

MiniMed® 630G

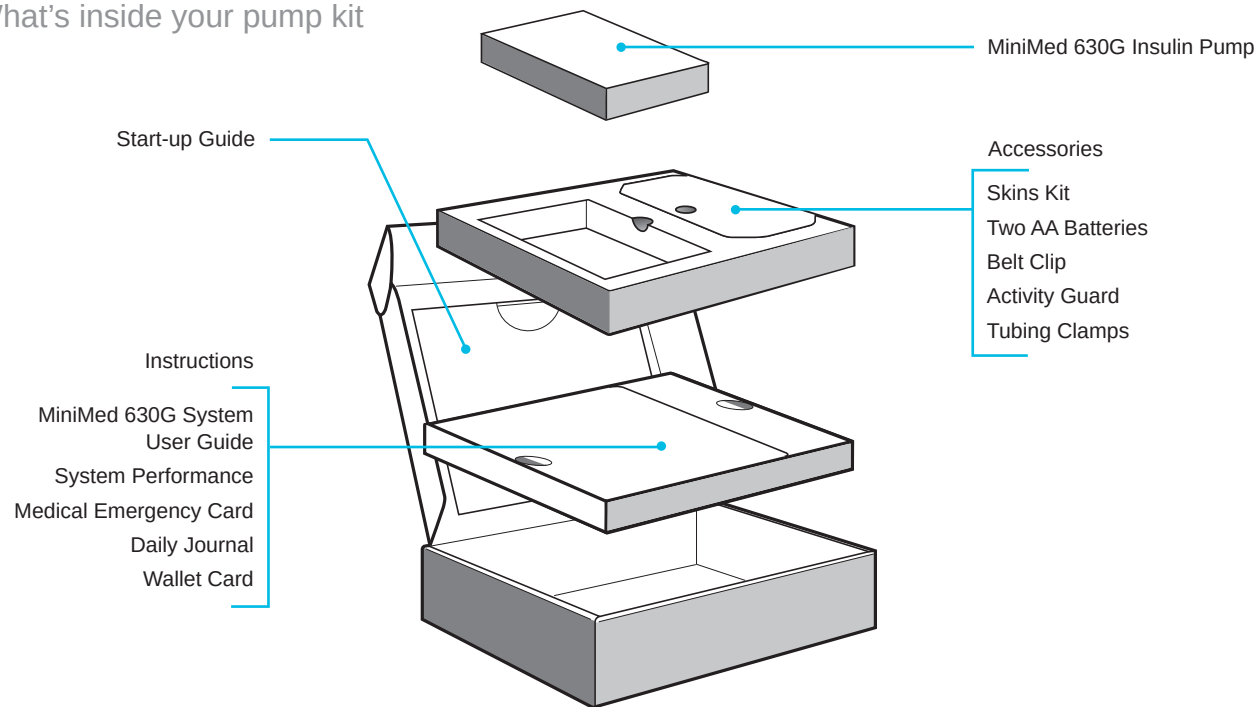
Start-up Guide



We at Medtronic are proud to introduce you to the MiniMed 630G system, our next great leap in diabetes management technology. We congratulate you on taking this important step on your journey to better glucose control. This easy-to-follow guide will help you get started.

Introducing your pump

What's inside your pump kit



Getting to know the basics

^ **Up**, v **Down**, < **Left**, and > **Right**

Press to scroll up or down through a menu or list, to get to a desired area on the screen, and to change the value in an area.

↶ **Back**

Press to return to a previous screen. Hold to return to the Home screen.

○ **Select**

Press to select or confirm a value or menu option that is highlighted. Press when directions say “Select.”

☰ **Menu**

Press to go to the Menu screen.



Applying the Skins

We recommend applying the skins that came with your pump. Your pump is designed to have skins attached to the back of the pump and the front of the belt clip. In addition to personalizing the look of your pump, skins provide additional protection against surface scratches.

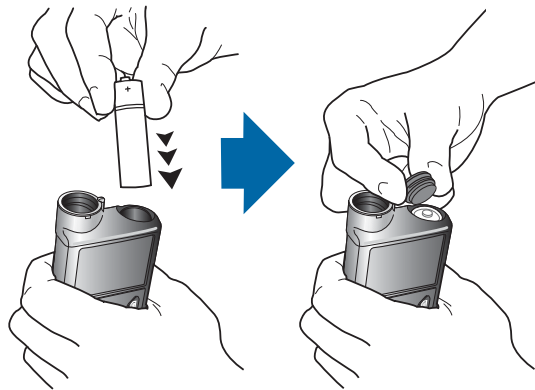
Apply the skins to the pump using the instructions provided in your skins kit.



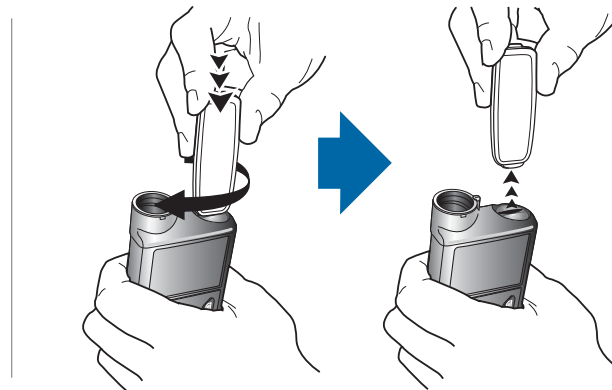
Powering on

Inserting the battery

Locate the battery cap found with your pump. Insert the new AA battery, making sure to insert the negative end (-) first. After you insert the battery, the positive end (+) is visible.



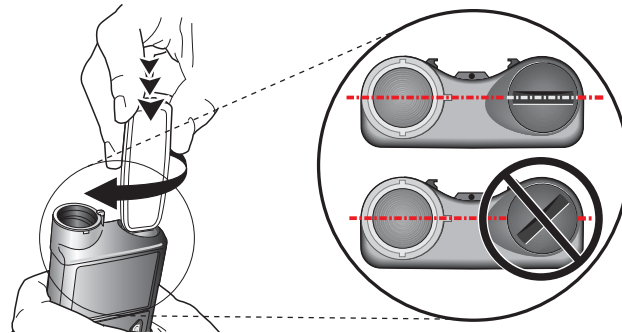
Place the battery cap on top of the battery.
Use the bottom tip of your belt clip to tighten the battery cap.





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.

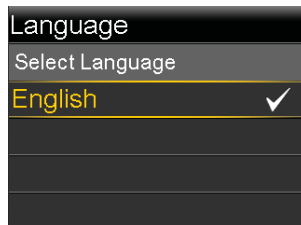


Startup settings

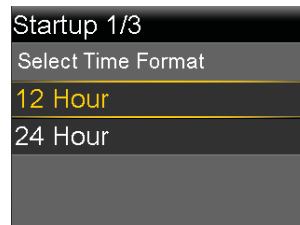
Your pump has a Startup Wizard that begins when you insert your battery for the first time.

The Startup Wizard guides you through setting the language, time format, current time, and the current date.

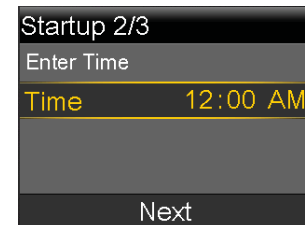
To use the Startup Wizard:



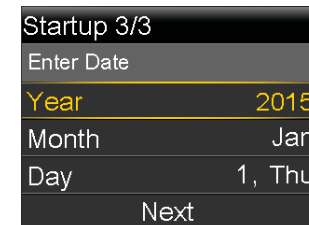
The Startup Wizard begins after the Welcome screen appears. When the Language screen appears, use the buttons on your pump to select your language.



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



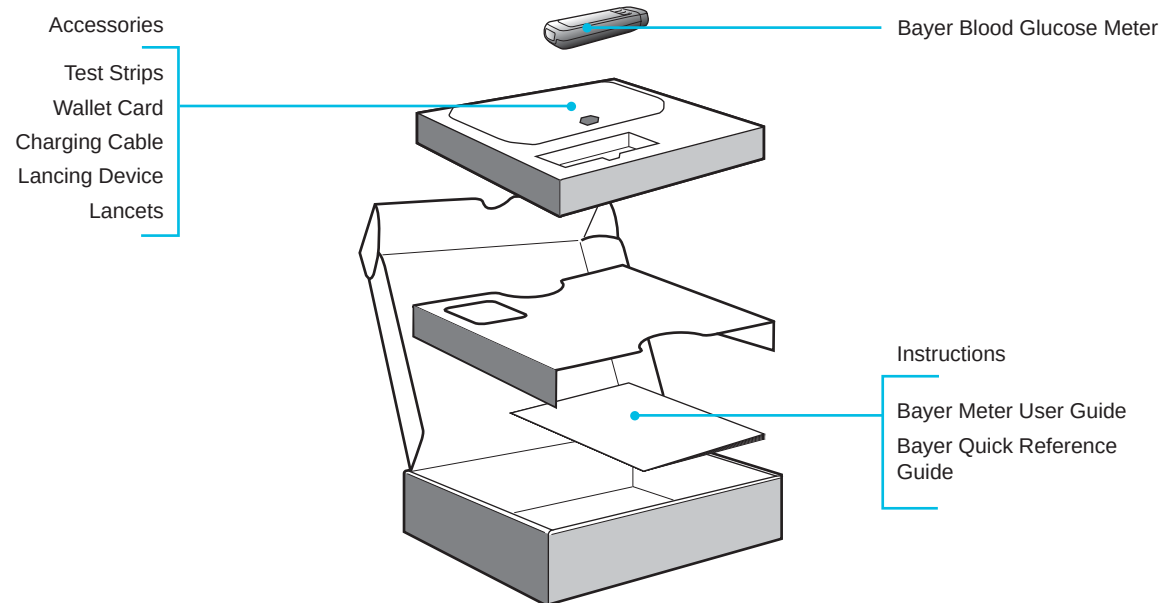
When the Enter Time screen appears, adjust the setting to the current time. If you are using a 12-hour clock, be sure to specify AM or PM. Select Next.



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.

Introducing your meter

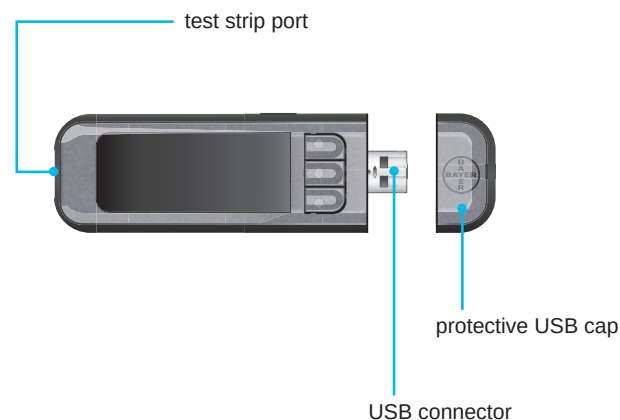
What's inside your meter kit



Charging your meter

1. Remove the protective USB cap.
2. Plug the USB connector into your computer*, or into the wall charger.
3. If you are using the wall charger, plug it into the wall outlet.
4. The meter screen displays “Do Not Test—charging,” and the test strip light flashes.
5. Charging is complete when the test strip port light turns off. Unplug your meter.

*Turn your computer on and make sure it is not in sleep, hibernate, or power saving mode.



What's next?

When you have finished setting up your pump, go to the **MiniMed 630G Training Packet** that came with your pump to begin familiarizing yourself with the insulin pump.

Note: If the Training Packet is not provided, please continue with your training as directed by your healthcare professional or pump trainer.

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MiniMed® 630G

System User Guide



MiniMed[®] 630G

System User Guide

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WARNING: The SmartGuard Suspend on low feature will cause the pump to temporarily suspend insulin delivery for two hours when the sensor glucose reaches a set threshold. Under some conditions of use the pump can suspend again resulting in very limited insulin delivery. Prolonged suspension can increase the risk of serious hyperglycemia, ketosis, and ketoacidosis. Before using the SmartGuard Suspend on low feature, it is important to read the SmartGuard Suspend on low information in the Getting Started Guide and the MiniMed 630G System User Guide and discuss proper use of the SmartGuard Suspend on low feature with your healthcare provider.

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 is 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 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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1



before you begin

1

Before you begin

This user guide is designed to help you understand the operation of your MiniMed® 630G system with SmartGuard™ technology. SmartGuard can temporarily suspend insulin delivery based on your sensor glucose values. Work closely with your healthcare professional when starting insulin pump therapy.

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 277*.

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.
Press and hold	To push and keep pressure on a button.
Bold text	To indicate screen items and buttons. For example, "Select Next to continue."

Convention	What it means
Note	 Note: 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.

Assistance

Department	Telephone number
24 Hour HelpLine (calls within the United States)	800 646 4633
24 Hour HelpLine (calls outside the United States)	+1 818 576 5555
Web site	www.medtronicdiabetes.com

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).
- Medical Emergency 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 insert the reservoir into your pump until you have been instructed to do so by your healthcare professional, and have received formal training with a certified product trainer. Attempting to use insulin in your pump before you have received training may result in the delivery of too little or too much insulin, which can cause hyperglycemia or hypoglycemia.

For details on pump safety, see *User safety*, on page 6.

Medical Emergency card and travel information

Your pump accessories are packaged with a Medical Emergency card that you should complete and carry with you at all times, especially when traveling.

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.

User safety

Indications

MiniMed® 630G system with SmartGuard™

The MiniMed 630G system with SmartGuard 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 diabetes mellitus in persons, sixteen 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 630G system includes SmartGuard, which can be programmed to temporarily suspend delivery of insulin for up to two hours when the sensor glucose value falls below a predefined threshold value.

The MiniMed 630G system consists of the following devices: MiniMed 630G Insulin Pump, Enlite® Sensor, one–press serter, the Guardian® Link transmitter system, CareLink® USB, Bayer’s CONTOUR® NEXT LINK 2.4 Wireless Meter, and Bayer’s CONTOUR® NEXT Test Strips. The system requires a prescription.

The MiniMed 630G system 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 MiniMed 630G system.

The MiniMed 630G system is not intended to be used directly for preventing or treating hypoglycemia but to suspend insulin delivery when the user is unable to respond to the SmartGuard Suspend on low alarm to take measures to prevent or treat hypoglycemia themselves. Therapy to prevent or treat hypoglycemia should be administered according to the recommendations of the user’s healthcare provider.



WARNING: Do not use the Suspend on low feature to prevent or treat low glucose. The Suspend on low feature is designed to suspend insulin delivery when you are unable to respond to the Suspend on low alarm. Always confirm your sensor glucose reading using your BG meter, and follow the instructions of your healthcare professional. Using Suspend on low to prevent or treat low glucose may result in prolonged hypoglycemia.

Contraindications

Pump therapy is not recommended for people who are unwilling or unable to perform a minimum of four blood glucose tests per day.

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

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

Potential risks

Risks related to insulin pump infusion

General risks related to insulin pump infusion set may include:

- Localized infection
- Skin irritation or redness
- Bruising
- Discomfort or pain
- Bleeding
- Irritation
- Rash

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

Risks related to sensor use

General risks related to sensor use may include:

- Skin irritation or reaction to adhesives
- Bruising
- Discomfort
- Redness
- Bleeding
- Pain
- Rash
- Infection
- Irritation from tapes used with glucose-sensing products
- Raised bump
- Appearance of a small "freckle-like" dot where needle was inserted
- Allergic reaction
- Fainting secondary to 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 and or tapes
- Scarring

Specific risks related to sensor use

During the conduct of the Performance Evaluation of the Enlite™ Glucose Sensor to Support a Full 144 Hours (6 Days) of Use¹, the following specific sensor risks were identified:

- Pain at sensor insertion site during sensor wear (1 incident reported)
- Dermatological risks (number of events/number of skin assessments performed):
 - Redness due to device insertion (abdomen, 35/213)
 - Redness in area of adhesive (abdomen, 63/213)
 - Bruising (abdomen, 2/213)
 - Bump (induration) (abdomen, 1/213)
 - Bleeding:
 - Bleeding immediately after insertion (abdomen, 2/213)
 - Bleeding at removal (abdomen, 5/213)
 - Fluid discharge (abdomen, 1/213)
 - Other, including indentation from device, e.g., transmitter (abdomen, 9/213)

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. Always use BG meter readings to verify your glucose level before making therapy decisions.

The Enlite Sensor is not approved for use in children or adolescents aged younger than 16 years, pregnant women, or persons on dialysis.

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.

Sensor placement and insertion is not approved for sites other than the belly (abdomen).

¹ Medtronic Inc., A Performance Evaluation of the Enlite™ Glucose Sensor to Support a Full 144 Hours (6 Days) of Use, CER247/Z25/C, May 2012.

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 insulin pump system

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

- Hypoglycemia
- Hyperglycemia

Specific risks related to the MiniMed insulin pump system

During the conduct of the In-Clinic, Randomized, Cross-Over Study to Assess the Efficacy of the Low Glucose Suspend (LGS) Feature in the MiniMed Paradigm® X54 System with Hypoglycemic Induction from Exercise ², the following specific system risks were identified:

- Bruising at sensor site (1 incident reported)
- Bleeding at sensor site (1 incident reported)
- Urine ketones resulting from improper connection of the tubing to the insulin pump (1 incident reported)

Benefits

The MiniMed 630G system provides advanced protection^{3, 4, 5} from dangerous low glucose levels through an integrated insulin pump and continuous glucose monitoring (CGM). Clinical studies show that integrated insulin pump and CGM systems are proven to provide better diabetes management, compared with multiple daily injections or with the pump alone. When you pair pump therapy with the information provided by the sensor, it can significantly improve HbA1C levels without increasing the risk of hypoglycemia.^{3, 4}

2 Medtronic Inc., An In-Clinic, Randomized, Cross-Over Study to Assess the Efficacy of the Low Glucose Suspend (LGS) Feature in the MiniMed Paradigm® X54 System with Hypoglycemic Induction from Exercise, CER235/Z25/A, November 2011.

3 Bergenstal RM, Tamborlane WV, Ahmann A, et al. Effectiveness of sensor-augmented insulin-pump therapy in type 1 diabetes [STAR 3 study]. *N Engl J Med.* 2010;363:311–320.

4 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.

5 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.

The MiniMed 630G system also features SmartGuard technology, which automatically suspends insulin when the sensor reaches a preset low limit, referred to as Suspend on low. When a Suspend on low event occurs, you can choose to continue to keep insulin suspended, or you can choose to resume insulin delivery. You can also personalize your low settings with up to eight different segments to fit your schedule and diabetes management needs.

Patients using Suspend on low experienced 35% less low sensor glucose exposure (<70 mg/dL), both day and night combined, as compared to patients without Suspend on low. While using Suspend on low at night, patients had a 37.5% reduction in the magnitude and duration of nocturnal low sensor glucose values compared to the control group.⁶

In addition to the clinical benefits of the system, the new design lets you personalize your diabetes management with customizable options and user-friendly menus. You now have the convenience of manual remote bolusing built into your compatible linked meter, an informative Bolus Wizard, a color screen, customizable alerts, and up to eight basal patterns.

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.
- 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 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.

⁶ 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.

- Do not use standard Luer sets with the MiniMed 630G insulin pump. Luer sets are not compatible with the pump. MiniMed reservoirs and MiniMed infusion sets are specifically designed for use with the MiniMed 630G 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.
- Only use U100 insulin 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 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 the MiniLink® transmitter (MMT-7703) with the MiniMed 630G insulin pump. This device does not communicate with this insulin pump. Lack of communication between the transmitter and the pump can cause the devices to malfunction, and result in serious injury.
- 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.

Pursuant to IEC60601-1-2:2007; subclause 5.2.2:

The MiniMed 630G insulin pump should not be used adjacent to other electrical equipment. If adjacent use becomes necessary, the MiniMed 630G insulin pump should be observed to verify normal system operation.

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 transmitter is 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.
- Always carry the Emergency Card provided with your device when you are traveling. The Emergency Card provides critical information about airport security systems, and using your pump on an airplane, that can help you and others. Not carrying the Emergency Card could result in serious injury.
- 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.

Reservoir and infusion sets

- Only use reservoir and infusion sets manufactured 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.

- Only use U100 insulin 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 refer to the reservoir and infusion set user guides for all precautions, warnings, and instructions relating to the reservoir and infusion set. Not referring to the reservoir and infusion set user guides can result in serious injury or damage to the sensor.

Sensor

- Do not attempt to remove the sensor yourself if you suspect that the sensor is broken. While there is no evidence of an Enlite® 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 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 serious injury or damage to the sensor.

Transmitter

- Do not allow children to put small parts in their mouth. This product poses a choking hazard for young children.
- 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 serious injury or damage to the transmitter.

Meter

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

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.

Electrostatic discharge

- Although your MiniMed 630G 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.

- For more information on pump alarms, see *Pump alarms, alerts, and messages, on page 204*. For more information on re-entering your pump settings, see *My pump is asking me to enter my settings, on page 232*. If you are unable to re-enter 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. Carefully inspect your pump to ensure there are no cracks. 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 241*.

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 Bayer® 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.

Notice

Radio Frequency (RF) communication

- 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.
- 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 the receiver.
- 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.
- 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.
- 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.

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.
2. 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.

Keeping track of your system information

The serial number (SN) is located on the back of your pump. If you are using the belt clip, you need to remove the belt 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 37*. 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 and purchase date
Serial Number:
Purchase Date:

Insulin guidelines



WARNING: Never start on insulin until directed by your healthcare professional. Doing so could result in an unintended delivery of insulin, which can cause hypoglycemia.

The MiniMed 630G insulin pump has been studied with and is intended for use with the following rapid-acting U100 insulins:

- U100 Humalog®
- U100 NovoLog®

The use of any other insulin in the MiniMed 630G insulin pump has not been tested and may not be appropriate for use with this device.



WARNING: Do not use any other insulin with your pump other than the above specified rapid-acting U100 insulins (Humalog, NovoLog). Use of the incorrect insulin, or insulin with a greater or lesser concentration, may result in over delivery or under delivery of insulin. This could lead to very low or very high blood glucose levels. Very high BG levels may lead to Diabetic Ketoacidosis and very low glucose levels may lead to coma and death. If you are unsure about whether you can use a specific insulin with this pump, please consult with your healthcare provider.

Consumables

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



WARNING: Only use reservoir and infusion sets manufactured 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 only Medtronic reservoirs.

Look on the back of your pump for your model number.

For the MMT-1715 pump model, use the MMT-332A, 3.0 ml (300-unit) reservoir.

- **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 630G system devices

- **Compatible Bayer blood glucose meter** – The 630G system comes with a compatible Bayer blood glucose 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 transmitter (MMT-7763)** – 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.
- **Enlite glucose sensor (MMT-7008)** – 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.
- **CareLink® 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 your MiniMed 630G system.

- **Belt clip (ACC-1599)** – used to wear the pump on your belt. Also, you can use the tip of the belt clip to open the battery compartment on your pump.
- **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 belt 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.

2



first steps

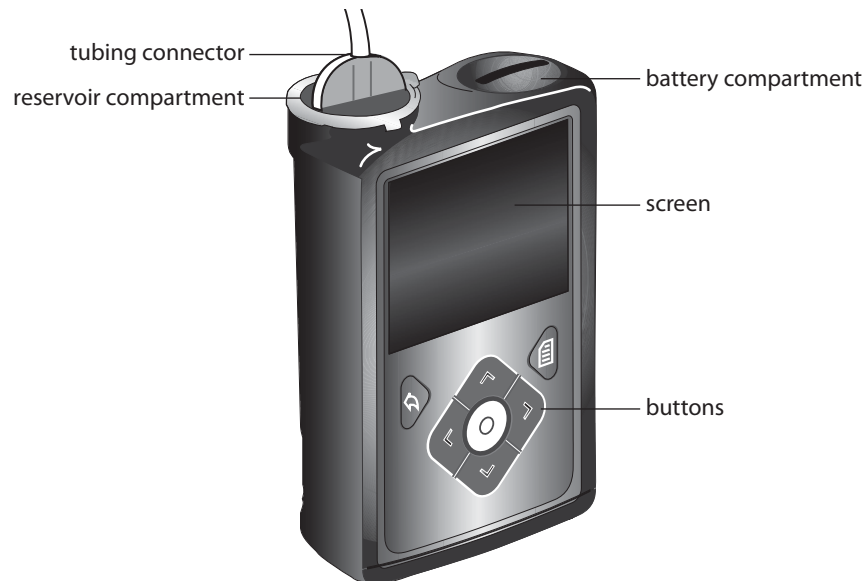
2

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 and initial setup 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, the notification light, and the light sensor on your pump. The notification light flashes when your pump has an alarm or alert. The notification light is not visible unless flashing.

The keypad has a backlight that lights up the buttons when in use.



Note: Do not cover the light sensor with your finger while using your pump. Covering the light sensor may adjust the brightness on the screen when brightness is set to Auto. See *Display Options*, on page 147 for more information.

The following table describes how to use the buttons.

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  ,  ,  , or  buttons to select the desired item, and then press the  button.
Enter a value into a field.	Press the  ,  ,  , or  buttons to select the desired field, and then press the  button. The field you select flashes. Press the  or  buttons to enter the desired value, and then press the  button.
Return to the previous screen.	Press the  button.
Display the Menu screen.	Press the  button.
Display the Home screen.	When you are on any screen other than the Home screen, press and hold the  button for about one second.
Put the pump in sleep mode.	Press and hold  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.



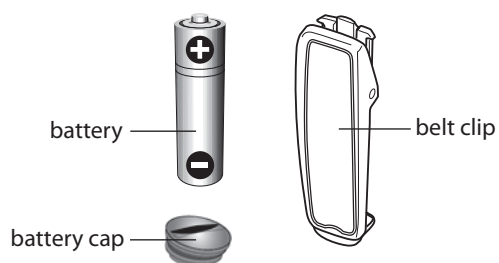
Caution: Do not use a carbon zinc battery in your pump. Carbon zinc batteries are not compatible with the pump. Use of carbon zinc batteries can cause the pump to report inaccurate battery levels.



Note: Do not use cold batteries because the battery life may incorrectly appear as low. This can cause a Battery Failed alarm on your pump. Allow cold batteries to reach room temperature before you insert them in your pump.

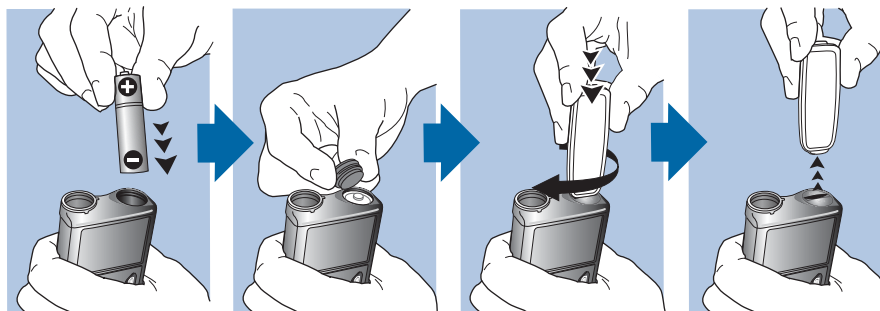
Inserting the battery

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:

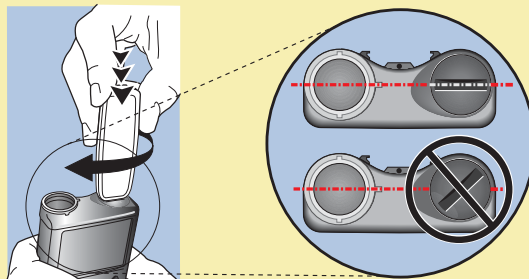
1. Insert the new or fully charged AA battery, making sure to insert the negative end (–) first. After you insert the battery, the positive end (+) is visible.



2. Use the belt 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.



3. 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 30. 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.

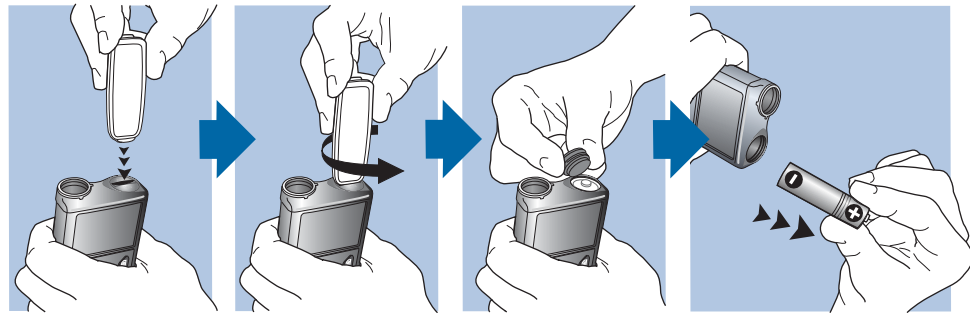
To remove the battery:

1. Before removing a battery from your pump, clear any active alarms or alerts.
2. Use the belt clip to loosen and remove the battery cap. See *Inserting the battery*, on page 28 for an illustration of battery parts.



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

3. Remove the battery.



4. Dispose of old batteries according to local disposal requirements, or contact your healthcare professional for disposal information.
5. 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 242 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

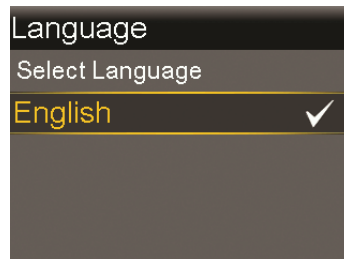
Your pump has a Startup Wizard that begins when you insert your battery for the first time. The Startup Wizard guides you through setting the language, the time format, the current time, and the current date.



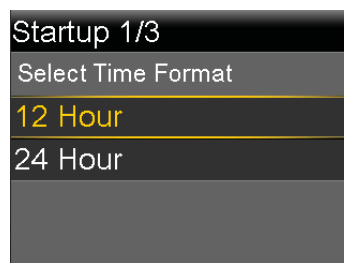
Note: Use this procedure when you are entering your settings for the first time. If this is not the first time you are entering your pump settings, and your pump is asking you to re-enter your settings, see *My pump is asking me to enter my settings*, on page 232.

To use the Startup Wizard:

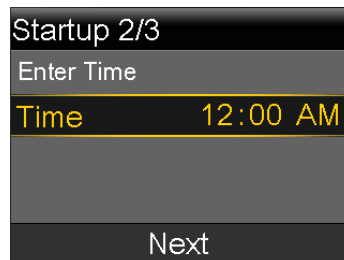
1. The Startup Wizard begins after the Welcome screen appears. When the Language screen appears, select English.



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**.



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

Startup 3/3	
Enter Date	
Year	2013
Month	Jan
Day	1, Tue
Next	

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

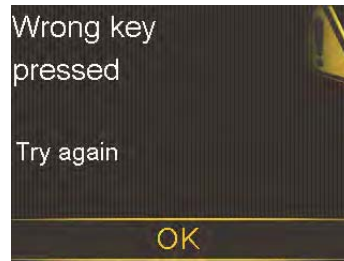
After you enter your initial settings, see the following sections in this chapter to become familiar with the buttons and screens on your pump.

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 away from the Home screen. When you press menu  or 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 following screen appears and you will need to select **OK** to return to your Home screen and try again.

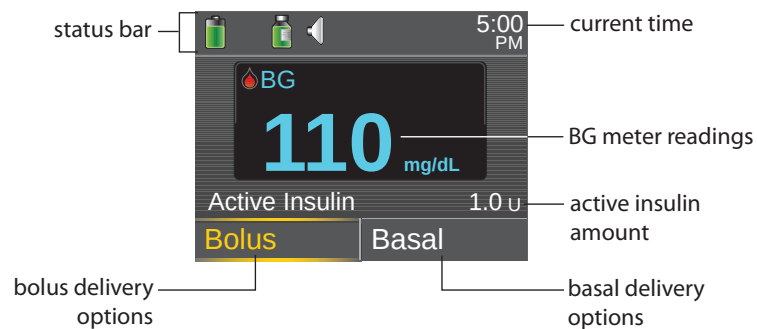


After your pump is unlocked, it will remain unlocked until you re-enter sleep mode. For information about the different power modes, or to put your pump to sleep, see *Power modes*, on page 40.

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. You can navigate to the Home screen from any other screen by pressing and holding the  button for about one second.

To see what your Home screen looks like if you use a sensor, see *Home screen with CGM*, on page 158.



