

MiniMed 780G

with Simplera Sync Sensor
System User Guide

Includes technology developed by **dreomed**
diabetes.ai

MiniMed™ 780G

System User Guide

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Icon table

	Follow instructions for use
	Caution: consult instructions for use for important warnings or precautions not found on the label
	Magnetic Resonance (MR) Unsafe
	Do not re-use
	Do not re-sterilize
	Do not use if package is damaged and consult instructions for use
	Single patient multiple use
	Importer
	Recyclable, contains recycled content
	Bluetooth® wireless technology or Bluetooth® enabled
	Single sterile barrier system
	Manufacturer
	Country of manufacture

	Date of manufacture (DoM)
	Open here
	Non-pyrogenic
	Do not dispose of this product in unsorted municipal waste stream
	Type BF applied part
	Use-by date
	Fragile, handle with care
	Keep dry
	Non-ionizing electromagnetic radiation
	RF Compliance Mark (RCM). Complies with ANZ radio-communications requirement.
	Humidity limitation
	Temperature limit
	Medical device

SN	Serial number
UDI	Unique Device Identifier
REF	Catalogue number
LOT	Batch code
EC REP	Authorized representative in the European Community/European Union
CH REP	Authorized Representative in Switzerland
STERILE EO	Sterilized using ethylene oxide
CE	Conformité Européenne (European Conformity). Device fully complies with applicable European Union Acts.
(1x)	One per container/package
IC	Complies with ISED Canada Radio Standards Specifications
IPX8	Protected against the effects of continuous immersion in water
RF	Identification number for global radio frequency certification

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Safety and indications

Safety and indications

This user guide describes the operation of the MiniMed™ 780G system with smart device connectivity and SmartGuard™ technology. SmartGuard technology adjusts insulin delivery based on sensor glucose (SG) values without the need to enter a blood glucose (BG) meter reading for confirmation. The MiniMed 780G insulin pump operates in Manual mode when the SmartGuard feature is not active.

The MiniMed 780G system is approved for use with the Simplerla Sync™ CGM (continuous glucose monitoring) device.

Consult a healthcare professional before starting insulin pump therapy.

Using this guide

Use the table of contents at the beginning of the user guide and the index at the end of the user guide to locate specific information.

Refer to the glossary for definitions of terms and acronyms used.

Conventions

Convention	Definition
Select	Press  to activate a screen item, accept a value, or initiate an action.
Select and hold	Press and hold  to perform an action.
Press	Press and release a button.
Press and hold	Press and hold a button.

Convention	Definition
Bold text	Indicates screen items and buttons, such as “Select Next to continue.”
X	Indicates a value that might appear differently on the pump screen.
Note	Note: A note provides helpful information.
Caution	 CAUTION: A caution informs of a potential hazard which, if not avoided, might result in minor or moderate injury, or damage to the equipment.
WARNING	 WARNING: A warning informs of a potential safety hazard which, if not avoided, may result in serious injury or death. It may also describe potential serious adverse reactions.

For instructions about setting up devices on the MiniMed 780G system, such as a sensor or infusion set, refer to the user guide for the related device.

Emergency kit

Keep an emergency kit available at all times and confirm that necessary supplies are available and not expired. Tell a family member or friend where to find the emergency kit.

When traveling, check blood glucose more frequently to accommodate for changes in activity levels and meal times.

Consult your healthcare professional on which of the following items to include in your emergency kit:

- Rapid-acting glucose
- Blood glucose (BG) testing supplies
- Urine or blood ketone monitoring supplies
- Extra infusion set and reservoir

- Extra new AA lithium or alkaline batteries, or fully charged NiMH batteries
- Insulin syringe
- Short-acting insulin, long-acting insulin, or both (with dosage instructions from a healthcare professional)
- Adhesive dressing
- Glucagon



WARNING: Do not use the Bolus Wizard feature 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. Using the Bolus Wizard feature too soon after a manual injection may result in over-delivery of insulin and may cause hypoglycemia. Consult a healthcare professional for how long to wait after a manual injection before using the Bolus Wizard feature.



WARNING: Do not use the SmartGuard feature 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. Using the SmartGuard feature too soon after a manual injection may result in over-delivery of insulin and may cause hypoglycemia. Consult a healthcare professional for how long to wait after a manual injection before using the SmartGuard feature.

User safety



WARNING: Do not use the MiniMed 780G system until appropriate training has been received from a healthcare professional. Training is essential to ensure the safe use of the MiniMed 780G system.

Intended use

The MiniMed 780G system is intended for use by patients 7 years and older with Type 1 diabetes, or patients 18 years and older with Type 2 diabetes, whose total daily dose of insulin is 8 units per day or more. The system is also intended to continuously monitor glucose values in the fluid under the skin. The MiniMed 780G system includes SmartGuard technology, which can be programmed to automatically adjust insulin delivery based on continuous glucose monitoring (CGM) sensor glucose values and can suspend delivery of insulin when the SG value falls below or is predicted to fall below predefined threshold values.

Do not use SG values to make therapy decisions while the pump is in Manual mode. SG values can only be used to make therapy decisions while the SmartGuard feature is active. These therapy decisions using SG refer only to boluses and Auto correction boluses while the SmartGuard feature is active. SG and BG values may differ. If the SG reading is low or high, or there are symptoms of low or high glucose, confirm the SG reading with a BG meter prior to making therapy decisions to avoid hypoglycemia or hyperglycemia.

The MiniMed 780G system is not intended to be used during pregnancy.

The MiniMed 780G system consists of the following devices:

- MiniMed 780G insulin pump
- Simplera Sync
- Accu-ChekTM* Guide Link blood glucose meter
- Accu-Chek Guide Test Strips



WARNING: Do not use the Suspend before low or Suspend on low features to prevent or treat low glucose. Always follow the instructions of a healthcare professional to treat low glucose. Using Suspend before low or Suspend on low features to prevent or treat low BG may result in prolonged hypoglycemia.

Treatment Decisions

Treatment decisions should be made based on all the information available, including the following:

- Glucose readings
- Trend arrows
- Glucose target ranges
- Active insulin
- Active alerts
- Recent activities such as medication, exercise, etc.

Simplera Sync sensor

The Simplera Sync sensor is intended for use with the MiniMed 780G system to monitor glucose levels for the management of diabetes.

The Simplera Sync sensor is intended for single use and is indicated for up to 7 days of continuous use.

The Simplera Sync sensor is not intended to be used directly to make therapy adjustments while the MiniMed 780G is operating in manual mode. All therapy adjustments in Manual mode should be based on measurements obtained using a blood glucose meter and not on values provided by the Simplera Sync sensor.



CAUTION: Do not use the sensor if there is a sudden rise in sensor temperature. When operating the sensor in air temperatures of 40 °C (104 °F), under certain fault conditions, the temperature of the sensor may briefly rise up to 50 °C (121 °F). If there is a sudden rise in temperature or the sensor becomes hot or uncomfortable, remove and discard the sensor.

The Simplera Sync sensor has been studied and is approved for use with the MiniMed 780G pump. For persons 7 years and older, sensor insertion is approved for the back of the upper arm.

Contraindications

The MiniMed 780G system is contraindicated for use in persons under age 7.

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

Insulin pump therapy is not recommended for persons who are unwilling or unable to perform BG meter readings.

The SmartGuard feature cannot be used for people who require less than eight units or more than 250 units of insulin a day.

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

Pump therapy is not recommended for people with a significant cognitive or physical impairment that affects their ability to safely operate the pump, including blindness, hearing impairment, or lack of physical dexterity.

Pump therapy is not recommended for children who are not under the care of a parent or caregiver who is capable of safely operating the pump for the patient.

Risks and side effects

Risks related to insulin administration and pump use

Risks related to insulin infusion and potential interruptions of insulin delivery include:

- Hypoglycemia
- Hyperglycemia
- Diabetic ketoacidosis
- Seizure
- Coma
- Death

Risks related to insulin pump infusion set

Risks related to insulin pump infusion set use include:

- Localized infection
- Skin irritation or redness
- Bruising
- Discomfort or pain
- Bleeding
- Irritation
- Rash
- Occlusions that may interrupt insulin delivery and lead to hyperglycemia and diabetic ketoacidosis

Follow the instructions in the provided user guides for the insertion and care of infusion sets. If an infusion site becomes irritated or inflamed, dispose of the infusion set in a sharps container, and select a different location to insert a new infusion set.

Risks related to sensor use

Risks related to sensor use include:

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

Specific risks related to sensor use

Do not use continuous glucose monitoring if hydroxyurea, also known as hydroxycarbamide, is taken. Hydroxyurea is used to treat certain diseases, such as cancer and sickle cell anemia. Hydroxyurea use results in higher sensor glucose readings compared to blood glucose readings. Taking hydroxyurea while using continuous glucose monitoring can result in hypoglycemia caused by over-delivery of insulin, inaccurate or missed

alarms and alerts, delay or loss of sensor-enabled insulin suspension, and substantially higher sensor glucose readings in reports than actual blood glucose readings.

Always check the label of any medication being taken to confirm if hydroxyurea or hydroxycarbamide is an active ingredient. If hydroxyurea is taken, consult a healthcare professional. Turn the Sensor feature off to disable continuous glucose monitoring. For more information, see *Deactivating the Sensor feature, page 181*. Use additional blood glucose meter readings to verify glucose levels.

Consult a healthcare professional if a medication that contains acetaminophen or paracetamol is taken while wearing the sensor. Medications that contain acetaminophen or paracetamol can falsely raise sensor glucose readings. The level of inaccuracy depends on the amount of acetaminophen or paracetamol active in the body and can differ for each person. Falsely elevated sensor readings can result in over-delivery of insulin, which can cause hypoglycemia. Medications that contain acetaminophen or paracetamol include, but are not limited to, cold medicines and fever reducers. Check the label of any medications being taken to see if acetaminophen or paracetamol is an active ingredient. Use additional blood glucose meter readings to confirm blood glucose levels.

If acetaminophen or paracetamol is taken, stop the use of the medication before using sensor glucose readings to make treatment decisions. Use additional BG meter readings to confirm BG levels. While the SmartGuard feature is active, if acetaminophen or paracetamol is taken, program a temp target for up to 8 hours, or the amount of time recommended by a healthcare provider. For more information, see *Setting a temp target, page 208*. Use blood glucose values instead of sensor glucose readings to calculate a meal bolus or correction bolus for up to 8 hours, or the duration recommended by a healthcare provider, after taking acetaminophen or paracetamol.

SG and BG values may differ. If symptoms do not match the SG value, use a BG meter to confirm glucose levels before making therapy decisions. Failure to confirm glucose levels when symptoms do not match the SG value can result in the infusion of too much or too little insulin, which may cause

hypoglycemia or hyperglycemia. If SG values continue to be different from symptoms, consult a healthcare professional.

Do not use SG values to make treatment decisions, including delivering a bolus, while the pump is in Manual mode. When the SmartGuard feature is active and you are no longer in Manual mode, the pump uses an SG value, when available, to calculate a bolus amount. However, if your symptoms do not match the SG value, use a BG meter to confirm the SG value. Failure to confirm glucose levels when your symptoms do not match the SG value can result in the infusion of too much or too little insulin, which may cause hypoglycemia or hyperglycemia. For more information on using CGM, see *Using CGM, page 183*. For more information on using the SmartGuard feature, see *SmartGuard, page 189*.

For persons 7 years and older, sensor insertion has been studied and is approved for the back of the upper arm. Do not insert the sensor into any other location.

Additional substances that may impact sensor glucose readings

- Gentisic acid
- L-Dopa
- Ascorbic acid
- Reduced glutathione
- Uric acid
- Methyldopa

Risks related to meter use

- For the most current risks, see the User's Manual that came with the device.

Risks related to the MiniMed 780G system

- Hypoglycemia
- Hyperglycemia
- Diabetic ketoacidosis

- Seizure
- Coma
- Death

Removing the pump for temporary storage

If there is a need or desire to remove the pump, use the following guidelines:

- Write down the current basal rates and use the Save Settings feature. For more information, see *Saving the settings*, page 219.
- Remove the battery. For more information, see *Storing the pump*, page 298.
- If the pump is disconnected for less than one hour, an insulin adjustment may not be required. If the pump is disconnected for more than one hour, consult a healthcare professional to determine an alternate method of insulin delivery.

General warnings

Pump

- Do not use the pump in the presence of anesthetic mixtures that include oxidizing agents such as oxygen or nitrous oxide. Exposure to these conditions may damage the pump and result in serious injury.
- Always use the fingertip for blood samples when entering a BG meter reading into the pump. All BG values are used for calibration. Do not use blood samples from the palm for BG values entered into the pump. The palm has not been studied for use with the SmartGuard feature and the performance of the system using such blood samples is not known.
- When the SmartGuard feature is active, SG readings are used to calculate basal insulin delivery and correction boluses. Do not use SG readings to make treatment decisions while the pump is in Manual mode. SG and BG values may differ.

The following circumstances may cause differences between SG readings and BG readings:

- Soon after eating or taking a bolus.
- During and after exercise.
- When glucose values are rapidly changing.
- When trend arrows appear on the Home screen.
- During the first day of use with a new sensor.
- After taking a medication that contains acetaminophen or paracetamol, which may falsely raise SG values.
- After taking a medication that contains hydroxyurea, which may falsely raise SG values.

Sensor performance may occasionally vary from sensor to sensor and in different situations for a sensor, such as on the first day of use.

A BG meter reading is required in the following situations:

- Before a correction bolus is given in Manual mode.
- The SG reading is lower than expected.
- The SG reading is higher than expected.
- Suspected hypoglycemia or symptoms of hypoglycemia.
- Suspected hyperglycemia or symptoms of hyperglycemia.
- Suspected diabetic ketoacidosis or symptoms of diabetic ketoacidosis.

Do not use SG readings to make treatment decisions while the pump is in Manual mode. If SG values continue to be different from symptoms, consult healthcare professional.

- The low SG alert functionality is distinct from the automated insulin dosing function of the MiniMed 780G system. When using the SmartGuard feature, the MiniMed 780G 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 the Low SG alarm, or the use of “Alert on Low” and

“Alert before Low” when those alerts are set at or below 3.4 mmol/L. At these BG levels, a low SG alarm or alert may not reflect the user’s true BG, and you may not be notified. Do not ignore symptoms of low glucose. Always confirm SG readings with a BG meter, and treat according to the recommendation of a healthcare professional. Solely relying on these SG alerts and readings for treatment decisions could result in missing severe hypoglycemia (low BG) events.

- Do not rely on the pump tones or vibrations to navigate the pump screens or menus. Relying on pump tones or vibrations may result in incorrect menu or setting selection. Always view the pump screen when selecting menus and entering information into the system.
- Only use compatible U-100 insulin (Admelog™*, Fiasp™*, Humalog™*, NovoLog™*, NovoRapid™*, and Trurapi™*) prescribed by a healthcare professional for use with an infusion pump. Use of any other drug or medication in the reservoir can cause serious injury.
- Confirm that the infusion set is disconnected from the body before rewinding the pump or filling the infusion set tubing. Never insert the reservoir into the pump while the tubing is connected to the body. Doing so may result in an accidental infusion of insulin, which may cause hypoglycemia.
- Do not insert the reservoir before rewinding the pump. Doing so may result in an accidental infusion of insulin, and may result in hypoglycemia.
- Do not use the MiniMed 780G insulin pump or additional system devices next to other electrical equipment, which may cause interference. This includes mobile communication devices such as cell phones that are not paired with the MiniMed 780G system, GPS navigation systems, anti-theft systems, and any electrical equipment that has an output transmitter power greater than 1 W. The recommended separation distance between the insulin pump and common RF emitters is 30 cm (12 in). For more information about recommended separation distance guidelines between the insulin pump and common RF emitters, see *Guidance and manufacturer’s declaration*, page 360. Other electrical

equipment that may compromise normal system operation has been contraindicated. For more information, see *Exposure to magnetic fields and radiation*, page 47.

- Do not unscrew or retighten the tubing connector on the reservoir while the infusion set is connected to the body. Doing so may result in an accidental infusion of insulin, and may cause hypoglycemia.
- Do not use Luer sets with the MiniMed 780G system. Only use MiniMed or Medtronic reservoirs and infusion sets that are specifically designed for use with the MiniMed 780G system.
- Do not change or modify the MiniMed or Medtronic reservoir and infusion set. Modification of these components may cause serious injury, interfere with device operation, and void the warranty.
- Do not rely on pump alerts, alarms, or reminders alone to check BG levels. Set additional reminders on other devices, such as a cell phone.
- Do not change or modify the internal RF transmitter or antenna. Doing so may interfere with the safe operation of the equipment.
- If other devices that employ radio frequencies are in use, such as cell phones that are not paired with the MiniMed 780G system, cordless phones, walkie-talkies, and wireless networks, they may prevent communication between the sensor and the insulin pump. This interference does not cause any incorrect data to be sent and does not cause any harm to devices. Moving away from, or turning off, these other devices may enable communication. Contact a local Medtronic support representative if RF interference continues.
- Special Precautions regarding Electromagnetic Compatibility (EMC): This body-worn device is intended to be operated within a residential, domestic, public or work environment, where common levels of radiated "E" (V/m) or "H" fields (A/m) exist. Technologies that emit these fields include: cellular phones that are not paired with the MiniMed 780G system, wireless technology, electric can openers, microwaves, and induction ovens. The MiniMed 780G system 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 the operation of the MiniMed 780G system. If interference occurs, move away from the RF transmitter.
- The MiniMed 780G insulin pump 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 MiniMed 780G insulin pump does cause interference to radio or television reception, try to correct the interference by one or more of the following measures:
 - Decrease the distance between the sensor and the insulin pump to 1.8 meters (6 feet) or less.
 - Decrease the distance between the meter and the insulin pump to 1.8 meters (6 feet) or less.
 - Increase the separation between the sensor and the device that is receiving/emitting interference.
- The safety of the MiniMed 780G system has not been studied in persons with impaired kidney function. Persons with kidney disease should consult a healthcare professional to determine if the potential benefits of pump therapy outweigh the risks.
- Monitor for diabetic retinopathy. During the beginning of insulin pump therapy, rapid improvement in glucose control and reduction in A1c may result in worsening of existing diabetic retinopathy. Use of the MiniMed 780G system has been associated with rapid improvement in glucose control. Monitor for diabetic retinopathy with retinal eye examinations and if necessary adequate treatment must be performed by a healthcare professional before beginning a treatment with the MiniMed 780G insulin pump.
- The SmartGuard feature has not been studied clinically during postpartum, including breastfeeding women with diabetes.

- The safety of using the Suspend before low and Suspend on low features in patients who have no pump experience is not known. The Suspend before low and Suspend on low features should not be used if insulin pump settings have not been previously established. Insulin pump settings include basal rates, insulin to carb ratio, and insulin sensitivity factors. Consult a healthcare professional before using the Suspend before low or Suspend on low features.
- If a serious incident related to the device occurs, immediately report the incident to a healthcare professional, Medtronic, or Health Canada. Serious incidents may include death, temporary or permanent serious decline in health, or a serious public health threat.
- The user must have adequate vision and hearing to recognize all functions of the pump, including alerts, alarms, and reminders. Not recognizing an alert, alarm, or reminder could result in a hypoglycemic or hyperglycemic event.
- Always monitor your blood glucose (BG) during air travel. Changes in air pressure that occur during flight takeoff and landing can cause over-delivery or under-delivery of insulin, which may result in hypoglycemia or hyperglycemia. Be ready to respond to alerts and symptoms. Talk with your healthcare professional to see if you need a different treatment plan in place.
- It is important to keep the location of your pump stable relative to your infusion site. Do not wear or place your pump more than 35.5 cm (14 in) above your infusion site. Doing so can cause an over-delivery of insulin, which may result in hypoglycemia.
- Always replace the batteries immediately when the Low Battery Pump alert sounds after a physical impact. Actions such as dropping or bumping the insulin pump against a hard surface can reduce the battery life. Failing to replace the batteries promptly could stop insulin delivery, potentially leading to hyperglycemia, which could be life-threatening.

Reservoir and infusion sets

See the user guides that came with the device for the most current warnings related to the reservoir and infusion set.

- If insulin, or any other liquid, gets inside the tubing connector, it can temporarily block the vents that allow the pump to properly fill the infusion set. This may result in the infusion of too little or too much insulin, and may result in hyperglycemia or hypoglycemia. If this occurs, start over with a new reservoir and infusion set.
- If a BG reading is unexpectedly high during the infusion of insulin or if an occlusion alarm occurs, check the infusion set for clogs and leaks. If in doubt, change the infusion set in case the soft cannula is dislodged, crimped, or partially clogged. Consult a healthcare professional to create a plan for rapid insulin replacement in the event this occurs. Check BG to confirm that the appropriate amount of insulin has been administered.
- Only use reservoir and infusion sets manufactured or distributed by Medtronic Diabetes. The pump has been tested to operate when used with compatible reservoirs and infusion sets. Medtronic Diabetes cannot guarantee appropriate operation if the pump is used with reservoirs or infusion sets offered by third parties. Medtronic Diabetes is not responsible for any injury or pump malfunction that may occur in association with the use of incompatible components.

Sensor

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

- Read the entire sensor user guide before attempting to insert the Simplera Sync sensor. The inserter portion of the sensor does not work the same way as other Medtronic insertion devices. The sensor is not inserted the same way as other Medtronic sensors. Failure to follow directions may result in improper insertion, pain, or injury.
- Do not use the Simplera Sync sensor adjacent to other electrical equipment that may cause interference with normal system operation.

For more information on electrical equipment that may cause interference with normal system operation, see the Exposure to magnetic fields and radiation section in the sensor user guide.

- Do not use continuous glucose monitoring if hydroxyurea, also known as hydroxycarbamide, is taken. Hydroxyurea is used to treat certain diseases, such as cancer and sickle cell anemia. Hydroxyurea use results in higher sensor glucose readings compared to blood glucose readings. Taking hydroxyurea while using continuous glucose monitoring can result in hypoglycemia caused by over-delivery of insulin, inaccurate or missed alarms and alerts, delay or loss of sensor-enabled insulin suspension, and substantially higher sensor glucose readings in reports than actual blood glucose readings.

Always check the label of any medication being taken to confirm if hydroxyurea or hydroxycarbamide is an active ingredient. If hydroxyurea is taken, consult a healthcare professional. Turn the Sensor feature off to disable continuous glucose monitoring. For more information, see *Deactivating the Sensor feature, page 181*. Use additional blood glucose meter readings to verify glucose levels.

- Consult a healthcare professional if a medication that contains acetaminophen or paracetamol is taken while wearing the sensor. Medications that contain acetaminophen or paracetamol can falsely raise sensor glucose readings. The level of inaccuracy depends on the amount of acetaminophen or paracetamol active in the body and can differ for each person. Falsely elevated sensor readings can result in over-delivery of insulin, which can cause hypoglycemia. Medications that contain acetaminophen or paracetamol include, but are not limited to, cold medicines and fever reducers. Check the label of any medications being taken to see if acetaminophen or paracetamol is an active ingredient. Use additional blood glucose meter readings to confirm blood glucose levels.

While the SmartGuard feature is active, if acetaminophen or paracetamol is taken, program a temp target for up to eight hours, or the amount of time recommended by a healthcare provider. For more information, see

Setting a temp target, page 208. Use blood glucose values instead of sensor glucose readings to calculate a meal bolus or correction bolus for up to eight hours, or the duration recommended by a healthcare provider, after taking acetaminophen or paracetamol.

- Always examine the Simplera Sync sensor box for damage. If the sensor box is open or damaged, examine the sensor for damage. If the sensor has visible damage, discard it to avoid possible contamination.
- Do not use the Simplera Sync sensor if any part of the device is damaged. If the device is damaged, discard the device to avoid possible contamination.
- Do not use the Simplera Sync sensor if the tamper band is broken, damaged, or is missing from the device. The sensor is sterile and non-pyrogenic unless the device is damaged. If the tamper band is broken, damaged, or is missing from the device, the sensor and needle can be exposed to contamination. A sensor and needle exposed to contamination can cause site infection if inserted into the body.
- Do not use the Simplera Sync sensor if the cap label is broken, damaged or missing from the device. The sensor is sterile and non-pyrogenic unless the device is damaged. If the cap label is broken, damaged, or missing from the device, the sensor and the needle can be exposed to contamination. A sensor and needle exposed to contamination can cause site infection if inserted into the body.
- Do not unscrew or remove the Simplera Sync sensor cap until the device is ready to be used. Do not remove the cap and store the device for future use. The sensor is sterile and non-pyrogenic unless the cap is removed from the device or the tamper band is broken. If the cap is not on the device or the tamper band is broken, the sensor and the needle can be exposed to contamination. A sensor and needle exposed to contamination can cause site infection if inserted into the body.
- Do not remove the cap and place it back on the device. Placing the cap back on the device could cause damage to the needle, prevent a successful insertion, and cause injury.

- Do not change or modify the Simplera Sync sensor. Changing or modifying the sensor can result in improper insertion, pain, or injury.
- Do not allow children to hold the Simplera Sync sensor without adult supervision. Do not allow children to put any part of the Simplera Sync sensor in their mouth. This product poses a choking hazard for young children that can result in serious injury or death.
- Watch for bleeding at the insertion site on top of the Simplera Sync sensor. If bleeding occurs, apply steady pressure with a sterile gauze pad or clean cloth placed on top of the sensor for up to three minutes. If bleeding continues, is significantly visible on top of the sensor, or if there is excessive pain or discomfort after insertion, follow these steps:
 1. Remove the Simplera Sync sensor and continue to apply steady pressure until the bleeding stops.
 2. Dispose of the Simplera Sync sensor. See the Disposal section in the sensor user guide.
 3. Check the site for redness, bleeding, irritation, pain, tenderness, or inflammation. If there is redness, bleeding, irritation, pain, tenderness, or inflammation, contact a healthcare professional.
 4. Insert a new Simplera Sync sensor in a different location.
- Some skin care products, such as sunscreens and insect repellents, can damage the Simplera Sync sensor. Do not allow skin care products to touch the sensor. Wash hands after using skin care products before touching the sensor. If any skin care products touch the sensor, immediately wipe the sensor with a clean cloth.
- Report any adverse reactions associated with the Simplera Sync sensor to a local Medtronic support representative. Adverse reactions can cause serious injury.
- The safety of sensor use in critically ill patients is not known. Sensor use in critically ill patients is not recommended.

Meter

For the most current warnings, see the User's Manual that came with the device.

Always use the fingertip for blood samples when entering a BG meter reading into the pump. All BG values are used for calibration. Do not use blood sample from the palm for BG values entered into the pump. The palm has not been studied for use with the SmartGuard feature and the performance of the system using such blood samples is not known.

Exposure to magnetic fields and radiation

- Do not expose the pump or sensor to MRI equipment, diathermy devices, or other devices that generate strong magnetic fields (for example, x-ray, CT scan, or other types of radiation). Strong magnetic fields can cause the system to malfunction, and result in serious injury. If the pump is exposed to a strong magnetic field, discontinue use and contact a local Medtronic support representative for further assistance. Magnetic fields, and direct contact with magnets, may affect the accurate functioning of the system which may lead to health risks such as hypoglycemia or hyperglycemia.
- Remove the pump, sensor, and meter before entering a room with x-ray, MRI, diathermy, or CT scan equipment. The magnetic fields and radiation in the immediate vicinity of this equipment can make the devices nonfunctional or damage the part of the pump that regulates insulin delivery, possibly resulting in over-delivery and severe hypoglycemia.
- Do not expose the 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.
- Do not send the pump or sensor through an x-ray scanning machine. The radiation can damage the pump components that regulate insulin delivery, and may result in over-delivery of insulin and hypoglycemia.

All system components, including the pump and sensor, must be removed prior to being screened with a full-body scanner. To avoid system removal, request an alternative screening method, if necessary.

- Carry the Medical emergency card provided with the device when traveling. The Medical emergency card provides critical information about airport security systems and pump use on an airplane. Not following the guidance on the Medical emergency card may result in serious injury.

General precautions

The pump does not notify the user of leaks in the infusion set or degradation of insulin. If BG is too high, check the pump and the infusion set to confirm that the necessary amount of insulin is being delivered.

Check for adverse reactions where the pump comes into contact with skin. These reactions include redness, swelling, irritation, sensitization, rash, and other allergic reactions. Do not allow the pump to come into contact with skin wounds, as the pump materials have only been evaluated for safe contact with intact skin.



Note: If you drop your pump, be sure to monitor your glucose levels for the next four hours.

Waterproof capabilities

- The pump is waterproof at the time of manufacture and when the reservoir and tubing are properly inserted. It is protected against the effects of being underwater to a depth of up to 2.4 meters (8 feet) for up to 30 minutes.
- 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 the pump is dropped or might be damaged, carefully inspect it to confirm that there are no cracks before exposing the pump to water.

- This waterproof capability rating applies only to the pump.
- If water may have entered the pump or other pump malfunction is observed, check BG and treat high BG as necessary using an alternative source of insulin. Contact a local Medtronic support representative for further assistance, and consult a healthcare professional about high or low BG levels or with any other questions about care.

Electrostatic discharge

- Very high levels of electrostatic discharge (ESD) can result in a reset of the pump's software and a pump error alarm. After clearing the alarm, confirm that the pump is set to the correct date and time, and that all other settings are programmed to the desired values. Following a pump reset, the SmartGuard feature may be unavailable for 5 hours to allow active insulin to be updated.
- For more information on pump alarms, see *Pump alarms, alerts, and messages*, page 305. Contact a local Medtronic support representative with any problems entering pump settings.

Extreme temperatures

Exposure to extreme temperatures can damage the device. Avoid the following conditions:

- Pump storage temperature above 50 °C (122 °F) or below -20 °C (-4 °F).
- Pump operating temperature above 37 °C (98.6 °F) or below 5 °C (41 °F).
- Insulin solutions freeze near 0 °C (32 °F) and degrade at temperatures higher than 37 °C (98.6 °F). In cold weather, wear the pump close to the body and cover it with warm clothing. In a warm environment, take measures to keep the pump and insulin cool.
- Do not steam, sterilize, autoclave, or otherwise heat the pump.

Skin care products

Some skin care products, such as lotion, sunscreen, and insect repellents, can damage the plastic in the pump case. After using skin care products,

wash hands prior to handling the pump. If a skin care product comes into contact with the pump, wipe it off as soon as possible with a damp cloth and mild soap. For instructions on cleaning the pump, see *Cleaning the pump*, page 297.

Infusion sets and sites, sensor, and meter

Refer to the corresponding device user guide for all warnings, precautions, and instructions relating to the device. Failure to reference the corresponding device user guide can result in minor injury, or damage to the device.

Adverse reactions

Refer to the sensor user guide for adverse reactions related to sensor use. Failure to reference the sensor user guide may result in minor injury, or damage to the sensor.

Cybersecurity

The MiniMed 780G insulin pump system is designed to help keep your information safe. It uses cybersecurity protections to make sure your data is secure, both in the pump and when communicating to other devices. These protections include things like encryption, integrity checks, and authentication checks. These safety features are already set up when you get your pump.

The MiniMed 780G insulin pump can notice when there is a security problem and will let you know if you need to take action. The pump uses Bluetooth®* Low Energy (BLE) to connect to other approved devices, like a CGM device or the MiniMed Mobile app. Refer to the user guides for these devices to learn how to keep them safe.

Medtronic will tell you when the pump reaches its end of life and when support will end. Medtronic will also let you know when new software for the pump is available.

To keep your MiniMed 780G insulin pump and your information safe, follow these guidelines:

- Connect your pump to other devices only in private places
- Only connect your pump to approved devices
- When connecting to a mobile device, make sure it is the intended device
- Do not leave your pump or CGM device unattended
- Do not share the serial number of your pump or CGM device
- Do not use a pump that is broken or has a cracked seal. A broken pump might not keep your data safe.
- Install new updates for your pump when they are available from Medtronic

If you have questions about keeping your pump safe, contact a local Medtronic support representative or visit www.minimed.com/security.

Insulin guidelines



WARNING: Do not insert an insulin-filled reservoir into the pump, or connect an insulin-filled infusion set into the body while training with the system. Doing so may result in the unintentional infusion of insulin, which may result in hypoglycemia. Start insulin therapy only when directed by a healthcare professional.

The MiniMed 780G system has been studied with, and is intended for use with, the following compatible U-100 insulins:

- U-100 Admelog
- U-100 Fiasp
- U-100 Humalog
- U-100 NovoLog
- U-100 NovoRapid
- U-100 Trurapi

The use of any other insulin in the MiniMed 780G system has not been tested and is contraindicated for use with this device.



WARNING: Only use compatible U-100 insulin (Admelog, Fiasp, Humalog, NovoLog, NovoRapid, and Trurapi), as prescribed by a healthcare professional, in the MiniMed 780G system. Use of the incorrect type of insulin, or insulin with a greater or lesser concentration may result in over-delivery or under-delivery of insulin, which may result in hypoglycemia or hyperglycemia. Consult a healthcare professional with any questions about the type of insulin that is compatible with the pump.

Consumables

The pump uses disposable, single-use MiniMed and Medtronic 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. Medtronic Diabetes cannot guarantee appropriate operation if the pump is used with reservoirs or infusion sets offered by third parties and therefore Medtronic Diabetes is not responsible for any injury or malfunctioning of the pump that may occur in association with such use.

- **Reservoirs**—If using a Medtronic Extended infusion set, use the Medtronic Extended reservoir MMT-342, 3.0 mL (300-unit). Otherwise, use the MiniMed reservoir MMT-332A, 3.0 mL (300-unit).

- **Infusion sets**–Contact a healthcare professional for help in choosing a Medtronic Diabetes infusion set. Change the infusion set per the duration of use in the infusion set user guide.

The following table lists the compatible infusion sets. The MMT numbers may change if other compatible infusion sets become available.

Type	MMT number
MiniMed Silhouette infusion set	MMT-368A600, MMT-377A600, MMT-378A600, MMT-381A600, MMT-382A600, MMT-383A600, MMT-384A600
MiniMed Quick-set	MMT-386A600, MMT-387A600, MMT-394A600, MMT-396A600, MMT-397A600, MMT-398A600, MMT-399A600
MiniMed Mio 30	MMT-905A600, MMT-906A600
MiniMed Mio Advance infusion set	MMT-242A600, MMT-243A600, MMT-244A600, MMT-213A600
MiniMed Sure-T infusion set	MMT-862A, MMT-864A, MMT-866A, MMT-874A
Medtronic Extended infusion set	MMT-430A, MMT-430AG600, MMT-430AH, MMT-430AJ, MMT-430AK600, MMT-431A, MMT-431AG600, MMT-431AH, MMT-431AJ, MMT-431AK600, MMT-432A, MMT-432AG600, MMT-432AH, MMT-432AJ, MMT-432AK600, MMT-433A, MMT-433AG600, MMT-433AH, MMT-433AJ, MMT-433AK600, MMT-440A, MMT-440AG600, MMT-440AH, MMT-440AJ, MMT-440AK600, MMT-441A, MMT-441AG600, MMT-441AH, MMT-441AJ, MMT-441AK600, MMT-442A, MMT-442AG600, MMT-442AH, MMT-442AJ, MMT-442AK600, MMT-443A, MMT-443AG600, MMT-443AH, MMT-443AJ, MMT-443AK600

Other MiniMed 780G system devices

- **Accu-Chek Guide Link meter**– The meter sends BG meter readings to the pump.

- **Simplera Sync sensor (MMT-5120)**–The sensor is a disposable, single-use device inserted just below the skin to measure glucose levels in interstitial fluid and collect the sensor data. The sensor wirelessly sends the collected sensor data to the pump or other compatible mobile device. This device is required for CGM. Change the sensor per the duration of use in the sensor user guide or when a Change sensor alert appears on the pump.

Optional items

The following items may be used with the MiniMed 780G system.

- **Pump clip**–The pump clip attaches to a belt and can be used to open the battery compartment.
- **Activity guard**–The activity guard helps to prevent the reservoir from being rotated or removed from the pump during physical activities.
- **MiniMed Mobile app (MMT-6101 for Android or MMT-6102 for iOS)**–The app provides a secondary display of insulin pump data and uploads system data to CareLink software. The app can check for eligible and available software updates for the pump. The Update pump feature in the app allows you to update the pump software remotely. The app can be installed on multiple mobile devices, but only one mobile device can be paired with the pump at a time.
- **CareLink Connect app (MMT-6111 for Android or MMT-6112 for iOS)**–The app can be downloaded onto compatible mobile devices from the app store. Refer to the app user guide for setup and operation within the app. This optional app is available to care partners to view patient therapy data and to be notified of selected patient alerts. This app does not replace the real-time display of insulin pump data on the primary display device. All therapy decisions should be based on the primary display device. Refer to the local Medtronic Diabetes website for information about supported devices and operating systems.

- **Blue Adapter**—The Blue Adapter uploads system data to CareLink software through a USB port on a computer. Refer to the CareLink software user guide for setup and operation of the Blue Adapter.

2

System overview

System overview

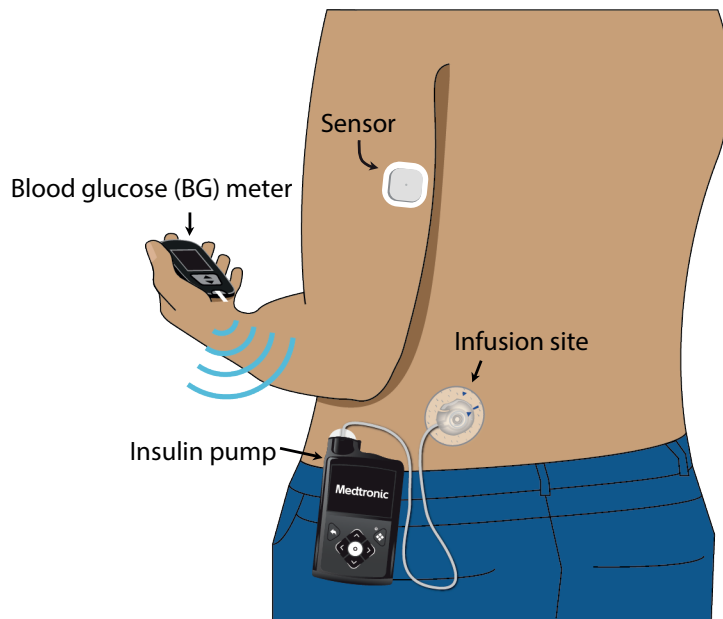
In this chapter, you will learn about the components of the system and some important concepts and terminology that you will need to understand when using the system.

What are the components of the MiniMed 780G system?

The following items are the main system components:

- **MiniMed 780G pump**—The pump delivers insulin into your body through the infusion set, based on the settings provided by your healthcare professional.
- **Infusion sets**—An infusion set connects to both the pump and your body. It carries the insulin as it is pushed out of the pump and delivers it.
- **Reservoirs**—The reservoir is filled with insulin and placed in the pump so that insulin can be delivered into your body through the infusion set.
- **Sensor**—The sensor measures glucose in the fluid under your skin and communicates with the pump through a wireless connection. The sensor makes up the continuous glucose monitoring (CGM) system.
- **Accu-Chek Guide Link meter**—Use this meter to measure the glucose in your blood. The meter sends this blood glucose (BG) information to your pump through a wireless connection.

The following diagram shows what the pump, meter, and sensor look like and how you may wear them on your body. A diagram later in chapter 3 will show you more details about the infusion set and reservoir.



Modes

Your pump operates in two different modes: Manual mode and SmartGuard mode (also called the SmartGuard feature).

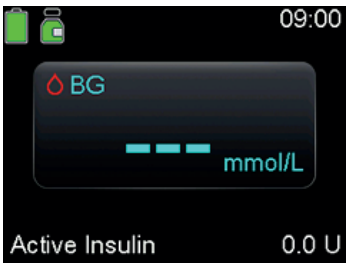
When you first use your MiniMed 780G insulin pump, it is in Manual mode.

Manual mode refers to a group of features that requires your input to deliver boluses for meals and to correct glucose levels. You may use Manual mode with or without CGM. When using CGM in Manual mode, you can see sensor glucose trends, receive low and high sensor glucose alerts, and suspend insulin delivery according to your settings.

After a few days of use in Manual mode, and at the direction of your healthcare provider, you can use SmartGuard. When in SmartGuard, the pump automatically adjusts and delivers basal insulin and can also deliver automatic correction boluses to regulate glucose levels to a target SG value. You will still need to enter carbs that you eat to deliver a food bolus.

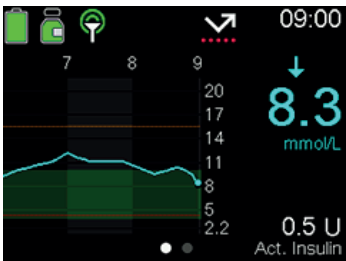
The following tables show the main features of Manual mode and SmartGuard. There are details on each of these topics throughout this guide.

Manual mode without CGM



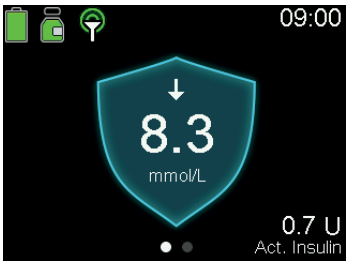
Bolus delivery	Basal delivery	Suspend
• Bolus Wizard calculates a bolus based on your settings - A blood glucose (BG) meter reading is needed for a correction bolus - A carb entry is needed for a food bolus • Manual bolus - You enter the number of units of insulin to cover food, high BG, or both	• Programmed basal delivery settings • A Temp basal rate can be used to temporarily increase or decrease basal insulin delivery	• Suspend all delivery - Choose this option to stop all delivery of insulin

Manual mode with CGM



Bolus delivery	Basal delivery	Suspend
Same as Manual mode without CGM	Same as Manual mode without CGM	- Suspend all delivery - Same as Manual mode without CGM - Suspend before low - Suspends insulin delivery and alerts based on your settings - Suspend on low - Suspends insulin delivery and alerts based on your settings

SmartGuard



Bolus delivery	Basal delivery	Suspend
- SmartGuard bolus feature delivers bolus insulin based on sensor glucose (SG) values and carb entries - A blood glucose (BG) meter reading may be required when a sensor glucose (SG) value	- The pump automatically delivers basal insulin based on recent insulin delivery needs, Sensor glucose (SG) values, and your glucose target - A Temp target can be set when less insulin	- Suspend all delivery - Same as Manual mode without CGM

Bolus delivery	Basal delivery	Suspend
does not appear on the Bolus screen - The bolus amount cannot be adjusted - The pump may automatically deliver an Auto Correction bolus to maximize the time in range.	is needed, such as for exercise	

Delivery settings

The delivery settings table describes whether or not each setting applies to the SmartGuard feature and Manual mode. Consult your healthcare professional before changing delivery settings.

Delivery setting	Impacts SmartGuard therapy	Impacts Manual mode
Active insulin time	Yes	Yes
Basal pattern and basal rates	No	Yes
BG target in Bolus Wizard	No	Yes
Bolus increment	No	Yes
Bolus speed	Yes	Yes
Carb ratio	Yes	Yes
Dual/Square Wave bolus	No	Yes
Insulin sensitivity factor	No	Yes
Max basal	No	Yes
Max bolus	No	Yes
Preset bolus	No	Yes
Preset temp	No	Yes

3

Pump basics

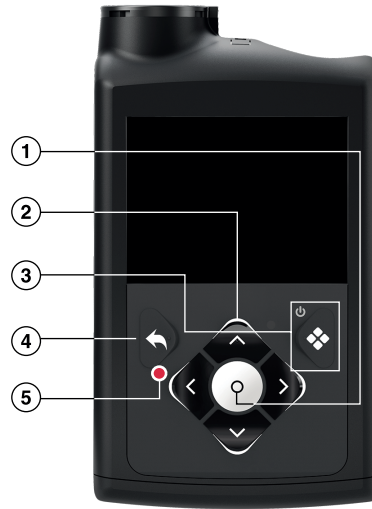
Pump basics

This chapter provides information about the basic features, buttons, and screens of the MiniMed 780G insulin pump.



CAUTION: Do not use sharp objects to press the pump buttons. The use of sharp objects can damage the pump.

Using the buttons



The following table describes the notification light and how to use the pump buttons.

Item	Description
①	Press to go to the Menu screen from the Home screen and to select a highlighted menu option.
②	Press or to scroll up or down, highlight an item on a screen, and to increase or decrease the value of a setting. Press or to move left or right on certain screens and to highlight the icons on the Menu screen.
③	Press to access the Graph screen. Press and hold to put the pump in Sleep mode.
④	Press to go back to the previous screen. Press and hold to return to the Home screen.
⑤	The notification light flashes when the pump has an alarm or alert. The notification light is not visible unless it flashes.

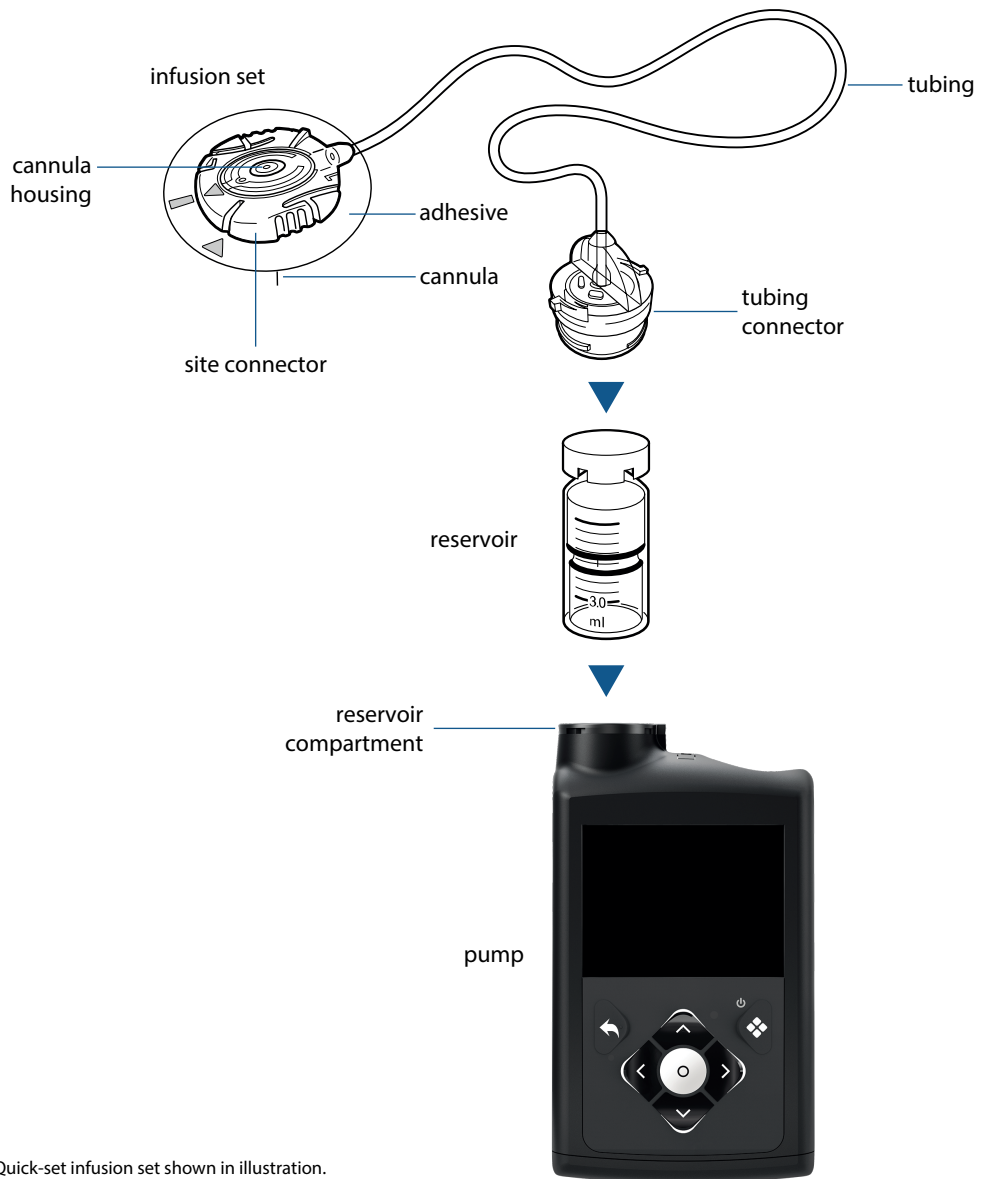
Sleep mode

The pump screen goes dark if there is no activity for the duration specified in the Backlight setting. Two minutes after the screen goes dark, the pump

enters Sleep mode to conserve battery power. Sleep mode does not affect insulin delivery. Press any button to wake up the pump. Press and hold  for two seconds to manually enter Sleep mode.

Pump delivery system

The following diagram shows the parts of the pump delivery system, including the infusion set*, reservoir, and pump.



*Quick-set infusion set shown in illustration.

Infusion set

The infusion set consists of the following components:

- The tubing carries insulin from the reservoir into the body.
- The tubing connector attaches to the reservoir.
- The insertion piece attaches to the body.

- The cannula is a small, flexible tube inserted into the body. Some infusion sets use a small needle instead of a cannula.
- The adhesive holds the infusion set in place.

Change the infusion set according to the user guide provided with the infusion set.

Reservoir

The reservoir stores insulin for delivery and is inserted into the pump reservoir compartment.

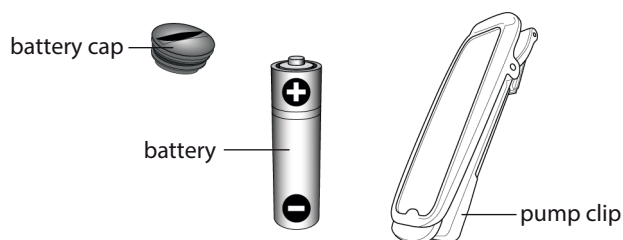
Pump

Underneath the reservoir compartment, a piston pushes up on the bottom of the reservoir to move insulin into the tubing, through the cannula, and into the body.

The pump delivers small doses of insulin. The smallest dose of insulin is 0.025 units. The piston inside the pump must be rewound each time a newly filled reservoir is inserted into the reservoir compartment.

Battery cap

The battery cap is located in the pump box with the accessories. It seals the battery compartment and ensures the pump is connected to the battery.



Inserting the battery

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.



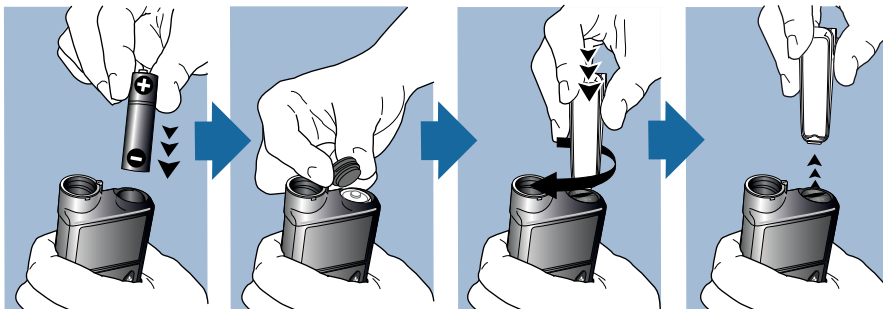
CAUTION: Do not use a carbon zinc battery in the pump. Carbon zinc batteries are not compatible with the pump and can cause the pump to report inaccurate battery levels.



Note: Do not use cold batteries because the battery life may incorrectly appear low. Allow cold batteries to reach room temperature before they are inserted into the pump.

To insert the battery:

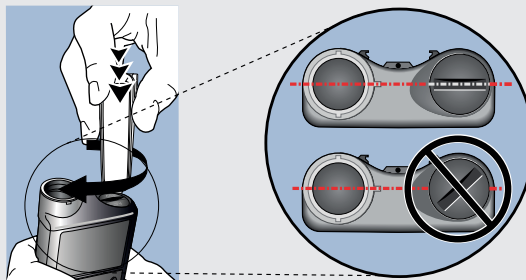
1. Insert a new or fully charged AA battery. Make sure to insert the negative end (–) first.



2. Place the battery cap onto the pump. Use the bottom edge of the pump clip or a coin to tighten the cap.



CAUTION: Do not overtighten or undertighten the battery cap. A battery cap that is too tight can cause damage to the pump case. A battery cap that is too loose can prevent detection of the new battery. Turn the battery cap clockwise until the cap slot is aligned horizontally with the pump case, as shown in the following example.



The first time a battery is inserted into the pump, the Startup Wizard begins. Any other time a battery is inserted into the pump, the Home screen appears and the pump resumes basal delivery.

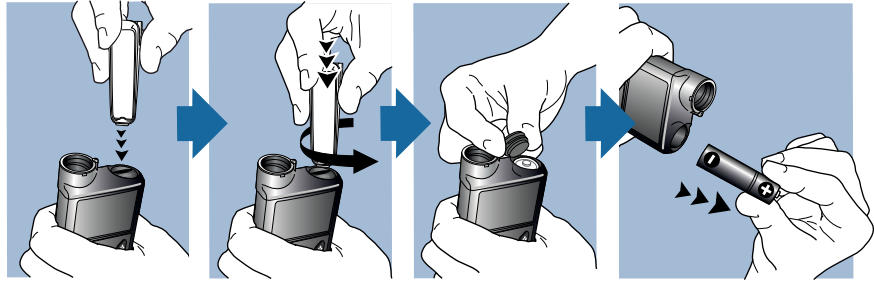
Removing the battery



CAUTION: Do not remove the battery unless a new battery needs to be inserted or to store the pump. The pump cannot deliver insulin while the battery is removed. After an old battery is removed, make 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 for an extended period of time, the time and date settings must be re-entered.

To remove the battery:

1. Before a battery is removed from the pump, clear any active alarms or alerts.
2. Use the pump clip or a coin to loosen and remove the battery cap.
3. Remove the battery.



4. Dispose of old batteries in an appropriate container and in accordance with local laws for battery disposal.
5. After a battery is removed, wait until the Insert Battery screen appears before inserting a new battery.

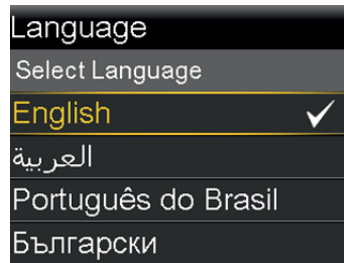
If a battery is removed to place the pump in storage, see *Storing the pump*, page 298 for more information.

Startup settings

The Startup Wizard appears after a battery is inserted for the first time. Use the Startup Wizard to set the language, time format, current time and date, and to rewind the pump. To re-enter these settings later, see *Pump issues*, page 288.

To use the Startup Wizard:

1. On the Select Language screen, select a language.

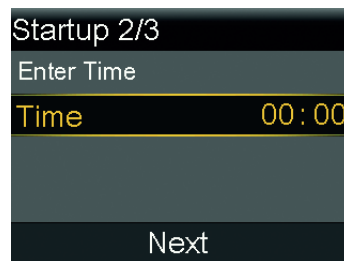


The Select Time Format screen appears.

2. Select a time format.



3. Enter the current time, and then select **Next**.



The Enter Date screen appears.

4. Enter the current date, and then select **Next**.

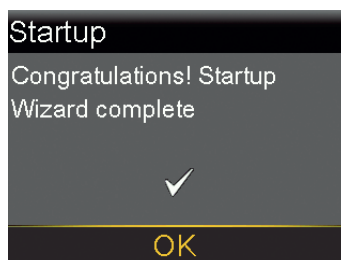


A “Rewinding” message appears. The piston returns to its start position in the reservoir compartment. This may take several seconds.



When rewinding is complete, a message appears to confirm the startup is complete.

