different conditions or medications common to the critically ill population may affect the performance of the system. Therefore, the use of this sensor in the critically ill population is not recommended.

#### **Transmitter**

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

- Do not allow children to put small parts in their mouth. This product poses a choking hazard for young children.
- Do not use the tester if it comes in contact with blood. Touching blood can cause infection. Dispose of the tester according to the local regulations for medical waste disposal, or contact your healthcare professional for disposal information.
- Bleeding may occur after inserting the sensor. Always make sure that the site is not bleeding before connecting the transmitter to the sensor. Blood can get into the transmitter connector and damage the device. Discard the device if damaged. If bleeding occurs, apply steady pressure with a sterile gauze or clean cloth at the insertion site until bleeding stops. After bleeding stops, connect the transmitter to the sensor.
- Do not use the transmitter adjacent to other electrical equipment which may cause interference with the normal system operation. This includes mobile communication devices such as cell phones, GPS navigation systems, and

- other devices that have an output transmitter power greater than 1W. Other electrical equipment that may compromise normal system operation has been contraindicated.
- Do not change or modify the device unless expressly approved by Medtronic Diabetes. Modifying the device can cause serious injury, interfere with your ability to operate the device, and void your warranty.

#### Meter

For the most current warnings, see the user guide that came with your device. Always use the fingertip for blood samples used for calibrating the sensor while in Auto Mode. The fingertip was the only site studied for use with Auto Mode. Do not use blood samples from the palm to calibrate the sensor as this site was not studied for use with Auto Mode and the performance of the system is not known.

#### Serious illness

- Capillary (fingerstick or Alternative Site) blood glucose testing may not be clinically appropriate when peripheral flow is decreased. Shock, severe hypotension, hyperosmolar hyperglycemia, diabetic ketoacidosis, and occurrence of severe dehydration are examples of clinical conditions that may adversely affect the measurement of glucose in peripheral blood.<sup>4, 5, 6</sup>
- Keep out of reach of children. This kit contains small parts which could cause suffocation if accidentally swallowed.

### Talk to your healthcare professional

- Before setting any Target ranges or High or Low Alerts on your meter.
- Before changing your medication based on test results.
- If your blood sugar reading is under 50 mg/dL, follow medical device immediately.

<sup>4</sup> Wickham NWR, Achar KN, Cove DH. Unreliability of capillary blood glucose in peripheral vascular disease. *Practical Diabetes*. 1986;3(2):100.

<sup>5</sup> Atkins, S. et al. Fingerstick Glucose Determination in Shock. Ann intern Med. 1991;114:1020-1024.

<sup>6</sup> Desachy A, Vuagnat AC, et al. Accuracy of bedside glucometry in critically ill patients: influence of clinical characteristics and perfusion index. *Mayo Clin Proc.* 2008;83(4):400-405.

- If you blood sugar reading is over 250 mg/dL, wash and dry your hands well and repeat the test with a new strip. If you get a similar result, call your healthcare professional as soon as possible.
- About whether Alternative Site Testing (AST) is appropriate for you.



# **Caution:** Do not use Alternative Site Testing under the following conditions. Use fingertip testing in any of these cases:

- If you think your blood glucose is low (hypoglycemia).
- When blood glucose is changing rapidly (after a meal, insulin dose or exercise).
- If you have hypoglycemic unawareness (lack of symptoms).
- If you get alternative site blood glucose results that do not agree with how you feel.
- During illness or times of stress.
- If you will be driving a car or operating machinery.
- For calibration of CGM system.

AST testing should not be used for Bolus Wizard, to calibrate a device or verify a low blood glucose level.

Consult your healthcare professional to determine if alternative site testing is right for you.

#### **Potential Biohazard**

- Always wash and dry your hands well with soap and water before and after testing, handling the meter, lancing device or test strips.
- The meter, lancing device and lancets are for single person use. Do not share them with anyone including other family members. Do not use on multiple persons.<sup>7, 8</sup>

<sup>7</sup> FDA Public Health Notification: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication: Update 11/29/2010. http://www.fda.gov/ MedicalDevices/Safety/AlertsandNotices/ucm224025.htm

<sup>8</sup> CDC Clinical Reminder: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens (2010). http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html

- The lancing device provided by Ascensia is intended for self-testing by a single patient. It must not be used on more than one person due to risk of infection.
- Use a new lancet each time you test because it is no longer sterile after use.
- Always dispose of test strips and lancets as medical waste or as advised by your healthcare professional. All products that come in contact with human blood should be handled as if capable of transmitting infectious diseases.

### Exposure to magnetic fields and radiation

- Do not expose your pump to MRI equipment, diathermy devices, or other devices that generate strong magnetic fields (for example, x-ray, CT scan, or other types of radiation). The strong magnetic fields can cause the devices to malfunction, and result in serious injury. If your pump is exposed to a strong magnetic field, discontinue use and contact the 24 Hour HelpLine for further assistance.
  - Magnetic fields, and direct contact with magnets, may affect the accurate functioning of your system, which may lead to health risks such as hypoglycemia or hyperglycemia.
- Do not expose your transmitter to MRI equipment, diathermy devices, or other
  devices that generate strong magnetic fields. Exposure to a strong magnetic
  field has not been evaluated and can cause the device to malfunction, result
  in serious injury, or be unsafe. If your transmitter is inadvertently exposed to a
  strong magnetic field, discontinue use and contact the 24 Hour HelpLine for
  further assistance.
- Do not expose your sensor to MRI equipment, diathermy devices, or other devices that generate strong magnetic fields as the performance of the sensor has not been evaluated under those conditions and may be unsafe. If your sensor is inadvertently exposed to a strong magnetic field, discontinue use and contact the 24 Hour HelpLine for further assistance.
- Always remove your pump, sensor, transmitter, and meter before entering a room that has x-ray, MRI, diathermy, or CT scan equipment. The magnetic fields and radiation in the immediate vicinity of this equipment can make your devices nonfunctional or damage the part of the pump that regulates insulin delivery, possibly resulting in over delivery and severe hypoglycemia.

- Do not expose your pump to a magnet, such as pump cases that have a
  magnetic clasp. Exposure to a magnet may interfere with the motor inside the
  pump. Damage to the motor can cause the device to malfunction, and result
  in serious injury.
- Always carry the Medical Emergency Card provided with your device when
  you are traveling. The Medical Emergency Card provides critical information
  about airport security systems, and using your pump on an airplane, that can
  help you and others. Not following the guidance on the Medical Emergency
  Card could result in serious injury.

### **General precautions**

Always test your blood glucose levels at least four times per day. Although the
pump has multiple safety alarms, it cannot notify you if the infusion set is
leaking, or the insulin has lost its potency. If your blood glucose is out of
range, check the pump and the infusion set to ensure that the necessary
amount of insulin is being delivered.

### **Waterproof capabilities**

- At the time of manufacture and when the reservoir and tubing are properly inserted, your pump is waterproof. It is protected against the effects of being underwater to a depth of up to 12 feet (3.6 meters) for up to 24 hours.
- If the pump is dropped, hit against a hard object, or otherwise damaged, the
  waterproof characteristics of the outer casing of the pump may be
  compromised. If your pump has been dropped or you suspect your pump is
  damaged, carefully inspect your pump to ensure there are no cracks before
  exposing your pump to water.
- This waterproof capability rating applies only to your pump.
- If you believe that water has entered your pump or you observe any other possible pump malfunction, check your blood glucose, and treat high blood glucose as necessary, using an alternative source of insulin. Contact the 24 Hour HelpLine for further assistance. Always contact your healthcare professional if you experience excessively high or low blood glucose levels or if you have any questions about your care.

Chapter 1

### **Electrostatic discharge**

- Although your MiniMed 670G insulin pump is designed to be unaffected by typical levels of electrostatic discharge (ESD), very high levels of ESD can result in a reset of the pump's software and a pump error alarm. After clearing the alarm, verify that your pump is set to the correct date and time, and that all other settings are programmed to the desired values. The software reset could erase your previously programmed settings. Following a pump reset, Auto Mode will be unavailable for 5 hours to allow active insulin to be updated.
- For more information on pump alarms, see *Pump alarms, alerts, and messages, on page 254*. For more information on re-entering your pump settings, see *My pump is asking me to enter my settings, on page 298*. If you are unable to reenter your pump settings, or otherwise believe there is a problem with your pump, contact the 24 Hour HelpLine.

### **Extreme temperatures**

Exposure to extreme temperatures can damage your device, which can adversely affect safety and effectiveness of your device. Avoid the following conditions:

- 1. Avoid exposing your pump to temperatures above 104 °F (40 °C) or below 41 °F (5 °C). This may damage your device.
- 2. Insulin solutions freeze near 32 °F (0 °C) and degrade at high temperatures. If you are outside in cold weather, wear your pump close to your body and cover it with warm clothing. If you are in a warm environment, take measures to keep your pump and insulin cool.
- 3. Do not steam, heat, sterilize, or autoclave your pump. Exposure to high temperatures may damage your device.

### Lotion, sunscreen, and insect repellent

• Some skin care products, such as lotion, sunscreen, and insect repellents, can cause damage to plastics, which is a material used in your pump case. After using such products, be sure to wash your hands prior to handling your pump. If you get any skin care products or insect repellents on your pump, wipe them off as soon as possible with a damp cloth and mild soap. For instructions on cleaning your pump, see *Cleaning your pump*, on page 307.

#### Infusion sets and sites

Always refer to the infusion set user guide for all precautions, warnings, and
instructions relating to the infusion set and your insertion sites. Not referring
to the infusion set user guide can result in minor injury or damage to the
infusion set.

#### Sensor

Always refer to the sensor user guide for all precautions, warnings, and
instructions relating to the sensor. Not referring to the sensor user guide can
result in minor injury or damage to the sensor.

#### **Transmitter**

Always refer to the transmitter user guide for all precautions, warnings, and
instructions relating to the transmitter. Not referring to the transmitter user
guide can result in minor injury or damage to the transmitter.

#### Meter

 Always refer to the meter user guide for all precautions, warnings, and instructions relating to compatible meters. Not referring to the meter user guide can result in minor injury or damage to the meter.

#### Adverse reactions

 Always refer to the sensor user guide for adverse reactions related to the sensor. Not referring to the sensor user guide can result in minor injury or damage to the sensor.

# Keeping track of your system information

The serial number (SN) is located on the back of your pump. If you are using the pump clip, you need to remove the pump clip to view the serial number. It also displays in your Pump status screen. For more details on the status screens, see *Status screens, on page 55.* You will need your pump serial number if you call the 24 Hour HelpLine. For future reference, enter the serial number of your pump and the purchase date in the following table:

Pump serial number	r and	purchase	date
--------------------	-------	----------	------

Serial Number:

Purchase Date:

# **Insulin guidelines**



WARNING: Never start on insulin until directed by your healthcare professional. Do not use insulin in your pump while you are practicing by either inserting an insulin filled reservoir into your pump, or connecting an insulin filled infusion set to your body. Doing so could result in an infusion of insulin, not prescribed by your healthcare professional, which may result in low or high BG.

The MiniMed 670G insulin pump has been studied with and is intended for use with the following rapid acting U100 insulins:

- U100 NovoLog®
- U100 Humalog®

The use of any other insulin in the MiniMed 670G insulin pump has not been tested and may not be appropriate for use with this device.



WARNING: Only use rapid acting U100 insulin (Humalog® and Novolog®) in the MiniMed 670G insulin pump. Use of the incorrect insulin, or insulin with a greater or lesser concentration, may result in over delivery or under delivery of insulin. Over delivery or under delivery of insulin may result in high or low blood glucose levels. High blood glucose levels may lead to Diabetic Ketoacidosis. Low blood glucose levels may lead to coma or death. If you are unsure about whether you can use a specific insulin with this pump, please contact your healthcare professional.

# **Consumables**

The pump uses disposable (single-use) MiniMed reservoirs and infusion sets for insulin delivery.



WARNING: Only use reservoir and infusion sets manufactured or distributed by Medtronic Diabetes. The pump has undergone extensive testing to confirm appropriate operation when used with compatible reservoirs and infusion sets manufactured or distributed by Medtronic Diabetes. We cannot guarantee appropriate operation if the pump is used with reservoirs or infusion sets offered by third parties and therefore we are not responsible for any injury or malfunctioning of the pump that may occur in association with such use.

- Reservoirs Use the MiniMed reservoir MMT-332A, 3.0 ml (300-unit).
- Infusion sets Medtronic Diabetes provides a variety of infusion sets to fit your needs. Contact your healthcare professional for help in choosing an infusion set. Change your infusion set every two to three days per your infusion set manufacturer's instructions.

# Additional MiniMed 670G system devices

- CONTOUR® NEXT LINK 2.4 meter the MiniMed 670G system comes with a compatible meter. It wirelessly connects to your pump, allowing you to send BG meter readings to your pump. The Remote Bolus feature allows you to use your meter to start a bolus on your pump. You can also use this meter to upload system data to your diabetes management software using the USB port on your computer. For more details, see your meter user guide.
- Guardian® Link (3) transmitter (MMT-7811) used with your pump for Continuous Glucose Monitoring (CGM). A device that connects to a glucose sensor. The transmitter collects data measured by the sensor and wirelessly sends this data to monitoring devices.
- Guardian® Sensor (3) (MMT-7020) used with your pump for CGM. The sensor is a small part of the continuous glucose monitoring system that you insert just below your skin to measure glucose levels in your interstitial fluid. The sensor is a disposable (single-use) device. Only use the Guardian Sensor (3) (MMT-7020) glucose sensor with the transmitter. Do not use any other sensor. Other sensors are not intended for use with the transmitter, and will damage the transmitter and the sensor.

• CareLink<sup>™</sup> USB (MMT-7306) – used to upload system data to the diabetes management software using a USB port on your computer.

### **Accessories**

The following accessories may be used with the MiniMed 670G system.

- Pump clip used to wear the pump on your belt. Also, you can use the tip of the pump clip to open the battery compartment on your pump. Refer to your pump clip user guide for instructions on using your pump clip.
- Activity guard (ACC-1520) used if you are active in sports, or if a child is wearing the pump. Using the activity guard prevents the reservoir from being rotated or removed from the pump.
- **Skins** used to personalize the look of your pump. Skins are decorative overlays. Your pump is designed to have skins attached to the back of the pump and the front of the pump clip. Skins also provide additional protection against surface scratches.

# Ordering supplies and accessories

To order supplies or accessories, call 800 646 4633, +1 818 362 5958 (outside U.S.), refer to the contacts list at the beginning of this user guide, or visit our website at www.medtronicdiabetes.com



First steps

# First steps

This chapter gives you an overview of your pump so you can become familiar with the buttons and screens. Read this entire chapter to understand the basic features before using your pump to deliver insulin.

# Your pump

The following illustration shows the different parts of your pump. The reservoir, with the tubing connector attached, is inserted into the reservoir compartment.



# **Using the buttons**



**Caution:** Do not use sharp objects to press the buttons on your pump. Using sharp objects can damage your pump.

The following picture shows the buttons and the notification light on your pump. The notification light flashes when your pump has an alarm or alert. The notification light is not visible unless flashing.



The following table describes how to use the buttons.

To do this:	Follow these steps:
Display the menu.	From the Home screen, press the © button.

To do this:	Follow these steps:
Scroll up or down a menu or list, or increase or decrease the value of a setting.	Press the ∧ or ∨ buttons.
Select an item on a screen or menu.	Press the $\wedge$ , $\vee$ , $\langle$ , or $\rangle$ buttons to select the desired item, and then press the $\bigcirc$ button.
Enter a value into a field.	Press the $\land$ , $\checkmark$ , $\lt$ , or $\gt$ buttons to select the desired field, and then press the $©$ button. The field you select flashes. Press the $\land$ or $\checkmark$ buttons to enter the desired value, and then press the $©$ button.
Return to the previous screen.	Press the 🥎 button.
Display the Home screen.	Press and hold the $\spadesuit$ button to return to the Home screen.
Put the pump in sleep mode.	Press and hold the \times button for about two seconds.
Wake up the pump.	Press any button.

### **About batteries**

The pump requires one new AA (1.5 V) battery. For best results, use a new AA lithium (FR6) battery. The pump also accepts an AA alkaline (LR6) or a fully charged AA NiMH (HR6) nickel-metal hydride rechargeable battery.



**Caution:** Do not use a carbon zinc battery in your pump. Carbon zinc batteries are not compatible with the pump. Use of carbon zinc batteries can cause the pump to report inaccurate battery levels.

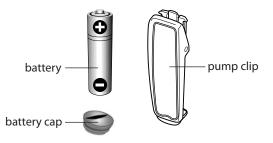
Carbon zinc batteries have a short shelf life, they deteriorate rapidly in cold weather, and oxidation of the zinc wall eventually causes the contents to leak out. They will not perform as well as other battery types to power the pump and may potentially damage your pump.



**Note:** Do not use cold batteries because the battery life may incorrectly appear as low. Allow cold batteries to reach room temperature before you insert them in your pump.

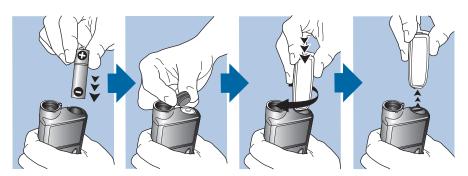
# Inserting the battery

Your pump does not ship with the battery cap on. The battery cap is located in the pump box, separate from the pump.



### To insert the battery:

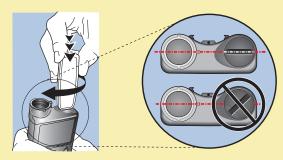
1. Insert the new or fully charged AA battery, making sure to insert the negative end (–) first. After you insert the battery, the positive end (+) is visible.



2. Use the pump clip to tighten the battery cap.



**Caution:** Do not overtighten or undertighten the battery cap. Overtightening the battery cap can cause damage to your pump case. Undertightening the battery cap will prevent the pump from recognizing the new battery. Turn the battery cap clockwise until the cap is aligned horizontally with the pump case, as shown in the following example.





**Note:** If this is the first time you have inserted a battery in your pump, the Startup Wizard begins. For more information about the Startup Wizard, see *Entering your startup settings, on page 46*. If this is not the first time you have inserted a battery into your pump, the Home screen appears and the pump resumes your basal delivery.

# Removing the battery



**Caution:** Do not remove the battery unless you are inserting a new one, or if you are storing your pump. Your pump cannot deliver insulin while the battery is removed. After removing an old battery, be sure to replace it with a new battery within 10 minutes to clear the Insert battery alarm and avoid a Power loss alarm. If power loss occurs, you must re-enter your time and date settings.

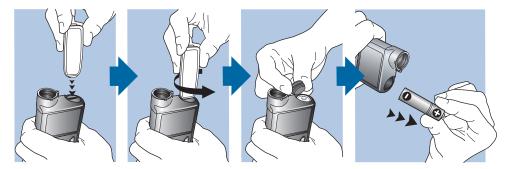
### To remove the battery:

- 1. Before removing a battery from your pump, clear any active alarms or alerts.
- 2. Use the pump clip to loosen and remove the battery cap.



**Note:** Use your pump clip to remove and retighten the battery cap. If the pump clip is unavailable, you may use a coin.

3. Remove the battery.



- 4. Dispose of old batteries according to local regulations for battery disposal (nonincineration), or contact your healthcare professional for disposal information.
- After removing your battery, wait until the Insert Battery screen appears
  before inserting a new battery.
   If you are removing the battery to place your pump in storage, see Storing
  - your pump, on page 308 for more information.

# Getting to know your pump

This section shows you how to navigate through the screens and menus on your pump. It also helps you learn how to enter information and view the status of your pump.

# **Entering your startup settings**

Your pump has a Startup Wizard that begins when you insert your battery for the first time. The Startup Wizard guides you through setting the language, the time format, the current time, and the current date.



**Note:** Use this procedure when you are entering your settings for the first time. If this is not the first time you are entering your pump settings, and your pump is asking you to re-enter your settings, see *My pump is asking me to enter my settings, on page 298*.

### To use the Startup Wizard:

1. The Startup Wizard begins after the Welcome screen appears. When the Language screen appears, select your language.



2. When the Select Time Format screen appears, select a **12 hour** or a **24 hour** time format.



3. When the Enter Time screen appears, adjust the setting to the current time. If you are using a 12-hour clock, be sure to specify AM or PM. Select **Next**.



 When the Enter Date screen appears, adjust the Year, Month and Day to the current date. Select Next.



A message confirms that your initial setup is complete, and then the Home screen appears.

After you enter your initial settings, see the following sections in this chapter to become familiar with the buttons and screens on your pump.

# **Unlocking your pump**

Your pump automatically locks when entering sleep mode. When you wake up your pump from sleep mode, you must unlock your pump before navigating to the menu. When you press select ©, you will be shown a screen asking you to unlock your pump. Press the highlighted button to unlock your pump.



The pump will take you to your selected screen after you press the correct button. If you press an incorrect button, the screen prompts you to try again. If you press the  $\spadesuit$  button, you will be taken back to the Home screen.

After your pump is unlocked, it will remain unlocked until you re-enter sleep mode. For information about the different power modes, or to put your pump to sleep, see *Power modes*, on page 63.

### Home screen

The Home screen appears by default after you change the battery, when you wake the pump from sleep mode, and when you are not actively using another screen.

To see what your Home screen looks like if you use a sensor, see *Home screen with CGM in Manual Mode, on page 179*.

To see what your Home screen looks like when you are in Auto Mode, see *Home screen with Auto Mode, on page 235*.



The following items appear on your Home screen:

ltem	Description
Status icons	Displays icons that show a quick status of your pump system. For more information, see <i>Status icons, on page 50</i> .
Current time	Displays the current time of day. For details on setting the time, see <i>Time and date, on page 174</i> .
BG meter readings	If you have taken a blood glucose (BG) meter reading using your CONTOUR NEXT LINK 2.4 meter or manually entered a BG meter reading within the last 12 minutes, the BG meter reading appears on the Home screen.
	You can enter your BG meter reading manually using the Enter BG feature, Event Markers feature, or when you use the Bolus Wizard to deliver a bolus. For details on using the Bolus Wizard, see <i>Bolus Wizard</i> , on page 94.
Active Insulin	Displays the amount of bolus insulin the pump estimates is still working to lower your blood glucose levels. For more details on active insulin, see <i>About active insulin, on page 100</i> .

# **Status icons**

The status icons appear at the top of the Home screen to provide a way for you to quickly check the status of your system. The status icons are described in the following table. For information on viewing detailed status screens, see *Status screens*, on page 55.

lcon	Icon name	What it means
	Battery	The color and fill level of the battery icon indicate the charge level of your pump battery.
		When a new battery is inserted and your battery is full, the icon is solid green indicating that approximately 100% of your battery capacity remains. In most cases, you can expect at least 7 days of use remaining.
		As the battery life is used, the icon changes from solid green in the following order . This indicates that the charge level of your battery is decreasing from 100% to 0%. The yellow icon indicates that the battery will soon need to be replaced. It is recommended that you have a new or fully charged battery available. The remaining charge level of your battery varies based on the battery type and how you use the pump.
		When your battery is low, the icon has a single red bar indicating that under typical use you have up to 10 hours of use remaining.
		When your battery needs to be replaced immediately, the icon is solid black with a red outline , indicating you have less than 30 minutes of use remaining.

lcon	Icon name	What it means
	Reservoir	Shows the approximate amount of insulin left in your reservoir. The color and the fill level of the icon indicate the status. The reservoir icon is representative of the Medtronic reservoir MMT-332A, 3.0 mL (300-unit). When your reservoir is full, the icon is solid green. As your insulin is used, the icon becomes emptier, and the color of the icon changes as shown in the following example. For more information about your reservoir, see Reservoir and infusion set on Setting up the reservoir and infusion set, on page 121.  Approximately 85-100% of the reservoir remains.  Approximately 71-84% of the reservoir remains.  Approximately 57-70% of the reservoir remains.  Approximately 43-56% of the reservoir remains.  Approximately 29-42% of the reservoir remains.  Approximately 15-28% of the reservoir remains.  The reservoir remaining amount is unknown.
•	Audio	The audio mode you are using: vibrate only 📲, audio only 📲, or vibrate and audio 📲.  When the Alert Silence feature is turned on, the audio mode icons appear as follows: vibrate only 🖏, audio only 🔩, or vibrate and audio 📲.

lcon	Icon name	What it means
<b>P</b>	Connection	The connection icon appears green when the Sensor feature is on and your transmitter is successfully communicating with your pump. The connection icon appears with a red X when the Sensor feature is turned on, but the transmitter is not connected or communication with your pump has been lost. For more information about the Sensor feature, see Understanding Continuous Glucose Monitoring (CGM), on page 177.
<b>*</b>	Airplane Mode	The Airplane Mode icon appears in place of the Connection icon if Airplane Mode is turned on. When Airplane Mode is turned on, the pump cannot receive wireless communication from other devices. For more information about using Airplane Mode, see Airplane Mode, on page 163.
\$	Temporary Network Connection	Replaces Connection icon while you are temporarily connected to a remote upload device.

lcon	Icon name	What it means
•	Calibration	The approximate time left until your next sensor calibration is due. Appears only when the Sensor feature is turned on. The color and the circle around the icon indicate the status. When your sensor is fully calibrated, the icon has a solid green circle around it. As the time for your next sensor calibration approaches, the green circle around the icon becomes smaller, and the color of the icon changes as shown in the following example. For more information about calibrating your sensor, on page 214.
		<ul> <li>Time to your next sensor calibration is more than 10 hours.</li> </ul>
		• Time to your next sensor calibration is 8 to 10 hours.
		• Time to your next sensor calibration is 6 to 8 hours.
		• Time to your next sensor calibration is 4 to 6 hours.
		<ul> <li>Time to your next sensor calibration is 2 to 4 hours.</li> </ul>
		• Time to your next sensor calibration is less than 2 hours.
		• Sensor calibration is required now.
		• 7 Time to your next sensor calibration is unavailable.
		<ul> <li>Sensor is not ready for a calibration. This occurs when a new sensor is connected or within 15 minutes of a Calibration not accepted alert.</li> </ul>

lcon	Icon name	What it means
7	Sensor Life	The number in the center of the Sensor Life icon indicates the number of days remaining in the life of your sensor. The icon appears only when the Sensor feature is turned on. When you insert a new sensor, the icon color is solid green. When one day is remaining in the life of your sensor, the icon color turns red.
		<b>Note:</b> For a short time after starting a new sensor, the Sensor Life icon may show an 8. When the Sensor Life icon changes to show a 7, the seven-day period of sensor life begins.
		7 6 5 4 3 2 1
		If the number of days remaining in the life of your sensor is unavailable, the Sensor Life icon appears with three dots
۰	Auto Mode Readiness	The Auto Mode Readiness icon indicates whether your pump is ready to enter Auto Mode. The icon appears with a loading symbol when the pump is updating a condition that requires you to wait. The icon appears with a question mark ? when the pump requires an action from you to enter Auto Mode. For more information about Auto Mode Readiness, see Auto Mode Readiness, on page 233.
<u>_</u>	Block Mode	Indicates that the pump is in Block Mode, and that certain functions are restricted. Caregivers, such as parents of a young child, can use Block Mode to restrict access to critical pump settings. For more information about Block Mode, see <i>Block Mode, on page 166</i> .

# Using the menu

The menu is where you access the various features and functions of your system. To display the menu, press © from the Home screen.



The following options are available from the menu:

Select this	Menu Indicators	To do this
Bolus	ē	Set up and deliver your bolus insulin delivery.
Enter BG	•	Enter your blood glucose value.
Basal	<u>.</u>	Set up your basal insulin delivery.
Audio Options	J	Set your audio, vibrate, and volume options for the notifications you receive.
Status		View information about your pump, any notifications you have received, your current settings, and optional sensor.
Suspend Delivery	0	Stop your current basal and bolus insulin delivery.
Options	<b>‡</b>	Set your SmartGuard settings, reminders, delivery settings, enter event markers, view your history, and access the Utilities menu.

#### **Status screens**

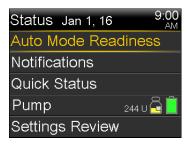
The Status screens provide information about your pump, any notifications you have received, your current settings, and optional sensor. The Status screens are described in the following table:

Status screen	Displays this information
Auto Mode Readiness	A list of conditions your pump has to meet before it can enter Auto Mode. For more information on Auto Mode, see the <i>Auto Mode</i> chapter.
Notifications	A list of alarms, alerts, and reminders that have occurred over the past 24 hours. You can display further details about a particular alarm, alert, or reminder by selecting it from the list. For more information on alarms and alerts, see the <i>Alarms, alerts, and messages</i> chapter.
Quick Status	A summary of status information, including your last bolus, last BG meter reading, current basal rate, reservoir level, and pump battery charge level. If you are using a sensor, this screen also displays the time that your next calibration is due and the SmartGuard status.
Pump	Provides a detailed view of your pump status, including whether your pump is in a specific mode, the reservoir status, battery status, the pump serial number, and other details about your pump.
Sensor	The Sensor status screen is available only if your sensor feature is turned on. The Sensor status screen indicates if any alert silence options are turned on. It also shows the status of your calibrations, your sensor life, ISIG, transmitter battery, serial number and version number of your transmitter, and the SmartGuard status.
Settings Review	The Settings Review screen provides a list of all your pump settings.  The settings are organized by where they appear in the menu for your pump. For example, your bolus settings appear under the Insulin Settings section, and your brightness level setting appears under the Utilities section.

# Viewing the Status screens

1. From the Home screen, press © and select **Status** from the menu.

The Status screen appears. The Reservoir icon shows the approximate amount of insulin left in your reservoir. For more information, see *Status icons*, on page 50.



2. Press ∧ or ∨ to move up or down the screen. Select the status screen that you want to view. Refer to the table at the beginning of this section for a description of the different status screens.

#### Modes

You can choose to use your pump in Manual Mode or in Auto Mode. The following tables show the differences between Manual Mode and Auto Mode. The tables also show delivery and suspend options available for each mode.

# **Manual Mode**

Mode CGM options	Bolus delivery options	Basal delivery	Suspend options
Pump without CGM  9:00 AM  BG  mg/dL  Active Insulin  1.0 U	Bolus Wizard, uses programmed carb ratio, insulin sensitivity, BG target, and active insulin time settings.     Normal bolus     Square Wave bolus     Dual Wave bolus     Remote bolus     Preset bolus     Easy bolus     For more information, see the Bolus chapter.	<ul> <li>Programmed basal delivery settings —         For more information, see Basal insulin settings, on page 68.</li> <li>Temporary basal rates —         For more information, see Temporary basal rates, on page 76.</li> <li>Preset temporary basal rates —         For more information, see Temporary basal rates for more information, see Preset temporary basal rates —         For more information, see Preset Temp basal rates, on page 78.</li> </ul>	Manual suspend — For more information, see Stopping and resuming your insulin delivery, on page 82.

Mode CGM options	Bolus delivery options	Basal delivery	Suspend options
Pump with CGM  9:00 AM  1 2 3 350 226 250 100 1.0 U Act. Insulin	Bolus Wizard, uses programmed carb ratio, insulin sensitivity, BG target, and active insulin time settings. Normal bolus Square Wave bolus Dual Wave bolus Remote bolus Preset bolus Easy bolus For more information, see the Bolus chapter.	<ul> <li>Programmed basal delivery settings —         For more information, see Basal insulin settings, on page 68.</li> <li>Temporary basal rates —         For more information, see Temporary basal rates, on page 76.</li> <li>Preset temporary basal rates —         For more information, see Temporary basal rates, on page 76.</li> </ul>	Manual suspend — For more information, see Stopping and resuming your insulin delivery, on page 82.

Mode CGM options	Bolus delivery options	Basal delivery	Suspend options
Pump with CGM and with Suspend before low or Suspend on low enabled  9:00 AM 7 8 350 165 250 M: mg/dL 150 100 0.5 U Act. Insulin	<ul> <li>Bolus Wizard, uses programmed carb ratio, insulin sensitivity, BG target, and active insulin time settings.</li> <li>Normal bolus</li> <li>Square Wave bolus</li> <li>Dual Wave bolus</li> <li>Remote bolus</li> <li>Preset bolus</li> <li>Easy bolus</li> <li>For more information, see the <i>Bolus</i> chapter.</li> </ul>	<ul> <li>Programmed basal delivery settings —         For more information, see Basal insulin settings, on page 68.</li> <li>Temporary basal rates —         For more information, see Temporary basal rates, on page 76.</li> <li>Preset temporary basal rates —         For more information, see Temporary basal rates for more information, see Preset Temp basal rates, on page 78.</li> </ul>	<ul> <li>Manual suspend — For more information, see Suspend and resuming your insulin delivery, on page 82.</li> <li>Suspend before low — For more information, see Suspend before low, on page 186.</li> <li>Suspend on low — For more information, see Suspend on low — For more information, see Suspend on low — For more information, see Suspend on low, on page 190.</li> </ul>

# **Auto Mode**

	Bolus delivery	Basal delivery	Suspend
	options		options
Auto Mode (Auto Basal delivery)  9:00 AM  135  mg/dL  O.9 U  Act. Insulin	<ul> <li>Auto Mode         Bolus impacted         by Carb Ratio         and Active         Insulin Time         settings</li> <li>Patient enters         carb grams and         BGs</li> <li>Pump may         recommend         bolus when         BG≥150 mg/dL</li> </ul>	Automatic delivery of basal insulin based on recent insulin delivery needs and SG values to target of 120 mg/dL     May set a temporary	options  Manual suspend – For more information, see Stopping and resuming your insulin delivery, on page 82.
	entered  • Patient accepts or cancels bolus  For more information, see the Auto Mode chapter.	target of 150 mg/dL for up to 12 hours  For more information, see the Auto Mode chapter.	

	Bolus delivery options	Basal delivery	Suspend options
Auto Mode (Safe Basal delivery)  9:00 BG required  0.1 U Act. Insulin	<ul> <li>Auto Mode         Bolus impacted         by Carb Ratio         and Active         Insulin Time         settings</li> <li>Patient enters         carb grams and         BGs</li> <li>Pump may         recommend         bolus when         BG≥150 mg/dL         entered</li> <li>Patient accepts         or cancels         bolus</li> <li>For more         information, see         the Auto Mode         chapter</li> </ul>	<ul> <li>Automatic delivery of basal insulin at a fixed rate</li> <li>Does not use SG values to adjust rate</li> <li>For more information, see the Auto Mode chapter</li> </ul>	Manual suspend – For more information, see Stopping and resuming your insulin delivery, on page 82.

# **Scroll bar**

The scroll bar is located on the right side of the display, as shown in the following example. It appears only when there is more information available to view on the screen. Press  $\wedge$  or  $\vee$  to move up or down the screen.



#### **Power modes**

Your pump is designed to conserve battery power when you are not actively using the pump screens.

In this mode	Your pump behaves like this
Awake	Your pump screen is on. Unless you are actively using another screen, your Home screen appears.
	To wake up your pump from being in power save or sleep mode, press any button. If your pump has been in sleep mode, the pump is locked. To unlock your pump, see <i>Unlocking your pump, on page 48</i> .
Power save	Your pump is fully functional, but the screen goes dark to save power. You can set how long it takes for your screen to enter power save mode by changing the Backlight setting. For more information, see <i>Display Options</i> , on page 167. If any button is pressed while the pump is in Power save mode, the pump returns to the screen that was last displayed.
Sleep	Your pump automatically enters sleep mode when you have not pressed any buttons for about two minutes after your screen goes dark (power save mode). Your pump is still fully functional. If any button is pressed while the pump is in sleep mode, you will be shown a screen asking you to unlock your pump. For details, see <i>Unlocking your pump</i> , on page 48.
	To put your pump into sleep mode, press and hold the \times button for about two seconds.

# If you remove your pump

You may have an occasion when you need or want to remove your pump. If you have to remove and store your pump, it is recommended that you do the following:

- Write down a record of your current basal rates and use the Save Settings feature. See *Saving your settings, on page 169* for more information.
- Remove the battery. See *Storing your pump, on page 308* for more information.

Remember, your body still needs insulin while your pump is removed.

Consult your healthcare professional to determine an alternate method of receiving insulin. Disconnecting from your pump for less than one hour may not require an insulin adjustment. If you remove your pump for more than one hour, you should take your insulin another way, as prescribed by your healthcare professional.

Chapter 2

Basal

# Basal

Basal insulin is the "background" insulin that you need throughout the day and night to maintain your target blood glucose values (BG) when you are not eating. Your basal insulin accounts for approximately one half of your daily insulin requirements. Your pump mimics a pancreas by delivering insulin continuously over 24 hours.



**Note:** In Manual Mode, your basal insulin is delivered according to your programmed basal pattern. In Auto Mode, insulin is delivered based on sensor values and your recent insulin delivery needs. For more information on Manual Mode, see *Manual Mode, on page 230*. For more information on Auto Mode, see *Auto Mode, on page 229*.

Your basal insulin is delivered according to a basal pattern. Basal patterns and other basal settings are described in the following sections.

#### **Basal rate**

Your basal rate is the specific amount of basal insulin that your pump continuously delivers each hour. While some people use one basal rate all day, others require different rates at different times of the day.

Your basal rates are set in one or more basal patterns. Each basal pattern covers 24 hours. For specific information about basal patterns, see *Basal patterns*, on page 70.

# **Basal insulin settings**

Your basal insulin delivery settings are described in the following table.

Setting	What it is	What it does for you
Basal Pattern	A set of one or more basal rates that cover a 24-hour period.	Determines the amount of insulin you receive per hour throughout the day and night. Allows you to vary your basal rate according to your needs. You can set up to eight basal patterns. For details on setting up basal patterns, see Adding a new basal pattern, on page 71. For details about starting a basal pattern, see Changing from one basal pattern to another, on page 74.
Temp Basal	A basal rate that you use in place of your scheduled basal rate for short-term situations.	Allows you to temporarily change your current basal rate for a duration of time that you specify. For details about starting a Temp Basal rate, see <i>Starting a Temp Basal rate</i> , on page 77.
Preset Temp	A temporary basal rate that you can define ahead of time.	Allows you to set and save temporary basal rates for known short-term situations, such as when you are sick or have times of increased or decreased activity. For details about setting up a Preset Temp basal rate, see Preset Temp basal rates, on page 78. For details about starting a Preset Temp basal rate, see Starting a Preset Temp basal rate, on page 80.
Max Basal Rate	Maximum amount of basal insulin that your pump can deliver per hour.	Provides a safety measure by limiting the total amount of basal insulin your pump can deliver per hour. For details about setting your Max Basal rate, see Max Basal Rate, on page 69.

#### Max Basal Rate

Max Basal Rate limits the amount of basal insulin that can be delivered per hour, based on the maximum rate you set. You are unable to set any basal rates, temp basal rates, or preset temp basal rates that exceed the max basal rate amount. You can set your max basal rate from 0 to 35 units per hour. Set your max basal rate as prescribed by your healthcare professional.



**Note:** If you are setting your max basal rate after you have set up your basal patterns or preset temp basal rates, you cannot set your max basal rate lower than any of your existing basal rates. You cannot access this feature during a Normal bolus delivery.

#### To set your Max Basal Rate:

- 1. Press © and go to the Max Basal/Bolus screen.
  - Options > Delivery Settings > Max Basal/Bolus
- 2. Select **Max Basal** to set the maximum number of basal insulin units that can be delivered each hour.
  - Because the Max Basal Rate setting determines your basal insulin limits, a warning message appears any time you enter the screen to change the value. To continue setting the value, select **Continue**.
- 3. In the Max Basal Rate screen, select **Max Basal** to set the maximum units per hour.
- 4. Select Save.

# Example 1: Max basal

Helen has a very low insulin requirement. Her highest basal rate is only 0.400 units per hour. As a safety measure, Helen's healthcare professional set her pump with a max basal rate of 1.00 units per hour.

#### **Example 2: Max basal**

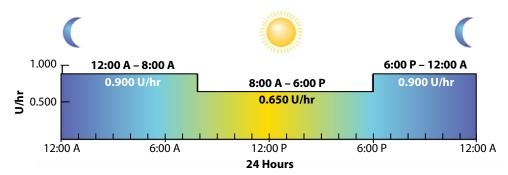
Rusty needs large amounts of insulin to control his blood glucose levels. His new pump was delivered from the factory with a max basal rate of 2.00 units per hour, but he needs 2.80 units per hour in the early morning. Rusty plans to consult his healthcare professional about increasing his max basal rate to 3.00 units per hour to accommodate his needs.