The following items appear on your Home screen:

Item	Description
Status bar	Displays icons that show a quick status of your pump system. For more information, see <i>Status bar, on page 35</i> . By selecting the status bar you can access more detailed status screens. For more information, see <i>Status screens, on page 37</i> .
Current time	Displays the current time of day. For details on setting the time, see <i>Time and date, on page 154</i> .
BG meter readings	If you have taken a BG meter reading using your compatible Bayer 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 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, on page 71</i>. For details on entering events, see <i>Event Markers, on page 130</i>.
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 78</i> .
Bolus	Allows you to access your bolus delivery options, and provides access to all of your insulin settings. For details about entering your bolus settings and delivering bolus insulin, see the Bolus chapter on <i>page 65</i>. If you have not set up the Bolus Wizard and Preset Bolus features, you only have access to Manual Bolus from this screen. For details about setting up the Bolus Wizard feature, see <i>Bolus Wizard, on page 71</i>. For details about setting up the Preset Bolus feature, see <i>Preset Bolus, on page 91</i>.
Basal	Allows you to access your basal delivery options, and provides access to all of your insulin settings. For details about entering your basal settings and delivering basal insulin, see the Basal chapter on <i>page 45</i>. To access all of your basal options from this screen, you must have set up a Preset Temp basal rate. For details about setting up Preset Temp basal rates, see <i>Preset Temp basal rates, on page 56</i>.

Status bar

The status bar appears at the top of the Home screen to provide a way for you to quickly check the status of your system. The status bar contains the icons that are described in the following table, along with the current time. For information on viewing detailed status screens, see *Status screens*, on page 37.

Icon	Icon name	What it means
	Battery	The charge level of your pump battery. The color and the fill level of the icon indicate the status. When your battery is full, the icon is solid green. As your battery life is used, the icon changes, as shown in the following example. For more details about batteries, see <i>About batteries</i> , on page 27.
		
	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 gray  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 <i>Understanding Continuous Glucose Monitoring (CGM)</i> , on page 157.
	Airplane Mode	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. The pump also cannot send wireless communication to other devices. For more information about using Airplane Mode, see <i>Airplane Mode</i> , on page 143.

Icon	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. 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 <i>Reservoir and infusion set</i> on page 99.
		
	Audio	The audio mode you are using: vibrate only  , audio only  , or vibrate and audio  . For more information about your audio settings, see <i>Audio Options</i> , on page 144.
	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 fill level of the icon indicate the status. When your sensor is fully calibrated, the icon is solid green. As the time for your next sensor calibration approaches, the icon becomes emptier, and the color of the icon changes as shown in the following example. For more information about calibrating your sensor, see <i>Calibrating your sensor</i> , on page 186.
		
When your sensor is initializing, the Calibration icon appears with three dots . If the time to your next sensor calibration is unavailable, the Calibration icon appears with a question mark .		

Icon	Icon name	What it means
	Sensor Life	The number of days remaining in the life of your sensor. 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. As your sensor life is used, the icon becomes emptier. The icon turns yellow when less than 24 hours remains in the life of your sensor. It turns red when less than 12 hours remains in the life of your sensor.  If the number of days remaining in the life of your sensor is unavailable, the Sensor Life icon appears with a question mark .
	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</i>, on page 145.
	Temporary Network Connection	Appears while you are temporarily connected to a remote upload device.

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
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.

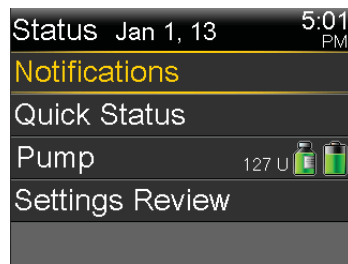
Status screen	Displays this information
Quick Status	A summary of status information, including your last bolus, last BG meter reading, current basal rate, reservoir level, and pump battery charge level. If you are using a sensor, this screen also displays the time that your next calibration is due and the SmartGuard suspend by sensor 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, the serial number and version number of your transmitter, and the SmartGuard suspend by sensor 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. Go to the Home screen.
2. Select the status bar that appears at the top of the Home screen.



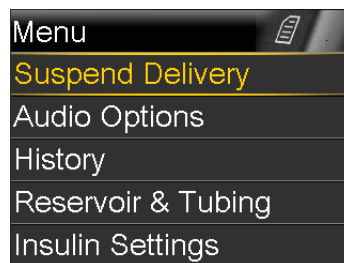
The Status screen appears.



3. 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.

Using the Menu screen

The Menu screen is where you access the various features and functions of your system. To display the Menu screen, press .



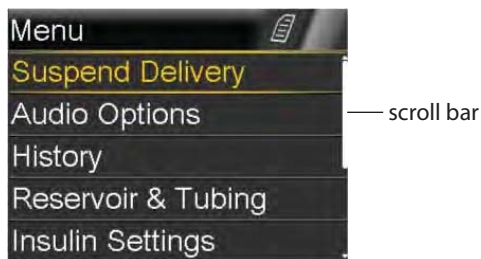
The following options are available from the Menu screen:

Select this	To do this
Suspend Delivery	Stop your current basal and bolus insulin delivery.
Audio Options	Set your audio, vibrate, and volume options for the notifications you receive.
History	Access the Summary, Daily History, and Alarm History screens. If you are using a sensor, you can access the SG Review and ISIG History screens.
Reservoir & Tubing	Start the process of changing your reservoir and infusion set.
Insulin Settings	Set up and manage your insulin delivery options, including your Basal and Bolus settings.

Select this	To do this
Sensor Settings	Set up your optional continuous glucose monitoring device settings.
Event Markers	Save information about events, such as exercise, blood glucose readings, carbs you eat, or injections you take. If you are using a sensor, the blood glucose readings may be used for calibration.
Reminders	Set up reminders to help monitor your system and to help you manage your diabetes. You can also create reminders for personal events.
Utilities	Set up and manage the features and functions of your system.

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 32</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, on page 147</i>. 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 about two minutes after your pump enters power save mode if no buttons are pressed. At this time, your pump automatically locks. If any button is pressed, your pump returns to the Home screen.



Note: In some cases, if there is an action you need to take, your pump returns to the screen last displayed. This includes startup settings, loading your reservoir, filling your tubing, filling your cannula, and any screen where you have an action pending.

To put your pump into sleep mode, press and hold the **Menu** 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 148* for more information.
- Remove the battery. See *Storing your pump, on page 242* 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.

3



basal

3

Basal

Basal insulin is the "background" insulin that you need throughout the day and night to maintain your target blood glucose values 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.

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 48.

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 <i>Adding a new basal pattern, on page 48</i> . For details about starting a basal pattern, see <i>Changing from one basal pattern to another, on page 52</i> .
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, on page 55</i> .
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 <i>Preset Temp basal rates, on page 56</i> . For details about starting a preset temp basal rate, see <i>Starting a Preset Temp basal rate, on page 58</i> .
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 <i>Max Basal Rate, on page 47</i> .

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 bolus delivery.

To set your Max Basal Rate:

1. Go to the Max Basal/Bolus screen.

Menu > Insulin 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 Maximum basal rate of 1.00 units per hour.

Example 2: Max basal

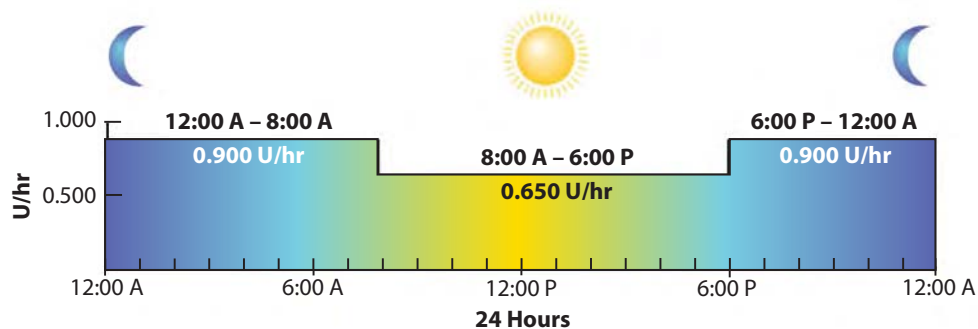
Rusty needs large amounts of insulin to control his blood glucose levels. His new pump was delivered from the factory with a Maximum basal rate of 2.00 units per hour, but he needs 2.80 units per hour in the early morning. Rusty will reprogram his Maximum basal to 3.00 units per hour to accommodate his 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 52.

Adding a new basal pattern

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

To add a new basal pattern:

1. Go to the Basal Pattern Setup screen.

Menu > Insulin 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.

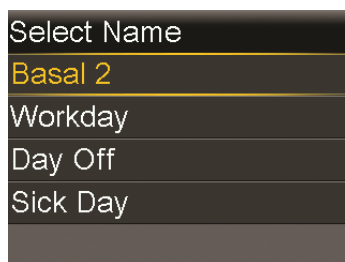


2. If this is your first time setting up a basal pattern, the unit amount will be 0.0. Select **Basal 1** and proceed to step 5.

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.

Edit Workday		
Start	End	U/hr
12:00 _A	12:00 _A	---



Caution: Always set your basal rate in units per hour. Insulin is delivered in units per hour, and does not adjust for shorter time periods. For example, if you set a basal rate of 0.025 U/hr for a 30-minute time period, this might result in no insulin delivered for that 30-minute period.

Use one hour as the minimum time period for a basal rate.

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.

Edit Workday		
Start	End	U/hr
12:00 _A	12:00 _A	0.025
Done		

- 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.

Edit Workday		
Start	End	U/hr
12:00 _A	7:30 _A	0.075
7:30 _A	8:00 _A	---

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 $\wedge$ or $\vee$ when a field is selected (flashing) adjusts the value of that field. When there is no field selected, pressing $\wedge$ or $\vee$ 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.

Edit Workday		
Start	End	U/hr
12:00 _A	7:30 _A	0.075
7:30 _A	6:00 _P	0.025
6:00 _P	12:00 _A	0.050
Done		

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 $\blacktriangleleft$ to return to the previous screen.

8. Select **Save**.

To activate your basal pattern, see *Changing from one basal pattern to another*, on page 52.

Editing, copying, or deleting a basal pattern

To edit, copy, or delete a basal pattern:

1. Go to the Basal Pattern Setup screen.

Menu > Insulin 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. Go to the Basal Patterns screen.

Home 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. He determines that he needs to have lower basal settings to receive less insulin during active times, such as his weekends.

He can use a second basal pattern 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 the Day Off pattern, which he can set with lower basal rates for the weekend. On Monday morning, he can return his pump to Basal 1 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 2 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. For her usual schedule, she uses the Basal 1 pattern.

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.

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.
Rate	Delivers a fixed basal insulin rate in units per hour for the duration of your temporary basal, limited by your max basal rate.

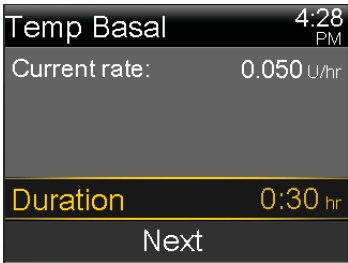
To use the Temp Basal feature, see *Starting a Temp Basal rate, on page 55*. To use the Preset Temp Basal feature, see *Preset Temp basal rates, on page 56*.

Starting a Temp Basal rate

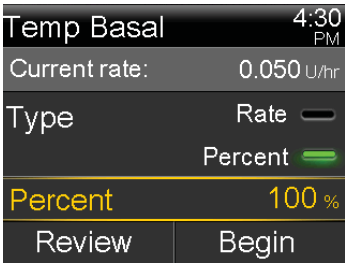
When you start a temp basal rate, your basal delivery changes to the temporary basal rate for the duration you set. When the duration is complete, your basal insulin automatically returns to the active basal pattern.

To start a temp basal rate:

1. Go to the Temp Basal screen.
- Home 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.



3. 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:

Temp Basal		4:30 PM
Current rate:		0.050 U/hr
Type	Rate	☐
	Percent	☒
Percent		50 %
Review	Begin	

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

Temp Basal		4:29 PM
Current rate:		0.050 U/hr
Type	Rate	☒
	Percent	☐
Rate		0.025 U/hr
Review	Begin	

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. The Basal option on the Home screen appears as Basal (T) during your temp basal delivery. Your scheduled basal rate automatically starts again when your Temp Basal rate finishes.



Note: If you need to cancel your temp basal, select **Basal (T)** from the Home screen, then select **Cancel Temp Basal**.

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 58.

To set up a preset temp basal rate:

- Go to the Preset Temp Setup screen.
Menu > Insulin Settings > Preset Temp Setup
- Select **Add New**.
- Select a name for the preset temp basal rate you want to set (Temp 1, High Activity, Moderate Activity, Low Activity, or Sick).
- The Type defaults to Percent. You can switch between Percent and Rate by selecting **Type**.
- 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.
- Set the **Duration** (from 30 minutes to 24 hours in 15 minute increments) that you want this preset temp basal to be active.
- Select **Save**.

To change, rename, or delete a preset temp basal rate:

- Go to the Preset Temp Setup screen.
Menu > Insulin Settings > Preset Temp Setup
- Select the desired preset temp basal.



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

- Select **Options**, and then 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 56*.

To start a preset temp basal rate:

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

Home screen > Basal > Preset Temp

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

Preset Temp	5:08 PM
Current rate:	0.025 U/hr
Temp 1	0.100 U/hr
High Activity	25 %
Moderate...	50 %



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 in the list, but are not available for use.

2. Select the preset temp basal rate that you want to use, and then select **Begin**.



Your preset temp basal rate continues for the duration you set. The Basal option on the Home screen appears as Basal (T) during your preset temp basal delivery. Your scheduled basal rate automatically starts again when your preset temp basal rate finishes.

Canceling a Temp Basal or Preset Temp basal rate

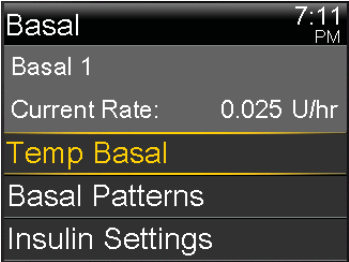
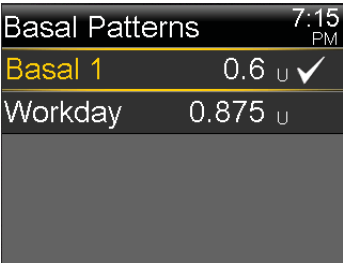
You can cancel a temp basal or preset temp basal rate at any time. When you do so, your scheduled basal pattern automatically starts again.

To cancel a temp basal rate:

1. Go to the Basal screen.
- Home screen > Basal (T)
- 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**.
3. Follow the instructions on the screen to confirm cancellation.

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	Go to the Basal screen: Home screen > Basal The active basal pattern and current basal rate appear at the top of the Basal screen.  You can also view your current basal rate by selecting the Status Bar at the top of the Home screen, and then selecting Quick Status.
View your basal patterns	Go to the Basal Patterns screen: Home screen > Basal > Basal Patterns The Basal Patterns 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.  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. When you suspend your insulin delivery, your pump beeps or vibrates, or both depending on your audio settings. This occurs every 15 minutes to remind you that insulin is not being delivered.

When you are ready 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 94.



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.



Caution: 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:

1. Go to the Suspend Delivery screen.
Menu > Suspend Delivery
A confirmation message appears.
2. 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:

1. While insulin is suspended, go to the **Home** screen.
2. Select **Resume**.
A confirmation message appears.
3. 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 127 for details about using the Daily History screen.

4



bolus

4

Bolus

A bolus is the amount of insulin taken to cover an expected rise in blood glucose, 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

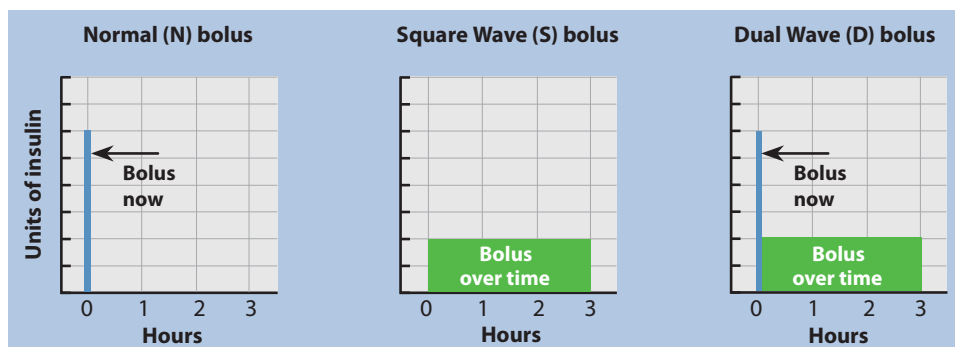
The following table provides general information about the available bolus types.

Type	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</i>, on page 79.

Type	How it works	When to use it
Square Wave®	Delivers a single bolus evenly over an extended period of time (30 minutes to 8 hours).	You might use a Square Wave bolus: • If you have delayed food digestion due to gastroparesis or meals high in fat. • When snacking over an extended period of time. • If a Normal bolus drops your blood glucose too rapidly. For details about using the Square Wave bolus feature, see <i>Square Wave bolus</i>, on page 82.
Dual Wave®	Delivers a combination of an immediate Normal bolus followed by a Square Wave bolus.	You might use a Dual Wave bolus: • When you eat meals that are both high in carbs and fat which may delay digestion. • When your meal bolus is combined with a correction bolus for an elevated blood glucose. For details about using a Dual Wave bolus, see <i>Dual Wave bolus</i>, on page 85.

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.

Delivery method	Type of bolus available	How it works
Bolus Wizard	Normal bolus, Square Wave bolus, Dual Wave bolus	You enter your BG meter reading and your carbs you plan to eat, and then the Bolus Wizard calculates an estimated bolus amount based on your individual settings. For details about using the Bolus Wizard feature, see <i>Bolus Wizard, on page 71</i>. To deliver a: • Normal bolus using Bolus Wizard, see <i>page 79</i>. • Square Wave bolus using Bolus Wizard, see <i>page 83</i>. • Dual Wave bolus using Bolus Wizard, see <i>page 86</i>.
Manual	Normal bolus, Square Wave bolus, Dual Wave bolus	You do your own calculation and manually enter your bolus amount. To deliver a: • Normal bolus, see <i>page 81</i> • Square Wave bolus, see <i>page 84</i> • Dual Wave bolus, see <i>page 87</i>
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 91</i>.

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</i>, on page 88.
Remote Bolus from your compatible Bayer meter	Normal bolus or any Preset Bolus set up on your pump.	For information on using the Remote Bolus feature on your compatible Bayer meter, see the user guide that came with your compatible Bayer meter. For information on turning on the Remote Bolus feature on your pump, see <i>Setting up Remote Bolus</i>, on page 118.

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 71.

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</i>, on page 69.

Setting	What it is	What it does for you
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 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</i> , on page 70.
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 71.

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.

To set your max bolus:

1. Go to the Max Basal/Bolus screen.
- Menu > Insulin Settings > Max Basal/Bolus
2. 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 Maximum 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 Maximum 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 89 for more information.

To set your Bolus Increment:

1. Go to the Bolus Increment screen.
Menu > Insulin Settings > Bolus Increment
2. Select **Increment** to set your desired increment value.
3. 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:

1. Go to the Bolus Speed screen.
Menu > Insulin Settings > Bolus Speed
2. 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 or exchange 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 *page 79*), Square Wave bolus (see *page 83*), or Dual Wave bolus (see *page 86*).

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 72*.

Setting	What it does
Carb Ratio	Used for food bolus calculations.
Exchange Ratio	• <i>If you count carbs:</i> the number of carb grams that are covered by 1 unit of insulin. • <i>If you count exchanges:</i> the number of insulin units that are needed to cover 1 carb exchange.
Insulin Sensitivity Factor	Used to calculate correction bolus amounts. 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</i>, on page 78.

Setting up the Bolus Wizard feature

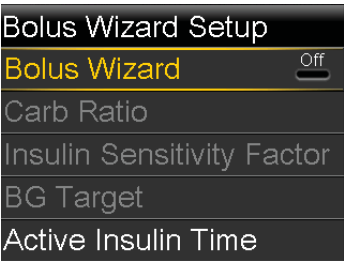
Before you can use the Bolus Wizard to calculate a bolus, you must turn on this feature and enter your Bolus Wizard settings.

To set up the Bolus Wizard feature:

1. Go to the Bolus Wizard Setup screen.

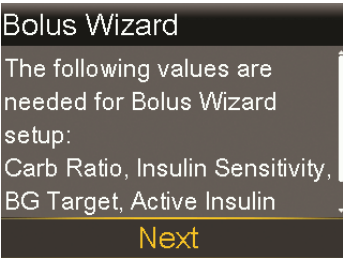
Menu > Insulin Settings > Bolus Wizard Setup

The Bolus Wizard 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. Click **Next** to continue when you have read each explanation.

3. When the Edit Carb Ratio screen appears, enter your carb ratio. If you are setting a carb ratio, set the grams per unit (g/U). If you are setting an exchange ratio, set the units per exchange (U/exch). You can set up to eight carb ratios using different time segments. The time segments must cover a 24-hour period.

Edit Carb Ratio 1/4		
Start	End	g/U
12:00 _A	12:00 _A	---



Note: Your pump uses grams as the default carb unit. If you would like to change your carb unit to exchanges, see *Carb Unit*, on page 147.

If your ratio value is outside the range of 5 to 50 grams per unit or 0.3 to 3 units per exchange, 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.

Edit Sensitivity 2/4		
Start	End	mg/dL per U
12:00 _A	12:00 _A	---

If the value you enter is outside the range of 20 to 100 mg/dL, 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.

Edit BG Target 3/4

Start	End	Lo-Hi (mg/dL)
12:00 A	12:00 A	--- --

If your 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.

Active Insulin Time 4/4

Duration

6:00 hr

Save

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. These settings are available only if the Bolus Wizard is turned on.

Changing your carb or exchange ratio

You can change either your carb ratio or exchange ratio setting, depending on whether you use grams or exchanges as your carb unit. The carb ratio and exchange ratio settings are available only if the Bolus Wizard is turned on.



Note:

Your pump uses grams as the default carb unit. If you would like to change your carb unit to exchanges, see *Carb Unit*, on page 147.

To change your carb or exchange ratio:

1. Go to the Carb Ratio screen or the Exchange Ratio screen, depending on the carb units you use.

Menu > Insulin Settings > Bolus Wizard Setup > Carb Ratio

or

Menu > Insulin Settings > Bolus Wizard Setup > Exchange Ratio

2. Select **Edit**.
3. Select the carb or exchange ratio to adjust the Start time, the End time, and the ratio. You can set up to eight different carb or exchange 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 or 0.3 to 3 units per exchange, 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. Go to the Sensitivity screen.

Menu > Insulin Settings > Bolus Wizard 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:

1. Go to the BG Target screen.
Menu > Insulin Settings > Bolus Wizard Setup > BG Target
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. Go to the Active Insulin Time screen.
Menu > Insulin Settings > Bolus Wizard 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 Carb Ratio, Insulin Sensitivity Factor, or BG Target settings from the Bolus Wizard Setup screen.

To turn off the Bolus Wizard feature:

1. Go to the Bolus Wizard Setup screen.
Menu > Insulin Settings > Bolus Wizard Setup

2. 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 250 mg/dL.	• Check for an occlusion. • Check ketones. • Consider an insulin injection. • Monitor your BG.

Warning:	What it means:	What to do:
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 No to cancel, or Yes to continue. If you select Yes, the bolus amount that you entered is reduced to your max bolus limit.

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, Insulin 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:

- 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.
- Go to the Bolus Wizard screen.

Home 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 78*. For more information, see *About your compatible Bayer meter, on page 117*.



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.

Bolus Wizard		9:08 AM
BG	130 mg/dL	0.3 U
Active Ins. adjust.		-0.3 U
Carbs	0 g	0.0 U
Bolus		0.0 U
Next		

3. If you are not using a wirelessly connected compatible Bayer 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.

Bolus Wizard		9:08 AM
BG	130 mg/dL	0.3 U
Active Ins. adjust.		-0.3 U
Carbs	35 g	2.3 U
Bolus		2.3 U
Next		

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.

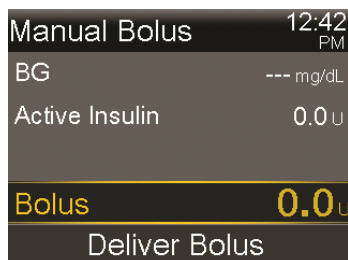
To deliver a Normal bolus using Manual Bolus:

1. Go to the Manual Bolus screen.

Home 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 78*.

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:

- Change the Max Bolus or the Active Insulin Time settings.
- Turn off or deliver Dual Wave or Square Wave boluses.
- Turn the Bolus Wizard feature on or off.
- 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. Go to the Dual/Square screen.
Menu > Insulin Settings > Dual/Square Wave
2. Select **Square Wave** to turn the feature on or off.
3. 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. Go to the Bolus Wizard screen.
Home 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 78*. For more information, see *About your compatible Bayer meter, on page 117*.



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.

2. If you are not using a wirelessly connected compatible Bayer 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 amounts.
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 **Bolus** button on your Home screen appears as Bolus (S). You can select **Bolus (S)** to stop the bolus, to see details on the insulin that has been delivered, or to access the Bolus menu. The Bolus menu provides access to the Bolus Wizard, Manual Bolus, Preset Bolus, and Insulin Settings options.

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. Go to the Manual Bolus screen.

Home 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 delivery, the **Bolus** button on your Home screen appears as **Bolus (S)**. You can select **Bolus (S)** to stop the bolus, to see details on the insulin that has been delivered, or to access the Bolus menu. The Bolus menu provides access to the Bolus Wizard, Manual Bolus, Preset Bolus, and Insulin Settings options.

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. Go to the Dual/Square screen.
Menu > Insulin 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. Go to the Bolus Wizard screen.

Home 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 78*. For more information, see *About your compatible Bayer meter, on page 117*.



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 compatible Bayer 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 **Bolus** button on your Home screen appears as Bolus (D). You can select **Bolus (D)** to stop the bolus, to see details on the amount of bolus insulin delivered, or to access the Bolus menu. The Bolus menu provides access to the Bolus Wizard, Manual Bolus, Preset Bolus, and Insulin Settings options.

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.

Go to the Manual Bolus screen.
- Home 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.

Manual Bolus			9:14 AM
Bolus			8.0 U
Now	50 %	4.0 U	
Square	50 %	4.0 U	
Duration			0:30 hr
Deliver Bolus			

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 **Bolus** button on your Home screen appears as **Bolus (D)**. You can select **Bolus (D)** to stop the bolus, to see details on the amount of bolus insulin delivered, or to access the Bolus menu. The Bolus menu provides access to the Bolus Wizard, Manual Bolus, Preset Bolus, and Insulin Settings options.

Easy Bolus

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

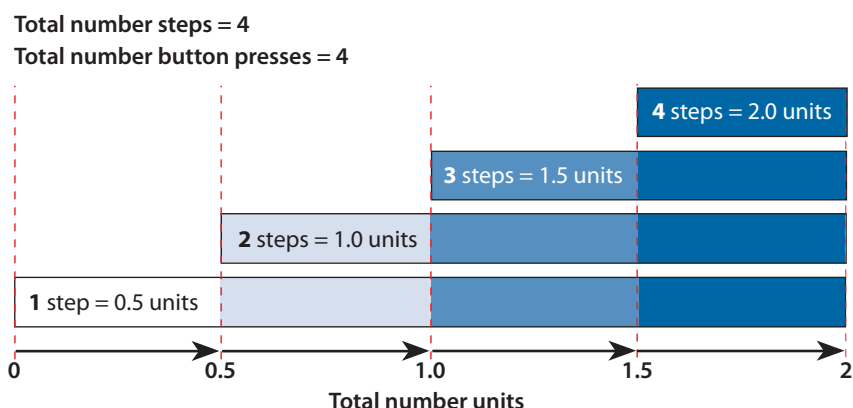
Before using Easy Bolus, you must turn on the feature and set the step size. The step size determines the number of units the bolus amount increases each time you press the $\wedge$ button. Your Easy Bolus delivery is limited to 20 steps or your max bolus limit, whichever comes first.

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.

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 **^** 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 **^** 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:

- Go to the Easy Bolus screen.
Menu > Insulin Settings > Easy Bolus
- Select **Easy Bolus** to turn on the feature.
- 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.
- 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.



Caution: Always check your pump if you hear any unanticipated beeps or vibrations. 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. This is most important when using the Easy Bolus feature, or when you have manually suspended insulin delivery, where a missed notification could result in the delivery of too much or too little insulin.

Contact the 24 Hour HelpLine with any concerns.

To use the Easy Bolus feature, you need to put your pump into sleep mode by pressing and holding the **Menu** button  for about two seconds.

To deliver a bolus using Easy Bolus:

1. While your pump screen is in sleep mode, press and hold $\wedge$ for about one second. After your pump beeps or vibrates, release $\wedge$. 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 $\wedge$ the number of times needed to set your bolus amount.
Each time you press $\wedge$, 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 $\vee$ to select the Easy Bolus values. Pressing $\vee$ cancels the Easy Bolus.

3. When you have reached the desired bolus amount, press and hold $\wedge$ 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 $\vee$ 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. Go to the Preset Bolus Setup screen.

Menu > Insulin 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**.

Changing, 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 change, rename, or delete a Preset Bolus:

1. Go to the Preset Bolus Setup screen.

Menu > Insulin 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 91.

To deliver a Preset Bolus:

1. Go to the Home screen.
2. Select **Bolus**.
The Bolus screen appears.
3. Select **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 78.
4. Select the Preset Bolus you want to deliver.
5. Verify your bolus amounts, and then select **Deliver Bolus**.
Your pump beeps or vibrates and displays a message when your bolus starts.

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 (Menu > 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, select **Stop Bolus** from the Home screen.



2. 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.

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

1. Select **Bolus (S)** or **Bolus (D)** from the Home screen.
2. Select **Stop Bolus**.
3. 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.

5



reservoir and infusion set

5

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. For details on changing the time and date on your pump, see *Time and date, on page 154*. You must also program your settings as instructed by your healthcare professional.

You will need these items:

- MiniMed 630G insulin pump
- Vial of insulin (U100)
- MiniMed reservoir
- MiniMed 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 150*.

Removing the reservoir

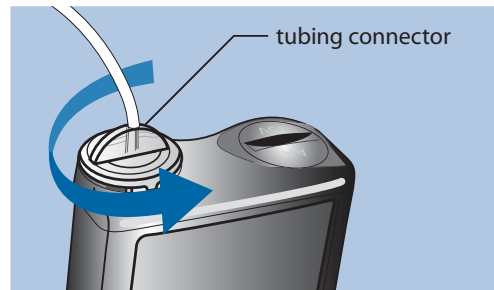
If this is the first time you are inserting a reservoir into your pump and you do not currently have a reservoir loaded, skip to *Rewinding your pump, on page 100*.



WARNING: Always make sure the infusion set is disconnected from your body before you remove the reservoir from your pump. Removing the reservoir from your pump with the infusion set still connected to your body could result in an accidental infusion of insulin, which can cause hypoglycemia.

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

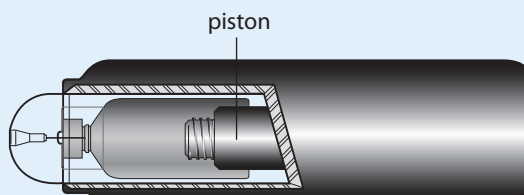


WARNING: Always make sure the infusion set is disconnected from your body before you rewind your pump or fill the infusion set tubing. Never insert the reservoir into the pump while the tubing is connected to your body. Doing so could result in an accidental infusion of insulin, which can cause hypoglycemia.

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.



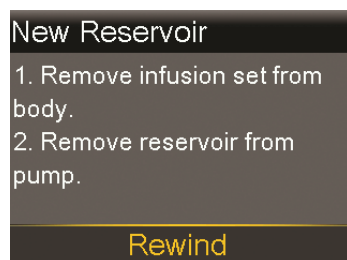
To rewind your pump:

1. Go to the New Reservoir screen.

Menu > 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.

New Reservoir

1. Fill reservoir.
2. Connect tubing to reservoir.

DO NOT CONNECT TO BODY.

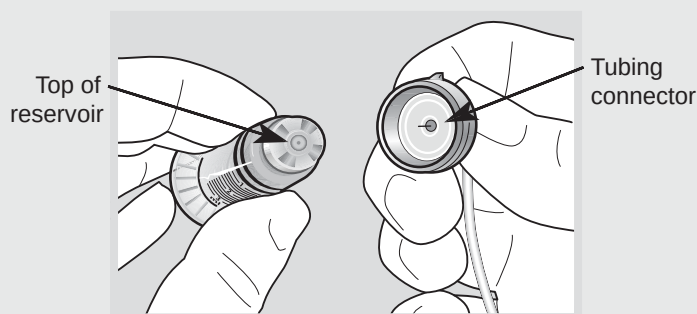
Next

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

Filling the reservoir



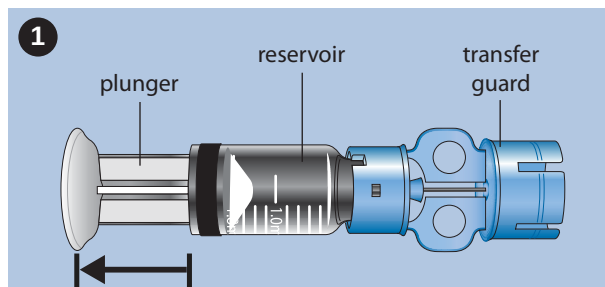
WARNING: Do not use the reservoir or infusion set if any liquid gets on the top of the reservoir or inside the tubing connector (as shown in the image). Liquid can temporarily block the vents. This may result in the delivery of too little or too much insulin, which can cause hyperglycemia or hypoglycemia.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



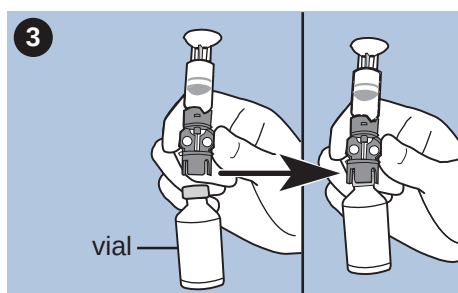
WARNING: Always allow your insulin to reach room temperature before use. Cold insulin can cause air bubbles in the reservoir and tubing, which may result in inaccurate insulin delivery.