5. Select **OK** to go to the Home screen.

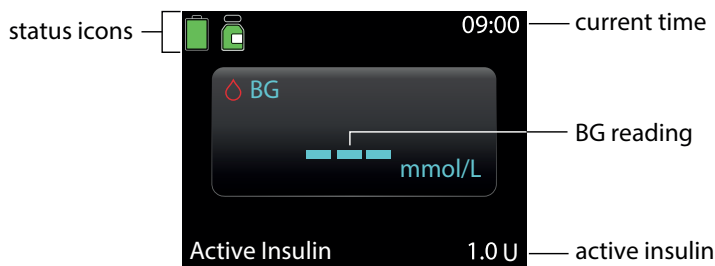


Home screen in Manual mode

The Home screen appears after the battery is changed, when the pump wakes from Sleep mode, and when another screen is not actively being used.



Note: This example shows the Home screen in Manual mode when the Sensor feature is turned off. For information about the Home screen when the Sensor feature is turned on, see *Home screen with CGM in Manual mode, page 183*. For information about the Home screen with the SmartGuard feature, see *Home screen with the SmartGuard feature, page 198*.



The following items appear on the Home screen:

Item	Description
Status icons	The status icons show a quick status of the pump system. For more information, see <i>Status icons, page 78</i> .
Current time	For details on setting the time, see <i>Time and date, page 215</i> .
BG readings	The current blood glucose (BG) meter reading is shown. The BG is either entered manually, or it is sent from a paired Accu-Chek Guide Link meter.
Active insulin	Active insulin is bolus insulin delivered by the insulin pump that continues to lower BG levels. Active insulin is not necessarily reflective of the pharmacokinetics and pharmacodynamics of rapid acting insulins. For more details on active insulin, see the description of Active Insulin Time in <i>Bolus Wizard feature in Manual mode, page 106</i> .

Shortcuts from the Home screen

The following table describes shortcuts that can be used to quickly access certain pump functions. These shortcuts only work on the Home screen.

Shortcut	Description
	Press this button to access the Status screen.
	Press this button to access the Time in Range screen when the Sensor feature is turned on.
	Press this button to access the Bolus screen. The Bolus screen that appears varies depending on the bolus feature that is currently active.

Status icons

The status icons provide the current status of the pump system. For information on viewing detailed status screens, see *Status screen*, page 83.

Icon name	Description
Active Insulin reset to zero	After the Active Insulin reset to zero alarm occurs,  appears on the Home screen and Bolus screens until the time shown in the alarm. For more information, see <i>Pump issues</i> , page 288.
Alert silence	The Alert silence icon  indicates that the Alert Silence feature is turned on and some alerts will not make a sound or vibration. Sensor alerts can be silenced for a specific duration using the Alert silence feature. For more information, see <i>Silencing sensor alerts</i> , page 171.
Battery	The color and fill level of the icon indicate the charge level of the pump battery. As the battery is used, the icon changes from solid green in the following order:   The battery is full.  The battery is low.  The battery can be used for less than 30 minutes and needs to be replaced.
Block mode	The Block mode icon  shows that the pump is locked. For more information about Block mode, see <i>Block mode</i> , page 216.
Connection	The connection icon shows the following information:

Icon name	Description
	•  The Sensor feature is on and communicating. •  The Sensor feature is on, but the sensor is not communicating with the pump.
Reservoir	The reservoir icon shows the fill status of the MiniMed reservoir MMT-332A or MMT-342, 3.0 mL (300-unit). •  Approximately 85%–100% of the insulin remains in the reservoir. •  Approximately 71%–84% of the insulin remains in the reservoir. •  Approximately 57%–70% of the insulin remains in the reservoir. •  Approximately 43%–56% of the insulin remains in the reservoir. •  Approximately 29%–42% of insulin remains in the reservoir. •  Approximately 15%–28% of the insulin remains in the reservoir. •  Approximately 1%–14% of the insulin remains in the reservoir. •  The amount of insulin remaining in the reservoir is unknown.
Sensor life	The number on the sensor life icon indicates the number of days that remain in the life of the sensor. When the Sensor feature is turned on, the icon appears on the Status screen. After a new sensor is inserted, the icon is solid green. When one day remains in the life of the sensor, the icon turns red and appears on the Home screen. When the sensor expires, the icon turns solid black with an X.



If the number of days that remain in the life of the sensor is not yet available, such as when the sensor is warming up, the sensor life icon appears with three dots. 

Icon name	Description
	If the number of days that remain in the life of the sensor is unknown, the sensor life icon appears with a question mark. 
Sensor status	The sensor status icon shows whether the sensor is warming up, is monitoring sensor glucose (SG) values, a BG is required, or the sensor status is unavailable. The icon appears only when the Sensor feature is turned on.  An icon with a green circle around it means the sensor is working and no action is required.  A red icon means a BG reading is required.  A question mark icon with a blue circle around it means that sensor information is unavailable.  An icon with three white dots on a black background means the pump is waiting for the sensor status to update.
Suspend by sensor	When the current low alert time segment has either the Suspend before low or Suspend on low feature turned on, the Suspend by sensor icon appears on the Home screen.  When Suspend before low or Suspend on low feature suspends insulin delivery, the icon flashes.  If the Suspend before low or Suspend on low feature is turned on but unavailable, the icon has a red X. This can be due to a recent suspend by sensor event or when no SG values are available.  For more information, see <i>The Suspend before low feature</i>, page 162 and <i>The Suspend on low feature</i>, page 164.
Temporary network connection	 The temporary network connection icon shows when the pump is temporarily connected to a remote upload device.



Note: Status icons provide limited information. For example, the reservoir icon may indicate the reservoir is low on insulin. The Status screen shows more detailed information about how many units are left. For more information about the status screens, see *Status screen*, page 83.

Menu screen

Use the menu to go to screens that show various features and functions of the system. Press  from the Home screen to go to the menu. The highlighted menu option appears in color. All other menu options appear in black and gray.



Use the menu to go to the following screens:

Menu selection	Menu icon	Description
Insulin		Deliver a bolus, set up and deliver basal insulin, suspend insulin delivery, and stop bolus during bolus delivery.
History & Graph		View history, SG review, graph, and time in range.
SmartGuard		Set up the SmartGuard feature.
Sound & Vibration		Set sound, vibrate, and volume options for notifications.
Reservoir & Set		Set up a new reservoir and infusion set, and fill a cannula.

Menu selection	Menu icon	Description
Blood Glucose		Enter a BG value.
Status		View the status of the pump and other system features.
Paired Devices		Pair devices or CareLink software.
Settings		Set up device settings, delivery settings, and alert settings.

Menu map

Refer to *Menu map, page 367* to see the menu map diagrams.

Sound & Vibration screen

The sound and vibration options are set on the Sound & Vibration screen. Sensor alerts can also be temporarily silenced. For information about silencing alerts, see *Silencing sensor alerts, page 171*. The alert silence icon on the Home screen indicates when alerts are silenced. For more information, see *Status icons, page 78*.

To adjust the sound and vibration settings:

1. From the Home screen, press , and then select .
2. Adjust the volume:
 - a. Select **Volume**.
 - b. Press , , , or , and then press .
3. Select **Sound**, and then press  to turn the sound on or off.
4. Select **Vibration**, and then press  to turn the vibration on or off.

Status screen

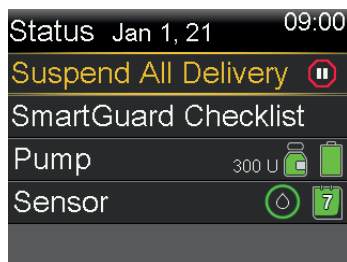
The Status screen provides access to information about the pump and information about the sensor, if applicable. The Status screen also provides the option to suspend all insulin delivery or resume basal insulin delivery.

Use the Status screen to access the following screens or options:

Screen or option	Description
Stop Bolus	This option appears when a bolus delivery is in progress. Select Stop Bolus to stop the active bolus.
Suspend All Delivery or Resume Basal	This option indicates whether insulin delivery is currently suspended. Select Suspend All Delivery to suspend insulin delivery. Select Resume Basal to resume basal insulin delivery. For more information see <i>Suspending all insulin delivery and resuming basal insulin delivery</i> , page 98.
SmartGuard Checklist screen	This screen shows a list of the required conditions before the pump can use the SmartGuard feature. For more information, see <i>SmartGuard Checklist</i> , page 195.
Pump status screen	This screen shows a detailed view of the pump status, the reservoir and infusion set status, battery status, pump serial number, pump name, model number, and other pump details.
Sensor status screen	If the Sensor feature is off, the Sensor menu appears gray and the sensor icons do not display. The Sensor status screen includes sensor life and shows the serial number, version number, and code of the sensor, among other details.

To view the status screens:

1. From the Home screen, press , and then select .



2. Press $\wedge$ or $\vee$ to highlight a status screen, and then press $\odot$.

4

Basal and bolus insulin
delivery

Basal and bolus insulin delivery

This chapter explains how to use different types of insulin delivery.

Setting up basal insulin

Basal insulin is the “background” insulin that the body needs throughout the day and night to maintain target blood glucose (BG) meter readings when food is not eaten. Basal insulin accounts for approximately one half of daily insulin requirements. The MiniMed 780G insulin pump simulates a pancreas by delivering insulin continuously over 24 hours.



WARNING: The pump is intended to be used with a basal pattern. The basal pattern must be manually entered and saved into the pump. The pump will operate with a basal rate of 0.0 U/hr until a basal pattern is entered and saved. There is no reminder message to program basal rates. Consult a healthcare professional to determine what basal pattern is needed. For more information about basal patterns, see *Basal patterns*, page 90.

Basal rate

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

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*, page 90.

Max basal rate

The Max basal rate setting applies to Manual mode only and does not affect how much insulin SmartGuard delivers. When using the SmartGuard feature, delivery limits are determined automatically.

The Max basal rate setting limits the maximum amount of basal insulin per hour that can be programmed. Consult with your healthcare professional to personalize your Max basal rate setting.

It is not possible to set a basal rate, a temp basal rate, or a preset temp basal rate that would exceed the Max basal rate limit. After the basal patterns or preset temp basal rates are set, the Max basal rate setting cannot be set lower than any existing basal rate.

If you require a Max basal rate higher than 6 units per hour, a message appears indicating that a Max basal rate higher than 6 units per hour is outside of the typical range. A Max basal rate of 6 U/hr can allow basal delivery of up to 144 units per day in Manual mode. This amount of insulin may not be safe. Consult with your healthcare professional to ensure your basal setting is appropriate for you.

If you require a Max basal rate higher than 10 units per hour, the system will not let you increase the Max basal rate setting from Delivery Settings >Max Basal Rate. The only time you will see a rate higher than 10 U/hr through Delivery Settings>Max Basal Rate is when you have either:

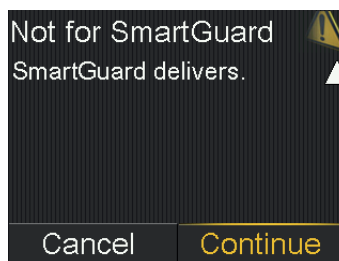
- Updated your pump software using the MiniMed Mobile app, and your previous Max basal rate was larger than 10 U/hr.
- Increased your Max basal rate as directed by your healthcare professional.

For more information on how to increase your Max basal rate above 10 U/hr, see *Max basal rate*, page 223.

To set the Max basal rate:

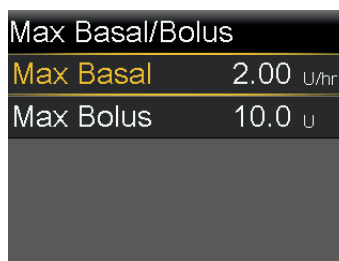
1. From the Home screen, press , and then select .
2. Select **Delivery Settings > Max Basal/Bolus**.

The Not for SmartGuard screen appears.

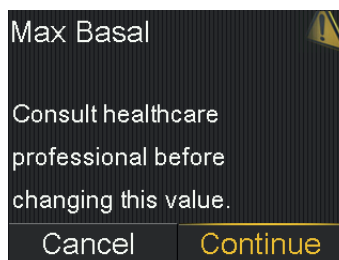


3. Select **Continue**.

The Max Basal/Bolus screen appears.



4. Select **Max Basal**.



5. To continue to the Max Basal Rate screen, select **Continue**.
6. Select **Max Basal**, and then set the maximum number of basal insulin units per hour.

Max Basal Rate	
Max Basal	2.00 U/hr
This applies to Manual mode. SmartGuard delivery not affected.	
Save	

- If you lower the Max basal rate setting below an existing basal rate, a Max Basal Error will appear.
- If you raise the Max basal rate setting above 6 U/hr, you are warned that the amount of insulin may not be safe.
- The system will stop you from raising the Max basal rate setting above 10 U/hr. If your healthcare professional has increased your rate above 10 U/hr, see *Max basal rate*, page 223.

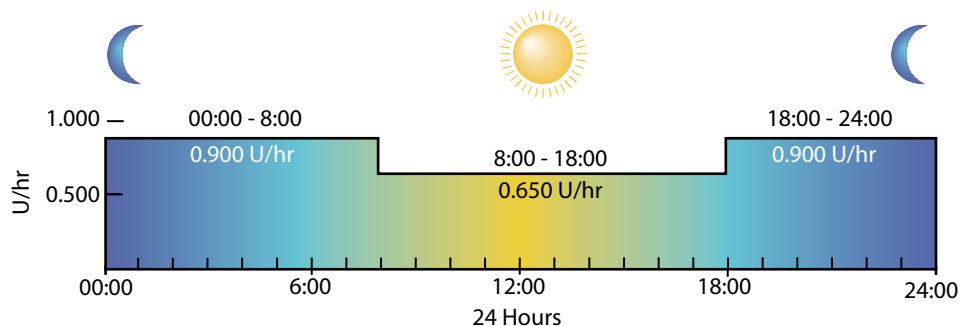
7. Select **Save**.

Basal patterns

Basal pattern settings apply to Manual mode only and do not affect how much insulin SmartGuard delivers.

The basal pattern determines the amount of basal insulin delivered throughout the day and night while in Manual mode. A basal pattern is made up of one to 48 basal rates that are set to cover a full 24-hour period. Because basal insulin needs can vary, up to eight basal patterns can be set.

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



Consult a healthcare professional to determine the basal pattern. The basal pattern must be manually entered into the pump. There will be no reminder message to program basal rates.



WARNING: Confirm a basal pattern is entered. If a basal pattern is needed but not entered and saved, this could result in an under-delivery of basal insulin. Under-delivery of insulin can potentially cause severe hyperglycemia, which may lead to diabetic ketoacidosis.

Setting up a basal pattern

This procedure shows how to set up a basal pattern for the first time. To add an additional basal pattern, see *Adding an additional basal pattern*, page 254.

To set up a basal pattern:

1. From the Home screen, press , and then select .
2. In Manual mode, select **Delivery Settings** > **Basal Pattern Setup**.
3. The system reminds you that basal patterns only apply to Manual mode. Select **Continue**.

Basal Pattern Setup		
Basal 1	0.0	U ✓
Add New		

4. Select **Basal 1**.
5. Select **Options**, and then select **Edit**.

Edit Basal 1		
Start	End	U/hr
00:00	24:00	0.025
Review		

6. For one basal rate, the End time does not need to change. Press  on the 24:00.



Note: For instructions on setting up multiple basal rates over a 24-hour period, see *Settings covering a 24-hour period*, page 93.

7. Enter the unit value for the time period.
8. Select **Review**.

If your basal pattern rate will deliver significantly more insulin than you typically need, the system displays a message. You can edit the basal pattern or, after consulting with a healthcare professional, you can continue.

Basal 1		
24 hr Total: 24 U		
Start	End	U/hr
00:00	24:00	1.00
Save		

Review the basal pattern. Press  to return to the previous screen to make changes.



Note: If  is pressed and **Save** is not selected, the changes are not saved.

9. Select **Save**. If you do not select Save, your changes are not saved. If this is an added basal pattern and you want to activate it, see *Changing from one basal pattern to another*, page 256.



CAUTION: If you have not pressed Save after settings are entered and the screen goes dark, the entered settings will not be saved.



Note: Programming a basal pattern is an important part of setting up the insulin pump for use. Please review the settings to confirm that these are programmed accurately based on settings provided from a healthcare professional.

Settings covering a 24-hour period

Some pump functions allow settings to change over a 24-hour period. Basal rates are one of those settings.

Setting up multiple values over a 24-hour period applies to the following settings:

- Basal patterns
See *Setting up a basal pattern* , page 91
- High SG settings
See *Setting up the high SG settings*, page 157
- Low SG settings
See *Setting up the low SG settings*, page 167
- Carb ratios, insulin sensitivities, and BG targets in the Bolus Wizard feature in Manual mode
See *Setting up the Bolus Wizard feature in Manual mode*, page 107.

This screen is an example of a basal pattern with different rates of basal insulin for specific times of the day:

Edit Basal 1		
Start	End	U/hr
00:00	08:00	0.900
08:00	18:00	0.650
18:00	24:00	0.900
Review		

To set up values over a 24-hour period:

1. On the appropriate settings screen, select the End time and enter the end time for the first time period. In this example, the first desired time period is 8 hours. The start time always begins at 00:00. To set an 8-hour period, enter an end time of 08:00.

Edit Basal 1		
Start	End	U/hr
00:00	24:00	0.025
Review		

2. Enter the unit value for the first time period.

Edit Basal 1		
Start	End	U/hr
00:00	08:00	0.900
Review		

3. Press .

The start time for the next time period appears.

Edit Basal 1		
Start	End	U/hr
00:00	08:00	0.900
08:00	08:30	---
Review		

4. Enter the end time for the next time period.

Edit Basal 1		
Start	End	U/hr
00:00	08:00	0.900
08:00	18:00	---
Review		

5. Enter the unit value for the next time period.

Edit Basal 1		
Start	End	U/hr
00:00	08:00	0.900
08:00	18:00	0.650
Review		

6. Press .

The start time for the next time period appears.

Edit Basal 1		
Start	End	U/hr
00:00	08:00	0.900
08:00	18:00	0.650
18:00	24:00	---
Review		

7. Repeat steps 3-5 for every desired time period until the end time of 24:00 is reached. This completes the 24-hour duration.

Edit Basal 1		
Start	End	U/hr
00:00	08:00	0.900
08:00	18:00	0.650
18:00	24:00	0.900
Review		

8. Select **Review**.

If your basal pattern rate will deliver significantly more insulin than you typically need, the system displays a message. You can edit the basal pattern or, after consulting with a healthcare professional, you can continue.

Edit Basal 1		
Start	End	U/hr
00:00	08:00	0.900
08:00	18:00	0.650
18:00	24:00	0.900
Review		

Review the basal pattern. Press  to return to the previous screen to make changes.



Note: If  is pressed and **Save** is not selected, the changes are not saved.

9. Select **Save**.

Viewing basal delivery information

To view the current basal rate:

1. From the Home screen, press , and then select .
2. Select **Basal**.

The current basal rate appears at the top of the screen.

To view basal patterns:

1. From the Home screen, press , and then select .
2. Select **Basal**.
3. Select **Basal Patterns**.

The Basal Patterns screen shows a list of configured basal patterns and the 24-hour insulin total for each basal pattern. A check mark appears next to the active basal pattern.

4. To view details for a basal pattern, select the basal pattern.

For more information about basal patterns, see *Basal patterns*, page 90.

Suspending all insulin delivery and resuming basal insulin delivery

Use this feature to suspend all active basal and bolus insulin deliveries. A reminder that insulin is not being delivered occurs every 15 minutes while this feature is active. The pump beeps, vibrates, or both every 15 minutes as a reminder that insulin is not being delivered.



Note: The first reminder occurs 15 minutes after the pump display times out. The pump beeps, vibrates, or both 15 minutes after the pump display times out. If a button is pressed to wake up the pump, the pump beeps, vibrates, or both 15 minutes after the pump display times out again. To adjust the timeout setting, see *Display options*, page 215.

To restart basal insulin delivery, use the Resume Basal feature. The pump starts the programmed basal pattern but does not start any previously programmed bolus deliveries.



Note: To stop a bolus delivery without stopping the basal delivery, see *Stopping a bolus delivery*, page 115.



WARNING: If insulin delivery is suspended during a bolus, check the pump daily history to determine the amount of insulin that was delivered before resuming insulin delivery. Bolus delivery and fill cannula do not restart when insulin delivery is resumed. If needed, program a new bolus or fill the cannula. Failure to resume basal insulin delivery can result in hyperglycemia and diabetic ketoacidosis.



WARNING: Do not rely solely on the sound or vibration notifications when using the sound or vibrate options. These notifications may not occur as expected if the speaker or vibrator in the pump malfunctions. A missed notification may result in the delivery of too much or too little insulin. This is most common when using the Easy bolus feature or when the pump is in manual suspend. Contact a local Medtronic support representative with any concerns.

To suspend all insulin delivery:

1. From the Home screen, press , and then select .

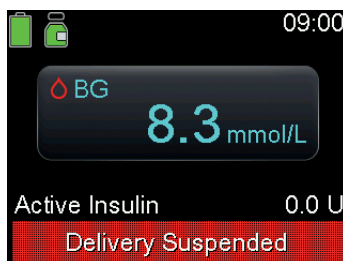
2. Select **Suspend All Delivery**.

A confirmation message appears.

3. Select **Yes** to suspend all insulin delivery.

The pump functions are limited until insulin delivery is resumed.

The Delivery Suspended banner appears on the Home screen while insulin is suspended.

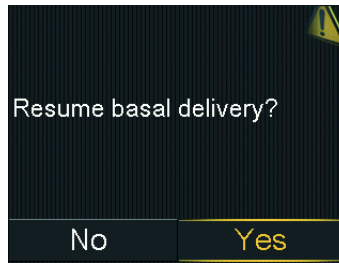


To resume basal insulin delivery:

1. While insulin delivery is suspended, from the Home screen press , and then select .

2. Select **Resume Basal**.

A confirmation message appears.



3. To resume basal insulin delivery, select **Yes**.

If a temp basal was active when the pump was suspended, it resumes, provided the time is still within the duration set.



Note: If a bolus delivery that was in progress before delivery was suspended is needed, check the Daily History screen for the actual bolus units delivered and the intended bolus amount. Then set up a new bolus amount as needed. For details about using the Daily History screen, see *Daily History screen*, page 231.

Temp basal rates

The temp basal feature is used to set and start a temporary basal rate that can be used immediately to manage blood glucose (BG) during short-term activities or conditions, such as exercise or meals.

The duration of the temp basal rate can range from 30 minutes to 24 hours. After the temp basal rate delivery is completed or canceled, the programmed basal pattern resumes. The temp basal rates and preset temp basal rates can be defined using either a percentage of the current basal pattern or by setting a specific rate, as described in the table:

Temp basal rate type	Description
Percent	Percent delivers a percentage of the basal rates programmed in the 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 the basal rate is set at less than 1 unit per hour, or to the next 0.05 units if the basal rate is set at more than 1 unit per hour.

Temp basal rate type	Description
	Temp basal rates can be set to deliver from 0% to 200% of the scheduled basal rate. The percentage used is based on the largest basal rate scheduled during the temp basal rate duration and is limited by the Max basal rate.
Rate	Rate delivers a fixed basal insulin rate in units per hour for the duration of the temp basal rate. The amount set is limited by the Max basal rate.

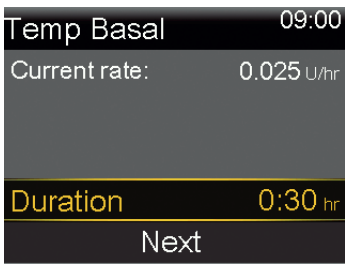
Preset temp basal rates can be set for recurring short term situations. For more information on Preset temp basal rates, see *Preset temp basal rates*, page 251.

Starting a temp basal rate

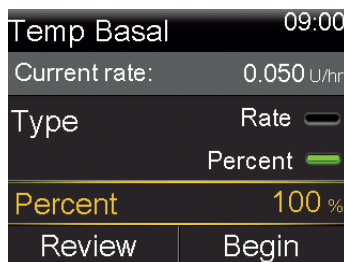
When a temp basal rate starts, basal delivery changes to the temp basal rate for the set duration. When the duration completes, the basal insulin returns to the active basal pattern.

To start a temp basal rate:

1. From the Home screen, press , and then select .
2. Select **Basal > Temp Basal**.
3. Set the **Duration**.



4. Select **Next**.
5. Select **Type** to select Rate or Percent.



6. Depending on the type selected, do one of the following:

- Enter a percentage.
- Enter a basal rate.

Select **Review** to review the temp basal setting.

7. Select **Begin** to start the temp basal rate.

The Temp Basal banner appears on the Home screen during delivery.



Entering a blood glucose (BG) meter reading

The system may request a blood glucose (BG) meter reading to continue use of sensor. Additionally, a blood glucose (BG) meter reading can be entered at any time, if desired.

The BG screen allows manual entry of a blood glucose (BG) meter reading. Previously entered manual or meter BG readings do not appear on the BG screen. A blood glucose (BG) meter reading received from a linked meter appears in a separate BG Meter screen that requires confirmation.

To manually enter blood glucose (BG) meter readings:

1. From the Home screen, press , and then select .

2. Enter a blood glucose (BG) meter reading. Do not enter a sensor glucose (SG) value in place of a blood glucose (BG) meter reading. A blood glucose (BG) meter reading must always come from a blood glucose meter. The entered glucose value is used to calibrate the sensor.
3. Select **Save**.

To manually enter blood glucose (BG) meter readings on the Bolus Wizard screen in Manual mode:

- From the Bolus Wizard screen in Manual mode, select **BG**.

To confirm a blood glucose (BG) meter reading from a blood glucose meter:

When the BG Meter screen with the message Confirm BG? shows, select **Yes** to confirm the blood glucose (BG) meter reading.

The BG received message shows.

Setting up bolus delivery

A bolus is given for two reasons: to cover food that contains carbohydrates or to correct glucose levels that are above the target range.

Manual mode bolus delivery options

Three types of bolus are available using the Bolus Wizard or Manual bolus feature, including normal bolus, Square Wave bolus, and Dual Wave bolus. Discuss these options with a healthcare professional to determine what is best. For more information, see *Bolus types*, page 261.



Note: Do not use a blood glucose (BG) meter reading if more than 12 minutes have passed since the last BG meter reading was taken. That BG meter reading and the calculated bolus amount may no longer be accurate.

The following table describes how to deliver a bolus using the Bolus Wizard feature or Manual bolus feature. These bolus options are only available in Manual mode.

Feature	Description
Bolus Wizard feature in Manual mode	Enter the BG meter value or the amount of carbs expected from a meal, or both. Then the Bolus Wizard feature in Manual mode calculates an estimated bolus amount based on the individual settings. For details about using the Bolus Wizard feature, see <i>Bolus Wizard feature in Manual mode, page 106</i> .
Manual bolus feature	Calculate and manually enter the bolus amount. For details about using the Manual bolus feature, see <i>Delivering a normal bolus using the Manual bolus feature, page 114</i> .

Max bolus

The Max bolus setting limits the amount of insulin that can be programmed by the user for a single bolus in Manual mode. The pump prevents single bolus insulin deliveries that exceed the Max bolus amount. The Max bolus can be set from 0 to 25 units. Set the Max bolus value as indicated by a healthcare professional.

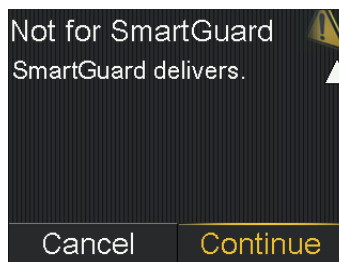
If the Max bolus is set up after the preset bolus deliveries are set, the Max bolus cannot be set lower than any of the existing preset bolus amounts.

The Max bolus setting applies to boluses programmed by the user in Manual mode.

When the SmartGuard feature is active, SmartGuard determines the limits for each auto correction bolus.

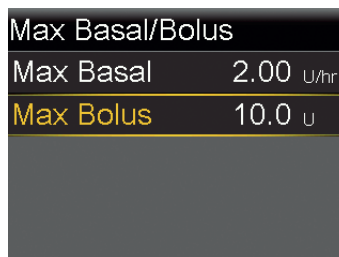
To set the Max bolus:

1. From the Home screen, press , and then select .
2. Select **Delivery Settings > Max Basal/Bolus**.
The Not for SmartGuard screen appears.

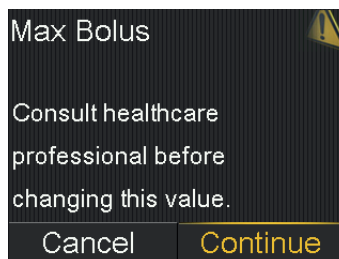


3. Select **Continue**.

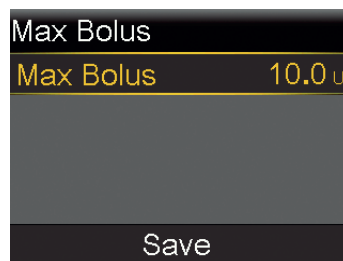
The Max Basal/Bolus screen appears.



4. Select **Max Bolus**.



5. To continue to the Max Bolus screen, select **Continue**.
6. Select **Max Bolus**, and then set the maximum number of insulin units the pump can deliver in one bolus.



7. Select **Save**.

Bolus Wizard feature in Manual mode

In Manual mode, the Bolus Wizard feature uses Bolus Wizard settings to calculate an estimated bolus amount based on the BG readings and carbs that are entered.

After the Bolus Wizard feature is set up, use a normal bolus to deliver a food bolus, a correction bolus, or a food plus correction bolus. For more information, see *Delivering a normal bolus with the Bolus Wizard feature*, page 112.

The Bolus Wizard feature can also be used to deliver a Dual Wave bolus or a Square Wave bolus. For more information, see *Bolus types*, page 261.

Bolus Wizard settings in Manual mode

To use the Bolus Wizard feature, consult a healthcare professional to determine the personal settings that should be used. The carb ratio, insulin sensitivity factor, BG target, and the active insulin time are needed to complete the setup. Always consult a healthcare professional before changes are made to the Bolus Wizard settings. The setup procedure begins on *Setting up the Bolus Wizard feature in Manual mode*, page 107.

Manual mode Setting	Description
Active Insulin Time	Active insulin is the bolus insulin that has been delivered by the pump and is still working to lower glucose levels. In the Bolus Wizard and SmartGuard Bolus feature, the Active Insulin Time setting is used to calculate a correction bolus by subtracting the estimated active insulin from each bolus. In SmartGuard, auto correction boluses are

Manual mode Setting	Description
	delivered up to every 5 minutes. A shorter Active Insulin Time setting may result in more insulin being delivered in correction boluses. A healthcare professional provides the personalized active insulin time based on historic glycemic control data for the individual user. When using SmartGuard, the recommended initial setting is an Active Insulin Time of 2-3 hours. The Active Insulin Time setting in the MiniMed 780G system is not necessarily reflective of the physiological insulin metabolism. Adjustments are not based on the pharmacokinetics and pharmacodynamics of the rapid-acting insulin. The current active insulin amount appears on the Home screen and includes only the bolus insulin received.
BG Target	In Manual mode, the Bolus Wizard feature calculates the estimated bolus based on the BG target range. The high and low values set are the values to which the BG is corrected. To use a single target value rather than a range, set the same value for the high and low value of the BG target. If the BG reading is above the high target value, a correction dose is calculated. If the BG reading is below the low target value, a negative correction is calculated and subtracted from the food bolus.
Carb Ratio	The carb ratio setting is used for food bolus calculations. The number of carb grams that are covered by 1 unit of insulin.
Insulin Sensitivity Factor	The insulin sensitivity factor setting is used to calculate correction bolus amounts. The insulin sensitivity factor is the amount that BG is reduced by 1 unit of insulin.

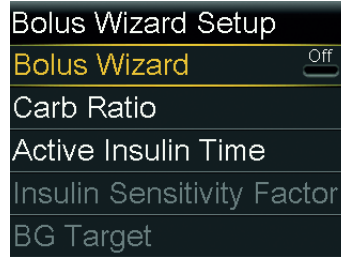
Setting up the Bolus Wizard feature in Manual mode

In Manual mode, to use the Bolus Wizard feature to calculate a bolus, first turn on the Bolus Wizard feature and enter the Bolus Wizard settings. There are four settings needed to set up the Bolus Wizard. Each setting is shown using 1/4, 2/4, 3/4, and 4/4 on the screens.

To set up the Bolus Wizard feature:

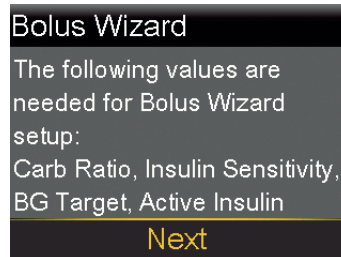
1. From the Home screen, press , and then select .
2. Select **Delivery Settings** > **Bolus Wizard Setup**.

This feature is only available in Manual mode. The Bolus Wizard Setup screen appears.

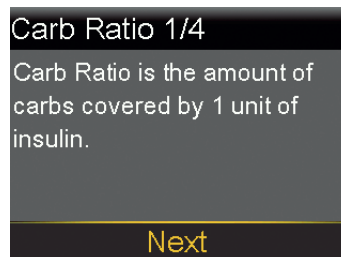


3. Select **Bolus Wizard** to turn on the feature.

If this is the first time the Bolus Wizard feature has been turned on, the following screen appears.



4. Confirm the values needed are ready to be entered, then select **Next**.
The Carb Ratio 1/4 screen appears.



5. Select **Next**.

The Edit Carb Ratio 1/4 screen appears.

Edit Carb Ratio 1/4		
Start	End	g/U
00:00	24:00	---

6. To enter one carb ratio, enter the g/U, and then press .



Note: For instructions on setting up more than one carb ratio over a 24-hour period, see *Settings covering a 24-hour period*, page 93.

7. Select **Next**.



Note: If the values are outside of the value range, a message asks to confirm the settings.

The Sensitivity 2/4 screen appears.

Sensitivity 2/4
Insulin Sensitivity Factor (Sensitivity) is the BG amount reduced by 1 unit of insulin.
Next

8. Select **Next**.

The Edit Sensitivity 2/4 screen appears.

Edit Sensitivity 2/4		
Start	End	mmol/L per U
00:00	24:00	---

9. For one sensitivity factor, enter the mmol/L per U, and then press .



Note: For instructions on setting up more than one sensitivity factor over a 24-hour period, see *Settings covering a 24-hour period*, page 93.

10. Select **Next**.

The BG Target 3/4 screen appears.

BG Target 3/4
BG Target is the value your blood glucose level will be corrected to.
Next

11. Select **Next**.

The Edit BG Target 3/4 screen appears.

Edit BG Target 3/4		
Start	End	Lo-Hi (mmol/L)
00:00	24:00	--- - ---

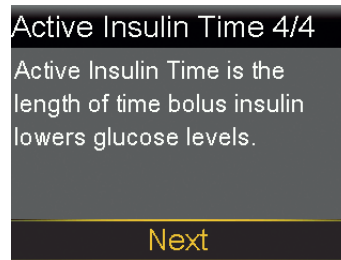
12. For one BG target range, enter the Lo and Hi target, and then press .



Note: For instructions on setting up more than one BG target range over a 24-hour period, see *Settings covering a 24-hour period*, page 93.

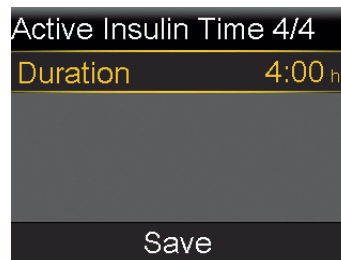
13. Select **Next**.

The Active Insulin Time 4/4 screen appears.



14. Select **Next**.

The Active Insulin Time 4/4 screen appears.



15. Enter the **Duration** of the active insulin time, and then press ⌂.

16. Select **Save**.

The Bolus Wizard feature setup is now complete.

Turning the Bolus Wizard feature off

The Bolus Wizard feature can be turned off at any time. The Bolus Wizard settings remain in the pump. When the Bolus Wizard feature is turned off, the Bolus Wizard menu selection does not appear on the Bolus screen, and the insulin sensitivity factor or BG target settings can not be edited on the Bolus Wizard Setup screen.

To turn the Bolus Wizard feature off:

- 1. From the Home screen, press , and then select .
- 2. Select **Delivery Settings > Bolus Wizard Setup**.
- 3. Select **Bolus Wizard** to turn the feature off.

Delivering a Normal bolus

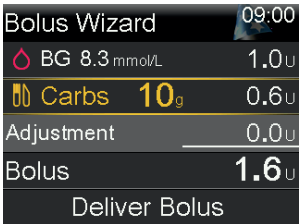
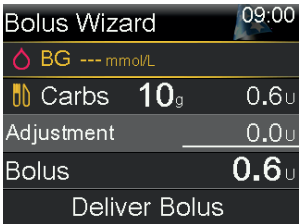
In Manual mode, a normal bolus provides a single immediate dose of insulin. Use a normal bolus to cover food intake or to correct a high BG meter reading or both.



Note: The pump can 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 feature

In Manual mode, the Bolus Wizard screen shows the most recent BG reading, if available. The table indicates the different ways that the Bolus Wizard screen shows the BG reading.

Bolus Wizard screen	Glucose reading information
	The  icon indicates that a recent blood glucose (BG) meter reading is used by the Bolus Wizard feature to calculate a correction bolus. DO NOT enter a sensor glucose (SG) value in place of a blood glucose (BG) meter reading.
	The BG appears as dashes when no BG is available for the Bolus Wizard feature to calculate a correction bolus.

To deliver a normal bolus using the Bolus Wizard feature:

1. From the Home screen, press , and then select .
2. Select **Bolus** > **Bolus Wizard**.

This feature is only available in Manual mode. The Bolus Wizard screen appears.

Bolus Wizard		09:00
	BG 8.3 mmol/L	1.0 U
	Carbs 0g	0.0 U
Adjustment		0.0 U
Bolus		1.0 U
Deliver Bolus		

3. For a correction bolus or a food bolus with a correction, use a blood glucose (BG) meter for a blood glucose (BG) meter reading. Do not enter a sensor glucose (SG) value in place of a blood glucose (BG) meter reading. A blood glucose (BG) meter reading must always come from a blood glucose meter. The entered glucose value is used to calibrate the sensor.



Note: A blood glucose (BG) meter reading can be entered on the Bolus Wizard screen. On the Bolus Wizard screen, select **BG**.

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

Bolus Wizard		09:00
🔴 BG	8.3 mmol/L	1.0 U
🍷 Carbs	30g	1.5 U
Adjustment		0.0 U
Bolus		2.5 U
Deliver Bolus		

5. If a change to the bolus amount is needed, select **Bolus** and modify the bolus amount.

Bolus Wizard		09:00
🔴 BG	8.3 mmol/L	1.0 U
🍷 Carbs	30g	1.5 U
Adjustment		0.0 U
Bolus	Modified	3.9 U
Deliver Bolus		

6. Select **Deliver Bolus** to start the bolus.

The pump beeps or vibrates and a message appears when the bolus starts. The Home screen shows the bolus amount as it is being delivered. The pump beeps or vibrates when bolus delivery is complete.

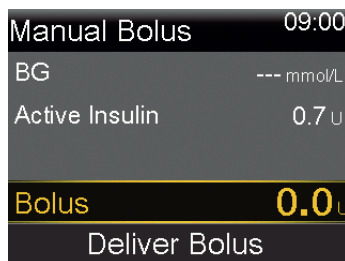
Delivering a normal bolus using the Manual bolus feature

The following procedure describes how to deliver a normal bolus using the Manual bolus feature.

To deliver a normal bolus using the Manual bolus feature:

1. From the Home screen, press , and then select .
2. In Manual mode, do one of the following:
 - Select **Bolus** if the Bolus Wizard feature is turned off.
 - Select **Bolus > Manual Bolus** if the Bolus Wizard feature is turned on.

The Manual Bolus screen appears.



3. Select **Bolus** to set the bolus delivery amount in units.
4. Select **Deliver Bolus** to start the bolus.

Stopping a bolus delivery

These procedures describe how to stop a bolus.



WARNING: Always press , select , and then select **Stop Bolus** to stop bolus insulin delivery. Do not use the Suspend All Delivery feature to stop bolus insulin. The Suspend All Delivery feature stops both basal insulin and bolus insulin delivery. Failure to resume basal insulin delivery could result in too little insulin, which may cause high BG.



Note: To stop all insulin delivery, use the Suspend All Delivery feature (press , select , and then select **Suspend All Delivery**). For more information on using the Suspend All Delivery feature, see *Suspending all insulin delivery and resuming basal insulin delivery*, page 98.

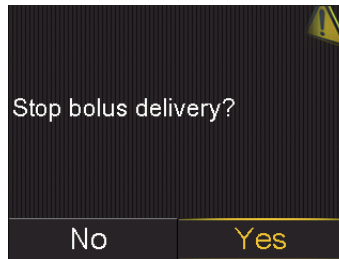
To stop a bolus delivery:

1. While the pump delivers a bolus, press  and then select .
The Insulin menu appears.



2. Select **Stop Bolus**.

A message appears confirming if bolus delivery should be stopped.



3. Select **Yes** to confirm.

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



4. Select **Done**.



Note: The delivered amount can be viewed in the insulin delivery history screen after the procedure is closed. For more information, see *Daily History screen*, page 231.

5

Reservoir and infusion set

Reservoir and infusion set

The pump has options to change the reservoir and infusion set, reservoir only, or infusion set only. This chapter provides information about setting up the reservoir and infusion set with the Reservoir & Set option.

If the reservoir runs out of insulin and the infusion set has not been used for the duration of use indicated for the infusion set, the New Reservoir Only option may be used to change the reservoir. If only the infusion set needs to be changed, the New Set Only option may be used to change the infusion set.

Refer to the infusion set user guide for the duration of use indicated for the infusion set. Refer to the reservoir user guide for the duration of use indicated for the reservoir.

Do not begin the steps to replace the reservoir and infusion set until training has been received.



WARNING: Always confirm that the infusion set tubing is disconnected from the body before doing the following steps:

- placing the reservoir into the pump
- rewinding the pump
- loading the reservoir
- filling the infusion set tubing

Failing to disconnect the infusion set tubing from the body may result in an accidental infusion of insulin, and may cause hypoglycemia.

Setting up the reservoir and infusion set

Confirm that the time and date on the pump are correct before insulin is used with the pump for the first time. For information about how to change the time and date on the pump, see *Time and date*, page 215. Consult a healthcare professional to determine the appropriate pump settings before insulin is used with the pump.

The following items are needed:

- MiniMed 780G insulin pump
- vial of rapid-acting U-100 insulin
- MiniMed or Medtronic reservoir
- MiniMed or Medtronic infusion set and its user guide



WARNING: Do not use the pump to deliver insulin for the first time until the active insulin has been cleared. If the pump has been used for training with bolus delivery before insulin is used, the active insulin value may be inaccurate. This may result in inaccurate insulin delivery, and serious injury. For details, see *Clearing the active insulin*, page 221.



Note: Different infusion sets may have different instructions for insertion into the body. All the procedures in the sections within this chapter must be followed to change the reservoir and infusion set.

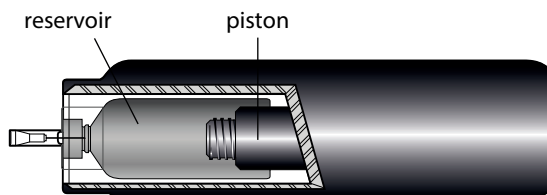
Removing the reservoir and rewinding the pump

If this is the first time a reservoir is inserted into the pump, proceed to the pump rewind instructions. For more information about the reservoir see the reservoir user guide.



WARNING: Always confirm that the infusion set is disconnected from the body before rewinding the pump or filling the infusion set tubing. Never insert the reservoir into the pump while the tubing is connected to the body. Doing so may result in an unintentional infusion of insulin, and may cause hypoglycemia.

When the pump rewinds, the piston in the reservoir compartment returns to its starting position and allows a new reservoir to be placed into the pump. The piston is located in the reservoir compartment of the pump. It engages the reservoir and pushes insulin through the tubing.



Start here:

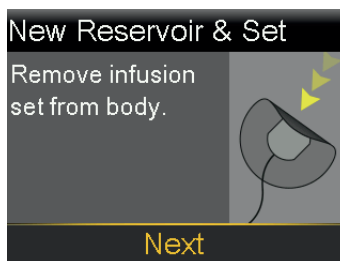
1. Wash hands with soap and water. On the pump, press  to go to the Menu screen.



2. Select , and then select **New Reservoir & Set**.

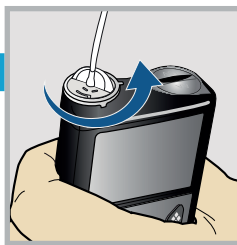
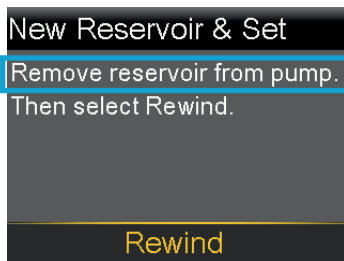


3. Remove the infusion set by loosening the adhesive and pulling the set away from the body. Select **Next**.



Note: For instructions on how to remove the infusion set from the body refer to the user guide that came with the infusion set.

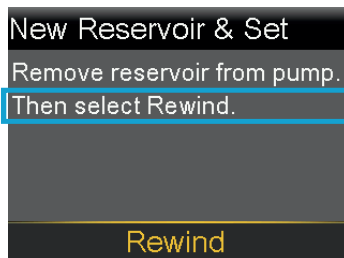
4. If the optional activity guard is attached to the reservoir compartment on the pump, remove it now.
5. Remove the used reservoir from the pump.



6. Dispose of the used reservoir and infusion set per the disposal information in the corresponding user guide.

7. Select **Rewind**.

Do not connect the infusion set to the body.

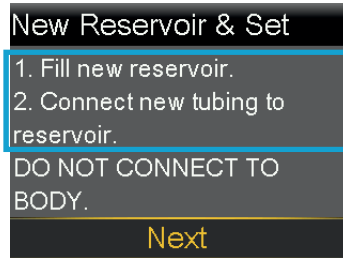


WARNING: Always confirm that the infusion set is disconnected from the body before rewinding the pump. Failing to disconnect the infusion set from the body may result in an accidental infusion of insulin, and may cause hypoglycemia.



8. Follow the next steps to fill the new reservoir with insulin and to connect the infusion set tubing.

Do not select **Next**.



Filling the reservoir and connecting it to the infusion set tubing

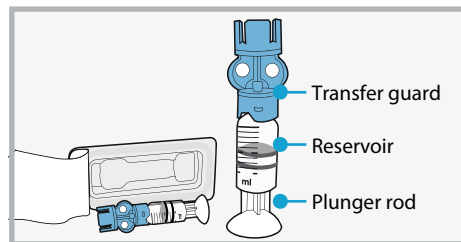


WARNING: Always allow the insulin to reach room temperature before use. Cold insulin may cause air bubbles in the reservoir and tubing, which may result in inaccurate insulin delivery.

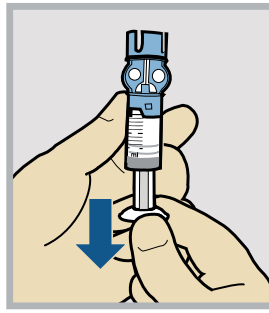
The following procedures must be performed in the order presented.

To fill the reservoir and connect it to the infusion set tubing:

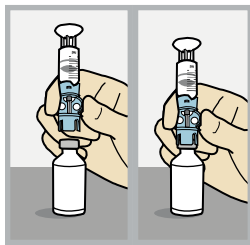
1. Remove the reservoir from the package. Make sure the insulin vial is at room temperature to reduce the risk of air bubbles.



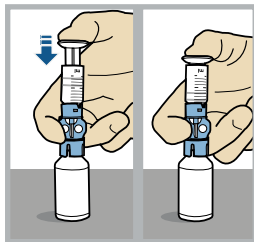
2. Pull the plunger down based on the planned insulin fill amount for the duration of use indicated for the reservoir.



3. Wipe the top of the vial with alcohol. Place the vial on a sturdy flat surface. Firmly press the transfer guard onto the vial.

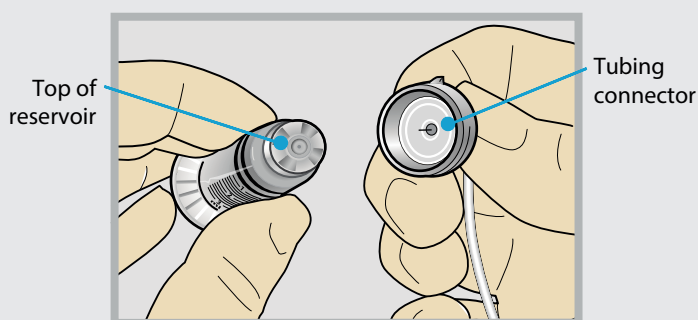


4. Push and hold the plunger down.

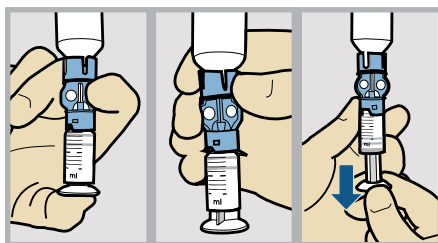




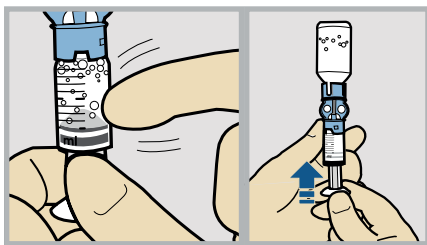
WARNING: Do not use the reservoir or infusion set if insulin or any liquid gets on the top of the reservoir or inside the tubing connector, as shown in the image. Insulin or any liquid may temporarily block the vents. This may result in the delivery of too little or too much insulin, which may cause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



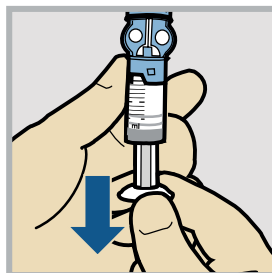
5. Keeping a thumb on the plunger, flip the vial over so the vial is on top. Release the thumb and pull the plunger down to fill the reservoir with insulin.



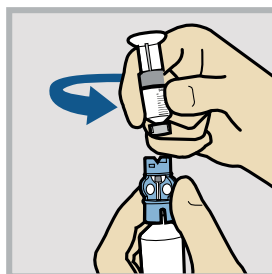
6. Tap the reservoir to move air bubbles to top of reservoir. Push the plunger up to move air into vial.



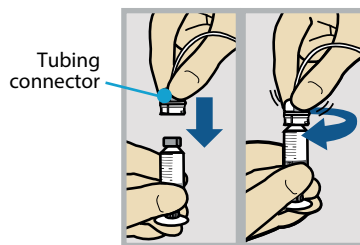
7. Pull the plunger back down to allow the reservoir to fill with the amount of insulin needed for the duration of use indicated for the reservoir.



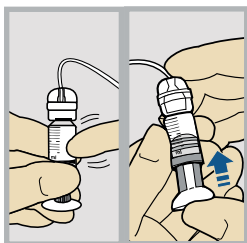
8. To avoid getting insulin on the top of the reservoir, **flip the vial over again so the reservoir is on top**. Hold the transfer guard and turn the reservoir counter-clockwise and remove the reservoir from the transfer guard.



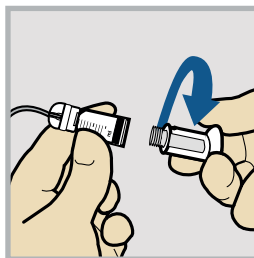
9. Follow the instructions in the infusion set user guide to access the infusion set tubing.
10. Gently push the tubing connector onto the reservoir. Turn the connector clockwise until it is locked into place.



11. Tap the reservoir to move any air bubbles to the top. Push the plunger slightly to move the bubbles into the tubing.



12. Twist the plunger counter-clockwise to loosen it and to remove it.



Placing the reservoir into the pump and filling the tubing with insulin



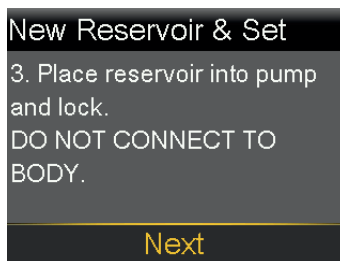
WARNING: Always rewind the pump before placing a new reservoir. Failing to rewind the pump may result in an unintentional infusion of insulin, which may cause hypoglycemia.

To place the reservoir into the pump and fill the tubing with insulin:



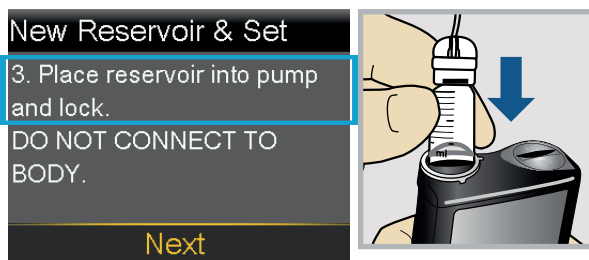
Note: The backlight may have turned off. Press any button to turn the screen back on. Press  to go to the Menu screen, and then select .

1. Select **Next**.



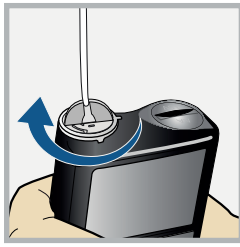
2. Place the reservoir into the pump.

Do not connect the infusion set to the body.



WARNING: Always confirm that the infusion set is disconnected from the body before placing the reservoir into the pump. Failing to disconnect the infusion set from the body may result in an accidental infusion of insulin, and may cause hypoglycemia.

3. Turn the reservoir clockwise until the reservoir locks into place, and select **Next**.



New Reservoir & Set

3. Place reservoir into pump and lock.
DO NOT CONNECT TO BODY.

Next

4. Select **Load** and hold  until the checkmark appears on the screen.
Do not connect the infusion set to the body.

Load Reservoir

Select Load and hold until complete.
DO NOT CONNECT TO BODY.



Load

Next

5. When the checkmark appears, select **Next**.

Load Reservoir

Complete

DO NOT CONNECT TO BODY.



Load

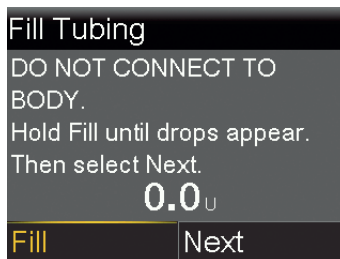
Next



WARNING: Always confirm that the infusion set is disconnected from the body before loading the reservoir and filling the tubing. Failing to disconnect the infusion set from the body may result in an accidental infusion of insulin, and may cause hypoglycemia.

6. Select **Fill** and keep holding  until there are no air bubbles visible in the tubing, and there are drops at the end of the tubing.

Do not connect the infusion set to the body.

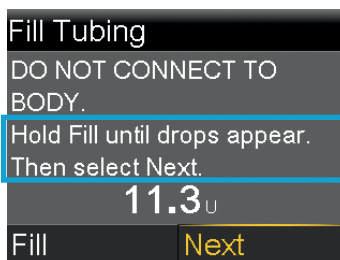


WARNING: Always check the tubing for air bubbles. Continue to press **Fill** until no bubbles remain in the tubing. Air bubbles may result in inaccurate insulin delivery.

7. After drops appear, press **>** and select **Next**.



Note: The location of the infusion set needle may be different depending on the type of infusion set being used.



8. Follow the steps in the infusion set user guide to insert the infusion set into the body before proceeding with the steps on the pump screen.

Fill Cannula?