### **Basal patterns**

Your basal pattern determines the amount of basal insulin you receive throughout the day and night. Because your basal insulin needs can vary, you can set up to eight basal patterns. For example, you might use one basal pattern during the week and a different basal pattern during the weekend.

A basal pattern is made up of one to 48 basal rates that you set up to cover a full 24-hour period. If you only need one basal rate throughout the day, you set only one rate for the 24-hour period. If you need the basal rates to change during the day or night to better match your insulin needs, you can set more than one rate, each with a separate start and end time.

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



Your healthcare professional will determine what rates are right for you.



**Note:** If you have already set up basal patterns and want to switch from using one basal pattern to another, see *Changing from one basal pattern to another, on page 74*.

#### Adding a new basal pattern

This procedure shows you how to add a new basal pattern.

#### To add a new basal pattern:

1. Press O and go to the Basal Pattern Setup screen.

#### Options > Delivery Settings > Basal Pattern Setup

The Basal Pattern Setup screen appears. Your active basal pattern appears with a check mark and the 24-hour delivery amount, as shown in the following example.



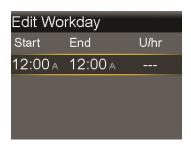
- 2. If this is your first time setting up a basal pattern, the unit amount will be 0.0. Select **Basal 1** and proceed to step 5.
  - If this is not your first time setting up a basal pattern, proceed to the next step to add a new pattern.
- 3. To add a new basal pattern, select **Add New**.
  - The Select Name screen appears.



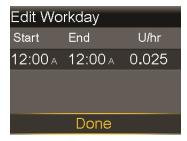


**Note:** The Workday, Day Off, and Sick Day patterns are available so that you can match a basal pattern name to your insulin needs on those particular days.

4. Select the basal pattern that you want to set up. An edit screen appears for the pattern you selected. The following example shows the Edit Workday screen.

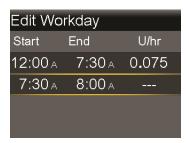


- 5. To create one continuous 24-hour basal rate for your basal pattern, continue with this step. To create more than one basal rate for your new basal pattern, skip to step 6.
  - a. Leave End time at 12:00 AM to set a 24-hour rate. The Start time of the first time segment is always 12:00 AM.
  - b. Set your rate in units per hour.



- c. Skip to Step 7.
- 6. To create more than one basal rate for your new basal pattern, enter one basal rate at a time, as described in the following steps:
  - a. Set the End time and the Rate for your first basal rate. You set your rates in 30-minute increments.
    - If you set the End time to anything other than 12:00 AM, a second basal rate setting appears.

Chapter 3



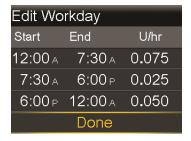
The Start time for the next rate is always the same as the End time of the previous rate.



**Note:** If you need to make a change, you can press  $\wedge$  to scroll up to the rate you want to change. Adjust the End time or Rate values as desired.

Note that pressing  $\land$  or  $\checkmark$  when a field is selected (flashing) adjusts the value of that field. When there is no field selected, pressing  $\land$  or  $\checkmark$  allows you to scroll up or down the list of basal rates.

b. Continue setting rates for different time periods as needed. The End time for your last rate must be 12:00 AM, as shown in the example below.



7. When you finish setting your basal pattern, select **Done**. (The Done option appears only when the last End time in your basal pattern is set to 12:00 AM). A screen appears that allows you to review your basal pattern. If you need to make any changes, press \( \bigcirc\) to return to the previous screen.



**Note:** If you press  $\spadesuit$  to return to the previous screen without saving, your changes will not be saved or implemented.

8. Select **Save**.

To activate your basal pattern, see *Changing from one basal pattern to another,* on page 74.

#### Editing, copying, or deleting a basal pattern

#### To edit, copy, or delete a basal pattern:

#### Options > Delivery Settings > Basal Pattern Setup

The Basal Pattern Setup screen displays all of your existing basal patterns.

- 2. Select the basal pattern you want to edit, copy, or delete.
- 3. Select **Options**.
- 4. Do one of the following:
  - Select **Edit** to adjust the End time or rate values for one or more of the basal rates in this basal pattern.
  - Select Copy to copy the basal rate information from the selected basal pattern to a new basal pattern. When the Select Name screen appears, you can select any available name from the list. Use the Edit option to adjust the new basal pattern as desired.
  - Select **Delete** to delete the selected basal pattern. You cannot delete the active basal pattern.

#### Changing from one basal pattern to another

When you change to a new basal pattern, your pump delivers your basal insulin according to the basal pattern you selected.

#### To change to a different basal pattern:

1. Press © and go to the Basal Patterns screen.

#### Basal > Basal Patterns

The Basal Patterns screen shows the basal patterns you have set up. The active basal pattern is indicated with a check mark.

2. Select the basal pattern you want to start.

The Basal screen displays the details for the selected basal pattern.

3. To start this pattern, select **Begin**.

# Example 1: Basal patterns

Ken has had his insulin pump for about a month. He tests his blood glucose 4–6 times a day and records his results in his logbook. He is happy with his glucose control during the week but on the weekends, he noticed that he has to eat more food to prevent his blood glucose from running too low.

Ken has realized that during the week while he is at work, he is very inactive and sits at a desk most of the time. On the weekends, though, he is busy with yard work, running errands, and playing with his kids. Ken plans to speak with his healthcare professional to see if he should add a different Basal Pattern to lower his basal settings to receive less insulin during active times, such as his weekends.

He can use the Basal Patterns feature to support his weekend change in activity. During the week, he can set his pump to deliver his Basal 1 pattern, and on Saturday morning, he can switch over to his Weekend pattern, which he can set with lower basal rates for the weekend. On Monday morning, he can return his pump to the Basal 1 pattern for his weekday insulin needs.

# Example 2: Basal patterns

Cynthia has had diabetes for about 12 years and has been on her pump for several weeks. Every Monday, Wednesday and Friday, Cynthia goes on a two mile walk in the morning. To prevent hypoglycemia on these days, she uses a different basal pattern. For those days, she simply switches over to Basal 2, which she has programmed with a lower set of basal rates. Before she learned to use the patterns feature, she would have to eat more food throughout the day to keep her blood glucose at a safe level. Cynthia has also noticed that a few days prior to menstruation, her blood glucose levels seem to rise, requiring more insulin. She has programmed a Sick Day pattern on her pump with higher basal rates for this time.

### **Temporary basal rates**

The Temp Basal feature and Preset Temp feature allow you to set temporary basal rates to manage blood glucose levels during short-term activities or conditions that require a basal rate different than your current one, such as an illness or a change in physical activity. You can make an immediate change to your basal insulin for a set period of time (30 minutes to 24 hours), up to your max basal rate.



**Note:** Auto Mode is not available if Temp Basal is active. If you wish to switch your pump to Auto Mode, you must first cancel Temp Basal. For more information on canceling a Temp Basal, see *Canceling a Temp Basal or Preset Temp basal rate, on page 81.* 

#### **About Temp Basal rates**

A temp basal rate temporarily overrides all other basal programming. Your programmed basal pattern resumes after the temp basal rate delivery is completed or cancelled.

The Temp Basal feature allows you to set and start a temporary basal rate immediately. The Preset Temp feature allows you to set up a temp basal rate ahead of time for known situations. You define temp basal rates and preset temp basal rates using either a percentage of your current basal pattern, or by setting a specific rate, as described in the following table.

This temp basal type:	Works like this:
Percent	Delivers a percentage of the basal rates programmed in your active basal pattern for the duration of the temp basal rate. The temp basal amount is rounded down to the next 0.025 units if your basal rate is set at less than 1 unit per hour, or to the next 0.05 units if your basal rate is set at more than 1 unit per hour.
	Temp basal rates can be set to deliver from 0 to 200% (twice the amount) of your scheduled basal rate. The percent amount you can use, however, is based on the largest basal rate scheduled during the temp basal duration, and is limited by your max basal rate.

This temp basal type:	Works like this:
Rate	Delivers a fixed basal insulin rate in units per hour for the duration of your temporary basal, limited by your max basal rate.

To use the Temp Basal feature, see *Starting a Temp Basal rate, on page 77*. To use the Preset Temp Basal feature, see *Preset Temp basal rates, on page 78*.

# Example 1: Temporary basal rates

Jessica enjoys her exercise classes, but finds that her glucose levels drop after she attends them. She is working with her healthcare professional to learn how to use the Temp Basal feature so that she receives a reduced percentage of her usual basal insulin while exercising.

#### Starting a Temp Basal rate

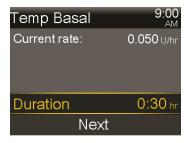
When you start a temp basal rate, your basal delivery changes to the temporary basal rate for the duration you set. When the duration is complete, your basal insulin automatically returns to the active basal pattern.

#### To start a temp basal rate:

1. Press © and go to the Temp Basal screen.

# Basal > Temp Basal

2. **Duration** is flashing. Set the Duration for this temp basal rate. The Duration can be set from 30 minutes to 24 hours, in 15-minute increments.



- Select Next.
- 4. The Type defaults to Percent. You can switch between Percent and Rate by selecting **Type**.



- 5. Depending on the Type you selected, do one of the following:
  - Enter a percentage:



• Enter a basal rate, making sure you do not exceed your max basal rate:



- 6. If desired, select **Review** to review your temp basal setting.
- 7. Select **Begin** to start the temp basal rate.

Your Temp Basal rate continues for the duration you set. A Temp Basal banner appears on the Home screen during your temp basal delivery. Your scheduled basal rate automatically starts again when your Temp Basal rate finishes.

#### **Preset Temp basal rates**

The Preset Temp feature allows you to set up basal rates for recurring short-term situations where you need to temporarily change your basal rate.

There are four names you can use to match your preset temp basal rate to a situation: High Activity, Moderate Activity, Low Activity, and Sick. There are also four additional preset temp rates available to use for other circumstances (Temp 1 through Temp 4).

#### Setting up and managing Preset Temp basal rates

This section describes how to set up, edit, rename, or delete a preset temp basal rate. For information on how to start using a preset temp basal rate, see *Starting a Preset Temp basal rate*, on page 80.

#### To set up a preset temp basal rate:

- 1. Press © and go to the Preset Temp Setup screen.
  - Options > Delivery Settings > Preset Temp Setup
- 2. Select **Add New**.
- 3. Select a name for the preset temp basal rate you want to set (Temp 1, High Activity, Moderate Activity, Low Activity, or Sick).
- 4. The Type defaults to Percent. You can switch between Percent and Rate by selecting **Type**.
- 5. If you are using Percent, enter the percentage you want to use. If you are using Rate, enter the rate in units per hour. You cannot exceed your max basal rate.
- 6. Set the **Duration** (from 30 minutes to 24 hours in 15 minute increments) that you want this preset temp basal to be active.
- 7. Select **Save**.

#### To edit, rename, or delete a preset temp basal rate:

- 1. Press © and go to the Preset Temp screen.
  - Options > Delivery Settings > Preset Temp Setup
- 2. Select the desired preset temp basal.



**Note:** You cannot select a preset temp basal rate that is currently in use.

3. The next screen displays the temp basal info. Do one of the following:

- Select **Edit** to adjust the Type (Percent or Rate), the Percentage or Rate amount, and the Duration for this preset temp basal rate.
- Select Rename to assign a different name to this preset temp basal rate.
   When the Select Name screen appears, you can select any available name from the list.
- Select **Delete** to delete this preset temp basal rate.

#### Starting a Preset Temp basal rate

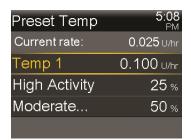
You must set up preset temp basal rates before you can use the Preset Temp feature. For more information, see *Preset Temp basal rates*, on page 78.

#### To start a preset temp basal rate:

1. Press ⊚ and go to the Preset Temp screen. The Preset Temp option only appears if you have set up preset temp basal rates.

#### Basal > Preset Temp

The Preset Temp screen displays the preset temp basal rates you have set up, along with their percentage or rate amounts.





**Note:** Depending on your active basal pattern, it is possible for a percentage preset temp basal rate to exceed your max basal limit. Because you cannot use a preset temp basal rate that exceeds your max basal limit, these rates appear grayed out in the list, and are not available for use.

2. Select the preset temp basal rate that you want to use.

#### 3. Select **Begin**.



Your preset temp basal rate continues for the duration you set. A Temp Basal banner appears on the Home screen during your preset temp basal delivery. Your scheduled basal rate automatically starts again when your preset temp basal rate finishes.

#### **Switching to Auto Mode from Temp Basal**

In order to switch to Auto Mode, you must first cancel any active Temp Basal rate. Auto Mode cannot begin while a Temp Basal rate is active. For information on how to cancel a Temp Basal rate, see *Canceling a Temp Basal or Preset Temp basal rate, on page 81*.

### Canceling a Temp Basal or Preset Temp basal rate

You can cancel a temp basal or preset temp basal rate at any time. When you do so, your scheduled basal pattern automatically starts again.

#### To cancel a Temp Basal rate:

- 1. From the Home screen, press © and go to the Cancel Temp Basal screen.

  The Temp Basal screen displays the name (Preset Temp only), current basal rate, the set duration, and the remaining time.
- 2. Select Cancel Temp Basal.

# Viewing your basal information

The following table describes how you can view your basal rates and patterns.

To do this:	Do this:	
View your current basal rate	From the Quick Status, you can view your current basal rate. Press © and go to the Quick Status screen.	
	Status > Quick Status	
View your basal patterns	Press ⊚ and go to the Basal Patterns screen:	
	Basal > Basal Patterns	
	The Basal Pattern screen shows the basal patterns you have set up, and the 24-hour insulin total for each basal pattern. A check mark appears next to the active basal pattern.	
	Basal Patterns  9:00 AM  Basal 1  0.6 ∪ ✓  Workday  0.875 ∪	
	To see the individual basal rates, select the desired basal pattern.	

# Stopping and resuming your insulin delivery

Use Suspend Delivery if you need to stop all active basal and bolus insulin deliveries. While your insulin delivery is suspended, your pump beeps, vibrates, or both depending on your audio settings. This reminder occurs every 15 minutes to remind you that insulin is not being delivered.



**Note:** The first reminder occurs 15 minutes after your pump display times out. If you press a button and wake up your pump, the reminder will not occur until 15 minutes after your pump display times out again. To adjust your timeout setting, see *Display Options*, on page 167.

To continue your basal insulin delivery, use the Resume feature. When you use the Resume feature, your pump starts your programmed basal pattern, but does not start any previously programmed bolus deliveries.



**Note:** If you want to stop a bolus delivery only, without stopping your basal delivery, see *Stopping a bolus delivery, on page 116.* 



WARNING: Always check the pump Daily History after you resume insulin delivery to determine the amount that was delivered. If needed, program a new bolus or fill the cannula. A bolus delivery or fill cannula that was suspended does not restart when you resume. Failing to resume insulin delivery can result in hyperglycemia and ketoacidosis.



WARNING: Do not rely solely on the Audio or Vibration notifications when using Audio or Vibrate. These notifications may not occur as expected if the speaker or vibrator in your pump malfunctions. A missed notification could result in the delivery of too much or too little insulin. This is most common when using the Easy Bolus™ feature, or when your pump is in Manual Suspend.

Contact the 24 Hour HelpLine with any concerns.

#### To suspend all insulin delivery:

- Press 
   and go to the Suspend Delivery screen.
   A confirmation message appears.
- Select Yes to suspend your pump and stop all insulin delivery.
   The Home screen indicates that your insulin is suspended. Your pump functions are limited until you resume your insulin delivery.

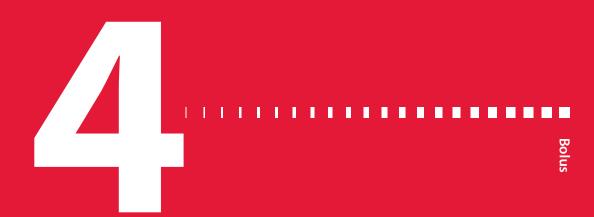
#### To resume basal insulin delivery:

While insulin is suspended, press 
 and go to the Resume Delivery screen.
 A confirmation message appears.

2. To resume your basal insulin delivery, select **Yes**. If a Temp Basal was active when you suspended your pump, it resumes if the time is still within the duration that you set.



**Note:** If you still need a bolus delivery that was in progress before you suspended your delivery, check the Daily History screen for the actual bolus units delivered and the intended bolus amount. Then you can set up a new bolus amount as needed. See *Daily History, on page 147* for details about using the Daily History screen.



# **Bolus**

A bolus is the amount of insulin taken to cover an expected rise in blood glucose (BG), typically when you eat a meal or snack. You can also use a bolus to correct a high blood glucose reading.

#### **About bolus deliveries**

There are different types of bolus deliveries you can use, depending on your insulin needs at the time. There are also different ways you can deliver a bolus. Discuss these options with your healthcare professional to determine what is best for you.

# **Bolus types**



Note: While in Auto Mode, you can only deliver a Normal bolus.

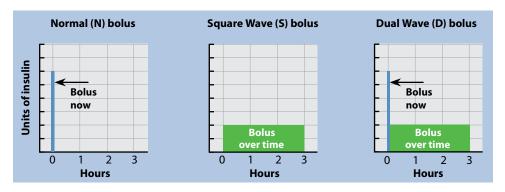
The following table provides general information about the available bolus types.

Туре	How it works	When to use it
Normal	Provides a single immediate dose of insulin.	This is the typical bolus type you use to cover your food intake, or to correct a high BG meter reading.
		For details about using the Normal bolus feature, see <i>Normal bolus, on page 101</i> .

Туре	How it works	When to use it
Square Delivers a single bolus  Wave® evenly over an extended period of time  (30 minutes to 8 hours		<ul> <li>You might use a Square Wave bolus:</li> <li>If you have delayed food digestion due to gastroparesis or meals high in fat.</li> <li>When snacking over an extended period of time.</li> <li>If a Normal bolus drops your blood glucose too rapidly.</li> </ul>
		For details about using the Square Wave bolus feature, see <i>Square Wave bolus, on page 104</i> .
Dual Wave®	Delivers a combination of an immediate Normal bolus followed by a Square Wave bolus.	<ul> <li>You might use a Dual Wave bolus:</li> <li>When you eat meals that are both high in carbs and fat which may delay digestion.</li> <li>When your meal bolus is combined with a correction bolus for an elevated blood glucose.</li> <li>For details about using a Dual Wave bolus, see Dual Wave bolus, on page 107.</li> </ul>

# **Bolus type example**

The following example shows how the different bolus types work.



# **Bolus delivery options**

The following table describes the different ways you can deliver a bolus.



**Note:** Different bolus delivery options are available depending on whether the pump is in Manual Mode or Auto Mode. For a list of delivery options available for each mode, see *Modes, on page 57*.

Delivery method	Type of bolus available	How it works
method		
Bolus Wizard	Normal bolus, Square Wave bolus, Dual Wave bolus	You enter your BG meter reading or your carbs you plan to eat, or both. Then the Bolus Wizard calculates an estimated bolus amount based on your individual settings.
		The Bolus Wizard feature is only available in Manual Mode.
		For details about using the Bolus Wizard feature, see <i>Bolus Wizard</i> , on page 94.
		To deliver a:
		• Normal bolus using Bolus Wizard, see Delivering a Normal bolus with the Bolus Wizard, on page 102.
		• Square Wave bolus using Bolus Wizard, see <i>Delivering a Square Wave bolus with the Bolus Wizard, on page 106</i> .
		<ul> <li>Dual Wave bolus using Bolus Wizard, see Delivering a Dual Wave bolus with the Bolus Wizard, on page 108.</li> </ul>

Delivery method	Type of bolus available	How it works
Auto Mode Bolus	Normal bolus	You enter your BG meter reading or your carbs you plan to eat, or both. Then the Auto Mode Bolus feature calculates a bolus amount to cover the meal or correction.
		The Auto Mode Bolus feature is only available in Auto Mode.
		For details about using the Auto Mode Bolus feature, see <i>Auto Mode Bolus, on page 242</i> .
Manual	Normal bolus, Square Wave bolus, Dual Wave	You do your own calculation and manually enter your bolus amount.
	bolus	To deliver a:
		Normal bolus, see Delivering a Normal bolus using Manual Bolus, on page 104
		• Square Wave bolus, see <i>Delivering a</i> Square Wave bolus using Manual Bolus, on page 107
		<ul> <li>Dual Wave bolus, see Delivering a Dual Wave Bolus using Manual Bolus, on page 110</li> </ul>
Preset Bolus	Normal bolus, Square Wave bolus, Dual Wave bolus	You select from specific bolus settings that you define ahead of time for recurring situations.
		For details about using the Preset Bolus feature, see <i>Preset Bolus, on page 113</i> .

Chapter 4

Delivery method	Type of bolus available	How it works	
Easy Bolus™	Normal bolus	After the Easy Bolus feature is set up, you can deliver a Normal bolus by using the $\wedge$ button when the pump is in sleep mode.	
		For details about using the Easy Bolus feature, see <i>Easy Bolus, on page 111</i> .	
Remote Bolus from your CONTOUR NEXT LINK 2.4 meter	Normal bolus or any Preset Bolus set up on your pump.	For information on using the Remote Bolus feature on your CONTOUR NEXT LINK 2.4 meter, see the user guide that came with your meter.	
		For information on turning on the Remote Bolus feature on your pump, see Setting up Remote Bolus, on page 138.	
		<b>Note:</b> The Remote Bolus feature is not available when in Auto Mode.	

# **Bolus settings**

The following table describes some bolus settings that may need to be changed before you use your bolus options. Consult with your healthcare professional for the settings that are right for you.



**Note:** There are additional settings required if you want to use the Bolus Wizard. These are described in the section, *Bolus Wizard, on page 94*.

Setting	What it is	What it does for you
Max Bolus	Maximum amount of bolus insulin (in units) your pump can deliver in a single bolus.	Provides a safety measure by limiting the total amount of bolus insulin you can program for a single bolus delivery.  For details about setting the max bolus amount, see <i>Max Bolus, on page 92</i> .
Bolus Increment	The amount of insulin (in units) that is increased or decreased with each button press when adjusting your bolus amount. The Bolus Wizard and Auto Mode Bolus will also use the increment to display the bolus total and adjustment amounts. This setting does not apply to Easy Bolus.	Allows you to set your increment value according to your typical bolus amounts.  For details about setting the bolus increment, see <i>Bolus Increment, on page 93</i> .
Bolus Speed	The speed that your pump delivers your bolus insulin.	Allows you to set your bolus insulin delivery speed to Standard or Quick.  For details about setting your bolus speed, see <i>Bolus Speed</i> , on page 94.

# **Max Bolus**

Max Bolus limits the amount of insulin that can be delivered in a single bolus. Your pump prevents single bolus insulin deliveries that exceed the max bolus you set. You can set your max bolus from 0 to 25 units. Set your max bolus as prescribed by your healthcare professional.

If you are setting your max bolus after you have set up your Preset Bolus deliveries, you cannot set your max bolus lower than any of your Preset Bolus amounts.

The max bolus setting applies to both Manual Mode and Auto Mode.

# To set your max bolus:

1. Press ◎ and go to the Max Basal/Bolus screen.

#### Options > Delivery Settings > Max Basal/Bolus

- Select Max Bolus.
- 3. Because the Max Bolus setting determines your bolus insulin limit, a warning message appears any time you go to the screen to change the value. To continue to the Max Bolus screen, select **Continue**.
- 4. Select **Max Bolus**, and then set the maximum number of insulin units your pump can deliver in one bolus.
- 5. Select **Save**.

## **Example 1: Max Bolus**

Shelby takes very small doses of insulin for her meal boluses. As a safety limit, her healthcare professional had her reset her pump with a Max Bolus of 5.0 units.

# **Example 2: Max Bolus**

David is a growing teenager. He loves to eat big meals and requires very large doses of insulin for his food. David's healthcare professional had him reset his pump with a Max Bolus of 20.0 units so he can take more insulin when needed.

## **Bolus Increment**

The Bolus Increment setting determines the number of units that are increased or decreased with each button press when you adjust your bolus delivery amount in the Bolus Wizard, Manual Bolus, and Preset Bolus screens. Depending on your typical bolus amount, you can set your increment to 0.1 units, 0.05 units, or 0.025 units.



**Note:** Easy Bolus uses a setting called Step Size to determine the number of insulin units for each button press. See *Setting up Easy Bolus, on page 111* for more information.

# To set your Bolus Increment:

- 1. Press © and go to the Bolus Increment screen.
  - Options > Delivery Settings > Bolus Increment
- 2. Select **Increment** to set your desired increment value.

Select Save.

# **Bolus Speed**

Bolus Speed sets the rate at which your pump delivers bolus insulin. You can set a Standard rate (1.5 units per minute), or a Quick rate (15 units per minute).

#### To set your Bolus Speed:

- Press ⊚ and go to the Bolus Speed screen.
   Options > Delivery Settings > Bolus Speed
- Select Standard or Quick.
- 3. Select **Save**.

#### **Bolus Wizard**

The Bolus Wizard is a feature that uses your individual Bolus Wizard settings to calculate an estimated bolus amount based on the BG values and carbs that you enter. Work with your healthcare professional to define your personal settings, which include your carb ratio, insulin sensitivity, BG target range, and active insulin time.



**Note:** If you do not know how to count carbs, consult with your healthcare professional before using the Bolus Wizard.

After you set up the Bolus Wizard, you can use it to calculate and deliver a food bolus, a correction bolus, or a food plus correction bolus using a Normal bolus (see *Delivering a Normal bolus with the Bolus Wizard, on page 102*), Square Wave bolus (see *Delivering a Square Wave bolus with the Bolus Wizard, on page 106*), or Dual Wave bolus (see *Delivering a Dual Wave bolus with the Bolus Wizard, on page 108*).

The following sections describe how to set up the Bolus Wizard. Bolus delivery instructions are provided in the individual sections for each bolus type.

# **Understanding your Bolus Wizard settings**

Your pump guides you through entering the following settings when you first turn on the Bolus Wizard feature. Get your prescribed settings from your healthcare professional, and always consult your healthcare professional before changing your settings. The setup procedure begins on *page 95*.

Setting	What it does		
Carb Ratio	Used for food bolus calculations.		
	The number of carb grams that are covered by 1 unit of insulin.		
Insulin Sensitivity	Used to calculate correction bolus amounts.		
Factor	Your insulin sensitivity factor is the amount that blood glucose is reduced by one unit of insulin.		
BG Target	The Bolus Wizard calculates your estimated bolus based on your BG target range. The high and low values you set are the values to which your blood glucose is corrected. To use a single target value rather than a range, set the same value for High and Low.		
	If your BG value is above the high target value, a correction dose is calculated. If your BG value is below the low target value, a negative correction is calculated and subtracted from your food bolus.		
Active Insulin Time	Active insulin is the bolus insulin that has been delivered by the pump and is still working to lower your blood glucose levels. Active insulin time is the length of time that bolus insulin is tracked as active insulin.		
	Work with your healthcare professional to get the active insulin time that best represents the insulin type you use and your physiological insulin absorption rate.		
	For more information about how the Bolus Wizard uses your active insulin amount, see <i>About active insulin, on page 100.</i>		

# **Setting up the Bolus Wizard feature**

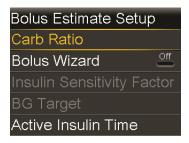
Before you can use the Bolus Wizard to calculate a bolus, you must turn on this feature and enter your Bolus Wizard settings.

# To set up the Bolus Wizard feature:

1. Press © and go to the Bolus Estimate Setup screen.

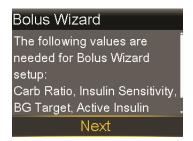
Options > Delivery Settings > Bolus Estimate Setup

The Bolus Estimate Setup screen appears with the Bolus Wizard turned off.



2. Select **Bolus Wizard** to turn on the feature.

If this is the first time you have turned on the Bolus Wizard feature, your pump displays information about the settings you need to enter.



Make sure you have the values you need, and then select **Next** to continue.

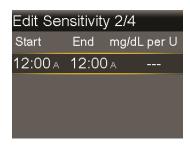


**Note:** As you enter your personal settings, your pump displays information about each setting. Select **Next** to continue when you have read each explanation.

3. When the Edit Carb Ratio screen appears, enter your carb ratio. You can set up to eight carb ratios using different time segments. The time segments must cover a 24-hour period.



- If your ratio value is outside the range of 5 to 50 grams per unit, a message appears asking you to confirm your setting.
- 4. When the Edit Sensitivity screen appears, enter your insulin sensitivity factor. You can set up to eight different sensitivity factors using different time segments. The time segments must cover a 24-hour period.



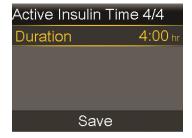
If the value you enter is outside the range of 20 to 100 mg/dL per U, a message appears asking you to confirm your setting.

5. When the Edit BG Target screen appears, enter your Bolus Wizard BG target range. You can set up to eight different BG target ranges using different time segments. The time segments must cover a 24-hour period.



If your Bolus Wizard BG target is outside the range of 90 to 140 mg/dL, a message appears asking you to confirm your setting.

6. When the Active Insulin Time screen appears, enter your active insulin time value. The default is 4 hours.



7. Select **Save**.

A message appears letting you know the Bolus Wizard setup is complete.

You can now use the Bolus Wizard to calculate a bolus.

# **Changing your Bolus Wizard settings**

This section shows you how to make changes to your personal settings after you initially set up the Bolus Wizard. Except for the carb ratio setting, these settings are available only if the Bolus Wizard is turned on. Always consult with your healthcare professional before making changes to your personal settings.

#### Changing your carb ratio

The carb ratio setting is always available whether or not you have the Bolus Wizard turned on.

#### To change your carb ratio:

- 1. Press 

  and go to the Carb Ratio screen.
  - Options > Delivery Settings > Bolus Estimate Setup > Carb Ratio
- Select Edit.
- 3. Select the carb ratio to adjust the Start time, the End time, and the ratio. You can set up to eight different carb ratios using different time segments. The time segments must cover a 24-hour period.
  - If you set a value outside the typical range of 5 to 50 grams per unit, a message appears asking you to confirm your setting.
- 4. When you have made your changes, select Save.

# Changing your insulin sensitivity factor

The Insulin Sensitivity Factor option is only available if the Bolus Wizard feature is turned on.

# To change your insulin sensitivity factor:

- 1. Press © and go to the Sensitivity screen.
  - Options > Delivery Settings > Bolus Estimate Setup > Insulin Sensitivity Factor
- 2. Select **Edit**.

- 3. Select the sensitivity factor to adjust the Start time, the End time, and the Sensitivity amount. You can set up to eight different sensitivity amounts using different time segments. The time segments must cover a 24-hour period. If you set a value that is outside the typical range of 20 to 100 mg/dL per unit, a message appears asking you to confirm your setting.
- 4. When you have made your changes, select Save.

## **Changing your Bolus Wizard BG target**

Your target range can be from 60 to 250 mg/dL. The Bolus Wizard BG Target option is only available if the Bolus Wizard feature is turned on.

#### To change your Bolus Wizard BG target range:

- 2. Select **Edit**.
- 3. Select the BG target to adjust the Start time, the End time, and the Lo (low) and Hi (high) BG Target values. Your high value cannot be less than your low value. You can set up to eight different values using different time segments. The time segments must cover a 24-hour period.
  - If your BG target is outside the typical range of 90 to 140 mg/dL, a message appears asking you to confirm your setting.
- 4. When you have made your changes, select **Save**.

# **Changing your Active Insulin Time**

The active insulin time setting lets the pump know which active insulin time to use in calculating the amount of active insulin to subtract before estimating a bolus. Your healthcare professional will prescribe the active insulin time that is best for you.

# To change your active insulin time:

- 1. Press © and go to the Active Insulin Time screen.
  - Options > Delivery Settings > Bolus Estimate Setup > Active Insulin Time
- 2. Select **Duration**, then adjust your active insulin time (in hours), using 15-minute increments.

3. Select Save.

## **Turning off the Bolus Wizard feature**

You can turn off the Bolus Wizard feature at any time. Your Bolus Wizard settings remain in your pump. When the Bolus Wizard is turned off, the Bolus Wizard option does not appear in the Bolus menu, and you cannot edit your Insulin Sensitivity Factor or BG Target settings from the Bolus Wizard Setup screen.

#### To turn off the Bolus Wizard feature:

- Select Bolus Wizard to turn the feature off.

#### About active insulin

Active insulin is the bolus insulin that has already been delivered to your body, and is still working to lower your blood glucose levels. The pump considers your active insulin time setting in determining if any active insulin is still in your body from prior boluses. This may help prevent hypoglycemia caused by over-correcting for high blood glucose.

Your current active insulin amount displays on the Home screen, and includes only the bolus insulin you have already received.

When you are using the Bolus Wizard, the Bolus Wizard calculator uses your current active insulin value to determine if there is an active insulin adjustment needed. The active insulin adjustment calculation considers both the bolus insulin that has already been delivered (the amount shown on the Home screen), as well as any insulin that is going to be delivered by an active Square Wave bolus.



WARNING: Do not use the Bolus Wizard to calculate a bolus for a period of time after giving a manual injection of insulin by syringe or pen. Manual injections are not accounted for in the active insulin amount. Therefore, the Bolus Wizard could prompt you to deliver more insulin than needed. Too much insulin can cause hypoglycemia. Consult with your healthcare professional for how long you need to wait after a manual injection of insulin before you can rely on the active insulin calculation of your Bolus Wizard.

# **Bolus Wizard warnings**

When you use the Bolus Wizard, there may be times when you see one of the following:

Warning:	What it means:	What to do:	
High BG	Your BG meter reading is above	Check infusion set.	
	250 mg/dL.	<ul> <li>Check ketones.</li> </ul>	
		• Consider an insulin injection.	
		• Monitor your BG.	
Low BG	Your BG meter reading is below 70 mg/dL.	Treat your low BG. Do not give yourself a bolus until your BG returns to normal.	
Max Bolus exceeded	The bolus amount entered exceeds your Max Bolus setting.	Check the bolus amount. Select <b>No</b> to cancel, or <b>Yes</b> to continue. If you select Yes, the bolus amount that you entered is reduced to your max bolus limit.	
		Let your healthcare professional know if you routinely receive the Max Bolus exceeded warning so that they can adjust your pump settings.	

# **Normal bolus**

A Normal bolus provides a single immediate dose of insulin. You use a Normal bolus to cover your food intake or to correct a high BG meter reading.

You cannot access the Reservoir & Tubing, Delivery Settings, or Sensor Settings menu options during a Normal bolus delivery.



**Note:** Your pump allows you to deliver a Normal bolus while a Square Wave bolus or the Square portion of a Dual Wave bolus is being delivered.

## Delivering a Normal bolus with the Bolus Wizard

#### To deliver a Normal bolus using the Bolus Wizard:

- 1. For a correction bolus or a food bolus with a correction, use your BG meter to check your blood glucose. For a food bolus only, skip this step.
- 2. Press © and go to the Bolus Wizard screen.

#### Bolus > Bolus Wizard

The Bolus Wizard screen shows your current BG meter reading (if applicable) and any insulin that is still active from previous boluses. For more information about active insulin, see *About active insulin, on page 100*. For more information, see *About your CONTOUR NEXT LINK 2.4 meter, on page 137*.



3. If you are not using a wirelessly connected meter, you can select **BG** to manually enter your BG meter reading.



**Note:** If you choose not to enter a BG value, three dashes appear on the screen in place of the BG value.

- 4. For a food bolus, select **Carbs** to enter the carb count of your meal. For a correction bolus where no food was eaten, leave the Carbs value at 0.
- 5. Your calculated bolus appears in the Bolus field.



If you want to change the bolus amount, select **Bolus** and make any desired adjustment. If you change your bolus amount, the word "Modified" appears next to the new bolus amount.



6. Select **Next** to review your bolus information.

Your bolus amount appears.



**Note:** If you modified your bolus amount in the previous step, **Bolus Calculated** displays your original bolus amount, **Modification** displays the amount you added or subtracted from your bolus, and **Bolus** displays the actual bolus amount.



7. Select **Deliver Bolus** to start your bolus.



Your pump beeps or vibrates and displays a message when your bolus starts. The Home screen shows your bolus amount as it is being delivered. Your pump beeps or vibrates when your bolus is complete.

## **Delivering a Normal bolus using Manual Bolus**

The following section describes how to deliver a Normal bolus using the Manual Bolus feature.

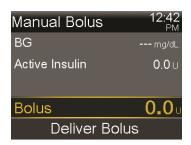
#### To deliver a Normal bolus using Manual Bolus:

1. Press © and go to the Manual Bolus screen.

Bolus > Manual Bolus



**Note:** If the Bolus Wizard is turned off, the Manual Bolus screen appears when you select Bolus.



The Manual Bolus screen shows your current BG value (if applicable) and any insulin that is still active from previous boluses. For more information about active insulin, see *About active insulin*, on page 100.

- 2. Select **Bolus** to set your bolus delivery amount (in units).
- 3. Select **Deliver Bolus** to start your bolus.

Your pump beeps or vibrates and displays a message when your bolus starts. The Home screen shows your bolus amount as it is being delivered. Your pump beeps or vibrates when your bolus is complete.

# **Square Wave bolus**

A Square Wave bolus delivers a bolus evenly over a period of time (30 minutes to 8 hours).

When using the Bolus Wizard, a Square Wave bolus is available only when giving a food bolus without a correction for an elevated BG. A Square Wave bolus is not available for a correction bolus alone, or a correction bolus with food bolus.

A Square Wave bolus can be useful in these situations:

- If you have delayed food digestion due to gastroparesis or meals high in fat.
- When you are snacking over an extended period of time.
- If a Normal bolus drops your blood glucose too rapidly.

Since the Square Wave bolus extends delivery over a period of time, the insulin is more likely to be available as you need it.



**Note:** You cannot perform these functions during a Square Wave bolus delivery:

- Enable Auto Mode.
- Change the Max Bolus or the Active Insulin Time settings.
- Set a second Square Wave or a Dual Wave bolus.
- Fill the cannula.
- Rewind your pump.
- Run a self-test.
- Access the Manage Settings menu.

All other functions are available during the Square Wave bolus.

# **Turning on or off Square Wave bolus**

The Square Wave bolus delivery option is available only after you turn on the Square Wave feature.

# To turn on or turn off the Square Wave feature:

- 1. Press © and go to the Dual/Square Wave screen.
  - Options > Delivery Settings > Dual/Square Wave
- 2. Select **Square Wave** to turn the feature on or off.
- Select Save.

## Delivering a Square Wave bolus with the Bolus Wizard

The Square Wave option is available in the Bolus Wizard only after you turn on the Square Wave feature. Also, you must have entered a Carbs value.

#### To deliver a Square Wave bolus with the Bolus Wizard:

1. Press O and go to the Bolus Wizard screen.

#### Bolus > Bolus Wizard

The Bolus Wizard screen shows your current BG meter reading (if applicable) and any insulin that is still active from previous boluses. For more information about active insulin, see *About active insulin, on page 100*. For more information, see *About your CONTOUR NEXT LINK 2.4 meter, on page 137*.

2. If you are not using a wirelessly connected meter, you can select **BG** to manually enter your BG meter reading.



**Note:** If you choose not to enter a BG meter reading, three dashes appear on the screen instead.

- 3. Select **Carbs** to enter the amount of carbs in your food.
- 4. Review your calculated bolus amount in the Bolus field. If you want to change the bolus amount, select **Bolus** and make your desired change. Remember, if there is a correction bolus amount calculated, you are not able to give a Square Wave bolus.



**Note:** If you change your bolus amount, the word "Modified" appears next to the new bolus amount.

- 5. Select **Next** to review your bolus information.
- 6. Select **Square**.

The Bolus Wizard screen appears with your bolus amount.

- 7. To change the time period over which your bolus is delivered, select **Duration** to adjust the time. The duration can be from 30 minutes to 8 hours, in 15 minute increments.
- 8. Select **Deliver Bolus** to start your bolus.

During a Square Wave bolus delivery, the Square Bolus banner displays on your Home screen until bolus delivery is complete. You can press © and select **Bolus** to stop the bolus, to see details on the insulin that has been delivered, or to access the Bolus menu.

## **Delivering a Square Wave bolus using Manual Bolus**

The Square Wave option is available in the Manual Bolus screen only after you turn on the Square Wave feature.