To fill the reservoir, do these steps:

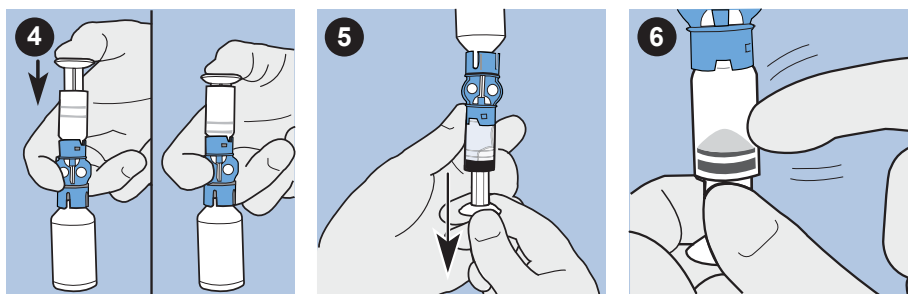
1. Remove the reservoir from the package, and fully extend the plunger.



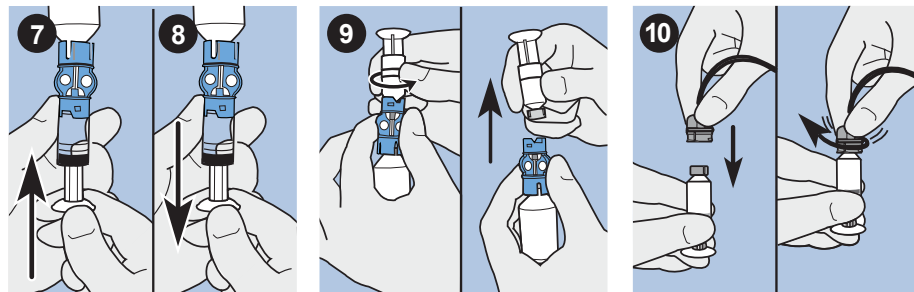
2. Swab the vial with alcohol (not shown).
3. Press the transfer guard onto the vial without pushing down on the plunger.



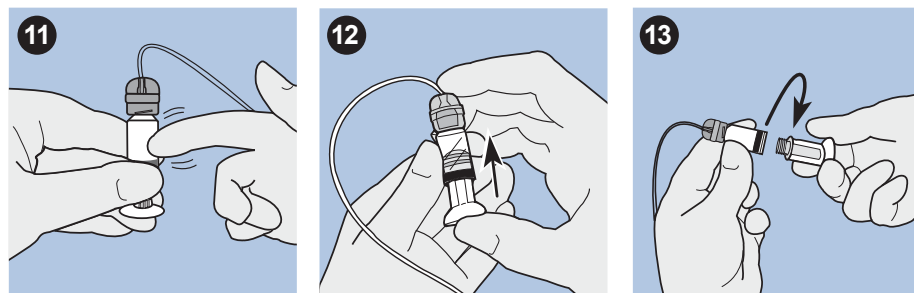
4. Push down on the plunger to pressurize the vial. Hold down the plunger rod.
5. While still holding down the plunger rod, flip the vial over so the vial is on top. Slowly pull down on the plunger to fill the reservoir.
6. Gently tap the side of the reservoir to make any air bubbles rise to the top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



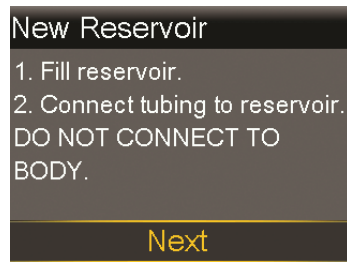
7. Slowly push up on the plunger just enough to remove any air bubbles from the reservoir.
8. Slowly pull down on the plunger to fill the reservoir to the number of units desired.
9. To avoid getting liquid on the top of the reservoir, flip the vial over so that it is upright. Turn the reservoir counter-clockwise, 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.



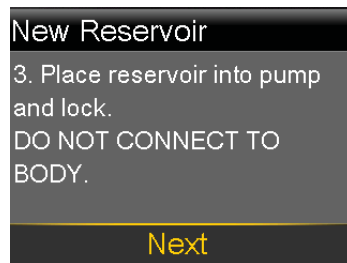
11. Tap the side of the reservoir to remove any air bubbles.
12. To purge air bubbles that have risen to the top of the reservoir, push up on the plunger until you see insulin in the tubing.
13. Without pulling, turn the plunger counter-clockwise to remove it from the reservoir.



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



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



Note: If the New Reservoir screen has timed out and the Home screen appears, select **Load Reservoir** from the Home screen.

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.



WARNING: Do not insert the reservoir into your pump until you have been instructed to do so by your healthcare professional, and have received formal training with a certified product trainer. Attempting to use insulin in your pump before you have received training may result in the delivery of too little or too much insulin, which can cause hyperglycemia or hypoglycemia.

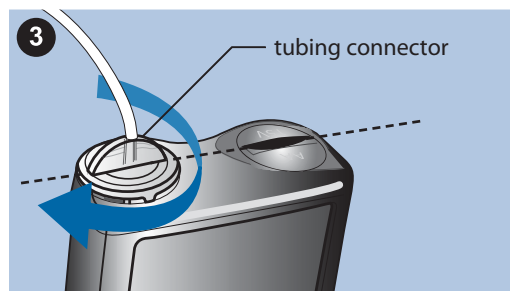
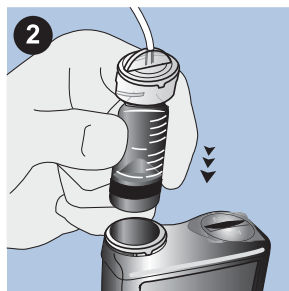


WARNING: Always rewind your pump before inserting a new reservoir. Failing to rewind your pump could result in an accidental infusion of insulin, which can cause hypoglycemia.

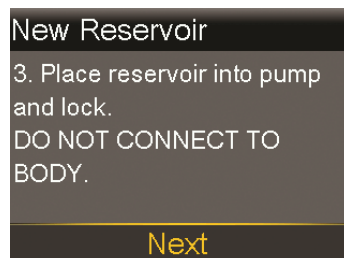
Never insert the reservoir into the pump while the tubing is connected to your body. Doing so could result in an accidental infusion of insulin, which can cause hypoglycemia.

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 100 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.





Note: If the New Reservoir screen has timed out and the Home screen appears, select **Load Reservoir** from the Home screen. After the New Reservoir screen appears, you may have to select **Next** to get to the screen shown previously.

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.



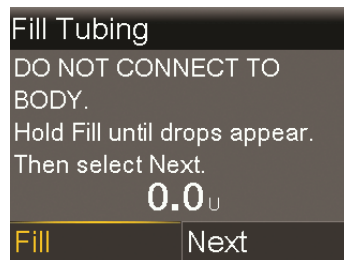
WARNING: Always make sure the infusion set is disconnected from your body before you rewind your pump or fill the infusion set tubing. Never insert the reservoir into the pump while the tubing is connected to your body. Doing so could result in an accidental infusion of insulin, which can cause hypoglycemia.



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:

1. 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 204, and see the description for Max Fill Reached.
3. 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 hyperglycemia or hypoglycemia.

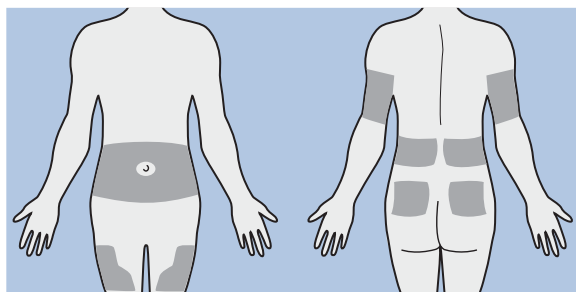
You must have completed the following procedures, as described previously, before inserting the infusion set into your body:

- 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.



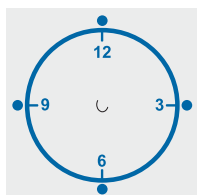
Caution: Do not use the same infusion set insertion site for an extended period of time. This can cause the site to become overused. Rotate the infusion set insertion sites regularly.



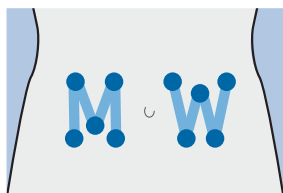
Caution: Always change your infusion set every two to three days. Using the same infusion set for an extended period of time can cause infusion set occlusion or site infection.

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. The instructions for the Quick-set infusion set are provided here as an example.

After your infusion set is inserted, see *Filling the cannula*, on page 111 to fill the infusion set cannula.

Quick-set infusion set (with Quick-serter®)

Always refer to the Quick-set user guide for instructions on how to insert the Quick-set infusion set.

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.



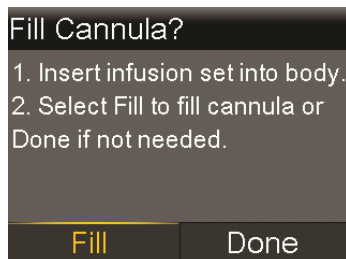
Note: If you are using an infusion set with a needle, you do not need to fill the cannula. Select **Done** when the system prompts you to continue with the fill process.



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.

2. 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.



3. 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.
4. 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**.

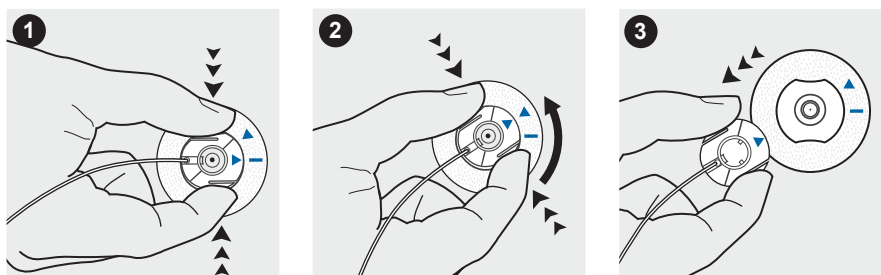
Disconnecting and reconnecting your infusion set

As an example, these steps show you how to disconnect and reconnect the Quick-set infusion set. If you are using an infusion set other than Quick-set, always refer to the instructions that shipped with the infusion set.

Disconnecting the Quick-set infusion set

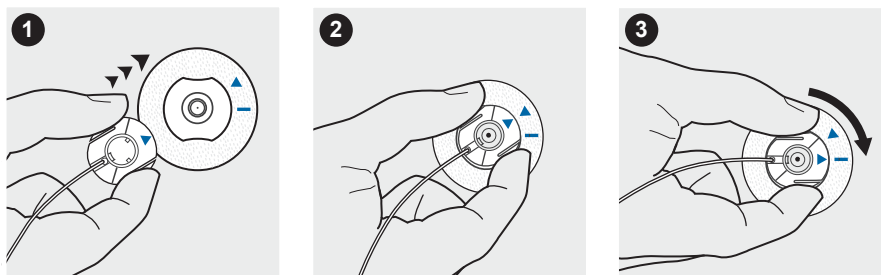
The Quick-set infusion set allows you the freedom to temporarily disconnect from your pump without removing the infusion set from your body.

1. Hold the side grips of the connector part with your fingers.
2. Twist the connector counter-clockwise.
3. Remove the connector from the site.



Reconnecting the Quick-set infusion set

Place the connector part (flat side facing down) on the infusion site until it is fully seated. Do not squeeze the connector part by the flat side grips.



6



meter

6

Meter

You can wirelessly connect up to six compatible Bayer meters to your pump. If you do not connect a meter to your pump, you must enter your blood glucose readings manually. To wirelessly connect your pump and meter, you will need the following items:

- MiniMed 630G insulin pump
- Bayer CONTOUR® NEXT LINK meter
- Bayer CONTOUR® NEXT LINK meter user guide

About your compatible Bayer meter

You can set up your pump to automatically receive blood glucose readings from your compatible Bayer meter. When the pump is on the Home screen, it beeps or vibrates when it receives a blood glucose reading from the meter. Your BG Meter screen appears, where you can view your current blood glucose reading and, if necessary, deliver a bolus. Once received, 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.

You can also deliver a Normal Bolus or Preset Bolus from your compatible Bayer meter. For more information about setting up your pump to use the Remote Bolus feature, see *Setting up Remote Bolus*, on page 118. Consult your healthcare professional before using the Remote Bolus feature.

Wirelessly connecting your pump and meter

Always refer to your compatible Bayer 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 compatible Bayer 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.

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 compatible Bayer meter.



Note: Remote Bolus default setting is on.

To turn on or off Remote Bolus:

1. Make sure that your pump and compatible Bayer meter are connected.
2. Go to the Remote Bolus screen.

Menu > 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 compatible Bayer meter from the pump.

To delete the meter from the pump:

1. Go to the Manage Devices screen.

Menu > Utilities > Device Options > Manage Devices

The Manage Devices screen appears.

2. Identify and select your meter by the serial number. See your compatible Bayer meter user guide for instructions on locating your serial number.
3. 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

7 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, 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.

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. Go to the Summary screen.
Menu > 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 five categories:

- overview
- bolus
- BG meter
- sensor
- SmartGuard suspend by sensor

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. • Percentage of insulin devoted to basal delivery.
Bolus	• Insulin units devoted to bolus delivery. • Percentage of insulin devoted to bolus delivery.
Total Carbs	Daily carbohydrate amount, in grams or exchanges.

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.

Name	Description
Carb bolus only	- Total insulin units delivered using the Bolus Wizard with food amount only. - Number of times the Bolus Wizard delivered a food bolus only.
BG Correction only	- Total insulin units delivered using the Bolus Wizard with BG correction amount only. - Number of times the Bolus Wizard delivered a BG correction bolus only.
Carb bolus + BG Correction	- Total insulin units delivered using the Bolus Wizard with food and BG correction amount. - Number of times the Bolus Wizard delivered a carb and BG correction bolus.
Manual Bolus	- Total bolus insulin units delivered using Manual Bolus, Preset Bolus, or Easy Bolus. - Number of bolus deliveries using Manual Bolus, Preset Bolus, or Easy Bolus.

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 compatible Bayer meter and BG meter readings entered manually.
Average BG	Average BG meter readings.
Meter Low	Lowest BG meter readings received from a compatible Bayer meter.

Name	Description
Meter High	Highest BG meter readings received from a compatible Bayer meter.
Manual Low	Lowest BG meter readings entered manually.
Manual High	Highest BG meter readings entered manually.

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.
Above High Limit	Percentage of SG readings that were above your high glucose alert limit. If you have not set a high glucose alert limit, your pump uses the default values. For more details on setting your high glucose alert limit, see <i>High settings, on page 161</i> .
Within Limits	Percentage of SG readings that were between your high and low glucose alert limits. If you have not set your high and low glucose alert limits, your pump uses the default values. For more details on setting your high and low glucose alert limits, see <i>High settings, on page 161</i> and <i>Low settings, on page 162</i> .
Below Low Limit	Percentage of SG readings that were below your low glucose alert limit. If you have not set a low glucose alert limit, your pump uses the default values. For more details on setting your low glucose alert limit, see <i>Low settings, on page 162</i> .
Alert before high	Number of Alert before high alerts that occurred.
Alert on high	Number of Alert on high alerts that occurred.
Rise Alert	Number of Rise alerts that occurred.
Alert before low	Number of Alert before low alerts that occurred.
Alert on low	Number of Alert on low alerts that occurred.

Summary screen: SmartGuard suspend by sensor

The following table describes the SmartGuard suspend by sensor portion of the Summary screen. For details on the suspend by sensor feature, see *SmartGuard Suspend on low*, on page 164.

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 events per day.
# SG readings	Number of SG readings 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. Go to the Daily History screen.
- Menu > 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. Go to the Alarm History screen.
Menu > 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. Go to the SG Review screen.
Menu > 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.

SG Review	10:00 PM
High Limit	180 mg/dL
Low Limit	70 mg/dL
Days to Average	1
Next	

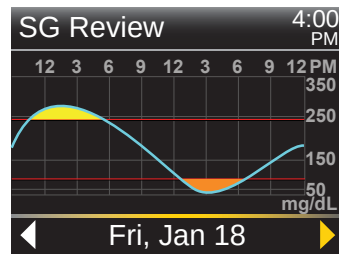
2. Enter the High Limit and Low Limit that you want to use for the sensor glucose review.

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

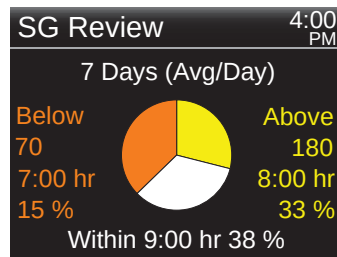
3. Enter the number of days of sensor glucose history to average, and select **Next**.

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 represents a signal measured by the sensor that is used to calculate your sensor glucose value. The ISIG History feature shows the history of your ISIG values over the previous 24-hour period. This information is primarily used by support personnel for troubleshooting, and is available only after you have turned on the Sensor feature.

To view your ISIG History:

1. Go to the ISIG History screen.
Menu > History > ISIG History
2. Select a time for which you want to view the ISIG history. The ISIG history appears for the hour you selected.

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. Go to the Event Markers screen.
Menu > Event Markers

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

BG  If you are not using the Bolus Wizard or a compatible Bayer 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  Enter the amount of carbohydrates that you have eaten or drunk that have not been entered in the Bolus Wizard. 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.

Exercise  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.

8



reminders

8 Reminders

Reminders help you remember to do important routine activities. There are specific reminders that prompt you to check your 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:

- Go to the Personal screen.
Menu > Reminders > Personal
- Select **Add New**.
The Select Name screen appears showing the available reminders.
- Select the reminder that you want to set.
The Edit screen appears for the selected reminder.
- Enter the time that you want the reminder to occur.
- Select **Save**. The Personal reminder occurs at the specified time each day unless you change or delete it.

To change, rename or delete an existing Personal reminder:

- Go to the Personal screen.

Menu > 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.



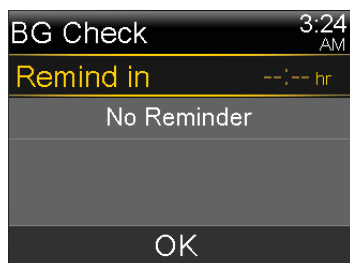
Note: The Bolus BG Check reminder is not available when you deliver a bolus using the Remote Bolus feature from your compatible Bayer meter.

To turn on or turn off Bolus BG Check reminders:

1. Go to the BG Check screen.
Menu > Reminders > Bolus BG Check
2. To turn the reminder on or off, select **Reminder**.
3. 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:



- 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:

- Go to the Missed Meal Bolus screen.
Menu > Reminders > Missed Meal Bolus
- Select **Add New**.
- Select **Start Time**, and enter a time.
- Select **End Time**, and enter a time. The time range is from one minute to 24 hours.
- Select **Save**.

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

- Go to the Missed Meal Bolus screen.
Menu > Reminders > Missed Meal Bolus
- Select one of the reminders that you have already created.
- 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 select one of the following types of Low Reservoir reminders:

- **Units** – alerts you when your reservoir has a specified number of units remaining, and then alerts you again when half of remaining units are used.
- **Time** – alerts you when there is a specified amount of time remaining before your reservoir is empty and then again one hour before insulin runs out, depending on your programmed basal insulin delivery.



Note: The amount of time or units remaining in your reservoir can be found on the Quick Status screen. For more information on accessing the Status Screens, see *Viewing the Status screens, on page 38*.

If you use Time for your Low Reservoir reminder, be aware that the reminder time is based only on your basal insulin delivery rate. If you give a bolus, the time remaining will decrease more quickly.

For example, if your reservoir has 10 hours remaining when you go to bed at night, and you sleep for eight hours without giving any bolus insulin, you will still have two hours of basal insulin remaining when you wake up. In contrast, suppose your reservoir has 10 hours remaining when you leave the house for work in the morning. If you give boluses to cover your mid-morning snack and your lunch, the number of hours remaining decreases accordingly, and your insulin will run out before you end your eight-hour work day.



WARNING: When a Low reservoir alert displays after a bolus or fill cannula delivery, always check the amount of insulin left in the reservoir. Not checking the amount of insulin left in the reservoir can lead to an under delivery of insulin, which can cause hyperglycemia.

Low Reservoir reminder setup:

- Go to the Low Reservoir screen.
Menu > Reminders > Low Reservoir
- Select **Type** to set the reminder using either **Units** or **Time**.
- Depending on the type you selected, do one of the following:
 - Select **Units** to enter the number of units. You can set a value from 5 units to 50 units.
 - Select **Time** to enter the number of hours you want to use for your reminder. You can enter from 2 to 24 hours.
- 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:

- Go to the Set Change screen.
Menu > Reminders > Set Change
- 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:

- Go to the Calibration screen.
Menu > Reminders > Calibration

Calibration	
Reminder	On
Time	1:00 hr
Save	

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.
4. Select **Save**.

9



general settings

9

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 sensor-enabled features, such as Suspend on low, when Airplane Mode is on. The sensor-enabled features do not work while Airplane Mode is on because the pump does not receive sensor readings from the transmitter. When using Airplane Mode, always rely on your blood glucose 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 device:	Do this:
Compatible Bayer meter	When Airplane Mode is turned on, the Remote Bolus feature is not available, and you must enter BG meter readings manually. When Airplane Mode is turned off, use your compatible Bayer 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. Your transmitter continues to collect your sensor readings, and can store up to 10 hours of sensor data. 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 the last 10 hours of your sensor information to the pump. When you turn off Airplane Mode: • If Airplane Mode was turned on for six hours or less, wait 15 minutes for the sensor and transmitter to wirelessly send your pump the missing sensor glucose readings. • If Airplane Mode was turned on for more than six hours, disconnect and reconnect the transmitter and sensor, and then select Reconnect Sensor when it appears on the pump screen.

To turn on or turn off Airplane Mode:

1. Go to the Airplane Mode screen.
Menu > Utilities > Airplane Mode
2. Select **Airplane Mode** to turn the feature on or off.
3. Select **Save**.

When Airplane Mode is turned on, the status bar shows the Airplane Mode icon  in place of the Connection icon.

Audio Options

The Audio Options screen lets you change the volume of most alerts and notifications, and set the audio and vibrate settings. You can choose one of the three audio options:

-  audio
-  vibrate
-  audio and vibrate

The audio option that you are currently using displays on the status bar. For more information, see *Status bar, on page 35*.

To adjust the audio and vibrate settings:

1. Go to the Audio Options screen.
Menu > Audio Options
2. Select the Audio or Vibrate option you want to use.
3. If Audio or Audio & Vibrate option is selected, the volume can be changed.
Select **Volume** and use left or right button 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.

To set up Auto Suspend:

1. Go to the Auto Suspend screen.
Menu > Insulin Settings > Auto Suspend
2. 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.



Caution: Always monitor pump use during Block Mode. The pump can still 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 a compatible Bayer meter, review history, test the pump, and clear alarms and alerts. However, you cannot change any settings.



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

To turn Block Mode on or off:

1. Go to the Block Mode screen.
Menu > 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  displays on the status bar.

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**.

Carb Unit

The Carb Unit setting determines whether to enter and display carbohydrates in grams (g) or exchanges (exch). You enter carbohydrate information when using the Bolus Wizard and recording food in Event Markers.

To change the Carb Unit setting:

1. Go to the Carb Unit screen.
Menu > Utilities > Carb Unit
2. Select either **Grams** or **Exchanges**.
3. 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. Go to the Display Options screen.
Menu > 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 15 seconds.

4. Select **Save**.

Language

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

To change the Language setting:

1. Go to the Language screen.
Menu > 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. Use this feature when you are ready to use your pump with insulin for the first time. 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. Go to the Manage Settings screen.
Menu > Utilities > Manage Settings
2. Simultaneously press and hold > and ↩ until the Manage Settings menu appears.
3. 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. Go to the Manage Settings screen.
Menu > 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 compatible Bayer meter.



Caution: Do not clear your settings on the pump unless directed by your healthcare professional. Clearing your settings could result in the delivery of too much or too little insulin. If you clear your settings, you must re-enter all your personal settings as directed by your healthcare professional.

To clear all your settings:

1. Make sure the pump is not connected to your body.
2. Go to the Manage Settings screen.
Menu > 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 30*.

Clearing your active insulin

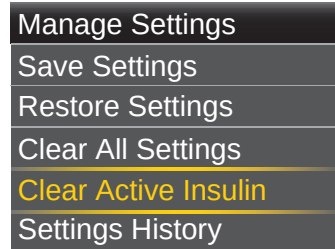
Use this feature when you are ready to use your pump with insulin for the first time. This feature clears any active insulin values that your pump has tracked, and sets the active insulin value to zero. If you have practiced delivering a bolus with your pump prior to using your pump with insulin, you 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. Go to the Manage Settings screen.
Menu > 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.

3. 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. Go to the Manage Settings screen.
Menu > Utilities > Manage Settings
2. Simultaneously press and hold > and ⬅ 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.



WARNING: Always monitor your blood glucose while using the Self Test feature. Your insulin is suspended for up to two minutes while your pump runs the self test. Limited insulin delivery can cause hyperglycemia.

Self Test includes the following tests:

Test	Description
Display	Turns on the display for up to 30 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. Go to the Self Test screen.

Menu > 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 193.



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 graphs:

1. Go to the Sensor Demo screen.

Menu > Utilities > Sensor Demo

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

2. Press **Select** to access the sensor graph examples.
3. From the sensor screen examples you can:
 - Press the < or > buttons to move the cursor across the graph. Examples of sensor data appear for the different time periods.
 - Press the ^ or v buttons to view graphs that cover different time periods. You can view 3-hour, 6-hour, 12-hour, and 24-hour graphs.

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 ↩.

To see and hear examples of sensor-related alerts:

1. Go to the Sensor Demo screen.
Menu > Utilities > Sensor Demo
2. Select **Alert Demo**.
3. To see and hear sensor-related alerts, select any of the listed alerts.
4. To exit an alert example, press ▼, then select **OK** to clear the alert. 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. Go to the Time & Date screen.
Menu > 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**.

10

■ setting up continuous glucose monitoring

10

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 630G insulin pump
- Sensor glucose settings (provided by your healthcare professional)
- Enlite sensor
- Guardian Link transmitter kit



WARNING: Do not make therapy treatment decisions based on sensor glucose values because sensor glucose and blood glucose 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 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

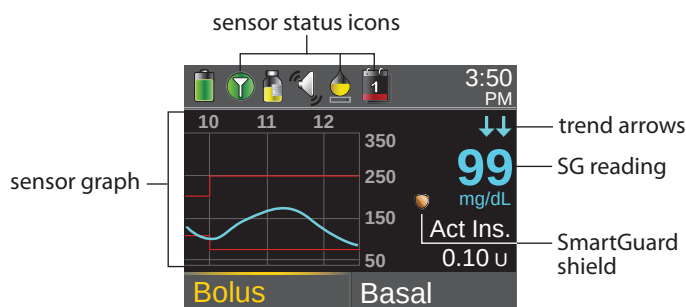


Note: If you lose sensor functionality, you will no longer have access to CGM features. For details on restoring sensor functionality, see *Troubleshooting sensor issues*, on page 234.

Sensor glucose (SG) readings and blood glucose (BG) meter readings are not the same. To learn more about the accuracy of SG readings versus BG reading, see the *CGM Performance* appendix.

Home screen with CGM

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 170.



The following items appear on your Home screen with CGM:

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. For more information about using Airplane Mode, see <i>Airplane Mode</i> , on page 143.

Item	Description
Calibration icon	The approximate time left until your next sensor calibration is due. The calibration icon appears only when the Sensor feature is turned on. The color and the fill level of the icon indicate the status. When your sensor is fully calibrated, the icon is solid green. As the time for your next sensor calibration approaches, the icon becomes emptier, and the color of the icon changes as shown in the following example. For more information about calibrating your sensor, see <i>Calibrating your sensor</i>, on page 186.  When your sensor is initializing, the Calibration icon appears with three dots . If the time to your next sensor calibration is unavailable, the Calibration icon appears with a question mark .
Connection icon	The connection icon appears green  when the Sensor feature is on and your transmitter is successfully communicating with your pump. The connection icon appears gray  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 <i>Understanding Continuous Glucose Monitoring (CGM)</i>, on page 157.
Sensor graph	Displays your SG readings over a period of 3 hours. The red lines represent your high and low SG limits. The blue line represents your SG trends during the specified period. For more information, see <i>The sensor graph</i>, on page 193.

Item	Description
Sensor Life icon	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. As your sensor life is used, the icon becomes emptier. The icon turns yellow when less than 24 hours remains in the life of your sensor. It turns red when less than 12 hours remains in the life of your sensor.  If the number of days remaining in the life of your sensor is unavailable, the Sensor Life icon appears with a question mark .
SG reading	Shows your current SG reading which is sent wirelessly to your pump by the transmitter.
SmartGuard shield (suspend by sensor)	The SmartGuard shield (suspend by sensor) appears only when the SmartGuard Suspend on low feature is set to on. For details on the Suspend on low feature, see <i>SmartGuard Suspend on low</i>, on page 164. The shield indicates the current status of the suspend by sensor feature, as follows: • The shield is solid gold  when Suspend on low is turned on and ready. • The gold shield flashes if your insulin delivery is currently suspended due to a Suspend on low event. • The shield appears gray with a line through it  when the suspend feature is unavailable. The suspend feature 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. For more information about trend arrows, see <i>Identifying rapid changes in sensor glucose</i> , on page 194.



Note: Several items appear on both your Home screen without CGM and your Home screen with CGM. For more information, see *Home screen*, on page 33, and *Status bar*, on page 35.

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 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 161. For details on low alerts and suspend options, see *Low settings*, on page 162.

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.

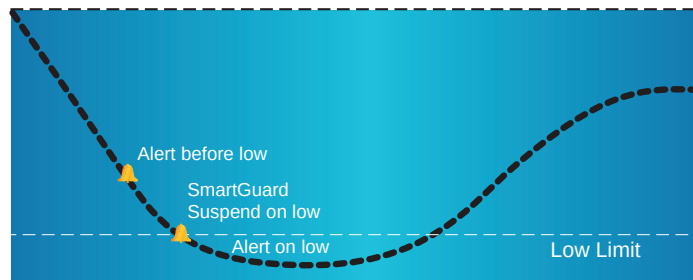
High glucose setting	Description
High limit	Your high limit is the value on which your other high settings are based. Your high limit can be set from 100 mg/dL to 400 mg/dL. You can set up to eight high limits for different time segments throughout the day or night.
Alert before high	When Alert before 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.
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.
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 170*.

Low settings

The low settings allow you to be alerted when you are either approaching or have reached your low limit. They also allow you to have your insulin delivery suspended when you have reached your low limit. This is done by using alerts and the SmartGuard Suspend on low feature. The Suspend on low feature is described on *page 164*.

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



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 is 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.

The following sections describe the Suspend on low feature and the low settings. For details on setting up Suspend on low and your low settings, see *Setting up the Low Settings*, on page 174.

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 up to eight low limits for different periods of the day or night.

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.

You receive the Alert before low 30 minutes before you reach your low limit.

You can also choose to have the Alert before low off.

SmartGuard Suspend on low

The SmartGuard 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 two hours when the sensor glucose reaches a set limit. 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 166.



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 SmartGuard Suspend on low event

When you clear the SmartGuard Suspend on low alarm, the shield  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 remains suspended for 2 hours, unless you manually resume your basal delivery. For details, see *Manually resuming basal delivery during a SmartGuard Suspend on low event*, on page 177.

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 SmartGuard Suspend on low is unavailable

After a SmartGuard Suspend on low event occurs, there is a period of time when the Suspend on low functionality is unavailable. This time will vary depending on whether or not you respond to the Suspend on low event.

When the Suspend on low feature is unavailable, you can still manually suspend insulin delivery at any time. For details, see *Stopping and resuming your insulin delivery*, on page 61.



Note: The maximum amount of time the Suspend on low feature will be unavailable is four hours.