1. Insert infusion set into body.
2. Select Fill to fill cannula or Done if not needed.

Fill Done



Note: If an infusion set with a steel cannula is used, the cannula does not need to be filled, and **Done** may be selected.

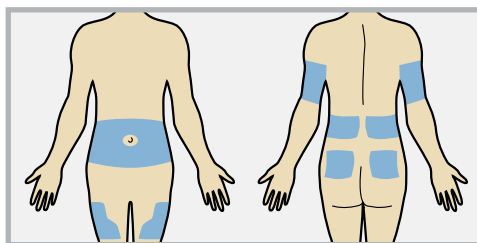
Inserting the infusion set into the body

Always refer to the infusion set user guide and the senter user guide, if needed, for instructions about how to insert an infusion set into the body.



WARNING: Do not remove the reservoir from the pump while the infusion set is connected to the body. Doing so may result in the delivery of too little or too much insulin, which may cause hyperglycemia or hypoglycemia.

Choose an insertion site from the shaded areas. Clean the insertion site with alcohol or other antiseptic as directed by a healthcare professional.



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



CAUTION: Always change the infusion set as indicated by the infusion set user guide. Using the same infusion set for an extended period of time beyond its product labeling can cause infusion set occlusion or site infection.

After the infusion set is inserted into the body follow the steps in the following section to fill the cannula.

Filling the cannula

Filling the soft cannula with insulin is required after the infusion set is inserted into the body and the introducer needle is pulled out. The insulin amount required to fill the cannula depends on the type of infusion set used. Refer to the user guide that came with the infusion set for more information.



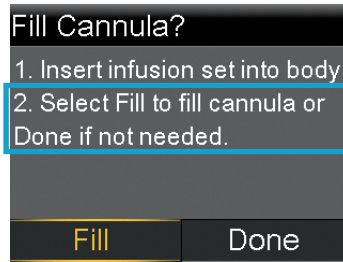
Note: The Fill Cannula action is not required during a reservoir only change. If performing a reservoir only change, select **Done** on the Fill Cannula? screen.



WARNING: Never leave the pump on the Fill Cannula? screen. Insulin delivery is suspended while on the Fill Cannula? screen. Always finish filling the cannula or return to the Home screen, to avoid continued insulin delivery suspension. Prolonged suspension of insulin delivery may cause hyperglycemia.

To fill the cannula:

1. After the infusion set is inserted into the body, select **Fill**.

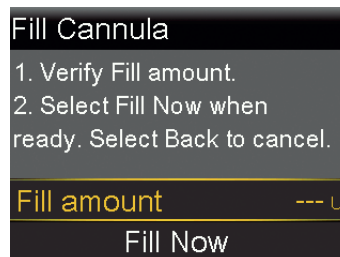


Note: Always verify that the amount shown in the Fill amount field is correct. The pump will remember the fill amount last used. Change the Fill amount if needed.

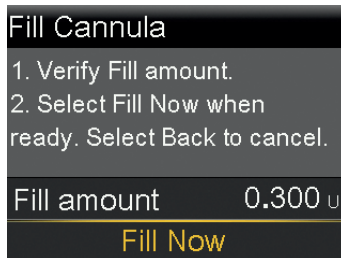
- If the Fill amount is correct, press ▼ to select **Fill Now** and then press Ⓞ.
- If the Fill amount is incorrect, press Ⓞ. Change to the correct amount and press Ⓞ. Then select **Fill Now**.

2. Select **Fill amount** and enter the amount per the infusion set user guide.

After entering the cannula size, press Ⓞ.



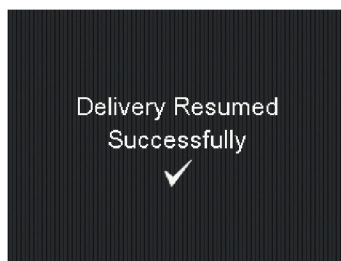
3. Select **Fill Now**.



The screen displays the insulin amount as insulin fills the cannula.

The reservoir and infusion set change is now complete.

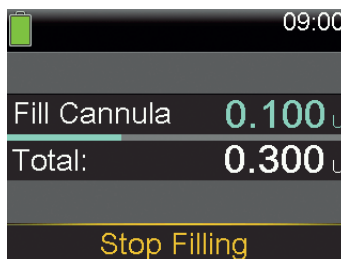
Always check blood glucose (BG) using a blood glucose meter one to three hours after changing the infusion set or reservoir.



Note: Use the following procedure only when it is necessary to stop filling the cannula.

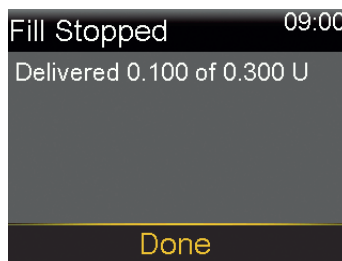
To stop filling the cannula:

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



2. Select **Yes**.

The Fill Stopped screen appears.



3. Select **Done**.

Disconnecting the infusion set

Refer to the infusion set user guide for instructions on how to disconnect the infusion set.

Reconnecting the infusion set

Refer to the infusion set user guide for instructions on how to reconnect the infusion set.

6

Paired devices

Paired devices

This chapter explains how to pair the MiniMed 780G insulin pump with compatible devices.

Pair the Simplera Sync sensor

After the sensor is inserted, pair the pump and sensor. For instructions to pair the pump and sensor, see *Pairing the pump and sensor*, page 178. Insert the sensor before pairing the pump and sensor. For instructions to insert the sensor, see *Inserting the sensor*, page 174.

Setting up the Accu-Chek Guide Link meter

The MiniMed 780G insulin pump with smart device connectivity can pair only with an Accu-Chek Guide Link meter to automatically receive blood glucose (BG) meter readings. If the Accu-Chek Guide Link meter is not paired with the pump, enter BG readings manually. The pump beeps, vibrates, or simultaneously beeps and vibrates when the pump receives a BG reading. Confirm the BG reading and deliver a bolus, if necessary. If a BG reading is not confirmed within 12 minutes, the BG will not be stored. If the BG reading is outside the range of 3.9 mmol/L to 13.9 mmol/L, an alert appears. Follow instructions from a healthcare professional to treat low BG or high BG.

To pair the pump and meter, use the following items:

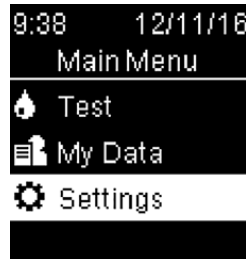
- MiniMed 780G insulin pump with smart device connectivity
- Accu-Chek Guide Link meter

Pairing the pump and meter

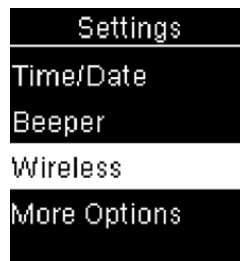
The MiniMed 780G insulin pump with smart device connectivity can pair with up to four Accu-Chek Guide Link meters.

To prepare the meter to pair with the pump:

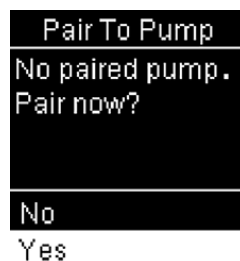
1. Press the **OK** button on the meter to turn on the meter.
2. Select **Settings**.



3. Select **Wireless**.



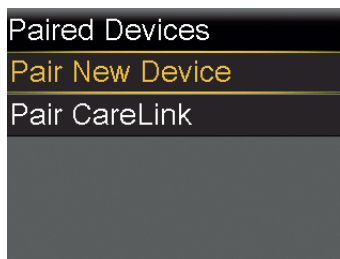
4. Select **Yes** if the confirmation screen appears on the meter screen. Or, if the confirmation screen does not appear, select **Pairing**.



The meter serial number appears on the meter screen. The meter is now ready to pair with the pump.

To prepare the pump to pair with the meter:

1. From the Home screen, press , and then select .
2. Select **Pair New Device**.



The Searching... screen appears. After the pump is done searching, the Select Device screen appears.

3. Select the meter that matches the serial number that displays on the meter screen.

If the correct serial number does not appear, select **Search Again**.



If the connection is successful, a "Pairing successful!" message appears on the pump. A "Paired with pump" message with the serial number of the pump appears on the meter screen. If a Device not found alert appears, see *Pump alarms, alerts, and messages*, page 305 for more information.

Unpair and delete the meter

Unpairing a meter from the pump

Follow this procedure to unpair the Accu-Chek Guide Link meter from the pump.

To unpair the meter from the pump:

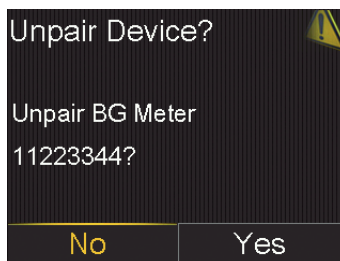
1. From the Home screen, press , and then select .
The Paired Devices screen appears.



2. Select the serial number of the meter to unpair the device. The Accu-Chek Guide Link meter serial number is located on the back of the meter.
The Device Info screen appears.



3. Select **Unpair**.
The Unpair Device? screen appears.



4. Select **Yes** to confirm. Select **No** to cancel.

Deleting the pump from a meter

For steps to delete the pump from a meter, see the Accu-Chek Guide Link User's Manual.

MiniMed Mobile app

The MiniMed Mobile app is an optional accessory that is compatible with the MiniMed 780G system. The app provides a secondary display that allows the user to view pump data. A compatible smartphone is required for the app to function. The app is available for both iOS and Android platforms. Consult the MiniMed Mobile app user guide for installation instructions.

Updating the pump software



Note: This feature may not be available in all geographies.

After an eligibility message for a pump software update is received, use the MiniMed Mobile app to perform the pump software update. The app provides instructions for each step of the process. Follow the instructions provided on the app screens to perform the update.



CAUTION: A stable internet connection is required throughout the entire update process. Avoid the use of unsecure Wi-Fi networks or public Wi-Fi hotspots.

Downloading the pump software update

To check if an update is available, ensure you are logged into the MiniMed Mobile app. The Software is Ready screen appears on the app when the download is complete.

Preparing to install the pump software update

To prepare to install the pump software update:



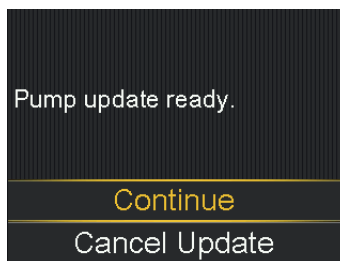
Note: After installation is complete, the SmartGuard feature requires a 5-hour warm-up period before it is active.

- Ensure glucose is within target before starting the update.
- Clear active alerts or alarms.
- If the pump is Suspended on low or Suspended before low, wait until insulin delivery resumes and BG recovers before starting the update.
- If a bolus delivery is in progress, wait until the bolus delivery completes before installing the pump software update.
- If the battery is low, the pump software update will not install. If the battery icon is not green, replace the battery before installing the pump software update.
- Insulin is not delivered and sensor glucose (SG) values are not shown for up to 20 minutes during the pump software installation. Manual injections are not accounted for in the active insulin amount. If an injection is needed during the software update, consult a healthcare professional for how long to wait after a manual injection before using the Bolus Wizard feature. Refer to *Emergency kit, page 28* for necessary supplies to use for backup insulin delivery if needed.

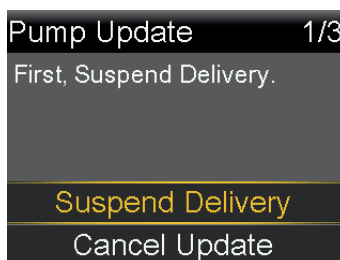
Installing the pump software update

1. When instructed by the app, go to the Home screen on the pump. On the pump, a screen appears when the pump is ready for the software update.

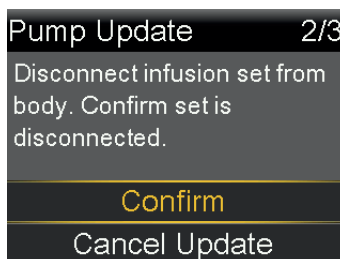
2. Select **Continue**.



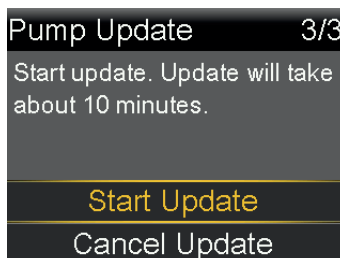
3. Select **Suspend Delivery** to suspend bolus and basal insulin delivery.



4. Disconnect the infusion set from the body, and then select **Confirm**.



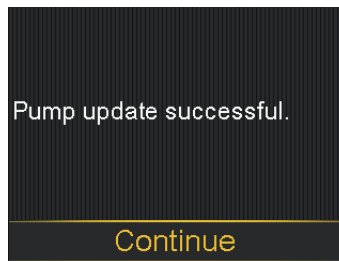
5. Select **Start Update**.



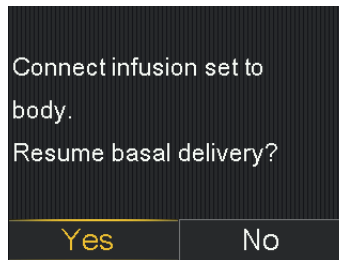
While the pump updates, a screen shows the progress.



6. Select **Continue**.



7. Reconnect the infusion set to the body.
8. Select **Yes** to resume basal insulin delivery.



Note: The previous version of the software is retained if the update is not successful.

Completing the pump software update

Follow the instructions on the app to complete the pump software update.

Uploading device data to CareLink software

Upload system data to CareLink software with the MiniMed Mobile app or the Blue Adapter. Follow the instructions found on the CareLink software to upload system data with the Blue Adapter. Refer to the MiniMed Mobile app user guide for instructions to upload MiniMed 780G system data to CareLink software with the app.

To prepare the pump to upload to CareLink software:

1. From the Home screen, press , and then select .
2. Select **Pair CareLink**.

Follow instructions on the CareLink uploader to complete steps.

Sharing device data with the CareLink Connect app

The CareLink Connect app works with CareLink software. Through the CareLink Connect app, care partners can see information sent from a connected MiniMed Mobile app. A compatible smartphone is required for the app to function. The app is available for both iOS and Android platforms. For more information about sharing data with the CareLink Connect app, see the MiniMed Mobile app user guide and the CareLink Connect app user guide.

7

Continuous glucose
monitoring

Continuous glucose monitoring

This chapter explains how to enter sensor settings and set up continuous glucose monitoring (CGM). CGM requires these items:

- MiniMed 780G insulin pump
- Sensor alert settings provided by a healthcare professional
- Simplera Sync sensor

CGM overview

What is CGM

CGM is a tool that uses a sensor to continuously measure the amount of glucose in interstitial fluid. CGM consists of the following:

- Sensor Glucose (SG) readings that are displayed every 5 minutes.
- Alerts based on current and predicted high and low glucose levels.
- Graphs that show glucose trends over time.
- Trend arrows that show the rate at which the most recent SG readings are (has been) rising or falling.

The sensor does not require calibration for use with the system. However, every blood glucose (BG) meter reading either entered manually or received from a paired meter is used to calibrate the sensor.



WARNING: Do not use SG values to make treatment decisions, including delivering a bolus, while the pump is in Manual mode. When the SmartGuard feature is active and you are no longer in Manual mode, the pump uses an SG value, when available, to calculate a bolus amount. However, if your symptoms do not match the SG value, use a BG meter to confirm the SG value. Failure to confirm glucose levels when your symptoms do not match the SG value can result in the infusion of too much or too little insulin, which may cause hypoglycemia or hyperglycemia. For more information on using the SmartGuard feature, see *SmartGuard*, page 189.



WARNING: Do not use continuous glucose monitoring if hydroxyurea, also known as hydroxycarbamide, is taken. Hydroxyurea is used to treat certain diseases, such as cancer and sickle cell anemia. Hydroxyurea use results in higher sensor glucose readings compared to blood glucose readings. Taking hydroxyurea while using continuous glucose monitoring can result in hypoglycemia caused by over-delivery of insulin, inaccurate or missed alarms and alerts, delay or loss of sensor-enabled insulin suspension, and substantially higher sensor glucose readings in reports than actual blood glucose readings.

Always check the label of any medication being taken to confirm if hydroxyurea or hydroxycarbamide is an active ingredient. If hydroxyurea is taken, consult a healthcare professional. Turn the Sensor feature off to disable continuous glucose monitoring. For more information, see *Deactivating the Sensor feature*, page 181. Use additional blood glucose meter readings to verify glucose levels.



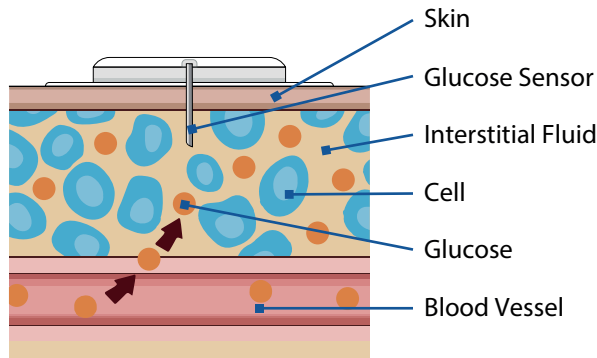
WARNING: Consult a healthcare professional if a medication that contains acetaminophen or paracetamol is taken while wearing the sensor. Medications that contain acetaminophen or paracetamol can falsely raise sensor glucose readings. The level of inaccuracy depends on the amount of acetaminophen or paracetamol active in the body and can differ for each person. Falsely elevated sensor readings can result in over-delivery of insulin, which can cause hypoglycemia. Medications that contain acetaminophen or paracetamol include, but are not limited to, cold medicines and fever reducers. Check the label of any medications being taken to see if acetaminophen or paracetamol is an active ingredient. Use additional blood glucose meter readings to confirm blood glucose levels.

While the SmartGuard feature is active, if acetaminophen or paracetamol is taken, program a temp target for up to eight hours, or the amount of time recommended by a healthcare provider. For more information, see *Setting a temp target*, page 208. Use blood glucose values instead of sensor glucose readings to calculate a meal bolus or correction bolus for up to eight hours, or the duration recommended by a healthcare provider, after taking acetaminophen or paracetamol.

What is blood glucose (BG) and sensor glucose (SG)?

Blood glucose and sensor glucose are measured in different places. It is important to understand the differences between the two, as there are times when the system requires you to enter a blood glucose and there are other times when the system will use a sensor glucose.

Glucose travels between the blood and interstitial fluid. The blood glucose (BG) meter measures glucose levels in your blood. The glucose sensor measures glucose in the interstitial fluid. Blood glucose (BG) meter readings and sensor glucose (SG) readings will be close but will rarely exactly match. This difference is normal and should be expected.



IMPORTANT: When a glucose value is entered into the pump, it must be from a blood glucose (BG) meter.

The system automatically uses the entered glucose value to calibrate the sensor, unless the system gives you the option to calibrate the sensor.

The following table shows when to use a blood glucose (BG) meter reading:

When to use a BG	Examples	
Anytime glucose is entered into the pump, it needs to be a blood glucose (BG) meter reading, not a sensor glucose (SG) value.		
Anytime you deliver a bolus in Manual Mode and you want to use a glucose for a correction.		
Anytime the system requests a blood glucose (BG) meter reading.		



Note: See when to use a blood glucose (BG) meter reading when SmartGuard is active in *Entering a BG value in the SmartGuard feature, page 200*.

Calibrating the sensor

Calibration is the process of using a blood glucose (BG) meter reading to help the sensor glucose (SG) readings more closely match the glucose measured in your blood. This blood glucose (BG) meter reading is not used until you confirm it on the screen. For more information, see *Entering a blood glucose (BG) meter reading*, page 102.

When you are using the MiniMed 780G system with the Simplerla Sync CGM, you do not need to calibrate. However, the system is designed to use every blood glucose (BG) meter reading either entered manually or received from glucose meter to calibrate the sensor.

CGM settings

Sensor alert settings

An SG alert occurs when an SG reading changes at a particular rate, reaches a specified high or low limit, or before a high or low limit is reached. The pump can also be set to suspend insulin delivery before or when a low limit is reached.

High SG settings

High SG settings provide alerts under the following conditions:

- When SG rises rapidly (Rise Alert).
- When SG approaches the high limit (Alert before high).
- When SG reaches the high limit (Alert on high).

The following graph shows the types of high SG settings.



 High SG alert settings

High glucose setting	Description
High limit	The high limit is used as a basis for some high SG settings. The high limit can be set from 5.6 to 22.2 mmol/L, for up to eight different time segments.
Alert before high	This setting provides an alert when SG is predicted to reach the high limit, raising awareness of potential high SG.
Time before high	This setting determines how long an Alert before high occurs before the high limit may be reached. It can be set between 5 and 30 minutes.
Alert on high	This setting provides an alert when SG reaches or exceeds the high limit.
High SG alert	This setting provides an alert when SG is at 13.9 mmol/L or higher for 3 hours. This is a fixed setting and cannot be changed.
Rise Alert	This setting provides an alert when glucose is rising rapidly, such as after a meal or if a bolus is missed. Set the rise rates to match the trend arrows, as shown below, or to a custom rise rate. •  - SG is rising at a rate of 0.06 mmol/L per minute or more. •  - SG is rising at a rate of 0.11 mmol/L per minute or more.

High glucose setting

Description

- **↑↑↑↑** - SG is rising at a rate of 0.17 mmol/L per minute or more.
- **Custom** - SG is rising at a custom rate, set from 0.06 mmol/L to 0.28 mmol/L per minute.

Rise Limit

This setting determines when a Rise Alert occurs.

Setting up the high SG settings

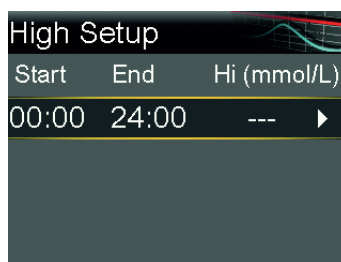
The Sensor feature must be turned on to set up the sensor settings. For more information, see *Turning on the Sensor feature*, page 182.

For details about high SG settings, see *High SG settings*, page 155.

To set up the high SG settings:

1. From the Home screen, press , and then select .
2. Select **Alert Settings > High Alert**.

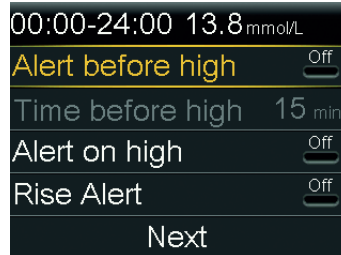
The High Setup screen appears.



3. Select the time segment. The end time flashes.
The start time of the first time segment is always 00:00. Up to eight time segments can be set, each with a different high limit. All the time segments must add up to a 24-hour period.
4. Set the End time.
5. Set your high limit. You can enter a value from 5.6 mmol/L to 22.2 mmol/L, in increments of 0.2 mmol/L.

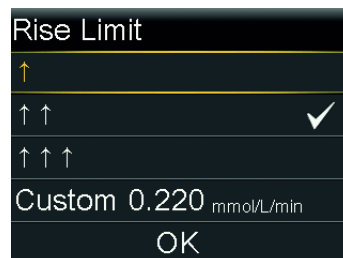
6. Select the arrow beside the End time to select the high alerts for the time segment.

A screen appears and shows the high alerts for the selected time segment.



7. Set the following alerts, as desired:
 - a. Select **Alert before high** to receive an alert before the high limit is reached.
 - b. Set the **Time before high** option between 5 to 30 minutes to receive an alert before the high limit is reached.
 - c. Select **Alert on high** to receive an alert when the high limit is reached.
 - d. Select **Rise Alert** to receive an alert when SG is rising quickly.
8. If Rise Alert is on, perform the following steps to set up the Rise Limit. Otherwise, proceed to step 9.
 - a. Scroll down and select **Rise Limit**.

The Rise Limit screen appears.



- b. Select one, two, or three arrows for the rise rate, or enter a custom rate.

Arrow selection	Minimum rate that SG is rising when an alert occurs.
↑	SG is rising at a rate of 0.06 mmol/L per minute or more.
↑↑	SG is rising at a rate of 0.11 mmol/L per minute or more.
↑↑↑	SG is rising at a rate of 0.17 mmol/L per minute or more.



Note: These arrows appear on the Home screen to indicate the rate at which SG is rising.

- c. To enter a custom rate, select **Custom**, enter the Rise Limit on the Custom Limit screen, and then select **OK**.
- d. Select **OK** again to confirm the Rise Limit settings.
9. Select **Next**.
10. If necessary, enter the remaining time segments to complete the 24-hour period.



Note: For instructions on setting up more than one high limit over a 24-hour period, see *Settings covering a 24-hour period*, page 93.

11. Select **Review**.
12. Review the high SG settings and select **Save**.

To change the high SG settings:

- From the Home screen, press , and then select .
- Select **Alert Settings** > **High Alert**.
The High Setup screen appears.

3. Select **Edit**.
4. Select and adjust the time segment.
5. Select any alert setting to make adjustments, or to turn the setting on or off.
6. Select **Next**.
7. Select **Review**.
8. Review the high SG settings and select **Save**.

High Snooze

The High Snooze feature sets the amount of time before a high alert repeats. The pump shows the high alert again if the high alert condition still exists after the specified snooze time.

To set the High Snooze:

1. From the Home screen, press , and then select .
2. Select **Alert Settings > Snooze High & Low**.
The Snooze screen appears.
3. Select **High Snooze** and enter a time in 5-minute increments from 5 minutes to 3 hours.
4. Select **Save**.

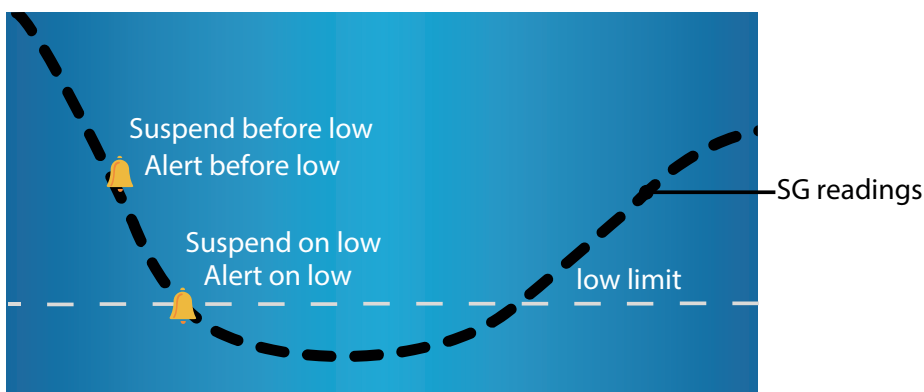
Low SG settings

Low SG settings alert or suspend insulin delivery when SG either approaches or reaches the low limit.



Note: The MiniMed Mobile app may be used to view the sensor graph on a mobile device. Always read and acknowledge all alarms and alerts on the pump. If the pump simultaneously generates more than one alarm or alert, only one of the alarms or alerts appears on the mobile device.

The following graph shows the available low SG settings.



 Low SG alert and suspend settings



WARNING: The Suspend before low and Suspend on low features are not intended to treat low BG. Suspending insulin delivery when SG is low may not bring BG back to the target range for several hours, which may cause hypoglycemia. If symptoms do not match the SG value, use a BG meter to confirm glucose levels before making treatment decisions.

For information about how to program low SG settings in Manual mode, see *Setting up the low SG settings*, page 167. The sensor must be turned on before low SG settings can be programmed.

Low limit

The low limit is used as a basis for optional low SG alerts and Suspend by sensor features. The low limit can be set from 2.8 mmol/L to 5.0 mmol/L, for up to eight different time segments.

The Low SG alarm appears when SG readings reach or fall below 3.0 mmol/L. This threshold may be higher than other sensors. Glucose detection and alert rates are less reliable below this threshold. This is a fixed

setting and cannot be changed. When the alarm appears, it shows the SG reading next to the Low SG alarm. This alarm does not stop insulin delivery.

The Suspend before low feature

The Suspend before low feature stops insulin delivery when SG is approaching the low limit. This feature can help minimize the amount of time spent with low glucose.



WARNING: Do not use the Suspend before low feature without first reading the information in this user guide and receiving training from a healthcare professional. The Suspend before low feature temporarily suspends insulin delivery for a maximum of two hours. Under some conditions of use, the pump can suspend insulin delivery again, resulting in under-delivery. Prolonged under-delivery of insulin may increase the risk of hyperglycemia and diabetic ketoacidosis. Always be aware of symptoms. If symptoms don't match SG readings, confirm SG with a BG meter reading.

The Suspend before low feature is turned off by default. Consult a healthcare professional before the Suspend before low feature is used.

If the Suspend before low feature is turned on, Alert on low is automatically turned on. Enabling Alert before low is optional.

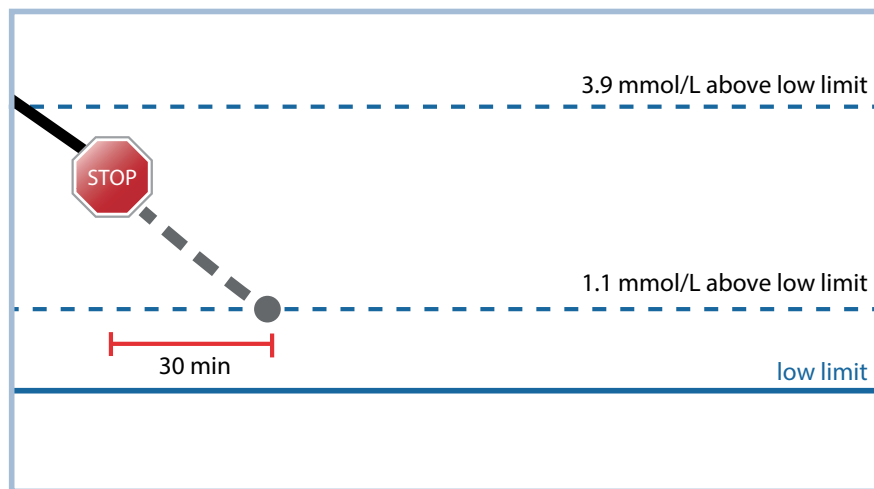
- If Alert before low is off, a Suspend before low alert occurs, but the pump does not beep or vibrate when insulin delivery is suspended.
- The Suspend before low and Suspend on low features cannot be on at the same time. When either feature is on, the Resume basal alert can be activated.

Suspend before low conditions

When a Suspend before low event occurs, insulin delivery is suspended. A Suspend before low event occurs if both of the following conditions are met:

- SG reading is at the low limit or is within 3.9 mmol/L above the low limit.
- SG is predicted to reach or fall below a level that is 1.1 mmol/L above the low limit within approximately 30 minutes.

The following image is an example of what can happen during a Suspend before low event.



Responding to a Suspend before low event

When the Suspend before low feature suspends insulin delivery, the icon flashes. If SG reaches the low limit, an Alert on low occurs.

When a Suspend before low event occurs, insulin delivery can be suspended for a minimum of 30 minutes or up to a maximum of two hours. Basal insulin delivery can be manually resumed at any time. For details, see *Manually resuming basal insulin delivery during a Suspend before low or Suspend on low event*, page 170. After 30 minutes, basal insulin delivery resumes if both of the following conditions are met:

- SG is at least 1.1 mmol/L above the low limit.
- SG is predicted to be more than 2.2 mmol/L above the low limit within 30 minutes.

If the Suspend before low alert is not cleared within two hours, the pump resumes insulin delivery and displays a Basal delivery resumed alert.

Alert before low

Alert before low provides an alert when SG is predicted to reach the low limit, and increases awareness of potential low SG.

The Alert before low feature works as follows:

- If Alert before low is on, and both suspend features are off, Alert before low occurs 30 minutes before the low limit is reached.
- If the Suspend on low feature is on and Alert before low is on, Alert before low occurs 30 minutes before the low limit is reached.
- If the Suspend before low feature is on and Alert before low is on, a Suspend before low alert occurs when insulin delivery is suspended. For details, see *The Suspend before low feature*, page 162.

The Suspend on low feature

The Suspend on low feature stops insulin delivery when SG readings reach or fall below the low limit. When a Suspend on low event occurs, insulin delivery is suspended. This feature is for situations when a person cannot respond to a low glucose condition and can help minimize the amount of time spent with low glucose.

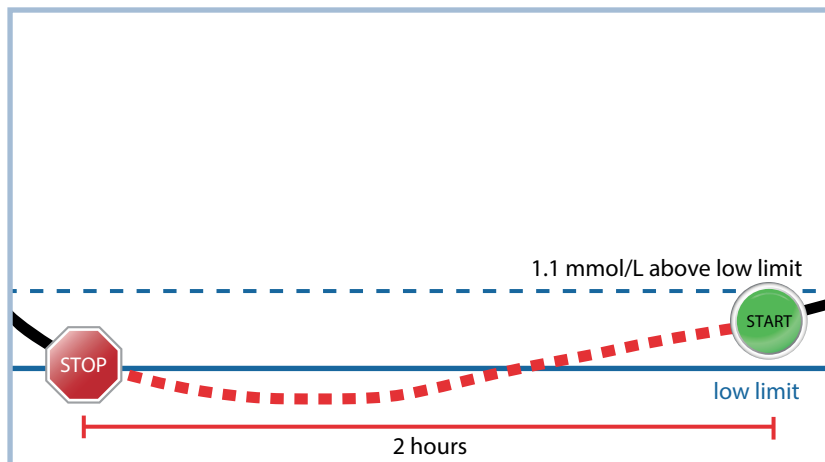


WARNING: Do not use the Suspend on low feature without first reading the information in this user guide and receiving training from a healthcare professional. The Suspend on low feature temporarily suspends insulin delivery for a maximum of two hours. Under some conditions of use, the pump can suspend insulin delivery again, resulting in under-delivery. Prolonged suspension of insulin delivery may increase the risk of serious hyperglycemia, ketosis, and ketoacidosis.

The Suspend on low feature is off by default. Consult a healthcare professional for guidance before the Suspend on low feature is used.

When the Suspend on low feature is on, Alert on low is activated automatically. For more information, see *Alert on low*, page 167.

The following image is an example of what can happen during a Suspend on low event.



Responding to a Suspend on low event

When the Suspend on low feature suspends insulin delivery, the icon flashes.

When a Suspend on low event occurs, a pump alarm occurs and insulin delivery remains suspended for a minimum of 30 minutes, up to a maximum of two hours. Insulin delivery can be resumed manually at any time. For details, see *Manually resuming basal insulin delivery during a Suspend before low or Suspend on low event*, page 170. After 30 minutes, basal insulin delivery resumes under the following conditions:

- SG is at least 1.1 mmol/L above the low limit.
- SG is predicted to be more than 2.2 mmol/L above the low limit within 30 minutes.

If the Suspend on low alarm is not cleared within two hours, the pump resumes insulin delivery and displays an emergency message.

When the Suspend before low or Suspend on low features are unavailable

After a Suspend before low or Suspend on low event, both features are not active for a period of time to help prevent prolonged suspension of insulin delivery. Insulin delivery is suspended for a maximum of two hours. Insulin delivery can be manually suspended at any time. For details, see *Suspending all insulin delivery and resuming basal insulin delivery*, page 98.

When the Suspend before low and the Suspend on low features are unavailable, the suspend by sensor icon on the Home screen appears with a red X .

Response to Suspend before low or Suspend on low events	Duration that the Suspend before low or Suspend on low feature is unavailable
The alert is cleared within two hours and the pump stays suspended for the maximum two-hour suspend time.	The feature is unavailable for 30 minutes after basal insulin delivery resumes.
The alert is cleared within two hours and insulin delivery automatically resumes due to rising SG levels.	The feature is unavailable for 30 minutes after basal insulin delivery resumes.
The alert is cleared within two hours and basal insulin delivery is manually resumed.	The feature is unavailable for 30 minutes after basal insulin delivery resumes.
The alert is not cleared within 2 hours.	Basal insulin delivery automatically resumes and the feature is available.
The alert is cleared within 30 minutes after basal insulin delivery is automatically resumed.	The feature is unavailable for the remaining time left in the 30 minutes after basal insulin delivery resumed.
The alert is cleared between 30 minutes and four hours after basal insulin delivery is resumed.	The feature is available.
The alert is not cleared.	The feature is unavailable for four hours after basal delivery automatically resumes.

Alert on low

The Suspend before low and the Suspend on low features automatically activate Alert on low. When Alert on low is on, the pump displays an alert when SG reaches or falls below the low limit. If insulin delivery is suspended by one of these features and the alert is not cleared, an emergency message appears.

Automatically resuming basal insulin delivery after a Suspend before low or Suspend on low event

If insulin delivery is suspended by either the Suspend before low or the Suspend on low feature, basal insulin delivery automatically resumes under one of the following conditions:

- If insulin delivery is suspended for a minimum of 30 minutes and SG readings are at least 1.1 mmol/L above the low limit and expected to be more than 2.2 mmol/L above the low limit within 30 minutes
- After a maximum of two hours

Resume basal alert

The Resume basal alert indicates when basal insulin is resumed automatically. When basal insulin delivery resumes and the Resume basal alert is off, a message appears indicating that basal insulin delivery has resumed.

If basal insulin delivery resumes after the maximum suspend time of two hours, an alert appears even if the Resume basal alert is off.

Setting up the low SG settings

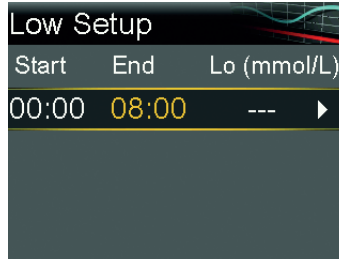
The Sensor feature must be turned on to set up the sensor settings. For more information, see *Turning on the Sensor feature*, page 182.

For information about the low SG settings, see *Low SG settings*, page 160.

To set up the low SG settings:

1. From the Home screen, press , and then select .
2. Select **Alert Settings** > **Low Alert**.

The Low Setup screen appears.



3. Select the time segment. The end time flashes.

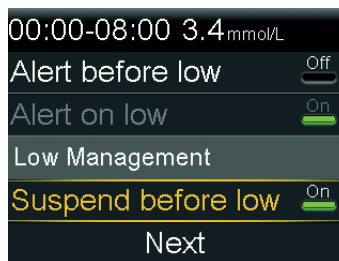
The start time of the first time segment is always 00:00. Up to eight time segments can be set, each with a different low limit. All the time segments must add up to a 24-hour period.

4. Set the End time.

5. Set your low limit. You can enter a value from 2.8 mmol/L to 5.0 mmol/L, in increments of 0.2 mmol/L.

6. Select the arrow beside the End time to select the low SG settings for the time segment.

A screen appears and shows the available settings for the selected time period.



7. Set the following alerts, as desired:

- a. Select **Suspend before low** to set the pump to suspend insulin delivery before the low limit is reached.
- b. Select **Alert before low** to receive an alert before the low limit is reached.

- c. Select **Suspend on low** to set the pump to suspend insulin delivery when SG reaches or falls below the low limit.
- d. Select **Alert on low** to receive an alert when SG reaches or falls below the low limit.
- e. Select **Resume basal alert** to receive an alert when basal insulin delivery resumes during a suspend event. When this alert is off, the Basal delivery resumed message still appears.



Note: The Suspend before low and the Suspend on low features cannot both be on during the same time segment.

- 8. Select **Next**.
- 9. If necessary, enter the remaining time segments to complete the 24-hour period.



Note: For instructions on setting up more than one low limit over a 24-hour period, see *Settings covering a 24-hour period*, page 93.

- 10. Select **Review**.
- 11. Review the low SG settings, and select **Save**.

To change the low SG settings:

- 1. From the Home screen, press , and then select .
- 2. Select **Alert Settings > Low Alert**.
The Low Setup screen appears.
- 3. Select **Edit**.
- 4. Select and adjust the time segment.
- 5. Select any alert setting to make adjustments, or to turn the setting on or off.

6. Select **Next**.
7. Select **Review**.
8. Review the low SG settings, and select **Save**.

Low Snooze

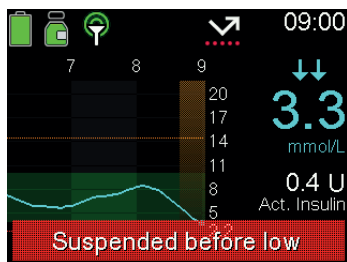
The Low Snooze feature sets the amount of time before a low alert repeats. The pump shows the low alert again if the low alert condition still exists after the specified snooze time.

To set the Low Snooze:

1. From the Home screen, press , and then select .
2. Select **Alert Settings** > **Snooze High & Low**.
The Snooze screen appears.
3. Select **Low Snooze** and enter a time in 5-minute increments from 5 minutes to 1 hour.
4. Select **Save**.

Manually resuming basal insulin delivery during a Suspend before low or Suspend on low event

When the pump suspends insulin due to a Suspend before low or Suspend on low event, the Home screen shows which event is active in the red banner.



Basal insulin delivery automatically resumes when certain conditions are met. Basal delivery can be manually resumed at any time.

To manually resume basal delivery:

1. From the Home screen, press , and then select .
2. Select **Resume Basal**.
3. Select **Yes** to resume basal insulin delivery.

Silencing sensor alerts

The Alert silence feature silences certain sensor alerts for a set period of time. When using this option, the Alert silence icon  appears on the Home screen. The system still displays any alerts that occur, but there is no sound or vibration if they are silenced. This information can be reviewed in the Alarm History screen.

The Alert silence feature does not silence:

- **High SG alert**—When your sensor glucose (SG) value is above 13.9 mmol/L for more than three hours
- **Low SG alarm**—When your sensor glucose (SG) value falls below 3.6 mmol/L
- **SmartGuard exit alert**—When the pump exits the SmartGuard feature

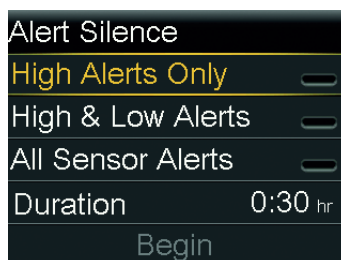
The following table describes the sensor alerts that are silenced with each option.

Option	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 Note: Alert on low cannot be silenced if the Suspend before low or Suspend on low features are turned on
All Sensor Alerts	All alerts listed previously for High & Low Alerts, as well as the following: • All calibration alerts, reminders, or error messages that may result from entering a BG reading

Option	Silences these alerts
	• All alerts related to sensor insertion, including alerts about sensor warm-up, changing the sensor, sensor expiration, sensor updating, and connection issues • All alerts related to the sensor, including connection issues

To silence sensor alerts:

1. From the Home screen, press , and then select .
2. Select **Silence Sensor Alerts**.



3. Select **High Alerts Only**, **High & Low Alerts**, or **All Sensor Alerts**. Refer to the previous table for details about the alerts silenced with each selection.



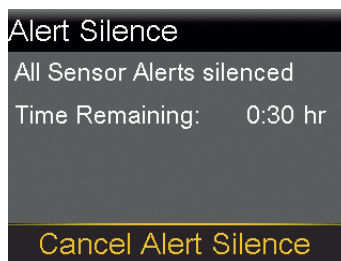
Note: Silencing All Sensor Alerts, prevents the sound and vibration of most alerts related to SG readings, and the sensor. Silencing All Sensor Alerts does not silence the SmartGuard exit alert, the High SG alert, or the Low SG alarm for when SG is below 3.6 mmol/L.

4. Set the **Duration**. The duration can be set in 15-minute increments from 30 minutes to 24 hours.
5. Select **Begin**.

To cancel Alert Silence:

1. From the Home screen, press , and then select .

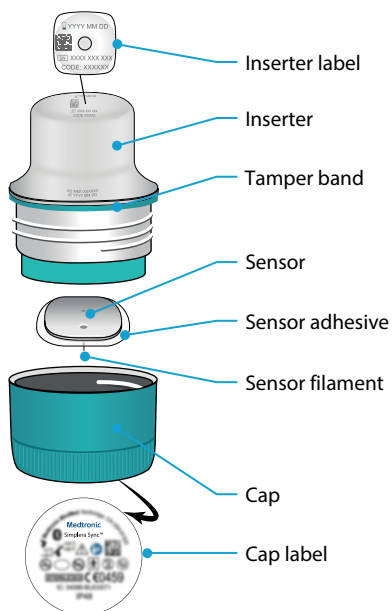
2. Select **Alert Silence**.



3. Select **Cancel Alert Silence**.

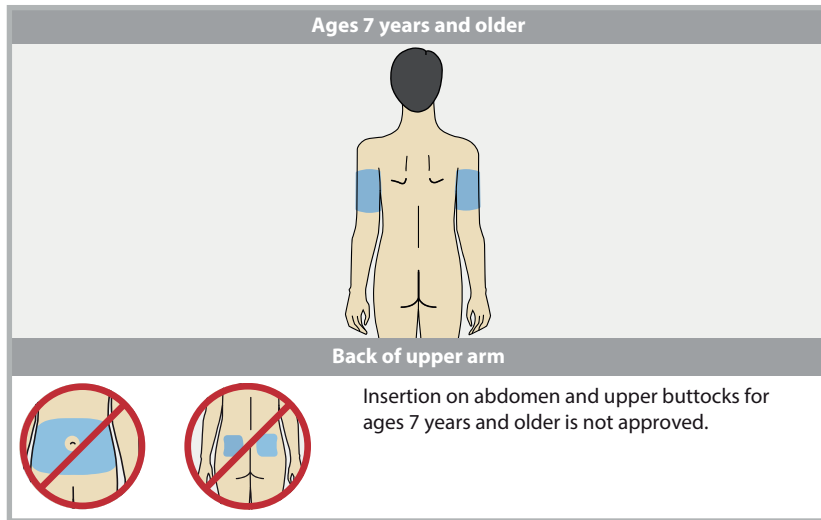
Simplera Sync sensor

Simplera Sync sensor components



Where to insert the sensor

The image that follows shows the insertion sites for ages 7 years and older. Target the shaded areas shown in the image, and make sure that the insertion site has a sufficient amount of fat.



Note: Assistance from another person may be needed for sensor insertion into the back of the upper arm. If assistance is not needed, a mirror may be helpful for self-insertion.

Inserting the sensor

To insert the sensor:

The inserter label is on the top of the inserter.

1. Before insertion, perform the following steps:
 - a. Inspect the expiration date on the inserter label, at the top of the inserter. Do not use an expired Simplera Sync sensor.
 - b. Make note of the serial number (SN) and the CODE. Both numbers will be used later to pair the sensor with the MiniMed 780G insulin pump.



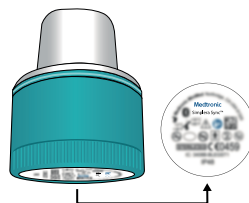
Note: The SN and CODE label is also on the inside of the Simplera Sync sensor box lid.



2. Inspect the cap label for damage before insertion.



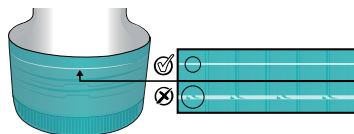
Note: Do not use the Simplera Sync sensor if the cap label is damaged or is missing from the cap.



3. Inspect the tamper band to make sure that it is not broken, damaged, or missing from the device.



Note: Do not use the Simplera Sync sensor if the tamper band is broken, damaged, or missing from the device.

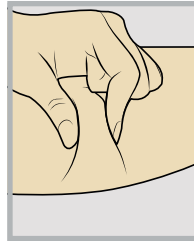


4. Wash hands thoroughly with soap and water.



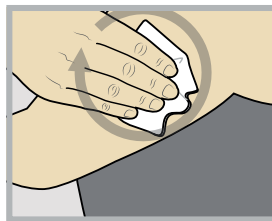
Note: Wear gloves when inserting the Simplera Sync sensor into another person to avoid accidental contact with patient blood. Minimal bleeding can occur.

5. Choose an insertion site that has a sufficient amount of fat. For insertion sites, see *Where to insert the sensor*, page 173.



For the best sensor performance, and to avoid accidental sensor removal, do not insert the Simplera Sync sensor into the following areas:

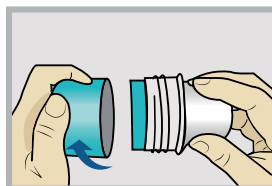
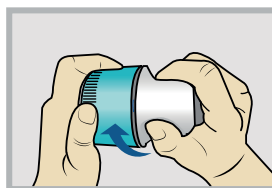
- muscle, tough skin, or scar tissue
 - areas that are constrained by clothing or accessories
 - areas subjected to rigorous movement during exercise
6. Clean the insertion site with alcohol or other antiseptic wipe as directed by your healthcare provider. Allow the insertion site to air dry.



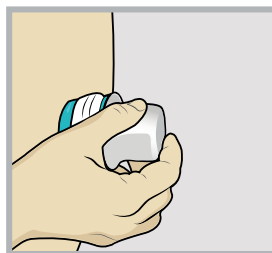
7. Unscrew the cap from the inserter, breaking the tamper band.



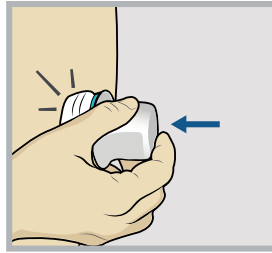
Note: Do not use the Simplerla Sync sensor if the tamper band is broken, damaged, or missing from the device.



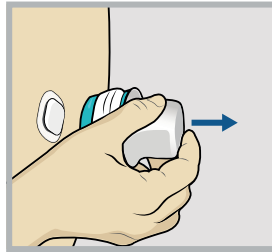
8. Place the inserter on top of the prepared insertion site.



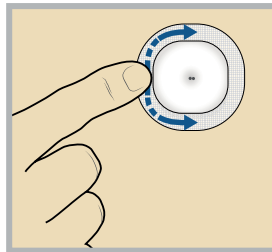
9. Press the inserter firmly against the body until there is a click.



10. Gently pull the inserter straight out of the body.



11. Smooth down the sensor adhesive with a finger to ensure the sensor stays on the body for the entire duration of use.



Note: Use over-the-counter tape if needed for additional adhesion.

12. Follow the steps in the next section to pair the pump and sensor.

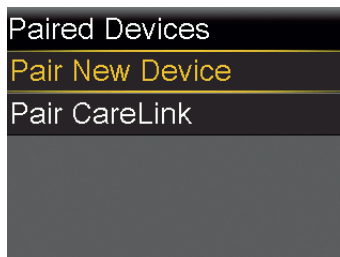
Pairing the pump and sensor

The pump and sensor must be paired to use the sensor. When paired, the pump and sensor communicate with each other through a wireless connection. Only one sensor can be paired with the pump.

When you pair a new sensor with the pump, the existing sensor is automatically unpaired.

To pair the pump and sensor:

1. Insert the sensor. For details, see *Inserting the sensor*, page 174.
2. From the Home screen, press , and then select .
3. Select **Pair New Device**.



The Searching... screen appears.



Note: The search process can take up to 20 seconds.

The Select Device screen appears with a list of available devices.

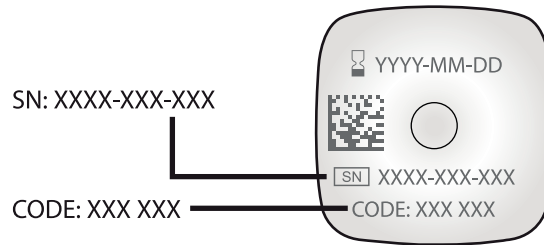
4. Select the CGM device that matches the serial number indicated on the inserter label on the top of the inserter.

If the serial number on the pump screen does not match, select **Search Again**.



The Confirm CODE screen appears.

5. If the code on the pump screen matches the code on the inserter label on the top of the inserter, select **Confirm**.



Select **Cancel** if the code is incorrect.

If the Simplera Sync sensor is not paired with the pump within 20 minutes after the cap is removed from the inserter, enter the code and select **Confirm** to pair the sensor. This is for security purposes.



Note: If the sensor is unintentionally unpaired, go to History > Paired Sensors to find the serial number and code, and pair the sensor again.

When the connection is successful, a "Pairing successful!" message appears on the pump. When the sensor is communicating with the pump, the Sensor feature is turned on and  appears on the Home screen. If a Device not found alert appears, see *Pump alarms, alerts, and messages*, page 305 for more information.

After the sensor is inserted, the “Sensor warm up X:XX hr” message appears on the Home screen until the sensor warm up is complete. After the warm up is complete, the pump begins receiving SG readings.

The “Waiting for warm up to start” message might appear briefly on the Home screen.



Note: It may take up to five minutes for the “Sensor warm up X:XX hr” message to appear. The warm up period lasts two hours.

Deactivating the Sensor feature

The Sensor feature may be turned off at any time. When the sensor is not used, turn off the Sensor feature to avoid a sensor alert. The Sensor feature must be turned on again before settings can be changed. The Sensor feature is turned on when the sensor is paired to the pump.

To deactivate the Sensor feature:

1. From the Home screen, press , and then select .
2. Select **Device Settings** > **Sensor**.
3. Select **Sensor**.
4. Select **Yes** to turn off the Sensor feature.

Unpairing the sensor from the pump

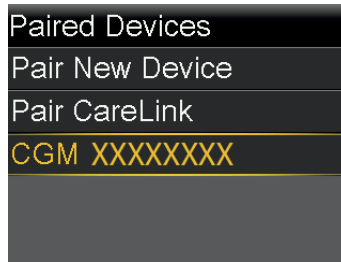
The sensor does not need to be unpaired from the pump before pairing a new sensor.

When you pair a new sensor with the pump, the existing sensor is automatically unpaired.

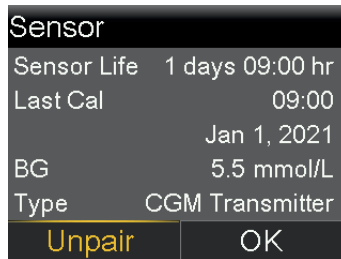
Follow this procedure to unpair the sensor from the pump.

To unpair the sensor from the pump:

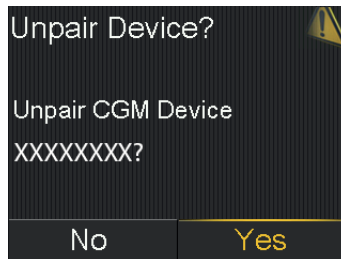
1. From the Home screen, press , and then select .
- The Paired Devices screen appears.



2. Select **CGM** with the correct serial number.
The Sensor screen appears.



3. Select **Unpair**.
The Unpair Device? screen appears.



4. Select **Yes** to confirm. Select **No** to cancel.
When the sensor is unpaired from the pump, a No Paired CGM banner appears on the Home screen.

Turning on the Sensor feature

The Sensor feature automatically turns on when a Simplerla Sync sensor is paired to the pump. These instructions can help you if you turn the Sensor feature off during sensor use and need to turn the feature back on. The

Sensor feature must be on before sensor alerts can be set up and SG levels can be monitored.

To turn on the Sensor feature:

1. From the Home screen, press , and then select .
2. Select **Device Settings** > **Sensor**.
3. Select **Sensor** to turn the feature on or off.

Removing the sensor

To remove the sensor:

1. Gently peel the sensor adhesive away from the body.
2. Dispose of the Simplera Sync sensor in accordance with all local laws and regulations. See the Disposal section in the sensor user guide.

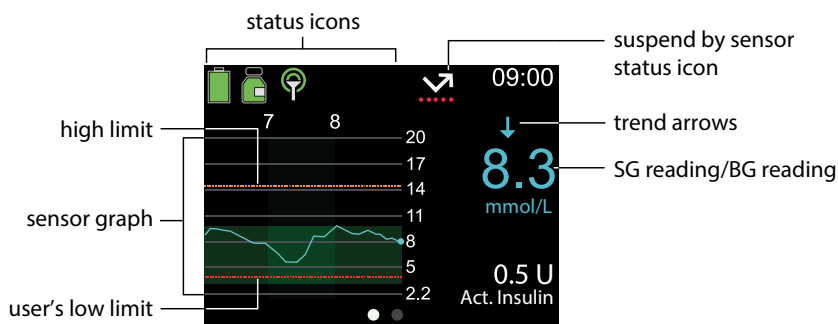
Using CGM

Home screen with CGM in Manual mode

When the Sensor feature is active, the Home screen displays a real-time graph that shows CGM information.