#### To deliver a Square Wave bolus manually:

1. Press © and go to the Manual Bolus screen.

#### Bolus > Manual Bolus

- 2. Set your bolus delivery amount (in units), and then select **Next**.
- 3. Select **Square**.
- 4. Select **Duration** and set the amount of time over which you want your Square Wave bolus to be delivered. The duration can be from 30 minutes to 8 hours, and is set in 15-minute increments.
- 5. Select **Deliver Bolus** to start your bolus.

During a Square Wave bolus delivery, the Square Bolus banner displays on your Home screen until bolus delivery is complete. You can press © and select **Bolus** to stop the bolus, to see details on the insulin that has been delivered, or to access the Bolus menu.

# **Dual Wave bolus**

The Dual Wave bolus feature meets both immediate and extended insulin needs by delivering a combination of an immediate Normal bolus followed by a Square Wave bolus.

A Dual Wave bolus can be useful in these situations:

- When you need to correct elevated blood glucose before a meal, and you
  also need a delayed bolus for food that is absorbed slowly.
- When you eat meals with mixed nutrients, such as carbs, fats and proteins, that are absorbed at different rates.

#### **Turning on or off Dual Wave bolus**

The Dual Wave bolus delivery option is available only after you turn on the Dual Wave feature

#### To turn on or turn off the Dual Wave feature:

- 1. Press © and go to the Dual/Square Wave screen.
  - Options > Delivery Settings > Dual/Square Wave
- 2. Select **Dual Wave** to turn the feature on or off.
- 3. Select **Save**.

# Delivering a Dual Wave bolus with the Bolus Wizard

The Dual Wave option is available in the Bolus Wizard only after you turn on the Dual Wave feature.

#### To deliver a Dual Wave bolus with the Bolus Wizard:

- 1. For a correction bolus or a food bolus with a correction, use your BG meter to check your blood glucose. For a food bolus only, skip this step.
- 2. Press © and go to the Bolus Wizard screen.

#### Bolus > Bolus Wizard

The Bolus Wizard screen shows your current BG meter reading (if applicable) and any insulin that is still active from previous boluses. For more information about active insulin, see *About active insulin, on page 100*. For more information, see *About your CONTOUR NEXT LINK 2.4 meter, on page 137*.



**Note:** Be aware that if you already have the Bolus Wizard open prior to wirelessly sending your BG meter reading to your pump, you must close the Bolus Wizard and open it again, in order for that reading to appear.

3. If you are not using a wirelessly connected meter, you can select **BG** to manually enter your BG meter reading.



**Note:** If you choose not to enter a BG value, three dashes appear on the screen in place of the BG value.

- 4. For a food bolus, select **Carbs** to enter the carb count of your meal. For a correction bolus where no food was eaten, leave the Carbs value as 0.
- 5. Review your calculated Bolus amount. If you want to change the amount, select **Bolus** and make your desired change.



**Note:** If you change your bolus amount, the word "Modified" appears next to the new bolus amount.

- 6. Select **Next** to review your bolus information.
- 7. Select **Dual**.

The Bolus Wizard screen appears, with the food amount split evenly between the Now and Square portions.

8. If you need to change the amounts, select the area of the screen with the Now value and adjust the **Now** amount.

When you adjust the Now amount, the Square amount adjusts automatically.



- 9. Adjust the **Duration** over which you want the Square Wave portion to be delivered. The duration can be from 30 minutes to 8 hours.
- 10. Select **Deliver Bolus** to start your bolus.

During a Dual Wave delivery, the Home screen shows the progress of the Now portion of your delivery. When the Now portion is complete, the Dual Bolus banner displays until bolus delivery is complete. You can press © and select **Bolus** to stop the bolus, to see details on the amount of bolus insulin delivered, or to access the Bolus menu.

## **Delivering a Dual Wave Bolus using Manual Bolus**

The Dual Wave option is available in the Manual Bolus screen only after you turn on the Dual Wave feature.

#### To deliver a Dual Wave bolus using Manual Bolus:

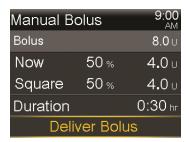
1. Press © and go to the Manual Bolus screen.

#### Bolus > Manual Bolus

The Manual Bolus screen appears.

- 2. Set your bolus delivery amount (in units), and then select **Next**.
- 3. Select **Dual**.

The Manual Bolus screen appears, with the Now and Square portions split evenly.



- 4. If you need to change the amounts, select the area of the screen with the Now value and adjust the **Now** amount. When you adjust the Now amount, the Square amount adjusts automatically.
- 5. Adjust the **Duration** over which you want the Square Wave portion to be delivered. The duration can be from 30 minutes to 8 hours.
- 6. Select **Deliver Bolus** to start your bolus.

During a Dual Wave delivery, the Home screen shows the progress of the Now portion of your delivery. When the Now portion is complete, the Dual Bolus banner displays until bolus delivery is complete. You can press © and select **Bolus** to stop the bolus, to see details on the amount of bolus insulin delivered, or to access the Bolus menu.

# **Easy Bolus**

The Easy Bolus feature allows you to quickly deliver a Normal bolus using only the button. Your pump must be in sleep mode to use the Easy Bolus feature.

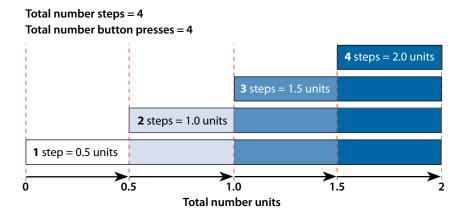
Before using Easy Bolus, you must turn on the feature and set the step size. The step size determines the number of units the bolus amount increases each time you press the \( \sigma \) button. Your Easy Bolus delivery is limited to 20 steps or your max bolus limit, whichever comes first.

To help you count your Easy Bolus steps, each time you press the  $\wedge$  button, your pump makes a different tone. There are five different tones that repeat in a pattern for every five steps you use. If your audio options are set to Vibrate only, the pump will not beep at all, and instead it will vibrate once with each key press.

## **Understanding Easy Bolus step sizes**

When setting up Easy Bolus, you can set the step size from 0.1 to 2.0 units. Your step size cannot be higher than your max bolus. Set the step size to a number that makes it easy for you to calculate your bolus amount.

The following example shows how your bolus amount is increased with each step, or each press of the  $\land$  button when using the Easy Bolus feature to deliver a bolus. In this example, the step size is 0.5 units. For a delivery of 2.0 units, you would need four steps, or press the  $\land$  button four times when using the Easy Bolus feature.



## **Setting up Easy Bolus**

The Easy Bolus option is available only after you turn on the feature.

#### To set up Easy Bolus:

- 1. Press © and go to the Easy Bolus screen.
  - Options > Delivery Settings > Easy Bolus
- 2. Select **Easy Bolus** to turn on the feature.
- 3. Set the **Step Size** amount (in units). You can set the step size from 0.1 to 2.0 units. Your step size cannot be higher than your max bolus.
- 4. Select **Save**.

## Delivering a bolus using Easy Bolus

Initially you should use the Easy Bolus feature while looking at the pump screen as you count the tones or vibrations.



WARNING: Never rely on beeps or vibrations alone while using the Easy Bolus feature. Always confirm your insulin delivery by looking at your pump screen. When using Audio or Vibrate, it is possible that an Audio or Vibration notification may not occur as expected if the speaker or vibrator in your pump malfunctions. Relying on beeps or vibrations while using Easy Bolus could result in over delivery of insulin.

To use the Easy Bolus feature, your pump must be in sleep mode. Your pump automatically goes into sleep mode two minutes after the screen turns off. You can manually put your pump into sleep mode by pressing and holding the button for about two seconds.

# To deliver a bolus using Easy Bolus:

1. While your pump screen is in sleep mode, press and hold ∧ for about one second. After your pump beeps or vibrates, release ∧. You can now start programming your Easy Bolus.



**Note:** If your pump does not respond when you press  $\wedge$ , it may not be in sleep mode, even if the screen is dark.

2. Press ∧ the number of times needed to set your bolus amount.

Each time you press A, your pump sounds a tone or vibrates, and your bolus amount increases by the number of units set for the step size.



**Note:** You cannot use  $\checkmark$  to select the Easy Bolus values. Pressing  $\checkmark$  cancels the Easy Bolus.

- 3. When you have reached the desired bolus amount, press and hold ∧ to confirm the amount. You should hear a confirmation tone or feel a vibration for each button press. Count to ensure the amount is correct. If the amount is not correct, press and hold ∨ until you hear a tone, and then start again from step 1.
- 4. When the bolus amount is confirmed, press and hold  $\wedge$  for about one second to deliver your bolus. Your pump beeps or vibrates. Your bolus starts immediately after the confirmation.



**Note:** If you do not start your bolus within 10 seconds, your Easy Bolus is cancelled, and you receive a message letting you know that your bolus was not delivered.

## **Preset Bolus**

The Preset Bolus feature allows you to set up in advance bolus deliveries you expect to use frequently. There are four Preset Bolus names that allow you to match a bolus to a meal with a known carb content: Breakfast, Lunch, Dinner, and Snack. There are four additional Preset Bolus names that can be set for other circumstances (Bolus 1 through Bolus 4).



**Note:** To set up a Dual Wave bolus or Square Wave bolus, the Dual Wave or Square Wave feature must be turned on.

## Setting up and managing Preset Bolus deliveries

# To set up Preset Bolus amounts:

1. Press © and go to the Preset Bolus Setup screen.

#### Options > Delivery Settings > Preset Bolus Setup

The Preset Bolus Setup screen appears, showing any existing Preset Bolus settings.

2. Select **Add New**.

The Select Name screen appears with the available Preset Bolus names.

3. Select the Preset Bolus you want to set.

The Edit screen for that particular Preset Bolus appears.

- 4. Select **Bolus** to set the bolus amount.
- 5. Select **Type** to set this as a Normal bolus, Square Wave bolus, or Dual Wave bolus.



**Note:** The **Type** field appears only when you have the Dual Wave bolus or Square Wave bolus features turned on.

If you set the type to Square Wave or Dual Wave, additional settings appear.

- 6. If you are setting up a Square Wave bolus or Dual Wave bolus, do the following:
  - For a Square Wave bolus, set the **Duration** of time for the bolus delivery.
  - For a Dual Wave bolus, adjust the Now/Square percentages as needed, then set the Duration of time for the Square Wave portion of the bolus.



**Note:** If you later turn off the Dual Wave or Square Wave feature, your existing Preset Bolus settings are still available for use.

7. Select **Save**.

# Editing, renaming, or deleting a Preset Bolus

You cannot delete, rename, or edit a Preset Bolus while it is delivering.



**Note:** You cannot edit a Dual Wave or Square Wave Preset Bolus when the Dual Wave or Square Wave features are turned off. You can, however, rename or delete a Dual Wave or Square Wave Preset Bolus when the features are turned off.

#### To edit, rename, or delete a Preset Bolus:

1. Press O and go to the Preset Bolus Setup screen.

#### Options > Delivery Settings > Preset Bolus Setup

The Preset Bolus Setup screen appears, showing any existing Preset Bolus settings.

- 2. Select the desired Preset Bolus.
- 3. Select **Options**.
- 4. Do one of the following:
  - Select Edit to adjust the Bolus value and Type, if applicable. If you change
    to a Square Wave bolus, you need to enter the Duration. If you change to
    a Dual Wave bolus, you need to enter the Now and Square amounts, and
    the Duration.
  - Select Rename to assign a different name to this Preset Bolus. When the Select Name screen appears, you can select any available name from the list.
  - Select **Delete** to delete this Preset Bolus.

## **Delivering a Preset Bolus**

Follow these steps to deliver a Preset Bolus. You must set up Preset Bolus deliveries before you can use the Preset Bolus feature. For more information, see *Setting up and managing Preset Bolus deliveries, on page 113.* 

#### To deliver a Preset Bolus:

1. Press © and go to the Preset Bolus screen.

#### Bolus > Preset Bolus

The existing preset bolus settings appear, showing your current BG value (if applicable) and any insulin that is still active from previous boluses. For more information about active insulin, see *About active insulin, on page 100*.

- 2. Select the Preset Bolus you want to deliver.
- 3. Verify your bolus amounts, and then select **Deliver Bolus**.

Your pump displays a progress bar on the Home screen when your bolus starts. The pump beeps or vibrates when delivery starts and when delivery finishes.

# Stopping a bolus delivery

The following procedures describe how to stop a Normal bolus or a Dual Wave bolus during the Now portion delivery, and how to stop a Square Wave bolus or a Dual Wave bolus during the Square portion delivery.



**Note:** This procedure describes how to stop a bolus that is in progress. It does not stop your basal insulin delivery. If you need to stop all insulin delivery, use the Suspend Delivery feature (press © and select **Suspend Delivery**).

# To stop a Normal bolus delivery or the Now portion of a Dual Wave bolus delivery:

1. While your pump is delivering your Normal bolus or the Now portion of a Dual Wave bolus, press © from the Home screen.



2. Select **Stop Bolus**, then select **Yes** to confirm.



**Note:** If you are delivering a Normal bolus and a Square Wave bolus at the same time, or a Normal bolus and the Square portion of a Dual Wave bolus at the same time, both boluses are stopped.

The Bolus Stopped screen appears and shows the amount of bolus delivered, and the original bolus amount you set up.



# To stop a Square Wave bolus delivery or the Square portion of a Dual Wave bolus delivery:

- 1. Press © from the Home screen.
- Select Bolus.
- 3. Select **Stop Bolus**.
- 4. To stop your bolus, select **Yes** to confirm.



**Note:** If you are delivering a Normal bolus and a Square Wave bolus at the same time, or a Normal bolus and the Square portion of a Dual Wave bolus at the same time, both boluses are stopped.

The Bolus Stopped screen appears and shows the amount of bolus delivered, and the original bolus amount you set up.



# Reservoir and infusion set

# Setting up the reservoir and infusion set

When you are ready to use your pump with insulin, make sure the time and date are correct on your pump. You must also program your settings as instructed by your healthcare professional.

You will need these items:

- MiniMed 670G insulin pump
- Vial of insulin (U100)
- MiniMed reservoir
- MiniMed-compatible infusion set and its user guide



WARNING: Clear the active insulin value before using your pump to deliver insulin for the first time. If you have practiced giving boluses on your pump before using insulin, the active insulin value could be inaccurate. This could result in inaccurate insulin delivery, and serious injury. For details, see *Clearing your active insulin, on page 170*.

## Removing the reservoir

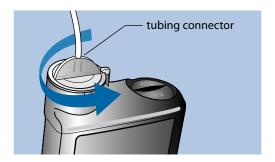
If this is the first time you are inserting a reservoir into your pump and you do not currently have a reservoir loaded, skip to *Rewinding your pump*, on page 122.



**WARNING:** Never insert the reservoir into the pump while the tubing is connected to your body. Doing so could result in an accidental infusion of insulin, which may cause low blood glucose (BG).

#### To remove your reservoir:

- 1. Wash your hands.
- 2. Remove the entire infusion set from your body.
- 3. If you have the optional activity guard attached to the reservoir compartment on your pump, remove it now.
- 4. Turn the tubing connector a half-turn counter-clockwise, then pull the reservoir and connector out from the pump.



5. Dispose of the used reservoir and infusion set according to local regulations, or contact your healthcare professional for disposal information.

# Rewinding your pump

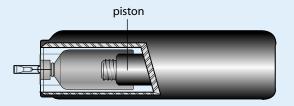


**WARNING:** Always make sure the infusion set is disconnected from your body before you rewind your pump or fill the infusion set tubing. Never insert the reservoir into the pump while the tubing is connected to your body. Doing so could result in an accidental infusion of insulin, which can cause hypoglycemia.

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



**Note:** The piston is located in the reservoir compartment of your pump. It engages the reservoir and pushes insulin through the tubing.



## To rewind your pump:

1. Press © and go to the New Reservoir screen.

## Options > Reservoir & Tubing > New Reservoir

The New Reservoir screen appears.

If you have not yet removed the infusion set and reservoir, do so now.



#### 2. Select **Rewind**.

The piston in the reservoir compartment of your pump returns to its starting position. This may take several seconds. During this process, a "Rewinding" message appears.

Another message appears to let you know that your pump has finished rewinding, and then the New Reservoir screen appears.

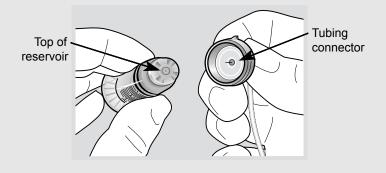


3. Follow the instructions in the next section to fill your reservoir.

## Filling the reservoir



WARNING: Do not use the reservoir or infusion set if any liquid gets on the top of the reservoir or inside the tubing connector (as shown in the image). Liquid can temporarily block the vents. This may result in the delivery of too little or too much insulin, which can cause hyperglycemia or hypoglycemia. If any liquid gets on the top of the reservoir or inside the tubing connector, start over with a new reservoir and infusion set.

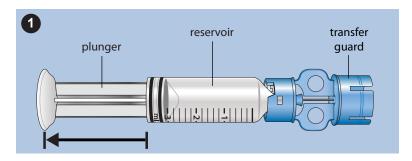




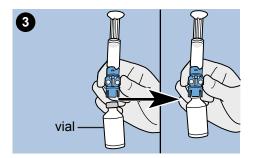
**WARNING:** Always allow your insulin to reach room temperature before use. Cold insulin can cause air bubbles in the reservoir and tubing, which may result in inaccurate insulin delivery.

#### To fill the reservoir, do these steps:

1. Remove the reservoir from the package, and fully extend the plunger.

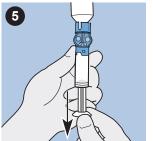


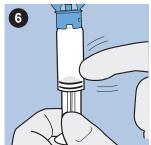
- 2. Swab the vial with alcohol (not shown).
- 3. Press the transfer guard onto the vial without pushing down on the plunger.



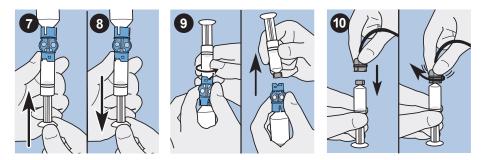
- 4. Push down on the plunger to pressurize the vial. Hold down the plunger rod.
- 5. While still holding down the plunger rod, flip the vial over so the vial is on top. Slowly pull down on the plunger to fill the reservoir.
- 6. Gently tap the side of the reservoir to make any air bubbles rise to the top of the reservoir.



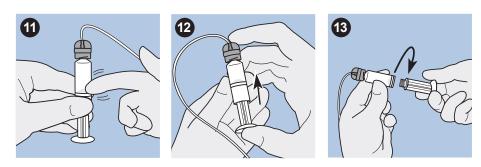




- 7. Slowly push up on the plunger just enough to remove any air bubbles from the reservoir.
- 8. Slowly pull down on the plunger to fill the reservoir to the number of units desired.
- 9. To avoid getting liquid on the top of the reservoir, flip the vial over so that it is upright. Turn the reservoir counter-clockwise, then pull straight up to remove the reservoir from the transfer guard.
- 10. Place the tubing connector onto the reservoir. Turn the connector clockwise, pressing gently against the reservoir until you feel it slide in. Push in and continue turning until the reservoir and the connector lock with a click.



- 11. Tap the side of the reservoir to remove any air bubbles.
- 12. To purge air bubbles that have risen to the top of the reservoir, push up on the plunger until you see insulin in the tubing.
- 13. Without pulling, turn the plunger counter-clockwise to remove it from the reservoir.



14. Select **Next** from the New Reservoir screen.



The New Reservoir screen now instructs you to place the reservoir in your pump.



15. Follow the instructions in the next section to insert the reservoir into the reservoir compartment of your pump immediately after filling it.

## Inserting the reservoir into your pump

Be sure to perform the following steps in the order they are presented.



**Note:** Do not insert the reservoir into your pump until you have received training.

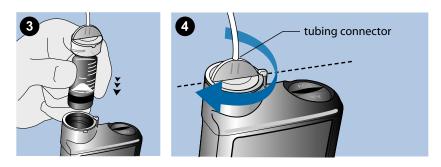


**WARNING:** Always rewind your pump before inserting a new reservoir. Failing to rewind your pump could result in an accidental infusion of insulin, which can cause hypoglycemia.

Never insert the reservoir into the pump while the tubing is connected to your body. Doing so could result in an accidental infusion of insulin, which can cause hypoglycemia.

#### To insert the reservoir into your pump:

- 1. If you are using the pump for the first time, remove the shipping cap from the reservoir compartment.
- 2. Rewind your pump if you have not yet done so. See *Rewinding your pump, on page 122* for more information.
- 3. Insert the reservoir into the top of the reservoir compartment.
- 4. Turn the tubing connector approximately a half-turn clockwise until the connector is locked. The tubing connector should be aligned horizontally with the pump case as shown in the following example.



5. Your pump should be displaying the New Reservoir screen shown in the following example. Select **Next** to continue.



6. Select and hold **Load** until you see a checkmark on the screen and your pump beeps or vibrates. Holding **Load** moves the piston up in the reservoir compartment until it engages with the bottom of the reservoir.





**Note:** If you press the **Back** button after the loading process begins, a Loading incomplete alarm will occur.

When the loading process is completed, the following screen appears.



- 7. Select **Next** to continue.
- 8. Follow the instructions in the next section to fill the tubing with insulin.

## Filling the tubing

You need to fill the infusion set tubing with insulin before you insert the set into the body.



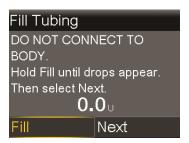
**WARNING:** Always make sure the infusion set is disconnected from your body before you rewind your pump or fill the infusion set tubing. Never insert the reservoir into the pump while the tubing is connected to your body. Doing so could result in an accidental infusion of insulin, which can cause low BG.



**WARNING:** Always check your tubing for air bubbles. Continue to press Fill until the bubbles have been removed from the tubing. Air bubbles may result in inaccurate insulin delivery.

#### To fill the tubing:

 After you load your reservoir and select **Next** from the Load Reservoir screen, the Fill Tubing screen appears.



- 2. Select and hold **Fill**. Your pump beeps six times to let you know it is positioning the reservoir. Continue holding **Fill** until insulin droplets form on the tip of the infusion set needle, then release. Your pump beeps as it fills the tubing, and the amount of insulin you are using appears on the screen.

  If you get the Max Fill Reached alarm, it means you have used more than 30 units of insulin to fill your tubing. For details, go to *Pump alarms, alerts, and messages, on page 254*, and see the description for Max Fill Reached.
- Select Next to continue.
- 4. Follow the instructions in the next section to insert the infusion set into your body before filling the cannula.

## Inserting the infusion set



**WARNING:** Do not remove the reservoir from the pump while the infusion set is connected to your body. Doing so could result in the delivery of too little or too much insulin, which can cause high BG or low BG.

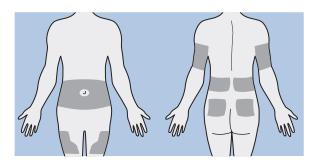
You must have completed the following procedures, as described previously, before inserting the infusion set into your body:

- Rewinding your pump.
- Filling your reservoir.
- Inserting the reservoir into pump.
- Filling the tubing with insulin.

Shown here are the best body areas (shaded) for infusion set insertion. Avoid the 2-inch (5.0 cm) area around the navel to help ensure a comfortable infusion site and to help with adhesion.



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

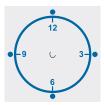




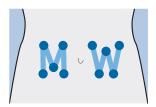
**Caution:** Always change your infusion set every two to three days. Using the same infusion set for an extended period of time can cause infusion set occlusion or site infection.

To keep sites healthy, some people find it helpful to use a visual scheme to help them rotate their insertion sites in an organized way. For example, here are two commonly used methods. For maximum effectiveness, use both methods, alternating between them:

• Visualize an imaginary clock drawn on your abdomen surrounding your belly button. Rotate infusion set insertion sites by starting at 12 o'clock and then rotate the site clockwise to 3 o'clock, 6 o'clock, and so on.



• Imagine a letter M or a letter W on either side of your belly button. Start at the end of one letter and proceed through the letter, rotating to each intersection in turn.



Medtronic Diabetes offers a variety of infusion sets for your pump.



**Note:** Always refer to your infusion set user guide for instructions on inserting an infusion set.

After your infusion set is inserted, see *Filling the cannula*, on page 132 to fill the infusion set cannula.

## Filling the cannula

Filling the soft cannula with insulin is required after the infusion set is inserted into your body and the introducer needle is pulled out. The insulin amounts required to fill the cannula depend on the type of infusion set you are using. Refer to your infusion set instructions for this information.



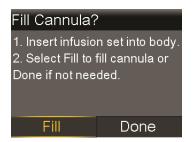
**Note:** If you are using an infusion set with a needle, you do not need to fill the cannula. Select **Done** when the system prompts you to continue with the fill process.



WARNING: Never leave your pump on the Fill Cannula? screen. Insulin delivery is suspended while on the Fill Cannula? screen. Always finish filling your cannula or return to the Home screen to avoid continued insulin delivery suspension. Failing to do this can result in hyperglycemia.

#### To fill the cannula:

1. After you fill your tubing and insert your infusion set, the Fill Cannula? screen appears.





**Note:** If your screen turns off before you are ready to fill your cannula, press any button on your pump to turn it on again.

 To fill your cannula now, select Fill. If you are using an infusion set with a needle, you do not need to fill the cannula. Select Done to skip this step.
 The Fill Cannula screen appears.



Adjust the Fill amount for your particular infusion set, and then select Fill
 Now. If you are unsure about the fill amount, see the instructions that came
 with your infusion set.

 As the cannula starts filling, your screen displays the amount of units being delivered. The pump beeps or vibrates when the delivery is complete.
 After the cannula is filled, the Home screen appears. Your pump is now ready to deliver insulin.

#### To stop filling the cannula:

1. Select **Stop Filling** to stop filling the cannula.



2. Select Yes.

The Fill Stopped screen appears confirming amount delivered.

3. Select **Done**.

## Disconnecting your infusion set

Always refer to your infusion set user guide for instructions on how to disconnect your infusion set.

## Reconnecting your infusion set

Always refer to your infusion set user guide for instructions on how to reconnect your infusion set.

## Meter

The MiniMed 670G insulin pump can only wirelessly connect with a CONTOUR® NEXT LINK 2.4 meter to receive remote blood glucose (BG) readings. If you do not connect a CONTOUR NEXT LINK 2.4 meter to your pump, you must enter your blood glucose readings manually. To wirelessly connect your pump and meter, you need the following items:

- MiniMed 670G insulin pump
- CONTOUR NEXT LINK 2.4 meter
- CONTOUR NEXT LINK 2.4 meter user guide

## **About your CONTOUR NEXT LINK 2.4 meter**

You can set up your pump to automatically receive blood glucose readings from your CONTOUR NEXT LINK 2.4 meter. When the pump is on the Home screen, it beeps or vibrates when it receives a blood glucose reading from the meter. After confirming the BG value, your BG Meter screen appears, where you can view your current blood glucose reading and, if necessary, deliver a bolus. Once received from the meter, you must confirm the value on your pump. Your BG values will appear on your pump screen for 12 minutes, along with any insulin that is still active from any previous boluses. If your blood glucose reading is outside the range of 70 to 250 mg/dL, the pump displays an alert. In this case, treat your low blood glucose or high blood glucose as directed by your healthcare professional.



**Note:** You can wirelessly connect up to six CONTOUR NEXT LINK 2.4 meters to your pump. Only one CONTOUR NEXT LINK 2.4 meter can communicate with your pump at a time. Your pump will only display the

blood glucose reading from the latest value received from the connected CONTOUR NEXT LINK 2.4 meter. In order for your pump to receive the blood glucose reading, you must confirm the reading on your pump.

The CONTOUR NEXT LINK 2.4 meter may not be available in all countries.

You can also deliver a Normal Bolus or Preset Bolus from your CONTOUR NEXT LINK 2.4 meter. For more information about setting up your pump to use the Remote Bolus feature, see *Setting up Remote Bolus*, *on page 138*. Consult your healthcare professional before using the Remote Bolus feature.



**Note:** The Remote Bolus feature is not available when in Auto Mode.

## Wirelessly connecting your pump and meter

Always refer to your CONTOUR NEXT LINK 2.4 meter user guide for instructions on connecting the meter to the pump.

## **Setting up Remote Bolus**

Remote Bolus allows you to send a Normal Bolus or Preset Bolus remotely from your meter. To access this option, your meter and pump must be wirelessly connected, and the Remote Bolus option on your pump must be turned on. Consult your healthcare professional before using the Remote Bolus feature.



**Note:** The Remote Bolus feature is not available in Auto Mode, even if the option is turned on.

The following procedure describes how to turn the Remote Bolus feature on or off. For information on using Remote Bolus, see the user guide that came with your CONTOUR NEXT LINK 2.4 meter.



**Note:** Remote Bolus default setting is on.

To turn on or off Remote Bolus:

- Make sure that your pump and CONTOUR NEXT LINK 2.4 meter are connected.
- 2. Press 

  and go to the Remote Bolus screen.

#### Options > Utilities > Remote Bolus

The Remote Bolus screen appears.

- 3. Select **Remote Bolus** to turn the feature on or off.
- 4. Select Save.

## Deleting a meter from your pump

Follow this procedure to delete your CONTOUR NEXT LINK 2.4 meter from the pump.

#### To delete the meter from the pump:

1. Press © and go to the Manage Devices screen.

## Options > Utilities > Device Options > Manage Devices

The Manage Devices screen appears.

- 2. Identify and select your meter by the serial number. See your CONTOUR NEXT LINK 2.4 meter user guide for instructions on locating your serial number.
- Select Delete.
- 4. A screen appears confirming that you would like to delete the device. Select **Yes** to confirm or **No** to cancel.

# **History and events**

This chapter describes the History and Event Markers features. The History screens provide personal pump therapy details, including information about your insulin deliveries, blood glucose (BG) meter readings, sensor glucose (SG) readings, and any alarms and alerts you received. The Event Markers feature allows you to enter and save information, such as manual BG readings, carbohydrates eaten, and exercise.

You can view updates on the Daily History summary screen to learn the following information about your therapy with your pump over a period of time:

- the automatic and manual transitions into and out of Auto Mode
- the start time and the end time for all your Temp Target events
- the correction boluses that your pump automatically calculates for you

For more information about the Auto Mode feature on your pump, refer to *Auto Mode, on page 229*.

## **History**

The History feature includes the Summary, Daily History, and Alarm History screens. The SG Review and ISIG History screens are available if you are using the Sensor feature.

## Summary screen

The Summary screen shows details about past insulin deliveries and meter readings. If you are using a sensor, the Summary screen also shows information about your sensor alerts and sensor glucose readings.

You can view historical details for a single day, or you can select multiple days to view an average of all the results for the number of days that you selected.

#### To view your Summary screen:

1. Press © and go to the Summary screen.

#### Options > History > Summary

- 2. Select the time period for the Summary screen.
  - The Summary screen appears, showing information for the number of days that you selected.
- 3. You can scroll down to view the entire screen. If you are using the 1 Day view, you can use the < and > buttons on your pump to view the results for each day in history.

## **Understanding the Summary screen**

The Summary screen separates information into these categories:

- Auto Mode
- overview
- bolus
- BG meter
- sensor
- low management mode

## **Summary screen: Auto Mode**

The following table describes the Auto Mode portion of the Summary screen.

Name	Description
Time in Auto Mode	number of hours / percent of time in Auto Mode
Time in target range	number of hours / percent of time in target range (70 mg/dL to 180 mg/dL)
Time below range	number of hours / percent of time below target range (below 70 mg/dL)
Time above range	number of hours / percent of time above target range (above 180 mg/dL)

#### Summary screen: overview

The following table describes the overview portion of the Summary screen.



**Note:** If you are viewing a single day of Summary results, then the values shown are the actual results for the selected day. If you are viewing more than one day of Summary results, then the value is an average of the days that you selected.

Name	Description
TDD	Total daily dose of insulin units.
Basal	Insulin units devoted to basal delivery.
	<ul> <li>Percentage of insulin devoted to basal delivery.</li> </ul>
Bolus	Insulin units devoted to bolus delivery.
	<ul> <li>Percentage of insulin devoted to bolus delivery.</li> </ul>
Total Carbs	Daily carbohydrate amount, in grams.

#### **Summary screen: bolus**

The following table describes the bolus portion of the Summary screen:



**Note:** If you are viewing a single day of Summary results, then the values shown are the actual results for the selected day. If you are viewing more than one day of Summary results, then the value is an average of the days that you selected.



**Note:** The Summary screen does not show a bolus that has had both Carb and BG corrections.

Name	Description
Carb bolus only	<ul> <li>Total insulin units delivered using the Bolus Wizard or Auto Mode Bolus with food amount only.</li> </ul>
	<ul> <li>Number of times the Bolus Wizard or Auto Mode Bolus delivered a food bolus only.</li> </ul>

Name	Description
BG Correction Only	<ul> <li>Total insulin units delivered using the Bolus Wizard or Auto Mode Bolus with BG correction amount only.</li> </ul>
	<ul> <li>Number of times the Bolus Wizard or Auto Mode Bolus delivered a BG correction bolus only.</li> </ul>

#### Summary screen: BG meter

The following table describes the BG meter portion of the Summary screen:

Name	Description
BG	Total number of BG meter readings, including readings from a CONTOUR NEXT LINK 2.4 meter and BG meter readings entered manually.
Average BG	Average BG meter readings.
BG Standard Dev	Standard deviation of BG meter readings.
Low BG	Lowest BG meter reading.
High BG	Highest BG meter reading.

#### Summary screen: sensor

The following table describes the sensor portion of the Summary screen. If the sensor feature has never been turned on, this portion of the screen does not appear. If the sensor feature was turned on at least once, but is currently turned off, this portion of the screen appears gray.

Name	Description
SG Average	Average sensor glucose value.
SG Std. Dev.	Standard deviation of the SG readings.

## Summary screen: low management mode

The following table describes the low management mode portion of the Summary screen. For details on the low management feature, see *SmartGuard Technology*, on page 178.

Name	Description
Suspend before low	The average number of Suspend before low events per day.

Name	Description
Suspend on low	The average number of Suspend on low events per day.
Time suspended by sensor	The average duration (amount of time) suspended as a result of Suspend on low or Suspend before low events per day.

## **Daily History**

The Daily History screen displays a list of actions you performed on your pump or event entries that you made for the selected day, such as your BG meter readings, SG calibrations, bolus deliveries, any temp basal rates you have used, and so on. The list displays the most recent action or event first. From this list, you can display further details about any action or event.

#### To view your Daily History:

1. Press 

and go to the Daily History screen.

#### Options > History > Daily History

A list of dates appears.

- 2. Select a specific date of history to view. A list appears with any pump actions or events entered on the specified day.
- 3. You can select any item in the list to open the Detail screen, which displays more information about the selected action or event. For example, if you view the details of a bolus delivered using the Bolus Wizard, the Detail screen shows you all of the data associated with that bolus, such as the BG correction amount, active insulin adjustment, carbs entered, and calculated bolus

## **Alarm History**

The Alarm History screen displays a list of alarms and alerts that occurred on the selected day. The list displays the most recent alarm or alert first. From this list, you can display further details about any alarm or alert.

## To view your Alarm History:

1. Press © and go to the Alarm History screen.

## Options > History > Alarm History

A list of dates appears.

- 2. Select a specific date of alarm history to view. A list appears showing any alarms or alerts that occurred on the specified day.
- 3. You can select any alarm or alert in the list to open the Alarm Detail screen, which displays more information about the selected alarm or alert.

## **Using Sensor Glucose Review**

The Sensor Glucose Review feature allows you to view a graph of your SG history, based on high and low limits you enter. You can view information for one day, or view an average of your SG data over a number of days.

This Sensor Glucose Review feature is available if you are using the Sensor feature.



**Note:** The high and low limits that you set are for the purpose of viewing your sensor glucose data only, and are not the same as the High and Low Alert Limits used for your sensor alerts. Changing your Sensor Glucose Review limits does not affect your high and low glucose limits.

#### To review your sensor glucose history:

1. Press © and go to the SG Review screen.

#### Options > History > Sensor Glucose Review

The SG Review screen appears. The high and low limits that appear are either the values you entered for the last SG Review, or the default values of 180 mg/dL for the High Limit and 70 mg/dL for the Low Limit.



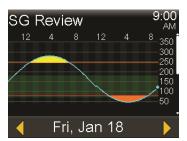
2. Enter the High Limit and Low Limit that you want to use for the sensor glucose review.

There must be a minimum of 20 mg/dL difference between the high and low SG limits.

3. Enter the number of days of sensor glucose history to average, and select **Next**.

A graph of your SG data appears. If you specified one day of history to view, the graph shows details about when your SG was above, below, or within your specified limits. You can scroll down to view the number of hours and percentage of time you were above, within, and below your SG limits.

If you have no data saved, a message appears on the screen letting you know there is no data available.



If you view information for multiple days, the graph shows the average percentage of time that your SG was above, below, or within your specific limits.



## **ISIG History**

ISIG is an electronic reading from your sensor that is used in conjunction with your calibration numbers to calculate the current glucose reading on your pump.

## To review your ISIG History:

1. Press © and go to the ISIG History screen.

## Options > History > ISIG History

The ISIG History screen displays an hourly sequence for one 24-hour day.

2. Scroll through the list to highlight an hour, then press © to select it.

Use the  $\wedge$  or  $\vee$  buttons to scroll through the listing of ISIG readings, which occur every five minutes.

#### **Event Markers**

The Event Markers feature allows you to electronically save certain types of information.

When using this feature, enter events when they happen because the system records the time of the entry. You cannot change entries after you have put the information into your pump. You can view your saved events in the Daily History screen.

The entered information can be sent to CareLink® Personal therapy management software. There it can be used to generate reports you can share with your healthcare professional.

#### To enter Event Markers:

1. Press O and go to the Event Markers screen.

#### Options > Event Markers

2. Select and enter event information for any of the following categories:

BG



If you are not using the Bolus Wizard, Auto Mode Bolus, manual entry, or a CONTOUR NEXT LINK 2.4 meter to record your BG meter readings in your pump, you can enter them here. If you are using a sensor, you may use a BG meter reading you enter here for calibration. You can also enter non-calibration BG meter readings, such as those readings taken when eating or when your BG is rising or falling rapidly.

Injection



Enter the number of units of any insulin you have given by injection.



**Note:** Insulin units entered using the injection event marker are not added to your Active Insulin amount tracked on the pump.

Food	7	Enter the amount of carbohydrates that you have eaten or drunk that have not been entered in the Bolus Wizard or Auto Mode Bolus. For example, you might enter carbs that you ate to correct a low BG.
		Do not enter carbs here that you have already entered in the Bolus Wizard or Auto Mode Bolus.
Exercise	Ž	Enter the length of time you exercised. It is helpful to be consistent and enter the information either before or after each time you exercise.
Other		Examples of Other event markers can include when you take medications, when you feel ill, or when you are under stress.



## Reminders

Reminders help you remember to do important routine activities. There are specific reminders that prompt you to check your blood glucose (BG) after a bolus, give a food bolus, check your reservoir level, and change your infusion set. There are also personal reminders you can use for any purpose. If you have the sensor feature turned on, the calibration reminder prompts you to calibrate your sensor.

#### Personal reminders

The Personal reminders include six numbered reminders, along with the specific reminders for BG Check and Medication.

#### To create a new Personal reminder:

1. Press © and go to the Personal screen.

Options > Reminders > Personal

Select Add New.

The Select Name screen appears showing the available reminders.

- 3. Select the reminder that you want to set.
  - The Edit screen appears for the selected reminder.
- 4. Enter the time that you want the reminder to occur.
- 5. Select **Save**. The Personal reminder occurs at the specified time each day unless you change or delete it.

## To edit, rename or delete an existing Personal reminder:

1. Press © and go to the Personal screen.

#### Options > Reminders > Personal

- 2. Select the reminder that you want to change.
- 3. Do one of the following:
  - Select **Reminder** to turn this reminder on or off.
  - Select **Edit** to change the time of the reminder.
  - Select **Rename** to select a new name for this reminder.
  - Select **Delete** to delete this reminder.

## **Bolus BG Check reminder**

Bolus BG Check reminder helps you remember to check your blood glucose after a bolus. After you start a bolus, the pump asks you when you want to be reminded to check your blood glucose. The timer counts down from the time the bolus started.



**Note:** The Bolus BG Check reminder is not available when you deliver a bolus using the Remote Bolus feature from your CONTOUR NEXT LINK meter.