When the Suspend on low feature is unavailable, the SmartGuard shield on the Home screen appears gray .

When a Suspend on low event occurs and you respond within two hours, the Suspend on low feature will be unavailable for a set duration once basal insulin delivery is resumed either automatically or manually. The duration the Suspend on low feature is unavailable is determined by your Low Snooze setting.

If your pump has been suspended for two hours and you have not responded, the Suspend on low feature is unavailable for 4 hours once basal insulin delivery automatically resumes.

If you then respond during the 4 hour period where the Suspend on low feature is unavailable, the 4 hour period will be reduced to equal the duration of your Low Snooze. For example:

- If your Low Snooze is set to 30 minutes and you respond 10 minutes after your basal insulin delivery automatically resumes, the Suspend on low feature will be unavailable for the remaining 20 minutes of your Low Snooze.

- If your Low Snooze is set to 30 minutes and you respond 50 minutes after your basal insulin delivery automatically resumes, the Suspend on low feature will be available immediately.

For more information about the Low Snooze function, see *Low Snooze*, on page 176.

Alert on low

The Alert on low feature is automatically turned on when the SmartGuard 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 on low event

In addition to suspending insulin delivery, the pump can also automatically resume delivery of basal insulin. If insulin has been suspended by the SmartGuard Suspend on low feature, insulin delivery will automatically resume after a maximum of two hours.

SmartGuard Suspend on low examples

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: No response to Suspend on low
- Example 2: Respond to Suspend on low within 2 hours and continue suspend
- Example 3: No response during a 2 hour suspend and then respond during 4 hour basal resume
- Example 4: Respond to Suspend on low within 2 hours and resume basal
- Example 5: Continuing Suspend on low without testing



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: No response to Suspend on low

Anna is retired and lives alone. At 2 AM her pump suspends insulin delivery due to a Suspend on low alarm. Anna does not respond to the alarm and after 2 minutes her pump begins to siren. She wakes up at 8 AM and clears the alarm on her pump. She sees that in addition to suspending her insulin delivery, her pump had also restarted her basal insulin.

Anna realizes that her pump had automatically suspended insulin delivery for 2 hours, and then automatically restarted her basal insulin when she had not responded after two hours of suspension. She then checks her blood glucose with her BG meter and acts as directed by her healthcare professional.

Anna knows that once her basal delivery had restarted, if after 4 hours her sensor glucose value was at or below her low limit, her pump would have suspended insulin delivery again for two hours if she had not responded.



Note: If you do not respond, this Suspend on low sequence will continue as long as your sensor calibrations are current and the pump battery has power. Calibration must be done a minimum of every 12 hours. For calibration guidelines, see *Calibrating your sensor*, on page 186.

For more information about how to respond to a Suspend on low alarm, see *Responding to a SmartGuard Suspend on low event*, on page 164.

Example 2: Respond to Suspend on low within 2 hours and continue suspend

Dave is 75 years old and lives with his daughter. He has been experiencing some low glucose values. Dave's doctor has recommended he use the Suspend on low feature. It is now 1 AM and Dave's sensor value has fallen to his low limit of 60 mg/dL. His daughter is awakened by the Suspend on low siren. She clears the alarm on the pump and leaves his insulin delivery suspended. His daughter checks Dave's finger stick, confirming his low blood glucose, and provides Dave with carbohydrates to treat the low blood glucose.

Dave's daughter continues to monitor his blood glucose while the pump is in the 2-hour Suspend on low period. Once she sees that Dave's blood glucose is stable and back within blood glucose target range, she manually resumes his basal.

Dave's daughter knows that if his sensor value reaches or falls below the low limit again after his Low Snooze time has passed, the pump will once again suspend his insulin delivery for two hours and the pump will siren.

For more information about how to respond to a Suspend on low alarm, see *Responding to a SmartGuard Suspend on low event, on page 164*.

Example 3: No response during a 2 hour suspend and then responds during 4 hour basal resume

Michael is on his college hockey team. He played in a hockey tournament all day and is so exhausted that he falls asleep in front of his television. His sensor glucose value begins to drop. When his sensor glucose value falls to his low limit, the pump automatically suspends all insulin delivery due to his Suspend on low settings. Michael does not respond to the alarm. After two minutes, his pump begins to siren and displays the emergency message.

About three hours later, his roommate comes home, hears the pump siren and wakes up Michael. Michael clears the alarm on the pump and sees that his basal insulin has automatically been restarted after a two hour suspend. He checks his blood glucose and acts as directed by his healthcare professional.

Michael knows that if his sensor value reaches or falls below his low limit again after his Low Snooze time has passed, the pump will suspend insulin delivery and siren again.

For more information about how to respond to a Suspend on low alarm, see *Responding to a SmartGuard Suspend on low event, on page 164*.

Example 4: Respond to Suspend on low within 2 hours and resume basal

Maria's Alert before low is set to on, her Suspend on low is active with a low limit of 60 mg/dL, and her Low Snooze is set to 20 minutes. While at work, Maria receives an Alert before low letting her know that her sensor glucose is approaching her low limit. She confirms her blood glucose with a meter and acts as directed by her healthcare professional.

A few minutes later, she receives a Suspend on low alarm on her pump when her sensor glucose reaches 60 mg/dL. Maria knows that she already treated her confirmed BG and that it will take a few more minutes to rise. She clears the Suspend on low alarm, then manually resumes her basal insulin delivery. If Maria's sensor glucose remains or falls below 60 mg/dL again after 20 minutes (her Low Snooze time), then her pump will again suspend insulin delivery for two hours.

For more information about how to respond to a Suspend on low alarm, see *Responding to a SmartGuard Suspend on low event, on page 164*.

Example 5: Continuing Suspend on low without testing

Mark lives alone. While asleep, his pump suspends insulin delivery with a Suspend on low alarm. The alarm wakes him and he clears it and leaves his insulin delivery suspended. He then goes back to sleep without checking his blood glucose even though he has been taught by his healthcare professional to always test his blood sugar when the Suspend on low alarm sounds.

After Mark's pump has been suspended for two hours, basal insulin delivery automatically resumes. Twenty minutes after the pump resumes basal insulin delivery (which is Mark's Low Snooze time), Mark's sensor glucose is still below his low limit. His pump alarms and insulin delivery is suspended again. This time Mark does not respond to the alarm and the pump remains suspended for an additional two hours. By not checking his blood glucose when he was aware of the alarm, Mark has missed the opportunity to appropriately address his blood glucose. If the sensor glucose was correctly reflecting Mark's blood glucose, suspending insulin delivery may not have been sufficient to address hypoglycemia (carbohydrates may have been needed) and Mark's blood glucose may have gone lower. If the sensor glucose did not correctly reflect Mark's blood glucose and his BG was actually above the low limit, Mark is now at risk for hyperglycemia and ketosis as he only received insulin for 20 minutes during a period of 4 hours and 20 minutes.



Note: Responding to the Suspend on low alarm enables the Low Snooze function. If insulin is suspended for 2 hours, the pump will suspend again for another 2 hours only after the Low Snooze time if the sensor glucose is at or below your low limit. For more information about the Low Snooze function, see *Low Snooze, on page 176*.

You should always respond to alarms when possible and check your blood glucose to avoid the risk of severe hypoglycemia or hyperglycemia with ketosis.

For more information about how to respond to a Suspend on low alarm, see *Responding to a SmartGuard Suspend on low event, on page 164*.

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. Go to the Sensor Settings screen.

Menu > 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 161*.



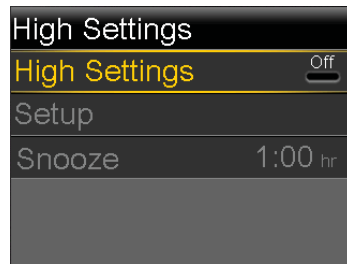
Note: When you enter your settings, you first define the time segment, and then select the high settings you want on during that time segment.

To set up the High Settings:

1. Go to the High Settings screen.

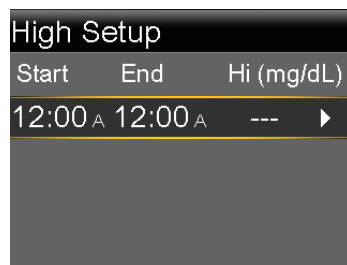
Menu > Sensor Settings > High Settings

The High Settings screen appears.



2. Select **High Settings** to turn on the feature.

The High Setup screen appears.

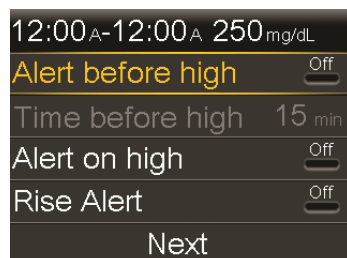


3. Select the time segment. The End time starts flashing.

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.

4. Set the End time.
5. Set your Hi limit. You can enter a value from 100 to 400 mg/dL, in increments of 5 mg/dL.
6. Select the arrow to the right of the End time to select the high settings for this time segment.

A screen appears showing the high alerts for the selected time segment.

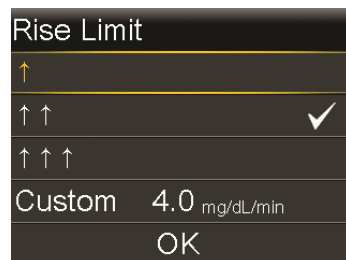


7. Set the following alerts as desired:
 - a. Select **Alert before high** if you want to receive an alert before you reach your high limit.
 - b. If you turned on Alert before high, enter the **Time before high** to set how soon you want to be alerted before reaching your high limit. You can enter a 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.

8. 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.



9. 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 **↑↑** for an alert when your SG has been rising at a rate of 2 mg/dL per minute or more.
 - Select **↑↑↑** 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.

10. 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.
11. When you have set all the high settings for the selected time segment, select **Next** to continue.
12. 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**.
13. Review your settings, and select **Save**.

To change your High Settings:

1. Go to the High Settings screen.
Menu > Sensor Settings > High Settings
 The High Settings screen appears.
2. Select **Setup**.
3. Select **Edit**.
4. Select and, if needed, adjust the time segment you would like to change.
5. Select any alert setting to turn it on or off or to adjust the setting.
6. Select **Next**.
7. Select **Done**.
8. 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. Go to the High Settings screen.

Menu > Sensor Settings > High Settings

The High Settings screen appears.

2. Select **Snooze** and enter a value from 5 minutes to 3 hours, in 5 minute increments.

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 162*.



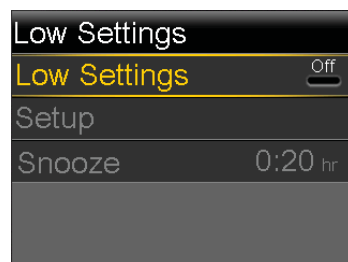
Note: When you enter your settings, you first define the time segment, and then select the low settings you want on during that time segment.

To set up the Low Settings:

1. Go to the Low Settings screen.

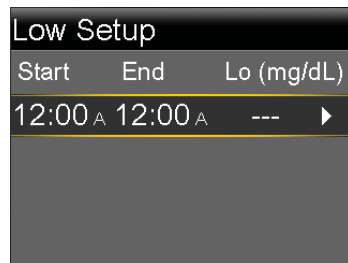
Menu > Sensor Settings > Low Settings

The Low Settings screen appears.



2. Select **Low Settings** to turn on the feature.

The Low Setup screen appears.

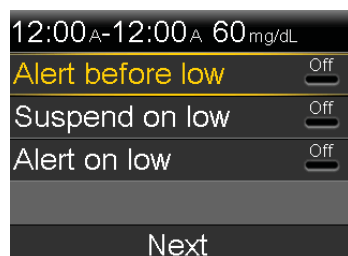


3. Select the time segment. The End time starts flashing.

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.

4. Set the End time.
5. Set your low limit. You can enter a value from 60 to 90 mg/dL, in increments of 5 mg/dL.
6. 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.



7. Set the following as desired:
 - a. Select **Alert before low** to receive an alert before you reach your low limit.
 - b. 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.

- c. 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.



Note: When setting your low alerts, if you turn on the Suspend on low feature, then the Alert on low feature is turned on automatically.

- 8. If you entered an End time of anything other than 12:00 A, another time segment appears.

When you are done entering your low settings, select **Done**.

- 9. Review your settings, and select **Save**.

To make changes to your Low Settings:

- 1. Go to the Low Settings screen.

Menu > Sensor Settings > Low Settings

The Low Settings screen appears.

- 2. Select **Setup**.
- 3. Select **Edit**.
- 4. Select, and if needed, adjust the time segment you would like to change.
- 5. Select any alert setting to turn it on or off or to adjust the setting.
- 6. Select **Next**.
- 7. Select **Done**.
- 8. 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. Go to the Low Settings screen.
Menu > Sensor Settings > Low Settings
 The Low Settings screen appears.
2. Select **Snooze** and enter a time between 5 minutes and 1 hour.

Manually resuming basal delivery during a SmartGuard Suspend on low event

When your pump suspends insulin due to a SmartGuard Suspend on low event, the bottom of your Home screen displays Suspended on low.

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:

1. From the Home screen, select **Suspended on low**.
 The Suspended screen appears.
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.

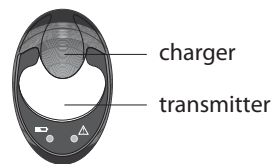
Note the following before trying to connect your pump and transmitter:

- 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 184.

- 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 181*.

Connecting your pump and transmitter using Auto Connect:

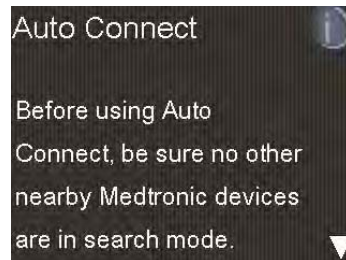
1. Attach your transmitter to the charger and make sure the transmitter is fully charged. Keep your transmitter attached to the charger.



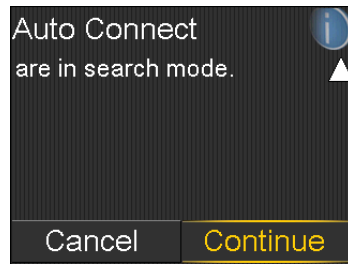
Note: Both lights on the charger are off when the transmitter is fully charged. For more information, see your transmitter user guide.

2. Go to the Auto Connect screen.

Menu > Utilities > Device Options > Connect Device > Auto Connect

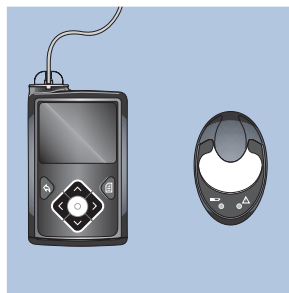


3. Make sure there are no other devices in search mode nearby, scroll down to the bottom of the Auto Connect screen, and select **Continue**.



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:

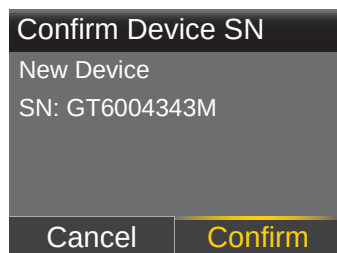
- On your pump, a message appears to let you know your pump is searching.
- On your transmitter, a green light flashes briefly and then turns off.



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  appears on the status bar.

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 180*.

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 181*.

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 181.

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.



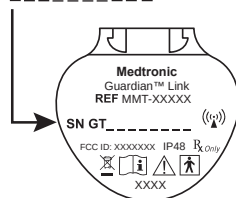
Note: You can connect only one transmitter to your pump. If you already have a transmitter connected to your pump, you must delete it before continuing. For instructions on deleting a transmitter from your pump, see *Deleting the transmitter from your pump*, on page 184.

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.

Find your serial number here: **Write it here:**

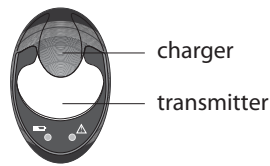
SN GTXXXXXXXX



Write your serial number here, include any letters:

SN GT _____

2. Attach your transmitter to the charger, and make sure the transmitter is fully charged. Keep your transmitter attached to the charger.

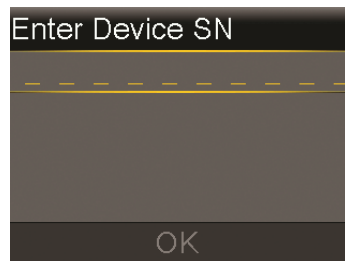


Note: Both lights on the charger are off when the transmitter is fully charged. For more information, see your transmitter user guide.

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, go to the Enter Device SN screen.

Menu > 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 briefly 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  appears on the status bar.

If your pump does not connect to your transmitter:

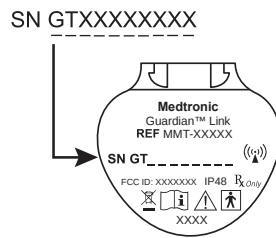
1. If your pump does not connect to the transmitter, do one of the following:
 - Select **Retry** to return to the Enter Device SN screen on your pump, and then return to step 4 of the procedure above and follow the instructions to search again.
 - Select **Cancel** to return to the Connect Device screen, 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 234.

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. Go to the Manage Devices screen.
Menu > 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 theserter user guide for instructions on how to insert the sensor.

Connecting the transmitter to the sensor

Always refer to your transmitter user guide for instructions on connecting 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:

1. Select **Start New Sensor** when it appears on the pump screen.
The "Sensor warm-up started" message appears.

2. 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. Go to the Sensor Connections screen.

Menu > Sensor Settings > Sensor Connections

2. 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.

4. Select **OK**.

5. The Sensor warm-up started message appears on the screen. Select **OK**.

"Warm up..." appears on the Home screen until the sensor is ready for first calibration. Your pump begins displaying SG data 10 to 15 minutes after you successfully calibrate your sensor. For details about calibration, see *Calibrating your sensor, on page 186*.

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. Calibrate your sensor regularly to ensure that you continue to receive sensor glucose data. For details, see *Guidelines for calibrating*, on page 188.

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 about 15 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.



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.

- Go to the Calibrate Sensor screen.

Menu > Sensor Settings > Calibrate Sensor
- Select **BG** and enter the value.
- Select **Calibrate**.

You can set up a reminder to notify you when your next calibration is due.
 For more information, see *Calibration reminders, on page 139*.

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, and your transmitter is wirelessly connected with your pump.

Pump screen	How to enter your calibration BG
Home screen When the calibration option is available, you can access the Calibrate Sensor screen. First highlight the sensor graph on the Home screen. Then press and hold the  button to access the calibration screen.	Enter a BG meter reading specifically for calibration.
Calibrate Sensor screen Menu > Sensor Settings > Calibrate Sensor	Enter a BG meter reading specifically for calibration.
BG Meter screen The BG Meter screen appears automatically when your compatible Bayer meter sends a BG meter readings to your pump.	Select the Calibrate Sensor option to calibrate your sensor with the current BG meter readings.
BG screen in Event Markers Menu > Event Markers > BG	When you enter a BG meter reading in Event Markers, the Event Markers screen has an option to use the BG value for calibration.

Pump screen	How to enter your calibration BG
BG field in the Bolus Wizard screen Home screen > Bolus > Bolus Wizard	When you enter a BG meter reading to deliver a bolus using the Bolus Wizard, the Bolus Wizard gives you the option 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
Two hours after starting a new sensor.	Do your first sensor calibration. Two hours after you start your new sensor, your pump sends a Calibrate now alert. Your first sensor glucose reading appears about 10 to 15 minutes after you calibrate.
Six hours after your first calibration.	Do your second sensor 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 about 10 to 15 minutes after you calibrate to receive SG values again.
Within 12 hours after your second calibration and at least every 12 hours thereafter.	After you do your second calibration, you need to calibrate at least every 12 hours. If you do not calibrate for more than 12 hours, a Calibrate now alert appears. It takes about 10 to 15 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 188*.
- You can calibrate anytime. However, calibrating with two or three down 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, on page 158*.

- 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. Go to the Sensor Settings screen.
Menu > Sensor Settings
2. Select **Sensor**.
3. Select **Yes** to turn off the sensor feature.

11

■ using continuous glucose monitoring

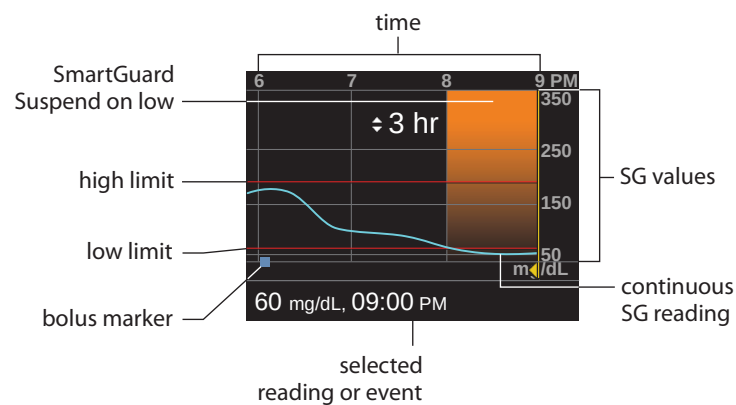
11

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 glucose alert limit
- 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:

1. Select the graph area of the Home screen.
A full-screen view of the 3-hour graph appears.
2. Select  to navigate to the 6-hour, 12-hour, and 24-hour graphs.
3. Select  to view SG readings and event details.
4. To exit the full-screen view, press .

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.

	SG has been rising at a rate of 1 mg/dL per minute or more, but less than 2 mg/dL per minute.
	SG has been falling at a rate of 1 mg/dL per minute or more, but less than 2 mg/dL per minute.

↑↑	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.
↑↑↑	SG has been rising at a rate of 3 mg/dL per minute or more.
↓↓↓	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, 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 128 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 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.

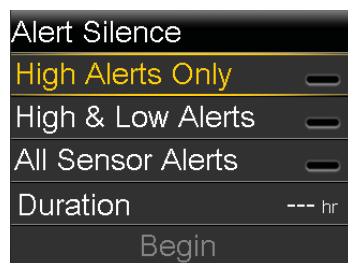
This Alert Silence setting	Silences these alerts
High Alerts Only	Alert on high, Alert before high, and Rise Alert
High & Low Alerts	Alert on high, Alert before high, Rise Alert, Alert on low, and Alert before low

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 • All alerts relating to sensor insertion, including alerts about sensor warm-up, changing your sensor, sensor expiration, sensor errors, connection issues, and so on • All alerts related to your transmitter, including all alerts about your transmitter battery and all connection issues

To silence Glucose alerts:

1. Go to the Alert Silence screen.

Menu > Sensor Settings > Alert Silence



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.



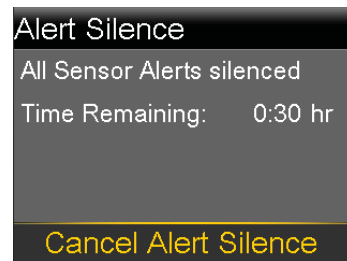
Note: If you select **All Sensor Alerts**, you will not receive any alerts related to your sensor glucose readings, your sensor, calibration requirements, or your transmitter. If a glucose alert occurs, the notification light flashes and a message appears on your pump to let you know a silenced alert occurred, but there is no vibration or beep. You can view the specific alert in Alarm History. For more information, see *Alarm History*, on page 128.

3. Set the **Duration** time (from 30 minutes to 24 hours) for which the alerts will be silenced, and then select **OK**.
4. Select **Begin**. The Alert Silence settings immediately take effect and you are returned to the Sensor Settings screen.

To cancel Alert Silence:

1. Go to the Alert Silence screen.

Menu > Sensor Settings > Alert Silence



2. Select **Cancel Alert Silence**.

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■ alarms, alerts, and messages

12

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.



Note: When you receive a notification while your pump is locked, you will be able to clear the alarm, alert, or message without having to unlock your pump. After you clear the notification, you will be redirected to the Home screen. You must unlock your pump before navigating away from the Home screen. For more information, see *Unlocking your pump*, on page 32.

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.

A white triangle in the lower-right corner means you must press  to continue.



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.

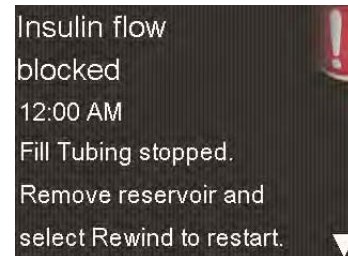
Remember, your body still needs insulin while your pump is removed. It is important that you consult your healthcare professional to determine an alternate method of receiving insulin while your pump is removed.

Alarms

An alarm warns you that the pump detected something that prevents insulin from being delivered. It is important that you respond to an alarm.



WARNING: Do not ignore your pump when it has an alarm. When your pump has an alarm, all insulin delivery stops. This can result in hyperglycemia and ketoacidosis.



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. The notification light is shown in *Using the buttons*, on page 26.

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 ▼ 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. For more information, see *Alarm and alert escalation*, on page 247.

Alerts

An alert makes you aware of a situation that may require your attention. An alert is less serious than an alarm.

When an alert occurs:

Display: The pump displays a notification with a yellow icon and instructions.



Notification light: The red notification light on your pump blinks once, followed by a pause, then blinks once again in a continuous repeating pattern. The notification light is shown in *Using the buttons*, on page 26.

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 ▼ 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. For more information, see *Alarm and alert escalation*, on page 247.



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  and make 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. If you get an alarm, alert, or message that is not listed, select OK to clear the alarm and call the 24 Hour HelpLine.

Title and text	Explanation	Next steps
Active Insulin cleared Any Active Insulin amount has been cleared.	An alarm has cleared your active insulin amount. Your active insulin amount is now at 0 units.	• Select OK to clear the alarm. • 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 • You can check Daily History for the time and amount of your last bolus. For more information, see <i>Daily History</i>, on page 127.

Title and text	Explanation	Next steps
Auto Suspend Insulin delivery suspended. No buttons pressed within time set in Auto Suspend.	You have not pressed any buttons during the time specified in the Auto Suspend settings.	- To clear the alarm and resume basal insulin delivery, select Resume Basal. - Check your BG and treat as necessary.
Battery failed Insert a new AA battery.	The pump battery does not have enough power.	- Select OK to clear the alarm. - Remove the old battery and insert a new AA battery. For details, see <i>About batteries</i>, on page 27.
Battery not compatible. See User Guide.	The battery that you inserted into the pump is not compatible.	- To clear the alarm, remove the incompatible battery. - Insert a new AA battery. For compatible battery types, see <i>About batteries</i>, on page 27.
Bolus not delivered. Bolus entry timed out before delivery. If bolus intended, enter values again.	Bolus values entered, but bolus was not delivered within 30 seconds.	- Select OK to clear the alert. - If bolus delivery was intended, check your BG, re-enter bolus values and deliver bolus.
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.	The battery power was exhausted while a bolus or Fill Cannula was in progress.	- Note the amount of insulin not delivered. - Replace the AA battery. - Select OK to clear the alarm. - Deliver the remaining bolus amount if needed.

Title and text	Explanation	Next steps
Cannot connect device This device is incompatible with your pump. See User Guide.	- You may be trying to connect a device that is not compatible with your pump. - You are trying to connect a transmitter to your pump but another transmitter is already wirelessly connected to your pump.	- Select OK to clear the alert. - Check the list of devices that are compatible with your pump in <i>Additional 630G system devices</i>, on page 21. - 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 <i>Deleting the transmitter from your pump</i>, on page 184.
Check settings Startup Wizard settings complete. Check and set up your other settings.	Some settings have been cleared or reverted to factory default values.	- Select OK to clear the alert. - Review any settings that you have not already set in Startup Wizard and re-enter the values, if necessary.
Critical pump error Delivery stopped. Pump not working properly. Stop using pump. Remove infusion set from body. Consider other insulin treatment. See User Guide.	Your pump has encountered a critical error.	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.

Title and text	Explanation	Next steps
Delivery limit exceeded Delivery stopped. Check BG. See User Guide for more information.	You have attempted to deliver more insulin than expected based on your Max Bolus and Max Basal settings.	• Check your BG. • Select Resume Basal. • Check Bolus History and reevaluate your need for insulin. • Continue to monitor your BG.
Fill Cannula? Select Fill to fill cannula or select Done if not needed.	You had the Fill Cannula screen displayed for 15 minutes.	• To proceed and fill the cannula, select Fill. • If you do not need to fill the cannula, select Done to skip this process.
Insert battery Delivery stopped. Insert a new battery now.	The battery was removed from the pump.	• Insert a new AA battery. • The alarm clears when you insert a new battery. • The pump powers off after 10 minutes unless you insert a new battery.

Title and text	Explanation	Next steps
Insulin flow blocked Check BG. Consider injection and testing ketones. Change reservoir and infusion set.	Your pump has detected that the basal or bolus insulin flow was blocked.	• Check your blood glucose. Consider checking ketones and take an injection if needed. • Remove your infusion set and reservoir. • Select Rewind to start the new reservoir process using a new infusion set and reservoir. If a bolus delivery was in progress when the alarm occurred: • Check the Daily History screen for the amount of bolus already delivered before the pump alarmed. • Consider delivering remaining bolus, if the bolus insulin was not included in an insulin injection.

Title and text	Explanation	Next steps
Insulin flow blocked Check BG. Consider injection and testing ketones. Estimated 0 U insulin in reservoir. Change reservoir and infusion set.	Your pump has detected that the insulin flow was blocked and there is no insulin in the reservoir.	• Check your blood glucose. Consider checking ketones and take an injection if needed. • Remove your infusion set and reservoir. • Select Rewind to start the new reservoir process using a new infusion set and reservoir. If a bolus delivery was in progress when the alarm occurred: • Check the Daily History screen for the amount of bolus already delivered before the pump alarmed. • Consider delivering remaining bolus, if the bolus insulin was not included in an insulin injection.
Insulin flow blocked Fill Cannula stopped. Remove infusion set from body. Change reservoir and infusion set.	Your pump has detected the insulin flow was blocked while filling the cannula.	• Check your blood glucose. Consider checking ketones and take an injection if needed. • Remove your infusion set and reservoir. • Select Rewind to start the new reservoir process using a new infusion set and reservoir.

Title and text	Explanation	Next steps
Insulin flow blocked Fill Tubing stopped. Remove reservoir and select Rewind to restart.	Your pump has detected the insulin flow was blocked while filling the tubing. Possible connection issue between the tubing and reservoir.	- Remove the reservoir and select Rewind to restart the fill tubing process. - Disconnect tubing from reservoir. - Be sure tubing is not crimped or bent. - Continue following the steps displayed on the pump using the same infusion set and reservoir. - If this alarm occurs again, use a new infusion set.
Loading incomplete Remove reservoir and select Rewind to restart loading.	You pressed  after loading began.	- Remove the reservoir to start again. - Select Rewind and follow the on-screen instructions.
Low battery Pump Replace battery soon.	The battery in the pump is low on power.	- Select OK to clear the alert. - Replace the AA battery as soon as possible. Otherwise, insulin delivery stops, and the Replace Battery Now alarm occurs. - If the pump is delivering a bolus or filling the cannula, wait until delivery is complete to replace battery.

Title and text	Explanation	Next steps
Low reservoir XX hours remaining. Change reservoir. or: XX units remaining. Change reservoir.	Your reservoir is low on insulin, according to the number of hours or units set in the Low Reservoir Reminder.	• Select OK to clear the alert. • Change the reservoir soon. • 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. For more details, see <i>Low Reservoir reminder, on page 138</i>.
Manage settings error Delivery stopped. Backup settings cleared from Manage Settings. Current settings are working properly. Select OK to restart. See User Guide.	A pump error has occurred, and you need to restart your pump. Your backup settings have been lost, but your current settings are unchanged.	• Select OK to restart your pump. Your current settings are unchanged. Only your backup settings are lost. • When the pump restarts, follow instructions on the pump display. • If the pump was delivering a bolus or filling the cannula, check Daily History and evaluate your need for insulin. • Consider saving your current settings. For details, see <i>Saving your settings, on page 148</i>.
Max Fill reached 3X.X U. Did you see drops at the end of tubing?	You have exceeded the number of units expected to fill the tubing. By now, insulin should be at the end of the tubing.	• If you see drops at the end of the tubing, select Yes. • If you do not see drops, select No. • Follow instructions displayed on the pump.

Title and text	Explanation	Next steps
Max Fill reached 4X.X U. Remove reservoir and select Rewind to restart New Reservoir procedure.	You have exceeded the number of units expected to fill the tubing. By now, insulin should be at the end of the tubing.	- Remove the reservoir. - Check if you still have insulin in the reservoir. If you do, you can continue using the same reservoir. - Select Rewind to restart the new reservoir procedure.
No reservoir detected Rewind before loading reservoir.	There is no reservoir in the pump or the reservoir is not properly locked into place.	- Select Rewind. - Ensure that your reservoir is filled with insulin. - When prompted, ensure that your reservoir is inserted and properly locked into place.
Power error detected Delivery stopped. Record your settings by uploading to CareLink or write your settings on paper. See User Guide.	The internal power source in your pump is unable to charge. Your pump is operating on the AA battery only.	- Select OK to clear the alert. - Check your BG and treat as necessary. - Record your settings as soon as possible because your AA battery may not last long. - Call the 24 Hour HelpLine for assistance with your pump.
Power loss AA battery was removed for more than 10 min or power was lost. Select OK to re-enter time and date.	Your pump battery has been out for more than ten minutes, and your pump has lost power. You must reset your time and date.	- Select OK to go to the Time & Date screen. - Enter the current time, time format, and date.