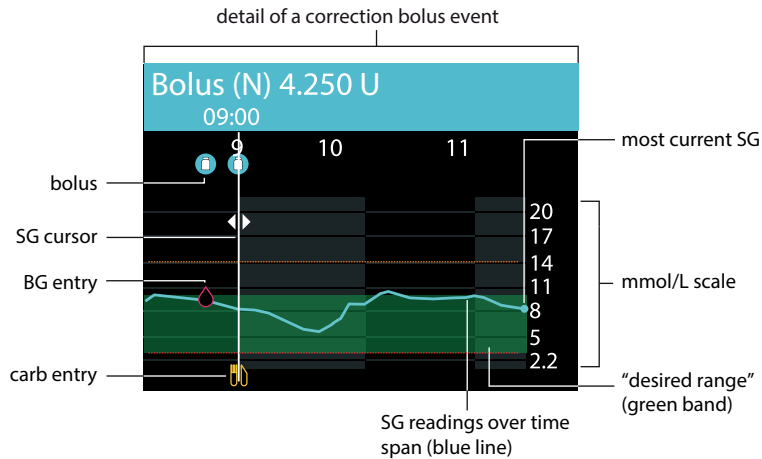


Note: To see the Home screen while the SmartGuard feature is active, see *Home screen with the SmartGuard feature*, page 198.



For more information about the icons that appear on the Home screen with CGM in Manual mode, see *Status icons*, page 78.

Sensor graph



The sensor graph includes the following information:

- The most recent SG reading.
- Historical SG readings for the last 3-hour, 6-hour, 12-hour, or 24-hour periods.
- High and low SG limits.
- Carb entries.
- Delivered boluses.
- Suspend events caused by Suspend before low or Suspend on low.
- BG entries.

There are several reasons why an SG reading may not appear on the graph:

- A recently inserted sensor is warming up.
- A recently connected or reconnected sensor is not ready.
- An error condition or a sensor-related alert has occurred or is occurring.
For a list of sensor alerts, see *CGM (sensor) alarms, alerts, and messages*, page 322.

When there is a significant difference between SG and BG readings

A difference of 40% or more between the SG and BG might indicate that a sensor is not working properly. If this occurs, a calibration of the sensor may fail and the SG values will be lost. You will need to wait at least 15 minutes before entering another BG.

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.

Trend arrows

The trend graph indicates how sensor glucose (SG) may have recently changed. The trend arrows indicate the rate at which the most recent SG readings are rising or falling. SG readings may trend up or down during certain activities, such as eating, giving a bolus, or when exercising. These icons appear only when the sensor feature is turned on.

- SG with no trend arrows: Rate of change of SG is less than 0.06 mmol/L per minute.
-  or : SG has been rising or falling at a rate of 1.11-2.22 mmol/L over the last 20 minutes, or 0.06-0.11 mmol/L per minute.
-  or : SG has been rising or falling at a rate of 2.22-3.33 mmol/L over the last 20 minutes, or 0.11-0.17 mmol/L per minute.

- **↑↑↑** or **↓↓↓**: SG has been rising or falling at a rate of more than 3.3 mmol/L over the last 20 minutes, or more than 0.17 mmol/L per minute.

Consider any active insulin that is available. Active insulin may cause SG to decrease and can affect treatment decisions. For more information about active insulin, see *Bolus Wizard settings in Manual mode, page 106*.

8

SmartGuard

SmartGuard

This chapter provides information about how to set up and start using the SmartGuard feature. The SmartGuard feature uses sensor glucose (SG) values provided by the SimplerA Sync sensor to automatically adjust insulin delivery.



WARNING: Do not use the SmartGuard feature for people who require less than 8 units or more than 250 units of total daily insulin per day. A total daily dose of at least 8 units, but no more than 250 units, is required to use the SmartGuard feature.

Introduction

The SmartGuard feature uses carb information, SG, and SmartGuard target values to control insulin delivery. It also can automatically deliver a correction bolus to help correct a high SG reading. The MiniMed 780G insulin pump requires a minimum of eight units and a maximum of 250 units per day to operate using the SmartGuard feature.



Note: The Auto correction feature uses SG values to determine bolus insulin doses. Auto correction boluses are delivered without user acknowledgment. The accuracy of SG values can be lower than the accuracy of blood glucose (BG) meter readings, which are checked with a blood glucose (BG) meter.

The SmartGuard feature is designed to maximize the amount of time that glucose levels stay in the range of 3.9 mmol/L to 10.0 mmol/L. The following table describes features that the system uses to maximize time in range.

Feature name	Description
SmartGuard target: 5.5 mmol/L, 6.1 mmol/L, or 6.7 mmol/L	Consult a healthcare provider to determine which SmartGuard target to use to maximize time in range. The default setting is 5.5 mmol/L.
Auto Basal	When using the SmartGuard feature, basal insulin is automatically delivered based on SG readings and recent insulin delivery needs.
Target for Auto correction bolus based on SG: 6.7 mmol/L	The MiniMed 780G system may deliver a bolus automatically, as frequently as every 5 minutes, if the SmartGuard feature determines that a correction bolus is necessary. The default setting for Auto correction is set to On.
Temp Target: 8.3 mmol/L	A temp target can be set for events such as exercise or other times when less insulin is needed. If a temp target is used for exercise, consider starting it one to two hours before beginning the exercise. Auto correction boluses are not delivered while a temp target is active.



Note: When using the SmartGuard feature, meal boluses are still required.

The SmartGuard feature requires accurate sensor measurements and carb information to deliver insulin for meals. This insulin therapy requires the use of the Bolus feature to deliver boluses to cover meals.

When using the SmartGuard feature:

- If an Enter BG now alert occurs, enter a BG meter reading.
- Do not enter an SG reading when the system requests a BG reading.
- Bolus amount cannot be modified when delivering a bolus in the SmartGuard feature. If SG readings do not match with symptoms, enter a BG value from a BG meter.

Auto Basal

When the SmartGuard feature is active, the basal insulin dose is calculated using SG values from the sensor. The automatic delivery of insulin is called Auto Basal.



Note: In Manual Mode, basal insulin will not be delivered if basal settings are not entered and saved. There will be no message that the basal rates are not programmed.

Auto Correction

The pump may deliver a bolus automatically when the SmartGuard feature determines it is needed for correction, to maximize the time in range, between 3.9 mmol/L and 10.0 mmol/L. Because this is an automated bolus, no action is required. The Home screen shows when an Auto Correction bolus occurs.

Auto Correction boluses will stop after the total correction insulin delivered in a 45 minute period exceeds 8% of Total Daily Dose (TDD). Be sure to take boluses for meals to prevent this from happening. Auto Correction boluses are not intended to replace meal boluses.

Giving a bolus when the SmartGuard feature is active

A meal bolus can be delivered while using the SmartGuard feature. For more information, see *Delivering a bolus in the SmartGuard feature*, page 202.



WARNING: Always confirm an SG value that does not match your symptoms. When the SmartGuard feature is active and you are no longer in Manual mode, the pump uses an available SG value to calculate a bolus amount. However, if your symptoms do not match, the SG value can result in the infusion of too much or too little insulin, which may cause hypoglycemia or hyperglycemia.

Preparing to set up the SmartGuard feature

The SmartGuard feature requires a 48-hour warm-up period before activation. This warm-up period begins at midnight after the pump starts delivering insulin and it does not require sensor use. During the warm-up period, the pump collects and processes data for use by the SmartGuard feature.



Note: A basal pattern must be programmed for use during the warm-up period and for instances when the pump is in manual mode. During the warm-up period the pump should also be used to give boluses.

To prepare the pump for the SmartGuard feature:

1. Cancel any active Temp Basal rates. See *Canceling a temp basal or preset temp basal*, page 254.
2. Confirm that insulin delivery is not suspended. See *Suspending all insulin delivery and resuming basal insulin delivery*, page 98.
3. Set the carb ratio. See *Changing the carb ratio*, page 264.
4. Review the high and low limit settings. High and low limit settings apply when in Manual mode and when using the SmartGuard feature. See *Sensor alert settings*, page 155 for details.
5. Enter a new BG reading.



WARNING: If the pump has been used in the last 21 days to practice button pressing, or if insulin that was programmed into the pump was not the user's actual insulin delivery, clear active insulin and the total daily doses tracked by the SmartGuard feature before using the SmartGuard feature. Failure to do so may result in the delivery of too little or too much insulin, which can cause hyperglycemia or hypoglycemia. The SmartGuard feature uses the recent delivery history on the pump to determine the insulin delivery amount.

Consult with your healthcare professional about using the Clear Active Insulin feature in the Manage Settings menu to clear both active insulin and the total daily dose for the SmartGuard feature.

Setting up the SmartGuard feature

The SmartGuard feature requires 48-hours of insulin delivery before the feature can be used. This warm up period begins at the first midnight after delivery has started. For more information, see *Preparing to set up the SmartGuard feature*, page 192.

To set up the SmartGuard feature:

1. From the Home screen, press , and then select .
2. Select **SmartGuard** to turn the feature on or off.



Note: Certain additional requirements must be met before the SmartGuard feature activates. For more information, see *SmartGuard Checklist*, page 195.

3. Select **SmartGuard Settings** and enter the following information:

- Select the SmartGuard target: 5.5 mmol/L, 6.1 mmol/L, or 6.7 mmol/L.
- Confirm that Auto Correction is on to activate automatic correction boluses.



Note: The Auto correction feature is turned on by default. When this setting is on, the pump automatically delivers correction boluses to help correct a high SG reading. For information, see *Delivering a bolus in the SmartGuard feature*, page 202.

4. Select **Save**.

Conditions to activate the SmartGuard feature

If the pump is turned off for more than 2 weeks and is turned back on, the pump requires a 48 hour warm-up period before the SmartGuard feature activates.

If the pump has been off for 2 weeks or less and is turned back on, a 5 hour warm-up period is required before the SmartGuard feature activates.

If the SmartGuard feature is on but not active, the SmartGuard Checklist screen indicates the requirements needed to activate the SmartGuard feature. See *SmartGuard Checklist*, page 195.

The system requires 5 hours for the SmartGuard active insulin amount to update. This update time begins under the following conditions:

- A complete pump reset caused by a loss of power or a software error.
- When the insulin is resumed after being manually suspended for 4 hours or longer.
- When you update the pump software.

SmartGuard active insulin information is valid until one of the conditions listed above occurs, which restarts the 5 hour update time. The SmartGuard feature is unavailable during this time.

Suspending manually while using the SmartGuard feature

For information about manually suspending insulin delivery, see *Suspending all insulin delivery and resuming basal insulin delivery*, page 98.

Suspend before low and Suspend on low features while using the SmartGuard feature

When the SmartGuard feature is active, the Suspend before low and the Suspend on low features are unavailable and automatically turn off. If the system exits the SmartGuard feature, the Suspend before low and the Suspend on low features return to the state they were in before using the SmartGuard feature. For information about turning on the Suspend before low or the Suspend on low feature, see *Low SG settings*, page 160.

SmartGuard Checklist

The SmartGuard Checklist screen indicates the requirements necessary to start or continue using the SmartGuard feature. For more information, see *Staying in the SmartGuard feature*, page 209.

The following table shows what to do when the wait icon  or the question icon  appear by items on the SmartGuard Checklist screen. In general, the wait icon  indicates the system is processing or waiting for information. In general, the question icon  indicates the system needs an action from you.

1

Enter BG

?

2

SmartGuard turned off

?

3

Sensor not ready

...

4

Bolus in progress

?

5

Delivery suspended

?

6

Carb ratio not set

?

7

Basal rate for Manual mode not set

?

8

SmartGuard updating

...

9

SmartGuard warming up

...

SmartGuard Checklist

Line	Item	Instructions
1	Calibrating... 	The system is using the recent BG meter reading to calibrate the sensor.
	Enter BG 	Enter a new BG meter reading.
	Wait to calibrate 	The system requires a BG reading and will ask when it is ready.
2	SmartGuard turned off 	Turn on the SmartGuard feature.

Line	Item	Instructions
3	Sensor not ready 	- Confirm the pump shows a sensor serial number on the Paired Devices screen. Example: CGM XXXXXXXXX Make sure the pump is paired with a sensor. For more information, see <i>Pairing the pump and sensor</i>, page 178. - Check the Home screen. If  displays, move the pump and sensor closer together. It may take 15 minutes to find the sensor signal. If after 30 minutes the pump and sensor are still not communicating, a Lost sensor signal alert appears. Check that the sensor is still inserted in the skin. Move the pump closer to the sensor.
	Sensor off 	Turn on the Sensor feature in Settings > Device Settings.
	No paired CGM 	Pair the pump and sensor. For more information, see <i>Pairing the pump and sensor</i> , page 178.
4	Bolus in progress 	Wait until the bolus is complete or stop the bolus before the SmartGuard feature can be used.
5	Delivery suspended 	If insulin delivery is suspended, the SmartGuard feature cannot be used. Treat low BG as instructed by a healthcare professional.
6	Carb ratio not set 	Enter a carb ratio in the Bolus Wizard feature or in the Bolus Wizard Setup screen.

Line	Item	Instructions
7	Basal rate for Manual mode not set 	When no basal pattern is set, the SmartGuard checklist will display “Basal rate for manual mode not set”. You must program, confirm, and save a basal pattern before the pump will enter SmartGuard.
	Temp Basal rate 	When a basal pattern is set and the pump is currently running a temp basal, the SmartGuard checklist will display “Temp Basal rate”. Stop the temp basal rate delivery before the SmartGuard feature can be used or wait until the temp basal rate delivery is complete.
8	SmartGuard updating 	If SmartGuard active insulin is updating, it will take up to five hours to complete. Wait for the update time to end before the SmartGuard feature can activate.
9	SmartGuard warming up 	Wait for the SmartGuard feature to gather insulin delivery history and determine the basal rate.

To view the SmartGuard Checklist:

1. From the Home screen, press , and then select .
2. Select **SmartGuard Checklist**.

Home screen with the SmartGuard feature

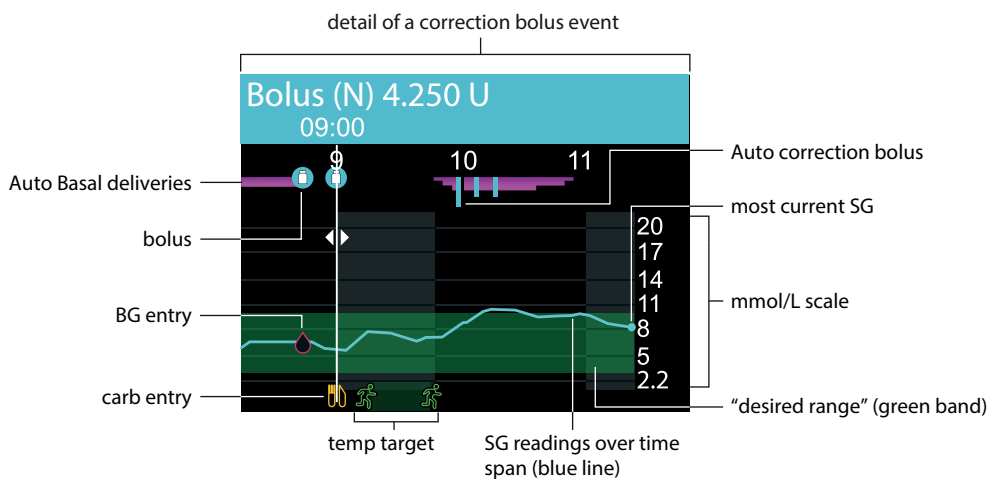
When the pump is using the SmartGuard feature, the Home screen displays a shield with the current SG, if available. When a BG is entered, it appears on the Home screen until either the next SG arrives or the BG is 12 minutes old.



Using the SmartGuard feature

The sensor graph with the SmartGuard feature

The sensor graph with the SmartGuard feature shows historical SG readings provided by the sensor.



The SmartGuard feature sensor graph includes the following information:

- When a location on the graph is selected, specific details of the SG or event appear, such as a correction bolus.
- Historical SG 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.
- Boluses are shown as white vials inside blue circles.

- Carb entries are shown as yellow knife and fork symbols. These represent any bolus amounts that include a carb entry.
- BG entries appear as red drop symbols.
- Magenta bands across the top represent Auto Basal deliveries provided by the SmartGuard feature.
- Blue vertical bars at the top represent Auto correction boluses delivered by the SmartGuard feature.
- A time change event appears as a white clock symbol.
- Temp target is shown as green runners.

To view the sensor graph:

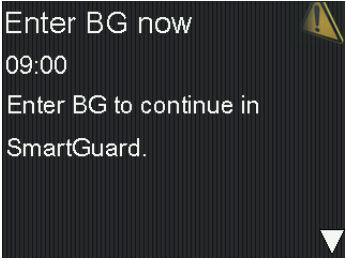
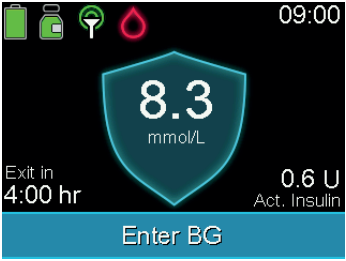
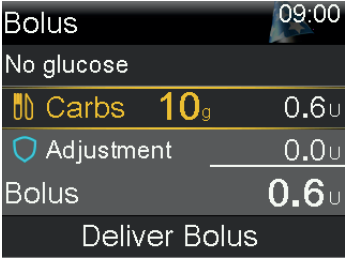
1. From the Home screen, press the  button to display the SG graph. A full-screen view of the 3-hour graph appears.
2. Press  to navigate to the 6-hour, 12-hour, and 24-hour graphs.
3. Press  to view SG readings and event details.
4. To exit the sensor graph, press  or press the  button again.

Entering a BG value in the SmartGuard feature

The pump may require a BG value to continue using the SmartGuard feature.

There are two ways to enter a BG value when using the SmartGuard feature. Manually enter a BG value or enter a BG value using the compatible Accu-Chek Guide Link meter. For more information on manually entering a BG, see *Entering a blood glucose (BG) meter reading*, page 102.

The following table shows when to use a blood glucose (BG) meter reading:

When to use a blood glucose (BG) meter reading	Examples
Anytime the system requests a blood glucose (BG) meter reading.	 
Anytime you deliver a bolus in SmartGuard when a sensor glucose (SG) value is not displayed and you want the bolus to be adjusted based on your glucose value.	
When using a medication that impacts glucose levels.	
When your sensor glucose (SG) values are different than the symptoms you are experiencing.	
The most recent sensor glucose (SG) reading is unavailable. Sensor glucose (SG) readings are unavailable in the following conditions: • A new sensor is started. • A Sensor Updating notification appears. • The sensor requires a new blood glucose (BG) meter reading to be entered because the system was unable to use the blood glu-	

When to use a blood glucose (BG) meter reading	Examples
cose (BG) meter reading that was entered to calibrate the sensor. All blood glucose (BG) meter readings that are entered are used to calibrate the sensor.	
There is doubt that sensor glucose (SG) values are correct.	



WARNING: Consult a healthcare professional if a medication that contains acetaminophen or paracetamol is taken while wearing the sensor. Medications that contain acetaminophen or paracetamol can falsely raise sensor glucose readings. The level of inaccuracy depends on the amount of acetaminophen or paracetamol active in the body and can differ for each person. Falsely elevated sensor readings can result in over-delivery of insulin, which can cause hypoglycemia. Medications that contain acetaminophen or paracetamol include, but are not limited to, cold medicines and fever reducers. Check the label of any medications being taken to see if acetaminophen or paracetamol is an active ingredient. Use additional blood glucose meter readings to confirm blood glucose levels.

While the SmartGuard feature is active, if acetaminophen or paracetamol is taken, program a temp target for up to eight hours, or the amount of time recommended by a healthcare provider. For more information, see *Setting a temp target*, page 208. Use blood glucose values instead of sensor glucose readings to calculate a meal bolus or correction bolus for up to eight hours, or the duration recommended by a healthcare provider, after taking acetaminophen or paracetamol.

Delivering a bolus in the SmartGuard feature

A current BG or SG reading is used to determine the bolus amount. A carb amount can be entered for a food bolus.



WARNING: Do not use the SmartGuard feature 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. Using the SmartGuard feature after a manual injection may result in over-delivery of insulin. Too much insulin may cause hypoglycemia. Consult a healthcare professional for how long to wait after a manual injection before resuming the SmartGuard feature.



Note: The SmartGuard feature only supports normal boluses. Square Wave, Dual Wave, Easy, Manual, and Preset bolus types are not available while using the SmartGuard feature.

If the BG or SG is under 6.7 mmol/L, or if the bolus is zero after the pump accounts for active insulin, or if the SmartGuard feature estimates current basal delivery is sufficient, no correction is recommended.

A paired Accu-Chek Guide Link meter sends BG readings directly to the pump. Confirm the BG reading for use in the SmartGuard feature. If an Accu-Chek Guide Link meter is not used, the BG value must be manually entered on the BG screen or the Bolus screen while using the SmartGuard feature.



Note: Do not use a blood glucose (BG) meter reading if more than 12 minutes have passed since the last BG meter reading was taken. That BG meter reading and the calculated bolus amount may no longer be accurate.



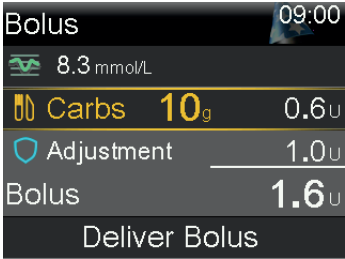
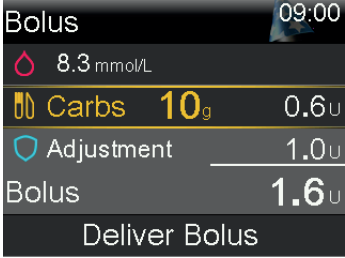
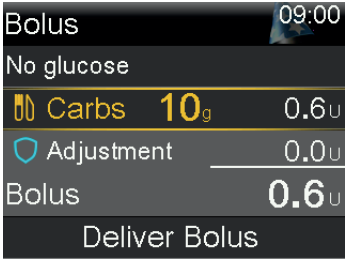
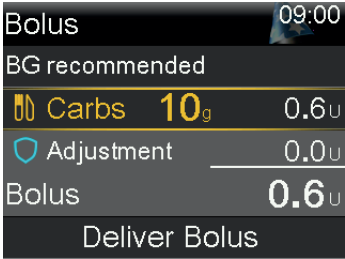
WARNING: SG readings are used to calculate meal boluses or correction boluses when delivering a bolus in the SmartGuard feature. SG is not the same as BG. Sensor performance may occasionally vary from sensor to sensor and in different situations for a sensor, such as on the first day of use.

When SG readings are used for meal boluses and for correction boluses, there is a risk of both hypoglycemia and hyperglycemia. If an SG reading is much lower than a BG reading would be at that time, there is a risk of hyperglycemia, because the amount of insulin delivered could be smaller. If an SG reading is much higher than a BG and there are symptoms of feeling low, but the SG reading is not low, and if there are symptoms of a severe hypoglycemic event, a severe hyperglycemic event, or diabetic ketoacidosis, a BG meter reading is needed.

This can also occur when SG readings are used when the Auto correction feature is turned on. For example, when an SG reading is much higher than a BG reading at that time, there is a risk of hypoglycemia, because the amount of insulin delivered could be larger.

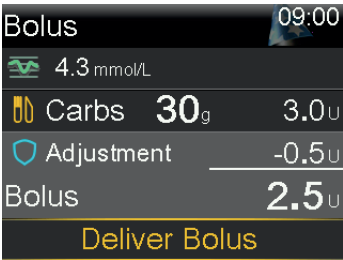
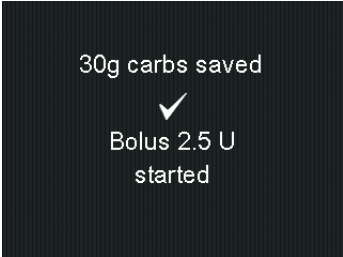
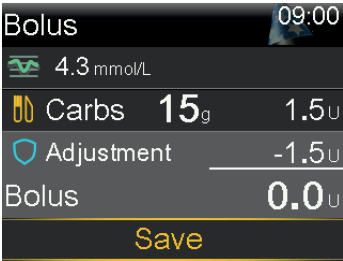
If there are symptoms of feeling low, but the SG reading is not low, and if there are symptoms of a severe hyperglycemic event or diabetic ketoacidosis, a BG meter reading is needed.

The following table describes how glucose readings are shown on the SmartGuard bolus screen.

Bolus screen	Glucose reading information
	The  icon indicates the sensor glucose (SG) value when there is no recent blood glucose (BG) meter reading available during the last 12 minutes. A blood glucose (BG) meter reading can be entered to calculate a correction bolus. The correction bolus is included in the Adjustment.
	A blood glucose (BG) meter reading is available to calculate a correction bolus. The correction bolus is included in the Adjustment.
	There are no blood glucose (BG) meter readings or sensor glucose (SG) values available. You can enter a carb amount for a food bolus or a blood glucose (BG) meter reading for a correction bolus.
	The BG recommended message indicates that neither a blood glucose (BG) meter reading nor a sensor glucose (SG) reading is available to calculate a correction bolus. Note: If a sensor glucose (SG) value shows on the Home screen, but does not show on the Bolus screen, the system determined that the sensor glucose (SG) value is not optimal to use to calculate a correction bolus. Enter a blood glucose (BG) meter reading if a correction bolus is desired.

Bolus adjustments in the SmartGuard feature

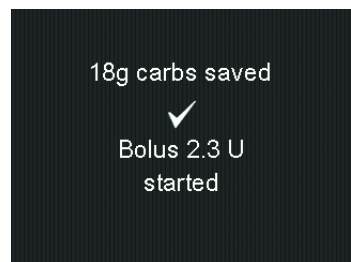
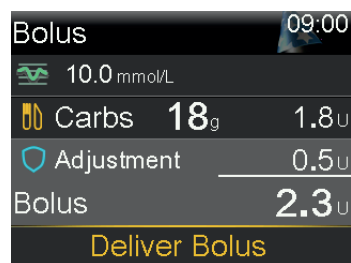
The SmartGuard feature calculates a bolus based on the current BG or SG reading and carbs, and may make an additional adjustment to the bolus.

Bolus adjustment	Example screens
The bolus amount is adjusted down if the SmartGuard feature predicts a risk of hypoglycemia after the meal. Carbs are saved for use in future bolus adjustment calculations.	 The screenshot shows the 'Bolus' screen with a glucose reading of 4.3 mmol/L. The calculated bolus is 3.0U for 30g of carbs. A downward arrow indicates an adjustment of -0.5U, resulting in a final bolus of 2.5U. The 'Deliver Bolus' button is highlighted in yellow.  The confirmation screen shows a checkmark and the text: '30g carbs saved' and 'Bolus 2.5 U started'.
If the bolus amount is adjusted down to 0.0 for the bolus, no bolus is delivered. Carbs are saved for use in future bolus adjustment calculations.	 The screenshot shows the 'Bolus' screen with a glucose reading of 4.3 mmol/L. The calculated bolus is 1.5U for 15g of carbs. A downward arrow indicates an adjustment of -1.5U, resulting in a final bolus of 0.0U. The 'Save' button is highlighted in yellow.  The confirmation screen shows a checkmark and the text: '15g carbs saved' and 'No bolus needed'.

Bolus adjustment

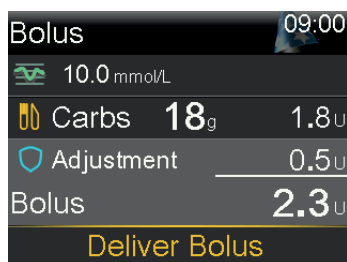
The bolus amount is adjusted up if a correction bolus is calculated based on high glucose and low active insulin.

Carbs are saved for use in future bolus adjustment calculations.

Example screens**To deliver a bolus with the SmartGuard feature:**

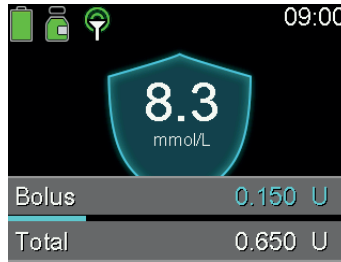
1. From the Home screen, press , and then select .
2. Select **Bolus**.
3. Enter a carb amount, if desired.

The screen indicates the amount of the calculated bolus.



4. Select **Deliver Bolus**.

A screen appears briefly to indicate the bolus delivery has started. The Home screen appears and shows the progress of the bolus delivery.



Note: To stop a bolus, press  from the Home screen, select , and then select **Stop Bolus**. Select **Yes** to confirm.

Setting a temp target

A temporary target (temp target) of 8.3 mmol/L can be set for events such as exercise or other times when less insulin is needed. Consult a healthcare professional before using a temp target.



Note: The Auto correction feature is not active during an active temp target. It resumes after the temp target completes.

To set a temp target:

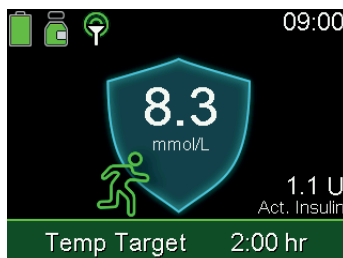
1. From the Home screen, press , and then select .
2. Select **Temp Target** to turn the feature on or off.

Temp Target	09:00
Duration	2:00 hr
Set target to 8.3 mmol/L	
Start	

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

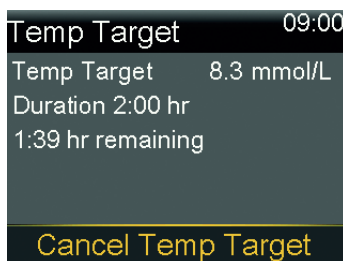
4. Select **Start**.

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



To cancel a temp target:

1. From the Home screen, press , and then select .



2. Select **Cancel Temp Target**.

Staying in the SmartGuard feature

When the pump requires an action to stay in the SmartGuard feature, it delivers insulin at a fixed basal rate for up to a maximum of 4 hours.

The message "Exit in X:XX hr" appears on the Home screen, showing the time remaining before the pump enters Manual mode. The basal rate delivered during this time is based on insulin delivery history and represents a delivery rate that minimizes the risk of hypoglycemia in situations when SG values are temporarily unavailable. The pump provides a notification of any required actions.



The pump resumes using SG readings for basal insulin delivery when certain conditions are met. The following table describes these conditions and the notification and required action to resume using SG readings for basal insulin delivery.

Condition	Notification and action
The SmartGuard feature has reached the time limit for minimum delivery. The minimum delivery time is 3 to 6 hours, depending on the reason.	A SmartGuard min delivery alert appears. Enter a BG.
The SmartGuard feature has been delivering basal insulin at its maximum limit for 7 hours.	A SmartGuard max delivery alert appears. Check the SmartGuard Checklist to determine the required steps. Enter a BG.
SG readings may be lower than actual glucose values.	An Enter BG now alert appears. Enter a BG.
No SG data has been received for more than 5 minutes.	- If SG data is not available, three dashes appear on the screen in place of the SG data. If the loss of SG data is intermittent, no action is required. - If an action is required, an alert appears such as a Lost sensor signal alert or the Enter BG now alert. Follow the instructions on the screen.
An entered BG while in SmartGuard is 40% or more different from your current SG values.	A calibration not accepted alert appears. Wait at least 15 minutes and enter another BG.



Note: To stay in the SmartGuard feature when changing the sensor, be sure the sensor warmup completes within four hours of the last available SG reading.

Exiting the SmartGuard feature

The SmartGuard feature may stop functioning under the following conditions:

- The SmartGuard feature is turned off.
- The pump is delivering basal insulin based on insulin delivery history, and not SG readings, for four hours. See *Staying in the SmartGuard feature*, page 209.
- All insulin delivery has been manually suspended and has not resumed for four hours.
- The Sensor feature is turned off.

The SmartGuard feature can be turned off at any time. For more information, see *Setting up the SmartGuard feature*, page 193.

Returning to the SmartGuard feature after an exit

The pump indicates any required actions on the Home screen, after an exit from the SmartGuard feature. In the example below, a BG entry is needed. Once the BG is entered, the pump resumes using the SmartGuard feature.



While in Manual mode, resume using the SmartGuard feature by meeting all requirements in the SmartGuard Checklist. For more information, see *SmartGuard Checklist*, page 195.

The SmartGuard feature can be resumed under the following conditions:

- The SmartGuard feature is turned on.
- The sensor is providing SG readings.
- A bolus is not in progress.
- A temp basal rate is not in progress.
- The 48-hour warm-up is complete.
- The SmartGuard feature is not in a 5-hour warm-up period.
- A new BG reading is entered.

If any of these conditions are not met, the SmartGuard feature cannot restart.

Using Block mode with the SmartGuard feature

Block mode lets caregivers lock the pump to restrict access to critical pump features. While the pump is locked, Auto Basal delivery is active, and Auto correction boluses can occur if the feature is turned on. BG readings received from the Accu-Chek Guide Link meter can be confirmed. For more information on Block mode, see *Block mode*, page 216.

Alert silence feature

The Alert silence feature silences certain sensor alerts for a set period of time. For more information, see *Silencing sensor alerts*, page 171.

9

General settings

General settings

This chapter provides information about common tasks for various settings.

Time and date

Confirm that the time and date are always set correctly on the MiniMed 780G insulin pump. Incorrect time and date settings can affect basal insulin delivery and the accuracy of pump history. Change the time or the date to match the time zone or daylight saving time. After the time and date are changed, the pump adjusts all settings automatically.

To change the time and the date:

1. From the Home screen, press , and then select .
2. Select **Device Settings** > **Time & Date**.
3. Select and change the **Time**, **Time Format**, or **Date** as necessary.
4. Select **Save**.

Display options

The brightness of the pump screen can be controlled from the Display Options screen. The duration the backlight is on can also be adjusted.

To adjust the display options:

1. From the Home screen, press , and then select .
2. Select **Device Settings** > **Display**.

3. Select **Brightness** to adjust the brightness of the screen. A level from 1 to 5 can be set, or select **Auto** for the screen to automatically adjust to the current environment.
4. Select **Backlight** to adjust the timeout for the backlight on the pump screen. Select 15 seconds, 30 seconds, 1 minute, or 3 minutes.
5. Select **Save**.



Note: The brightness and backlight can affect the life of the battery. Use a lower brightness level setting, and set the backlight timeout to 15 or 30 seconds to help the battery last longer.



CAUTION: If you have not pressed **Save** after settings are entered and the screen goes dark, the entered settings will not be saved.

Block mode

Block mode lets caregivers lock the pump to restrict access to critical pump features. While the pump is in Block mode, the pump automatically locks two minutes after the screen goes dark from inactivity.



WARNING: Always monitor the pump while it is locked. The pump can still be manually suspended while locked using the shortcut to the Status screen, which could result in hyperglycemia and ketoacidosis.

When Block mode is on, the following actions are not allowed:

- Cannot access the Menu screen
- Cannot start a bolus delivery
- Cannot start a temp basal rate delivery
- Cannot cancel a temp basal rate delivery

- Cannot start a temp target
- Cannot cancel a temp target
- Cannot rewind the pump, load the reservoir, or fill the cannula
- Cannot change general settings

When Block mode is on, the following actions can be performed:

- Suspend insulin delivery
- Resume insulin delivery
- Stop a bolus delivery
- View the pump status
- View the SG graph
- View the Summary screen
- Use the Easy bolus feature, if it was enabled before Block mode was turned on

To turn Block mode on or off:

1. From the Home screen, press , and then select .
2. Select **Device Settings** > **Block Mode**.
3. Select **Block Mode** to turn the feature on or off.
4. Select **Save**.

The pump is in Block mode, but it is not yet locked.

To lock the pump:

Press and hold  to manually enter Sleep mode.

The pump locks when it goes to sleep. While the pump is locked,  appears on the Home screen.

To unlock the pump:

1. Press any button to wake up the pump.

2. Press .
- The Screen locked message appears.
3. Press and hold .



Note: When the pump goes to sleep it will lock again.

Self Test

The Self Test option can be used to confirm the pump is operating properly. Self test is additional to the routine tests that run independently while the pump operates.



Note: Insulin delivery is suspended for up to two minutes while the pump runs a self test.

The Self Test option includes the following tests. Observe the pump during these tests.

Test	Description
Display	The display turns on for up to 45 seconds.
Notification light	The notification light turns on for three seconds, and then it turns off.
Vibration	Two vibration tones are generated.
Tone	An alert tone, an Easy bolus step tone, and an alarm tone are generated.

To run the self test:

1. From the Home screen, press , and then select .
2. Select **Device Settings > Self Test**.
A message confirms 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 then beeps.

If self test does not detect a problem, the Device Settings screen appears. If a problem is detected, a message appears with more information.

If an error message appears or the pump does not perform as indicated during the test, contact a local Medtronic support representative.

Manage Settings

The Manage Settings screen includes the following options:

- Save Settings
- Restore Settings
- Clear All Settings
- Clear Active Insulin
- Settings History
- Max basal rate

For information on how to use these options, see the procedures in this section.

Saving the settings

The Save Settings option saves a record of the settings to restore the settings at a later date, if necessary.

To save the current settings:

1. From the Home screen, press , and then select .
2. Select **Device Settings** > **Manage Settings**.
3. Simultaneously press and hold  and  until the Manage Settings screen appears.
4. Select **Save Settings**.

If these are the first settings saved, a message confirms that the settings are saved.

If the settings have been saved previously, a screen asks to replace the previous settings with the current settings. Select **Yes** to accept. Select **No** to cancel.

Restoring the settings

The Restore Settings option replaces the current pump settings with the last settings that were saved. The Restore Settings option is available only if settings were previously saved.

To restore the previous settings:

1. From the Home screen, press , and then select .
2. Select **Device Settings** > **Manage Settings**.
3. Simultaneously press and hold  and  until the Manage Settings screen appears.
4. Select **Restore Settings**.
A screen asks to confirm.
5. Select **Yes** to accept. Select **No** to cancel.

Clearing the settings

The Clear All Settings option erases the current settings and returns them to the factory defaults. After the settings are cleared, the Startup Wizard appears and pump settings can be re-entered. The settings must be entered to continue using the pump.

The Clear All Settings option does not delete paired devices, such as the sensor or meter.



CAUTION: Do not clear the pump settings unless directed by a healthcare professional. If pump settings are cleared they must be re-programmed as directed by a healthcare professional.

To clear all settings:

1. Disconnect the pump from the body.
 2. From the Home screen, press , and then select .
 3. Select **Device Settings > Manage Settings**.
 4. Simultaneously press and hold  and  until the Manage Settings screen appears.
 5. Select **Clear All Settings**.
A screen asks to confirm.
 6. Select **Yes** to continue. Select **No** to cancel.
- After the settings are cleared, the Startup Wizard appears. For more details on entering the startup settings, see *Startup settings*, page 74.

Clearing the active insulin

Use the Clear Active Insulin option to use the pump with insulin for the first time. This option clears the SmartGuard therapy history and any active insulin values that the pump has tracked.

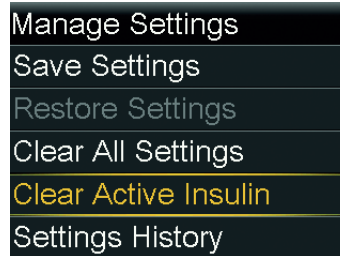
After the existing insulin values are cleared, it sets the active insulin value to zero. If bolus delivery was practiced with the pump prior to using the pump with insulin, the active insulin must be cleared. Clearing active insulin confirms that the Bolus Wizard feature has an accurate active insulin amount for bolus calculations.

Active insulin can be cleared only once. After the active insulin is cleared, this option is no longer available.

To clear the active insulin:

1. From the Home screen, press , and then select .
2. Select **Device Settings > Manage Settings**.
3. Simultaneously press and hold  and  until the Manage Settings screen appears.

The Manage Settings screen appears. If the active insulin has never been cleared, the Clear Active Insulin option appears.



Note: If the Clear Active Insulin option does not appear on the Manage Settings screen, the active insulin has already been cleared.

4. Select **Clear Active Insulin**.

A screen asks to confirm.

5. To clear the active insulin, select **Clear**. If the active insulin should not be cleared, select **Cancel**.

A message confirms that the active insulin is cleared.

Viewing the pump setting history

The Settings History option shows a history of activities performed through the Manage Settings screen, such as when pump settings were saved, restored, or cleared.

To view the pump setting history:

1. From the Home screen, press , and then select .
2. Select **Device Settings** > **Manage Settings**.
3. Simultaneously press and hold  and  until the Manage Settings screen appears.
4. Select **Settings History**.

Max basal rate

If after consulting with your healthcare professional, you require a Manual mode Max basal rate higher than 10 units per hour, use Manage Settings > Max Basal Rate.

To set your Max basal rate, see *Max basal rate*, page 88.

To increase the Max basal rate above 10 U/hr:

1. From the Home screen, press , and then select .
2. Select **Device Settings** > **Manage Settings**.
3. Simultaneously press and hold  and  until the Manage Settings screen appears.
4. Select **Max Basal Rate**.

A message appears indicating that changing this value will also change the Max basal rate setting in Delivery Settings. Consult a healthcare professional before changing this value.

Select **Continue** to change the Max basal rate setting or click **Cancel** to return to the previous screen.

5. Change the Max basal rate setting and select **Save**.

The Max basal rate setting applies to Manual mode only. SmartGuard insulin delivery is not affected by this value.

Auto suspend

Auto suspend is a safety feature that stops all insulin delivery and sounds an alarm if a button is not pressed within a specified period of time. Consult a healthcare professional about how to best use this feature.

Auto suspend continues to work if the SmartGuard feature is active.

To set up auto suspend:

1. From the Home screen, press , and then select .
2. Select **Device Settings** > **Auto Suspend**.

3. Select **Alarm**.
4. Select **Time** and enter the number of hours.
5. Select **Save**.

Language

The language that the pump uses to show information can be updated after the startup.

To change the language:

1. From the Home screen, press , and then select .
A checkmark indicates which language is active.
2. Select **Device Settings > Language**.
3. Select a language.
A screen asks to confirm.
4. Select **Yes** to accept. Select **No** to cancel.

10

History and graph

History and graph

This chapter provides information about how to read historical data in the MiniMed 780G system.

Introduction

The History screens provide details about personal therapy history in the MiniMed 780G insulin pump. The SG Review and Graph screens are available if the Sensor feature is turned on. The Time in Range screen shows the percent of time glucose levels are between 3.9 mmol/L and 10.0 mmol/L.

History & Graph menu

The History & Graph menu provides information about insulin delivery, blood glucose (BG) meter readings, sensor glucose (SG) values, paired sensors, and any alarms and alerts received.

History

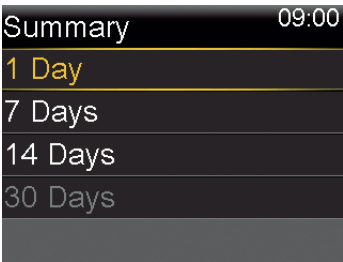
Summary screen

The Summary screen displays information about past insulin deliveries, SG readings, and meter readings. Historical details can be viewed for a single day or for multiple days.

To view the Summary screen:

1. From the Home screen, press , and then select .

2. Select **History** > **Summary**.



3. Select the desired time period for the Summary screen.

The Summary screen appears and displays information for the number of days selected.



4. Scroll down to view the entire screen. In the **1 Day** view, use the < and > buttons on the pump to view the history of a specific day.

Understanding the Summary screen

The Summary screen separates information into the following categories:

- Time in range information
- Insulin delivery overview
- Bolus Wizard
- Bolus in the SmartGuard feature
- BG
- Sensor
- Low management mode

Summary screen: Time in SmartGuard and Time in range information

The following table describes the Time in SmartGuard, Time in Target Range, Time below range, and Time above range portions of the Summary screen.

Name	Description
Time in SmartGuard	number of hours / percent of time in the SmartGuard feature
Time in Target Range	number of hours / percent of time in target range (3.9 mmol/L to 10 mmol/L)
Time below range	number of hours / percent of time below target range (below 3.9 mmol/L)
Time above range	number of hours / percent of time above target range (above 10 mmol/L)

Summary screen: insulin delivery overview

This summary screen appears when in Manual mode. If **1 Day** view is selected, the values are shown for that day. If multiple days are selected, the values shown are an average of the values for the selected number of days.

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 Wizard

This summary screen appears when in Manual mode. If **1 Day** view is selected, the values are shown for that day. If multiple days are selected, the values shown are an average of the values for the selected number of days.

Name	Description
Carb bolus	- Total insulin units delivered using the Bolus Wizard feature in Manual mode with a food amount or with a food and glucose correction. - Number of times the Bolus Wizard feature delivered a food bolus or a food plus correction bolus in Manual mode.

Name	Description
Glucose correction only	- Total insulin units delivered using the Bolus Wizard feature in Manual mode or a bolus with BG correction amount only. - Number of times the Bolus Wizard feature delivered a correction bolus in Manual mode.

Summary screen: SmartGuard

If **1 Day** view is selected, the values are shown for that day. If multiple days are selected, the values shown are an average of the values for the selected number of days.

Name	Description
Auto Correction	Total insulin units delivered by the Auto correction feature.
Bolus	- Total insulin units delivered using the SmartGuard bolus feature. - Number of times the SmartGuard bolus feature was used.

Summary screen: BG

The pump is only compatible with the Accu-Chek Guide Link meter.

Name	Description
BG	Total number of BG meter readings, including readings from an Accu-Chek Guide Link meter and BG meter readings entered manually.
Average BG	Average BG meter readings.
BG Std. Dev.	Standard deviation of BG meter readings.
Low BG	Lowest BG meter reading.
High BG	Highest BG meter reading.

Summary screen: sensor

The sensor portion appears if a sensor has been used at least once.

Name	Description
SG Average	Average SG reading.
SG Std. Dev.	Standard deviation of the SG readings.

Summary screen: low management mode

For information about the Suspend before low and Suspend on low features, see *Low SG settings, page 160*.

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

Daily History screen

Actions performed on the pump can be viewed on the Daily History screen for the selected day. The list shown on the screen provides further details and shows the most recent action first.

Daily History	09:00
Temp Target Comp..	22:45
Temp Target	22:40
SmartGuard Active	22:35
SmartGuard Exit	22:30
◀ Thu, Jan 22 ▶	

To view the Daily History screen:

1. From the Home screen, press , and then select .
2. Select **History** > **Daily History**.
A list of dates appears.

3. Select a specific date. A list appears with any pump actions or events entered on the specified day.
4. Select any item in the list to open the Detail screen and view more information about the selected action or event.

Alarm History screen

Select a specific day to view the history of alarms and alerts that occurred on the selected day. The list provides further details and shows the most recent alarm or alert first.

To view the Alarm History screen:

1. From the Home screen, press , and then select .
2. Select **History** > **Alarm History**.
A list of dates appears.
3. Select a specific date. A list appears showing any alarms or alerts that occurred on the specified day.
4. Select any alarm or alert in the list to open the Detail screen and view more information about the selected alarm or alert.

Paired Sensors screen

The Paired Sensors screen displays the serial number, code, date, and time of the current sensor paired to the pump. The screen also provides a history of the sensors that were paired with and unpaired from the pump.

Paired Sensors		09:00
- XXXXXXXX -		
CODE	XXXXXX	
Version	X.XX (X)	
Paired	09:00	
(current)	Jan 1	
- YYYYYYYY -		

To view the Paired Sensors screen:

1. From the Home screen, press , and then select .
2. Select **History > Paired Sensors**.
A list of sensors appears.
3. Scroll down to view the entire screen.

SG Review screen

Pair the pump with a sensor to view a graph of SG history based on high and low limits entered. Information can be viewed for 1 day or refer to an average of SG data over multiple days.

High and low limits set in the SG Review screen are only used to view SG data. These limits are not the same as the high and low glucose limits used for SG alerts. Changing the limits in the SG Review screen will not affect the high and low glucose limits used for the SG alerts.

To review the SG history:

1. From the Home screen, press , and then select .
2. Select **Sensor Glucose Review**.

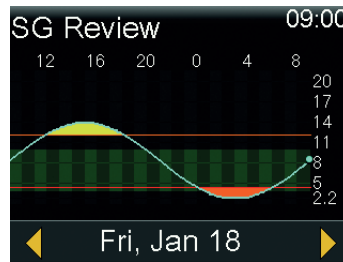
The SG Review screen appears. The high and low limits that appear are either the values entered for the last SG Review, or the default values of 10.0 mmol/L for the high limit and 3.9 mmol/L for the low limit.

SG Review	09:00
High Limit	10.0 mmol/L
Low Limit	3.9 mmol/L
Days to Average	1
Next	

3. Enter the High Limit and Low Limit for the SG data review.
There must be a minimum of 1.1 mmol/L difference between the High Limit and the Low Limit.

4. Enter the number of days of SG history to average, and select **Next**.

If only one day is entered, the graph shows details about when the SG was above, below, or within the specified limits. Use the arrow keys to see the data for specific dates. Press **▼** to see information about the time that SG was above, within, or below range. A message appears and states there is no data available if no data was saved.

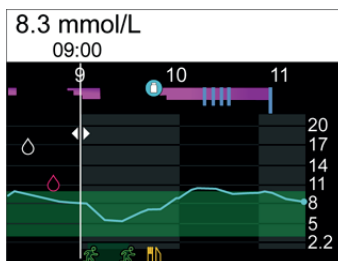


If multiple days are entered, the pie chart shows the average percentage of time that the SG was above, below, or within the specific limits over an average of multiple days. A message appears and states there is no data available if no data was saved.



Graph screen

The graph shows information about the SG readings and trends, BG entries, auto correction bolus deliveries, and bolus entries. The below screen is an example of the graph screen using the SmartGuard feature.



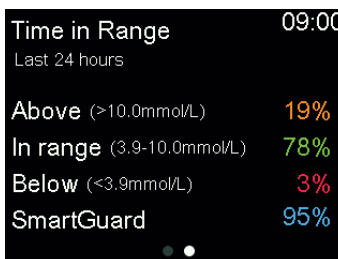
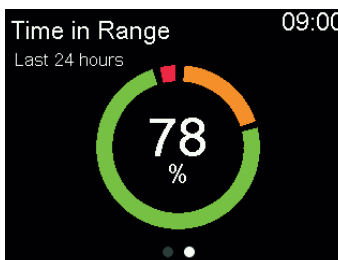
To view the Graph screen:

- Press , or select **Graph** on the History & Graph screen.

Time in Range screen

Time in range is the percentage of time SG is between 3.9 mmol/L and 10.0 mmol/L. These values cannot be changed. Use the Time in Range screen to see how much time is spent below, above, and within range in the last 24 hours.

When using CGM, the following information can be viewed:



To view the Time in Range screen:

1. From the Home screen, press , and then select .
2. Select **Time in Range**.

11

Notifications and
reminders

Notifications and reminders

This chapter describes how to use reminders. It also covers the general behavior of the most common and the most serious notifications and how to resolve them.

Notifications in the MiniMed Mobile app

If the MiniMed Mobile app is used, alarms, alerts, and messages can be viewed on the paired mobile device. For information about how to set the notification preferences in the app, see the MiniMed Mobile app user guide. For a table that describes the meaning, consequences, reasons, and resolutions for the most common or serious notifications, see *Pump alarms, alerts, and messages*, page 305.



WARNING: Do not rely on the MiniMed Mobile app to view all alerts. Alerts will not appear on the MiniMed Mobile app during reservoir set up. Some alerts may only appear on the pump. In some cases, alerts could be sent to the MiniMed Mobile app after they appear on the pump. Relying on the MiniMed Mobile app for all alerts could result in an alert being missed, which may lead to hypoglycemia or hyperglycemia.

Reminders

There are several specific reminders that prompt a specific action. Personal reminders can be used for any purpose.

Personal reminders

Up to 5 personal reminders can be set, along with the specific reminders for blood glucose (BG) meter readings and medication.

To create a new Personal reminder:

1. From the Home screen, press , and then select .
2. Select **Alert Settings** > **Reminders** > **Personal**.
3. Select **Add New**.

The Select Name screen shows the available reminders.

4. Select a reminder.

An edit screen appears for the selected reminder.

5. Enter the time the reminder should occur.
6. Select **Save**.

The Personal reminder occurs at the specified time each day unless it is edited or deleted.

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

1. From the Home screen, press , and then select .
2. Select **Alert Settings** > **Reminders** > **Personal**.
3. Select a reminder.
4. Do any of the following:
 - Select **Reminder** to turn the reminder on or off.
 - Select **Edit** to change the time of the reminder.
 - Select **Rename** to assign a different name to the reminder. When the Select Name screen appears, select any available name from the list.
 - Select **Delete** to delete the reminder.

Bolus BG Check reminder

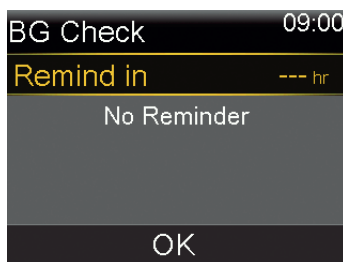
The Bolus BG Check reminder notifies when BG needs to be checked after a bolus delivery. After a bolus is started, the BG Check screen appears and the timer must be set for the reminder. The timer counts down from the time the bolus was started.

To turn on or turn off Bolus BG Check reminders:

1. From the Home screen, press , and then select .
2. Select **Alert Settings > Reminders > Bolus BG Check**.
3. To turn the reminder on or off, select **Reminder**.
4. Select **Save**.

To use a Bolus BG Check reminder if a bolus is being delivered:

1. If the Bolus BG Check reminder is on, the BG Check screen appears each time a bolus is started.



2. Enter a time between 30 minutes and 5 hours and select **OK**. If no reminder is necessary after the bolus delivery, select the dashes without adding a time, and select **OK**.

Missed Meal Bolus reminder

Missed Meal Bolus reminders can be set up around typical meal times. Up to 8 reminders can be set.

To create a new Missed Meal Bolus reminder:

1. From the Home screen, press , and then select .
2. Select **Alert Settings** > **Reminders** > **Missed Meal Bolus**.
3. Select **Add New**.
4. Select **Start Time** and enter a time.
5. Select **End Time** and enter a time.
6. Select **Save**.

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

1. From the Home screen, press , and then select .
2. Select **Alert Settings** > **Reminders** > **Missed Meal Bolus**.
3. Select a reminder.
4. 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

Set a Low Reservoir reminder to occur when the insulin level in the reservoir reaches a specified number of units and again when half of those units have been used.



Note: The number of units that remain in the reservoir can be found on the Pump status screen. For more information, see *Status screen, page 83*.



WARNING: Always check the amount of insulin left in the reservoir when the Low reservoir alert occurs. Confirm that the MiniMed 780G insulin pump has sufficient insulin. The insulin level in the reservoir can reach a low level during a bolus delivery or fill cannula delivery. If this occurs, the Low reservoir alert displays. If the pump does not have sufficient insulin, under-delivery of insulin can occur, which may cause hyperglycemia.

To set up the Low Reservoir reminder:

1. From the Home screen, press , and then select .
2. Select **Alert Settings** > **Reminders** > **Low Reservoir**.
3. Select **Units** to enter the number of units. Set a value from 5 to 50 units.
4. Select **Save**.

Set Change reminder

The Set Change reminder tracks the time between infusion set changes and provides a reminder to change the infusion set.

