MINIMED™ 670G
SYSTEM USER GUIDE

Medtronic

MiniMed™ 670G
SYSTEM USER GUIDE

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WARNING:

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

Warranty

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

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

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

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

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

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

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

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Glossary

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Before you begin

1 Before you begin

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

In this user guide, the term Auto Mode refers to the automatic control of insulin delivery. For more information, see *About Auto Mode, on page 225*. When your pump is not operating in Auto Mode, the term Manual Mode is used to describe its functions.

Using this user guide

This user guide contains valuable information about using your new insulin pump. To help you find the information you need, you can use the table of contents at the beginning of the user guide and the index at the end of the user guide. There is also a glossary of terms, which starts on *page 339*.

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

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

Convention	What it means
Press and hold	To push and keep pressure on a button.
Bold text	To indicate screen items and buttons. For example, "Select **Next** to continue."
X	To indicate a numeric value.
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.**

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

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

Acronyms and abbreviations

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

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

Emergency kit

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

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

Your emergency kit should include these items:

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

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

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

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

User safety

Indications

MiniMed 670G System

The Medtronic MiniMed 670G system is intended for continuous delivery of basal insulin (at user selectable rates) and administration of insulin boluses (in user selectable amounts) for the management of Type 1 diabetes mellitus in persons, seven years of age and older, requiring insulin as well as for the continuous monitoring and trending of glucose levels in the fluid under the skin. The MiniMed 670G System includes SmartGuard technology, which can be programmed to automatically adjust delivery of basal insulin based on Continuous Glucose Monitor sensor glucose values, and can suspend delivery of insulin when the sensor glucose value falls below or is predicted to fall below predefined threshold values

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

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

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

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

Guardian Sensor (3)

The Guardian Sensor (3) is intended for use with the Medtronic MiniMed 670G, MiniMed 630G, and Guardian Connect systems to continuously monitor glucose levels in persons with diabetes. It is intended to be used for detecting trends and tracking patterns, and to be used by the MiniMed 670G system to automatically adjust basal insulin levels.

The Guardian Sensor (3) is approved for use with each of the following Medtronic systems by persons of the following ages:

System	Indicated Age
MiniMed 670G	7 and above
Guardian Connect MiniMed 630G	14 and above

The Guardian Sensor (3) is indicated for use as an adjunctive device to complement, not replace, information obtained from standard blood glucose monitoring devices. The sensor is intended for single use and requires a prescription. The Guardian Sensor (3) is indicated for 7 days of continuous use.

One-press Serter

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

Guardian Link (3) Transmitter

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

CONTOUR NEXT LINK 2.4 Glucose Meter

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

Contraindications

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

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

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

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

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

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

Potential risks

Risks related to insulin pump infusion set

General risks related to insulin pump infusion set may include:

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

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

Risks related to insulin administration and pump use

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

- Hypoglycemia
- Hyperglycemia
- Diabetic Ketoacidosis
- Seizure
- Coma

- Death

Risks related to sensor use

General risks related to sensor use may include:

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

Specific risks related to sensor use

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

levels, and consider exiting Auto Mode. Do not use these additional BG meter readings to calibrate the sensor. Always check the label of any medications to confirm whether acetaminophen is an active ingredient.

For persons seven to thirteen years of age, sensor placement and insertion has been studied in the belly (abdomen) and buttock only and is not approved for other sites.

For persons that are fourteen years of age and older, sensor placement and insertion has been studied in the belly (abdomen) and back of upper arm only and is not approved for other sites.

Specific risks related to meter use

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

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

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

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

Risks related to serter use

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

Risks related to the MiniMed 670G insulin pump system

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

- Hypoglycemia

- Hyperglycemia
- Diabetic Ketoacidosis
- Seizure
- Coma
- Death

General warnings

Pump

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

programmed while the screen is broken or unreadable, this could result in high or low blood glucose levels. If your screen is damaged, contact the 24 Hour HelpLine to arrange for shipment of a replacement pump.

- Only use rapid acting U100 insulin (Humalog and Novolog) that has been prescribed by your healthcare professional for use with an infusion pump. Do not put any other drugs or medications inside your reservoir for use with this pump. Other drugs or medications are not intended for use with this pump. Use of other drugs or medications can cause serious injury.
- Always make sure the infusion set is disconnected from your body before you rewind your pump or fill the infusion set tubing. Never insert the reservoir into the pump while the tubing is connected to your body. Doing so could result in an accidental infusion of insulin.
- Do not insert the reservoir in the pump if you did not rewind your pump. Doing so could result in an accidental infusion of insulin.
- Do not use the MiniMed 670G insulin pump or additional system devices adjacent to other electrical equipment which may cause interference with the normal system operation. This includes mobile communication devices such as cell phones, GPS navigation systems, anti-theft systems, and any electrical equipment that has an output transmitter power greater than 1W. For more information about recommended separation distance guidelines between the insulin pump and common RF emitters, see *Guidance and manufacturer's declaration, on page 323*. The recommended separation distance between the insulin pump and common RF emitters is 12 inches. Other electrical equipment that may compromise normal system operation has been contraindicated. For more information, see *Exposure to magnetic fields and radiation, on page 25*.
- Do not unscrew or retighten the tubing connector on the reservoir while the infusion set is connected to your body. Doing so could result in an accidental infusion of insulin.
- Do not use standard Luer sets with the MiniMed 670G insulin pump. Luer sets are not compatible with the pump. MiniMed reservoirs and MiniMed infusion sets are specifically designed for use with the MiniMed 670G insulin pump.

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

- Do not rely on glucose sensor-enabled features when Airplane Mode is on because the pump does not receive sensor readings from the transmitter. Glucose sensor-enabled features include CGM, SmartGuard, and Auto Mode. When using Airplane Mode, always rely on your blood glucose (BG) values when making therapy decisions to avoid hypoglycemia or hyperglycemia.
- This device can generate, use, and radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. If the device does cause interference to radio or television reception, you are encouraged to try to correct the interference by one or more of the following measures:
    - Decrease the distance between the transmitter and the insulin pump to 6 feet (1.8 meters) or less.
    - Decrease the distance between the meter and the insulin pump to 6 feet (1.8 meters) or less.
    - Increase the separation between the transmitter and the device that is receiving/emitting interference.

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

- The safety of the MiniMed 670G system has not been studied in people with impaired kidney function. Please let your healthcare professional know if you have kidney disease so you and your healthcare professional can determine if the potential benefits of using the system outweigh the risks.
- The safety of the MiniMed 670G system has not been studied in pregnant women, people with type 2 diabetes, or in people using other anti-hyperglycemic therapies apart from insulin. Please let your healthcare professional know if any of these conditions apply to you so you and your healthcare professional can determine if the potential benefits of using the system outweigh the risks.

- The safety of using Auto Mode, Suspend before low, and Suspend on low in people who have no pump experience is not known. Auto Mode, Suspend before low, and Suspend on low should not be used if insulin pump settings have not been previously established. Insulin pump settings include basal rates, insulin to carb ratio, or insulin sensitivity factors. Always discuss with your healthcare professional before using Auto Mode, Suspend before low, or Suspend on low.

Reservoir and infusion sets

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

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

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

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

For MiniMed 670G System Users Ages 7-13:

- The low sensor glucose alert functionality is distinct from the automated insulin dosing function of the MiniMed 670G System. When used in Auto Mode, the MiniMed 670G System has been shown to be safe and effective for its intended use in this population. However, do not rely solely on the use of a low sensor glucose (SG) value for “Alert on Low” or “Alert before Low” for alerts set at 50 mg/dL and 60 mg/dL. A low sensor glucose alert may not reflect the user’s true blood glucose at these levels, or may not alert. Do not

ignore symptoms of low glucose. Always confirm your sensor glucose readings with your blood glucose meter, and treat according to the recommendations of your healthcare professional. Solely relying on these sensor glucose alerts and readings for treatment decisions could result in missing severe hypoglycemia (low blood glucose) events.

Sensor and serter

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

- Keep the sensor away from children. This product contains small parts and may pose a choking hazard.
- Keep the serter away from children. This product contains small parts and may pose a choking hazard.
- A retractable needle is attached to the sensor and minimal blood splatter may occur. If you are a healthcare professional or caregiver, wrap sterile gauze around the sensor to minimize contact with blood. Keep as much distance as possible between you and the patient when removing the needle.
- Do not attempt to remove the sensor yourself if you suspect that the sensor is broken. While there is no evidence of a sensor breaking in a patient's body, sensor breakage can result in serious injury. Contact your healthcare professional for assistance in removing the sensor.
- Always inspect the packaging for damage prior to use. Sensors are sterile and non-pyrogenic, unless the package has been opened or damaged. Do not use the sensor if the sterile package has been opened or damaged. Use of an unsterile sensor can cause site infection.
- If bleeding continues, causes excessive pain or discomfort, or is significantly visible in the plastic base of the sensor, do the following:
    a. Remove the sensor and continue to apply steady pressure until the bleeding stops. Discard the sensor in a sharps container .
    b. Check the site for redness, bleeding, irritation, pain, tenderness, or inflammation. Treat based on instructions from your healthcare professional.
    c. Insert a new sensor in a different location.

- The One-press serter (MMT-7512) does not work the same as other Medtronic insertion devices. Failure to follow directions or using a different serter may result in improper insertion, pain, or injury.
- Keep the needle housing within sight at all times to avoid an accidental needlestick or puncture.
- Taking medications with acetaminophen while wearing the sensor may falsely raise your sensor glucose readings. The level of inaccuracy depends on the amount of acetaminophen active in your body and may be different for each person.
- Make sure the sensor is securely placed in the serter to avoid improper insertion, pain, or minor injury.
- Watch for bleeding at the insertion site (under, around, or on top of the sensor). If bleeding occurs, do the following:
    a. Apply steady pressure, using sterile gauze or a clean cloth placed on top of the sensor, for up to three minutes. The use of unsterile gauze can cause site infection.
    b. If bleeding stops, connect the transmitter (or recorder) to the sensor. If bleeding does not stop, do not connect the transmitter to the sensor because blood can get into the transmitter connector, and could damage the device.
- The sensor is designed to work with Guardian Link (3) transmitter only. It is not interchangeable with transmitters and recorders that are not compatible with the sensor. Connecting your sensor to a transmitter or recorder that is not approved for use with the sensor may cause damage to the components or inaccurate sensor glucose values.
- It is not known how different conditions or medications common to the critically ill population may affect the performance of the system. Therefore, the use of this sensor in the critically ill population is not recommended.

Transmitter

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

- Do not allow children to put small parts in their mouth. This product poses a choking hazard for young children.

- Do not use the tester if it comes in contact with blood. Touching blood can cause infection. Dispose of the tester according to the local regulations for medical waste disposal, or contact your healthcare professional for disposal information.
- Bleeding may occur after inserting the sensor. Always make sure that the site is not bleeding before connecting the transmitter to the sensor. Blood can get into the transmitter connector and damage the device. Discard the device if damaged. If bleeding occurs, apply steady pressure with a sterile gauze or clean cloth at the insertion site until bleeding stops. After bleeding stops, connect the transmitter to the sensor.
- Do not use the transmitter adjacent to other electrical equipment which may cause interference with the normal system operation. This includes mobile communication devices such as cell phones, GPS navigation systems, and other devices that have an output transmitter power greater than 1W. Other electrical equipment that may compromise normal system operation has been contraindicated.
- Do not change or modify the device unless expressly approved by Medtronic Diabetes. Modifying the device can cause serious injury, interfere with your ability to operate the device, and void your warranty.

Meter

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

Always use the fingertip for blood samples used for calibrating the sensor while in Auto Mode. The fingertip was the only site studied for use with Auto Mode. Do not use blood samples from the palm to calibrate the sensor as this site was not studied for use with Auto Mode and the performance of the system is not known.

Serious illness

- Capillary (fingerstick or Alternative Site) blood glucose testing may not be clinically appropriate when peripheral flow is decreased. Shock, severe hypotension, hyperosmolar hyperglycemia, diabetic ketoacidosis, and occurrence of severe dehydration are examples of clinical conditions that may adversely affect the measurement of glucose in peripheral blood.[1, 2, 3]
- Keep out of reach of children. This kit contains small parts which could cause suffocation if accidentally swallowed.

Talk to your healthcare professional

- Before setting any Target ranges or High or Low Alerts on your meter.
- Before changing your medication based on test results.
- If your blood sugar reading is under 50 mg/dL, follow medical device immediately.
- If you blood sugar reading is over 250 mg/dL, wash and dry your hands well and repeat the test with a new strip. If you get a similar result, call your healthcare professional as soon as possible.
- About whether Alternative Site Testing (AST) is appropriate for you.

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

2 Atkins, S. et al. Fingerstick Glucose Determination in Shock. *Ann intern Med.* 1991;114:1020-1024.

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

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

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

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

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

Potential Biohazard

- Always wash and dry your hands well with soap and water before and after testing, handling the meter, lancing device or test strips.
- The meter, lancing device and lancets are for single person use. Do not share them with anyone including other family members. Do not use on multiple persons.[4, 5]
- The lancing device provided by Ascensia is intended for self-testing by a single patient. It must not be used on more than one person due to risk of infection.
- Use a new lancet each time you test because it is no longer sterile after use.

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

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

- Always dispose of test strips and lancets as medical waste or as advised by your healthcare professional. All products that come in contact with human blood should be handled as if capable of transmitting infectious diseases.

Exposure to magnetic fields and radiation

- Do not expose your pump to MRI equipment, diathermy devices, or other devices that generate strong magnetic fields (for example, x-ray, CT scan, or other types of radiation). The strong magnetic fields can cause the devices to malfunction, and result in serious injury. If your pump is exposed to a strong magnetic field, discontinue use and contact the 24 Hour HelpLine for further assistance.

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

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

General precautions

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

Waterproof capabilities

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

Electrostatic discharge

- Although your MiniMed 670G insulin pump is designed to be unaffected by typical levels of electrostatic discharge (ESD), very high levels of ESD can result in a reset of the pump's software and a pump error alarm. After clearing the alarm, verify that your pump is set to the correct date and time, and that all

other settings are programmed to the desired values. The software reset could erase your previously programmed settings. Following a pump reset, Auto Mode will be unavailable for 5 hours to allow active insulin to be updated.

- For more information on pump alarms, see *Pump alarms, alerts, and messages, on page 250*. For more information on re-entering your pump settings, see *My pump is asking me to enter my settings, on page 292*. 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. 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 301*.

Infusion sets and sites

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

Sensor

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

Transmitter

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

Meter

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

Adverse reactions

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

Keeping track of your system information

The serial number (SN) is located on the back of your pump. If you are using the pump clip, you need to remove the pump clip to view the serial number. It also displays in your Pump status screen. For more details on the status screens, see *Status screens, on page 49*. 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. Do not use insulin in your pump while you are practicing by either inserting an insulin filled reservoir into your pump, or connecting an insulin filled infusion set to your body. Doing so could result in an infusion of insulin, not prescribed by your healthcare professional, which may result in low or high BG.

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

- U100 NovoLog
- U100 Humalog

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

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

Consumables

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

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

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

Additional MiniMed 670G system devices

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

- **CareLink USB (MMT-7306)** – used to upload system data to the diabetes management software using a USB port on your computer.

Accessories

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

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

Ordering supplies and accessories

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

2

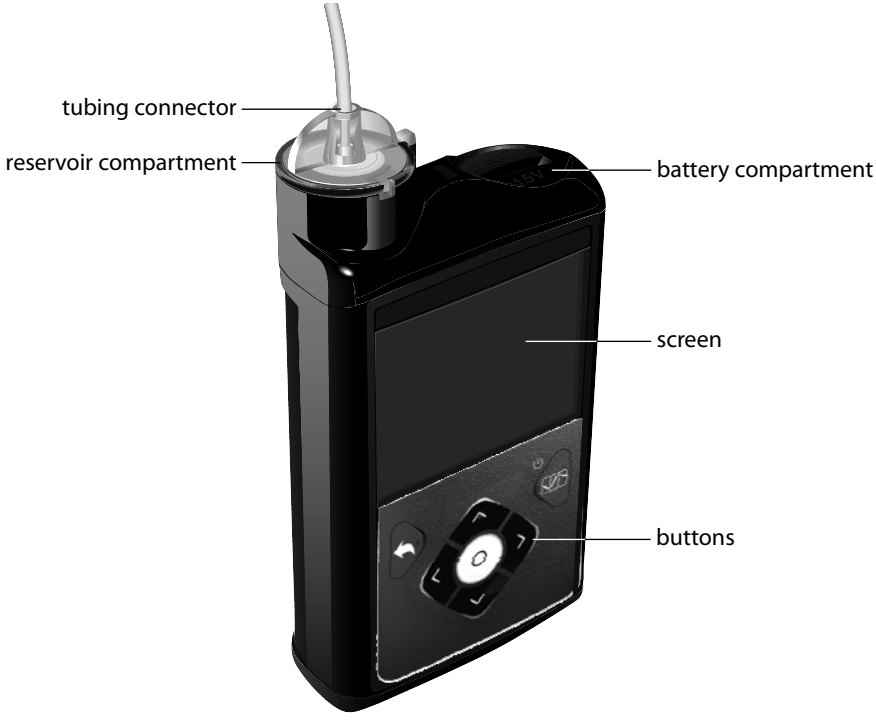
First steps

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 before using your pump to deliver insulin.

Your pump

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



Using the buttons

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

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

The following table describes how to use the buttons.

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

To do this:	Follow these steps:
Scroll up or down a menu or list, or increase or decrease the value of a setting.	Press the ∧ or ∨ buttons.
Select an item on a screen or menu.	Press the ∧, ∨, <, 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 Home screen.	Press and hold the ↩ button to return to the Home screen.
Put the pump in sleep mode.	Press and hold the ⎍ button for about two seconds.
Wake up the pump.	Press any button.

About batteries

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

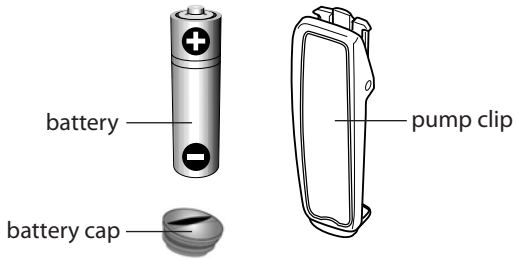
Caution: Do not use a carbon zinc battery in your pump. Carbon zinc batteries are not compatible with the pump. Use of carbon zinc batteries can cause the pump to report inaccurate battery levels.

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

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

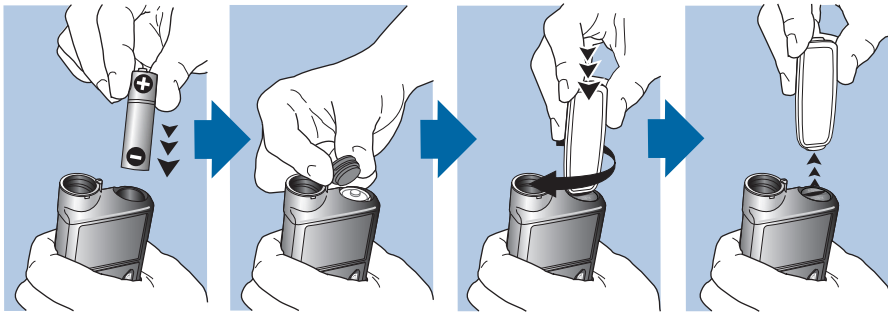
Inserting the battery

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



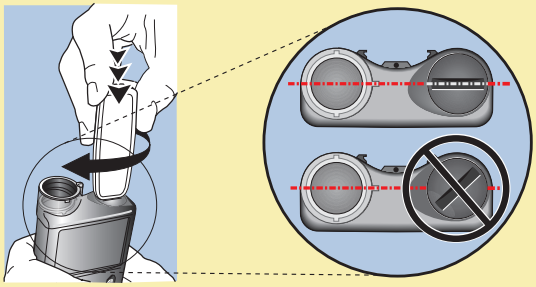
To insert the battery:

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



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

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



Note: If this is the first time you have inserted a battery in your pump, the Startup Wizard begins. For more information about the Startup Wizard, see *Entering your startup settings, on page 40*. If this is not the first time you have inserted a battery into your pump, the Home screen appears and the pump resumes your basal delivery.

Removing the battery

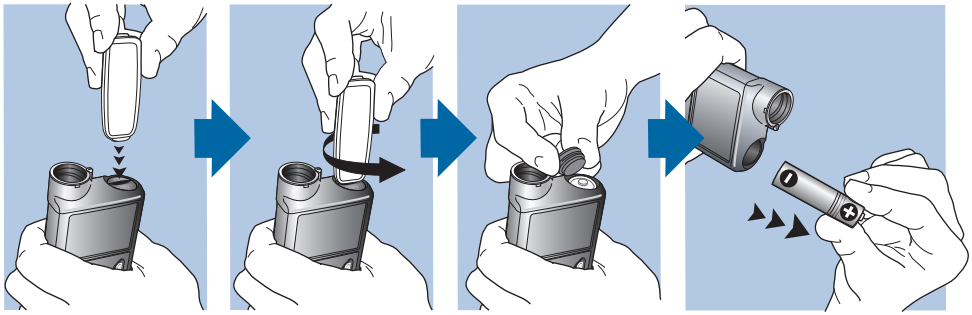
Caution: Do not remove the battery unless you are inserting a new one, or if you are storing your pump. Your pump cannot deliver insulin while the battery is removed. After removing an old battery, be sure to replace it with a new battery within 10 minutes to clear the Insert battery alarm and avoid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

To remove the battery:

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

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

3. Remove the battery.



4. Dispose of old batteries according to local regulations for battery disposal (nonincineration), or contact your healthcare professional for disposal information.
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 302* 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.

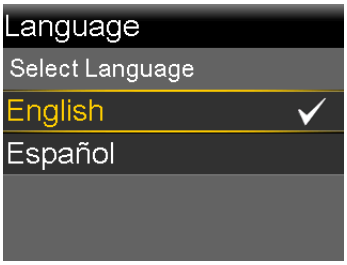
Entering your startup settings

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.

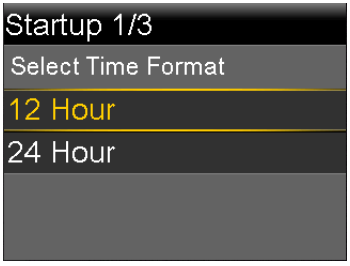
Note: Use this procedure when you are entering your settings for the first time. If this is not the first time you are entering your pump settings, and your pump is asking you to re-enter your settings, see *My pump is asking me to enter my settings, on page 292*.

To use the Startup Wizard:

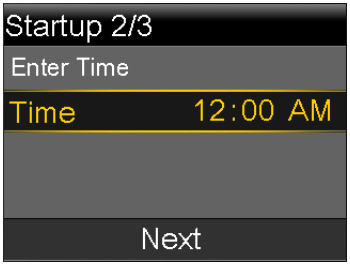
1. The Startup Wizard begins after the Welcome screen appears. When the Language screen appears, select your language.



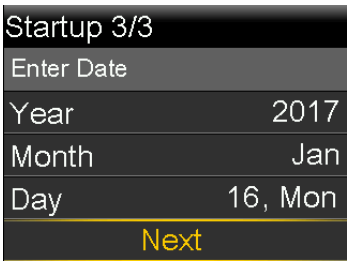
2. When the Select Time Format screen appears, select a **12 hour** or a **24 hour** time format.



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



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



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

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

Unlocking your pump

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

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

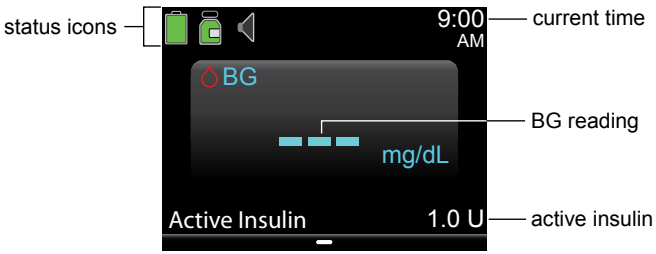
After your pump is unlocked, it will remain unlocked until you re-enter sleep mode. For information about the different power modes, or to put your pump to sleep, see *Power modes, on page 57*.

Home screen

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

To see what your Home screen looks like if you use a sensor, see *Home screen with CGM in Manual Mode, on page 175*.

To see what your Home screen looks like when you are in Auto Mode, see *Home screen with Auto Mode, on page 231*.



The following items appear on your Home screen:

Item	Description
Status icons	Displays icons that show a quick status of your pump system. For more information, see *Status icons, on page 44*.
Current time	Displays the current time of day. For details on setting the time, see *Time and date, on page 170*.
BG meter readings	If you have taken a blood glucose (BG) meter reading using your CONTOUR NEXT LINK 2.4 meter or manually entered a BG meter reading within the last 12 minutes, the BG meter reading appears on the Home screen. You can enter your BG meter reading manually using the Enter BG feature, Event Markers feature, or when you use the Bolus Wizard to deliver a bolus. For details on using the Bolus Wizard, see *Bolus Wizard, on page 88*.
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 *About active insulin, on page 95*.

Status icons

The status icons appear at the top of the Home screen to provide a way for you to quickly check the status of your system. The status icons are described in the following table. For information on viewing detailed status screens, see *Status screens, on page 49*.

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

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. The reservoir icon is representative of the Medtronic reservoir MMT-332A, 3.0 mL (300-unit). When your reservoir is full, the icon is solid green. As your insulin is used, the icon becomes emptier, and the color of the icon changes as shown in the following example. For more information about your reservoir, see *Reservoir and infusion set* on *Setting up the reservoir and infusion set, on page 117*. •  Approximately 85-100% of the reservoir remains. •  Approximately 71-84% of the reservoir remains. •  Approximately 57-70% of the reservoir remains. •  Approximately 43-56% of the reservoir remains. •  Approximately 29-42% of the reservoir remains. •  Approximately 15-28% of the reservoir remains. •  Approximately 1-14% of the reservoir remains. •  The reservoir remaining amount is unknown.
	Audio	The audio mode you are using: vibrate only  , audio only  , or vibrate and audio  . When the Alert Silence feature is turned on, the audio mode icons appear as follows: vibrate only  , audio only  , or vibrate and audio  .

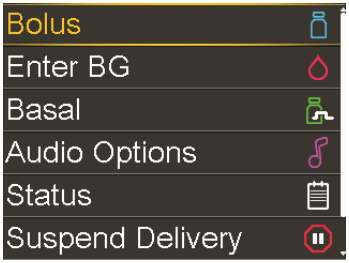
Icon	Icon name	What it means
	Connection	The connection icon appears green  when the Sensor feature is on and your transmitter is successfully communicating with your pump. The connection icon appears with a red X  when the Sensor feature is turned on, but the transmitter is not connected or communication with your pump has been lost. For more information about the Sensor feature, see *Understanding Continuous Glucose Monitoring (CGM), on page 173*.
	Airplane Mode	The Airplane Mode icon  appears in place of the Connection icon if Airplane Mode is turned on. When Airplane Mode is turned on, the pump cannot receive wireless communication from other devices. For more information about using Airplane Mode, see *Airplane Mode, on page 159*.
	Temporary Network Connection	Replaces Connection icon while you are temporarily connected to a remote upload device.

Icon	Icon name	What it means
	Calibration	The approximate time left until your next sensor calibration is due. Appears only when the Sensor feature is turned on. The color and the circle around the icon indicate the status. When your sensor is fully calibrated, the icon has a solid green circle around it. As the time for your next sensor calibration approaches, the green circle around the icon becomes smaller, and the color of the icon changes as shown in the following example. For more information about calibrating your sensor, see *Calibrating your sensor, on page 210*. •  Time to your next sensor calibration is more than 10 hours. •  Time to your next sensor calibration is 8 to 10 hours. •  Time to your next sensor calibration is 6 to 8 hours. •  Time to your next sensor calibration is 4 to 6 hours. •  Time to your next sensor calibration is 2 to 4 hours. •  Time to your next sensor calibration is less than 2 hours. •  Sensor calibration is required now. •  Time to your next sensor calibration is unavailable. •  Sensor is not ready for a calibration. This occurs when a new sensor is connected or within 15 minutes of a Calibration not accepted alert.

Icon	Icon name	What it means
	Sensor Life	The number in the center of the Sensor Life icon indicates the number of days remaining in the life of your sensor. The icon appears only when the Sensor feature is turned on. When you insert a new sensor, the icon color is solid green. When one day is remaining in the life of your sensor, the icon color turns red.  **Note:** For a short time after starting a new sensor, the Sensor Life icon may show an 8. When the Sensor Life icon changes to show a 7, the seven-day period of sensor life begins.  If the number of days remaining in the life of your sensor is unavailable, the Sensor Life icon appears with three dots  .
	Auto Mode Readiness	The Auto Mode Readiness icon indicates whether your pump is ready to enter Auto Mode. The icon appears with a loading symbol  when the pump is updating a condition that requires you to wait. The icon appears with a question mark  when the pump requires an action from you to enter Auto Mode. For more information about Auto Mode Readiness, see *Auto Mode Readiness, on page 229*.
	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 *Block Mode, on page 162*.

Using the menu

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



The following options are available from the menu:

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

Status screens

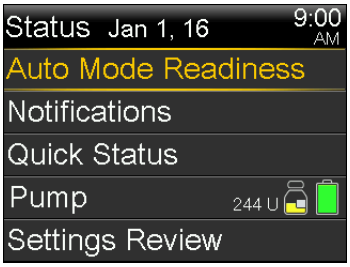
The Status screens provide information about your pump, any notifications you have received, your current settings, and optional sensor. The Status screens are described in the following table:

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

Viewing the Status screens

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

   The Status screen appears. The Reservoir icon shows the approximate amount of insulin left in your reservoir. For more information, see *Status icons, on page 44*.



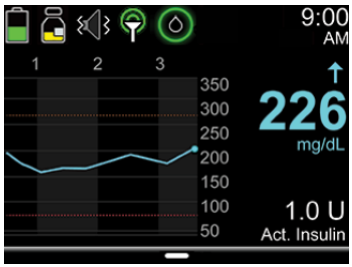
2. Press ^ or v to move up or down the screen. Select the status screen that you want to view. Refer to the table at the beginning of this section for a description of the different status screens.

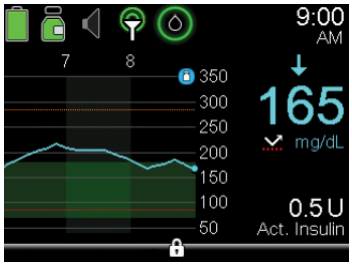
Modes

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

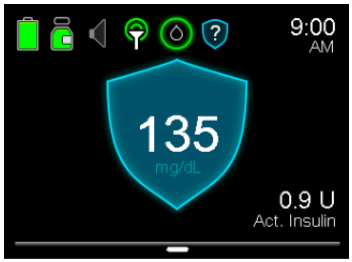
Manual Mode

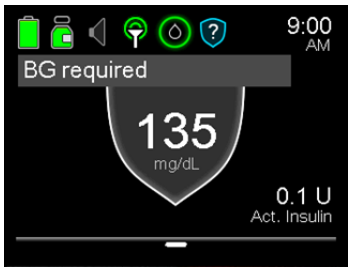
Mode CGM options	Bolus delivery options	Basal delivery	Suspend options
Pump without CGM  	• Bolus Wizard, uses programmed carb ratio, insulin sensitivity, BG target, and active insulin time settings. • Normal bolus • Square Wave bolus • Dual Wave bolus • Remote bolus • Preset bolus • Easy bolus For more information, see the *Bolus* chapter.	• Programmed basal delivery settings — For more information, see *Basal insulin settings, on page 62*. • Temporary basal rates — For more information, see *Temporary basal rates, on page 70*. • Preset temporary basal rates — For more information, see *Preset Temp basal rates, on page 72*.	Manual suspend — For more information, see *Stopping and resuming your insulin delivery, on page 76*.

Mode CGM options	Bolus delivery options	Basal delivery	Suspend options
Pump with CGM  	• Bolus Wizard, uses programmed carb ratio, insulin sensitivity, BG target, and active insulin time settings. • Normal bolus • Square Wave bolus • Dual Wave bolus • Remote bolus • Preset bolus • Easy bolus For more information, see the *Bolus* chapter.	• Programmed basal delivery settings — For more information, see *Basal insulin settings, on page 62*. • Temporary basal rates — For more information, see *Temporary basal rates, on page 70*. • Preset temporary basal rates — For more information, see *Preset Temp basal rates, on page 72*.	Manual suspend — For more information, see *Stopping and resuming your insulin delivery, on page 76*.

Mode CGM options	Bolus delivery options	Basal delivery	Suspend options
Pump with CGM and with Suspend before low or Suspend on low enabled 	• Bolus Wizard, uses programmed carb ratio, insulin sensitivity, BG target, and active insulin time settings. • Normal bolus • Square Wave bolus • Dual Wave bolus • Remote bolus • Preset bolus • Easy bolus For more information, see the *Bolus* chapter.	• Programmed basal delivery settings — For more information, see *Basal insulin settings, on page 62*. • Temporary basal rates — For more information, see *Temporary basal rates, on page 70*. • Preset temporary basal rates — For more information, see *Preset Temp basal rates, on page 72*.	• Manual suspend — For more information, see *Stopping and resuming your insulin delivery, on page 76*. • Suspend before low — For more information, see *Suspend before low, on page 182*. • Suspend on low — For more information, see *Suspend on low, on page 186*.

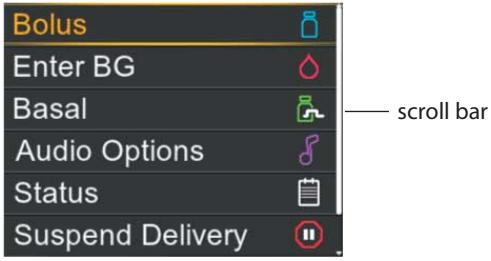
Auto Mode

	Bolus delivery options	Basal delivery	Suspend options
Auto Mode (Auto Basal delivery)  	• Auto Mode Bolus impacted by Carb Ratio and Active Insulin Time settings • Patient enters carb grams and BGs • Pump may recommend bolus when BG≥150 mg/dL entered • Patient accepts or cancels bolus For more information, see the *Auto Mode* chapter.	• Automatic delivery of basal insulin based on recent insulin delivery needs and SG values to target of 120 mg/dL • May set a temporary target of 150 mg/dL for up to 12 hours For more information, see the *Auto Mode* chapter.	Manual suspend – For more information, see *Stopping and resuming your insulin delivery, on page 76*.

	Bolus delivery options	Basal delivery	Suspend options
Auto Mode (Safe Basal delivery)  	• Auto Mode Bolus impacted by Carb Ratio and Active Insulin Time settings • Patient enters carb grams and BGs • Pump may recommend bolus when BG≥150 mg/dL entered • Patient accepts or cancels bolus For more information, see the *Auto Mode* chapter	• Automatic delivery of basal insulin at a fixed rate • Does not use SG values to adjust rate For more information, see the *Auto Mode* chapter	Manual suspend – For more information, see *Stopping and resuming your insulin delivery, on page 76.*

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 ∧ or ∨ 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 *Unlocking your pump, on page 42*.
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 *Display Options, on page 163*. If any button is pressed while the pump is in Power save mode, the pump returns to the screen that was last displayed.
Sleep	Your pump automatically enters sleep mode when you have not pressed any buttons for about two minutes after your screen goes dark (power save mode). Your pump is still fully functional. If any button is pressed while the pump is in sleep mode, you will be shown a screen asking you to unlock your pump. For details, see *Unlocking your pump, on page 42*. To put your pump into sleep mode, press and hold the  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 165* for more information.
- Remove the battery. See *Storing your pump, on page 302* 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 (BG) when you are not eating. Your basal insulin accounts for approximately one half of your daily insulin requirements. Your pump mimics a pancreas by delivering insulin continuously over 24 hours.

Note: In Manual Mode, your basal insulin is delivered according to your programmed basal pattern. In Auto Mode, insulin is delivered based on sensor values and your recent insulin delivery needs. For more information on Manual Mode, see *Manual Mode, on page 226*. For more information on Auto Mode, see *Auto Mode, on page 225*.

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 64*.

Basal insulin settings

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

Setting	What it is	What it does for you
Basal Pattern	A set of one or more basal rates that cover a 24-hour period.	Determines the amount of insulin you receive per hour throughout the day and night. Allows you to vary your basal rate according to your needs. You can set up to eight basal patterns. For details on setting up basal patterns, see *Adding a new basal pattern, on page 65*. For details about starting a basal pattern, see *Changing from one basal pattern to another, on page 68*.
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 *Starting a Temp Basal rate, on page 71*.
Preset Temp	A temporary basal rate that you can define ahead of time.	Allows you to set and save temporary basal rates for known short-term situations, such as when you are sick or have times of increased or decreased activity. For details about setting up a Preset Temp basal rate, see *Preset Temp basal rates, on page 72*. For details about starting a Preset Temp basal rate, see *Starting a Preset Temp basal rate, on page 74*.
Max Basal Rate	Maximum amount of basal insulin that your pump can deliver per hour.	Provides a safety measure by limiting the total amount of basal insulin your pump can deliver per hour. For details about setting your Max Basal rate, see *Max Basal Rate, on page 63*.

Max Basal Rate

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

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

To set your Max Basal Rate:

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

   Options > Delivery Settings > Max Basal/Bolus

2. Select **Max Basal** to set the maximum number of basal insulin units that can be delivered each hour.

   Because the Max Basal Rate setting determines your basal insulin limits, a warning message appears any time you enter the screen to change the value. To continue setting the value, select **Continue**.

3. In the Max Basal Rate screen, select **Max Basal** to set the maximum units per hour.

4. Select **Save**.

Example 1: Max basal

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

Example 2: Max basal

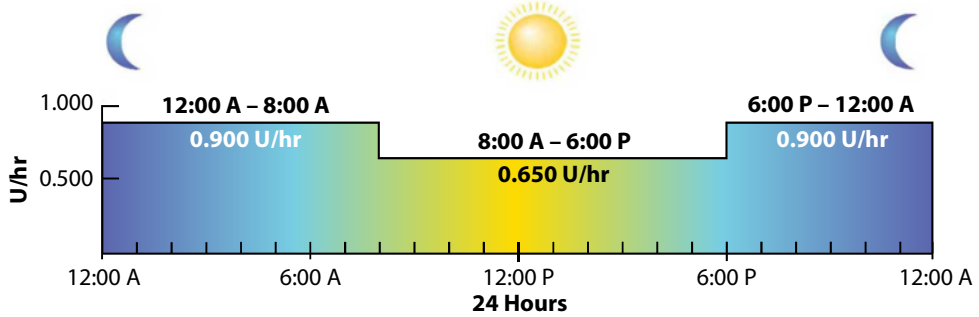
Rusty needs large amounts of insulin to control his blood glucose levels. His new pump was delivered from the factory with a max basal rate of 2.00 units per hour, but he needs 2.80 units per hour in the early morning. Rusty plans to consult his healthcare professional about increasing his max basal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

Basal patterns

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

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

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



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

Note: If you have already set up basal patterns and want to switch from using one basal pattern to another, see *Changing from one basal pattern to another, on page 68*.

Adding a new basal pattern

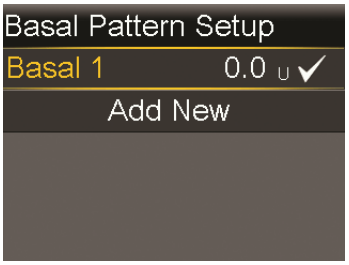
This procedure shows you how to add a new basal pattern.

To add a new basal pattern:

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

   Options > Delivery Settings > Basal Pattern Setup

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

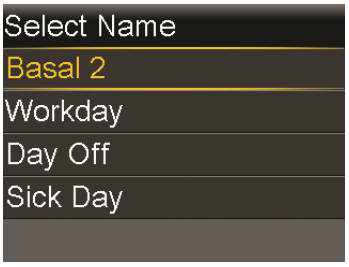


2. If this is your first time setting up a basal pattern, the unit amount will be 0.0. Select **Basal 1** and proceed to step 5.

   If this is not your first time setting up a basal pattern, proceed to the next step to add a new pattern.

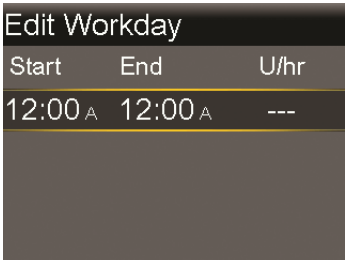
3. To add a new basal pattern, select **Add New**.

   The Select Name screen appears.



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

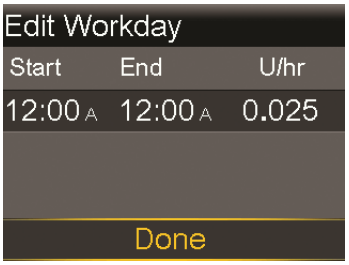
4. Select the basal pattern that you want to set up. An edit screen appears for the pattern you selected. The following example shows the Edit Workday screen.



5. To create one continuous 24-hour basal rate for your basal pattern, continue with this step. To create more than one basal rate for your new basal pattern, skip to step 6.

   a. Leave End time at 12:00 AM to set a 24-hour rate. The Start time of the first time segment is always 12:00 AM.

   b. Set your rate in units per hour.

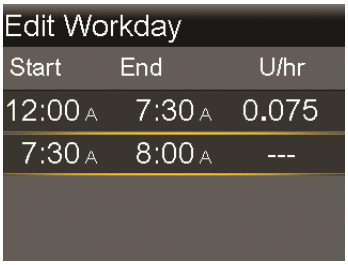


   c. Skip to Step 7.

6. To create more than one basal rate for your new basal pattern, enter one basal rate at a time, as described in the following steps:

   a. Set the End time and the Rate for your first basal rate. You set your rates in 30-minute increments.

      If you set the End time to anything other than 12:00 AM, a second basal rate setting appears.

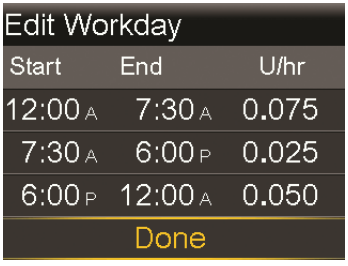


The Start time for the next rate is always the same as the End time of the previous rate.

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

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

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



7. When you finish setting your basal pattern, select **Done**. (The Done option appears only when the last End time in your basal pattern is set to 12:00 AM).

A screen appears that allows you to review your basal pattern. If you need to make any changes, press ↩ to return to the previous screen.

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

8. Select **Save**.

   To activate your basal pattern, see *Changing from one basal pattern to another, on page 68*.

Editing, copying, or deleting a basal pattern

To edit, copy, or delete a basal pattern:

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

   Options > Delivery Settings > Basal Pattern Setup

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

Changing from one basal pattern to another

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

To change to a different basal pattern:

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

   Basal > Basal Patterns

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

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

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

Example 1: Basal patterns

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

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

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

Example 2: Basal patterns

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

Temporary basal rates

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

Note: Auto Mode is not available if Temp Basal is active. If you wish to switch your pump to Auto Mode, you must first cancel Temp Basal. For more information on canceling a Temp Basal, see *Canceling a Temp Basal or Preset Temp basal rate, on page 75*.

About Temp Basal rates

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

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

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

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

To use the Temp Basal feature, see *Starting a Temp Basal rate, on page 71*. To use the Preset Temp Basal feature, see *Preset Temp basal rates, on page 72*.

Example 1: Temporary basal rates

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

Starting a Temp Basal rate

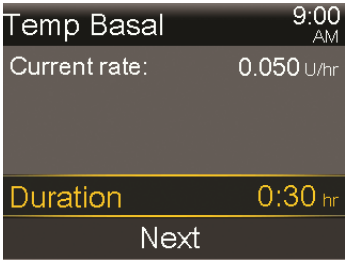
When you start a temp basal rate, your basal delivery changes to the temporary basal rate for the duration you set. When the duration is complete, your basal insulin automatically returns to the active basal pattern.

To start a temp basal rate:

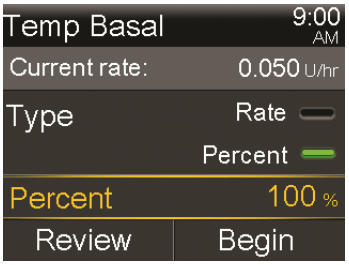
1. Press ◎ and go to the Temp Basal screen.

   Basal > Temp Basal

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

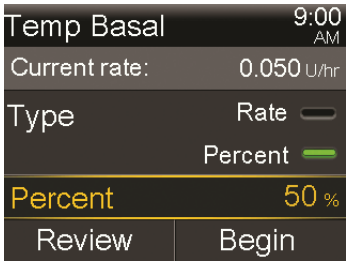


3. Select **Next**.
4. The Type defaults to Percent. You can switch between Percent and Rate by selecting **Type**.

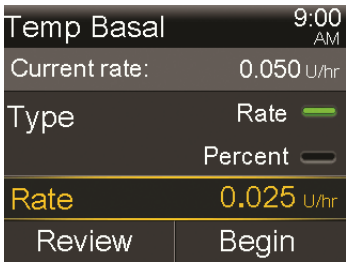


5. Depending on the Type you selected, do one of the following:

   - Enter a percentage:



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



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

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

Preset Temp basal rates

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

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

Setting up and managing Preset Temp basal rates

This section describes how to set up, edit, rename, or delete a preset temp basal rate. For information on how to start using a preset temp basal rate, see *Starting a Preset Temp basal rate, on page 74*.

To set up a preset temp basal rate:

1. Press ◎ and go to the Preset Temp Setup screen.

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

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

1. Press ◎ and go to the Preset Temp screen.

   Options > Delivery Settings > Preset Temp Setup
2. Select the desired preset temp basal.

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

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

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

Starting a Preset Temp basal rate

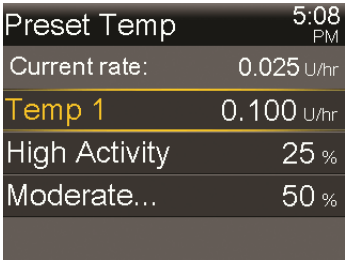
You must set up preset temp basal rates before you can use the Preset Temp feature. For more information, see *Preset Temp basal rates, on page 72*.

To start a preset temp basal rate:

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

   Basal > Preset Temp

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



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

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

3. Select **Begin**.

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

Switching to Auto Mode from Temp Basal

In order to switch to Auto Mode, you must first cancel any active Temp Basal rate. Auto Mode cannot begin while a Temp Basal rate is active. For information on how to cancel a Temp Basal rate, see *Canceling a Temp Basal or Preset Temp basal rate, on page 75*.

Canceling a Temp Basal or Preset Temp basal rate

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

To cancel a Temp Basal rate:

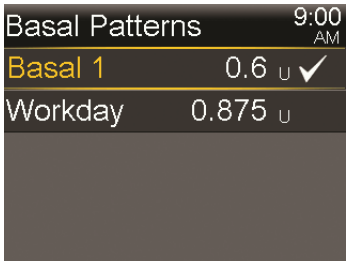
1. From the Home screen, press ◎ and go to the Cancel Temp Basal screen.

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

2. Select **Cancel Temp Basal**.

Viewing your basal information

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

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

Stopping and resuming your insulin delivery

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

Note: The first reminder occurs 15 minutes after your pump display times out. If you press a button and wake up your pump, the reminder will not occur until 15 minutes after your pump display times out again. To adjust your timeout setting, see *Display Options, on page 163*.

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 111*.

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

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

Contact the 24 Hour HelpLine with any concerns.

To suspend all insulin delivery:

1. Press ◎ and go to the **Suspend Delivery** screen.

   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, press ◎ and go to the **Resume Delivery** screen.

   A confirmation message appears.

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

Note: If you still need a bolus delivery that was in progress before you suspended your delivery, check the Daily History screen for the actual bolus units delivered and the intended bolus amount. Then you can set up a new bolus amount as needed. See *Daily History, on page 143* 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 (BG), typically when you eat a meal or snack. You can also use a bolus to correct a high blood glucose reading.

About bolus deliveries

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

Bolus types

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

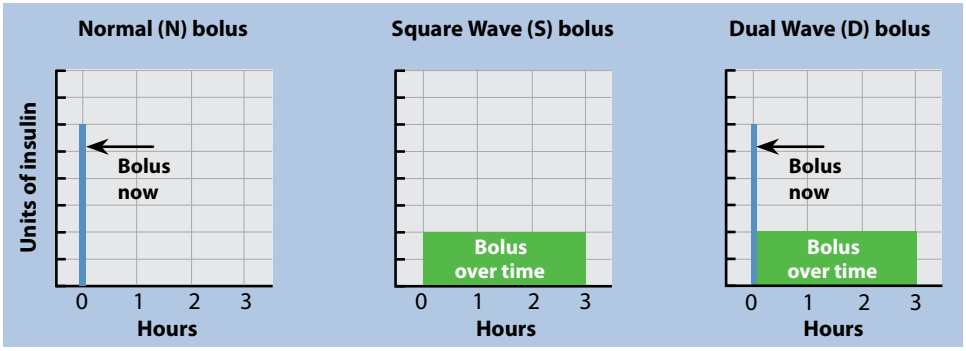
The following table provides general information about the available bolus types.

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 *Normal bolus, on page 96*.

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 *Square Wave bolus, on page 100*.
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 *Dual Wave bolus, on page 103*.

Bolus type example

The following example shows how the different bolus types work.



Bolus delivery options

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

Note: Different bolus delivery options are available depending on whether the pump is in Manual Mode or Auto Mode. For a list of delivery options available for each mode, see *Modes, on page 51*.

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 or your carbs you plan to eat, or both. Then the Bolus Wizard calculates an estimated bolus amount based on your individual settings. The Bolus Wizard feature is only available in Manual Mode. For details about using the Bolus Wizard feature, see *Bolus Wizard, on page 88*. To deliver a: • Normal bolus using Bolus Wizard, see *Delivering a Normal bolus with the Bolus Wizard, on page 97*. • Square Wave bolus using Bolus Wizard, see *Delivering a Square Wave bolus with the Bolus Wizard, on page 101*. • Dual Wave bolus using Bolus Wizard, see *Delivering a Dual Wave bolus with the Bolus Wizard, on page 103*.

Delivery method	Type of bolus available	How it works
Auto Mode Bolus	Normal bolus	You enter your BG meter reading or your carbs you plan to eat, or both. Then the Auto Mode Bolus feature calculates a bolus amount to cover the meal or correction. The Auto Mode Bolus feature is only available in Auto Mode. For details about using the Auto Mode Bolus feature, see *Auto Mode Bolus, on page 238*.
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 *Delivering a Normal bolus using Manual Bolus, on page 99* • Square Wave bolus, see *Delivering a Square Wave bolus using Manual Bolus, on page 102* • Dual Wave bolus, see *Delivering a Dual Wave Bolus using Manual Bolus, on page 105*
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 *Preset Bolus, on page 109*.

Delivery method	Type of bolus available	How it works
Easy Bolus feature	Normal bolus	After the Easy Bolus feature is set up, you can deliver a Normal bolus by using the ^ button when the pump is in sleep mode. For details about using the Easy Bolus feature, see *Easy Bolus, on page 106*.
Remote Bolus from your CONTOUR NEXT LINK 2.4 meter	Normal bolus or any Preset Bolus set up on your pump.	For information on using the Remote Bolus feature on your CONTOUR NEXT LINK 2.4 meter, see the user guide that came with your meter. For information on turning on the Remote Bolus feature on your pump, see *Setting up Remote Bolus, on page 134*.
Remote Bolus from your CONTOUR NEXT LINK 2.4 meter	Normal bolus or any Preset Bolus set up on your pump.	For information on using the Remote Bolus feature on your CONTOUR NEXT LINK 2.4 meter, see the user guide that came with your meter. For information on turning on the Remote Bolus feature on your pump, see *Setting up Remote Bolus, on page 134*.

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

Bolus settings

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

Note: There are additional settings required if you want to use the Bolus Wizard. These are described in the section, *Bolus Wizard, on page 88*.

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 *Max Bolus, on page 86*.
Bolus Increment	The amount of insulin (in units) that is increased or decreased with each button press when adjusting your bolus amount. The Bolus Wizard and Auto Mode Bolus will also use the increment to display the bolus total and adjustment amounts. This setting does not apply to Easy Bolus.	Allows you to set your increment value according to your typical bolus amounts. For details about setting the bolus increment, see *Bolus Increment, on page 87*.
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 *Bolus Speed, on page 88*.

Max Bolus

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

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

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

To set your max bolus:

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

   Options > Delivery Settings > Max Basal/Bolus
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 Max Bolus of 5.0 units.

Example 2: Max Bolus

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

Bolus Increment

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

Note: Easy Bolus uses a setting called Step Size to determine the number of insulin units for each button press. See *Setting up Easy Bolus, on page 107* for more information.

To set your Bolus Increment:

1. Press ◎ and go to the Bolus Increment screen.

   Options > Delivery Settings > Bolus Increment

2. Select **Increment** to set your desired increment value.
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. Press ◎ and go to the Bolus Speed screen.

   Options > Delivery 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 ratio, insulin sensitivity, BG target range, and active insulin time.

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

After you set up the Bolus Wizard, you can use it to calculate and deliver a food bolus, a correction bolus, or a food plus correction bolus using a Normal bolus (see *Delivering a Normal bolus with the Bolus Wizard, on page 97*), Square Wave bolus (see *Delivering a Square Wave bolus with the Bolus Wizard, on page 101*), or Dual Wave bolus (see *Delivering a Dual Wave bolus with the Bolus Wizard, on page 103*).

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 90*.

Setting	What it does
Carb Ratio	Used for food bolus calculations. The number of carb grams that are covered by 1 unit of insulin.
Insulin Sensitivity 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.

Setting	What it does
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 *About active insulin, on page 95*.

Setting up the Bolus Wizard feature

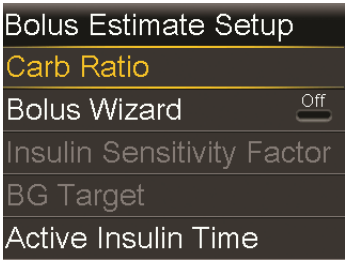
Before you can use the Bolus Wizard to calculate a bolus, you must turn on this feature and enter your Bolus Wizard settings.

To set up the Bolus Wizard feature:

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

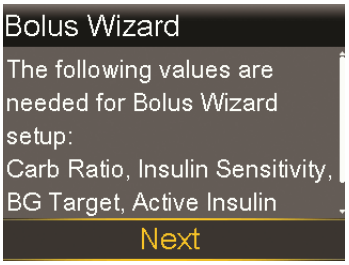
   Options > Delivery Settings > Bolus Estimate Setup

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



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

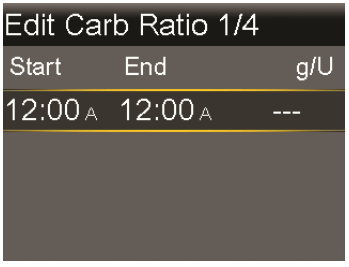
   If this is the first time you have turned on the Bolus Wizard feature, your pump displays information about the settings you need to enter.



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

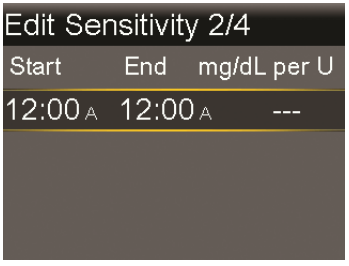
Note: As you enter your personal settings, your pump displays information about each setting. Select **Next** to continue when you have read each explanation.

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



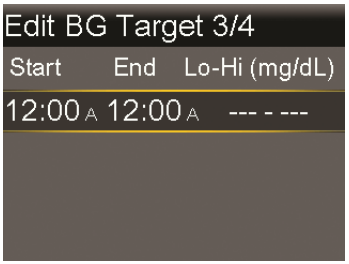
If your ratio value is outside the range of 5 to 50 grams per unit, a message appears asking you to confirm your setting.

4. When the Edit Sensitivity screen appears, enter your insulin sensitivity factor. You can set up to eight different sensitivity factors using different time segments. The time segments must cover a 24-hour period.



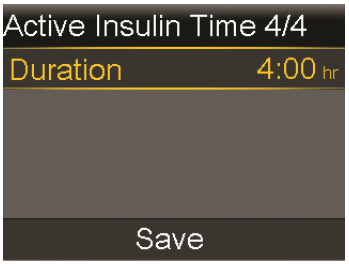
If the value you enter is outside the range of 20 to 100 mg/dL per U, a message appears asking you to confirm your setting.

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



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

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



7. Select **Save**.

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

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

Changing your Bolus Wizard settings

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

Changing your carb ratio

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

To change your carb ratio:

1. Press ◎ and go to the Carb Ratio screen.

   Options > Delivery Settings > Bolus Estimate Setup > Carb Ratio

2. Select **Edit**.
3. Select the carb ratio to adjust the Start time, the End time, and the ratio. You can set up to eight different carb ratios using different time segments. The time segments must cover a 24-hour period.

   If you set a value outside the typical range of 5 to 50 grams per unit, a message appears asking you to confirm your setting.

4. When you have made your changes, select **Save**.

Changing your insulin sensitivity factor

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

To change your insulin sensitivity factor:

1. Press ◎ and go to the Sensitivity screen.

   Options > Delivery Settings > Bolus Estimate Setup > Insulin Sensitivity Factor

2. Select **Edit**.
3. Select the sensitivity factor to adjust the Start time, the End time, and the Sensitivity amount. You can set up to eight different sensitivity amounts using different time segments. The time segments must cover a 24-hour period.

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

4. When you have made your changes, select **Save**.

Changing your Bolus Wizard BG target

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

To change your Bolus Wizard BG target range:

1. Press ◎ and go to the BG Target screen.

   Options > Delivery Settings > Bolus Estimate 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. Press ◎ and go to the Active Insulin Time screen.

   Options > Delivery Settings > Bolus Estimate Setup > Active Insulin Time
2. Select **Duration**, then adjust your active insulin time (in hours), using 15-minute increments.
3. Select **Save**.

Turning off the Bolus Wizard feature

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

To turn off the Bolus Wizard feature:

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

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

Normal bolus

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

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

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

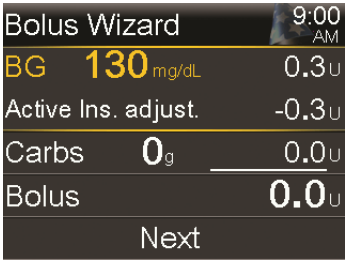
Delivering a Normal bolus with the Bolus Wizard

To deliver a Normal bolus using the Bolus Wizard:

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

   Bolus > Bolus Wizard

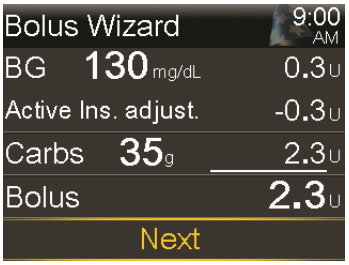
   The Bolus Wizard screen shows your current BG meter reading (if applicable) and any insulin that is still active from previous boluses. For more information about active insulin, see *About active insulin, on page 95*. For more information, see *About your CONTOUR NEXT LINK 2.4 meter, on page 133*.



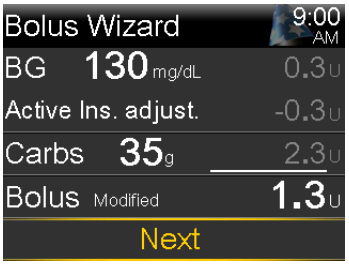
3. If you are not using a wirelessly connected meter, you can select **BG** to manually enter your BG meter reading.

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

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



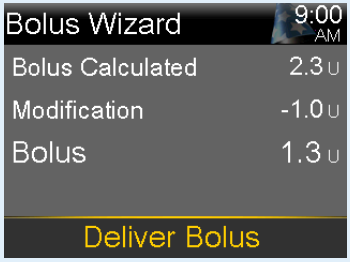
If you want to change the bolus amount, select **Bolus** and make any desired adjustment. If you change your bolus amount, the word "Modified" appears next to the new bolus amount.



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

   Your bolus amount appears.

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



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

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

Delivering a Normal bolus using Manual Bolus

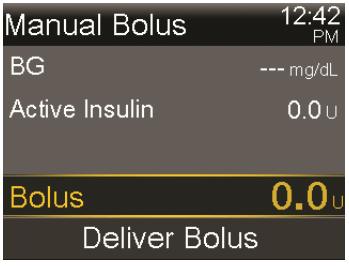
The following section describes how to deliver a Normal bolus using the Manual Bolus feature.

To deliver a Normal bolus using Manual Bolus:

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

   Bolus > Manual Bolus

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



The Manual Bolus screen shows your current BG value (if applicable) and any insulin that is still active from previous boluses. For more information about active insulin, see *About active insulin, on page 95*.

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

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

Square Wave bolus

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

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

A Square Wave bolus can be useful in these situations:

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

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

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

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

All other functions are available during the Square Wave bolus.