Title and text	Explanation	Next steps
Pump error Delivery stopped. Current settings cleared. Pump restart needed. Select OK to restart and then re-enter your settings. See User Guide.	Your pump encountered an error and will restart. Your pump settings will return to factory default values.	• When the pump restarts, follow instructions on the pump display. • After restart, check settings and re-enter values as needed. • If you recently saved backup settings in Manage Settings, use Restore Settings. • If the pump was delivering a bolus or filling the cannula, check Daily History and reevaluate your need for insulin. • 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 the 24 Hour HelpLine.
Pump error Delivery stopped. Settings unchanged. Pump restart needed. Select OK to restart. See User Guide.	A pump error has occurred, you need to restart your pump.	• Select OK to restart your pump. • If the pump was delivering a bolus or filling the cannula, check Daily History and reevaluate your need for insulin. • 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 the 24 Hour HelpLine.

Title and text	Explanation	Next steps
Pump error Delivery stopped. Settings unchanged. Select OK to continue. See User Guide.	Your pump encountered an error but a restart is not necessary. The issue is resolved. Your settings are not changed.	• Select OK to resume basal delivery. • If the pump was delivering a bolus or filling the cannula, check Daily History and reevaluate your need for insulin. • 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 the 24 Hour HelpLine.
Pump restarted Delivery stopped. Settings unchanged. Select OK to continue. See User Guide.	Your pump has encountered a problem and has restarted. Your settings have not been changed.	• Select OK to continue. • If the pump was delivering a bolus or filling the cannula, check Daily History and re-evaluate your need for insulin. • 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.
Replace battery Battery life less than 30 minutes. To ensure insulin delivery, replace battery now.	Battery life is low and will be exhausted within 30 minutes.	• Select OK to clear the alert. • Replace the AA battery.
Replace battery now Delivery stopped. Battery must be replaced to resume delivery.	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. For details, see <i>Removing the battery</i> , on page 29.

Title and text	Explanation	Next steps
Reservoir estimate at 0 U To ensure insulin delivery, change reservoir.	Your reservoir level is estimated at 0 units.	• Select OK to clear the alert. • Change the reservoir now.
Resume bolus? XXX of YYY U delivered. Resume delivery of ZZZ U?	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.	• Check the message to see how much of the bolus was actually delivered. • To cancel remaining amount of bolus, select Cancel. • To resume remaining amount of bolus, select Resume.
Resume Dual bolus? XX of YY U delivered. Resume delivery of ZZ U for XX:XX hr?	The Square portion of Dual Bolus delivery has been interrupted. If it is within 10 minutes since this interruption, you can resume this bolus.	• Check the message to see how much of the Dual Wave bolus was actually delivered. • To cancel remaining amount of bolus, select Cancel. • To resume remaining amount of bolus, select Resume.
Resume Dual bolus? XX of YY U delivered. Resume delivery of ZZ U now, and AA U Square for XX:XX hr?	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.	• Check the message to see how much of the Dual Wave bolus was actually delivered. • To cancel remaining amount of bolus, select Cancel. • To resume remaining amount of bolus, select Resume.

Title and text	Explanation	Next steps
Resume Square bolus? XX of YY U delivered for XX:XX hr. Resume delivery of ZZ U for XX:XX hr?	The Square Wave bolus delivery was interrupted. If it is within 10 minutes since this interruption, you can resume this bolus.	• Check the message to see how much of the Square Wave bolus was actually delivered. • To cancel remaining amount of bolus, select Cancel. • To resume remaining amount of bolus, select Resume.
Rewind required Delivery stopped. Rewind was required due to pump error. Select OK to continue. See User Guide.	Your pump encountered an error.	• Select OK to clear the alarm. • Select Reservoir & Tubing from the Home screen to start the new reservoir process using a new infusion set and reservoir. For details, see <i>Setting up the reservoir and infusion set</i>, on page 99.
Stuck button Button pressed for more than 3 minutes	The pump has detected that a button has been pressed for an unusually long time.	• Select OK to clear the alarm. • If this alarm occurs again, call the 24 Hour HelpLine for assistance with your pump. If you are unable to clear the alarm: • Consider another form of insulin, because your pump is not delivering insulin. • Check your BG and treat as necessary. • Call the 24 Hour HelpLine for assistance with your pump.

Title and text	Explanation	Next steps
Wrong key pressed Try again	Wrong button selected while unlocking the pump.	- Select OK to clear the alert. - Try to unlock the pump. Select the highlighted key when prompted. For more information, see <i>Unlocking your pump, on page 32.</i>

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. If you get an alarm, alert, or message that is not listed, select OK to clear the alarm and call the 24 Hour HelpLine.

Title and text	Explanation	Next steps
Alert before high Sensor glucose approaching High Limit. Check BG.	Your SG value is approaching your specified high limit.	- Select OK to clear the alert. - Check your BG. - Follow instructions from your healthcare professional and continue to monitor your BG.
Alert before low Sensor glucose approaching Low Limit. Check BG.	Your SG value is approaching your specified low limit.	- Select OK to clear the alert. - Check your BG. - Follow instructions from your healthcare professional and continue to monitor your BG.
Alert on high XXX mg/dL High sensor glucose. Check BG.	Your SG value is at or above your specified high limit.	- Select OK to clear the alert. - Check your BG. - Follow instructions from your healthcare professional and continue to monitor your BG.

Title and text	Explanation	Next steps
Alert on low XXX mg/dL Low sensor glucose. Check BG.	Your SG value is at or below your specified low limit.	• Select OK to clear the alert. • Check your BG. • Follow instructions from your healthcare professional and continue to monitor your BG.
Alert on low XXX mg/dL Low sensor glucose. Insulin delivery suspended since XX:XX AM/PM. Check BG.	Your SG value is at or below your specified low limit, and the pump has suspended insulin delivery due to a Suspend on low event.	• Select OK to clear the alert. • Check your BG. • Follow instructions from your healthcare professional and continue to monitor your BG.
Basal delivery resumed Low settings change caused basal to be resumed at XX:XX AM/PM. Check BG.	Your pump is resuming basal insulin delivery after a Suspend on low event occurred, because you have turned off the Suspend on low feature.	• Select OK to clear the alert. • Check your BG. • Follow instructions from your healthcare professional and continue to monitor your BG.
Basal delivery resumed Maximum 2 hour suspend time reached. Check BG.	Your pump is resuming basal insulin delivery two hours after a Suspend on low event occurred.	• Select OK to clear the alert. • Check your BG. • Follow instructions from your healthcare professional and continue to monitor your BG.

Title and text	Explanation	Next steps
Basal delivery resumed Maximum 2 hour suspend time reached. SG is still under Low limit. Check BG.	Your pump is resuming basal insulin delivery two hours after a Suspend on low event occurred.	- Your pump has resumed basal insulin delivery; however, your SG value is still at or below your low limit. - Select OK to clear the alert. - Check your BG. - Follow instructions from your healthcare professional and continue to monitor your BG.
BG not received Place pump close to transmitter. Select OK to resend BG to transmitter.	The transmitter was unable to receive the calibration BG meter readings from the pump.	- Move your pump and transmitter closer together. - Select OK. Your pump tries again to send your BG to your transmitter for sensor calibration.
Calibrate now Check BG and calibrate sensor.	A BG meter reading is needed immediately to calibrate your sensor so that you can continue receiving sensor glucose readings.	- Take a BG meter reading and enter for calibration. After you receive a Calibrate now alert, it takes about 15 minutes after you calibrate for your pump to receive SG values. For details, see <i>Calibrating your sensor, on page 186</i>. - If you are unable to calibrate now, you can use the Snooze feature. Set the desired time, and select Snooze. If you do not calibrate before the Snooze time is up, the Calibrate Now alert occurs again.

Title and text	Explanation	Next steps
Calibration not accepted Recheck BG and calibrate sensor.	Your system was unable to use the BG meter readings you entered to calibrate your sensor.	- Wash and dry hands thoroughly. See <i>Guidelines for calibrating</i>, on page 188. - Enter a new BG meter reading for calibration as instructed in <i>Calibrating your sensor</i>, on page 186. If you receive a Calibration not accepted alert on your second calibration, a Change sensor alert occurs. - Call the 24 Hour HelpLine if you have questions.
Cannot find sensor signal Disconnect and reconnect transmitter, then select OK. Notice if transmitter light blinks.	The pump has not received a signal from the transmitter.	- Disconnect and reconnect your transmitter and sensor. - See if the light on your transmitter blinks when connected to the sensor. You may need this information for troubleshooting later. - 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.
Change sensor Insert new sensor and Start New Sensor.	You selected No in the Check sensor insertion message, indicating that your sensor is not fully inserted.	- Select OK to clear the alert. - Change your sensor. For details, see your sensor user guide. - After you change your sensor, refer to <i>Starting the sensor</i>, on page 184.

Title and text	Explanation	Next steps
Change sensor Second calibration not accepted. Insert new sensor.	This alert occurs when you receive two Calibration not accepted errors in a row.	• Select OK to clear the alert. • Change your sensor. For details, see your sensor user guide.
Check connection Ensure transmitter and sensor connection is secure, then select OK.	The pump fails to detect the transmitter and is unable to receive sensor signal.	• Select OK to clear the alert. • If your sensor is fully inserted, select Yes. If your sensor is not fully inserted, select No. • If your sensor was not fully inserted, insert a new sensor. • If you still cannot connect your sensor, see <i>My pump cannot find the sensor signal, on page 234</i>.
Lost sensor signal Move Pump closer to transmitter. May take 15 minutes to find signal.	Transmitter signal has not been received for 30 minutes during or after initialization.	• Move your pump closer to your transmitter. It can take up to 15 minutes for your pump to start communicating with your transmitter. • Select OK to clear the alert.
Low battery transmitter Recharge transmitter within 24 hours.	The battery in the transmitter needs to be recharged within 24 hours.	• Select OK to clear the alert. • Recharge your transmitter as soon as possible.

Title and text	Explanation	Next steps
No calibration occurred Confirm sensor signal. Calibrate by XX:XX AM/PM.	The transmitter was unable to receive the calibration BG meter readings from the pump.	• Select OK to clear the alert. • Check the status bar on your pump to ensure that your pump has a signal from your sensor. If there is no sensor signal, see <i>My pump cannot find the sensor signal, on page 234</i>. • Calibrate again by the time shown on the pump screen to ensure you continue SG monitoring.
No calibration occurred Confirm sensor signal. Check BG again to calibrate sensor.	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.	• Select OK to clear the alert. • Take another BG meter reading and calibrate again.
Possible signal interference Move away from electronic devices. May take 15 minutes to find signal.	There may be interference from another electronic device that is affecting the communication between your pump and transmitter.	• Move away from other electronic devices. It can take up to 15 minutes for your pump to start communicating with your transmitter. • Select OK to clear the alert.

Title and text	Explanation	Next steps
Rise Alert Sensor glucose rising rapidly.	Your SG value has been rising as fast or faster than your preset Rise Alert Limit.	• Select OK to clear the alert. • Monitor trend and glucose level. • Follow instructions from your healthcare professional.
Sensor alert occurred Check Alarm History for silenced alerts.	Sensor alert occurred when Alert Silence is on.	• Select OK to clear the alert. • Check the Alarm History screen to see which alerts were silenced. For more information about accessing the Alarm History screen, see <i>Alarm History, on page 128</i>. • Select the alert to open the Alarm Detail screen. • Take action based on the selected alert.
Sensor connected If new sensor, select Start New. If not, select Reconnect.	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.	• If you have connected a new sensor, select Start New Sensor. • If you have reconnected a sensor you have been using, select Reconnect Sensor. • In either case, a "warm-up" messages appears on your Home screen, and you are prompted to calibrate your sensor. Your pump starts receiving your SG values again after the two-hour initialization is complete.
Sensor connected Start new sensor.	The transmitter has detected that you have connected a sensor.	• Select Start New Sensor. • For more information, see <i>Starting the sensor, on page 184</i>.

Title and text	Explanation	Next steps
Sensor expired Insert new sensor.	The sensor has been used for 6 days (144 hours). It 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?	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 Yes or No and follow the instructions on the screen.
Sensor signal not found See User Guide.	After multiple attempts, the pump failed to detect the transmitter and is unable to receive sensor signal.	• Select OK to clear the alert. • Repeat the connection process. Remove the transmitter from the sensor for about ten seconds, and then reconnect it to the sensor. • It can take up to 15 minutes for your pump to find the sensor signal. • Move your pump closer to your transmitter to improve reception. • Make sure you are away from any electronic devices that might cause interference, such as cellular phones and other wireless devices. • If your pump still cannot find the sensor signal, call the 24 Hour HelpLine for assistance.

Title and text	Explanation	Next steps
SG value not available If problem continues, see User Guide.	The sensor signals are either too high or too low.	- Select OK to clear the alert. - You do not need to change the sensor. If the alert persists, test your transmitter with the tester. Refer to your transmitter user guide for instructions on testing the transmitter.
Sensor warm-up started Warm-up takes up to 2 hours. You will be notified when calibration is needed.	Your sensor is warming up.	- Select OK to clear the message. - For more information, see <i>Starting the sensor, on page 184</i>.
Suspend on low Delivery stopped. Sensor glucose XXX mg/dL. Check BG.	Your SG value is at or below the low limit you specified.	- Select OK to clear the alert. - Check your BG. If necessary, treat your BG as directed by your healthcare professional.
Transmitter battery depleted Recharge transmitter now.	The battery in the transmitter needs to be recharged. SG values are not recorded or transmitted until you recharge transmitter.	- Select OK to clear the alert. - Recharge your transmitter.

CareLink alert and message

The following table lists the most common or serious alarms, 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 alarm and call the 24 Hour HelpLine.

Title and text	Explanation	Next steps
Connect Device? Device with SN <XXXXXXXXXX> is trying to connect to your pump. Allow connection?	The CareLink USB software is attempting to connect to your pump in preparation for data download.	• Select Yes to allow connection, only if you are expecting or performing a data download. • Select No to deny connection. If no selection is made, the screen will timeout after 30 seconds and will automatically reject the request.
Download slow Insulin delivery not affected. CareLink download may take longer than usual. Select OK to continue. See User Guide.	The download of pump data is taking longer than expected. Data will not be affected.	• Select OK to clear the alert. • Wait for the data to finish downloading. • If problem still persists or if there is no progress in download, call the 24 Hour HelpLine for assistance.

13

troubleshooting

13 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 204.

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.

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: 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.

You always 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 minor 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 by going to:

Menu > Utilities > Self Test

For details, see *Self Test, on page 152*.

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

If you go to Menu > 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:

1. **Menu > Utilities > Manage Settings**
2. Simultaneously press and hold > and ⬅ for about two seconds. The Manage Settings screen appears. For more information, see *Managing your pump settings, on page 148*.

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. Go to **Menu > Utilities > Display Options**, and then adjust the Backlight setting as desired. For more information, see *Display Options, on page 147*.



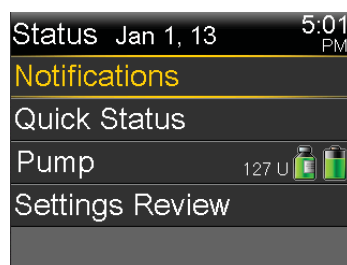
Note: Be aware that using a longer Backlight time causes your pump to use more battery power. When your pump battery is low, the timeout for the backlight on your pump screen is automatically reduced.

Where is my pump status screen?

1. To go to the Status screen, highlight and select the status bar at the top of your Home screen.



The Status screen appears.



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 37*.

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
- Carb unit
- Active Insulin Time

- Basal patterns

After you enter your pump settings, you have the option of entering the following Bolus Wizard settings:

- Carb ratio or Exchange ratio
- Insulin sensitivity factor
- BG target

To enter your pump settings:

1. Begin entering your settings by selecting English. Click **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 Select Carb Unit screen appears, select **Grams** or **Exchanges** as the unit your pump uses to display carbohydrate information.
6. When the Active Insulin Time screen appears, enter the **Duration**.
For details, see *About active insulin*, on page 78.
7. 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 48.
After you complete your basal pattern, a screen appears to allow you to review your basal information.
8. 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.
2. Depending on the Carb Unit you set earlier, either the Carb Ratio or the Exch Ratio screen appears. Enter your carb ratio or exchange ratio by entering the End time and the Rate. You can adjust your carb or exchange ratio at any time.

For details, see *Changing your carb or exchange ratio, on page 75*.

3. 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 76*.

4. 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 76*.

A message appears confirming that your setup is complete.

5. Select **Next** to display the Home screen, and continue using your pump.

Troubleshooting sensor issues

My pump cannot find the sensor signal

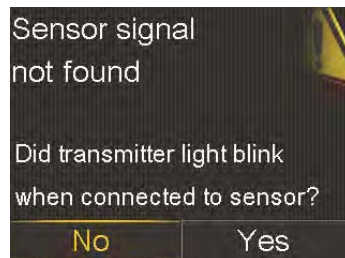
If your pump cannot find the sensor signal after you connect your sensor and transmitter, follow the instructions on the pump screen to troubleshoot the issue as described below.

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 Alert Silence and currently have all sensor alerts silenced, your pump does not display the troubleshooting screens. Any glucose alerts you received are displayed in the Alarm History screen.

1. Make sure your setup meets the following requirements:
 - 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 184.
 - 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 177.
 - The Airplane Mode is turned off on your pump.
 - You have applied the tape correctly, as instructed in the senter 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 184*.
 - 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 the following happens:

- System was unable to use the BG meter readings you entered to calibrate your sensor.

For details on when and how to calibrate your sensor, see *Calibrating your sensor, on page 186*.

Why does the SmartGuard shield on my Home screen appear gray?

The SmartGuard shield appears gray  on the Home screen when the Suspend on low feature is unavailable. The Suspend on low feature may be unavailable due to the following conditions:

- A Suspend on low event has occurred recently.
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. The Suspend on low feature will be unavailable for the duration set by your Low Snooze after your basal insulin delivery is resumed. For details, see *When SmartGuard Suspend on low is unavailable, on page 165*.

- No SG values are available.

SG values may be unavailable because:

- Your pump is in Airplane Mode.

For more information, see *Airplane Mode*, on page 143.

- Sensor calibration is required.

For details on when and how to calibrate your sensor, see *Calibrating your sensor*, on page 186.

- 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 234.

- 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.

14



maintenance

14

Maintenance

Read your warranty statement included with your pump for information about what is covered during your warranty period.

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. An internal 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 29.



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  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 28.
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 149.

Storing your transmitter

Always refer to your transmitter user guide for instructions on storing your transmitter.

15

product specifications and safety information

15

Product specifications and safety information

This chapter provides detailed product specifications and safety information.

Product specifications

This section provides detailed information on product specifications.

Alarm and alert escalation

The following alerts may escalate to a siren if not cleared:

- Alert before high
- Alert before low
- Alert on high
- Alert on low
- Basal delivery resumed
- BG not received
- Calibration not accepted
- Calibrate now
- Cannot find sensor signal
- Change sensor
- Check connection
- Lost sensor signal
- No calibration occurred
- Possible signal interference
- Rise Alert
- Sensor expired
- Sensor signal not found
- SG value not available
- Transmitter battery depleted

Minutes from alarm or alert	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.

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 tolerance (+/- 1%)
Alarm	1655 Hz followed by 3310 Hz
Alternate Alarm	1850 Hz
Siren (escalated alarm)	1655 Hz, followed by 3310 Hz
Alert	934 Hz

Tone name	Frequency tolerance (+/- 1%)
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

Type	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

BG meter value

The most recent BG value received from the meter. If you are using a compatible Bayer 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

Bolus Speed options	• Standard: 1.5 units/minute • Quick: 15 units/minute
Bolus programming increments	• 0.025 units • 0.05 units • 0.1 units

Fluid delivered/stroke	• 0.25 µL (microliter) for 0.025 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 (or exchange) ratio	None	1–200 g/u (0.075–15.0 u/exch)	0.1 g/u for 1–9.9 g/u; 1 g/u for ratios of 10 g/u to 200 g/u (0.001 u/exch for 0.075–0.099 u/exch; 0.01 u/exch for 0.10–9.99 u/exch; 0.1 u/exch for 10–15 u/exch)
Insulin Sensitivity Factor	None	5–400 mg/dL	1 mg/dL
BG Target	None	60–250 mg/dL	1 mg/dL
Active Insulin Time	6 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.

$$\text{total bolus estimate} = \frac{\text{(food estimate)}}{\frac{A}{B}} + \frac{\text{(correction estimate)}}{\frac{C - D}{E}} - \text{active insulin}$$

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) ÷ 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.

$$\text{total bolus estimate} = \frac{\text{(food estimate)}}{\frac{A}{B}} + \frac{\text{(correction estimate)}}{\frac{C - D}{E}}$$

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) ÷ Insulin sensitivity = Units of insulin

Total bolus estimate:

Food estimate + Correction estimate = Units of insulin

3. If your current BG is within your High or Low BG Target, the total bolus estimate is based only on the food estimate.

$$\text{total bolus estimate} = \frac{\text{food (grams)}}{\text{carb ratio}}$$

Food estimate:

Carb grams ÷ Carb ratio = Units of insulin



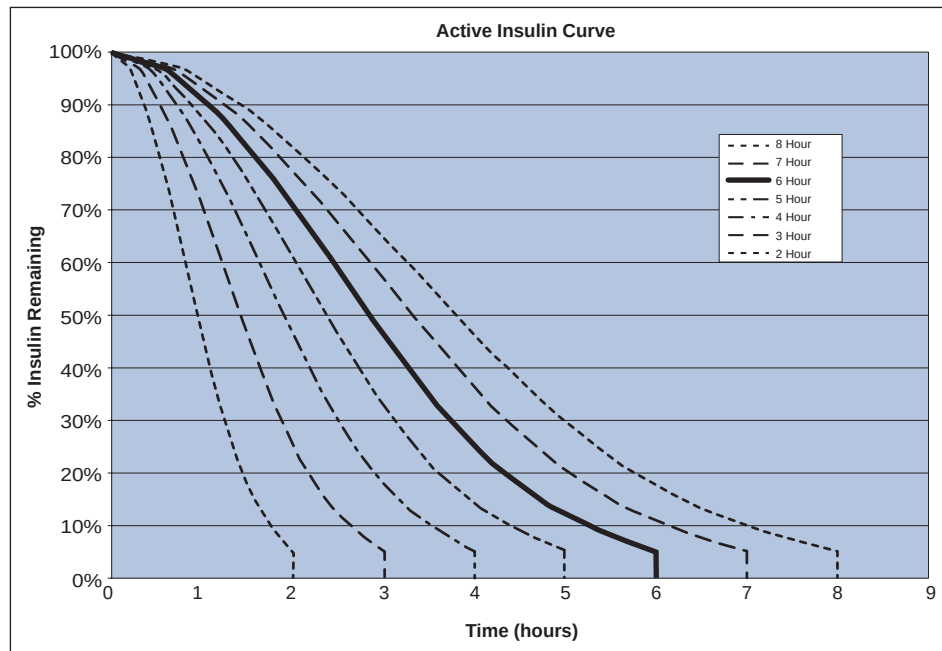
Note: When the current BG is below the Low BG Target, an active insulin amount is not considered in the Bolus Wizard feature calculations.

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.

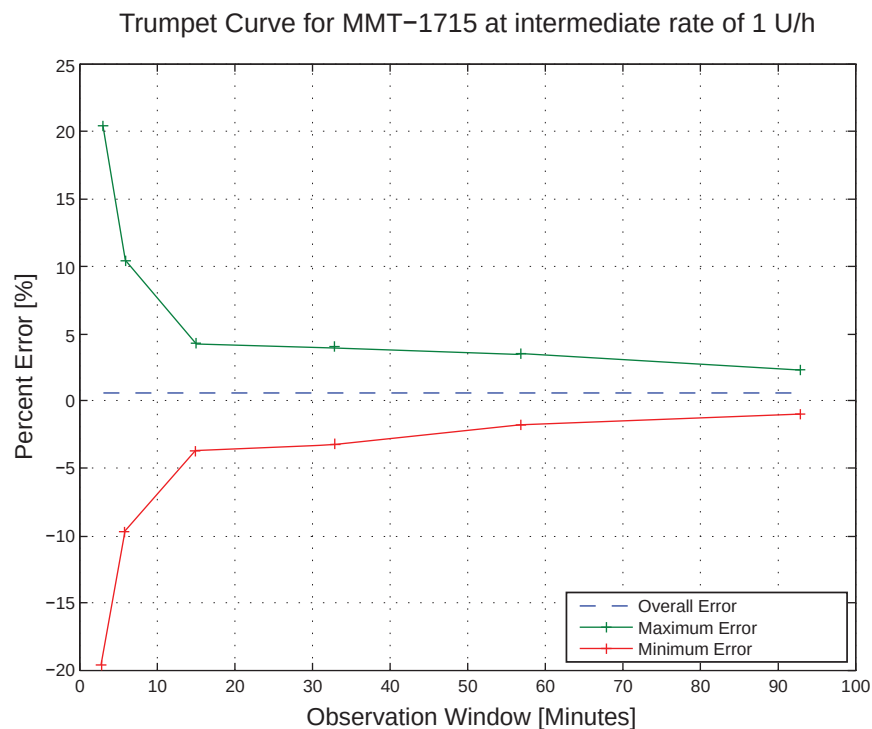
Carb ratios

Maximum ratio settings	Range
8	1 to 200 grams/unit
	0.075 to 15 units/exch

Delivery accuracy

- For a basal rate of 1.0 U/h, the delivery accuracy is $\pm 5\%$.
For a basal rate of 0.025 U/h, the delivery accuracy is $\pm 10\%$.
Delivery accuracy for bolus volumes < 0.1 unit is $\pm 20\%$ and delivery accuracy for bolus volumes ≥ 0.1 unit is $\pm 5\%$.
- 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.
- 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

Your MiniMed 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 6*.

- Pump operating temperature range is from 41 °F (5 °C) to 104 °F (40 °C).
- Air pressure range is from 10.2 psi to 15.4 psi (700 kPa to 1060 kPa).
- 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%).

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, and thereafter at every 10 units.
- 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

Item	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

Item	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%

Item	Default setting	Limits	Increments
Temp Basal Rate	Current basal rate	0.0 U/hr to Max Basal Rate	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

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

Low Reservoir reminder

The values are based on displayed amount, not actual amount.

Alert type	Alert range	Increment	Default value
Time	First reminder occurs at 2 to 24 hours. Second reminder occurs one hour before empty. The second reminder is automatic and cannot be changed by the user.	30 min	8 hours
Units	First reminder occurs at 5 to 50 units. Second reminder occurs at 50 percent of the remaining specified amount. The second reminder is automatic and cannot be changed by the user.	1 unit	20 units

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 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 MMT-1715 pump dimensions in inches are approximately 2.1 width x 3.78 length x 0.96 depth.

The MMT-1715 pump dimensions in centimeters are approximately 5.3 width x 9.6 length x 2.44 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 MiniMed 630G insulin pump (MMT-1715) is approximately 95.7 grams.

Sensor default settings

High sensor settings			
Item	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	• 1 up arrow (1 mg/dL/min) • 2 up arrows (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			
Item	Default setting	Limits	Increments
Low SG alert limit	60 mg/dL	60 to 90 mg/dL	5 mg/dL
Suspend on low	Off	-	-
Alert before low	Off	-	-
Alert on low	Off	-	-
Low Snooze	20 minutes	5 minutes to 1 hour	5 minutes

Guidance and manufacturer's declaration

Guidance and Manufacturer's Declaration - Electromagnetic Emissions		
The MiniMed 630G 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)	• 6 dB and 99% Bandwidths: Pass • Maximum Output Power: Pass • TX Spurious Emissions: Pass • Power Spectral Density: Pass	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 and in all establishments, including domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
RTCA DO 160G (2010) 20.5 and 21.5	Complies	
ARIB STD-T66	Complies	

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The MiniMed 630G 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_T (>95% dip in U_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 630G 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 Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment 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: $d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 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^a, should be less than the compliance level in each frequency range^b. Interference may occur in the vicinity of equipment marked with the following symbol: 

Guidance and Manufacturer's Declaration - Electromagnetic Immunity	
The MiniMed 630G 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 630G 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 630G 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 $d=1.2\sqrt{P}$	800 MHz to 6 GHz $d=2.3\sqrt{P}$
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-1715 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.

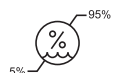
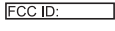
Pump frequency	2.4 GHz; proprietary Medtronic protocol; range up to 6 feet (1.8 meters)
Maximum output power (EIRP)	-1.59 dBm (693 μ W)
Operating frequencies	2420 MHz, 2435 MHz, 2450 MHz, 2465 MHz, 2480 MHz
Bandwidth	5 MHz which is allocated channel bandwidth per the IEEE protocol

Data security

The MiniMed 630G 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 630G system ensures data security via proprietary means and ensures data integrity using error checking processes, such as cyclic redundancy checks.

Icon table

Follow instructions for use	
Manufacturer	
Date of manufacture	
Use by	
Catalogue or model number	
Serial number	
Storage temperature range	
Storage humidity range	
Magnetic Resonance (MR) Unsafe: keep away from magnetic resonance imaging (MRI) equipment	
Type BF Device (protection from electrical shock)	
Radio communication	
Pump: Protected against the effects of continuous immersion in water (12 feet or 3.6 meters for 24 hours).	IPX8
Requires prescription in the United States	R_x Only
Recycle: Electronic Equipment	
One per container/package	(1x)
Complies with United States Radio communication requirements	

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 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 <i>blood glucose</i> .
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 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.
carb unit	The unit of measure for carbohydrates, either grams (g) or exchanges (exch).
CGM	Abbreviation for continuous glucose monitoring. See <i>continuous glucose monitoring</i> .
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.
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.

exchange ratio	The number of insulin units that are needed to cover 1 carbohydrate exchange. The exchange ratio is based on your individual needs and is used to calculate bolus amounts.
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 of a low sensor glucose condition, and also used for determining if insulin delivery should be suspended.
Manual Bolus	A feature that allows you to enter and deliver a dose of insulin in the amount that you have determined is necessary.
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.
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 <i>insulin sensitivity factor</i> .

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 <i>sensor glucose</i> .
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™	SmartGuard refers to all automated insulin delivery and suspension actions by Medtronic sensor integrated insulin pump systems.
Square Wave® Bolus	A bolus delivered evenly over a specified time period.
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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MiniMed® 630G

Enlite® Sensor Performance for the MiniMed® 630G Insulin Pump

CGM performance

The MiniMed® 630G insulin pumps (MMT-1715) are integrated with CGM (Continuous Glucose Monitoring) technology. CGM enables your pump to display sensor glucose readings, glucose trend arrows, glucose trend graphs, as well as sensor glucose alerts; for example, High and Low Limit alerts (also known as Alert on high and Alert on low), High and Low Predicted alerts (also known as Alert before high and Alert before low), and Rise rate-of-change alert (also known as Rise Alert). With CGM, you can also enable your pump to automatically suspend insulin delivery (the Threshold Suspend feature, also known as Suspend on low) when your sensor glucose value reaches or falls below the Low Limit that you set.

Clinical study description

The performance of the Enlite® sensor was evaluated in a clinical study¹. This inpatient (in-clinic) and outpatient (at home) study included subjects 18 to 75 years in age. The study design was a multi-center, prospective single-sample correlational design without controls. All subjects were assigned to treatment. Each subject was instructed to wear two Enlite sensors connected to two MiniLink® transmitters and two Revel™ 2.0 pumps (which use the same CGM technology as the MiniMed 630G insulin pump). Bayer's CONTOUR® NEXT LINK Wireless Meter was used as the study meter, and was used for all calibrations in this study. This system was tested with Bayer's CONTOUR® NEXT LINK Wireless Meter, but has not been tested with other meters. Therefore, the performance of this system with other blood glucose meters may differ from the performance with the Bayer's CONTOUR® NEXT LINK Wireless Meter described below.

On days 1, 3, and 6, frequent sample testing (FST) was performed. Reference blood (plasma) glucose values were obtained with a Yellow Springs Instrument (YSI®) Glucose Analyzer every 5-15 minutes and compared with sensor glucose values. During the FSTs, the subjects were instructed to calibrate one sensor three to four times spread throughout the day, and calibrate the other sensor, once every 12 hours. During home use (outside the clinic), subjects were instructed to calibrate both sensors three to four times spread throughout the day.