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

1. From the Home screen, press , and then select .
2. Select **Alert Settings** > **Reminders** > **Set Change**.
3. Select **Reminder** to turn the reminder on or off.
4. Select **Time** and choose the number of days needed for the reminder.
5. Select **Save**.



WARNING: When changing the Set Change reminder, do not set a duration greater than what is indicated on the infusion set labeling. If the infusion set is labeled for three days then the reminder must only be set to two or three days.

Alarms, alerts, and messages

The pump has a sophisticated safety network. If this safety network detects anything unusual, it communicates this information in the form of notifications. Notifications include alarms, alerts, and messages. When more than one notification is received, and there are multiple messages to view, a small white flap appears on the notification icon . When the first notification is cleared, the next notification becomes visible. A white triangle means that  must be pressed to continue.



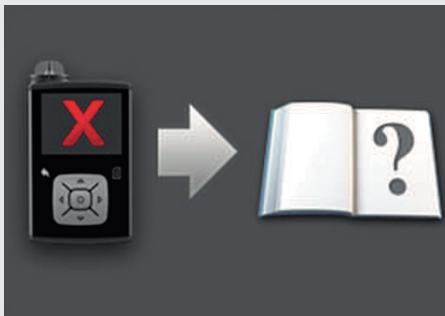
Note: The notification light flashes when the pump has an alarm or alert.



Note: Promptly address all notifications and confirmations that appear on the pump screen. The notification will remain on the pump screen until it is cleared. When responding to a message, there may be times when another message appears.



WARNING: When the critical pump error occurs, the following screen appears and the pump siren goes off:

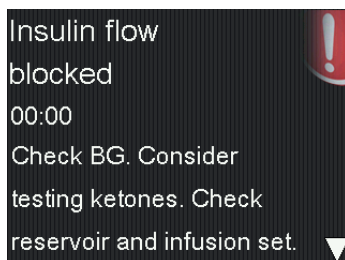


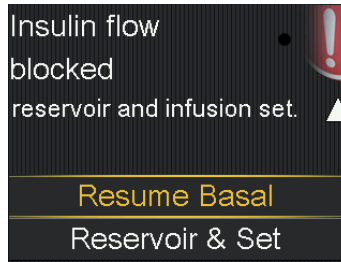
Immediately disconnect the pump and discontinue use.
Contact a local Medtronic support representative.

Insulin delivery is still required when the pump is removed.
Consult a healthcare professional to determine an alternate method of insulin delivery while the pump is removed.

Alarms

An alarm warns of a condition that requires 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:

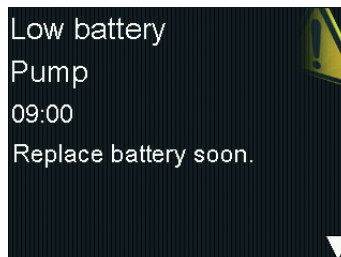
Display: The pump displays a notification with a red icon and instructions.

Notification light: The red notification light blinks twice, followed by a pause, in a continuous repeating pattern.

Audio: Depending on the sound and vibration settings, the pump emits a series of alarm tones and vibrations.

The underlying problem that triggered the alarm must be resolved. In most cases, press ▼ and then make a selection to clear the alarm. Sometimes the underlying problem is not resolved when the alarm is cleared. The alarm repeats until the underlying problem is fixed. If the alarm condition is not resolved after 10 minutes, the alarm tone escalates to a loud emergency siren.

Alerts



Alerts indicate that a situation may require attention. When an alert occurs, check the 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 the pump blinks once, followed by a pause, then blinks once again in a continuous repeating pattern.

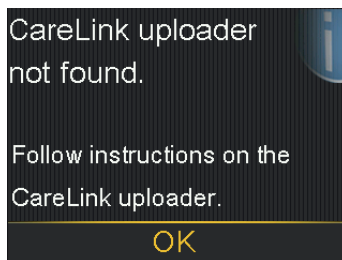
Audio: Depending on the sound and vibration settings, the pump generates a series of tones and vibrations.

To clear an alert, press ✓ and then make a selection. The pump beeps every 5 minutes or every 15 minutes, depending on the alert, until the alert is resolved. Some alerts will also escalate to a loud emergency siren after 10 minutes.



Note: If an alert occurs when the pump is on a screen other than the Home screen, the alert message may only appear after the pump returns to the Home screen.

Messages



A message is a notification that shows the status of the pump or displays when a decision needs to be made.

When a message occurs:

Display: The pump displays a notification with a blue icon and instructions. Some messages show a yellow icon.

Notification light: The red notification light on the pump does not blink.

Audio: Depending on the sound and vibration settings, the pump emits a tone, a one-pulse-only vibration, or it emits a tone and a one-pulse-only vibration. To clear a message, press ✓ and then make a selection.

Pump alarms, alerts, and messages

For a table that describes the meaning, consequences, reasons, and resolutions for the most common or serious notifications, see *Pump alarms, alerts, and messages, page 305*.

12

Additional basal features

Additional basal features

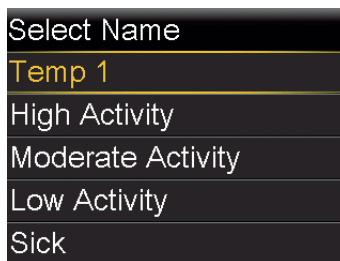
This chapter provides information about setting up additional features for basal insulin delivery.

Preset temp basal rates

Set up preset temp basal rates for reoccurring short-term situations. Up to four preset temp basal rates can be set up for specific situations. There are also four additional preset temp rates available for use in other circumstances (Temp 1 through Temp 4).

To set up a preset temp basal rate:

1. From the Home screen, press , and then select .
2. Select **Delivery Settings > Preset Temp Setup**.
3. Select **Add New**.



4. Select a name for the preset temp basal rate.

5. Select **Type** to select **Percent** or **Rate**, and then enter the percentage or the rate in units per hour.
6. Set the **Duration** for the preset temp basal rate to be active.
7. Select **Save**.

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

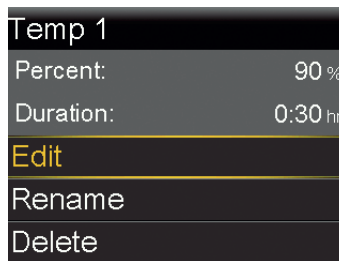
1. From the Home screen, press , and then select .
2. Select **Delivery Settings > Preset Temp Setup**.

The Preset Temp Setup screen appears and shows the settings for any existing preset temp basal rate.



3. Select a preset temp basal rate.

A screen appears that shows the preset temp basal rate information.



4. Do any of the following:
 - Select **Edit** to adjust the type (Percent or Rate), the percent or rate amount, and the duration.

- Select **Rename** to assign a different name to the preset temp basal rate. When the Select Name screen appears, select any available name from the list.
- Select **Delete** to delete the preset temp basal rate.

Starting a preset temp basal delivery

Follow the steps to use the preset temp basal rate for basal insulin delivery. If a preset temp basal rate has not yet been set up, see *Preset temp basal rates*, page 251. After the preset temp basal delivery is completed or canceled, basal insulin delivery resumes using the programmed basal rate.

To start a preset temp basal delivery:

1. From the Home screen, press , and then select .
2. Select **Basal > Preset Temp**.

The Preset Temp screen appears and shows the preset temp basal rates set up, along with their percentage or rate amounts.

Preset Temp	09:00
Current rate:	0.025 U/hr
Temp 1	0.100 U/hr
High Activity	25 %
Moderate...	50 %



Note: If a percentage preset temp basal rate was set up so that it could exceed the current Max basal limit, that preset temp is grayed out in the list and cannot be selected.

3. Select a preset temp basal rate to start.
4. Select **Begin**.

The Temp Basal banner appears on the Home screen during delivery.



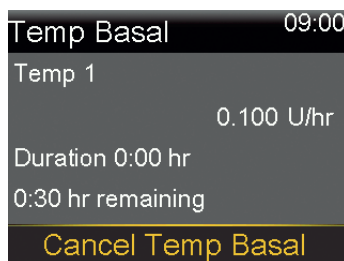
Canceling a temp basal or preset temp basal

A temp basal rate or preset temp basal rate can be canceled at any time. After it is canceled, the scheduled basal pattern automatically resumes.

To cancel a temp basal rate:

1. From the Home screen, press , and then select .
2. Select **Cancel Temp Basal**.

The Temp Basal screen appears.



3. Select **Cancel Temp Basal**.

Additional basal patterns

Adding an additional basal pattern

This procedure shows how to add a new basal pattern after at least one basal pattern has been set. If this is the first time a basal pattern is being set, see *Setting up a basal pattern*, page 91.

The following basal patterns can be set up:

- Basal 1
- Basal 2
- Workday
- Day Off
- Sick Day

To add an additional basal pattern:

1. From the Home screen, press , and then select .
2. Select **Basal** > **Basal Pattern Setup**.
The Basal Pattern Setup screen appears.
3. To add a new basal pattern, select **Add New**.
The Select Name screen appears.
4. Select a name for the basal pattern.
5. Set the basal rate.
6. Select **Review**.
7. Select **Save**.

Editing, copying, or deleting a basal pattern

To edit, copy, or delete a basal pattern:

1. From the Home screen, press , and then select .
2. Select **Delivery Settings** > **Basal Pattern Setup**.
The Basal Pattern Setup screen appears



3. Select a basal pattern.
4. Select **Options**.
5. Do any of the following:
 - Select **Edit** to adjust the end time or rate values.
 - Select **Copy** to copy the basal rate information from the selected basal pattern to a new basal pattern. When the Select Name screen appears, select any available name from the list.
 - Select **Delete** to delete the selected basal pattern. The active basal pattern cannot be deleted.

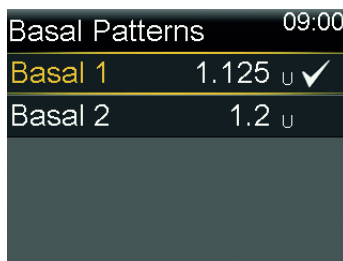
Changing from one basal pattern to another

If more than one basal pattern has been set, the basal pattern can be changed. The MiniMed 780G insulin pump delivers basal insulin according to the selected basal pattern.

To change to a different basal pattern:

1. From the Home screen, press , and then select .
2. Select **Basal** > **Basal Patterns**.

The Basal Patterns screen appears. A check mark displays next to the active basal pattern.



Basal Patterns		09:00
Basal 1	1.125 U	✓
Basal 2	1.2 U	

3. Select a basal pattern.

Basal 2		09:00
24 hr Total: 1.2 U		
Start	End	Rate (U/hr)
00:00	24:00	0.050
Begin		

4. Select **Begin**.

13

Additional bolus features

Additional bolus features

This chapter provides information about additional features for bolus delivery. Square Wave, Dual Wave, Easy, Manual, and Preset bolus are only available in Manual mode. Since these bolus types are only available in Manual mode, remember that you must enter a blood glucose (BG) meter reading when setting up the bolus delivery. Do not use a sensor glucose (SG) value when delivering a bolus in Manual mode.

Bolus types



Note: While the SmartGuard feature is active, only a normal bolus can be delivered.

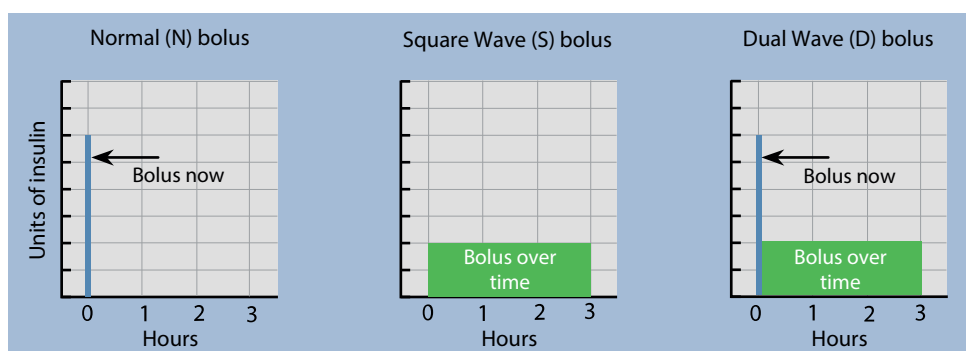
The following table provides general information about the available bolus types.

Bolus type	Description	Purpose
Normal	Normal bolus provides a single immediate dose of insulin.	This is the typical bolus type used to cover food intake or to correct a high blood glucose (BG) meter reading. For details about delivering a normal bolus, see <i>Delivering a Normal bolus</i> , page 112.
Square Wave bolus	Square Wave bolus delivers a single bolus evenly over an ex-	A Square Wave bolus can be used for the following reasons:

Bolus type	Description	Purpose
	tended period of time from 30 minutes up to 8 hours.	• A delayed food digestion due to gastroparesis or meals high in fat. • Snacking over an extended period of time. • A normal bolus drops the BG too rapidly. For details about using the Square Wave bolus feature, see <i>Square Wave bolus</i>, page 267.
Dual Wave bolus	Dual Wave bolus delivers a combination of an immediate normal bolus followed by a Square Wave bolus.	A Dual Wave bolus can be used for the following reasons: • When meals are high in carbs and fat, which may delay digestion. • When a meal bolus is combined with a correction bolus for an elevated BG. For details about using a Dual Wave bolus, see <i>Dual Wave bolus</i>, page 271.

Bolus type example

The following example shows how the different bolus types work.



Bolus settings

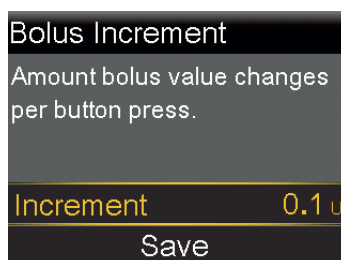
Additional settings are required to use the Bolus Wizard feature in Manual mode. These are described in the section, *Manual mode bolus delivery options*, page 103.

Bolus increment

The Bolus increment is the number of units that are increased or decreased with each button press for the bolus delivery amount in the Bolus Wizard, Manual Bolus, and Preset Bolus screens. Depending on the typical bolus amount, the increment can be set to 0.1 units, 0.05 units, or 0.025 units.

To set the bolus increment:

1. From the Home screen, press , and then select .
2. In Manual mode, select **Delivery Settings** > **Bolus Increment**.
3. Select **Increment** to set the desired increment value.



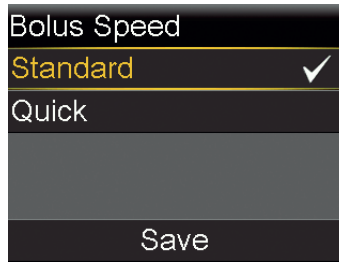
4. Select **Save**.

Bolus speed

The bolus speed sets the rate at which the pump delivers bolus insulin. Set a standard rate (1.5 units per minute), or a quick rate (15 units per minute).

To set the bolus speed:

1. From the Home screen, press , and then select .
2. Select **Delivery Settings** > **Bolus Speed**.
3. Select **Standard** or **Quick**.



4. Select **Save**.

Changing the Bolus Wizard settings in Manual mode

This section shows how to make changes to personal settings after the initial Bolus Wizard feature setup. Consult a healthcare professional before changes are made to the personal settings.

Changing the carb ratio

The carb ratio can be set whether or not the Bolus Wizard feature is turned on.

To change the carb ratio:

1. From the Home screen, press , and then select .
2. In Manual mode, select **Delivery Settings > Bolus Wizard Setup > Carb Ratio**.
3. Select **Edit**.
4. Select the carb ratio. For one carb ratio, enter the g/U, and then press .

For more than one carb ratio, enter one carb ratio at a time to complete the full 24 hours, which ends at 24:00.



Note: For instructions on setting up more than one carb ratio over a 24-hour period, see *Settings covering a 24-hour period*, page 93.

5. Select **Save**.

Changing the insulin sensitivity factor

The insulin sensitivity factor can be set only if the Bolus Wizard feature is turned on.

To change the insulin sensitivity factor:

1. From the Home screen, press , and then select .
2. In Manual mode, select **Delivery Settings > Bolus Wizard Setup > Insulin Sensitivity Factor**.
3. Select **Edit**.
4. Select the insulin sensitivity factor. For one insulin sensitivity factor, press  and  to enter the mmol/L per U, and then press .

For more than one insulin sensitivity factor, press  or  to enter one insulin sensitivity factor at a time to complete the full 24 hours, which ends at 24:00.



Note: For instructions on setting up more than one insulin sensitivity factor over a 24-hour period, see *Settings covering a 24-hour period*, page 93.

5. Select **Save**.

Changing the BG target

The BG target can be from 3.3 to 13.9 mmol/L. The BG target can be set only if the Bolus Wizard feature is turned on.

To change the BG target:

1. From the Home screen, press , and then select .
2. In Manual mode, select **Delivery Settings > Bolus Wizard Setup > BG Target**.
3. Select **Edit**.

4. Select the BG target. For one BG target, enter the low BG limit and the high BG limit, and then press .

For more than one BG target, enter one BG target at a time to complete the full 24 hours, which ends at 24:00.



Note: For instructions on setting up more than one BG target over a 24-hour period, see *Settings covering a 24-hour period*, page 93.

5. Select **Save**.

Changing the active insulin time

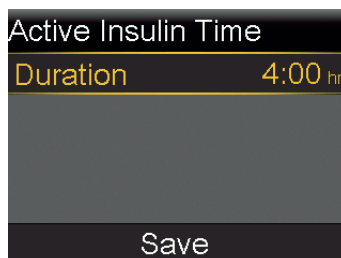
Active insulin is the bolus insulin that has been delivered by the pump and is still working to lower glucose levels. In the Bolus Wizard and SmartGuard Bolus feature, the Active Insulin Time setting is used to calculate a correction bolus by subtracting the estimated active insulin from each bolus. In SmartGuard, auto correction boluses are delivered up to every 5 minutes. A shorter Active Insulin Time setting may result in more insulin being delivered in correction boluses.

A healthcare professional provides the personalized active insulin time based on historic glycemic control data for the individual user. When using SmartGuard, the recommended initial setting is an Active Insulin Time of 2-3 hours. The Active Insulin Time setting in the MiniMed 780G system is not necessarily reflective of the physiological insulin metabolism. Adjustments are not based on the pharmacokinetics and pharmacodynamics of the rapid-acting insulin. The current active insulin amount appears on the Home screen and includes only the bolus insulin received.

To change the active insulin time:

1. From the Home screen, press , and then select .
2. In Manual mode, select **Delivery Settings > Bolus Wizard Setup > Active Insulin Time**.

3. Select **Duration**, and adjust the active insulin time in hours, using 15-minute increments.



4. Select **Save**.

Square Wave bolus

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

When using the Bolus Wizard feature in Manual mode, 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 normal bolus can be delivered while a Square Wave bolus is being delivered, as needed.

A Square Wave bolus can be useful in the following situations:

- Delayed food digestion due to gastroparesis or meals high in fat.
- When snacking over an extended period of time.
- A normal bolus drops BG too rapidly.

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

Turning the Square Wave bolus feature on or off

A Square Wave bolus can be set up and delivered only after the Square Wave bolus feature is turned on.

To turn the Square Wave bolus feature on or off:

1. From the Home screen, press , and then select .
2. In Manual mode, select **Delivery Settings** > **Dual/Square Wave**.
3. Select **Square Wave** to turn the feature on or off.
4. Select **Save**.

Delivering a Square Wave bolus using the Bolus Wizard feature

In Manual mode, the Bolus Wizard feature only delivers a Square Wave bolus if the Square Wave bolus feature is turned on and a carb value is entered. If a BG reading causes the Bolus Wizard feature to calculate that a correction bolus is necessary, then a Square Wave bolus cannot be delivered.

To deliver a Square Wave bolus using the Bolus Wizard feature:

1. From the Home screen, press , and then select .
2. In Manual mode, select **Bolus** > **Bolus Wizard**.

The Bolus Wizard screen appears.

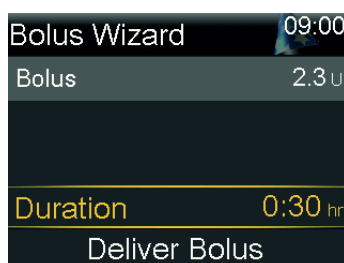


Bolus Wizard		09:00
BG	---	mmol/L
Carbs	10 _g	0.6 _U
Adjustment		0.0 _U
Bolus		0.6 _U
Next		

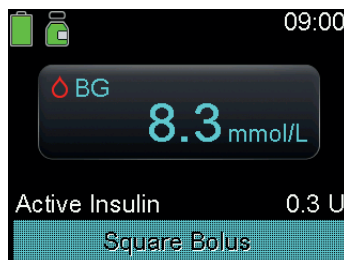
3. For a food bolus, select **Carbs** to enter the carb count of the meal.
4. The calculated bolus appears in the Bolus field. To modify the bolus amount, select **Bolus**.
5. Select **Next** to review the bolus information.



6. Select **Square**.
7. Select **Duration** to adjust the time period when the Square Wave bolus needs to be delivered.



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



Note: To stop bolus delivery or to see details on the insulin that has been delivered, see *Stopping a Square Wave or Dual Wave bolus delivery*, page 282.

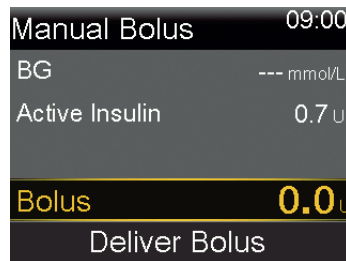
Delivering a Square Wave bolus using the Manual bolus feature

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

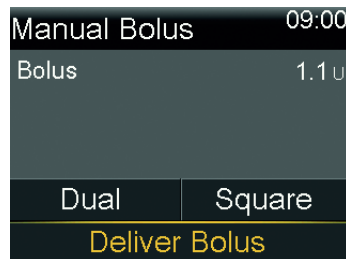
To deliver a Square Wave bolus using the Manual bolus feature:

1. From the Home screen, press , and then select .
2. In Manual mode, do one of the following:
 - Select **Bolus** if the Bolus Wizard feature is turned off.
 - Select **Bolus > Manual Bolus** if the Bolus Wizard feature is turned on.

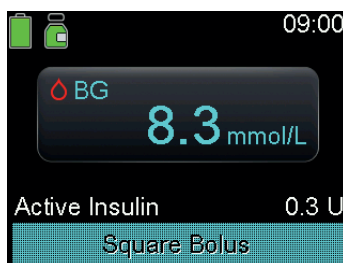
The Manual Bolus screen appears.



3. Set the bolus delivery amount in units, and then select **Next**.



4. Select **Square**.
5. Select **Duration** to adjust the time period when the Square Wave bolus is to be delivered.
6. Select **Deliver Bolus** to start the bolus.



Note: To stop bolus delivery or to see details on the insulin that has been delivered, see *Stopping a Square Wave or Dual Wave bolus delivery*, page 282.

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 normal bolus can be delivered while the Square portion of a Dual Wave bolus is being delivered, as needed.

A Dual Wave bolus can be useful in these situations:

- When an elevated BG needs to be corrected before a meal, and a delayed bolus is needed for food that is absorbed slowly.
- When eating meals with mixed nutrients, such as carbs, fats and proteins, that are absorbed at different rates.

Turning the Dual Wave bolus feature on or off

A Dual Wave bolus can be delivered only after the Dual Wave bolus feature is turned on.

To turn the Dual Wave feature on or off:

1. From the Home screen, press , and then select .
2. In Manual mode, select **Delivery Settings** > **Dual/Square Wave**.
3. Select **Dual Wave** to turn the feature on or off.
4. Select **Save**.

Delivering a Dual Wave bolus using the Bolus Wizard feature

In Manual mode, a Dual Wave bolus with the Bolus Wizard feature can be delivered only after the Dual Wave bolus feature is turned on.

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

1. For a correction bolus or a food bolus with a correction, use a BG meter to check BG. For a food bolus only, go to step 2.
2. From the Home screen, press , and then select .
3. In Manual mode, select **Bolus** > **Bolus Wizard**.

The Bolus Wizard screen appears.



Bolus Wizard		09:00
	BG	--- mmol/L
	Carbs	10 _g 0.6 _U
Adjustment		0.0 _U
Bolus		0.6 _U
Next		



Note: For more information on how to manually enter the BG meter reading, see *Entering a blood glucose (BG) meter reading*, page 102.

4. For a food bolus, select **Carbs** to enter the carb count of the meal. For a correction bolus where no food was eaten, leave the carbs value as 0. The calculated bolus appears in the Bolus field.
5. To modify the bolus amount, select **Bolus**.
6. Select **Next** to review the bolus information.

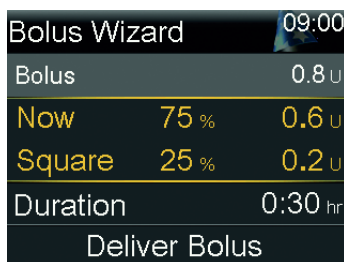


7. Select **Dual**.

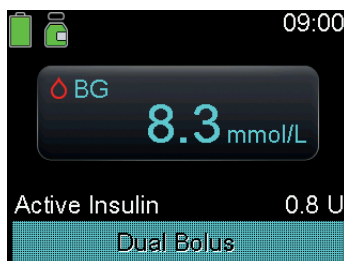
The Bolus Wizard screen appears.

8. To change the amounts, select the area of the screen with the Now % and Square % values and adjust the **Now** % amount.

When adjusting the Now amount, the Square amount adjusts automatically.



9. Adjust the **Duration** of the square portion of the bolus to be delivered.
10. Select **Deliver Bolus** to start the bolus.





Note: To stop bolus delivery or to see details on the insulin that has been delivered, see *Stopping a Square Wave or Dual Wave bolus delivery*, page 282.

Delivering a Dual Wave bolus using the Manual bolus feature

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

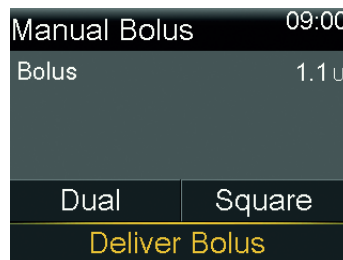
To deliver a Dual Wave bolus using the Manual bolus feature:

1. From the Home screen, press , and then select .
2. In Manual mode, do one of the following:
 - Select **Bolus** if the Bolus Wizard feature is turned off.
 - Select **Bolus > Manual Bolus** if the Bolus Wizard feature is turned on.

The Manual Bolus screen appears.

3. Set the bolus delivery amount in units, and then select **Next**.

The Manual Bolus screen appears, with the option to select the bolus type.



Manual Bolus		09:00
Bolus		1.1 U
Dual	Square	
Deliver Bolus		

4. Select **Dual**.

The Manual Bolus screen appears.

5. To change the amounts, select the area of the screen with the Now % and Square % values and adjust the **Now** % value. When the Now amount is adjusted, the Square amount adjusts automatically.

Manual Bolus		09:00
Bolus		0.8 U
Now	50 %	0.4 U
Square	50 %	0.4 U
Duration		0:30 hr
Deliver Bolus		

6. Select **Duration** to adjust the time period when the Square Wave bolus is to be delivered.
7. Select **Deliver Bolus** to start the bolus.

		09:00
BG		8.3 mmol/L
Active Insulin		0.4 U
Dual Bolus		



Note: To stop bolus delivery or to see details on the insulin that has been delivered, see *Stopping a Square Wave or Dual Wave bolus delivery*, page 282.

Easy bolus

The Easy bolus feature can be used to deliver a normal bolus using only the $\wedge$ button. The Easy bolus feature only works when the pump is in Sleep mode.

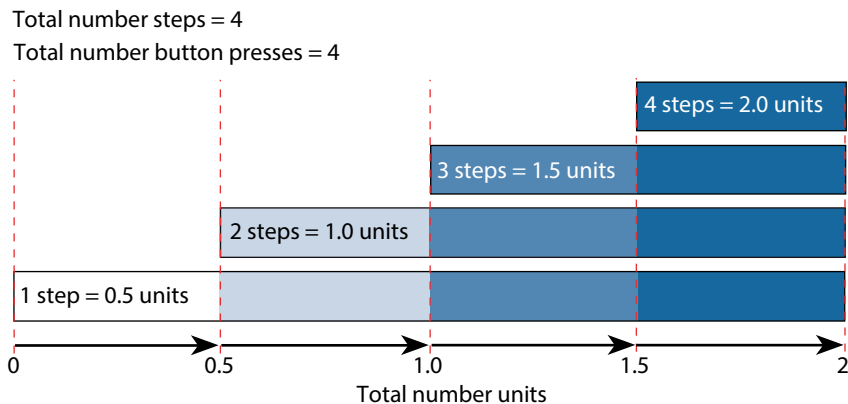
When the $\wedge$ button is pressed while the Easy bolus feature is used, the bolus amount increases by a certain amount. This amount, or step size, can be set from 0.1 to 2.0 units of insulin. The pump makes a tone or vibration each time the $\wedge$ button is pressed to help keep count of the steps.



Note: The step size cannot be greater than the Max bolus amount. The maximum number of steps is 20 for each bolus delivery.

Setting up the Easy bolus feature

The following graph provides an example of setting up a bolus of 2.0 units of insulin using a step size of 0.5 units.



To set up the Easy bolus feature:

1. From the Home screen, press , and then select .
2. Select **Device Settings** > **Easy Bolus**.
3. Select **Easy Bolus** to turn on the feature.
4. Set the **Step Size** amount in units.

Select a step size to a number that makes it easy to calculate the total bolus amount.



5. Select **Save**.

Delivering a bolus using the Easy bolus feature



WARNING: Never rely on beeps or vibrations alone while using the Easy bolus feature. Always confirm the insulin delivery by looking at the pump screen. When using the Sound & Vibration options, it is possible that a sound or vibration notification may not occur as expected if the speaker or vibrator in the pump malfunctions. Relying on beeps or vibrations while using the Easy bolus feature may result in over-delivery of insulin.

To deliver a bolus using the Easy bolus feature:

1. While the pump is in Sleep mode, press and hold $\wedge$ for one second or until the pump beeps or vibrates. The bolus can now be set up.



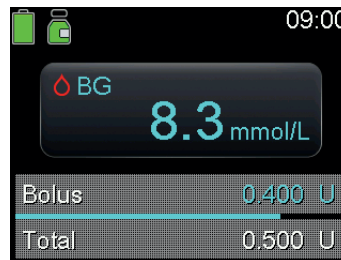
Note: If the pump does not respond when $\wedge$ is pressed, it may not be in Sleep mode, even if the screen is dark. For more information, see *Sleep mode*, page 68.

2. Press $\wedge$ the number of times needed to set the bolus amount. Count the tones or vibrations for each button press to confirm the total bolus amount.



Note: If ^ is pressed too many times and the bolus amount is too high, press v to cancel the Easy bolus delivery and start at step 1 to set up a new bolus.

3. When the needed bolus amount is reached, press and hold ^ to confirm the amount.
4. Press and hold ^ for one second, or until the pump beeps or vibrates, to deliver the bolus.



Note: If the ^ button is not pressed within 10 seconds after the bolus amount is confirmed, the bolus is canceled and a message appears that the bolus was not delivered.

Preset bolus

The Preset Bolus feature allows frequently used bolus deliveries to be set up in advance. There are four preset bolus names that can be used to match a bolus to a meal that has a known carb content. Four additional preset bolus names can be set for other circumstances. These are numbered from Bolus 1 to Bolus 4.



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

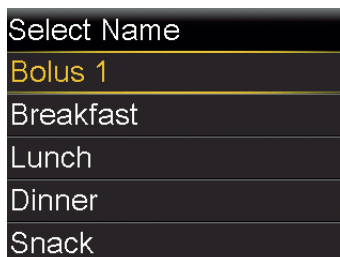
Setting up and managing preset bolus deliveries

To set up preset bolus amounts:

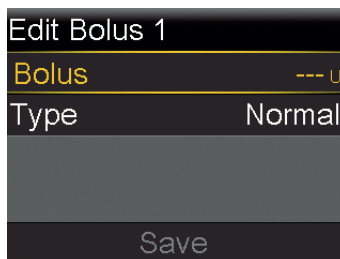
1. From the Home screen, press , and then select .
2. Select **Delivery Settings** > **Preset Bolus Setup**.



3. Select **Add New**.



4. Select a preset bolus.
An edit screen appears.



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

6. Select **Type** to set this as a normal bolus, Square Wave bolus, or Dual Wave bolus.



Note: Square Wave and Dual Wave can be selected in the Type field only if the Square Wave bolus and Dual Wave bolus features are turned on.

If the type is set to Square or Dual, 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** % amount. When the Now amount is adjusted, the Square amount adjusts automatically. Then set the **Duration** of time for the Square portion of the bolus.



Note: If the Dual Wave bolus feature or Square Wave bolus feature is turned off, the existing Preset Bolus settings are still available for use.

7. Select **Save**.

Editing, renaming, or deleting a preset bolus

Dual Wave Preset Boluses and Square Wave Preset Boluses can only be edited when the Dual Wave Bolus and Square Wave Bolus features are turned on.



Note: A preset bolus cannot be edited, renamed, or deleted during preset bolus delivery.

To edit, rename, or delete a preset bolus:

1. From the Home screen, press , and then select .
2. Select **Delivery Settings > Preset Bolus Setup**.
3. Select a preset bolus.

4. Select **Options**.
5. Do any of the following:
 - Select **Edit** to adjust the bolus value and type, if applicable. If changing to a Square Wave bolus, enter the duration. If changing to a Dual Wave bolus, enter the Now and Square values and the Duration.
 - Select **Rename** to assign a different name to this preset bolus. When the Select Name screen appears, select any available name from the list.
 - Select **Delete** to delete this preset bolus.

Delivering a preset bolus

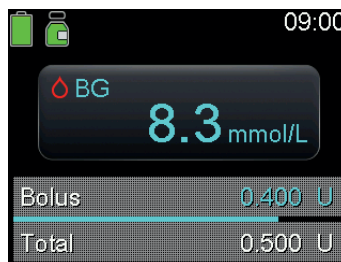
A preset bolus must be set before the Preset Bolus feature can be used. For more information, see *Setting up and managing preset bolus deliveries*, page 279.

To deliver a preset bolus:

1. From the Home screen, press , and then select .
2. Select **Bolus > Preset Bolus**.
3. Select the preset bolus to be delivered.

Preset Bolus		09:00
BG		--- mmol/L
Active Insulin		0.0 U
Bolus 1	N	0.5 U

4. Review the bolus amount, and then select **Deliver Bolus** to start the bolus.



Stopping a Square Wave or Dual Wave bolus delivery

This section describes how to stop a bolus in progress. It does not stop basal insulin delivery. To stop all insulin delivery, use the Suspend All Delivery feature (press , select , and select **Suspend All Delivery**).

This section describes how to stop the following bolus deliveries:

- A Dual Wave bolus during the Now portion delivery
- A Square Wave bolus delivery or a Dual Wave bolus during the Square portion delivery

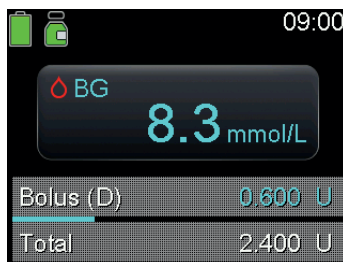
To stop a normal bolus delivery see *Stopping a bolus delivery*, page 115.



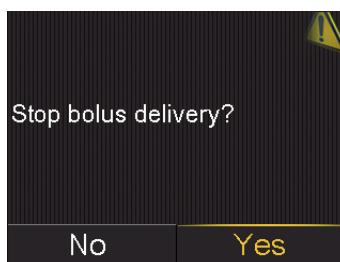
Note: When delivering a normal bolus and a Square Wave bolus at the same time, or a normal bolus and the Square portion of a Dual Wave bolus at the same time, both boluses are stopped.

To stop a Dual Wave bolus delivery during the Now portion:

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



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



The Bolus Stopped screen appears and shows the amount of bolus delivered, and bolus amount that was originally set up.



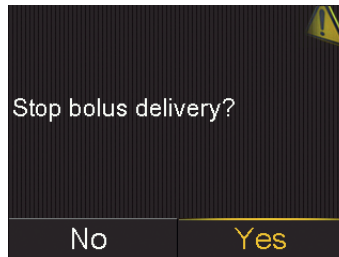
Note: When a Dual Wave bolus is stopped during the Now portion, the Now portion is stopped and the Square portion is canceled.



4. Select **Done**.

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

1. While the pump is delivering a Square Wave bolus delivery or the Square portion of a Dual Wave bolus delivery, press  from the Home screen.
2. Select , and then select **Bolus**.
3. Select **Stop Bolus**, then select **Yes** to confirm.



The Bolus Stopped screen appears and shows the amount of bolus delivered, and the bolus amount that was originally set up.

4. Select **Done**.



14

Troubleshooting

Troubleshooting

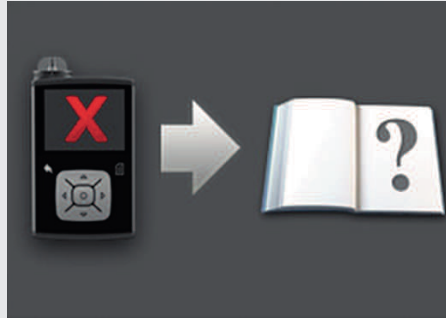
This chapter provides information about common MiniMed 780G insulin pump and sensor issues, as well as possible resolutions.

For a list of alarms, alerts, and messages, see *List of alarms, alerts, and messages, page 305*.

Pump issues



WARNING: When the critical pump error occurs, the following screen appears and the pump siren goes off:



Immediately disconnect the pump and discontinue use.
Contact a local Medtronic support representative.

Insulin delivery is still required when the pump is removed.
Consult a healthcare professional to determine an alternate method of insulin delivery while the pump is removed.

The following table provides troubleshooting information for the insulin pump:

Issue	Resolution
 appears on the Home screen or Bolus screens after an Active Insulin reset to zero alarm occurs.	Select OK to clear the alarm. Contact a local Medtronic support representative for assistance with the following steps: 1. Check the Daily History screen or the sensor graph for the recent bolus amounts, and when they were delivered, before giving any bolus. 2. Consult a healthcare professional for how long to wait after active insulin has been reset to zero before relying on the active insulin calculation of the Bolus Wizard feature. The

Issue	Resolution
	active insulin tracked prior to the Active Insulin reset to zero alarm is not included in new Bolus Wizard calculations. 3. Check blood glucose (BG) using a blood glucose meter and treat as needed.
	 WARNING: Do not rely on active insulin tracked in the pump when giving any bolus after active insulin has been reset to zero. Relying on the active insulin shown on the pump screen can result in the infusion of too much insulin, which can cause hypoglycemia.
The pump buttons are stuck during airplane travel.	During atmospheric pressure changes, the pump buttons may not work for up to 45 minutes. For example, during airplane travel, pump buttons may get stuck and the pump will alarm. This is rare. If this occurs, either wait for the problem to correct itself, or confirm the AA battery connection: 1. Remove the battery cap. 2. Place the battery cap back onto the pump. The pump will check the AA battery power, and may require a new AA battery. 3. If prompted, insert a new AA battery. For more information about changing the battery, see <i>Removing the battery</i>, page 73. If these steps do not correct the problem, contact a local Medtronic support representative for assistance.
The pump was dropped or there are concerns that the pump may be damaged.	 CAUTION: Always inspect the pump for cracks before exposing the pump to water, especially if the pump was dropped or damaged. Water leakage can cause the pump to malfunction and result in injury. 1. Disconnect the pump from body. Confirm all infusion set and reservoir connections are secure. 2. Disconnect the pump from body. Check the infusion set, including the tubing connector and tubing, for cracks or damage.

Issue	Resolution
	3. Check the display, button area, and pump case for cracks or damage. 4. Confirm the information on the Status screen. 5. Confirm the settings for the basal rates and the pump are correct. 6. Perform a self test. For more information, see <i>Self Test</i>, page 218. 7. If necessary, contact a local Medtronic support representative and check BG. For health-related questions or concerns, consult a healthcare professional.
The pump experienced physical impact, such as a drop or bump against a hard surface and the battery life seems shorter than usual.	Even with new batteries, the battery life may be very short. Take the following actions to address the issue: 1. Replace pump batteries immediately if a Low Battery Pump alert occurs. 2. Keep spare AA lithium, alkaline, or fully charged NiMH batteries stored in your emergency kit and ensure they are easily accessible. If necessary, contact a local Medtronic support representative.
The pump display times out too quickly.	In order to conserve battery, the pump display times out after 15 seconds. To increase the time, see <i>Display options</i> , page 215.
The pump displays a Check Settings alarm.	The pump has reset to factory settings. Review any settings that were not already set in the Startup Wizard and re-enter them, if necessary.
The pump settings have been cleared and need to be re-entered.	Do not clear pump settings unless directed to do so by a healthcare professional. Certain pump errors may cause the pump to reset to factory default values, which clears the current pump settings. To restore saved pump settings, see <i>Restoring the settings</i> , page 220. Consult a healthcare professional to determine the necessary settings. Have the settings that need to be entered into the pump ready before starting the procedure below.

Issue	Resolution
	Use the following procedure to re-enter personalized pump settings using the Startup Wizard: 1. After the pump resets, the Startup Wizard appears. Select a language, and then press . 2. Select a time format, and then press . 3. Enter the current time, and then select Next. 4. Enter the current date, and then select Next. 5. Select the carb unit, and then press . 6. When the Active Insulin Time screen appears, select Next. For more information, see <i>Bolus Wizard feature in Manual mode, page 106</i>. 7. Enter the Duration, and then select Next. 8. Enter the basal rates for the new basal pattern, and then select Next. For more information, see <i>Setting up a basal pattern , page 91</i>. 9. Review the basal pattern information, and then select Next. 10. On the Startup screen, a message displays to ask to set up Bolus Wizard now. Do one of the following: • Select Yes to enter the Bolus Wizard settings in Manual mode. For more information. see <i>Bolus Wizard feature in Manual mode, page 106</i>. • Select No to skip the Bolus Wizard setup.

Sensor issues

Issue	Resolution
The pump has lost connection with the sensor.	After 30 minutes without a signal, the Lost sensor signal alert appears. Follow the steps on the pump screen or the steps below to try to resolve the issue. Note: If alerts are silenced and a sensor alert occurs, the alert still appears on the screen. 1. Move the pump closer to the sensor, and then select OK. It can take up to 15 minutes for the pump to find the sensor

Issue	Resolution
	signal. If the pump still cannot find the sensor signal, the Possible signal interference alert appears. 2. Move away from electronic devices that may cause interference, and then select OK. 3. Do one of the following: • If the pump cannot find the sensor signal within 15 minutes or if the “Sensor signal not found - See User Guide” alert appears on the SG graph, contact a local Medtronic support representative. • If a Change sensor alert appears, select OK and change the sensor.
A calibration is not accepted. A Calibration not accepted alert occurs in one of the following situations:	The sensor does not require calibration for use with the system. However, every BG reading entered into the pump is used to calibrate the sensor. • The system cannot use the entered BG meter reading. Only a BG value between 2.8 mmol/L and 22.2 mmol/L can be used to calibrate the sensor. Wait at least 15 minutes, wash hands, and try again. • The entered BG meter reading differs too greatly (greater than 40%) from the most recent SG reading. Check the accuracy of the BG meter reading and try again. • The sensor cannot receive the calibration BG meter readings from the pump due to a failed sensor signal. Troubleshoot the failed sensor signal.
The suspend by sensor icon appears with a red X. 	The suspend by sensor icon appears with a red X when the Suspend before low or the Suspend on low feature is unavailable. This can occur in the following situations: • A suspend event recently occurred. For information about the availability of the suspend functionality, see <i>The Suspend before low feature, page 162</i> or <i>The Suspend on low feature, page 164</i>. • SG readings are unavailable. SG readings may be unavailable in the following situations:

Issue	Resolution
	• A BG meter reading is required. • The pump has lost communication with the sensor. Restore pump communication with the sensor. • The sensor is updating. Clear the alert and wait up to 3 hours for the SG readings to resume. If necessary, insert a new sensor. If the issue continues after a new sensor is inserted, contact a local Medtronic support representative.

15

Pump Care

Pump Care

The pump does not require preventative maintenance. This chapter provides information about caring for the components of the MiniMed 780G system.

Clean, store, and dispose of the pump

Cleaning the pump

Prepare the following supplies to clean the pump:

- four small, clean, soft cloths
- mixture of water and mild detergent
- clean water
- 70% alcohol
- clean cotton swabs
- clean cotton balls



CAUTION: Never use organic solvents, such as lighter fluid, nail polish remover, or paint thinner to clean the MiniMed 780G insulin pump. Never use lubricants with the pump. When the pump is being cleaned, be sure to keep the reservoir compartment dry and away from moisture. If organic solvents are used to clean the pump, they can cause the pump to malfunction and result in minor injury.

To clean the pump:

1. Dampen a cloth with water mixed with a mild detergent.
2. Use the cloth to wipe the outside of the pump while keeping the inside of the reservoir compartment dry.
3. Dampen a clean cloth with water and wipe to remove any detergent residue.
4. Dry with a clean cloth.
5. Wipe the pump with a 70% alcohol wipe.
6. Use a dry, clean cotton swab to remove any battery residue from the battery cap.
7. Use a dry, clean cotton swab to remove any battery residue from the battery compartment housing.

Storing the pump

The pump can be stored when it is not in use.

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 may experience decreased performance.



WARNING: After the pump is stored, 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 may result in inaccurate insulin delivery and serious injury.

To place the pump in storage mode:

1. Remove the AA battery from the pump. For details, see *Removing the battery*, page 73.



Note: When the battery is removed, the pump issues an Insert Battery alarm for 10 minutes or until the pump is in storage mode.

2. Press and hold  until the screen turns off.

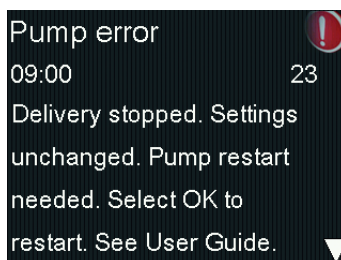


CAUTION: Never expose the pump to temperatures below -20 °C (-4 °F) or above 50 °C (122 °F). Storing the pump in temperatures outside of this range can damage the pump.

To use the pump after it has been stored:

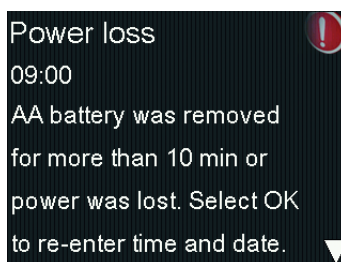
1. Insert a new AA battery into the pump. For details, see *Inserting the battery*, page 71.

A Pump Error alarm appears.



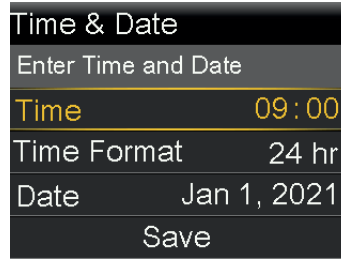
2. Select **OK**.

The pump displays a Power Loss alarm.



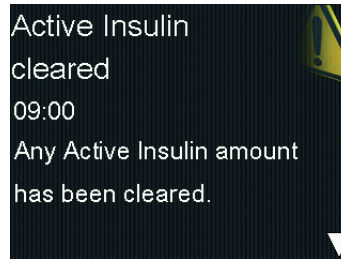
3. Select **OK**.

The Time & Date screen appears.



4. Enter the current **Time**, **Time Format**, and **Date**.
5. Select **Save**.

The pump displays an Active Insulin Cleared alert.



6. Select **OK**.

Confirm that all the settings, such as basal rate, are set as desired. Use the Restore Settings option to reapply the last saved settings, if needed. For more information, see *Restoring the settings*, page 220.

7. Repeat the pairing process for the sensor and meter. For sensor details, see *Pairing the pump and sensor*, page 178. For meter details, see *Pairing the pump and meter*, page 140.

Pump disposal

Contact a local Medtronic support representative for information on proper disposal of the MiniMed 780G system. Always follow local laws and regulations for the disposal of medical devices.

Do not dispose of the insulin pump in an unsorted municipal waste stream. The pump uses an AA battery and an internal battery.

Waste batteries, waste battery packs, electronics, and packaging are accepted by many recyclers. For information about recycling programs, contact local authorities. In addition, Medtronic and its distributors engage with many national recycling programs.

For information on the disposal of the components used with the MiniMed 780G system, refer to the corresponding user guide.

Appendix A: List of alarms, alerts, and messages

Appendix A: List of alarms, alerts, and messages

This appendix provides information about alarms, alerts, and messages that can occur in the MiniMed 780G system.

Pump alarms, alerts, and messages

The following table lists the most common or serious alarms, alerts, and messages related to the MiniMed 780G insulin pump. The table also explains the meaning, consequences, and the reasons why these notifications appear, and provides steps for problem resolution.



Note: Use the MiniMed Mobile app to view the sensor graph on a mobile device. Always read and acknowledge all alarms and alerts on the pump. If the pump simultaneously generates more than one alarm or alert, only one of the alarms or alerts appears on the mobile device.

Title and text	Type	Explanation	Next steps
Active Insulin cleared Any Active Insulin amount has been cleared.	Alert	The pump shows the active insulin amount at 0 units. The pump shows this alert when the active insulin is cleared from the Clear Active Insulin option	• Select OK to clear the alert. • The active insulin tracked prior to pump restart is not included in new Bolus Wizard

Title and text	Type	Explanation	Next steps
		on the Manage Settings screen or if the pump has been shut down and is powered back on.	calculations. Consult a healthcare professional for how long to wait after active insulin is cleared before relying on the active insulin calculation of the Bolus Wizard feature. • Check Daily History for the last bolus amount and when it was delivered.
Active Insulin reset to zero  Call local Medtronic support for assistance. See User Guide for phone numbers. Pump Active Insulin may be incorrect until XX:XX due to a pump error. Monitor glucose.	Alarm	The pump shows the active insulin amount at 0 units. This occurs when a pump error clears active insulin in the pump. After the Active Insulin reset to zero alarm occurs,  appears on the Home screen and Bolus screens until the time shown in the alarm.	Select OK to clear the alarm. Contact a local Medtronic support representative for assistance.
Active Insulin Reminder  Call local Medtronic support for assistance if needed. See User Guide for	Message	The Active Insulin Reminder message occurs when the Bolus Wizard screen or the Manual Bolus screen is accessed before the time shown in the message. After the Active Insulin reset to zero alarm occurs,  appears	Select OK to clear the message. Contact a local Medtronic support representative for assistance with the following steps: • Check the Daily History screen or the sensor graph for the re-

Title and text	Type	Explanation	Next steps
phone numbers. Pump Active Insulin was reset to zero at XX:XX. Active insulin may be incorrect until XX:XX. Monitor glucose.		on the Home screen and Bolus screens until the time shown in the Active Insulin reset to zero alarm or the Active Insulin Reminder message.	cent bolus amounts, and when they were delivered, before giving any bolus. - Consult a healthcare professional for how long to wait after active insulin has been reset to zero before relying on the active insulin calculation of the Bolus Wizard feature. The active insulin tracked prior to the Active Insulin reset to zero alarm is not included in new Bolus Wizard calculations. - Check blood glucose (BG) using a blood glucose meter and treat as needed.
Auto Suspend Insulin delivery suspended. No buttons pressed within time set in Auto Suspend.	Alarm	Insulin delivery is currently suspended by Auto Suspend. The Auto Suspend feature automatically suspends insulin delivery and triggers an alarm after no buttons are pressed for a specified period of time. Insulin delivery is suspended until the alarm is cleared and basal insulin delivery resumed.	- Select Resume Basal to clear the alarm and resume basal insulin delivery. - Check BG and treat as needed.

Title and text	Type	Explanation	Next steps
Battery failed Insert a new AA battery.	Alarm	The battery in the pump is low on 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 inserted battery is not compatible with the pump.	• Remove the incompatible battery to clear the alarm. • Insert a new AA battery.
Bolus not delivered Bolus entry timed out before delivery. If bolus intended, enter values again.	Alert	A bolus value was entered, but a bolus was not delivered within 30 seconds.	• Select OK to clear the alert. • If a bolus delivery was intended, check BG, re-enter bolus values and redeliver the 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 delivery or Fill Cannula procedure was in progress or the Resume bolus? message appeared and was not cleared.	• Note the amount of insulin not delivered. • Replace the AA battery. • Select OK to clear the alarm. • Deliver the remaining bolus amount if needed.
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 have not already been 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	The pump has encountered an error that cannot be resolved. For example, the pump may have a mechanical problem.	The pump is not able to deliver insulin. Disconnect the infusion set and stop using the pump. • Consider another form of insulin delivery. • Check BG, and treat as necessary. • Write down the error code that appears on the alarm screen. • Contact a local Medtronic support representative for assistance with the pump.
Delivery limit exceeded Delivery stopped. Check BG. See User Guide for more information.	Alarm	The pump has suspended insulin delivery because the hourly delivery limit was reached. 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 BG. • Select Resume Basal. • Check Bolus History and re-evaluate insulin needs. • Continue to monitor BG.
Device Limit You must delete an existing device (device type) before you can pair a new one (device type).	Message	The pump is already paired with the maximum number of devices for this type. The following list describes the maximum number of each device type to pair with the pump:	• Select OK to clear the message. • Go to the Paired Devices screen and select the device to unpair from the list of devices.

Title and text	Type	Explanation	Next steps
		• Meter-four Accu-Chek Guide Link meters • Mobile Device—one compatible mobile device	Select Unpair, and then select Yes to confirm or No to cancel. Pair the pump and the desired device.
Device not compatible Device cannot be used with this pump.	Alert	The pump cannot pair with the selected device.	• Select OK to clear the alert. • Contact a local Medtronic support representative for assistance.
Device not found Make sure device is in range and in pairing mode.	Alert	The pump did not pair with the device.	• Select OK to clear the alert. • Confirm that the device is not already paired with a pump. • Confirm that the device is ready to pair with the pump. • Make sure the pump is away from any electronic devices that might cause interference, such as cellular phones that are not paired with the MiniMed 780G system and other wireless devices. • Move the device closer to the pump. • Try to pair the pump with the device again.

Title and text	Type	Explanation	Next steps
Fill Cannula? Select Fill to fill cannula or select Done if not needed.	Alarm	The Fill Cannula? screen has been active for 15 minutes.	- To fill the cannula, select Fill. - If the cannula does not need to be filled, select Done to skip this process.
High BG XX.X mmol/L Check infusion set. Check ketones. Consider insulin injection. Monitor BG. Confirm BG?	Alert	The BG meter reading is above 13.9 mmol/L. This alert appears in Manual mode. For High BG XX.X mmol/L while the SmartGuard feature is on, see <i>SmartGuard feature alerts and messages</i> , page 333.	- Select No to prevent the remote BG from being used by the pump. Select Yes to confirm the BG reading. - Check 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? message appears and a tone sounds when a new battery is inserted. The message indicates how much of the bolus was delivered.	- Insert a new AA battery. - The alarm clears when a new battery is inserted. - The pump powers off after 10 minutes unless a new battery is inserted.
Insulin flow blocked Check BG. Consider testing ketones. Check reservoir and infusion set.	Alarm	The pump has detected that the basal or bolus insulin flow was blocked.	- Check BG and ketones. Administer an insulin injection if necessary. - Remove the infusion set and reservoir. - Select Reservoir & Set to start the process with a new infusion set and reservoir.