Turning on or off Square Wave bolus

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

To turn on or turn off the Square Wave feature:

1. Press ◎ and go to the Dual/Square Wave screen.

   Options > Delivery Settings > Dual/Square Wave

2. Select **Square Wave** to turn the feature on or off.
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. Press ◎ and go to the Bolus Wizard screen.

   Bolus > Bolus Wizard

   The Bolus Wizard screen shows your current BG meter reading (if applicable) and any insulin that is still active from previous boluses. For more information about active insulin, see *About active insulin, on page 95*. For more information, see *About your CONTOUR NEXT LINK 2.4 meter, on page 133*.

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

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

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

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

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

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

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

Delivering a Square Wave bolus using Manual Bolus

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

To deliver a Square Wave bolus manually:

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

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

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

Dual Wave bolus

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

A Dual Wave bolus can be useful in these situations:

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

Turning on or off Dual Wave bolus

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

To turn on or turn off the Dual Wave feature:

1. Press ◎ and go to the Dual/Square Wave screen.

   Options > Delivery Settings > Dual/Square Wave
2. Select **Dual Wave** to turn the feature on or off.
3. Select **Save**.

Delivering a Dual Wave bolus with the Bolus Wizard

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

To deliver a Dual Wave bolus with the Bolus Wizard:

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

   Bolus > Bolus Wizard

   The Bolus Wizard screen shows your current BG meter reading (if applicable) and any insulin that is still active from previous boluses. For more information about active insulin, see *About active insulin, on page 95*. For more information, see *About your CONTOUR NEXT LINK 2.4 meter, on page 133*.

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

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

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

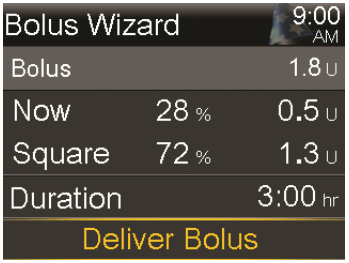
4. For a food bolus, select **Carbs** to enter the carb count of your meal. For a correction bolus where no food was eaten, leave the Carbs value as 0.
5. Review your calculated Bolus amount. If you want to change the amount, select **Bolus** and make your desired change.

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

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

   The Bolus Wizard screen appears, with the food amount split evenly between the Now and Square portions.
8. If you need to change the amounts, select the area of the screen with the Now value and adjust the **Now** amount.

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



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

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

Delivering a Dual Wave Bolus using Manual Bolus

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

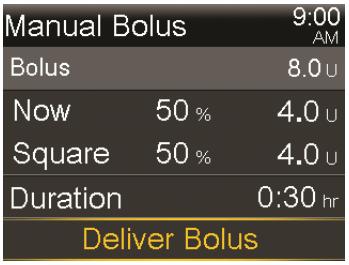
To deliver a Dual Wave bolus using Manual Bolus:

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

   Bolus > Manual Bolus

   The Manual Bolus screen appears.
2. Set your bolus delivery amount (in units), and then select **Next**.
3. Select **Dual**.

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



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

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

Easy Bolus

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

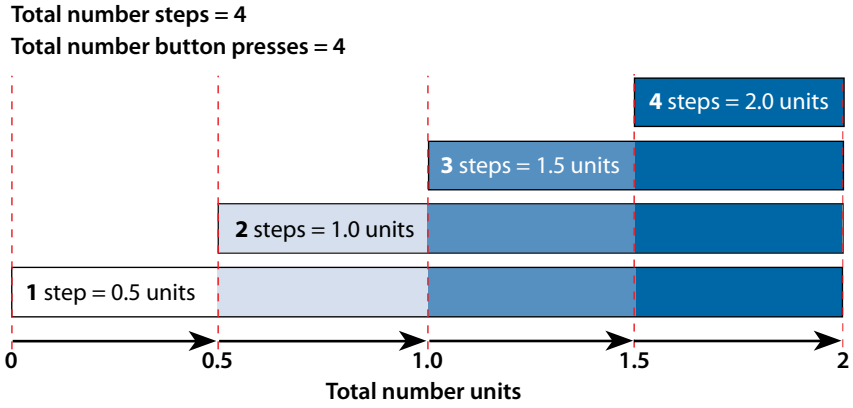
Before using Easy Bolus, you must turn on the feature and set the step size. The step size determines the number of units the bolus amount increases each time you press the ∧ button. Your Easy Bolus delivery is limited to 20 steps or your max bolus limit, whichever comes first.

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

Understanding Easy Bolus step sizes

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

The following example shows how your bolus amount is increased with each step, or each press of the ∧ 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:

1. Press ◎ and go to the Easy Bolus screen.

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

Delivering a bolus using Easy Bolus

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

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

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

To deliver a bolus using Easy Bolus:

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

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

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

   Each time you press ∧, 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 ∨ to select the Easy Bolus values. Pressing ∨ cancels the Easy Bolus.

3. When you have reached the desired bolus amount, press and hold ∧ to confirm the amount. You should hear a confirmation tone or feel a vibration for each button press. Count to ensure the amount is correct. If the amount is not correct, press and hold ∨ until you hear a tone, and then start again from step 1.

4. When the bolus amount is confirmed, press and hold ^ for about one second to deliver your bolus. Your pump beeps or vibrates. Your bolus starts immediately after the confirmation.

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

Preset Bolus

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

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

Setting up and managing Preset Bolus deliveries

To set up Preset Bolus amounts:

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

   Options > Delivery Settings > Preset Bolus Setup

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

2. Select **Add New**.

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

3. Select the Preset Bolus you want to set.

   The Edit screen for that particular Preset Bolus appears.

4. Select **Bolus** to set the bolus amount.

5. Select **Type** to set this as a Normal bolus, Square Wave bolus, or Dual Wave bolus.

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

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

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

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

7. Select **Save**.

Editing, renaming, or deleting a Preset Bolus

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

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

To edit, rename, or delete a Preset Bolus:

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

   Options > Delivery Settings > Preset Bolus Setup

   The Preset Bolus Setup screen appears, showing any existing Preset Bolus settings.
2. Select the desired Preset Bolus.
3. Select **Options**.
4. Do one of the following:

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

Delivering a Preset Bolus

Follow these steps to deliver a Preset Bolus. You must set up Preset Bolus deliveries before you can use the Preset Bolus feature. For more information, see *Setting up and managing Preset Bolus deliveries, on page 109*.

To deliver a Preset Bolus:

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

   Bolus > Preset Bolus

   The existing preset bolus settings appear, showing your current BG value (if applicable) and any insulin that is still active from previous boluses. For more information about active insulin, see *About active insulin, on page 95*.
2. Select the Preset Bolus you want to deliver.
3. Verify your bolus amounts, and then select **Deliver Bolus**.

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

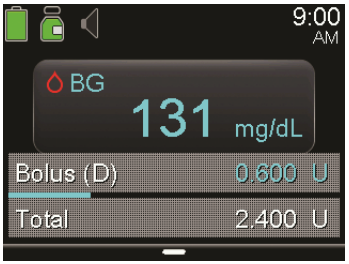
Stopping a bolus delivery

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

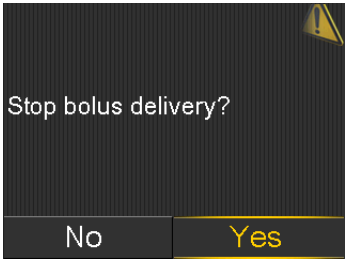
Note: This procedure describes how to stop a bolus that is in progress. It does not stop your basal insulin delivery. If you need to stop all insulin delivery, use the Suspend Delivery feature (press ◎ and select **Suspend Delivery**).

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

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



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



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

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

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

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

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

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

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. You must also program your settings as instructed by your healthcare professional.

You will need these items:

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

WARNING: Clear the active insulin value before using your pump to deliver insulin for the first time. If you have practiced giving boluses on your pump before using insulin, the active insulin value could be inaccurate. This could result in inaccurate insulin delivery, and serious injury. For details, see *Clearing your active insulin, on page 166*.

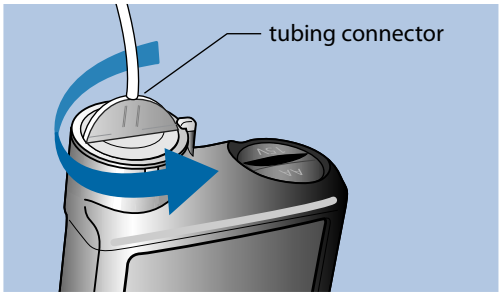
Removing the reservoir

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 118*.

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

To remove your reservoir:

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



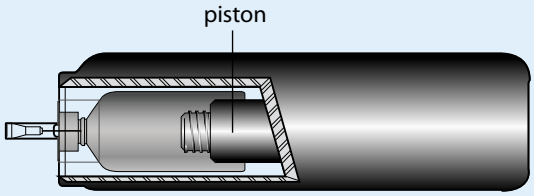
5. Dispose of the used reservoir and infusion set according to local regulations, or contact your healthcare professional for disposal information.

Rewinding your pump

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

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

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



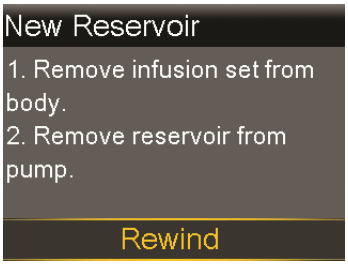
To rewind your pump:

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

   Options > Reservoir & Tubing > New Reservoir

   The New Reservoir screen appears.

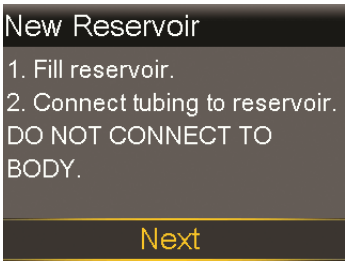
   If you have not yet removed the infusion set and reservoir, do so now.



2. Select **Rewind**.

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

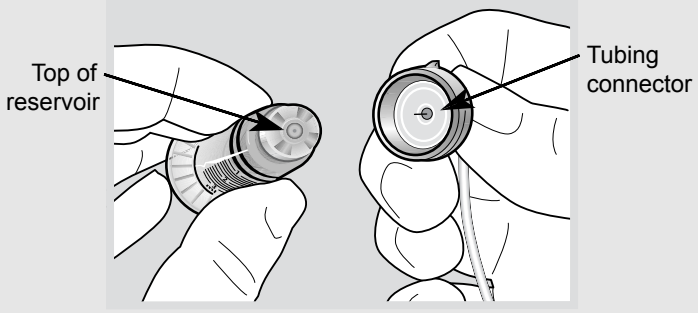
   Another message appears to let you know that your pump has finished rewinding, and then the New Reservoir screen appears.



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

Filling the reservoir

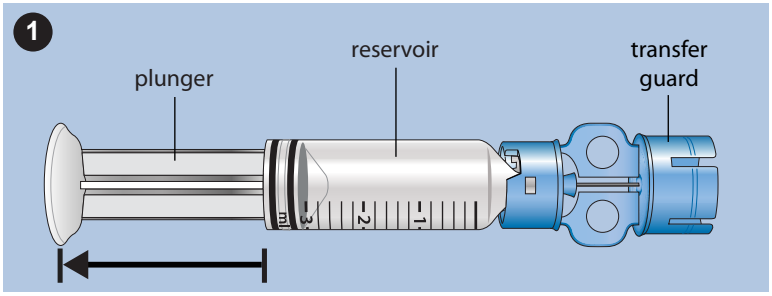
WARNING: Do not use the reservoir or infusion set if any liquid gets on the top of the reservoir or inside the tubing connector (as shown in the image). Liquid can temporarily block the vents. This may result in the delivery of too little or too much insulin, which can cause hyperglycemia or hypoglycemia.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



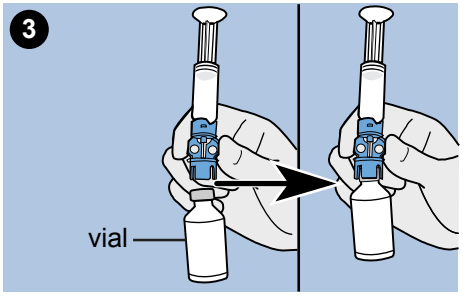
WARNING: Always allow your insulin to reach room temperature before use. Cold insulin can cause air bubbles in the reservoir and tubing, which may result in inaccurate insulin delivery.

To fill the reservoir, do these steps:

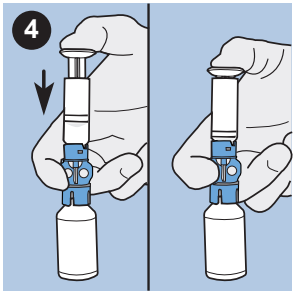
1. Remove the reservoir from the package, and fully extend the plunger.

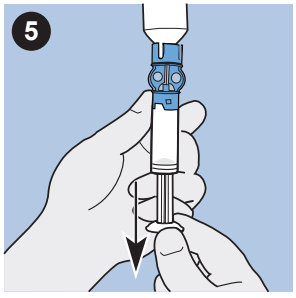


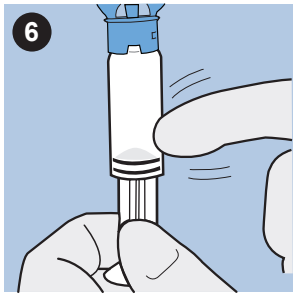
2. Swab the vial with alcohol (not shown).
3. Press the transfer guard onto the vial without pushing down on the plunger.



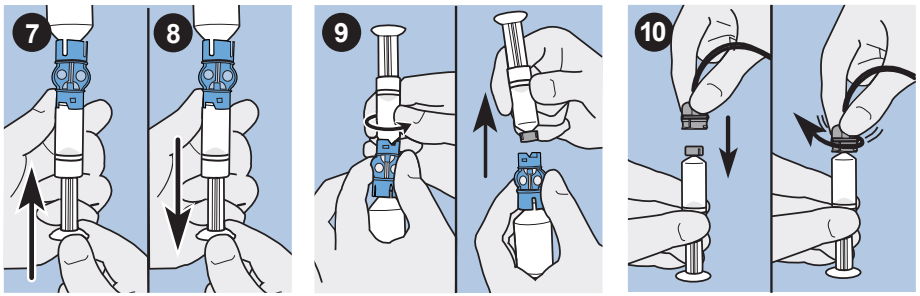
4. Push down on the plunger to pressurize the vial. Hold down the plunger rod.
5. While still holding down the plunger rod, flip the vial over so the vial is on top. Slowly pull down on the plunger to fill the reservoir.
6. Gently tap the side of the reservoir to make any air bubbles rise to the top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



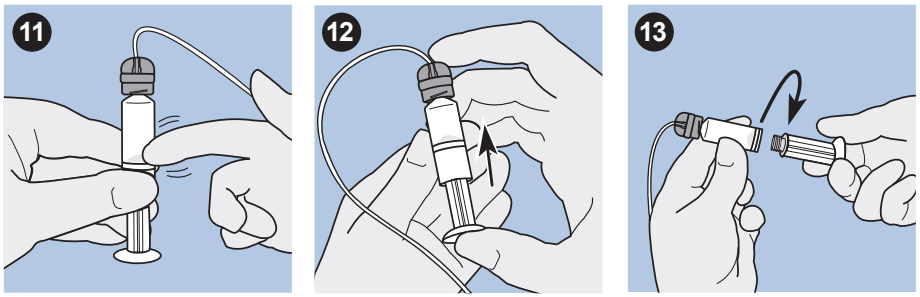




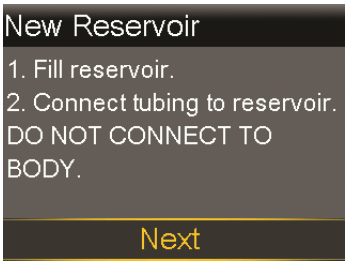
7. Slowly push up on the plunger just enough to remove any air bubbles from the reservoir.
8. Slowly pull down on the plunger to fill the reservoir to the number of units desired.
9. To avoid getting liquid on the top of the reservoir, flip the vial over so that it is upright. Turn the reservoir counter-clockwise,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



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



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



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

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

Inserting the reservoir into your pump

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

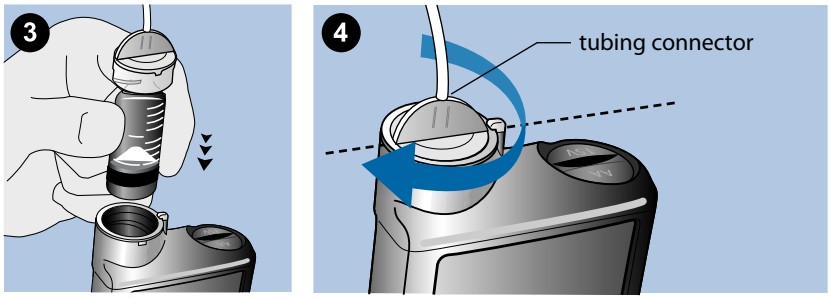
Note: Do not insert the reservoir into your pump until you have received training.

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

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

To insert the reservoir into your pump:

1. If you are using the pump for the first time, remove the shipping cap from the reservoir compartment.
2. Rewind your pump if you have not yet done so. See *Rewinding your pump, on page 118* for more information.
3. Insert the reservoir into the top of the reservoir compartment.
4. Turn the tubing connector approximately a half-turn clockwise until the connector is locked. The tubing connector should be aligned horizontally with the pump case as shown in the following example.



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

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

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

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

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

Filling the tubing

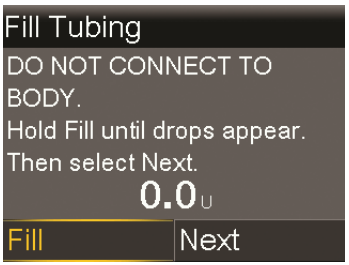
You need to fill the infusion set tubing with insulin before you insert the set into the body.

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

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

To fill the tubing:

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 250*, 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

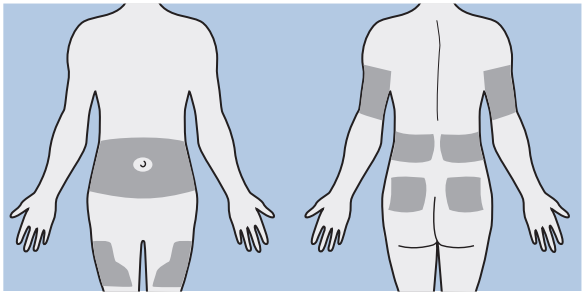
WARNING: Do not remove the reservoir from the pump while the infusion set is connected to your body. Doing so could result in the delivery of too little or too much insulin, which can cause high BG or low BG.

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

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

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

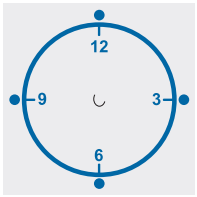
Caution: Do not use the same infusion set insertion site for an extended period of time. This can cause the site to become overused. Rotate the infusion set insertion sites regularly.



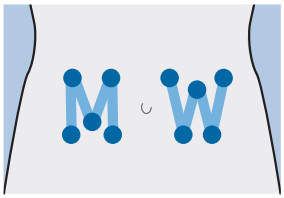
Caution: Always change your infusion set every two to three days. Using the same infusion set for an extended period of time can cause infusion set occlusion or site infection.

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

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



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



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

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

After your infusion set is inserted, see *Filling the cannula, on page 128* to fill the infusion set cannula.

Filling the cannula

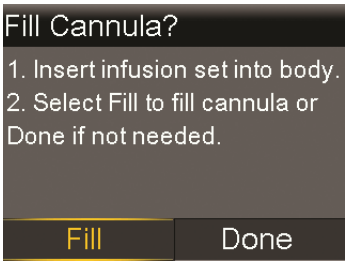
Filling the soft cannula with insulin is required after the infusion set is inserted into your body and the introducer needle is pulled out. The insulin amounts required to fill the cannula depend on the type of infusion set you are using. Refer to your infusion set instructions for this information.

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

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

To fill the cannula:

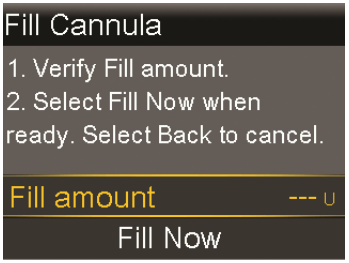
1. After you fill your tubing and insert your infusion set, the Fill Cannula? screen appears.



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

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.



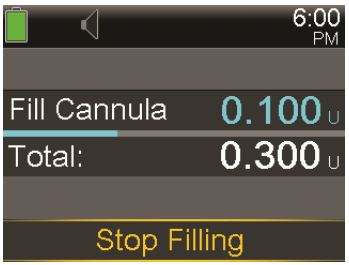
3. Adjust the Fill amount for your particular infusion set, and then select **Fill Now**. If you are unsure about the fill amount, see the instructions that came with your infusion set.

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 your infusion set

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

Reconnecting your infusion set

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

6

Meter

6 Meter

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

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

About your CONTOUR NEXT LINK 2.4 meter

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

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

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

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

You can also deliver a Normal Bolus or Preset Bolus from your CONTOUR NEXT LINK 2.4 meter. For more information about setting up your pump to use the Remote Bolus feature, see *Setting up Remote Bolus, on page 134*. Consult your healthcare professional before using the Remote Bolus feature.

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

Wirelessly connecting your pump and meter

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

Setting up Remote Bolus

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

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

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

Note: Remote Bolus default setting is on.

To turn on or off Remote Bolus:

1. Make sure that your pump and CONTOUR NEXT LINK 2.4 meter are connected.
2. Press ◎ and go to the Remote Bolus screen.

   Options > Utilities > Remote Bolus

   The Remote Bolus screen appears.
3. Select **Remote Bolus** to turn the feature on or off.
4. Select **Save**.

Deleting a meter from your pump

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

To delete the meter from the pump:

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

   Options > Utilities > Device Options > Manage Devices

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

7

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, blood glucose (BG) meter readings, sensor glucose (SG) readings, and any alarms and alerts you received. The Event Markers feature allows you to enter and save information, such as manual BG readings, carbohydrates eaten, and exercise.

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

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

For more information about the Auto Mode feature on your pump, refer to *Auto Mode, on page 225*.

History

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

Summary screen

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

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

To view your Summary screen:

1. Press ◎ and go to the Summary screen.

   Options > History > Summary

2. Select the time period for the Summary screen.

   The Summary screen appears, showing information for the number of days that you selected.

3. You can scroll down to view the entire screen. If you are using the 1 Day view, you can use the < and > buttons on your pump to view the results for each day in history.

Understanding the Summary screen

The Summary screen separates information into these categories:

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

Summary screen: Auto Mode

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

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

Summary screen: overview

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

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

Name	Description
TDD	Total daily dose of insulin units.
Basal	• Insulin units devoted to basal delivery. • 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.

Summary screen: bolus

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

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

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

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

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

Summary screen: BG meter

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

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

Summary screen: sensor

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

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

Summary screen: low management mode

The following table describes the low management mode portion of the Summary screen. For details on the low management feature, see *SmartGuard Technology, on page 174*.

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

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

Daily History

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

To view your Daily History:

1. Press ◎ and go to the Daily History screen.

   Options > History > Daily History

   A list of dates appears.

2. Select a specific date of history to view. A list appears with any pump actions or events entered on the specified day.

3. You can select any item in the list to open the Detail screen, which displays more information about the selected action or event. For example, if you view the details of a bolus delivered using the Bolus Wizard, the Detail screen shows you all of the data associated with that bolus, such as the BG correction amount, active insulin adjustment, carbs entered, and calculated bolus.

Alarm History

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

To view your Alarm History:

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

   Options > History > Alarm History

   A list of dates appears.

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

Using Sensor Glucose Review

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

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

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

To review your sensor glucose history:

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

   Options > History > Sensor Glucose Review

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

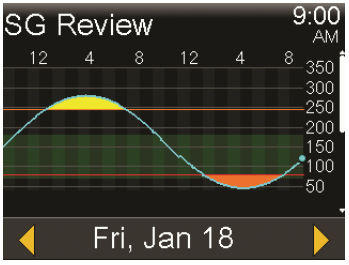
2. Enter the High Limit and Low Limit that you want to use for the sensor glucose review.

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

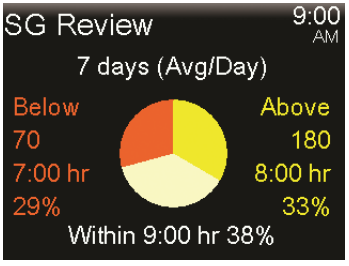
3. Enter the number of days of sensor glucose history to average, and select **Next**.

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

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



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



ISIG History

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

To review your ISIG History:

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

   Options > History > ISIG History

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

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

Use the ∧ or ∨ buttons to scroll through the listing of ISIG readings, which occur every five minutes.

Event Markers

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

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

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

To enter Event Markers:

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

   Options > Event Markers

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

BG		If you are not using the Bolus Wizard, Auto Mode Bolus, manual entry, or a CONTOUR NEXT LINK 2.4 meter to record your BG meter readings in your pump, you can enter them here. If you are using a sensor, you may use a BG meter reading you enter here for calibration. You can also enter non-calibration BG meter readings, such as those readings taken when eating or when your BG is rising or falling rapidly.
Injection		Enter the number of units of any insulin you have given by injection.  **Note:** Insulin units entered using the injection event marker are not added to your Active Insulin amount tracked on the pump.

Food		Enter the amount of carbohydrates that you have eaten or drunk that have not been entered in the Bolus Wizard or Auto Mode Bolus. For example, you might enter carbs that you ate to correct a low BG. Do not enter carbs here that you have already entered in the Bolus Wizard or Auto Mode Bolus.
Exercise		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 blood glucose (BG) after a bolus, give a food bolus, check your reservoir level, and change your infusion set. There are also personal reminders you can use for any purpose. If you have the sensor feature turned on, the calibration reminder prompts you to calibrate your sensor.

Personal reminders

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

To create a new Personal reminder:

1. Press ◎ and go to the Personal screen.

   Options > Reminders > Personal

2. Select **Add New**.

   The Select Name screen appears showing the available reminders.

3. Select the reminder that you want to set.

   The Edit screen appears for the selected reminder.

4. Enter the time that you want the reminder to occur.

5. Select **Save**. The Personal reminder occurs at the specified time each day unless you change or delete it.

To edit, rename or delete an existing Personal reminder:

1. Press ◎ and go to the Personal screen.

Options > Reminders > Personal

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

Bolus BG Check reminder

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

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

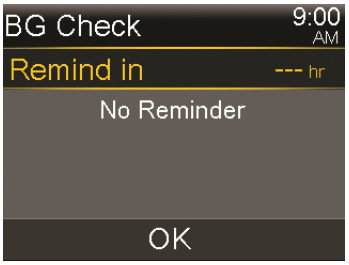
To turn on or turn off Bolus BG Check reminders:

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

   Options > Reminders > Bolus BG Check
2. To turn the reminder on or off, select **Reminder**.
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:



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

Missed Meal Bolus reminder

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

To create a new Missed Meal Bolus reminder:

1. Press ◎ and go to the Missed Meal Bolus screen.

   Options > Reminders > Missed Meal Bolus

2. Select **Add New**.
3. Select **Start Time**, and enter a time.
4. Select **End Time**, and enter a time. The time range is from one minute to 24 hours.
5. Select **Save**.

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

1. Press ◎ and go to the Missed Meal Bolus screen.

   Options > Reminders > Missed Meal Bolus

2. Select one of the reminders that you have already created.
3. Change any of the following:
   - Select **Reminder** to turn this reminder on or off.
   - Select **Edit** to change the time of this reminder.

- Select **Delete** to delete this reminder.

Low Reservoir reminder

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

Note: The number of units remaining in your reservoir can be found on the Quick Status screen. For more information on accessing the Status Screens, see *Status screens, on page 49*.

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

Low Reservoir reminder setup:

1. Press ◎ and go to the Low Reservoir screen.

   Options > Reminders > Low Reservoir
2. Select **Units** to enter the number of units. You can set a value from 5 units to 50 units.
3. Select **Save**.

Set Change reminder

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

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

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

   Options > Reminders > Set Change

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

3. Select **Save**.

Calibration reminders

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

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

1. Press ◎ and go to the Calibration screen.

   Options > Reminders > Calibration

2. Select **Reminder** to turn the reminder on or off.

3. If you turn on the reminder, select **Time** and enter a time between 5 minutes and 6 hours. The time can be set in 5 minute increments.

4. Select **Save**.

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

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

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

When using this device:	Do this:
CONTOUR NEXT LINK 2.4 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 meter normally.

When using this device:	Do this:
Non-linked BG meter	Use your non-linked BG meter normally whether Airplane Mode is on or off.
Sensor and transmitter	When Airplane Mode is turned on, your pump does not receive sensor readings from your transmitter. When Airplane Mode is turned off, it can take up to 15 minutes before the pump and the transmitter start to wirelessly communicate again. The transmitter begins to send up to the last 10 hours of sensor data to the pump. When you turn off Airplane Mode: • 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. Press ◎ and go to the Airplane Mode screen.

   Options > Utilities > Airplane Mode
2. Select **Airplane Mode** to turn the feature on or off.
3. Select **Save**.

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

Note: Airplane Mode cannot be used while in Auto Mode. To use Airplane Mode, you must be in Manual Mode. To return to Auto Mode after using Airplane Mode, Auto Mode must be turned on and a BG must be entered. For instructions on turning Auto Mode on or off, see *Setting up Auto Mode, on page 227*. Additional steps may be

required before you can return to Auto Mode. Follow the instructions on your pump screen. For more information, see *Auto Mode Readiness, on page 229*.

Audio Options

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

The audio setting that you are currently using appears on the Home screen. An audio icon will indicate if your settings are audio only, vibrate only, or audio and vibrate both. For more information, see *Status icons, on page 44*.

To adjust the audio and vibrate settings:

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

Auto Suspend

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

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

To set up Auto Suspend:

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

   Options > Delivery Settings > Auto Suspend

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.

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

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

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

Note: The Block Mode feature has some differences when your pump is in Auto Mode. See *Block Mode when in Auto Mode, on page 234*.

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

To turn Block Mode on or off:

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

   Options > Utilities > Block

2. Select **Block Mode** to turn the feature on or off.
3. Select **Save**. While Block Mode is turned on, a lock icon appears on the Home screen.

   If you are turning on Block Mode, a message appears asking if you would like to change your Remote Bolus setting as well. This message appears only if the Remote Bolus setting was on.
4. Select **Yes** to change Remote Bolus setting.
5. Select **Remote Bolus** to turn the feature on or off.
6. Select **Save**.

Display Options

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

To adjust the display options:

1. Press ◎ and go to the Display Options screen.

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

   Note: The brightness setting you select can affect the life of your battery. For a longer lasting battery, consider using a lower level setting.
3. Select **Backlight** to adjust the timeout for the backlight on your pump screen. You can select 15 seconds, 30 seconds, 1 minute, or 3 minutes.

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

Language

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

To change the Language setting:

1. Press ◎ and go to the Language screen.

   Options > Utilities > Language

   A checkmark indicates which language is active.
2. Select your desired language.
3. Select **Yes** when the confirmation message appears.

Managing your pump settings

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

The following table describes the Manage Settings options:

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

Saving your settings

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

To save your current settings:

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

   Options > Utilities > Manage Settings

2. Simultaneously press and hold > and ↩ until the Manage Settings menu appears.
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. Press ◎ and go to the Manage Settings screen.

   Options > Utilities > Manage Settings

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

Clearing your settings

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

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

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

To clear all your settings:

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

   Options > Utilities > Manage Settings
3. Simultaneously press and hold > and ↩ until the Manage Settings menu appears.
4. Select **Clear All Settings**.

   A confirmation screen appears asking if you want to clear all your settings.
5. To continue clearing your settings, select **Yes**. If you do not want to clear your settings, select **No**.

   If you clear your settings, your pump displays the Welcome screen and continues to the Startup Wizard. For more details on entering your startup settings, see *Entering your startup settings, on page 40*.

Clearing your active insulin

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

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

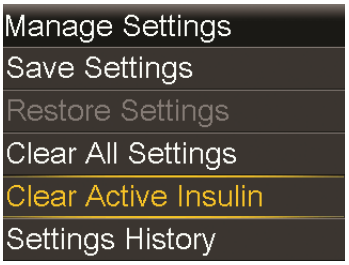
You can clear your active insulin only once. After you clear your active insulin, the feature is no longer available.

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

   Options > Utilities > Manage Settings

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

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



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

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. Press ◎ and go to the Manage Settings screen.

Options > Utilities > Manage Settings

2. Simultaneously press and hold > and ↩ until the Manage Settings menu appears.
3. Select **Settings History**.

   The Settings History screen appears.

Self Test

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

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

Self Test includes the following tests:

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

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

To run the Self Test:

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

   Options > Utilities > Self Test

   A message indicates that the Self Test is in progress.

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

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

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

Sensor Demo

Sensor Demo lets you see what the Home screen would look like if you were using the optional Continuous Glucose Monitoring (CGM) feature. For more information about sensor graphs, please see *The sensor graph, on page 217*.

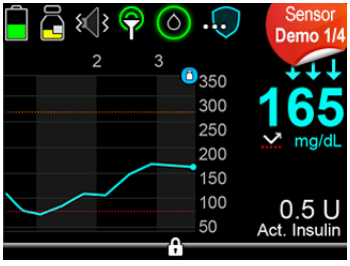
WARNING: Do not use Sensor Demo to make any decisions related to your therapy. Information seen in the Sensor Demo is not real data. It is an example of the type of information you can access when using the sensor feature. Making treatment decisions based on data that is not real can cause hypoglycemia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

To view the sensor graph example screens:

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

   Options > Utilities > Sensor Demo

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



2. Press > to view the sensor graph examples.

3. Press the < or > buttons to view the different sensor screen examples.

   Sensor Demo simulates a sensor glucose graph, showing an example of the general trend of glucose as it rises and falls over time. The top of the graph indicates the time of day, while the side bar shows the sensor glucose (SG) reading markers.

4. To exit Sensor Demo, press ↩.

Time and date

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

To change the time and the date:

1. Press ◎ and go to the Time & Date screen.

   Options > **Utilities** > **Time & Date**

2. Select and change the **Time**, **Time Format**, or **Date** as necessary. If you are using a 12-hour clock, be sure to specify AM or PM.

3. Select **Save**.

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

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

Understanding Continuous Glucose Monitoring (CGM)

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

- Recording your glucose values throughout the day and night

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

Note: If you lose sensor functionality, you will no longer have access to CGM features. For details on restoring sensor functionality, see *Troubleshooting sensor issues, on page 294*.

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

SmartGuard Technology

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

Auto Mode is also part of SmartGuard technology. When your pump is in Auto Mode, your basal insulin delivery is automatically controlled. For details, see *About Auto Mode, on page 225*.

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

To learn more about:	Go to this section:
How to use SmartGuard technology to automatically suspend your insulin delivery before you reach your low limit.	*Suspend before low, on page 182.*

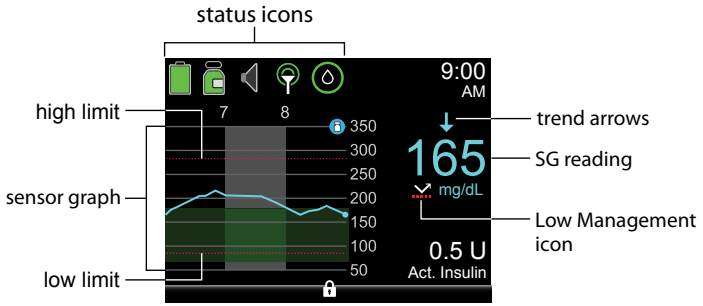
To learn more about:	Go to this section:
How to use SmartGuard technology to automatically suspend your insulin delivery when you reach your low limit.	*Suspend on low, on page 186.*
How SmartGuard technology automatically resumes your basal insulin delivery after a suspend by sensor event.	*Automatically resuming basal delivery after a SmartGuard suspend by sensor event, on page 188.*
Auto Mode	*About Auto Mode, on page 225*

To set up SmartGuard suspend by sensor settings, see *Setting up the Low Settings, on page 198.*

Home screen with CGM in Manual Mode

When you turn on the Sensor feature, the Home screen on your pump changes to display a real-time graph that shows your sensor glucose (SG) information. For more information, see *Turning on the Sensor feature, on page 194.*

Note: To see the Home screen in Auto Mode, see *Home screen with Auto Mode, on page 231.*



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

Item	Description
Airplane Mode icon	The Airplane Mode icon  appears in place of the Connection icon if Airplane Mode is turned on. When Airplane Mode is turned on, the pump cannot receive wireless communication from other devices.  **WARNING: Do not rely on glucose sensor-enabled features when Airplane Mode is on because the pump does not receive sensor readings from the transmitter. Glucose sensor-enabled features include CGM, SmartGuard, and Auto Mode. When using Airplane Mode, always rely on your blood glucose (BG) values when making therapy decisions to avoid hypoglycemia or hyperglycemia.**

Item	Description
Calibration icon	The approximate time left until your next sensor calibration is due. Appears only when the Sensor feature is turned on. The color and the circle around the icon indicate the status. When your sensor is fully calibrated, the icon has a solid green circle around it. As the time for your next sensor calibration approaches, the green circle around the icon becomes smaller, and the color of the icon changes as shown in the following example. For more information about calibrating your sensor, see *Calibrating your sensor, on page 210*. • Time to your next sensor calibration is more than 10 hours. • Time to your next sensor calibration is 8 to 10 hours. • Time to your next sensor calibration is 6 to 8 hours. • Time to your next sensor calibration is 4 to 6 hours. • Time to your next sensor calibration is 2 to 4 hours. • Time to your next sensor calibration is less than 2 hours. • Sensor calibration is required now. • Time to your next sensor calibration is unavailable. • Sensor is not ready for a calibration. This occurs when a new sensor is connected or within 15 minutes of a Calibration not accepted alert.
Connection 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 with a red X when the Sensor feature is turned on, but the transmitter is not connected or communication with your pump has been lost. For more information about the Sensor feature, see *Understanding Continuous Glucose Monitoring (CGM), on page 173*.

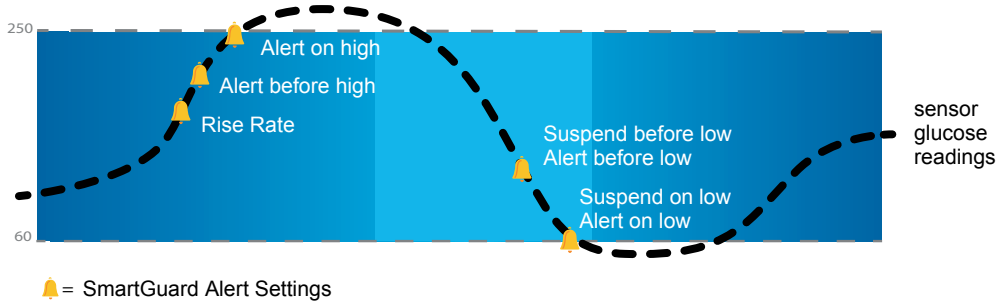
Item	Description
Auto Mode Readiness	The Auto Mode Readiness icon indicates whether your pump is ready to enter Auto Mode. The icon appears with a loading symbol when the pump is updating a condition that requires you to wait. The icon appears with a question mark when the pump requires an action from you to enter Auto Mode. For more information about Auto Mode Readiness, see *Auto Mode Readiness, on page 229*. When your pump is in Auto Mode, the Auto Mode shield appears in the center of your Home screen. For more information, see *Home screen with Auto Mode, on page 231*.
Sensor graph	Displays your SG readings over a period of 3 hours. The orange line represents your high SG limit, and the red line represents your low SG limit. The blue line represents your SG trends during the specified period. For more information, see *The sensor graph, on page 217*.
Sensor Life	The number of days remaining in the life of your sensor. The Sensor Life icon appears only when the Sensor feature is turned on. The color and the fill level of the icon indicate the status. When you insert a new sensor, the icon is solid green. When one day is remaining in the life of your sensor, the icon color turns red. **Note:** For a short time after starting a new sensor, the Sensor Life icon may show an 8. When the Sensor Life icon changes to show a 7, the seven-day period of sensor life begins.  If the number of days remaining in the life of your sensor is unavailable, the Sensor Life icon appears with three dots .
SG reading	Shows your current SG reading which is sent wirelessly to your pump by the transmitter.

Item	Description
Low Management icon	The Low Management icon appears only when either the Suspend before low or Suspend on low feature is set to on. For details on SmartGuard technology, see *SmartGuard Technology, on page 174*. The Low Management icon indicates the current status of the suspend features, as follows: • The icon is a white arrow with a dotted red line  when either the Suspend on low or Suspend before low is turned on and ready. • The arrow icon flashes if your insulin delivery is currently suspended due to a Suspend on low or Suspend before low event. • The icon appears as a gray cross with a dotted line under it  when neither suspend feature is available. The suspend features might be unavailable due to a recent suspend or because there are no SG values available. It might also be unavailable because the pump is not currently delivering insulin.
Trend arrows	Shows the rate at which the most recent sensor glucose level is rising or falling. • ↑ or ↑↑ or ↑↑↑ - Rising trend arrows • ↓ or ↓↓ or ↓↓↓ - Falling trend arrows For more information about trend arrows, see *Identifying rapid changes in sensor glucose, on page 218*.

Understanding glucose settings

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

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



The high alerts are described in the *High settings* section on *page 180*. For details on low alerts and suspend options, see *Low settings, on page 181*.

High settings

These settings alert you if your sensor glucose:

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

The following table describes the High Settings.

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

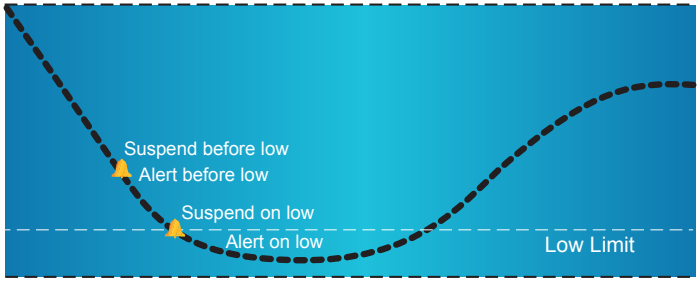
High glucose setting	Description
Alert on high	When Alert on high is on, your system alerts you when your SG reading reaches or exceeds your High Limit.
Rise Alert	The Rise Alert notifies you when your glucose is rising rapidly. This alert helps you understand how much your glucose levels are affected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

To set up your high settings, see *Setting up the High Settings, on page 194*.

Low settings

The low settings allow you to be alerted and/or have insulin delivery suspended when you are either approaching or have reached your low limit. This is done by using alerts and SmartGuard technology described on *page 174*.

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



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

The following sections describe Auto Mode and the low settings. For details on setting up Auto Mode and your low settings, see *Setting up the Low Settings, on page 198*.

Low limit

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

Suspend before low

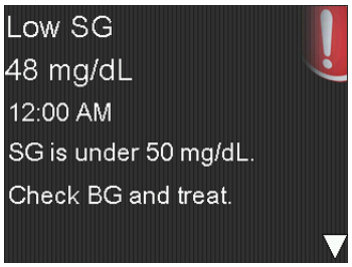
The Suspend before low feature stops insulin delivery when your sensor glucose values are approaching your low limit. This feature is intended to suspend insulin delivery to minimize the amount of time spent low.

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

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

- If Alert before low is on, your pump alerts you when insulin delivery is suspended. For details, see *Alert before low, on page 185*.
- If Alert before low is off, then Suspend before low appears on the screen, but the pump will not beep or vibrate when insulin delivery is suspended.
- The user can enable Alert before low, Alert on low, Suspend before low, and Suspend on low. There is an additional fixed low alert at 50 mg/dL that cannot be turned off.
- Suspend before low and Suspend on low cannot be enabled at the same time. When either is enabled, the user can enable the Resume basal alert.

- The Low SG alert appears when your sensor glucose values reach or fall below 50 mg/dL. This alert cannot be turned off. When the alert appears on your screen, it shows your sensor glucose value next to your Low SG alert. In this user guide, the sensor glucose value will be represented as “Low SG XX” for this alert.



WARNING: Always confirm your sensor glucose readings with your BG meter and treat according to the recommendations of your healthcare professional. The Suspend before low feature uses the sensor glucose value, not your blood glucose value, to automatically suspend insulin delivery. Your pump automatically suspends insulin delivery when your sensor glucose is approaching the low limit. However your blood glucose reading may be higher or lower than the sensor glucose value. Assuming that your sensor glucose value is accurate may result in the delivery of too little or too much insulin, which can cause hyperglycemia or hypoglycemia.

Suspend before low conditions

When a Suspend before low event occurs, all insulin delivery is suspended. A Suspend before low event occurs when:

- Your SG value is at or within 70 mg/dL above your low limit.
- Your SG is predicted to reach or fall below a level that is 20 mg/dL above your low limit within approximately 30 minutes.

Responding to a Suspend before low event

When you clear the Suspend before low alert, the SmartGuard Suspend by sensor icon flashes and "Suspended before low" appears on your Home screen. If your SG reaches your low limit, an Alert on low occurs.

When a Suspend before low event occurs, insulin delivery will remain suspended for at least 30 minutes. Insulin delivery will be suspended for a maximum of two hours. You can manually resume insulin delivery at any time. For details, see *Manually resuming basal delivery during a suspend by sensor event, on page 201*. After the minimum 30-minute suspend time, basal insulin delivery will automatically resume if the following conditions are met:

- Your SG is at least 20 mg/dL above your low limit.
- Your SG is estimated to be more than 40 mg/dL above your low limit within 30 minutes.

If you do not respond to the Suspend before low alert, your pump resumes insulin delivery after two hours and displays a Basal delivery resumed alert.

When Suspend before low is unavailable

After a Suspend before low event occurs, there is a period of time when the Suspend before low functionality is unavailable. This is to prevent prolonged suspended basal delivery. The length of time it is unavailable will vary. For details, see *Stopping and resuming your insulin delivery, on page 76*.

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

When the SmartGuard suspend by sensor features are unavailable, the SmartGuard suspend by sensor icon on the Home screen appears as a gray cross  .

When a Suspend before low event occurs and you respond within two hours and:

- Stay suspended for the two hour maximum suspend time, the SmartGuard suspend by sensor features will be unavailable for 30 minutes after your basal insulin delivery resumes.
- Your insulin automatically resumes due to your rising SG levels, the SmartGuard suspend by sensor features will be unavailable for 30 minutes after your basal insulin delivery resumes.
- Manually resume your basal insulin delivery, the SmartGuard suspend by sensor features will be unavailable for 30 minutes after your basal insulin delivery resumes.

If your pump has been suspended for two hours and you have not responded, basal insulin delivery automatically resumes.

If you respond within 30 minutes of basal insulin delivery being resumed, the SmartGuard suspend by sensor features will be unavailable for a total of 30 minutes. For example:

- If you respond 10 minutes after your basal insulin delivery resumes, the SmartGuard suspend by sensor features will be unavailable for an additional 20 minutes.
- If you respond 20 minutes after your basal insulin delivery resumes, the SmartGuard suspend by sensor features will be unavailable for an additional 10 minutes.

If you respond 30 minutes to four hours after your basal insulin delivery resumes, the SmartGuard suspend by sensor features will be available immediately.

If you do not respond, the SmartGuard suspend by sensor features will be unavailable for four hours after basal delivery resumes.

Alert before low

When Alert before low is on, you will receive an alert when you are approaching your low limit. This makes you aware of potential lows before they occur.

The Alert before low feature can be used with the Suspend before low and Suspend on low features. The Alert before low feature works as follows:

- If Alert before low is on, and both suspend by sensor features are off, you receive the Alert before low 30 minutes before you reach your low limit.
- If Suspend on low is on, and Alert before low is on, you receive an Alert before low 30 minutes before you reach your low limit.
- If Suspend before low is on, and Alert before low is on, you receive a Suspend before low alert when insulin delivery is suspended. For details, see *Suspend before low, on page 182*.

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

Suspend on low

The Suspend on low feature stops insulin delivery when your sensor glucose value reaches or falls below the low limit that you set. When a Suspend on low event occurs, all insulin delivery is suspended. This feature is used for situations when you cannot respond to a low glucose condition. It is intended to suspend insulin delivery and minimize the amount of time spent low.

WARNING: Do not use the Suspend on low feature until you have read the information in this user guide and received instructions from your healthcare professional. The Suspend on low feature causes the pump to temporarily suspend insulin delivery for a maximum of two hours. Under some conditions of use, the pump can suspend again, resulting in limited insulin delivery. Prolonged suspension can increase the risk of serious hyperglycemia, ketosis, and ketoacidosis.

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

If you turn on Suspend on low, then Alert on low is turned on automatically. For more information, see *Alert on low, on page 188*.

WARNING: Always confirm your sensor glucose readings with your BG meter and treat according to the recommendations of your healthcare professional. The Suspend on low feature uses the sensor glucose value, not your blood glucose value, to automatically suspend your pump. Your pump may automatically suspend when your sensor glucose is at or below the low limit, while your blood glucose is above that limit. Assuming that your sensor glucose value is accurate may result in the delivery of too little or too much insulin, which can cause hyperglycemia or hypoglycemia.

Responding to a Suspend on low event

When you clear the Suspend on low alarm, the SmartGuard suspend by sensor icon  flashes and "Suspended on low" appears on your Home screen.

When a Suspend on low event occurs, the pump alerts you.

When a Suspend on low event occurs, insulin delivery will remain suspended for at least 30 minutes. Insulin delivery will be suspended for a maximum of two hours. You can manually resume insulin delivery at any time. For details, see *Manually resuming basal delivery during a suspend by sensor event, on page 201*. After the minimum 30-minute suspend time, basal insulin delivery will automatically resume if the following conditions are met:

- Your SG is at least 20 mg/dL above your low limit.
- Your SG is estimated to be more than 40 mg/dL above your low limit within 30 minutes.

If you do not respond to the Suspend on low alarm, your pump resumes insulin delivery after two hours and continues to display an emergency message.

When Suspend on low is unavailable

After a Suspend on low event occurs, there is a period of time when the suspend functionality is unavailable. This time will vary depending on whether or not you respond to the Suspend on low event. You can manually suspend insulin delivery at any time. For details, see *Stopping and resuming your insulin delivery, on page 76*.

Note: The maximum amount of time the Suspend on low feature will be unavailable is four hours. After this time period, the Suspend on low feature automatically enables.

When the SmartGuard suspend by sensor features are unavailable, the SmartGuard suspend by sensor icon on the Home screen appears gray  .

When a Suspend on low event occurs and you respond within two hours and

- Stay suspended for the two hour maximum suspend time, the SmartGuard suspend by sensor features will be unavailable for 30 minutes after your basal insulin delivery resumes.
- Your insulin automatically resumes due to your rising SG levels, the SmartGuard suspend by sensor features will be unavailable for 30 minutes after your basal insulin delivery resumes.
- Manually resume your basal insulin delivery, the SmartGuard suspend by sensor features will be unavailable for 30 minutes after your basal insulin delivery resumes.

If your pump has been suspended for two hours and you have not responded, basal insulin delivery automatically resumes.

If you respond within 30 minutes of basal insulin delivery being resumed, the SmartGuard suspend by sensor features will be unavailable for a total of 30 minutes. For example:

- If you respond 10 minutes after your basal insulin delivery resumes, the SmartGuard suspend by sensor features will be unavailable for an additional 20 minutes.
- If you respond 20 minutes after your basal insulin delivery resumes, the SmartGuard suspend by sensor features will be unavailable for an additional 10 minutes.

If you respond 30 minutes to four hours after your basal insulin delivery resumes, the SmartGuard suspend by sensor features will be available immediately.

If you do not respond, the SmartGuard suspend by sensor features will be unavailable for four hours after basal delivery resumes.

Alert on low

The Alert on low feature is automatically turned on when either the Suspend before low or the Suspend on low feature is turned on.

When Alert on low is set to on, you receive an alert when your SG reading reaches or falls below your low limit. If your pump is suspended and you have not responded, an emergency message appears.

Automatically resuming basal delivery after a SmartGuard suspend by sensor event

In addition to suspending insulin delivery, the pump can also automatically resume delivery of basal insulin. If insulin has been suspended by either the Suspend before low or the Suspend on low feature, insulin delivery will automatically be resumed if either of the following conditions are met:

- if insulin has been suspended for a minimum of 30 minutes and SG values are at least 20 mg/dL above the low limit and expected to be more than 40 mg/dL above the low limit in 30 minutes.
- after a maximum of two hours.

Resume basal alert

When the Resume basal alert is on, you will be alerted when insulin is automatically resumed. If the Resume basal alert is off, basal insulin resumes, but you do not receive an alert. However, you will get a message indicating that the basal has automatically resumed.

If basal resumes after the maximum suspend time of two hours, you will be alerted even if the Resume basal alert is set to off. It is important that you check your BG and ensure your glucose is at a safe level.

For details on setting up the Resume basal alert, see *Setting up the Low Settings, on page 198*.

SmartGuard suspend by sensor examples

The following table shows the different scenarios that occur during and after a Suspend before low or Suspend on low event. Examples of scenarios are shown after the table.

	Suspend features	
What happens	**Suspend on low**	**Suspend before low**
The pump suspends insulin delivery.	Your sensor glucose value reaches or falls below the low limit that you set. The pump suspends insulin delivery for at least 30 minutes and up to a maximum of 2 hours. The pump automatically resumes basal insulin delivery between 30 minutes and 2 hours if your sensor glucose value is predicted to go above the low limit that you set.	Your sensor glucose value is approaching your low limit and is predicted to be reached within 30 minutes. The pump suspends insulin delivery for at least 30 minutes and up to a maximum of 2 hours. The pump automatically resumes basal insulin delivery between 30 minutes and 2 hours if your sensor glucose value is predicted to go above the low limit that you set.

	Suspend features	
What happens	**Suspend on low**	**Suspend before low**
You manually resume insulin delivery.	Your pump resumes insulin delivery at the programmed basal rate. The suspend by sensor features are unavailable for 30 minutes after insulin delivery resumes. The pump will not automatically suspend insulin again until after the suspend features are available and your sensor glucose value is below the low limit that you set.	Your pump resumes insulin delivery at the programmed basal rate. The suspend by sensor features are unavailable for 30 minutes after insulin delivery resumes. The pump will not automatically suspend insulin again until after the suspend features are available and your sensor glucose value is approaching the low limit that you set.
Your sensor glucose value is predicted to go above your low limit while insulin is automatically suspended.	The pump automatically resumes insulin delivery after 30 minutes and if your sensor glucose values are at least 20 mg/dL above your low limit and predicted to be more than 40 mg/dL above your low limit in 30 minutes.	The pump automatically resumes insulin delivery after 30 minutes and if your sensor glucose values are at least 20 mg/dL above your low limit and predicted to be more than 40 mg/dL above your low limit in 30 minutes.
You respond to the alert that occurs while insulin delivery is suspended. Insulin delivery is suspended for the maximum two hour suspend time.	Your pump resumes insulin delivery at the programmed basal rate. The suspend by sensor features are unavailable for 30 minutes after insulin delivery resumes. The pump will not automatically suspend insulin again until after the suspend features are available and your sensor glucose value is below the low limit that you set.	Your pump resumes insulin delivery at the programmed basal rate. The suspend by sensor features are unavailable for 30 minutes after insulin delivery resumes. The pump will not automatically suspend insulin again until after the suspend features are available and your sensor glucose value is approaching the low limit that you set.

	Suspend features	
What happens	**Suspend on low**	**Suspend before low**
The pump resumes insulin delivery after the maximum two hour suspend time. You respond to the alert that occurs after insulin delivery resumes.	Your pump resumes insulin delivery at the programmed basal rate. The suspend by sensor features are unavailable for 30 minutes. The pump will not automatically suspend insulin again until after the suspend features are available and your sensor glucose value is below the low limit that you set.	Your pump resumes insulin delivery at the programmed basal rate. The suspend by sensor features are unavailable for 30 minutes. The pump will not automatically suspend insulin again until after the suspend features are available and your sensor glucose value is approaching the low limit that you set.
You do not respond to the alerts that occur while insulin delivery is suspended. Insulin delivery is suspended for the maximum two hour suspend time.	Your pump resumes insulin delivery at the programmed basal rate. The suspend by sensor features are unavailable for 4 hours after insulin delivery resumes. The pump will not automatically suspend insulin again until after the suspend features are available and your sensor glucose value is below the low limit that you set.	Your pump resumes insulin delivery at the programmed basal rate. The suspend by sensor features are unavailable for 4 hours after insulin delivery resumes. The pump will not automatically suspend insulin again until after the suspend features are available and your sensor glucose value is approaching the low limit that you set.

The following examples describe several scenarios that illustrate different types of suspend events, user actions in response to these events, and what happens to insulin delivery in each case.

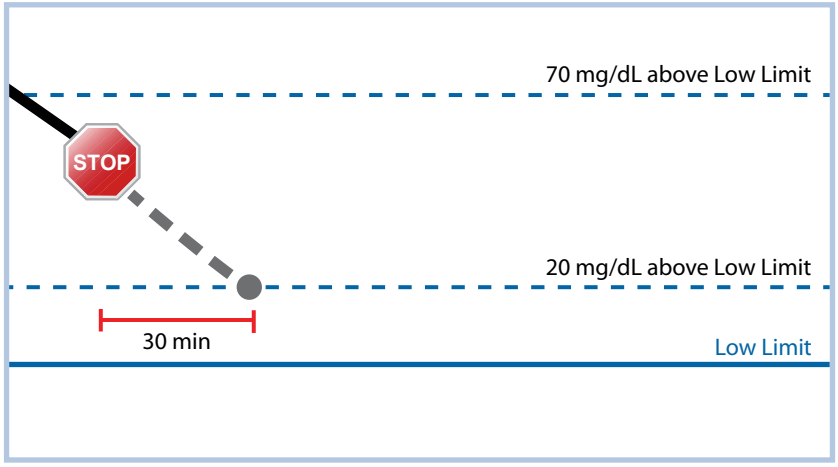
The examples cover the following:

- Example 1: Suspend before low, non-responsive, auto resume basal (trending upwards)
- Example 2: Suspend before low, responsive, manually resume basal
- Example 3: Suspend before low, responsive, stays suspended
- Example 4: Suspend on low, response after basal delivery resumes

Note: During the Suspend on low siren, you can press any button to silence your pump for two minutes. The temporary silencing of the alarm does not affect the suspension or delivery of insulin.

Example 1: Suspend before low, non-responsive, auto resume basal (trending upwards)

Sarah has been experiencing low sensor glucose values. Her healthcare professional has recommended she use the Suspend before low feature. While at a concert, Sarah's sensor glucose values are approaching her low limit. Her pump recognizes that her glucose will be at or within 20 mg/dL above her low limit within 30 minutes and suspends her insulin. Sarah has her Alert before low set to off so that she is not alerted when this occurs.



An hour later, her sensor glucose values are 21 mg/dL above her low limit. Her pump estimates her sensor glucose values will be 45 mg/dL above her low limit within 30 minutes. Her pump automatically resumes her basal insulin delivery.

When the concert ends, Sarah sees that her pump automatically suspended and resumed her insulin delivery and a potential low was avoided. She clears the messages by selecting OK.

Example 2: Suspend before low, responsive, manually resume basal

Kate decides to meet her friends at the mall. While shopping, she gets a Suspend before low alert. This indicates that her sensor glucose values are approaching the low limit she has set. She clears the alert and sees that her insulin has been

suspended. Kate checks her BG to confirm. Based on her healthcare professional's recommendation, Kate stops for a snack to help avoid hypoglycemia. Knowing the carbohydrate will make her glucose rise, Kate manually resumes her basal insulin delivery by selecting Suspended before low from the Home screen and choosing Resume basal.

Kate knows that after she has manually resumed her basal insulin delivery, the suspend functions will be unavailable for 30 minutes. However, she will be alerted if she reaches her low limit.

Example 3: Suspend before low, responsive, stays suspended

Doug has just finished his evening jog on the beach. As he is walking home, he receives a Suspend before low alert. He sees that his pump has automatically suspended his insulin delivery. Doug clears the alert by selecting OK on his pump. He knows that his pump is now suspended and insulin delivery has been stopped. He checks his BG to confirm and keeps his insulin suspended.

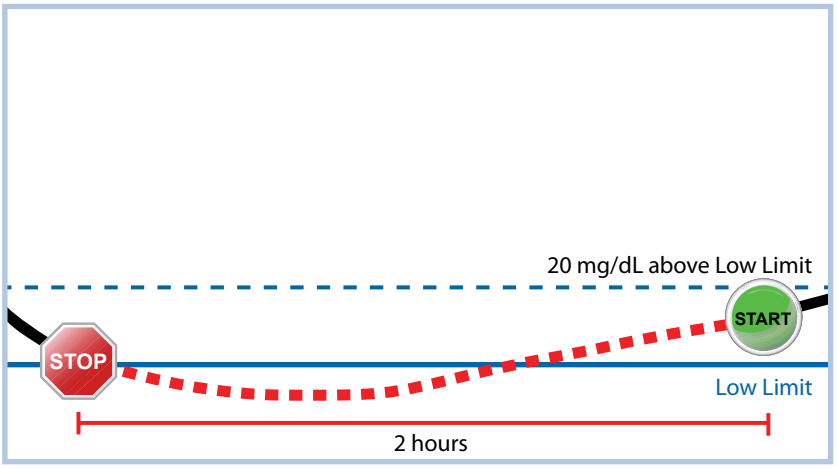
A while later, Doug receives another alert. He looks at his pump and sees that he has received an Alert on low. His SG has reached his low limit. He clears the alert and checks his BG to confirm. He eats carbohydrates to treat the low glucose as instructed by his healthcare professional.