#### To turn on or turn off Bolus BG Check reminders:

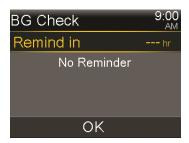
1. Press © and go to the BG Check screen.

Options > Reminders > Bolus BG Check

- 2. To turn the reminder on or off, select **Reminder**.
- Select Save.

## To use a Bolus BG Check reminder when delivering a bolus:

1. After you turn on the Bolus BG Check reminder, each time you start a bolus, the following screen appears:



2. Enter a time from 30 minutes to 5 hours, in 30 minute increments. Select **OK**. If you do not want a reminder after the bolus, select the dashes without adding a time, and then select **OK**. If needed, press ∨ to return to the dashes.

#### Missed Meal Bolus reminder

The Missed Meal Bolus reminder alerts you if a bolus is not delivered within a time period that you set. These time periods are usually set around your typical meal times to help ensure a meal bolus is not missed. You can set up to eight Missed Meal Bolus reminders.

#### To create a new Missed Meal Bolus reminder:

- 1. Press ◎ and go to the Missed Meal Bolus screen.
  - Options > Reminders > Missed Meal Bolus
- Select Add New.
- 3. Select **Start Time**, and enter a time.
- 4. Select **End Time**, and enter a time. The time range is from one minute to 24 hours.
- 5. Select **Save**.

## To turn on or off, edit, or delete existing Missed Meal Bolus reminders:

- 1. Press © and go to the Missed Meal Bolus screen.
  - Options > Reminders > Missed Meal Bolus
- 2. Select one of the reminders that you have already created.
- 3. Change any of the following:
  - Select Reminder to turn this reminder on or off.
  - Select **Edit** to change the time of this reminder.

Select **Delete** to delete this reminder.

#### Low Reservoir reminder

The Low Reservoir reminder alerts you when the insulin level in your reservoir is low. This feature allows you to program your pump to generate a reminder before your reservoir is empty. You can adjust the Units amount to notify you when your reservoir has a specified number of units remaining, and then alert you again when half of the remaining units are used.



**Note:** The number of units remaining in your reservoir can be found on the Quick Status screen. For more information on accessing the Status Screens, see *Status screens*, on page 55.



WARNING: When the pump detects a low reservoir condition during a bolus or fill cannula delivery, the Low reservoir alert displays. When delivery has finished, check the amount left in the reservoir to make sure your pump does not run out of insulin, as this could lead to an under delivery of insulin, which may cause hyperglycemia.

## Low Reservoir reminder setup:

- 1. Press © and go to the Low Reservoir screen.
  - Options > Reminders > Low Reservoir
- 2. Select **Units** to enter the number of units. You can set a value from 5 units to 50 units.
- Select Save.

## **Set Change reminder**

The Set Change reminder helps you remember to change your infusion set. After you turn on this reminder, it automatically tracks the time between infusion set changes and reminds you to change your infusion set.

#### To turn on or off, or change the Set Change reminder:

1. Press © and go to the Set Change screen.

#### Options > Reminders > Set Change

- 2. Select **Reminder** to turn the reminder on or off. If you turn on the reminder, select **Time** and choose two or three days for the reminder.
- Select Save.

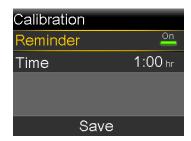
#### **Calibration reminders**

The Calibration reminder is available if you are using the Sensor feature. This feature helps you remember to calibrate your sensor. For example, if you set your reminder to four hours, you receive a Calibrate By alert four hours before the next BG meter reading is due.

#### To turn on or off, or change the Calibration reminder:

1. Press © and go to the Calibration screen.

## Options > Reminders > Calibration



- 2. Select **Reminder** to turn the reminder on or off.
- 3. If you turn on the reminder, select **Time** and enter a time between 5 minutes and 6 hours. The time can be set in 5 minute increments.
- 4. Select Save.



# **General settings**

This chapter provides information about common tasks for various settings.

# **Airplane Mode**

Airplane Mode temporarily stops wireless communication with your pump. Use this mode during airline travel when you are instructed to turn off wireless devices.



WARNING: Do not rely on glucose sensor-enabled features when Airplane Mode is on because the pump does not receive sensor readings from the transmitter. Glucose sensor-enabled features include CGM, SmartGuard, and Auto Mode. When using Airplane Mode, always rely on your blood glucose (BG) values when making therapy decisions to avoid hypoglycemia or hyperglycemia.

Check airline policies for specific instructions about operating medical devices during a flight. Check local airport policies for specific instructions about medical devices and security procedures.

The following table provides special instructions when using Airplane Mode and additional devices with your pump:

When using this	Do this:	
device:		
CONTOUR NEXT	When Airplane Mode is turned on, the Remote Bolus feature is not	
LINK 2.4 meter	available, and you must enter BG meter readings manually. When	
	Airplane Mode is turned off, use your meter normally.	

When using this device:	Do this:
Non-linked BG meter	Use your non-linked BG meter normally whether Airplane Mode is on or off.
Sensor and transmitter	When Airplane Mode is turned on, your pump does not receive sensor readings from your transmitter.
	When Airplane Mode is turned off, it can take up to 15 minutes before the pump and the transmitter start to wirelessly communicate again. The transmitter begins to send up to the last 10 hours of sensor data to the pump.
	When you turn off Airplane Mode:
	<ul> <li>If Airplane Mode was turned on for six hours or less, wait</li> <li>15 minutes for the sensor and transmitter to wirelessly send your pump the missing sensor glucose readings.</li> </ul>
	• If Airplane Mode was turned on for more than six hours, disconnect and reconnect the transmitter and sensor, and then select <b>Reconnect Sensor</b> when it appears on the pump screen.

## To turn on or turn off Airplane Mode:

I. Press ◎ and go to the Airplane Mode screen.

Options > Utilities > Airplane Mode

- 2. Select **Airplane Mode** to turn the feature on or off.
- 3. Select **Save**.

When Airplane Mode is turned on, the Home screen shows the Airplane Mode icon in place of the Connection icon.



**Note:** Airplane Mode cannot be used while in Auto Mode. To use Airplane Mode, you must be in Manual Mode. To return to Auto Mode after using Airplane Mode, Auto Mode must be turned on and a BG must be entered. For instructions on turning Auto Mode on or off, see *Setting up Auto Mode, on page 231*. Additional steps may be

required before you can return to Auto Mode. Follow the instructions on your pump screen. For more information, see *Auto Mode Readiness, on page 233*.

# **Audio Options**

The Audio Options screen lets you set the audio and vibrate options. It also lets you change the volume of most alerts and notifications if audio is enabled.

The audio setting that you are currently using appears on the Home screen. An audio icon will indicate if your settings are audio only , vibrate only ., or audio and vibrate both . For more information, see *Status icons*, *on page 50*.

## To adjust the audio and vibrate settings:

- 1. Press © and select **Audio Options** to go to the Audio Options screen.
- 2. Select **Audio** or **Vibrate** for the option you want to use. You can use one option or both.
- 3. If the Audio option is enabled, the volume can be changed. Select **Volume** and use the left or right button to adjust to the desired level.
- 4. Select **Save**.

# **Auto Suspend**

Auto Suspend is a safety feature that stops all insulin delivery and sounds an alarm if you do not press any buttons for a specified period of time. For example, your healthcare professional may have you set the time based on the number of hours that you typically sleep at night. Discuss with your healthcare professional how to best use this feature



**Note:** The Auto Suspend feature continues working when your pump switches to Auto Mode.

# To set up Auto Suspend:

1. Press © and go to the Auto Suspend screen.

Options > Delivery Settings > Auto Suspend

- Select Alarm.
- 3. Select **Time** and enter the number of hours that you want to set.
- 4. Select Save.

# **Block Mode**

The Block Mode feature allows caregivers, such as parents of a young child, to restrict access to critical pump settings.



**WARNING:** Always monitor pump use during Block Mode. You can manually suspend while in Block Mode. This could result in hyperglycemia and ketoacidosis.

When Block Mode is on, you cannot start a new bolus delivery, start a new basal pattern, or start a new temp basal delivery. However, any previous bolus and basal deliveries continue normally, and the pump user can stop a bolus delivery at any time.

When your pump is in Block Mode, you can suspend insulin delivery, receive SG values, receive BG values from your CONTOUR NEXT LINK 2.4 meter, review history, test the pump, and clear alarms and alerts. However, you cannot change any settings.



**Note:** The Block Mode feature has some differences when your pump is in Auto Mode. See *Block Mode when in Auto Mode, on page 238.* 



WARNING: Always monitor pump use during Block Mode. Block Mode does not prevent Remote Bolus deliveries from your CONTOUR NEXT LINK 2.4 meter. When your pump is in Block Mode, you can still deliver a bolus from your CONTOUR NEXT LINK 2.4 meter using the Remote Bolus feature.

#### To turn Block Mode on or off:

1. Press @ and go to the Block Mode screen.

Options > Utilities > Block

- 2. Select **Block Mode** to turn the feature on or off.
- 3. Select **Save**. While Block Mode is turned on, a lock icon appears on the Home screen.
  - If you are turning on Block Mode, a message appears asking if you would like to change your Remote Bolus setting as well. This message appears only if the Remote Bolus setting was on.
- 4. Select Yes to change Remote Bolus setting.
- 5. Select **Remote Bolus** to turn the feature on or off.
- 6. Select **Save**.

# **Display Options**

The Display Options allow you to increase or decrease the brightness of your screen. From the Display Options screen, you can also adjust the amount of time the backlight stays on after you press a button.

# To adjust the display options:

- 1. Press © and go to the Display Options screen.
  - Options > Utilities > Display Options
- 2. Select **Brightness** to adjust the brightness of your screen. You can set a level from 1 to 5, or select **Auto** to have the screen automatically adjust to your current environment.



**Note:** The brightness setting you select can affect the life of your battery. For a longer lasting battery, consider using a lower level setting.

3. Select **Backlight** to adjust the timeout for the backlight on your pump screen. You can select 15 seconds, 30 seconds, 1 minute, or 3 minutes.



**Note:** The backlight can affect the life of your battery. For a longer lasting battery, consider setting the screen timeout to 30 seconds.

4. Select Save.

# Language

You can change the language that your pump uses to display information.

# To change the Language setting:

1. Press ◎ and go to the Language screen.

Options > Utilities > Language

A checkmark indicates which language is active.

- 2. Select your desired language.
- 3. Select **Yes** when the confirmation message appears.

# Managing your pump settings

Manage Settings lets you save, restore, or clear your settings.

The following table describes the Manage Settings options:

Save Settings	Saves a record of your current settings that you can use if a future event requires you to re-enter your settings.
Restore Settings	Allows you to restore your settings, using the backup settings that you saved using the Save Settings feature.
Clear All Settings	Erases your settings and returns them to the factory defaults.  To use your pump again after clearing all settings, you must use Restore Settings. This enables you to restore a previous version of your settings or enter your settings again.
Clear Active Insulin	This option appears only if you have never cleared your active insulin. It clears both Active Insulin and sets your Total Daily Dose to 0 for Auto Mode. Use this option when you are ready to use your pump with insulin for the first time or when directed by your healthcare professional. You can only clear your active insulin once.
Settings History	Displays a history of recent activities that relate to managing your settings, such as saving, clearing, and restoring your settings.

# Saving your settings

Saving a record of your settings allows you to restore your settings at a later date, if necessary.

## To save your current settings:

1. Press 

and go to the Manage Settings screen.

#### Options > Utilities > Manage Settings

- 2. Simultaneously press and hold > and \ until the Manage Settings menu appears.
- Select Save Settings.

If these are the first settings you have saved, a message appears telling you that your settings are saved.

If you have previously saved settings, a message appears asking if you would like to replace your previous settings with your current settings. Select **Yes** to accept. Select **No** to cancel.

# **Restoring your settings**

This option allows you to replace your current pump settings with the last settings that you have saved. The Restore Settings menu option is available only if you have previously saved your settings.

# To restore your previous settings:

1. Press © and go to the Manage Settings screen.

# Options > Utilities > Manage Settings

- 2. Simultaneously press and hold > and \ until the Manage Settings menu appears.
- 3. Select **Restore Settings**.
- 4. To replace your current settings with your previous settings, select **Yes**. To cancel, select **No**.

# **Clearing your settings**

The Clear All Settings feature erases your current settings and returns them to the factory defaults. After you clear your settings, your pump displays the Startup Wizard, where you can re-enter your pump settings. You must re-enter your settings to continue using your pump.

The Clear All Settings feature does not delete wireless connections to other devices, such as your transmitter or meter.



**Caution:** Do not clear your pump settings unless directed by your healthcare professional. If you clear your pump settings, it will be necessary to reprogram all your personal pump settings as directed by your healthcare professional.

#### To clear all your settings:

- 1. Make sure the pump is not connected to your body.
- 2. Press © and go to the Manage Settings screen.

#### Options > Utilities > Manage Settings

- 3. Simultaneously press and hold > and \ until the Manage Settings menu appears.
- 4. Select Clear All Settings.
  - A confirmation screen appears asking if you want to clear all your settings.
- 5. To continue clearing your settings, select **Yes**. If you do not want to clear your settings, select **No**.
  - If you clear your settings, your pump displays the Welcome screen and continues to the Startup Wizard. For more details on entering your startup settings, see *Entering your startup settings, on page 46*.

# Clearing your active insulin

Use this feature when you are ready to use your pump with insulin for the first time. This feature clears the total daily dose and any active insulin values that your pump has tracked, and then sets the active insulin value to zero. If you have

practiced delivering a bolus with your pump prior to using your pump with insulin, you must clear the active insulin. This ensures that the Bolus Wizard has an accurate active insulin amount for bolus calculations.

You can clear your active insulin only once. After you clear your active insulin, the feature is no longer available.

1. Press © and go to the Manage Settings screen.

#### Options > Utilities > Manage Settings

2. Simultaneously press and hold > and \ until the Manage Settings menu appears.

The Manage Settings screen appears. If you have never cleared your active insulin, the Clear Active Insulin option appears.





**Note:** If the Clear Active Insulin selection does not appear on the Manage Settings screen, it means that you have already cleared your active insulin on the pump.

Select Clear Active Insulin.

A confirmation screen appears asking if you want to continue.

4. Select **Clear** to clear your active insulin value from your pump. If you do not want to clear your active insulin at this time, select **Cancel**.

A message appears confirming that your active insulin value is cleared.

# Viewing your pump setting history

The Settings History shows you a history of activities you have performed in the Manage Settings area, such as saving, restoring, or clearing your settings.

1. Press © and go to the Manage Settings screen.

#### Options > Utilities > Manage Settings

- 2. Simultaneously press and hold > and  $\spadesuit$  until the Manage Settings menu appears.
- 3. Select **Settings History**.

The Settings History screen appears.

## **Self Test**

Self Test is a safety utility that allows you to check if your pump is operating properly. This self-diagnostic feature can be used for maintenance or to check that your pump is operating properly. Self Test is additional to the routine tests that run independently while the pump operates.



**Note:** Your insulin delivery suspends for up to two minutes while your pump runs self test.

Self Test includes the following tests:

Test	Description
Display	Turns on the display for up to 45 seconds.
Notification light	Turns on the notification light for three seconds and then turns it off.
Vibration	Generates two vibration cycles.
Tone	Generates an alert tone, an Easy Bolus (step 1) tone, and an alarm tone.

The pump will run through a series of tests as listed in the previous table. Self Test requires you to observe the pump during the test.

#### To run the Self Test:

1. Press © and go to the Self Test screen.

# Options > Utilities > Self Test

A message indicates that the Self Test is in progress.

Self Test takes up to two minutes to complete. During that time, the display briefly turns white, the notification light blinks, the pump vibrates, and the pump beeps.

2. If Self Test does not detect a problem, the display returns to the Utilities screen.

If Self Test detects a problem, a message appears with more information about the problem. If Self Test displays an error message or you observe the pump not behaving as indicated during the test, contact the 24 Hour HelpLine.

# **Sensor Demo**

Sensor Demo lets you see what the Home screen would look like if you were using the optional Continuous Glucose Monitoring (CGM) feature. For more information about sensor graphs, please see *The sensor graph*, on page 221.



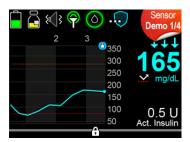
WARNING: Do not use Sensor Demo to make any decisions related to your therapy. Information seen in the Sensor Demo is not real data. It is an example of the type of information you can access when using the sensor feature. Making treatment decisions based on data that is not real can cause hypoglycemia or hyperglycemia.

# To view the sensor graph example screens:

1. Press © and go to the Sensor Demo screen.

# Options > Utilities > Sensor Demo

The Sensor Demo screen appears as an example of what your Home screen looks like when you are using the optional CGM feature.



2. Press > to view the sensor graph examples.

- 3. Press the < or > buttons to view the different sensor screen examples.
  Sensor Demo simulates a sensor glucose graph, showing an example of the general trend of glucose as it rises and falls over time. The top of the graph indicates the time of day, while the side bar shows the sensor glucose (SG) reading markers.
- 4. To exit Sensor Demo, press 🐀.

## Time and date

Make sure the time and date are always set correctly on your pump. This is necessary to ensure the correct basal insulin delivery and to keep an accurate record of pump functions. You may need to change the time or the date if you travel to a different time zone or practice daylight saving time. After the time and date are changed, the pump adjusts all settings automatically.

#### To change the time and the date:

- 1. Press © and go to the Time & Date screen.
  - Options > Utilities > Time & Date
- 2. Select and change the **Time**, **Time Format**, or **Date** as necessary. If you are using a 12-hour clock, be sure to specify AM or PM.
- 3. Select **Save**.

# Setting up Continuous Glucose Monitoring

This chapter explains how to wirelessly connect your pump and transmitter, and how to enter your sensor settings and set up continuous glucose monitoring (CGM) on your pump. You will need the following:

- MiniMed 670G insulin pump
- Sensor glucose settings (provided by your healthcare professional)
- Guardian Sensor (3)
- Guardian Link (3) transmitter kit



WARNING: Do not make therapy treatment decisions based on sensor glucose values. Sensor glucose (SG) and blood glucose (BG) values may differ. If your sensor glucose reading is low or high, or if you feel symptoms of low or high glucose, confirm your sensor glucose reading with your BG meter prior to making therapy decisions to avoid hypoglycemia or hyperglycemia.

# **Understanding Continuous Glucose Monitoring (CGM)**

The Sensor feature on the pump lets you integrate and use continuous glucose monitoring (CGM). CGM is a sensor glucose monitoring tool that uses a glucose sensor that is placed below your skin to continuously measure the amount of glucose in your interstitial fluid. CGM helps you better manage your diabetes by:

Recording your glucose values throughout the day and night

- Showing the effects that your diet, exercise, and medication can have on your glucose levels
- Giving you additional tools to help you prevent high and low glucose levels



**Note:** If you lose sensor functionality, you will no longer have access to CGM features. For details on restoring sensor functionality, see *Troubleshooting sensor issues, on page 300.* 

Sensor glucose (SG) readings and blood glucose (BG) meter readings are not the same.

# **SmartGuard Technology**

SmartGuard technology automatically adjusts insulin delivery based on your sensor glucose values. SmartGuard technology has two features, Manual Mode and Auto Mode. This chapter describes SmartGuard technology used in Manual Mode, with the Low Management features. Low Management features can automatically stop and resume insulin delivery based on your sensor glucose values and low limit. When your pump suspends insulin delivery based on your sensor glucose values and your low limit, it is called a suspend by sensor event. Your low limit should be set based on recommendations from your healthcare professional. When a SmartGuard suspend by sensor event occurs, basal insulin delivery automatically resumes if your sensor glucose values are rising and have met the specified criteria, or if the maximum suspend time of two hours is reached.

Auto Mode is also part of SmartGuard technology. When your pump is in Auto Mode, your basal insulin delivery is automatically controlled. For details, see *About Auto Mode, on page 229*.

The following table shows the different Low Management settings you can use and where to find more information.

To learn more about:	Go to this section:
How to use SmartGuard technology to	Suspend before low, on page 186.
automatically suspend your insulin delivery before	
you reach your low limit.	

To learn more about:	Go to this section:
How to use SmartGuard technology to automatically suspend your insulin delivery when you reach your low limit.	Suspend on low, on page 190.
How SmartGuard technology automatically resumes your basal insulin delivery after a suspend by sensor event.	Automatically resuming basal delivery after a SmartGuard suspend by sensor event, on page 192.
Auto Mode	About Auto Mode, on page 229

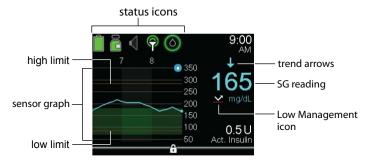
To set up SmartGuard suspend by sensor settings, see Setting up the Low Settings, on page 202.

# Home screen with CGM in Manual Mode

When you turn on the Sensor feature, the Home screen on your pump changes to display a real-time graph that shows your sensor glucose (SG) information. For more information, see *Turning on the Sensor feature, on page 198*.



**Note:** To see the Home screen in Auto Mode, see *Home screen with Auto Mode, on page 235.* 



The following items appear on your Home screen with CGM in Manual Mode:

#### Item Description

Airplane Mode icon

The Airplane Mode icon appears in place of the Connection icon if Airplane Mode is turned on. When Airplane Mode is turned on, the pump cannot receive wireless communication from other devices.



WARNING: Do not rely on glucose sensor-enabled features when Airplane Mode is on because the pump does not receive sensor readings from the transmitter. Glucose sensor-enabled features include CGM, SmartGuard, and Auto Mode. When using Airplane Mode, always rely on your blood glucose (BG) values when making therapy decisions to avoid hypoglycemia or hyperglycemia.

# **Item** Description Calibration The approximate time left until your next sensor calibration is due. Appears only when the Sensor feature is turned on. The color and the icon circle around the icon indicate the status. When your sensor is fully calibrated, the icon has a solid green circle around it. As the time for your next sensor calibration approaches, the green circle around the icon becomes smaller, and the color of the icon changes as shown in the following example. For more information about calibrating your sensor, see Calibrating your sensor, on page 214. Time to your next sensor calibration is more than 10 hours. Time to your next sensor calibration is 8 to 10 hours. Time to your next sensor calibration is 6 to 8 hours. Time to your next sensor calibration is 4 to 6 hours. Time to your next sensor calibration is 2 to 4 hours. Time to your next sensor calibration is less than 2 hours. Sensor calibration is required now. Time to your next sensor calibration is unavailable. Sensor is not ready for a calibration. This occurs when a new sensor is connected or within 15 minutes of a Calibration not accepted alert. Connection The connection icon appears green $\P$ when the Sensor feature is on icon and your transmitter is successfully communicating with your pump. The connection icon appears with a red X 💥 when the Sensor feature is turned on, but the transmitter is not connected or communication

with your pump has been lost. For more information about the Sensor feature, see *Understanding Continuous Glucose Monitoring* 

(CGM), on page 177.

Item	Description	
Auto Mode Readiness	The Auto Mode Readiness icon indicates whether your pump is ready to enter Auto Mode. The icon appears with a loading symbol when the pump is updating a condition that requires you to wait. The icon appears with a question mark ? when the pump requires an action from you to enter Auto Mode. For more information about Auto Mode Readiness, see <i>Auto Mode Readiness</i> , on page 233.	
	When your pump is in Auto Mode, the Auto Mode shield appears in the center of your Home screen. For more information, see <i>Home screen with Auto Mode, on page 235</i> .	
Sensor graph	Displays your SG readings over a period of 3 hours. The orange line represents your high SG limit, and the red line represents your low SG limit. The blue line represents your SG trends during the specified period. For more information, see <i>The sensor graph, on page 221</i> .	
Sensor Life	The number of days remaining in the life of your sensor. The Sensor Life icon appears only when the Sensor feature is turned on. The color and the fill level of the icon indicate the status. When you insert a new sensor, the icon is solid green. When one day is remaining in the life of your sensor, the icon color turns red.	
	<b>Note:</b> For a short time after starting a new sensor, the Sensor Life icon may show an 8. When the Sensor Life icon changes to show a 7, the seven-day period of sensor life begins.	
	7 6 5 4 3 2 1	
	If the number of days remaining in the life of your sensor is unavailable, the Sensor Life icon appears with three dots	
SG reading	Shows your current SG reading which is sent wirelessly to your pump by the transmitter.	

ltem	Description
Low Management icon	The Low Management icon appears only when either the Suspend before low or Suspend on low feature is set to on. For details on SmartGuard technology, see SmartGuard Technology, on page 178.  The Low Management icon indicates the current status of the suspend features, as follows:
	<ul> <li>The icon is a white arrow with a dotted red line when either the Suspend on low or Suspend before low is turned on and ready.</li> <li>The arrow icon flashes if your insulin delivery is currently suspended due to a Suspend on low or Suspend before low event.</li> </ul>
	• The icon appears as a gray cross with a dotted line under it when neither suspend feature is available. The suspend features might be unavailable due to a recent suspend or because there are no SG values available. It might also be unavailable because the pump is not currently delivering insulin.
Trend arrows	Shows the rate at which the most recent sensor glucose level is rising or falling.
	· ↑ or ↑↑ or ↑↑↑ - Rising trend arrows
	• or to or to - Falling trend arrows
	For more information about trend arrows, see <i>Identifying rapid changes</i> in sensor glucose, on page 222.

# **Understanding glucose settings**

There are several types of glucose alerts you can set to notify you if your glucose values are changing at a particular rate, or if they are approaching or have reached a specified low or high limit. You can also set your pump to automatically suspend insulin delivery before or when you reach your low limit.

The following graph shows the different high and low glucose alerts you can use.



The high alerts are described in the *High settings* section on *page 184*. For details on low alerts and suspend options, see *Low settings*, on page 185.

# **High settings**

These settings alert you if your sensor glucose:

- is rising rapidly (Rise Alert)
- is approaching your high limit (Alert before high)
- has reached your high limit (Alert on high)

The following table describes the High Settings.

High glucose setting	Description
High limit	Your high limit is the value on which your other high settings are based. Your high limit can be set from 100 mg/dL to 400 mg/dL. You can set a different high limit for up to eight time segments throughout the day or night.
Alert before high	When Alert before high is on, you will receive an alert any time the sensor glucose is predicted to reach the high limit. This makes you aware of potential highs before they occur.
Time before high	Time before high is only available when using Alert before high. Time before high determines when you will receive an Alert before high. You can set a time between 5 and 30 minutes.

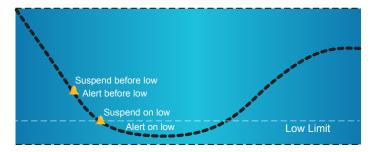
	Description
High glucose setting	Description
Alert on high	When Alert on high is on, your system alerts you when your SG reading reaches or exceeds your High Limit.
Rise Alert	The Rise Alert notifies you when your glucose is rising rapidly. This alert helps you understand how much your glucose levels are affected by meals or, for example, when forgetting to give a bolus. You can set the rise rate to match the arrows that display on the Home screen during a glucose rise, or to a custom rise rate.
	• 🕇 - SG is rising at a rate of 1 mg/dL per minute or more.
	• † - SG is rising at a rate of 2 mg/dL per minute or more.
	• † † - SG is rising at a rate of 3 mg/dL per minute or more.
	• Custom - SG is rising at the rate that you set which can be set from 1.0 to 5.0 mg/dL per minute.
Rise Limit	The Rise Limit determines when you will receive a Rise Alert. Rise Limit is only available when using Rise Alert.

To set up your high settings, see Setting up the High Settings, on page 198.

# **Low settings**

The low settings allow you to be alerted and/or have insulin delivery suspended when you are either approaching or have reached your low limit. This is done by using alerts and SmartGuard technology described on *page 178*.

The following graph shows the different low settings you can use:





WARNING: Suspend before low and Suspend on low are not intended to be a treatment for low blood glucose. Having insulin suspended when glucose is low may not bring your blood glucose back to your target range for several hours. In that case, you run the risk of hypoglycemia. Always confirm your blood glucose readings with your BG meter and treat according to the recommendations of your healthcare professional.

The following sections describe Auto Mode and the low settings. For details on setting up Auto Mode and your low settings, see *Setting up the Low Settings*, on page 202.

#### Low limit

The low limit is the value on which the other low settings are based. The low limit can be set from 50 mg/dL to 90 mg/dL. You can set a different low limit for up to eight time segments throughout the day or night.

#### Suspend before low

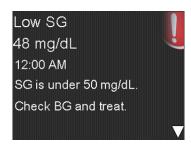
The Suspend before low feature stops insulin delivery when your sensor glucose values are approaching your low limit. This feature is intended to suspend insulin delivery to minimize the amount of time spent low.

The default setting for the Suspend before low feature is off. Consult your healthcare professional for the Suspend before low setting that is best for you.

If you turn on Suspend before low, then Alert on low is automatically turned on. You also have the option to turn on Alert before low.

- If Alert before low is on, your pump alerts you when insulin delivery is suspended. For details, see *Alert before low, on page 189*.
- If Alert before low is off, then Suspend before low appears on the screen, but the pump will not beep or vibrate when insulin delivery is suspended.
- The user can enable Alert before low, Alert on low, Suspend before low, and Suspend on low. There is an additional fixed low alert at 50 mg/dL that cannot be turned off.
- Suspend before low and Suspend on low cannot be enabled at the same time. When either is enabled, the user can enable the Resume basal alert.

• The Low SG alert appears when your sensor glucose values reach or fall below 50 mg/dL. This alert cannot be turned off. When the alert appears on your screen, it shows your sensor glucose value next to your Low SG alert. In this user guide, the sensor glucose value will be represented as "Low SG XX" for this alert.





WARNING: Always confirm your sensor glucose readings with your BG meter and treat according to the recommendations of your healthcare professional. The Suspend before low feature uses the sensor glucose value, not your blood glucose value, to automatically suspend insulin delivery. Your pump automatically suspends insulin delivery when your sensor glucose is approaching the low limit. However your blood glucose reading may be higher or lower than the sensor glucose value. Assuming that your sensor glucose value is accurate may result in the delivery of too little or too much insulin, which can cause hyperglycemia or hypoglycemia.

# Suspend before low conditions

When a Suspend before low event occurs, all insulin delivery is suspended. A Suspend before low event occurs when:

- Your SG value is at or within 70 mg/dL above your low limit.
- Your SG is predicted to reach or fall below a level that is 20 mg/dL above your low limit within approximately 30 minutes.

# Responding to a Suspend before low event

When you clear the Suspend before low alert, the SmartGuard Suspend by sensor icon flashes and "Suspended before low" appears on your Home screen. If your SG reaches your low limit, an Alert on low occurs.

When a Suspend before low event occurs, insulin delivery will remain suspended for at least 30 minutes. Insulin delivery will be suspended for a maximum of two hours. You can manually resume insulin delivery at any time. For details, see *Manually resuming basal delivery during a suspend by sensor event, on page 205.* After the minimum 30-minute suspend time, basal insulin delivery will automatically resume if the following conditions are met:

- Your SG is at least 20 mg/dL above your low limit.
- Your SG is estimated to be more than 40 mg/dL above your low limit within 30 minutes.

If you do not respond to the Suspend before low alert, your pump resumes insulin delivery after two hours and displays a Basal delivery resumed alert.

#### When Suspend before low is unavailable

After a Suspend before low event occurs, there is a period of time when the Suspend before low functionality is unavailable. This is to prevent prolonged suspended basal delivery. The length of time it is unavailable will vary. For details, see *Stopping and resuming your insulin delivery, on page 82*.



**Note:** The maximum amount of time the Suspend before low feature will be unavailable is four hours.

When the SmartGuard suspend by sensor features are unavailable, the SmartGuard suspend by sensor icon on the Home screen appears as a gray cross X.

# When a Suspend before low event occurs and you respond within two hours and:

- Stay suspended for the two hour maximum suspend time, the SmartGuard suspend by sensor features will be unavailable for 30 minutes after your basal insulin delivery resumes.
- Your insulin automatically resumes due to your rising SG levels, the SmartGuard suspend by sensor features will be unavailable for 30 minutes after your basal insulin delivery resumes.
- Manually resume your basal insulin delivery, the SmartGuard suspend by sensor features will be unavailable for 30 minutes after your basal insulin delivery resumes.

If your pump has been suspended for two hours and you have not responded, basal insulin delivery automatically resumes.

If you respond within 30 minutes of basal insulin delivery being resumed, the SmartGuard suspend by sensor features will be unavailable for a total of 30 minutes. For example:

- If you respond 10 minutes after your basal insulin delivery resumes, the SmartGuard suspend by sensor features will be unavailable for an additional 20 minutes.
- If you respond 20 minutes after your basal insulin delivery resumes, the SmartGuard suspend by sensor features will be unavailable for an additional 10 minutes.

If you respond 30 minutes to four hours after your basal insulin delivery resumes, the SmartGuard suspend by sensor features will be available immediately.

**If you do not respond**, the SmartGuard suspend by sensor features will be unavailable for four hours after basal delivery resumes.

#### Alert before low

When Alert before low is on, you will receive an alert when you are approaching your low limit. This makes you aware of potential lows before they occur.

The Alert before low feature can be used with the Suspend before low and Suspend on low features. The Alert before low feature works as follows:

- If Alert before low is on, and both suspend by sensor features are off, you receive the Alert before low 30 minutes before you reach your low limit.
- If Suspend on low is on, and Alert before low is on, you receive an Alert before low 30 minutes before you reach your low limit.
- If Suspend before low is on, and Alert before low is on, you receive a Suspend before low alert when insulin delivery is suspended. For details, see *Suspend before low, on page 186*.

You can also choose to have the Alert before low off.

#### Suspend on low

The Suspend on low feature stops insulin delivery when your sensor glucose value reaches or falls below the low limit that you set. When a Suspend on low event occurs, all insulin delivery is suspended. This feature is used for situations when you cannot respond to a low glucose condition. It is intended to suspend insulin delivery and minimize the amount of time spent low.



WARNING: Do not use the Suspend on low feature until you have read the information in this user guide and received instructions from your healthcare professional. The Suspend on low feature causes the pump to temporarily suspend insulin delivery for a maximum of two hours. Under some conditions of use, the pump can suspend again, resulting in limited insulin delivery. Prolonged suspension can increase the risk of serious hyperglycemia, ketosis, and ketoacidosis.

The default setting for the Suspend on low feature is off. Consult your healthcare professional for the Suspend on low setting that is best for you.

If you turn on Suspend on low, then Alert on low is turned on automatically. For more information, see *Alert on low, on page 192*.



WARNING: Always confirm your sensor glucose readings with your BG meter and treat according to the recommendations of your healthcare professional. The Suspend on low feature uses the sensor glucose value, not your blood glucose value, to automatically suspend your pump. Your pump may automatically suspend when your sensor glucose is at or below the low limit, while your blood glucose is above that limit. Assuming that your sensor glucose value is accurate may result in the delivery of too little or too much insulin, which can cause hyperglycemia or hypoglycemia.

# Responding to a Suspend on low event

When you clear the Suspend on low alarm, the SmartGuard suspend by sensor icon flashes and "Suspended on low" appears on your Home screen.

When a Suspend on low event occurs, the pump alerts you.

When a Suspend on low event occurs, insulin delivery will remain suspended for at least 30 minutes. Insulin delivery will be suspended for a maximum of two hours. You can manually resume insulin delivery at any time. For details, see *Manually resuming basal delivery during a suspend by sensor event, on page 205*. After the minimum 30-minute suspend time, basal insulin delivery will automatically resume if the following conditions are met:

- Your SG is at least 20 mg/dL above your low limit.
- Your SG is estimated to be more than 40 mg/dL above your low limit within 30 minutes.

If you do not respond to the Suspend on low alarm, your pump resumes insulin delivery after two hours and continues to display an emergency message.

#### When Suspend on low is unavailable

After a Suspend on low event occurs, there is a period of time when the suspend functionality is unavailable. This time will vary depending on whether or not you respond to the Suspend on low event. You can manually suspend insulin delivery at any time. For details, see *Stopping and resuming your insulin delivery, on page 82*.



**Note:** The maximum amount of time the Suspend on low feature will be unavailable is four hours. After this time period, the Suspend on low feature automatically enables.

When the SmartGuard suspend by sensor features are unavailable, the SmartGuard suspend by sensor icon on the Home screen appears gray ...

# When a Suspend on low event occurs and you respond within two hours and

- Stay suspended for the two hour maximum suspend time, the SmartGuard suspend by sensor features will be unavailable for 30 minutes after your basal insulin delivery resumes.
- Your insulin automatically resumes due to your rising SG levels, the SmartGuard suspend by sensor features will be unavailable for 30 minutes after your basal insulin delivery resumes.
- Manually resume your basal insulin delivery, the SmartGuard suspend by sensor features will be unavailable for 30 minutes after your basal insulin delivery resumes.

If your pump has been suspended for two hours and you have not responded, basal insulin delivery automatically resumes.

If you respond within 30 minutes of basal insulin delivery being resumed, the SmartGuard suspend by sensor features will be unavailable for a total of 30 minutes. For example:

- If you respond 10 minutes after your basal insulin delivery resumes, the SmartGuard suspend by sensor features will be unavailable for an additional 20 minutes.
- If you respond 20 minutes after your basal insulin delivery resumes, the SmartGuard suspend by sensor features will be unavailable for an additional 10 minutes.

If you respond 30 minutes to four hours after your basal insulin delivery resumes, the SmartGuard suspend by sensor features will be available immediately.

If you do not respond, the SmartGuard suspend by sensor features will be unavailable for four hours after basal delivery resumes.

#### Alert on low

The Alert on low feature is automatically turned on when either the Suspend before low or the Suspend on low feature is turned on.

When Alert on low is set to on, you receive an alert when your SG reading reaches or falls below your low limit. If your pump is suspended and you have not responded, an emergency message appears.

# Automatically resuming basal delivery after a SmartGuard suspend by sensor event

In addition to suspending insulin delivery, the pump can also automatically resume delivery of basal insulin. If insulin has been suspended by either the Suspend before low or the Suspend on low feature, insulin delivery will automatically be resumed if either of the following conditions are met:

- if insulin has been suspended for a minimum of 30 minutes and SG values are at least 20 mg/dL above the low limit and expected to be more than 40 mg/dL above the low limit in 30 minutes.
- after a maximum of two hours.

#### Resume basal alert

When the Resume basal alert is on, you will be alerted when insulin is automatically resumed. If the Resume basal alert is off, basal insulin resumes, but you do not receive an alert. However, you will get a message indicating that the basal has automatically resumed.

If basal resumes after the maximum suspend time of two hours, you will be alerted even if the Resume basal alert is set to off. It is important that you check your BG and ensure your glucose is at a safe level.

For details on setting up the Resume basal alert, see *Setting up the Low Settings, on page 202*.

## SmartGuard suspend by sensor examples

The following table shows the different scenarios that occur during and after a Suspend before low or Suspend on low event. Examples of scenarios are shown after the table.

	Suspend features		
What happens	Suspend on low	Suspend before low	
The pump suspends insulin delivery.	Your sensor glucose value reaches or falls below the low limit that you set.  The pump suspends insulin delivery for at least 30 minutes and up to a maximum of 2 hours. The pump automatically resumes basal insulin delivery between 30 minutes and 2 hours if your sensor glucose value is predicted to go above the low limit that you set.	Your sensor glucose value is approaching your low limit and is predicted to be reached within 30 minutes.  The pump suspends insulin delivery for at least 30 minutes and up to a maximum of 2 hours. The pump automatically resumes basal insulin delivery between 30 minutes and 2 hours if your sensor glucose value is predicted to go above the low limit that you set.	

	Suspend features	
What happens	Suspend on low	Suspend before low
You manually resume insulin delivery.	Your pump resumes insulin delivery at the programmed basal rate. The suspend by sensor features are unavailable for 30 minutes after insulin delivery resumes. The pump will not automatically suspend insulin again until after the suspend features are available and your sensor glucose value is below the low limit that you set.	Your pump resumes insulin delivery at the programmed basal rate. The suspend by sensor features are unavailable for 30 minutes after insulin delivery resumes. The pump will not automatically suspend insulin again until after the suspend features are available and your sensor glucose value is approaching the low limit that you set.
Your sensor glucose value is predicted to go above your low limit while insulin is automatically suspended.	The pump automatically resumes insulin delivery after 30 minutes and if your sensor glucose values are at least 20 mg/dL above your low limit and predicted to be more than 40 mg/dL above your low limit in 30 minutes.	The pump automatically resumes insulin delivery after 30 minutes and if your sensor glucose values are at least 20 mg/dL above your low limit and predicted to be more than 40 mg/dL above your low limit in 30 minutes.
You respond to the alert that occurs while insulin delivery is suspended. Insulin delivery is suspended for the maximum two hour suspend time.	Your pump resumes insulin delivery at the programmed basal rate. The suspend by sensor features are unavailable for 30 minutes after insulin delivery resumes. The pump will not automatically suspend insulin again until after the suspend features are available and your sensor glucose value is below the low limit that you set.	Your pump resumes insulin delivery at the programmed basal rate. The suspend by sensor features are unavailable for 30 minutes after insulin delivery resumes. The pump will not automatically suspend insulin again until after the suspend features are available and your sensor glucose value is approaching the low limit that you set.