A total of 111 subjects previously diagnosed with type 1 or 2 diabetes were enrolled in the study, 20 subjects failed the screening, 61 subjects with abdominal insertions completed the study, and one subject enrolled after the study was completed. During each FST, subjects with an established insulin sensitivity ratio and insulin carbohydrate ratio underwent a hypoglycemic challenge and a hyperglycemic challenge. Subjects were instructed to continue with their current diabetes regimen (including glucose monitoring with their own meter when desired) independent of their use of the study devices. The Revel 2.0 pumps were not used to infuse insulin or manage diabetes during this study. The meter was used for confirmation of alarms, treatment decisions and sensor calibrations.

Refer to the www.fda.gov/medicaldevices for more information on the Threshold Suspend feature.

1 Medtronic Inc., A Performance Evaluation of the Enlite® Glucose Sensor to Support a Full 144 hours (6 Days) of Use, CER247/Z25/C, May 2012.

Results

Sensor accuracy

The following information highlights the sensor performance during normal use. Compared to calibrating every 12 hours, the data indicates that calibrating three to four times a day at any time, will result in a 1.1% MARD improvement.

Mean and median absolute relative difference, by number of daily calibrations

The overall mean absolute relative difference (ARD) between the Enlite sensor (CGM readings) and the reference YSI values was 13.6% and the median ARD was 10.1%, from inpatient frequent sample testing (FST) during hypoglycemic and hyperglycemic challenges.

Table 1. CGM difference to YSI within YSI glucose ranges; Calibrating three to four times daily, Abdomen insertion site.

YSI glucose ranges (mg/dL)	Number of paired CGM-YSI	Mean percent difference (%)	Median percent difference (%)	Mean absolute percent difference (%)	Median absolute percent difference (%)
Overall	7415	2.05	0.93	13.63	10.10
<40*	3	28.18	31.65	28.18	31.65
40-60*	618	6.50	5.45	10.06	7.85
61-80*	1419	4.81	3.80	11.43	9.05
81-180	3241	1.95	1.72	12.38	9.09
181-300	1648	-2.79	-2.47	11.72	8.96
301-350	325	-6.32	-5.36	11.36	8.43
351-400	137	-11.99	-9.23	13.48	10.11
>400	24	-28.38	-26.78	28.38	26.78

* For YSI reference range ≤ 80 mg/dL, the differences in mg/dL are included instead of percent difference (%).

Note: CGM Readings are within 40-400 mg/dL.

Table 2. CGM difference to YSI within YSI glucose ranges; Calibrating every 12 hours, Abdomen insertion site.

YSI glucose ranges (mg/dL)	Number of paired CGM-YSI	Mean percent difference (%)	Median percent difference (%)	Mean absolute percent difference (%)	Median absolute percent difference (%)
Overall	7432	0.75	0.74	14.71	10.80
<40*	3	27.18	27.65	27.18	27.65
40-60*	515	6.56	4.75	11.07	9.15
61-80*	1349	1.36	-0.15	12.04	9.90
81-180	3158	2.14	3.00	13.95	10.45

YSI glucose ranges (mg/dL)	Number of paired CGM-YSI	Mean percent difference (%)	Median percent difference (%)	Mean absolute percent difference (%)	Median absolute percent difference (%)
181-300	1895	-3.02	-1.03	12.62	8.54
301-350	346	-6.50	-2.08	12.27	6.97
351-400	132	-12.06	-7.98	13.68	8.29
>400	34	-28.08	-19.87	28.08	19.87

* For YSI reference range ≤ 80 mg/dL, the differences in mg/dL are included instead of percent difference (%).

Note: CGM Readings are within 40-400 mg/dL.

Table 3. CGM difference to YSI within CGM glucose ranges; Calibrating three to four times a day, Abdomen insertion site.

CGM glucose ranges (mg/dL)	Number of paired CGM-YSI	Mean percent difference (%)	Median percent difference (%)	Mean absolute percent difference (%)	Median absolute percent difference (%)
Overall	7415	1.61	-0.93	13.99	10.00
40-60*	620	9.07	6.30	10.38	7.25
61-80*	1240	-0.86	-3.67	10.37	8.05
81-180	3497	-0.02	-2.03	13.96	9.82
181-300	1675	1.99	0.68	12.29	9.17
301-350	266	-1.71	-1.50	9.47	6.89
351-400	117	-6.68	-6.66	9.31	7.77

* For CGM range ≤ 80 mg/dL, the differences in mg/dL are included instead of percent difference (%).

Table 4. CGM difference to YSI within CGM glucose ranges; Calibrating every 12 hours, Abdomen insertion site.

CGM glucose ranges (mg/dL)	Number of paired CGM-YSI	Mean percent difference (%)	Median percent difference (%)	Mean absolute percent difference (%)	Median absolute percent difference (%)
Overall	7432	4.42	-0.73	16.69	10.56
40-60*	755	15.88	10.70	17.24	11.05
61-80*	975	1.85	-0.90	10.99	7.50
81-180	3423	2.08	-2.80	16.95	11.40
181-300	1810	0.16	-1.34	11.32	7.69
301-350	342	-2.57	-1.57	8.35	6.20
351-400	127	-6.00	-6.11	10.68	9.01

* For CGM range ≤ 80 mg/dL, the differences in mg/dL are included instead of percent difference (%).

Percent agreement, by number of daily calibrations

The accuracy of the Enlite sensor (CGM) was also evaluated by calculating the percentage of CGM readings within $\pm 15\%$, $\pm 20\%$, $\pm 30\%$, and $\pm 40\%$ of the YSI values (or within ± 15 , ± 20 , ± 30 , or ± 40 mg/dL in the low glucose range of 40–80 mg/dL). These results are shown for various YSI glucose ranges when calibrating three to four times a day and also for calibrating every 12 hours. For example, 93.2% of all Enlite sensors readings (from 40 to 400 mg/dL) were within 30% of the YSI value when calibrating three to four times per day.

Table 5. Agreement (%) of CGM-YSI paired points within YSI Glucose Ranges, Abdomen insertion site, calibrating three to four times a day.

YSI glucose ranges (mg/dL)	Number of paired CGM-YSI	Percent of CGM within 15/15% of YSI	Percent of CGM within 20/20% of YSI	Percent of CGM within 30/30% of YSI	Percent of CGM within 40/40% of YSI	Percent of CGM greater than 40/40% of YSI
Overall	7415	72.7	83.7	93.2	97.0	3.0
<40*	3	33.3	33.3	33.3	66.7	33.3
≥ 40-60*	618	79.6	91.1	96.1	97.9	2.1
>60-80*	1419	76.3	86.9	94.9	96.9	3.1
>80-180	3241	70.9	80.7	91.8	96.9	3.1
>180-300	1648	72.5	84.9	94.1	97.6	2.4
>300-350	325	71.4	84.9	94.5	98.2	1.8
>350-400	137	63.5	79.6	89.1	94.9	5.1
>400	24	33.3	41.7	54.2	66.7	33.3

* For YSI reference range ≤ 80 mg/dL, agreement was based on 15/20/30/40 mg/dL.

Note: CGM Readings are within 40-400 mg/dL.

Table 6. Agreement (%) of sensor-YSI paired points within YSI Glucose Ranges, Abdomen insertion site, calibrating every 12 hours.

YSI glucose ranges (mg/dL)	Number of paired CGM-YSI	Percent of CGM within 15/15% of YSI	Percent of CGM within 20/20% of YSI	Percent of CGM within 30/30% of YSI	Percent of CGM within 40/40% of YSI	Percent of CGM greater than 40/40% of YSI
Overall	7432	68.1	79.0	90.2	96.3	3.7
<40*	3	33.3	33.3	66.7	100.0	0.0
≥ 40-60*	515	76.3	85.8	92.4	99.0	1.0
>60-80*	1349	70.5	82.5	92.8	98.8	1.2
>80-180	3158	64.9	76.5	89.0	95.9	4.1
>180-300	1895	68.9	78.9	90.2	95.4	4.6
>300-350	346	72.3	80.6	91.0	94.2	5.8

YSI glucose ranges (mg/dL)	Number of paired CGM-YSI	Percent of CGM within 15/15% of YSI	Percent of CGM within 20/20% of YSI	Percent of CGM within 30/30% of YSI	Percent of CGM within 40/40% of YSI	Percent of CGM greater than 40/40% of YSI
>350-400	132	72.0	79.5	87.9	93.2	6.8
>400	34	38.2	52.9	67.6	79.4	20.6

* For YSI reference range ≤ 80 mg/dL, agreement was based on 15/20/30/40 mg/dL.

Note: CGM Readings are within 40-400 mg/dL.

Similarly, the accuracy of the Enlite (CGM) sensor was also evaluated by calculating the percentage of Enlite sensor readings within $\pm 15\%$, $\pm 20\%$, $\pm 30\%$, and $\pm 40\%$ (or within ± 15 , ± 20 , ± 30 , or ± 40 mg/dL in the low glucose range of 40–80 mg/dL) of the YSI values. These results are shown for various CGM glucose ranges when calibrating three to four times a day and also for calibrating every 12 hours. For example, 93.0% of all Enlite sensors readings (from 40 to 400 mg/dL) were within 30% of the YSI value when calibrating three to four times per day.

Table 7. Agreement (%) of sensor-YSI paired points within CGM glucose ranges, Abdomen insertion site, calibrating three to four times a day.

CGM glucose ranges (mg/dL)	Number of paired CGM-YSI	Percent of CGM within 15/15% of YSI	Percent of CGM within 20/20% of YSI	Percent of CGM within 30/30% of YSI	Percent of CGM within 40/40% of YSI	Percent of CGM greater than 40/40% of YSI
Overall	7415	72.5	83.2	93.0	96.4	3.6
≥ 40 -60*	620	80.0	87.7	94.7	97.9	2.1
>60-80*	1240	81.9	90.9	95.9	97.0	3.0
>80-180	3497	68.3	79.6	91.2	95.3	4.7
>180-300	1675	70.3	81.9	92.8	97.1	2.9
>300-350	266	77.8	88.0	96.6	99.2	0.8
>350-400	117	77.8	93.2	100.0	100.0	0.0

* For CGM reference range ≤ 80 mg/dL, agreement was based on 15/20/30/40 mg/dL.

Table 8. Agreement (%) of sensor-YSI paired points within CGM glucose ranges, Abdomen insertion site, calibrating every 12 hours.

CGM glucose ranges (mg/dL)	Number of paired CGM-YSI	Percent of CGM within 15/15% of YSI	Percent of CGM within 20/20% of YSI	Percent of CGM within 30/30% of YSI	Percent of CGM within 40/40% of YSI	Percent of CGM greater than 40/40% of YSI
Overall	7432	68.3	78.9	90.2	95.5	4.5
≥ 40 -60*	755	66.9	80.0	92.2	96.6	3.4
>60-80*	975	80.9	88.2	94.7	97.0	3.0
>80-180	3423	60.5	72.3	85.6	93.2	6.8

CGM glucose ranges (mg/dL)	Number of paired CGM-YSI	Percent of CGM within 15/15% of YSI	Percent of CGM within 20/20% of YSI	Percent of CGM within 30/30% of YSI	Percent of CGM within 40/40% of YSI	Percent of CGM greater than 40/40% of YSI
>180-300	1810	73.6	83.0	93.6	97.5	2.5
>300-350	342	83.6	90.6	98.0	100.0	0.0
>350-400	127	72.4	86.6	97.6	100.0	0.0

* For CGM reference range ≤ 80 mg/dL, agreement was based on 15/20/30/40 mg/dL.

Tables 9 and 10. The number and percentage of YSI values collected when CGM readings displayed 'Low' (less than 40 mg/dL) and 'High' (greater than 400 mg/dL); Calibrating three to four times a day, Abdomen insertion site.

YSI mg/dL							
CGM readings	CGM-YSI pairs	<55	<60	<70	<80	>80	Total
'LOW'	Cumulative, n	8	13	22	23	0	23
'LOW'	Cumulative %	35%	57%	96%	100%	0%	

YSI mg/dL							
CGM readings	CGM-YSI pairs	>340	>320	>280	>240	<240	Total
'HIGH'	Cumulative, n	9	10	11	12	0	12
'HIGH'	Cumulative %	75%	83%	92%	100%	0%	

Tables 11 and 12. The number and percentage of YSI values collected when CGM readings displayed 'Low' (less than 40 mg/dL) and 'High' (greater than 400 mg/dL); Calibrating every 12 hours, Abdomen insertion site.

YSI mg/dL							
CGM readings	CGM-YSI pairs	<55	<60	<70	<80	>80	Total
'LOW'	Cumulative, n	16	23	27	45	0	45
'LOW'	Cumulative %	36%	51%	60%	100%	0%	

YSI mg/dL							
CGM readings	CGM-YSI pairs	>340	>320	>280	>240	<240	Total
'HIGH'	Cumulative, n	70	80	89	90	0	90
'HIGH'	Cumulative %	78%	89%	99%	100%	0%	

The following tables show the percentage of concurring CGM readings with YSI reference values. With ideal performance the CGM readings would match the YSI values, therefore the shaded boxes would ideally be 100 percent.

Table 13. The concurrence of YSI values and CGM readings using YSI glucose ranges; Calibrating three to four times a day, Abdomen insertion site.

	Percent of matched pairs-in each CGM glucose range for each YSI glucose range CGM (mg/dL)											
YSI glucose ranges (mg/dL)	Number of paired CGM-YSI	<40	>=40-60	>60-80	>80-120	>120-160	>160-200	200-250	>250-300	>300-350	>350-400	>400
A) <40	3	0.0%	33.3%	66.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
B) >=40-60	631	2.1%	49.0%	43.9%	4.3%	0.8%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
C) >60-80	1429	0.7%	19.3%	54.3%	23.9%	1.7%	0.1%	0.0%	0.0%	0.0%	0.0%	0.0%
D) >80-120	1429	0.0%	2.0%	11.6%	67.2%	18.3%	0.8%	0.1%	0.0%	0.0%	0.0%	0.0%
E) >120-160	1271	0.0%	0.3%	1.3%	14.5%	64.5%	17.7%	1.4%	0.2%	0.0%	0.0%	0.0%
F) >160-200	981	0.0%	0.1%	0.1%	2.2%	21.4%	57.7%	17.1%	1.0%	0.3%	0.0%	0.0%
G) >200-250	689	0.0%	0.1%	0.0%	2.2%	4.1%	24.4%	54.6%	12.9%	1.7%	0.0%	0.0%
H) >250-300	520	0.0%	0.0%	0.2%	0.6%	0.6%	3.7%	32.9%	45.6%	12.9%	3.5%	0.2%
I) >300-350	328	0.0%	0.0%	0.0%	0.0%	0.3%	1.8%	11.0%	33.8%	38.7%	13.4%	0.9%
J) >350-400	142	0.0%	0.0%	0.0%	0.7%	1.4%	1.4%	3.5%	19.7%	36.6%	33.1%	3.5%
K) >400	27	0.0%	0.0%	0.0%	3.7%	3.7%	0.0%	18.5%	14.8%	18.5%	29.6%	11.1%

Table 14. The concurrence of YSI values and CGM readings using YSI glucose ranges; Calibrating every 12 hours, Abdomen insertion site.

	Percent of matched pairs-in each CGM glucose range for each YSI glucose range CGM (mg/dL)											
YSI glucose ranges (mg/dL)	Number of paired CGM-YSI	<40	>=40-60	>60-80	>80-120	>120-160	>160-200	200-250	>250-300	>300-350	>350-400	>400
A) <40	3	0.0%	33.3%	66.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
B) >=40-60	538	4.3%	52.4%	33.3%	10.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
C) >60-80	1371	1.6%	30.0%	45.3%	22.8%	0.4%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
D) >80-120	1300	0.0%	3.2%	11.6%	60.0%	23.5%	1.7%	0.0%	0.0%	0.0%	0.0%	0.0%
E) >120-160	1327	0.0%	0.5%	1.3%	16.1%	61.4%	18.8%	2.0%	0.0%	0.0%	0.0%	0.0%
F) >160-200	1002	0.0%	0.3%	0.1%	3.7%	27.7%	48.2%	18.3%	1.6%	0.1%	0.0%	0.0%
G) >200-250	839	0.0%	0.0%	0.2%	3.1%	6.8%	20.3%	52.0%	15.6%	1.8%	0.2%	0.0%
H) >250-300	589	0.0%	0.2%	0.2%	0.8%	1.2%	5.1%	23.3%	49.6%	16.8%	2.2%	0.7%
I) >300-350	369	0.0%	1.1%	0.0%	0.8%	1.4%	2.4%	6.8%	23.0%	45.0%	13.3%	6.2%

	Percent of matched pairs-in each CGM glucose range for each YSI glucose range CGM (mg/dL)											
YSI glucose ranges (mg/dL)	Number of paired CGM-YSI	<40	>=40-60	>60-80	>80-120	>120-160	>160-200	200-250	>250-300	>300-350	>350-400	>400
J) >350-400	174	0.0%	0.6%	0.6%	0.0%	0.6%	1.1%	5.7%	9.2%	31.6%	26.4%	24.1%
K) >400	55	0.0%	7.3%	0.0%	0.0%	1.8%	1.8%	1.8%	7.3%	10.9%	30.9%	38.2%

Table 15. The concurrence of CGM readings and YSI values using CGM glucose ranges; Calibrating three to four times a day, Abdomen insertion site.

	Percent of matched pairs-in each YSI glucose range for each sensor glucose range YSI (mg/dL)											
CGM glucose ranges (mg/dL)	Number of paired CGM-YSI	<40	>=40-60	>60-80	>80-120	>120-160	>160-200	200-250	>250-300	>300-350	>350-400	>400
A) <40	23	0.0%	56.5%	43.5%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
B) >=40-60	620	0.2%	49.8%	44.5%	4.5%	0.6%	0.2%	0.2%	0.0%	0.0%	0.0%	0.0%
C) >60-80	1240	0.2%	22.3%	62.6%	13.4%	1.4%	0.1%	0.0%	0.1%	0.0%	0.0%	0.0%
D) >80-120	1555	0.0%	1.7%	22.0%	61.7%	11.8%	1.4%	1.0%	0.2%	0.0%	0.1%	0.1%
E) >120-160	1355	0.0%	0.4%	1.8%	19.3%	60.5%	15.5%	2.1%	0.2%	0.1%	0.1%	0.1%
F) >160-200	999	0.0%	0.0%	0.1%	1.2%	22.5%	56.7%	16.8%	1.9%	0.6%	0.2%	0.0%
G) >200-250	781	0.0%	0.0%	0.0%	0.3%	2.3%	21.5%	48.1%	21.9%	4.6%	0.6%	0.6%
H) >250-300	482	0.0%	0.0%	0.0%	0.0%	0.6%	2.1%	18.5%	49.2%	23.0%	5.8%	0.8%
I) >300-350	266	0.0%	0.0%	0.0%	0.0%	0.0%	1.1%	4.5%	25.2%	47.7%	19.5%	1.9%
J) >350-400	117	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	15.4%	37.6%	40.2%	6.8%
K) >400	12	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	8.3%	25.0%	41.7%	25.0%

Table 16. The concurrence of CGM readings and YSI values using CGM glucose ranges; Calibrating every 12 hours, Abdomen insertion site.

	Percent of matched pairs-in each YSI glucose range for each sensor glucose range YSI (mg/dL)											
CGM glucose ranges (mg/dL)	Number of paired CGM-YSI	<40	>=40-60	>60-80	>80-120	>120-160	>160-200	200-250	>250-300	>300-350	>350-400	>400
A) <40	45	0.0%	51.1%	48.9%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
B) >=40-60	755	0.1%	37.4%	54.4%	5.6%	0.8%	0.4%	0.0%	0.1%	0.5%	0.1%	0.5%

CGM glucose ranges (mg/dL)	Percent of matched pairs-in each YSI glucose range for each sensor glucose range YSI (mg/dL)											
	Number of paired CGM-YSI	<40	>=40-60	>60-80	>80-120	>120-160	>160-200	200-250	>250-300	>300-350	>350-400	>400
C) >60-80	975	0.2%	18.4%	63.7%	15.5%	1.7%	0.1%	0.2%	0.1%	0.0%	0.1%	0.0%
D) >80-120	1430	0.0%	3.8%	21.8%	54.5%	14.9%	2.6%	1.8%	0.4%	0.2%	0.0%	0.0%
E) >120-160	1474	0.0%	0.0%	0.3%	20.7%	55.3%	18.9%	3.9%	0.5%	0.3%	0.1%	0.1%
F) >160-200	966	0.0%	0.0%	0.0%	2.3%	25.8%	50.0%	17.6%	3.1%	0.9%	0.2%	0.1%
G) >200-250	819	0.0%	0.0%	0.0%	0.0%	3.3%	22.3%	53.2%	16.7%	3.1%	1.2%	0.1%
H) >250-300	544	0.0%	0.0%	0.0%	0.0%	0.0%	2.9%	24.1%	53.7%	15.6%	2.9%	0.7%
I) >300-350	342	0.0%	0.0%	0.0%	0.0%	0.0%	0.3%	4.4%	28.9%	48.5%	16.1%	1.8%
J) >350-400	127	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	1.6%	10.2%	38.6%	36.2%	13.4%
K) >400	90	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	4.4%	25.6%	46.7%	23.3%

Sensor life

After calibration, 82.3% of sensors operated more than five days and up to the full six days of wear (120–144 hours).

Safety

There were no moderate or severe device-related or procedure-related adverse events, device-related or procedure-related serious adverse events, or unanticipated adverse device effects after six days of use.

Alert performance

Event analysis

The high and low limit alerts let the user know when the sensor glucose is at or above the high limit/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 or low limit setting. The earliest warning is 30 minutes before reaching a high or low limit, but users can reduce the amount of warning down to 5 minutes. 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.

Hypoglycemic alert performance within ± 30 minutes of event, by number of daily calibrations

The following tables show the percent of YSI hypoglycemic events detected by a CGM alert and the percent of CGM alerts for which the YSI value did not reach the CGM hypoglycemic alert setting (false alerts). For example, if the CGM Alert Setting is at 70 mg/dL, 89.9% of YSI hypoglycemic events below 70 mg/dL were detected within 30 minutes of the event, and for 27.4% the CGM alerts there was no YSI value below 70 mg/dL within 30 minutes of the alert.

Table 17. Both Threshold and Predictive alerts turned-on, Calibrating three to four times a day, Abdomen insertion site.

CGM alert setting (mg/dL)	Hypoglycemic events correctly detected (%)	Hypoglycemic events not detected (%)	Alerts verified by hypoglycemic events (%)	False alerts (%)
	± 30 Min	± 30 Min	± 30 Min	± 30 Min
60	84.7	15.3	55.4	44.6
70	89.9	10.1	72.6	27.4
80	96.7	3.3	77.9	22.1
90	98.3	1.7	81.6	18.4

Table 18. Only Threshold alerts turned-on, Calibrating three to four times a day, Abdomen insertion site.

CGM alert setting (mg/dL)	Hypoglycemic events correctly detected (%)	Hypoglycemic events not detected (%)	Alerts verified by hypoglycemic events (%)	False alerts (%)
	± 30 Min	± 30 Min	± 30 Min	± 30 Min
60	63.1	36.9	67.5	32.5
70	79.5	20.5	81.9	18.1
80	91.0	9.0	85.4	14.6
90	95.4	4.6	89.3	10.7

Table 19. Only Predictive alerts turned-on, Calibrating three to four times a day, Abdomen insertion site.

CGM alert setting (mg/dL)	Hypoglycemic events correctly detected (%)	Hypoglycemic events not detected (%)	Alerts verified by hypoglycemic events (%)	False alerts (%)
	± 30 Min	± 30 Min	± 30 Min	± 30 Min
60	82.9	17.1	58.6	41.4
70	88.3	11.7	75.2	24.8
80	95.6	4.4	79.8	20.2

CGM alert setting (mg/dL)	Hypoglycemic events correctly detected (%)	Hypoglycemic events not detected (%)	Alerts verified by hypoglycemic events (%)	False alerts (%)
	±30 Min	±30 Min	±30 Min	±30 Min
90	97.5	2.5	83.0	17.0

Table 20. Both Threshold and Predictive alerts turned-on, Calibrating every 12 hours, Abdomen insertion site.

CGM alert setting (mg/dL)	Hypoglycemic events correctly detected (%)	Hypoglycemic events not detected (%)	Alerts verified by hypoglycemic events (%)	False alerts (%)
	±30 Min	±30 Min	±30 Min	±30 Min
60	82.8	17.2	43.3	56.7
70	90.6	9.4	66.0	34.0
80	95.1	4.9	76.3	23.7
90	96.8	3.2	80.4	19.6

Table 21. Only Threshold alerts turned-on, Calibrating every 12 hours, Abdomen insertion site.

CGM alert setting (mg/dL)	Hypoglycemic events correctly detected (%)	Hypoglycemic events not detected (%)	Alerts verified by hypoglycemic events (%)	False alerts (%)
	±30 Min	±30 Min	±30 Min	±30 Min
60	70.2	29.8	51.4	48.6
70	83.1	16.9	74.5	25.5
80	89.8	10.2	83.5	16.5
90	94.9	5.1	87.6	12.4

Table 22. Only Predictive alerts turned-on, Calibrating every 12 hours, Abdomen insertion site.

CGM alert setting (mg/dL)	Hypoglycemic events correctly detected (%)	Hypoglycemic events not detected (%)	Alerts verified by hypoglycemic events (%)	False alerts (%)
	±30 Min	±30 Min	±30 Min	±30 Min
60	81.3	18.7	46.8	53.2
70	90.1	9.9	69.4	30.6
80	94.5	5.5	78.6	21.4
90	96.1	3.9	81.9	18.1

Hyperglycemic alert performance within ± 30 minutes of event, by number of daily calibrations

The following tables show the percent of YSI hyperglycemic events detected by and the percent of CGM alerts for which the YSI value did not reach the CGM hyperglycemic alert setting (false alerts). For example, if the CGM Alert Setting is at 250 mg/dL, 94.6% of YSI hyperglycemic events greater than 250 mg/dL were detected within 30 minutes of the event, and for 14.5% the CGM alerts there was no YSI value above 250 mg/dL within 30 minutes of the alert (false alerts).

Table 23. Both Threshold and Predictive alerts turned-on, Calibrating three to four times a day, Abdomen insertion site.

CGM alert setting (mg/dL)	Hyperglycemic events correctly detected (%)	Hyperglycemic events not detected (%)	Alerts verified by hyperglycemic events (%)	False alerts (%)
	± 30 Min	± 30 Min	± 30 Min	± 30 Min
300	88.5	11.5	73.5	26.5
250	94.6	5.4	85.5	14.5
220	95.1	4.9	84.5	15.5
180	97.5	2.5	88.3	11.7

Table 24. Only Threshold alerts turned-on, Calibrating three to four times a day, Abdomen insertion site.

CGM alert setting (mg/dL)	Hyperglycemic events correctly detected (%)	Hyperglycemic events not detected (%)	Alerts verified by hyperglycemic events (%)	False alerts (%)
	± 30 Min	± 30 Min	± 30 Min	± 30 Min
300	77.0	23.0	87.5	12.5
250	87.4	12.6	93.2	6.8
220	92.4	7.6	91.5	8.5
180	94.1	5.9	94.9	5.1

Table 25. Only Predictive alerts turned-on, Calibrating three to four times a day, Abdomen insertion site.

CGM alert setting (mg/dL)	Hyperglycemic events correctly detected (%)	Hyperglycemic events not detected (%)	Alerts verified by hyperglycemic events (%)	False alerts (%)
	± 30 Min	± 30 Min	± 30 Min	± 30 Min
300	87.7	12.3	74.1	25.9
250	93.2	6.8	85.6	14.4
220	94.5	5.5	85.1	14.9
180	96.7	3.3	88.8	11.2

Table 26. Both Threshold and Predictive alerts turned-on, Calibrating every 12 hours, Abdomen insertion site.

CGM alert setting (mg/dL)	Hyperglycemic events correctly detected (%)	Hyperglycemic events not detected (%)	Alerts verified by hyperglycemic events (%)	False alerts (%)
	±30 Min	±30 Min	±30 Min	±30 Min
300	89.1	10.9	73.2	26.8
250	94.5	5.5	84.5	15.5
220	94.3	5.7	85.2	14.8
180	94.6	5.4	88.6	11.4

Table 27. Only Threshold alerts turned-on, Calibrating every 12 hours, Abdomen insertion site.

CGM alert setting (mg/dL)	Hyperglycemic events correctly detected (%)	Hyperglycemic events not detected (%)	Alerts verified by hyperglycemic events (%)	False alerts (%)
	±30 Min	±30 Min	±30 Min	±30 Min
300	82.0	18.0	84.7	15.3
250	87.9	12.1	92.3	7.7
220	90.1	9.9	92.8	7.2
180	91.1	8.9	94.6	5.4

Table 28. Only Predictive alerts turned-on, Calibrating every 12 hours, Abdomen insertion site.

CGM alert setting (mg/dL)	Hyperglycemic events correctly detected (%)	Hyperglycemic events not detected (%)	Alerts verified by hyperglycemic events (%)	False alerts (%)
	±30 Min	±30 Min	±30 Min	±30 Min
300	88.2	11.8	75	25
250	93.8	6.2	85.9	14.1
220	93.7	6.3	86.2	13.8
180	93.7	6.3	89.2	10.8

Hypoglycemic alert performance within ± 15 minutes of event, by number of daily calibrations

Table 29. Both Threshold and Predictive alerts turned-on, Calibrating three to four times a day, Abdomen insertion site.

CGM alert setting (mg/dL)	Hypoglycemic events correctly detected (%)	Hypoglycemic events not detected (%)	Alerts verified by hypoglycemic events (%)	False alerts (%)
	± 15 Min	± 15 Min	± 15 Min	± 15 Min
60	73.9	26.1	38.9	61.1
70	83.2	16.8	58.6	41.4
80	93.3	6.7	67.0	33.0
90	95.6	4.4	70.2	29.8

Table 30. Only Threshold alerts turned-on, Calibrating three to four times a day, Abdomen insertion site.

CGM alert setting (mg/dL)	Hypoglycemic events correctly detected (%)	Hypoglycemic events not detected (%)	Alerts verified by hypoglycemic events (%)	False alerts (%)
	± 15 Min	± 15 Min	± 15 Min	± 15 Min
60	58.4	41.6	59.6	40.4
70	73.8	26.2	76.4	23.6
80	87.3	12.7	81.9	18.1
90	92.8	7.2	85.1	14.9

Table 31. Only Predictive alerts turned-on, Calibrating three to four times a day, Abdomen insertion site.

CGM alert setting (mg/dL)	Hypoglycemic events correctly detected (%)	Hypoglycemic events not detected (%)	Alerts verified by hypoglycemic events (%)	False alerts (%)
	± 15 Min	± 15 Min	± 15 Min	± 15 Min
60	69.2	30.8	43.4	56.6
70	78.9	21.1	61.9	38.1
80	89.6	10.4	69.6	30.4
90	92.6	7.4	72.9	27.1

Table 32. Both Threshold and Predictive alerts turned-on, Calibrating every 12 hours, Abdomen insertion site.

CGM alert setting (mg/dL)	Hypoglycemic events correctly detected (%)	Hypoglycemic events not detected (%)	Alerts verified by hypoglycemic events (%)	False alerts (%)
	±15 Min	±15 Min	±15 Min	±15 Min
60	76.2	23.8	29.8	70.2
70	85.7	14.3	52.1	47.9
80	92.0	8.0	64.0	36.0
90	94.9	5.1	69.7	30.3

Table 33. Only Threshold alerts turned-on, Calibrating every 12 hours, Abdomen insertion site.

CGM alert setting (mg/dL)	Hypoglycemic events correctly detected (%)	Hypoglycemic events not detected (%)	Alerts verified by hypoglycemic events (%)	False alerts (%)
	±15 Min	±15 Min	±15 Min	±15 Min
60	66.2	33.8	44.9	55.1
70	78.0	22.0	68.0	32.0
80	87.3	12.7	78.8	21.2
90	92.7	7.3	83.3	16.7

Table 34. Only Predictive alerts turned-on, Calibrating every 12 hours, Abdomen insertion site.

CGM alert setting (mg/dL)	Hypoglycemic events correctly detected (%)	Hypoglycemic events not detected (%)	Alerts verified by hypoglycemic events (%)	False alerts (%)
	±15 Min	±15 Min	±15 Min	±15 Min
60	71.6	28.4	34.5	65.5
70	81.7	18.3	56.8	43.2
80	88.0	12.0	67.5	32.5
90	91.5	8.5	72.8	27.2

Hyperglycemic alert performance within ± 15 minutes of event, by number of daily calibrations

Table 35. Both Threshold and Predictive alerts turned-on, Calibrating three to four times a day, Abdomen insertion site.