Doug keeps his insulin suspended as directed by his healthcare professional. He knows that once his SG is above his low limit and trending upward, or reaches the maximum suspend time of two hours, basal insulin delivery will automatically resume.

Example 4: Suspend on low, response after basal delivery resumes

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

About three hours later, Michael's roommate comes home. He hears the pump sirening and wakes up Michael. Michael clears any messages by selecting OK. He sees that his basal insulin was suspended for the two hour maximum and had automatically resumed delivery. He checks his blood sugar and sees that it is within the target range.



Michael has responded to his alert. The pump will suspend insulin delivery and alarm again if his sensor value reaches or falls below his low limit again.

Turning on the Sensor feature

You must turn on the Sensor feature before you can set up your glucose alerts and start monitoring your sensor glucose.

To turn on the Sensor feature:

1. Press ◎ and go to the Sensor Settings screen.

   Options > Utilities > Sensor Settings

2. Select **Sensor** to turn on the sensor feature. The sensor settings become accessible.

Setting up the High Settings

The steps below guide you through setting up your high settings. For details on your high settings, see *High settings, on page 180*.

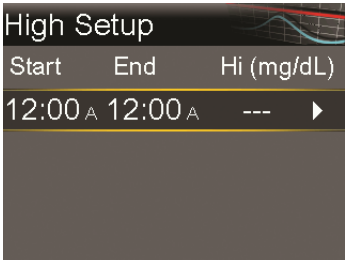
Note: When you enter your settings, you first define the time segment, and then select the high settings you want on during that time segment.

To set up the High Settings:

1. Press ◎ and go to the High Setup screen.

   Options > SmartGuard > High Setup

   The High Setup screen appears.



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

   The Start time of the first time segment is always 12:00 A. You can set up to eight time segments, each with a different high limit. If you set more than one time segment, the time segments must cover a 24-hour period.

3. Set the End time.

4. Set your High limit. You can enter a value from 100 to 400 mg/dL, in increments of 5 mg/dL.

5. Select the arrow to the right of the End time to select the high alerts for this time segment.

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

6. Set the following alerts as desired:

   a. Select **Alert before high** if you want to receive an alert before you reach your high limit.

b. If you turned on Alert before high, enter the **Time before high** to set how soon you want to be alerted before reaching your high limit. You can enter a value from 5 to 30 minutes.

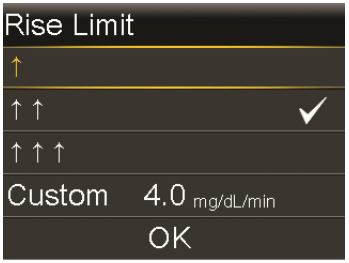
c. Select **Alert on high** if you want an alert when you reach your high limit.

d. Select **Rise Alert** if you want to receive an alert when your SG is rising quickly.

Skip to step 11 if you do not select Rise Alert.

7. If you turned on the Rise Alert, you need to set the Rise Limit. Scroll down and select **Rise Limit** to access this option.

The Rise Limit screen appears.



8. Select the arrow option (one, two, or three arrows) that corresponds to the rise rate you want to use. To use a custom rate, skip to the next step.

- Select ↑ for an alert when your SG has been rising at a rate of 1 mg/dL per minute or more.
- Select ↑↑ 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.

9. To enter a custom rise limit, do the following:

a. Select **Custom**. The Custom Limit screen appears.

b. Select **Rise Limit** and set a rise rate from 1 to 5 mg/dL/min. You set the rate in 0.1 mg/dL/min increments.

c. Select **OK** to return to the Rise Limit screen and then select **OK** again to confirm your settings.

10. When you have set all the high settings for the selected time segment, select **Next** to continue.
11. If you entered an End time of anything other than 12:00 A, another time segment appears. When you are finished entering high settings, select **Done**.
12. Review your settings, and select **Save**.

To change your High Settings:

1. Press ◎ and go to the High Setup screen.

   Options > SmartGuard > High Setup

   The High Setup screen appears.
2. Select **Edit**.
3. Select and, if needed, adjust the time segment you would like to change.
4. Select any alert setting to turn it on or off or to adjust the setting.
5. Select **Next**.
6. Select **Review**.
7. Review your settings, and select **Save**.

High Snooze

High Snooze is available once you have set your High Settings. High Snooze allows you to set the amount of time that you want to wait before you are reminded that an alert condition still exists. After a high alert is received and cleared, you will be alerted again only if the high alert condition still exists after the snooze time you have set.

Setting the High Snooze:

1. Press ◎ and go to the Snooze screen.

   Options > SmartGuard > Snooze

   The Snooze screen appears.

2. Select **High Snooze** and enter a value from 5 minutes to 3 hours, in 5 minute increments.
3. Select **Save** to save your Snooze settings.

Setting up the Low Settings

The steps below guide you through setting up the Low Settings. For details on the Low Settings, see *Low settings, on page 181*.

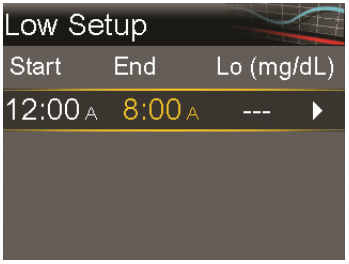
Note: When you enter your settings, you first define the time segment and then select the low settings you want during that time segment.

To set up the Low Settings:

1. Press ◎ and go to the Low Setup screen.

   Options > SmartGuard > Low Setup

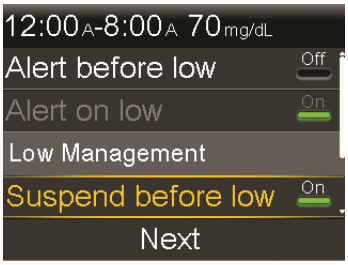
   The Low Setup screen appears.



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

   The Start time of the first time segment is always 12:00 A. You can set up to eight time segments, each with a different low limit. If you set more than one time segment, the time segments must cover a 24-hour period.
3. Set the End time.
4. Set your low limit. You can enter a value from 50 to 90 mg/dL, in increments of 5 mg/dL.
5. Select the arrow to the right of the End time to select the low settings for this time segment.

   A screen appears showing the available settings for the selected time period.



6. Set the following as desired:

   a. Select **Suspend before low** to have insulin suspended before you reach your low limit. The Alert on low alert is automatically turned on and cannot be turned off.

   b. Select **Alert before low** to receive an alert before you reach your low limit. If Suspend before low is also on, you are alerted when insulin is suspended.

   c. Select **Suspend on low** to have insulin suspended when you reach or fall below your low limit. The Alert on low alert is automatically turned on and cannot be turned off.

   d. Select **Alert on low** if you want to receive an alert when your SG reaches or falls below your low limit. If either suspend feature is on, this will already be on.

   e. Select **Resume basal alert** if you want an alert when basal insulin delivery is resumed based on SG values during a suspend by sensor event. If you do not turn on the alert, the Basal delivery resumed message will still appear on the pump, but you will not be alerted.

Note: When setting your low alerts:

- If you turn on the Suspend before low or the Suspend on low feature, then the Alert on low feature is turned on automatically.
- Only one suspend by sensor feature can be used during each time segment. You cannot use both the Suspend before low and the Suspend on low features in the same time segment.

7. When you have set all the low settings for the selected time segment, select **Next** to continue.
8. If you entered an End time of anything other than 12:00 A, another time segment appears.

   When you are finished entering your low settings, select **Done**.
9. Review your settings, and select **Save**.

To make changes to your Low Settings:

1. Press ◎ and go to the Low Setup screen.

   Options > SmartGuard > Low Setup

   The Low Setup screen appears.
2. Select **Edit**.
3. Select, and if needed, adjust the time segment you would like to change.
4. Select any alert setting to turn it on or off or to adjust the setting.
5. Select **Next**.
6. Select **Done**.
7. Review your settings, and select **Save**.

Low Snooze

Low Snooze is available once you have set your Low Settings. Low Snooze allows you to set the amount of time that you want to wait before you are reminded that an alert condition still exists. After a low alert is received and cleared, you will be alerted again only if the low alert condition still exists after the snooze time you have set.

Setting the Low Snooze:

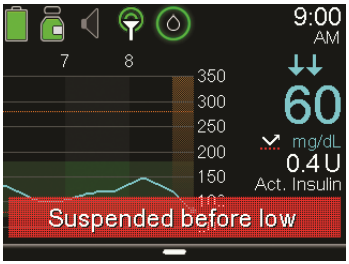
1. Press ◎ and go to the Snooze screen.

   Options > SmartGuard > Snooze

   The Snooze screen appears.
2. Select **Low Snooze** and enter a time between 5 minutes and 1 hour.

Manually resuming basal delivery during a suspend by sensor event

When your pump suspends insulin due to a Suspend before low or Suspend on low event, the bottom of your Home screen displays either Suspended before low or Suspended on low depending on which is active.



If you do not want to wait for your pump to automatically resume your basal insulin, you can follow the procedure below to manually resume your basal delivery.

To manually resume basal delivery:

1. Press ◎ and select **Suspended before low** or **Suspended on low**.

   The SmartGuard 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.

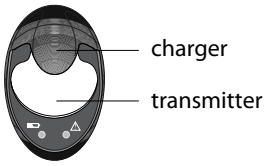
Note the following before trying to connect your pump and transmitter:

- 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 208*.

- 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 205*.

Connecting your pump and transmitter using Auto Connect:

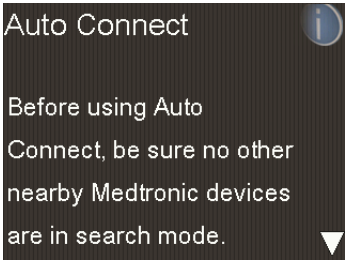
1. Attach your transmitter to the charger and make sure the transmitter is fully charged. Keep your transmitter attached to the charger.



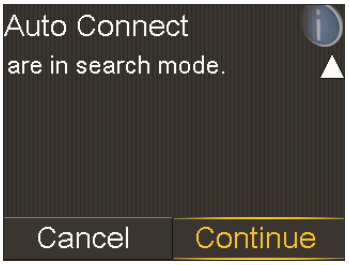
Note: Both lights on the charger are off when the transmitter is fully charged. For more information, see your transmitter user guide.

2. Press ◎ and go to the Auto Connect screen.

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

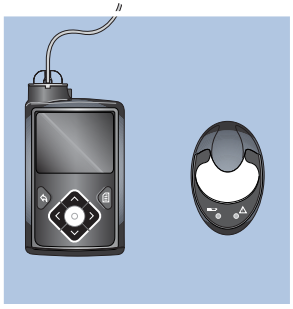


3. Make sure there are no other devices in search mode nearby, scroll down to the bottom of the Auto Connect screen, and select **Continue**.

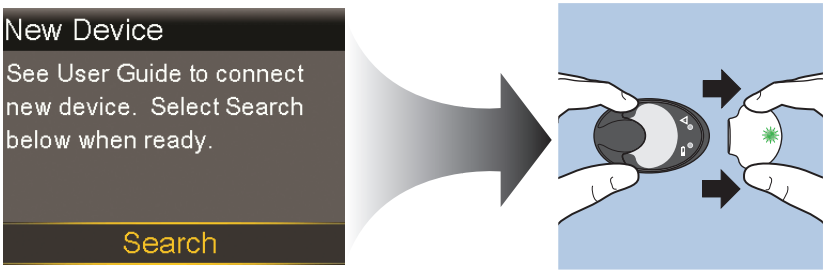


The New Device screen appears.

4. Place the transmitter (still attached to the charger) next to the pump.



5. Select **Search** on your pump and immediately remove the transmitter from the charger.



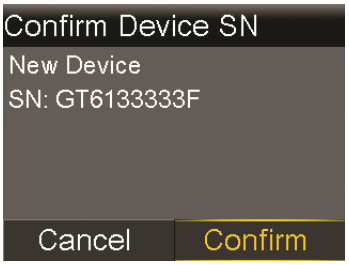
The following happens when you start the search process:

- On your pump, a message appears to let you know your pump is searching.
- On your transmitter, a green light flashes 10 times and then turns off.

Note: The search process can take up to two minutes. You cannot access your pump screens or suspend your pump during the search process.

When your pump finds the transmitter, the Confirm Device SN screen appears.

6. Ensure the transmitter serial number on your pump screen matches the serial number on the back of your transmitter and then select **Confirm**.



If the connection is successful, your pump displays a success message. If the Sensor feature is turned on, the Connection icon appears on the Home screen.

If your pump does not find your transmitter, see the following procedure, *If your pump does not find your transmitter*. If your pump finds multiple devices, skip to the steps on *page 204*.

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 205*.

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 205*.

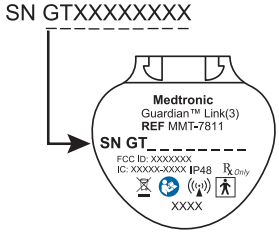
Wirelessly connecting your pump and transmitter using Manual Connect

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.

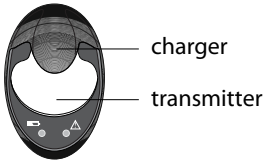
Note: You can connect only one transmitter to your pump. If you already have a transmitter connected to your pump, you must delete it before continuing. For instructions on deleting a transmitter from your pump, see *Deleting the transmitter from your pump, on page 208*.

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:
	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.

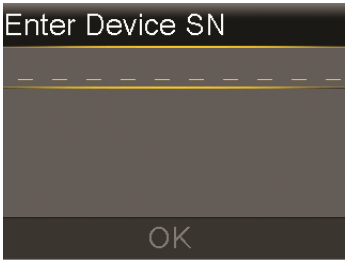


Note: Both lights on the charger are off when the transmitter is fully charged. For more information, see your transmitter user guide.

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, press ◎ and go to the Enter Device SN screen.

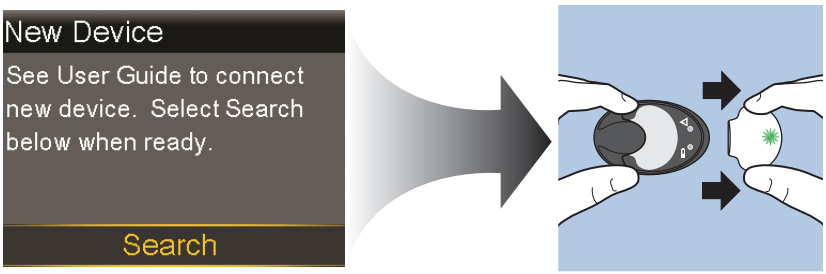
   Options > Utilities > Device Options > Connect Device > Manual Connect



4. Use the pump navigation buttons to enter the serial number of the transmitter and select **OK**.

   The New Device screen appears.

5. Select **Search** on your pump and immediately remove the transmitter from the charger.



The following happens when you start the search process:

- On your pump, a message appears to let you know your pump is searching.
- On your transmitter, a green light flashes 10 times and then turns off.

Note: The search process can take up to two minutes. You cannot access your pump screens or suspend your pump during the search process.

6. Place the transmitter next to the pump.

   If the connection is successful, your pump displays a success message. If the Sensor feature is turned on, the Connection icon appears on the Home screen.

If your pump does not connect to your transmitter:

1. If your pump does not connect to the transmitter, do one of the following:
   - Select **Retry** to return to the Enter Device SN screen on your pump, and then return to step 4 of the procedure above and follow the instructions to search again.
   - Select **Cancel** to return to the Connect Device screen, where you can search again using Manual Connect or Auto Connect.
2. If you have tried to connect multiple times without success, see *My pump cannot find the sensor signal, on page 294*.

Deleting the transmitter from your pump

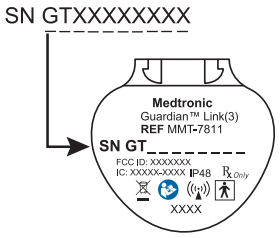
Follow this procedure to delete the transmitter from your pump. Use this process when you are replacing your transmitter.

To delete your transmitter from your pump:

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

   Options > Utilities > Device Options > Manage Devices

2. Identify and select your transmitter by the serial number. The serial number can be found on the back of the transmitter.



3. Select **Delete**.
4. A screen appears confirming that you would like to delete the device. Select **Yes** to confirm or **No** to cancel.

Inserting the sensor

Always refer to your sensor user guide for instructions on how to insert the sensor.

Connecting the transmitter to the sensor

Refer to your transmitter user guide for instructions on how to connect the transmitter to the sensor.

Starting the sensor

After you insert your sensor and connect your sensor and transmitter, your pump starts communicating with the transmitter. The pump notifies you when the sensor is ready to use.

To start a new sensor using the Start New Sensor message:

1. Select **Start New Sensor** when it appears on the pump screen.

   The "Sensor warm-up started" message appears.

Note: It may take up to 5 minutes for the "Sensor warm-up started" message to appear.

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. Press ◎ and go to the Sensor Connections screen.

   Options > Utilities > 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**.

   If you receive a message that your pump cannot find the sensor signal, continue to the next section.

If your pump cannot find the sensor signal:

1. If your pump cannot find the sensor signal, follow the instructions on your pump screen. Your pump guides you through the following steps:

a. Disconnect and reconnect the transmitter from the sensor. Pay attention to the transmitter, and notice if the transmitter light blinks when connected to the sensor. If the transmitter light does not blink, you need to charge your transmitter.

b. Move your pump closer to your transmitter. It can take up to 15 minutes for your pump to find the sensor signal.

c. If your pump is still unable to find the sensor signal, make sure you are away from any electronic devices that might cause interference.

2. If you have gone through all of the troubleshooting on your pump screen and your pump still cannot find the sensor signal, call the 24 Hour HelpLine for assistance.

Calibrating your sensor

Calibration is the process of entering a BG meter reading to calculate sensor glucose values. You must calibrate your sensor regularly to ensure you continue to receive sensor glucose data. For details, see *Guidelines for calibrating, on page 213*.

Within two hours after you use your pump to start the sensor, your pump displays a Calibrate now alert to let you know that a calibration is due. This BG meter reading is the first calibration for your sensor. It takes up to five minutes after calibration to see the first sensor glucose reading on your Home screen. You enter your second calibration within six hours after your first calibration.

After you have entered your first two calibrations, you must calibrate your sensor again within 12 hours. If you do not enter a BG meter reading within 12 hours, your pump displays the Calibrate now alert and stops calculating sensor glucose values until a calibration BG is successfully entered. The sensor must be calibrated at a minimum of every 12 hours throughout the life of the sensor. For better sensor performance, it is recommended that you calibrate your sensor three or four times each day.

You may also receive additional Calibrate now alerts to let you know that another calibration is required to improve performance.

When the Calibrate now alert appears, the system stops calculating SG values until a calibration BG is successfully entered.

Note: Sensor calibration is successful only if your BG entry is in the range of 40 to 400 mg/dL. Remember to calibrate three to four times throughout the day for optimal results.

To calibrate your sensor:

1. Take a BG meter reading.
2. Press ◎ and go to the Calibrate Sensor screen.

   Options > Utilities > Sensor Settings > Calibrate Sensor
3. Select **BG** and enter the value.
4. Select **Calibrate**.

Where to enter your calibration BG meter reading

There are several screens on the pump where you can enter a BG meter reading for calibration. These screens are described in the following table. These options are available only if you are using a sensor.

Note: After your CONTOUR NEXT LINK 2.4 meter wirelessly transmits your BG reading to your pump, you will be required to confirm your BG on your pump before you can use it for calibration.

Pump screen	How to enter your calibration BG
BG screen When you manually enter a BG, the pump will prompt if you want to calibrate your sensor with the BG reading. Press ◎ then select **Enter BG**.	Enter a BG meter reading specifically for calibration.
Calibrate Sensor screen Press ◎, then select: Options > Utilities > Sensor Settings > Calibrate Sensor	Enter a BG meter reading specifically for calibration.

Pump screen	How to enter your calibration BG
BG Meter screen The BG Meter screen appears when your CONTOUR NEXT LINK 2.4 meter sends a BG meter reading to your pump, and you confirm the BG.	Select the Calibrate Sensor option to calibrate your sensor with the current BG meter reading.
BG screen in Event Markers Press ◎, then select: **Options > 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.
BG field in the Bolus Wizard screen Press ◎, then select: **Bolus > Bolus Wizard** The Bolus Wizard is only available in Manual Mode.	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.
BG field in the Auto Mode Bolus screen Press ◎, then select **Bolus**. Auto Mode Bolus is only available in Auto Mode.	When you enter a BG meter reading to deliver a bolus using the Auto Mode Bolus feature, Auto Mode 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
After warm-up is complete.	Do your first sensor calibration. Your pump displays a Calibrate now alert within two hours after starting a new sensor. Your first sensor glucose reading appears up to five minutes after you calibrate.

Calibrate	Description
Six hours after your 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 up to five 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. For better sensor performance, it is recommended that you calibrate your sensor three or four times each day. If you do not calibrate for more than 12 hours, a Calibrate now alert appears. It takes up to five minutes after you calibrate to receive SG values again.
When the Calibrate now alert appears.	You may also receive additional Calibrate now alerts to let you know that another calibration is required to improve performance. It takes up to five minutes after you calibrate to receive SG values again.

Guidelines for calibrating

Follow these guidelines for best sensor calibration results:

- Calibrate three to four times spread out throughout the day to improve accuracy. For details, see *When to calibrate, on page 212*.
- You can calibrate anytime. However, calibrating with two or three trend arrows may temporarily decrease accuracy until the next calibration. For an example of trend arrows on the Home screen, see *Home screen with CGM in Manual Mode, on page 175*.
- Always calibrate immediately after testing your BG. Never calibrate with a BG meter reading that you have taken more than 12 minutes earlier as that BG value would no longer be considered valid.
- Always use clean, dry fingers when you test your blood glucose levels.
- Use only your fingertips when obtaining blood samples for calibration.

Note: If your BG meter readings are significantly different than your sensor glucose readings, you need to wash your hands and calibrate again.

Disconnecting the transmitter from the sensor

Always refer to your transmitter user guide for instructions on disconnecting the transmitter from the sensor.

Removing the sensor

Always refer to the sensor user guide for instructions on how to remove the sensor.

Turning off Sensor Settings

You can turn off Sensor Settings at any time. If you disconnect the transmitter from the sensor, turn off the Sensor Settings to avoid getting a sensor alert. Your sensor settings remain in your pump. You cannot make changes to the settings until you turn on the Sensor Settings again.

To turn off Sensor Settings:

1. Press ◎ and go to the Sensor Settings screen.

   Options > Utilities > Sensor Settings
2. Select **Sensor**.
3. Select **Yes** to turn off the sensor feature.

11

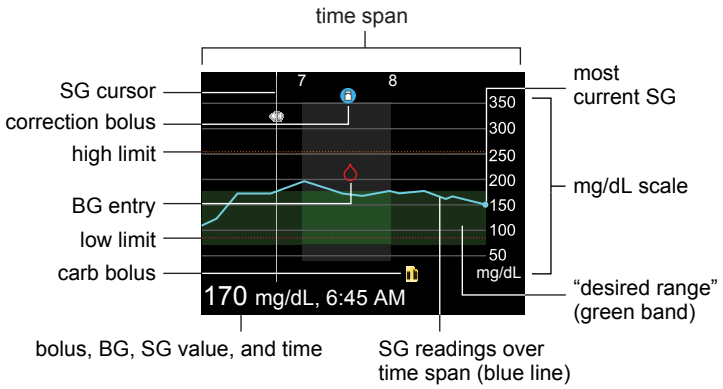
Using continuous glucose monitoring

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 limits
- The bolus deliveries you have given during the time period shown on the graph
- Any suspend events that have occurred

If an SG reading does not appear on the graph, some possible reasons for this include:

- An error condition or a sensor-related alert is occurring.
- A new sensor that you just inserted is still initializing.
- A new sensor that just initialized is still calibrating.
- An existing sensor that you have recently reconnected is not ready.
- More than six hours have passed since the initial sensor calibration.
- More than 12 hours have passed since the last sensor calibration.

To view the sensor graph:

1. From the Home screen, press the button.

   A full-screen view of the 3-hour graph appears.
2. Press ^ to navigate to the 6-hour, 12-hour, and 24-hour graphs.
3. Press < to view SG readings and event details.
4. To exit the full-screen view, press , or press the button again.

Identifying rapid changes in sensor glucose

When you use a sensor, trend arrows appear on the Home screen if your SG has been rising or falling faster than a certain per-minute rate. The number of arrows that appear tell you how quickly your SG has been changing.

The following table shows the trend arrows and their corresponding rates.

↑	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, one of the following status icons appears on the Home screen, depending on your Audio Options settings: vibrate only, audio only, or vibrate and audio. Your system still records the time and glucose value for any alerts that occur. You can view this information in the Alarm History screen.

Note: Alert Silence does not silence Auto Mode exit, High SG, Auto Mode off, and Low SG XX mg/dL (XX represents 50 mg/dL or below) alerts. These alerts are based on set glucose thresholds and cannot be silenced.

If a glucose alert occurs when you are using the Alert Silence feature, the notification light begins to flash and the Sensor alert occurred message appears letting you know an alert was silenced, but there is no vibration or beep. If you have not cleared the alert by the end of the preset alert silence duration, your pump begins to beep or vibrate periodically until the alert is cleared.

The following table describes the glucose alerts that are silenced with each option.

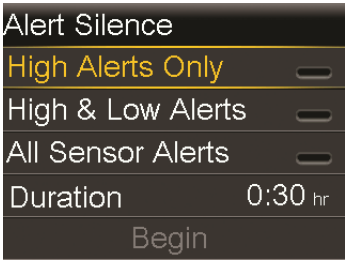
This Alert Silence setting	Silences these alerts
High Alerts Only	Alert on high, Alert before high, and Rise Alert
High & Low Alerts	Alert on high, Alert before high, Rise Alert, Alert on low, Alert before low, Suspend before low, and Resume Basal Alert

This Alert Silence setting	Silences these alerts
All Sensor Alerts	All of the alerts listed previously for High & Low Alerts, plus the following: • All calibration alerts, reminders, or error messages • 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. Press ◎ and go to the Alert Silence screen.

   Audio Options > Alert Silence Options



2. Select High Alerts Only, High & Low Alerts, or All Sensor Alerts to set the alerts you want silenced. Refer to the previous table for details about the alerts silenced with each selection.

Note: If you select **All Sensor Alerts**, you will not receive most alerts related to your sensor glucose readings, your sensor, calibration requirements, or your transmitter. Low SG XX mg/dL (XX represents 50 mg/dL or below), Auto Mode off, Auto Mode exit, and High SG alerts cannot be silenced. You will still hear these alerts when Alert Silence is on. You will still receive alerts for Auto Mode off, Auto Mode exit, High SG, and Low SG XX mg/dL (XX represents 50 mg/dL or below). If a silenced glucose alert occurs, the notification light flashes and a message appears on your pump to let you know a

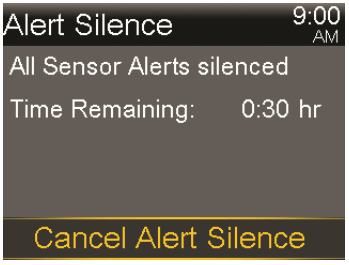
silenced alert occurred, but there is no vibration or beep. You can view the specific alert in Alarm History. For more information on how to view the Alarm History screen, see *Alarm History, on page 143*.

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

To cancel Alert Silence:

1. Press ◎ and go to the Alert Silence screen.

   Audio Options > Alert Silence Options



2. Select **Cancel Alert Silence**.

12

Auto Mode

12 Auto Mode

The Auto Mode feature is part of SmartGuard technology. It automatically controls basal insulin delivery. However, the Auto Mode feature still requires your input for meals, calibrations, and times when you need the target value raised.

Note: The pump requires a minimum of 8 units and a maximum of 250 units per day to operate in Auto Mode.

About Auto Mode

Auto Mode is an insulin delivery feature designed to help people on intensive insulin therapy to achieve better control 24 hours a day. This is achieved by automatically controlling basal insulin delivery to regulate glucose levels to a target sensor glucose (SG) amount. The standard target SG setting is 120 mg/dL and the target can be set temporarily to 150 mg/dL for exercise and other events.

When Auto Mode is active, the sensor glucose values it receives from the transmitter are used to automatically calculate the basal insulin dose. This process of automatic delivery of insulin is called Auto Basal.

Auto Mode depends on reliable, accurate sensor measurements and your accurate entry of carbs to deliver insulin for meals. Therefore, the basic management of the therapy requires the following activities:

- Periodic blood glucose (BG) readings using a BG meter to calibrate the sensor. The minimum calibration is every 12 hours. For better sensor performance, it is recommended that you calibrate your sensor three or four times each day. You may also receive periodic requests from your pump for BG readings without the need for calibration.
- Use of the Auto Mode Bolus feature to deliver boluses to cover meals, and when your pump recommends a bolus.

Note: Delivering a bolus in Auto Mode is similar to delivering a bolus with the Bolus Wizard feature in Manual Mode.

A BG reading above 150 mg/dL causes Auto Mode to automatically calculate if a correction bolus is needed to bring BG down to the 150 mg/dL BG correction target. If needed, a correction bolus will be recommended.

Manual Mode

In this user guide, the term Manual Mode refers to system functions other than Auto Mode. In other words, if Auto Mode is not functioning, the system is in Manual Mode.

Before using Auto Mode

Auto Mode can be enabled at any time, but it does not activate until the system completes a 48-hour warm-up period while you use the pump to deliver insulin. This warm-up period begins the midnight after the pump starts delivering insulin and it does not require sensor use. During the warm-up period, your Auto Mode system collects and processes data that help enable its automatic function. Some alarms that occur during warm-up, including a Suspend before low alert or a Suspend on low alert, will turn off Auto Mode.

WARNING: Do not put your pump into Auto Mode if you have used the pump in the last 3 days to practice button pressing, or if basal insulin that was programmed into your pump was not your actual basal delivery. Doing so may result in the delivery of too little or too much insulin, which can cause hyperglycemia or hypoglycemia. Auto Mode uses the recent delivery history on your pump to determine the Auto Basal delivery amount you receive. If you have been practicing with your pump, you must clear the active insulin and the total daily doses in the pump before using Auto Mode. Use the Clear Active Insulin option in the Manage settings menu to clear both active insulin and the total daily dose.

To ready your pump for Auto Mode, you must:

1. Cancel any active Temp Basal rates. See *Canceling a Temp Basal or Preset Temp basal rate, on page 75*.
2. Ensure your delivery is not suspended. See *Stopping and resuming your insulin delivery, on page 76*.
3. Set your carb ratio. See *Changing your carb ratio, on page 93*.
4. Review your high and low limit settings. Your high and low limit settings apply to Auto Mode. See *Setting up Continuous Glucose Monitoring, on page 173* for details.
5. Enter a BG reading if you have not entered one in the past 12 minutes. If necessary, calibrate your sensor. If you have just started a new sensor, calibrate your sensor, and then wait 30 minutes before you enter a BG for Auto Mode. For more information about calibrating your sensor, see *Calibrating your sensor, on page 210*.

Setting up Auto Mode

Auto Mode can be enabled at any time but will not activate until the 48-hour warm-up period has been completed. For details about the warm-up period, see *Before using Auto Mode, on page 226*. Once enabled, Auto Mode begins automatically when all conditions are met and a BG is entered. For more information, see *Auto Mode Readiness, on page 229*.

To set up Auto Mode:

1. Press ◎ and go to the Auto Mode Settings screen.

   Options > SmartGuard > Auto Mode

2. Select **Auto Mode** to turn the feature on or off.
3. Select **Auto Mode BG alert** to turn it on or off.

Note: The Auto Mode BG alert is set to On by default. When this setting is on, your pump alerts you when Auto Mode requires a BG to remain active. For information about the conditions that cause Auto Mode to require a BG, see *Safe Basal, on page 232*.

4. Select **Save**.

Conditions to activate Auto Mode

If you have been using Auto Mode and you turn off your pump for less than two weeks, there will only be a five hour warm up period once the pump is restarted. The other conditions must still be met before Auto Mode will activate.

If you have turned off your pump for more than two weeks, a new 48 hour warm-up period will be required.

If Auto Mode is enabled but not active, the Auto Mode Readiness screen indicates the reason why Auto Mode has not yet activated. See *Auto Mode Readiness, on page 229*.

It takes 5 hours for the Auto Mode Active Insulin to be updated. This update time happens under the following conditions:

- when your pump is turned on the first time
- may occur following a complete pump reset caused by a loss of power or a software error
- following a Suspend lasting 4 hours or longer

Once the Active Insulin is updated, it will be valid unless one of the conditions above happens, which will restart the update period. Auto Mode will then be locked out for another 5 hours.

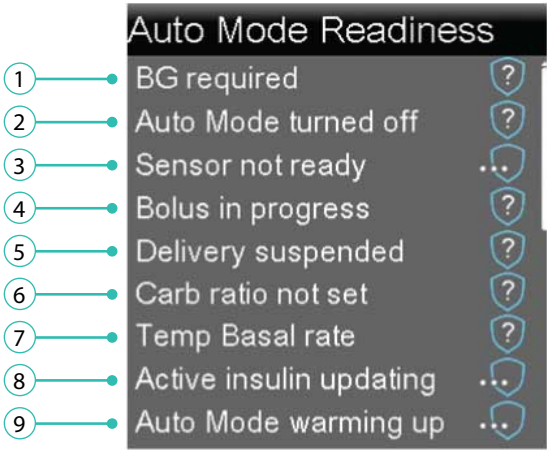
Low Management and Auto Mode

When Auto Mode is active, then the Low Management features are unavailable and automatically turned off. If you are using Suspend before low or Suspend on low, they are automatically turned off when Auto Mode becomes active. If your pump exits Auto Mode, the Low Management features are not active until you turn them on after you exit Auto Mode. If you want to use these features, you must manually turn them on after you exit Auto Mode. See *Low settings, on page 181*.

Auto Mode Readiness

The Auto Mode Readiness screen indicates whether your pump is ready to enter Auto Mode, or return to Auto Basal from Safe Basal.

The following table shows what to do when the wait icon or the question icon appear by items on the Auto Mode Readiness status screen.



Line	If this appears	Do this
1	Calibration required	Perform a fingerstick and calibrate your sensor.
	BG required	Perform a fingerstick and enter a new BG.
	Wait to enter BG...	Wait until the pump prompts you to enter a BG.
	Processing BG...	Wait until the BG has processed.

Line	If this appears	Do this
2	Auto Mode turned off	Turn on Auto Mode in the SmartGuard Auto Mode screen.
3	Sensor not ready	Do the following: • Check to see if your pump has a transmitter ID entered in Utilities, Device Options. For example, GT6133333M. Make sure your pump is connected to a transmitter. For more information, see *Wirelessly connecting your pump and transmitter using Auto Connect, on page 201*. • Check your Home screen. If you see  , move your pump and transmitter closer together. The pump will try to find the transmitter signal. If after 30 minutes the pump and transmitter are still not communicating, you will receive a Lost sensor signal alert. Check that the sensor is still inserted in the skin, and the transmitter and sensor are still connected. Move your pump closer to your transmitter. • If your SG is outside of the 40-400 mg/dL range, your pump will not enter Auto Mode.
	Sensor off	Turn on the sensor in the Utilities, Sensor Settings screen.
	Airplane mode on	Turn off the Airplane Mode in the Utilities, Airplane Mode screen.
4	Bolus in progress	Wait until the bolus is complete or stop the bolus yourself before Auto Mode can activate.
5	Delivery suspended	If insulin delivery is suspended, Auto Mode cannot activate. Treat low BG if necessary as instructed by your healthcare professional.

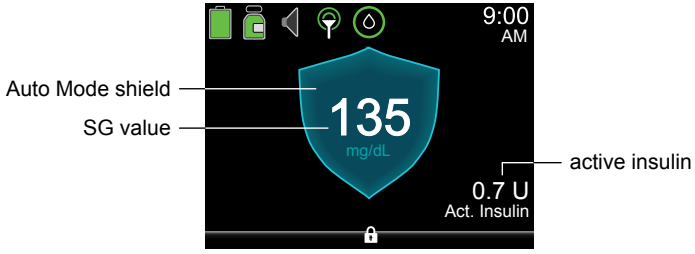
Line	If this appears	Do this
6	Carb ratio not set	Enter your Carb Ratio in the Bolus Estimate Setup screen or the Bolus Wizard Setup screen.
7	Temp Basal rate	If a temp basal is currently active, you must wait until it has completed or cancel the temp basal yourself before Auto Mode can activate.
8	Active insulin updating	If active insulin is currently updating, it may take up to 5 hours to complete. You must wait until this amount is updated before Auto Mode can activate.
9	Auto Mode warming up	Auto Mode is gathering information on your insulin delivery history in order to personalize its automatic delivery of insulin.

To check Auto Mode Readiness:

1. Press ◎ and select **Status** to go to the Status screen.
2. Select **Auto Mode Readiness**.

Home screen with Auto Mode

When your pump transitions into Auto Mode, the Home screen on your pump changes to display a shield that contains a real-time display of your current SG level. The Home screen also displays your current Active Insulin value.



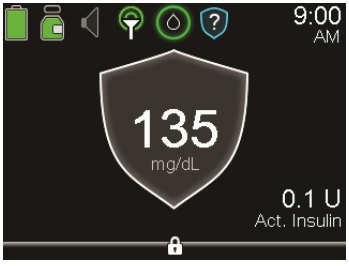
Using Auto Mode

The following sections provide information on how to use Auto Mode and how to view your SG data. This information helps you identify SG trends, including indications that your SG is falling or rising rapidly. You can also view historical SG readings in a graph format.

Safe Basal

Safe Basal is an automatic function within Auto Mode and cannot be modified. The Safe Basal rate is determined by the Auto Mode feature based on your insulin delivery history. It allows you time to perform additional actions required to ensure Auto Mode remains active. Safe Basal covers your basal needs by delivering insulin at a constant rate. Safe Basal does not adjust insulin delivery based on your current SG values.

When the pump is in Safe Basal, the Auto Mode shield appears with a white outline.



Several conditions can cause a transition into Safe Basal. The following table describes these conditions and the actions you must take to resume Auto Basal delivery. An optional setting called the Auto Mode BG alert can be set to have the pump alert you when a BG entry is required. This setting is turned on by default. For more information about setting the Auto Mode BG alert, see *Setting up Auto Mode, on page 227*.

Condition	Actions to take
Auto Mode has been at the minimum delivery limit for 2 1/2 hours.	• Enter a BG. If your Auto Mode BG alert setting is enabled, you will receive an Auto Mode min delivery alert.

Condition	Actions to take
Auto Mode has been at the maximum delivery limit for 4 hours.	• Enter a BG. If your Auto Mode BG alert setting is enabled, you will receive an Auto Mode max delivery alert.
Auto Mode detects that your sensor might be under-reading.	• Enter a BG. If your Auto Mode BG alert setting is enabled, you will receive a BG entry required alert.
An entered BG is 35% or more different than your current SG value.	• Enter another BG or calibration if prompted. If your Auto Mode BG alert setting is enabled, you will receive a BG entry required or Cal required for Auto Mode alert.
No SG data has been received for more than 5 minutes.	• If SG data is not available due to a signal interference, three dashes appear on the screen in place of the SG data. If the interference is intermittent, the Auto Mode shield appears with a white outline, and no action will be required. • If your pump has not received SG data for 30 minutes or more, you will receive a Lost sensor signal alert. For more information about what to do in case of a lost sensor signal, see *CGM (sensor) alarms, alerts, and messages, on page 268*. • If the SG data is not available because the SG calibration has expired, you will receive a Calibrate Now alert. Calibrate your sensor. See *CGM (sensor) alarms, alerts, and messages, on page 268*. The Auto Mode BG alert does not apply to this condition.

After 90 minutes in Safe Basal, if the condition that caused the pump to transition into Safe Basal has not been resolved, the pump will enter Manual Mode.

Note: When you change your sensor, your pump will switch to Safe Basal for up to 90 minutes. The pump will guide you through calibrating and entering a BG for Auto Mode.

Example: Safe Basal

Alex's pump is in Auto mode. Before lunch, he checks his BG, and enters the value into his pump. Alex notices the BG he entered was much higher than his current SG reading. His pump displays a gray shield, indicating that Auto mode is now in Safe Basal delivery. Alex also received a BG Required for Auto Mode alert. He washes his hands, repeats his fingerstick, and enters the new BG into the pump.

After his pump enters Safe Basal, Alex checks his user guide and realizes that his pump entered Safe Basal because the difference between his SG and BG entry was greater than 35%.

Block Mode when in Auto Mode

The Block Mode feature allows a caregiver to block the patient from changing settings or delivering a bolus directly on the pump. In Auto Mode, the Block Mode feature still allows:

- Auto Basal delivery
- BG correction bolus if BG was sent from your CONTOUR NEXT LINK 2.4 meter
- Calibration if BG was sent from your CONTOUR NEXT LINK 2.4 meter

The Block Mode feature does not allow:

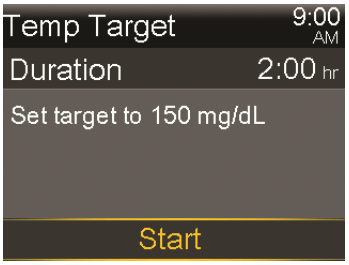
- Bolus delivery or entry unless prompted by the Bolus Recommended screen
- Changes to Auto Mode settings
- Manual BG entry

Setting Temp Target

You may set a temporary SG target (Temp Target) of 150 mg/dL for situations in which you would like your target to be temporarily higher, such as exercise. Check with your healthcare professional regarding use of a Temp Target.

To set a Temp Target:

1. Press ◎ and select Temp Target to go to the Temp Target screen.



2. Set the duration. The default is 2 hours and the maximum duration is 12 hours. Use ∧ and ∨ to set the duration in 30-minute increments.
3. Select **Start**.

   The screen will show Temp Target Started, then change to the Home screen, where a banner will show the remaining Temp Target time.

   When the Temp Target time has run out, the banner will disappear from the Home screen.

To cancel Temp Target:

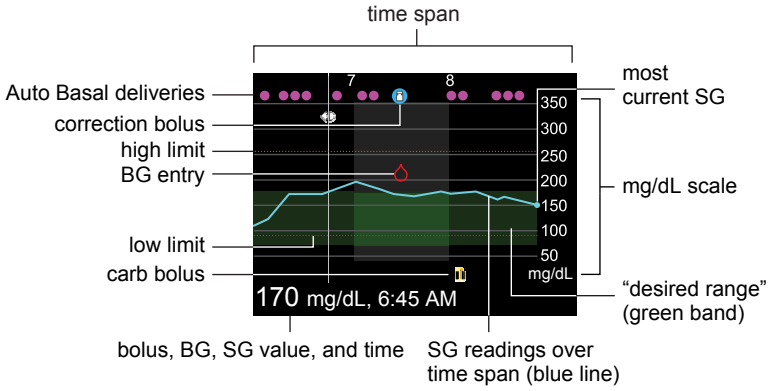
1. Press ◎ and select **Cancel Temp Target** to go to the Cancel Temp Target screen.

2. Select **Cancel Temp Target**.

The Temp Target will be cancelled and the Home screen will appear, with no Temp Target banner.

Auto Mode sensor graph

Your Auto Mode sensor graph displays your current sensor glucose (SG) reading that is wirelessly sent to your pump by your transmitter.



The Auto Mode sensor graph includes the following information:

- The selected SG or event details are displayed at the bottom of the screen.
- Historical sensor glucose readings are displayed for the last 3-hour, 6-hour, 12-hour, or 24-hour periods. They appear as a blue line across the screen.
- Correction boluses are shown as white vials inside blue circles.
- Meal (carb) boluses are shown as yellow knife and fork symbols. These represent any bolus amounts that include a carb entry.
- Blood glucose entries appear as red drop symbols.
- The numerous small magenta dots along the top represent the automatically delivered basal insulin (Auto Basal or Safe Basal) delivered by Auto Mode.
- A time change event appears as a white clock symbol.

If an SG reading does not appear on the graph, some possible reasons for this include:

- An error condition or a sensor-related alert is occurring.
- A new sensor that you just inserted is still initializing.

- A new sensor that just initialized is still calibrating.
- An existing sensor that you have recently reconnected is not ready.
- More than six hours have passed since the initial sensor calibration.
- More than 12 hours have passed since the last sensor calibration.

To view the sensor graph:

1. From the Home screen, press the button to display the SG graph.

   A full-screen view of the 3-hour graph appears.
2. Press ^ to navigate to the 6-hour, 12-hour, and 24-hour graphs.
3. Press < to view SG readings and event details.
4. To exit the full-screen view, press or press the button again.

Enter BG

The BG screen lets you manually enter a BG value. When you access the BG screen, it does not show any previously entered manual or linked meter BG values. If a BG value is received from a linked meter, that value will immediately display in a separate BG Meter screen and you will be prompted to confirm the BG value.

When you enter a BG while in Auto Mode, a correction bolus may be suggested if necessary.

To manually enter Blood Glucose (BG) readings:

1. Press ◎ and select **Enter BG** to go to the BG screen.
2. Select **Enter BG**.
3. Enter a BG value.
4. Select **Save**.
5. A screen appears prompting you to calibrate your sensor with the BG value if you want. Select **Yes** or **No**.

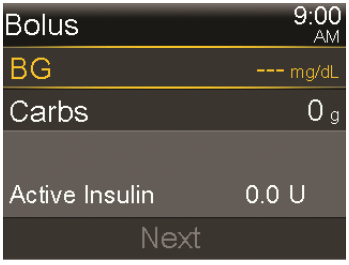
Auto Mode Bolus

Delivering a bolus in Auto Mode is similar to delivering a bolus using the Bolus Wizard feature in Manual Mode. The Bolus feature in Auto Mode requires you to enter either carbs or a BG value. You may also choose to enter both. Auto Mode then calculates the bolus amount needed to cover the meal or correction. Once you confirm this amount, Auto Mode will deliver the bolus.

The Auto Mode Bolus screen shows your current Active Insulin value.

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

Note: Auto Mode Bolus only supports Normal boluses. Square Wave, Dual Wave, Easy, Manual, Remote, and Preset bolus types cannot be delivered while in Auto Mode.



If you are using a CONTOUR NEXT LINK 2.4 meter, you may send your BG meter readings directly to your pump. A confirmation screen will appear asking you to confirm the BG value on the pump. Confirmed BG values will automatically be used in the BG selection of the Auto Mode Bolus screen. These entries will be valid for up to 12 minutes after sending them to the pump. If you wish to enter your BG using a CONTOUR NEXT LINK 2.4 meter, do this prior to using the Auto Mode Bolus screen. If you are not using a CONTOUR NEXT LINK 2.4 meter, you must manually enter your BG value.

Note: In order to ensure accuracy, do not use a BG meter reading in the Auto Mode Bolus screen if more than 12 minutes have passed since you have taken the reading. That BG reading and the corresponding bolus amount may no longer be accurate.

To use the Auto Mode Bolus feature:

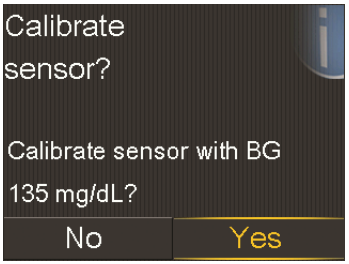
1. Press ◎ and select Bolus to go to the Auto Mode Bolus screen.
2. If you are using a CONTOUR NEXT LINK 2.4 meter, skip to step 3. Otherwise, enter your BG amount. You can enter a range from 20 mg/dL to 600 mg/dL.
3. Enter your Carb amount in grams. If you choose not to enter a Carb amount, skip to step 4.
4. Select **Next**.

   The screen indicates the amount of the calculated bolus.
5. Select **Deliver Bolus**.

   A screen appears briefly to indicate the bolus delivery has started. Then, the Home screen appears and shows the progress of the bolus delivery.

Note: You can stop a bolus at any point by pressing ◎ and selecting **Stop Bolus**.

6. If a new BG value is used in the Auto Mode Bolus feature, the following screen also appears, prompting you to calibrate your sensor. Select **Yes** or **No**.



Correction Boluses

When a BG reading over 150 mg/dL is received and confirmed while your pump is in Auto Mode, your pump automatically calculates and recommends a correction bolus if needed. The calculation takes into account any active insulin that has already been delivered by the pump. If the BG is not above 150 mg/dL, or if the bolus would be zero after accounting for active insulin, no correction will be recommended. If your pump calculates that a correction bolus is needed, the Bolus Recommended screen appears.

To administer a correction bolus from the Bolus Recommended screen, select the Bolus option. If you do not wish to bolus at this time, you may select Cancel to reject the correction bolus. Selecting Bolus will take you to the Auto Mode Bolus screen where you can confirm and deliver the correction bolus. For more information, see *Auto Mode Bolus, on page 238*.

Alert Silence

The Alert Silence feature allows you to temporarily silence SG alerts. This is useful in situations where you do not want to disturb others, such as when you are in a business meeting or in a movie theater. When using this feature, your system still records the time and glucose value for any alerts that occur. You can view this information in the Alarm History screen. See *Alarm History, on page 143* for details.

If a glucose alert occurs when you are using the Alert Silence feature, the notification light begins to flash and the *Sensor alert occurred* message appears, but there is no vibration or sound. If you have not cleared the alert by the end of the preset alert silence duration, your pump begins to beep or vibrate periodically until the alert is cleared.

Note: The following alerts are never silenced:

- Low SG XX mg/dL (XX represents 50 mg/dL or below)
- Auto Mode exit
- High SG
- Auto Mode off

For more information about the Auto Mode exit, High SG, and Auto Mode off alerts, see *Auto Mode alerts and messages, on page 280*. For more information about the Low SG XX mg/dL (XX represents 50 mg/dL or below) alert, see *CGM (sensor) alarms, alerts, and messages, on page 268*.

You can check the status of the Alert Silence feature in the Sensor Status Screen. For more information, see *Status screens, on page 49*.

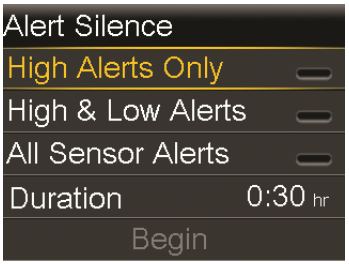
The following table describes the glucose alerts that are silenced with each option.

This Alert Silence setting	Silences these alerts
High Alerts Only	Alert on high, Alert before high, and Rise Alert
High and Low Alerts	Alert on high, Alert before high, Rise Alert, Alert on low, and Alert before low
All Sensor Alerts	All of the alerts listed previously for High and Low Alerts, plus the following: • All calibration alerts, reminders, or error messages • 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 set Alert Silence in Auto Mode:

1. Press ◎ and go to the Alert Silence Options screen.

   Audio Options > Alert Silence Options



2. Select High Alerts Only, High and Low Alerts, or All Sensor Alerts to set the alerts you want silenced. Refer to the previous table for details about the alerts silenced with each selection.

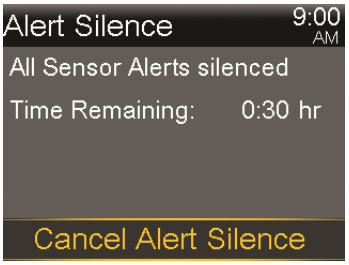
> **Note:** If you select **All Sensor Alerts**, you will not receive any alerts related to your SG readings, your sensor, calibration requirements, or your transmitter. You will still receive the Auto Mode exit, High SG, Auto Mode off, and Low SG XX mg/dL (XX represents 50 mg/dL or below) alerts, which cannot be silenced. If a glucose alert occurs, the notification light flashes and a message appears on your pump to let you know an alert occurred, but there is no vibration or beep. You can view the specific alert in Alarm History. For more information, see *Alarm History, on page 143*.

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

To cancel Alert Silence:

1. Press ◎ and go to the Alert Silence screen.

   Audio Options > Alert Silence



2. Select **Cancel Alert Silence**.

Exiting Auto Mode

Auto Mode is turned off automatically after most pump alarms, except for the following alarms:

- Auto Suspend
- Battery failed
- Power loss
- Battery not compatible
- Insert battery
- Replace battery now
- Loading incomplete
- No reservoir detected
- Max fill reached
- Fill Cannula

If an alarm has initiated a pump reset, you must turn on Auto Mode again and go through a 5-hour warm-up period. For more information about pump alarms, see *Pump alarms, alerts, and messages, on page 250*.

Auto Mode may stop working because:

- You manually turned off the feature through the Auto Mode settings.
- Auto Mode has been in Safe Basal for 90 minutes. See *Safe Basal, on page 232*.
- Any suspend event has not been cleared within 4 hours.
- You manually turned off the Sensor feature or disconnected the transmitter.

You can turn off Auto Mode at any time. For more information, see *Setting up Auto Mode, on page 227*.

Returning to Auto Mode

If you have automatically transitioned to Manual Mode, you can return to Auto Mode if all readiness conditions are satisfied and you enter a BG. For more information, see *Auto Mode Readiness, on page 229*.

Note: If you have turned Auto Mode off, you cannot return to Auto Mode until you turn Auto Mode on again.

You may return to Auto Mode if:

- Auto Mode is enabled on your pump.
- Your sensor is providing good SG values.
- A bolus is not in progress.
- A Temp Basal rate is not in progress.
- 48 hour warm-up is complete.
- Auto Mode is not in a 5-hour warm-up period.
- You have entered a new BG reading.

If any of these conditions are not met, Auto Mode cannot restart.

13

Alarms, alerts, and messages

13 Alarms, alerts, and messages

This chapter describes the general behavior of the most common and the most serious notifications and how to resolve them.

About alarms, alerts, and messages

Your pump has a sophisticated safety network. If this safety network detects anything unusual, it conveys this information in the form of notifications. Notifications include alarms, alerts, and messages.

When you have received more than one notification and there are multiple messages to view, a small white flap appears on the notification icon in the upper-right corner of the screen  . When you clear the first notification, the next notification becomes visible.

Note: It is important that you promptly respond to all notifications and confirmations that appear on your pump. In the event that you do not respond, your pump may remain on that screen until addressed.

When you respond to a message, there may be times when another message appears. Always be sure to address all notifications you have received.

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

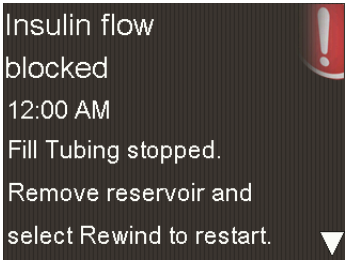
WARNING: If you receive a Critical pump error alarm on your pump, the following screen displays and the pump sirens.

Immediately disconnect from your insulin pump and discontinue use. Contact the 24 Hour HelpLine for assistance.

Remember, your body still needs insulin while your pump is removed. It is important that you consult your healthcare professional to determine an alternate method of receiving insulin while your pump is removed. For more information on the Critical pump error alarm, see *Pump alarms, alerts, and messages, on page 250*.

Alarms

An alarm warns you of a condition that needs your immediate attention. Stopped insulin delivery and low glucose levels are the most common reasons for alarms.



WARNING: Always address alarms immediately when they occur. Ignoring an alarm can result in hyperglycemia or hypoglycemia.

When an alarm occurs:

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

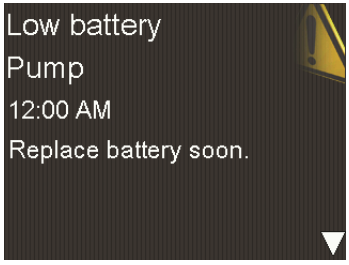
Notification light: The red notification light blinks twice, followed by a pause, in a continuous repeating pattern.

Audio: Depending on your Audio Options settings, the pump emits an alarm tone, a continuous three-pulse-and-pause vibration pattern, or both the alarm tone and vibration.

You must resolve the underlying problem that triggered the alarm. In most cases, you clear an alarm by pressing ✓ and then you make a selection. In some cases, however, clearing the alarm does not fix the underlying problem. The alarm repeats until the underlying problem is fixed.

If you do not respond to an alarm, after ten minutes the alarm tone escalates to a loud emergency siren.

Alerts



An alert makes you aware of a situation that may require your attention. When an alert occurs, always check your pump screen to see if any action is required.

When an alert occurs:

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

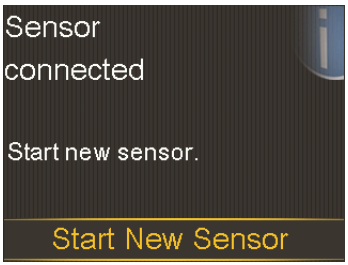
Notification light: The red notification light on your pump blinks once, followed by a pause, then blinks once again in a continuous repeating pattern.

Audio: Depending on your Audio Options settings, the pump either beeps or vibrates in a continuous three-pulse-and-pause pattern, or does both.

To clear an alert, press ✓ and then make a selection. If you do not respond to an alert, the pump beeps every five minutes or every fifteen minutes, depending on the alert. Some alerts will also escalate to a loud emergency siren after ten minutes.

Note: If an alert occurs when you are in a screen other than the Home screen, the alert message may appear after you return to the Home screen.

Messages



A message informs you about the status of your pump or if you need to make a decision.

When a message occurs:

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

Notification light: Does not illuminate or blink.

Audio: Depending on the message, the pump emits a message tone, an alert tone, or no tone. Depending on your Audio Options settings, you may hear a tone, feel a one-pulse-only vibration, or hear a tone and feel a vibration.

You clear the message by pressing ⌄ and making a selection.

Pump alarms, alerts, and messages

The following table lists the most common or serious alarms, alerts, and messages related to your pump. The table also explains the meaning, consequences, and the reasons why these notifications appear, and provides steps for problem resolution. For a list of the alarms that do not turn off Auto Mode, see *Exiting Auto Mode, on page 243*.

Title and text	Type	Explanation	Next steps
Active Insulin cleared Any Active Insulin amount has been cleared.	Alert	Your active insulin amount is now at 0 units. This may occur because certain alarms automatically clear active insulin to ensure the pump returns to a known state.	• 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.
Auto Suspend Insulin delivery suspended. No buttons pressed within time set in Auto Suspend.	Alarm	Insulin delivery is currently suspended by Auto Suspend. Auto Suspend is a feature you enabled to automatically suspend insulin delivery and trigger an alarm after no buttons are pressed for a specified period of time. Auto Suspend does not disable Auto Mode. Insulin delivery is suspended until you clear the alarm and resume basal delivery.	• To clear the alarm and resume basal insulin delivery, select **Resume Basal**. • Check your blood glucose (BG) and treat as necessary.

Title and text	Type	Explanation	Next steps
Battery failed Insert a new AA battery.	Alarm	The pump battery does not have enough power.	• Select **OK** to clear the alarm. • Remove the old battery and insert a new AA battery.
Battery not compatible. See User Guide.	Alarm	The battery that you inserted into the pump is not compatible.	• To clear the alarm, remove the incompatible battery. • Insert a new AA battery.
Bolus not delivered. Bolus entry timed out before delivery. If bolus intended, enter values again.	Alert	Bolus values entered, but bolus was not delivered within 30 seconds.	• 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.	Alarm	The battery power was exhausted while a bolus or Fill Cannula was in progress, or you did not respond to the Resume bolus alert after replacing the battery.	• 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	Type	Explanation	Next steps
Cannot connect device This device is incompatible with your pump. See User Guide.	Alert	• 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 *Additional MiniMed 670G system devices, on page 30*. • If you are replacing your transmitter, make sure that you first delete the old transmitter from your pump before you try to connect your new transmitter. Only one transmitter can be connected to your pump. For details, see *Deleting the transmitter from your pump, on page 208*.
Check settings Startup Wizard settings complete. Check and set up your other settings.	Alert	Some settings have been cleared or reverted to factory default values.	• 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.

Title and text	Type	Explanation	Next steps
Critical pump error Delivery stopped. Pump not working properly. Stop using pump. Remove infusion set from body. Consider other insulin treatment. See User Guide.	Alarm	Your pump has encountered an error that cannot be resolved. For example, your pump may have a mechanical problem.	The pump is not able to deliver insulin. Remove your infusion set and stop using your pump. • Consider another form of insulin delivery. • Check your BG, and treat as necessary. • Write down the error code that appears on the alarm screen. • Call the 24 Hour HelpLine for assistance with your pump.
Delivery limit exceeded Delivery stopped. Check BG. See User Guide for more information.	Alarm	Your pump has suspended because the hourly delivery limit was met. This limit is based on the maximum bolus and maximum basal setting. If this alarm occurs during a bolus, the bolus is canceled before it can complete.	• 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.	Alarm	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.