	Suspend features	
What happens	Suspend on low	Suspend before low
The pump resumes insulin delivery after the maximum two hour suspend time. You respond to the alert that occurs after insulin delivery resumes.	Your pump resumes insulin delivery at the programmed basal rate. The suspend by sensor features are unavailable for 30 minutes. The pump will not automatically suspend insulin again until after the suspend features are available and your sensor glucose value is below the low limit that you set.	Your pump resumes insulin delivery at the programmed basal rate. The suspend by sensor features are unavailable for 30 minutes. The pump will not automatically suspend insulin again until after the suspend features are available and your sensor glucose value is approaching the low limit that you set.
You do not respond to the alerts that occur while insulin delivery is suspended. Insulin delivery is suspended for the maximum two hour suspend time.	Your pump resumes insulin delivery at the programmed basal rate. The suspend by sensor features are unavailable for 4 hours after insulin delivery resumes. The pump will not automatically suspend insulin again until after the suspend features are available and your sensor glucose value is below the low limit that you set.	Your pump resumes insulin delivery at the programmed basal rate. The suspend by sensor features are unavailable for 4 hours after insulin delivery resumes. The pump will not automatically suspend insulin again until after the suspend features are available and your sensor glucose value is approaching the low limit that you set.

The following examples describe several scenarios that illustrate different types of suspend events, user actions in response to these events, and what happens to insulin delivery in each case.

The examples cover the following:

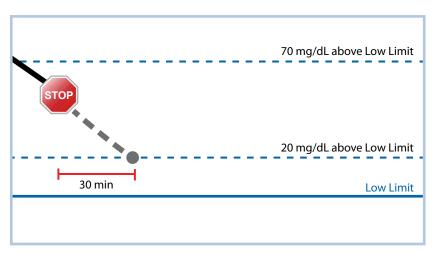
- Example 1: Suspend before low, non-responsive, auto resume basal (trending upwards)
- Example 2: Suspend before low, responsive, manually resume basal
- Example 3: Suspend before low, responsive, stays suspended
- Example 4: Suspend on low, response after basal delivery resumes



**Note:** During the Suspend on low siren, you can press any button to silence your pump for two minutes. The temporary silencing of the alarm does not affect the suspension or delivery of insulin.

# Example 1: Suspend before low, non-responsive, auto resume basal (trending upwards)

Sarah has been experiencing low sensor glucose values. Her healthcare professional has recommended she use the Suspend before low feature. While at a concert, Sarah's sensor glucose values are approaching her low limit. Her pump recognizes that her glucose will be at or within 20 mg/dL above her low limit within 30 minutes and suspends her insulin. Sarah has her Alert before low set to off so that she is not alerted when this occurs.



An hour later, her sensor glucose values are 21 mg/dL above her low limit. Her pump estimates her sensor glucose values will be 45 mg/dL above her low limit within 30 minutes. Her pump automatically resumes her basal insulin delivery.

When the concert ends, Sarah sees that her pump automatically suspended and resumed her insulin delivery and a potential low was avoided. She clears the messages by selecting OK.

# Example 2: Suspend before low, responsive, manually resume basal

Kate decides to meet her friends at the mall. While shopping, she gets a Suspend before low alert. This indicates that her sensor glucose values are approaching the low limit she has set. She clears the alert and sees that her insulin has been

suspended. Kate checks her BG to confirm. Based on her healthcare professional's recommendation, Kate stops for a snack to help avoid hypoglycemia. Knowing the carbohydrate will make her glucose rise, Kate manually resumes her basal insulin delivery by selecting Suspended before low from the Home screen and choosing Resume basal.

Kate knows that after she has manually resumed her basal insulin delivery, the suspend functions will be unavailable for 30 minutes. However, she will be alerted if she reaches her low limit.

#### Example 3: Suspend before low, responsive, stays suspended

Doug has just finished his evening jog on the beach. As he is walking home, he receives a Suspend before low alert. He sees that his pump has automatically suspended his insulin delivery. Doug clears the alert by selecting OK on his pump. He knows that his pump is now suspended and insulin delivery has been stopped. He checks his BG to confirm and keeps his insulin suspended.

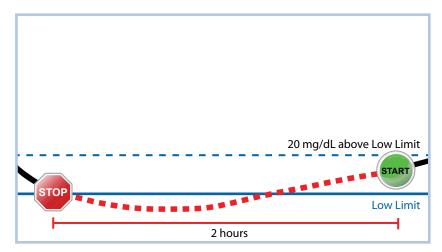
A while later, Doug receives another alert. He looks at his pump and sees that he has received an Alert on low. His SG has reached his low limit. He clears the alert and checks his BG to confirm. He eats carbohydrates to treat the low glucose as instructed by his healthcare professional.

Doug keeps his insulin suspended as directed by his healthcare professional. He knows that once his SG is above his low limit and trending upward, or reaches the maximum suspend time of two hours, basal insulin delivery will automatically resume.

# Example 4: Suspend on low, response after basal delivery resumes

Michael is on his college hockey team. He played in a hockey tournament all day and is so exhausted that he falls asleep watching television. His sensor glucose value begins to drop. When his sensor glucose value reaches his low limit, the pump begins to alarm. His pump automatically suspends all insulin delivery. Michael does not respond to the alarm. After ten minutes, his pump begins to siren and displays the emergency message.

About three hours later, Michael's roommate comes home. He hears the pump sirening and wakes up Michael. Michael clears any messages by selecting OK. He sees that his basal insulin was suspended for the two hour maximum and had automatically resumed delivery. He checks his blood sugar and sees that it is within the target range.



Michael has responded to his alert. The pump will suspend insulin delivery and alarm again if his sensor value reaches or falls below his low limit again.

# **Turning on the Sensor feature**

You must turn on the Sensor feature before you can set up your glucose alerts and start monitoring your sensor glucose.

#### To turn on the Sensor feature:

1. Press © and go to the Sensor Settings screen.

Options > Utilities > Sensor Settings

2. Select **Sensor** to turn on the sensor feature. The sensor settings become accessible.

# Setting up the High Settings

The steps below guide you through setting up your high settings. For details on your high settings, see *High settings*, on page 184.



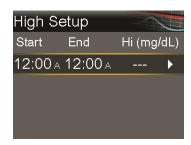
**Note:** When you enter your settings, you first define the time segment, and then select the high settings you want on during that time segment.

#### To set up the High Settings:

1. Press © and go to the High Setup screen.

#### Options > SmartGuard > High Setup

The High Setup screen appears.



2. Select the time segment. The End time starts flashing.

The Start time of the first time segment is always 12:00 A. You can set up to eight time segments, each with a different high limit. If you set more than one time segment, the time segments must cover a 24-hour period.

- 3. Set the End time.
- 4. Set your High limit. You can enter a value from 100 to 400 mg/dL, in increments of 5 mg/dL.
- 5. Select the arrow to the right of the End time to select the high alerts for this time segment.

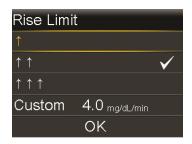
A screen appears showing the high alerts for the selected time segment.



- 6. Set the following alerts as desired:
  - a. Select **Alert before high** if you want to receive an alert before you reach your high limit.

- b. If you turned on Alert before high, enter the **Time before high** to set how soon you want to be alerted before reaching your high limit. You can enter a value from 5 to 30 minutes.
- c. Select **Alert on high** if you want an alert when you reach your high limit.
- d. Select **Rise Alert** if you want to receive an alert when your SG is rising quickly.
  - Skip to step 11 if you do not select Rise Alert.
- 7. If you turned on the Rise Alert, you need to set the Rise Limit. Scroll down and select **Rise Limit** to access this option.

The Rise Limit screen appears.



- 8. Select the arrow option (one, two, or three arrows) that corresponds to the rise rate you want to use. To use a custom rate, skip to the next step.
  - Select 
     for an alert when your SG has been rising at a rate of 1 mg/dL
     per minute or more.
  - Select  $\uparrow \uparrow$  for an alert when your SG has been rising at a rate of 2 mg/dL per minute or more.
  - Select  $\uparrow \uparrow \uparrow \uparrow$  for an alert when your SG has been rising at a rate of 3 mg/dL per minute or more.

Select **OK**, and skip to step 11.



**Note:** These arrows appear on your Home screen to let you know the rate at which your SG has been rising.

- 9. To enter a custom rise limit, do the following:
  - a. Select **Custom**. The Custom Limit screen appears.

- b. Select **Rise Limit** and set a rise rate from 1 to 5 mg/dL/min. You set the rate in 0.1 mg/dL/min increments.
- c. Select **OK** to return to the Rise Limit screen and then select **OK** again to confirm your settings.
- 10. When you have set all the high settings for the selected time segment, select **Next** to continue.
- 11. If you entered an End time of anything other than 12:00 A, another time segment appears. When you are finished entering high settings, select **Done**.
- 12. Review your settings, and select **Save**.

#### To change your High Settings:

1. Press © and go to the High Setup screen.

Options > SmartGuard > High Setup

The High Setup screen appears.

- 2. Select **Edit**.
- 3. Select and, if needed, adjust the time segment you would like to change.
- 4. Select any alert setting to turn it on or off or to adjust the setting.
- 5. Select **Next**.
- 6. Select **Review**.
- 7. Review your settings, and select **Save**.

#### **High Snooze**

High Snooze is available once you have set your High Settings. High Snooze allows you to set the amount of time that you want to wait before you are reminded that an alert condition still exists. After a high alert is received and cleared, you will be alerted again only if the high alert condition still exists after the snooze time you have set.

#### Setting the High Snooze:

1. Press © and go to the Snooze screen.

Options > SmartGuard > Snooze

The Snooze screen appears.

- 2. Select **High Snooze** and enter a value from 5 minutes to 3 hours, in 5 minute increments.
- 3. Select **Save** to save your Snooze settings.

#### **Setting up the Low Settings**

The steps below guide you through setting up the Low Settings. For details on the Low Settings, see *Low settings*, on page 185.



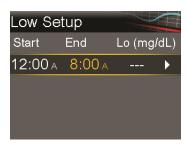
**Note:** When you enter your settings, you first define the time segment and then select the low settings you want during that time segment.

#### To set up the Low Settings:

1. Press © and go to the Low Setup screen.

#### Options > SmartGuard > Low Setup

The Low Setup screen appears.



2. Select the time segment. The End time starts flashing.

The Start time of the first time segment is always 12:00 A. You can set up to eight time segments, each with a different low limit. If you set more than one time segment, the time segments must cover a 24-hour period.

- 3. Set the End time.
- 4. Set your low limit. You can enter a value from 50 to 90 mg/dL, in increments of 5 mg/dL.
- 5. Select the arrow to the right of the End time to select the low settings for this time segment.

A screen appears showing the available settings for the selected time period.



#### 6. Set the following as desired:

- a. Select **Suspend before low** to have insulin suspended before you reach your low limit. The Alert on low alert is automatically turned on and cannot be turned off.
- b. Select **Alert before low** to receive an alert before you reach your low limit. If Suspend before low is also on, you are alerted when insulin is suspended.
- c. Select **Suspend on low** to have insulin suspended when you reach or fall below your low limit. The Alert on low alert is automatically turned on and cannot be turned off.
- d. Select **Alert on low** if you want to receive an alert when your SG reaches or falls below your low limit. If either suspend feature is on, this will already be on.
- e. Select **Resume basal alert** if you want an alert when basal insulin delivery is resumed based on SG values during a suspend by sensor event. If you do not turn on the alert, the Basal delivery resumed message will still appear on the pump, but you will not be alerted.



**Note:** When setting your low alerts:

- If you turn on the Suspend before low or the Suspend on low feature, then the Alert on low feature is turned on automatically.
- Only one suspend by sensor feature can be used during each time segment. You cannot use both the Suspend before low and the Suspend on low features in the same time segment.

- 7. When you have set all the low settings for the selected time segment, select **Next** to continue.
- 8. If you entered an End time of anything other than 12:00 A, another time segment appears.
  - When you are finished entering your low settings, select **Done**.
- 9. Review your settings, and select **Save**.

#### To make changes to your Low Settings:

1. Press © and go to the Low Setup screen.

#### Options > SmartGuard > Low Setup

The Low Setup screen appears.

- 2. Select **Edit**.
- 3. Select, and if needed, adjust the time segment you would like to change.
- 4. Select any alert setting to turn it on or off or to adjust the setting.
- Select Next.
- 6. Select **Done**.
- 7. Review your settings, and select **Save**.

#### **Low Snooze**

Low Snooze is available once you have set your Low Settings. Low Snooze allows you to set the amount of time that you want to wait before you are reminded that an alert condition still exists. After a low alert is received and cleared, you will be alerted again only if the low alert condition still exists after the snooze time you have set.

#### Setting the Low Snooze:

1. Press @ and go to the Snooze screen.

#### Options > SmartGuard > Snooze

The Snooze screen appears.

2. Select **Low Snooze** and enter a time between 5 minutes and 1 hour.

#### Manually resuming basal delivery during a suspend by sensor event

When your pump suspends insulin due to a Suspend before low or Suspend on low event, the bottom of your Home screen displays either Suspended before low or Suspended on low depending on which is active.



If you do not want to wait for your pump to automatically resume your basal insulin, you can follow the procedure below to manually resume your basal delivery.

#### To manually resume basal delivery:

- 2. Select Resume Basal.
- 3. Select **Yes** to resume basal delivery.

## Wirelessly connecting your pump and transmitter using Auto Connect

Before you can start using your sensor, you must first wirelessly connect your pump to your transmitter so they can begin communicating with each other.

The Auto Connect process locates your transmitter without having to enter the serial number of the transmitter into your pump manually.

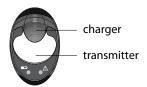
Note the following before trying to connect your pump and transmitter:

• You can connect only one transmitter to your pump. If you already have a transmitter connected to your pump, you must delete it before continuing. For instructions on deleting a transmitter from your pump, see *Deleting the transmitter from your pump, on page 212*.

• Ensure that you are not close to other Medtronic devices that are in search mode before using Auto Connect. (For example, if another household member is connecting a BG meter or transmitter to his or her insulin pump.) If you know multiple people are connecting devices, such as in a training class, use the Manual Connect process on *page 209*.

#### Connecting your pump and transmitter using Auto Connect:

1. Attach your transmitter to the charger and make sure the transmitter is fully charged. Keep your transmitter attached to the charger.



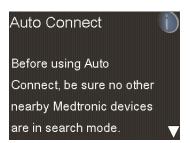


**Note:** Both lights on the charger are off when the transmitter is fully charged. For more information, see your transmitter user guide.

2. Press 

and go to the Auto Connect screen.

Options > Utilities > Device Options > Connect Device > Auto Connect



3. Make sure there are no other devices in search mode nearby, scroll down to the bottom of the Auto Connect screen, and select **Continue**.

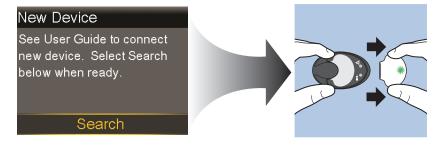


The New Device screen appears.

4. Place the transmitter (still attached to the charger) next to the pump.



5. Select **Search** on your pump and immediately remove the transmitter from the charger.



The following happens when you start the search process:

- On your pump, a message appears to let you know your pump is searching.
- On your transmitter, a green light flashes 10 times and then turns off.



**Note:** The search process can take up to two minutes. You cannot access your pump screens or suspend your pump during the search process.

When your pump finds the transmitter, the Confirm Device SN screen appears.

6. Ensure the transmitter serial number on your pump screen matches the serial number on the back of your transmitter and then select **Confirm**.



If the connection is successful, your pump displays a success message. If the Sensor feature is turned on, the Connection icon  $\P$  appears on the Home screen.

If your pump does not find your transmitter, see the following procedure, *If* your pump does not find your transmitter. If your pump finds multiple devices, skip to the steps on page 208.

#### If your pump does not find your transmitter:

- 1. Place the transmitter back on the charger and make sure your transmitter is fully charged before continuing.
- 2. Place your pump and transmitter within an arm's length of each other.
- 3. Select **Retry** on your pump and immediately remove the transmitter from the charger to start the search process.
- 4. If the search is unsuccessful the second time, select **Cancel** when the No Devices Found message appears and then follow the instructions in *Wirelessly connecting your pump and transmitter using Manual Connect, on page 209.*

#### If your pump found multiple devices:

- 1. Write down the serial number for your transmitter. The serial number can be found on the back of your transmitter.
- 2. Place the transmitter back on the charger and make sure your transmitter is fully charged before continuing.

- 3. Select **Next** from the Multiple Devices Found message to display the Enter Device SN screen.
- 4. Manually enter your device serial number by following the instructions, starting with step 4 in *Wirelessly connecting your pump and transmitter using Manual Connect, on page 209.*

# Wirelessly connecting your pump and transmitter using Manual Connect

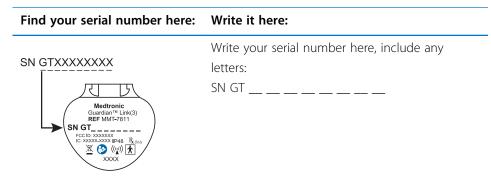
The Manual Connect process requires you to enter the serial number of the transmitter into your pump. Use this process if you are unsuccessful using the Auto Connect process, or when multiple people in close range are connecting their pumps with other devices, such as a group training session.



**Note:** You can connect only one transmitter to your pump. If you already have a transmitter connected to your pump, you must delete it before continuing. For instructions on deleting a transmitter from your pump, see *Deleting the transmitter from your pump, on page 212*.

#### Connecting your pump and transmitter using Manual Connect:

1. You need the serial number for your transmitter during the connection process. Write down the serial number in the following space provided.



2. Attach your transmitter to the charger, and make sure the transmitter is fully charged. Keep your transmitter attached to the charger.





**Note:** Both lights on the charger are off when the transmitter is fully charged. For more information, see your transmitter user guide.

If you remove the transmitter from the charger to write down the serial number, the green charger light may start flashing when you attach the transmitter to the charger again. You can continue the connection process without waiting for the charger light to stop flashing.

3. On the pump, press © and go to the Enter Device SN screen.

Options > Utilities > Device Options > Connect Device > Manual Connect



- 4. Use the pump navigation buttons to enter the serial number of the transmitter and select **OK**.
  - The New Device screen appears.
- 5. Select **Search** on your pump and immediately remove the transmitter from the charger.



The following happens when you start the search process:

- On your pump, a message appears to let you know your pump is searching.
- On your transmitter, a green light flashes 10 times and then turns off.



**Note:** The search process can take up to two minutes. You cannot access your pump screens or suspend your pump during the search process.

6. Place the transmitter next to the pump.

If the connection is successful, your pump displays a success message. If the Sensor feature is turned on, the Connection icon  $\P$  appears on the Home screen.

#### If your pump does not connect to your transmitter:

- 1. If your pump does not connect to the transmitter, do one of the following:
  - Select **Retry** to return to the Enter Device SN screen on your pump, and then return to step 4 of the procedure above and follow the instructions to search again.
  - Select **Cancel** to return to the Connect Device screen, where you can search again using Manual Connect or Auto Connect.
- 2. If you have tried to connect multiple times without success, see *My pump* cannot find the sensor signal, on page 300.

#### Deleting the transmitter from your pump

Follow this procedure to delete the transmitter from your pump. Use this process when you are replacing your transmitter.

#### To delete your transmitter from your pump:

1. Press © and go to the Manage Devices screen.

#### Options > Utilities > Device Options > Manage Devices

2. Identify and select your transmitter by the serial number. The serial number can be found on the back of the transmitter.



- 3. Select **Delete**.
- 4. A screen appears confirming that you would like to delete the device. Select **Yes** to confirm or **No** to cancel.

#### Inserting the sensor

Always refer to your sensor user guide for instructions on how to insert the sensor.

#### Connecting the transmitter to the sensor

Refer to your transmitter user guide for instructions on how to connect the transmitter to the sensor

#### Starting the sensor

After you insert your sensor and connect your sensor and transmitter, your pump starts communicating with the transmitter. The pump notifies you when the sensor is ready to use.

#### To start a new sensor using the Start New Sensor message:

Select Start New Sensor when it appears on the pump screen.
 The "Sensor warm-up started" message appears.



**Note:** It may take up to 5 minutes for the "Sensor warm-up started" message to appear.

#### Select OK.

"Warm up..." appears on the Home screen until the sensor is ready for first calibration.



**Note:** If you do not see the **Start New Sensor** option, then follow the procedure for manual connection described below.

#### To start a new sensor using manual connect:

1. Press © and go to the Sensor Connections screen.

Options > Utilities > Sensor Settings > Sensor Connections

Select Start New Sensor.

The Start New Sensor screen appears.

3. If you have not done so already, connect the transmitter to your sensor. For details about connecting your transmitter and sensor, see your transmitter user guide.

Your pump searches for your transmitter signal. It can take up to six minutes for your pump and transmitter to start communicating.

- Select OK.
- 5. The Sensor warm-up started message appears on the screen. Select **OK**. If you receive a message that your pump cannot find the sensor signal, continue to the next section.

#### If your pump cannot find the sensor signal:

1. If your pump cannot find the sensor signal, follow the instructions on your pump screen. Your pump guides you through the following steps:

- a. Disconnect and reconnect the transmitter from the sensor. Pay attention to the transmitter, and notice if the transmitter light blinks when connected to the sensor. If the transmitter light does not blink, you need to charge your transmitter.
- b. Move your pump closer to your transmitter. It can take up to 15 minutes for your pump to find the sensor signal.
- c. If your pump is still unable to find the sensor signal, make sure you are away from any electronic devices that might cause interference.
- 2. If you have gone through all of the troubleshooting on your pump screen and your pump still cannot find the sensor signal, call the 24 Hour HelpLine for assistance.

#### Calibrating your sensor

Calibration is the process of entering a BG meter reading to calculate sensor glucose values. You must calibrate your sensor regularly to ensure you continue to receive sensor glucose data. For details, see *Guidelines for calibrating, on page 217*.

Within two hours after you use your pump to start the sensor, your pump displays a Calibrate now alert to let you know that a calibration is due. This BG meter reading is the first calibration for your sensor. It takes up to five minutes after calibration to see the first sensor glucose reading on your Home screen. You enter your second calibration within six hours after your first calibration.

After you have entered your first two calibrations, you must calibrate your sensor again within 12 hours. If you do not enter a BG meter reading within 12 hours, your pump displays the Calibrate now alert and stops calculating sensor glucose values until a calibration BG is successfully entered. The sensor must be calibrated at a minimum of every 12 hours throughout the life of the sensor. For better sensor performance, it is recommended that you calibrate your sensor three or four times each day.

You may also receive additional Calibrate now alerts to let you know that another calibration is required to improve performance.

When the Calibrate now alert appears, the system stops calculating SG values until a calibration BG is successfully entered.



**Note:** Sensor calibration is successful only if your BG entry is in the range of 40 to 400 mg/dL. Remember to calibrate three to four times throughout the day for optimal results.

#### To calibrate your sensor:

- 1. Take a BG meter reading.
- 2. Press © and go to the Calibrate Sensor screen.

Options > Utilities > Sensor Settings > Calibrate Sensor

- 3. Select **BG** and enter the value.
- Select Calibrate.

#### Where to enter your calibration BG meter reading

There are several screens on the pump where you can enter a BG meter reading for calibration. These screens are described in the following table. These options are available only if you are using a sensor.



**Note:** After your CONTOUR NEXT LINK 2.4 meter wirelessly transmits your BG reading to your pump, you will be required to confirm your BG on your pump before you can use it for calibration.

Pump screen	How to enter your calibration BG
BG screen	Enter a BG meter reading specifically for
When you manually enter a BG, the pump will prompt if you want to calibrate your sensor with the BG reading.	calibration.
Press © then select <b>Enter BG</b> .	
Calibrate Sensor screen	Enter a BG meter reading specifically for
Press ©, then select:	calibration.
Options > Utilities > Sensor Settings > Calibrate Sensor	

Pump screen	How to enter your calibration BG	
BG Meter screen	Select the Calibrate Sensor option to	
The BG Meter screen appears when your CONTOUR NEXT LINK 2.4 meter sends a BG meter reading to your pump, and you confirm the BG.	calibrate your sensor with the current BG meter reading.	
BG screen in Event Markers	When you enter a BG meter reading in	
Press ©, then select:	Event Markers, the Event Markers screen has an option to use the BG value for	
Options > Event Markers > BG	calibration.	
BG field in the Bolus Wizard screen	When you enter a BG meter reading to	
Press ©, then select:	deliver a bolus using the Bolus Wizard, the Bolus Wizard gives you the option to use	
Bolus > Bolus Wizard	the BG value for calibration after the bolus	
The Bolus Wizard is only available in Manual Mode.	is delivered.	
BG field in the Auto Mode Bolus screen	When you enter a BG meter reading to	
Press ◎, then select <b>Bolus</b> .	deliver a bolus using the Auto Mode Bolus feature, Auto Mode gives you the option	
Auto Mode Bolus is only available in Auto Mode.	to use the BG value for calibration after the bolus is delivered.	

#### When to calibrate

The following table describes when to calibrate your sensor.

Calibrate	Description	
After warm-up is	Do your first sensor calibration.	
complete.	Your pump displays a Calibrate now alert within two hours after starting a new sensor. Your first sensor glucose reading appears up to five minutes after you calibrate.	

Calibrate	Description
Six hours after your	Do your second sensor calibration.
first calibration.	Six hours after you calibrate for the first time, a Calibrate now alert appears, and your pump stops calculating your SG values. It takes up to five minutes after you calibrate to receive SG values again.
Within 12 hours after your second calibration and at least every 12	After you do your second calibration, you need to calibrate at least every 12 hours. For better sensor performance, it is recommended that you calibrate your sensor three or four times each day.
hours thereafter.	If you do not calibrate for more than 12 hours, a Calibrate now alert appears. It takes up to five minutes after you calibrate to receive SG values again.
When the Calibrate now alert appears.	You may also receive additional Calibrate now alerts to let you know that another calibration is required to improve performance. It takes up to five minutes after you calibrate to receive SG values again.

#### **Guidelines for calibrating**

Follow these guidelines for best sensor calibration results:

- Calibrate three to four times spread out throughout the day to improve accuracy. For details, see *When to calibrate, on page 216*.
- You can calibrate anytime. However, calibrating with two or three trend arrows may temporarily decrease accuracy until the next calibration. For an example of trend arrows on the Home screen, see *Home screen with CGM in Manual Mode, on page 179*.
- Always calibrate immediately after testing your BG. Never calibrate with a BG meter reading that you have taken more than 12 minutes earlier as that BG value would no longer be considered valid.
- Always use clean, dry fingers when you test your blood glucose levels.
- Use only your fingertips when obtaining blood samples for calibration.



**Note:** If your BG meter readings are significantly different than your sensor glucose readings, you need to wash your hands and calibrate again.

#### Disconnecting the transmitter from the sensor

Always refer to your transmitter user guide for instructions on disconnecting the transmitter from the sensor.

#### Removing the sensor

Always refer to the sensor user guide for instructions on how to remove the sensor.

#### **Turning off Sensor Settings**

You can turn off Sensor Settings at any time. If you disconnect the transmitter from the sensor, turn off the Sensor Settings to avoid getting a sensor alert. Your sensor settings remain in your pump. You cannot make changes to the settings until you turn on the Sensor Settings again.

#### To turn off Sensor Settings:

- 1. Press © and go to the Sensor Settings screen.
  - Options > Utilities > Sensor Settings
- Select Sensor.
- 3. Select **Yes** to turn off the sensor feature.

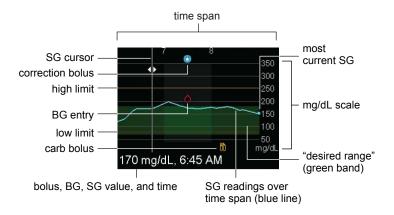


# Using continuous glucose monitoring

This chapter provides information on how to use CGM on your pump and view your sensor glucose data. This information helps you identify sensor glucose trends, including being notified if your sensor glucose is falling or rising rapidly. You can also view historical sensor glucose readings in a graph format. Information is also included on how to silence your glucose alerts.

#### The sensor graph

The sensor graph displays your current sensor glucose (SG) reading that is wirelessly sent to your pump by the transmitter.



The sensor graph includes the following information:

The most recent sensor glucose reading

- Historical sensor glucose readings for the last 3-hour, 6-hour, 12-hour, or 24-hour periods
- Your high and low limits
- The bolus deliveries you have given during the time period shown on the graph
- Any suspend events that have occurred

If an SG reading does not appear on the graph, some possible reasons for this include:

- An error condition or a sensor-related alert is occurring.
- A new sensor that you just inserted is still initializing.
- A new sensor that just initialized is still calibrating.
- An existing sensor that you have recently reconnected is not ready.
- More than six hours have passed since the initial sensor calibration.
- More than 12 hours have passed since the last sensor calibration.

#### To view the sensor graph:

- From the Home screen, press the button.
   A full-screen view of the 3-hour graph appears.
- 2. Press ∧ to navigate to the 6-hour, 12-hour, and 24-hour graphs.

2 mg/dL per minute.

4. To exit the full-screen view, press 👆, or press the 🛂 button again.

#### Identifying rapid changes in sensor glucose

When you use a sensor, trend arrows appear on the Home screen if your SG has been rising or falling faster than a certain per-minute rate. The number of arrows that appear tell you how quickly your SG has been changing.

The following table shows the trend arrows and their corresponding rates.

<b>↑</b>	SG has been rising at a rate of 1 mg/dL per minute or more, but less than 2 mg/dL per minute.
<b>+</b>	SG has been falling at a rate of 1 mg/dL per minute or more, but less than

<b>†</b> †	SG has been rising at a rate of 2 mg/dL per minute or more, but less than 3 mg/dL per minute.
++	SG has been falling at a rate of 2 mg/dL per minute or more, but less than 3 mg/dL per minute.
<b>††</b> †	SG has been rising at a rate of 3 mg/dL per minute or more.
$\downarrow\downarrow\downarrow\downarrow$	SG has been falling at a rate of 3 mg/dL per minute or more.

#### **Silencing Glucose Alerts**

The Alert Silence feature allows you to make sensor glucose alerts silent for a set period of time. This is useful in situations where you do not want to disturb others, such as when you are in a business meeting or in a movie theater. When using this feature, one of the following status icons appears on the Home screen, depending on your Audio Options settings: vibrate only \$\circ\*, audio only \$\circ\$, or vibrate and audio \$\circ\*. Your system still records the time and glucose value for any alerts that occur. You can view this information in the Alarm History screen.



**Note:** Alert Silence does not silence Auto Mode exit, High SG, Auto Mode off, and Low SG XX mg/dL (XX represents 50 mg/dL or below) alerts. These alerts are based on set glucose thresholds and cannot be silenced.

If a glucose alert occurs when you are using the Alert Silence feature, the notification light begins to flash and the Sensor alert occurred message appears letting you know an alert was silenced, but there is no vibration or beep. If you have not cleared the alert by the end of the preset alert silence duration, your pump begins to beep or vibrate periodically until the alert is cleared.

The following table describes the glucose alerts that are silenced with each option.

This Alert Silence setting	Silences these alerts
High Alerts Only	Alert on high, Alert before high, and Rise Alert
High & Low Alerts	Alert on high, Alert before high, Rise Alert, Alert on low, Alert before low, Suspend before low, and Resume Basal Alert

This Alert Silence setting	Silences these alerts
All Sensor Alerts	All of the alerts listed previously for High & Low Alerts, plus the following:
	All calibration alerts, reminders, or error messages
	<ul> <li>All alerts relating to sensor insertion, including alerts about sensor warm-up, changing your sensor, sensor expiration, sensor errors, connection issues, and so on</li> </ul>
	<ul> <li>All alerts related to your transmitter, including all alerts about your transmitter battery and all connection issues</li> </ul>

#### To silence Glucose alerts:

1. Press O and go to the Alert Silence screen.

#### Audio Options > Alert Silence Options



2. Select High Alerts Only, High & Low Alerts, or All Sensor Alerts to set the alerts you want silenced. Refer to the previous table for details about the alerts silenced with each selection.



**Note:** If you select **All Sensor Alerts**, you will not receive most alerts related to your sensor glucose readings, your sensor, calibration requirements, or your transmitter. Low SG XX mg/dL (XX represents 50 mg/dL or below), Auto Mode off, Auto Mode exit, and High SG alerts cannot be silenced. You will still hear these alerts when Alert Silence is on. You will still receive alerts for Auto Mode off, Auto Mode exit, High SG, and Low SG XX mg/dL (XX represents 50 mg/dL or below). If a silenced glucose alert occurs, the notification light flashes and a message appears on your pump to let you know a

silenced alert occurred, but there is no vibration or beep. You can view the specific alert in Alarm History. For more information on how to view the Alarm History screen, see *Alarm History, on page 147*.

- 3. Set the **Duration** time (from 30 minutes to 24 hours) for which the alerts will be silenced.
- 4. Select **Begin**. The Alert Silence settings immediately take effect and you are returned to the Sensor Settings screen.

#### To cancel Alert Silence:

1. Press © and go to the Alert Silence screen.

Audio Options > Alert Silence Options



2. Select Cancel Alert Silence.

# Auto Mode

### **Auto Mode**

The Auto Mode feature is part of SmartGuard technology. It automatically controls basal insulin delivery. However, the Auto Mode feature still requires your input for meals, calibrations, and times when you need the target value raised.



**Note:** The pump requires a minimum of 8 units and a maximum of 250 units per day to operate in Auto Mode.

#### **About Auto Mode**

Auto Mode is an insulin delivery feature designed to help people on intensive insulin therapy to achieve better control 24 hours a day. This is achieved by automatically controlling basal insulin delivery to regulate glucose levels to a target sensor glucose (SG) amount. The standard target SG setting is 120 mg/dL and the target can be set temporarily to 150 mg/dL for exercise and other events.

When Auto Mode is active, the sensor glucose values it receives from the transmitter are used to automatically calculate the basal insulin dose. This process of automatic delivery of insulin is called Auto Basal.

Auto Mode depends on reliable, accurate sensor measurements and your accurate entry of carbs to deliver insulin for meals. Therefore, the basic management of the therapy requires the following activities:

- Periodic blood glucose (BG) readings using a BG meter to calibrate the sensor.
  The minimum calibration is every 12 hours. For better sensor performance, it is recommended that you calibrate your sensor three or four times each day.
  You may also receive periodic requests from your pump for BG readings without the need for calibration.
- Use of the Auto Mode Bolus feature to deliver boluses to cover meals, and when your pump recommends a bolus.



**Note:** Delivering a bolus in Auto Mode is similar to delivering a bolus with the Bolus Wizard feature in Manual Mode.

A BG reading above 150 mg/dL causes Auto Mode to automatically calculate if a correction bolus is needed to bring BG down to the 150 mg/dL BG correction target. If needed, a correction bolus will be recommended.

#### Manual Mode

In this user guide, the term Manual Mode refers to system functions other than Auto Mode. In other words, if Auto Mode is not functioning, the system is in Manual Mode.

#### **Before using Auto Mode**

Auto Mode can be enabled at any time, but it does not activate until the system completes a 48-hour warm-up period while you use the pump to deliver insulin. This warm-up period begins the midnight after the pump starts delivering insulin and it does not require sensor use. During the warm-up period, your Auto Mode system collects and processes data that help enable its automatic function. Some alarms that occur during warm-up, including a Suspend before low alert or a Suspend on low alert, will turn off Auto Mode.



WARNING: Do not put your pump into Auto Mode if you have used the pump in the last 3 days to practice button pressing, or if basal insulin that was programmed into your pump was not your actual basal delivery. Doing so may result in the delivery of too little or too much insulin, which can cause hyperglycemia or hypoglycemia. Auto Mode uses the recent delivery history on your pump to determine the Auto Basal delivery amount you receive. If you have been practicing with your pump, you must clear the active insulin and the total daily doses in the pump before using Auto Mode. Use the Clear Active Insulin option in the Manage settings menu to clear both active insulin and the total daily dose.

#### To ready your pump for Auto Mode, you must:

- 1. Cancel any active Temp Basal rates. See *Canceling a Temp Basal or Preset Temp basal rate, on page 81*.
- 2. Ensure your delivery is not suspended. See *Stopping and resuming your insulin delivery, on page 82.*
- 3. Set your carb ratio. See Changing your carb ratio, on page 98.
- 4. Review your high and low limit settings. Your high and low limit settings apply to Auto Mode. See *Setting up Continuous Glucose Monitoring, on page 177* for details.
- 5. Enter a BG reading if you have not entered one in the past 12 minutes. If necessary, calibrate your sensor. If you have just started a new sensor, calibrate your sensor, and then wait 30 minutes before you enter a BG for Auto Mode. For more information about calibrating your sensor, see *Calibrating your sensor, on page 214*.

#### **Setting up Auto Mode**

Auto Mode can be enabled at any time but will not activate until the 48-hour warm-up period has been completed. For details about the warm-up period, see *Before using Auto Mode, on page 230.* Once enabled, Auto Mode begins automatically when all conditions are met and a BG is entered. For more information, see *Auto Mode Readiness, on page 233.* 

#### To set up Auto Mode:

1. Press ◎ and go to the Auto Mode Settings screen.

Options > SmartGuard > Auto Mode

- 2. Select **Auto Mode** to turn the feature on or off.
- Select Auto Mode BG alert to turn it on or off.



**Note:** The Auto Mode BG alert is set to On by default. When this setting is on, your pump alerts you when Auto Mode requires a BG to remain active. For information about the conditions that cause Auto Mode to require a BG, see *Safe Basal*, on page 236.

Select Save.

#### **Conditions to activate Auto Mode**

If you have been using Auto Mode and you turn off your pump for less than two weeks, there will only be a five hour warm up period once the pump is restarted. The other conditions must still be met before Auto Mode will activate.

If you have turned off your pump for more than two weeks, a new 48 hour warm-up period will be required.

If Auto Mode is enabled but not active, the Auto Mode Readiness screen indicates the reason why Auto Mode has not yet activated. See *Auto Mode Readiness, on page 233*.

It takes 5 hours for the Auto Mode Active Insulin to be updated. This update time happens under the following conditions:

- when your pump is turned on the first time
- may occur following a complete pump reset caused by a loss of power or a software error
- following a Suspend lasting 4 hours or longer

Once the Active Insulin is updated, it will be valid unless one of the conditions above happens, which will restart the update period. Auto Mode will then be locked out for another 5 hours.

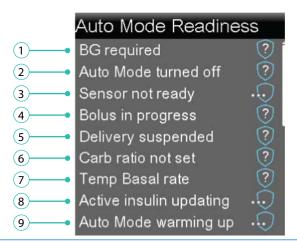
#### Low Management and Auto Mode

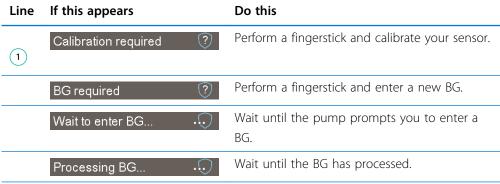
When Auto Mode is active, then the Low Management features are unavailable and automatically turned off. If you are using Suspend before low or Suspend on low, they are automatically turned off when Auto Mode becomes active. If your pump exits Auto Mode, the Low Management features are not active until you turn them on after you exit Auto Mode. If you want to use these features, you must manually turn them on after you exit Auto Mode. See *Low settings, on page 185*.

#### **Auto Mode Readiness**

The Auto Mode Readiness screen indicates whether your pump is ready to enter Auto Mode, or return to Auto Basal from Safe Basal.

The following table shows what to do when the wait icon ... or the question icon appear by items on the Auto Mode Readiness status screen.