Title and text	Type	Explanation	Next steps
			If the alarm occurs during a bolus delivery: • 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 the SmartGuard feature 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. Using the SmartGuard feature too soon after a manual injection may result in over-delivery of insulin and may cause hypoglycemia. Consult a healthcare professional for how long to wait after a manual injection before using the SmartGuard feature.			
Insulin flow blocked Reservoir is empty. No insulin delivery. Change the reservoir and infusion set now. Check BG. Consider testing ketones.	Alarm	The pump has detected that the insulin flow is blocked and there is no insulin in the reservoir.	• Check BG and ketones. Administer an insulin injection if necessary. • Remove the infusion set and reservoir. • Select Reservoir & Set to start the process with a new infusion set and reservoir. If the alarm occurs during a bolus delivery: • Check the Daily History screen for the amount of bo-

Title and text	Type	Explanation	Next steps
			lus already delivered before the pump alarmed. • Consider delivering remaining bolus, if the bolus insulin was not included in an insulin injection.
Insulin flow blocked Fill Cannula stopped. Restart the Reservoir & Set procedure.	Alarm	The pump has detected that the insulin flow is blocked while filling the cannula.	• Check BG and ketones. Administer an insulin injection if necessary. • Remove the infusion set and reservoir. • Select Reservoir & Set to start the process with a new infusion set and reservoir.
Insulin flow blocked Fill Tubing stopped. Restart the Reservoir & Set procedure.	Alarm	The pump has detected that the insulin flow is blocked while filling the tubing. Possible connection issue between the tubing and reservoir.	• Remove the reservoir and select Reservoir & Set to restart the fill tubing process. • Disconnect the tubing from the reservoir. • Confirm that the tubing is not crimped or bent. • Continue to follow the steps displayed on the pump using the same infusion set and reservoir. • If this alarm occurs again, replace the infusion set.

Title and text	Type	Explanation	Next steps
Loading in-complete Restart the Reservoir & Set procedure.	Alarm	 was pressed after loading began.	- Remove the reservoir to start again. - Select Reservoir & Set 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 fewer.	- 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 X.X mmol/L Treat Low BG. Do not bolus until BG is normal. Monitor BG. Confirm BG?	Alert	The BG meter reading is below 3.9 mmol/L.	- Select No to prevent the remote BG reading from being used by the pump. Select Yes to confirm the BG reading. - Check BG and treat as necessary.
Low reservoir XX units remaining. Change reservoir.	Alert	The 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 the reservoir is not changed after this alert is received, a second Low reservoir alert appears when

Title and text	Type	Explanation	Next steps
			the insulin level reaches half of the 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 occurred and the pump needs to be restarted. The backup settings have been lost, but the current settings are unchanged.	• Select OK to restart the pump. The current settings are unchanged. Only the 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 if insulin is needed.
Max Fill reached 3X.X U. Did you see drops at the end of tubing?	Alarm	The number of units expected to fill the tubing has been exceeded. By now, insulin should be visible at the end of the tubing.	• If there are drops of insulin at the end of the tubing, select Yes. • If there are no drops of insulin at the end of the tubing, select No. • Follow instructions displayed on the pump.
Max Fill reached 4X.X U. Restart the Reservoir & Set procedure.	Alarm	The number of units expected to fill the tubing has been exceeded. By now, insulin should be visible at the end of the tubing.	• Remove the reservoir. • Check if there is still insulin in the reservoir. If there is insulin in

Title and text	Type	Explanation	Next steps
			the reservoir the same reservoir can be used. • Select Reservoir & Set to restart the new reservoir procedure.
No reservoir detected Restart the Reservoir & Set procedure.	Alarm	There is no reservoir in the pump or the reservoir is not properly locked into place.	• Select Reservoir & Set. • Confirm that the reservoir is filled with insulin. • When prompted, confirm that the 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 the pump is unable to charge. The pump is operating on the AA battery only.	• Select OK to clear the alarm. • Check BG and treat as necessary. • Record the pump settings as soon as possible because the AA battery may not last long. • Contact a local Medtronic support representative for assistance with the pump.
Power loss AA battery was removed for more than 10 min or power was lost. Select OK to re-enter time and date.	Alarm	The battery has been out of the pump for more than ten minutes and the pump has lost power. The date and time must be reset.	• Select OK to go to the Time & Date screen. • Enter the current time, time format, and date.

Title and text	Type	Explanation	Next steps
Pump error Delivery stopped. Current settings cleared. Pump restart needed. Select OK to restart and then re-enter your settings. See User Guide.	Alarm	The pump encountered an error and will restart. The pump settings will return to factory default values.	• Select OK to restart the pump. • When the pump restarts, follow instructions on the pump display. • After the pump restarts, check settings and re-enter values as needed. • If the backup settings were recently saved in Manage Settings, use Restore Settings. • If the pump was delivering a bolus or filling the cannula, check Daily History and re-evaluate if insulin is needed. • If this alarm recurs frequently, write down the error code on the alarm screen (it can also be found in the Alarm History) and contact a local Medtronic support representative for assistance.
Pump error Delivery stopped. Settings unchanged. Pump restart needed. Select	Alarm	A pump error has occurred, the pump needs to be restarted.	• Select OK to restart the pump. • If the pump was delivering a bolus or filling the cannula, check Daily History

Title and text	Type	Explanation	Next steps
OK to restart. See User Guide.			and re-evaluate if insulin is needed. • If this alarm recurs frequently, write down the error code on the alarm screen (it can also be found in the Alarm History) and contact a local Medtronic support representative for assistance.
Pump error Delivery stopped. Settings unchanged. Select OK to continue. See User Guide.	Alarm	The pump encountered an error but a restart is not necessary. The issue is resolved. The settings are not changed.	• Select OK to resume basal insulin delivery. • If the pump was delivering a bolus or filling the cannula, check Daily History and re-evaluate if insulin is needed. • If this alarm recurs frequently, write down the error code on the alarm screen (it can also be found in the Alarm History) and contact a local Medtronic support representative for assistance.
Pump restarted Delivery stopped. Settings unchanged. Select OK to con-	Alarm	The pump has encountered a problem and has restarted. The 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 if insulin is needed.

Title and text	Type	Explanation	Next steps
tinue. See User Guide.			If this alarm recurs frequently, write down the error code on the alarm screen (it can also be found in the Alarm History) and contact a local Medtronic support representative for assistance.
Replace battery Battery life less than 30 minutes. To ensure insulin delivery, replace battery now.	Alert	Battery power 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. The battery was not replaced after the Low battery Pump alert.	Replace the battery immediately to resume insulin delivery.
Reservoir estimate at 0 U To ensure insulin delivery, change reservoir.	Alert	The reservoir level is estimated at 0 U.	- Select OK to clear the alert. - Change the reservoir.

Title and text	Type	Explanation	Next steps
Resume bolus? XXX of YYY U delivered. Resume delivery of ZZZ U?	Message	A normal bolus delivery has been interrupted because the pump battery was removed. If it is within ten minutes since this interruption, the bolus can be resumed.	• Check the message to see how much of the bolus was delivered. • To cancel the remaining bolus delivery, select Cancel. • To resume the bolus delivery, select Resume.
Resume Dual bolus? XX of YY U delivered. Resume delivery of ZZ U for XX:XX hr?	Message	The Square portion of Dual Bolus delivery has been interrupted. If it is within ten minutes since this interruption, the bolus can be resumed.	• Check the message to see how much of the Dual Wave bolus was delivered. • To cancel the remaining bolus delivery, select Cancel. • To resume the bolus delivery, select Resume.
Resume Dual bolus? XX of YY U delivered. Resume delivery of ZZ U now, and AA U Square for XX:XX hr?	Message	The Now portion of a Dual Wave bolus delivery has been interrupted because the pump battery was removed. If it is within ten minutes since this interruption, the bolus can be resumed.	• Check the message to see how much of the Dual Wave bolus was delivered. • To cancel the remaining bolus delivery, select Cancel. • To resume the bolus delivery, select Resume.
Resume Square bolus? XX of YY U delivered for XX:XX hr. Resume delivery	Message	The Square Wave bolus delivery was interrupted. If it is within ten minutes since this interruption, the bolus can be resumed.	• Check the message to see how much of

Title and text	Type	Explanation	Next steps
of ZZ U for XX:XX hr?			the Square Wave bolus was delivered. - To cancel the remaining bolus delivery, select Cancel. - To resume the bolus delivery, select Resume.
Rewind required Delivery stopped. Rewind was required due to pump error. Select OK to continue. See User Guide.	Alarm	The pump encountered an error.	- Select OK to clear the alarm. - Use the Reservoir & Set Menu to start the new reservoir process or new set process. For details, see <i>Setting up the reservoir and infusion set</i>, page 120. - After resuming insulin delivery, if this alarm recurs frequently, contact a local Medtronic support representative for assistance.
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, contact a local Medtronic support representative for assistance with the pump. If the alarm cannot be cleared

Title and text	Type	Explanation	Next steps
			• See <i>Pump issues</i>, page 288. • Consider another form of insulin, because the pump is not delivering insulin. • Check BG and treat as necessary. • Contact a local Medtronic support representative for assistance with the pump.

CGM (sensor) alarms, alerts, and messages

The following table lists the most common or serious alarms, alerts, and messages related to sensor glucose (SG) values, as well as the status of the 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	The SG reading is approaching the specified high limit.	• Select OK to clear the alert. • Check BG. • Follow instructions from a healthcare professional and continue to monitor BG.
Alert before low Sensor glucose approaching Low Limit. Check BG.	Alert	The SG reading is approaching the specified low limit.	• Select OK to clear the alert. • Check BG. • Follow instructions from a healthcare professional and continue to monitor BG.

Title and text	Type	Explanation	Next steps
Alert on high XX.X mmol/L High sensor glucose. Check BG.	Alert	The SG reading is at or above the specified high limit.	• Select OK to clear the alert. • Check BG. • Follow instructions from a healthcare professional and continue to monitor BG.
Alert on low X.X mmol/L Low sensor glucose. Check BG.	Alert	The SG reading is at or below the specified low limit.	• Select OK to clear the alert. • Check BG. • Follow instructions from a healthcare professional and continue to monitor BG.
Alert on low X.X mmol/L Low sensor glucose. Insulin delivery suspended since XX:XX. Check BG.	Alarm	The SG reading is at or below the specified low limit, and the pump has suspended insulin delivery due to a Suspend before low or Suspend on low.	• Select OK to clear the alarm. • Check BG. • Follow instructions from a healthcare professional and continue to monitor BG.
Basal delivery resumed Basal delivery resumed at XX:XX after suspend by sensor. Check BG.	Message	The pump is resuming basal insulin delivery after a Suspend before low or Suspend on low event occurred.	• Select OK to clear the message. • Check BG. • Follow instructions from a healthcare professional and continue to monitor BG.
Basal delivery resumed Low settings change caused basal to be resumed at XX:XX. Check BG.	Alert	The pump is resuming basal insulin delivery after a Suspend before low or a Suspend on low event occurred, because the Suspend before low	• Select OK to clear the alert. • Check BG. • Follow instructions from a healthcare professional and continue to monitor BG.

Title and text	Type	Explanation	Next steps
		or the Suspend on low feature was turned off.	
Basal delivery resumed Maximum 2 hour suspend time reached. Check BG.	Alert	The 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 BG. • Follow instructions from a healthcare professional and continue to monitor BG.
Basal delivery resumed Maximum 2 hour suspend time reached. SG is still under Low limit. Check BG.	Alarm	The pump is resuming basal insulin delivery two hours after a Suspend before low or Suspend on low event occurred.	• The pump has resumed basal insulin delivery; however, the SG reading is still at or below the low limit. • Select OK to clear the alarm. • Check BG. • Follow instructions from a healthcare professional and continue to monitor BG.
BG not received Place pump close to sensor. Select OK to re-send BG to sensor.	Alert	The sensor was unable to receive the BG meter reading from the pump.	• Move the pump and sensor closer together. • Select OK to clear the alert, and then enter a new BG meter reading.
Calibration not accepted Sensor information is unavailable for up to 2 hours. Entered BGs may not calibrate the sensor but can still be used for therapy.	Alert	The system was unable to use the BG meter readings entered to calibrate the sensor. This alert occurs on the first day only.	• Wash and dry hands thoroughly. • Select OK to clear the alert. • Consider waiting up to two hours, and then enter a new BG meter reading. • Contact a local Medtronic support representative for assistance, if needed.

Title and text	Type	Explanation	Next steps
Calibration not accepted Wait at least 15 minutes. Wash hands, test BG again and calibrate.	Alert	The system was unable to use the BG meter readings entered to calibrate the sensor.	- Wash and dry hands thoroughly. - Select OK to clear the alert. - After 15 minutes, enter a new BG meter reading. If a Calibration not accepted alert is received on the second calibration after 15 minutes, a Change sensor alert occurs. - Contact a local Medtronic support representative for assistance, if needed.
Change sensor Insert and pair new sensor.	Alert	This alert occurs if the battery on the sensor fails, or Yes was selected from the Lost sensor signal alert, indicating that the sensor was removed from the body.	- Select OK to clear the alert. - Change the sensor. For details, see <i>Inserting the sensor</i>, page 174.
Change sensor Second calibration not accepted. Insert new sensor.	Alert	A Calibration not accepted alert occurs if the entered BG meter reading differs too greatly from the most recent SG reading. This alert occurs when two Calibration not accepted alerts are received in a row.	- Select OK to clear the alert. - Change the sensor. For details, see <i>Inserting the sensor</i>, page 174.

Title and text	Type	Explanation	Next steps
Change sensor Sensor not working properly. Insert new sensor.	Alert	This alert occurs when the pump diagnoses a problem with the sensor that cannot be resolved.	• Select OK to clear the alert. • Change the sensor. For details, see <i>Inserting the sensor</i>, page 174.
Enter BG now Enter BG to calibrate sensor. Sensor information is no longer available	Alert	A BG meter reading is required to calibrate the sensor. SG readings cannot be received until the sensor is calibrated.	• Select OK to clear the alert. If no BG meter reading is entered within 30 minutes, the Enter BG now alert occurs again. • Select Snooze, enter the desired snooze time, and select OK. If no BG meter reading is entered before the Snooze time has ended, the Enter BG now alert occurs again. • Enter a BG meter reading to calibrate the sensor.
High SG Glucose was 13.9 mmol/L or higher for more than 3 hours. Check infusion set. Check ketones. Monitor glucose.	Alert	SG was 13.9 mmol/L or higher for three hours.	• Select OK to clear the alert. • Check BG and treat as necessary.
Lost sensor signal Move pump closer to sensor. May take 15 minutes to find signal.	Alert	A sensor signal has not been received for 30 minutes during or after sensor initialization.	• Move the pump closer to the sensor. It can take up to 15 minutes for the pump to establish communication with the sensor. • Select OK to clear the alert.

Title and text	Type	Explanation	Next steps
Low SG X.X mmol/L SG is under 3.0 mmol/L. Check BG and treat.	Alarm	The SG reading has fallen below 3.0 mmol/L. This alarm is factory set and cannot be changed or turned off. This alarm cannot be silenced and is always active, whether the pump is using the SmartGuard feature or Manual mode.	- Select OK to clear the alarm. - Check BG and treat as necessary.

Note: This alarm does not suspend insulin delivery.

Note: X.X represents the current SG reading that appears on the pump. This alarm remains until the alarm is cleared, even if glucose values reach or rise above 3.0 mmol/L.



WARNING: For MiniMed 780G 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” or the “Low SG” alarm. 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 sensor glucose readings with a blood glucose meter, and treat according to the recommendations of a healthcare professional. Solely relying on these sensor glucose alerts and readings for treatment decisions could result in missing severe hypoglycemia (low blood glucose) events.

Max Basal Consult health-care professional before changing this value.	Message	The Max basal rate setting is being changed.	Select Continue or Cancel to clear the message.
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Title and text	Type	Explanation	Next steps
Max Basal Error Your max basal rate cannot be lower than an existing basal rate.	Alert	You are trying to lower the Max basal rate setting lower than existing basal rates.	• Select OK to clear the alert. • Lower other basal rates before changing the Max basal rate.
Medical device CALL FOR EMERGENCY ASSISTANCE. I have diabetes.	Alarm	The pump is suspended due to low SG and there has been no response to the alarm within 10 minutes.	• Select Dismiss. • Immediately call for emergency assistance.
No calibration occurred Confirm sensor signal. Calibrate by XX:XX.	Alert	The sensor was unable to receive the calibration BG meter readings from the pump.	• Select OK to clear the alert. • Check the status icons on the Home screen to confirm that the pump has a signal from the sensor. If there is no sensor signal, see <i>Sensor issues</i>, page 291. • For SG readings to be monitored without interruption, enter or confirm a BG meter reading by the time displayed on the pump screen.
No calibration occurred Confirm sensor signal. Check BG again to calibrate sensor.	Alert	The sensor was unable to receive the required calibration BG meter readings from the pump. Calibration is required by the system for SG readings to resume. "Calibration required" appears	• Select OK to clear the alert. • Take another BG meter reading and calibrate again.

Title and text	Type	Explanation	Next steps
		on the sensor graph.	
Not for SmartGuard These settings apply to Manual mode only and do not affect how much insulin SmartGuard delivers.	Message	The Max basal or Max bolus rate settings or basal pattern settings are being accessed.	Select Continue or Cancel to clear the message.
Outside typical range Max Basal of 6.00 U/hr can allow basal delivery of up to 144 U/day in Manual mode. This amount of insulin may not be safe.	Alert	The Max basal rate setting is being increased past 6 U/hr.	- Select OK to clear the alert. - Consult your healthcare professional before increasing the Max basal rate.
Pair new sensor? Only one sensor can be paired to the pump. Select Continue to pair new sensor. The existing sensor will be unpaired.	Alert	This alert occurs when an existing sensor is already paired with the pump and a new sensor is selected for pairing. Only one sensor can be paired with the pump.	- Select Continue to pair the new sensor with the pump. - Select Cancel to keep the existing sensor paired with the pump.
Possible signal interference Move away from electronic devices. May take	Alert	There may be interference from another electronic device that is affecting the communication	- Move away from other electronic devices. It can take up to 15 minutes for the pump to start communicating with the sensor. - Select OK to clear the alert.

Title and text	Type	Explanation	Next steps
15 minutes to find signal.		between the pump and the sensor.	
Rise Alert Sensor glucose rising rapidly.	Alert	The SG reading has been rising as fast or faster than the preset Rise Alert limit.	• Select OK to clear the alert. • Check BG using a meter. • Follow instructions from a healthcare professional.
Safety Alert The sensor was paired and calibrated previously. Did you enter BG X mmol/L at XX:XX on WWW, MMM DD?	Alert	While pairing the sensor, the pump detects that the sensor is not new and may have been previously calibrated. Confirm that the BG reading used to calibrate the sensor is correct. If the BG reading is incorrect, entering a new BG value will not fix the sensor.	• If the BG reading is incorrect, select No. A Safety Alert alert appears. Discard the sensor and insert a new sensor. Note: If not sure, select No and check the pump history or BG log to confirm that the BG reading is correct. • If the BG reading is correct, select Yes.
Safety Alert If you are not sure or did not enter BG X mmol/L at XX:XX on WWW, MMM DD, this sensor is NOT SAFE to use. The sensor will not be accurate, and entering a new BG will not fix the sensor. Did you enter BG	Alert	No was selected from the first Safety Alert alert, indicating that the BG reading was not used to calibrate the sensor.	• If the BG reading is incorrect, select No. A Change sensor alert appears. Discard the sensor and insert a new sensor. Note: If not sure, select No and check the pump history or BG log to confirm that the BG reading is correct. • If the BG reading is correct, select Yes.

Title and text	Type	Explanation	Next steps
X mmol/L at XX:XX on WWW, MMM DD?			
Sensor expired Insert new sensor.	Alert	The sensor has reached the end of its useful life.	- Select OK to clear the alert. - Change the sensor. For details, see <i>Inserting the sensor</i>, page 174.
Sensor signal not found See User Guide.	Alert	After multiple attempts, the pump failed to detect the sensor and is unable to receive sensor signal.	- Select OK to clear the alert. - If the pump still cannot find the sensor signal, contact a local Medtronic support representative for assistance.
Sensor updating Updating can take X. Monitor BG. Entered BGs will not calibrate the sensor, but can still be used for therapy.	Alert	The SG reading is unavailable due to a temporary situation.	- Select OK to clear the alert. - Follow the instructions on the pump screen. The sensor does not need to be changed.
Suspend before low Delivery stopped. Sensor glucose approaching Low Limit. Check BG.	Alert	The SG reading is falling. Insulin delivery is suspended according to the Suspend before low setting and the SG is approaching the specified low limit. The Suspend before low feature is not available with the SmartGuard feature.	- Select OK to clear the alert. - Check BG. If necessary, treat BG as directed by a health-care professional.

Title and text	Type	Explanation	Next steps
Suspend on low Delivery stopped. Sensor glucose X.X mmol/L. Check BG.	Alarm	The SG reading is at or below the specified low limit. The Suspend on low feature is not available with the SmartGuard feature.	• Select OK to clear the alarm. • Check BG. If necessary, treat BG as directed by a health-care professional.
Very high Basal setting Basal X will deliver YY.YY U per day when active in Manual mode. This basal pattern may not be safe because it delivers significantly more insulin than you typically need. Consult health-care professional before changing this value.	Message	When selecting, adding, or editing a basal pattern and the system calculates the pattern would deliver significantly more insulin than typically needed.	• Select Edit or, if selecting a basal pattern, click Back to change the basal pattern. • Select Continue to save or select the basal pattern.
Warm up not started Warm up not started after new sensor was paired. If sensor is not inserted, insert it now. If it is more than 30 minutes since insertion, change sensor.	Alert	This alert occurs when the sensor is unable to detect interstitial fluid to begin warm-up.	• Select OK to clear the alert. • If the sensor is not inserted, insert the sensor. • If the sensor is inserted, change the sensor. For details, see <i>Inserting the sensor</i>, page 174.

SmartGuard feature alerts and messages

The following table lists the most common or serious alerts and messages related to the SmartGuard feature. 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
Enter BG now SmartGuard has been at maximum delivery rate for 7 hours. Enter BG to continue in SmartGuard.	Alert	SmartGuard has been delivering at the maximum SmartGuard basal delivery rate for seven hours. This rate is determined automatically by the system.	• Select OK to clear the alert. • Enter a BG meter reading to return to Auto Basal. • Follow instructions from a healthcare professional and continue to monitor BG.
Enter BG now SmartGuard has been at maximum delivery rate for 7 hours. Enter BG to continue in SmartGuard. This event occurred while pump was suspended, and action is required to resume delivery.	Alert	The pump is suspended and the SmartGuard feature has been unable to lower the SG reading. SG is predicted to remain above the SmartGuard target.	• Select OK to clear the alert. • Enter a BG meter reading. • Follow instructions from a healthcare professional and continue to monitor BG.
Notes: • The title of the alert appears the same as the previous SmartGuard max delivery alert in the table. • If the pump is suspended, there will be no delivery. However, the alert may still occur.			

Title and text	Type	Explanation	Next steps
Enter BG now SmartGuard has reached the time limit for minimum delivery rate. Enter BG to continue in SmartGuard.	Alert	The SmartGuard feature has reached the time limit for minimum delivery. The minimum delivery time is three to six hours, depending on the reason for the minimum delivery rate.	• Select OK to clear the alert. • Enter a BG meter reading to return to Auto Basal. • Follow instructions from a healthcare professional and continue to monitor BG.
Enter BG now SmartGuard has reached the time limit for minimum delivery rate. Enter BG to continue in SmartGuard. This event occurred while pump was suspended, and action is required to resume delivery.	Alert	SmartGuard has reached the time limit for minimum delivery. The minimum delivery time is three to six hours, depending on the reason for the minimum delivery rate.	• Select OK to clear the alert. • Enter a BG meter reading. • Follow instructions from a healthcare professional and continue to monitor BG.
Notes: • The title of the alert appears the same as the previous SmartGuard min delivery alert in the table. • If the pump is suspended, there will be no delivery. However, the alert may still occur.			
Enter BG now Enter BG to continue in SmartGuard.	Alert	The SmartGuard feature requires a BG reading to check the reliability of the sensor.	• Select OK to clear the alert. • Enter a BG meter reading to return to Auto Basal, or to enter the SmartGuard feature from Manual mode.

Title and text	Type	Explanation	Next steps
Enter BG now Glucose values may be lower than current SG. Enter BG to continue in SmartGuard.	Alert	The SmartGuard feature requires a BG reading to check the reliability of the sensor.	- Select OK to clear the alert. - Enter a BG meter reading to return to Auto Basal, or to enter the SmartGuard feature from Manual mode.
High BG XX.X mmol/L Check infusion set. Check ketones. Monitor BG. Confirm BG?	Alert	The BG meter reading is above 13.9 mmol/L. This alert applies only to the SmartGuard feature. There is a similar alert for Manual mode when the SmartGuard feature is off. See <i>SmartGuard</i> , page 189.	- Select No to prevent the remote BG from being used by the pump. - Select Yes to confirm the BG reading.
SmartGuard exit Basal X started. Would you like to review the SmartGuard Checklist?	Alert	The pump has exited the SmartGuard feature because: - the sensor has been turned off - the pump has been delivering basal insulin based on insulin delivery history, and not SG readings for the maxi-	- Select No to clear the alert. Select Yes to view the SmartGuard Checklist. - Enter a BG meter reading. - Follow instructions from a healthcare professional and continue to monitor BG. For details, see <i>Exiting the SmartGuard feature</i>, page 211 and <i>Returning to the SmartGuard feature after an exit</i>, page 211.

Title and text	Type	Explanation	Next steps
		mum of four hours. This alert cannot be silenced, and is always active whenever the system is using the SmartGuard feature.	
SmartGuard exit Insulin delivery is still suspended.	Alert	The pump has exited the SmartGuard feature because: - the sensor has been turned off - a suspend event message has not been cleared within four hours - the pump has been delivering basal insulin based on insulin delivery history, and not SG readings for the maximum of four hours. This alert cannot be silenced, and is always active whenever the sys-	- Enter a BG meter reading. - Manually resume basal insulin delivery, when appropriate. - Follow instructions from a healthcare professional and continue to monitor BG. For details, see <i>Exiting the SmartGuard feature</i>, page 211 and <i>Returning to the SmartGuard feature after an exit</i>, page 211.

Title and text	Type	Explanation	Next steps
		tem is using the SmartGuard feature.	
SmartGuard exit Manual mode Basal X started. Check basal setting. Monitor glucose.	Alert	The pump has exited the SmartGuard feature and the system has detected a basal pattern that delivers significantly more insulin than you typically need.	• Select OK to clear the alert. • Check the active basal pattern.
SmartGuard started Current action canceled.	Alert	An operation that is not allowed while transitioning to the SmartGuard feature has been selected.	• Select OK to clear the alert. • Allow the pump to complete its transition to the SmartGuard feature.
Very high Basal setting SmartGuard is no longer active. Manual mode Basal X started and will deliver YY.YY U per day. Basal X may not be safe because it delivers significantly more insulin than you typically need. Consult healthcare professional for basal setting. Monitor glucose.	Alert	The SmartGuard feature has exited and the system has detected that the current basal pattern would deliver significantly more insulin than you typically need.	• Select OK to clear the alert. • Check all basal patterns and consult with your healthcare professional.

Title and text	Type	Explanation	Next steps
Very high Basal setting Basal X will deliver YY.YY U per day when active in Manual mode. Basal X may not be safe because it delivers significantly more insulin than you typically need. Consult health-care professional for basal settings.	Alert	The system has determined that if SmartGuard exists, the active basal pattern will deliver significantly more insulin than you typically need.	• Select Snooze to postpone receiving this message for a set period of time. • Select OK to clear the alert. • Check all basal patterns and consult with your healthcare professional.
Very high Basal setting Basal X is active and delivers YY.YY U per day. Basal X may not be safe because it delivers significantly more insulin than you typically need. Consult health-care professional for basal settings. Monitor glucose.	Alert	The pump has detected the current Manual mode basal pattern that delivers significantly more insulin than you typically need.	• Select Snooze to postpone receiving this message for a set period of time. • Select OK to clear the alert. • Check all basal patterns and consult with your healthcare professional.

CareLink software alert and message

The following table lists the most common or serious alerts and messages related to CareLink software. The table also explains the meaning, consequences, and the reasons why these notifications appear, and provides steps for problem resolution. If an alarm, alert, or message occurs that is not

listed, select **OK** to clear the notification and contact a local Medtronic support representative.

Title and text	Type	Explanation	Next steps
CareLink uploader not found. Follow instructions on the CareLink uploader.	Message	The pump cannot find the CareLink uploader because the wrong pump code was entered, or the search timed out before the pump found the uploader.	• Select OK to clear the message. • Follow the instructions on the CareLink uploader. For details, see <i>Uploading device data to CareLink software</i>, page 147.
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 a local Medtronic support representative for assistance.

Appendix B: Product specifications

Appendix B: Product specifications

This appendix provides detailed product specifications.

Specifications and default settings

Alarm and alert escalation

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

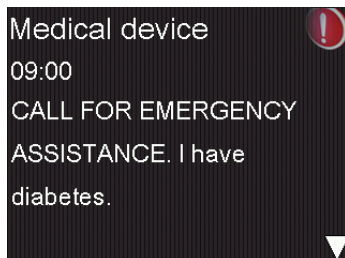
- Alert before high
- Alert before low
- Alert on high
- Alert on low
- Basal delivery resumed
- Calibration not accepted
- Change sensor
- Enter BG now
- Lost sensor signal
- No calibration occurred
- Possible signal interference
- High SG
- Rise Alert
- Sensor expired
- Sensor signal not found
- Low SG X.X mmol/L (X.X is a value below 3.0 mmol/L)
- Sensor updating
- Warm up not started
- Very high basal setting

The MiniMed 780G insulin pump may generate a siren if the alert is not cleared within ten minutes. Before ten minutes, the pump beeps, vibrates, or both, depending on the sound and vibration settings.

Minutes	Sound	Vibration	Sound and vibration
0-5	Beep	Vibrate	Beep and vibrate
6-9	Beep and vibrate	Sound and vibrate	Beep and vibrate
10	Siren and vibrate	Siren and vibrate	Siren and vibrate



Note: The Medical device alarm plays a siren when this screen appears.



Altitude range

- Operating range: 70.33 kPa (10.2 psiA) to 106.18 kPa (15.4 psiA)
- Storage range: 49.64 kPa (7.2 psiA) to 106.18 kPa (15.4 psiA)

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

The basal delivery specifications do not affect the amount of insulin delivered by SmartGuard. These specifications relate to Manual mode only.

Delivery rate range	0 to 35 units per hour or the Max Basal Rate amount, whichever is lower. The default range is 0 to 10 U/hr.
Max Basal Rate default	2 units per hour

Basal patterns	Maximum of 8 patterns for Manual mode. 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 meter reading

The BG meter reading refers to the most recent blood glucose (BG) meter reading received from the blood glucose meter after it is accepted by the pump user. When an Accu-Chek Guide Link meter is used, the reading appears on the Home screen when the Sensor feature is off. The reading also appears in the Bolus Wizard and SmartGuard Bolus screens when a bolus is programmed.

Expiration	12 minutes
Range	1.1 to 33.3 mmol/L

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 in Manual mode default settings



Note: When using the SmartGuard feature, the Bolus Wizard feature is called the Bolus feature.

Item	Default	Limits	Maximum available segments	Increments
Carb units	grams	-	8	-
Insulin to carb ratio	None	1-200 g/U	8	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	0.3-22.2 mmol /L	8	0.1 mmol/L
BG Target*	None	3.3-13.9 mmol /L	8	0.1 mmol/L
Active Insulin Time	4 hours	2 to 8 hours	1	15 minutes

*Applies to Manual mode only.

Bolus Wizard feature in Manual mode specifications

The Bolus Wizard feature uses four formulas to estimate a bolus, depending on the current BG reading. The following formulas apply only when the carb units are in grams.

1. If the current BG reading is higher than the High BG Target, the Bolus Wizard feature subtracts active insulin from the BG correction estimate, then adds this value to the food estimate to get the total bolus estimate. However, if the result of subtracting the active insulin amount from the BG correction estimate is a negative number (less than zero), the total bolus estimate is based only on the food estimate.

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

where: A = food (grams)
 B = carb ratio
 C = current BG
 D = High BG Target
 E = insulin sensitivity

Food estimate:

Carb grams ÷ Carb ratio = Units of insulin

Correction estimate:

(Current BG - High BG Target) ÷ Insulin sensitivity - Active insulin = Units of insulin

Total bolus estimate:

Food estimate + Correction estimate = Units of insulin

2. If the current BG is less than the Low BG Target, the Bolus Wizard feature adds the BG correction estimate to the food estimate to get the total bolus estimate.

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

where: A = food (grams)
 B = carb ratio
 C = current BG
 D = Low BG Target
 E = insulin sensitivity

Food estimate:

Carb grams ÷ Carb ratio = Units of insulin

Correction estimate:

(Current BG - Low BG Target) ÷ Insulin sensitivity = Units of insulin

Total bolus estimate:

Food estimate + Correction estimate = Units of insulin

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

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

Food estimate:

Carb grams ÷ Carb ratio = Units of insulin



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

Total bolus estimate = Food estimate

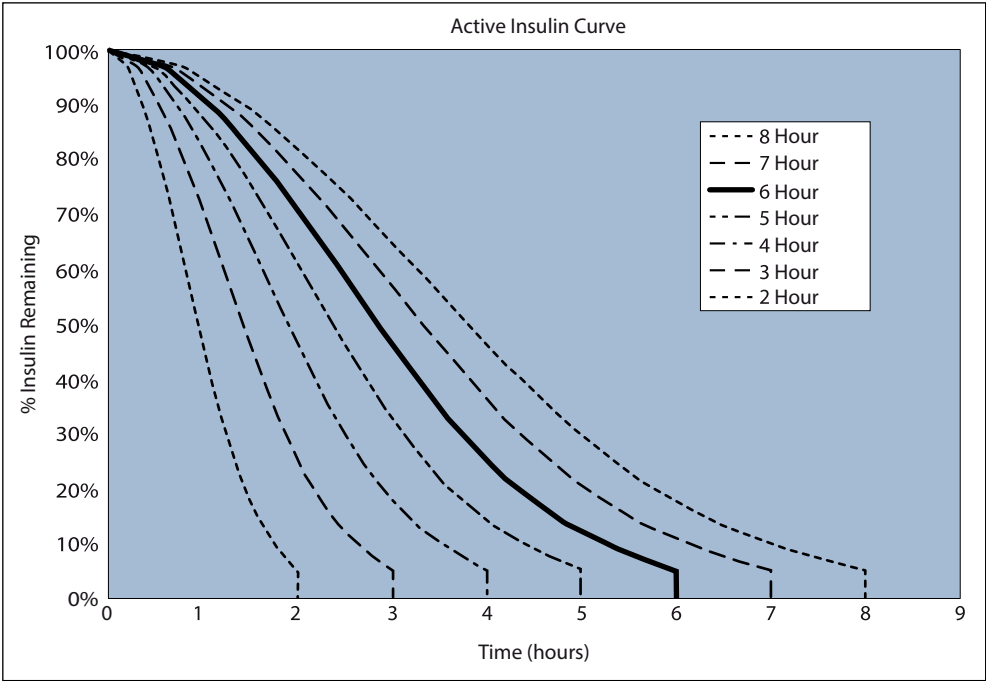
4. If no BG reading is entered, the total bolus estimate is based only on the food estimate.

The following list includes additional conditions to consider when using the Bolus Wizard feature in Manual mode.

- If a Dual Wave bolus amount is less than the estimate due to the Max bolus limit or a change that is made, the Square portion of the bolus is reduced first.
- Active insulin is the bolus insulin that has been delivered by the pump and is still working to lower glucose levels. In the Bolus Wizard and SmartGuard Bolus feature, the Active Insulin Time setting is used to calculate a correction bolus by subtracting the estimated active insulin from each bolus. This is shown as Active Insulin, or Act. Insulin, on the

Home screen, Bolus screen, Manual Bolus screen, Preset Bolus screen, and Daily History screen. This prevents over-infusion of insulin and reduces the risk of hypoglycemia.

- The Bolus Wizard feature may use the current BG reading, carb units, and active insulin to calculate the estimated bolus.
- The Active Insulin Curve graph shows how the Active Insulin Time setting affects the active insulin amount that is subtracted from correction boluses over time. The percentage of insulin remaining changes at varying rates depending on the Active Insulin Time setting.



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 g/U

Easy bolus feature

Use the Easy bolus feature to set up and deliver a normal bolus when the pump is in Sleep mode. This is done using  and with the help of sound and vibration cues.

Sound 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 780G system is designed to withstand most conditions encountered in daily life. For more details about environmental conditions, such as exposure to magnetic fields and radiation, waterproof capabilities, and extreme temperatures, see *User safety*, page 30.

- Pump storage and transport temperature range without a AA battery is from -20 °C (-4 °F) to 50 °C (122 °F).
- Pump operating temperature range is from 5 °C (41 °F) to 37 °C (98.6 °F).
- Operating air pressure range is from 700 hPa (10.2 psi) to 1060 hPa (15.4 psi).
- Storage and transport air pressure range is from 496.4 hPa (7.2 psi) to 1060 hPa (15.4 psi).
- Relative humidity (RH) range during operation is from 20% to 90%.
- RH range during storage and transport is from 5% to 95%.

Essential performance

The pump will maintain the following functionalities to avoid under-infusion and over-infusion:

- Delivery accuracy
- Occlusion detection
- Empty reservoir detection
- Detection of power loss
- Pump therapy status-UI component: LCD
- Notification annunciation and display-UI components: piezo-electric speaker, LCD-applies to all features above

Expected service life

The overall expected service life for the MiniMed 780G insulin pump is four years when used in accordance with this guide.

If there are concerns that the insulin pump may be damaged, contact a local Medtronic support representative.

For additional information, see *Pump issues*, page 288.

For health-related questions or concerns, consult a healthcare professional.

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 indicating that the pump must be rewound.
- Insulin used to fill the infusion set is recorded in the Daily History. This insulin is NOT included in the Total Daily Delivery (TDD) totals on the Summary screen.

Simplera Sync sensor performance characteristics

For information about Simplera Sync sensor performance characteristics, see the sensor user guide.

Insulin delivery default settings

Bolus settings

Item	Default setting	Limits	Increments
Bolus Wizard feature:	Off	-	-
Easy bolus feature:	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	0:30 to 5:00	0:30

Basal settings for Manual mode

Item	Default setting	Limits	Increments
Max Basal Rate	2 U/hr	0–35 U/hr Default limit 10 U/hr	0.025 U for 0.025–0.975 U/hr 0.05 U for 1.00–9.95 U/hr 0.1 U for rates of 10.0 U/hr or more
Basal Rate	0.000 U/hr	0.000 U/hr to Max Basal Rate	0.025 U for 0.025–0.975 U/hr 0.05 U for 1.00–9.95 U/hr 0.1 U for rates of 10.0 U/hr 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/hr 0.05 U for 1.00–9.95 U/hr 0.1 U for rates of 10.0 U/hr or more

Low Reservoir reminder

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

Alert range	Increment	Default value
The first reminder occurs at 5 to 50 units. The second reminder occurs at half of the remaining specified amount. The second reminder is automatic and cannot be changed.	1 unit	20 units

Max bolus

The bolus delivery specifications do not affect the amount of insulin delivered by SmartGuard. These specifications relate to Manual mode only.

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.

Percent temp basal

The default value is 100 percent of basal programming. For example, if six units of basal insulin are delivered per day, the default temp basal amount will be six units per day.

Range	0 to 200%
Default	100% of basal programming
Increment	5%

Program safety checks

A single fault condition causes 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 4.0 length x 2.3 width x 1.1 depth.

The pump dimensions in centimeters are no greater than 10.2 length x 5.8 width x 2.8 depth.

Pump memory

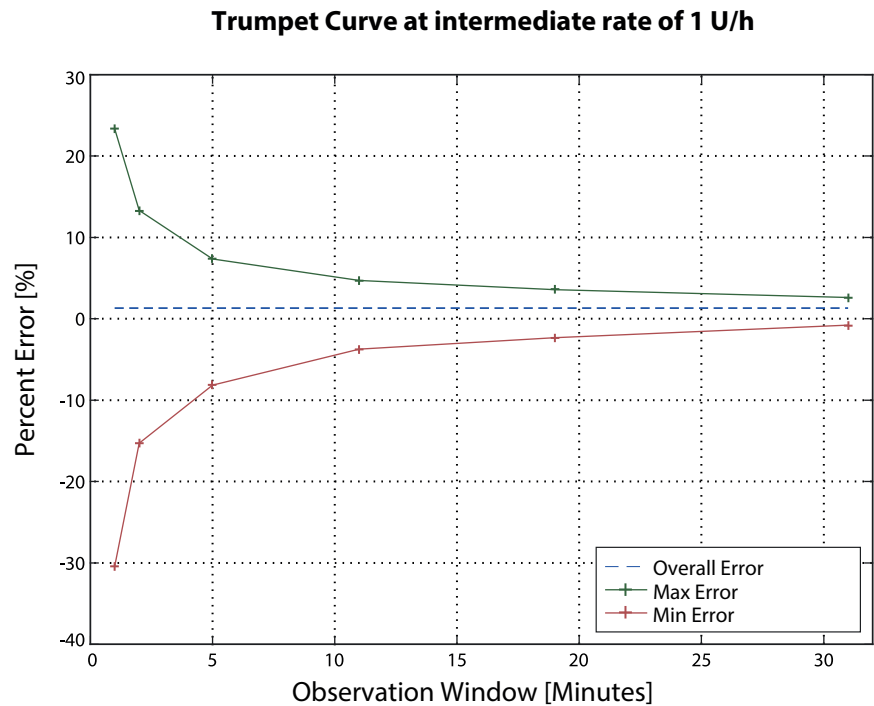
User settings and pump history are stored in pump memory. The pump keeps at least 35 days of history.

Pump performance characteristics

Delivery accuracy

- For a basal rate of 1.0 U/hr, the delivery accuracy is $\pm 5\%$.
For a basal rate of 0.025 U/hr, the delivery accuracy is $\pm 10\%$.
Delivery accuracy for bolus volumes < 0.1 unit is $\pm 20\%$ and delivery accuracy for bolus volumes ≥ 0.1 unit is $\pm 5\%$.
- All normal boluses are delivered within 16 minutes, 41 seconds ± 3 seconds at Standard rate (25 units, at 1.5 units per minute), and within 1 minute, 41 seconds ± 3 seconds at Quick rate (25 units, at 15 units per minute).
- During delivery, the maximum infusion pressure generated and the occlusion threshold pressure using a 3.0-mL reservoir does not exceed 90.67 kPa (13.15 psi). The average resulting bolus volume generated upon clearing the occlusion is 0.0112 mL (equivalent to 1.12 units of U-100 insulin).
- The following image 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.



Infusion pressure

The maximum infusion pressure and occlusion pressure during the fill tubing process are 172.4 kPa (25 psi).

Occlusion detection

When occlusion is detected, the Insulin flow blocked alarm occurs. The occlusion alarm is triggered by an average of 2.98 units of missed insulin (standard bolus) or 2.45 units of missed insulin (quick bolus). This table shows occlusion detection for four different situations when using U-100 insulin.

Rate	Minimum time before alarm	Average time before alarm	Maximum time before alarm
bolus delivery (10 units at standard speed)	77 seconds	124 seconds	173 seconds
bolus delivery (10 units at quick speed)	10 seconds	13 seconds	20 seconds
basal delivery (1.0 U/hr)	2 hours 27 minutes	3 hours 21 minutes	4 hours 21 minutes
basal delivery (0.025 U/hr)	131 hours 5 minutes	181 hours 16 minutes	211 hours 30 minutes



Note: Certain factors, such as ambient temperature changes or the presence of air in the infusion set or the reservoir, can delay an occlusion alarm.

Sound frequency

The following table lists audible tones that the pump emits, 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 SG	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
Suspend message tone	2100 Hz, followed by 1800 Hz and 2100 Hz
Reminder tone	934 Hz
Fill tubing tone	1850 Hz

Tone name	Frequency
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

Pump weight

The mass of the insulin pump without battery and consumables is less than 117 grams.

Sensor default settings

High sensor settings			
Item	Default setting	Limits	Increments
High SG alert limit	13.8 mmol/L	5.6 to 22.2 mmol/L	0.2 mmol/L
High SG fixed alert	On (cannot be turned off)	13.9 mmol/L for 3 hours	-
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 (0.056 mmol/L/min) 2 up arrows (0.111 mmol/L/min)	

High sensor settings			
Item	Default setting	Limits	Increments
		3 up arrows (0.167 mmol/L/min) - Custom limit (0.050 to 0.275 mmol/L/min)	
High Snooze	1 hour	5 minutes to 3 hours	5 minutes
Low sensor settings			
Item	Default setting	Limits	Increments
Low SG alert limit	3.4 mmol/L	2.8 to 5.0 mmol/L	0.2 mmol/L
Low SG alarm	On (cannot be turned off)	3.0 mmol/L	-
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	-	-
The SmartGuard feature settings			
Item	Default setting	Limits	Increments
SmartGuard	Off	-	-
Target	5.5 mmol/L	5.5 to 6.7 mmol/L	0.6 mmol/L
Auto Correction	On	6.7 mmol/L	-
Temp Target	Off	8.3 mmol/L	-

The SmartGuard feature settings			
Item	Default set- ting	Limits	Increments
Temp Target Du- ration	2 hours	30 minutes to 24 hours	30 minutes

IEC 60601-1-2

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 that are not paired with the MiniMed 780G system, Wi-Fi networks, Bluetooth®* wireless technology, 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 RF interference from a mobile or stationary RF transmitter is encountered, move away from the RF transmitter that is causing the interference.

IEC 60601-1-2

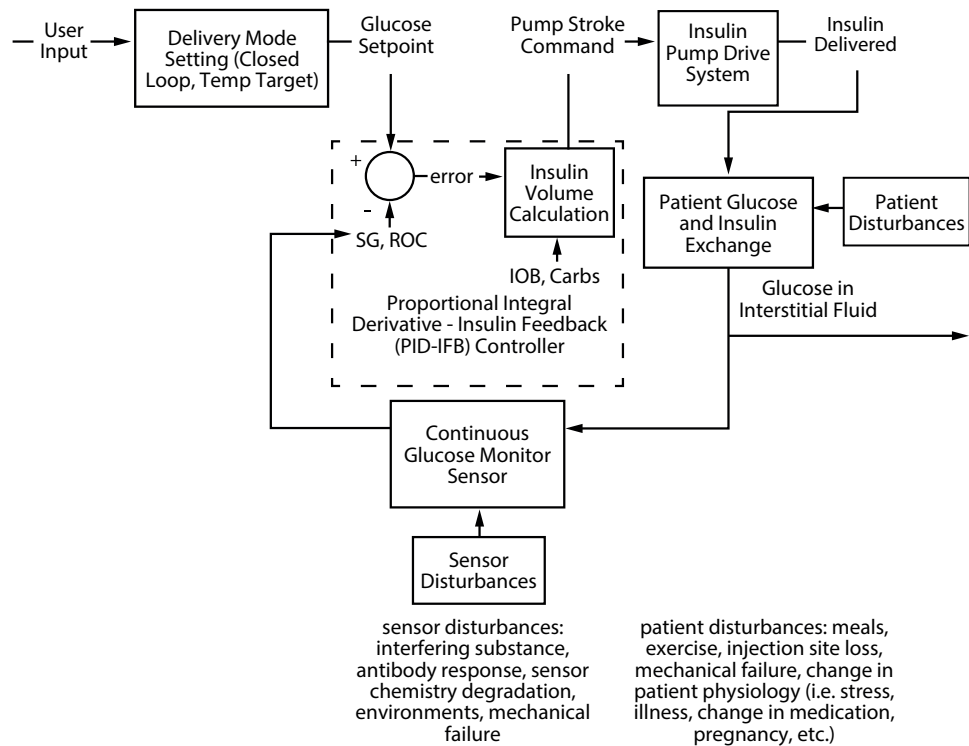
The MiniMed 780G system should not be used adjacent to other electrical equipment. If adjacent use becomes necessary, the MiniMed 780G system should be observed to confirm normal system operation.

IEC 60601-1-10: PCLCS

The MiniMed 780G is a Physiological Closed-Loop Controlled system (PCLCS).

Auto Mode manages basal delivery using a closed loop control algorithm based on a Proportional Integral Derivative controller with insulin feedback

(PID-IFB). The PID-IFB monitors the Rate Of Change (ROC) of sensor glucose (SG) and calculates the insulin volume using the Insulin On Board (IOB) and the reported Carbs. The closed loop controller uses continual feedback of SG values to calculate the insulin delivery rate for basal insulin control. The control algorithm is part of the pump application code. SG values are received by the pump via RF from the CGM sensor. This theory of operation is described in the following block diagram.



Guidance and manufacturer's declaration

Guidance and Manufacturer's Declaration - Electromagnetic Emissions
The MiniMed 780G insulin pump is intended for use in the electromagnetic environment specified below. Make sure that the MiniMed 780G insulin pump is used in such an environment.

Guidance and Manufacturer's Declaration - Electromagnetic Emissions		
Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions Test: 47 CFR Part 15, Subpart C Section 15.247/FCC Part 15 Subpart B Section 15.109	• 6 dB and 99% Bandwidths: Complies • Maximum Output Power: Complies • TX Spurious Emissions: Complies • Power Spectral Density: Complies • Radiated Emissions at Band Edge: Complies	The MiniMed 780G insulin pump must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not applicable	
RF emissions CISPR 11	Complies Group 1 Class B	The MiniMed 780G insulin pump is suitable for use in aircraft and in all establishments, including domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
RTCA DO 160G Radio Frequency Susceptibility (Radiated and Conducted) and Emission of Radio Frequency Energy	Complies	

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The MiniMed 780G insulin pump is intended for use in the electromagnetic environment specified below. Make sure that the MiniMed 780G insulin pump is used in such an environment.			
Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment - Guidance

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2, 4, 8, 15 kV air	±8 kV contact ±2, 4, 8, 15 kV air	For use in a typical domestic, commercial, or hospital environment.
Conducted disturbances induced by RF fields IEC 61000-4-6	3 V _{RMS} 150 kHz to 80 MHz 6 V _{RMS} ISM bands between 150 kHz to 80 MHz	Not applicable	Requirement does not apply to this battery powered device.
Electrical fast transient/burst IEC 61000-4-4	±2 kV 100 kHz repetition frequency	Not applicable	Requirement does not apply to this battery powered device.
Surge IEC 61000-4-5	Line to Line: ±0.5 kV, ±1 kV Line to Ground: ±0.5 kV, ±1 kV, ±2 kV	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	0% U _T ; 0.5 cycle (at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315°) 0% U _T ; 1 cycle (at 0°) 70% for 25/30 cycles (at 0°) 0% for 250/300 cycles	Not applicable	Requirement does not apply to this battery powered device.
Power frequency (50/60 Hz) electromagnetic field IEC 61000-4-8	30 A/m (continuous field at 60 seconds)	30 A/m 400 A/m per IEC 60601-2-24	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
Proximity fields from RF wireless communications equipment IEC 61000-4-39	IEC 60601-1-2	IEC 60601-1-2	For use in a typical domestic, 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 780G insulin pump is intended for use in the electromagnetic environment specified below. The customer or user of the MiniMed 780G insulin pump should assure that it is used in such an electromagnetic environment.			
Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment Guidance
Radiated RF IEC 61000-4-3 EN 301 489-17	10 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz	10 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz	Portable and mobile RF communications equipment should be used no closer to any part of the MiniMed 780G insulin pump, including cables, than the recommended separation distance of 30 cm (12 in). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 

Wireless communication

The MiniMed 780G insulin pump communicates using smart device connectivity.

Operating frequency/Modulation type(s)	2.4 GHz band, GFSK
Effective radiated power (ERP)	1.48 mW (1.69 dBm)
Effective isotropic radiated power (EIRP)	2.42 mW (3.83 dBm)

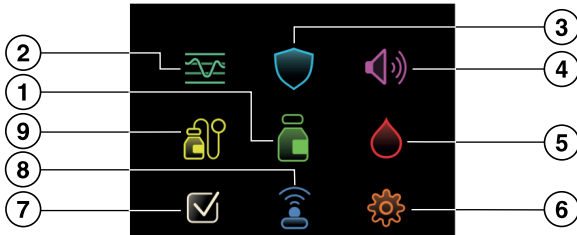
Appendix C: Menu map

Appendix C: Menu map

Menu map

The following diagrams provide a map to the screens and features that are available from the Menu screen.

1 Insulin Bolus/Stop Bolus* • Bolus Wizard* • Manual Bolus • Preset Bolus* • Delivery Settings ➔ Basal/Cancel Temp Basal* • Temp Basal • Preset Temp* • Basal Patterns • Basal Pattern Setup ➔ Suspend All Delivery/Re-suspend Basal* Delivery Settings ➔	2 History & Graph History • Summary • Daily History • Alarm History • Paired Sensors Sensor Glucose Review • High Limit • Low Limit • Days to Average Graph Time in Range	3 SmartGuard SmartGuard Checklist Temp Target/Cancel Temp Target* SmartGuard Settings • Target • Auto Correction SmartGuard (On and Off) 4 Sound & Vibration Silence Sensor Alerts Volume Sound Vibration Alert Settings ➔ 5 Blood Glucose BG
* indicates an item that is shown when applicable. For example, Stop Bolus is shown when a bolus is being delivered. Preset Bolus is shown when the Preset Bolus feature is set up. The ➔ icon indicates a shortcut to the screen.		

		
6  Settings Alert Settings - High Alert - Low Alert - Snooze High & Low - Reminders Delivery Settings - Bolus Wizard Setup - Basal Pattern Setup - Max Basal/Bolus - Dual/Square Wave - Bolus Increment - Bolus Speed - Preset Bolus Setup - Preset Temp Setup	6  Settings continued Device Settings - Sensor (On and Off) - Time & Date - Device Info - Display - Block Mode - Self Test - Review Settings - Manage Settings - Easy Bolus - Auto Suspend - Language	7  Status Stop Bolus* Suspend All Delivery/Resume Basal* SmartGuard Checklist Pump Sensor 8  Paired Devices Pair New Device Pair CareLink Mobile Meter CGM 9  Reservoir & Set New Reservoir & Set New Reservoir Only New Set Only Fill Cannula
* indicates an item that is shown when applicable. For example, Resume Basal is shown when insulin delivery is suspended.		

Appendix D: Performance data

Appendix D: Performance data

MiniMed 780G system device performance

The MiniMed 780G system adjusts insulin delivery based on sensor glucose (SG) readings from CGM, while alleviating the complexity of trying to maintain glucose levels around meals. Clinical studies have shown that integrated insulin pump and CGM systems may provide better diabetes management, compared with multiple daily injections, or with a pump alone. Studies suggest that pump therapy, when regulated by sensor information, can improve HbA1C levels significantly without increasing the risk of hypoglycemia.^{1,2,3}

The MiniMed 780G system continues to use the SmartGuard feature, which is designed to keep patient blood sugar levels in range by automatically adjusting basal insulin dosage every five minutes, delivering more or less

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.

insulin when it predicts that SG values are trending too high or too low. The SmartGuard feature has been updated to adjust how auto correction boluses and daily user adaptations are calculated. The system continues to offer the following features:

1. **Adjustable glycemic target settings.** With the help of a healthcare provider, patients can program the device to one of three setpoints to target their ideal SG value (5.5, 6.1, or 6.7 mmol/L). The device uses the programmed setpoint as a reference to adjust the rate of insulin delivered, which helps maintain control according to patient needs.
2. **Automatic correction boluses.** Mealtimes can be stressful and require that patients calculate boluses prior to and after meals to avoid hyperglycemia. The SmartGuard feature also includes an Auto correction feature that can calculate and deliver correction boluses every five minutes if the patient underestimates the amount of carbs in a meal or if they accidentally forget to deliver a meal bolus prior to eating.