Title and text	Type	Explanation	Next steps
High BG XXX mg/dL Check infusion set. Check ketones. Consider injection. Monitor BG. Confirm BG?	Message	Your BG meter reading is above 250 mg/dL. This alert applies only to Manual Mode. For High BG XXX mg/dL in Auto Mode, see *Auto Mode alerts and messages, on page 280*.	• Select **No** to prevent the remote BG from being used by your pump. Select **Yes** to confirm the BG reading. • Check your BG and treat as necessary.
Insert battery Delivery stopped. Insert a new battery now.	Alarm	The battery was removed from the pump. If a bolus was in progress when the battery was removed, a **Resume bolus?** alarm sounds when a new battery is inserted. A message also appears, indicating how much bolus was delivered.	• 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	Type	Explanation	Next steps
Insulin flow blocked Check BG. Consider injection and testing ketones. Change reservoir and infusion set.	Alarm	Your pump has detected that the basal or bolus insulin flow was blocked.	• 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.

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

Title and text	Type	Explanation	Next steps
Insulin flow blocked Check BG. Consider injection and testing ketones. Estimated 0 U insulin in reservoir. Change reservoir and infusion set.	Alarm	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.

Title and text	Type	Explanation	Next steps
Insulin flow blocked Fill Cannula stopped. Remove infusion set from body. Change reservoir and infusion set.	Alarm	Your pump has detected the insulin flow was blocked while filling the cannula.	• 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.
Insulin flow blocked Fill Tubing stopped. Remove reservoir and select Rewind to restart.	Alarm	Your pump has detected the insulin flow was blocked while filling the tubing. Possible connection issue between the tubing and reservoir.	• 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.

Title and text	Type	Explanation	Next steps
Loading incomplete Remove reservoir and select Rewind to restart loading.	Alarm	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.	Alert	The battery in the pump is low on power. Remaining battery life is 10 hours or less.	• 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.
Low BG XX mg/dL Treat low BG. Do not bolus until BG is normal. Monitor BG. Confirm BG?	Message	Your BG meter reading is below 70 mg/dL.	• Select **No** to prevent the remote BG from being used by your pump. Select **Yes** to confirm the BG reading. • Check your BG and treat as necessary.

Title and text	Type	Explanation	Next steps
Low reservoir *XX* units remaining. Change reservoir.	Alert	Your reservoir is low on insulin, according to the number of units set in the Low Reservoir Reminder.	• 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.
Manage settings error Delivery stopped. Backup settings cleared from Manage Settings. Current settings are working properly. Select **OK** to restart. See User Guide.	Alarm	A pump error has occurred, and you need to restart your pump. Your backup settings have been lost, but your current settings are unchanged.	• 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.
Max Fill reached 3*X.X* U. Did you see drops at the end of tubing?	Alarm	You have exceeded the number of units expected to fill the tubing. By now, insulin should be at the end of the tubing.	• 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	Type	Explanation	Next steps
Max Fill reached *4X.X* U. Remove reservoir and select Rewind to restart New Reservoir procedure.	Alarm	You have exceeded the number of units expected to fill the tubing. By now, insulin should be at the end of the tubing.	• 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.	Alarm	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.	Alarm	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.

Title and text	Type	Explanation	Next steps
Power loss AA battery was removed for more than 10 min or power was lost. Select OK to re-enter time and date.	Alarm	Your pump battery has been out for more than ten minutes, and your pump has lost power. You must reset your time and date.	• Select **OK** to go to the Time & Date screen. • Enter the current time, time format, and date.
Pump error Delivery stopped. Current settings cleared. Pump restart needed. Select OK to restart and then re-enter your settings. See User Guide.	Alarm	Your pump encountered an error and will restart. Your pump settings will return to factory default values.	• 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 24 Hour HelpLine.

Title and text	Type	Explanation	Next steps
Pump error Delivery stopped. Settings unchanged. Pump restart needed. Select OK to restart. See User Guide.	Alarm	A pump error has occurred, you need to restart your pump.	• 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 24 Hour HelpLine.
Pump error Delivery stopped. Settings unchanged. Select OK to continue. See User Guide.	Alarm	Your pump encountered an error but a restart is not necessary. The issue is resolved. Your settings are not changed.	• 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 24 Hour HelpLine.

Title and text	Type	Explanation	Next steps
Pump restarted Delivery stopped. Settings unchanged. Select OK to continue. See User Guide.	Alarm	Your pump has encountered a problem and has restarted. Your settings have not been changed.	• 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.	Alert	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.	Alarm	Insulin delivery has stopped due to low power. Battery was not replaced after the Low battery Pump alert.	Replace the battery immediately to resume insulin delivery.

Title and text	Type	Explanation	Next steps
Reservoir estimate at 0 U To ensure insulin delivery, change reservoir.	Alert	Your reservoir level is estimated at 0 units.	• Select **OK** to clear the alert. • Change the reservoir now.
Resume bolus? *XXX* of *YYY* U delivered. Resume delivery of *ZZZ* U?	Alarm	A normal bolus delivery has been interrupted because the pump battery was removed. If it is within 10 minutes since this interruption, you can resume this bolus.	• 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?	Alarm	The Square portion of Dual Bolus delivery has been interrupted. If it is within 10 minutes since this interruption, you can resume this bolus.	• 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	Type	Explanation	Next steps
Resume Dual bolus? *XX* of *YY* U delivered. Resume delivery of *ZZ* U now, and *AA* U Square for *XX:XX* hr?	Alarm	The Now portion of a Dual Wave bolus delivery has been interrupted because the pump battery was removed. If it is within 10 minutes since this interruption, you can resume this bolus.	• 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 Square bolus? *XX* of *YY* U delivered for *XX:XX* hr. Resume delivery of *ZZ* U for *XX:XX* hr?	Alarm	The Square Wave bolus delivery was interrupted. If it is within 10 minutes since this interruption, you can resume this bolus.	• 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.	Alarm	Your pump encountered an error.	• Select **OK** to clear the alarm after the pump has completed rewinding. • Select **Reservoir & Tubing** from the Home screen to start the new reservoir process using a new infusion set and reservoir. For details, see *Setting up the reservoir and infusion set, on page 117*.

Title and text	Type	Explanation	Next steps
Stuck button Button pressed for more than 3 minutes.	Alarm	The pump has detected that a button has been pressed for an unusually long time.	• Select **OK** to clear the alarm. • If this alarm occurs again, call 24 Hour HelpLine for assistance with your pump. If you are unable to clear the alarm: • If you are unable to clear the alarm, see *Troubleshooting pump issues, on page 289*. • 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.

CGM (sensor) alarms, alerts, and messages

The following table lists the most common or serious alarms, alerts, and messages related to your sensor glucose readings, as well as the status of your transmitter and sensor. The table also explains the meaning, consequences, and the reasons why these notifications appear, and provides steps for problem resolution.

Title and text	Type	Explanation	Next steps
Alert before high Sensor glucose approaching High Limit. Check BG.	Alert	Your SG value is approaching your specified high limit.	• 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.	Alert	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.	Alert	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.
Alert on low XXX mg/dL Low sensor glucose. Check BG.	Alert	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.

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

Title and text	Type	Explanation	Next steps
Basal delivery resumed Maximum 2 hour suspend time reached. Check BG.	Alert	Your pump is resuming basal insulin delivery two hours after a Suspend before low or Suspend on low event occurred.	• 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. SG is still under Low limit. Check BG.	Alarm	Your pump is resuming basal insulin delivery two hours after a Suspend before low or Suspend on low event occurred.	• Your pump has resumed basal insulin delivery; however, your SG value is still at or below your low limit. • Select **OK** to clear the alarm. • 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.	Alert	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.	Alert	A BG meter reading is needed immediately to calibrate your sensor so that you can continue receiving sensor glucose readings.	• If you are unable to calibrate now, you can use the Snooze feature. Set the desired time, and select **Snooze**. If you do not calibrate before the Snooze time is up, the Calibrate Now alert occurs again.

Title and text	Type	Explanation	Next steps
Calibration not accepted Wait at least 15 minutes. Wash hands, test BG again and calibrate.	Alert	Your system was unable to use the BG meter readings you entered to calibrate your sensor.	• Wash and dry hands thoroughly. See *Guidelines for calibrating, on page 213*. • Select **OK** to clear the alert. • After 15 minutes, enter a new BG meter reading for calibration as instructed in *Calibrating your sensor, on page 210*. If you receive a Calibration not accepted alert on your second calibration after 15 minutes, 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.	Alert	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.

Title and text	Type	Explanation	Next steps
Change sensor Insert new sensor and Start New Sensor.	Alert	You selected No in the Check sensor insertion message, indicating that your sensor is not fully inserted.	• Select **OK** to clear the alert. • Change your sensor. For details, see your sensor user guide. • After you change your sensor, refer to *Starting the sensor, on page 208*.
Change sensor Second calibration not accepted. Insert new sensor.	Alert	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.	Alert	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 *My pump cannot find the sensor signal, on page 294*.
Lost sensor signal Move Pump closer to transmitter. May take 15 minutes to find signal.	Alert	Transmitter signal has not been received for 30 minutes during or after initialization.	• 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.

Title and text	Type	Explanation	Next steps
Low battery transmitter Recharge transmitter within 24 hours.	Alert	The battery in the transmitter needs to be recharged within 24 hours.	• Select **OK** to clear the alert. • Recharge your transmitter as soon as possible.

Title and text	Type	Explanation	Next steps
Low SG XX mg/dL SG is under 50 mg/dL. Check BG and treat.	Alarm	Your sensor glucose value has reached or fallen below 50 mg/dL. This alert is factory set and cannot be changed or turned off. This alert cannot be silenced and is always enabled, whether the pump is in Auto Mode or Manual Mode.	• Select **OK** to clear the alarm. • Check your BG and treat as necessary.

Note: XX represents the sensor glucose value that appears on your pump.

WARNING: For MiniMed 670G Users Ages 7-13: Do not rely solely on the use of a low sensor glucose (SG) value for "Alert on Low" or "Alert before Low" for alerts set at 50 mg/dL and 60 mg/dL. A low sensor glucose alert may not reflect the user's true blood glucose at these levels, or may not alert. Do not ignore symptoms of low glucose. Always confirm your sensor glucose readings with your blood glucose meter, and treat according to the recommendations of your healthcare professional. Solely relying on these sensor glucose alerts and readings for treatment decisions could result in missing severe hypoglycemia (low blood glucose) events.

Title and text	Type	Explanation	Next steps
Medical device CALL FOR EMERGENCY ASSISTANCE. I have diabetes.	Alarm	Your pump is suspended due to low SG, and you have not responded to the alarm within 10 minutes.	• Select **Dismiss**. • Immediately call for emergency assistance.
No calibration occurred Confirm sensor signal. Calibrate by XX:XX AM/PM.	Alert	The transmitter was unable to receive the calibration BG meter readings from the pump.	• Select **OK** to clear the alert. • Check the status icons on your Home screen to ensure that your pump has a signal from your sensor. If there is no sensor signal, see *My pump cannot find the sensor signal, on page 294*. • 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.	Alert	The transmitter was unable to receive the required calibration BG from the pump. Calibration is required by the system for SG values to resume. "Calibration required" appears on your sensor graph.	• Select **OK** to clear the alert. • Take another BG meter reading and calibrate again.

Title and text	Type	Explanation	Next steps
Possible signal interference Move away from electronic devices. May take 15 minutes to find signal.	Alert	There may be interference from another electronic device that is affecting the communication between your pump and transmitter.	• 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.
Rise Alert Sensor glucose rising rapidly.	Alert	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.	Alert	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. • Select the alert to open the Alarm Detail screen. • Take action based on the selected alert.

Title and text	Type	Explanation	Next steps
Sensor connected If new sensor, select Start New. If not, select Reconnect.	Message	The transmitter has detected that you have connected a sensor. The pump needs to know if this is a new sensor or if you have reconnected your old sensor.	• If you have connected a new sensor, select **Start New**. • If you have reconnected a sensor you have been using, select **Reconnect**. • In either case, a "warm-up" message appears on your Home screen, and you will be prompted to enter a BG value when your sensor is ready for calibration. Your pump starts receiving your SG values again after the two-hour initialization is complete.
Sensor connected Start new sensor.	Message	The pump has detected that this is a new sensor, which needs to be started and warmed-up.	• Select **Start New Sensor**. The alert will close and a "warm-up" message appears on the sensor graph with a progress bar.
Sensor expired Insert new sensor.	Alert	The sensor has reached the end of its useful life.	Change your sensor. For details, see your sensor user guide.
Sensor signal not found Did transmitter light blink when connected to sensor?	Alert	The pump has still not received a signal from the transmitter.	When you reconnected the transmitter to the sensor, did you see a blinking green light on the transmitter? • Select **Yes** or **No** and follow the instructions on the screen.

Title and text	Type	Explanation	Next steps
Sensor signal not found See User Guide.	Alert	After multiple attempts, the pump failed to detect the transmitter and is unable to receive sensor signal.	• 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.
Sensor warm-up started Warm-up takes up to 2 hours. You will be notified when calibration is needed.	Alert	The sensor warm-up has begun.	• Select **OK** to close the alert. A "Warm-up" message with a progress bar appears on the sensor graph during warm-up, which takes up to 2 hours. You will be notified when calibration is needed.
Sensor updating Do not calibrate unless notified. This could take up to 3 hours.	Alert	The SG value is unavailable due to a temporary situation.	• Select **OK** to clear the alert. • Follow the instructions on the pump screen. You do not need to change the sensor.

Title and text	Type	Explanation	Next steps
Suspend before low Delivery stopped. Sensor glucose approaching Low Limit. Check BG.	Alert	Your SG value is falling. Insulin delivery is suspended according to your Suspend before low setting and your SG is approaching your specified low limit. Suspend before low is not available in Auto Mode.	• Select **OK** to clear the alert. • Check your BG. If necessary, treat your BG as directed by your healthcare professional.
Suspend on low Delivery stopped. Sensor glucose XXX mg/dL. Check BG.	Alarm	Your SG value is at or below the low limit you specified. Suspend on low is not available in Auto Mode.	• Select **OK** to clear the alarm. • Check your BG. If necessary, treat your BG as directed by your healthcare professional.
Transmitter battery depleted Recharge transmitter now.	Alert	The battery in the transmitter needs to be recharged. SG values are not recorded or transmitted until you recharge transmitter.	• Select **OK** to clear the alert. • Recharge your transmitter.

Auto Mode alerts and messages

The following table lists the most common or serious alerts and messages related to Auto Mode. The table also explains the meaning, consequences, and the reasons why these notifications appear, and provides any necessary steps for problem resolution.

Title and text	Type	Explanation	Next steps
Auto Mode started Current action canceled.	Alert	This alert happens when the user starts an operation that is not allowed in Auto Mode while the pump is transitioning to Auto Mode.	• Select **OK** to clear the alert. • Allow your pump to complete its transition to Auto Mode.
Auto Mode started The following SmartGuard settings are now turned off: - Suspend before low - Suspend on low	Alert	Your pump has started Auto Mode. The Suspend before low and Suspend on low settings are now turned off.	• Select **OK** to clear the alert. • Allow your pump to complete the transition into Auto Mode.

Title and text	Type	Explanation	Next steps
Auto Mode exit Basal Name started. Would you like to review the Auto Mode Readiness screen?	Alert	Your pump has exited Auto Mode because you have turned off your sensor, a suspend has not been cleared within 4 hours, or you have been in Safe Basal the maximum of 90 minutes. This alert cannot be silenced, and is always enabled whenever the system is in Auto Mode.	• Select **No** to clear the alert. Select **Yes** to view the Auto Mode Readiness screen. • Check your BG. • Calibrate your sensor. • Follow instructions from your healthcare professional and continue to monitor your BG. For details, see *Exiting Auto Mode, on page 243* and *Returning to Auto Mode, on page 244*.

Title and text	Type	Explanation	Next steps
High SG SG has been high for over 1 hour. Check infusion set. Check ketones. Monitor BG. Followed by **Auto Mode exit** Monitor BG and treat as necessary. Basal Name started. Enter BG to continue in Auto Mode.	Alert	Your pump has exited Auto Mode based on a set glucose threshold and length of time: • 300 mg/dL or higher for one hour • 250 mg/dL or higher for three hours. This alert cannot be silenced and is always enabled whenever the pump is in Auto Mode.	• Select **OK** to clear the alert. • Check your BG and treat as necessary.
Auto Mode max delivery Auto Mode has been at maximum delivery for 4 hours. Enter BG to continue in Auto Mode.	Alert	Auto Mode has been delivering at your maximum Auto Mode basal delivery rate for four hours. This rate is determined automatically by your system.	• Select **OK** to clear the alert. • Check your BG and enter it into your pump to exit Safe Basal and return to Auto Basal. • Follow instructions from your healthcare professional and continue to monitor your BG.

Title and text	Type	Explanation	Next steps
Auto Mode max delivery Auto Mode has been unable to bring your SG down. Enter BG and resume delivery to continue in Auto Mode.	Alert	Auto Mode has been unable to lower your SG value. Your pump is suspended, and your predicted SG is above target.	• Select **OK** to clear the alert. • Check your BG and enter it into your pump. • Follow instructions from your healthcare professional and continue to monitor your BG.

Note:

- The title of the alert appears the same as the previous Auto Mode max delivery alert in the table.
- If you have suspended your pump, you will have no delivery. However, the alert may still occur.

Auto Mode min delivery Auto Mode has been at minimum delivery for 2:30 hr. Enter BG to continue in Auto Mode.	Alert	Your pump has been delivering at your minimum Auto Mode basal delivery rate for two and a half hours. This rate is determined automatically by your system.	• Select **OK** to clear the alert. • Check your BG and enter it into your pump to exit Safe Basal and return to Auto Basal. • Follow instructions from your healthcare professional and continue to monitor your BG.

Title and text	Type	Explanation	Next steps
Auto Mode min delivery Your SG has been below target for 2:30 hr. Enter BG and resume delivery when ready to continue in Auto Mode.	Alert	Your pump is suspended, and your predicted SG has been below target for two and a half hours.	• Select **OK** to clear the alert. • Check your BG and enter it into your pump. • Follow instructions from your healthcare professional and continue to monitor your BG.

Note:

- The title of the alert appears the same as the previous Auto Mode min delivery alert in the table.
- If you have suspended your pump, you will have no delivery. However, the alert may still occur.

Auto Mode off Basal Name started. Would you like to review the Auto Mode Readiness screen?	Alert	The Auto Mode setting in the SmartGuard menu is turned off.	• Select **Yes** to check the Auto Mode Readiness status screen for information to re-enter Auto Mode. • Select **No** to clear the alert.
BG required Enter a new BG for Auto Mode.	Alert	Auto Mode requires a BG to check the reliability of the sensor.	• Select **OK** to clear the alert. • Enter a BG to return to Auto Basal from Safe Basal, or to enter Auto Mode from Manual Mode.

Title and text	Type	Explanation	Next steps
Bolus recommended For XXX mg/dL entered, a correction bolus is recommended. Select Bolus to program a bolus.	Alert	Auto Mode calculated that a bolus is recommended based on the BG value that you entered.	• Select **Bolus** to program a correction bolus. • Select **Cancel** if you do not want to deliver a correction bolus.
Cal required for Auto Mode Enter a BG and calibrate sensor for Auto Mode.	Alert	Calibration may be required by Auto Mode, even when SG values are available.	• Select **OK** to clear the alert. • Check your BG and enter it into your pump. • Calibrate your sensor using the BG that you entered.
High BG XXX mg/dL Check infusion set. Check ketones. Monitor BG. Confirm BG?	Alert	Your BG meter reading is above 250 mg/dL. This alert applies only to Auto Mode. There is an equivalent alert for Manual Mode. See *Pump alarms, alerts, and messages, on page 250.*	• Select **No** to Prevent the remote BG from being used by your pump. Select **Yes** to confirm the BG reading.

CareLink alert and message

The following table lists the most common or serious alerts and messages related to CareLink. The table also explains the meaning, consequences, and the reasons why these notifications appear, and provides steps for problem resolution. If you get an alarm, alert, or message that is not listed, select OK to clear the notification and call the 24 Hour HelpLine.

Title and text	Type	Explanation	Next steps
Connect Device? Device with SN <XXXXXXXXXX> is trying to connect to your pump. Allow connection?	Message	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.	Alert	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.

14

Troubleshooting

14 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 250*.

Troubleshooting pump issues

WARNING: If you receive a critical error on your pump, the following screen displays and the pump sirens.

Immediately disconnect from your insulin pump and discontinue use. Contact the 24 Hour HelpLine for assistance.

Remember, your body still needs insulin while your pump is removed. It is important that you consult your healthcare professional to determine an alternate method of receiving insulin while your pump is removed. For more information on pump alarms, see *Pump alarms, alerts, and messages, on page 250*.

My pump buttons are stuck

During atmospheric pressure changes, your pump buttons may not work for up to 45 minutes. For example, during airplane travel your pump buttons may get stuck. This is rare. If this occurs, either wait for the problem to correct itself, or if you have a new AA battery with you:

1. Remove the battery cap.
2. Place the battery cap back onto the pump.

   Your pump will check the AA battery power, and may require a new AA battery.
3. If prompted, insert a new AA battery.

If these steps do not correct the problem, contact your local representative for assistance.

What is a Check Settings alarm?

This alarm occurs when a condition causes your pump to reset to factory settings. You see this alarm after your pump guides you through re-entering the Startup Wizard settings.

The Check Settings alarm is letting you know that other settings may have been cleared or reverted to factory default values. Review any settings that you have not already set in Startup Wizard and re-enter the values, if necessary.

My pump is asking me to rewind

WARNING: Do not insert the reservoir into your pump until you have received training for your pump. Doing so could damage your reservoir. Damaging your reservoir could cause an inaccurate insulin delivery, which may cause hypoglycemia.

You must rewind your pump when changing the reservoir. Rewinding returns the piston in the reservoir compartment to its starting position. It is normal for your pump to ask you to rewind anytime you must remove and replace the reservoir, such as when resolving an Insulin Flow Blocked alarm or addressing a problem loading the reservoir.

I dropped my pump

Caution: Always inspect your pump to ensure there are no cracks before exposing your pump to water, especially if your pump has been dropped, or you suspect your pump is damaged. Water leakage can cause the pump to malfunction, and result in injury.

Do the following:

1. Check that all connections are still tightly in place.
2. Check the display, button area, and pump case for cracks or damage.
3. Check the infusion set, including the tubing connector and tubing for cracks or damage.
4. Review the status screen, basal rates and other pump settings.
5. Perform the Self Test procedure. Press ◎ and select:

   Options > Utilities > Self Test
6. If the Self Test does not complete successfully, or if you are concerned about your pump, call our 24 Hour HelpLine for assistance and check your BG.

I cannot get to the Manage Settings screen

These personalized settings, under the Manage Settings screen, should be provided by your healthcare professional in your training session. If you go to **Options > Utilities > Manage Settings**, a message appears telling you that the feature is not normally accessible and to consult your user guide. To access the Manage Settings screen press ◎ and select:

1. **Options > Utilities > Manage Settings**
2. Simultaneously press and hold › and ↩ for about two seconds. The Manage Settings screen appears.

My pump display times out too quickly

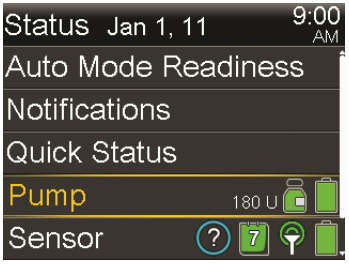
Your pump display times out after 15 seconds by default in order to conserve battery power. You can increase this setting up to three minutes. Press ◎ and select **Options > Utilities > Display Options**, and then adjust the Backlight setting as desired.

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

Where is my pump status screen?

1. Press ◎ and select Status to go to the Status 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 49*.

My pump is asking me to enter my settings

Certain pump errors can clear your settings and return them to their factory default values. This also happens if you intentionally clear your settings. Do not clear your settings unless directed to do so by your healthcare professional.

If you have saved your settings using the Save Settings option, you can restore them using the Restore Settings option. If you restore your settings, ensure the restored settings match the settings prescribed most recently by your healthcare professional.

The Startup Wizard appears automatically when your pump restarts. The wizard guides you through entering the following information. Be sure to have these values ready when you begin.

- Time format, time, and date
- Active Insulin Time
- Basal patterns

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

- Carb ratio
- Insulin sensitivity factor
- BG target

To enter your pump settings:

1. Begin entering your settings by selecting English. Select **Next** to go to each new screen.
2. When the Select Time Format screen appears, select a 12-hour or a 24-hour time format.
3. When the Enter Time screen appears, adjust the setting to the current time. If you are using a 12-hour clock, be sure to specify AM or PM.
4. When the Enter Date screen appears, adjust the **Year**, **Month** and **Day** to the current date.
5. When the Active Insulin Time screen appears, enter the **Duration**.

   For details, see *About active insulin, on page 95*.
6. Enter your first basal rate by entering the End time and the Rate. You can enter more basal patterns after you complete the startup wizard.

   For details, see *Adding a new basal pattern, on page 65*.

   After you complete your basal pattern, a screen appears to allow you to review your basal information.
7. When the message appears asking if you want to setup the Bolus Wizard settings, do one of the following:
   - Select **Yes** to continue entering your settings, then continue to the next section.
   - Select **No** if you do not want to enter your Bolus Wizard settings. A message appears letting you know that your settings are complete. Select **OK** to continue using your pump.

To enter your Bolus Wizard settings:

1. When your pump shows a list of settings for the Bolus Wizard, make sure you have the values you need before continuing.
2. When the Carb Ratio screen appears, enter your carb ratio by entering the End time and the Rate. You can adjust your carb ratio at any time.

   For details, see *Changing your carb ratio, on page 93*.
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 93*.
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 94*.

   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.

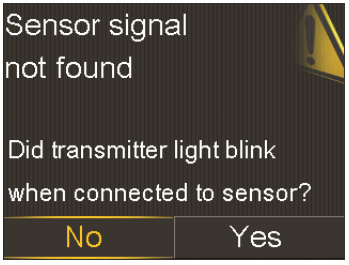
If your pump finds the sensor signal at any time during troubleshooting, your pump beeps or vibrates, and "Warm up" appears on your sensor graph. It can take up to two hours for your sensor to warm up.

Note: If you are using the Alert Silence feature and a glucose alert occurs, the notification light begins to flash and the *Sensor alert occurred* message appears, but no explanatory text is displayed. All silenced alerts are displayed with explanatory text in the Alarm History screen.

1. Make sure your system 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 208*.
   - 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 201*.
   - The Airplane Mode is turned off on your pump.
   - You have applied the tape correctly, as instructed in the serter user guide.
2. Disconnect the transmitter from the sensor for at least 10 seconds.
3. Reconnect the transmitter with the sensor to restart communication. While the light on the transmitter is blinking, select **OK** on the pump to acknowledge the alert.
4. Depending on whether the light blinked when you connected the transmitter to the sensor, select **Yes** or **No** on your pump and do one of the following:



   - If the transmitter light did not blink, you need to charge your transmitter. When your transmitter is charged, start your sensor. For details, see *Starting the sensor, on page 208*.
   - If your transmitter light blinked, but you still have no sensor signal, continue to the next step.

5. Move your pump closer to your transmitter and select **OK**. It can take up to 15 minutes for your pump to find the sensor signal.
6. If your pump still cannot find the sensor signal, make sure you are away from any electronic devices that might cause interference, such as cellular phones and other wireless devices, and select **OK**.
7. If you have gone through all the troubleshooting steps on your pump screen, and your pump still cannot find the sensor signal, or if your sensor graph displays "Sensor signal not found. See User Guide," call the 24 Hour HelpLine for assistance.

Calibration not accepted

Calibration not accepted alert occurs when one of the following happens:

- System was unable to use the BG meter readings you entered to calibrate your sensor.
- System rejects two calibrations in a row from the same sensor.
- The transmitter was unable to receive the calibration BG meter readings from the pump due to failed sensor signal.

For details on when and how to calibrate your sensor, see *Calibrating your sensor, on page 210*.

Why does the SmartGuard suspend by sensor icon on my Home screen appear gray?

The SmartGuard suspend by sensor icon appears gray  on the Home screen when either the Suspend on low or Suspend before low feature is unavailable. The suspend features may be unavailable due to the following conditions:

- A suspend event has occurred recently.

  After a Suspend before low or Suspend on low event occurs, there is a period of time when the suspend functionality is unavailable. This time will vary depending on whether or not you respond to the suspend event. Typically, the suspend features will be unavailable for 30 minutes after your basal insulin delivery is resumed. For details, see *When Suspend before low is unavailable, on page 184* or *When Suspend on low is unavailable, on page 187*.
- No SG values are available.

SG values may be unavailable because:

- Your pump is in Airplane Mode.
- Sensor calibration is required.

  For details on when and how to calibrate your sensor, see *Calibrating your sensor, on page 210*.
- 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 294*.
- 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.

15

Maintenance

15 Maintenance

Cleaning your pump

Caution: Never use organic solvents, such as lighter fluid, nail polish remover, or paint thinner to clean your pump. Never use lubricants with your pump. When cleaning your pump, be sure to keep the reservoir compartment dry and away from moisture. Cleaning your pump with organic solvents can cause the pump to malfunction, and result in minor injury.

Make sure you have the following supplies ready for cleaning your pump: three or four small, clean, soft cloths, a mixture of water with a mild detergent, clean water, 70% alcohol, and a few clean cotton tips and cotton balls.

To clean your pump:

1. Dampen a cloth with water mixed with a mild detergent.
2. Using the cloth, wipe the outside of the pump.
3. Dampen a clean cloth with water and wipe to remove any detergent residue.
4. Dry with a clean cloth.
5. Wipe your pump with a 70% alcohol wipe.
6. Using a dry clean cotton tip, remove any battery residue from the battery cap.
7. Using a dry clean cloth, remove any battery residue from the battery compartment opening.

Cleaning your transmitter

Always refer to your transmitter user guide for instructions on cleaning the transmitter.

Storing your pump

Storage mode allows you to safely place your pump in storage while not in use.

Note: If you place your pump in storage mode, it is important to insert a new AA battery for 8 to 12 hours every six months to ensure that the internal battery does not discharge to a deep discharge. A battery that is deeply discharged takes longer to charge than a normal battery.

WARNING: After placing your pump in storage mode, do not rely on active insulin tracked in the pump when making new Bolus Wizard calculations. Storage mode clears active insulin. Inaccurate Bolus Wizard calculations could result in inaccurate insulin delivery, and serious injury.

Placing your pump in storage mode:

1. Remove the AA battery from the pump. For details, see *Removing the battery, on page 39*.

   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 38*.

   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 165*.

7. You must repeat the connection process for your transmitter and meter. For details, see *Wirelessly connecting your pump and transmitter using Auto Connect, on page 201*. Always refer to your CONTOUR NEXT LINK 2.4 meter user guide for instructions on connecting the meter to the pump.

Storing your transmitter

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

16

Product specifications and safety information

16 Product specifications and safety information

This chapter provides detailed product specifications and safety information.

Product specifications

Alarm and alert escalation

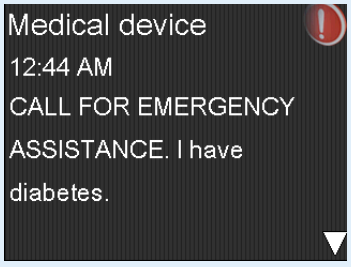
The following alerts may escalate to a siren if not cleared:

- 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
- High SG
- Rise Alert
- Sensor expired
- Sensor signal not found
- Low SG XX mg/dL (XX represents 50 mg/dL or below) alert
- SG value not available
- Transmitter battery depleted

For alerts that escalate to a siren, the pump will begin to siren if the alert is not cleared in 10 minutes. Before the siren occurs, your pump will beep, vibrate, or both, depending on your audio settings.

Minutes	Audio	Audio and vibration	Vibration
0	Audio	Audio and vibrate	Vibrate
1	Audio	Audio and vibrate	Vibrate
2	Audio	Audio and vibrate	Vibrate
3	Audio	Audio and vibrate	Vibrate
4	Audio	Audio and vibrate	Vibrate
5	Audio	Audio and vibrate	Vibrate
6	Audio and vibrate	Audio and vibrate	Audio and vibrate
7	Audio and vibrate	Audio and vibrate	Audio and vibrate
8	Audio and vibrate	Audio and vibrate	Audio and vibrate
9	Audio and vibrate	Audio and vibrate	Audio and vibrate
10	Siren and vibrate	Siren and vibrate	Siren and vibrate

Note: The Medical device alarm sirens immediately when this screen displays.



Altitude range

- Pump operating range is from 10.2 psiA (70.33 kPa) to 15.4 psiA (106.18 kPa)
- Storage range is from 7.2 psiA (49.64 kPa) to 15.4 psiA (106.18 kPa)

Audio frequency

The following table lists the various audible tones and their corresponding frequencies:

Tone name	Frequency
Alarm	1655 Hz followed by 3310 Hz
Alternate Alarm	1850 Hz
Siren (escalated alarm)	1655 Hz, followed by 3310 Hz
Alert	934 Hz
High Sensor Glucose	1312 Hz, followed by 1410 Hz, 1500 Hz, 1619 Hz, 1722 Hz
Low SG	1722 Hz, 1619 Hz, 1500 Hz, 1410 Hz, 1312 Hz
Lost SG	1485 Hz, followed by 1395 Hz, 1320 Hz, 1395 Hz
Message tone	1655 Hz
Reminder tone	934 Hz
Fill tubing tone	1850 Hz
Bolus delivery cancellation tone	1485 Hz, followed by 1655 Hz and 1485 Hz
Loading complete tone	934 Hz
Reservoir loading in progress tone	1850 Hz
Easy Bolus activation	1045 Hz
Easy Bolus step 1 increment	1175 Hz
Easy Bolus step 2 increment	1320 Hz
Easy Bolus step 3 increment	1395 Hz
Easy Bolus step 4 increment	1570 Hz
Easy Bolus step 5 increment	1760 Hz

Backlight

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

Note: Auto Mode uses a fixed BG Target of 150 mg/dL.

BG meter value

The most recent BG value received from the meter. If you are using a CONTOUR NEXT LINK 2.4 meter, this value appears on the Home screen when the Sensor feature is off. This value also appears in the Bolus Wizard screen when setting up a bolus.

Expiration	12 minutes
Range	20 to 600 mg/dL

Bolus delivery

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 ratio	None	1–200 g/u	0.1 g/u for 1–9.9 g/u; 1 g/u for ratios of 10 g/u to 200 g/u
Insulin Sensitivity Factor	None	5–400 mg/dL	1 mg/dL
BG Target	None	60–250 mg/dL	1 mg/dL
Active Insulin Time	4 hours	2 to 8 hours	15 minutes

Bolus Wizard feature specifications

There are four different formulas the Bolus Wizard feature uses to estimate a bolus, depending on your current BG. The following formulas apply only when the carb units are in grams.

1. If your current BG is greater than your High BG Target, the Bolus Wizard feature subtracts active insulin from the BG correction estimate, then adds this to the food estimate to get the total bolus estimate. However, if the result of subtracting active insulin from BG correction estimate is a negative number (less than zero), the total bolus estimate is based only on the food estimate.

(food estimate) (correction estimate)

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

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.

(food estimate) (correction estimate)

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

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.

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

Food estimate:

Carb grams ÷ Carb ratio = Units of insulin

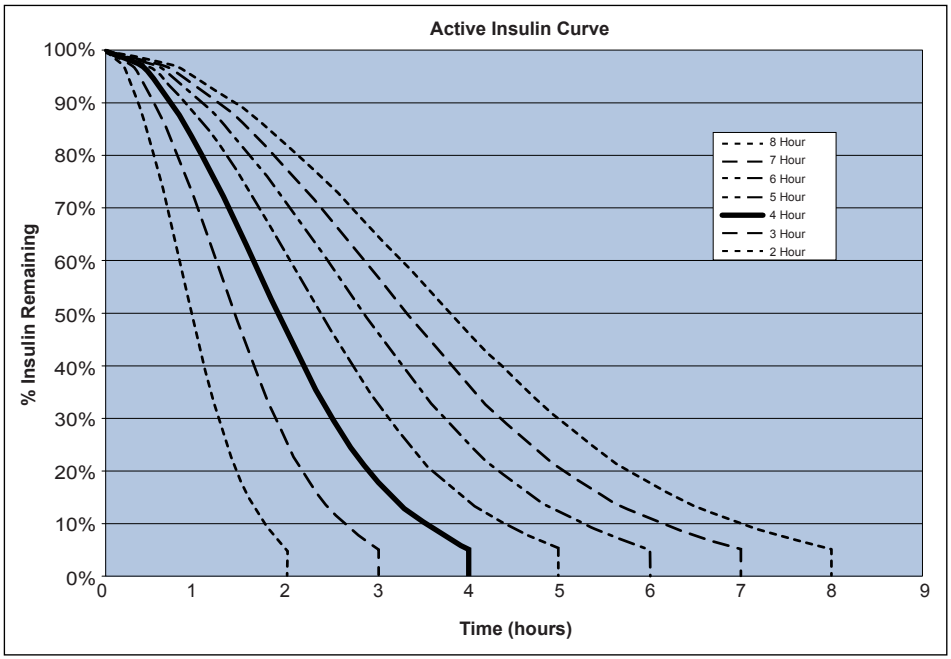
Note: When the current BG is below the Low BG Target, an active insulin amount is not considered in the Bolus Wizard feature calculations.

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

Delivery accuracy

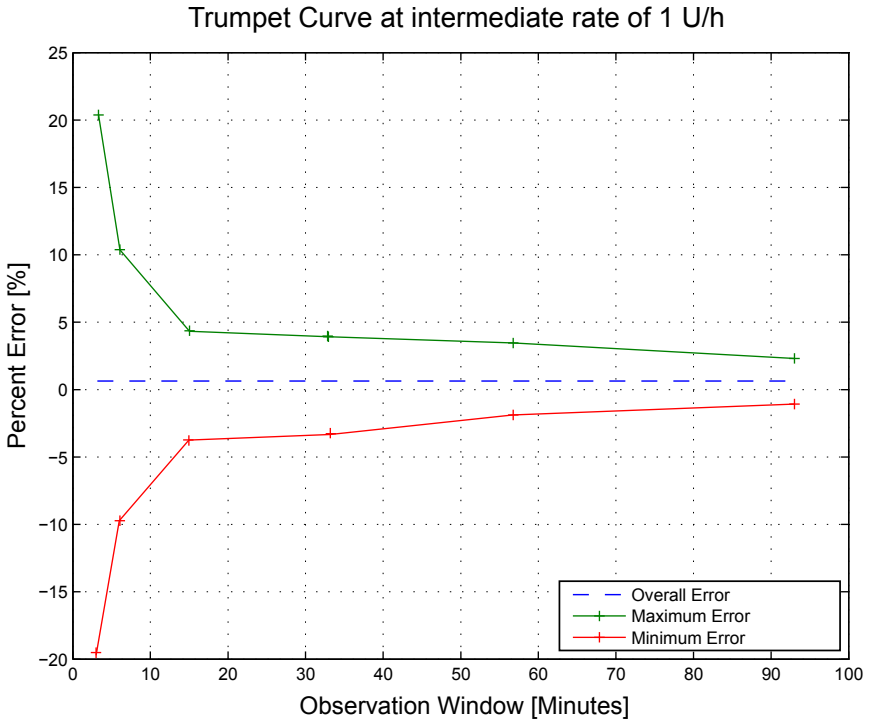
- For a basal rate of 1.0 U/h, the delivery accuracy is ±5%.

  For a basal rate of 0.025 U/h, the delivery accuracy is ±10%.

  Delivery accuracy for bolus volumes < 0.1 unit is ±20% and delivery accuracy for bolus volumes ≥ 0.1 unit is ±5%.

- All Normal boluses are delivered within 16 minutes, 41 seconds ±3 seconds at Standard rate (25 units, at 1.5 units per minute), and within 1 minute, 41 seconds ±3 seconds at Quick rate (25 units, at 15 units per minute).

- The maximum infusion pressure generated and the occlusion threshold pressure using a 3 mL reservoir is 13.15 psi (90.67 kPa) . The average resulting bolus volume generated upon clearing the occlusion is 0.0112 mL (equivalent to 1.12 units of U100 insulin).
- The following is a representative delivery accuracy curve. The Trumpet Curve represents the maximum percentage change from the expected insulin dosage for a given time interval, known as the observation window, during the infusion of insulin. The upper curve corresponds to positive changes, and the lower curve corresponds to negative changes.



Easy Bolus

Allows user to set up and deliver a Normal Bolus when the pump is in Sleep Mode. This is done using the ∧ and with the help of audio and vibration cues.

Audio mode range	0 to 20 increments or Max Bolus limit, whichever comes first
Vibrate mode range	0 to 20 increments or Max Bolus limit, whichever comes first

Default step size	0.1 unit
Adjustable step size	0.1 to 2 units per increment up to Max Bolus limit

Environmental conditions

The MiniMed 670G insulin pump system is designed to withstand most conditions encountered in your daily life. For more details about environmental conditions, such as exposure to magnetic fields and radiation, waterproof capabilities, and extreme temperatures, see *User safety, on page 7*.

- Pump storage temperature range is from -4 °F (-20 °C) to 122 °F (50 °C).
- Pump operating temperature range with insulin is from 41 °F (5 °C) to 98.6 °F (37 °C).
- Air pressure range is from 700 hPa to 1060 hPa (10.2 psi to 15.4 psi).
- Operating relative humidity (RH) range of the pump: 20% to 90%.
  This requirement exceeds IEC 60601-1, subclause 7.9.3.1 (30% to 75%).
- Non-operating relative humidity range of the pump: 5% to 95%

Essential performance

The insulin pump maintains insulin delivery accuracy in the specified environmental conditions.

Filling the infusion set and cannula

- The cannula can be filled from 0.025 units to 5.1 units, in increments of 0.025 units.
- The standard fill rate is 1.5 units per minute.

  The quick fill rate is 15 units per minute.
- When filling the tubing, a warning occurs at 30 units. A second warning occurs at 40 units instructing you to rewind the pump.
- Insulin used to fill the infusion set is recorded in the Daily History.

Infusion pressure

The maximum infusion pressure and occlusion pressure are 13.15 psi (90.67 kPa).

Insulin delivery default settings

Bolus settings

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

Note: The insulin sensitivity factor only applies while the pump is in Manual Mode.

Low Reservoir reminder

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

Alert range	Increment	Default value
First reminder occurs at 5 to 50 units. Second reminder 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 670G insulin pump is intended for use with U100 insulin. This table shows occlusion detection for four different situations when using U100 insulin.

Rate	Minimum time before alarm	Average time before alarm	Maximum time before alarm
bolus delivery (10 units at standard speed)	71 seconds	95 seconds	136 seconds
bolus delivery (10 units at quick speed)	9 seconds	10 seconds	14 seconds
basal delivery (1.0 u/h)	2.00 hours	2.50 hours	3.80 hours
basal delivery (0.025 u/h)	123.38 hours	142.03 hours	178.33 hours

Percent temp basal

The default value is 100 percent of basal programming. For example, if you program six units of basal per day, the default temp basal will be six units per day.

Range	0 to 200%
Default	100% of basal programming
Increment	5%

Program safety checks

A single fault condition will cause the pump to suspend insulin delivery. Maximum infusion with a single fault condition is 0.2 units.

Pump dimensions

The pump dimensions in inches are no greater than 3.81 length x 2.11 width x 0.98 depth.

The pump dimensions in centimeters are no greater than 9.68 length x 5.36 width x 2.49 depth.

Pump memory

User settings and pump history are stored in non-volatile memory which will retain data. The memory size will hold 90 days of pump history before it becomes full and has to be written over. This means that at any time the user can review a maximum of 90 days of history.

Pump weight

The mass of the insulin pump without battery and consumables is less than 106 grams.

Sensor default settings

High sensor settings			
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	50 to 90 mg/dL	5 mg/dL
Suspend before low	Off	-	-
Suspend on low	Off	-	-
Alert before low	Off	-	-
Alert on low	Off	-	-
Low Snooze	20 minutes	5 minutes to 1 hour	5 minutes
Resume basal alert	Off	-	-

Auto Mode settings			
Item	**Default setting**	**Limits**	**Increments**
Auto Mode enable	Off	-	-
Auto Mode BG alert	On	-	-

IEC60601-1-2:2007 notice

IEC60601-1-2:2007; Special EMC Precautions for Medical Electrical Equipment

1. Special Precautions regarding Electromagnetic Compatibility (EMC): This body worn device is intended to be operated within a reasonable residential, domestic, public or work environment, where common levels of radiated "E" (V/m) or "H" fields (A/m) exist; such as cellular phones, WiFi, Bluetooth, electric can openers, microwave and induction ovens. This device generates, uses,

and can radiate radio frequency energy and, if not installed and used in accordance with the provided instructions, may cause harmful interference to radio communications.

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.

IEC60601-1-2:2007; subclause 5.2.2:

The MiniMed 670G insulin pump should not be used adjacent to other electrical equipment. If adjacent use becomes necessary, the MiniMed 670G insulin pump should be observed to verify normal system operation.

Guidance and manufacturer's declaration

Guidance and Manufacturer's Declaration - Electromagnetic Emissions		
The MiniMed 670G insulin pump is intended for use in the electromagnetic environment specified below. The customer or the user of the MiniMed insulin pump should make sure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions Test: 47 CFR Part 15, Subpart C Section 15.247(a)(2)/RSS-210 FHSS– DAOO-705, DTS-KDB 558074, ANSI C63.4, RSS-Gen, FCC Part 15 Section 15.109, Class B/ANSI c63.4 (2009)	• 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 (in Airplane Mode) 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 670G insulin pump is intended for use in the electromagnetic environment specified below. The customer or the user of the MiniMed insulin pump should assure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air @ (30-60% Relative Humidity)	±8 kV contact ±15 kV air @ (30-60% Relative Humidity)	For use in a typical domestic, commercial, or hospital environment.
Electrical fast transient/ burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/ output lines	Not applicable	Requirement does not apply to this battery powered device.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Not applicable	Requirement does not apply to this battery powered device.
Voltage dips, short interruptions and voltage variations on power supply lines IEC 61000-4-11	<5% U_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 670G insulin pump is intended for use in the electromagnetic environment specified below. The customer or user of the MiniMed insulin pump should assure that it is used in such an electromagnetic environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The MiniMed 670G insulin pump is intended for use in the electromagnetic environment specified below. The customer or user of the MiniMed insulin pump should assure that it is used in such an electromagnetic environment.			
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 strength from fixed RF transmitters should be less than the compliance level in each frequency range.[a] The field strength values could be determined by an electromagnetic site survey.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The MiniMed 670G insulin pump is intended for use in the electromagnetic environment specified below. The customer or user of the MiniMed insulin pump should assure that it is used in such an electromagnetic environment.

Note: *At 80 MHz and 800 MHz, the higher frequency range applies.*

Note: *These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption, and reflection from structures, objects and people.*

Note: The table is per IEC (EN) 60601-1-2 Edition 3.

a. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

b. Field strength 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 MiniMed insulin pump is used exceeds the applicable RF compliance level above, the insulin pump should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the MiniMed insulin pump.

Recommended separation distances between the MiniMed 670G insulin pump and common household radio transmitters			
Household RF Transmitter	Frequency	Recommended Separation Distance (meter)	Recommended Separation Distance (inch)
Telephones			
Cordless Household	2.4 GHz	0.3	12
Cordless Household	5.8 GHz	0.3	12
TDMA-50 Hz (cell phone)	1.9 GHz	0.3	12
TDMA-50 Hz (cell phone)	800 MHz	0.3	12
PCS (cell phone)	1.9 MHz	0.3	12
DCS (cell phone)	1.8 MHz	0.3	12
GSM (cell phone)	900 MHz	0.3	12
GSM (cell phone)	850 MHz	0.3	12
CDMA (cell phone)	800 MHz	0.3	12
Analog (cell phone)	824 MHz	0.3	12
CDMA (cell phone)	1.9 MHz	0.3	12
WiFi Networks			
802.11b	2.4 GHz	1	39.5
802.11g	2.4 GHz	1	39.5
802.11n	2.4 GHz	1	39.5
Bluetooth 500 kb/s	2.4 GHz	0.1	3.93
ZigBee 250 kb/s	2.4 GHz	0.1	3.93

Recommended separation distances between portable and mobile RF communications equipment and the MiniMed 670G insulin pump

The insulin pump is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the MiniMed insulin pump can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the MiniMed insulin pump as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to the frequency of transmitter (m)	
	80 MHz to 800 MHz $d=1.2\sqrt{P}$	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-1580/1780 pump will assess channel changing needs based on "noise" levels detected during

an energy scan. The pump will perform the energy scan if after 10 minutes no CGM transmitter signal has been received. If the channel change occurs the pump will send beacons on the new channel.

The CGM transmitter will initiate a channel search when beacon detection fails on the associated channel. The search will be conducted across all five channels. When the beacon is located the transmitter will rejoin on the identified channel. Upon re-association any missed packets (up to 10 hours) will be transmitted from the CGM transmitter to the pump.

In normal operation the CGM transmitter will transmit a packet every 5 minutes and retransmit the packet if the data is corrupted or missed.

Radio frequency (RF) communications specifications

Utilizes the IEEE 802.15.4 protocol with the proprietary data format.

Pump frequency	2.4 GHz; proprietary Medtronic protocol; range up to 6 feet (1.8 meters)
Maximum output power (EIRP)	-4 dBm (.398 mW)
Operating frequencies	2420 MHz, 2435 MHz, 2450 MHz, 2465 MHz, 2480 MHz
Bandwidth	5 MHz which is allocated channel bandwidth per the IEEE protocol

FCC notice

This device complies with the United States Federal Communications Commission (FCC) and international standards for electromagnetic compatibility. This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation. These standards are designed to provide reasonable protection against excessive radio frequency interference, and prevent undesirable operation of the devices from unwanted electromagnetic interference.

Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio

frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Decrease the distance between the transmitter and the insulin pump to 6 feet (1.8 meters) or less.
- Decrease the distance between the meter and the insulin pump to 6 feet (1.8 meters) or less.
- Increase the separation between the transmitter and the device that is receiving/emitting interference.

IMPORTANT: Do not change or modify the internal RF transmitter or antenna unless expressly approved by Medtronic Diabetes. Doing so could interfere with your ability to operate the equipment.

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

Data security

The MiniMed 670G insulin pump is designed to only accept radio frequency (RF) communications from recognized and linked devices (you must program your pump to accept information from a specific device).

The MiniMed 670G system ensures data security via encryption and proprietary means and ensures data integrity using error checking processes, such as cyclic redundancy checks.

Icon glossary

For a definition of the symbols displayed on the device and package labels, see www.medtronicdiabetes.com/symbol-definitions.

Appendix A: End user software license agreement

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

Glossary

active insulin	Bolus insulin that has been delivered by the pump and is still working to lower your blood glucose levels.
active insulin adjustment	The amount of insulin that is subtracted from your BG correction bolus to account for the active insulin that is tracked by the Bolus Wizard.
Active Insulin Time	A Bolus Wizard setting that lets you set the length of time that bolus insulin is tracked as active insulin.
Activity Guard	An attachment that can be used to ensure that the reservoir stays secure during activity, or when the pump is worn by a child.
Airplane Mode	A feature that temporarily stops your device from communicating wirelessly.
alarm	An audible beep or vibration with a message to inform you that the pump is no longer delivering insulin. Alarms require immediate action.
Alarm History	A feature that stores information about recent alarms and alerts.
alert	An audible beep or vibration with a message to inform you of a situation that may require your attention.
Alert before low	An alert that occurs when you are approaching your low sensor glucose value.
Alert Limits	The values that you set to determine when low and high glucose alerts are triggered.

Alert on low	An alert that occurs when your sensor glucose value reaches or falls below your low limit.
Auto Basal	The automatically adjusted basal insulin delivered by Auto Mode based on your sensor glucose values.
Auto Mode	Auto Mode is an insulin delivery feature that automatically controls basal insulin delivery to regulate blood glucose (BG) levels to a target sensor glucose (SG) value.
Auto Suspend	An alarm that you set to suspend insulin delivery and trigger an alarm if no buttons are pressed for a specified period of time. Clearing the alarm resumes insulin delivery.
Awake mode	A state in which the pump screen is on. Unless you are actively using another screen, your Home screen appears.
basal insulin	Insulin that is continuously delivered by the pump to meet your individual insulin needs between meals and during sleep.
basal pattern	A set of one or more basal rates that covers a 24-hour period.
basal rate	The amount of continuous basal insulin that you program your pump to automatically deliver per hour.
BG	Abbreviation for blood glucose. See *blood glucose*.
BG Targets	The high and low values to which your blood glucose is corrected when using the Bolus Wizard.
Block Mode	A feature that restricts the ability to change all settings. You can still perform certain functions, such as suspending insulin delivery, reviewing history, testing your pump, or clearing alarms and alerts.
blood glucose (BG)	Refers to glucose (sugar) that is present in the blood, commonly measured by a blood glucose meter.
blood glucose meter	A device that measures glucose levels in the blood.

Bolus BG Check reminder	A reminder that you set just after you program a bolus. The reminder notifies you to check your blood glucose when the time period that you specified has passed.
Bolus Entry function	The Bolus Entry function in Auto Mode assists the user in calculating a recommended bolus amount based on optional carbohydrate intake and optional BG measurement. The user may enter one or both of the two optional inputs. This function utilizes the Carb Ratio setting to compute the bolus.
bolus insulin	Insulin used to cover an expected rise in glucose levels from carbohydrates, or to lower a high blood glucose value down to your target range.
Bolus Speed	A feature that lets you choose the speed at which your device delivers bolus insulin.
Bolus Wizard	A feature that uses your individual Bolus Wizard settings to calculate an estimated bolus amount based on the BG values and carbs that you enter. These settings include Carb Ratio, Insulin Sensitivity Factor, BG Target Range, and Active Insulin Time.
calibrate	The process of using a meter blood glucose reading to calculate sensor glucose values.
Calibration reminder	A reminder you can set to let you know when your next calibration is due.
cannula	Short, thin, and flexible tube placed in the tissue below the skin. Insulin is delivered through the cannula into the body.
carb ratio	The number of grams of carbohydrates covered by one unit of insulin. The carb ratio is used to calculate bolus amounts.
CGM	Abbreviation for continuous glucose monitoring. See *continuous glucose monitoring*.
continuous glucose monitoring (CGM)	A monitoring tool that uses a glucose sensor placed below the skin to continuously measure the amount of glucose in your interstitial fluid.

correction bolus	Insulin used to lower a high blood glucose value down to your target range.
Daily History	A feature that displays the actions that you performed using your device.
Diabetic Ketoacidosis (DKA)	A serious condition that occurs when the insulin levels are low, blood glucose level are elevated, and the body uses fat for energy. This process produces ketones which upset the body's acid-base balance leading to a potentially life threatening situation.
Dual Wave® Bolus	A type of bolus that provides a dose of insulin delivered as a combination of a Normal Bolus followed by a Square Wave Bolus.
Easy Bolus™	A feature that lets you deliver a Normal Bolus in preset increments using only audio or vibrate confirmation.
Event Marker	A feature that allows you to record events, such as blood glucose readings, injections, carbohydrates, and exercise.
food bolus	A dose of insulin you give to cover an expected rise in glucose levels from carbohydrates.
High limit	The value you set to determine when the pump will alert you of a high sensor glucose condition.
infusion set	Tubing that connects to the reservoir on one end, and has a needle or cannula on the other end, that you insert into your body. Insulin travels from the pump through the infusion set into your body.
infusion site	The location on the body where the infusion set is inserted.
insulin sensitivity factor	The amount that blood glucose is reduced by one unit of insulin. The insulin sensitivity factor is used to calculate correction bolus amounts.
interstitial fluid	The fluid that surrounds the cells in the body.
ISIG	The signal created by the sensor that is used to calculate your sensor glucose value. Typically used by Medtronic technical support representatives when troubleshooting.

lock	A pump feature that prevents accidental button presses.
Low limit	The value you set to determine when the pump will alert you of a low sensor glucose condition, and also used for determining if insulin delivery should be suspended.
Low management	Low management features include Suspend before low and Suspend on low.
Manual Bolus	A feature that allows you to enter and deliver a dose of insulin in the amount that you have determined is necessary.
Manual Mode	Manual Mode refers to system functions other than Auto Mode. In other words, if Auto Mode is not functioning, the system is in Manual Mode.
Max Basal Rate	A feature that allows you to set the maximum amount of basal insulin that can be delivered per hour.
Max Bolus	A feature that allows you to set the maximum bolus amount that can be delivered in one dose.
meter	A term for any blood glucose meter.
Missed Meal Bolus reminder	A reminder that a bolus was not delivered during time periods that you specify, often set around your meal times.
Normal Bolus	A type of bolus that provides an entire dose of insulin immediately.
notifications	All notifications are designed to get your attention and convey different types of information. They include alarms, alerts, reminders, and messages.
occlusion	A blockage or crimp of the cannula or tubing that prevents proper insulin flow.
piston	The part of the insulin pump that engages the reservoir and moves insulin through the tubing.
Power save mode	A state in which your pump is fully functional, but the screen goes dark to save power. You can set how long it

	takes for your screen to enter power save mode by changing the Backlight setting.
Preset Bolus	A feature that allows you to set up and save a bolus for specific meals or snacks that you frequently eat or drink.
Preset Temp Basal	A feature that allows you to set up and save temporary basal rates for repeated use.
Rate alert	An alert that notifies you if your sensor glucose value has been rising or falling faster than the Rise Limit or Fall Limit that you have set.
reminder	A type of notification that you can set to help you remember to do something.
reservoir	The small container that you fill with insulin and insert into your delivery device.
Resume basal alert	An alert that can be set to occur when your pump has automatically resumed basal insulin delivery after a Suspend before low or Suspend on low event because your sensor glucose values have met the necessary criteria. This alert will always occur if basal insulin delivery has resumed because the two hour maximum suspend time has elapsed.
Rewind	A feature used when changing a reservoir. It returns the piston to its starting position and allows a new reservoir to be placed into the pump.
sensitivity	See *insulin sensitivity factor*.
sensor (glucose sensor)	The small part of the continuous glucose monitoring system that you insert just below your skin to measure glucose levels in your interstitial fluid.
sensor glucose (SG)	Refers to glucose (sugar) that is present in the interstitial fluid and is measured by a glucose sensor.
Set Change reminder	A reminder that you can set to change your infusion set.
SG	Abbreviation for sensor glucose. See *sensor glucose*.
Sleep mode	A state in which your pump is fully functional, but the screen is dark. Your pump automatically enters sleep

	mode when you have not pressed any buttons for about two minutes.
SmartGuard™	A feature that can automatically stop and resume insulin delivery based on your sensor glucose values and low limit. In Auto Mode, SmartGuard can automatically adjust basal insulin delivery based on SG inputs.
Square Wave® Bolus	A bolus delivered evenly over a specified time period.
Suspend before low	A feature that suspends insulin delivery when the sensor predicts sensor glucose value is approaching your low limit.
Suspend Delivery	This feature stops all insulin delivery until you resume it. Only the basal insulin restarts when delivery is resumed.
Suspend on low	A feature that suspends insulin delivery when your sensor glucose value reaches or falls below your low limit.
Temp Basal Rate (temporary basal rate)	A feature that allows you to temporarily increase or decrease your current basal rate for a duration of time that you specify.
transfer guard	The plastic piece that comes attached to the reservoir. It is used to connect the reservoir to the insulin vial while filling the reservoir with insulin.
transmitter	A device that connects to a glucose sensor. The transmitter collects data measured by the sensor and wirelessly sends this data to monitoring devices.

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MINIMED™ 670G

MiniMed™ 670G System
Performance data

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I. Performance data for users 14 years old and older

A. Device performance for users 14 years and older

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

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

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

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

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

2 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.

3 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.

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

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

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

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

Data from this in-clinic study demonstrated that the Suspend before low feature is safe to use. Study success criteria, as defined in the protocol, were met (i.e. there were no device related serious adverse events, no diabetic ketoacidosis events related to the Suspend before low feature, and no unanticipated adverse device effects). The second level of SmartGuard technology was evaluated under a pivotal, single-arm, multi-center, home and hotel study in subjects with type 1 diabetes on insulin pump therapy. Study subjects included persons aged 14-75 years diagnosed with type 1 diabetes mellitus for two years or more that had used pump therapy for more than 6 months prior to screening. Study subjects had an HbA1C value of less than 10.0% at the time of screening.