Line	If this appears	Do this
2	Auto Mode turned off	Turn on Auto Mode in the SmartGuard Auto Mode screen.
(3)	Sensor not ready	Do the following:  • Check to see if your pump has a transmitter
		ID entered in Utilities, Device Options. For example, GT61333333M.
		Make sure your pump is connected to a transmitter. For more information, see Wirelessly connecting your pump and transmitter using Auto Connect, on page 205.
		• Check your Home screen. If you see 🧩,
		move your pump and transmitter closer together. The pump will try to find the transmitter signal.
		If after 30 minutes the pump and transmitter are still not communicating, you will receive a Lost sensor signal alert. Check that the sensor is still inserted in the skin, and the transmitter and sensor are still connected.  Move your pump closer to your transmitter.
		• If your SG is outside of the 40-400 mg/dL range, your pump will not enter Auto Mode.
	Sensor off	Turn on the sensor in the Utilities, Sensor Settings screen.
	Airplane mode on ?	Turn off the Airplane Mode in the Utilities, Airplane Mode screen.
4	Bolus in progress ?	Wait until the bolus is complete or stop the bolus yourself before Auto Mode can activate.
5	Delivery suspended ?	If insulin delivery is suspended, Auto Mode cannot activate. Treat low BG if necessary as instructed by your healthcare professional.

Line	If this appears	Do this
6	Carb ratio not set	Enter your Carb Ratio in the Bolus Estimate Setup screen or the Bolus Wizard Setup screen.
7	Temp Basal rate	If a temp basal is currently active, you must wait until it has completed or cancel the temp basal yourself before Auto Mode can activate.
8	Active insulin updating	If active insulin is currently updating, it may take up to 5 hours to complete. You must wait until this amount is updated before Auto Mode can activate.
9	Auto Mode warming up	Auto Mode is gathering information on your insulin delivery history in order to personalize its automatic delivery of insulin.

#### To check Auto Mode Readiness:

- 1. Press O and select **Status** to go to the Status screen.
- 2. Select Auto Mode Readiness.

# Home screen with Auto Mode

When your pump transitions into Auto Mode, the Home screen on your pump changes to display a shield that contains a real-time display of your current SG level. The Home screen also displays your current Active Insulin value.



# **Using Auto Mode**

The following sections provide information on how to use Auto Mode and how to view your SG data. This information helps you identify SG trends, including indications that your SG is falling or rising rapidly. You can also view historical SG readings in a graph format.

#### Safe Basal

Safe Basal is an automatic function within Auto Mode and cannot be modified. The Safe Basal rate is determined by the Auto Mode feature based on your insulin delivery history. It allows you time to perform additional actions required to ensure Auto Mode remains active. Safe Basal covers your basal needs by delivering insulin at a constant rate. Safe Basal does not adjust insulin delivery based on your current SG values.

When the pump is in Safe Basal, the Auto Mode shield appears with a white outline.



Several conditions can cause a transition into Safe Basal. The following table describes these conditions and the actions you must take to resume Auto Basal delivery. An optional setting called the Auto Mode BG alert can be set to have the pump alert you when a BG entry is required. This setting is turned on by default. For more information about setting the Auto Mode BG alert, see *Setting up Auto Mode, on page 231*.

Condition	Actions to take
Auto Mode has been at the minimum delivery limit for 2 1/2 hours.	<ul> <li>Enter a BG.</li> <li>If your Auto Mode BG alert setting is enabled, you will receive an Auto Mode min delivery alert.</li> </ul>

Condition	Actions to take
Auto Mode has been at the	• Enter a BG.
maximum delivery limit for 4	If your Auto Mode BG alert setting is enabled, you will
hours.	receive an Auto Mode max delivery alert.
Auto Mode detects that	• Enter a BG.
your sensor might be under-	If your Auto Mode BG alert setting is enabled, you will
reading.	receive a BG entry required alert.
An entered BG is 35% or	Enter another BG or calibration if prompted.
more different than your	If your Auto Mode BG alert setting is enabled, you will
current SG value.	receive a BG entry required or Cal required for Auto
	Mode alert.
No SG data has been	• If SG data is not available due to a signal interference,
received for more than 5	three dashes appear on the screen in place of the SG
minutes.	data. If the interference is intermittent, the Auto Mode shield appears with a white outline, and no action will
	be required.
	<ul> <li>If your pump has not received SG data for 30 minutes</li> </ul>
	or more, you will receive a Lost sensor signal alert. For
	more information about what to do in case of a lost
	sensor signal, see CGM (sensor) alarms, alerts, and
	messages, on page 271.
	• If the SG data is not available because the SG
	calibration has expired, you will receive a Calibrate
	Now alert. Calibrate your sensor. See CGM (sensor)
	alarms, alerts, and messages, on page 271.
	The Auto Mode BG alert does not apply to this
	condition.

After 90 minutes in Safe Basal, if the condition that caused the pump to transition into Safe Basal has not been resolved, the pump will enter Manual Mode.



**Note:** When you change your sensor, your pump will switch to Safe Basal for up to 90 minutes. The pump will guide you through calibrating and entering a BG for Auto Mode.

### **Example: Safe Basal**

Alex's pump is in Auto mode. Before lunch, he checks his BG, and enters the value into his pump. Alex notices the BG he entered was much higher than his current SG reading. His pump displays a gray shield, indicating that Auto mode is now in Safe Basal delivery. Alex also received a BG Required for Auto Mode alert. He washes his hands, repeats his fingerstick, and enters the new BG into the pump.

After his pump enters Safe Basal, Alex checks his user guide and realizes that his pump entered Safe Basal because the difference between his SG and BG entry was greater than 35%.

#### Block Mode when in Auto Mode

The Block Mode feature allows a caregiver to block the patient from changing settings or delivering a bolus directly on the pump. In Auto Mode, the Block Mode feature still allows:

- Auto Basal delivery
- BG correction bolus if BG was sent from your CONTOUR NEXT LINK 2.4 meter
- Calibration if BG was sent from your CONTOUR NEXT LINK 2.4 meter

The Block Mode feature does not allow:

- Bolus delivery or entry unless prompted by the Bolus Recommended screen
- Changes to Auto Mode settings
- Manual BG entry

# **Setting Temp Target**

You may set a temporary SG target (Temp Target) of 150 mg/dL for situations in which you would like your target to be temporarily higher, such as exercise. Check with your healthcare professional regarding use of a Temp Target.

# To set a Temp Target:

1. Press ◎ and select Temp Target to go to the Temp Target screen.



- 2. Set the duration. The default is 2 hours and the maximum duration is 12 hours. Use ∧ and ∨ to set the duration in 30-minute increments.
- Select Start.

The screen will show Temp Target Started, then change to the Home screen, where a banner will show the remaining Temp Target time.



When the Temp Target time has run out, the banner will disappear from the Home screen.

# To cancel Temp Target:

1. Press ◎ and select **Cancel Temp Target** to go to the Cancel Temp Target screen.

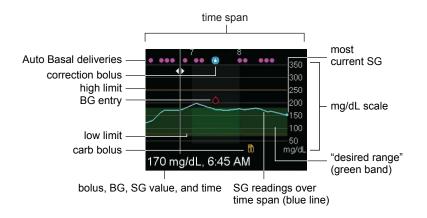


2. Select Cancel Temp Target.

The Temp Target will be cancelled and the Home screen will appear, with no Temp Target banner.

# Auto Mode sensor graph

Your Auto Mode sensor graph displays your current sensor glucose (SG) reading that is wirelessly sent to your pump by your transmitter.



The Auto Mode sensor graph includes the following information:

- The selected SG or event details are displayed at the bottom of the screen.
- Historical sensor glucose readings are displayed for the last 3-hour, 6-hour, 12-hour, or 24-hour periods. They appear as a blue line across the screen.
- Correction boluses are shown as white vials inside blue circles.
- Meal (carb) boluses are shown as yellow knife and fork symbols. These represent any bolus amounts that include a carb entry.
- Blood glucose entries appear as red drop symbols.
- The numerous small magenta dots along the top represent the automatically delivered basal insulin (Auto Basal or Safe Basal) delivered by Auto Mode.
- A time change event appears as a white clock symbol.

If an SG reading does not appear on the graph, some possible reasons for this include:

- An error condition or a sensor-related alert is occurring.
- A new sensor that you just inserted is still initializing.

- A new sensor that just initialized is still calibrating.
- An existing sensor that you have recently reconnected is not ready.
- More than six hours have passed since the initial sensor calibration.
- More than 12 hours have passed since the last sensor calibration.

#### To view the sensor graph:

- 1. From the Home screen, press the \times button to display the SG graph.

  A full-screen view of the 3-hour graph appears.
- 2. Press  $\wedge$  to navigate to the 6-hour, 12-hour, and 24-hour graphs.
- 3. Press < to view SG readings and event details.

#### **Enter BG**

The BG screen lets you manually enter a BG value. When you access the BG screen, it does not show any previously entered manual or linked meter BG values. If a BG value is received from a linked meter, that value will immediately display in a separate BG Meter screen and you will be prompted to confirm the BG value.

When you enter a BG while in Auto Mode, a correction bolus may be suggested if necessary.

# To manually enter Blood Glucose (BG) readings:

- 1. Press © and select **Enter BG** to go to the BG screen.
- Select Enter BG.
- 3. Enter a BG value.
- 4. Select **Save**.
- 5. A screen appears prompting you to calibrate your sensor with the BG value if you want. Select **Yes** or **No**.

#### **Auto Mode Bolus**

Delivering a bolus in Auto Mode is similar to delivering a bolus using the Bolus Wizard feature in Manual Mode. The Bolus feature in Auto Mode requires you to enter either carbs or a BG value. You may also choose to enter both. Auto Mode then calculates the bolus amount needed to cover the meal or correction. Once you confirm this amount, Auto Mode will deliver the bolus.

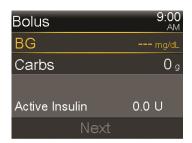
The Auto Mode Bolus screen shows your current Active Insulin value.



WARNING: Do not use Auto Mode for a period of time after giving a manual injection of insulin by syringe or pen. Manual injections are not accounted for in Auto Mode. Therefore, Auto Mode could deliver too much insulin. Too much insulin may cause hypoglycemia. Consult with your healthcare professional for how long you need to wait after a manual injection of insulin before you resume Auto Mode.



**Note:** Auto Mode Bolus only supports Normal boluses. Square Wave, Dual Wave, Easy, Manual, Remote, and Preset bolus types cannot be delivered while in Auto Mode.



If you are using a CONTOUR NEXT LINK 2.4 meter, you may send your BG meter readings directly to your pump. A confirmation screen will appear asking you to confirm the BG value on the pump. Confirmed BG values will automatically be used in the BG selection of the Auto Mode Bolus screen. These entries will be valid for up to 12 minutes after sending them to the pump. If you wish to enter your BG using a CONTOUR NEXT LINK 2.4 meter, do this prior to using the Auto Mode Bolus screen. If you are not using a CONTOUR NEXT LINK 2.4 meter, you must manually enter your BG value.



**Note:** In order to ensure accuracy, do not use a BG meter reading in the Auto Mode Bolus screen if more than 12 minutes have passed since you have taken the reading. That BG reading and the corresponding bolus amount may no longer be accurate.

#### To use the Auto Mode Bolus feature:

- 1. Press © and select Bolus to go to the Auto Mode Bolus screen.
- 2. If you are using a CONTOUR NEXT LINK 2.4 meter, skip to step 3. Otherwise, enter your BG amount. You can enter a range from 20 mg/dL to 600 mg/dL.
- 3. Enter your Carb amount in grams. If you choose not to enter a Carb amount, skip to step 4.
- 4. Select **Next**.

The screen indicates the amount of the calculated bolus.

Select Deliver Bolus.

A screen appears briefly to indicate the bolus delivery has started. Then, the Home screen appears and shows the progress of the bolus delivery.





**Note:** You can stop a bolus at any point by pressing  $\odot$  and selecting **Stop Bolus**.

6. If a new BG value is used in the Auto Mode Bolus feature, the following screen also appears, prompting you to calibrate your sensor. Select **Yes** or **No**.



## **Correction Boluses**

When a BG reading over 150 mg/dL is received and confirmed while your pump is in Auto Mode, your pump automatically calculates and recommends a correction bolus if needed. The calculation takes into account any active insulin that has already been delivered by the pump. If the BG is not above 150 mg/dL, or if the bolus would be zero after accounting for active insulin, no correction will be recommended. If your pump calculates that a correction bolus is needed, the Bolus Recommended screen appears.

To administer a correction bolus from the Bolus Recommended screen, select the Bolus option. If you do not wish to bolus at this time, you may select Cancel to reject the correction bolus. Selecting Bolus will take you to the Auto Mode Bolus screen where you can confirm and deliver the correction bolus. For more information, see *Auto Mode Bolus*, on page 242.

# **Alert Silence**

The Alert Silence feature 4 allows you to temporarily silence SG alerts. This is useful in situations where you do not want to disturb others, such as when you are in a business meeting or in a movie theater. When using this feature, your system still records the time and glucose value for any alerts that occur. You can view this information in the Alarm History screen. See *Alarm History*, on page 147 for details.

If a glucose alert occurs when you are using the Alert Silence feature, the notification light begins to flash and the *Sensor alert occurred* message appears, but there is no vibration or sound. If you have not cleared the alert by the end of the preset alert silence duration, your pump begins to beep or vibrate periodically until the alert is cleared.



**Note:** The following alerts are never silenced:

- Low SG XX mg/dL (XX represents 50 mg/dL or below)
- Auto Mode exit
- High SG
- Auto Mode off

For more information about the Auto Mode exit, High SG, and Auto Mode off alerts, see *Auto Mode alerts and messages, on page 283*. For more information about the Low SG XX mg/dL (XX represents 50 mg/dL or below) alert, see *CGM (sensor) alarms, alerts, and messages, on page 271*.

You can check the status of the Alert Silence feature in the Sensor Status Screen. For more information, see *Status screens*, on page 55.

The following table describes the glucose alerts that are silenced with each option.

This Alert Silence setting	Silences these alerts
High Alerts Only	Alert on high, Alert before high, and Rise Alert
High and Low Alerts	Alert on high, Alert before high, Rise Alert, Alert on low, and Alert before low
All Sensor Alerts	All of the alerts listed previously for High and Low Alerts, plus the following:  • All calibration alerts, reminders, or error messages
	<ul> <li>All alerts relating to sensor insertion, including alerts about sensor warm-up, changing your sensor, sensor expiration, sensor errors, connection issues, and so on</li> </ul>
	<ul> <li>All alerts related to your transmitter, including all alerts about your transmitter battery and all connection issues</li> </ul>

#### To set Alert Silence in Auto Mode:

1. Press © and go to the Alert Silence Options screen.

# Audio Options > Alert Silence Options



2. Select High Alerts Only, High and Low Alerts, or All Sensor Alerts to set the alerts you want silenced. Refer to the previous table for details about the alerts silenced with each selection.



**Note:** If you select **All Sensor Alerts**, you will not receive any alerts related to your SG readings, your sensor, calibration requirements, or your transmitter. You will still receive the Auto Mode exit, High SG, Auto Mode off, and Low SG XX mg/dL (XX represents 50 mg/dL or below) alerts, which cannot be silenced. If a glucose alert occurs, the notification light flashes and a message appears on your pump to let you know an alert occurred, but there is no vibration or beep. You can view the specific alert in Alarm History. For more information, see *Alarm History, on page 147*.

- 3. Set the **Duration** time (from 30 minutes to 24 hours) for which the alerts will be silenced.
- 4. Select **Begin**. The Alert Silence settings immediately take effect and you are returned to the Sensor Settings screen.

#### To cancel Alert Silence:

1. Press © and go to the Alert Silence screen.

Audio Options > Alert Silence



#### 2. Select Cancel Alert Silence.

# **Exiting Auto Mode**

Auto Mode is turned off automatically after most pump alarms, except for the following alarms:

- Auto Suspend
- Battery failed
- Power loss
- Battery not compatible
- Insert battery
- Replace battery now
- Loading incomplete
- No reservoir detected
- Max fill reached
- Fill Cannula

If an alarm has initiated a pump reset, you must turn on Auto Mode again and go through a 5-hour warm-up period. For more information about pump alarms, see *Pump alarms, alerts, and messages, on page 254*.

Auto Mode may stop working because:

- You manually turned off the feature through the Auto Mode settings.
- Auto Mode has been in Safe Basal for 90 minutes. See Safe Basal, on page 236.
- Any suspend event has not been cleared within 4 hours.
- You manually turned off the Sensor feature or disconnected the transmitter.

You can turn off Auto Mode at any time. For more information, see *Setting up Auto Mode, on page 231*.

# **Returning to Auto Mode**

If you have automatically transitioned to Manual Mode, you can return to Auto Mode if all readiness conditions are satisfied and you enter a BG. For more information, see *Auto Mode Readiness, on page 233*.



**Note:** If you have turned Auto Mode off, you cannot return to Auto Mode until you turn Auto Mode on again.

You may return to Auto Mode if:

- Auto Mode is enabled on your pump.
- Your sensor is providing good SG values.
- A bolus is not in progress.
- A Temp Basal rate is not in progress.
- 48 hour warm-up is complete.
- Auto Mode is not in a 5-hour warm-up period.
- You have entered a new BG reading.

If any of these conditions are not met, Auto Mode cannot restart.

# Alarms, al

# Alarms, alerts, and messages

This chapter describes the general behavior of the most common and the most serious notifications and how to resolve them.

# About alarms, alerts, and messages

Your pump has a sophisticated safety network. If this safety network detects anything unusual, it conveys this information in the form of notifications. Notifications include alarms, alerts, and messages.

When you have received more than one notification and there are multiple messages to view, a small white flap appears on the notification icon in the upper-right corner of the screen . When you clear the first notification, the next notification becomes visible.



**Note:** It is important that you promptly respond to all notifications and confirmations that appear on your pump. In the event that you do not respond, your pump may remain on that screen until addressed.

When you respond to a message, there may be times when another message appears. Always be sure to address all notifications you have received.

A white triangle in the lower-right corner means you must press  $\checkmark$  to continue.



**WARNING:** If you receive a Critical pump error alarm on your pump, the following screen displays and the pump sirens.



Immediately disconnect from your insulin pump and discontinue use. Contact the 24 Hour HelpLine for assistance.

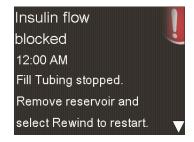
Remember, your body still needs insulin while your pump is removed. It is important that you consult your healthcare professional to determine an alternate method of receiving insulin while your pump is removed. For more information on the Critical pump error alarm, see *Pump alarms, alerts, and messages, on page 254*.

#### Alarms

An alarm warns you of a condition that needs your immediate attention. Stopped insulin delivery and low glucose levels are the most common reasons for alarms.



WARNING: Always address alarms immediately when they occur. Ignoring an alarm can result in hyperglycemia or hypoglycemia.



When an alarm occurs:

**Display:** The pump displays a notification with a red icon and instructions.

**Notification light:** The red notification light blinks twice, followed by a pause, in a continuous repeating pattern.

**Audio:** Depending on your Audio Options settings, the pump emits an alarm tone, a continuous three-pulse-and-pause vibration pattern, or both the alarm tone and vibration.

You must resolve the underlying problem that triggered the alarm. In most cases, you clear an alarm by pressing  $\vee$  and then you make a selection. In some cases, however, clearing the alarm does not fix the underlying problem. The alarm repeats until the underlying problem is fixed.

If you do not respond to an alarm, after ten minutes the alarm tone escalates to a loud emergency siren.

#### **Alerts**

An alert makes you aware of a situation that may require your attention. When an alert occurs, always check your pump screen to see if any action is required.

When an alert occurs:

**Display:** The pump displays a notification with a yellow icon and instructions.

Low battery
Pump
12:00 AM
Replace battery soon.

**Notification light:** The red notification light on your pump blinks once, followed by a pause, then blinks once again in a continuous repeating pattern.

**Audio:** Depending on your Audio Options settings, the pump either beeps or vibrates in a continuous three-pulse-and-pause pattern, or does both.

To clear an alert, press  $\vee$  and then make a selection. If you do not respond to an alert, the pump beeps every five minutes or every fifteen minutes, depending on the alert. Some alerts will also escalate to a loud emergency siren after ten minutes.



**Note:** If an alert occurs when you are in a screen other than the Home screen, the alert message may appear after you return to the Home screen.

## Messages

A message informs you about the status of your pump or if you need to make a decision.

When a message occurs:

**Display:** The pump displays a notification with a blue icon and instructions.

Notification light: Does not illuminate or blink.



**Audio:** Depending on the message, the pump emits a message tone, an alert tone, or no tone. Depending on your Audio Options settings, you may hear a tone, feel a one-pulse-only vibration, or hear a tone and feel a vibration.

You clear the message by pressing  $\vee$  and making a selection.

# Pump alarms, alerts, and messages

The following table lists the most common or serious alarms, alerts, and messages related to your pump. The table also explains the meaning, consequences, and the reasons why these notifications appear, and provides steps for problem resolution. For a list of the alarms that do not turn off Auto Mode, see *Exiting Auto Mode, on page 247*.

Title and text	Туре	Explanation	Next steps
Active Insulin cleared  Any Active Insulin amount has been cleared.	Alert	Your active insulin amount is now at 0 units. This may occur because certain alarms automatically clear active insulin to ensure the pump returns to a known state.	<ul> <li>Select OK to clear the alarm.</li> <li>The active insulin tracked prior to pump restart is not included in new Bolus Wizard calculations. Consult your healthcare professional for how long you need to wait after active insulin is cleared before you can rely on the active insulin calculation of your Bolus Wizard.</li> <li>You can check Daily History for the time and amount of your last bolus.</li> </ul>
Auto Suspend Insulin delivery suspended. No buttons pressed within time set in Auto Suspend.	Alarm	Insulin delivery is currently suspended by Auto Suspend. Auto Suspend is a feature you enabled to automatically suspend insulin delivery and trigger an alarm after no buttons are pressed for a specified period of time. Auto Suspend does not disable Auto Mode. Insulin delivery is suspended until you clear the alarm and resume basal delivery.	<ul> <li>To clear the alarm and resume basal insulin delivery, select Resume Basal.</li> <li>Check your blood glucose (BG) and treat as necessary.</li> </ul>

Title and text	Туре	Explanation	Next steps
Battery failed Insert a new AA battery.	Alarm	The pump battery does not have enough power.	<ul> <li>Select <b>OK</b> to clear the alarm.</li> <li>Remove the old battery and insert a new AA battery.</li> </ul>
Battery not compatible. See User Guide.	Alarm	The battery that you inserted into the pump is not compatible.	<ul> <li>To clear the alarm, remove the incompatible battery.</li> <li>Insert a new AA battery.</li> </ul>
Bolus not delivered. Bolus entry timed out before delivery. If bolus intended, enter values again.	Alert	Bolus values entered, but bolus was not delivered within 30 seconds.	<ul> <li>Select <b>OK</b> to clear the alert.</li> <li>If bolus delivery was intended, check your BG, re-enter bolus values and deliver bolus.</li> </ul>
Bolus stopped Cannot resume bolus or cannula fill. XX.XXX of YY.YYY U delivered. ZZ.ZZZ U not delivered. If needed, enter values again.	Alarm	The battery power was exhausted while a bolus or Fill Cannula was in progress, or you did not respond to the Resume bolus alert after replacing the battery.	<ul> <li>Note the amount of insulin not delivered.</li> <li>Replace the AA battery.</li> <li>Select OK to clear the alarm.</li> <li>Deliver the remaining bolus amount if needed.</li> </ul>

Title and text	Type	Explanation	Next steps
Cannot connect device This device is incompatible with your pump. See User Guide.	Alert	<ul> <li>You may be trying to connect a device that is not compatible with your pump.</li> <li>You are trying to connect a transmitter to your pump but another transmitter is already wirelessly connected to your pump.</li> </ul>	<ul> <li>Select OK to clear the alert.</li> <li>Check the list of devices that are compatible with your pump in Additional MiniMed 670G system devices, on page 36.</li> <li>If you are replacing your transmitter, make sure that you first delete the old transmitter from your pump before you try to connect your new transmitter. Only one transmitter can be connected to your pump. For details, see Deleting the transmitter from your pump, on page 212.</li> </ul>
Check settings Startup Wizard settings complete. Check and set up your other settings.	Alert	Some settings have been cleared or reverted to factory default values.	<ul> <li>Select <b>OK</b> to clear the alert.</li> <li>Review any settings that you have not already set in Startup Wizard and reenter the values, if necessary.</li> </ul>

Title and text	Туре	Explanation	Next steps
Critical pump error  Delivery stopped. Pump not working properly. Stop using pump. Remove infusion set from body. Consider other insulin treatment. See User Guide.	Alarm	Your pump has encountered an error that cannot be resolved. For example, your pump may have a mechanical problem.	The pump is not able to deliver insulin. Remove your infusion set and stop using your pump.  Consider another form of insulin delivery.  Check your BG, and treat as necessary.  Write down the error code that appears on the alarm screen.  Call the 24 Hour HelpLine for assistance with your pump.
Delivery limit exceeded  Delivery stopped. Check BG. See User Guide for more information.	Alarm	Your pump has suspended because the hourly delivery limit was met. This limit is based on the maximum bolus and maximum basal setting. If this alarm occurs during a bolus, the bolus is canceled before it can complete.	<ul> <li>Check your BG.</li> <li>Select Resume Basal.</li> <li>Check Bolus History and reevaluate your need for insulin.</li> <li>Continue to monitor your BG.</li> </ul>
Fill Cannula?  Select Fill to fill cannula or select Done if not needed.	Alarm	You had the Fill Cannula screen displayed for 15 minutes.	<ul> <li>To proceed and fill the cannula, select Fill.</li> <li>If you do not need to fill the cannula, select Done to skip this process.</li> </ul>

Title and text	Туре	Explanation	Next steps
High BG XXX mg/dL	Message	Your BG meter reading is above 250 mg/dL.	• Select <b>No</b> to prevent the remote BG from being
Check infusion set. Check ketones.		This alert applies only to Manual Mode. For High BG XXX mg/dL in Auto Mode,	used by your pump. Select <b>Yes</b> to confirm the BG reading.
Consider injection. Monitor BG. Confirm BG?		see Auto Mode alerts and messages, on page 283.	Check your BG and treat as necessary.
Insert battery	Alarm	The battery was removed	• Insert a new AA battery.
Delivery stopped. Insert a new battery now.		from the pump.  If a bolus was in progress when the battery was removed, a Resume bolus? alarm sounds when a new battery is inserted. A message also appears, indicating how much bolus was delivered.	<ul> <li>The alarm clears when you insert a new battery.</li> <li>The pump powers off after 10 minutes unless you insert a new battery.</li> </ul>

Title and text	Type	Explanation	Next steps
Insulin flow blocked Check BG. Consider injection and testing ketones. Change reservoir and infusion set.	Alarm	Your pump has detected that the basal or bolus insulin flow was blocked.  WARNING: Do not use Auto Mode for a period of time after giving a manual injection of insulin by syringe or pen. Manual injections are not accounted for in Auto Mode.  Therefore, Auto Mode could deliver too much insulin. Too much insulin may cause hypoglycemia. Consult with your healthcare professional for how long you need to wait after a manual injection of insulin before you resume Auto Mode.	<ul> <li>Check your blood glucose. Consider checking ketones and take an injection if needed.</li> <li>Remove your infusion set and reservoir.</li> <li>Select Rewind to start the new reservoir process using a new infusion set and reservoir.</li> <li>If a bolus delivery was in progress when the alarm occurred:</li> <li>Check the Daily History screen for the amount of bolus already delivered before the pump alarmed.</li> <li>Consider delivering remaining bolus, if the bolus insulin was not included in an insulin injection.</li> </ul>

Title and text	Type	Explanation	Next steps
Insulin flow blocked Check BG. Consider injection and	Alarm	Your pump has detected that the insulin flow was blocked and there is no insulin in the reservoir.	<ul> <li>Check your blood glucose. Consider checking ketones and take an injection if needed.</li> </ul>
testing ketones. Estimated 0 U			<ul> <li>Remove your infusion set and reservoir.</li> </ul>
insulin in reservoir. Change reservoir and infusion set.			<ul> <li>Select Rewind to start the new reservoir process using a new infusion set and reservoir.</li> </ul>
			If a bolus delivery was in progress when the alarm occurred:
			<ul> <li>Check the Daily History screen for the amount of bolus already delivered before the pump alarmed.</li> </ul>
			<ul> <li>Consider delivering remaining bolus, if the bolus insulin was not included in an insulin injection.</li> </ul>

Title and text	Туре	Explanation	Next steps
Insulin flow blocked Fill Cannula stopped. Remove infusion set from body. Change reservoir and infusion set.	Alarm	Your pump has detected the insulin flow was blocked while filling the cannula.	<ul> <li>Check your blood glucose. Consider checking ketones and take an injection if needed.</li> <li>Remove your infusion set and reservoir.</li> <li>Select Rewind to start the new reservoir process using a new infusion set and reservoir.</li> </ul>
Insulin flow blocked Fill Tubing stopped. Remove reservoir and select Rewind to restart.	Alarm	Your pump has detected the insulin flow was blocked while filling the tubing. Possible connection issue between the tubing and reservoir.	<ul> <li>Remove the reservoir and select Rewind to restart the fill tubing process.</li> <li>Disconnect tubing from reservoir.</li> <li>Be sure tubing is not crimped or bent.</li> <li>Continue following the steps displayed on the pump using the same infusion set and reservoir.</li> <li>If this alarm occurs again, use a new infusion set.</li> </ul>

Title and text	Туре	Explanation	Next steps
Loading incomplete	Alarm	You pressed 🔷 after loading began.	• Remove the reservoir to start again.
Remove reservoir and select Rewind to restart loading.			<ul> <li>Select Rewind and follow the on-screen instructions.</li> </ul>
Low battery Pump	Alert	The battery in the pump is low on power. Remaining	• Select <b>OK</b> to clear the alert.
Replace battery soon.		battery life is 10 hours or less.	<ul> <li>Replace the AA battery as soon as possible.</li> <li>Otherwise, insulin delivery stops, and the Replace Battery Now alarm occurs.</li> </ul>
			<ul> <li>If the pump is delivering a bolus or filling the cannula, wait until delivery is complete to replace battery.</li> </ul>
Low BG XX mg/dL	Message	Your BG meter reading is below 70 mg/dL.	• Select <b>No</b> to prevent the remote BG from being
Treat low BG. Do not bolus until BG is normal. Monitor BG. Confirm			used by your pump. Select <b>Yes</b> to confirm the BG reading.  Check your BG and treat as necessary.

Title and text	Туре	Explanation	Next steps
Low reservoir  XX units remaining. Change reservoir.	Alert	Your reservoir is low on insulin, according to the number of units set in the Low Reservoir Reminder.	<ul> <li>Select OK to clear the alert.</li> <li>Change the reservoir soon.</li> <li>If you do not change the reservoir after you receive this alert, you will receive a second Low reservoir alert when the insulin level reaches half of your original alert amount.</li> </ul>
Manage settings error  Delivery stopped. Backup settings cleared from Manage Settings. Current settings are working properly. Select OK to restart. See User Guide.	Alarm	A pump error has occurred, and you need to restart your pump. Your backup settings have been lost, but your current settings are unchanged.	<ul> <li>Select OK to restart your pump. Your current settings are unchanged. Only your backup settings are lost.</li> <li>When the pump restarts, follow instructions on the pump display.</li> <li>If the pump was delivering a bolus or filling the cannula, check Daily History and evaluate your need for insulin.</li> </ul>
Max Fill reached  3X.X U. Did you see drops at the end of tubing?	Alarm	You have exceeded the number of units expected to fill the tubing. By now, insulin should be at the end of the tubing.	<ul> <li>If you see drops at the end of the tubing, select Yes.</li> <li>If you do not see drops, select No.</li> <li>Follow instructions displayed on the pump.</li> </ul>

Title and text	Type	Explanation	Next steps
Max Fill reached  4X.X U. Remove reservoir and select Rewind to restart New Reservoir procedure.	Alarm	You have exceeded the number of units expected to fill the tubing. By now, insulin should be at the end of the tubing.	<ul> <li>Remove the reservoir.</li> <li>Check if you still have insulin in the reservoir. If you do, you can continue using the same reservoir.</li> <li>Select Rewind to restart the new reservoir procedure.</li> </ul>
No reservoir detected Rewind before loading reservoir.	Alarm	There is no reservoir in the pump or the reservoir is not properly locked into place.	<ul> <li>Select Rewind.</li> <li>Ensure that your reservoir is filled with insulin.</li> <li>When prompted, ensure that your reservoir is inserted and properly locked into place.</li> </ul>
Power error detected  Delivery stopped. Record your settings by uploading to CareLink or write your settings on paper. See User Guide.	Alarm	The internal power source in your pump is unable to charge. Your pump is operating on the AA battery only.	<ul> <li>Select OK to clear the alert.</li> <li>Check your BG and treat as necessary.</li> <li>Record your settings as soon as possible because your AA battery may not last long.</li> <li>Call the 24 Hour HelpLine for assistance with your pump.</li> </ul>

Title and text	Туре	Explanation	Next steps
Power loss  AA battery was removed for more than 10 min or power was lost. Select OK to re-enter time and date.	Alarm	Your pump battery has been out for more than ten minutes, and your pump has lost power. You must reset your time and date.	<ul> <li>Select <b>OK</b> to go to the Time &amp; Date screen.</li> <li>Enter the current time, time format, and date.</li> </ul>
Pump error Delivery stopped. Current settings cleared. Pump restart needed. Select OK to restart and then re-enter your settings. See User Guide.	Alarm	Your pump encountered an error and will restart. Your pump settings will return to factory default values.	<ul> <li>When the pump restarts, follow instructions on the pump display.</li> <li>After restart, check settings and re-enter values as needed.</li> <li>If you recently saved backup settings in Manage Settings, use Restore Settings.</li> <li>If the pump was delivering a bolus or filling the cannula, check Daily History and reevaluate your need for insulin.</li> <li>If this alarm recurs frequently, write down the error code displayed on the alarm screen (you can also find it in your Alarm History) and call 24 Hour HelpLine.</li> </ul>

Title and text	Туре	Explanation	Next steps
Pump error  Delivery stopped. Settings unchanged. Pump restart needed. Select OK to restart. See User Guide.	Alarm	A pump error has occurred, you need to restart your pump.	<ul> <li>Select OK to restart your pump.</li> <li>If the pump was delivering a bolus or filling the cannula, check Daily History and reevaluate your need for insulin.</li> <li>If this alarm recurs frequently, write down the error code displayed on the alarm screen (you can also find it in your Alarm History) and call 24 Hour HelpLine.</li> </ul>
Pump error  Delivery stopped. Settings unchanged. Select OK to continue. See User Guide.	Alarm	Your pump encountered an error but a restart is not necessary. The issue is resolved. Your settings are not changed.	<ul> <li>Select OK to resume basal delivery.</li> <li>If the pump was delivering a bolus or filling the cannula, check Daily History and reevaluate your need for insulin.</li> <li>If this alarm recurs frequently, write down the error code displayed on the alarm screen (you can also find it in your Alarm History) and call 24 Hour HelpLine.</li> </ul>

Title and text	Туре	Explanation	Next steps
Pump restarted Delivery stopped. Settings unchanged. Select OK to continue. See User Guide.	Alarm	Your pump has encountered a problem and has restarted. Your settings have not been changed.	<ul> <li>Select OK to continue.</li> <li>If the pump was delivering a bolus or filling the cannula, check Daily History and reevaluate your need for insulin.</li> <li>If this alarm recurs frequently, write down the error code displayed on the alarm screen (you can also find it in your Alarm History) and call 24 Hour HelpLine.</li> </ul>
Replace battery Battery life less than 30 minutes. To ensure insulin delivery, replace battery now.	Alert	Battery life is low and will be exhausted within 30 minutes.	<ul><li>Select <b>OK</b> to clear the alert.</li><li>Replace the AA battery.</li></ul>
Replace battery now  Delivery stopped. Battery must be replaced to resume delivery.	Alarm	Insulin delivery has stopped due to low power. Battery was not replaced after the Low battery Pump alert.	Replace the battery immediately to resume insulin delivery.

Title and text	Type	Explanation	Next steps
Reservoir estimate at 0 U To ensure insulin delivery, change reservoir.	Alert	Your reservoir level is estimated at 0 units.	<ul> <li>Select <b>OK</b> to clear the alert.</li> <li>Change the reservoir now.</li> </ul>
Resume bolus?  XXX of YYY U delivered. Resume delivery of ZZZ U?	Alarm	A normal bolus delivery has been interrupted because the pump battery was removed. If it is within 10 minutes since this interruption, you can resume this bolus.	<ul> <li>Check the message to see how much of the bolus was actually delivered.</li> <li>To cancel remaining amount of bolus, select Cancel.</li> <li>To resume remaining amount of bolus, select Resume.</li> </ul>
Resume Dual bolus?  XX of YY U delivered. Resume delivery of ZZ U for XX:XX hr?	Alarm	The Square portion of Dual Bolus delivery has been interrupted. If it is within 10 minutes since this interruption, you can resume this bolus.	<ul> <li>Check the message to see how much of the Dual Wave bolus was actually delivered.</li> <li>To cancel remaining amount of bolus, select Cancel.</li> <li>To resume remaining amount of bolus, select Resume.</li> </ul>

Title and text	Type	Explanation	Next steps
Resume Dual bolus?  XX of YY U delivered. Resume delivery of ZZ U now, and AA U Square for XX:XX hr?	Alarm	The Now portion of a Dual Wave bolus delivery has been interrupted because the pump battery was removed. If it is within 10 minutes since this interruption, you can resume this bolus.	<ul> <li>Check the message to see how much of the Dual Wave bolus was actually delivered.</li> <li>To cancel remaining amount of bolus, select Cancel.</li> <li>To resume remaining amount of bolus, select Resume.</li> </ul>
Resume Square bolus?  XX of YY U delivered for XX:XX hr. Resume delivery of ZZ U for XX:XX hr?	Alarm	The Square Wave bolus delivery was interrupted. If it is within 10 minutes since this interruption, you can resume this bolus.	<ul> <li>Check the message to see how much of the Square Wave bolus was actually delivered.</li> <li>To cancel remaining amount of bolus, select Cancel.</li> <li>To resume remaining amount of bolus, select Resume.</li> </ul>
Rewind required  Delivery stopped. Rewind was required due to pump error. Select OK to continue. See User Guide.	Alarm	Your pump encountered an error.	<ul> <li>Select OK to clear the alarm after the pump has completed rewinding.</li> <li>Select Reservoir &amp; Tubing from the Home screen to start the new reservoir process using a new infusion set and reservoir. For details, see Setting up the reservoir and infusion set, on page 121.</li> </ul>

Title and text	Туре	Explanation	Next steps
Stuck button  Button pressed for more than 3 minutes.	Alarm	The pump has detected that a button has been pressed for an unusually long time.	<ul> <li>Select <b>OK</b> to clear the alarm.</li> <li>If this alarm occurs again, call 24 Hour HelpLine for assistance with your pump.</li> </ul>
			If you are unable to clear the alarm:
			<ul> <li>If you are unable to clear the alarm, see</li> <li>Troubleshooting pump issues, on page 295.</li> </ul>
			<ul> <li>Consider another form of insulin, because your pump is not delivering insulin.</li> </ul>
			<ul> <li>Check your BG and treat as necessary.</li> </ul>
			<ul> <li>Call the 24 Hour     HelpLine for assistance     with your pump.</li> </ul>

#### CGM (sensor) alarms, alerts, and messages

The following table lists the most common or serious alarms, alerts, and messages related to your sensor glucose readings, as well as the status of your transmitter and sensor. The table also explains the meaning, consequences, and the reasons why these notifications appear, and provides steps for problem resolution.