The MiniMed 780G system retains the Suspend on low and Suspend before low features that were introduced in prior Medtronic insulin pumps. These features temporarily stop insulin delivery when SG values reach a preset low target (Suspend on low) or are predicted to reach the preset low target within 15 or 30 minutes (Suspend before low). Insulin delivery also resumes when SG values return to a safe range. These optional features are available when the pump is in Manual mode and function as a backup for the SmartGuard feature.

The SmartGuard feature

Clinical study overview

Type 1 Diabetes Pivotal Clinical Study Overview

The SmartGuard feature with modifications (that controls insulin dosing in the MiniMed 780G system) was studied with subjects who wore the MiniMed 780G pump with the Simplera Sync sensor and the Extended infusion set and reservoir at home for 3 months.⁴ The study did not include a

control group. The study included subjects from different clinics around the US who were between 7 and 80 years old. Subjects had to have been diagnosed with type 1 diabetes mellitus for at least one year for subjects aged 7 to 13 years, and at least two years for subjects aged 14 to 80 years. All subjects in the study had to have used pump therapy for at least 6 months prior to screening and had an HbA1C value of less than 10.0% at the time of screening.

This study started with a run-in (baseline) period. During run-in, subjects with no prior automated insulin delivery (AID) pump experience were instructed to use the MiniMed 780G system with only the sensor augmented pump (SAP) function activated (i.e., SmartGuard feature turned OFF). Subjects with AID pump experience were instructed to use the MiniMed 780G system with the SmartGuard feature turned ON and the Auto correction feature turned OFF. The intent of the run-in period was to allow subjects to become familiar with the new study devices while using their own insulin.

After the run-in period, subjects were instructed to use the study devices with both the SmartGuard feature and the Auto correction feature turned ON during a study period comprising 3 stages. In the first two stages, subjects were instructed to use the study pump with the 6.7 mmol/L Auto basal target setpoint and active insulin time set to 4 hours (stage 1), then to change the pump settings to the 5.5 mmol/L setpoint and active insulin time set to 2–3 hours (stage 2). In stage 3, subjects were instructed to use the study pump with the Auto basal target setpoint and active insulin time set as considered best by the investigator for the individual subject.

A total of 250 subjects were enrolled, and 212 subjects completed the study.

SmartGuard Performance: HbA1C and Time in Target Range

Table 1 shows the mean HbA1C from Baseline to the end of the 3-month study period. This data helps explain how using the 780G SmartGuard

⁴ Medtronic Inc., Clinical Study Report: CIP337 Safety and Effectiveness Evaluation of the MiniMed 780G System Used in Combination with the DS5 CGM.

feature with the Auto correction feature enabled might affect a patient's HbA1C.

Table 1. Mean HbA1C from Baseline to End of 3-month Study Period

Category	Age 7-17 Years		Age 18-80 Years	
	Baseline	End of Study	Baseline	End of Study
HbA1C (%) Mean ± SD (Median) [N]	7.7 ± 1.0 (7.8) [112]	7.3 ± 0.8 (7.2) [111]	7.4 ± 0.9 (7.3) [110]	6.7 ± 0.5 (6.7) [106]

Table 2 reports the mean percentage of time spent in range (TIR, 3.9-10.0 mmol/L) in stage 3 of the study period.

Table 2. Mean Percentage of Time Spent in Range (3.9-10.0 mmol/L) in Study Period Stage 3

Subject Age	Number of Subjects	Mean	95% Confidence Interval
7-17 Years	109	71.4%	(69.5%, 73.3%)
18-80 Years	107	80.2%	(78.7%, 81.8%)

Safety

Table 3 lists the device-related adverse events reported at screening, and during the run-in and study periods. For subjects ages 7-17 years and 18-80 years, 59 device-related adverse events were reported. For subjects ages 7-17 years, there were no reports of device-related severe hypoglycemia, unanticipated serious or non-serious adverse device effects during the study. For adult subjects, there were no reports of unanticipated adverse device effects. Two severe hypoglycemia events and 1 diabetic ketoacidosis event were reported for adult subjects but none of these were device-related.

Table 3. Device-Related Adverse Events

Adverse Events	Age 7-17 Years (N = 125)			Age 18-80 Years (N = 125)		
	Screening peri- od	Run-in period	Study period	Screening peri- od	Run-in period	Study period
Bleeding at infusion site	0	0	1	0	0	0
Bleeding at sensor site	0	2	2	0	1	1
Discomfort/irritation with in- fusion set	0	2	1	0	6	5
Discomfort/irritation with sensor	0	3	2	0	1	1
Infusion site infection	0	4	15	0	0	0
Mild ketonemia	0	0	0	0	1	0
Rash/contact dermatitis (in- fusion set related)	0	0	1	0	2	2

Table 3. Device-Related Adverse Events (continued)

Adverse Events	Age 7-17 Years (N = 125)			Age 18-80 Years (N = 125)		
	Screening period	Run-in period	Study period	Screening period	Run-in period	Study period
Rash/contact dermatitis (sensor/tape related)	0	0	1	0	0	0
Severe hyperglycemia	0	1	3	0	0	1
Total	0	12	26	0	11	10

Table 4 lists the study-period related adverse events. A total of 83 adverse events during the study period were reported from all investigational sites for 7-17-year-old study subjects enrolled in the study. There were no serious adverse events, no reports of severe hypoglycemia, 8 reports of severe hyperglycemia, no reports of diabetic ketoacidosis, and there were no reports of unanticipated adverse device effects (UADEs).

A total of 50 adverse events during the study period were reported from all investigational sites for 18-80-year-old study subjects enrolled in the study. Out of 50 events, there were 3 serious adverse events, 2 reports of hypoglycemia and 1 report of a hyperglycemia event, there was 1 report of a diabetic ketoacidosis event, and no reports of unanticipated adverse device effects (UADEs).

Table 4. Study Period Related Adverse Events

Category	Age 7-17 Years (N = 112)	Age 18-80 Years (N = 110)
Total number of adverse events	83	50
Study Exit		
Led to study exit	0	1
Did not lead to study exit	83	49
Seriousness		
Serious adverse events (SAEs)	0	3
Death	0	0
Non-death	0	3

Table 4. Study Period Related Adverse Events (continued)

Category	Age 7-17 Years (N = 112)	Age 18-80 Years (N = 110)
Non-serious adverse events	83	47
Diagnosis		
Severe hypoglycemia	0	2
Severe hyperglycemia	8	1
Diabetic ketoacidosis (DKA)	0	1
None of the above	75	46
Study procedure and device relatedness		
Related to study procedure only	0	0
Related to study device only	26	10
Unanticipated adverse device effects (UADE) / Unanticipated serious adverse device effects (US-ADE)	0	0
Unanticipated non-serious adverse device effects	0	0
Anticipated adverse device effects (ADEs)	26	10
Related to both study procedure and study device	0	0
Unanticipated adverse device effects (UADE) / Unanticipated serious adverse device effects (US-ADE)	0	0
Unanticipated non-serious adverse device effects	0	0

Table 4. Study Period Related Adverse Events (continued)

Category	Age 7-17 Years (N = 112)	Age 18-80 Years (N = 110)
Anticipated adverse device effects (ADEs)	0	0
Not related to study procedure or study device	57	40

SmartGuard Use

During the study period, subjects had access to the study device and were instructed to use SmartGuard with Auto correction ON. *Table 5* presents the percentage of time that subjects spent using the sensor and the percentage of time spent using the SmartGuard (Auto mode) feature with the Auto correction feature turned ON during study period stage 3. This information shows that the SmartGuard feature was ON greater than 92% of the time during study period stage 3.

Table 5. Sensor and SmartGuard Usage (Percentage of Time) During Study Period, Stage 3

Category	Age 7-17 Years (N = 109)	Age 18-80 Years (N = 107)
Time spent using sensor	92.9%	95.8%
Time spent not using sensor	7.1%	4.2%
Time spent in SmartGuard	93.5%	96.6%
Time spent in Manual mode	6.5%	3.4%

SmartGuard Performance

Table 6 shows the mean percentage of SG values in specific glucose ranges during the run-in period and during stage 3 of the study period by all subjects using the 780G system with the Simpler Sync sensor. An international group of diabetes experts and the American Diabetes Association (ADA) consider patients in good control when patients are in the target glucose range of 3.9-10.0 mmol/L for more than 70% of the day.⁵

⁵ Battelino T, Danne T, Bergenstal RM, et al. Clinical Targets for Continuous Glucose Monitoring Data Interpretation: Recommendations From the

The data in *Table 6* show that using the SmartGuard feature with the Auto correction feature kept SG values in range and reduced time above range. Specifically, adult subjects spent more time in range (3.9-10.0 mmol/L) and less time in hypoglycemia (<3.9 mmol/L) and hyperglycemia (>10.0 mmol/L) during stage 3 of the study period compared with the run-in period. Pediatric subjects spent more time in range (3.9-10.0 mmol/L) and less time in hyperglycemia (>10.0 mmol/L) without significantly increasing time in hypoglycemia (<3.9 mmol/L) during stage 3 of the study period compared with the run-in period.

Table 6. Percentage of SG values in Different Ranges during the Run-in Period and Study Period Stage 3

Category	SG Range (mmol/L)	Age 7-17 Years		Age 18-80 Years	
		Run-in Period (N = 112)	Study Period Stage 3 (N = 109)	Run-in Period (N = 110)	Study Period Stage 3 (N = 107)
Low SG Value	<3.0	0.3 ± 0.6 (0.2, 0.4)	0.4 ± 0.3 (0.3, 0.4)	0.3 ± 0.5 (0.2, 0.4)	0.2 ± 0.4 (0.1, 0.3)
	<3.9	1.6 ± 1.7 (1.3, 1.9)	1.9 ± 1.4 (1.7, 2.2)	1.7 ± 1.9 (1.4, 2.1)	1.5 ± 1.4 (1.3, 1.8)
Target SG Value	3.9 - 7.8	32.1 ± 14.1 (29.5, 34.7)	49.2 ± 9.7 (47.4, 51.0)	39.2 ± 13.0 (36.8, 41.7)	56.1 ± 10.5 (54.1, 58.1)
	3.9 - 10.0	54.4 ± 15.7 (51.5, 57.3)	71.4 ± 9.9 (69.5, 73.3)	66.5 ± 12.6 (64.1, 68.8)	80.2 ± 8.1 (78.7, 81.8)
High SG Value	> 7.8	66.3 ± 14.7 (63.5, 69.0)	48.9 ± 10.0 (47.0, 50.8)	59.1 ± 13.9 (56.4, 61.7)	42.4 ± 11.0 (40.3, 44.5)
	> 10.0	44.0 ± 16.1 (41.0, 47.0)	26.7 ± 10.1 (24.7, 28.6)	31.8 ± 13.1 (29.4, 34.3)	18.2 ± 8.4 (16.6, 19.9)
	> 13.9	16.4 ± 11.1 (14.3, 18.5)	8.0 ± 6.6 (6.8, 9.3)	7.4 ± 6.1 (6.2, 8.5)	3.4 ± 3.0 (2.8, 4.0)
	> 19.4	2.4 ± 3.5 (1.8, 3.1)	1.3 ± 2.2 (0.9, 1.8)	0.4 ± 0.7 (0.3, 0.5)	0.3 ± 0.5 (0.2, 0.4)
Note: Values are presented by Mean ± SD (95% CI) except Number of subjects.					

Table 7 shows the difference in mean sensor glucose from baseline to the end of the study period for all subjects using the 780G system with the Simplerla Sync sensor. The data shows that, compared to the run-in period, the subjects' mean glucose levels during stage 3 of the study period were closer to the center of the target range.

International Consensus on Time in Range. Diabetes Care. 2019 Aug; 42(8): 1593-1603. doi: 10.2337/ dci19-0028. Epub 2019 Jun 8.

Table 7. Difference in Mean Sensor Glucose Values (mmol/L) between the Run-in Period and Study Period Stage 3

Category	Age 7-17 Years			Age 18-80 Years		
	Run-in Period (N = 112)	Study Period Stage 3 (N = 109)	Difference between Run-in Period and Study Peri- od Stage 3 (N = 109)	Run-in Period (N = 110)	Study Period Stage 3 (N = 107)	Difference between Run-in Period and Study Peri- od Stage 3 (N = 107)
Mean Glucose Value	10.0 ± 1.5 (9.7, 10.3)	8.6 ± 1.0 (8.4, 8.8)	-1.5 ± 1.2 (-1.7, -1.2)	8.9 ± 1.0 (8.7, 9.1)	7.9 ± 0.7 (7.8, 8.0)	-1.0 ± 0.8 (-1.2, -0.9)
Note: Values are presented as Mean ± SD (95% CI) except Number of subjects.						

During the study period, some subjects wore the study pump with the SmartGuard feature and the Auto correction feature turned ON, and with the target setpoint set to either 5.5 mmol/L, 6.1 mmol/L, 6.7 mmol/L, or 8.3 mmol/L (Temp Target). *Table 8* shows the mean sensor glucose (SG) value for each target setpoint option when that setpoint was used for the entire day during the overall study period. The data in *Table 8* shows that using the SmartGuard feature with the Auto correction feature and the 5.5 mmol/L target setpoint resulted in a lower mean SG value than when the features were used with the 6.7 mmol/L target setpoint.

Table 8. Mean Sensor Glucose Values (mmol/L) during SmartGuard Use Stratified by Target Glucose Setpoint during the Study Period

Category	Age 7- 17 Years					Age 18-80 Years				
	Overall (N = 112)	Target Glucose (mmol/L)				Overall (N = 109)	Target Glucose (mmol/L)			
		5.5 (N = 109)	6.1 (N = 12)	6.7 (N = 111)	8.3 (N = 52)		5.5 (N = 107)	6.1 (N = 5)	6.7 (N = 108)	8.3 (N = 48)
Mean Glucose Values During SmartGuard	8.5 ± 0.8 (8.4, 8.7)	8.4 ± 0.8 (8.3, 8.6)	8.3 ± 0.9 (7.7, 8.9)	8.8 ± 0.8 (8.6, 8.9)	8.7 ± 2.5 (8.1, 9.4)	8.0 ± 0.7 (7.9, 8.1)	7.8 ± 0.7 (7.7, 8.0)	7.8 ± 0.6 (7.0, 8.5)	8.4 ± 0.7 (8.2, 8.5)	7.6 ± 1.6 (7.2, 8.1)
Note 1: Values are presented by Mean ± SD (95% CI).										
Note 2: Analysis of data was only performed when SmartGuard Glucose target was used the entire day (e.g., 5.5 mmol/L set point used for entire day versus 6.1 mmol/L set point used for entire day versus 6.7 mmol/L set point used for entire day). Any day with partial usage was excluded from this analysis.										
Note 3: For the 8.3 mmol/L set point (Temp Target), all the available periods of temp target were included in the analysis.										

Figure 1 below shows the percentage of subjects that had an HbA1C that was less than 7% during the run-in (baseline) and study periods. The ADA considers a HbA1C target of less than 7% appropriate for non-pregnant adults and many children.^{6,7} *Figure 1* shows that a greater percentage of

subjects had an HbA1C that was less than 7% at the end of the study than at baseline.

Figure 1. Percentage of Patients with less than 7% HbA1C

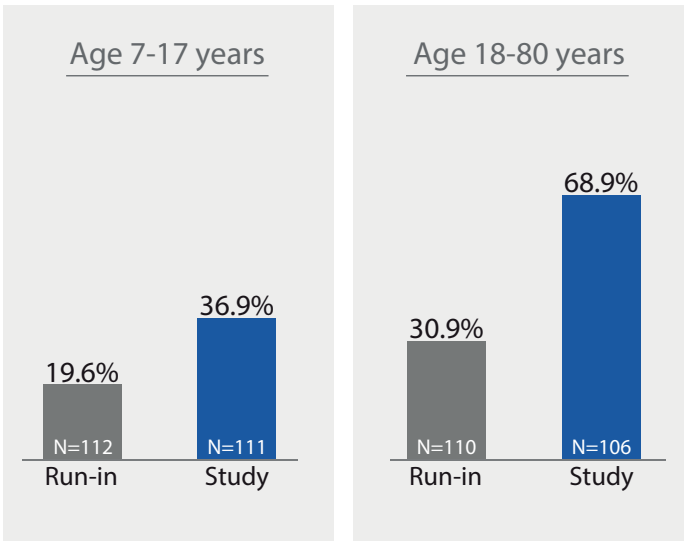


Table 9 shows the change in total daily dose of insulin (TDD) from the run-in period to study period stage 3, and the change in weight and BMI Z-score (for pediatrics) from baseline to the end of the study. Mean TDD increased for both pediatric and adult subjects. Mean weight increased slightly for pediatric subjects and remained unchanged for adult subjects. In the pediatric population, 33 subjects gained more than 2.5 kg (5.5 lbs) in weight over the 3-month study period, and of these, 13 subjects gained 5 kg (11 lbs) or more. This data helps explain how using the SmartGuard feature with the

⁶ American Diabetes Association Professional Practice Committee; 6. Glycemic Goals and Hypoglycemia: Standards of Care in Diabetes–2025. Diabetes Care 2025; 48 (Supplement_1): S128-S145.

⁷ American Diabetes Association Professional Practice Committee; 14. Children and Adolescents: Standards of Care in Diabetes–2025. Diabetes Care 2025; 48 (Supplement_1): S283-S305

Auto correction feature, childhood and pubertal growth, and elevated glucose levels may affect a patient's TDD and weight.

Table 9. Changes in Mean TDD and Weight

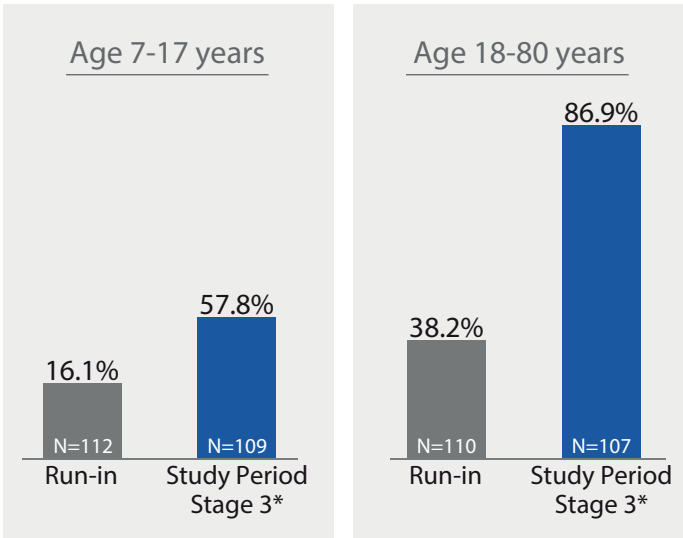
Category	Age 7-13 Years		Age 14-17 Years		Age 18-80 Years	
TDD (U), Mean $\pm$ SD (Median)	Run-in Period (N = 57)	Study Period Stage 3 (N = 55)	Run-in Period (N = 55)	Study Period Stage 3 (N = 54)	Run-in Period (N = 110)	Study Period Stage 3 (N = 107)
	43.2 $\pm$ 24.0 (35.7)	50.3 $\pm$ 29.7 (40.6)	64.3 $\pm$ 23.7 (59.0)	75.0 $\pm$ 29.3 (71.9)	54.7 $\pm$ 27.1 (50.9)	57.8 $\pm$ 28.0 (50.0)
Weight* (kg), Mean $\pm$ SD (Median)	Baseline (N = 57)	End of Study (N = 56)	Baseline (N = 55)	End of Study (N = 55)	Baseline (N = 110)	End of Study (N = 108)
	47.1 $\pm$ 17.9 (44.1)	49.0 $\pm$ 19.2 (45.8)	68.7 $\pm$ 14.0 (66.7)	70.3 $\pm$ 14.6 (68.9)	84.8 $\pm$ 19.5 (82.3)	84.8 $\pm$ 19.3 (82.0)
BMI Z-score*, Mean $\pm$ SD (Median)	Baseline (N = 57)	End of Study (N = 56)	Baseline (N = 55)	End of Study (N = 55)	–	–
	0.6 $\pm$ 1.0 (0.6)	0.7 $\pm$ 1.1 (0.7)	0.5 $\pm$ 1.0 (0.6)	0.6 $\pm$ 1.0 (0.8)	–	–

*Note: Weight and height were not collected in-clinic for some subjects.

Figure 2 below shows the percentage of subjects that spent more than 70% of time in range (3.9-10.0 mmol/L), which is considered good glucose control by diabetes experts and the ADA, during the run-in (baseline) and study period stage 3. The system offers three SG target setpoint options that allow users to customize insulin delivery. For the study period, percentages are shown for subjects that used the SmartGuard feature with the Auto correction feature.

In both pediatric and adult patients, the percentage of subjects who spent more than 70% of time in range when using the SmartGuard feature with the Auto correction feature increased in study period stage 3 from the run-in period. This data shows that most pediatric subjects and adult subjects using the SmartGuard feature with the Auto correction feature during study period stage 3 spent more than 70% time in range.

Figure 2. Percentage of Subjects who spent More than 70% of Time in Range (3.9-10.0 mmol/L)



*During this period, subjects were instructed to use the study device with the Auto basal target as well as Active insulin time (AIT) set to what is best for the individual subject, at the investigator’s discretion. Note that 38% (41/109) of pediatric patients and 41% (44/107) of adult patients used the study device with the Auto Basal target with setpoint 5.5 mmol/L and AIT set to 2 hours during study period stage 3.

Overall, the clinical study suggested that the 780G system was safe, and subjects showed improvements in HbA1C (compared to baseline) and time in the target range with use of the updated 780G pump and the Simplerla Sync sensor. However, the study had the following limitation:

It did not compare subjects who were using the SmartGuard feature and the Auto correction feature to those who were not on a system (control group). Instead, the study compared how subjects did before using the Auto correction feature (run in period -2 weeks) against results while using the Auto correction feature (study period -3 months).

Due to this limitation, the results of the study should be interpreted with caution and you should understand that your individual results may vary.

Clinical Study Overview, SmartGuard with Fiasp

The SmartGuard feature, without modifications, was studied in subjects with type 1 diabetes who used the ultra-rapid-acting insulin Fiasp (insulin aspart) with the MiniMed 780G pump, the Guardian 4 sensor and the Extended infusion set and reservoir at home for 3 months.⁸ The study did not include a control group. The study included subjects from different clinics around the United States, Canada and Australia who were between 7 and 80 years old. Subjects had to have been diagnosed with type 1 diabetes mellitus for at least one year for subjects aged 7 to 13 years, and at least two years for subjects aged 14 to 80 years. All subjects in the study had to have used pump therapy for at least 6 months prior to screening and had an HbA1C value of less than 10.0% at the time of screening.

This study started with a run-in (baseline) period. During run-in, subjects with no prior automated insulin delivery (AID) pump experience were instructed to use the MiniMed 780G system with only the sensor augmented pump (SAP) function activated (i.e., SmartGuard feature turned OFF). Subjects with Medtronic AID pump experience were instructed to use the MiniMed 780G system with the SmartGuard feature turned ON and the Auto correction feature turned OFF. The intent of the run-in period was to allow subjects to become familiar with the new study devices while using their own insulin, either Humalog (insulin lispro injection) or NovoLog/NovoRapid^{TM*} (insulin aspart solution for injection).

After the run-in period, subjects were instructed to use the study devices with Fiasp insulin and both the SmartGuard feature and the Auto correction feature turned ON during a study period comprising 3 stages. In the first two stages, subjects were instructed to use the study pump with the 6.7 mmol/L Auto basal target setpoint and active insulin time set to 4 hours, then adjusted towards 2-3 hours as considered best by the investigator for the individual subject (stage 1). Next, subjects were instructed to change the

⁸ Medtronic Inc., Clinical Study Report: Evaluation of the MiniMedTM 780G System in Type 1 Adult and Pediatric Subjects Utilizing Insulin Fiasp[®] (Insulin Aspart Injection).

pump settings to the 5.5 mmol/L setpoint and active insulin time set to 2-3 hours (stage 2). In stage 3, subjects were instructed to use the study pump with the Auto basal target setpoint and active insulin time set as considered best by the investigator for the individual subject. A total of 240 subjects were enrolled, and 215 subjects completed the study.

The updated MiniMed 780G pump is compatible with both the Guardian 4 Sensor and Guardian 4 Transmitter and the Simplerla Sync devices. The clinical study tested the MiniMed 780G pump without the modifications to the SmartGuard feature and the Guardian 4 sensor and transmitter.

SmartGuard Performance: HbA1C and Time in Target Range

Table 10 shows the mean HbA1C from baseline to the end of the 3-month study period. This data helps explain how using the 780G SmartGuard feature and the Auto correction feature enabled with Fiasp insulin might affect a patient’s HbA1C.

Table 10. Mean HbA1C from Baseline to End of 3-month Study Period

Category	Age 7-17 Years		Age 18-80 Years	
	Baseline	End of Study	Baseline	End of Study
HbA1C (%) Mean ± SD (Median) [N]	7.8 ± 0.9 (7.7) [107]	7.6 ± 0.8 (7.5) [104]	7.4 ± 0.8 (7.4) [116]	7.0 ± 0.7 (7.0) [114]

Table 11 reports the mean percentage of time spent in range (TIR, 3.9-10.0 mmol/L) in stage 3 of the study period.

Table 11. Mean Percentage of Time Spent in Range (3.9-10.0 mmol/L) in Study Period Stage 3

Subject Age	Number of Subjects	Mean	95% Confidence Interval
7-17 Years	106	65.7%	(63.5%, 67.9%)
18-80 Years	113	77.1%	(75.4%, 78.9%)

Safety

Table 12 lists the device-related adverse events reported at screening, and during the run-in and study periods. For subjects ages 7-17 years and 18-80 years, 39 device-related adverse events were reported. There were no reports of device-related unanticipated serious or non-serious adverse device effects during the study. For subjects ages 7-17 years, no severe

hypoglycemia events and 1 diabetic ketoacidosis event was reported, but this was not device-related. For adult subjects, 1 severe hypoglycemia event was reported.

Table 12. Device-Related Adverse Events

Adverse Events	Age 7-17 Years (N = 115)			Age 18-80 Years (N = 125)		
	Screening period	Run-in period	Study period	Screening period	Run-in period	Study period
Discomfort/irritation with infusion set	0	2	8	0	0	1
Hyperglycemia	0	1	0	0	0	0
Infusion site infection	0	1	4	0	0	1
Ketonemia	0	0	1	0	0	0
Rash/contact dermatitis (infusion set related)	0	1	0	0	3	1
Rash/contact dermatitis (sensor/tape related)	0	0	2	0	0	3
Sensor site pain	0	2	0	0	0	0
Severe hyperglycemia	0	4	3	0	1	0
Total	0	11	18	0	4	6

Table 13 lists the study-period related adverse events. A total of 51 adverse events during the study period were reported from all investigational sites for 7-17-year-old study subjects enrolled in the study. There were no serious adverse events, no reports of severe hypoglycemia, 5 reports of severe hyperglycemia, 1 report of diabetic ketoacidosis, and no reports of unanticipated adverse device effects (UADEs).

A total of 37 adverse events during the study period were reported from all investigational sites for 18-80-year-old study subjects enrolled in the study. Out of 37 events, there were no serious adverse events, 1 report of severe hypoglycemia, no reports of severe hyperglycemia events, no reports of diabetic ketoacidosis, and no reports of unanticipated adverse device effects (UADEs).

Table 13. Study Period Related Adverse Events

Category	Age 7-17 Years (N = 107)	Age 18-80 Years (N = 116)
Total number of adverse events	51	37
Study Exit		

Table 13. Study Period Related Adverse Events (continued)

Category	Age 7-17 Years (N = 107)	Age 18-80 Years (N = 116)
Led to study exit	0	1
Did not lead to study exit	51	36
Seriousness		
Serious adverse events (SAEs)	0	0
Death	0	0
Non-death	0	0
Non-serious adverse events	51	37
Diagnosis		
Severe hypoglycemia	0	1
Severe hyperglycemia	5	0
Diabetic ketoacidosis (DKA)	1	0
None of the above	45	36
Study procedure and device relatedness		
Related to study procedure only	0	0
Related to study device only	18	6
Unanticipated adverse device effects (UADE) / Unanticipated serious adverse device effects (US-ADE)	0	0
Unanticipated non-serious adverse device effects	0	0
Anticipated adverse device effects (ADEs)	18	6

Table 13. Study Period Related Adverse Events (continued)

Category	Age 7-17 Years (N = 107)	Age 18-80 Years (N = 116)
Related to both study procedure and study device	0	0
Unanticipated adverse device effects (UADE) / Unanticipated serious adverse device effects (US-ADE)	0	0
Unanticipated non-serious adverse device effects	0	0
Anticipated adverse device effects (ADEs)	0	0
Not related to study procedure or study device	33	31

SmartGuard Use

During the study period, subjects were instructed to use Fiasp insulin with the SmartGuard feature and Auto correction ON. *Table 14* presents the percentage of time that subjects spent using the sensor and the percentage of time spent using the SmartGuard feature. This information shows that the SmartGuard feature was ON greater than 87% of the time during the study period.

Table 14. Sensor and SmartGuard Usage (Percentage of Time) Overall Study Period

Category	Age 7-17 Years (N = 107)	Age 18-80 Years (N = 116)
Time spent using sensor	89.3%	94.1%
Time spent not using sensor	10.7%	5.9%
Time spent in SmartGuard	87.4%	95.1%
Time spent in Manual mode	12.6%	4.9%

SmartGuard Performance

Table 15 shows the mean percentage of SG values in specific glucose ranges during the run-in period and during stage 3 of the study period for all

subjects using the 780G system with the Guardian 4 sensor and Fiasp insulin. An international group of diabetes experts and the American Diabetes Association (ADA) consider patients in good control when patients are in the target glucose range of 3.9–10.0 mmol/L for more than 70% of the day.⁹

The data in *Table 15* show that using Fiasp insulin with the SmartGuard feature and the Auto correction feature enabled kept SG values in range and reduced time above range. Specifically, adult subjects spent more time in the target range (TIR, 3.9–10.0 mmol/L) and less time in hypoglycemia (<3.9 mmol/L) and hyperglycemia (>10.0 mmol/L) during stage 3 of the study period compared with the run-in period. Pediatric subjects also spent more time in range (3.9–10.0 mmol/L) and less time in hyperglycemia (>10.0 mmol/L) and less time in hypoglycemia (<3.9 mmol/L) during stage 3 of the study period compared with the run-in period.

Table 15. Percentage of SG values in Different Ranges during the Run-in Period and Study Period Stage 3

Category	SG Range (mmol/L)	Age 7–17 Years		Age 18–80 Years	
		Run-in Period (N = 107)	Study Period Stage 3 (N = 106)	Run-in Period (N = 116)	Study Period Stage 3 (N = 113)
Low SG Value	< 3.0	0.6 ± 0.7 (0.4, 0.7)	0.3 ± 0.3 (0.3, 0.4)	0.5 ± 1.0 (0.3, 0.7)	0.3 ± 0.4 (0.2, 0.4)
	< 3.9	2.2 ± 2.0 (1.8, 2.6)	1.7 ± 1.3 (1.5, 1.9)	2.4 ± 2.9 (1.9, 3.0)	1.7 ± 1.3 (1.4, 1.9)
Target SG Value	3.9 – 7.8	31.2 ± 11.9 (28.9, 33.4)	43.0 ± 10.1 (41.1, 45.0)	41.5 ± 11.9 (39.3, 43.7)	51.4 ± 10.6 (49.5, 53.4)
	3.9 – 10.0	53.0 ± 14.5 (50.2, 55.7)	65.7 ± 11.3 (63.5, 67.9)	68.0 ± 12.2 (65.7, 70.2)	77.1 ± 9.6 (75.4, 78.9)
High SG Value	> 7.8	66.7 ± 12.8 (64.2, 69.1)	55.3 ± 10.6 (53.2, 57.3)	56.0 ± 12.9 (53.6, 58.4)	46.9 ± 11.0 (44.8, 48.9)
	> 10.0	44.9 ± 15.1 (42.0, 47.8)	32.6 ± 11.6 (30.3, 34.8)	29.6 ± 12.6 (27.2, 31.9)	21.2 ± 9.8 (19.3, 23.0)
	> 13.9	17.1 ± 10.5 (15.1, 19.1)	10.6 ± 7.7 (9.1, 12.0)	6.5 ± 5.6 (5.5, 7.6)	3.9 ± 3.7 (3.2, 4.6)
	> 19.4	2.4 ± 2.9 (1.9, 3.0)	1.7 ± 2.2 (1.3, 2.1)	0.4 ± 0.7 (0.2, 0.5)	0.2 ± 0.4 (0.2, 0.3)
Note: Values are presented by Mean ± SD (95% CI) except Number of subjects.					

⁹ Battelino T, Danne T, Bergenstal RM, et al. Clinical Targets for Continuous Glucose Monitoring Data Interpretation: Recommendations From the International Consensus on Time in Range. *Diabetes Care*. 2019 Aug; 42(8): 1593-1603. doi: 10.2337/ dci19-0028. Epub 2019 Jun 8.

Table 16 shows the difference in mean sensor glucose from baseline to the end of the study period for all subjects using Fiasp insulin with the 780G pump and the Guardian 4 sensor. The data shows that, compared to the run-in period, the subjects' mean glucose levels during stage 3 of the study period were closer to the center of the target glucose range.

Table 16. Difference in Mean Sensor Glucose Values (mmol/L) between the Run-in Period and Study Period Stage 3

Category	Age 7-17 Years			Age 18-80 Years		
	Run-in Period (N = 107)	Study Period Stage 3 (N = 106)	Difference between Run-in Period and Study Period Stage 3 (N = 106)	Run-in Period (N = 116)	Study Period Stage 3 (N = 113)	Difference between Run-in Period and Study Period Stage 3 (N = 113)
Mean Glucose Value	10.1 ± 1.4 (9.8, 10.3)	9.1 ± 1.1 (8.9, 9.3)	-1.0 ± 1.2 (-1.2, -0.8)	8.7 ± 1.0 (8.5, 8.9)	8.1 ± 0.8 (8.0, 8.3)	-0.5 ± 0.7 (-0.7, -0.4)
Note: Values are presented by Mean ± SD (95% CI) except Number of subjects.						

While using Fiasp insulin during the study period, some subjects wore the study pump with the SmartGuard feature and the Auto correction feature turned ON, and with the target setpoint set to either 5.5 mmol/L, 6.1 mmol/L, 6.7 mmol/L, or 8.3 mmol/L (Temp Target). Table 17 shows the mean sensor glucose (SG) value for each target setpoint option when that setpoint was used for the entire day during the overall study period. The data in Table 17 shows that using Fiasp insulin with the SmartGuard feature, the Auto correction feature enabled, and the 5.5 mmol/L target setpoint resulted in a lower mean SG value than when the features were used with Fiasp insulin at the 6.7 mmol/L target setpoint.

Table 17. Mean Sensor Glucose Values (mmol/L) during SmartGuard Use Stratified by Target Glucose Setpoint during the Study Period

Category	Age 7- 17 Years					Age 18-80 Years				
	Overall (N = 107)	Target Glucose (mmol/L)				Overall (N = 115)	Target Glucose (mmol/L)			
		5.5 (N = 100)	6.1 (N = 5)	6.7 (N = 106)	8.3 (N = 21)		5.5 (N = 109)	6.1 (N = 2)	6.7 (N = 111)	8.3 (N = 34)
Mean Glucose Values During SmartGuard	8.9 ± 0.9 (8.8, 9.1)	8.8 ± 1.0 (8.6, 9.0)	8.9 ± 1.0 (7.7, 10.1)	9.1 ± 0.9 (9.0, 9.3)	9.3 ± 3.2 (7.9, 10.8)	8.2 ± 0.7 (8.1, 8.4)	8.1 ± 0.7 (7.9, 8.2)	8.8 ± 2.2 (-11.3, 28.9)	8.7 ± 0.8 (8.5, 8.8)	7.1 ± 1.7 (6.5, 7.7)
Note 1: Values are presented by Mean ± SD (95% CI).										
Note 2: Analysis of data was only performed when SmartGuard Glucose target was used the entire day (e.g., 5.5 mmol/L set point used for entire day versus 6.1 mmol/L set point used for entire day versus 6.7 mmol/L set point used for entire day). Any day with partial usage was excluded from this analysis.										

Table 17. Mean Sensor Glucose Values (mmol/L) during SmartGuard Use Stratified by Target Glucose Setpoint during the Study Period (continued)

	Age 7- 17 Years	Age 18-80 Years
Note 3: For the 8.3 mmol/L set point (Temp Target), all the available periods of temp target were included in the analysis.		

Table 18 shows the change in total daily dose of insulin (TDD) from the run-in period to study period stage 3 and weight from baseline to the end of the study. TDD increased slightly in patients ages 7-17 years while no change was reported for patients ages 18-80 years. Mean weight in the pediatric subjects increased slightly and remained unchanged for adult subjects. This data helps explain how using the SmartGuard feature and the Auto correction feature with Fiasp insulin might affect a patient’s TDD and weight.

Table 18. Changes in Mean TDD and Weight

Category	Age 7-17 Years		Age 18-80 Years	
TDD (U), Mean ± SD (Median)	Run-in Period (N = 107)	Study Period Stage 3 (N = 106)	Run-in Period (N = 116)	Study Period Stage 3 (N = 114)
	56.1 ± 21.0 (56.1)	61.7 ± 24.6 (59.0)	57.1 ± 35.2 (46.9)	57.6 ± 34.8 (48.1)
Weight (kg), Mean ± SD (Median)	Baseline (N = 107)	End of Study (N = 104)	Baseline (N = 116)	End of Study (N = 114)
	61.6 ± 16.9 (61.3)	62.4 ± 16.8 (61.3)	86.2 ± 19.1 (87.2)	86.2 ± 19.7 (87.1)

Overall, the clinical study suggested that the 780G system was safe when used with Fiasp insulin, and subjects showed improvements in HbA1C (compared to baseline) and time in the target glucose range with use of the unmodified 780G pump and the Guardian 4 sensor. However, the study had the following limitations:

It did not compare subjects who were using the SmartGuard feature and the Auto correction feature to those who were not on a system (control group). Instead, the study compared how subjects did before using the Auto correction feature (run in period - 2 weeks) against results while using the Auto correction feature (study period - 3 months). Additionally, subjects experienced two simultaneous changes between the run-in period and the study period: the SmartGuard feature modifications and an ultra-rapid-acting insulin. Since these changes occurred together, it is not possible to attribute the improvements to one specific change.

Due to these limitations, the results of the study should be interpreted with caution and you should understand that your individual results may vary.

Type 2 Diabetes Pivotal Clinical Study Overview

The SmartGuard feature

The SmartGuard feature, with and without modifications, was studied in adult subjects with type 2 diabetes who wore the MiniMed 780G system and the Extended infusion set and reservoir at home for 3 months.^{10,11} The study was conducted in two phases. In Phase 1 of the study, the unmodified SmartGuard feature was studied with the Guardian 4 sensor, and the modified SmartGuard feature was studied with the Simplerla Sync sensor in Phase 2. The study did not include a control group. The study included subjects from different clinics around the US who were between 18 and 80 years old. Subjects had to have been diagnosed with insulin-requiring type 2 diabetes mellitus for at least two years. All subjects in the study also had to have been on a multiple daily injection (MDI) regimen (basal/bolus regimen with long-acting insulin and rapid-acting analogs) for at least 3 months prior to study, or on Continuous Subcutaneous Insulin Infusion (CSII) pump therapy with or without CGM, and had an HbA1C value of less than 10.0% at the time of screening.

Subjects were included in the study if thyroid hormone levels were under control and were excluded if undergoing treatment for hyperthyroidism. Subjects were excluded if they had a history of 2 or more episodes of severe hypoglycemia, or an episode of diabetic ketoacidosis or of the hyperosmolar/hyperglycemic state during the 6 months prior to screening. Subjects who had been hospitalized or who had visited the emergency room for uncontrolled diabetes during the 6 months prior to screening were also excluded. Subjects who had any of the following conditions, or who were undergoing the following treatments, were also excluded from the study: pregnancy, adrenal insufficiency, blood disorder or recent or planned blood

¹⁰ Medtronic Inc., CIP341 Clinical Study Report – Phase 1

¹¹ Medtronic Inc., CIP341 Clinical Study Report – Phase 2

transfusion, hydroxyurea treatment, eating disorder, glucocorticoid treatment, inadequately treated celiac disease, chronic kidney disease greater than stage 2 or undergoing dialysis, history of cardiovascular events (unless cleared for enrollment by a board certified cardiologist).

Both study phases had a run-in (baseline) period and a study period. During run-in, subjects with no prior automated insulin delivery (AID) experience were instructed to use the MiniMed 780G system with only the sensor augmented pump (SAP) function activated (i.e., SmartGuard feature turned OFF). Subjects with AID pump experience were instructed to use the MiniMed 780G system with the SmartGuard feature turned ON and the Auto correction feature turned OFF. The intent of the run-in period was to allow subjects to become familiar with the study devices while using their own insulin.

After the run-in period, subjects were instructed to use the study devices with both the SmartGuard feature and the Auto correction feature turned ON during a study period comprising 3 stages. In the first two stages, subjects were instructed to use the study pump with the 6.7 mmol/L Auto basal target setpoint and active insulin time (AIT) set to 4 hours (stage 1), then to change the pump settings to the 5.5 mmol/L setpoint and active insulin time set to 2-3 hours (stage 2). In stage 3, subjects were instructed to use the study pump with the Auto basal target setpoint and active insulin time set as considered best by the investigator for the individual subject.

Subjects who participated in Phase 1 of the study underwent meal and exercise challenges during the run-in and study periods and had the opportunity to participate in a continued access period. Phase 1 subjects had the opportunity to transition into Phase 2 upon completion of the Phase 1 study period or during the continued access period. Subjects who transitioned from Phase 1 to Phase 2 of the study experienced a shortened run-in period in Phase 2 due to their previous exposure to MiniMed 780G system therapy during Phase 1. Phase 2 of the study did not include meal and exercise challenges or a continued access period. For Phase 1 of the study, a total of 165 subjects were enrolled, 89 subjects completed the study period,

and 72 subjects transitioned to Phase 2. For Phase 2, a total of 481 subjects were enrolled, and 292 subjects completed the study period under Phase 2.

SmartGuard Performance: HbA1C and Time in Target Range

Table 19 shows the mean HbA1C from Baseline to the end of the 3-month study period. This data helps explain how using the 780G SmartGuard feature with the Auto correction feature enabled might affect a patient's HbA1C.

Table 19. Mean HbA1C from Baseline to End of 3-month Study Period

Category	Phase 1		Phase 2 (Transition Subjects)		Phase 2 (Naïve Subjects)	
	Baseline	End of Study	Baseline ^a	End of Study	Baseline	End of Study
HbA1C (%)	7.9 ± 1.0	7.2 ± 0.7	7.1 ± 0.7	6.8 ± 0.6	7.7 ± 0.9	6.9 ± 0.7
Mean ± SD	(7.9)	(7)	(6.9)	(6.7)	(7.7)	(6.9)
(Median)	[95]	[88]	[66]	[65]	[236]	[229]
[N]						

^a Baseline reflects data gathered at Phase 2 screening and is therefore not a true baseline.

Table 20 reports the mean percentage of time spent in target range (3.9-10.0 mmol/L) in stage 3 of the study period.

Table 20. Mean Percentage of Time Spent in Range (3.9-10.0 mmol/L) in Study Period Stage 3

Phase	Number of Subjects	Mean TIR ^a	95% Confidence Interval ^a
1	91	80.9%	(78.4%, 83.1%)
2	298	85.4%	(84.3%, 86.4%)

^a Hodges-Lehmann method used to compute Mean TIR and 95% confidence interval.

Safety

Table 21 lists the device-related adverse events reported at screening, and during the run-in, study and continued access periods. For Phase 1 and Phase 2 combined, 72 device-related adverse events were reported. There were 9 reports of device-related, anticipated, non-serious adverse device effects during Phase 1 of the study. One diabetic ketoacidosis (DKA) event was reported for an adult subject, but this was not device-related. There were 63 reports of device-related, anticipated, non-serious adverse device effects during Phase 2 of the study. Two severe hypoglycemia events and 1 DKA event were reported for adult subjects but none of these were device-related.

Table 21. Device-Related Adverse Events

Adverse Events	Phase 1 (N = 165) ^a				Phase 2 (N = 481) ^b		
	Screening pe- riod	Run-in period	Study period	Continued Access period	Screening pe- riod	Run-in period	Study period
Abrasion	0	0	1	0	0	0	0
Bleeding at infusion site	0	0	0	0	0	1	0
Bleeding at sensor site	0	0	0	0	0	6	9
Bruising at sensor site	0	2	1	1	0	0	1
Discomfort/irritation with infusion set	0	1	0	0	0	11	11
Discomfort/irritation with insulin infusion	0	0	0	0	0	0	1
Discomfort/irritation with sensor	0	0	1	0	0	4	3
Excoriation	0	1	0	0	0	0	0
Infusion site bruising	0	0	0	0	0	1	1
Infusion site infection	0	0	0	0	0	1	1
Rash/contact dermatitis (infusion set related)	0	1	0	0	0	6	4
Rash/contact dermatitis (sensor/tape related)	0	0	0	0	0	1	0
Sensor site infection	0	0	0	0	0	1	0
Total	0	5	3	1	0	32	31

^a Adverse Events which occurred on the last date of Study Period participation and the first date of Continued Access Period participation were attributed to the Study Period. Adverse Events which occurred after the first date of Continued Access Period participation were attributed to the Continued Access Period.

^b For subjects transitioning from Phase 1 to Phase 2, events occurring between Phase 2 screening date and the first date of Phase 2 Study Period participation contributed to the Phase 2 Run-in period.

Table 22 lists the study-period related adverse events. A total of 67 adverse events during the study period and four serious adverse events during the study period were reported from all investigational sites for phase 1 subjects enrolled in the study, while 216 total adverse events and 11 serious adverse events were reported for phase 2 during the study period. There were no reports of severe hypoglycemia or severe hyperglycemia, no reports of diabetic ketoacidosis, and there were no reports of unanticipated adverse device effects (UADEs) in phase 1 during the study period. There were 2 reports of severe hypoglycemia and 1 of severe hyperglycemia, no reports of diabetic ketoacidosis, and there were no reports of unanticipated adverse device effects (UADEs) in phase 2.

Table 22. Study Period Related Adverse Events

Category	Phase 1 (N=95) ^a	Phase 2 (N=302)
Total number of adverse events	67	216
Study Exit		
Led to study exit	1	2
Did not lead to study exit	66	214
Seriousness		
Serious adverse events (SAEs)	4	11
<i>Death</i>	0	1
<i>Non-death</i>	4	10
Non-serious adverse events	63	205
Diagnosis		
Severe hypoglycemia	0	2
Severe hyperglycemia	0	1
Diabetic ketoacidosis (DKA)	0	0
Hyperosmolar hyperglycemic state	0	0
None of the above	67	213
Study procedure and device relatedness		
Related to study procedure only	2	0
Related to study device only	3	31
<i>Unanticipated adverse device effects (UADE) / Unanticipated serious ad-</i>	0	0

Table 22. Study Period Related Adverse Events (continued)

Category	Phase 1 (N=95) ^a	Phase 2 (N=302)
<i>verse device effects (US-ADE)</i>		
<i>Unanticipated non-serious adverse device effects</i>	0	0
<i>Anticipated adverse device effects (ADEs)</i>	3	31
Related to both study procedure and study device	0	0
<i>Unanticipated adverse device effects (UADE) / Unanticipated serious adverse device effects (US-ADE)</i>	0	0
<i>Unanticipated non-serious adverse device effects</i>	0	0
<i>Anticipated adverse device effects (ADEs)</i>	0	0
Not related to study procedure or study device	62	185

^a Adverse Events which occurred on the last date of Study Period participation and the first date of Continued Access Period participation were attributed to the Study Period.

SmartGuard Use

During the study period, subjects had access to the study device and were instructed to use SmartGuard with Auto correction ON. *Table 23* presents the percentage of time that subjects spent using the sensor and the percentage of time spent using the SmartGuard feature with the Auto correction feature turned ON during stage 3 of the study period. This information shows that the SmartGuard feature was ON greater than 91% during stage 3 of the study

period for Phase 1 and greater than 92% during stage 3 of the study period for Phase 2.

Table 23. Sensor and SmartGuard Usage (Percentage of Time) During Study Period Stage 3

Category	Phase 1	Phase 2
	Study Period Stage 3 (N = 91)	Study Period Stage 3 (N = 298)
Time spent using sensor	92.9%	94.5%
Time spent not using sensor	7.1%	5.5%
Time spent in SmartGuard	91.2%	92.8%
Time spent in Manual mode	8.8%	7.2%

SmartGuard Performance

Table 24 shows the mean percentage of SG values in specific glucose ranges during the run-in period (baseline) and during stage 3 of the study period by all subjects using the unmodified 780G pump with the Guardian 4 sensor in Phase 1 and by all transition and naïve subjects using the modified 780G pump with the Simplerla Sync sensor in Phase 2. An international group of diabetes experts and the American Diabetes Association (ADA) consider patients in good control when patients are in the target glucose range of 3.9–10.0 mmol/L for more than 70% of the day.¹²

The data in Table 24 show that using the SmartGuard feature with the Auto correction feature kept SG values in the target range and reduced time above range for subjects with type 2 diabetes. Specifically, subjects spent more time in range (3.9–10.0 mmol/L) and less time in hyperglycemia (>10.0 mmol/L) during stage 3 of the study period compared with the run-in period for both study Phases 1 and 2 (both transition and naïve subjects).

¹² Battelino T, Danne T, Bergenstal RM, et al. Clinical Targets for Continuous Glucose Monitoring Data Interpretation: Recommendations From the International Consensus on Time in Range. Diabetes Care. 2019 Aug; 42(8): 1593-1603. doi: 10.2337/ dci19-0028. Epub 2019 Jun 8.

Table 24. Percentage of SG values in Different Ranges during the Run-in Period and Study Period Stage 3

Category	SG Range (mmol/L)	Phase 1		Phase 2 (Transition Subjects)		Phase 2 (Naïve Subjects)	
		Run-in Period (N = 95)	Study Period Stage 3 (N = 91)	Run-in Period ^a (N = 62)	Study Period Stage 3 (N = 66)	Run-in Period (N = 236)	Study Period Stage 3 (N = 232)
Low SG Value	<3.0	0.0 ± 0.1 (0.0, 0.1)	0.0 ± 0.1 (0.0, 0.1)	0.0 ± 0.1 (0.0, 0.1)	0.0 ± 0.0 (0.0, 0.0)	0.0 ± 0.1 (0.0, 0.0)	0.0 ± 0.1 (0.0, 0.0)
	<3.9	0.4 ± 0.7 (0.3, 0.6)	0.3 ± 0.4 (0.2, 0.4)	0.2 ± 0.5 (0.1, 0.4)	0.3 ± 0.3 (0.2, 0.3)	0.3 ± 0.5 (0.2, 0.4)	0.3 ± 0.4 (0.2, 0.4)
Target SG Value	3.9 – 7.8	41.5 ± 19.5 (37.6, 45.5)	50.9 ± 13.7 (48.1, 53.8)	49.0 ± 15.4 (45.1, 52.9)	56.5 ± 11.4 (53.7, 59.3)	45.3 ± 19.7 (42.8, 47.8)	58.1 ± 13.6 (56.4, 59.9)
	3.9 – 10.0	72.2 ± 17.1 (68.7, 75.7)	79.8 ± 11.4 (77.4, 82.2)	78.5 ± 14.0 (75.0, 82.1)	83.7 ± 8.9 (81.5, 85.9)	76.4 ± 15.9 (74.3, 78.4)	84.9 ± 9.7 (83.7, 86.2)
High SG Value	> 7.8	58.0 ± 19.7 (54.0, 62.0)	48.8 ± 13.7 (45.9, 51.6)	50.8 ± 15.4 (46.9, 54.7)	43.3 ± 11.4 (40.5, 46.1)	54.4 ± 19.8 (51.9, 56.9)	41.6 ± 13.6 (39.8, 43.3)
	> 10.0	27.3 ± 17.2 (23.8, 30.9)	19.9 ± 11.5 (17.5, 22.3)	21.2 ± 14.1 (17.6, 24.8)	16.0 ± 8.9 (13.8, 18.2)	23.4 ± 15.9 (21.3, 25.4)	14.8 ± 9.7 (13.5, 16.0)
	> 13.9	4.5 ± 5.7 (3.4, 5.7)	2.6 ± 3.8 (1.8, 3.4)	2.8 ± 4.3 (1.7, 3.9)	1.7 ± 2.1 (1.2, 2.2)	3.5 ± 5.2 (2.8, 4.1)	1.7 ± 2.5 (1.3, 2.0)
	> 19.4	0.2 ± 0.9 (0.0, 0.4)	0.1 ± 0.4 (0.0, 0.2)	0.1 ± 0.3 (-0.0, 0.2)	0.0 ± 0.1 (0.0, 0.1)	0.1 ± 0.4 (0.1, 0.2)	0.1 ± 0.2 (0.0, 0.1)
Note: Values are presented by Mean ± SD (95% CI) except Number of subjects							

^a Baseline reflects data gathered at Phase 2 screening and is therefore not a true baseline.

Table 25 shows the difference in mean sensor glucose from run-in to study period stage 3 for all subjects using the unmodified 780G pump with the Guardian 4 sensor (Phase 1) and the modified 780G pump with the Simplerla Sync sensor (Phase 2). The data shows that, compared to the run-in period, the subjects' mean glucose levels during stage 3 of the study period were closer to the center of the target range.

Table 25. Difference in Mean Glucose Value (mmol/L) between the Run-in Period and Study Period Stage 3

Category	Phase 1			Phase 2 (Transition Subjects)			Phase 2 (Naïve Subjects)		
	Run-in period (N=95)	Study Period Stage 3 (N = 91)	Difference between Run-in Period and Study Period Stage 3 (N = 91)	Run-in period ^a (N = 62)	Study Period Stage 3 (N = 66)	Difference between Run-in Period and Study Period Stage 3 (N = 62)	Run-in period (N = 236)	Study Period Stage 3 (N = 232)	Difference between Run-in Period and Study Period Stage 3 (N = 232)
Mean Glucose Value	8.7 ± 1.2 (8.5, 9.0)	8.2 ± 0.8 (8.0, 8.4)	-0.5 ± 1.0 (-0.7, -0.3)	8.3 ± 1.0 (8.1, 8.6)	7.9 ± 0.6 (7.7, 8.0)	-0.4 ± 0.7 (-0.6, -0.2)	8.5 ± 1.2 (8.3, 8.6)	7.8 ± 0.7 (7.7, 7.9)	-0.7 ± 1.1 (-0.8, -0.5)
Note: Values are presented by Mean ± SD (95% CI) except Number of subjects									

^a Baseline reflects data gathered at Phase 2 screening and is therefore not a true baseline.

During the study period, some subjects wore the study pump with the SmartGuard feature and the Auto correction feature turned ON, and with the target setpoint set to either 5.5 mmol/L, 6.1 mmol/L, 6.7 mmol/L, or 8.3 mmol/L (Temp Target).

Table 26 shows the mean sensor glucose (SG) value for each target setpoint option when that setpoint was used during the overall study period. The data in Table 26 shows that using the SmartGuard feature with the Auto correction feature and the 5.5 mmol/L target setpoint resulted in a lower mean SG value than when the features were used with the 6.7 mmol/L target setpoint.