CGM alert setting (mg/dL)	Hyperglycemic events correctly detected (%)	Hyperglycemic events not detected (%)	Alerts verified by hyperglycemic events (%)	False alerts (%)
	± 15 Min	± 15 Min	± 15 Min	± 15 Min
300	82.6	17.4	63.2	36.8
250	90.9	9.1	79.0	21.0
220	93.0	7.0	79.6	20.4
180	95.0	5.0	83.1	16.9

Table 36. Only Threshold alerts turned-on, Calibrating three to four times a day, Abdomen insertion site.

CGM alert setting (mg/dL)	Hyperglycemic events correctly detected (%)	Hyperglycemic events not detected (%)	Alerts verified by hyperglycemic events (%)	False alerts (%)
	± 15 Min	± 15 Min	± 15 Min	± 15 Min
300	70.9	29.1	80.3	19.7
250	83.3	16.7	89.9	10.1
220	89.4	10.6	88.6	11.4
180	91.6	8.4	91.8	8.2

Table 37. Only Predictive alerts turned-on, Calibrating three to four times a day, Abdomen insertion site.

CGM alert setting (mg/dL)	Hyperglycemic events correctly detected (%)	Hyperglycemic events not detected (%)	Alerts verified by hyperglycemic events (%)	False alerts (%)
	± 15 Min	± 15 Min	± 15 Min	± 15 Min
300	79.5	20.5	65.6	34.4
250	87.4	12.6	80.4	19.6
220	90.2	9.8	81.3	18.7
180	92	8	84.9	15.1

Table 38. Both Threshold and Predictive alerts turned-on, Calibrating every 12 hours, Abdomen insertion site.

CGM alert setting (mg/dL)	Hyperglycemic events correctly detected (%)	Hyperglycemic events not detected (%)	Alerts verified by hyperglycemic events (%)	False alerts (%)
	±15 Min	±15 Min	±15 Min	±15 Min
300	85.6	14.4	65.6	34.4
250	91.1	8.9	78.3	21.7
220	91.6	8.4	80.4	19.6
180	92.0	8.0	83.7	16.3

Table 39. Only Threshold alerts turned-on, Calibrating every 12 hours, Abdomen insertion site.

CGM alert setting (mg/dL)	Hyperglycemic events correctly detected (%)	Hyperglycemic events not detected (%)	Alerts verified by hyperglycemic events (%)	False alerts (%)
	±15 Min	±15 Min	±15 Min	±15 Min
300	77.8	22.2	79.4	20.6
250	84.8	15.2	88.4	11.6
220	87.6	12.4	89.9	10.1
180	88.6	11.4	91.8	8.2

Table 40. Only Predictive alerts turned-on, Calibrating every 12 hours, Abdomen insertion site.

CGM alert setting (mg/dL)	Hyperglycemic events correctly detected (%)	Hyperglycemic events not detected (%)	Alerts verified by hyperglycemic events (%)	False alerts (%)
	±15 Min	±15 Min	±15 Min	±15 Min
300	82.8	17.2	68.6	31.4
250	88.9	11.1	81.2	18.8
220	89.6	10.4	82.4	17.6
180	89.3	10.7	85.7	14.3

Table 41. Hypoglycemic alert performance within ±30 minutes of event; Only Threshold alerts turned-on (Threshold-only).

Sensor (during the trial)	Alert level (mg/dL)	Hypoglycemic events correctly detected (%)	Hypoglycemic events not detected (%)	Alerts verified by hypoglycemic events (%)	False alerts (%)
Sof-Sensor²	70	68.8	31.2	82.6	17.4
Enlite Sensor¹	70	79.5	20.5	81.9	18.1

Table 42. Hypoglycemic alert performance within ± 15 minutes of event; Only Threshold alerts turned-on (Threshold-only).

Sensor (during the trial)	Alert level (mg/dL)	Hypoglycemic events correctly detected (%)	Hypoglycemic events not detected (%)	Alerts verified by hypoglycemic events (%)	False alerts (%)
Sof-Sensor ²	70	64.2	35.8	76.4	23.6
Enlite Sensor ¹	70	73.8	26.2	76.4	23.6

Comparisons of the Enlite and Sof-sensor are made because the reference study² uses the Sof-sensor and this system uses the Enlite sensor.

The tables in this section show: ^{1, 2}

- The percent of hypoglycemic events correctly detected tells you how often you can expect the device to turn off when your actual blood glucose is below 70 mg/dL.
- The percent of hypoglycemic events not detected tells you how often you can expect the device **not** to turn off if your actual blood glucose is below 70 mg/dL.
- The percent of alerts verified by hypoglycemic events tells you if your system suspends, how often you can expect your blood glucose to actually be below 70 mg/dL.
- The percent of false alerts tells you if your system suspends, how often you can expect your blood glucose to be **above** 70 mg/dL.

Please be aware that sensor accuracy may be less on the first day of use and this could affect Threshold Suspend performance.

Table 43. Agreement (%) of CGM-YSI paired points within YSI glucose range on Frequent Sample Testing (FST) 1, Abdomen insertion site, calibrating three to four times a day.

YSI glucose ranges (mg/dL)	Number of paired CGM-YSI	Percent of CGM within 15/15% of YSI	Percent of CGM within 20/20% of YSI	Percent of CGM within 30/30% of YSI	Percent of CGM within 40/40% of YSI	Percent of CGM greater than 40/40% of YSI
Overall	2525	66.6	78.2	90.4	95.8	4.2
<40*	2	0	0	0	50	50
≥ 40 -60*	235	82.6	87.7	93.6	97	3
>60-80*	558	64.2	78.3	92.7	95.5	4.5
>80-180	1019	62.6	73.5	87.3	95	5
>180-300	566	67.8	78.6	91.2	96.8	3.2
>300-350	89	76.4	93.3	94.4	96.6	3.4

- 1 Medtronic Inc., A Performance Evaluation of the Enlite® Glucose Sensor to Support a Full 144 hours (6 Days) of Use, CER247/Z25/C, May 2012.
- 2 Medtronic Inc., An In-clinic, Randomized, Cross-Over Study to Assess the Efficacy of the Low Glucose Suspend (LGS) Feature in the MiniMed Paradigm® X54 System with Hypoglycemic Induction from Exercise, CER235/Z25/A, November 2011.

YSI glucose ranges (mg/dL)	Number of paired CGM-YSI	Percent of CGM within 15/15% of YSI	Percent of CGM within 20/20% of YSI	Percent of CGM within 30/30% of YSI	Percent of CGM within 40/40% of YSI	Percent of CGM greater than 40/40% of YSI
>350-400	54	70.4	96.3	100	100	0
>400	2	100	100	100	100	0

* For YSI reference range ≤ 80 mg/dL, agreement was based on 15/20/30/40 mg/dL.

Note: CGM Readings are within 40-400 mg/dL.

Table 44. Agreement (%) of CGM-YSI paired points within YSI glucose range on Frequent Sample Testing (FST) 3, Abdomen insertion site, calibrating three to four times a day.

YSI glucose ranges (mg/dL)	Number of paired CGM-YSI	Percent of CGM within 15/15% of YSI	Percent of CGM within 20/20% of YSI	Percent of CGM within 30/30% of YSI	Percent of CGM within 40/40% of YSI	Percent of CGM greater than 40/40% of YSI
Overall	2493	77.9	87.3	94.9	98	2
<40*	1	100	100	100	100	0
≥ 40 -60*	198	92.4	94.9	99	100	0
>60-80*	467	87.4	92.9	96.1	98.1	1.9
>80-180	1148	71.9	81.3	92	96.9	3.1
>180-300	521	77.7	91.9	98.3	99.4	0.6
>300-350	111	74.8	91	96.4	99.1	0.9
>350-400	40	80	85	97.5	100	0
>400	7	85.7	100	100	100	0

* For YSI reference range ≤ 80 mg/dL, agreement was based on 15/20/30/40 mg/dL.

Note: CGM Readings are within 40-400 mg/dL.

Table 45. Agreement (%) of CGM-YSI paired points within YSI glucose range on Frequent Sample Testing (FST) 6, Abdomen insertion site, calibrating three to four times a day.

YSI glucose ranges (mg/dL)	Number of paired CGM-YSI	Percent of CGM within 15/15% of YSI	Percent of CGM within 20/20% of YSI	Percent of CGM within 30/30% of YSI	Percent of CGM within 40/40% of YSI	Percent of CGM greater than 40/40% of YSI
Overall	2397	73.8	85.8	94.2	97.3	2.7
≥ 40 -60*	185	62.2	91.4	96.2	96.8	3.2
>60-80*	394	80.2	91.9	96.4	97.5	2.5
>80-180	1074	77.7	87.1	95.9	98.7	1.3
>180-300	561	72.2	84.7	93	96.8	3.2
>300-350	125	64.8	73.6	92.8	98.4	1.6

YSI glucose ranges (mg/dL)	Number of paired CGM-YSI	Percent of CGM within 15/15% of YSI	Percent of CGM within 20/20% of YSI	Percent of CGM within 30/30% of YSI	Percent of CGM within 40/40% of YSI	Percent of CGM greater than 40/40% of YSI
>350-400	43	39.5	53.5	67.4	83.7	16.3
>400	15	0	6.7	26.7	46.7	53.3

* For YSI reference range ≤ 80 mg/dL, agreement was based on 15/20/30/40 mg/dL.

Note: CGM Readings are within 40-400 mg/dL.

Table 46. Agreement (%) of CGM-YSI paired points within YSI glucose range on Frequent Sample Testing (FST) 1, Abdomen insertion site, calibrating every 12 hours.

YSI glucose ranges (mg/dL)	Number of paired CGM-YSI	Percent of CGM within 15/15% of YSI	Percent of CGM within 20/20% of YSI	Percent of CGM within 30/30% of YSI	Percent of CGM within 40/40% of YSI	Percent of CGM greater than 40/40% of YSI
Overall	2553	64.9	77.9	90.9	96.9	3.1
<40*	2	0	0	50	100	0
≥ 40 -60*	196	67.3	80.6	91.3	98	2
>60-80*	552	67.9	81.7	91.1	98.6	1.4
>80-180	963	58.7	71.4	88.1	94.7	5.3
>180-300	680	68.1	81.2	92.8	97.8	2.2
>300-350	107	76.6	86.9	99.1	99.1	0.9
>350-400	43	83.7	95.3	97.7	100	0
>400	10	30	50	100	100	0

* For YSI reference range ≤ 80 mg/dL, agreement was based on 15/20/30/40 mg/dL.

Note: CGM Readings are within 40-400 mg/dL.

Table 47. Agreement (%) of CGM-YSI paired points within YSI glucose range on Frequent Sample Testing (FST) 3, Abdomen insertion site, calibrating every 12 hours.

YSI glucose ranges (mg/dL)	Number of paired CGM-YSI	Percent of CGM within 15/15% of YSI	Percent of CGM within 20/20% of YSI	Percent of CGM within 30/30% of YSI	Percent of CGM within 40/40% of YSI	Percent of CGM greater than 40/40% of YSI
Overall	2565	72.4	83.2	93.6	97.9	2.1
<40*	1	100	100	100	100	0
≥ 40 -60*	177	86.4	94.4	98.3	100	0
>60-80*	513	74.5	85.2	97.3	99.8	0.2
>80-180	1129	68.6	80.2	91.3	97.3	2.7
>180-300	602	72.8	83.7	94.5	97.3	2.7
>300-350	103	78.6	87.4	93.2	98.1	1.9

YSI glucose ranges (mg/dL)	Number of paired CGM-YSI	Percent of CGM within 15/15% of YSI	Percent of CGM within 20/20% of YSI	Percent of CGM within 30/30% of YSI	Percent of CGM within 40/40% of YSI	Percent of CGM greater than 40/40% of YSI
>350-400	33	72.7	75.8	81.8	93.9	6.1
>400	7	57.1	57.1	57.1	85.7	14.3

* For YSI reference range ≤ 80 mg/dL, agreement was based on 15/20/30/40 mg/dL.

Note: CGM Readings are within 40-400 mg/dL.

Table 48. Agreement (%) of CGM-YSI paired points within YSI glucose range on Frequent Sample Testing (FST) 6, Abdomen insertion site, calibrating every 12 hours.

YSI glucose ranges (mg/dL)	Number of paired CGM-YSI	Percent of CGM within 15/15% of YSI	Percent of CGM within 20/20% of YSI	Percent of CGM within 30/30% of YSI	Percent of CGM within 40/40% of YSI	Percent of CGM greater than 40/40% of YSI
Overall	2314	66.8	75.6	85.7	93.9	6.1
<40*	142	76.1	82.4	86.6	99.3	0.7
≥ 40 -60*	284	68.3	79.2	88	97.5	2.5
>60-80*	1066	66.7	77.3	87.3	95.7	4.3
>80-180	613	65.9	71.6	83	90.9	9.1
>300-350	136	64	70.6	83.1	87.5	12.5
>350-400	56	62.5	69.6	83.9	87.5	12.5
>400	17	35.3	52.9	52.9	64.7	35.3

* For YSI reference range ≤ 80 mg/dL, agreement was based on 15/20/30/40 mg/dL.

Note: CGM Readings are within 40-400 mg/dL.

Table 49. Agreement (%) of CGM-YSI paired points within CGM glucose range on Frequent Sample Testing (FST) 1, Abdomen insertion site, calibrating three to four times a day.

CGM glucose ranges (mg/dL)	Number of paired CGM-YSI	Percent of CGM within 15/15% of YSI	Percent of CGM within 20/20% of YSI	Percent of CGM within 30/30% of YSI	Percent of CGM within 40/40% of YSI	Percent of CGM greater than 40/40% of YSI
Overall	2525	65.5	77.5	91.1	95.9	4.1
≥ 40 -60*	295	65.8	79.7	91.2	96.3	3.7
>60-80*	397	81.1	87.2	93.2	95.2	4.8
>80-180	1164	57.6	70.8	88	94.4	5.6
>180-300	529	69.8	82.4	95.1	98.7	1.3
>300-350	82	65.9	78	92.7	98.8	1.2
>350-400	58	77.6	91.4	100	100	0

* For CGM reference range ≤ 80 mg/dL, agreement was based on 15/20/30/40 mg/dL.

Table 50. Agreement (%) of CGM-YSI paired points within CGM glucose range on Frequent Sample Testing (FST) 3, Abdomen insertion site, calibrating three to four times a day.

CGM glucose ranges (mg/dL)	Number of paired CGM-YSI	Percent of CGM within 15/15% of YSI	Percent of CGM within 20/20% of YSI	Percent of CGM within 30/30% of YSI	Percent of CGM within 40/40% of YSI	Percent of CGM greater than 40/40% of YSI
Overall	2493	78.8	87.7	95.6	98.2	1.8
≥40-60*	211	95.7	97.2	98.6	99.1	0.9
>60-80*	432	86.8	91	94.9	96.1	3.9
>80-180	1165	74.4	85.1	94.8	98.1	1.9
>180-300	541	72.6	85	95.6	99.1	0.9
>300-350	114	89.5	94.7	100	100	0
>350-400	30	83.3	100	100	100	0

* For CGM reference range ≤ 80 mg/dL, agreement was based on 15/20/30/40 mg/dL.

Table 51. Agreement (%) of CGM-YSI paired points within CGM glucose range on Frequent Sample Testing (FST) 6, Abdomen insertion site, calibrating three to four times a day.

CGM glucose ranges (mg/dL)	Number of paired CGM-YSI	Percent of CGM within 15/15% of YSI	Percent of CGM within 20/20% of YSI	Percent of CGM within 30/30% of YSI	Percent of CGM within 40/40% of YSI	Percent of CGM greater than 40/40% of YSI
Overall	2397	73.3	84.4	92.2	95.1	4.9
≥40-60*	114	87.7	91.2	96.5	100	0
>60-80*	411	77.6	94.4	99.5	99.8	0.2
>80-180	1168	72.9	82.8	90.9	93.3	6.7
>180-300	605	68.6	78.5	88.3	93.9	6.1
>300-350	70	72.9	88.6	95.7	98.6	1.4
>350-400	29	72.4	89.7	100	100	0

* For CGM reference range ≤ 80 mg/dL, agreement was based on 15/20/30/40 mg/dL.

Table 52. Agreement (%) of CGM-YSI paired points within CGM glucose range on Frequent Sample Testing (FST) 1, Abdomen insertion site, calibrating every 12 hours.

CGM glucose ranges (mg/dL)	Number of paired CGM-YSI	Percent of CGM within 15/15% of YSI	Percent of CGM within 20/20% of YSI	Percent of CGM within 30/30% of YSI	Percent of CGM within 40/40% of YSI	Percent of CGM greater than 40/40% of YSI
Overall	2553	63.8	77.2	92	97.8	2.2
≥40-60*	293	62.1	78.2	91.5	98.3	1.7
>60-80*	392	77.8	86.5	96.2	98.2	1.8

CGM glucose ranges (mg/dL)	Number of paired CGM-YSI	Percent of CGM within 15/15% of YSI	Percent of CGM within 20/20% of YSI	Percent of CGM within 30/30% of YSI	Percent of CGM within 40/40% of YSI	Percent of CGM greater than 40/40% of YSI
>80-180	1062	53.8	69.2	88.1	96.5	3.5
>180-300	639	70.9	82.9	95.3	99.1	0.9
>300-350	127	74.8	85.8	94.5	100	0
>350-400	40	55	72.5	95	100	0

*For CGM reference range ≤ 80 mg/dL, agreement was based on 15/20/30/40 mg/dL.

Table 53. Agreement (%) of CGM-YSI paired points within CGM glucose range on Frequent Sample Testing (FST) 3, Abdomen insertion site, calibrating every 12 hours.

CGM glucose ranges (mg/dL)	Number of paired CGM-YSI	Percent of CGM within 15/15% of YSI	Percent of CGM within 20/20% of YSI	Percent of CGM within 30/30% of YSI	Percent of CGM within 40/40% of YSI	Percent of CGM greater than 40/40% of YSI
Overall	2565	73.9	84.2	93	96.5	3.5
$\geq 40-60^*$	298	68.8	81.5	96.6	98	2
>60-80*	356	86.8	93	96.3	97.5	2.5
>80-180	1167	67.1	79.3	89.6	95.4	4.6
>180-300	588	78.1	86.2	94.2	96.4	3.6
>300-350	111	92.8	98.2	100	100	0
>350-400	45	80	97.8	97.8	100	0

* For CGM reference range ≤ 80 mg/dL, agreement was based on 15/20/30/40 mg/dL.

Table 54. Agreement (%) of CGM-YSI paired points within CGM glucose range on Frequent Sample Testing (FST) 6, Abdomen insertion site, calibrating every 12 hours.

CGM glucose ranges (mg/dL)	Number of paired CGM-YSI	Percent of CGM within 15/15% of YSI	Percent of CGM within 20/20% of YSI	Percent of CGM within 30/30% of YSI	Percent of CGM within 40/40% of YSI	Percent of CGM greater than 40/40% of YSI
Overall	2314	67.2	74.8	85	91.9	8.1
$\geq 40-60^*$	164	72	80.5	85.4	90.9	9.1
>60-80*	227	77.1	83.7	89.4	94.3	5.7
>80-180	1194	60.1	68.2	79.4	88.2	11.8
>180-300	583	72.2	79.9	91.1	96.7	3.3
>300-350	104	84.6	88.5	100	100	0
>350-400	42	81	88.1	100	100	0

* For CGM reference range ≤ 80 mg/dL, agreement was based on 15/20/30/40 mg/dL.

Table 55. Combined agreement rates for every 2 hour post calibration period.

	No. paired YSI-sensor points	± 15% (± 15 mg/dL)	± 20% (± 20 mg/dL)	± 30% (± 30 mg/dL)	± 40% (± 40 mg/dL)	> ±40% (± 40 mg/dL)
0–2 hours	1676	71.1	82.9	93.2	97.8	2.2
2–4 hours	1711	68.7	80.5	92.3	97.3	2.7
4–6 hours	1203	61.8	74	89.1	95.5	4.5
6–8 hours	446	55.4	68.6	84.1	93.7	6.3
8–10 hours	361	55.4	64	78.9	90	10
10–12 hours	296	60.5	65.9	81.8	91.2	8.8

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Important Message to Patients

The Medtronic MiniMed® 630G with Enlite® is an integrated system, combining an insulin pump with Continuous Glucose Monitoring (CGM) technology and an automated insulin suspension feature known as Suspend on low. This feature is designed to respond automatically to a potential low sensor glucose event when a patient is unable to respond. It is not designed to treat or prevent hypoglycemia.

The Suspend on low feature in the MiniMed® 630G system is the same feature as the Threshold Suspend feature included in the MiniMed® 530G. The Threshold Suspend feature was tested in a clinical study called ASPIRE (Automation to Simulate Pancreatic Insulin Response). The purpose of this study was to see if this feature could help certain people with diabetes who experience low sensor glucose (SG) levels at night (defined as SG less than or equal to 65 mg/dL). In the study, Threshold Suspend significantly reduced the nighttime low sensor glucose levels and raised the lowest point (referred to as the minimum sensor glucose value) of these low sensor glucose events.

While the study results help explain the benefit of Threshold Suspend, it is important to understand that this study, like many clinical studies, has important limitations.

The study is based on glucose values from CGM not blood glucose values (BG).

- CGM uses a special sensor to measure sugar levels just below the skin (subcutaneous). These sensor glucose (SG) values are different from blood glucose (BG) measurements using a BG meter.
- Sensor glucose values should not be used to make treatment decisions. Patients should always do a BG finger-stick to make treatment decisions.

The study only included patients who had a history of nighttime low sensor glucose values.

- To be included in the study, patients had to have at least two low sensor glucose events (≤ 65 mg/dL) that lasted 20 minutes or longer during a pre-study assessment (referred to as the Run-in Phase).
- 18% (57 out of 320 patients) did not meet the criteria of the Run-in Phase to enter the study, either because they did not wear a sensor for at least 80% of the time or they did not have at least two low sensor glucose events during the Run-in Phase.

The study did not collect enough information to determine how Threshold Suspend affects glycemic control.

- The study lasted three months and subjects were only required to turn on the Threshold Suspend feature at night, which does not allow adequate exposure to the Threshold Suspend feature in order to measure the full impact on A1C.
- The study did not collect enough blood glucose or ketone test results from patients who may have been experiencing symptoms associated with hyperglycemia to determine if Threshold Suspend increased the risk of high blood sugars (hyperglycemia).
- The study results did suggest that ketones were more common in patients using Threshold Suspend. Ketones are an important measure of risk associated with high blood sugar and are an early sign of risk for diabetic ketoacidosis (DKA), a rare but serious condition associated with prolonged periods of high blood sugars and insufficient amounts of insulin.
- The study results found a trend towards higher glucose level in patients using Threshold Suspend (as measured by AUC Hyperglycemia). This measure is important because patients using insulin pump therapy, whether using Threshold Suspend or not, are typically using rapid-acting insulin. Since stopping the delivery of rapid-acting insulin can quickly lead to increased blood sugars the automatic suspension of insulin delivery associated with Threshold Suspend can increase this risk.

MiniMed® 530G with Enlite® Threshold Suspend Performance

The ASPIRE In-Home Study

NOTE: You should review the information in this appendix with your healthcare professional.

The ASPIRE In-Home¹ study was designed to evaluate the safety and efficacy of an automated insulin suspension feature (Threshold Suspend or TS, also known as Suspend on low) in type 1 diabetes patients with a history of nighttime low sensor glucose events. The goal of the study was to determine whether TS could reduce the magnitude and duration of nighttime low sensor glucose events without causing a significant increase in A1C. Magnitude refers to the lowest sensor glucose (such as, minimum) value for a low sensor glucose event. The study was not designed to support conclusions regarding overall glycemic control. There were several reasons for this including (a) study duration of 3 months was too short to assess impact on A1C (b) glycemic control is based on more than A1C measurements (c) the study protocol was not designed to measure BG and ketones every time there was a potential hyperglycemic event.

Since the study was limited to patients with a history of nighttime low sensor glucose events (sensor glucose values ≤ 65 mg/dL for more than 20 minutes), the results of this study may not be generalizable to all patients using the MiniMed 630G system.

Clinical Study Description

Study Design

The ASPIRE In-Home study was a three-month, in-home, randomized control trial. Subjects with type 1 diabetes (ages 16-70) were randomly assigned to sensor-augmented insulin-pump (SAP) therapy with Threshold Suspend (Threshold Suspend Group) or SAP alone without Threshold Suspend (Control Group). The Threshold Suspend Group used a device equivalent to MiniMed® 530G insulin pump with a Threshold Suspend feature. The Control Group used the same pump as the Threshold Suspend Group but with the Threshold Suspend feature turned OFF. Both groups used the Enlite sensor and calibrated the sensor with the Bayer Contour® NEXT LINK Meter and test strips.

The study had a six-week Pre-Study Phase and a three-month Study Phase. The Pre-Study Phase established eligibility for the Study Phase and required that participants wear a sensor for a prescribed amount of time ($\geq 80\%$). It also required participants to have had at least two nighttime low sensor glucose events (≤ 65 mg/dL for more than 20 minutes) over the course of a two-week Run-in Phase.

The Study Phase included an initial and final office visit, two interim telephone visits and weekly uploads of device data to CareLink Therapy Management Software.

A total of 247 participants, ages 16 to 70, with type 1 diabetes and documented nighttime low sensor glucose events met the eligibility requirements and were randomized into two groups: 121 in the Threshold Suspend Group and 126 in the Control Group. For participants in the Threshold Suspend Group, the Threshold Suspend feature was initially set to 70 mg/dL, after which the setting could range from 70-90 mg/dL.

Study Population Baseline Characteristics

Study population demographic and baseline characteristics are provided in **Table 1** and **Table 2**.

Table 1 - Baseline Characteristics, of Subjects Who Underwent Randomization.

Characteristic	All Subjects	Threshold Suspend Group	Control Group
Number of Subjects Randomized (N)	247	121	126
Age (Years)			
N	247	121	126
Mean (SD)	43.3 (13.41)	41.6 (12.83)	44.8 (13.82)

1 Bergenstal RM, Klonoff DC, Garg SK, et al. Threshold-based insulin-pump interruption for reduction of hypoglycemia. N Engl J Med 2013;369:224-232.

Characteristic	All Subjects	Threshold Suspend Group	Control Group
Median	44.0	43.0	46.5
Min, Max	16.0, 70.0	16.0, 69.0	16.0, 70.0
Gender N(%)			
Female	151 (61.1%)	75 (62.0%)	76 (60.3%)
Male	96 (38.9%)	46 (38.0%)	50 (39.7%)
Race N(%)			
White	241 (97.6%)	119 (98.3%)	122 (96.8%)
Asian	2 (0.8%)	2 (1.7%)	0 (0.0%)
Black/African American	4 (1.6%)	0 (0.0%)	4 (3.2%)
Ethnicity N(%)			
Hispanic/Latino	6 (2.4%)	2 (1.7%)	4 (3.2%)
Non-Hispanic/Latino	241 (97.6%)	119 (98.3%)	122 (96.8%)
Diabetes History (Years)			
N	243	120	123
Mean (SD)	26.9 (12.58)	27.1 (12.49)	26.7 (12.72)
Median	25.9	25.8	25.9
Min, Max	2.4, 61.8	2.4, 61.8	3.1, 58.0
More than 3 Months of CGM Experience N(%)			
Yes	142 (57.5%)	74 (61.2%)	68 (54.0%)
No	105 (42.5%)	47 (38.8%)	58 (46.0%)
Insulin Type N(%)			
Insulin Lispro	113 (45.7%)	64 (52.9%)	49 (38.9%)
Insulin Aspart	134 (54.3%)	57 (47.1%)	77 (61.1%)
Height (cm)			
N	247	121	126
Mean (SD)	170.0 (9.57)	169.5 (9.90)	170.4 (9.26)
Median	168.2	167.6	169.7
Min, Max	150.2, 195.6	150.2, 192.0	151.4, 195.6
Weight (kg)			
N	247	121	126
Mean (SD)	79.3 (15.49)	79.6 (15.91)	79.1 (15.13)

Characteristic	All Subjects	Threshold Suspend Group	Control Group
Median	78.3	76.3	78.7
Min, Max	48.7, 126.5	49.1, 126.5	48.7, 120.4
BMI (kg/m ²)			
N	247	121	126
Mean (SD)	27.4 (4.50)	27.6 (4.72)	27.1 (4.27)
Median	26.7	26.2	26.8
Min, Max	19.2, 44.0	19.6, 44.0	19.2, 42.0
A1C at Screening (%)			
N	247	121	126
Mean (SD)	7.5 (0.89)	7.5 (0.86)	7.6 (0.91)
Median	7.4	7.4	7.5
Min, Max	5.8, 10.0	5.8, 10.0	5.9, 9.9
A1C at Randomization (%)			
N	246	120	126
Mean (SD)	7.2 (0.74)	7.3 (0.71)	7.2 (0.77)
Median	7.1	7.2	7.1
Min, Max	5.7, 9.7	5.9, 9.7	5.7, 9.6

Table 2 - Baseline Demographic Characteristics of Subjects Who Underwent Randomization, Stratified by Age and BMI.

Demographic Characteristic	All Subjects	Threshold Suspend Group	Control Group
Number of Subjects Randomized	(N=247)	(N=121)	(N=126)
Age			
16-21 years	14 (5.7%)	6 (5.0%)	8 (6.3%)
≥22 years	233 (94.3%)	115 (95.0%)	118 (93.7%)
BMI			
Morbidly Obese Subjects (BMI ≥ 40 kg/m ²)	3 (1.2%)	2 (1.7%)	1 (0.8%)
Normal Weight Subjects (BMI 18.5 to 24.99 kg/m ²)	74 (30.0%)	34 (28.1%)	40 (31.7%)
Overweight and Obese Subjects (BMI 25 to 40 kg/m ²)	170 (68.8%)	85 (70.2%)	85 (67.5%)

Due to the relatively small number of pediatric subjects, no conclusions can be made regarding whether or not the safety and efficacy of the Threshold Suspend feature is the same for patients 16 through 21 years old as for patients 22 years and older.

At the randomization visit, the mean A1C measurement was 7.26% in the 120 TS group participants and 7.21% in the 126 Control group participants who had available A1C data (**Table 3**). At the end of study, the mean A1C measurement was 7.24% in the 116 TS group participants and 7.14% in the 124 Control group participants who had available A1C data. For participants with both randomization and end-of-study A1C (N=116 in TS group, N=124 in Control group), the mean of A1C change from randomization to end of study was 0.00% in the TS group and -0.04% in the Control group.

Table 3 - Summary of Change in A1C (%) from Randomization to End of 3-Month Study.

	Threshold Suspend Group		Control Group	
	Randomization A1C	End of Study A1C	Randomization A1C	End of Study A1C
A1C Summary				
Number of subjects	120	116	126	124
Mean(SD)	7.26(0.71)	7.24(0.67)	7.21(0.77)	7.14(0.77)

Table 4 - Additional Descriptive Statistics for A1C Analysis of Study Groups.

	Threshold Suspend Group	Control Group
Change in A1C Summary		
Number of Subjects with both randomization and end-of-study A1C	116	124
Mean(SD)	0.00(0.44)	-0.04(0.42)
Difference in the mean change in A1C (Threshold Suspend – Control)	0.04	

Primary Endpoints

The study compared A1C and CGM-based Area Under the Curve (AUC) of low sensor glucose events for the two study groups:

- Primary safety endpoint: Difference in the Change of A1C from randomization to study end between the Threshold Suspend group and the Control group is less than 0.4%.
- Primary efficacy endpoint: Area Under the Curve (AUC) for nighttime low sensor glucose events (≤ 65 mg/dL) during the 3-month Study Phase (Superiority).

AUC is a measure of the combined magnitude and duration of the recorded nighttime low sensor glucose events defined as sensor glucose (SG) values of 65 mg/dL or less that lasted more than 20 minutes without pump interaction (i.e. meter blood glucose entries, carbohydrate entries, or insulin-delivery changes). Events that occurred within 30 minutes of each other were regarded as a single event.

AUC for nighttime low sensor glucose events included events that started between 10:00 PM and 8:00 AM. AUC for combined day and nighttime included low sensor glucose events that started any time during a 24 hour period.

NOTE: While AUC is the statistical endpoint, it should not be relied on to directly assess the clinical exposure to magnitude or duration of hypoglycemia. As such, the clinical results for magnitude and duration of low sensor glucose values are provided.

Clinical Study Results

The study successfully met both safety and efficacy primary endpoints. It demonstrated that sensor-augmented insulin pump (SAP) therapy with Threshold Suspend is superior to SAP therapy alone in reducing nighttime low sensor glucose events (≤ 65 mg/dL for more than 20 minutes) for patients with documented nighttime low sensor glucose events. While the A1C results met the criteria of the study, A1C is not sufficient to assess glycemic control. In addition, the size and duration of the study are not sufficient to determine the effect of Threshold Suspend on A1C.

Primary Endpoint Results: Change in A1C

The use of the Threshold Suspend did not result in a significant change in A1C during the Study Phase. The changes in A1C from randomization to study end were negligible in both groups. The between-group difference in change in mean A1C was 0.05% (**Figure 1**). The 97.5% upper confidence interval was 0.15% and was less than the pre-specified non-inferiority margin (<0.4%).