Title and text	Type	Explanation	Next steps
Alert before high Sensor glucose approaching High Limit. Check BG.	Alert	Your SG value is approaching your specified high limit.	<ul> <li>Select OK to clear the alert.</li> <li>Check your BG.</li> <li>Follow instructions from your healthcare professional and continue to monitor your BG.</li> </ul>
Alert before low  Sensor glucose approaching Low Limit. Check BG.	Alert	Your SG value is approaching your specified low limit.	<ul> <li>Select OK to clear the alert.</li> <li>Check your BG.</li> <li>Follow instructions from your healthcare professional and continue to monitor your BG.</li> </ul>
Alert on high XXX mg/dL High sensor glucose. Check BG.	Alert	Your SG value is at or above your specified high limit.	<ul> <li>Select <b>OK</b> to clear the alert.</li> <li>Check your BG.</li> <li>Follow instructions from your healthcare professional and continue to monitor your BG.</li> </ul>
Alert on low XXX mg/dL Low sensor glucose. Check BG.	Alert	Your SG value is at or below your specified low limit.	<ul> <li>Select <b>OK</b> to clear the alert.</li> <li>Check your BG.</li> <li>Follow instructions from your healthcare professional and continue to monitor your BG.</li> </ul>
Alert on low XXX mg/dL Low sensor glucose. Insulin delivery suspended since XX:XX AM/PM. Check BG.	Alarm	Your SG value is at or below your specified low limit, and the pump has suspended insulin delivery due to a Suspend on low or Suspend before low event.	<ul> <li>Select <b>OK</b> to clear the alarm.</li> <li>Check your BG.</li> <li>Follow instructions from your healthcare professional and continue to monitor your BG.</li> </ul>

Title and text	Туре	Explanation	Next steps
Basal delivery resumed  Basal delivery resumed at XX:XX AM/PM after suspend by sensor. Check BG.	Alert	Your pump is resuming basal insulin delivery after a Suspend on low or Suspend before low event occurred.	<ul> <li>Select OK to clear the alert.</li> <li>Check your BG.</li> <li>Follow instructions from your healthcare professional and continue to monitor your BG.</li> </ul>
Basal delivery resumed  Low settings change caused basal to be resumed at XX:XX AM/PM. Check BG.	Alert	Your pump is resuming basal insulin delivery after a Suspend before low or a Suspend on low event occurred, because you have turned off the Suspend before low or the Suspend on low feature.	<ul> <li>Select OK to clear the alert.</li> <li>Check your BG.</li> <li>Follow instructions from your healthcare professional and continue to monitor your BG.</li> </ul>
Basal delivery resumed Maximum 2 hour suspend time reached. Check BG.	Alert	Your pump is resuming basal insulin delivery two hours after a Suspend before low or Suspend on low event occurred.	<ul> <li>Select <b>OK</b> to clear the alert.</li> <li>Check your BG.</li> <li>Follow instructions from your healthcare professional and continue to monitor your BG.</li> </ul>

Title and text	Type	Explanation	Next steps
Basal delivery resumed Maximum 2 hour suspend time reached. SG is still under Low limit. Check BG.	Alarm	Your pump is resuming basal insulin delivery two hours after a Suspend before low or Suspend on low event occurred.	<ul> <li>Your pump has resumed basal insulin delivery; however, your SG value is still at or below your low limit.</li> <li>Select OK to clear the alarm.</li> <li>Check your BG.</li> <li>Follow instructions from your healthcare professional and continue to monitor your BG.</li> </ul>
Place pump close to transmitter. Select OK to resend BG to transmitter.	Alert	The transmitter was unable to receive the calibration BG meter readings from the pump.	<ul> <li>Move your pump and transmitter closer together.</li> <li>Select OK. Your pump tries again to send your BG to your transmitter for sensor calibration.</li> </ul>
Calibrate now Check BG and calibrate sensor.	Alert	A BG meter reading is needed immediately to calibrate your sensor so that you can continue receiving sensor glucose readings.	• If you are unable to calibrate now, you can use the Snooze feature. Set the desired time, and select <b>Snooze</b> . If you do not calibrate before the Snooze time is up, the Calibrate Now alert occurs again.

Title and text	Туре	Explanation	Next steps
Calibration not accepted Wait at least 15 minutes. Wash hands, test BG again and calibrate.	Alert	Your system was unable to use the BG meter readings you entered to calibrate your sensor.	<ul> <li>Wash and dry hands thoroughly. See Guidelines for calibrating, on page 217.</li> <li>Select OK to clear the alert.</li> <li>After 15 minutes, enter a new BG meter reading for calibration as instructed in Calibrating your sensor, on page 214. If you receive a Calibration not accepted alert on your second calibration after 15 minutes, a Change sensor alert occurs.</li> <li>Call the 24 Hour HelpLine if you have questions.</li> </ul>
Cannot find sensor signal Disconnect and reconnect transmitter, then select OK. Notice if transmitter light blinks.	Alert	The pump has not received a signal from the transmitter.	<ul> <li>Disconnect and reconnect your transmitter and sensor.</li> <li>See if the light on your transmitter blinks when connected to the sensor. You may need this information for troubleshooting later.</li> <li>Select OK. Your pump searches for your sensor. If your pump receives a signal from your sensor, you do not need to do anything else. If your pump does not receive a signal from the sensor, another message appears to let you know.</li> </ul>

Title and text	Туре	Explanation	Next steps
Change sensor Insert new sensor and Start New Sensor.	Alert	You selected No in the Check sensor insertion message, indicating that your sensor is not fully inserted.	<ul> <li>Select OK to clear the alert.</li> <li>Change your sensor. For details, see your sensor user guide.</li> <li>After you change your sensor, refer to Starting the sensor, on page 212.</li> </ul>
Change sensor Second calibration not accepted. Insert new sensor.	Alert	This alert occurs when you receive two Calibration not accepted errors in a row.	<ul> <li>Select <b>OK</b> to clear the alert.</li> <li>Change your sensor. For details, see your sensor user guide.</li> </ul>
Check connection Ensure transmitter and sensor connection is secure, then select OK.	Alert	The pump fails to detect the transmitter and is unable to receive sensor signal.	<ul> <li>Select OK to clear the alert.</li> <li>If your sensor is fully inserted, select Yes. If your sensor is not fully inserted, select No.</li> <li>if your sensor was not fully inserted, insert a new sensor.</li> <li>If you still cannot connect your sensor, see My pump cannot find the sensor signal, on page 300.</li> </ul>
Lost sensor signal Move Pump closer to transmitter. May take 15 minutes to find signal.	Alert	Transmitter signal has not been received for 30 minutes during or after initialization.	<ul> <li>Move your pump closer to your transmitter. It can take up to 15 minutes for your pump to start communicating with your transmitter.</li> <li>Select OK to clear the alert.</li> </ul>

Title and text	Type	Explanation	Next steps
Low battery transmitter Recharge transmitter within 24 hours.	Alert	The battery in the transmitter needs to be recharged within 24 hours.	<ul> <li>Select <b>OK</b> to clear the alert.</li> <li>Recharge your transmitter as soon as possible.</li> </ul>
Low SG XX mg/dL SG is under 50 mg/dL. Check BG and treat.	Alarm	Your sensor glucose value has reached or fallen below 50 mg/dL. This alert is factory set and cannot be changed or turned off.  This alarm cannot be silenced and is always enabled, whether the pump is in Auto Mode or Manual Mode.	Select <b>OK</b> to clear the alarm.     Check your BG and treat as necessary.
		Note: XX represent the sensor glucose value tha appears	S

on your pump.

Title and text	Туре	Explanation	Next steps
Medical device  CALL FOR  EMERGENCY  ASSISTANCE. I  have diabetes.	Alarm	Your pump is suspended due to low SG, and you have not responded to the alarm within 10 minutes.	<ul> <li>Select <b>Dismiss</b>.</li> <li>Immediately call for emergency assistance.</li> </ul>
No calibration occurred  Confirm sensor signal. Calibrate by XX:XX AM/PM.	Alert	The transmitter was unable to receive the calibration BG meter readings from the pump.	<ul> <li>Select OK to clear the alert.</li> <li>Check the status icons on your Home screen to ensure that your pump has a signal from your sensor. If there is no sensor signal, see My pump cannot find the sensor signal, on page 300.</li> <li>Calibrate again by the time shown on the pump screen to ensure you continue SG monitoring.</li> </ul>
No calibration occurred  Confirm sensor signal. Check BG again to calibrate sensor.	Alert	The transmitter was unable to receive the required calibration BG from the pump. Calibration is required by the system for SG values to resume. "Calibration required" appears on your sensor graph.	<ul> <li>Select <b>OK</b> to clear the alert.</li> <li>Take another BG meter reading and calibrate again.</li> </ul>

Title and text	Туре	Explanation	Next steps
Possible signal interference  Move away from electronic devices. May take 15 minutes to find signal.	Alert	There may be interference from another electronic device that is affecting the communication between your pump and transmitter.	<ul> <li>Move away from other electronic devices. It can take up to 15 minutes for your pump to start communicating with your transmitter.</li> <li>Select <b>OK</b> to clear the alert.</li> </ul>
Rise Alert Sensor glucose rising rapidly.	Alert	Your SG value has been rising as fast or faster than your preset Rise Alert Limit.	<ul> <li>Select <b>OK</b> to clear the alert.</li> <li>Monitor trend and glucose level.</li> <li>Follow instructions from your healthcare professional.</li> </ul>
Sensor alert occurred Check Alarm History for silenced alerts.	Alert	Sensor alert occurred when Alert Silence is on.	<ul> <li>Select OK to clear the alert.</li> <li>Check the Alarm History screen to see which alerts were silenced.</li> <li>Select the alert to open the Alarm Detail screen.</li> <li>Take action based on the selected alert.</li> </ul>

Title and text	Туре	Explanation	Next steps
Sensor connected  If new sensor, select Start New.  If not, select Reconnect.	Message	The transmitter has detected that you have connected a sensor. The pump needs to know if this is a new sensor or if you have reconnected your old sensor.	<ul> <li>If you have connected a new sensor, select Start New.</li> <li>If you have reconnected a sensor you have been using, select Reconnect.</li> <li>In either case, a "warm-up" message appears on your Home screen, and you will be prompted to enter a BG value when your sensor is ready for calibration. Your pump starts receiving your SG values again after the two-hour initialization is complete.</li> </ul>
Sensor connected Start new sensor.	Message	The pump has detected that this is a new sensor, which needs to be started and warmed-up.	<ul> <li>Select Start New Sensor.</li> <li>The alert will close and a "warm-up" message appears on the sensor graph with a progress bar.</li> </ul>
Sensor expired Insert new sensor.	Alert	The sensor has reached the end of its useful life.	Change your sensor. For details, see your sensor user guide.
Sensor signal not found Did transmitter light blink when connected to sensor?	Alert	The pump has still not received a signal from the transmitter.	When you reconnected the transmitter to the sensor, did you see a blinking green light on the transmitter?  • Select <b>Yes</b> or <b>No</b> and follow the instructions on the screen.

Title and text	Туре	Explanation	Next steps
Sensor signal not found See User Guide.	Alert	After multiple attempts, the pump failed to detect the transmitter and is unable to receive sensor signal.	<ul> <li>Select OK to clear the alert.</li> <li>Repeat the connection process. Remove the transmitter from the sensor for about ten seconds, and then reconnect it to the sensor.</li> <li>It can take up to 15 minutes for your pump to find the sensor signal.</li> <li>Move your pump closer to your transmitter to improve reception.</li> <li>Make sure you are away from any electronic devices that might cause interference, such as cellular phones and other wireless devices.</li> <li>If your pump still cannot find the sensor signal, call the 24 Hour HelpLine for assistance.</li> </ul>
Sensor warm-up started Warm-up takes up to 2 hours. You will be notified when calibration is needed.	Alert	The sensor warm-up has begun.	Select <b>OK</b> to close the alert.  A "Warm-up" message with a progress bar appears on the sensor graph during warm-up, which takes up to 2 hours.  You will be notified when calibration is needed.
Sensor updating  Do not calibrate unless notified.  This could take up to 3 hours.	Alert	The SG value is unavailable due to a temporary situation.	<ul> <li>Select <b>OK</b> to clear the alert.</li> <li>Follow the instructions on the pump screen. You do not need to change the sensor.</li> </ul>

Title and text	Type	Explanation	Next steps
Suspend before low  Delivery stopped. Sensor glucose approaching Low Limit. Check BG.	Alert	Your SG value is falling. Insulin delivery is suspended according to your Suspend before low setting and your SG is approaching your specified low limit.  Suspend before low is not available in Auto Mode.	<ul> <li>Select <b>OK</b> to clear the alert.</li> <li>Check your BG. If necessary, treat your BG as directed by your healthcare professional.</li> </ul>
Suspend on low Delivery stopped. Sensor glucose XXX mg/dL. Check BG.	Alarm	Your SG value is at or below the low limit you specified. Suspend on low is not available in Auto Mode.	<ul> <li>Select <b>OK</b> to clear the alarm.</li> <li>Check your BG. If necessary, treat your BG as directed by your healthcare professional.</li> </ul>
Transmitter battery depleted Recharge transmitter now.	Alert	The battery in the transmitter needs to be recharged. SG values are not recorded or transmitted until you recharge transmitter.	Select <b>OK</b> to clear the alert.     Recharge your transmitter.

#### **Auto Mode alerts and messages**

The following table lists the most common or serious alerts and messages related to Auto Mode. The table also explains the meaning, consequences, and the reasons why these notifications appear, and provides any necessary steps for problem resolution.

Title and text	Type	Explanation	Next steps
Auto Mode started Current action canceled.	Alert	This alert happens when the user starts an operation that is not allowed in Auto Mode while the pump is transitioning to Auto Mode.	<ul> <li>Select <b>OK</b> to clear the alert.</li> <li>Allow your pump to complete its transition to Auto Mode.</li> </ul>
Auto Mode started The following SmartGuard settings are now turned off: - Suspend before low - Suspend on low	Alert	Your pump has started Auto Mode. The Suspend before low and Suspend on low settings are now turned off.	<ul> <li>Select <b>OK</b> to clear the alert.</li> <li>Allow your pump to complete the transition into Auto Mode.</li> </ul>

Title and text	Туре	Explanation	Next steps
Auto Mode exit  Basal Name started. Would you like to review the Auto Mode Readiness screen?	Alert	Your pump has exited Auto Mode because you have turned off your sensor, a suspend has not been cleared within 4 hours, or you have been in Safe Basal the maximum of 90 minutes.	<ul> <li>Select No to clear the alert. Select Yes to view the Auto Mode Readiness screen.</li> <li>Check your BG.</li> <li>Calibrate your sensor.</li> <li>Follow instructions from your healthcare professional and continue to monitor your BG.</li> <li>For details, see Exiting Auto Mode, on page 247 and Returning to Auto Mode, on page 248.</li> </ul>
		This alert cannot be silenced, and is always enabled whenever the system is in Auto Mode.	

Title and text	Type	Explanation	Next steps
High SG SG has been high for over 1 hour. Check infusion set. Check ketones. Monitor BG. Followed by	Alert	Your pump has exited Auto Mode based on a set glucose threshold and length of time:  • 300 mg/dL or higher for one hour	<ul> <li>Select OK to clear the alert.</li> <li>Check your BG and treat as necessary.</li> </ul>
Auto Mode exit  Monitor BG and treat as necessary. Basal Name started. Enter BG to continue in Auto Mode.		<ul> <li>250 mg/dL or higher for three hours.</li> <li>This alert cannot be silenced and is always enabled whenever the pump is in Auto Mode.</li> </ul>	
Auto Mode max delivery  Auto Mode has been at maximum delivery for 4 hours. Enter BG to continue in Auto Mode.	Alert	Auto Mode has been delivering at your maximum Auto Mode basal delivery rate for four hours. This rate is determined automatically by your system.	<ul> <li>Select OK to clear the alert.</li> <li>Check your BG and enter it into your pump to exit Safe Basal and return to Auto Basal.</li> <li>Follow instructions from your healthcare professional and continue to monitor your BG.</li> </ul>

Title and text	Туре	Explanation	Next steps
Auto Mode max delivery  Auto Mode has been unable to bring your SG down. Enter BG and resume delivery to continue in Auto	Alert	Auto Mode has been unable to lower your SG value. Your pump is suspended, and your predicted SG is above target.	<ul> <li>Select OK to clear the alert.</li> <li>Check your BG and enter it into your pump.</li> <li>Follow instructions from your healthcare professional and continue to monitor your BG.</li> </ul>
Mode.		Note:	
		The title of the alert appears the same as the previous Auto Mode of delivery alert in the table.  If you have suspend your pump, you will have not delivery. However the alert may still occur.	e.  ded

Title and text	Type	Explanation	Next steps
Auto Mode min delivery  Auto Mode has been at minimum delivery for 2:30 hr. Enter BG to continue in Auto Mode.	Alert	Your pump has been delivering at your minimum Auto Mode basal delivery rate for two and a half hours. This rate is determined automatically by your system.	<ul> <li>Select OK to clear the alert.</li> <li>Check your BG and enter it into your pump to exit Safe Basal and return to Auto Basal.</li> <li>Follow instructions from your healthcare professional and continue to monitor your BG.</li> </ul>

Title and text	Type	Explanation	Next steps	
Auto Mode min delivery  Your SG has been below target for 2:30 hr. Enter BG and resume delivery when ready to continue in Auto Mode.	Alert	Your pump is suspended, and your predicted SG has been below target for two and a half hours.  Note:  • The title	<ul> <li>Select OK to clear the alert.</li> <li>Check your BG and enter it into your pump.</li> <li>Follow instructions from your healthcare professional and continue to monitor your BG.</li> </ul>	
		of the alert appears the same as the previous Auto Mode medivery alert in the table. If you have suspend your pump, you will have not delivery. Howeved the alert may still occur.	ne s nin e. ded	

Title and text	Type	Explanation	Next steps
Auto Mode off  Basal Name started. Would you like to review the Auto Mode Readiness screen?	Alert	The Auto Mode setting in the SmartGuard menu is turned off.	<ul> <li>Select Yes to check the Auto Mode Readiness status screen for information to re-enter Auto Mode.</li> <li>Select No to clear the alert.</li> </ul>
BG required  Enter a new BG for Auto Mode.	Alert	Auto Mode requires a BG to check the reliability of the sensor.	<ul> <li>Select <b>OK</b> to clear the alert.</li> <li>Enter a BG to return to Auto Basal from Safe Basal, or to enter Auto Mode from Manual Mode.</li> </ul>
Bolus recommended For XXX mg/dL entered, a correction bolus is recommended. Select Bolus to program a bolus.	Alert	Auto Mode calculated that a bolus is recommended based on the BG value that you entered.	<ul> <li>Select Bolus to program a correction bolus.</li> <li>Select Cancel if you do not want to deliver a correction bolus.</li> </ul>
Cal required for Auto Mode Enter a BG and calibrate sensor for Auto Mode.	Alert	Calibration may be required by Auto Mode, even when SG values are available.	<ul> <li>Select OK to clear the alert.</li> <li>Check your BG and enter it into your pump.</li> <li>Calibrate your sensor using the BG that you entered.</li> </ul>

Title and text	Туре	Explanation	Next steps
High BG XXX mg/dL	Alert	Your BG meter reading is above	Select <b>No</b> to Prevent the remote  BG from being used by your  The second to the
Check infusion set. Check ketones. Monitor BG. Confirm BG?		250 mg/dL.  This alert applies only to Auto Mode. There is an equivalent alert for Manual Mode. See <i>Pump</i>	pump. Select <b>Yes</b> to confirm the BG reading.
		alarms, alerts, and messages, on page 254.	

#### CareLink alert and message

The following table lists the most common or serious alerts and messages related to CareLink. The table also explains the meaning, consequences, and the reasons why these notifications appear, and provides steps for problem resolution. If you get an alarm, alert, or message that is not listed, select OK to clear the notification and call the 24 Hour HelpLine.

Title and text	Туре	Explanation	Next steps
Connect Device?  Device with SN <xxxxxxxxxx allow="" connect="" connection?<="" is="" pump.="" td="" to="" trying="" your=""><td>Message</td><td>The CareLink USB software is attempting to connect to your pump in preparation for data download.</td><td><ul> <li>Select Yes to allow connection, only if you are expecting or performing a data download.</li> <li>Select No to deny connection. If no selection is made, the screen will timeout after 30 seconds and will automatically reject the request.</li> </ul></td></xxxxxxxxxx>	Message	The CareLink USB software is attempting to connect to your pump in preparation for data download.	<ul> <li>Select Yes to allow connection, only if you are expecting or performing a data download.</li> <li>Select No to deny connection. If no selection is made, the screen will timeout after 30 seconds and will automatically reject the request.</li> </ul>

Title and text	Туре	Explanation	Next steps
Download slow Insulin delivery not affected. CareLink download may take longer than usual. Select OK to continue. See User Guide.	Alert	The download of pump data is taking longer than expected. Data will not be affected.	<ul> <li>Select OK to clear the alert.</li> <li>Wait for the data to finish downloading.</li> <li>If problem still persists or if there is no progress in download, call the 24 Hour HelpLine for assistance.</li> </ul>

# Troubleshooting

### **Troubleshooting**

This chapter contains procedures and information to help you understand and address conditions that might occur with your pump.

For a list of alarms, alerts, and messages that may appear on your pump, see *Pump alarms, alerts, and messages, on page 254*.

#### Troubleshooting pump issues



**WARNING:** If you receive a critical error on your pump, the following screen displays and the pump sirens.



Immediately disconnect from your insulin pump and discontinue use. Contact the 24 Hour HelpLine for assistance.

Remember, your body still needs insulin while your pump is removed. It is important that you consult your healthcare professional to determine an alternate method of receiving insulin while your pump is removed. For more information on pump alarms, see *Pump alarms, alerts, and messages, on page 254*.

#### My pump buttons are stuck

During atmospheric pressure changes, your pump buttons may not work for up to 45 minutes. For example, during airplane travel your pump buttons may get stuck. This is rare. If this occurs, either wait for the problem to correct itself, or if you have a new AA battery with you:

- 1. Remove the battery cap.
- Place the battery cap back onto the pump.
   Your pump will check the AA battery power, and may require a new AA battery.
- 3. If prompted, insert a new AA battery.

If these steps do not correct the problem, contact your local representative for assistance.

#### What is a Check Settings alarm?

This alarm occurs when a condition causes your pump to reset to factory settings. You see this alarm after your pump guides you through re-entering the Startup Wizard settings.

The Check Settings alarm is letting you know that other settings may have been cleared or reverted to factory default values. Review any settings that you have not already set in Startup Wizard and re-enter the values, if necessary.

#### My pump is asking me to rewind



**WARNING:** Do not insert the reservoir into your pump until you have received training for your pump. Doing so could damage your reservoir. Damaging your reservoir could cause an inaccurate insulin delivery, which may cause hypoglycemia.

You must rewind your pump when changing the reservoir. Rewinding returns the piston in the reservoir compartment to its starting position. It is normal for your pump to ask you to rewind anytime you must remove and replace the reservoir, such as when resolving an Insulin Flow Blocked alarm or addressing a problem loading the reservoir.

#### I dropped my pump



**Caution:** Always inspect your pump to ensure there are no cracks before exposing your pump to water, especially if your pump has been dropped, or you suspect your pump is damaged. Water leakage can cause the pump to malfunction, and result in injury.

#### Do the following:

- 1. Check that all connections are still tightly in place.
- 2. Check the display, button area, and pump case for cracks or damage.
- 3. Check the infusion set, including the tubing connector and tubing for cracks or damage.
- 4. Review the status screen, basal rates and other pump settings.
- 5. Perform the Self Test procedure. Press © and select:

#### Options > Utilities > Self Test

6. If the Self Test does not complete successfully, or if you are concerned about your pump, call our 24 Hour HelpLine for assistance and check your BG.

#### I cannot get to the Manage Settings screen

These personalized settings, under the Manage Settings screen, should be provided by your healthcare professional in your training session. If you go to **Options > Utilities > Manage Settings**, a message appears telling you that the feature is not normally accessible and to consult your user guide. To access the Manage Settings screen press  $\odot$  and select:

- 1. Options > Utilities > Manage Settings
- 2. Simultaneously press and hold > and \( \bigcirc \) for about two seconds. The Manage Settings screen appears.

#### My pump display times out too quickly

Your pump display times out after 15 seconds by default in order to conserve battery power. You can increase this setting up to three minutes. Press © and select **Options** > **Utilities** > **Display Options**, and then adjust the Backlight setting as desired.



**Note:** Be aware that using a longer Backlight time causes your pump to use more battery power. When your pump battery is low, the timeout for the backlight on your pump screen is automatically reduced.

#### Where is my pump status screen?



2. From the Status screen, you can select the type of status information you want to view. For example, to see a quick status of your pump and recent insulin deliveries, go to Quick Status. For details, see *Status screens*, on page 55.

#### My pump is asking me to enter my settings

Certain pump errors can clear your settings and return them to their factory default values. This also happens if you intentionally clear your settings. Do not clear your settings unless directed to do so by your healthcare professional.

If you have saved your settings using the Save Settings option, you can restore them using the Restore Settings option. If you restore your settings, ensure the restored settings match the settings prescribed most recently by your healthcare professional.

The Startup Wizard appears automatically when your pump restarts. The wizard guides you through entering the following information. Be sure to have these values ready when you begin.

- Time format, time, and date
- Active Insulin Time
- Basal patterns

After you enter your pump settings, you have the option of entering the following Bolus Wizard settings:

- Carb ratio
- Insulin sensitivity factor
- BG target

#### To enter your pump settings:

- 1. Begin entering your settings by selecting English. Select **Next** to go to each new screen.
- 2. When the Select Time Format screen appears, select a 12-hour or a 24-hour time format.
- 3. When the Enter Time screen appears, adjust the setting to the current time. If you are using a 12-hour clock, be sure to specify AM or PM.
- 4. When the Enter Date screen appears, adjust the **Year**, **Month** and **Day** to the current date.
- 5. When the Active Insulin Time screen appears, enter the **Duration**. For details, see *About active insulin*, on page 100.
- 6. Enter your first basal rate by entering the End time and the Rate. You can enter more basal patterns after you complete the startup wizard.
  - For details, see Adding a new basal pattern, on page 71.
  - After you complete your basal pattern, a screen appears to allow you to review your basal information.
- 7. When the message appears asking if you want to setup the Bolus Wizard settings, do one of the following:
  - Select **Yes** to continue entering your settings, then continue to the next section.
  - Select No if you do not want to enter your Bolus Wizard settings. A
    message appears letting you know that your settings are complete. Select
    OK to continue using your pump.

#### To enter your Bolus Wizard settings:

- 1. When your pump shows a list of settings for the Bolus Wizard, make sure you have the values you need before continuing.
- When the Carb Ratio screen appears, enter your carb ratio by entering the End time and the Rate. You can adjust your carb ratio at any time.
  - For details, see Changing your carb ratio, on page 98.
- When the Edit Sensitivity screen appears, enter your insulin sensitivity factor by entering the End time and the mg/dL per unit. You can adjust your insulin sensitivity factor at any time.
  - For details about entering insulin sensitivity factors, including how to set multiple time periods, see Changing your insulin sensitivity factor, on page 98.
- When the BG Target screen appears, enter your BG Target range by entering the End time and your Lo (low) and Hi (high) limits. You can adjust your BG Target ranges at any time.
  - For details, see Changing your Bolus Wizard BG target, on page 99.
  - A message appears confirming that your setup is complete.
- Select **Next** to display the Home screen, and continue using your pump.

#### **Troubleshooting sensor issues**

#### My pump cannot find the sensor signal

If your pump cannot find the sensor signal after you connect your sensor and transmitter, follow the instructions on the pump screen to troubleshoot the issue as described below.

If your pump finds the sensor signal at any time during troubleshooting, your pump beeps or vibrates, and "Warm up" appears on your sensor graph. It can take up to two hours for your sensor to warm up.



**Note:** If you are using the Alert Silence feature and a glucose alert occurs, the notification light begins to flash and the Sensor alert occurred message appears, but no explanatory text is displayed. All silenced alerts are displayed with explanatory text in the Alarm History screen.

Make sure your system meets the following requirements:

Chapter 14

- Your transmitter is fully charged.
   If both lights on the charger are off, your transmitter is fully charged. For details, see your transmitter user guide.
- You have only one transmitter connected to your pump.
   Delete the current transmitter that is connected to your pump before continuing. For details, see *Deleting the transmitter from your pump, on page 212*.
- Your transmitter is placed next to your pump.
- Your transmitter is reconnected to the pump, if your pump has been recently reset. For details, see *Wirelessly connecting your pump and transmitter using Auto Connect, on page 205.*
- The Airplane Mode is turned off on your pump.
- You have applied the tape correctly, as instructed in the serter user guide.
- 2. Disconnect the transmitter from the sensor for at least 10 seconds.
- 3. Reconnect the transmitter with the sensor to restart communication. While the light on the transmitter is blinking, select **OK** on the pump to acknowledge the alert.
- 4. Depending on whether the light blinked when you connected the transmitter to the sensor, select **Yes** or **No** on your pump and do one of the following:



- If the transmitter light did not blink, you need to charge your transmitter. When your transmitter is charged, start your sensor. For details, see *Starting the sensor, on page 212.*
- If your transmitter light blinked, but you still have no sensor signal, continue to the next step.

- 5. Move your pump closer to your transmitter and select **OK**. It can take up to 15 minutes for your pump to find the sensor signal.
- 6. If your pump still cannot find the sensor signal, make sure you are away from any electronic devices that might cause interference, such as cellular phones and other wireless devices, and select **OK**.
- 7. If you have gone through all the troubleshooting steps on your pump screen, and your pump still cannot find the sensor signal, or if your sensor graph displays "Sensor signal not found. See User Guide," call the 24 Hour HelpLine for assistance.

#### Calibration not accepted

Calibration not accepted alert occurs when one of the following happens:

- System was unable to use the BG meter readings you entered to calibrate your sensor.
- System rejects two calibrations in a row from the same sensor.
- The transmitter was unable to receive the calibration BG meter readings from the pump due to failed sensor signal.

For details on when and how to calibrate your sensor, see *Calibrating your sensor*, on page 214.

## Why does the SmartGuard suspend by sensor icon on my Home screen appear gray?

The SmartGuard suspend by sensor icon appears gray Mon the Home screen when either the Suspend on low or Suspend before low feature is unavailable. The suspend features may be unavailable due to the following conditions:

- A suspend event has occurred recently.

  After a Suspend before low or Suspend on low event occurs, there is a period of time when the suspend functionality is unavailable. This time will vary depending on whether or not you respond to the suspend event. Typically, the suspend features will be unavailable for 30 minutes after your basal insulin delivery is resumed. For details, see When Suspend before low is unavailable, on page 188 or When Suspend on low is unavailable, on page 191.
- No SG values are available.

SG values may be unavailable because:

- Your pump is in Airplane Mode.
- Sensor calibration is required.
  - For details on when and how to calibrate your sensor, see *Calibrating your* sensor, on page 214.
- Your pump has lost connection to the sensor.
   Move your pump closer to the sensor. For more details, see My pump cannot find the sensor signal, on page 300.
- The sensor glucose value received was outside the expected range and was not displayed.
  - Select **OK** to clear the alert. If the issue continues, you may need to replace the sensor.

If the issue persists, call the 24 Hour HelpLine for assistance.

## Maintenance

# **Maintenance**

# Cleaning your pump



**Caution:** Never use organic solvents, such as lighter fluid, nail polish remover, or paint thinner to clean your pump. Never use lubricants with your pump. When cleaning your pump, be sure to keep the reservoir compartment dry and away from moisture. Cleaning your pump with organic solvents can cause the pump to malfunction, and result in minor injury.

Make sure you have the following supplies ready for cleaning your pump: three or four small, clean, soft cloths, a mixture of water with a mild detergent, clean water, 70% alcohol, and a few clean cotton tips and cotton balls.

#### To clean your pump:

- 1. Dampen a cloth with water mixed with a mild detergent.
- 2. Using the cloth, wipe the outside of the pump.
- 3. Dampen a clean cloth with water and wipe to remove any detergent residue.
- 4. Dry with a clean cloth.
- 5. Wipe your pump with a 70% alcohol wipe.
- 6. Using a dry clean cotton tip, remove any battery residue from the battery cap.
- 7. Using a dry clean cloth, remove any battery residue from the battery compartment opening.

# **Cleaning your transmitter**

Always refer to your transmitter user guide for instructions on cleaning the transmitter.

# Storing your pump

Storage mode allows you to safely place your pump in storage while not in use.



**Note:** If you place your pump in storage mode, it is important to insert a new AA battery for 8 to 12 hours every six months to ensure that the internal battery does not discharge to a deep discharge. A battery that is deeply discharged takes longer to charge than a normal battery.



WARNING: After placing your pump in storage mode, do not rely on active insulin tracked in the pump when making new Bolus Wizard calculations. Storage mode clears active insulin. Inaccurate Bolus Wizard calculations could result in inaccurate insulin delivery, and serious injury.

#### Placing your pump in storage mode:

1. Remove the AA battery from the pump. For details, see *Removing the battery*, on page 45.



**Note:** When you remove the battery, your pump issues an Insert Battery alarm for 10 minutes or until you place your pump into storage mode.

2. Press and hold  $\spadesuit$  until your screen turns off.



**Caution:** Always store your pump at room temperature. While in storage, the pump should never be exposed to temperatures below 41 °F (5 °C) or above 104 °F (40 °C). Storing your pump in temperatures outside of this range can damage your pump.

#### Waking your pump from storage mode

1. Insert a new AA battery into your pump. For details, see *Inserting the battery,* on page 44.

A Pump Error message appears.

2. Select **OK**.

Your pump displays a Power Loss alarm.

3. Select **OK**.

The Time & Date screen appears.

- 4. Enter the current **Time**, **Time Format** and **Date**.
- 5. Select **Save**.

Your pump displays an Active Insulin Cleared alert.

6. Select **OK**.

Make sure that all of your settings, such as basal rate, are set as desired. If you need to, reapply your last saved settings by using the Restore Settings option as instructed in *Restoring your settings*, on page 169.

7. You must repeat the connection process for your transmitter and meter. For details, see *Wirelessly connecting your pump and transmitter using Auto Connect, on page 205*. Always refer to your CONTOUR NEXT LINK 2.4 meter user guide for instructions on connecting the meter to the pump.

# Storing your transmitter

Always refer to your transmitter user guide for instructions on storing your transmitter.

# Product specifications and safety information

This chapter provides detailed product specifications and safety information.

# **Product specifications**

#### Alarm and alert escalation

The following alerts may escalate to a siren if not cleared:

	Alort	before	hiah	
•	Aleit	perore	man	

- Lost sensor signal
- Alert before low
- No calibration occurred
- Alert on high
- Possible signal interference
- Alert on low
- High SG
- Basal delivery resumed
- Rise Alert

alert

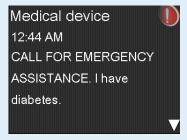
- BG not received
- · Sensor expired
- Calibration not accepted
- · Sensor signal not found
- Calibrate now
- Low SG XX mg/dL (XX represents 50 mg/dL or below)
- Cannot find sensor signal
- SG value not available
- Change sensor
- Check connection
- Transmitter battery depleted

For alerts that escalate to a siren, the pump will begin to siren if the alert is not cleared in 10 minutes. Before the siren occurs, your pump will beep, vibrate, or both, depending on your audio settings.

Minutes	Audio	Audio and vibration	Vibration
0	Audio	Audio and vibrate	Vibrate
1	Audio	Audio and vibrate	Vibrate
2	Audio	Audio and vibrate	Vibrate
3	Audio	Audio and vibrate	Vibrate
4	Audio	Audio and vibrate	Vibrate
5	Audio	Audio and vibrate	Vibrate
6	Audio and vibrate	Audio and vibrate	Audio and vibrate
7	Audio and vibrate	Audio and vibrate	Audio and vibrate
8	Audio and vibrate	Audio and vibrate	Audio and vibrate
9	Audio and vibrate	Audio and vibrate	Audio and vibrate
10	Siren and vibrate	Siren and vibrate	Siren and vibrate



**Note:** The Medical device alarm sirens immediately when this screen displays.



# Altitude range

- Pump operating range is from 10.2 psiA (70.33 kPa) to 15.4 psiA (106.18 kPa)
- Storage range is from 7.2 psiA (49.64 kPa) to 15.4 psiA (106.18 kPa)

# **Audio frequency**

The following table lists the various audible tones and their corresponding frequencies:

Tone name	Frequency
Alarm	1655 Hz followed by 3310 Hz
Alternate Alarm	1850 Hz
Siren (escalated alarm)	1655 Hz, followed by 3310 Hz
Alert	934 Hz
High Sensor Glucose	1312 Hz, followed by 1410 Hz, 1500 Hz, 1619 Hz, 1722 Hz
Low SG	1722 Hz, 1619 Hz, 1500 Hz, 1410 Hz, 1312 Hz
Lost SG	1485 Hz, followed by 1395 Hz, 1320 Hz, 1395 Hz
Message tone	1655 Hz
Reminder tone	934 Hz
Fill tubing tone	1850 Hz
Bolus delivery cancellation tone	1485 Hz, followed by 1655 Hz and 1485 Hz
Loading complete tone	934 Hz
Reservoir loading in progress tone	1850 Hz
Easy Bolus activation	1045 Hz
Easy Bolus step 1 increment	1175 Hz
Easy Bolus step 2 increment	1320 Hz
Easy Bolus step 3 increment	1395 Hz
Easy Bolus step 4 increment	1570 Hz
Easy Bolus step 5 increment	1760 Hz

# Backlight

Туре	LED (Light-emitting Diode)
Time out	15 seconds (default), 30 seconds, one minute, three minutes
Time out when battery is low	15 seconds (default), 30 seconds

# **Basal delivery**

Delivery rate range	0 to 35 units per hour or the Max Basal Rate amount, whichever is lower.
Max Basal Rate default	2 units per hour
Basal patterns	Maximum of 8 patterns. Each pattern covers a 24 hour period and can have up to 48 rates. Rates are set in 30 minute increments.
Basal pattern names	Fixed names: Basal 1, Basal 2, Basal 3, Basal 4, Basal 5, Workday, Day Off, Sick Day
Increments	• 0.025 units per hour for basal amounts in the range 0 to 0.975 units
	• 0.05 units per hour for basal amounts in the range 1 to 9.95 units
	• 0.1 units per hour for basal amounts of 10 to 35 units

# **BG Target**

Maximum targets	8
Range	60 to 250 mg/dL
Default value for High BG targets and Low BG targets	None



**Note:** Auto Mode uses a fixed BG Target of 150 mg/dL.

#### **BG** meter value

The most recent BG value received from the meter. If you are using a CONTOUR NEXT LINK 2.4 meter, this value appears on the Home screen when the Sensor feature is off. This value also appears in the Bolus Wizard screen when setting up a bolus.

Expiration	12 minutes
Range	20 to 600 mg/dL

#### **Bolus delivery**

<ul> <li>Bolus Speed options         <ul> <li>Standard: 1.5 units/minute</li> <li>Quick: 15 units/minute</li> </ul> </li> <li>Bolus programming increments         <ul> <li>0.025 units</li> <li>0.05 units</li> <li>0.1 units</li> </ul> </li> <li>Fluid delivered/stroke         <ul> <li>0.25 μL (microliter) for 0.025 unit pump stroke</li> <li>0.5 μL for 0.05 unit pump stroke</li> <ul> <li>2.0 μL for 0.2 unit pump stroke</li> <li>2.0 μL for 0.2 unit</li></ul></ul></li></ul>			
<ul> <li>Bolus programming increments         <ul> <li>0.025 units</li> <li>0.05 units</li> </ul> </li> <li>Fluid delivered/stroke         <ul> <li>0.25 μL (microliter) for 0.025 unit pump stroke</li> <li>0.5 μL for 0.05 unit pump stroke</li> </ul> </li> </ul>	Bolus Speed options	Standard: 1.5 units/minute	
<ul> <li>0.05 units</li> <li>0.1 units</li> <li>Fluid delivered/stroke</li> <li>0.25 μL (microliter) for 0.025 unit pump stroke</li> <li>0.5 μL for 0.05 unit pump stroke</li> </ul>		• Quick: 15 units/minute	
<ul> <li>0.1 units</li> <li>Fluid delivered/stroke</li> <li>0.25 μL (microliter) for 0.025 unit pump stroke</li> <li>0.5 μL for 0.05 unit pump stroke</li> </ul>	Bolus programming increments	• 0.025 units	
Fluid delivered/stroke  • 0.25 µL (microliter) for 0.025 unit pump stroke  • 0.5 µL for 0.05 unit pump stroke		• 0.05 units	
• 0.5 μL for 0.05 unit pump stroke		• 0.1 units	
	Fluid delivered/stroke	• 0.25 μL (microliter) for 0.025 unit pump stroke	
• 2.0 μL for 0.2 unit pump stroke		• 0.5 μL for 0.05 unit pump stroke	
		• 2.0 μL for 0.2 unit pump stroke	

#### **Bolus Wizard feature default settings**

Item	Default	Limits	Increments
Carb units	grams	-	-
Insulin to carb ratio	None	1–200 g/u	0.1 g/u for 1–9.9 g/u; 1 g/u for ratios of 10 g/u to 200 g/u
Insulin Sensitivity Factor	None	5-400 mg/dL	1 mg/dL
BG Target	None	60-250 mg/dL	1 mg/dL
Active Insulin Time	4 hours	2 to 8 hours	15 minutes

## **Bolus Wizard feature specifications**

There are four different formulas the Bolus Wizard feature uses to estimate a bolus, depending on your current BG. The following formulas apply only when the carb units are in grams.