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

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

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

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

Table A-1: Device Related Adverse Events

Event	Run-In Period	Study Period
Severe hyperglycemia	5	12
Hyperglycemia	0	6
Skin irritation	3	0
Irritation on sensor site	0	1
Rash	0	1

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

Table A-2: Time Spent in Specific Glucose Ranges During the Run-In and Study Phases by All Subjects		
Glucose Range (mg/dL)	**Run-In Phase Time in Glucose Range Mean±SD**	**Study Phase Time in Glucose Range Mean±SD**
≤ 50	12.8 mins ± 14.5 mins	7.7 mins ± 7.6 mins
≤ 60	35.2 mins ± 31.2 mins	19.9 mins ± 14.8 mins
≤ 70	1 hr 18.6 mins ± 55.3 mins	42.9 mins ± 25.4 mins
70 - 180	14 hrs 54.4 mins ± 3 hrs 1.4 min	16 hrs 2.2 mins ± 2 hrs 35.6 mins
> 180	6 hrs 2.1 mins ± 2 hrs 52.7 mins	5 hrs 20.7 mins ± 1 hr 46.9 mins
> 250	1 hr 30.4 mins ± 1 hr 32.3 mins	1 hr 12.1 mins ± 52.6 mins
> 300	29.6 mins ± 51.7 mins	21.1 mins ± 22.2 mins
> 350	8.9 mins ± 20.7 mins	6.1 mins ± 8.35 mins

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

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

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

Table A-4: Number of Subjects that Spent a Certain Time Range in Each Glucose Range During the Study Phase

Time Range	Number of Subjects (% of Subjects) in the Glucose Range (mg/dL) Indicated							
	≤ 50	≤ 60	≤ 70	70 to 180	> 180	> 250	> 300	> 350
0 to 15 mins	105 (84.7%)	58 (46.8%)	12 (9.7%)	0 (0.0%)	0 (0.0%)	8 (6.5%)	66 (53.2%)	112 (90.3%)
15 to 30 mins	16 (12.9%)	43 (34.7%)	33 (26.6%)	0 (0.0%)	0 (0.0%)	16 (12.9%)	31 (25.0%)	6 (4.8%)
30 to 45 mins	3 (2.4%)	12 (9.7%)	29 (23.4%)	0 (0.0%)	0 (0.0%)	24 (19.4%)	12 (9.7%)	6 (4.8%)
45 mins to 1hr	0 (0.0%)	10 (8.1%)	25 (20.2%)	0 (0.0%)	0 (0.0%)	17 (13.7%)	6 (4.8%)	0 (0.0%)
1 to 4 hr	0 (0.0%)	1 (0.8%)	25 (20.2%)	0 (0.0%)	34 (27.4%)	58 (46.8%)	9 (7.3%)	0 (0.0%)
4 to 8 hr	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	83 (66.9%)	1 (0.8%)	0 (0.0%)	0 (0.0%)
8 to 12 hr	0 (0.0%)	0 (0.0%)	0 (0.0%)	12 (9.7%)	7 (5.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
12 to 16 hr	0 (0.0%)	0 (0.0%)	0 (0.0%)	38 (30.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
16 to 20 hr	0 (0.0%)	0 (0.0%)	0 (0.0%)	70 (56.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
20 to 24 hr	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (3.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

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

Table A-5: Time Spent in Auto Mode at Different Glucose Ranges during the Study Phase	
Glucose Range (mg/dL)	**Study Phase Time in Glucose Range Mean±SD (95% CI)**
≤ 50	4.8 mins ± 4.6 mins (4.0 mins, 5.6 mins)
≤ 60	13.2 mins ± 10.1 mins (11.4 mins, 15.0 mins)
≤ 70	29.9 mins ± 18.8 mins (26.6 mins, 33.2 mins)
70 to 180	13 hrs 50.3 mins ± 3 hrs 1.4 mins (13 hrs 18.1 min, 14 hrs 22.5 mins)
> 180	4 hrs 5.2 mins ± 1 hr 5.0 mins (3 hrs 53.7 mins, 4 hrs, 16.8 mins)
> 250	44.8 mins ± 24.9 mins (40.4 mins, 49.2 mins)
> 300	9.3 mins ± 7.6 mins (8.0 mins, 10.7 mins)
> 350	1.7 mins ± 2.0 mins (1.3 mins, 2.0 mins)
All	18 hrs 25.4 mins ± 2 hrs 44.4 mins (17 hrs 56.2 mins, 18 hrs 54.7 mins)

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

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

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

B. Guardian™ Sensor (3) Performance for 14 years old and older

CGM performance

The use of the Guardian™ Sensor (3) with the Guardian™ Link (3) transmitter enables CGM (Continuous Glucose Monitoring) technology. The transmitter transmits sensor glucose values calculated by the real-time algorithm to a primary display device, allowing you to monitor your sensor glucose values.

Clinical study description

The performance of the Guardian™ Sensor (3) was evaluated in a clinical study[1]. This inpatient (in-clinic) and outpatient (at home) study included subjects 14 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. Three sensors were worn at the same time by each subject.

Each subject was instructed to wear two real-time CGM systems in the abdomen area:

1. one Guardian™ Sensor (3) connected to the Guardian™ Link (3) transmitter, which transmitted to the insulin pump (for display purposes only)
2. one Guardian™ Sensor (3) connected to the Guardian™ Connect transmitter which transmitted to the Guardian™ Connect app, a standalone CGM display device

Each subject was also instructed to wear another Guardian™ Sensor (3) in the arm area that was connected to a blinded glucose sensor recorder (GSR).

The sensor glucose data collected by the blinded GSRs were retrospectively processed through the real-time CGM algorithm. This is the same algorithm used in the Guardian™ Connect and pump CGM systems. Thus all data is representative of real-time sensor usage.

The CONTOUR®NEXT LINK 2.4 Wireless Meter was the study meter used for all calibrations in this study, and was the only meter evaluated with the Guardian™ Sensor (3) CGM systems. The sensor has not been tested with other meters. Therefore, the performance with other blood glucose meters may differ from the performance with the CONTOUR NEXT LINK 2.4 Wireless Meter described below.

Frequent Sample Testing (FST) was performed on days 1, 3, and 7 over the life of the sensor. Reference blood (plasma) glucose values were obtained with a Yellow Springs Instrument (YSI®) Glucose Analyzer every 5 to 15 minutes. During the FSTs, the subjects were instructed to calibrate the sensors once every 12 hours, or as requested by the display device. During home use (outside the clinic), subjects were instructed to calibrate both sensors 3 or 4 times spread throughout the day.

A total of 93 subjects previously diagnosed with type 1 or 2 diabetes were enrolled in the study, and 88 subjects participated in at least one day of FST. The overall number of subjects that participated in FST procedures on days 1, 3, and 7 were 88, 87, and 79, respectively. During each FST period, subjects with an

established insulin sensitivity ratio and insulincarbohydrate ratio underwent a hypoglycemic challenge and a hyperglycemic challenge to evaluate performance at high and low glycemic ranges.

During the study, subjects were instructed to continue with their current diabetes regimen (including glucose monitoring with their own meter when appropriate) independent of theiruse of the study devices. The insulin pumps were not used to infuse insulin, and neither of the two real-time CGM systems nor the blinded GSR system was used to manage diabetes duringthis study. The study meter was used for confirmation of alerts, treatment decisions and sensor calibrations.

Results

Sensor accuracy

The following information highlights the Guardian™ Sensor (3) performance from 88subjects only during frequent sample testing (FST).

Mean absolute relative difference, by number of dailycalibrations

Table 1 shows the sensor accuracy measured by the mean absolute relative difference (MARD). MARD represents the average relative difference (regardless if positive or negative) between the sensor glucose (SG) values and the paired blood glucose values measured byYSI.

Table B- 1. SG MARD Versus YSI (within YSI glucose ranges).

YSI glucose ranges (mg/dL)	Abdomen Insertion Site				Arm Insertion Site			
	Calibration every 12 hours		Calibration 3 or 4 times a day		Calibration every 12 hours		Calibration 3 or 4 times a day	
	Number of paired SG-YSI	Mean Absolute Relative Difference	Number of paired SG-YSI	Mean Absolute Relative Difference	Number of paired SG-YSI	Mean Absolute Relative Difference	Number of paired SG-YSI	Mean Absolute Relative Difference
Overall	12090	10.55	11664	9.64	10526	9.09	10771	8.68
<40*	12	17.03	11	16.41	7	17.24	7	17.24
40–60*	353	7.96	324	7.53	335	6.44	349	6.42
61–80*	1445	9.44	1403	8.81	1345	7.76	1372	7.44
81–180	6505	9.94	6342	9.33	5644	8.64	5795	8.35
181–300	3277	10.00	3114	8.57	2766	8.58	2785	7.95
301–350	366	9.63	341	8.13	308	9.09	338	8.27
351–400	117	9.58	114	8.56	111	8.47	115	8.23
>400	15	10.85	15	10.92	10	10.71	10	11.44

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

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

Percent agreement, by number of daily calibrations

In Tables 2 through 9, the agreement of the SG values to paired YSI values was assessed by calculating the percentage of YSI values that were within 15%, 20%, 30%, 40% and greater than 40% of the paired SG values. For readings less than or equal to 80 mg/dL, the absolute difference in mg/dL between the SG and paired YSI values was calculated.

Results are shown for defined SG ranges when calibrating every 12 hours and calibrating three or four times a day for sensors.

Table B-2. Overall agreement (%) of SG-YSI paired points within SG ranges on FST Days 1, 3, and 7; Calibration every 12 hours, Abdomen.

SG ranges (mg/dL)	Number of paired SG-YSI	Percent of YSI within 15/15% of SG (%)	Percent of YSI within 20/20% of SG (%)	Percent of YSI within 30/30% of SG (%)	Percent of YSI within 40/40% of SG (%)	Percent of YSI greater than 40/40% of SG (%)
Overall	12090	76.6	85.7	94.3	97.3	2.7
≥40–60*	781	57.7	73.2	90.7	96.9	3.1
>60–80*	1350	76.1	83.4	93.4	96.8	3.2
>80–180	6769	76.5	85.3	93.5	96.5	3.5
>180–300	2833	80.8	90	97.1	98.9	1.1
>300–350	286	86.4	95.1	99.7	100	0
>350–400	71	93	100	100	100	0

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

Note: SG Readings are within 40–400 mg/dL.

Table B-3. Agreement (%) of SG paired points within SG ranges on FST Day 1; Calibration every 12 hours, Abdomen.

SG ranges (mg/dL)	Number of paired SG-YSI	Percent of YSI within 15/15% of SG (%)	Percent of YSI within 20/20% of SG (%)	Percent of YSI within 30/30% of SG (%)	Percent of YSI within 40/40% of SG (%)	Percent of YSI greater than 40/40% of SG (%)
Overall	4294	65.3	76.6	89.5	94.7	5.3
≥40–60*	278	46.8	61.9	83.5	94.2	5.8
>60–80*	474	61	71.7	88	93.5	6.5
>80–180	2443	64.9	75.4	87.6	93.2	6.8
>180–300	985	71.6	83.8	95.5	98.5	1.5
>300–350	90	82.2	95.6	100	100	0
>350–400	24	91.7	100	100	100	0

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

Note: The overall number of available paired SG-YSI points on FST Day 1 was from 88 subjects. SG Readings are within 40–400 mg/dL.

Table B-4. Overall agreement (%) of SG-YSI paired points within SG ranges on FST Days 1, 3, and 7; Calibration 3 or 4 times a day, Abdomen.

SG ranges (mg/dL)	Number of paired SG-YSI	Percent of YSI within 15/15% of SG (%)	Percent of YSI within 20/20% of SG (%)	Percent of YSI within 30/30% of SG (%)	Percent of YSI within 40/40% of SG (%)	Percent of YSI greater than 40/40% of SG (%)
Overall	11664	80.6	88.9	95.9	98.2	1.8
≥40–60*	686	60.2	75.1	92	98.1	1.9
>60–80*	1303	78.7	85.7	93.5	96.7	3.3
>80–180	6549	79.9	88.5	95.7	98	2
>180–300	2782	86.4	93.5	98	99.4	0.6
>300–350	279	92.5	97.8	99.6	100	0
>350–400	65	95.4	100	100	100	0

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

Note: SG Readings are within 40–400 mg/dL.

Table B-5. Agreement (%) of SG paired points within SG ranges on FST Day 1; Calibration 3 or 4 times a day, Abdomen.

SG ranges (mg/dL)	Number of paired SG-YSI	Percent of YSI within 15/15% of SG (%)	Percent of YSI within 20/20% of SG (%)	Percent of YSI within 30/30% of SG (%)	Percent of YSI within 40/40% of SG (%)	Percent of YSI greater than 40/40% of SG (%)
Overall	4136	71.4	81.9	92.3	96.3	3.7
≥40–60*	247	50.2	64.4	84.6	95.5	4.5
>60–80*	429	66.2	73.9	86.5	92.8	7.2
>80–180	2353	70.6	81.4	91.8	95.5	4.5
>180–300	988	78.6	89.1	97.2	99.5	0.5
>300–350	97	88.7	96.9	100	100	0
>350–400	22	100	100	100	100	0

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

Note: The overall number of available paired SG-YSI points on FST Day 1 was from 88 subjects. SG Readings are within 40–400 mg/dl

Table B-6. Overal agreement (%) of SG-YSI paired points within SG ranges on FST Days 1, 3, and 7; Calibration every 12 hours, Arm.

SG ranges (mg/dL)	Number of paired SG-YSI	Percent of YSI within 15/15% of SG (%)	Percent of YSI within 20/20% of SG (%)	Percent of YSI within 30/30% of SG (%)	Percent of YSI within 40/40% of SG (%)	Percent of YSI greater than 40/40% of SG (%)
Overall	10526	82.5	90.3	96.3	98.7	1.3
≥40–60*	520	77.1	86.9	96	99.6	0.4
>60–80*	1238	88.2	92.5	96.4	99	1
>80–180	5957	80.3	88.5	95.5	98.2	1.8
>180–300	2495	85	93.2	98	99.4	0.6
>300–350	256	90.6	96.9	100	100	0
>350–400	60	90	93.3	100	100	0

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

Note: SG Readings are within 40–400 mg/dL.

Table B-7. Agreement (%) of SG-YSI paired points within SG ranges on FST Day 1; Calibration every 12 hours, Arm.

SG ranges (mg/dL)	Number of paired SG-YSI	Percent of YSI within 15/15% of SG (%)	Percent of YSI within 20/20% of SG (%)	Percent of YSI within 30/30% of SG (%)	Percent of YSI within 40/40% of SG (%)	Percent of YSI greater than 40/40% of SG (%)
Overall	3390	74.7	84.2	93.2	97.8	2.2
≥40–60*	168	60.1	73.2	90.5	98.8	1.2
>60–80*	339	75.5	79.4	88.8	97.3	2.7
>80–180	2017	73.2	83.1	92	97	3
>180–300	760	80.5	90.8	98.2	99.6	0.4
>300–350	91	84.6	93.4	100	100	0
>350–400	15	60	73.3	100	100	0

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

Note: The overall number of available paired SG-YSI points on FST Day 1 was from 82 subjects. SG Readings are within 40–400 mg/dL.

Table B-8. Overall agreement (%) of SG-YSI paired points within SG ranges on FST Days 1, 3, and 7; Calibration 3 or 4 times a day, Arm.

SG ranges (mg/dL)	Number of paired SG-YSI	Percent of YSI within 15/15% of SG (%)	Percent of YSI within 20/20% of SG (%)	Percent of YSI within 30/30% of SG (%)	Percent of YSI within 40/40% of SG (%)	Percent of YSI greater than 40/40% of SG (%)
Overall	10771	84.3	91.6	97.3	99.1	0.9
≥40–60*	503	77.1	87.5	96.6	99.6	0.4
>60–80*	1291	89.3	93.4	97.7	99.1	0.9
>80–180	6076	82	90	96.7	98.7	1.3
>180–300	2569	87	94.4	98.3	99.7	0.3
>300–350	271	94.8	98.5	100	100	0
>350–400	61	95.1	96.7	100	100	0

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

Note: SG Readings are within 40–400 mg/dL.

Table B-9. Agreement (%) of SG-YSI paired points within SG ranges on FST Day 1; Calibration 3 or 4 times a day, Arm.

SG ranges (mg/dL)	Number of paired SG-YSI	Percent of YSI within 15/15% of SG (%)	Percent of YSI within 20/20% of SG (%)	Percent of YSI within 30/30% of SG (%)	Percent of YSI within 40/40% of SG (%)	Percent of YSI greater than 40/40% of SG (%)
Overall	3591	76.8	86	95	98.5	1.5
≥40–60*	162	62.3	75.3	91.4	98.8	1.2
>60–80*	346	76.3	81.5	92.8	97.4	2.6
>80–180	2108	75.1	85	94.2	98	2
>180–300	869	81.8	91	97.7	99.9	0.1
>300–350	93	92.5	96.8	100	100	0
>350–400	13	84.6	84.6	100	100	0

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

Note: The overall number of available paired SG-YSI points on FST Day 1 was from 83 subjects. SG Readings are within 40–400 mg/dL.

Agreement when CGM reads "Below 40 mg/dL" or "Above 400 mg/dL"

The real-time CGM systems display glucose values between 40 mg/dL and 400 mg/dL. It displays "Below 40 mg/dL" when the SG value detected is below 40 mg/dL. It displays "Above 400 mg/dL" when the SG value detected is above 400 mg/dL. Tables 10, 11, 12, and 13 illustrate the number and percentage of the paired YSI values in different blood glucose levels when the CGM system displays "Below 40 mg/dL" (LOW) or "Above 400 mg/dL" (HIGH).

Table B-10. The number and percentage of YSI values collected when CGM displays 'Below 40 mg/dL' (LOW); Calibration every 12 hours.

				YSI (mg/dL)				
CGM Display	Insertion Site	CGM-YSI pairs	<55	<60	<70	<80	>80	Total
LOW	Abdomen	Cumulative, n	42	77	139	150	4	154
		Cumulative %	27%	50%	90%	97%	3%	100%
	Arm	Cumulative, n	17	35	67	74	1	75
		Cumulative %	23%	47%	89%	99%	1%	100%

Table B-11. The number and percentage of YSI values collected when CGM displays 'Below 40 mg/dL' (LOW); Calibration 3 or 4 times a day.

				YSI (mg/dL)				
CGM Display	Insertion Site	CGM-YSI pairs	<55	<60	<70	<80	>80	Total
LOW	Abdomen	Cumulative, n	33	64	108	119	4	123
		Cumulative %	27%	52%	88%	97%	3%	100%
	Arm	Cumulative, n	18	35	66	72	1	73
		Cumulative %	25%	48%	90%	99%	1%	100%

Table B-12. The number and percentage of YSI values collected when CGM displays 'Above 400 mg/dL' (HIGH); Calibration every 12 hours.

				YSI (mg/dL)				
CGM Display	Insertion Site	CGM-YSI pairs	<340	<320	<280	<240	>240	Total
HIGH	Abdomen	Cumulative, n	8	9	9	9	0	9
		Cumulative %	89%	100%	100%	100%	0%	100%
	Arm	Cumulative, n	8	8	9	9	0	9
		Cumulative %	89%	89%	100%	100%	0%	100%

Table B-13. The number and percentage of YSI values collected when CGM displays 'Above 400 mg/dL' (HIGH); Calibration 3 or 4 times a day.

				YSI (mg/dL)				
CGM Display	Insertion Site	CGM-YSI pairs	<340	<320	<280	<240	>240	Total
HIGH	Abdomen	Cumulative, n	8	9	9	9	0	9
		Cumulative %	89%	100%	100%	100%	0%	100%
	Arm	Cumulative, n	8	8	8	8	0	8
		Cumulative %	100%	100%	100%	100%	0%	100%

Concurrence of SG and YSI values

Tables 14 through 21 show, for each SG range, the percentage of concurring data points where the paired YSI values were in different blood glucose ranges.

Table B-14. Overall concurrence of YSI values and SG readings using SG ranges on FST Days 1, 3, and 7; Calibration every 12 hours, Abdomen

Percent of matched pairs in each YSI glucose range for each SG range (mg/dL)												
SG ranges (mg/dL)	Number of paired SG-YSI	YSI Glucose Range (mg/dL)										
		<40	≥40–60	>60–80	>80–120	>120–160	>160–200	>200–250	>250–300	>300–350	>350–400	>400
A) <40	154	0.0% (0/0)	50.0% (77/154)	47.4% (73/154)	2.6% (4/154)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
B) ≥40–60	781	1.2% (9/781)	30.7% (240/781)	57.2% (447/781)	10.6% (83/781)	0.3% (2/781)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
C) >60–80	1350	0.2% (3/1350)	8.3% (112/1350)	60.1% (811/1350)	29.2% (394/1350)	2.1% (28/1350)	0.1% (2/1350)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
D) >80–120	2953	0.0% (0/0)	0.0% (1/2953)	6.3% (185/2953)	73.0% (2157/2953)	18.2% (537/2953)	2.0% (60/2953)	0.4% (13/2953)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
E) >120–160	2784	0.0% (0/0)	0.0% (0/0)	0.1% (2/2784)	8.8% (245/2784)	67.7% (1885/2784)	20.3% (565/2784)	2.8% (79/2784)	0.3% (8/2784)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
F) >160–200	1875	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.1% (2/1875)	10.0% (188/1875)	60.2% (1128/1875)	28.2% (529/1875)	1.5% (28/1875)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
G) >200–250	1382	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.3% (4/1382)	8.0% (111/1382)	61.1% (844/1382)	28.1% (389/1382)	2.3% (32/1382)	0.1% (2/1382)	0.0% (0/0)
H) >250–300	608	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.3% (2/608)	10.9% (66/608)	61.2% (372/608)	25.5% (155/608)	2.1% (13/608)	0.0% (0/0)
I) >300–350	286	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	1.0% (3/286)	19.9% (57/286)	55.2% (158/286)	22.4% (64/286)	1.4% (4/286)
J) >350–400	71	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	1.4% (1/71)	29.6% (21/71)	53.5% (38/71)	15.5% (11/71)
K) >400	9	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	11.1% (1/9)	77.8% (7/9)	11.1% (1/9)

Table B-15. Concurrence of YSI values and SG readings using SG ranges on FST Day 1; Calibration every 12 hours, Abdomen

Percent of matched pairs in each YSI glucose range for each SG range (mg/dL)													
SG ranges (mg/dL)	Number of paired SG-YSI	YSI Glucose Range (mg/dL)											
		<40	≥40–60	>60–80	>80–120	>120–160	>160–200	>200–250	>250–300	>300–350	>350–400	>400
A) <40	71	0.0% (0/0)	38.0% (27/71)	57.7% (41/71)	4.2% (3/71)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
B) ≥40–60	278	2.2% (6/278)	23.0% (64/278)	55.8% (155/278)	18.7% (52/278)	0.4% (1/278)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
C) >60–80	474	0.4% (2/474)	12.0% (57/474)	47.7% (226/474)	34.8% (165/474)	4.6% (22/474)	0.4% (2/474)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
D) >80–120	1071	0.0% (0/0)	0.1% (1/1071)	4.6% (49/1071)	66.6% (713/1071)	23.4% (251/1071)	4.5% (48/1071)	0.8% (9/1071)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
E) >120–160	978	0.0% (0/0)	0.0% (0/0)	0.1% (1/978)	8.3% (81/978)	58.4% (571/978)	26.8% (262/978)	5.9% (58/978)	0.5% (5/978)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
F) >160–200	662	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.3% (2/662)	9.1% (60/662)	52.6% (348/662)	35.3% (234/662)	2.7% (18/662)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
G) >200–250	515	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	6.2% (32/515)	56.3% (290/515)	33.8% (174/515)	3.3% (17/515)	0.4% (2/515)	0.0% (0/0)
H) >250–300	202	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	9.4% (19/202)	55.0% (111/202)	32.2% (65/202)	3.5% (7/202)	0.0% (0/0)
I) >300–350	90	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	20.0% (18/90)	54.4% (49/90)	23.3% (21/90)	2.2% (2/90)
J) >350–400	24	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	4.2% (1/24)	37.5% (9/24)	50.0% (12/24)	8.3% (2/24)
K) >400	1	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	100.0% (1/1)

Note: *The overall number of available paired SG-YSI points on FST Day 1 was from 88 subjects.*

Table B-16. Overall concurrence of YSI values and SG readings using SG ranges on FST Days 1, 3, and 7; Calibration 3 or 4 times a day, Abdomen.

Percent of matched pairs in each YSI glucose range for each SG range (mg/dL)												
SG ranges (mg/dL)	Number of paired SG-YSI	YSI Glucose Range (mg/dL)										
		<40	≥40–60	>60–80	>80–120	>120–160	>160–200	>200–250	>250–300	>300–350	>350–400	>400
A) <40	123	0.0% (0/0)	52.0% (64/123)	44.7% (55/123)	3.3% (4/123)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
B) ≥40–60	686	1.3% (9/686)	31.6% (217/686)	57.0% (391/686)	9.9% (68/686)	0.1% (1/686)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
C) >60–80	1303	0.2% (2/1303)	8.1% (106/1303)	63.4% (826/1303)	26.2% (342/1303)	1.9% (25/1303)	0.2% (2/1303)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
D) >80–120	2864	0.0% (0/0)	0.0% (1/2864)	6.5% (186/2864)	74.5% (2133/2864)	17.5% (502/2864)	1.3% (36/2864)	0.2% (6/2864)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
E) >120–160	2681	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	9.0% (241/2681)	69.9% (1874/2681)	19.1% (512/2681)	1.8% (49/2681)	0.2% (5/2681)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
F) >160–200	1820	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.1% (2/1820)	10.3% (188/1820)	63.6% (1157/1820)	24.9% (454/1820)	1.0% (19/1820)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
G) >200–250	1314	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.5% (7/1314)	8.5% (112/1314)	65.3% (858/1314)	24.6% (323/1314)	1.1% (14/1314)	0.0% (0/0)	0.0% (0/0)
H) >250–300	652	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.3% (2/652)	11.3% (74/652)	63.5% (414/652)	22.9% (149/652)	2.0% (13/652)	0.0% (0/0)
I) >300–350	279	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	17.9% (50/279)	59.5% (166/279)	21.1% (59/279)	1.4% (4/279)
J) >350–400	65	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	18.5% (12/65)	64.6% (42/65)	16.9% (11/65)
K) >400	9	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	11.1% (1/9)	77.8% (7/9)	11.1% (1/9)

Table B-17. Concurrence of YSI values and SG readings using SG ranges on FST Day 1; Calibration 3 or4 times a day, Abdomen.

Percent of matched pairs in each YSI glucose range for each SG range (mg/dL)												
		YSI Glucose Range (mg/dL)										
SG ranges (mg/dL)	Number of paired SG-YSI	<40	≥40–60	>60–80	>80–120	>120–160	>160–200	>200–250	>250–300	>300–350	>350–400	>400
A) <40	62	0.0% (0/0)	37.1% (23/62)	58.1% (36/62)	4.8% (3/62)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
B) ≥40–60	247	2.4% (6/247)	21.5% (53/247)	58.7% (145/247)	17.0% (42/247)	0.4% (1/247)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
C) >60–80	429	0.2% (1/429)	12.6% (54/429)	52.0% (223/429)	30.3% (130/429)	4.4% (19/429)	0.5% (2/429)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
D) >80–120	1014	0.0% (0/0)	0.1% (1/1014)	5.3% (54/1014)	70.7% (717/1014)	20.4% (207/1014)	3.1% (31/1014)	0.4% (4/1014)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
E) >120–160	973	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	9.1% (89/973)	61.6% (599/973)	24.8% (241/973)	4.0% (39/973)	0.5% (5/973)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
F) >160–200	633	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.3% (2/633)	10.7% (68/633)	56.7% (359/633)	30.3% (192/633)	1.9% (12/633)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
G) >200–250	497	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.2% (1/497)	7.8% (39/497)	64.6% (321/497)	26.4% (131/497)	1.0% (5/497)	0.0% (0/0)	0.0% (0/0)
H) >250–300	224	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	12.9% (29/224)	58.0% (130/224)	23.7% (53/224)	5.4% (12/224)	0.0% (0/0)
I) >300–350	97	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	19.6% (19/97)	59.8% (58/97)	18.6% (18/97)	2.1% (2/97)
J) >350–400	22	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	27.3% (6/22)	63.6% (14/22)	9.1% (2/22)
K) >400	1	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	100.0% (1/1)

Note: The overall number of available SG-YSI points on FST Day 1 was from 88 subjects.

Table B-18. Overall concurrence of YSI values and SG readings using SG ranges on FST Days 1, 3, and 7; Calibration every 12 hours, Arm.

Percent of matched pairs in each YSI glucose range for each SG range (mg/dL)												
		YSI Glucose Range (mg/dL)										
SG ranges (mg/dL)	Number of paired SG-YSI	<40	≥40–60	>60–80	>80–120	>120–160	>160–200	>200–250	>250–300	>300–350	>350–400	>400
A) <40	75	2.7% (2/75)	44.0% (33/75)	52.0% (39/75)	1.3% (1/75)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
B) ≥40–60	520	1.0% (5/520)	41.9% (218/520)	51.7% (269/520)	5.4% (28/520)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
C) >60–80	1238	0.2% (2/1238)	9.2% (114/1238)	70.3% (870/1238)	20.0% (247/1238)	0.4% (5/1238)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
D) >80–120	2722	0.0% (0/0)	0.1% (3/2722)	7.5% (203/2722)	74.0% (2014/2722)	17.7% (481/2722)	0.8% (21/2722)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
E) >120–160	2348	0.0% (0/0)	0.0% (0/0)	0.1% (3/2348)	9.2% (215/2348)	70.4% (1652/2348)	18.0% (423/2348)	2.3% (54/2348)	0.0% (1/2348)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
F) >160–200	1614	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.1% (2/1614)	9.4% (151/1614)	64.7% (1044/1614)	24.8% (400/1614)	0.9% (14/1614)	0.2% (3/1614)	0.0% (0/0)	0.0% (0/0)
G) >200–250	1212	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.6% (7/1212)	6.8% (83/1212)	63.9% (774/1212)	27.3% (331/1212)	1.4% (17/1212)	0.0% (0/0)	0.0% (0/0)
H) >250–300	556	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.2% (1/556)	9.4% (52/556)	65.1% (362/556)	23.9% (133/556)	1.4% (8/556)	0.0% (0/0)
I) >300–350	256	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	18.0% (46/256)	56.6% (145/256)	24.6% (63/256)	0.8% (2/256)
J) >350–400	60	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	3.3% (2/60)	16.7% (10/60)	66.7% (40/60)	13.3% (8/60)
K) >400	9	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	11.1% (1/9)	55.6% (5/9)	33.3% (3/9)

Table B-19. Concurrence of YSI values and SG readings using SG ranges on FST Day 1; Calibration every 12 hours, Arm.

Percent of matched pairs in each YSI glucose range for each SG range (mg/dL)												
SG ranges (mg/dL)	Number of paired SG-YSI	YSI Glucose Range (mg/dL)										
		<40	≥40–60	>60–80	>80–120	>120–160	>160–200	>200–250	>250–300	>300–350	>350–400	>400
A) <40	54	3.7% (2/54)	29.6% (16/54)	64.8% (35/54)	1.9% (1/54)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
B) ≥40–60	168	1.8% (3/168)	22.0% (37/168)	64.3% (108/168)	11.9% (20/168)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
C) >60–80	339	0.6% (2/339)	11.2% (38/339)	58.1% (197/339)	29.2% (99/339)	0.9% (3/339)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
D) >80–120	895	0.0% (0/0)	0.3% (3/895)	6.6% (59/895)	69.8% (625/895)	21.6% (193/895)	1.7% (15/895)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
E) >120–160	803	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	10.0% (80/803)	64.6% (519/803)	21.4% (172/803)	4.0% (32/803)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
F) >160–200	549	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.2% (1/549)	8.9% (49/549)	61.4% (337/549)	28.1% (154/549)	1.5% (8/549)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
G) >200–250	355	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.3% (1/355)	7.9% (28/355)	63.9% (227/355)	27.0% (96/355)	0.8% (3/355)	0.0% (0/0)	0.0% (0/0)
H) >250–300	175	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	10.9% (19/175)	65.7% (115/175)	21.1% (37/175)	2.3% (4/175)	0.0% (0/0)
I) >300–350	91	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	20.9% (19/91)	52.7% (48/91)	24.2% (22/91)	2.2% (2/91)
J) >350–400	15	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	13.3% (2/15)	33.3% (5/15)	53.3% (8/15)	0.0% (0/0)
K) >400	1	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	100.0% (1/1)	0.0% (0/0)	0.0% (0/0)

Note: The overall number of available paired SG-YSI points on FST Day 1 was from 82 subjects.

Table B-20. Overall concurrence of YSI values and SG readings using SG ranges on FST Days 1, 3, and 7; Calibration 3 or 4 times a day, Arm.

Percent of matched pairs in each YSI glucose range for each SG range (mg/dL)												
SG ranges (mg/dL)	Number of paired SG-YSI	YSI Glucose Range (mg/dL)										
		<40	≥40–60	>60–80	>80–120	>120–160	>160–200	>200–250	>250–300	>300–350	>350–400	>400
A) <40	73	2.7% (2/73)	45.2% (33/73)	50.7% (37/73)	1.4% (1/73)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
B) ≥40– 60	503	1.0% (5/503)	45.9% (231/503)	48.3% (243/503)	4.8% (24/503)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
C) >60– 80	1291	0.2% (2/1291)	8.9% (115/1291)	72.3% (933/1291)	18.4% (237/1291)	0.3% (4/1291)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
D) >80– 120	2756	0.0% (0/0)	0.1% (3/2756)	7.0% (194/2756)	75.9% (2092/2756)	16.5% (456/2756)	0.4% (11/2756)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
E) >120– 160	2442	0.0% (0/0)	0.0% (0/0)	0.1% (2/2442)	9.3% (228/2442)	71.4% (1743/2442)	18.0% (439/2442)	1.2% (30/2442)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
F) >160– 200	1588	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.1% (2/1588)	9.4% (150/1588)	66.3% (1053/1588)	23.5% (373/1588)	0.6% (9/1588)	0.1% (1/1588)	0.0% (0/0)	0.0% (0/0)
G) >200– 250	1246	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.5% (6/1246)	7.4% (92/1246)	65.7% (818/1246)	25.1% (313/1246)	1.4% (17/1246)	0.0% (0/0)	0.0% (0/0)
H) >250– 300	613	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.2% (1/613)	8.6% (53/613)	65.1% (399/613)	24.6% (151/613)	1.5% (9/613)	0.0% (0/0)
I) >300– 350	271	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	16.2% (44/271)	59.8% (162/271)	23.2% (63/271)	0.7% (2/271)
J) >350– 400	61	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	4.9% (3/61)	11.5% (7/61)	70.5% (43/61)	13.1% (8/61)
K) >400	8	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	62.5% (5/8)	37.5% (3/8)

Table B-21. Concurrence of YSI values and SG readings using SG ranges on FST) Day 1; Calibration 3 or4 times a day, Arm.

Percent of matched pairs in each YSI glucose range for each SG range (mg/dL)												
SG ranges (mg/dL)	Number of paired SG-YSI	YSI Glucose Range (mg/dL)										
		<40	≥40–60	>60–80	>80–120	>120–160	>160–200	>200–250	>250–300	>300–350	>350–400	>400
A) <40	54	3.7% (2/54)	29.6% (16/54)	64.8% (35/54)	1.9% (1/54)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
B) ≥40–60	162	1.9% (3/162)	25.3% (41/162)	61.7% (100/162)	11.1% (18/162)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
C) >60–80	346	0.6% (2/346)	11.6% (40/346)	61.3% (212/346)	25.7% (89/346)	0.9% (3/346)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
D) >80–120	899	0.0% (0/0)	0.3% (3/899)	6.3% (57/899)	74.0% (665/899)	18.2% (164/899)	1.1% (10/899)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
E) >120–160	878	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	10.0% (88/878)	67.0% (588/878)	21.0% (184/878)	2.1% (18/878)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
F) >160–200	571	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.2% (1/571)	9.3% (53/571)	62.3% (356/571)	27.3% (156/571)	0.9% (5/571)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
G) >200–250	427	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.2% (1/427)	8.2% (35/427)	62.5% (267/427)	27.6% (118/427)	1.4% (6/427)	0.0% (0/0)	0.0% (0/0)
H) >250–300	202	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	9.9% (20/202)	59.9% (121/202)	26.7% (54/202)	3.5% (7/202)	0.0% (0/0)
I) >300–350	93	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	16.1% (15/93)	59.1% (55/93)	22.6% (21/93)	2.2% (2/93)
J) >350–400	13	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	15.4% (2/13)	7.7% (1/13)	76.9% (10/13)	0.0% (0/0)
K) >400	0	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)

Note: The overall number of available paired SG-YSI points on FST Day 1 was from 83 subjects.

Percent agreement post calibration

The agreement of the SG values to paired YSI values was assessed for every 2-hour period post sensor calibration. For readings less than or equal to 80 mg/dL, the absolute difference in mg/dL between the SG and paired YSI values was calculated.

Tables 22 and 23 show the percent agreement rates post calibration for sensors inserted into the abdomen. Performance when sensors are inserted in the arm is at least comparable to results when sensors are inserted in the abdomen.

Table B-22. Agreement rates for every 2-hour period post calibration period; Calibration every 12 hours, Abdomen.

		Percent Agreement (%)				
Time after calibration	Number of paired SG-YSI	Percent of SG within 15/15% of YSI	Percent of SG within 20/20% of YSI	Percent of SG within 30/30% of YSI)	Percent of SG within 40/40% of YSI	Percent of SG greater than 40/40% of YSI
0–2 hours	2999	85	92.6	97.8	99.6	0.4
2–4 hours	2667	75.1	85.9	95.3	98.8	1.2
4–6 hours	2138	71.4	82	92.7	97.6	2.4
6–8 hours	1521	77.6	88.4	97	99.3	0.7
8–10 hours	1523	84.2	91.1	97.6	99.3	0.7
10–12 hours	1242	79.8	89.5	96.3	98.6	1.4

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

Note: SG Readings are within 40–400 mg/dL.

Table B-23. Agreement rates for every 2-hour period post calibration; Calibration 3 or 4 times a day, Abdomen.

		Percent Agreement (%)				
Time after calibration	Number of paired SG-YSI	Percent of SG within 15/15% of YSI	Percent of SG within 20/20% of YSI	Percent of SG within 30/30% of YSI	Percent of SG within 40/40% of YSI	Percent of SG greater than 40/40% of YSI
0–2 hours	4585	87	93.5	98.1	99.7	0.3
2–4 hours	3949	80.7	89.9	96.7	99	1
4–6 hours	2856	78.7	87.6	95.5	98.5	1.5
6–8 hours	227	74.9	86.3	96.9	99.6	0.4
8–10 hours	35	82.9	85.7	91.4	94.3	5.7
10–12 hours	12	91.7	91.7	91.7	100	0

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

Note: SG Readings are within 40–400 mg/dL

Trend accuracy

Tables 24 and 25 show, for each SG rate-of-change range (indicated on display by number of arrows), percentage of SG-YSI paired values that fell into different YSI rate-of-change ranges. The tables show the trend accuracy for sensors inserted into the abdomen. Performance when sensors are inserted in the arm is at least comparable to results when sensors are inserted into the abdomen.

Table B-24. Trend accuracy; Calibration every 12 hours, Abdomen.

	Percent of Matched Pairs-in Each YSI Rate-of-Change Range for Each SG Rate-of-Change Range						
	YSI Rate-of-Change Ranges (mg/dL/min)						
SG Rate- of-Change Range (mg/dL/min)	Number of Paired SG-YSI	<-2	[-2, -1]	[-1, 0]	[0, 1]	[1, 2]	>2
A) <-2	162	38.3% (62/162)	40.1% (65/162)	20.4% (33/162)	0.6% (1/162)	0.6% (1/162)	0.0% (0/162)
B) [-2, -1]	1001	4.8% (48/1001)	39.9% (399/1001)	51.3% (514/1001)	3.7% (37/1001)	0.3% (3/1001)	0.0% (0/1001)
C) [-1, 0]	5960	0.5% (30/5960)	3.8% (228/5960)	77.6% (4627/5960)	17.1% (1020/5960)	0.8% (49/5960)	0.1% (6/5960)
D) [0, 1]	3517	0.2% (7/3517)	0.5% (18/3517)	25.7% (903/3517)	63.4% (2231/3517)	9.3% (326/3517)	0.9% (32/3517)
E) [1, 2]	1059	0.1% (1/1059)	0.4% (4/1059)	4.5% (48/1059)	37.9% (401/1059)	48.6% (515/1059)	8.5% (90/1059)
F) >2	391	0.0% (0/391)	0.0% (0/391)	2.8% (11/391)	7.4% (29/391)	40.9% (160/391)	48.8% (191/391)

Table B- 25. Trend accuracy; Calibration 3 or 4 times a day, Abdomen.

	Percent of Matched Pairs-in Each YSI Rate-of-Change Range for Each SG Rate-of-Change Range						
	YSI Rate-of-Change Ranges (mg/dL/min)						
SG Rate- of-Change Range (mg/dL/min)	Number of Paired SG-YSI	<-2	[-2, -1]	[-1, 0]	[0, 1]	[1, 2]	>2
A) <-2	159	39.0% (62/159)	39.6% (63/159)	19.5% (31/159)	0.6% (1/159)	1.3% (2/159)	0.0% (0/159)
B) [-2, -1]	967	5.1% (49/967)	38.7% (374/967)	51.9% (502/967)	4.0% (39/967)	0.3% (3/967)	0.0% (0/967)
C) [-1, 0]	5753	0.5% (28/5753)	4.0% (228/5753)	77.5% (4456/5753)	17.2% (990/5753)	0.8% (46/5753)	0.1% (5/5753)
D) [0, 1]	3387	0.2% (8/3387)	0.5% (18/3387)	26.5% (898/3387)	62.5% (2118/3387)	9.3% (316/3387)	0.9% (29/3387)
E) [1, 2]	1024	0.0% (0/1024)	0.2% (2/1024)	5.0% (51/1024)	38.8% (397/1024)	47.5% (486/1024)	8.6% (88/1024)
F) >2	374	0.0% (0/374)	0.0% (0/374)	2.4% (9/374)	8.0% (30/374)	42.8% (160/374)	46.8% (175/374)

Precision

Precision of the System was evaluated by comparing the results from two separate sensors worn in the abdomen on the same subject at the same time. A total of 83 subjects provided 30,350 paired SG-YSI measurements, with a mean Percent Absolute Relative Difference (PARD) of 9.07% with a coefficient of variation (%CV) of 6.5%.

Though precision in the arm has not been specifically assessed, arm vs. arm and arm vs. abdomen is likely comparable to the abdomen precision based on internal evaluation by Medtronic.

Sensor life

After the first successful calibration, 72.3% of sensors worn operated more than six days and up to the full seven days of wear (144 to 168 hours). The mean functional sensor life for sensors worn in the abdomen insertion site over the course of the study was 144.2 hours, with a median functional life of 167.6 hours.

The mean functional sensor life for sensors worn in the arm insertion site over the course of the study was 146.1 hours, with a median functional life of 167.9 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 through seven days of use.

C. Alert performance for users 14 years and older

CGM enables your device to display sensor glucose readings, glucose trend arrows, glucose trend graphs, and sensor glucose alerts (for example, High and Low Limit Threshold alerts, High and Low Predictive alerts, and Rise and Fall rate-of-change alerts).
The high and low limit alerts (Threshold alerts) let the user know when the sensor glucose is at or above the high limit or at or below the low limit. Using only a high or low limit alert may reduce the number of false alerts, but does not provide a warning before reaching a high or low limit.

Predictive alerts notify users that their sensor glucose level may soon reach a high or low limit setting. Users may select how early they would like to be notified before their sensor glucose level reaches a high limit setting. The earliest warning is 30 minutes before reaching a high, but users can reduce the amount of warning down to 5 minutes. Users will receive a warning approximately 30 minutes prior to when their sensor glucose level is predicted to reach their low limit setting. In general, the earlier the warning, the more time a user will have to react to a potential high or low, but this also increases the potential for false alerts.

A predictive alert is simply an estimation of a future sensor glucose level compared to the high or low limit setting. If the predicted sensor glucose value is above the high limit or below the low limit, then a predictive alert is sounded even though the current sensor glucose level has not crossed the high or low limit. The predicted sensor glucose level is calculated using the current sensor glucose level, the derivative of previous sensor glucose readings (the trend or slope of the sensor glucose readings) and the amount of early warning duration the user selects.

The device will always alert the user when the CGM reads that the user is below 50 mg/dL, regardless of the high/low threshold and/or predictive alerts that the user sets.

Glucose TRUE Alert Rate

The glucose true alert rate is the rate at which the blood glucose confirmed that the CGM alert was triggered correctly. For example:

1. True Threshold Hypoglycemic alert rate alerted when the CGM read that the user was below the low threshold and the user's blood glucose was actually below that low threshold.
2. True Threshold Hyperglycemic alert rate alerted when the CGM read that the user was above the high threshold and the user's blood glucose was actually above that high threshold.
3. True Predictive Hypoglycemic alert rate alerted when the CGM predicted that the user would reach below the low threshold and the user's blood glucose was actually below that low threshold within 15 or 30 minutes.

True Predictive Hyperglycemic alert rate alerted when the CGM predicted that the user would reach above the high threshold and the user's blood glucose was actually above that high threshold within 15 or 30 minutes.

The true alert rate is important because it is necessary that users be notified when their blood glucose is low (or high) so that they can correct the low (or high) blood glucose. A high true alert rate indicates that when the CGM says that their glucose values are, or will reach a specified threshold, the user's blood glucose is likely to be at or approaching that threshold.

For example, per the following table, the low glucose alerts would have correctly indicated that the user was below (i.e. threshold only), or predicted to reach below the threshold (i.e. predictive only) or both (predictive and threshold) 66.9%, 52.7%, or 58.3% of the time within 30 minutes (or 66.9%, 47.7% or 55.2% of the time within 15 minutes) when the user had blood glucose values lower than 70 mg/dL for a sensor inserted in the abdomen.

Table C-1. Glucose TRUE Alert Performance using Calibration every 12 hours

		Glucose TRUE Alert Rate					
mg/dL	Insertion Site	Threshold Only		Predictive Only		Threshold & Predictive	
		30 min	15 min	30 min	15 min	30 min	15 min
50	Abdomen	25.0%	25.0%	15.2%	12.3%	18.2%	16.2%
	Arm	36.8%	36.8%	21.9%	16.7%	26.1%	22.4%
60	Abdomen	53.5%	51.9%	40.7%	37.1%	46.2%	43.4%
	Arm	69.0%	67.8%	47.5%	45.6%	55.1%	53.5%
70	Abdomen	66.9%	66.9%	52.7%	47.7%	58.3%	55.2%
	Arm	77.4%	75.3%	57.4%	54.5%	65.6%	63.0%
80	Abdomen	69.3%	69.3%	57.8%	51.1%	62.2%	58.2%
	Arm	77.5%	76.4%	59.9%	53.0%	66.5%	61.9%
90	Abdomen	75.1%	74.4%	64.0%	58.5%	67.9%	64.3%
	Arm	74.9%	74.9%	69.0%	63.2%	71.3%	68.0%
180	Abdomen	93.7%	92.8%	70.5%	66.9%	78.0%	75.4%
	Arm	92.9%	92.9%	68.0%	63.2%	76.5%	73.7%
220	Abdomen	91.9%	91.9%	68.9%	66.3%	76.6%	74.8%
	Arm	92.2%	92.2%	65.7%	62.2%	74.5%	72.2%
250	Abdomen	90.2%	90.2%	64.0%	60.1%	72.5%	69.8%
	Arm	91.4%	91.4%	62.0%	59.8%	71.1%	69.6%
300	Abdomen	81.3%	81.3%	57.8%	54.0%	65.4%	62.7%
	Arm	81.9%	80.6%	51.7%	49.7%	61.2%	59.3%

Glucose FALSE Alert Rate

The glucose false alert rate is the rate at which the blood glucose did not confirm that the CGM alert was triggered correctly. For example:

1. False Threshold Hypoglycemic alert rate the alarm alerted when the CGM read that the user was below the low threshold but the users blood glucose was actually above that low threshold ; or
2. False Threshold Hyperglycemic alert rate the alarm alerted when the CGM read that the user was above the high threshold but the user's blood glucose was actually below that high threshold; or
3. False Predictive Hypoglycemic alert rate the alarm alerted when the CGM predicted that the user would be below the low threshold but the user's blood glucose was actually above that low threshold within 15 or 30 minutes
4. False Predictive Hyperglycemic alert rate the alarm alerted when the CGM predicted that the user would be above the high threshold but the user's blood glucose was actually below the high threshold within 15 or 30 minutes.

The false alert rate is important because it is necessary that users be correctly notified when their blood glucose is low (or high) so that they can correct the low (or high) blood glucose. A low false alert rate indicates that when the CGM says that their glucose values are, or will reach a specified threshold, the user's blood glucose is likely to be at or approaching that threshold.
For example, per the following table, the high glucose threshold alerts would have incorrectly indicated that the user was above (i.e. threshold only), or predicted to reach above the threshold (i.e. predictive only), or both (threshold and predictive) 6.30%, 29.5% or 22% of the time within 30 minutes (or 7.2%, 33.1%, or 24.6% of the time within 15 minutes) when the user had blood glucose less than 180 mg/dL for a sensor inserted in the abdomen.

Table C- 2. Glucose FALSE Alert Performance using Calibration every 12 hours							
		Glucose FALSE Alert Rate					
mg/dL	Insertion Site	Threshold Only		Predictive Only		Threshold & Predictive	
		30 min	15 min	30 min	15 min	30 min	15 min
50	Abdomen	75.0%	75.0%	84.8%	87.7%	81.8%	83.8%
	Arm	63.2%	63.2%	78.1%	83.3%	73.9%	77.6%
60	Abdomen	46.5%	48.1%	59.3%	62.9%	53.8%	56.6%
	Arm	31.0%	32.2%	52.5%	54.4%	44.9%	46.5%
70	Abdomen	33.1%	33.1%	47.3%	52.3%	41.7%	44.8%
	Arm	22.6%	24.7%	42.6%	45.5%	34.4%	37.0%
80	Abdomen	30.7%	30.7%	42.2%	48.9%	37.8%	41.8%
	Arm	22.5%	23.6%	40.1%	47.0%	33.5%	38.1%
90	Abdomen	24.9%	25.6%	36.0%	41.5%	32.1%	35.7%
	Arm	25.1%	25.1%	31.0%	36.8%	28.7%	32.0%
180	Abdomen	6.30%	7.20%	29.5%	33.1%	22.0%	24.6%
	Arm	7.10%	7.10%	32.0%	36.8%	23.5%	26.3%
220	Abdomen	8.10%	8.10%	31.1%	33.7%	23.4%	25.2%
	Arm	7.80%	7.80%	34.3%	37.8%	25.5%	27.8%
250	Abdomen	9.80%	9.80%	36.0%	39.9%	27.5%	30.2%
	Arm	8.60%	8.60%	38.0%	40.2%	28.9%	30.4%
300	Abdomen	18.8%	18.8%	42.2%	46.0%	34.6%	37.3%
	Arm	18.1%	19.4%	48.3%	50.3%	38.8%	40.7%

Glucose Correct Detection Rate

Glucose Correct Detection Rate is the rate that the device alerted when it should have alerted. For example, the blood glucose was below the hypoglycemic threshold, or above the hyperglycemic threshold, and the device sounded an alert.

Glucose detection rates are important because it is necessary that users be notified when their blood glucose is low (or high) so that they can correct the low (or high) blood glucose. A high glucose correct detection rate indicates that users can have confidence that they will be notified by the device if their blood glucose is low or high.

For example, per the following table, the threshold alert, the predictive alert, or both (threshold and predictive) notified the user 64%, 76% or 76% of the time within 30 minutes (or 64%, 68%, or 68% within 15 minutes) when the user had blood glucose less than 50 mg/dL for a sensor inserted in the abdomen.

Table C-3. Glucose Correct Detection Alert Performance using Calibration every 12 hours

		Glucose Correct Detection Rate					
mg/dL	Insertion Site	Threshold Only		Predictive Only		Threshold & Predictive	
		30 min	15 min	30 min	15 min	30 min	15 min
50	Abdomen	64.0%	64.0%	76.0%	68.0%	76.0%	68.0%
	Arm	66.7%	66.7%	95.2%	71.4%	95.2%	76.2%
60	Abdomen	83.3%	82.1%	94.0%	88.1%	94.0%	89.3%
	Arm	86.3%	83.6%	98.6%	94.5%	98.6%	97.3%
70	Abdomen	90.5%	90.5%	94.2%	89.8%	94.2%	92.0%
	Arm	90.2%	88.6%	92.7%	90.2%	93.5%	91.9%
80	Abdomen	87.2%	87.2%	93.6%	87.2%	93.6%	89.9%
	Arm	89.0%	88.4%	94.8%	86.6%	95.9%	92.4%
90	Abdomen	91.1%	88.7%	94.6%	89.5%	95.7%	92.2%
	Arm	91.7%	90.4%	96.9%	91.7%	97.8%	95.6%
180	Abdomen	93.1%	91.4%	96.6%	93.4%	96.9%	95.4%
	Arm	93.2%	92.2%	98.1%	94.2%	98.7%	96.4%
220	Abdomen	90.1%	89.2%	94.8%	93.5%	95.3%	94.4%
	Arm	90.1%	89.2%	96.1%	93.6%	96.1%	95.6%
250	Abdomen	81.5%	80.9%	96.5%	91.3%	96.5%	93.6%
	Arm	80.9%	79.6%	96.7%	90.8%	96.7%	91.4%
300	Abdomen	75.3%	75.3%	95.3%	92.9%	95.3%	94.1%
	Arm	74.4%	71.8%	93.6%	89.7%	93.6%	89.7%

Glucose Missed Detection Rate

The Missed Detection Rate is the rate that the device did not alert when it should have. For example, the blood glucose was below the hypoglycemic threshold, or above the hyperglycemic threshold, and the device did not sound a threshold or predictive alert.

Missed detection rates are important because it is necessary that users be notified when their blood glucose is low (or high), so that they can correct the low (or high) blood glucose. A low missed detection rate indicates that users can have confidence that they will be notified by the device if their blood glucose is low or high.

For example, per the following table, the threshold alert, predictive alert, or both alerts (threshold and predictive) did not sound 36%, 24% or 24% of the time within 30 minutes (or 36%, 32% or 32% within 15 minutes) when the user had blood glucose less than 50 mg/dL for a sensor inserted in the abdomen.

Table C-4. Glucose Missed Detection Alert Performance using Calibration every 12 hours

		Glucose Missed Detection Rate					
mg/dL	Insertion Site	Threshold Only		Predictive Only		Threshold & Predictive	
		30 min	15 min	30 min	15 min	30 min	15 min
50	Abdomen	36.0%	36.0%	24.0%	32.0%	24.0%	32.0%
	Arm	33.3%	33.3%	4.8%	28.6%	4.8%	23.8%
60	Abdomen	16.7%	17.9%	6.0%	11.9%	6.0%	10.7%
	Arm	13.7%	16.4%	1.4%	5.5%	1.4%	2.7%
70	Abdomen	9.5%	9.5%	5.8%	10.2%	5.8%	8.0%
	Arm	9.8%	11.4%	7.3%	9.8%	6.5%	8.1%
80	Abdomen	12.8%	12.8%	6.4%	12.8%	6.4%	10.1%
	Arm	11.0%	11.6%	5.2%	13.4%	4.1%	7.6%
90	Abdomen	8.9%	11.3%	5.4%	10.5%	4.3%	7.8%
	Arm	8.3%	9.6%	3.1%	8.3%	2.2%	4.4%
180	Abdomen	6.9%	8.6%	3.4%	6.6%	3.1%	4.6%
	Arm	6.8%	7.8%	1.9%	5.8%	1.3%	3.6%
220	Abdomen	9.9%	10.8%	5.2%	6.5%	4.7%	5.6%
	Arm	9.9%	10.8%	3.9%	6.4%	3.9%	4.4%
250	Abdomen	18.5%	19.1%	3.5%	8.7%	3.5%	6.4%
	Arm	19.1%	20.4%	3.3%	9.2%	3.3%	8.6%
300	Abdomen	24.7%	24.7%	4.7%	7.1%	4.7%	5.9%
	Arm	25.6%	28.2%	6.4%	10.3%	6.4%	10.3%

II. Performance data for users ages 7 through 13

D. Device Performance data for users ages 7 through 13

The SmartGuard technology has two levels that include the 1) Suspend on low and Suspend before low that automatically suspends insulin based on CGM and 2) Auto mode that automatically calculates insulin dosing using CGM. A study was performed to evaluate for safety in a multi-center, single arm, home and hotel clinical investigation. Study subjects included persons aged 7 to13 years of age diagnosed with type 1 diabetes mellitus and who were on pump therapy for more than 6 months prior to screening. All study subjects had an HbA1C less than 10.0% at the time of screening.

The first level of SmartGuard technology included evaluation of the 'Suspend before low' feature. A total of 105 subjects were asked to exercise in an in-clinic setting, in order to lower blood sugars sufficiently to trigger Suspend before Low. Activation was followed by an observation period to ensure subject safety. The target for Suspend before Low was set to 65 mg/dL. Subjects underwent frequent sample testing (FST) for a maximum of 12 hours, which included the exercise period, insulin suspension and approximately 4 hours after resumption of insulin delivery (which may also have included insulin re-suspension).

Data from this in-clinic study demonstrated that the Suspend before low feature is safe to use. Study success criteria, as defined in the protocol, were met (i.e. there were no device related serious adverse events, no diabetic ketoacidosis events related to the Suspend before low feature, and no unanticipated adverse device effects).

The second level of SmartGuard was the evaluation of Auto Mode, which was accomplished during the 3-month study phase. A total of 105 subjects first used the MiniMed 670G System in Manual Mode (approximately 2 weeks during the run-in phase and 1 additional week at the start of the study phase), before transitioning to Auto Mode at specific points in time during the study phase. The timing of the transition to Auto Mode was based on the scheduling of a 6 day/5 night Hotel/House stay during the study phase. At the hotel or house, subjects underwent daytime and nighttime frequent sample testing for a total of approximately 24 hours. Subjects were allowed to eat as they normally would, and participated in a daily exercise/activity regimen for a minimum of 4 hours per day, spread throughout the day. All subjects participated in a hotel/house stay and finished the study. During this study, the 670G System was used for over 15,353 patient days (including the 2-week Run-In phase + the 3-month study phase) without any reported device- related serious adverse events, such as severe hypoglycemia or diabetic ketoacidosis. Compared to Manual Mode used during the Run-In phase, use of Auto Mode was associated with reduction in mean sensor glucose values, an increase within the range of 71 to 180 mg/dL and a lower percentage of glucose values in the hypergly cemic and hypoglycemic ranges. There was a significant reduction in mean HbA1c from7.9±0.8 (median 7.9) at the start of study to 7.5±0.6

(median 7.5) at the end of study. There was a small change in mean total daily dose of insulin/kg (0.8±0.2 baseline to 0.9±0.2 end of study) and modest increase in weight. Weight gain would also be expected for pediatric patients 7-13 years of age as part of the normal growth process.

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

Of the 203 adverse events reported through the end of the Study period, 39% (N=80) were classified as device related. Of the 80 device-related adverse events, 65 were glycemic events (hyperglycemia, severe hyperglycemia, and severe hyperglycemia with ketosis) and 14 were related to skin issues (cellulitis, skin infection at the infusion set site, infection at the sensor insertion site, pump site infection on lower abdomen, eczema, and skin irritation). Five adverse events were classified as procedure related (these included neurocardiogenic syncope, headache, and angioedema) and 2 of the adverse events (hyperglycemia and skin irritation) were classified as both device and procedure related.

There were 104 reports of severe hyperglycemia and there was no diabetic ketoacidosis while on the MiniMed 670G System during the study. The majority of these severe hyperglycemic events (77/104) were mild in intensity. Ketone levels were available for 102 of the 104 severe hyperglycemia episodes and the majority of ketone levels (83/104) were low (0.6 – 1.5 mmol/L).

One severe hyperglycemic event was associated with an emergency room visit, however, the ER visit was primarily due to concurrent acute gastroenteritis.

Of the 62 device related episodes of severe hyperglycemia, 51 were believed to be due to infusion set issues such as occlusion, bent cannula or cannula pull out. These issues are typically seen in relatively high rates in the pediatric population (causes provided in Table 1 and Table 2). Unlike insulin pump therapy which may or may not have alerts associated with infusion set failure, the 670G System has fixed alarms (high alerts) that serve as an additional mitigation for subjects.