While the study results successfully achieved its goal, the study did not collect enough information to determine how Threshold Suspend affects glycemic control.

- The study lasted 3 months and subjects were only required to turn on the Threshold Suspend feature at night, which does not allow adequate exposure to the Threshold Suspend feature in order to measure the full impact on A1C.
- The study did not collect enough blood glucose or ketone test results from patients who may have been experiencing symptoms associated with hyperglycemia to determine if Threshold Suspend increased the risk of high blood sugars (hyperglycemia).
- The study results did suggest that ketones were more common in patients using Threshold Suspend. Ketones are an important measure of risk associated with high blood sugar and are an early sign of risk for diabetic ketoacidosis (DKA), a rare but serious condition associated with prolonged periods of high blood sugars.
- The study results found a trend towards higher glucose level in patients using Threshold Suspend (as measured by AUC Hyperglycemia). This measure is important because patients using insulin pump therapy, whether using Threshold Suspend or not, are typically using rapid-acting insulin. Since stopping the delivery of rapid-acting insulin can quickly lead to increased blood sugars the automatic suspension of insulin delivery associated with Threshold Suspend can increase this risk.

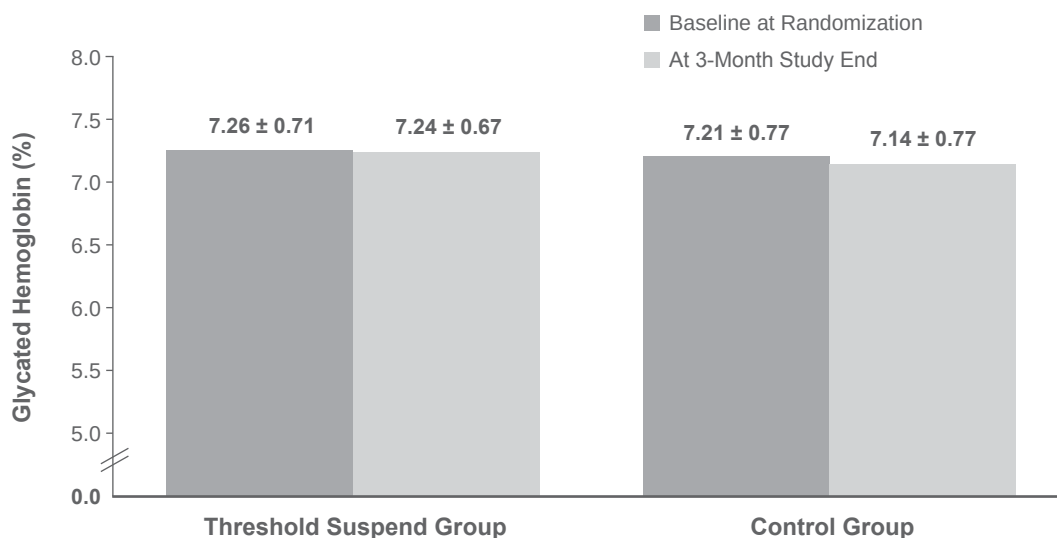


Figure 1 - Primary Safety Endpoint: Between Group Difference of Mean Change in A1C (% , mean ± SD).*

* The baseline mean A1Cs were based on 120 subjects from the Threshold Suspend Group and 126 from the Control Group. The A1Cs at end of the Study Phase were based on 116 subjects from the Threshold Suspend Group and 124 from the Control Group.

Primary Efficacy Endpoint Results: Superiority of Reduction in Low Sensor Glucose Event

Sensor-augmented insulin pump (SAP) therapy with Threshold Suspend was superior to SAP alone in reducing nighttime low sensor glucose events (≤ 65 mg/dL for more than 20 minutes), as measured by mean AUC. The mean AUC for these nighttime low sensor glucose events during the 3-month Study Phase was 37.5% lower in the Threshold Suspend Group as compared to the Control Group ($980 \pm 1,200$ vs. $1,568 \pm 1,995$ mg/dL $\times$ min, $p < 0.001$, **Figure 2**). A qualified event was defined as having a sensor glucose value less than or equal to 65mg/dL and lasting more than 20 minutes.

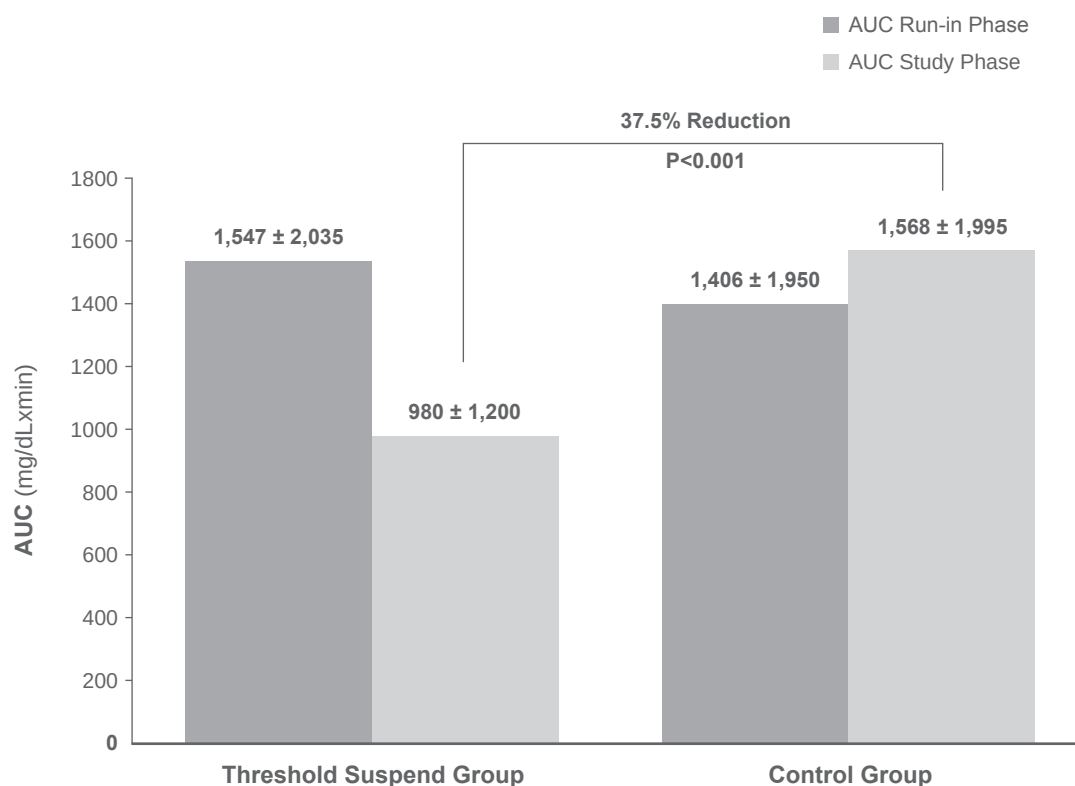


Figure 2 - Primary Efficacy Endpoint, Change in Mean AUC of Nighttime Low Sensor Glucose Events (mean ± SD).**

** The mean and standard deviation (SD) calculations for the Study Phase are based on total numbers of events: 2,025 for the Threshold Suspend Group and 3,002 for the Control Group.

The mean duration and magnitude of the low sensor glucose events that were included in the primary efficacy endpoint calculation (AUC of nighttime low sensor glucose events) are reported below (**Table 5**) for both study groups.

Table 5 - Comparison of Nighttime Low Sensor Glucose Events (SG ≤ 65 mg/dL), Lasting More Than 20 Minutes.

	Threshold Suspend Group	Control Group
Number of Events	2,025	3,002
Mean Duration (min)	85.1	119.3
Mean Minimum sensor glucose value (mg/dL)	50.4	48.8

Secondary Endpoint and Exploratory Analysis (Intent-to-Treat Population)

Duration and Magnitude of Low Sensor Glucose Events during Day and Nighttime

An analysis of all Study Phase low sensor glucose events was performed, with events categorized by SG value as follows:

- Any SG value ≤ 70 mg/dL
- Any SG value ≤ 60 mg/dL
- Any SG value ≤ 50 mg/dL

A low sensor glucose event was defined in this analysis as having any duration, occurring either at day or

nighttime, and having at least one sensor glucose value equal to or less than the specified thresholds. As indicated in **Table 6** below, the duration of low sensor glucose events was shorter and the minimum sensor glucose values was higher in the Threshold Suspend Group vs. the Control Group.

Table 6 - Comparison of All Low Sensor Glucose Events in the Study Phase, Categorized by Sensor Glucose Minimum Sensor Glucose Value (Threshold Suspend Group vs. the Control Group). Day and Night Without Any Duration Restriction.

	Number of Events		Duration (minutes)		Minimum Sensor Glucose Value (mg/dL)	
	TS	Control	TS	Control	TS	Control
SG ≤ 50	1,984	3,433	28.2	35.1	44.9	44.5
SG ≤ 60	4,751	6,537	31.2	37.7	52.3	51.7
SG ≤ 70	7,971	9,468	36.6	43.6	59.8	58.7

Duration and Magnitude of Low Sensor Glucose Events During Nighttime

A similar analysis for the duration and magnitude of low glucose sensor events (regardless of duration) occurring at night (between 10:00 PM and 8:00 AM) is provided in **Table 7** below.

Table 7 - Comparison of All Low Sensor Glucose Events in the Study Phase, Categorized by Sensor Glucose Minimum Sensor Glucose Value (Threshold Suspend Group vs. the Control Group). Nighttime Without Any Duration Restriction.

	Number of Events		Duration (minutes)		Minimum Sensor Glucose Value (mg/dL)	
	TS	Control	TS	Control	TS	Control
SG ≤ 50	879	1,623	41.1	50.0	44.6	44.2
SG ≤ 60	1,897	2,677	45.9	55.3	51.7	51.1
SG ≤ 70	3,225	3,665	50.6	61.8	59.4	58.3

Rate of Any Low Sensor Glucose Event at Night (Study Phase, SG ≤65 mg/dL):

Over the course of the Study Phase, approximately one out of every four to five nights of sensor wear had at least one low glucose sensor event (event rate). This event rate was 20.3% in the Threshold Suspend Group and 26.9% in the Control Group (**Table 8**).

Table 8 - Summary of Nighttime Low Sensor Glucose Event Rate Based on Sensor Glucose Values ≤ 65 mg/dL (Intention-to-Treat Population).

	Threshold Suspend Group (N=121)	Control Group (N=126)
Total number of event nights (Number of nights with 1 or more low glucose sensor events)	1,839	2,489
Total number of sensor-wearing nights (Includes any night where a subject wore a sensor for any period of time)	9,052	9,247
Event rate (Total number of event nights/ total number of sensor-wearing nights)	20.3%	26.9%

Threshold Suspend Event Comparison: Nighttime Only vs. Combined Day and Nighttime (Study Phase)

Threshold Suspend Group):

- **TS Frequency:** TS events were less common at night (mean of 0.77 per patient night only vs. 2.08 combined day and night, **(Table 9)**).
- **TS Duration:** The mean duration of TS events was about 50% longer at night (39.4 minutes night only vs. 25.5 minutes combined day and night) and the median duration was more than five times longer at night (11.9 minutes night only vs. 1.42 minutes combined day and night). TS events lasting less than five minutes were slightly less common at night only than combined day and night (43.1% vs. 56.3%). However, TS events lasting for two hours were twice as common at night only (19.6% vs. 9.4% combined day and night, **Table 9**).
- **Two-hour TS Events:** There were a total of 1,873 two-hour TS events, of which 1,444 occurred at night and the remaining 429 occurred during the day (**Table 9**). 91.7% of subjects in the Threshold Suspend Group had at least one 2-hour Threshold Suspend event at night (111 of 121 subjects, **Table 9**).

Table 9 - Automatic Insulin-Suspension Events (Nighttime Only vs. Combined Day and Night).

	Night Only	Combined Day and Night
Number of Threshold Suspend events per patient night (Mean)	0.77	2.08
Duration of Threshold Suspend events (Minutes, median)	11.9	1.42
Duration of Threshold Suspend events (Minutes, mean)	39.4	25.5
Percent of Threshold Suspend events that lasted less than 5 minutes	43.1%	56.3%
Percent of Threshold Suspend events that lasted for 2 hours	19.6%	9.4%
Number of 2-hour Threshold Suspend events	1,444	1,873

Duration of Insulin Suspension (Study Phase, Threshold Suspend Group):

- Nighttime Only: Insulin was most likely (49.2%) to be suspended for 10 minutes or less but one out of five (20.5%) TS events lasted for 110 minutes or longer (**Figure 3**).

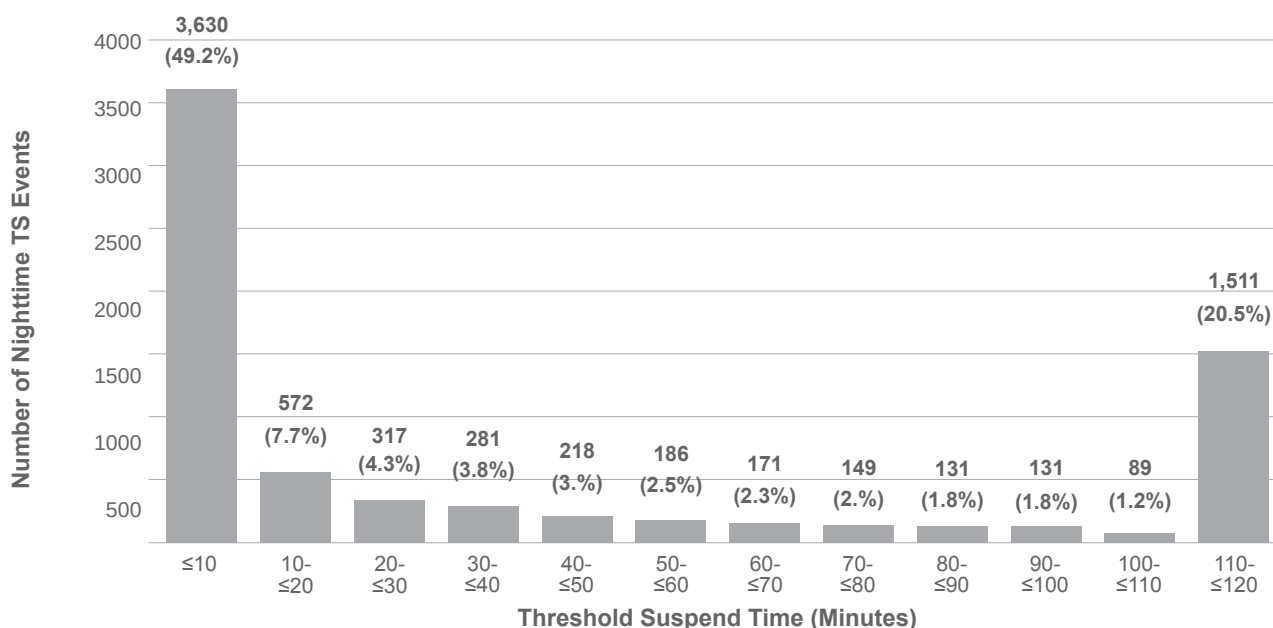


Figure 3 - Threshold Suspend duration (Minutes).²

- 2 15 Threshold Suspend events lasted more than 122 minutes and were found to be out of specification. None of these events resulted in an adverse event and they are not included in this distribution.

Glucose Trends During Two-Hour Insulin Suspension Events (Study Phase, Threshold Suspend Group):

- On average, SG was about 120 mg/dL at one hour before the TS alarm was triggered and remained below 70 mg/dL for the first hour after the TS alarm was triggered (**Figure 4**). The number (N) associated with **Figure 4** is provided in **Table 10**.
- At the end of the two-hour TS event, SG was above 92.6 mg/dL and continued to rise for the next 2 hours, reaching 168.8 mg/dL before leveling off (**Table 11**).
- Similarly, in the two hours after a two-hour TS event, the number of SG values <70 mg/dL dropped from 33.1% to 3.9% and the number of SG values >200 mg/dL increased from 2.2% to 26.0% (**Table 11**).

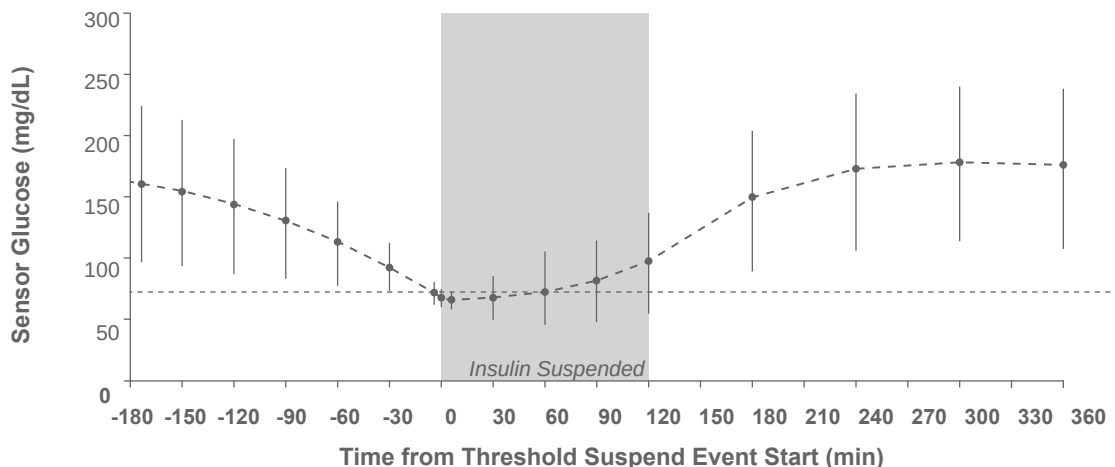


Figure 4 - Sensor Glucose Values for Two-Hour Threshold Suspend Events at Night.

Table 10 - Number (N) Associated With **Figure 4**.

Time Point	N	Mean	SD
-180	895	158.7	62.8
-175	904	158.0	62.5
-150	933	150.9	59.1
-120	977	139.2	53.3
-90	1012	126.2	44.1
-60	1057	109.3	32.5
-30	1156	88.8	19.7
-5	1423	69.2	8.4
0	1438	65.6	6.7
5	1435	64.1	7.1
30	1426	65.2	16.9
60	1408	69.8	24.7
90	1393	78.2	32.1
120	1385	92.6	40.7
180	1185	144.7	57.5
240	1136	168.8	64.6

Time Point	N	Mean	SD
300	1074	174.3	65.0
360	1042	171.6	64.9

Table 11 - Sensor Glucose Distribution after a Two-Hour Threshold Suspend Event.

	Immediately After Two-Hour TS Event	Two-Hours After Two-Hour TS Event
SG values <70 mg/dL	33.1%	3.9%
SG values 70-200 mg/dL	64.8%	70.2%
SG values >200 mg/dL	2.2%	26.0%
Average SG (mg/dL, mean $\pm$ SD)	92.6 $\pm$ 40.7	168.8 $\pm$ 64.6

Weekly Low Sensor Glucose Event Rates:

- Nighttime Only: The rate of nighttime low sensor glucose events was 31.8% lower in the Threshold Suspend Group vs. the Control Group (1.5 vs. 2.2 low sensor glucose events per patient-week, $p < 0.001$, **Figure 5**).
- Combined Day and Nighttime: Similarly, the rate of combined day and nighttime low sensor glucose events was 29.8% lower in the Threshold Suspend Group vs. the Control Group (3.3 vs. 4.7 low sensor glucose events per patient-week, $p < 0.001$, **Figure 6**).

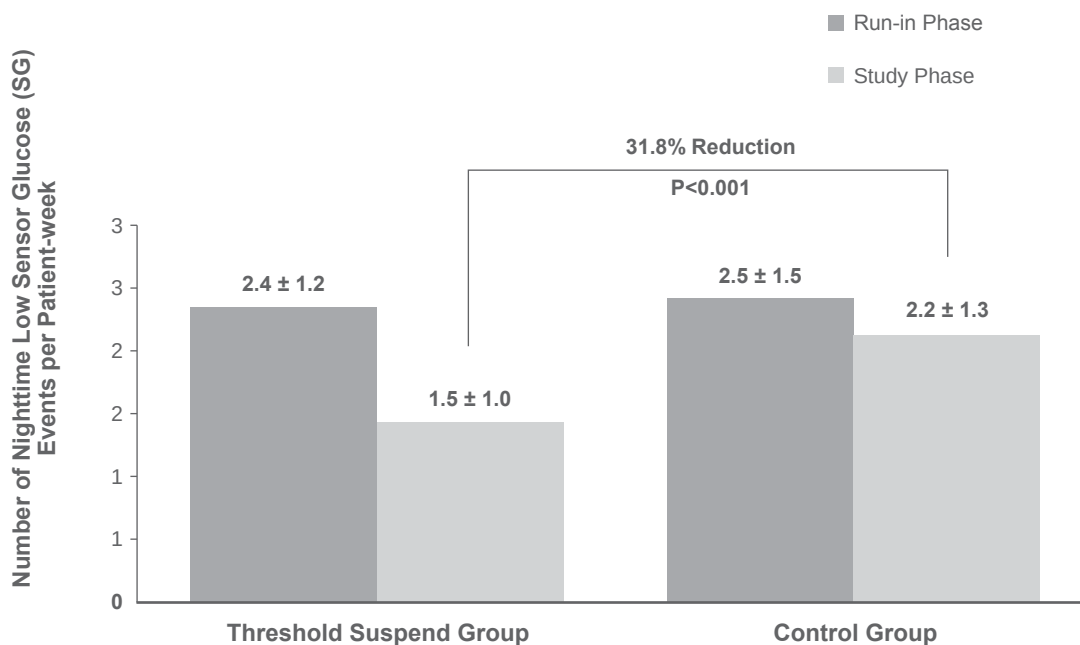


Figure 5 - Number of Nighttime Low Glucose Sensor Events per Patient-Week (mean $\pm$ SD).

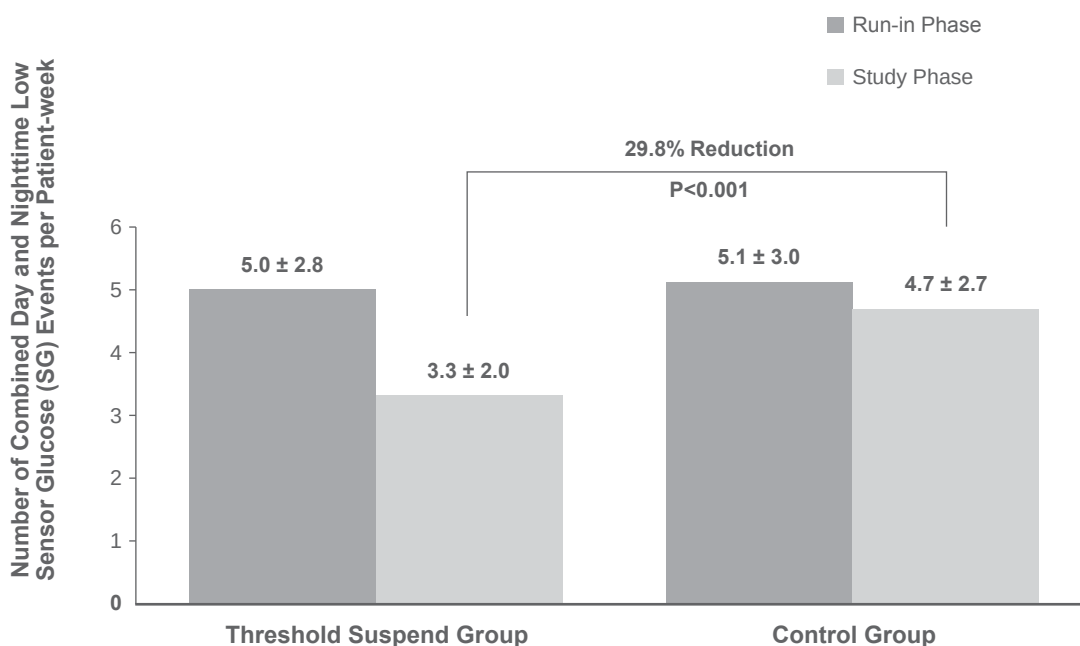


Figure 6 - Number of Combined Day and Nighttime Low Sensor Glucose Events per Patient-Week (mean ± SD).

Percentage of Sensor Glucose Values in Low Sensor Glucose Range (Study Phase):

- Nighttime Only: The Threshold Suspend Group had a 40.0% reduction in sensor glucose (SG) values <70 mg/dL at night vs. the Control Group (6.0% vs. 10.0%, p<0.001, **Table 12**).
- Combined Day and Nighttime: Similarly, the Threshold Suspend Group had a 34.6% reduction in SG values <70 mg/dL combined day and night vs. the Control Group (5.3% vs. 8.1%, p<0.001, **Table 13**). The reduction was observed across each of the glucose ranges evaluated (p<0.001).

Table 12 - Sensor Glucose Distribution, Nighttime (<70mg/dL).

Sensor Glucose Range	Threshold Suspend Group	Control Group	Change
<50 mg/dL	1.2%	2.8%	-1.6% p<0.001
50 to <60 mg/dL	1.8%	3.1%	-1.3% p<0.001
60 to <70 mg/dL	3.0%	4.1%	-1.1% p<0.001
Total (<70 mg/dL)	6.0%	10.0%	-4.0% p<0.001

Table 13 - Sensor Glucose Distribution, Combined Day and Nighttime (<70mg/dL).

Sensor Glucose Range	Threshold Suspend Group	Control Group	Change
<50 mg/dL	0.9%	1.9%	-1.0% p<0.001

Sensor Glucose Range	Threshold Suspend Group	Control Group	Change
50 to <60 mg/dL	1.6%	2.5%	-0.9% p<0.001
60 to <70 mg/dL	2.8%	3.7%	-0.9% p<0.001
Total (<70 mg/dL)	5.3%	8.1%	-2.8% p<0.001

Safety and Adverse Events

- There were no reports of subject death during the study.
- There were no reports of unanticipated adverse device effects (UADEs) during the study.
- There were no reports of diabetic ketoacidosis (DKA) during the study
 - A limitation of the study was that blood tests of serum bicarbonate and pH levels were not always obtained when symptoms of potential DKA were present. As a result, the actual number of episodes of mild or severe DKA may have exceeded the number of reported events and therefore it cannot be conclusively determined that the use of the Threshold Suspend feature is not associated with an increased risk of hyperglycemia and mild or severe DKA.
- There were 8 severe hypoglycemic events during the course of the study.
 - 4 severe hypoglycemic events occurred prior to the Study Phase.
 - 4 severe hypoglycemic events occurred in the Control Group during the Study Phase.
 - No severe hypoglycemic events occurred in the Threshold Suspend Group.
- There were 19 device- or procedure-related adverse events during the 3-month Study Phase.
 - 1 patient had prolonged pump suspensions (a device performance issue) that did not result in an adverse event.
- A summary of adverse events can be found in **Table 14**.

Table 14 - Summary of All Adverse Events Reported During Run-in and Study Phases.

	Run-in Phase	Study Phase	
		Threshold Suspend Group	Control Group
Serious adverse events related to study device or study procedure	0	0	0
Serious adverse events not related to study device or study procedure	4	0	2
Adverse events not related to study device or study procedure	114	46	53
Adverse events related to study device or study procedure			
Skin-related*	20	4	12
Infusion set-related, resulting in severe hyperglycemia (BG>300 mg/dL with ketones >0.6mmol/L, and did not meet the criteria for DKA)	2	3	0
Infusion set-related, resulting in hyperglycemia	1	0	0
Syncope	1	0	0

		Run-in Phase	Study Phase	
			Threshold Suspend Group	Control Group
	Emesis from mixed meal tolerance test used to assess C-peptide	1	0	0
	Pump priming issue and hypoglycemia	1	0	0
Total		144	53	67
* Skin related events included skin irritation, skin infection, rash, bleeding, bruising (ecchymosis), redness, rash, abrasion, dermatitis and pruritus.				

Severe Hypoglycemia:

Severe hypoglycemia was defined as a low blood glucose (BG) resulting in coma, seizure or requiring medical assistance.

Run-in Phase

- 4 severe hypoglycemic events occurred during the Run-in Phase (**Table 15**).
 - In 3 of these events, the subject was not wearing a sensor at time of incident.
 - In the 4th event, the subject received multiple low glucose alerts with no treatment noted.

Study Phase

- No severe hypoglycemic events occurred in the Threshold Suspend Group during the Study Phase.
- 4 severe hypoglycemic events occurred in Control Group (rate of 0.13 severe hypoglycemic events per patient year (**Table 15**)).
 - In 1 of these events, the subject had a seizure that was determined to be related to hypoglycemia. Several hours before this event an over-correction occurred while treating hyperglycemia.
- No severe hypoglycemic events or seizures were related to study device or study procedure.

Severe Hyperglycemia

Severe hyperglycemia was defined as blood glucose (BG) >300 mg/dL with blood ketones >0.6mmol/L or accompanied by symptoms of nausea, vomiting or abdominal pain.

There were a total of 12 severe hyperglycemic events reported by investigators during the course of the study. Of the 12 reported events (**Table 15**), 6 occurred prior to the start of the Study Phase and 6 occurred during the Study Phase including 4 in the TS Group and 2 in the Control Group.

Table 15 - Summary of Severe Hypoglycemia, Severe Hyperglycemia and Seizures Reported During Run-in and Study Phases.

		Run-in Phase	Study Phase	
			Threshold Suspend Group	Control Group
Severe Hypoglycemic Events*		4	0	4
Seizures**		0	0	1
Severe Hyperglycemic Events***		6	4	2
* Severe hypoglycemia defined as low blood glucose resulting in coma or seizure or requiring medical assistance.				
** This incidence of seizure was related to severe hypoglycemia.				
*** Severe hyperglycemia defined as blood glucose >300 mg/dL with blood ketones >0.6mmol/L or accompanied by symptoms of nausea, vomiting or abdominal pain.				

In addition to documented severe hyperglycemic events, there were increased measurements of ketones and higher overall Hyperglycemia AUC in the Threshold Suspend Group. These data suggested an increased incidence of ketonuria and higher mean blood ketone values in the Threshold Suspend group. An increased incidence of ketonuria or high mean blood ketone values could suggest an increased risk of hyperglycemia and diabetic ketoacidosis (DKA).

Patients during the study were instructed to check their urine ketones daily. Data provided in **Table 16** provides average daily urine ketone values. **Table 17** provides a summary of mean blood ketone measurements taken from patients when they were hyperglycemic. **Table 18** provides a summary of mean blood ketone measurements taken from patients who had symptoms attributed to DKA such as nausea, vomiting and abdominal pain. The results in these three tables suggest a trend toward higher urine and blood ketone levels in the Threshold Suspend arm. These results, however, should be interpreted with caution since these values were self-reported and the study was not designed to prospectively detect the statistical difference in ketone measurements between the sensor augmented insulin pump group versus the Threshold Suspend group. Providers should be aware that higher ketone values may indicate an increase in the risk for diabetic ketoacidosis (DKA).

Table 16 - Summary of Daily Urine Ketone Values in Each Arm (Threshold Suspend Group vs. Control Group).

Category	Threshold Suspend Group (Number of Values)	Control Group (Number of Values)
Negative	94.84% (8479)	96.23% (8889)
Trace	3.31% (296)	2.68% (296)
Small	1.12% (100)	0.62% (57)
Moderate	0.53% (47)	0.27% (25)
Large	0.20% (18)	0.19% (18)

Table 17 - Summary of Blood Ketone Values (mmol/L) in Each Arm (Threshold Suspend Group vs. Control Group).

Category	Threshold Suspend Group	Control Group
Number of times ketones were reported	340	242
Mean (SD)	0.31 (0.48)	0.28 (0.55)

Table 18 - Summary of Blood Ketone Values (mmol/L) Only When Subjects Had Symptoms of Nausea, Vomiting and Abdominal Pain Each Arm (Threshold Suspend Group vs. Control Group).

Category	Threshold Suspend Group	Control Group
Number of times ketones were reported	24*	3
Mean (SD)	0.65 (0.98)	0.13 (0.06)
* In the TS group, there were 15 blood ketone measurements collected from 1 subject with symptom of abdominal pain attributed to Gallstones.		

Hyperglycemia AUC

Combined (day and night), the subject mean percent of time when the sensor glucose values were in the >180 mg/dL range was higher in the TS group compared to the Control group (31.1% vs. 30.0%); in the >240 mg/dL range the percentages are the same between the two groups (11.1% vs. 11.1%); in the >300 mg/dL range, the percentage is lower in the TS group compared to the Control group (3.2% vs. 3.5%). In terms of sensor glucose AUC and duration in the hyperglycemic range, the TS users experienced a greater AUC of 2.3% at night and a longer duration of 3.7% combined day and night as compared to the Control group in the >180 mg/dL range.

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