1. If your current BG is greater than your High BG Target, the Bolus Wizard feature subtracts active insulin from the BG correction estimate, then adds this to the food estimate to get the total bolus estimate. However, if the result of subtracting active insulin from BG correction estimate is a negative number (less than zero), the total bolus estimate is based only on the food estimate.

C-D E

- active insulin

where: A = food (grams)

B = carb ratio C = current BG D = High BG Target E = insulin sensitivity

Food estimate:

Carb grams ÷ Carb ratio = Units of insulin

Correction estimate:

(Current BG - High BG Target)  $\div$  Insulin sensitivity - Active insulin = Units of insulin

Total bolus estimate:

Food estimate + Correction estimate = Units of insulin

2. If your current BG is less than your Low BG Target, the Bolus Wizard feature adds the BG correction estimate to the food estimate to get the total bolus estimate.

(food estimate)

(correction estimate)

total bolus estimate =

A

 $\frac{C - D}{E}$ 

where: A = food (grams)

B = carb ratio

C = current BG

D = Low BG Target E = insulin sensitivity

Food estimate:

Carb grams ÷ Carb ratio = Units of insulin

Correction estimate:

(Current BG - Low BG Target)  $\div$  Insulin sensitivity = Units of insulin

Total bolus estimate:

Food estimate + Correction estimate = Units of insulin

B. If your current BG is within your High or Low BG Target, the total bolus estimate is based only on the food estimate.

(food estimate)

total bolus estimate = food (grams)

Food estimate:

Carb grams ÷ Carb ratio = Units of insulin



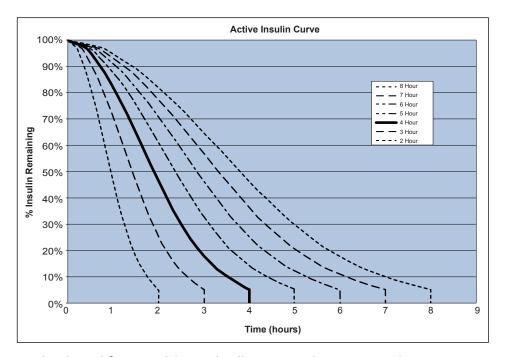
**Note:** When the current BG is below the Low BG Target, an active insulin amount is not considered in the Bolus Wizard feature calculations.

Total bolus estimate = Food estimate

4. If you do not enter a BG, the total bolus estimate is based only on the food estimate.

Following are some notes about using the Bolus Wizard:

- If a Dual Wave bolus is less than the estimate due to the Max Bolus limit or a change that you make, the Square portion is reduced first.
- Based on the Active Insulin Time setting you choose, your pump keeps track of how much insulin is still active in your body. This is shown as Active Insulin or Act. Ins. on the Home screen, Bolus screen, Manual Bolus screen, Preset Bolus, and Daily History screens. This prevents stacking of insulin, and lowers the chances of hypoglycemia.
- The Bolus Wizard feature may utilize your current BG measurement, carbohydrate consumption, and active insulin to calculate your estimated bolus.
- The following Active Insulin Curve represents how long a bolus of insulin lowers your glucose after the bolus is given. The percentage of insulin remaining lowers at varying rates depending on how long the insulin is active in your body.



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

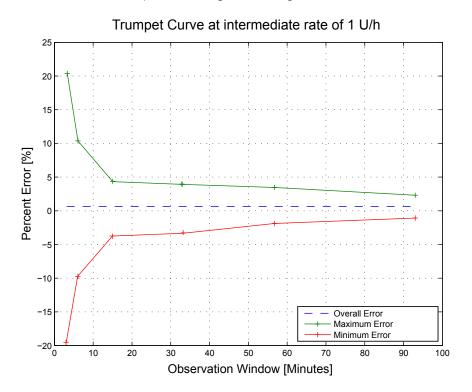
#### **Carb ratios**

Maximum ratio settings	Range
8	1 to 200 grams/unit

#### **Delivery accuracy**

- For a basal rate of 1.0 U/h, the delivery accuracy is ±5%.
   For a basal rate of 0.025 U/h, the delivery accuracy is ±10%.
   Delivery accuracy for bolus volumes < 0.1 unit is ±20% and delivery accuracy for bolus volumes ≥ 0.1 unit is ±5%.</li>
- All Normal boluses are delivered within 16 minutes, 41 seconds ±3 seconds at Standard rate (25 units, at 1.5 units per minute), and within 1 minute,
   41 seconds ±3 seconds at Quick rate (25 units, at 15 units per minute).

- The maximum infusion pressure generated and the occlusion threshold pressure using a 3 mL reservoir is 13.15 psi (90.67 kPa). The average resulting bolus volume generated upon clearing the occlusion is 0.0112 mL (equivalent to 1.12 units of U100 insulin).
- The following is a representative delivery accuracy curve. The Trumpet Curve represents the maximum percentage change from the expected insulin dosage for a given time interval, known as the observation window, during the infusion of insulin. The upper curve corresponds to positive changes, and the lower curve corresponds to negative changes.



# **Easy Bolus**

Allows user to set up and deliver a Normal Bolus when the pump is in Sleep Mode. This is done using the  $\wedge$  and with the help of audio and vibration cues.

Audio mode range	0 to 20 increments or Max Bolus limit, whichever comes first
Vibrate mode range	0 to 20 increments or Max Bolus limit, whichever comes first

Default step size	0.1 unit
Adjustable step size	0.1 to 2 units per increment up to Max Bolus limit

#### **Environmental conditions**

The MiniMed 670G insulin pump system is designed to withstand most conditions encountered in your daily life. For more details about environmental conditions, such as exposure to magnetic fields and radiation, waterproof capabilities, and extreme temperatures, see *User safety, on page 7*.

- Pump storage temperature range is from -4 °F (-20 °C) to 122 °F (50 °C).
- Pump operating temperature range with insulin is from 41 °F (5 °C) to 98.6 °F (37 °C).
- Air pressure range is from 700 hPa to 1060 hPa (10.2 psi to 15.4 psi).
- Operating relative humidity (RH) range of the pump: 20% to 90%. This requirement exceeds IEC 60601-1, subclause 7.9.3.1 (30% to 75%).
- Non-operating relative humidity range of the pump: 5% to 95%

## **Essential performance**

The insulin pump maintains insulin delivery accuracy in the specified environmental conditions.

#### Filling the infusion set and cannula

- The cannula can be filled from 0.025 units to 5.1 units, in increments of 0.025 units.
- The standard fill rate is 1.5 units per minute.
   The quick fill rate is 15 units per minute.
- When filling the tubing, a warning occurs at 30 units. A second warning occurs at 40 units instructing you to rewind the pump.
- Insulin used to fill the infusion set is recorded in the Daily History.

#### Infusion pressure

The maximum infusion pressure and occlusion pressure are 13.15 psi (90.67 kPa).

# Insulin delivery default settings Bolus settings

ltem	Default setting	Limits	Increments
Bolus Wizard feature:	Off	-	-
Easy bolus:	Off	-	-
Easy bolus step size:	0.1 U	0.1 U to 2 U	-
Bolus increment:	0.10 U	0.025 U 0.05 U 0.10 U	-
Dual/Square bolus:	Off	-	-
Max bolus:	10 U	0 to 25 U (per single bolus)	-
Bolus BG Check Reminder:	Off	0:00 to 5:00	0:30

# **Basal settings**

ltem	Default setting	Limits	Increments
Max Basal Rate	2 U/h	0–35 U/h	0.025 U for 0.025–0.975 U/h 0.05 U for 1.00–9.95 U/h 0.1 U for rates of 10.0 U/h
			or more
Basal Rate	0.000 U/h	0.000 U/h to Max Basal Rate setting	0.025 U for 0.025–0.975 U/h 0.05 U for 1.00–9.95 U/h 0.1 U for rates of 10.0 U/h or more
Temp Basal Type	Percent	Percent, Rate	N/A
Temp Basal Percent	100%	0-200%	5%

ltem	Default setting	Limits	Increments
Temp Basal Rate	Current basal	0.0 U/hr to Max	0.025 U for
	rate	Basal Rate	0.025-0.975 U/h
			0.05 U for 1.00-9.95 U/h
			0.1 U for rates of 10.0 U/h
			or more

# **Insulin sensitivity factor**

Maximum settings	8
Default	None. Insulin sensitivity is set during Startup of the Bolus Wizard.
Range	5 to 400 mg/dL/unit



**Note:** The insulin sensitivity factor only applies while the pump is in Manual Mode.

#### Low Reservoir reminder

The values are based on displayed amount, not actual amount.

Alert range	Increment	Default
		value
First reminder occurs at 5 to 50 units. Second reminder	1 unit	20 units
occurs at 50 percent of the remaining specified amount.		
The second reminder is automatic and cannot be changed		
by the user.		

#### **Max Bolus**

Range	0 to 25 units
Default	10 units

#### **Normal bolus**

Range is 0.025 to 25 units of insulin, and limited by the Max Bolus setting.

#### **Occlusion detection**

When occlusion is detected, the Insulin flow blocked alarm occurs. The occlusion alarm is triggered by an average of 2.23 units of missed insulin (standard bolus) or 1.97 units of missed insulin (quick bolus). The MiniMed 670G insulin pump is intended for use with U100 insulin. This table shows occlusion detection for four different situations when using U100 insulin.

Rate	Minimum time before alarm	Average time before alarm	Maximum time before alarm
bolus delivery (10 units at standard speed)	71 seconds	95 seconds	136 seconds
bolus delivery (10 units at quick speed)	9 seconds	10 seconds	14 seconds
basal delivery (1.0 u/h)	2.00 hours	2.50 hours	3.80 hours
basal delivery (0.025 u/h)	123.38 hours	142.03 hours	178.33 hours

#### Percent temp basal

The default value is 100 percent of basal programming. For example, if you program six units of basal per day, the default temp basal will be six units per day.

Range	0 to 200%
Default	100% of basal programming
Increment	5%

# **Program safety checks**

A single fault condition will cause the pump to suspend insulin delivery. Maximum infusion with a single fault condition is 0.2 units.

## **Pump dimensions**

The pump dimensions in inches are no greater than 3.81 length  $\times$  2.11 width  $\times$  0.98 depth.

The pump dimensions in centimeters are no greater than 9.68 length  $\times$  5.36 width  $\times$  2.49 depth.

#### **Pump memory**

User settings and pump history are stored in non-volatile memory which will retain data. The memory size will hold 90 days of pump history before it becomes full and has to be written over. This means that at any time the user can review a maximum of 90 days of history.

# **Pump weight**

The mass of the insulin pump without battery and consumables is less than 106 grams.

# Sensor default settings

High sensor settings				
ltem	Default setting	Limits	Increments	
High SG alert limit	250 mg/dL	100 to 400 mg/dL	5 mg/dL	
Alert before high	Off	-	-	
Alert on high	Off	-	-	
Time before high	15 minutes	5 to 30 minutes	5 minutes	
Rise Alert	Off	-	-	
Rise Limit	Two up arrows	<ul><li>1 up arrow</li><li>(1 mg/dL/min)</li><li>2 up arrows</li></ul>		
		(2 mg/dL/min)		
		• 3 up arrows (3 mg/dL/min)		
		• Custom limit (1.0 to 5.0 mg/dL/min)		
High Snooze	1 hour	5 minutes to 3 hours	5 minutes	

Low sensor settings				
ltem	Default setting	Limits	Increments	
Low SG alert limit	60 mg/dL	50 to 90 mg/dL	5 mg/dL	
Suspend before low	Off	-	-	
Suspend on low	Off	-	-	
Alert before low	Off	-	-	
Alert on low	Off	-	-	
Low Snooze	20 minutes	5 minutes to 1 hour	5 minutes	
Resume basal alert	Off	-	-	

#### **Auto Mode settings**

ltem	Default setting	Limits	Increments
Auto Mode enable	Off	-	-
Auto Mode BG alert	On	-	-

# Alert performance

CGM enables your device to display sensor glucose readings, glucose trend arrows, glucose trend graphs, and sensor glucose alerts (for example, High and Low Limit Threshold alerts, High and Low Predictive alerts, and Rise and Fall rate-of-change alerts).

The high and low limit alerts (**Threshold alerts**) let the user know when the sensor glucose is at or above the high limit or at or below the low limit. Using only a high or low limit alert may reduce the number of false alerts, but does not provide a warning before reaching a high or low limit.

Predictive alerts notify users that their sensor glucose level may soon reach a high or low limit setting. Users may select how early they would like to be notified before their sensor glucose level reaches a high limit setting. The earliest warning is 30 minutes before reaching a high, but users can reduce the amount of warning down to 5 minutes. Users will receive a warning approximately 30 minutes prior to when their sensor glucose level is predicted to reach their low limit setting. In general, the earlier the warning, the more time a user will have to react to a potential high or low, but this also increases the potential for false alerts.

A predictive alert is simply an estimation of a future sensor glucose level compared to the high or low limit setting. If the predicted sensor glucose value is above the high limit or below the low limit, then a predictive alert is sounded even though the current sensor glucose level has not crossed the high or low limit. The predicted sensor glucose level is calculated using the current sensor glucose level, the derivative of previous sensor glucose readings (the trend or slope of the sensor glucose readings) and the amount of early warning duration the user selects.

The device will always alert the user when the CGM reads that the user is below 50 mg/dL, regardless of the high/low threshold and/or predictive alerts that the user sets.

#### **Glucose TRUE Alert Rate**

The glucose true alert rate is the rate at which the blood glucose confirmed that the CGM alert was triggered correctly. For example:

- 1. True Threshold Hypoglycemic alert rate alerted when the CGM read that the user was below the low threshold and the user's blood glucose was actually below that low threshold.
- 2. True Threshold Hyperglycemic alert rate alerted when the CGM read that the user was above the high threshold and the user's blood glucose was actually above that high threshold.
- 3. True Predictive Hypoglycemic alert rate alerted when the CGM predicted that the user would reach below the low threshold and the user's blood glucose was actually below that low threshold within 15 or 30 minutes.
- 4. True Predictive Hyperglycemic alert rate alerted when the CGM predicted that the user would reach above the high threshold and the user's blood glucose was actually above that high threshold within 15 or 30 minutes.

The true alert rate is important because it is necessary that users be notified when their blood glucose is low (or high) so that they can correct the low (or high) blood glucose. A high true alert rate indicates that when the CGM says that their glucose values are, or will reach a specified threshold, the user's blood glucose is likely to be at or approaching that threshold.

For example, per the following table, the low glucose alerts would have correctly indicated that the user was below (i.e. threshold only), or predicted to reach below the threshold (i.e. predictive only) or both (predictive and threshold) 66.9%, 52.7%, or 58.3% of the time within 30 minutes (or 66.9%, 47.7% or 55.2% of the time within 15 minutes) when the user had blood glucose values lower than 70 mg/dL.

Table 1. Glucose TRUE Alert Performance using Calibration every 12 hours									
	Threshold Only		Pred	Predictive Only			Threshold & Predictive		
	mg/dL	30	15	mg/dL	30	15	mg/dL	30	15
		min	min		min	min		min	min
Glucose	50	25.0%	25.0%	50	15.2%	12.3%	50	18.2%	16.2%
True	60	53.5%	51.9%	60	40.7%	37.1%	60	46.2%	43.4%
Alert Rate	70	66.9%	66.9%	70	52.7%	47.7%	70	58.3%	55.2%
, idee	80	69.3%	69.3%	80	57.8%	51.1%	80	62.2%	58.2%
	90	75.1%	74.4%	90	64.0%	58.5%	90	67.9%	64.3%
	300	81.3%	81.3%	300	57.8%	54.0%	300	65.4%	62.7%
	250	90.2%	90.2%	250	64.0%	60.1%	250	72.5%	69.8%
	220	91.9%	91.9%	220	68.9%	66.3%	220	76.6%	74.8%
	180	93.7%	92.8%	180	70.5%	66.9%	180	78.0%	75.4%

#### **Glucose FALSE Alert Rate**

The glucose false alert rate is the rate at which the blood glucose did not confirm that the CGM alert was triggered correctly. For example:

1. False Threshold Hypoglycemic alert rate the alarm alerted when the CGM read that the user was below the low threshold but the users blood glucose was actually above that low threshold; or

- 2. False Threshold Hyperglycemic alert rate the alarm alerted when the CGM read that the user was above the high threshold but the user's blood glucose was actually below that high threshold; or
- 3. False Predictive Hypoglycemic alert rate the alarm alerted when the CGM predicted that the user would be below the low threshold but the user's blood glucose was actually above that low threshold within 15 or 30 minutes
- 4. **False Predictive Hyperglycemic alert rate** the alarm alerted when the CGM predicted that the user would be above the high threshold but the user's blood glucose was actually below the high threshold within 15 or 30 minutes.

The false alert rate is important because it is necessary that users be correctly notified when their blood glucose is low (or high) so that they can correct the low (or high) blood glucose. A low false alert rate indicates that when the CGM says that their glucose values are, or will reach a specified threshold, the user's blood glucose is likely to be at or approaching that threshold.

For example, per the following table, the high glucose threshold alerts would have incorrectly indicated that the user was above (i.e. threshold only), or predicted to reach above the threshold (i.e. predictive only), or both (threshold and predictive) 6.30%, 29.5% or 22% of the time within 30 minutes (or 7.2%, 33.1%, or 24.6% of the time within 15 minutes) when the user had blood glucose less than 180 mg/dL.

Table 2. Glucose FALSE Alert Performance using Calibration every 12 hours									
	Thre	Threshold Only		Predictive Only			Threshold & Predictive		
	mg/dL	30	15	mg/dL	30	15	mg/dL	30	15
		min	min		min	min		min	min
Glucose	50	75.0%	75.0%	50	84.8%	87.7%	50	81.8%	83.8%
False	60	46.5%	48.1%	60	59.3%	62.9%	60	53.8%	56.6%
Alert Rate	70	33.1%	33.1%	70	47.3%	52.3%	70	41.7%	44.8%
	80	30.7%	30.7%	80	42.2%	48.9%	80	37.8%	41.8%
	90	24.9%	25.6%	90	36.0%	41.5%	90	32.1%	35.7%
	300	18.8%	18.8%	300	42.2%	46.0%	300	34.6%	37.3%
	250	9.80%	9.80%	250	36.0%	39.9%	250	27.5%	30.2%
	220	8.10%	8.10%	220	31.1%	33.7%	220	23.4%	25.2%
	180	6.30%	7.20%	180	29.5%	33.1%	180	22.0%	24.6%

#### **Glucose Correct Detection Rate**

Glucose Correct Detection Rate is the rate that the device alerted when it should have alerted. For example, the blood glucose was below the hypoglycemic threshold, or above the hyperglycemic threshold, and the device sounded an alert.

Glucose detection rates are important because it is necessary that users be notified when their blood glucose is low (or high) so that they can correct the low (or high) blood glucose. A high glucose correct detection rate indicates that users can have confidence that they will be notified by the device if their blood glucose is low or high.

For example, per the following table, the threshold alert, the predictive alert, or both (threshold and predictive) notified the user 64%, 76% or 76% of the time within 30 minutes (or 64%, 68%, or 68% within 15 minutes) when the user had blood glucose less than 50 mg/dL.

Table 3. Glucose Correct Detection Alert Performance using Calibration every 12 hours

	Threshold Only		Predictive Only		Threshold & Predictive		dictive		
	mg/dL	30	15	mg/dL	30	15	mg/dL	30	15
		min	min		min	min		min	min
Glucose	50	64.0%	64.0%	50	76.0%	68.0%	50	76.0%	68.0%
Correct	60	83.3%	82.1%	60	94.0%	88.1%	60	94.0%	89.3%
Detection Rate	70	90.5%	90.5%	70	94.2%	89.8%	70	94.2%	92.0%
, week	80	87.2%	87.2%	80	93.6%	87.2%	80	93.6%	89.9%
	90	91.1%	88.7%	90	94.6%	89.5%	90	95.7%	92.2%
	300	75.3%	75.3%	300	95.3%	92.9%	300	95.3%	94.1%
	250	81.5%	80.9%	250	96.5%	91.3%	250	96.5%	93.6%
	220	90.1%	89.2%	220	94.8%	93.5%	220	95.3%	94.4%
	180	93.1%	91.4%	180	96.6%	93.4%	180	96.9%	95.4%

#### **Glucose Missed Detection Rate**

The Missed Detection Rate is the rate that the device **did not** alert when it should have. For example, the blood glucose was below the hypoglycemic threshold, or above the hyperglycemic threshold, and the device did not sound a threshold or predictive alert.

Missed detection rates are important because it is necessary that users be notified when their blood glucose is low (or high), so that they can correct the low (or high) blood glucose. A low missed detection rate indicates that users can have confidence that they will be notified by the device if their blood glucose is low or high.

For example, per the following table, the threshold alert, predictive alert, or both alerts (threshold and predictive) did not sound 36%, 24% or 24% of the time within 30 minutes (or 36%, 32% or 32% within 15 minutes) when the user had blood glucose less than 50 mg/dL.

Table 4. Glucose Missed Detection Alert Performance using Calibration every
12 hours

Threshold Only Predictive Only Threshold & Predictive

	Threshold Only		Predictive Only		Threshold & Predictive		dictive		
	mg/dL	30	15	mg/dL	30	15	mg/dL	30	15
		min	min		min	min		min	min
Glucose	50	36.0%	36.0%	50	24.0%	32.0%	50	24.0%	32.0%
Missed	60	16.7%	17.9%	60	6.0%	11.9%	60	6.0%	10.7%
Detection Rate	70	9.5%	9.5%	70	5.8%	10.2%	70	5.8%	8.0%
	80	12.8%	12.8%	80	6.4%	12.8%	80	6.4%	10.1%
	90	8.9%	11.3%	90	5.4%	10.5%	90	4.3%	7.8%
	300	24.7%	24.7%	300	4.7%	7.1%	300	4.7%	5.9%
	250	18.5%	19.1%	250	3.5%	8.7%	250	3.5%	6.4%
	220	9.9%	10.8%	220	5.2%	6.5%	220	4.7%	5.6%
	180	6.9%	8.6%	180	3.4%	6.6%	180	3.1%	4.6%

#### IEC60601-1-2:2007 notice

# IEC60601-1-2:2007; Special EMC Precautions for Medical Electrical Equipment

- 1. Special Precautions regarding Electromagnetic Compatibility (EMC): This body worn device is intended to be operated within a reasonable residential, domestic, public or work environment, where common levels of radiated "E" (V/m) or "H" fields (A/m) exist; such as cellular phones, WiFi, Bluetooth, electric can openers, microwave and induction ovens. This device generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the provided instructions, may cause harmful interference to radio communications.
- Portable and mobile RF communications equipment can affect Medical Electrical Equipment as well. If you encounter RF interference from a mobile or stationary RF transmitter, move away from the RF transmitter that is causing the interference.

# IEC60601-1-2:2007; subclause 5.2.2:

The MiniMed 670G insulin pump should not be used adjacent to other electrical equipment. If adjacent use becomes necessary, the MiniMed 670G insulin pump should be observed to verify normal system operation.

# Guidance and manufacturer's declaration

#### Guidance and Manufacturer's Declaration - Electromagnetic Emissions

The MiniMed 670G insulin pump is intended for use in the electromagnetic environment specified below. The customer or the user of the MiniMed insulin pump should make sure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions  Test: 47 CFR Part 15, Subpart C Section 15.247(a)(2)/RSS-210 FHSS- DAOO-705, DTS-KDB 558074, ANSI C63.4, RSS-Gen, FCC Part 15 Section 15.109, Class B/ANSI c63.4 (2009)	<ul> <li>6 dB and 99% Bandwidths: Pass</li> <li>Maximum Output Power: Pass</li> <li>TX Spurious Emissions: Pass</li> <li>Power Spectral Density: Pass</li> </ul>	The MiniMed insulin pump must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emissions EN55011 (2009)+A1	Class B	The MiniMed insulin pump is suitable for use in aircraft (in Airplane Mode) and in all establishments, including
RTCA DO 160G (2010) 20.5 and 21.5	Complies	domestic and those directly connected to the public low-voltage power
ARIB STD-T66	Complies	supply network that supplies buildings used for domestic purposes.

# Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The MiniMed 670G insulin pump is intended for use in the electromagnetic environment specified below. The customer or the user of the MiniMed insulin pump should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air @ (30-60% Relative Humidity)	±8 kV contact ±15 kV air @ (30-60% Relative Humidity)	For use in a typical domestic, commercial, or hospital environment.
Electrical fast transient/ burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/ output lines	Not applicable	Requirement does not apply to this battery powered device.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Not applicable	Requirement does not apply to this battery powered device.
Voltage dips, short interruptions and voltage variations on power supply lines  IEC 61000-4-11	<5% $U_{\rm T}$ (>95% dip in $U_{\rm T}$ ) for 0.5 cycle	Not applicable	Requirement does not apply to this battery powered device.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	400 A/m (continuous field at 60 seconds)	400 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

**Note:**  $U_T$  is the a.c. mains voltage prior to application of the test level.

# Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The MiniMed 670G insulin pump is intended for use in the electromagnetic environment specified below. The customer or user of the MiniMed insulin pump should assure that it is used in such an electromagnetic environment.

Immunity	IEC 60601	Compliance	Electromagnetic Environment
Test	Test Level	Level	Guidance
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.5 GHz	10 V/m 80 MHz to 6 GHz	Portable and mobile RF communications equipment should be used no closer to any part of the MiniMed insulin pump, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.  Recommended separation distance:  d = 1.2 \P 80 MHz to 800 MHz  d = 2.3 \P 800 MHz to 6 GHz  Where P is the maximum output power rating of the transmitter in Watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).  Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey <sup>a</sup> , should be less than the compliance level in each frequency range <sup>b</sup> .  Interference may occur in the vicinity of equipment marked with the following symbol:  ((**))

#### Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The MiniMed 670G insulin pump is intended for use in the electromagnetic environment specified below. The customer or user of the MiniMed insulin pump should assure that it is used in such an electromagnetic environment.

**Note:** At 80 MHz and 800 MHz, the higher frequency range applies.

**Note:** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption, and reflection from structures, objects and people.

Note: The table is per IEC (EN) 60601-1-2 Edition 3.

- a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcasts and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Guardian Link transmitter is used exceeds the applicable RF compliance level above, the Guardian Link transmitter should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Guardian Link transmitter.
- b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between the MiniMed 670G insulin pump and common household radio transmitters					
Household RF Transmitter	Frequency	Recommended Separation Distance (meter)	Recommended Separation Distance (inch)		
Telephones					
Cordless Household	2.4 GHz	0.3	12		
Cordless Household	5.8 GHz	0.3	12		
TDMA-50 Hz (cell phone)	1.9 GHz	0.3	12		
TDMA-50 Hz (cell phone)	800 MHz	0.3	12		
PCS (cell phone)	1.9 MHz	0.3	12		
DCS (cell phone)	1.8 MHz	0.3	12		
GSM (cell phone)	900 MHz	0.3	12		
GSM (cell phone)	850 MHz	0.3	12		
CDMA (cell phone)	800 MHz	0.3	12		
Analog (cell phone)	824 MHz	0.3	12		
CDMA (cell phone)	1.9 MHz	0.3	12		
WiFi Networks					
802.11b	2.4 GHz	1	39.5		
802.11g	2.4 GHz	1	39.5		
802.11n	2.4 GHz	1	39.5		
Bluetooth 500 kb/s	2.4 GHz	0.1	3.93		
ZigBee 250 kb/s	2.4 GHz	0.1	3.93		

# Recommended separation distances between portable and mobile RF communications equipment and the MiniMed 670G insulin pump

The insulin pump is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the MiniMed insulin pump can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the MiniMed insulin pump as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to the frequency of transmitter (m)				
	80 MHz to 800 MHz	800 MHz to 6 GHz			
	d=1.2√P	d=2.3√P			
0.01	0.12	0.23			
0.1	0.38	0.73			
1	1.2	2.3			
10	3.8	7.3			
100	12	23			

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where p is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

**Note:** At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

**Note:** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

#### Wireless communication

# **Quality of service**

The CGM transmitter and MiniMed insulin pump are associated as part of an 802.15.4 network for which the pump functions as the coordinator and the CGM transmitter as an end node. In an adverse RF environment the MMT-1580/1780 pump will assess channel changing needs based on "noise" levels detected during

an energy scan. The pump will perform the energy scan if after 10 minutes no CGM transmitter signal has been received. If the channel change occurs the pump will send beacons on the new channel.

The CGM transmitter will initiate a channel search when beacon detection fails on the associated channel. The search will be conducted across all five channels. When the beacon is located the transmitter will rejoin on the identified channel. Upon re-association any missed packets (up to 10 hours) will be transmitted from the CGM transmitter to the pump.

In normal operation the CGM transmitter will transmit a packet every 5 minutes and retransmit the packet if the data is corrupted or missed.

#### Radio frequency (RF) communications specifications

Utilizes the IEEE 802.15.4 protocol with the proprietary data format.

Pump frequency	2.4 GHz; proprietary Medtronic protocol; range up to 6 feet (1.8 meters)
Maximum output power (EIRP)	-4 dBm (.398 mW)
Operating frequencies	2420 MHz, 2435 MHz, 2450 MHz, 2465 MHz, 2480 MHz
Bandwidth	5 MHz which is allocated channel bandwidth per the IEEE protocol

#### **FCC** notice

This device complies with the United States Federal Communications Commission (FCC) and international standards for electromagnetic compatibility. This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation. These standards are designed to provide reasonable protection against excessive radio frequency interference, and prevent undesirable operation of the devices from unwanted electromagnetic interference.

Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio

frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Decrease the distance between the transmitter and the insulin pump to 6 feet (1.8 meters) or less.
- Decrease the distance between the meter and the insulin pump to 6 feet (1.8 meters) or less.
- Increase the separation between the transmitter and the device that is receiving/emitting interference.

IMPORTANT: Do not change or modify the internal RF transmitter or antenna unless expressly approved by Medtronic Diabetes. Doing so could interfere with your ability to operate the equipment.

Note: Harmful interference is defined by the FCC as follows. Any emission, radiation or induction that endangers the functioning of a radio navigation service or of other safety services or seriously degrades, obstructs or repeatedly interrupts a radio communications service operating in accordance with FCC rules.

#### **Data security**

The MiniMed 670G insulin pump is designed to only accept radio frequency (RF) communications from recognized and linked devices (you must program your pump to accept information from a specific device).

The MiniMed 670G system ensures data security via encryption and proprietary means and ensures data integrity using error checking processes, such as cyclic redundancy checks.

### **Icon glossary**

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

# End user software license agreement

#### End user software license agreement

NOTICE TO USER: Certain portions of software contained in this product may be covered by the GNU General Public License, Version 2 or Version 3 ("Open Source"), which can be obtained through the GNU web site at www.gnu.org/copyleft/gpl.html. The source code for any Open Source can be obtained, for a nominal fee to cover the cost of shipping and media, by contacting Medtronic MiniMed, Inc., Director of Software Development, 18000 Devonshire Street, Northridge, CA 91325-1219, USA, tel: +1-866-948-6633.

# **Glossary**

active insulin	Bolus insulin that has been delivered by the pump and is still working to lower your blood glucose levels.
active insulin adjustment	The amount of insulin that is subtracted from your BG correction bolus to account for the active insulin that is tracked by the Bolus Wizard.
Active Insulin Time	A Bolus Wizard setting that lets you set the length of time that bolus insulin is tracked as active insulin.
Activity Guard	An attachment that can be used to ensure that the reservoir stays secure during activity, or when the pump is worn by a child.
Airplane Mode	A feature that temporarily stops your device from communicating wirelessly.
alarm	An audible beep or vibration with a message to inform you that the pump is no longer delivering insulin. Alarms require immediate action.
Alarm History	A feature that stores information about recent alarms and alerts.
alert	An audible beep or vibration with a message to inform you of a situation that may require your attention.
Alert before low	An alert that occurs when you are approaching your low sensor glucose value.
Alert Limits	The values that you set to determine when low and high glucose alerts are triggered.

Alert on low	An alert that occurs when your sensor glucose value reaches or falls below your low limit.
Auto Basal	The automatically adjusted basal insulin delivered by Auto Mode based on your sensor glucose values.
Auto Mode	Auto Mode is an insulin delivery feature that automatically controls basal insulin delivery to regulate blood glucose (BG) levels to a target sensor glucose (SG) value.
Auto Suspend	An alarm that you set to suspend insulin delivery and trigger an alarm if no buttons are pressed for a specified period of time. Clearing the alarm resumes insulin delivery.
Awake mode	A state in which the pump screen is on. Unless you are actively using another screen, your Home screen appears.
basal insulin	Insulin that is continuously delivered by the pump to meet your individual insulin needs between meals and during sleep.
basal pattern	A set of one or more basal rates that covers a 24-hour period.
basal rate	The amount of continuous basal insulin that you program your pump to automatically deliver per hour.
BG	Abbreviation for blood glucose. See blood glucose.
BG Targets	The high and low values to which your blood glucose is corrected when using the Bolus Wizard.
Block Mode	A feature that restricts the ability to change all settings. You can still perform certain functions, such as suspending insulin delivery, reviewing history, testing your pump, or clearing alarms and alerts.
blood glucose (BG)	Refers to glucose (sugar) that is present in the blood, commonly measured by a blood glucose meter.
blood glucose meter	A device that measures glucose levels in the blood.

Bolus BG Check reminder	A reminder that you set just after you program a bolus. The reminder notifies you to check your blood glucose when the time period that you specified has passed.
Bolus Entry function	The Bolus Entry function in Auto Mode assists the user in calculating a recommended bolus amount based on optional carbohydrate intake and optional BG measurement. The user may enter one or both of the two optional inputs. This function utilizes the Carb Ratio setting to compute the bolus.
bolus insulin	Insulin used to cover an expected rise in glucose levels from carbohydrates, or to lower a high blood glucose value down to your target range.
Bolus Speed	A feature that lets you choose the speed at which your device delivers bolus insulin.
Bolus Wizard	A feature that uses your individual Bolus Wizard settings to calculate an estimated bolus amount based on the BG values and carbs that you enter. These settings include Carb Ratio, Insulin Sensitivity Factor, BG Target Range, and Active Insulin Time.
calibrate	The process of using a meter blood glucose reading to calculate sensor glucose values.
Calibration reminder	A reminder you can set to let you know when your next calibration is due.
cannula	Short, thin, and flexible tube placed in the tissue below the skin. Insulin is delivered through the cannula into the body.
carb ratio	The number of grams of carbohydrates covered by one unit of insulin. The carb ratio is used to calculate bolus amounts.
CGM	Abbreviation for continuous glucose monitoring. See continuous glucose monitoring.
continuous glucose monitoring (CGM)	A monitoring tool that uses a glucose sensor placed below the skin to continuously measure the amount of glucose in your interstitial fluid.

correction bolus	Insulin used to lower a high blood glucose value down to your target range.
Daily History	A feature that displays the actions that you performed using your device.
Diabetic Ketoacidosis (DKA)	A serious condition that occurs when the insulin levels are low, blood glucose level are elevated, and the body uses fat for energy. This process produces ketones which upset the body's acid-base balance leading to a potentially life threatening situation.
Dual Wave® Bolus	A type of bolus that provides a dose of insulin delivered as a combination of a Normal Bolus followed by a Square Wave Bolus.
Easy Bolus™	A feature that lets you deliver a Normal Bolus in preset increments using only audio or vibrate confirmation.
Event Marker	A feature that allows you to record events, such as blood glucose readings, injections, carbohydrates, and exercise.
food bolus	A dose of insulin you give to cover an expected rise in glucose levels from carbohydrates.
High limit	The value you set to determine when the pump will alert you of a high sensor glucose condition.
infusion set	Tubing that connects to the reservoir on one end, and has a needle or cannula on the other end, that you insert into your body. Insulin travels from the pump through the infusion set into your body.
infusion site	The location on the body where the infusion set is inserted.
insulin sensitivity factor	The amount that blood glucose is reduced by one unit of insulin. The insulin sensitivity factor is used to calculate correction bolus amounts.
interstitial fluid	The fluid that surrounds the cells in the body.
ISIG	The signal created by the sensor that is used to calculate your sensor glucose value. Typically used by Medtronic technical support representatives when troubleshooting.

lock	A pump feature that prevents accidental button presses.
Low limit	The value you set to determine when the pump will alert you of a low sensor glucose condition, and also used for determining if insulin delivery should be suspended.
Low management	Low management features include Suspend before low and Suspend on low.
Manual Bolus	A feature that allows you to enter and deliver a dose of insulin in the amount that you have determined is necessary.
Manual Mode	Manual Mode refers to system functions other than Auto Mode. In other words, if Auto Mode is not functioning, the system is in Manual Mode.
Max Basal Rate	A feature that allows you to set the maximum amount of basal insulin that can be delivered per hour.
Max Bolus	A feature that allows you to set the maximum bolus amount that can be delivered in one dose.
meter	A term for any blood glucose meter.
Missed Meal Bolus reminder	A reminder that a bolus was not delivered during time periods that you specify, often set around your meal times.
Normal Bolus	A type of bolus that provides an entire dose of insulin immediately.
notifications	All notifications are designed to get your attention and convey different types of information. They include alarms, alerts, reminders, and messages.
occlusion	A blockage or crimp of the cannula or tubing that prevents proper insulin flow.
piston	The part of the insulin pump that engages the reservoir and moves insulin through the tubing.
Power save mode	A state in which your pump is fully functional, but the screen goes dark to save power. You can set how long it

	takes for your screen to enter power save mode by changing the Backlight setting.
Preset Bolus	A feature that allows you to set up and save a bolus for specific meals or snacks that you frequently eat or drink.
Preset Temp Basal	A feature that allows you to set up and save temporary basal rates for repeated use.
Rate alert	An alert that notifies you if your sensor glucose value has been rising or falling faster than the Rise Limit or Fall Limit that you have set.
reminder	A type of notification that you can set to help you remember to do something.
reservoir	The small container that you fill with insulin and insert into your delivery device.
Resume basal alert	An alert that can be set to occur when your pump has automatically resumed basal insulin delivery after a Suspend before low or Suspend on low event because your sensor glucose values have met the necessary criteria. This alert will always occur if basal insulin delivery has resumed because the two hour maximum suspend time has elapsed.
Rewind	A feature used when changing a reservoir. It returns the piston to its starting position and allows a new reservoir to be placed into the pump.
sensitivity	See insulin sensitivity factor.
sensor (glucose sensor)	The small part of the continuous glucose monitoring system that you insert just below your skin to measure glucose levels in your interstitial fluid.
sensor glucose (SG)	Refers to glucose (sugar) that is present in the interstitial fluid and is measured by a glucose sensor.
Set Change reminder	A reminder that you can set to change your infusion set.
SG	Abbreviation for sensor glucose. See sensor glucose.
Sleep mode	A state in which your pump is fully functional, but the screen is dark. Your pump automatically enters sleep

	mode when you have not pressed any buttons for about two minutes.
SmartGuard™	A feature that can automatically stop and resume insulin delivery based on your sensor glucose values and low limit. In Auto Mode, SmartGuard can automatically adjust basal insulin delivery based on SG inputs.
Square Wave® Bolus	A bolus delivered evenly over a specified time period.
Suspend before low	A feature that suspends insulin delivery when the sensor predicts sensor glucose value is approaching your low limit.
Suspend Delivery	This feature stops all insulin delivery until you resume it. Only the basal insulin restarts when delivery is resumed.
Suspend on low	A feature that suspends insulin delivery when your sensor glucose value reaches or falls below your low limit.
Temp Basal Rate (temporary basal rate)	A feature that allows you to temporarily increase or decrease your current basal rate for a duration of time that you specify.
transfer guard	The plastic piece that comes attached to the reservoir. It is used to connect the reservoir to the insulin vial while filling the reservoir with insulin.
transmitter	A device that connects to a glucose sensor. The transmitter collects data measured by the sensor and wirelessly sends this data to monitoring devices.

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