Table 1. Run in Period Severe Hyperglycemia:

Cause	Total
Infusion set change	9
Occlusion alarm	3
Infusion set fell out	2
Bent /Kinked Cannula	1
Total	15

Table 2. Study Period Severe Hyperglycemia

Cause	Total
Infusion set change	28
Occlusion alarm	12
Infusion set fell out	7
Bent /Kinked Cannula	5
Infusion set change/safe basal	3
Safe basal	2
Suspend before low suspension	1
Automatic & manual suspensions	1
Unclipped infusion set	1
Internal Battery Connector Resistance	1
Manual suspension and safe basal	1
Total	62

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

Table D-1: Time Spent in Specific Glucose Ranges During the Run-In and Study Phases by All Subjects

Glucose Range	Run-In Phase Time in Glucose Range (min) Mean±SD	Study Phase Time in Glucose Range (min) Mean±SD
≤ 50	12.2±16.9	7.8±7.3
≤ 60	32.3±32.7	20.3±14.2
≤ 70	68.3±55.4	43.1±23.6
70 – 180	808.6±163.5	936.2±110.4
>180	563.1±184.3	460.7±110.5
>250	191.0±111.5	148.4±74.1
> 300	68.1±54.8	53.7±39.4
> 350	23.0±24.9	17.4±17.1

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

Table D-2: Number of Subjects with Change in HbA1C at Different Baselines

HbA1C Change Range	Number of Subjects (% of Subjects) with Change in A1C				
Baseline A1C (%)	**Decrease > 1%**	**Decrease 0 to 1%**	**No Chang**	**Increase 0 to1%**	**Increase > 1%**
5% ≤ A1C < 6%	0(0.0%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)
6% ≤ A1C < 7%	0(0.0%)	1(1.0%)	0(0.0%)	9(8.6%)	0(0.0%)
7% ≤ A1C < 8%	3(2.9%)	22(21.0%)	6(5.7%)	16(15.2%)	0(0.0%)
8% ≤ A1C < 9%	9(8.6%)	21(20.0%)	3(2.9%)	4(3.8%)	0(0.0%)
9% ≤ A1C < 10%	4(3.8%)	6(5.7%)	0(0.0%)	0(0.0%)	0(0.0%)
Overall	16(15.2%)	50(47.6%)	9(8.6%)	30(28.6%)	0(0.0%)

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

Table D-3: Number of Subjects that Spent a Certain Time Range in Each Glucose Range During the Study Phase

Time Range	Number of Subjects (% of Subjects) in the Glucose Range (mg/dL) Indicated					
	≤ 50 mg/dL	**≤ 60 mg/dL**	**≤ 70 mg/dL**	**70 to 180 mg/dL**	**> 180 mg/dL**	**> 250 mg/dL**
0 to 15 mins	93(88.6%)	41(39.0%)	13(12.4%)	0(0.0%)	0(0.0%)	1(1.0%)
15 to 30 mins	10(9.5%)	46(43.8%)	23(21.9%)	0(0.0%)	0(0.0%)	1(1.0%)
30 to 45 mins	2(1.9%)	12(11.4%)	24(22.9%)	0(0.0%)	0(0.0%)	4(3.8%)
45 mins to 1 hr	0(0.0%)	3(2.9%)	23(21.9%)	0(0.0%)	0(0.0%)	2(1.9%)
1-4 hr	0(0.0%)	3(2.9%)	22(21.0%)	0(0.0%)	2(1.9%)	83(79.0%)
4-8 hr	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	54(51.4%)	14(13.3%)
8-12 hr	0(0.0%)	0(0.0%)	0(0.0%)	5(4.8%)	49(46.7%)	0(0.0%)
12-16 hr	0(0.0%)	0(0.0%)	0(0.0%)	54(51.4%)	0(0.0%)	0(0.0%)
16-20 hr	0(0.0%)	0(0.0%)	0(0.0%)	45(42.9%)	0(0.0%)	0(0.0%)
20-24 hr	0(0.0%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)

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

Table D-4: Time Spent in Auto Mode at Different Glucose Ranges during the Study Phase

Glucose Range (mg/dL)	Study Phase Time in Glucose Range (min) Mean±SD
≤ 50	5.0±4.0
≤ 60	14.0±9.0
≤ 70	31.2±16.8
70 – 180	797.0±142.2
>180	321.9±59.2
>250	84.2±32.4
All	1150.1±132.9

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

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

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

E. Guardian™ Sensor (3) Performance in 7 to 13 year old

CGM performance

The use of the Guardian Sensor (3) with the Guardian Link (3) transmitter enables CGM (Continuous Glucose Monitoring) technology. The transmitter transmits sensor glucose values calculated by the real-time algorithm to a primary display device, allowing you to monitor your sensor glucose values.

Clinical study description

The performance of the Guardian Sensor (3) was evaluated in a clinical study[1]. This in-patient (in-clinic) and outpatient (at home) study included subjects 7 to 13 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 Guardian™ Sensor (3) sensors in the abdomen and/or buttock.

1. one Guardian Sensor (3) connected to the Guardian Connect Transmitter, which transmitted to the Guardian Connect app, a standalone CGM display device
2. one Guardian Sensor (3) connected to the Guardian Link (3) transmitter, which served as a glucose sensor recorder (GSR, transmitter/recorder for sensor integrated pump systems).

The sensor glucose data collected by the blinded GSRs were retrospectively processed through the real-time CGM algorithm. This is the same algorithm used in the Guardian™ Connect and pump CGM systems. Thus all data is representative of real-time sensor usage.

The CONTOUR® NEXT LINK 2.4 Wireless Meter was the study meter used for all calibrations in this study, and was the only meter evaluated with the Guardian Sensor (3) CGM systems. The sensor has not been tested with other meters. Therefore, the performance with other blood glucose meters may differ from the performance with the CONTOUR NEXT LINK 2.4 Wireless Meter described below.

Frequent Sample Testing (FST) was performed on day 1, 3, or 7, for 6 hours each, over the life of the sensor. Reference blood (plasma) glucose values were obtained with a Yellow Springs Instrument (YSI®) Glucose Analyzer every 5 to 15 minutes. During the FSTs, the subjects were instructed to calibrate the sensors once every 12 hours, or as requested by the display device. During home use (outside the clinic), subjects were instructed to calibrate both sensors three to four times spread throughout the day.

The overall number of subjects that participated in FST procedures on day 1, 3, or 7 were 21, 13, and 10, respectively.

During the study, the meter was used for confirmation of alarms, treatment decisions and sensor calibrations.

1. Medtronic Inc., A Performance Evaluation of the Enlite™ and Enlite™ 3 Glucose Sensor to Support Use in Children; CEP249 Data From Subjects 7-13 Years of Age 10703807DOC. November 2017.

Results

Sensor accuracy

The following information highlights the Guardian Sensor (3) performance from 50 subjects (7to 13 years old) wearing the Guardian Link (3) Transmitter that served as a glucose sensor recorder (GSR, transmitter/recorder for sensor-integrated pump systems and the Guardian Connect Transnmitter, which transmitted to the Guardian Connect app, a standalone CGM display device) during FST.

Mean absolute relative difference, by number of daily calibrations

Table 1 shows the sensor accuracy measured by the mean absolute relative difference (MARD). MARD represents the average relative difference (regardless if positive or negative) between the sensor glucose (SG) values and the paired blood glucose values measured by YSI.

Table 1: SG MARD Versus YSI (within YSI glucose ranges)

YSI Glucose Ranges (mg/dL)	Abdomen Insertion Site				Buttock Insertion Site			
	Calibration every 12 hours		Calibration 3 or 4 times a day		Calibration every 12 hours		Calibration 3 or 4 times a day	
	Number of Paired SG-YSI	Mean Absolute Relative Difference (%)	Number of Paired SG-YSI	Mean Absolute Relative Difference (%)	Number of Paired SG-YSI	Mean Absolute Relative Difference (%)	Number of Paired SG-YSI	Mean Absolute Relative Difference (%)
Overall	733	10.46	710	9.84	710	9.14	686	8.79
40-60*	4	19.16	2	31.9	7	5.43	7	3.61
61-80*	20	10.59	18	8.54	34	10.85	28	7.86
81-180	378	11.59	367	11.04	393	9.63	374	8.99
181-300	290	8.76	282	8.4	255	7.92	253	8.56
301-350	32	7.11	32	5.63	15	4.64	18	7.67
351-400	9	8.59	9	5.57	6	5.05	6	3.01

*For YSI reference range ≤ 80 mg/dL, the differences in mg/dL are included instead of percent difference (%).
Note: SG Readings are within 40-400 mg/dL

Percent agreement, by number of daily calibrations

In Tables 2 through 9, the agreement of the SG values to paired YSI values was assessed by calculating the percentage of YSI values that were within 15%, 20%, 30%, 40% and greater than 40% of the paired SG values. For readings less than or equal to 80 mg/dL, the absolute difference in mg/dL between the SG and paired YSI values was calculated.

Results are shown for defined SG ranges when calibrating every 12 hours and calibrating three or four times a day for sensors.

Table 2: Agreement (%) of SG-YSI paired points within YSI glucose ranges on Frequent Sample Testing (FST) Days 1, 3, and 7; Calibration every 12 hours, Abdomen (Table 22 in SSED v4)

YSI Glucose Ranges (mg/dL)	Number of Paired SG-YSI	Percent of SG Within 15/15% of YSI	Percent of SG Within 20/20% of YSI	Percent of SG Within 30/30% of YSI	Percent of SG Within 40/40% of YSI	Percent of SG Within >40/40% of YSI
Overall	733	78.9	87.7	95.9	98.9	1.1
≥40-60*	4	50	50	75	100	0
>60-80*	20	70	80	90	95	5
>80-180	378	74.1	83.1	92.9	98.1	1.9
>180-300	290	83.1	93.1	100	100	0
>300-350	32	100	100	100	100	0
>350-400	9	100	100	100	100	0

**For glucose ranges ≤ 80 mg/dL, agreement was based on 15/20/30/40 mg/dL.*
Note: Sensor glucose readings are within 40-400 mg/dL

Table 3: Agreement (%) of SG-YSI paired points within YSI glucose ranges on Frequent Sample Testing (FST) Day 1; Calibration every 12 hours, Abdomen (Table 23 in SSED v4)

YSI Glucose Ranges (mg/dL)	Number of Paired SG-YSI	Percent of SG Within 15/15% of YSI	Percent of SG Within 20/20% of YSI	Percent of SG Within 30/30% of YSI	Percent of SG Within 40/40% of YSI	Percent of SG Within >40/40% of YSI
Overall	403	81.9	90.6	96.5	99	1
≥40-60*	2	100	100	100	100	0
>60-80*	11	63.6	72.7	90.9	100	0
>80-180	196	75.5	84.2	93.4	98	2
>180-300	160	86.9	97.5	100	100	0
>300-350	27	100	100	100	100	0
>350-400	7	100	100	100	100	0

**For glucose ranges ≤ 80 mg/dL, agreement was based on 15/20/30/40 mg/dL. Note: The overall number of available paired SG-YSI points on FST Day 1 was from 16 subjects. Sensor glucose readings are within 40-400 mg/dL*

Table 4: Agreement (%) of SG-YSI paired points within YSI glucose ranges on Frequent Sample Testing (FST) Days 1, 3, and 7; Calibration 3 or 4 times a day, Abdomen (Table 26 in SSED v4)

YSI Glucose Ranges (mg/dL)	Number of Paired SG-YSI	Percent of SG Within 15/15% of YSI	Percent of SG Within 20/20% of YSI	Percent of SG Within 30/30% of YSI	Percent of SG Within 40/40% of YSI	Percent of SG Within >40/40% of YSI
Overall	710	81.7	90	97.2	99.4	0.6
≥40-60*	2	0	0	50	100	0
>60-80*	18	83.3	88.9	94.4	94.4	5.6
>80-180	367	74.9	84.5	95.1	99.2	0.8
>180-300	282	88.3	96.5	100	100	0
>300-350	32	100	100	100	100	0
>350-400	9	100	100	100	100	0

**For glucose ranges ≤ 80 mg/dL, agreement was based on 15/20/30/40 mg/dL.*
Note: Sensor glucose readings are within 40-400 mg/dL

Table 5: Agreement (%) of SG-YSI paired points within YSI glucose ranges on Frequent Sample Testing Day 1; Calibration 3 or 4 times a day, Abdomen (Table 27 in SSED v4)

YSI Glucose Ranges (mg/dL)	Number of Paired SG-YSI	Percent of SG Within 15/15% of YSI	Percent of SG Within 20/20% of YSI	Percent of SG Within 30/30% of YSI	Percent of SG Within 40/40% of YSI	Percent of SG Within >40/40% of YSI
Overall	372	83.9	92.2	97.3	99.5	0.5
>60-80*	9	77.8	88.9	100	100	0
>80-180	182	76.9	86.3	94.5	98.9	1.1
>180-300	147	89.1	98	100	100	0
>300-350	27	100	100	100	100	0
>350-400	7	100	100	100	100	0

**For glucose ranges ≤ 80 mg/dL, agreement was based on 15/20/30/40 mg/dL. Note: The overall number of available paired SG-YSI points on FST Day 1 was from 15 subjects. Sensor glucose readings are within 40-400 mg/dL*

Table 6: Agreement (%) of SG-YSI paired points within YSI glucose ranges on Frequent Sample Testing (FST) Days 1, 3, and 7; Calibration every 12 hours, Buttock (Table 60 in SSED v4)

YSI Glucose Ranges (mg/dL)	Number of Paired SG-YSI	Percent of SG Within 15/15% of YSI	Percent of SG Within 20/20% of YSI	Percent of SG Within 30/30% of YSI	Percent of SG Within 40/40% of YSI	Percent of SG Within >40/40% of YSI
Overall	710	84.8	92.3	96.8	98.6	1.4
≥40-60*	7	100	100	100	100	0
>60-80*	34	70.6	79.4	94.1	100	0
>80-180	393	80.9	89.8	94.9	97.5	2.5
>180-300	255	91	96.9	99.6	100	0
>300-350	15	100	100	100	100	0
>350-400	6	100	100	100	100	0

**For glucose ranges ≤ 80 mg/dL, agreement was based on 15/20/30/40 mg/dL.*
Note: Sensor glucose readings are within 40-400 mg/dL

Table 7: Agreement (%) of SG-YSI paired points within YSI glucose ranges on Frequent Sample Testing (FST) Day 1; Calibration every 12 hours, Buttock (Table 61 in SSED v4)

YSI Glucose Ranges (mg/dL)	Number of Paired SG-YSI	Percent of SG Within 15/15% of YSI	Percent of SG Within 20/20% of YSI	Percent of SG Within 30/30% of YSI	Percent of SG Within 40/40% of YSI	Percent of SG Within >40/40% of YSI
Overall	335	78.8	87.2	93.7	97	3
>60-80*	19	52.6	63.2	89.5	100	0
>80-180	178	71.9	82.6	89.9	94.4	5.6
>180-300	133	91	96.2	99.2	100	0
>300-350	3	100	100	100	100	0
>350-400	2	100	100	100	100	0

**For glucose ranges ≤ 80 mg/dL, agreement was based on 15/20/30/40 mg/dL. Note: The overall number of available paired SG-YSI points on FST Day 1 was from 14 subjects. Sensor glucose readings are within 40-400 mg/dL*

Table 8: Agreement (%) of SG-YSI paired points within YSI glucose ranges on Frequent Sample Testing

(FST) Days 1, 3, and 7; Calibration 3 or 4 times a day, Buttock (Table 64 in SSED v4)

YSI Glucose Ranges (mg/dL)	Number of Paired SG-YSI	Percent of SG Within 15/15% of YSI	Percent of SG Within 20/20% of YSI	Percent of SG Within 30/30% of YSI	Percent of SG Within 40/40% of YSI	Percent of SG Within >40/40% of YSI
Overall	686	84.7	92.7	97.1	99.1	0.9
≥40-60*	7	100	100	100	100	0
>60-80*	28	85.7	89.3	100	100	0
>80-180	374	82.4	90.4	95.7	98.4	1.6
>180-300	253	87.4	96	98.4	100	0
>300-350	18	83.3	94.4	100	100	0
>350-400	6	100	100	100	100	0

**For glucose ranges ≤ 80 mg/dL, agreement was based on 15/20/30/40 mg/dL.*
Note: Sensor glucose readings are within 40-400 mg/dL

Table 9: Agreement (%) of SG-YSI paired points within YSI glucose ranges on Frequent Sample Testing Day 1; Calibration 3 or 4 times a day, Buttock (Table 65 in SSED v4)

YSI Glucose Ranges (mg/dL)	Number of Paired SG-YSI	Percent of SG Within 15/15% of YSI	Percent of SG Within 20/20% of YSI	Percent of SG Within 30/30% of YSI	Percent of SG Within 40/40% of YSI	Percent of SG Within >40/40% of YSI
Overall	311	80.7	90.4	95.5	98.7	1.3
>60-80*	13	69.2	76.9	100	100	0
>80-180	159	77.4	86.8	92.5	97.5	2.5
>180-300	131	87	96.2	98.5	100	0
>300-350	6	50	83.3	100	100	0
>350-400	2	100	100	100	100	0

**For glucose ranges ≤ 80 mg/dL, agreement was based on 15/20/30/40 mg/dL. Note: The overall number of available paired SG-YSI points on FST Day 1 was from 13 subjects. Sensor glucose readings are within 40-400 mg/dL*

Agreement when CGM reads "Below 40 mg/dL" or "Above 400 mg/dL"

The real-time CGM systems display glucose values between 40 mg/dL and 400 mg/dL. It displays "Below 40 mg/dL" when the SG value detected is below 40 mg/dL. It displays "Above 400 mg/dL" when the SG value detected is above 400 mg/dL. Tables 10 through 13 illustrate the number and percentage of the paired YSI values in different blood glucose levels when the CGM system displays "Below 40 mg/dL" (LOW) or "Above 400 mg/dL" (HIGH).

Table 10: The number and percentage of YSI values collected when CGM displays 'Below 40 mg/dL' (LOW); Calibration every 12 hours (Table 30 and Table 68 from SSED v4).

CGM Readings	Insertion Site	CGM-YSI pairs	<55	<60	<70	<80	>80	Total
LOW	Abdomen	Cumulative, n	2	2	2	2	0	2
		Cumulative %	100%	100%	100%	100%	0%	
	Buttocks	Cumulative, n	3	4	7	7	1	8
		Cumulative %	38%	50%	88%	88%	13%	

Table 11: The number and percentage of YSI values collected when CGM displays 'Below 40 mg/dL' (LOW); Calibration 3 or 4 times a day (Table 32 and Table 70 from SSED v4).

CGM Readings	Insertion Site	CGM-YSI pairs	<55	<60	<70	<80	>80	Total
LOW	Abdomen	Cumulative, n	0	0	0	0	0	0
		Cumulative %	0%	0%	0%	0%	0%	
	Buttocks	Cumulative, n	3	4	6	6	1	7
		Cumulative %	43%	57%	86%	86%	14%	

Table 12: The number and percentage of YSI values collected when CGM displays 'Above 400 mg/dL' (HIGH); Calibration every 12 hours (Table 31 and Table 69 from SSED v4).

CGM Readings	Insertion Site	CGM-YSI pairs	>340	>320	>280	>240	<240	Total
HIGH	Abdomen	Cumulative, n	0	0	0	0	0	0
		Cumulative %	0%	0%	0%	0%	0%	
	Buttocks	Cumulative, n	0	0	0	0	0	0
		Cumulative %	0%	0%	0%	0%	0%	

Table 13. The number and percentage of YSI values collected when CGM displays 'Above 400 mg/dL' (HIGH); Calibration 3 or 4 times a day. (Table 33 and Table 71 from SSED v4).

CGM Readings	Insertion Site	CGM-YSI pairs	>340	>320	>280	>240	<240	Total
HIGH	Abdomen	Cumulative, n	0	0	0	0	0	0
		Cumulative %	0%	0%	0%	0%	0%	
	Buttocks	Cumulative, n	0	0	0	0	0	0
		Cumulative %	0%	0%	0%	0%	0%	

Concurrence of SG and YSI values

The following tables show the percentage of concurring SG readings with FST reference values.

Table 14: Overall concurrence of YSI values and SG readings using YSI ranges on FST Days 1, 3, and 7; Calibration every 12 hours, Abdomen (Table 34 of SSED v4)

YSI Glucose Ranges (mg/dL)	Percent of Matched Pairs-in Each SG Glucose Range for Each YSI Glucose Range											
	SG (mg/dL)											
	Number of Paired SG-YSI	**<40**	**≥40-60**	**>60-80**	**>80-120**	**>120-160**	**>160-200**	**>200-250**	**>250-300**	**>300-350**	**>350-400**	**>400**
B) >=40-60	6	33.3% (2/6)	33.3% (2/6)	0.0% (0/0)	33.3% (2/6)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
C) >60-80	20	0.0% (0/0)	10.0% (2/20)	55.0% (11/20)	35.0% (7/20)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
D) >80-120	124	0.0% (0/0)	4.8% (6/124)	13.7% (17/124)	66.1% (82/124)	15.3% (19/124)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
E) >120-160	169	0.0% (0/0)	0.0% (0/0)	0.6% (1/169)	21.3% (36/169)	62.1% (105/169)	15.4% (26/169)	0.6% (1/169)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
F) >160-200	160	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	1.9% (3/160)	25.0% (40/160)	64.4% (103/160)	8.8% (14/160)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
G) >200-250	151	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	1.3% (2/151)	40.4% (61/151)	56.3% (85/151)	2.0% (3/151)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
H) >250-300	64	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	32.8% (21/64)	64.1% (41/64)	3.1% (2/64)	0.0% (0/0)	0.0% (0/0)
I) >300-350	32	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	40.6% (13/32)	59.4% (19/32)	0.0% (0/0)	0.0% (0/0)
J) >350-400	9	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	88.9% (8/9)	11.1% (1/9)	0.0% (0/0)

Table 15: Overall concurrence of YSI values and SG readings using YSI ranges on FST Day 1; Calibration every 12 hours, Abdomen (Table 35 of SSED v4)

	Percent of Matched Pairs-in Each SG Glucose Range for Each YSI Glucose Range											
	SG (mg/dL)											
YSI Glucose Ranges (mg/dL)	**Number of Paired SG-YSI**	**<40**	**≥40-60**	**>60-80**	**>80-120**	**>120-160**	**>160-200**	**>200-250**	**>250-300**	**>300-350**	**>350-400**	**>400**
B) ≥40-60	4	50.0% (2/4)	50.0% (2/4)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
C) >60-80	11	0.0% (0/0)	18.2% (2/11)	45.5% (5/11)	36.4% (4/11)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
D) >80-120	50	0.0% (0/0)	6.0% (3/50)	8.0% (4/50)	62.0% (31/50)	24.0% (12/50)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
E) >120-160	94	0.0% (0/0)	0.0% (0/0)	1.1% (1/94)	19.1% (18/94)	58.5% (55/94)	20.2% (19/94)	1.1% (1/94)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
F) >160-200	95	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	2.1% (2/95)	17.9% (17/95)	69.5% (66/95)	10.5% (10/95)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
G) >200-250	83	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	1.2% (1/83)	27.7% (23/83)	68.7% (57/83)	2.4% (2/83)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
H) >250-300	34	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	44.1% (15/34)	52.9% (18/34)	2.9% (1/34)	0.0% (0/0)	0.0% (0/0)
I) >300-350	27	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	37.0% (10/27)	63.0% (17/27)	0.0% (0/0)	0.0% (0/0)
J) >350-400	7	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	100.0% (7/7)	0.0% (0/0)	0.0% (0/0)

Note: The overall number of available paired SG-YSI points on FST Day 1 was from 16 subjects.

Table 16: Overall concurrence of YSI values and SG readings using YSI ranges on FST Days 1, 3, and 7; Calibration 3 or 4 times a day, Abdomen (Table 36 of SSED v4)

	Percent of Matched Pairs-in Each SG Glucose Range for Each YSI Glucose Range											
	SG (mg/dL)											
YSI Glucose Ranges (mg/dL)	**Number of Paired SG-YSI**	**<40**	**≥40-60**	**>60-80**	**>80-120**	**>120-160**	**>160-200**	**>200-250**	**>250-300**	**>300-350**	**>350-400**	**>400**
B) ≥40-60	2	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	100.0% (2/2)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
C) >60-80	18	0.0% (0/0)	0.0% (0/0)	61.1% (11/18)	38.9% (7/18)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
D) >80-120	120	0.0% (0/0)	3.3% (4/120)	15.8% (19/120)	67.5% (81/120)	13.3% (16/120)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
E) >120-160	162	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	17.9% (29/162)	64.8% (105/162)	16.7% (27/162)	0.6% (1/162)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
F) >160-200	161	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	1.2% (2/161)	25.5% (41/161)	65.2% (105/161)	8.1% (13/161)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
G) >200-250	145	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	1.4% (2/145)	42.8% (62/145)	53.8% (78/145)	2.1% (3/145)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
H) >250-300	61	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	32.8% (20/61)	65.6% (40/61)	1.6% (1/61)	0.0% (0/0)	0.0% (0/0)
I) >300-350	32	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	37.5% (12/32)	62.5% (20/32)	0.0% (0/0)	0.0% (0/0)
J) >350-400	9	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	55.6% (5/9)	44.4% (4/9)	0.0% (0/0)

Table 17: Overall concurrence of YSI values and SG readings using YSI ranges on FST Day 1; Calibration 3 or 4 times a day, Abdomen (Table 37 of SSED v4)

	Percent of Matched Pairs-in Each SG Glucose Range for Each YSI Glucose Range											
	SG (mg/dL)											
YSI Glucose Ranges (mg/dL)	**Number of Paired SG-YSI**	**<40**	**≥40-60**	**>60-80**	**>80-120**	**>120-160**	**>160-200**	**>200-250**	**>250-300**	**>300-350**	**>350-400**	**>400**
C) >60-80	9	0.0% (0/0)	0.0% (0/0)	55.6% (5/9)	44.4% (4/9)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
D) >80-120	46	0.0% (0/0)	2.2% (1/46)	10.9% (5/46)	67.4% (31/46)	19.6% (9/46)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
E) >120-160	85	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	16.5% (14/85)	60.0% (51/85)	22.4% (19/85)	1.2% (1/85)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
F) >160-200	91	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	2.2% (2/91)	16.5% (15/91)	70.3% (64/91)	11.0% (10/91)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
G) >200-250	76	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	1.3% (1/76)	27.6% (21/76)	68.4% (52/76)	2.6% (2/76)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
H) >250-300	31	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	38.7% (12/31)	58.1% (18/31)	3.2% (1/31)	0.0% (0/0)	0.0% (0/0)
I) >300-350	27	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	29.6% (8/27)	70.4% (19/27)	0.0% (0/0)	0.0% (0/0)
J) >350-400	7	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	57.1% (4/7)	42.9% (3/7)	0.0% (0/0)

Note: The overall number of available paired SG-YSI points on FST Day 1 was from 15 subjects.

Table 18. Overall concurrence of YSI values and SG readings using YSI ranges on FST Days 1, 3, and 7; Calibration every 12 hours, Buttock (Table 72 of SSED v4)

	Percent of Matched Pairs-in Each SG Glucose Range for Each YSI Glucose Range											
	SG (mg/dL)											
YSI Glucose Ranges (mg/dL)	**Number of Paired SG-YSI**	**<40**	**>=40-60**	**>60-80**	**>80-120**	**>120-160**	**>160-200**	**>200-250**	**>250-300**	**>300-350**	**>350-400**	**>400**
B) >=40-60	11	36.4% (4/11)	63.6% (7/11)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
C) >60-80	37	8.1% (3/37)	24.3% (9/37)	43.2% (16/37)	24.3% (9/37)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
D) >80-120	156	0.6% (1/156)	5.1% (8/156)	9.0% (14/156)	75.6% (118/156)	9.6% (15/156)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
E) >120-160	170	0.0% (0/0)	0.0% (0/0)	2.9% (5/170)	16.5% (28/170)	67.6% (115/170)	12.9% (22/170)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
F) >160-200	144	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	16.0% (23/144)	75.7% (109/144)	8.3% (12/144)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
G) >200-250	130	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	2.3% (3/130)	38.5% (50/130)	56.2% (73/130)	3.1% (4/130)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
H) >250-300	49	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	40.8% (20/49)	53.1% (26/49)	6.1% (3/49)	0.0% (0/0)	0.0% (0/0)
I) >300-350	15	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	33.3% (5/15)	60.0% (9/15)	6.7% (1/15)	0.0% (0/0)
J) >350-400	6	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	50.0% (3/6)	50.0% (3/6)	0.0% (0/0)

Table 19. Overall concurrence of YSI values and SG readings using YSI ranges on FST Day 1; Calibration every 12 hours, Buttock (Table 73 of SSED v4)

	Percent of Matched Pairs-in Each SG Glucose Range for Each YSI Glucose Range											
	SG (mg/dL)											
YSI Glucose Ranges (mg/dL)	**Number of Paired SG-YSI**	**<40**	**>=40-60**	**>60-80**	**>80-120**	**>120-160**	**>160-200**	**>200-250**	**>250-300**	**>300-350**	**>350-400**	**>400**
B) >=40-60	4	100.0% (4/4)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
C) >60-80	22	13.6% (3/22)	27.3% (6/22)	31.8% (7/22)	27.3% (6/22)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
D) >80-120	68	1.5% (1/68)	11.8% (8/68)	13.2% (9/68)	58.8% (40/68)	14.7% (10/68)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
E) >120-160	74	0.0% (0/0)	0.0% (0/0)	6.8% (5/74)	23.0% (17/74)	56.8% (42/74)	13.5% (10/74)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
F) >160-200	76	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	18.4% (14/76)	72.4% (55/76)	9.2% (7/76)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
G) >200-250	67	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	3.0% (2/67)	19.4% (13/67)	73.1% (49/67)	4.5% (3/67)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
H) >250-300	27	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	44.4% (12/27)	48.1% (13/27)	7.4% (2/27)	0.0% (0/0)	0.0% (0/0)
I) >300-350	3	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	100.0% (3/3)	0.0% (0/0)	0.0% (0/0)
J) >350-400	2	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	50.0% (1/2)	50.0% (1/2)	0.0% (0/0)

Note: The overall number of available paired SG-YSI points on FST Day 1 was from 14 subjects.

Table 20. Overall concurrence of YSI values and SG readings using YSI ranges on FST Days 1, 3, and 7; Calibration 3 or 4 times a day, Buttock (Table 74 of SSED v4)

	Percent of Matched Pairs-in Each SG Glucose Range for Each YSI Glucose Range											
	SG (mg/dL)											
YSI Glucose Ranges (mg/dL)	**Number of Paired SG-YSI**	**<40**	**>=40-60**	**>60-80**	**>80-120**	**>120-160**	**>160-200**	**>200-250**	**>250-300**	**>300-350**	**>350-400**	**>400**
B) >=40-60	11	36.4% (4/11)	63.6% (7/11)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
C) >60-80	30	6.7% (2/30)	10.0% (3/30)	50.0% (15/30)	33.3% (10/30)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
D) >80-120	144	0.7% (1/144)	1.4% (2/144)	7.6% (11/144)	80.6% (116/144)	9.7% (14/144)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
E) >120-160	164	0.0% (0/0)	0.0% (0/0)	1.8% (3/164)	16.5% (27/164)	67.1% (110/164)	14.0% (23/164)	0.6% (1/164)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
F) >160-200	140	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	14.3% (20/140)	75.0% (105/140)	10.7% (15/140)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
G) >200-250	127	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	1.6% (2/127)	42.5% (54/127)	51.2% (65/127)	4.7% (6/127)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
H) >250-300	53	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	41.5% (22/53)	39.6% (21/53)	17.0% (9/53)	1.9% (1/53)	0.0% (0/0)
I) >300-350	18	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	38.9% (7/18)	38.9% (7/18)	22.2% (4/18)	0.0% (0/0)
J) >350-400	6	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	16.7% (1/6)	83.3% (5/6)	0.0% (0/0)

Table 21. Overall concurrence of YSI values and SG readings using YSI ranges on FST Day 1; Calibration 3 or 4 times a day, Buttock (Table 75 of SSED v4)

	Percent of Matched Pairs-in Each SG Glucose Range for Each YSI Glucose Range											
	SG (mg/dL)											
YSI Glucose Ranges (mg/dL)	**Number of Paired SG-YSI**	**<40**	**>=40-60**	**>60-80**	**>80-120**	**>120-160**	**>160-200**	**>200-250**	**>250-300**	**>300-350**	**>350-400**	**>400**
B) >=40-60	4	100.0% (4/4)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
C) >60-80	15	13.3% (2/15)	0.0% (0/0)	40.0% (6/15)	46.7% (7/15)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
D) >80-120	56	1.8% (1/56)	3.6% (2/56)	12.5% (7/56)	66.1% (37/56)	16.1% (9/56)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
E) >120-160	68	0.0% (0/0)	0.0% (0/0)	4.4% (3/68)	25.0% (17/68)	57.4% (39/68)	13.2% (9/68)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
F) >160-200	72	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	15.3% (11/72)	75.0% (54/72)	9.7% (7/72)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
G) >200-250	64	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	1.6% (1/64)	29.7% (19/64)	62.5% (40/64)	6.3% (4/64)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
H) >250-300	31	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	45.2% (14/31)	29.0% (9/31)	22.6% (7/31)	3.2% (1/31)	0.0% (0/0)
I) >300-350	6	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	50.0% (3/6)	50.0% (3/6)	0.0% (0/0)	0.0% (0/0)
J) >350-400	2	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	50.0% (1/2)	50.0% (1/2)	0.0% (0/0)

Note: *The overall number of available paired SG-YSI points on FST Day 1 was from 13 subjects.*

Percent Agreement Post Calibration

The agreement of the SG values to paired YSI values was assessed for every 2-hour period post sensor calibration. For readings less than or equal to 80 mg/dL, the absolute difference in mg/dL between the SG and paired YSI values was calculated.

Tables 22 through 25 show the percent agreement rates post calibration for sensors inserted into the abdomen and buttock.

Table 22. Agreement rates for every 2-hour period post calibration period; Calibration every 12 hours, Abdomen (Table 44 of SSED v4)

Time after calibration	No. paired YSI-sensor points	Percentage (%) Agreement				
		± 15% (± 15 mg/dL)	± 20% (± 20 mg/dL)	± 30% (± 30 mg/dL)	± 40% (± 40 mg/dL)	> ±40% (± 40 mg/dL)
0–2 hours	224	84.4	93.3	98.7	99.6	0.4
2–4 hours	181	77.9	85.1	94.5	98.3	1.7
4–6 hours	145	72.4	84.1	94.5	98.6	1.4
6–8 hours	77	74	83.1	97.4	100	0
8–10 hours	52	80.8	82.7	86.5	96.2	3.8
10–12 hours	54	81.5	94.4	100	100	0

Table 23. Agreement rates for every 2-hour period post calibration period; Calibration 3 or 4 times a day, Abdomen (Table 45 of SSED v4)

Time after calibration	No. paired YSI-sensor points	Percentage (%) Agreement				
		± 15% (± 15	± 20% (± 20	± 30% (± 30	± 40% (± 40	> ±40% (± 40
0-2 hours	360	83.3	90.8	97.8	99.4	0.6
2-4 hours	174	83.9	92.5	98.3	100	0
4-6 hours	53	75.5	90.6	98.1	100	0
6-8 hours	64	73.4	82.8	96.9	100	0
8-10 hours	36	75	77.8	83.3	94.4	5.6
10-12 hours	23	87	95.7	100	100	0

Table 24. Agreement rates for every 2-hour period post calibration period; Calibration every 12 hours, Buttock (Table 82 of SSED v4)

Time after calibration	No. paired YSI-sensor points	Percentage (%) Agreement				
		± 15% (± 15 mg/dL)	± 20% (± 20 mg/dL)	± 30% (± 30 mg/dL)	± 40% (± 40 mg/dL)	> ±40% (± 40 mg/dL)
0–2 hours	196	81.6	94.9	96.4	98.5	1.5
2–4 hours	195	78.5	85.1	92.8	96.9	3.1
4–6 hours	157	87.9	91.1	99.4	99.4	0.6
6–8 hours	76	96.1	100	100	100	0
8–10 hours	45	97.8	100	100	100	0
10–12 hours	41	82.9	95.1	97.6	100	0

Table 25. Agreement rates for every 2-hour period post calibration period; Calibration 3 or 4 times a day, Buttock (Table 83 of SSED v4)

Time after calibration	No. paired YSI-sensor points	Percentage (%) Agreement				
		± 15% (± 15 mg/dL)	± 20% (± 20 mg/dL)	± 30% (± 30 mg/dL)	± 40% (± 40 mg/dL)	> ±40% (± 40 mg/dL)
0–2 hours	314	81.8	92.4	95.9	98.1	1.9
2–4 hours	195	79.5	88.2	96.4	100	0
4–6 hours	70	94.3	95.7	100	100	0
6–8 hours	52	94.2	100	100	100	0
8–10 hours	37	100	100	100	100	0
10–12 hours	18	94.4	100	100	100	0

Trend Accuracy

Tables 26 through 29 show, for each SG rate-of-change range (indicated on display by number of arrows), percentage of SG-YSI paired values that fell into different YSI rate-of-changeranges. The tables show the trend accuracy for sensors inserted into the abdomen or buttock.

Table 26. Trend Accuracy; Calibration every 12 hours, Abdomen (Table 46 of SSED v4)

	Percent of Matched Pairs-in Each YSI Rate Range for Each SG Rate Range						
	YSI (mg/dL/min)						
SG Rate Ranges (mg/dL/min)	**Number of Paired SG-YSI**	**<-2**	**[-2, -1)**	**[-1, 0)**	**[0, 1]**	**(1, 2]**	**>2**
<-2	19	47.4% (9/19)	47.4% (9/19)	0.0% (0/19)	5.3% (1/19)	0.0% (0/19)	0.0% (0/19)
[-2, -1)	107	2.8% (3/107)	31.8% (34/107)	60.7% (65/107)	3.7% (4/107)	0.9% (1/107)	0.0% (0/107)
[-1, 0)	276	0.7% (2/276)	5.8% (16/276)	71.7% (198/276)	21.0% (58/276)	0.7% (2/276)	0.0% (0/276)
[0, 1]	209	0.0% (0/209)	1.0% (2/209)	22.5% (47/209)	62.2% (130/209)	13.9% (29/209)	0.5% (1/209)
(1, 2]	98	0.0% (0/98)	0.0% (0/98)	1.0% (1/98)	37.8% (37/98)	59.2% (58/98)	2.0% (2/98)
>2	23	0.0% (0/23)	0.0% (0/23)	4.3% (1/23)	8.7% (2/23)	30.4% (7/23)	56.5% (13/23)

Table 27. Trend Accuracy; Calibration 3 or 4 times a day, Abdomen (Table 47 of SSED v4)

	Percent of Matched Pairs-in Each YSI Rate Range for Each SG Rate Range						
	YSI (mg/dL/min)						
SG Rate Ranges (mg/dL/min)	**Number of Paired SG-YSI**	**<-2**	**[-2, -1)**	**[-1, 0)**	**[0, 1]**	**(1, 2]**	**>2**
<-2	17	41.2% (7/17)	47.1% (8/17)	5.9% (1/17)	5.9% (1/17)	0.0% (0/17)	0.0% (0/17)
[-2, -1)	105	2.9% (3/105)	32.4% (34/105)	60.0% (63/105)	3.8% (4/105)	1.0% (1/105)	0.0% (0/105)
[-1, 0)	273	0.4% (1/273)	6.2% (17/273)	72.5% (198/273)	20.1% (55/273)	0.7% (2/273)	0.0% (0/273)
[0, 1]	199	0.5% (1/199)	0.5% (1/199)	22.6% (45/199)	63.3% (126/199)	12.6% (25/199)	0.5% (1/199)
(1, 2]	98	0.0% (0/98)	0.0% (0/98)	2.0% (2/98)	36.7% (36/98)	59.2% (58/98)	2.0% (2/98)
>2	17	0.0% (0/17)	0.0% (0/17)	5.9% (1/17)	11.8% (2/17)	41.2% (7/17)	41.2% (7/17)

Table 28. Trend Accuracy; Calibration every 12 hours, Buttock (Table 84 of SSED v4)

	Percent of Matched Pairs-in Each YSI Rate Range for Each SG Rate Range						
	YSI (mg/dL/min)						
SG Rate Ranges (mg/dL/min)	**Number of Paired SG-YSI**	**<-2**	**[-2, -1)**	**[-1, 0)**	**[0, 1]**	**(1, 2]**	**>2**
<-2	35	37.1% (13/35)	45.7% (16/35)	17.1% (6/35)	0.0% (0/35)	0.0% (0/35)	0.0% (0/35)
[-2, -1)	83	7.2% (6/83)	31.3% (26/83)	59.0% (49/83)	2.4% (2/83)	0.0% (0/83)	0.0% (0/83)
[-1, 0)	272	0.0% (0/272)	4.8% (13/272)	69.9% (190/272)	21.7% (59/272)	2.9% (8/272)	0.7% (2/272)
[0, 1]	199	0.0% (0/199)	0.5% (1/199)	22.1% (44/199)	60.8% (121/199)	15.6% (31/199)	1.0% (2/199)
(1, 2]	97	0.0% (0/97)	0.0% (0/97)	4.1% (4/97)	36.1% (35/97)	54.6% (53/97)	5.2% (5/97)
>2	23	0.0% (0/23)	0.0% (0/23)	0.0% (0/23)	26.1% (6/23)	34.8% (8/23)	39.1% (9/23)

Table 29. Trend Accuracy; Calibration 3 or 4 times a day, Buttock (Table 85 of SSED v4)

	Percent of Matched Pairs-in Each YSI Rate Range for Each SG Rate Range						
	YSI (mg/dL/min)						
SG Rate Ranges (mg/dL/min)	**Number of Paired SG-YSI**	**<-2**	**[-2, -1)**	**[-1, 0)**	**[0, 1]**	**(1, 2]**	**>2**
<-2	31	41.9% (13/31)	38.7% (12/31)	19.4% (6/31)	0.0% (0/31)	0.0% (0/31)	0.0% (0/31)
[-2, -1)	83	7.2% (6/83)	32.5% (27/83)	56.6% (47/83)	3.6% (3/83)	0.0% (0/83)	0.0% (0/83)
[-1, 0)	261	0.0% (0/261)	5.0% (13/261)	71.6% (187/261)	21.1% (55/261)	2.3% (6/261)	0.0% (0/261)
[0, 1]	194	0.0% (0/194)	0.5% (1/194)	22.2% (43/194)	62.9% (122/194)	13.4% (26/194)	1.0% (2/194)
(1, 2]	94	0.0% (0/94)	0.0% (0/94)	4.3% (4/94)	36.2% (34/94)	56.4% (53/94)	3.2% (3/94)
>2	22	0.0% (0/22)	0.0% (0/22)	0.0% (0/22)	22.7% (5/22)	36.4% (8/22)	40.9% (9/22)

Precision

Precision of the System was evaluated by comparing the results from two separate sensors worn on the same subject at the same time.

Data from two sensors worn at the same time for 11 subjects in the abdomen/abdomen insertion locations provided 772 pairs of CGM Measurements, with a mean Percent Absolute Relative Difference (PARD) during the study of 7.83% and a coefficient of variation (%CV) of 5.7%.

Data from two sensors worn at the same time for 18 subjects in the abdomen/buttock insertions location provided 1302 pairs of CGM Measurements, with a mean PARD during the study of 11.33% and a coefficient of variation (%CV) 7.8%.

Data from two sensors worn at the same time for 10 subjects in the buttock/buttock insertions location provided 695 pairs of CGM Measurements, with a mean PARD during the study of 10.93% and a coefficient of variation (%CV) 8.1%.

Sensor life

After the first successful calibration, 64.3% of sensors worn in the abdomen operated more than six days and up to the full seven days of wear (144 to 168 hours). The mean functional sensor life for sensors worn in the abdomen insertion site over the course of the study was 122.1 hours, with a median functional life of 128.4 hours.

After the first successful calibration, 81.3% of sensors worn in the buttock operated more than six days and up to the full seven days of wear (144 to 168 hours). The mean functional sensor life for sensors worn in the buttock insertion site over the course of the study was 142.7 hours, with a median functional life of 158.1 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 through seven days of use.

F. Alert performance for user ages 7 through 13

CGM enables your device to display sensor glucose readings, glucose trend arrows, glucose trend graphs, and sensor glucose alerts (for example, High and Low Limit Threshold alerts, High and Low Predictive alerts, and Rise and Fall rate-of-change alerts).

The high and low limit alerts (**Threshold alerts**) let the user know when the sensor glucose is at or above the high limit or at or below the low limit. Using only a high or low limit alert may reduce the number of false alerts, but does not provide a warning before reaching a high or low limit.

Predictive alerts notify users that their sensor glucose level may soon reach a high or low limit setting. Users may select how early they would like to be notified before their sensor glucose level reaches a high limit setting. The earliest warning is 30 minutes before reaching a high, but users can reduce the amount of warning down to 5 minutes. Users will receive a warning approximately 30 minutes prior to when their sensor glucose level is predicted to reach their low limit setting. In general, the earlier the warning, the more time a user will have to react to a potential high or low, but this also increases the potential for false alerts.

A predictive alert is simply an estimation of a future sensor glucose level compared to the high or low limit setting. If the predicted sensor glucose value is above the high limit or below the low limit, then a predictive alert is sounded even though the current sensor glucose level has not crossed the high or low limit. The predicted sensor glucose level is calculated using the current sensor glucose level, the derivative of previous sensor glucose readings (the trend or slope of the sensor glucose readings) and the amount of early warning duration the user selects.

The device will always alert the user when the CGM reads that the user is below 50 mg/dL, regardless of the high/low threshold and/or predictive alerts that the user sets.

Glucose TRUE Alert Rate

The glucose true alert rate is the rate at which the blood glucose confirmed that the CGM alert was triggered correctly. For example

True Threshold Hypoglycemic alert rate alerted when the CGM read that the user was below the low threshold and the user's blood glucose was actually below that low threshold.

True Threshold Hyperglycemic alert rate alerted when the CGM read that the user was above the high threshold and the user's blood glucose was actually above that high threshold.

True Predictive Hypoglycemic alert rate alerted when the CGM predicted that the user would reach below the low threshold and the user's blood glucose was actually below that low threshold within 15 or 30 minutes.

True Predictive Hyperglycemic alert rate alerted when the CGM predicted that the user would reach above the high threshold and the user's blood glucose was actually above that high threshold within 15

or 30 min

The true alert rate is important because it is necessary that users be notified when their blood glucose is low (or high) so that they can correct the low (or high) blood glucose. A high true alert rate indicates that when the CGM says that their glucose values are, or will reach a specified threshold, the user's blood glucose is likely to be at or approaching that threshold.

For example, per the following table, when wearing the sensor in the abdomen, the low glucose alerts would have correctly indicated that the user was below (i.e. threshold only), or predicted to reach below the threshold (i.e. predictive only) or both (predictive and threshold) 44.4%, 28.6%, or 36.4% of the time within 30 minutes (or 44.4%, 14.3% or 27.3% of the time within 15 minutes) when the user had blood glucose values lower than 70 mg/dL.

Table 1. Glucose TRUE Alert Performance using Calibration every 12 hours

		Glucose TRUE Alert Rate					
mg/dL	Insertion Site	Threshold Only		Predictive Only		Threshold & Predictive	
		30 min	15 min	30 min	15 min	30 min	15 min
50	Abdomen	33.3%	33.3%	12.5%	12.5%	18.2%	18.2%
	Buttock	25.0%	25.0%	11.1%	11.1%	16.7%	16.7%
60	Abdomen	25.0%	25.0%	8.3%	8.3%	12.5%	12.5%
	Buttock	60.0%	60.0%	25.0%	16.7%	35.3%	29.4%
70	Abdomen	44.4%	44.4%	28.6%	14.3%	36.4%	27.3%
	Buttock	60.0%	60.0%	36.8%	26.3%	40.7%	33.3%
80	Abdomen	33.3%	33.3%	31.6%	15.8%	32.3%	22.6%
	Buttock	61.1%	61.1%	46.2%	38.5%	51.2%	46.5%
90	Abdomen	55.0%	55.0%	46.2%	30.8%	47.7%	38.6%
	Buttock	70.8%	70.8%	58.3%	44.4%	62.5%	53.6%
180	Abdomen	78.4%	78.4%	66.2%	66.2%	70.5%	70.5%
	Buttock	83.3%	81.3%	64.3%	62.9%	70.6%	68.8%
220	Abdomen	87.5%	87.5%	60.0%	57.8%	68.2%	66.7%
	Buttock	75.0%	75.0%	51.0%	49.0%	58.3%	56.9%
250	Abdomen	81.3%	81.3%	53.1%	46.9%	63.0%	58.7%
	Buttock	73.3%	73.3%	41.2%	35.3%	50.0%	45.7%
300	Abdomen	77.8%	77.8%	44.4%	44.4%	55.6%	55.6%
	Buttock	57.1%	57.1%	31.3%	31.3%	38.1%	38.1%

Note: Given the small sample size of data available in the low range, the alert performance in the 50 mg/dL and 60 mg/dL should be interpreted with caution and may not reflect actual use performance.

Glucose FALSE Alert Rate

The glucose false alert rate is the rate at which the blood glucose did not confirm that the CGM alert was triggered correctly. For example:

False Threshold Hypoglycemic alert rate the alarm alerted when the CGM read that the user was below the low threshold but the users blood glucose was actually above that low threshold ; or

False Threshold Hyperglycemic alert rate the alarm alerted when the CGM read that the user was above the high threshold but the user's blood glucose was actually below that high threshold; or

False Predictive Hypoglycemic alert rate the alarm alerted when the CGM predicted that the user would be below the low threshold but the user's blood glucose was actually above that low threshold within 15 or 30 minutes

False Predictive Hyperglycemic alert rate the alarm alerted when the CGM predicted that the user would be above the high threshold but the user's blood glucose was actually below the high threshold within 15 or 30 minutes.

The false alert rate is important because it is necessary that users be correctly notified when their blood glucose is low (or high) so that they can correct the low (or high) blood glucose. A low false alert rate indicates that when the CGM says that their glucose values are, or will reach a specified threshold, the user's blood glucose is likely to be at or approaching that threshold.

For example, per the following table, when wearing the sensor in the abdomen, the high glucose threshold alerts would have incorrectly indicated that the user was above (i.e. threshold only), or predicted to reach above the threshold (i.e. predictive only), or both (threshold and predictive) 21.6%, 33.8% or 29.5% of the time within 30 minutes (or 21.6%, 33.8%, or 29.5% of the time within 15 minutes) when the user had blood glucose less than 180 mg/dL.

Table 2. Glucose FALSE Alert Performance using Calibration every 12 hours

		Glucose FALSE Alert Rate					
Mg/dL	Insertion Site	Threshold Only		Predictive Only		Threshold & Predictive	
		30 min	15 min	30 min	15 min	30 min	15 min
50	Abdomen	66.7%	66.7%	87.5%	87.5%	81.8%	81.8%
	Buttock	75.0%	75.0%	88.9%	88.9%	83.3%	83.3%
60	Abdomen	75.0%	75.0%	91.7%	91.7%	87.5%	87.5%
	Buttock	40.0%	40.0%	75.0%	83.3%	64.7%	70.6%
70	Abdomen	55.6%	55.6%	71.4%	85.7%	63.6%	72.7%
	Buttock	40.0%	40.0%	63.2%	73.7%	59.3%	66.7%
80	Abdomen	66.7%	66.7%	68.4%	84.2%	67.7%	77.4%
	Buttock	38.9%	38.9%	53.8%	61.5%	48.8%	53.5%
90	Abdomen	45.0%	45.0%	53.8%	69.2%	52.3%	61.4%
	Buttock	29.2%	29.2%	41.7%	55.6%	37.5%	46.4%
180	Abdomen	21.6%	21.6%	33.8%	33.8%	29.5%	29.5%

Table 2. Glucose FALSE Alert Performance using Calibration every 12 hours							
		Glucose FALSE Alert Rate					
Mg/dL	Insertion Site	Threshold Only		Predictive Only		Threshold & Predictive	
		30 min	15 min	30 min	15 min	30 min	15 min
	Buttock	16.7%	18.8%	35.7%	37.1%	29.4%	31.2%
220	Abdomen	12.5%	12.5%	40.0%	42.2%	31.8%	33.3%
	Buttock	25.0%	25.0%	49.0%	51.0%	41.7%	43.1%
250	Abdomen	18.8%	18.8%	46.9%	53.1%	37.0%	41.3%
	Buttock	26.7%	26.7%	58.8%	64.7%	50.0%	54.3%
300	Abdomen	22.2%	22.2%	55.6%	55.6%	44.4%	44.4%
	Buttock	42.9%	42.9%	68.8%	68.8%	61.9%	61.9%

Note: Given the small sample size of data available in the low range, the alert performance in the 50 mg/dL and 60 mg/dL should be interpreted with caution and may not reflect actual use performance.

Glucose Correct Detection Rate

Glucose Correct Detection Rate is the rate that the device alerted when it should have alerted. For example, the blood glucose was below the hypoglycemic threshold, or above the hyperglycemic threshold, and the device sounded an alert.

Glucose detection rates are important because it is necessary that users be notified when their blood glucose is low (or high) so that they can correct the low (or high) blood glucose. A high glucose correct detection rate indicates that users can have confidence that they will be notified by the device if their blood glucose is low or high.

For example, per the following table, when wearing the sensor in the abdomen, the threshold alert, the predictive alert, or both (threshold and predictive) notified the user 100%, 100% or 100% of the time within 30 minutes (or 100%, 100%, or 100% within 15 minutes) when the user had blood glucose less than 50 mg/dL.

Table 3. Glucose Correct Detection Alert Performance using Calibration every 12 hours							
		Glucose Correct Detection Rate					
mg/dL	Insertion Site	Threshold Only		Predictive Only		Threshold & Predictive	
		30 min	15 min	30 min	15 min	30 min	15 min
50	Abdomen	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
	Buttock	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
60	Abdomen	50.0%	50.0%	50.0%	50.0%	50.0%	50.0%
	Buttock	100.0%	100.0%	100.0%	66.7%	100.0%	100.0%
70	Abdomen	80.0%	80.0%	80.0%	40.0%	80.0%	80.0%
	Buttock	85.7%	85.7%	85.7%	71.4%	85.7%	85.7%
80	Abdomen	66.7%	66.7%	83.3%	50.0%	83.3%	66.7%
	Buttock	85.7%	85.7%	85.7%	78.6%	85.7%	85.7%
90	Abdomen	91.7%	91.7%	91.7%	66.7%	91.7%	91.7%

Table 3. Glucose Correct Detection Alert Performance using Calibration every 12 hours							
		Glucose Correct Detection Rate					
mg/dL	Insertion Site	Threshold Only		Predictive Only		Threshold & Predictive	
		30 min	15 min	30 min	15 min	30 min	15 min
	Buttock	86.4%	86.4%	90.9%	72.7%	95.5%	86.4%
180	Abdomen	95.1%	95.1%	100.0%	100.0%	100.0%	100.0%
	Buttock	97.5%	95.0%	100.0%	100.0%	100.0%	100.0%
220	Abdomen	92.6%	85.2%	96.3%	88.9%	96.3%	88.9%
	Buttock	95.7%	95.7%	100.0%	95.7%	100.0%	100.0%
250	Abdomen	77.8%	77.8%	88.9%	83.3%	88.9%	83.3%
	Buttock	68.8%	62.5%	100.0%	93.8%	100.0%	100.0%
300	Abdomen	80.0%	80.0%	100.0%	90.0%	100.0%	90.0%
	Buttock	60.0%	60.0%	100.0%	100.0%	100.0%	100.0%

Note: Given the small sample size of data available in the low range, the alert performance in the 50 mg/dL and 60 mg/dL should be interpreted with caution and may not reflect actual use performance.

Glucose Missed Detection Rate

The Missed Detection Rate is the rate that the device did not alert when it should have. For example, the blood glucose was below the hypoglycemic threshold, or above the hyperglycemic threshold, and the device did not sound a threshold or predictive alert.

Missed detection rates are important because it is necessary that users be notified when their blood glucose is low (or high), so that they can correct the low (or high) blood glucose. A low missed detection rate indicates that users can have confidence that they will be notified by the device if their blood glucose is low or high.

For example, per the following table, when wearing the sensor in the abdomen, the threshold alert, predictive alert, or both alert (threshold and predictive) did not sound 0%, 0% or 0% of the time within 30 minutes (or 0%, 0% or 0% within 15 minutes) when the user had blood glucose less than 50 mg/dL.

Table 4. Glucose Missed Detection Alert Performance using Calibration every 12 hours							
		Glucose Missed Detection Rate					
mg/dL	Insertion Site	Threshold Only		Predictive Only		Threshold & Predictive	
		30 min	15 min	30 min	15 min	30 min	15 min
50	Abdomen	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
	Buttock	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
60	Abdomen	50.0%	50.0%	50.0%	50.0%	50.0%	50.0%
	Buttock	0.0%	0.0%	0.0%	33.3%	0.0%	0.0%
70	Abdomen	20.0%	20.0%	20.0%	60.0%	20.0%	20.0%
	Buttock	14.3%	14.3%	14.3%	28.6%	14.3%	14.3%
80	Abdomen	33.3%	33.3%	16.7%	50.0%	16.7%	33.3%
	Buttock	14.3%	14.3%	14.3%	21.4%	14.3%	14.3%
90	Abdomen	8.3%	8.3%	8.3%	33.3%	8.3%	8.3%
	Buttock	13.6%	13.6%	9.1%	27.3%	4.5%	13.6%
180	Abdomen	4.9%	4.9%	0.0%	0.0%	0.0%	0.0%
	Buttock	2.5%	5.0%	0.0%	0.0%	0.0%	0.0%

Table 4. Glucose Missed Detection Alert Performance using Calibration every 12 hours							
		Glucose Missed Detection Rate					
mg/dL	Insertion Site	Threshold Only		Predictive Only		Threshold & Predictive	
		30 min	15 min	30 min	15 min	30 min	15 min
220	Abdomen	7.4%	14.8%	3.7%	11.1%	3.7%	11.1%
	Buttock	4.3%	4.3%	0.0%	4.3%	0.0%	0.0%
250	Abdomen	22.2%	22.2%	11.1%	16.7%	11.1%	16.7%
	Buttock	31.3%	37.5%	0.0%	6.3%	0.0%	0.0%
300	Abdomen	20.0%	20.0%	0.0%	10.0%	0.0%	10.0%
	Buttock	40.0%	40.0%	0.0%	0.0%	0.0%	0.0%

Note: Given the small sample size of data available in the low range, the alert performance in the 50 mg/dL and 60 mg/dL should be interpreted with caution and may not reflect actual use performance.

GETTING STARTED WITH MINIMED™ 670G CONTINUOUS GLUCOSE MONITORING

Medtronic

Continuous Glucose Monitoring

Getting started with continuous glucose monitoring

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Getting started with continuous glucose monitoring

Section 1: Welcome to continuous glucose monitoring

Continuous glucose monitoring (CGM) gives you a more complete picture of your glucose control than blood glucose monitoring alone. Using a sensor allows you to receive up to 288 sensor glucose readings every 24 hours, filling the gaps between your BG tests. CGM alerts notify you of high and low glucose values. Graphs and trend arrows show the speed and direction your glucose levels are moving.

The MiniMed® 670G includes SmartGuard™ technology, our latest advancement in diabetes management. SmartGuard is pump technology that automatically adjusts insulin delivery based on sensor glucose values. SmartGuard can be used in two modes: Manual Mode or Auto Mode. In this section, you will learn about using CGM and SmartGuard low management in Manual Mode. You will learn about SmartGuard in Auto Mode later.

The first step in using CGM is understanding the items included in your CGM system.

Your CGM system includes 3 key items:

1. **Transmitter***
   Guardian™ Link (3) Transmitter connects to the glucose sensor and sends glucose readings to your insulin pump.

2. **Glucose sensor**
   The Guardian™ Sensor (3) measures glucose levels in the body.

3. **Insulin pump**
   The MiniMed® 670G insulin pump displays glucose readings.

   Other items include: One-press serter, Oval Tape, charger, and tester.

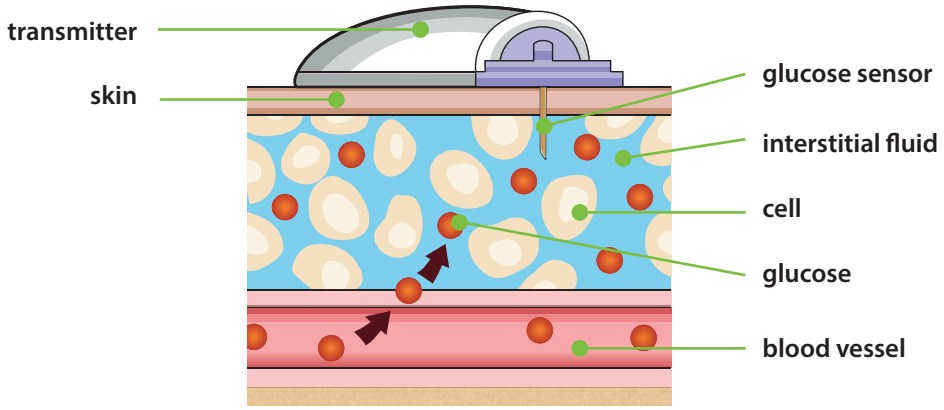
   Always use the components that were sent with your MiniMed® 670G.

Drawings throughout this document are only generic representations of the system components.
* The transmitter must be within 6 feet (1.8 meters) of the insulin pump in order to communicate sensor readings.

Section 2: Sensor glucose (SG) and blood glucose (BG)

Your **BG meter** measures glucose levels in your blood. The glucose sensor measures glucose in the fluid surrounding the cells of your tissue, called **interstitial fluid**.

Glucose travels between these two areas (blood and interstitial fluid). Most of the time, it travels to your blood first, and then to your interstitial fluid. Because of how glucose moves, **your BG meter readings (BG) and sensor glucose readings (SG) will be close, but will rarely match exactly**. This difference is normal and should be expected.



When glucose levels are rising or falling quickly, you should expect to see an even larger difference between your BG meter readings and the sensor glucose readings.

Examples of times when this larger difference may occur include:

- after meals or taking a bolus of insulin.
- during exercise.
- when arrows appear on your pump screen, as explained in *"Trends" on page 3*.

WARNING: Sensor glucose is not the same as blood glucose. Your SG and BG readings will be close to one another, but will rarely match exactly.

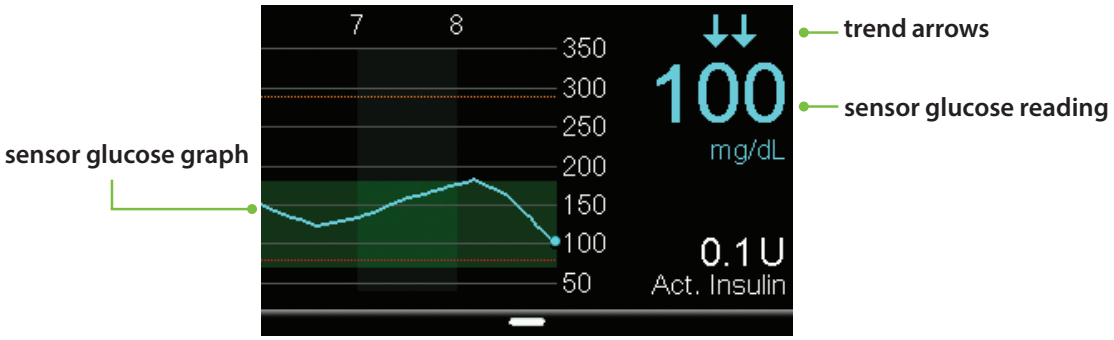
Do not make treatment decisions, such as determining your insulin dose for meals, using the 670G continuous glucose monitor (CGM) values, as they are not intended to be used to make such treatment decisions. The MiniMed 670G CGM does not replace a blood glucose meter. Always use the values from your blood glucose meter for treatment decisions. Blood glucose values may differ from sensor glucose values. Using the sensor glucose readings for treatment decisions could lead to high or low blood glucose.

Section 3: Trends

When using CGM, you will want to focus on sensor glucose trends. These trends give insight into the direction and the speed that your glucose is changing. The sensor graph and trend arrows are used to show your trend information.

Note: When using CGM, focus less on each individual glucose number and more on the direction and speed that your glucose is changing.

Example of sensor information on the Home screen



By looking at the sensor information above, you can see that the current glucose reading is 100 mg/dL. When you look at the graph, you can see that it is trending downward.

In this example, you see arrows above the number. The arrows indicate the rate that the glucose values are moving up or down:

↑ or ↓ - SG has been rising or falling by at least 1 but less than 2 mg/dL per minute.

↑↑ or ↓↓ - SG has been rising or falling by at least 2 but less than 3 mg/dL per minute.

↑↑↑ or ↓↓↓ - SG has been rising or falling by at least 3 or more mg/dL per minute.

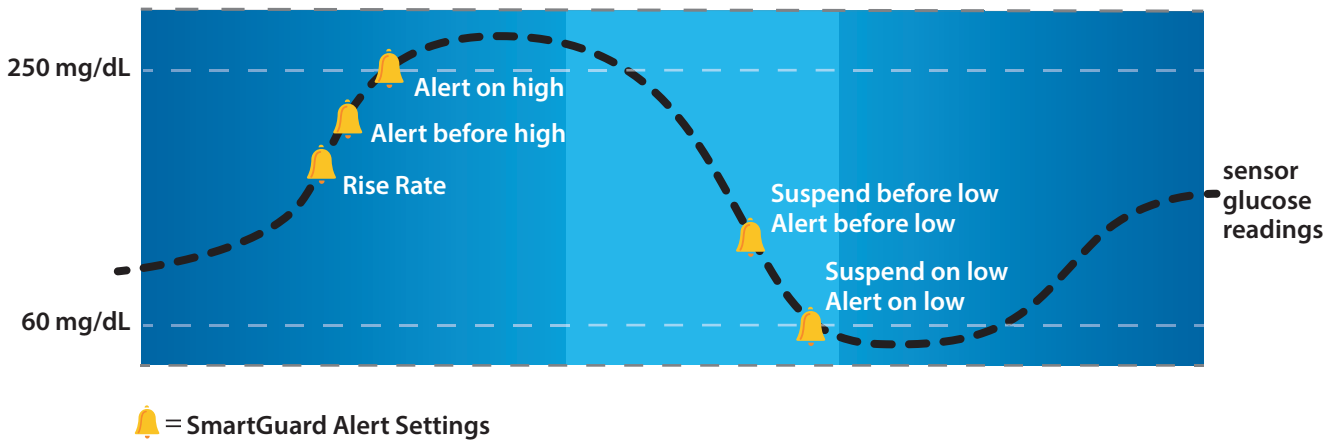
Note: You may be likely to notice your glucose trending up or down after eating, giving a bolus, or when exercising.

Section 4: Personalized alerts

Your SmartGuard alert and suspend settings are most beneficial if they are personalized for your needs. Settings will be set during your CGM training. They can then be adjusted as you learn more from the information provided by your sensor while you wear it. Your healthcare professional will work with you to determine your initial settings and help with adjustments that need to be made.

Your alert settings in SmartGuard apply to both Manual Mode and Auto Mode. However, the SmartGuard suspend settings apply only to Manual Mode. When the pump switches from Manual Mode into Auto Mode, the SmartGuard suspend settings turn off. See *Getting Started with Auto Mode* for information on how Auto Mode works.

The graph below shows the different settings that can be personalized for both High and Low sensor glucose readings.



Note: Please make sure the settings prescribed for you by your healthcare professional are available at the time of your in-person training.

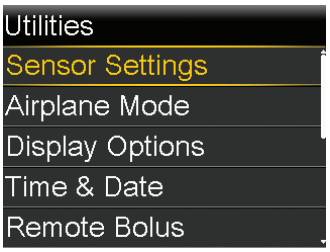
Turning sensor feature on

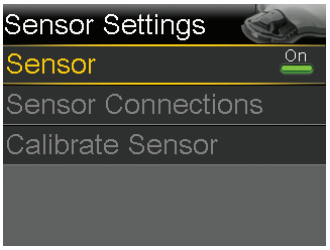
Before entering any of the SmartGuard settings, you must first turn the sensor feature on.

To turn the sensor feature on:

1) Press ○.
2) Select **Options**.
3) Select **Utilities**.
4) Select **Sensor Settings**.
5) Select **Sensor** to turn feature **On**.

   You can now access the SmartGuard menu and enter the settings.

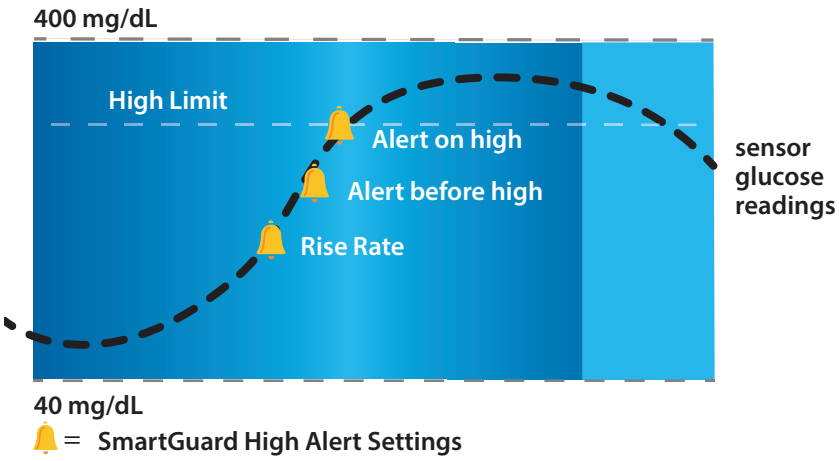




High Setup

Let's now look at the **High Setup**. These settings allow you to be alerted 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**).



High Limit

The first step is to set the high (**Hi**) limit. The high limit can be set from 100 to 400 mg/dL. This is the value on which other high settings are based. You can set up to eight high limits for different time segments throughout the day or night. The high (**Hi**) limit(s) that you enter also apply to Auto Mode.

Note: Your high limit is not the same as your glucose target. Your healthcare professional will help you determine the best setting, so that you are alerted only when needed.

Alert before high

When **Alert before high** is on, you will receive an alert any time the sensor glucose is predicted to reach your high limit, making you aware of a potential high before it occurs. This can help you to evaluate what has occurred and take any necessary action as directed by your healthcare professional.

Time before high

Time before high determines how many minutes before reaching the high limit that you will receive an **Alert before high**. This can be set from 5 to 30 minutes.

Alert on high

When the **Alert on high** is on, you will receive an alert any time your SG reading reaches or exceeds your high limit. This allows you to evaluate and treat if necessary as instructed by your healthcare professional.

Alert on high...

Sara has been working hard to keep her glucose levels under control. Her healthcare professional has set her high limit at 225 mg/dL and instructed her to use the **Alert on high**. If her glucose reaches this limit, she tests her BG and takes insulin if necessary to help make sure her glucose levels return to her normal range.

Rise alert

The **Rise Alert** will notify you when your glucose is rising rapidly. This alert can help you understand how much your glucose levels are affected by meals or, for example, when forgetting to give a bolus.

The **Rise Alert** can be set to alert if glucose is rising as follows:

↑ - SG is rising at a rate of 1 mg/dL per minute or more.

↑↑ - SG is rising at a rate of 2 mg/dL per minute or more.

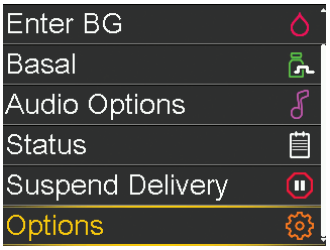
↑↑↑ - SG is rising at a rate of 3 mg/dL per minute or more.

Custom - SG is rising at the rate that you set. This can be set from 1.0 to 5.0 mg/dL per minute.

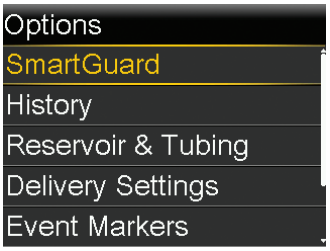
Setting up your High Setup

1) Press ⊙.

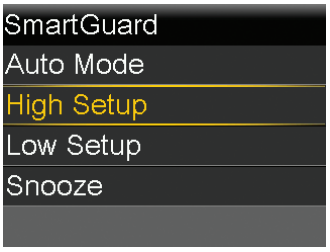
2) Select **Options**.



3) Select **SmartGuard**.



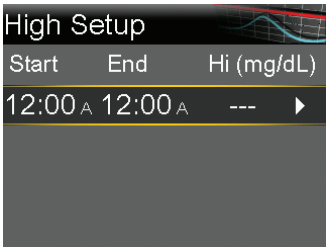
4) Select **High Setup**.



5) Press ⊙ on the time segment.

   If you are setting multiple time segments with different high limits and alerts, press ⌃ to set the first **End** time and press ⊙.

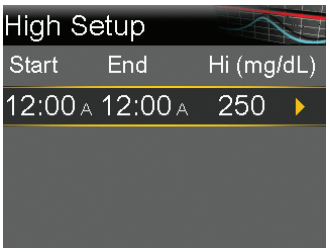
   In this example, only one time segment is set.



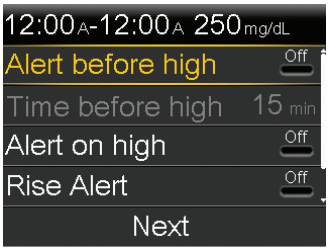
6) Press ⌃ or ⌄ to set **Hi** limit and press ⊙.

   In this example, the limit is set to 250 mg/dL.

7) Press ⊙ to continue onto the next screen.

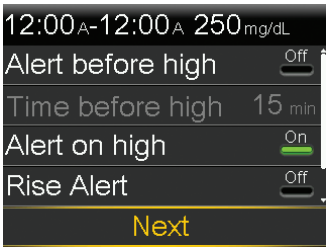


8) Select each feature you wish to turn on. If a feature is on, select it again to turn it back off.

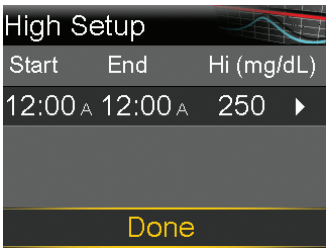


9) Once settings are selected, select **Next**.

In this example, the Alert on high has been turned on.



10) Select **Done**.



11) Verify that settings are correct and select **Save**.

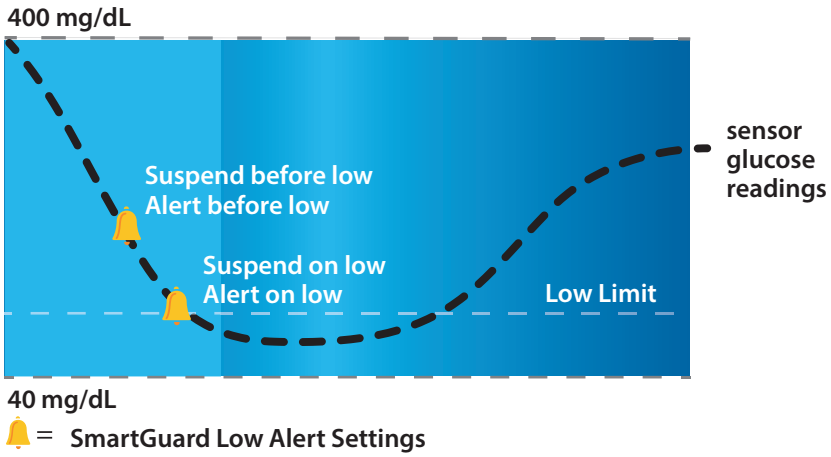
Your High Setup is now complete.

WARNING: Do not make treatment decisions, such as determining your insulin dose for meals, using the 670G continuous glucose monitor (CGM) values, as they are not intended to be used to make such treatment decisions. The MiniMed 670G CGM does not replace a blood glucose meter. Always use the values from your blood glucose meter for treatment decisions. Blood glucose values may differ from sensor glucose values. Using the sensor glucose readings for treatment decisions could lead to high or low blood glucose.

Note: You can set up to 8 different time segments throughout the day and night. Each time segment can have different high limits and high alerts that work best for you during that time of day or night.

Low Setup

Let's now look at the **Low Setup**. You can choose to be alerted before and/or when you have reached your low limit. You can also use the SmartGuard low management suspend features that can automatically suspend insulin if you are approaching or have reached your low limit. The low settings that can be chosen are shown here:



Low Limit

The first step is to set the low (**Lo**) limit. This can be set from 50 to 90 mg/dL. This is the value on which the other low settings are based. You can think of this limit as the lowest sensor glucose value that you would like to avoid reaching. Furthermore, if you do reach it, you would like to spend as little time at or below it as possible. You can set up to eight low limits for different periods of the day or night.

Suspend before low

Suspend before low is a low management feature of SmartGuard. When **Suspend before low** is on, your pump will temporarily stop delivering insulin if the sensor glucose value is approaching your low limit. This will keep you from getting additional insulin that would continue to lower your sensor glucose level.

Note: Insulin delivery will not be suspended if you are more than 70 mg/dL above your low limit.

Alert before low

When **Alert before low** is set to on, you will receive an alert when you are approaching your low limit, making you aware of potential lows before they occur. **Alert before low** behaves differently depending on your low management suspend settings:

- If **Suspend before low** is on, you will be alerted when insulin is suspended.
- If **Suspend before low** is off, you will be alerted when the sensor predicts you will reach your low limit in 30 minutes.

Suspend before low...

Sam uses **Suspend before low** during the night. He knows that if his sensor glucose values are approaching his low limit, his insulin delivery will stop. He has the **Alert before low** set to off – he doesn't want to be alerted when this occurs. He is comfortable knowing the pump will stop insulin delivery and he will receive an **Alert on low** if he reaches his low limit.

Suspend on low

Suspend on low is a low management feature of SmartGuard. When **Suspend on low** is set to on, your pump will temporarily stop delivering insulin if your sensor glucose has reached or fallen below your low limit. This keeps additional insulin from being delivered.

Note: Only one suspend feature can be used during each time segment; you cannot turn both **Suspend before low** and **Suspend on low** on.

Alert on Low

When **Alert on low** is on, you will receive an alert any time your SG reading reaches or falls below your low limit. This allows you to test your BG and treat if necessary as instructed by your healthcare professional.

Note: If either **Suspend on low** or **Suspend before low** is turned on, **Alert on low** will automatically be set to on so you know that your glucose is at or below your low limit.

Low SG XX mg/dL (50 mg/dL or below):

Your system also has a fixed **Low SG XX mg/dL** (50 mg/dL or below) alert. This fixed alert is factory set and cannot be changed or turned off. You will receive this alert if your SG reaches or falls below 50 mg/dL. This alert occurs in both Manual Mode and Auto Mode.

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 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.

Suspend on low...

Alexa's healthcare professional advised her to use the **Alert before low** and the **Suspend on low** during the daytime. If she receives an alert before she reaches her low, she tests her BG and treats with carbohydrates if necessary. In case her sensor glucose still reaches her low limit, she knows she will be alerted and her pump will suspend insulin.

Resume basal alert

In addition to suspending insulin delivery, the pump can also automatically resume delivery of basal insulin. If insulin has been suspended by either **Suspend before low** or **Suspend on low**, basal insulin delivery will automatically be resumed if either of these conditions apply:

- if SG values are above the low limit and are trending upward
- after a maximum suspend time of 2 hours

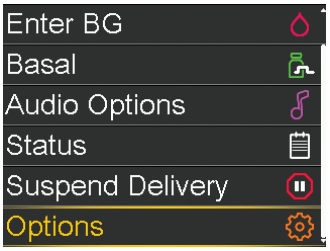
When the **Resume basal alert** is on, you will be alerted when basal insulin is automatically resumed because SG values are above the low limit and trending upward. If the **Resume basal alert** is off, basal insulin will still be resumed, you just won't receive an alert.

If basal insulin is resumed after the maximum 2 hour suspend time, you will be alerted even if the **Resume basal alert** is off. It is important that you check your BG and ensure your glucose is at a safe level.

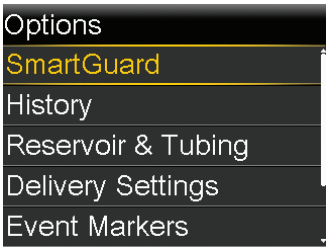
IMPORTANT: The maximum time insulin will be suspended is 2 hours. Additional information regarding SmartGuard™ low management suspend features can be found in *Sensor alerts and suspend on page 41*.

Setting up your Low Setup

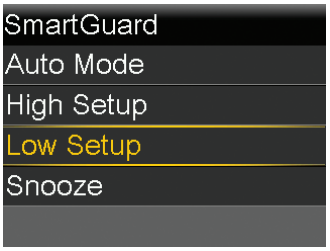
1) Press ○.
2) Select **Options**.



3) Select **SmartGuard**.



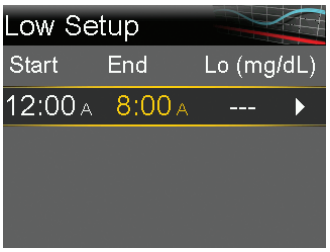
4) Select **Low Setup**.



5) Press ⊙ on the time segment.

If you are setting only one time segment, press ⊙. If you are setting multiple time segments, press ^ to the end of the first segment, and press ⊙.

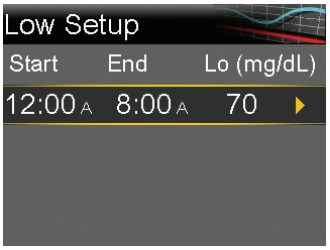
In this example, multiple time segments are set.



6) Press ^ or v to set **Lo** limit and press ⊙.

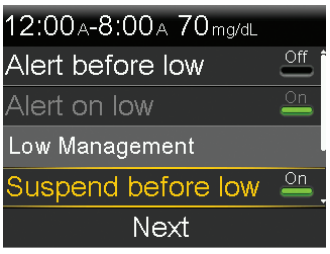
In this example, the limit is set to 70 mg/dL.

7) Press ⊙ to continue onto the next screen.

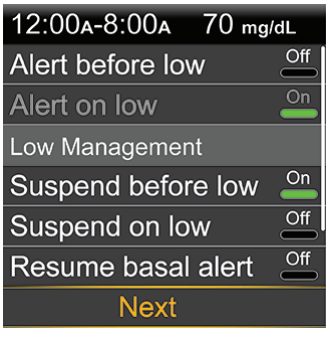


8) Select each feature you wish to turn on. If a feature is on, select it again to turn it back off.

*In this example, **Suspend before low** has been turned on.*



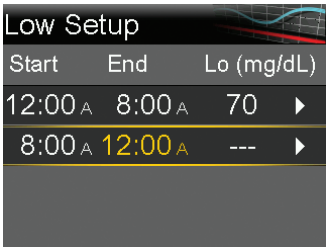
9) Once settings are selected, select **Next**.



Note: Only one Suspend feature can be used during each time segment. If either Suspend feature is turned on, **Alert on low** will automatically be turned on.

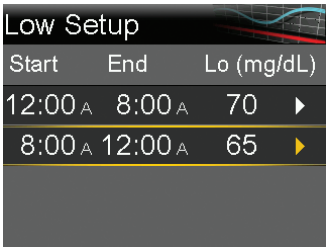
10) Press ⊙ on the time segment.

11) Press ⌃ to set the **End** time of the second segment and press ⊙.



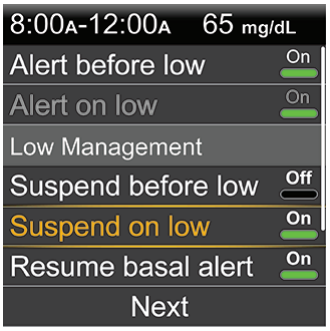
12) Press ⌃ or ⌄ to set the **Lo** limit and press ⊙.

13) Press ⊙ to continue onto the next screen.

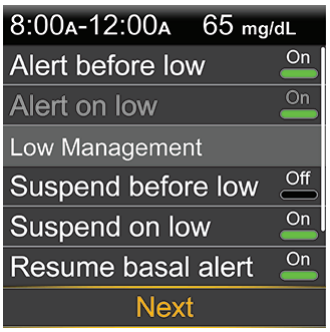


14) Select each feature you wish to turn on. If a feature is on, you can select it again to turn it back off.

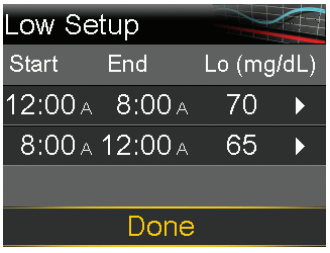
*In this example, **Alert before low**, **Suspend on low**, and **Resume basal alert** have been turned on.*



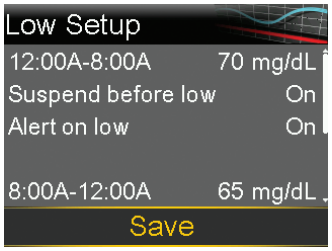
15) Select **Next**.

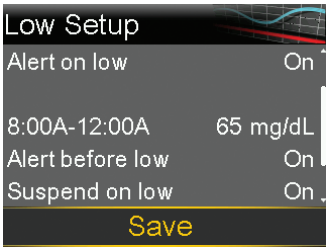


16) Select **Done**.



17) Verify that settings are correct and select **Save**.





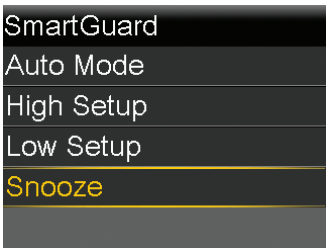
Your Low Setup is now complete.

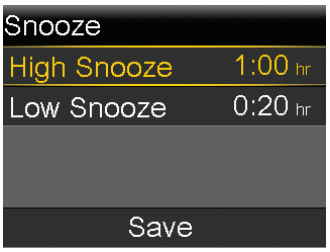
Note: You can set up to 8 different time segments throughout the day and night. Each time segment can have different low limits and low alerts that work best for you during that time of day or night.

Snooze

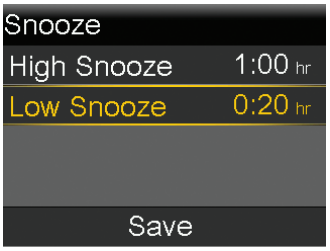
The **High Snooze** and **Low Snooze** is set for the amount of time that you want to wait to be reminded that an alert condition still exists. Once a high or low alert is received and cleared, you will be alerted again only if the alert condition still exists after the snooze time you have set. The high snooze time can be set from 5 minutes to 3 hours. The low snooze time can be set from 5 minutes to 1 hour.

1) Press ⊙.
2) Select **Options**.
3) Select **SmartGuard**.
4) Select **Snooze**.
5) Select **High Snooze**.
6) Press ⌃ or ⌄ to set the desired time and press ⊙.





7) Select **Low Snooze**.
8) Press ⌃ or ⌄ to set the desired time and press ⊙.
9) Verify that the settings are correct and select **Save**.



Note: Additional details about the SmartGuard low management suspend features can be found in the *Training handouts on page 56*. See the *MiniMed® 670G System User Guide* for a complete explanation of the technical and operational aspects of your pump.

Note: The SmartGuard low management suspend features, **Suspend on low** and **Suspend before low**, are automatically turned off when Auto Mode becomes active.

Snooze...

Robert's healthcare professional instructed him to turn **Alert on high** on with a **Snooze** of 2 hours. If his sensor glucose reaches his high limit, he checks his BG and gives a bolus if he needs it. His pump will check again in 2 hours and alert him if he is still at or above his high limit.

Changing High or Low Setup

As you use CGM, you and your healthcare professional may find that changes need to be made to the existing settings. To make these changes:

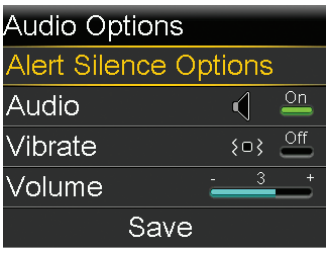
1) Press ⊙.
2) Select **Options**.
3) Select **SmartGuard**.
4) Select **High Setup** or **Low Setup**.
5) Select **Edit**.
6) Select time segment you wish to change.
   a. Change **End** time if necessary and press ⊙.
   b. Change **Hi** or **Lo** limit if necessary and press ⊙.
   c. Press ⊙ when the arrow is highlighted to continue onto the next screen.
7) Select any feature that is off if you wish to turn it on. Select any feature that is on if you wish to turn it off.
8) Select **Next**.
9) When finished, select **Done**.
10) Verify settings are correct and select **Save**.

Alert Silence

The **Alert Silence** feature allows you to silence sensor alerts for a set period of time. If a sensor alert occurs when **Alert Silence** is on, a sensor alert occurred message is displayed and the notification light flashes, but there is no beep or vibration. You can go to Alarm History in the History menu to see which sensor alert or alerts occurred. If you have not cleared the message when the **Alert Silence** period ends, the pump will beep and/or vibrate until cleared.

To set Alert Silence

1) Press ⊙.
2) Select **Audio Options**.
3) Select **Alert Silence Options**.

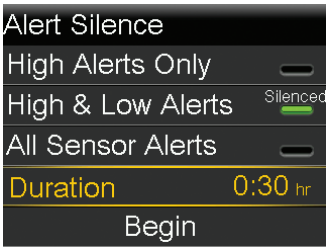


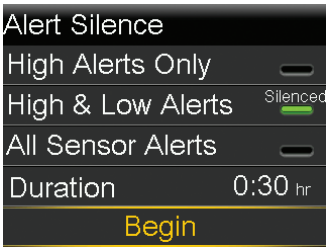
4) Select the alerts that you want to be silenced.

5) Select **Duration**.

6) Press ^ to set the time that you want alerts to be silenced and press ○.

7) Select **Begin**.





Alerts will automatically return to audio and/or vibrate at the end of the duration that you set. The **Low SG XX mg/dL** (50 mg/dL or below) and **Alert on Low** alerts cannot be silenced.

Silencing alerts...

Sandra uses the **Alert Silence** feature when she is in class so that she does not disrupt her classmates if an alert occurs. She routinely looks at her pump to check for alerts, and can take action if necessary.

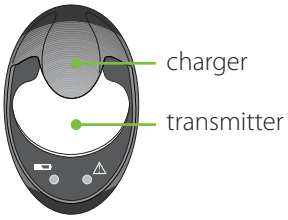
Section 5: Connecting your pump and transmitter

Before using the sensor for the first time, you will need to wirelessly connect the pump and transmitter so that they can communicate with each other. This allows the sensor information to be displayed on the pump screen.

To wirelessly connect your pump and transmitter:

1) Attach your transmitter to the charger and make sure it is fully charged.*

   For more information on charging the transmitter, see *Charging and storing the Guardian Link transmitter on page 45*.



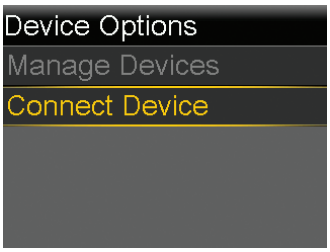
2) Press ○.

3) Select **Options**.

4) Select **Utilities**.

5) Select **Device Options**.

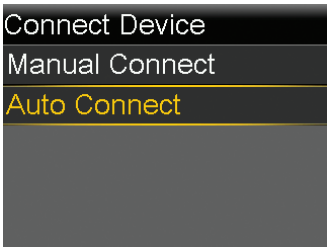
6) Select **Connect Device**.



   Only one transmitter can be connected to the pump at one time. When you need to connect a new transmitter, you must first select **Manage Devices**, select the old transmitter number and select **Delete.**

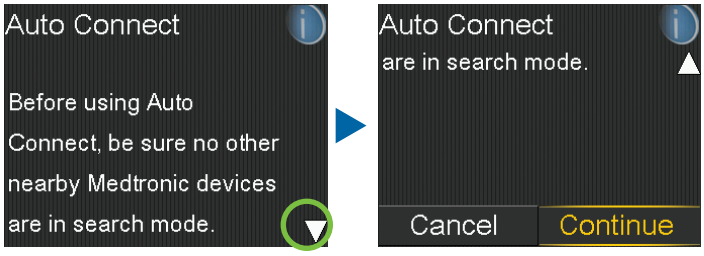
7) Select **Auto Connect**.

   Steps for Manual Connect can be found in the *MiniMed® 670G User Guide*.

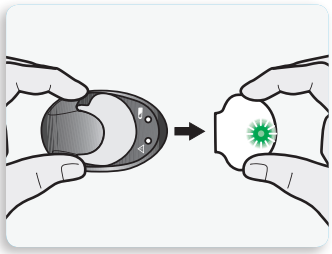


8) Press ⌄.

9) Select **Continue**.

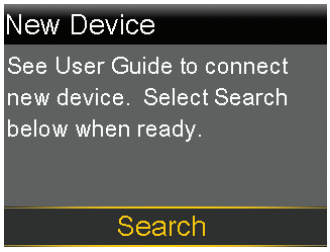


10) Make sure the transmitter is on the charger before proceeding. Now start the search processes on both devices.



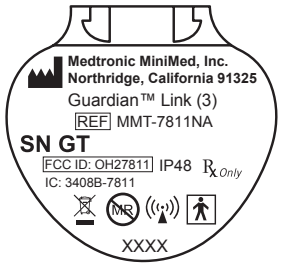
a) Remove transmitter from charger. If green light on transmitter does not flash, reconnect to charger until fully charged.

b) Immediately select **Search** on the pump.



The search can take up to 2 minutes.

11) When the device is found, confirm that the serial number (SN) shown on the pump is the serial number on the back of your transmitter.



If you receive the **No devices found** message, place the transmitter back onto the charger. Then remove the transmitter from the charger and immediately select **Retry** on the pump.

12) If SN matches, select **Confirm**.

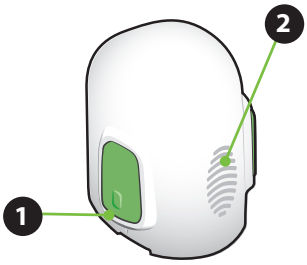
13) Connection is now complete. The transmitter serial number will be displayed on the pump screen.

Note: These steps only need to be done as a first time set-up. You will not have to repeat them with each new sensor you start.

Section 6: Inserting and starting the sensor

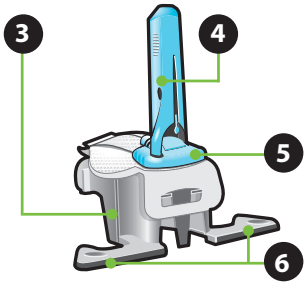
Before you insert your sensor, gather all of your supplies:

Guardian Sensor System components*



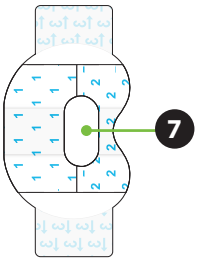
One-press serter

1. Bump on button
2. Thumb print



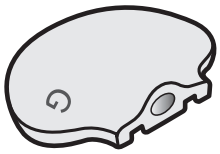
Guardian Sensor (3) & Pedestal

3. Pedestal
4. Needle housing
5. Sensor
6. Pedestal feet



Oval Tape

7. Pre cut hole



Guardian Link (3) transmitter

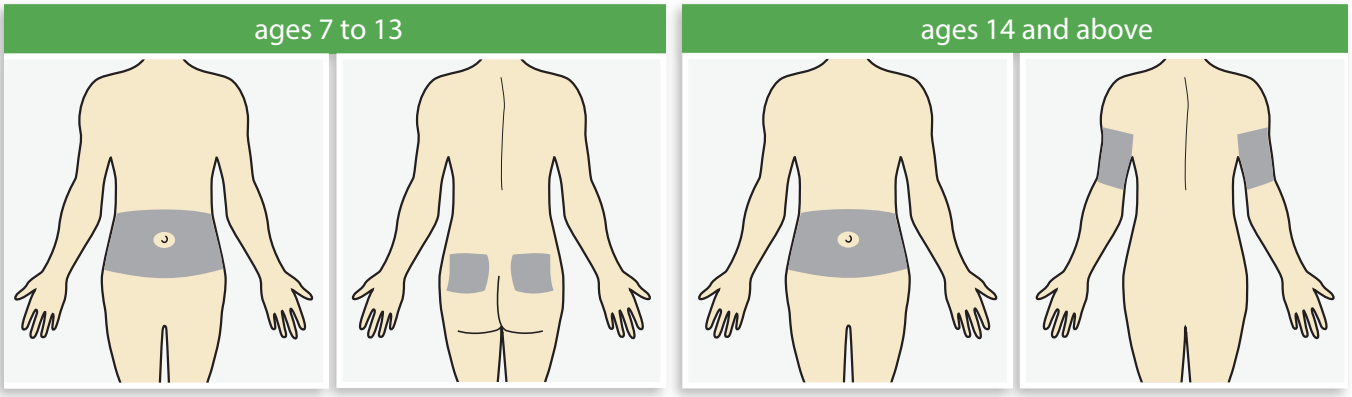
- **One-press serter** is required in order to insert the sensor properly.
- **Guardian Sensor (3)** is individually packaged and comes attached to a plastic pedestal which is necessary for proper loading into the serter.
- **Oval Tape** is required to keep the sensor securely in place.
- **Guardian Link (3) transmitter** is connected after the sensor is inserted and covered with the Oval Tape.

*For more details on the Guardian Sensor (3) components, consult the user guides for Guardian Link (3) transmitter, Guardian Sensor (3), and One-press serter.

Selecting your site

Your sensor can be inserted in any of the shaded areas according to your age.

Note: Assistance will likely be needed for sensor insertion into the back of the upper arm and into the buttocks. Some users found it difficult to insert the sensor into their arm/buttocks by themselves.



The Guardian Sensor (3) has been studied and is approved for use in the following sensor insertion sites by person of the following ages:

Approved Age	Sensor Insertion Site
7-13	Abdomen and Buttock
14 and above	Abdomen and Arm

The sensor insertion site should be at least:

- 2 inches (5 centimeters) from your navel.
- 1 inch (2.5 centimeters) from your insulin pump infusion site.
- 1 inch (2.5 centimeters) from any manual insulin injection site.

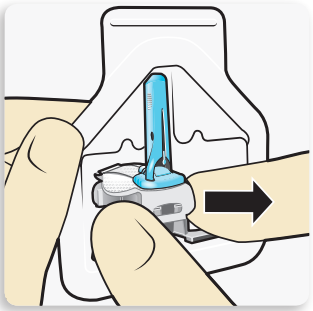
For best sensor glucose performance, avoid sites:

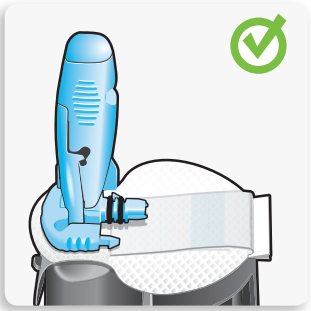
- where clothing may rub or constrict (for example, your belt line).
- where your body naturally bends a great deal which may cause the sensor to pull out.
- that are scarred or have hardened tissue or stretch marks.
- where there is a great deal of motion or friction.

Preparing your site

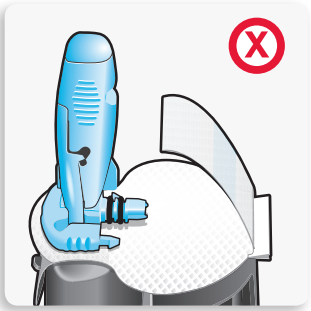
- Wash your hands with soap and water.
- Clean the selected site with an alcohol swab and allow the alcohol to dry. Do not use IV prep or the sensor may not work properly.

Inserting your sensor





Correct



Incorrect

1 **Open the sensor package.** Pull the corner of the paper covering to open the sensor package.

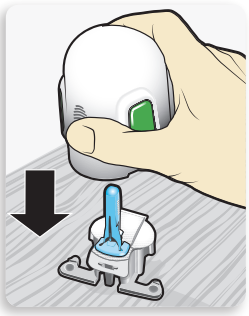
2a **Hold sensor by plastic pedestal.** Remove the sensor with attached pedestal by holding the pedestal only. Place the sensor/pedestal on a clean, flat surface (such as a table).

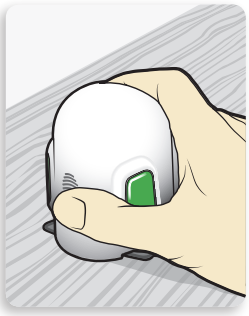
2b **Tuck adhesive tab.** Make sure that the sensor's adhesive tab is tucked under the sensor connector and snaps.

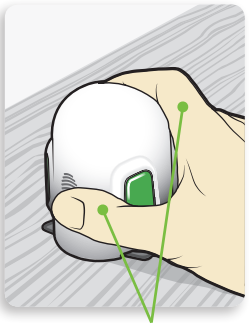
Note: Refer to the illustrations for correct and incorrect ways to hold serter for loading.

Correct

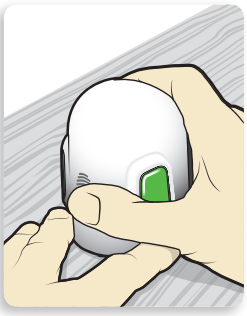
Incorrect

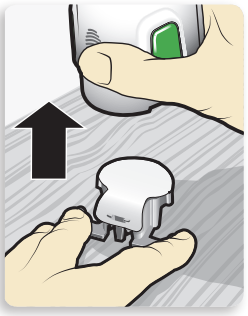






Fingers are NOT holding the side buttons.





3 **Load sensor into serter.** Grip the serter exactly as shown **with your thumb placed on the thumb print on the serter. Do not hold the side buttons.** Push the serter down onto the pedestal until the base of the serter sits flat on the table.

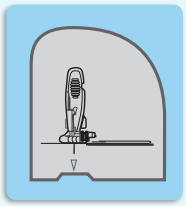
4 **Detach serter from pedestal.** To detach the serter from the pedestal, grip the serter as shown with thumb placed on thumb print on the serter. With the other hand, place two fingers on the pedestal arms, and slowly pull the serter straight up.

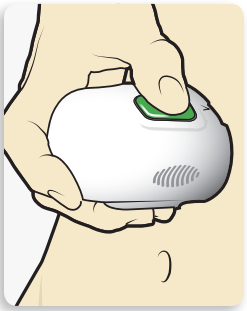
Note: Make sure that the pedestal is firmly on the table before pulling the serter away

CAUTION: Do not detach the pedestal from the serter in mid-air as this may damage the sensor.

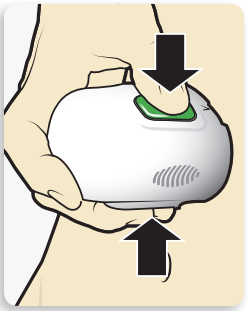
Note: The thumb print on the serter can be used for either left-handed or right-handed insertion.

Note: The sensor remains inside the serter after removing the pedestal. The arrow on both sides of serter indicate location of the sensor needle.

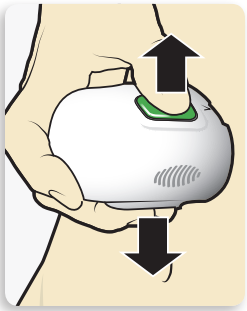




5a Place serter on body. Hold the serter steadily against your cleaned insertion site, without pushing the serter too deeply into the skin.



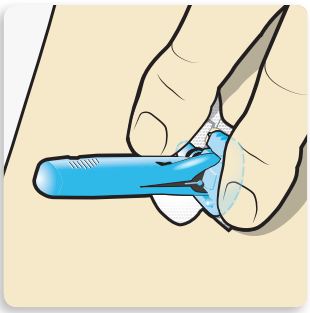
5b Insert sensor. Press and release the **bump** on both buttons at the same time. Do not pull the serter away from your body just yet.

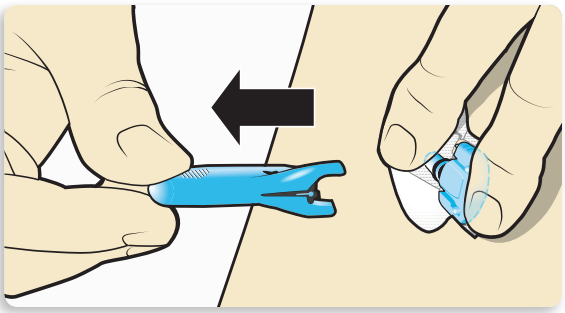


5c Hold serter against body. Continue to hold the serter against your body for at least five seconds to allow the adhesive to stick to your skin.

5d Remove serter from body. Slowly pull the serter away from the skin, making sure the buttons are not pressed.

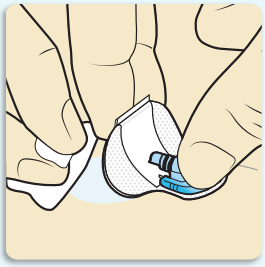
Note: Failing to hold the serter securely flat against the body may allow the serter to spring back after pressing the buttons and result in improper insertion of the sensor.



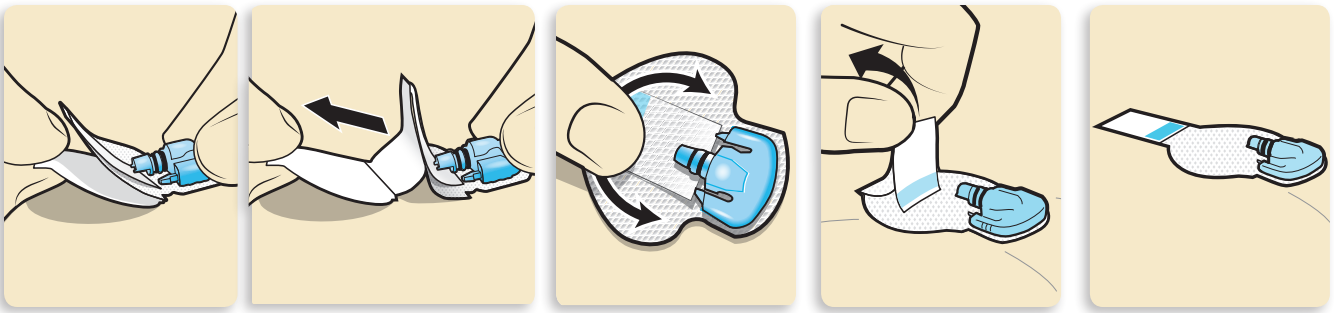


6 **Remove needle housing.** Gently hold the base of the sensor against the skin with one hand. With other hand, hold the needle housing at the top and slowly pull it straight away from the sensor. Dispose of the needle housing in a sharps container.

Note: Apply additional liquid adhesive. You may use an optional adhesive such as Skin Tac™ under the adhesive pad, prior to removing the liner. Allow it to dry.



IMPORTANT: All sensor tapes and adhesives stick best when you apply pressure after putting them on your skin. Doing so helps the sensor stay securely placed and fully inserted.



7a **Remove adhesive pad liner**. Hold the sensor in place and gently remove the adhesive liner from under the adhesive pad. Do not remove the liner on the rectangular adhesive tab yet.

7b **Press entire adhesive pad to skin.** Firmly press the adhesive against the skin and smooth the entire adhesive pad so that it sticks to your skin.

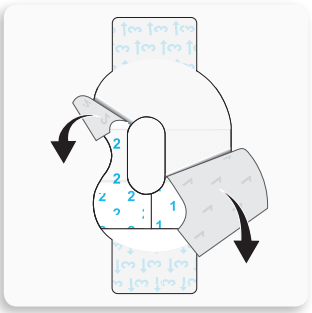
8a **Untuck adhesive tab**. Untuck the adhesive tab from under the sensor connector.

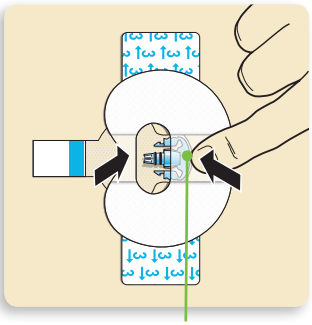
8b **Straighten adhesive tab**. Straighten the adhesive tab so that it lies flat against your skin, but do not remove the adhesive liner yet.

Note: The Guardian sensor adhesive is sensitive to pressure. Continue applying pressure on the adhesive to ensure that the sensor remains inserted in the skin for 7 days of wear.

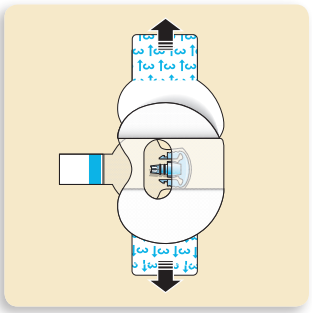
Taping your sensor

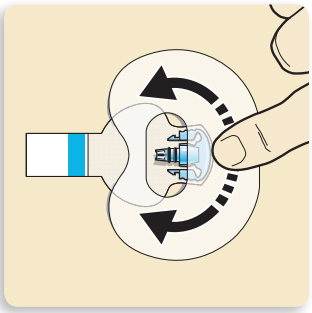
Before you connect the transmitter to your sensor it is very important that you properly secure the sensor against your skin using the provided tape.





Wide part of tape covers half of sensor base.





1 **Remove liner 1 and liner 2.**

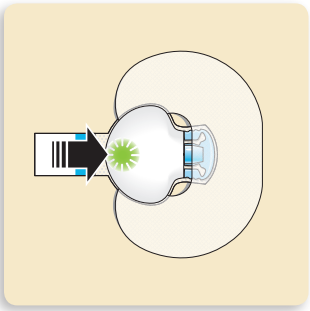
2 **Apply the tape as shown and press down firmly.**

3 **Remove liner 2 from each side.**

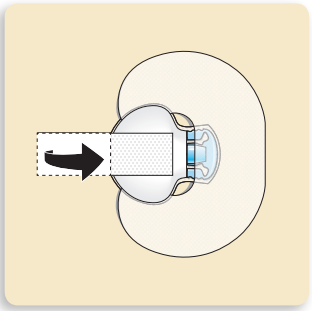
4 **Smooth the tape.**

IMPORTANT: **All Guardian sensor tapes and adhesives stick best when you continue to apply pressure after putting them on your skin. Doing so helps the sensor stay securely placed and fully inserted.**

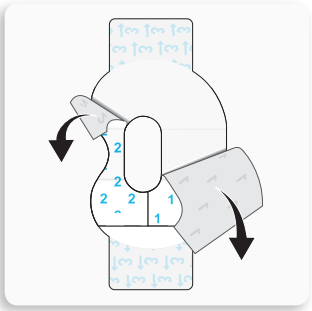
Connecting your transmitter



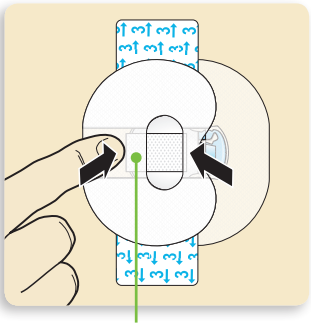
1 **Connect the transmitter to the sensor**.



2 **Remove the liner from the adhesive tab. Cover the transmitter with the adhesive tab. Do not pull the tab too tightly**.



3 **To apply the 2nd tape, remove liner 1.**

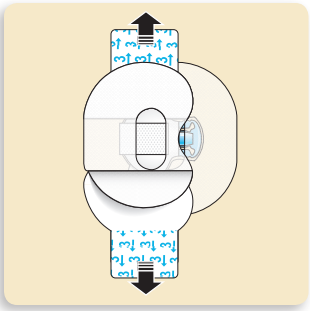


Wide part of tape covers end of transmitter and skin.

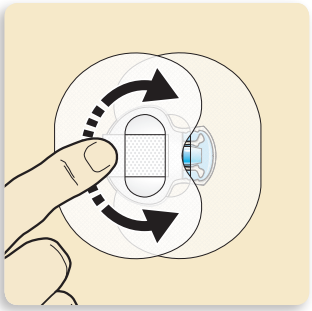
4 **Rotate the 2nd tape and place the tape over the transmitter. Press down firmly.**

Note: Wait for the green light on the transmitter to flash. If the green light does not flash, refer to the Troubleshooting section of your transmitter user guide.

IMPORTANT: If you do not see a green light flashing on the transmitter after it is connected to the sensor, then disconnect the transmitter and place it back on the charger to ensure that it is fully charged. Then reconnect the transmitter to the sensor.



5 **Remove liner 3 from each side**.



6 **Smooth the tape**.

Note: Check your sensor site regularly. Apply additional off-the-shelf tape if the sensor and transmitter are not secure.

It is very helpful to remember the order of these four steps when changing your sensor.

1. **Insert** the sensor.
2. **Tape** the sensor in place.
3. **Connect** the transmitter.
4. **Apply** a second Oval Tape.

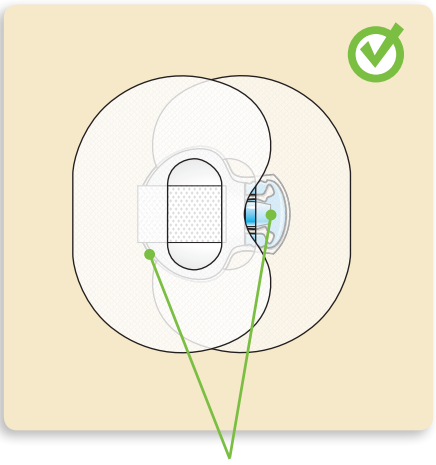
Note: When your transmitter is connected to your sensor they form a water-tight seal to a depth of 8 feet (2.4 meters) for up to 30 minutes. You can shower and swim without removing them.

Note: Properly applying the Oval Tape is key to ensuring your success with the sensor. Due to the sensor's small size and flexible nature, the Oval Tape helps to secure it from body motion or physical activity that can cause it to be pulled out.

Checking proper tape application

It is important to check your sensor site periodically to make sure the sensor is still secure and has not been pulled out. If the sensor has been pulled out, do not try to push it back into place. A new sensor may need to be inserted.

Correct



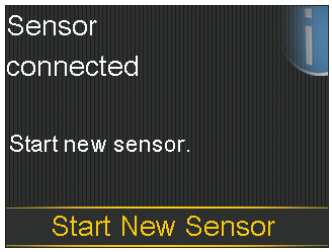
Oval Tape is covering, the sensor, skin around sensor, and back of transmitter.

Starting the sensor

Once you have inserted the sensor and connected the transmitter, the pump and transmitter will begin to communicate.

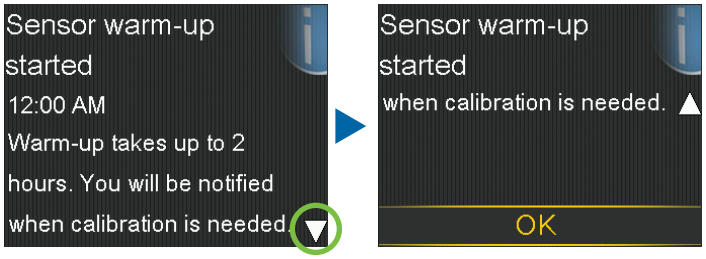
Make sure your pump is on the Home screen so that the message below will be displayed when the sensor is ready to be started. *This typically takes less than a minute, but may take up to 10 minutes.*

1) Select **Start New Sensor**.



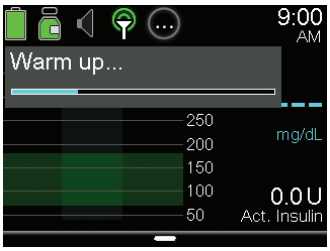
2) The **Sensor warm up started** message will appear.

3) Press ⌄ and then ○ to clear.

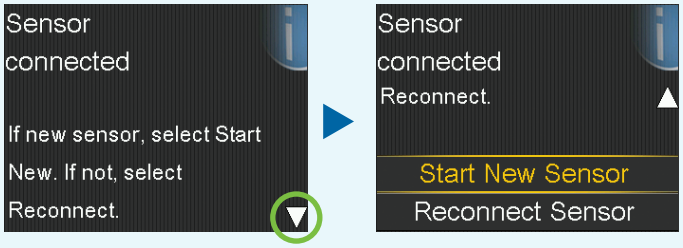


4) **Warm up...** will appear on the Home screen until sensor is ready for the first calibration.

*If 15 minutes have passed and the Warm up bar does not appear or it looks like it is not progressing, look into the **Quick Status** screen. If you see the time of **Next cal** listed, the sensor is in Warm up.*



Note: The next time you connect a transmitter, you will see these screens. Select **Start New Sensor** if you have just inserted a new sensor. Select **Reconnect Sensor** if you have only disconnected and reconnected the transmitter.



Note: A *Quick Reference Guide for using the One-press serter with Guardian sensor* is available in *Training handouts on page 52* to help guide you during your sensor setup and insertions.

Section 7: Calibration

Your continuous glucose monitoring system requires BG meter readings in order to provide you with sensor glucose readings. These BG meter readings are entered into the pump and are for sensor calibrations. Calibration is essential for optimal CGM performance. CGM does not eliminate the need for BG meter tests.

To calibrate, you must use a *fingerstick* blood sample to test your BG on your meter, and then enter that value into your pump. The pump will accept BG meter readings between 40 mg/dL to 400 mg/dL.

WARNING: Always use the fingertip for blood samples used for calibrating the sensor while in Auto Mode. The fingertip was the only site studied for use with Auto Mode. Do not use blood samples from the palm to calibrate the sensor as this site was not studied for use with Auto Mode and the performance of the system is not known.

After inserting a new sensor, a calibration is needed:

- Within 2 hours after you connect the transmitter to your sensor and start the **Warm up** period. Your pump will notify you with a **Calibrate now** alert when it is ready for its first calibration.
- Again within 6 hours (first day of inserting sensor only).
- Again every 12 hours.
- When the system detects that a calibration is needed for optimal performance.

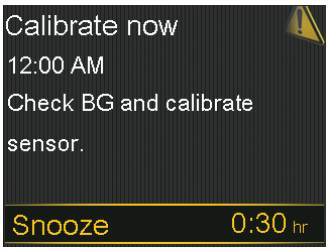
After the first day, the minimum number of calibrations required is one every 12 hours, but you may receive a **Calibrate now** alert if one is needed sooner. Calibrating three to four times per day is optimal. It is best to calibrate when your glucose is not changing rapidly. For example, before meals is often a good time to calibrate. Calibrating when there are ↑↑, ↓↓, ↑↑↑, ↓↓↓ may decrease sensor accuracy.

IMPORTANT: Blood glucose readings should be entered immediately. Avoid using an old BG or reusing BG readings from previous calibrations.

Wait at least 15 minutes in between calibration attempts.

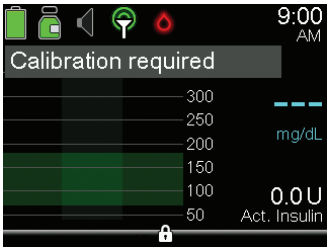
Note: Calibrations are necessary in order to continue to receive sensor glucose readings, alerts, and alarms.

Within two hours after starting a new sensor, or any other time a calibration is necessary, you will receive a **Calibrate now** alert. If you cannot calibrate right away (for example, if you are driving or in a meeting), you can set the **Snooze** to remind you to calibrate in the time that you set. You can change the time if you desire.



If you plan to test BG and calibrate right away, simply select **Snooze**.

Once you select Snooze, **Calibration required** will appear on the Home screen until you enter a BG to calibrate.



You will not receive sensor glucose readings or sensor alerts and alarms until a calibration BG is entered.

Calibrating the sensor

There are several different ways that you can enter a BG reading to calibrate the sensor.

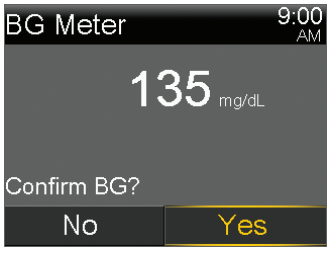
Calibrate by using the CONTOUR®NEXT LINK 2.4 Meter

When you use the compatible Ascensia meter, the meter value automatically appears on the BG Meter screen.

1) Check your BG. You may need to make a selection on your meter to send the BG reading to the pump, depending on your meter setting for sending over BG results.

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

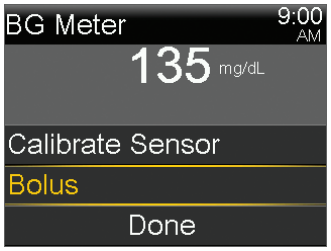
   If you do not believe the meter result is accurate, do not confirm now. Select **No**, wash your hands, and re-test your BG.



3) Select **Calibrate Sensor** to calibrate using the BG value.

   If you plan to give a bolus using Bolus Wizard®, select **Bolus**.

4) Select **Done** if you wish to do neither.

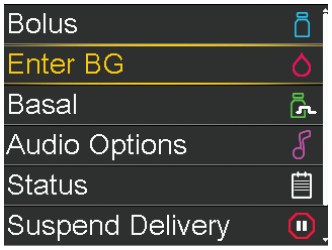


Calibrate through Enter BG

You are able to calibrate through Enter BG.

1) Press ⊙.

2) Select **Enter BG**.



3) Select **Enter BG**.

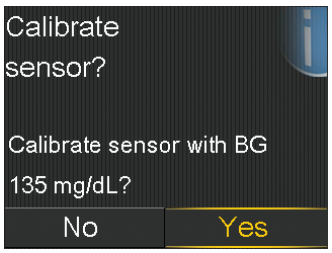
4) Press ⌃ or ⌄ to enter your BG reading. and press ⊙.

5) Select **Save**.

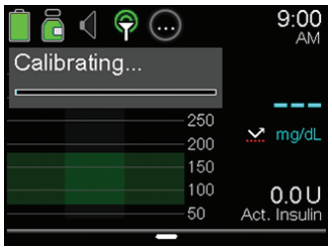
A message appears asking if you want to calibrate using the entered BG.

6) Select **Yes** if you want to calibrate.

Select **No** if you do not want to calibrate.



7) The Home screen appears, indicating that your pump is calibrating.

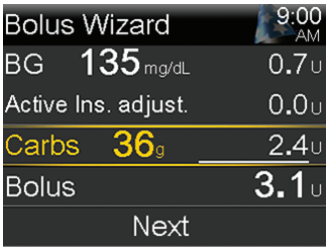


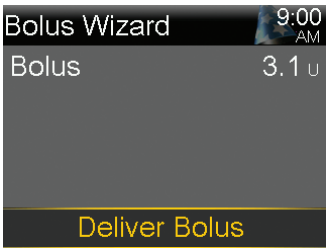
Note: You can perform other tasks while your pump is calibrating.

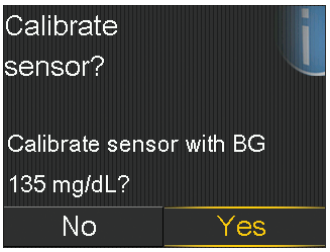
Calibrating through the Bolus Wizard

You are able to calibrate when using the Bolus Wizard.

1) Press ⊙.
2) Select **Bolus**.
3) Select **Bolus Wizard**.
4) Press ⊙.
5) Press ⌃ or ⌄ to enter BG value and press ⊙.
6) Press ⊙.
7) Press ⌃ to enter your carbs and press ⊙.
8) Select **Next**.
9) Select **Deliver Bolus**.
10) Press › and select **Yes** to calibrate sensor.



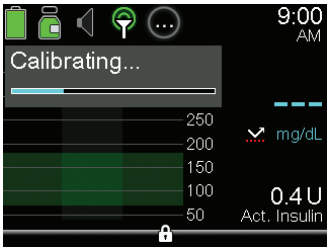




You can also calibrate through the Sensor Settings and Event Markers menu. For complete instructions, see the *MiniMed® 670G User Guide*.

Once you have entered a calibration BG, the Home screen will show you that the system is calibrating.

You will start seeing sensor glucose readings again within five minutes.



WARNING: If you notice a large difference between your BG meter reading and sensor glucose readings, wash your hands and do another BG fingerstick test to help ensure a more accurate reading. Check the sensor site to ensure the sensor overtape is still holding the sensor in place. If it is not, you will need to remove and insert a new sensor.

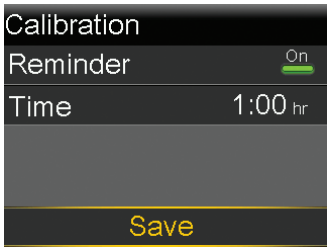
Calibration Reminder

You can use the **Calibration Reminder** to give you notice before the next calibration is necessary. For example, let's say you calibrated at 7:00a and your reminder is set for 4 hours. Since your next calibration would be due at 7:00p (12 hours), you would receive a **Calibration Reminder** at 3:00p, which is 4 hours before the calibration is due. This can help ensure that you calibrate 3-4 times a day. The **Calibration Reminder** defaults to On with a reminder time of 1:00 hour.

To change the Calibration Reminder

1) Press ⊙.
2) Select **Options**.
3) Select **Reminders**.
4) Select **Calibration**.
5) Press ⌄ to **Time** and press ⊙.
6) Press ⌃ or ⌄ to desired time and press ⊙.

   In this example, the reminder is set for 1 hour.
7) Select **Save**.

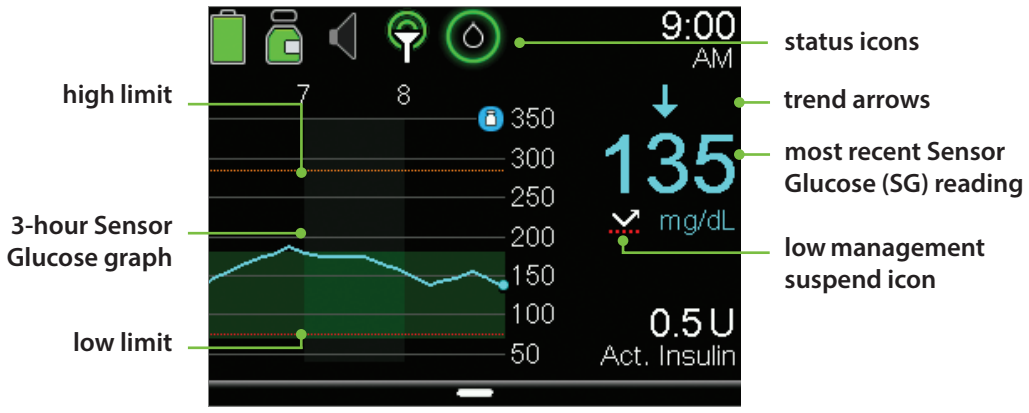


Calibrate before bed...

Pam does not want to be awakened during the night by a **Calibrate now** alert, so she tests her BG and calibrates her sensor before she goes to bed.

Section 8: Reading the sensor display

Once the sensor has started giving you sensor glucose readings, the Home screen will display your readings in a way that is similar to the example shown below.



Note: This is the sensor display when your pump is in Manual Mode. The display is different when your pump is in Auto Mode. See *Getting Started with Auto Mode* for information about Auto Mode display.

Status icons

In addition to the pump icons, you will see additional sensor icons when using CGM.

Connection: The connection icon appears green when the Sensor feature is on and your transmitter is successfully communicating with your pump. The connection icon appears with a red cross when the Sensor feature is turned on, but the transmitter is not connected, or communication with your pump has been lost.

Calibration: Shows the approximate time left until your next sensor calibration is due. Appears only when the Sensor feature is turned on. The color and the circle around the icon indicate the status. When your sensor is fully calibrated, the icon has a solid green circle around it. As the time for your next sensor calibration approaches, the green circle around the icon becomes smaller, and the color of the icon changes. When the icon turns red, a sensor calibration is required. If the time until your next sensor calibration is unavailable, the icon has a solid blue circle around a question mark. When the sensor is not ready for a calibration, the circle shows three dashes.

Audio icon: If Alert Silence is on: audio  , vibrate  , or audio and vibrate  .

SmartGuard low management suspend icon

During any time segment when either **Suspend before low** or **Suspend on low** is set to On, you will see the low management suspend icon on the Home screen.

Suspend before low or **Suspend on low** is on and ready. If either suspend becomes active, the icon will flash while insulin delivery is stopped.

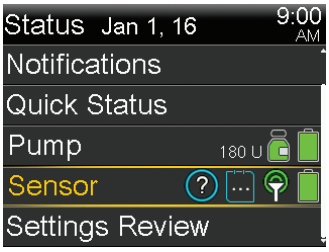
Suspend before low or **Suspend on low** is on but unavailable. This can be due to a recent suspend or when no SG values are available.

Sensor status

You can go to the Sensor status menu to see, for example, when your next calibration is due, time left on your sensor, and battery life remaining on your transmitter.

1) From the Home screen, press ○.
2) Select **Status**.
3) Select **Sensor**.

You will also see additional sensor status information in **Notifications**, **Quick Status**, and **Settings Review** screens.



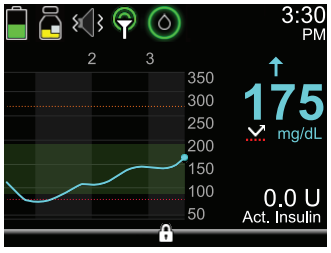
Current sensor value

The most current sensor reading is displayed on the Home screen. This is updated every 5 minutes. The sensor reads glucose values from 40 mg/dL to 400 mg/dL.

Note: One, two or three trend arrows may sometimes appear above the SG reading. These give you insight on the speed and direction that your sensor glucose is moving. See *"Trends" on page 3* to review these arrows.

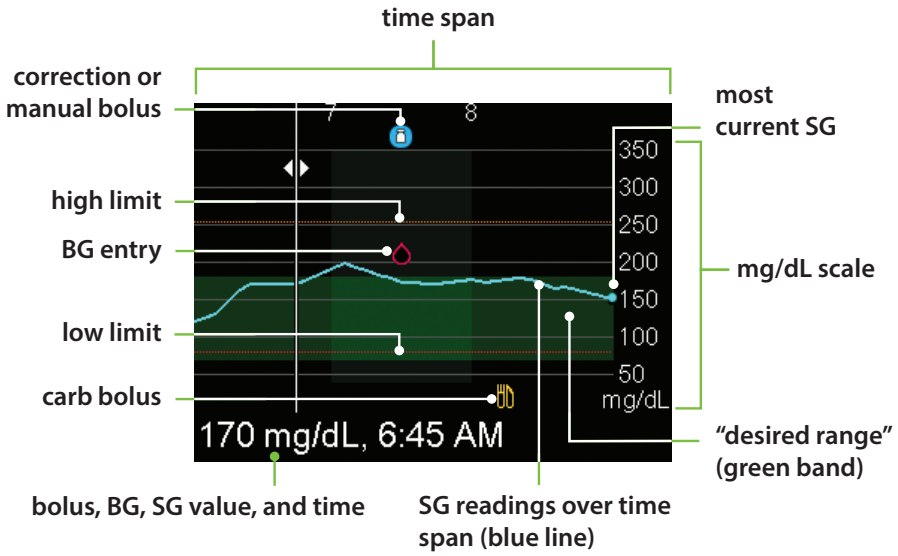
Sensor graph

A graph that shows the last 3 hours of sensor glucose readings is displayed on the Home screen. Your high glucose limit entered in your sensor settings will be shown in orange, and your low glucose limit will be shown in red.



Additional sensor graphs

In addition to the 3-hour graph, you can also view 6-hour, 12-hour, and 24-hour glucose trend graphs.



The graph shows a range of SG values from 40 mg/dL to 400 mg/dL. The green band across the screen represents an SG range from 70 mg/dL to 180 mg/dL. The blue line shows your actual SG values over the time span. At the right end of the blue line is a blue dot representing the most current SG value.

Details about correction bolus, BG entry, and meal (carb) bolus are shown on the graph. To locate details for an icon, look for the icon on the graph, and press ◁ or ▷ to scroll to that icon. The details for that icon are located along the bottom of the screen. Icons shown on the graph are:

- – indicates either a correction bolus or manual bolus
- – indicates a BG entered either manually or using a meter
- – indicates a bolus that includes a carb entry; it displays for a carb only or a carb plus correction bolus

Press ◁ or ▷ to cycle through the time span. The SG values and times, BG readings and times, and Bolus amounts display along the bottom of the screen.

A bolus amount followed by an (N) indicates a normal bolus delivered through the bolus feature. A BG entry is labeled BG, for example: BG, 121 mg/dL, 12:30pm. An SG is displayed with the value and time only, for example: 121 mg/dL, 12:35pm.

Press △ or ▽ to change the time span shown on the graph. The choices are 3 hours, 6 hours, 12 hours, and 24 hours.

To access these graphs:

1) From the Home screen, press .
2) Press to scroll back over the graph. Sensor values will be shown at the bottom of the graph.
3) Press to see the 6-hour, 12-hour and 24-hour graphs.
4) Press to return to the Home screen.

Section 9: Sensor alerts and suspend

Receiving alerts is an important part of wearing CGM. We discussed some of these alerts earlier in *"Section 4: Personalized alerts" on page 4*. There are other alerts that you will receive as well.

When a sensor alert or low management insulin suspend occurs:

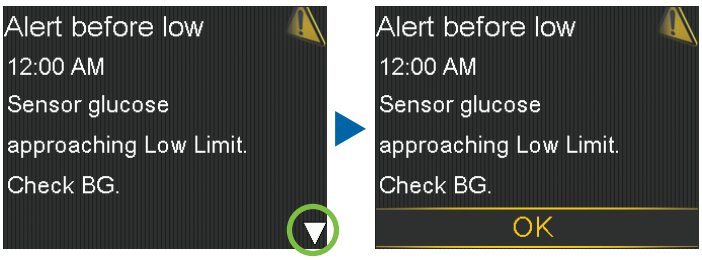
- the notification light will flash.
- the pump will beep or vibrate or both depending on your Audio Options setting.
- the pump will display a message describing what is occurring.

Follow these steps when you receive an alert:

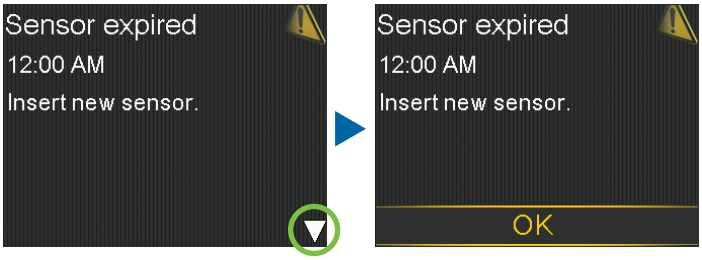
1. Read the text on the screen. Take any action necessary.
2. Press ⌄.
3. Press ○ on the desired option.

Sensor alerts

This is an example of the **Alert before low** alert message.



This is an example of the **Sensor expired** alert message.

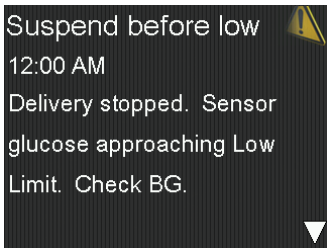


A table of the most common alerts that you can expect to receive when using CGM can be found in *Training handouts on pages 50 and 51*.

SmartGuard: low management suspend

Suspend before low

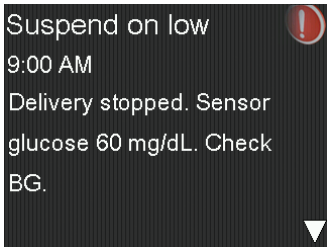
When **Suspend before low** occurs, this alert message will be displayed. Notice insulin delivery has been stopped. Press ◡ and ○ to clear. Insulin will remain suspended. If **Alert before low** is on, the pump will beep and/or vibrate every minute until cleared. If the alert is not cleared in 10 minutes, the pump will begin to siren.



Note: If sensor glucose still reaches the low limit, you will receive an **Alert on low** to notify you.

Suspend on low

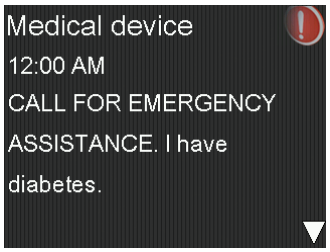
When **Suspend on low** occurs, you will receive this alarm message. Notice insulin delivery has stopped. The pump will continue to beep and/or vibrate every minute for 10 minutes until you press ◡ and ○ to clear the alarm.



If the **Suspend on low** alarm is not cleared after 10 minutes:

- The pump will begin to siren.
- This emergency message will appear on the pump screen.

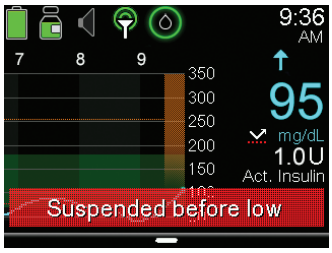
Insulin will remain suspended for a maximum of 2 hours.



Suspended by sensor Home screen

After the **Suspended before low** or **Suspended on low** message is cleared and insulin delivery has stopped, the Home screen will display:

- **Suspended before low** or **Suspended on low** at the bottom of the screen in a red banner.
- A shaded area on the graph to represent the time when insulin has been suspended.
- A flashing SmartGuard low management suspend icon.



Resuming basal insulin

There are two ways insulin can be restarted when a low management suspend is active: automatic and manual resume.

Automatic basal resume

Basal rates will automatically resume if:

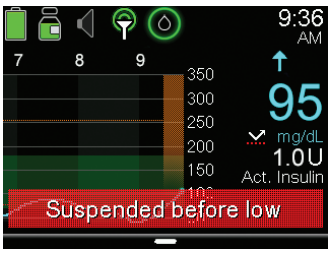
- SG values are above the low limit and are trending upward. If you have the **Resume basal alert** on, you will be alerted when this occurs.
- Insulin has been suspended for the maximum of 2 hours. You will always receive a message and be alerted when this occurs.

Note: Any bolus that was delivering at the time the suspend occurred will not restart when insulin delivery resumes. The basal pattern active at the time the suspend occurred will restart when insulin delivery is resumed. If a Temp Basal was running, the Temp Basal will resume if there is still time remaining.

Manual basal resume

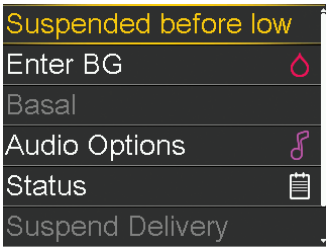
There may be times when you choose to resume basal insulin delivery yourself. Perhaps your healthcare professional has advised you to eat carbohydrates to bring your glucose level up, and does not want insulin to continue to be suspended. You can take these steps to resume basal delivery:

1) From the Home screen, press ○.



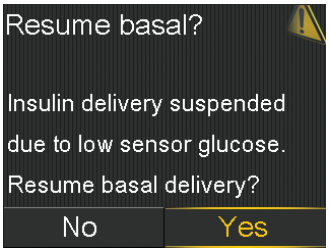
2) Select **Suspended before low** or **Suspended on low**.

*The example to the right shows how to resume a **Suspended before low.***



3) Select **Resume Basal**.

4) Select **Yes**.



Low management suspend features unavailable

SmartGuard low management suspend features will be unavailable for a period of time after basal delivery has been resumed following a Suspend on low or Suspend before low event.

The amount of time that low management suspend features will be unavailable is determined by the following:

Unavailable for 30 minutes if any of the following occurs:

- You have manually resumed the basal insulin
- Basal insulin is automatically resumed based on the SG
- You have responded to the alert, and the suspend reaches the 2 hour maximum suspend time

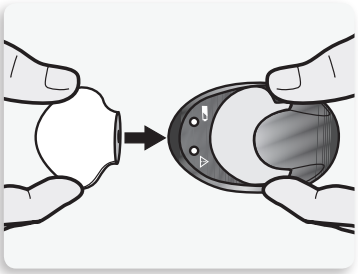
Unavailable for 4 hours if all of the following occur:

- SG has reached the low limit
- You did not respond to the alert
- Basal insulin was suspended for the 2 hour maximum suspend time

Note: If the alert is cleared during the 4 hour unavailable period, the low management suspend feature will be available after 30 minutes has passed.

Section 10: Charging and storing the Guardian Link transmitter

Charge the transmitter before each use. When the transmitter is charging, a green light will flash on the charger. When charging is complete, the green light on the charger will stay on, without flashing, for 15 to 20 seconds and then turn off. You will need to charge the transmitter after each sensor use. A fully charged transmitter can be used for a maximum of seven days without recharging. It can take up to two hours to fully recharge.



When you remove the transmitter from the charger, a green light should flash on the transmitter. This indicates that it has enough battery power to be connected to the sensor. If you do not see the green flashing light on the transmitter, place it back on the charger until it is fully charged.

Store the transmitter, charger, and test plug in a clean, dry location at room temperature. Although not required, you may store the transmitter on the charger.

CAUTION: The transmitter must be charged every 60 days. Do not store the transmitter on the charger for more than 60 days. Otherwise, the transmitter battery will be permanently damaged. Disconnect and reconnect to the charger to re-charge again before use.

If you connect your transmitter to the charger and you see no lights on the charger: Replace the battery in the charger. If there are still no lights on the charger after replacing batteries, the transmitter pins may be damaged. Contact the 24 Hour Helpline.

While charging your transmitter, if you see a flashing red light on the charger: Replace the battery in the charger.

While charging your transmitter, if you see a mix of short and long flashing red lights on the charger: Charge the transmitter for one hour. If the red lights continue to flash, charge the transmitter for eight hours. If the red lights continue to flash after eight hours of charging, please call the 24 Hour Helpline.

Refer to your Guardian Link transmitter and charger User Guides for more information.

Section 11: Traveling by air

If you wear a CGM device, it is safe for use on commercial airlines. If questioned by airline personnel about the use of your device, please show them your airport information card. If they still request that you turn off your CGM device, you must comply. The transmitter cannot be turned off. It can be put on Airplane Mode.

If you need to temporarily stop wireless communication during the flight:

1) Press ⊙.
2) Select **Options**.
3) Select **Utilities**.
4) Select **Airplane Mode**.
5) Select **Airplane Mode** to turn **On**.
6) Select **Save**.

The transmitter continues to measure glucose levels when in Airplane Mode.

To resume wireless communication:

1) Press ⊙.
2) Select **Options**.
3) Select **Utilities**.
4) Select **Airplane Mode**.
5) Select **Airplane Mode** to turn **Off**.
6) Select **Save**.

When Airplane Mode is turned off and communication resumes, the transmitter will send up to 10 hours of sensor data to your pump.

If Airplane Mode was on for fewer than six hours:

1) Wait 15 minutes for sensor data to appear on pump screen.

If Airplane Mode was on for more than six hours:

1) Disconnect transmitter from sensor and then reconnect it.
2) Select **Reconnect Sensor** when it appears on the pump screen to begin sensor warm-up.
3) The sensor data (up to 10 hours) will appear on the pump.
4) You will be asked to calibrate in up to 2 hours to resume sensor readings.

It is important to be extra attentive to monitoring your glucose levels while traveling. Always be prepared to respond to changes in glucose if needed.

Section 12: X-rays, MRI, or CT scan

WARNING: Do not expose your pump to MRI equipment, diathermy devices or other devices that generate strong magnetic fields (for example, x-ray, CT scan, or other types of radiation). The strong magnetic fields can cause the devices to malfunction, and result in serious injury. If your pump is exposed to a strong magnetic field, discontinue use and contact the 24 hour HelpLine for further assistance. Magnetic fields, and direct contact with magnets, may affect the accurate functioning of your system, which may lead to health risks such as hypoglycemia or hyperglycemia.

Cannula infusion sets such as the Quick-Set®, Silhouette® and Mio® can be left in place during the procedure. However, infusion sets that use a needle instead of a cannula to infuse insulin such as the Sure-T®, must be removed prior to the procedure.

Do not expose your sensor or transmitter to MRI equipment, diathermy devices, or other devices that generate strong magnetic fields. Exposure to a strong magnetic field has not been evaluated and can cause the device to malfunction, result in serious injury, or be unsafe. If your sensor or transmitter are inadvertently exposed to a strong magnetic field, discontinue use and contact the 24 Hour HelpLine for further assistance.

Training handouts

This section contains handouts that you can use during or after your training.

- The **Quick Reference Guide for sensor alerts** provides information about alerts that you might receive.
- The **Quick Reference Guide for using the One-press serter with Guardian sensor** reminds you of the steps to take when inserting a new sensor.
- **SmartGuard low management suspend features** provides further details about the low management suspend features.

Feel free to remove these handouts and keep them in a place where they are easily accessible.

Sensor Alerts

This table shows some of the most common alerts that you may receive when using CGM.

Note: To silence an alert, press ⌄, and then press ○ on the desired option.

Alert	Reason	Steps to take
Alert on high	Sensor glucose value is equal to or higher than the high limit that you set.	Do not treat your glucose based on SG. Confirm it using your BG meter. Treat if necessary based on instructions from your healthcare professional and continue to monitor.
Alert on low	Sensor glucose value is equal to or lower than the low limit that you set.	Do not treat your glucose based on SG. Confirm it using your BG meter. Treat if necessary based on instructions from your healthcare professional and continue to monitor.
Alert before high	Sensor glucose reading is expected to reach the high glucose limit in the length of time you set for the Time before high.	Do not treat your glucose based on SG. Confirm it using your BG meter. Treat if necessary based on instructions from your healthcare professional and continue to monitor.
Alert before low	Sensor glucose reading is expected to reach the low glucose limit within 30 minutes.	Do not treat your glucose based on SG. Confirm it using your BG meter. Treat if necessary based on instructions from your healthcare professional and continue to monitor.
Rise Alert	Sensor glucose reading is increasing at a rate that is equal to or faster than the Rate Limit that you set.	Do not treat your glucose based on SG. Confirm it using your BG meter. Treat if necessary based on instructions from your healthcare professional and continue to monitor.

Quick Reference Guide for sensor alerts

Alert	Reason	Steps to take
Calibrate now	A calibration is needed in order to receive sensor glucose readings.	Enter BG value into your pump to calibrate.
Lost sensor signal	Communication between pump and transmitter has been lost for 30 minutes during or after warm-up.	Check that the sensor is still inserted in the skin and the transmitter and sensor are still connected. Move your pump closer to your transmitter.
Calibration not accepted	Your system was unable to use the BG meter reading you entered to calibrate your sensor.	In 15 minutes, your pump will prompt you to enter a new BG meter reading for calibration. Wash your hands and dry thoroughly before checking BG.
BG not received	The transmitter was unable to receive the calibration BG reading from the pump.	Move your pump closer to your transmitter and select OK. The pump will try sending the BG again.
Sensor expired	Sensor has reached its maximum usage of 7 full days.	Remove the sensor and follow the instructions for inserting and starting a new sensor.
Sensor updating	The sensor is updating.	Do not calibrate unless notified. This could take up to 3 hours.
Change sensor	You have received two Calibration not accepted alerts in a row.	Remove the sensor and follow the instructions for inserting and starting a new sensor.
Cannot find sensor signal	The pump has not received a signal from the transmitter.	Disconnect and reconnect your transmitter and sensor and select OK.

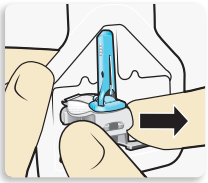
Quick Reference Guide for using the One-press serter with Guardian sensor

Inserting a new sensor

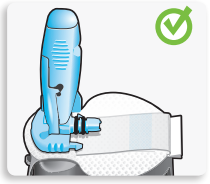
Wash your hands and clean insertion site with alcohol.

1. Open sensor package. Pull corner of paper covering to open sensor package.

2a. Hold sensor by plastic pedestal. Remove sensor with attached pedestal from packaging by holding pedestal only. Place sensor/pedestal on a clean, flat surface (such as a table).



2b. Tuck adhesive tab. Make sure that sensor's adhesive tab is tucked under sensor connector and snaps.



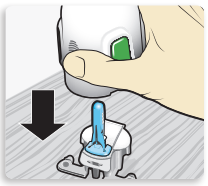
Correct

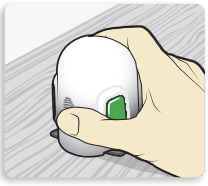
Incorrect

3. Load sensor into serter. Grip serter exactly as shown **with thumb on thumb print on serter. Do not hold the side buttons**. Push serter down onto pedestal until base of serter sits flat on table.

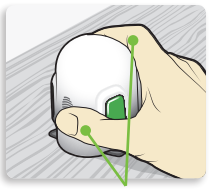
Correct

Incorrect

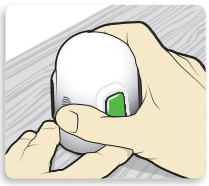


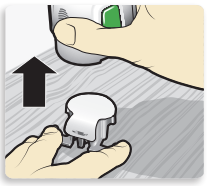


4. Detach serter from pedestal. To detach serter from the pedestal, grip serter as shown with thumb on thumb print on serter. With other hand, place two fingers on pedestal arms, and slowly pull serter straight up.



Fingers are NOT holding the side buttons.





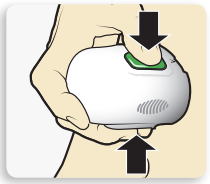
Note: Make sure that the pedestal is firmly on the table before pulling the serter away

CAUTION: Do not detach pedestal from serter in mid-air as this may damage the sensor.

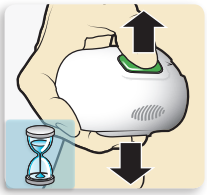
5a. Place serter on body. Hold serter steadily against your cleaned insertion site, without pushing serter too deeply into skin.

Note: Failing to hold serter securely flat against body may allow serter to spring back after pressing buttons and result in improper insertion of sensor.

5b. Insert sensor. Press and release **bump** on both buttons at same time.

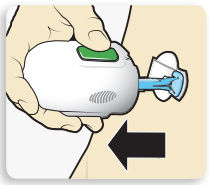


5c. Hold serter against body. Continue holding serter against body for at least five seconds to allow adhesive to stick to skin.

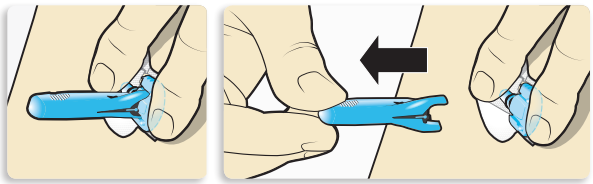


Quick Reference Guide for using the One-press serter with Guardian sensor

5d. Remove serter from body. Slowly pull serter away from skin, making sure buttons are not pressed.

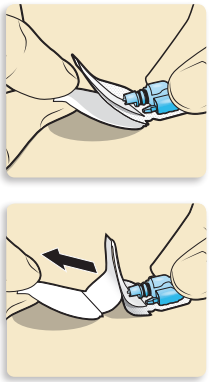


6. Remove needle housing. Gently hold base of sensor against skin with one hand. With other hand, hold needle housing **at top** and slowly pull it straight away from sensor. Dispose of needle housing in sharps container.

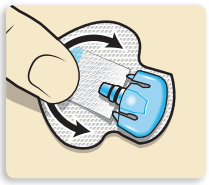


Note: Apply additional liquid adhesive. You may use an optional adhesive such as Skin Tac™ under the adhesive pad, prior to removing the liner. Allow it to dry.

7a. Remove adhesive pad liner. Hold sensor in place and gently remove adhesive liner from under adhesive pad.

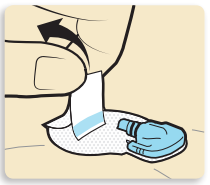


7b. Press entire adhesive pad to skin. Firmly press adhesive against skin and smooth entire adhesive pad so it sticks to skin.

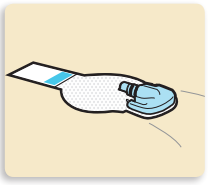


Note: The Guardian sensor adhesive is sensitive to pressure. Continue applying pressure on the adhesive to ensure that the sensor remains inserted in the skin for 7 days of wear.

8a. Untuck adhesive tab. Untuck adhesive tab from under sensor connector.

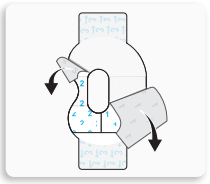


8b. Straighten adhesive tab. Straighten adhesive tab so it lies flat against your skin, but do not remove adhesive liner yet.

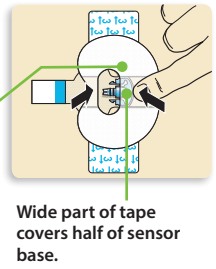


Taping your sensor

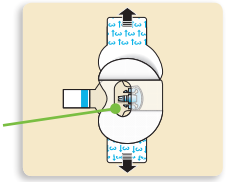
1. Remove liner 1 and liner 2.



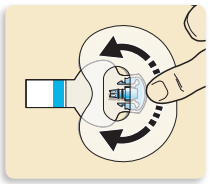
2. Apply tape as shown and press down firmly.



3. Remove liner 3 from each side.



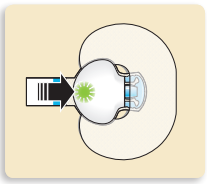
4. Smooth the tape.



Quick Reference Guide for using the One-press serter with Guardian sensor

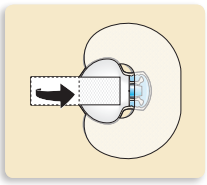
Connecting your transmitter

1. Connect the transmitter to the sensor.



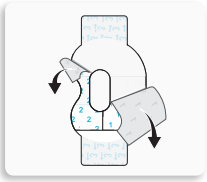
Note: Wait for green light on transmitter to flash. If green light does not flash, refer to Troubleshooting section of your transmitter user guide.

2. Remove liner from adhesive tab. Cover transmitter with adhesive tab.



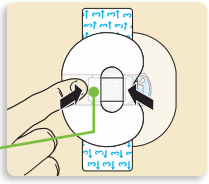
Note: Do not pull tab too tightly.

3. To apply 2nd tape, remove liner 1 and liner 2.

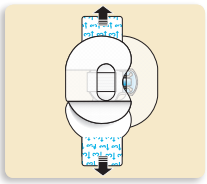


4. Rotate 2nd tape and place tape over transmitter. Press down firmly.

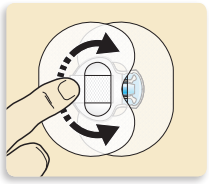
Wide part of tape covers end of transmitter and skin.



5. Remove liner 3 from each side.

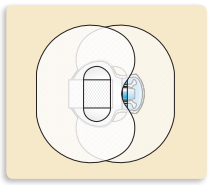


6. Smooth the tape.



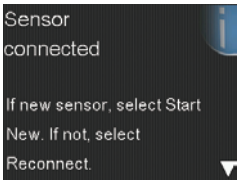
Note: Check your site regularly. Apply additional off-the-shelf tape if sensor and transmitter not secure.

7. This image is an example of Oval Tape applied correctly.

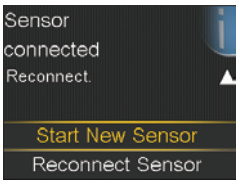


Starting the sensor

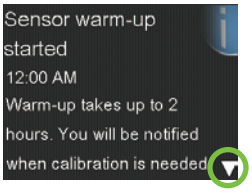
1. Once **Sensor connected** message appears, press ✓. *This typically takes less than a minute, but may take up to 10 minutes.*



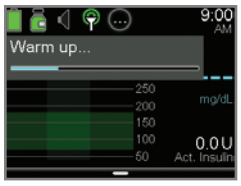
2. Select **Start New Sensor**.



3. The **Sensor warm-up started** message will appear. Press ✓ and then ○ to clear.



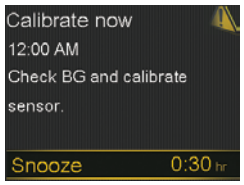
4. **Warm up...** will appear on the Home screen until sensor is ready for the first calibration.



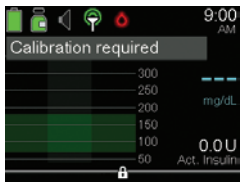
Quick Reference Guide for using the One-press serter with Guardian sensor

Calibrating

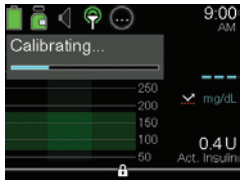
1. Select **Snooze**.



2. Pump will display this screen. Test BG and use to calibrate the sensor. See *"Calibration" on page 32* if you need help calibrating.

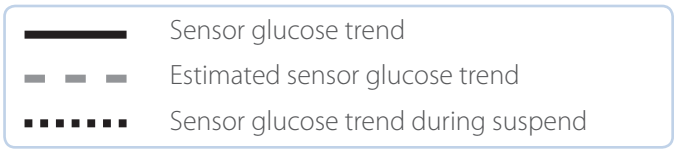


3. Once calibration BG is entered, this screen will display. You will begin receiving sensor glucose readings in 10 minutes.

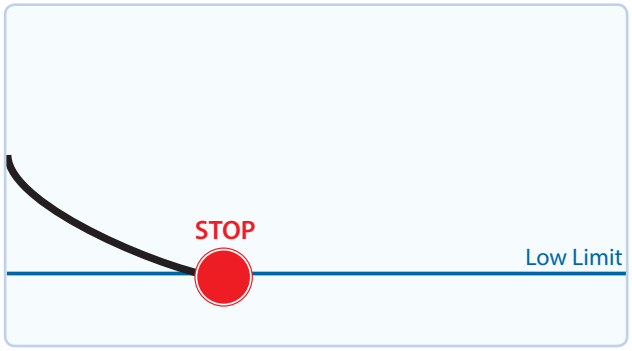


SmartGuard™ low management suspend features

The images below show additional detail about using the SmartGuard low management suspend features of your MiniMed® 670G System.



Suspend on low event:

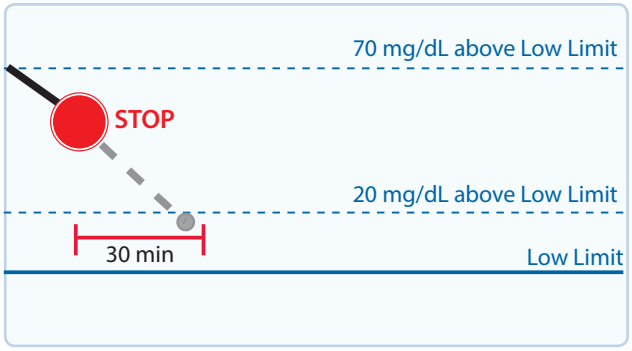


If sensor glucose (SG) reaches your low limit, insulin delivery will be stopped.

You will always receive a message and alarm when this occurs.

You will have 10 minutes to respond before the pump begins to siren and emergency message appears.

Suspend before low event:

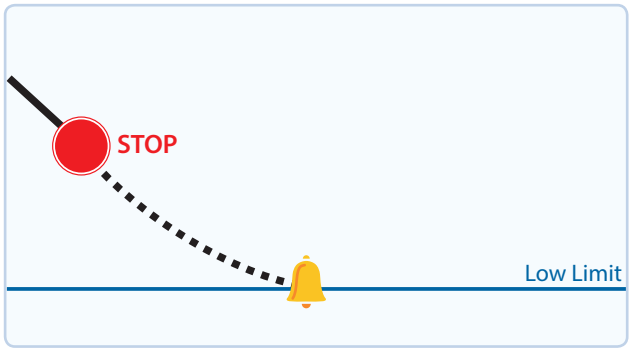


To help keep sensor glucose (SG) from reaching your low limit, insulin delivery will be stopped if SG is:

- At or within 70 mg/dL above the low limit.
- Predicted to be approaching the low limit in 30 minutes.

If **Alert before low** is on, you will receive an alert when insulin is suspended.

Alert on low during **Suspend before low**:



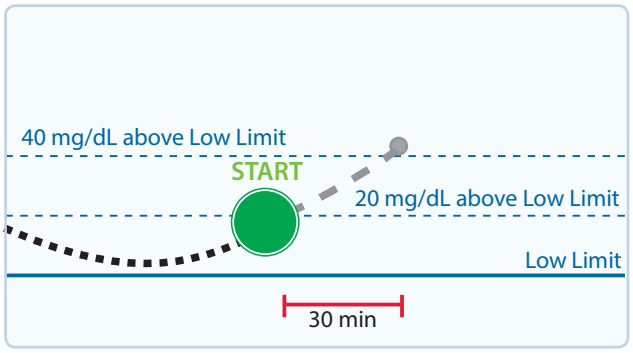
If insulin delivery has stopped due to **Suspend before low**, SG may still reach your low limit.

You will always be alerted when this occurs.

You will have 10 minutes to respond before the pump begins to siren and emergency message appears.

SmartGuard™ low management suspend features

Automatic basal resume based on sensor glucose (SG) value:

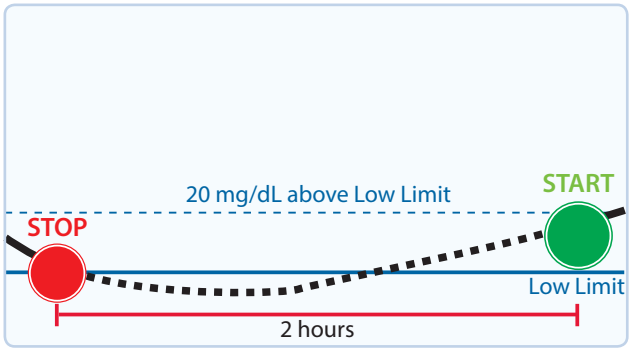


During **Suspend before low** or **Suspend on low**, basal insulin will automatically resume if:

- SG is above the low limit and trending upward.
- Insulin has been suspended by low management for at least 30 minutes.

If **Resume basal alert** is on, you will receive an alert when this occurs. Remember, you can manually resume basal insulin at any time.

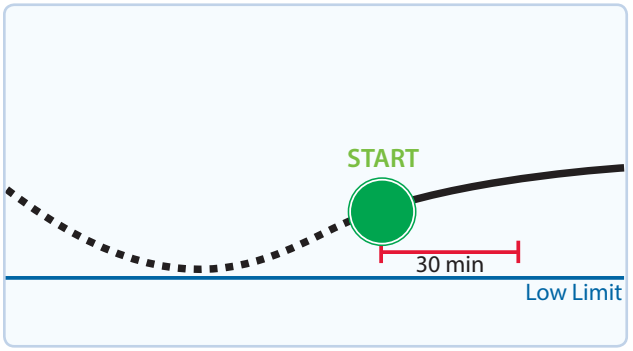
Automatic basal resume due to 2 hour maximum suspend:



During either **Suspend before low** or **Suspend on low**, if basal insulin is not resumed due to SG values, it will automatically resume after 2 hours.

You will always receive an alert when you reach the 2 hour maximum suspend time, even if the **Resume basal alert** is set to Off. Remember, you can manually resume basal insulin at any time.

Low management suspend unavailable:



Once basal insulin resumes following either **Suspend before low** or **Suspend on low**, there will be a period of time when low management suspend is unavailable.

This will most often be 30 minutes if you respond to the suspend alarm, but can be up to 4 hours. See *Suspend before low* in your insulin pump user guide for more specific information about this unavailable period.

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818 576 5555
www.medtronicdiabetes.com

℞ *Only*

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6026133-014_1

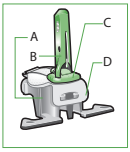
Guardian™ Sensor (3)

User Guide

Medtronic

Introduction

The Guardian™ Sensor (3) glucose sensor is part of your Continuous Glucose Monitoring (CGM) system. The sensor continuously converts tiny amounts of glucose from the interstitial fluid under your skin into an electronic signal. Your system then uses these signals to provide sensor glucose values.



A. pedestal
B. needle housing
C. sensor
D. clear liner

Potential risks related to sensor use

General risks with sensor use include:

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

Indications for use

The Guardian™ Sensor (3) is intended for use with the Medtronic MiniMed™ 630G, MiniMed™ 670G, and Guardian™ Connect systems to continuously monitor glucose levels in persons with

diabetes. It is intended to be used for detecting trends and tracking patterns, and to be used by the MiniMed™ 670G system to automatically adjust basal insulin levels.

The Guardian Sensor (3) is approved for use with each of the following Medtronic systems by persons of the following ages:

System	Indicated Age
MiniMed 670G	7 and above
Guardian Connect MiniMed 630G	14 and above

The Guardian Sensor (3) is indicated for use as an adjunctive device to complement, not replace, information obtained from standard blood glucose monitoring devices. The sensor is intended for single use and requires a prescription. The Guardian Sensor (3) is indicated for 7 days of continuous use.

Contraindications

None known.

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
Website	www.medtronicdiabetes.com

General warnings

Read this entire user guide before attempting to insert the sensor. The one-press serter (MMT-7512) does not work the same as other Medtronic™ insertion devices. Failure to follow directions or using a different serter may result in improper insertion, pain, or injury.

The Guardian™ Sensor (3) was developed, and its performance evaluated, for use with the approved system only. The sensor should not be used as part of unapproved systems, as it may provide inaccurate sensor glucose readings.

The sensor is designed to work with approved transmitters only. It is not interchangeable with transmitters and recorders that are not compatible with the sensor. Connecting your sensor to a transmitter or recorder that is not approved for use with the sensor

may cause damage to the components or inaccurate sensor glucose values.

Do not make therapy decisions based on sensor glucose values because sensor glucose (SG) and blood glucose (BG) values may differ. If your sensor glucose reading is low or high, or if you feel symptoms of low or high glucose, confirm your blood glucose with your meter using a fingerstick blood sample prior to making therapy decisions.

Taking medications with acetaminophen, such as Tylenol™*, fever reducers, or cold medicine, while wearing the sensor may falsely raise your sensor glucose readings. The level of inaccuracy depends on the amount of acetaminophen active in your body and may be different for each person. Always check the label of any medications to confirm whether acetaminophen is an active ingredient.

Do not expose your sensor to MRI equipment, diathermy devices, or other devices that generate strong magnetic fields as the performance of the sensor has not been evaluated under those conditions and may be unsafe. If your sensor is inadvertently exposed to a strong magnetic field, discontinue use and contact the 24 Hour HelpLine for further assistance.

A retractable needle is attached to the sensor, and minimal blood splatter may occur. If you are a healthcare professional or caregiver, wrap sterile gauze around the sensor to minimize contact with blood. Keep as much distance as possible between you and the patient when removing the needle.

Keep the needle housing within sight at all times to avoid an accidental needlestick or puncture.

Always inspect the packaging for damage prior to use. Sensors are sterile and non-pyrogenic, unless the package has been opened or damaged. Do not use the sensor if the sterile package has been opened or damaged. Use of an unsterile sensor can cause site infection.

This product contains small parts and may pose a choking hazard for children.

Watch for bleeding at the insertion site (under, around, or on top of the sensor).

For MiniMed 670G Users Ages 7 - 13

The low sensor glucose alert functionality is distinct from the automated insulin dosing function of the 670G System. When used in Auto Mode, the MiniMed 670G System has been shown

to be safe and effective for its intended use in this population. However, do not rely solely on the use of a low sensor glucose (SG) value for “Alert on Low” or “Alert before Low” for alerts set at 50 mg/dL and 60 mg/dL. A low sensor glucose alert may not reflect the user’s true blood glucose at these levels, or may not alert. Do not ignore symptoms of low glucose. Always confirm your sensor glucose readings with your blood glucose meter, and treat according to the recommendations of your healthcare professional. Solely relying on these sensor glucose alerts and readings for treatment decisions could result in missing severe hypoglycemia (low blood glucose) events.

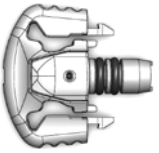
If bleeding occurs, do the following:

1. Apply steady pressure, using sterile gauze or a clean cloth placed on top of the sensor, for up to three minutes. The use of unsterile gauze can cause site infection.
2. If bleeding stops, connect the transmitter to the sensor.

   If bleeding does not stop, do not connect the transmitter to the sensor. This can allow blood to get into the transmitter connector, and could damage the device.

If bleeding continues, causes excessive pain or discomfort, or is significantly visible in the plastic base of the sensor, do the following:

1. Remove the sensor and continue to apply steady pressure until the bleeding stops. Discard the sensor in a sharps container.


plastic base

2. Check the site for redness, bleeding, irritation, pain, tenderness, or inflammation. Treat based on instructions from your healthcare professional.
3. Insert a new sensor in a different location.

General precautions

Wash your hands with soap and water before inserting the sensor to help prevent site infection.

Wear gloves when inserting the sensor into someone other than yourself to avoid contact with patient blood.

Do not insert the sensor through tape. Inserting the sensor through tape may cause improper sensor insertion and function.

Only use alcohol to prepare the insertion site, to ensure that residue is not left on the skin.

Rotate the sensor insertion site so that sites do not become

overused.

Discard used sensors and needle housings in a sharps container after each use to avoid accidental needlestick or puncture.

Do not clean, resterilize, or try to extract the needle from the needle housing. An accidental needlestick or puncture may occur.

Do not reuse sensors. Reuse of a sensor may cause damage to the sensor surface and lead to inaccurate glucose values, site irritation, or infection.

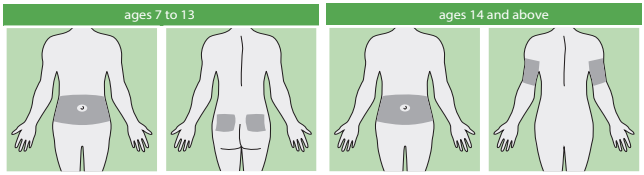
Where to insert the sensor

CAUTION: Avoid the 2 inch (5.0 cm) area around the navel to help ensure a comfortable insertion site and to help with sensor adhesion.

Choose an insertion site that has an adequate amount of subcutaneous fat. The Guardian Sensor (3) has been studied and is approved for use in the following sensor insertion sites by persons of the following ages:

Approved Age	Sensor Insertion Site
7 - 13	Abdomen and Buttock
14 and above	Abdomen and Arm

Shown below are the best body areas (shaded) for sensor insertion.



Note: Assistance will likely be needed for sensor insertion into the back of the upper arm and into the buttocks. Some users found it difficult to insert the sensor into their arm by themselves.

Do not insert the sensor in muscle or areas constrained by clothing or accessories, areas with tough skin or scar tissue, sites subjected to rigorous movement during exercise, or in sites under a belt or on the waistline for best sensor performance and to avoid accidental sensor removal.

Removing the sensor

When you are ready to change your sensor, disconnect the transmitter from the sensor as described in your transmitter user guide. Gently pull the sensor from your body to remove it. Place the sensor in a sharps container.

Reagents

The sensor contains two biological reagents: glucose oxidase, and human serum albumin (HSA). Glucose oxidase is derived from *Aspergillus niger* and manufactured to meet industry requirements for extraction and purification of enzymes for use in diagnostic, immunodiagnostic, and biotechnical applications. The HSA used on the sensor consists of purified and dried albumin fraction V, derived from pasteurized human serum which is cross-linked via glutaraldehyde. Approximately 3 µg of glucose oxidase and approximately 10 µg of HSA are used to manufacture each sensor. HSA is approved for IV infusion in humans at quantities much larger than in the sensor.

Storage and handling

CAUTION: Do not freeze the sensor, or store it in direct sunlight, extreme temperatures, or humidity. These conditions may damage the sensor.

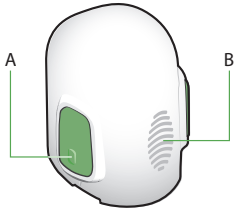
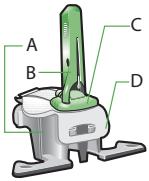
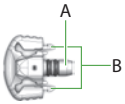
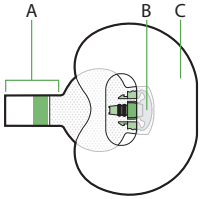
Only store sensors at room temperature between 36°F to 80°F (2°C to 27°C).

Discard sensor after the “Use by date” indicated on the label, if the package is damaged, or the seal is broken.

Sensor life

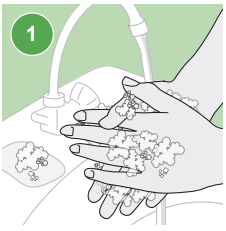
The sensor can be used one time, and it has a maximum life of 170 hours (seven days). The 170-hour life span of the sensor begins when the sensor is connected to the transmitter.

Components

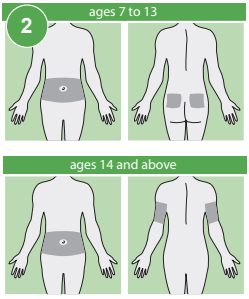
	One-press serter A. bump on both buttons B. thumbprint marking
	Glucose sensor assembly A. pedestal B. needle housing C. sensor D. clear liner
	Sensor base A. sensor connector B. sensor snaps
	Transmitter
	Tape and sensor components A. adhesive tab B. sensor base C. oval tape

Inserting the sensor

WARNING: Wear gloves when inserting the sensor into someone other than yourself to avoid contact with patient blood. Minimal bleeding may occur. Contact with patient blood can cause infection.



1. Wash your hands.



2. Choose an insertion site that has an adequate amount of subcutaneous fat. The Guardian Sensor (3) has been studied and is approved for use in the following sensor insertion sites by persons of the following ages:

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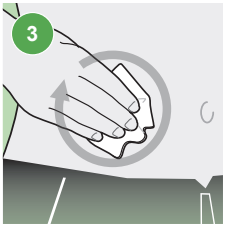
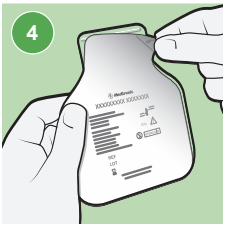
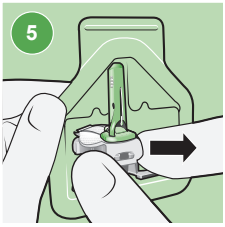
Note: Assistance will likely be needed for sensor insertion into the back of the upper arm and into the buttocks. Some users found it difficult to insert the sensor into their arm by themselves.



3. Clean the insertion site with alcohol. Let the area air dry.



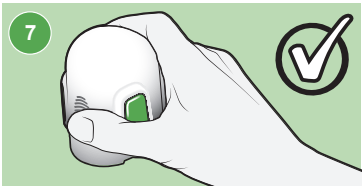
4. Open the sensor package.

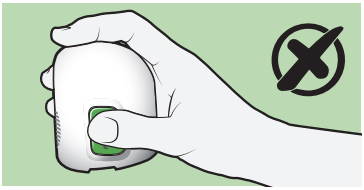


5. Hold the pedestal and remove the glucose sensor assembly from the package. Place the pedestal on a flat surface.

Note: The pedestal and glucose sensor assembly are the established definitions in the component table.

6. Make sure that the adhesive tab of the sensor is tucked under the sensor connector and sensor snaps.



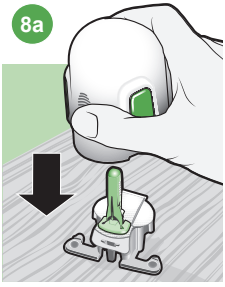


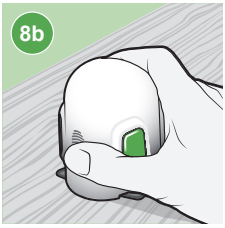
7. Holding serter correctly

Place your thumb on the thumbprint marking to hold the serter without touching the buttons.

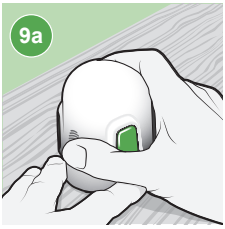
Holding serter incorrectly

Your fingers should not be touching the buttons.

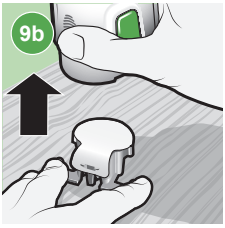




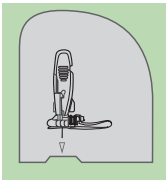
8a–8b. Grip the serter, placing your thumb on the thumbprint marking, **without holding the buttons**. Carefully push the serter down onto the pedestal until the base of the serter sits flat on the table and you hear a click.



9a. To detach the serter from the pedestal, place the thumb of one hand on the thumbprint marking and grip the serter **without touching any buttons**. With your other hand, place two fingers on the pedestal arms.

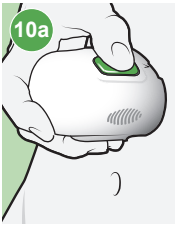


9b. Slowly pull the serter straight up without holding the buttons. Do not detach the pedestal from the serter in midair, as this might damage the sensor.



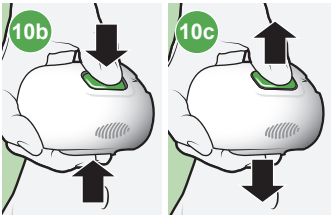
Note: The arrow on the side of the serter aligns with the needle inside the serter.

WARNING: Never point a loaded serter toward any body part where insertion is not desired. An accidental button-push may cause the needle to inject the sensor in an undesired location, causing minor injury.



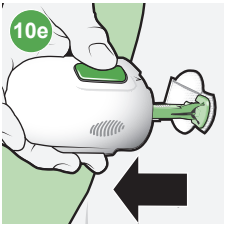
10a. Hold the serter steady against your cleaned insertion site, without pushing the serter too deeply into your skin.

Note: Failing to hold the serter securely flat against your body during insertion may let the serter spring back after pressing the buttons, and result in improper insertion of the sensor.



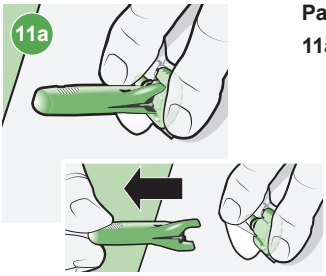
10b-10c. Press and release the bump on both buttons at the same time, while holding the serter flat against your body.

10d. Continue holding the serter flat against your body for at least five seconds to let the adhesive stick to your skin.



10e. Slowly lift the serter away from your body, making sure that the buttons are not pressed.

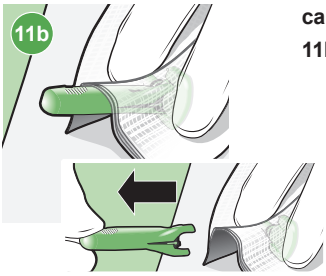
If you inserted the sensor into yourself, complete step 11a. If you are a healthcare professional or caregiver who inserted the sensor into a patient, complete step 11b.



Patient:

11a. Gently hold the sensor base against the skin at the sensor connector and the opposite end of sensor base. Hold the needle housing **at the top** and slowly pull straight out, away from the sensor.

OR

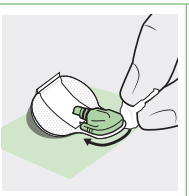


Healthcare professional or caregiver:

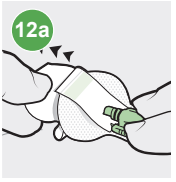
11b. Wrap sterile gauze around the sensor (as shown in image 11b). Gently hold the sensor base against the skin at the sensor connector and the opposite end of sensor base. Hold the needle housing **at the top** and slowly pull straight out, away from the sensor.

WARNING: Watch for bleeding at the insertion site. If bleeding occurs under, around, or on top of the sensor, apply steady pressure using sterile gauze or a clean cloth placed on top of the sensor for up to three minutes. The use of unsterile gauze can cause an infection. If bleeding does not stop, remove the sensor and apply steady pressure until the bleeding stops.

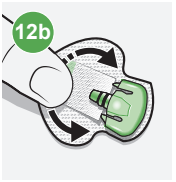
Note: Medtronic™ adhesives are pressure-sensitive. Pressing the adhesive against the skin ensures that the sensor remains adhered to the skin throughout the wear period.



Note: After insertion, use of adhesive products such as Skin Tac™* in addition to the tape is optional. If optional adhesive products are used, apply to the skin under the adhesive pad prior to removing the liner. It can also be applied to the adhesive pad or the skin around the sensor base. Allow for product to dry.

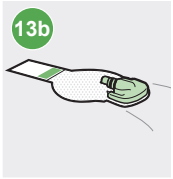


12a. Hold the sensor in place and gently remove the adhesive liner from under the adhesive pad. Do not remove the adhesive liner from the rectangular adhesive tab. This tab will be used to secure the transmitter in a later step.



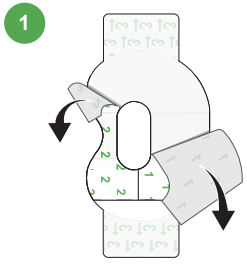
12b. Firmly press the adhesive pad against the skin to make sure that the sensor remains adhered to the skin.

13a. Untuck the adhesive tab from under the connector.

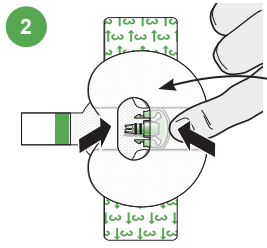


13b. Straighten the sensor adhesive tab so that it lies flat against the skin.

Applying Oval Tape

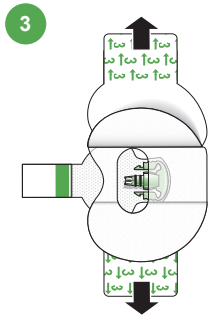


1. Remove liner 1 and liner 2.

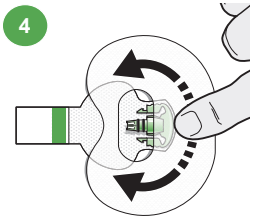


2. Apply the tape as shown and press it down firmly.

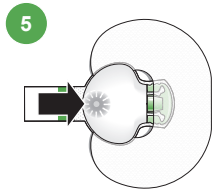
The wide part of tape covers half of sensor base.



3. Remove liner marked 3 from each side.

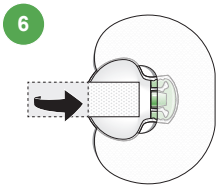


4. Smooth the tape.



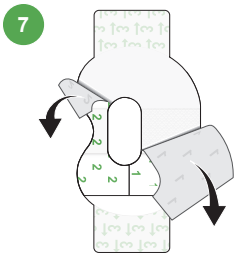
5. Connect the transmitter to the sensor.

Note: Wait for the green light on the transmitter to flash. If the green light does not flash, refer to the Troubleshooting section of your transmitter user guide.

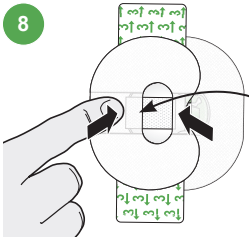


6. Cover the transmitter with the adhesive tab.

Note: Do not pull the tab too tightly.

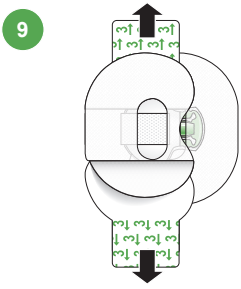


7. To apply a 2nd tape, remove liner 1 and liner 2.

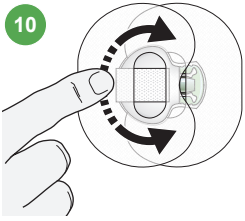


8. Apply the 2nd tape in the opposite direction to the first tape and place it on the transmitter. Press it down firmly.

Wide part of tape covers end of transmitter and skin.



9. Remove liner 3 from each side.



10. Smooth the tape.

Note: Be sure to regularly check your sensor site. If the device is not secure, apply an additional off-the-shelf adhesive.

11. For details on how to enter your sensor settings into your pump or mobile device, refer to the corresponding user guide.

Icon glossary

For a definition of the symbols on the device and package labels, see www.medtronicdiabetes.com/symbols-definitions

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For MiniMed™ 670G System Users Ages 7-13:

The low sensor glucose alert functionality is distinct from the automated insulin dosing function of the MiniMed™ 670G System. When used in Auto Mode, the MiniMed™ 670G System has been shown to be safe and effective for its intended use in this population. However, do not rely solely on the use of a low sensor glucose (SG) value for "Alert on Low" or "Alert before Low" for alerts set at 50 mg/dL and 60 mg/dL. A low sensor glucose alert may not reflect the user's true blood glucose at these levels, or may not alert. Do not ignore symptoms of low glucose. Always confirm your sensor glucose readings with your blood glucose meter, and treat according to the recommendations of your healthcare professional. Solely relying on these sensor glucose alerts and readings for treatment decisions could result in missing severe hypoglycemia (low blood glucose) events.

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