Table 26. Mean Sensor Glucose Values (mmol/L) during SmartGuard Use Stratified by Target Glucose Setpoint during the Study Period

Phase 1					
Category	Overall (N = 94)	Target Glucose (mmol/L)			
		5.5 (N = 88)	6.1 (N = 4)	6.7 (N = 94)	8.3 (N = 8)
Mean Glucose Values During SmartGuard	8.4 ± 0.8 (8.2, 8.5)	8.2 ± 0.7 (8.0, 8.3)	8.4 ± 0.7 (7.2, 9.6)	8.6 ± 0.8 (8.5, 8.8)	9.9 ± 4.5 (6.2, 13.7)
Phase 2					
Category	Overall (N = 302)	Target Glucose (mmol/L)			
		5.5 (N = 291)	6.1 (N = 12)	6.7 (N = 287)	8.3 (N = 25)
Mean Glucose Values During SmartGuard	7.9 ± 0.6 (7.8, 8.0)	7.8 ± 0.6 (7.7, 7.9)	7.9 ± 0.6 (7.5, 8.3)	8.3 ± 0.8 (8.2, 8.4)	8.2 ± 2.2 (7.3, 9.1)
Note: Values are presented by Mean ± SD (95% CI).					

Figure 3 shows the percentage of subjects that had an HbA1C that was less than 7% during the run-in (baseline) and study periods. The ADA considers a HbA1C target of less than 7% appropriate for non-pregnant adults and many children.^{13,14} Figure 3 shows that a greater percentage of subjects had an HbA1C that was less than 7% at the end of the study than at baseline for Phase 1 and Phase 2.

¹³ American Diabetes Association Professional Practice Committee; 6. Glycemic Goals and Hypoglycemia: Standards of Care in Diabetes–2025. Diabetes Care 2025; 48 (Supplement_1): S128-S145.

¹⁴ American Diabetes Association Professional Practice Committee; 14. Children and Adolescents: Standards of Care in Diabetes–2025. Diabetes Care 2025; 48 (Supplement_1): S283-S305.

Figure 3. Percentage of Patients with less than 7% HbA1C

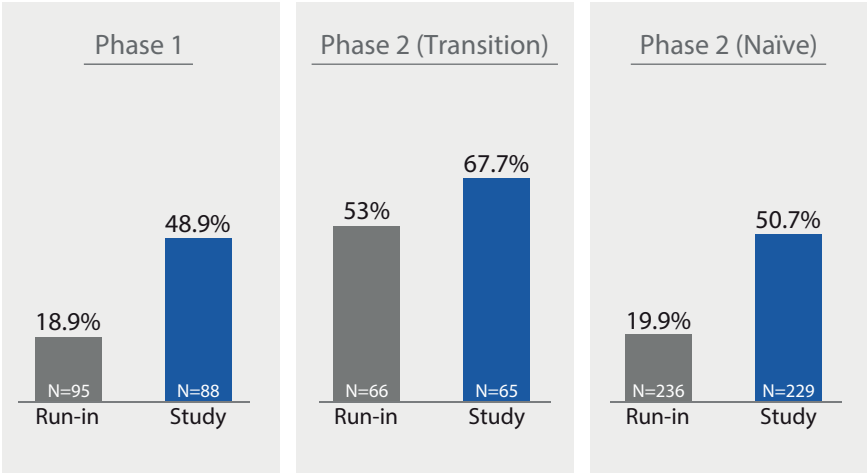


Table 27 shows the change in total daily dose of insulin (TDD) from the run-in period to study period stage 3, and the change in weight from baseline to the end of the study. The mean TDD increased for subjects in both phases of the study, and the mean weight increased slightly for Phase 1 and Phase 2 transition subjects but remained relatively unchanged for Phase 2 naïve subjects. This data helps explain how using the SmartGuard feature with the Auto correction feature might affect a patient’s TDD and weight.

Table 27. Changes in Mean TDD and Weight

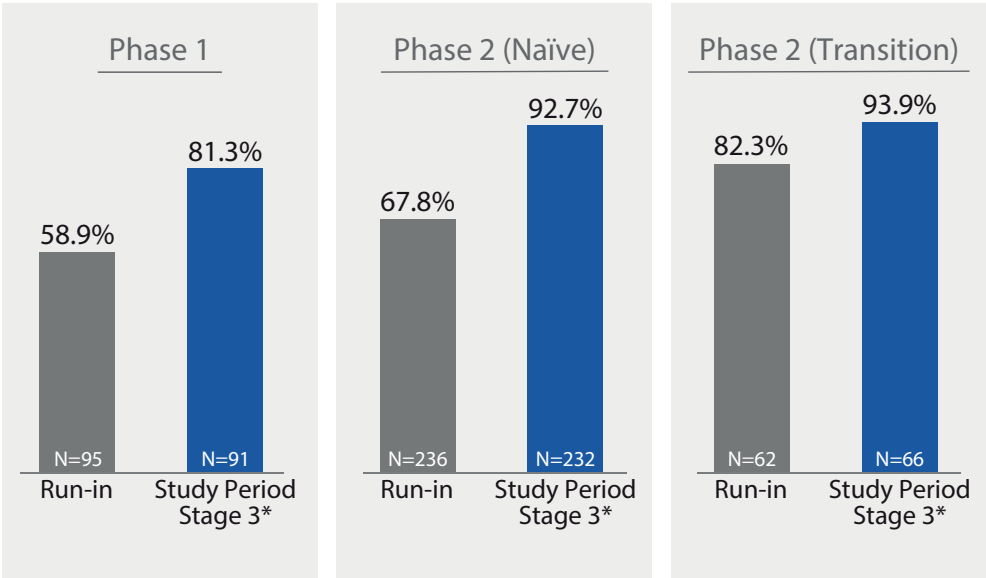
Category	Phase 1		Phase 2 (Transition Subjects)		Phase 2 (Naïve Subjects)	
	Run-in Period (N = 95)	Study Period Stage 3 (N = 91)	Run-in Period ^a (N = 63)	Study Period Stage 3 (N = 66)	Run-in Period (N = 236)	Study Period Stage 3 (N = 232)
TDD (U), Mean ± SD (Median)	77.4 ± 38.5 (70.8)	91.8 ± 49.3 (84)	93.9 ± 47.8 (88.3)	97.1 ± 42.9 (93.9)	61.0 ± 36.1 (55.5)	76.1 ± 44.1 (64.8)
Weight (kg), Mean ± SD (Median)	Baseline (N = 95)	End of Study (N = 92)	Baseline ^a (N = 66)	End of Study (N = 65)	Baseline (N = 235)	End of Study (N = 229)
	105.8 ± 21.8 (103.1)	107.3 ± 22.0 (105)	109.4 ± 24.1 (105.2)	110.3 ± 23.7 (104.8)	98.0 ± 22.8 (96.1)	98.4 ± 23.0 (96.1)

^aBaseline reflects data gathered at Phase 2 screening and is therefore not a true baseline.
Note: Values are presented by Mean ± SD (95% CI) except Number of subjects.

Figure 4 shows the percentage of subjects that spent more than 70% of time in range (3.9-10.0 mmol/L), which is considered good glucose control by diabetes experts and the ADA, during the run-in (baseline) and study period

stage 3. The system offers three SG target setpoint options that allow users to customize insulin delivery. For the study period, percentages are shown for subjects that used the SmartGuard feature with the Auto correction feature. For all phases, the percentage of subjects who spent more than 70% of time in range (3.9-10.0 mmol/L) when using the SmartGuard feature with the Auto correction feature increased in study period stage 3 from the run-in period. This data shows that a greater percentage of subjects using the SmartGuard feature with the Auto correction feature at the 5.5 mmol/L setpoint spent more time in range.

Figure 4. Percentage of Subjects who spent More than 70% of Time in Range (3.9-10.0 mmol/L)



*During this period, subjects were instructed to use the study device with the Auto basal target as well as Active insulin time (AIT) set to what is best for the individual subject, at the investigator’s discretion. Note that 14% (13/91) of Phase 1, 31% (72/232) of Phase 2 (Naïve) and 30% (20/66) of Phase 2 (Transition) patients used the study device with the Auto Basal target with setpoint 5.5 mmol/L and AIT set to 2 hours during study period stage 3.

Overall, the clinical study suggested that the 780G system was safe in adults with insulin-requiring type 2 diabetes, and subjects showed improvements in HbA1C (compared to baseline) and time in the target glucose range with use of the updated 780G pump and the Simplera Sync sensor. However, the study had the following limitations:

It did not compare subjects who were using the SmartGuard feature and the Auto correction feature to those who were not on a system (control group). Instead, the study compared how subjects did using manual mode or auto-mode (run in period -2 weeks) without Auto correction against results while using the Auto correction feature (study period -3 months).

Additionally, subjects experienced two simultaneous changes (SmartGuard feature modifications and a sensor change) between Phase 1 and Phase 2. Since these changes occurred together, it is not possible to attribute the improvements to one specific change.

Due to these limitations, the results of the study should be interpreted with caution and you should understand that your individual results may vary.

The Suspend before low feature

Clinical study overview (Ages 14-75 Years)

The Suspend before low feature was evaluated for safety in a multi-center, single-arm, in-clinic study of the MiniMed 640G System.¹⁵ This feature is the same in the MiniMed 780G system. Study subjects included persons aged 14 to 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 3.6 mmol/L, using the rate of change basal increase algorithm. The Suspend before low feature was activated with the Low Limit setting for the Suspend

¹⁵ Buckingham BA, Bailey TS, Christiansen M, et al. Evaluation of a Predictive Low-Glucose Management System In-Clinic. *Diabetes Technology and Therapeutics*. 2017;19(5):288-292.

before low feature ON set to 3.6 mmol/L, and the subject was observed with frequent sample testing (FST, or frequent blood sampling for glucose measurements) for a maximum of 19 hours. The observation period included the suspension period, the insulin resumption period, and if applicable, an insulin resuspension after basal insulin delivery resumed.

Feature performance and safety

Of the 71 subjects with induced hypoglycemia, 69 inductions were successful, 27 subjects experienced a hypoglycemic event and 42 subjects did not; a prevention rate of 60%. At 120 minutes after the start of the pump suspension events, the mean reference glucose value (measured using a Yellow Springs Instrument [YSI™*]) was 5.7 ± 1.9 mmol/L.

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).

Clinical study overview (Ages 7-13 Years)

The Suspend before low feature was also evaluated in a study of the MiniMed 670G system that included subjects 7-13 years, diagnosed with type 1 diabetes mellitus.¹⁶ This feature is the same in the MiniMed 780G system.

A total of 105 study subjects were observed overnight after exercise/activity while using the system with the Suspend before low feature activated. The Low Limit setting for the Suspend before low feature turned ON was set to

¹⁶ Forlenza G, Shulman D, Wood M, et al. Evaluation of the MiniMed™ 670G system predictive low glucose management feature in children. *Diabetes Technology and Therapeutics*. 2018;20:A19-A20.

3.6 mmol/L and the subjects were observed with FST for a maximum of 12 hours.

Feature performance and safety

In 79.7% of cases, after activation of the Suspend before low feature, the threshold of ≤ 3.6 mmol/L was avoided, indicating prevention of hypoglycemia as defined in the study protocol. Mean glucose levels up to six hours after the suspend feature was activated remained below the starting glucose levels.

Data from this in-clinic evaluation demonstrated that the Suspend before low feature is safe to use in a pediatric population.

Simplera Sync System Performance



Note: You should review the information in this section with your healthcare professional to understand the performance of the Simplera Sync system.

Clinical study overview

The performance of the Simplera Sync system was evaluated using data collected during a multi-center prospective clinical study.¹⁷ The study included participants ages 7 to 80 years old. Within the 7 to 80 years age range, the study enrolled a total of 219 subjects previously diagnosed with type 1 or type 2 diabetes (76.7% with type 1 diabetes, 12.3% with type 2 insulin requiring, 11.0% with type 2 non-insulin requiring diabetes) and 209 of these subjects completed the study. Among the enrolled subjects aged 7-17 years, 89.6% was White; 1.0% was Asian; 1.0% was Asian and White, 7.3% was Black or African American; and 1.0% was Other race (e.g., Sri Lankan). Among the subjects aged 18-80 years, 84.6% was White; 3.3% was Asian; 8.1% was Black or African American; 0.8% was Native Hawaiian or

Other Pacific Islander; 0.8% was American Indian or Alaska Native; and 2.4% was Other race (e.g., Mexican American).

Subjects ages 18 years and older were instructed to wear a total of two sensors in the arm. Subjects ages 7 to 17 years old were instructed to wear a total of three sensors in the arm(s) and buttock(s). For all subjects, the sensors were used to record raw sensor signals during the study and there was no real-time calculation of sensor glucose values.

Frequent sample testing (FST) was performed on four occasions for subjects 14 and older and on two occasions for subjects 7 to 13 years of age.

Reference blood (plasma) glucose values were obtained with a Yellow Springs Instrument (YSI™*) Glucose Analyzer every 5-15 minutes for subjects 7 years and older. During each FST, subjects 14 years and older with an established insulin sensitivity ratio and insulin carbohydrate ratio underwent a hypoglycemic challenge or a hyperglycemic challenge.

Data collected during the study was post-processed after the study using the Simplera Sync system sensor algorithm to convert the raw sensor information to sensor glucose values every five minutes. For the accuracy information presented in the following sections, YSI reference values were paired with the closest sensor glucose reading within five minutes of the time of the reference value measurement.

Table 28 shows the overall accuracy of the Simplera Sync system when compared to the reference YSI Glucose Analyzer for subjects ages 7 years and older.

Sensor accuracy

Sensor accuracy was calculated for sensors compared to a YSI reference for subjects ages 7 years and older.

¹⁷ 10976639DOC: CIP330 - Evaluation of Updated Continuous Glucose Monitoring (CGM) Form Factor in Adults, Adolescents and Pediatrics.

Table 28. Overall Accuracy Compared to YSI

Patient Population (Years)	Insertion Site	Number of Subjects	Number of paired SG-YSI Points	Percent of SG within 20%* of YSI (95% lower bound)*	Mean Absolute Relative Difference (%)
Adults (18+)	Arm	116	15405	90.7 (90.3)	10.2
Pediatrics (7-17)	Arm	89	8282	89.0 (88.4)	10.8
	Buttock	86	7569	89.9 (89.3)	10.1

CGM readings are within 2.8-22.2 mmol/L, inclusive.

*For 20% agreement, 1.1 mmol/L used when YSI < 3.9 mmol/L.

In *Table 29*, *Table 30*, and *Table 31*, the agreement of the SG values to paired YSI values was assessed by calculating the percentage of SG values that were within 15%, 20%, and 40% of the paired YSI values. For SG readings less than 3.9 mmol/L, the absolute difference in mmol/L between the SG and paired YSI values was calculated.

Table 29. Overall accuracy of SG-YSI paired points within SG ranges; Adults, Arm

CGM Glucose Range (mmol/L)*	Number of Subjects	Number of paired CGM-YSI Points	Percent of SG within 0.83 mmol /L YSI	Percent of SG within 1.11 mmol /L YSI	Percent of SG within 2.22 mmol /L YSI	Percent of SG within 15% YSI	Percent of SG within 20% YSI	Percent of SG within 40% YSI	Bias (mmol/L)	MARD (%)
A) < 3.0	29	164	84.1	90.9	98.2				-0.4	14.6
B) 3.0-<3.9	72	1609	90.1	94.7	98.2				-0.1	10.6
C) 3.9-10.0	116	9655				74.3	85.7	98.6	-0.1	11.0
D) >10.0-13.9	101	2593				85.6	94.8	99.6	-0.5	8.6
E) > 13.9	79	1384				89.8	96.7	100.0	-0.8	7.4

CGM readings are within 2.8-22.2 mmol/L, inclusive.

* For reference range < 3.9 mmol/L, agreement was based on 0.83/1.11/2.22 mmol/L.

Table 30. Overall accuracy of SG-YSI paired points within SG ranges; Pediatrics (7-17 Years), Arm

CGM Glucose Range (mmol/L)*	Number of Subjects	Number of paired CGM-YSI Points	Percent of SG within 0.83 mmol /L YSI	Percent of SG within 1.11 mmol /L YSI	Percent of SG within 2.22 mmol /L YSI	Percent of SG within 15% YSI	Percent of SG within 20% YSI	Percent of SG within 40% YSI	Bias (mmol/L)	MARD (%)
A) < 3.0	22	91	90.1	97.8	100.0				-0.3	11.2
B) 3.0-<3.9	49	941	94.0	97.3	99.8				-0.1	9.5
C) 3.9-10.0	88	4484				68.4	79.9	96.9	-0.2	12.8

Table 30. Overall accuracy of SG-YSI paired points within SG ranges; Pediatrics (7-17 Years), Arm (continued)

CGM Glucose Range (mmol/L)*	Number of Subjects	Number of paired CGM-YSI Points	Percent of SG within 0.83 mmol /L YSI	Percent of SG within 1.11 mmol /L YSI	Percent of SG within 2.22 mmol /L YSI	Percent of SG within 15% YSI	Percent of SG within 20% YSI	Percent of SG within 40% YSI	Bias (mmol/L)	MARD (%)
D) >10.0-13.9	87	1547				83.3	92.5	99.3	-0.6	8.8
E) > 13.9	73	1219				91.3	97.0	100.0	-0.8	7.1

CGM readings are within 2.8-22.2 mmol/L, inclusive.

* For reference range < 3.9 mmol/L, agreement was based on 0.83/1.11/2.22 mmol/L.

Table 31. Overall accuracy of SG-YSI paired points within SG ranges; Pediatrics (7-17 Years), Buttock

CGM Glucose Range (mmol/L)*	Number of Subjects	Number of paired CGM-YSI Points	Percent of SG within 0.83 mmol /L YSI	Percent of SG within 1.11 mmol /L YSI	Percent of SG within 2.22 mmol /L YSI	Percent of SG within 15% YSI	Percent of SG within 20% YSI	Percent of SG within 40% YSI	Bias (mmol/L)	MARD (%)
A) < 3.0	22	85	75.3	85.9	91.8				-0.6	17.7
B) 3.0-<3.9	46	797	92.3	97.1	99.5				-0.1	9.9
C) 3.9-10.0	85	4008				71.2	81.5	97.7	-0.0	11.9
D) >10.0-13.9	82	1492				86.5	93.2	99.5	-0.4	7.9
E) > 13.9	71	1187				91.9	97.9	99.7	-0.5	6.4

CGM readings are within 2.8-22.2 mmol/L, inclusive.

* For reference range < 3.9 mmol/L, agreement was based on 0.83/1.11/2.22 mmol/L.

Agreement when CGM reads "Below 2.8 mmol/L" or "Above 22.2 mmol/L"

The real-time CGM systems display glucose values between 2.8 mmol/L and 22.2 mmol/L. It displays "Below 2.8 mmol/L" when the SG value detected is below 2.8 mmol/L. It displays "Above 22.2 mmol/L" when the SG value detected is above 22.2 mmol/L. *Table 32* and *Table 33* illustrate the number and percentage of the paired YSI values in different blood glucose (BG) levels when the CGM system displays "Below 2.8 mmol/L" (LOW) or "Above 22.2 mmol/L" (HIGH).

Table 32. The number and percentage of YSI values collected when CGM displays "Below 2.8 mmol/L" (LOW)

CGM Display	Population	Insertion site	CGM-YSI pairs	YSI (mmol/L)					Total
				< 3.1	< 3.3	< 3.9	< 4.4	≥ 4.4	
LOW	Adult	Arm	Cumulative, n	67	119	169	197	10	207
			Cumulative, %	32%	57%	82%	95%	5%	
	Pediatrics*	Arm	Cumulative, n	72	100	112	114	0	114
			Cumulative, %	63%	88%	98%	100%	0%	
		Buttock	Cumulative, n	78	110	142	152	4	156
			Cumulative, %	50%	71%	91%	97%	3%	

*Includes pediatric subjects 7-17 years of age.

Table 33. The number and percentage of YSI values collected when CGM displays "Above 22.2 mmol/L" (HIGH)

CGM Display	Population	Insertion site	CGM-YSI pairs	YSI (mmol/L)					Total
				> 18.9	> 17.8	> 15.5	> 13.3	≤ 13.3	
HIGH	Adult	Arm	Cumulative, n	14	14	14	14	0	14
			Cumulative, %	100%	100%	100%	100%	0%	
	Pediatrics*	Arm	Cumulative, n	9	9	9	9	0	9
			Cumulative, %	100%	100%	100%	100%	0%	
		Buttock	Cumulative, n	34	34	34	34	0	34
			Cumulative, %	100%	100%	100%	100%	0%	

*Includes pediatric subjects 7-17 years of age.

Concurrence of SG and YSI values

Table 34 through Table 36 show, for each SG range, the percentage of concurring data points where the paired YSI values were in different blood glucose ranges.

Table 34. Overall concurrence of YSI values and SG readings using SG ranges; Adults, Arm

Percent of matched pairs in each YSI glucose range for each SG range (mmol/L)											
SG ranges (mmol/L)	Number of paired SG-YSI	YSI glucose ranges (mmol/L)									
		< 2.8	≥ 2.8-3.3	> 3.3-4.4	> 4.4-6.7	> 6.7-8.9	> 8.9-11.1	> 11.1-13.9	> 13.9-16.7	> 16.7-19.4	> 19.4-22.2
A) < 2.8	207	15.0% (31/207)	42.5% (88/207)	37.7% (78/207)	4.3% (9/207)	0.5% (1/207)	0.0% (0/207)	0.0% (0/207)	0.0% (0/207)	0.0% (0/207)	0.0% (0/207)
B) ≥ 2.8-3.3	684	5.8% (40/684)	43.4% (297/684)	47.1% (322/684)	2.3% (16/684)	1.3% (9/684)	0.0% (0/684)	0.0% (0/684)	0.0% (0/684)	0.0% (0/684)	0.0% (0/684)
C) > 3.3-4.4	2285	1.9% (44/2285)	15.6% (356/2285)	68.5% (1566/2285)	12.6% (288/2285)	1.3% (29/2285)	0.1% (2/2285)	0.0% (0/2285)	0.0% (0/2285)	0.0% (0/2285)	0.0% (0/2285)
D) > 4.4-6.7	3693	0.1% (2/3693)	0.9% (34/3693)	12.6% (465/3693)	68.8% (2542/3693)	16.9% (625/3693)	0.5% (19/3693)	0.1% (4/3693)	0.1% (2/3693)	0.0% (0/3693)	0.0% (0/3693)
E) > 6.7-8.9	3532	0.0% (0/3532)	0.0% (0/3532)	0.1% (2/3532)	17.6% (622/3532)	66.3% (2342/3532)	15.3% (539/3532)	0.6% (22/3532)	0.1% (5/3532)	0.0% (0/3532)	0.0% (0/3532)
F) > 8.9-11.1	2149	0.0% (0/2149)	0.0% (0/2149)	0.0% (0/2149)	0.3% (6/2149)	15.0% (323/2149)	59.7% (1282/2149)	24.2% (521/2149)	0.7% (14/2149)	0.1% (3/2149)	0.0% (0/2149)
G) > 11.1-13.9	1678	0.0% (0/1678)	0.0% (0/1678)	0.0% (0/1678)	0.0% (0/1678)	0.7% (11/1678)	12.5% (210/1678)	63.6% (1068/1678)	21.8% (366/1678)	1.1% (19/1678)	0.2% (4/1678)
H) > 13.9-16.7	879	0.0% (0/879)	0.0% (0/879)	0.0% (0/879)	0.0% (0/879)	0.0% (0/879)	0.1% (1/879)	11.1% (98/879)	53.8% (473/879)	31.6% (278/879)	3.0% (26/879)
I) > 16.7-19.4	404	0.0% (0/404)	0.0% (0/404)	0.0% (0/404)	0.0% (0/404)	0.0% (0/404)	0.0% (0/404)	0.2% (1/404)	7.4% (30/404)	66.3% (268/404)	25.5% (103/404)
J) > 19.4-22.2	101	0.0% (0/101)	0.0% (0/101)	0.0% (0/101)	0.0% (0/101)	0.0% (0/101)	0.0% (0/101)	0.0% (0/101)	0.0% (0/101)	13.9% (14/101)	78.2% (79/101)
K) > 22.2	14	0.0% (0/14)	0.0% (0/14)	0.0% (0/14)	0.0% (0/14)	0.0% (0/14)	0.0% (0/14)	0.0% (0/14)	0.0% (0/14)	0.0% (0/14)	71.4% (10/14)

Table 35. Overall concurrence of YSI values and SG readings using SG ranges; Pediatrics (7-17 Years), Arm

Percent of matched pairs in each YSI glucose range for each SG range (mmol/L)											
SG ranges (mmol/L)	Number of paired SG-YSI	YSI glucose ranges (mmol/L)									
		< 2.8	≥ 2.8-3.3	> 3.3-4.4	> 4.4-6.7	> 6.7-8.9	> 8.9-11.1	> 11.1-13.9	> 13.9-16.7	> 16.7-19.4	> 19.4-22.2
A) < 2.8	114	36.8% (42/114)	50.9% (58/114)	12.3% (14/114)	0.0% (0/114)	0.0% (0/114)	0.0% (0/114)	0.0% (0/114)	0.0% (0/114)	0.0% (0/114)	0.0% (0/114)
B) ≥ 2.8-3.3	388	7.0% (27/388)	49.0% (190/388)	42.3% (164/388)	1.8% (7/388)	0.0% (0/388)	0.0% (0/388)	0.0% (0/388)	0.0% (0/388)	0.0% (0/388)	0.0% (0/388)

Table 35. Overall concurrence of YSI values and SG readings using SG ranges; Pediatrics (7-17 Years), Arm (continued)

Percent of matched pairs in each YSI glucose range for each SG range (mmol/L)												
SG ranges (mmol/L)	Number of paired SG-YSI	YSI glucose ranges (mmol/L)										
		< 2.8	≥ 2.8-3.3	> 3.3-4.4	> 4.4-6.7	> 6.7-8.9	> 8.9-11.1	> 11.1-13.9	> 13.9-16.7	> 16.7-19.4	> 19.4-22.2	> 22.2
C) > 3.3-4.4	1382	0.4% (5/1382)	15.6% (215/1382)	69.2% (957/1382)	14.1% (195/1382)	0.7% (9/1382)	0.0% (0/1382)	0.0% (0/1382)	0.1% (1/1382)	0.0% (0/1382)	0.0% (0/1382)	0.0%
D) > 4.4-6.7	1705	0.2% (3/1705)	0.9% (16/1705)	18.3% (312/1705)	60.5% (1031/1705)	17.8% (304/1705)	2.1% (36/1705)	0.0% (0/1705)	0.1% (1/1705)	0.1% (2/1705)	0.0% (0/1705)	0.0%
E) > 6.7-8.9	1398	0.0% (0/1398)	0.0% (0/1398)	0.4% (5/1398)	11.1% (155/1398)	62.7% (876/1398)	23.0% (322/1398)	2.2% (31/1398)	0.4% (6/1398)	0.1% (2/1398)	0.1% (1/1398)	0.0%
F) > 8.9-11.1	1170	0.0% (0/1170)	0.0% (0/1170)	0.0% (0/1170)	0.3% (4/1170)	13.3% (156/1170)	56.5% (661/1170)	27.4% (320/1170)	1.1% (13/1170)	0.9% (10/1170)	0.3% (4/1170)	0.2% (2/1170)
G) > 11.1-13.9	1020	0.0% (0/1020)	0.0% (0/1020)	0.0% (0/1020)	0.1% (1/1020)	0.7% (7/1020)	8.6% (88/1020)	62.8% (641/1020)	25.2% (257/1020)	2.5% (26/1020)	0.0% (0/1020)	0.0%
H) > 13.9-16.7	706	0.0% (0/706)	0.0% (0/706)	0.0% (0/706)	0.0% (0/706)	0.0% (0/706)	0.1% (1/706)	9.2% (65/706)	58.2% (411/706)	29.9% (211/706)	2.5% (18/706)	0.0% (0/706)
I) > 16.7-19.4	424	0.0% (0/424)	0.0% (0/424)	0.0% (0/424)	0.0% (0/424)	0.0% (0/424)	0.0% (0/424)	0.2% (1/424)	9.4% (40/424)	59.7% (253/424)	29.7% (126/424)	0.9% (4/424)
J) > 19.4-22.2	89	0.0% (0/89)	0.0% (0/89)	0.0% (0/89)	0.0% (0/89)	0.0% (0/89)	0.0% (0/89)	0.0% (0/89)	0.0% (0/89)	6.7% (6/89)	67.4% (60/89)	25.8% (23/89)
K) > 22.2	9	0.0% (0/9)	0.0% (0/9)	0.0% (0/9)	0.0% (0/9)	0.0% (0/9)	0.0% (0/9)	0.0% (0/9)	0.0% (0/9)	0.0% (0/9)	22.2% (2/9)	77.8% (7/9)

Table 36. Overall concurrence of YSI values and SG readings using SG ranges; Pediatrics (7-17 Years), Buttock

Percent of matched pairs in each YSI glucose range for each SG range (mmol/L)												
SG Ranges (mmol/L)	Number of paired SG-YSI	YSI glucose ranges (mmol/L)										
		< 2.8	≥ 2.8-3.3	> 3.3-4.4	> 4.4-6.7	> 6.7-8.9	> 8.9-11.1	> 11.1-13.9	> 13.9-16.7	> 16.7-19.4	> 19.4-22.2	> 22.2
A) < 2.8	156	25.6% (40/156)	44.9% (70/156)	26.9% (42/156)	2.6% (4/156)	0.0% (0/156)	0.0% (0/156)	0.0% (0/156)	0.0% (0/156)	0.0% (0/156)	0.0% (0/156)	0.0%
B) ≥ 2.8-3.3	398	6.5% (26/398)	42.5% (169/398)	47.7% (190/398)	3.3% (13/398)	0.0% (0/398)	0.0% (0/398)	0.0% (0/398)	0.0% (0/398)	0.0% (0/398)	0.0% (0/398)	0.0%
C) > 3.3-4.4	1106	0.6% (7/1106)	19.0% (210/1106)	68.7% (760/1106)	11.5% (127/1106)	0.2% (2/1106)	0.0% (0/1106)	0.0% (0/1106)	0.0% (0/1106)	0.0% (0/1106)	0.0% (0/1106)	0.0%
D) > 4.4-6.7	1412	0.1% (2/1412)	1.5% (21/1412)	19.7% (278/1412)	63.5% (897/1412)	14.5% (205/1412)	0.6% (8/1412)	0.1% (1/1412)	0.0% (0/1412)	0.0% (0/1412)	0.0% (0/1412)	0.0%

Table 36. Overall concurrence of YSI values and SG readings using SG ranges; Pediatrics (7-17 Years), Buttock (continued)

Percent of matched pairs in each YSI glucose range for each SG range (mmol/L)												
SG Ranges (mmol/L)	Number of paired SG-YSI	YSI glucose ranges (mmol/L)										
		< 2.8	≥ 2.8-3.3	> 3.3-4.4	> 4.4-6.7	> 6.7-8.9	> 8.9-11.1	> 11.1-13.9	> 13.9-16.7	> 16.7-19.4	> 19.4-22.2	> 22.2
E) > 6.7-8.9	1382	0.0% (0/1382)	0.1% (1/1382)	0.4% (5/1382)	13.5% (186/1382)	65.6% (907/1382)	19.1% (264/1382)	1.3% (18/1382)	0.1% (1/1382)	0.0% (0/1382)	0.0% (0/1382)	0.0%
F) > 8.9-11.1	1110	0.0% (0/1110)	0.0% (0/1110)	0.0% (0/1110)	0.2% (2/1110)	15.8% (175/1110)	61.3% (680/1110)	21.9% (243/1110)	0.7% (8/1110)	0.0% (0/1110)	0.2% (2/1110)	0.0% (0/1110)
G) > 11.1-13.9	974	0.0% (0/974)	0.0% (0/974)	0.0% (0/974)	0.1% (1/974)	0.5% (5/974)	10.2% (99/974)	67.5% (657/974)	19.4% (189/974)	2.1% (20/974)	0.2% (2/974)	0.1% (1/974)
H) > 13.9-16.7	677	0.0% (0/677)	0.0% (0/677)	0.0% (0/677)	0.0% (0/677)	0.0% (0/677)	0.4% (3/677)	12.7% (86/677)	62.9% (426/677)	22.9% (155/677)	1.0% (7/677)	0.0% (0/677)
I) > 16.7-19.4	382	0.0% (0/382)	0.0% (0/382)	0.0% (0/382)	0.0% (0/382)	0.0% (0/382)	0.0% (0/382)	0.5% (2/382)	11.0% (42/382)	63.1% (241/382)	24.6% (94/382)	0.8% (3/382)
J) > 19.4-22.2	128	0.0% (0/128)	0.0% (0/128)	0.0% (0/128)	0.0% (0/128)	0.0% (0/128)	0.0% (0/128)	0.0% (0/128)	0.8% (1/128)	18.8% (24/128)	64.8% (83/128)	15.6% (20/128)
K) > 22.2	34	0.0% (0/34)	0.0% (0/34)	0.0% (0/34)	0.0% (0/34)	0.0% (0/34)	0.0% (0/34)	0.0% (0/34)	0.0% (0/34)	0.0% (0/34)	29.4% (10/34)	70.6% (24/34)

Trend accuracy

Table 37. Trend accuracy compared to YSI over time; Adults, Arm

SG Rate Ranges (mmol/L/min)	YSI (mmol/L/min)						
	No. of Paired Points SG-YSI	< -0.111	[-0.111, -0.056]	[-0.056, 0]	[0, 0.056]	(0.056, 0.111]	> 0.111
< -0.111	201	58.2% (117/201)	33.8% (68/201)	6.5% (13/201)	1.5% (3/201)	0.0% (0/201)	0.0% (0/201)
[-0.111, -0.056]	838	7.9% (66/838)	48.8% (409/838)	40.9% (343/838)	2.3% (19/838)	0.0% (0/838)	0.1% (1/838)
[-0.056, 0]	7350	0.2% (18/7350)	4.1% (301/7350)	75.9% (5581/7350)	19.1% (1407/7350)	0.5% (35/7350)	0.1% (8/7350)
[0, 0.056]	5484	0.1% (3/5484)	0.6% (33/5484)	22.9% (1257/5484)	68.5% (3757/5484)	7.6% (416/5484)	0.3% (18/5484)
(0.056, 0.111]	1156	0.0% (0/1156)	0.1% (1/1156)	2.5% (29/1156)	31.5% (364/1156)	56.5% (653/1156)	9.4% (109/1156)
> 0.111	350	0.0% (0/350)	0.0% (0/350)	0.6% (2/350)	4.6% (16/350)	36.0% (126/350)	58.9% (206/350)

CGM readings are within 2.8-22.2 mmol/L, inclusive.

Table 38. Trend accuracy compared to YSI over time; Pediatrics (7-17 Years), Arm

SG Rate Ranges (mmol/L/min)	YSI (mmol/L/min)						
	No. of Paired Points SG-YSI	< -0.111	[-0.111, -0.056)	[-0.056, 0)	[0, 0.056]	(0.056, 0.111]	> 0.111
< -0.111	158	44.9% (71/158)	46.2% (73/158)	8.9% (14/158)	0.0% (0/158)	0.0% (0/158)	0.0% (0/158)
[-0.111, -0.056)	756	5.3% (40/756)	58.3% (441/756)	33.9% (256/756)	2.2% (17/756)	0.1% (1/756)	0.1% (1/756)
[-0.056, 0)	3507	0.5% (17/3507)	6.9% (243/3507)	74.5% (2612/3507)	17.5% (615/3507)	0.5% (19/3507)	0.0% (1/3507)
[0, 0.056]	2769	0.0% (1/2769)	1.0% (27/2769)	21.1% (584/2769)	69.2% (1915/2769)	7.9% (218/2769)	0.9% (24/2769)
(0.056, 0.111]	801	0.1% (1/801)	0.5% (4/801)	1.9% (15/801)	29.5% (236/801)	57.7% (462/801)	10.4% (83/801)
> 0.111	283	0.0% (0/283)	0.4% (1/283)	0.7% (2/283)	4.6% (13/283)	30.0% (85/283)	64.3% (182/283)

CGM readings are within 2.8-22.2 mmol/L, inclusive.

Table 39. Trend accuracy compared to YSI over time; Pediatrics (7-17 Years), Buttock

SG Rate Ranges (mmol/L/min)	YSI (mmol/L/min)						
	No. of Paired Points SG-YSI	< -0.111	[-0.111, -0.056)	[-0.056, 0)	[0, 0.056]	(0.056, 0.111]	> 0.111
< -0.111	193	43.5% (84/193)	46.6% (90/193)	8.3% (16/193)	1.6% (3/193)	0.0% (0/193)	0.0% (0/193)
[-0.111, -0.056)	720	5.0% (36/720)	56.5% (407/720)	35.1% (253/720)	2.5% (18/720)	0.6% (4/720)	0.3% (2/720)
[-0.056, 0)	3077	0.1% (4/3077)	6.7% (207/3077)	75.0% (2309/3077)	17.4% (536/3077)	0.6% (20/3077)	0.0% (1/3077)
[0, 0.056]	2536	0.2% (4/2536)	0.9% (23/2536)	22.4% (568/2536)	67.7% (1716/2536)	7.8% (198/2536)	1.1% (27/2536)
(0.056, 0.111]	750	0.1% (1/750)	0.5% (4/750)	3.1% (23/750)	32.9% (247/750)	52.4% (393/750)	10.9% (82/750)
> 0.111	284	0.0% (0/284)	0.7% (2/284)	1.4% (4/284)	6.0% (17/284)	30.6% (87/284)	61.3% (174/284)

CGM readings are within 2.8-22.2 mmol/L, inclusive.

Accuracy over time

The wear period was defined as: beginning (Elapsed day 1, 2), middle (Elapsed day 3, 4, 5), and end (Elapsed day 6, 7).

Table 40. Sensor Accuracy Compared to YSI Over Time; Adults, Arm

Wear Period	Number of paired SG-YSI	Percent of SG within 15% of YSI (%)*	Percent of SG within 20% of YSI (%)*	Percent of SG within 40% of YSI (%)*	MARD (%)
Beginning	4377	75.1	86.7	98.6	12
Middle	8207	82.4	92.5	99.7	9.5
End	2821	82.9	91.7	99.0	9.6

CGM readings are within 2.8-22.2 mmol/L, inclusive.

* For reference range < 3.9 mmol/L, agreement was based on 0.83/1.11/2.22 mmol/L.

Table 41. Sensor Accuracy Compared to YSI Over Time; Pediatrics (7-17 Years), Arm

Wear Period	Number of paired SG-YSI	Percent of SG within 15% of YSI (%)*	Percent of SG within 20% of YSI (%)*	Percent of SG within 40% of YSI (%)*	MARD (%)
Beginning	2452	70.8	84.2	98.5	13.1
Middle	4337	82.4	91.5	98.8	9.7
End	1493	83.1	89.7	98.7	10.1

CGM readings are within 2.8-22.2 mmol/L, inclusive.

* For reference range < 3.9 mmol/L, agreement was based on 0.83/1.11/2.22 mmol/L.

Table 42. Sensor Accuracy Compared to YSI Over Time; Pediatrics (7-17 Years), Buttock

Wear Period	Number of paired SG-YSI	Percent of SG within 15% of YSI (%)*	Percent of SG within 20% of YSI (%)*	Percent of SG within 40% of YSI (%)*	MARD (%)
Beginning	2271	72.1	83.7	98.8	12.5
Middle	3962	85.7	92.3	99.2	9.1
End	1336	85	93.3	99.8	8.9

CGM readings are within 2.8-22.2 mmol/L, inclusive.

* For reference range < 3.9 mmol/L, agreement was based on 0.83/1.11/2.22 mmol/L.

Reading capture rate

Table 43. Reading Capture Rate by Functional Wear Day; Adults, Arm

Functional Wear Day	Number of Sensors	Capture Rate* (%)
1	118	98.5

Table 43. Reading Capture Rate by Functional Wear Day; Adults, Arm
(continued)

Functional Wear Day	Number of Sensors	Capture Rate* (%)
2	114	99.8
3	110	99.9
4	110	99.8
5	104	99.1
6	99	97.7
7	88	96.7

* The capture rate is based on the sensor’s functional end time.

Table 44. Reading Capture Rate by Functional Wear Day; Pediatrics (7-17 Years), Arm

Functional Wear Day	Number of Sensors	Capture Rate* (%)
1	94	98.6
2	92	100
3	92	100
4	92	98.1
5	87	96.5
6	78	97.5
7	63	90.1

* The capture rate is based on the sensor’s functional end time.

Table 45. Reading Capture Rate by Functional Wear Day; Pediatrics (7-17 Years) Buttock

Functional Wear Day	Number of Sensors	Capture Rate* (%)
1	90	98
2	88	97.7
3	87	98.7
4	87	97.9

Table 45. Reading Capture Rate by Functional Wear Day; Pediatrics (7-17 Years) Buttock (continued)

Functional Wear Day	Number of Sensors	Capture Rate* (%)
5	82	97.8
6	72	91.8
7	54	94.7

* The capture rate is based on the sensor’s functional end time.

Precision

Precision of the system was evaluated by comparing the results from two separate sensors worn in the location on the same subject at the same time.

Table 46. Sensor precision

	Number of paired points	Percent Absolute Relative Difference (PARD)	Coefficient of variation (%CV)
7-17 YO Arm	9723	8.2	5.9
7-17 YO Buttock	8268	8.1	5.8
18+ YO Arm	36459	9.0	6.2

Sensor life

Adults (18-80 Years)

The mean functional sensor life for sensors worn in the arm insertion site over the course of the study was 147.8 hours, with a median functional life of 167.9 hours. 74.4% of sensors remained functional after 6 or more days.

Pediatrics (7-17 Years)

For subjects ages 7 to 17 years old, the mean functional sensor life for sensors worn in the arm insertion site over the course of the study was 146.3 hours, with a median functional life of 162.5 hours. 64.5% of sensors remained functional after 6 or more days.

For subjects ages 7 to 17 years old, 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 161.0 hours. 60.7% of sensors remained functional after 6 or more days.

Safety

Device related adverse events were limited to pain or bruising at the sensor insertion site.

Alert performance

CGM enables a device to display SG readings, glucose trend arrows, glucose trend graphs, and SG alerts, for example, High and Low Sensor Glucose alerts, High and Low Predicted alerts, and Rise and Fall alerts for rate-of-change.

The high and low SG alerts (**Threshold alerts**) let the user know when the SG is at or above the high limit or at or below the low limit. Using only a high or low Threshold 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 SG level may soon reach a high or low limit setting. Users may select how early they would like to be notified before their SG level reaches a high or low limit. The earliest warning is 60 minutes before reaching a high or low limit, but users can reduce the amount of warning down to 10 minutes. Users receive a Predictive alert when their SG level is predicted to reach their high or low limit in the Time Before High or Time Before Low setting they select. In general, the earlier the warning, the more time a user has 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 SG level compared to the high or low limit setting. If the predicted future SG value is at or above the high limit or is at or below the low limit, then a predictive alert is sounded even though the current SG level has not crossed the high or low limit. The predicted SG level is calculated using the current SG level, the derivative of current and previous SG readings (the trend or slope of the SG readings) and the Time Before High or Time Before Low duration the user selects.

The device always alerts the user with an Urgent Low glucose alert when the CGM reads that the user is at or below 3.0 mmol/L, 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 (BG) confirmed that the CGM alert was triggered correctly. For example:

- **True Threshold Hypoglycemic alert rate** is a measure of how often the CGM read that the user was at or below the low threshold and the user’s BG was actually at or below that low threshold.
- **True Threshold Hyperglycemic alert rate** is a measure of how often the CGM read that the user was at or above the high threshold and the user’s BG was actually at or above that high threshold.
- **True Predictive Hypoglycemic alert rate** is a measure of how often the CGM predicted that the user would reach or go below the low threshold and the user’s BG was actually at or below that low threshold within 15 or 30 minutes.
- **True Predictive Hyperglycemic alert rate** is a measure of how often the CGM predicted that the user would reach or go above the high threshold and the user’s BG was actually at or 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 at or below (i.e. threshold only), or predicted to reach or go below the threshold (i.e. predictive only) or both (threshold and predictive) 81.0%, 58.7%, or 66.7% of the time within 30 minutes (or 80.4%, 54.4% or 63.7% of the time within 15 minutes) when the

user had BG values at or lower than 3.9 mmol/L for a sensor inserted in the adult arm.

Table 47. Glucose TRUE Alert Performance, Adults

Glucose TRUE Alert Rate							
mmol/L	Insertion Site	Threshold Only		Predictive Only		Threshold and Predictive	
		30 min	15 min	30 min	15 min	30 min	15 min
2.8	Arm	31.8%	31.8%	21.7%	21.0%	24.2%	23.6%
3.0	Arm	51.7%	51.7%	34.5%	29.8%	38.9%	35.4%
3.3	Arm	72.2%	71.3%	50.7%	45.4%	58.1%	54.3%
3.9	Arm	81.0%	80.4%	58.7%	54.4%	66.7%	63.7%
4.4	Arm	79.4%	78.0%	56.3%	53.6%	65.0%	62.8%
5.0	Arm	75.9%	75.9%	61.7%	56.3%	67.7%	64.5%
10.0	Arm	88.5%	88.3%	63.0%	60.5%	72.5%	70.8%
12.2	Arm	89.8%	89.1%	60.8%	58.5%	71.2%	69.5%
13.9	Arm	90.1%	89.5%	57.7%	55.2%	68.5%	66.7%
16.7	Arm	95.7%	95.7%	62.0%	57.2%	72.5%	69.2%

Table 48. Glucose TRUE Alert Performance, Pediatrics (7-17 Years of Age)

Glucose TRUE Alert Rate							
mmol/L	Insertion Site	Threshold Only		Predictive Only		Threshold and Predictive	
		30 min	15 min	30 min	15 min	30 min	15 min
2.8	Buttock	48.1%	48.1%	22.9%	17.7%	28.5%	24.4%
	Arm	52.4%	52.4%	23.6%	18.0%	29.1%	24.5%
3.0	Buttock	71.0%	71.0%	30.4%	23.5%	39.0%	33.6%
	Arm	65.6%	65.6%	27.7%	24.1%	36.1%	33.3%
3.3	Buttock	85.7%	85.7%	48.9%	42.1%	58.8%	53.8%
	Arm	69.1%	69.1%	46.0%	39.6%	53.6%	49.3%
3.9	Buttock	78.7%	78.7%	58.0%	54.0%	65.3%	62.7%
	Arm	75.7%	74.8%	54.2%	50.2%	61.7%	58.8%
4.4	Buttock	78.6%	77.8%	59.8%	55.3%	67.1%	64.0%
	Arm	71.9%	71.2%	55.7%	52.7%	62.1%	60.0%
5.0	Buttock	83.3%	82.1%	65.3%	61.3%	72.9%	70.0%
	Arm	76.5%	76.0%	62.1%	59.5%	67.9%	66.1%
10.0	Buttock	88.8%	88.8%	68.9%	66.3%	76.8%	75.3%
	Arm	89.5%	89.1%	73.2%	69.8%	79.9%	77.8%
12.2	Buttock	93.2%	93.2%	67.3%	64.0%	77.0%	75.0%
	Arm	93.9%	93.4%	68.6%	65.4%	78.2%	76.0%
13.9	Buttock	91.3%	90.6%	61.3%	56.4%	72.2%	68.8%
	Arm	90.3%	89.7%	63.8%	59.0%	73.4%	70.1%
16.7	Buttock	88.1%	88.1%	52.7%	50.0%	65.2%	63.4%
	Arm	89.7%	89.7%	57.2%	55.0%	68.6%	67.1%

Glucose FALSE Alert Rate

The glucose false alert rate is the rate at which the BG did not confirm that the CGM alert was triggered correctly. For example:

- **False Threshold Hypoglycemic alert rate** is a measure of how often the CGM read that the user was at or below the low threshold, but the user’s BG was actually above that low threshold.
- **False Threshold Hyperglycemic alert rate** is a measure of how often the CGM read that the user was at or above the high threshold, but the user’s BG was actually below that high threshold.
- **False Predictive Hypoglycemic alert rate** is a measure of how often the CGM predicted that the user would be at or below the low threshold, but the user’s BG was actually above that low threshold within 15 or 30 minutes.
- **False Predictive Hyperglycemic alert rate** is a measure of how often the CGM predicted that the user would be at or above the high threshold, but the user’s BG 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 glucose is low or high so that they can correct the low or high 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 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 at or above (i.e. threshold only), or predicted to reach or go above the threshold (i.e. predictive only), or both (threshold and predictive) for adults 11.5%, 37.0% or 27.5% of the time within 30 minutes (or 11.8%, 39.5%, or 29.2% of the time within 15 minutes) when the user had a BG at or greater than 10.0 mmol/L for a sensor inserted in the arm.

Table 49. Glucose FALSE Alert Performance, Adults

Glucose FALSE Alert Rate							
mmol/L	Insertion Site	Threshold Only		Predictive Only		Threshold and Predictive	
		30 min	15 min	30 min	15 min	30 min	15 min
2.8	Arm	68.2%	68.2%	78.3%	79.0%	75.8%	76.4%

Table 49. Glucose FALSE Alert Performance, Adults (continued)

Glucose FALSE Alert Rate							
mmol/L	Insertion Site	Threshold Only		Predictive Only		Threshold and Predictive	
		30 min	15 min	30 min	15 min	30 min	15 min
3.0	Arm	48.3%	48.3%	65.5%	70.2%	61.1%	64.6%
3.3	Arm	27.8%	28.7%	49.3%	54.6%	41.9%	45.7%
3.9	Arm	19.0%	41.3%	41.3%	45.6%	33.3%	36.3%
4.4	Arm	20.6%	22.0%	43.7%	46.4%	35.0%	37.2%
5.0	Arm	24.1%	24.1%	38.3%	43.7%	32.3%	35.5%
10.0	Arm	11.5%	11.8%	37.0%	39.5%	27.5%	29.2%
12.2	Arm	10.2%	10.9%	39.2%	41.5%	28.8%	30.5%
13.9	Arm	9.9%	10.5%	42.3%	44.8%	31.5%	33.3%
16.7	Arm	4.3%	4.3%	38.0%	42.8%	27.5%	30.8%

Table 50. Glucose FALSE Alert Performance, Pediatrics (7-17 Years of Age)

Glucose FALSE Alert Rate							
mmol/L	Insertion Site	Threshold Only		Predictive Only		Threshold and Predictive	
		30 min	15 min	30 min	15 min	30 min	15 min
2.8	Buttock	51.9%	51.9%	77.1%	82.3%	71.5%	75.6%
	Arm	47.6%	47.6%	76.4%	82.0%	70.9%	75.5%
3.0	Buttock	29.0%	29.0%	69.6%	76.5%	61.0%	66.4%
	Arm	34.4%	34.4%	72.3%	75.9%	63.9%	66.7%
3.3	Buttock	14.3%	14.3%	51.1%	57.9%	41.2%	46.2%
	Arm	30.9%	30.9%	54.0%	60.4%	46.4%	50.7%
3.9	Buttock	21.3%	21.3%	42.0%	46.0%	34.7%	37.3%
	Arm	24.3%	25.2%	45.8%	49.8%	38.3%	41.2%
4.4	Buttock	21.4%	22.2%	40.2%	44.7%	32.9%	36.0%
	Arm	28.1%	28.8%	44.3%	47.3%	37.9%	40.0%
5.0	Buttock	16.7%	17.9%	34.7%	38.7%	27.1%	30.0%
	Arm	23.5%	24.0%	37.9%	40.5%	32.1%	33.9%
10.0	Buttock	11.2%	11.2%	31.1%	33.7%	23.2%	24.7%
	Arm	10.5%	10.9%	26.8%	30.2%	20.1%	22.2%
12.2	Buttock	6.8%	6.8%	32.7%	36.0%	23.0%	25.0%
	Arm	6.1%	6.6%	31.4%	34.6%	21.8%	24.0%
13.9	Buttock	8.8%	9.4%	38.7%	43.6%	27.8%	31.2%
	Arm	9.7%	10.3%	36.2%	41.0%	26.6%	29.9%
16.7	Buttock	11.9%	11.9%	47.3%	50.0%	34.8%	36.6%
	Arm	10.3%	10.3%	42.8%	45.0%	31.4%	32.9%

Glucose Correct Detection Rate

Glucose Correct Detection Rate is the rate that the device alerted when it should have alerted. For example, the BG was at or below the hypoglycemic threshold, or at or above the hyperglycemic threshold, and the device sounded a threshold or predictive alert.

The correct detection rates are important because it is necessary that users be notified when their glucose is low or high so that they can correct the low or high glucose. A high glucose correct detection rate indicates that users can have confidence that they will be notified by the device if their glucose is low or high.

For example, per the following table, the threshold alert, the predictive alert, or both (threshold and predictive) for adults notified the user 90.2%, 98.4% or 98.6% of the time within 30 minutes (or 88.3%, 95.1% or 95.8% within 15 minutes) when the user had a BG at or greater than 10.0 mmol/L for a sensor inserted in the arm.

Table 51. Glucose CORRECT DETECTION Alert Performance, Adults

Glucose CORRECT DETECTION Alert Rate							
mmol/L	Insertion Site	Threshold Only		Predictive Only		Threshold and Predictive	
		30 min	15 min	30 min	15 min	30 min	15 min
2.8	Arm	41.2%	41.2%	85.3%	85.3%	85.3%	85.3%
3.0	Arm	47.6%	47.6%	90.5%	81.0%	90.5%	81.0%
3.3	Arm	65.5%	64.7%	90.5%	81.9%	90.5%	82.8%
3.9	Arm	82.2%	82.2%	93.4%	89.5%	93.4%	91.4%
4.4	Arm	86.8%	84.9%	93.9%	91.0%	94.3%	91.0%
5.0	Arm	84.9%	84.6%	90.9%	84.6%	91.2%	88.1%
10.0	Arm	90.2%	88.3%	98.4%	95.1%	98.6%	95.8%
12.2	Arm	85.9%	85.6%	95.8%	93.3%	96.1%	94.0%
13.9	Arm	80.3%	80.3%	93.6%	90.6%	93.6%	91.6%
16.7	Arm	74.6%	73.7%	94.9%	89.0%	94.9%	89.8%

Table 52. Glucose CORRECT DETECTION Alert Performance, Pediatrics (7-17 Years of Age)

Glucose CORRECT DETECTION Rate							
mmol/L	Insertion Site	Threshold Only		Predictive Only		Threshold and Predictive	
		30 min	15 min	30 min	15 min	30 min	15 min
2.8	Buttock	52.0%	52.0%	92.0%	68.0%	92.0%	72.0%
	Arm	42.3%	42.3%	84.6%	65.4%	84.6%	65.4%
3.0	Buttock	53.5%	53.5%	88.4%	67.4%	88.4%	69.8%
	Arm	51.2%	51.2%	79.1%	67.4%	79.1%	69.8%
3.3	Buttock	57.5%	57.5%	86.3%	80.0%	86.3%	81.3%
	Arm	61.7%	59.3%	86.4%	77.8%	86.4%	80.2%
3.9	Buttock	80.4%	79.3%	96.7%	92.4%	96.7%	94.6%
	Arm	80.0%	79.0%	95.0%	92.0%	95.0%	93.0%
4.4	Buttock	91.4%	90.5%	99.1%	94.0%	99.1%	95.7%
	Arm	92.0%	91.2%	97.6%	96.0%	97.6%	96.8%
5.0	Buttock	91.0%	91.0%	96.5%	93.1%	96.5%	94.4%
	Arm	87.4%	86.8%	96.9%	93.7%	96.9%	95.6%

Table 52. Glucose CORRECT DETECTION Alert Performance, Pediatrics (7-17 Years of Age) (continued)

Glucose CORRECT DETECTION Rate							
mmol/L	Insertion Site	Threshold Only		Predictive Only		Threshold and Predictive	
		30 min	15 min	30 min	15 min	30 min	15 min
10.0	Buttock	94.4%	93.4%	98.3%	95.5%	98.3%	97.9%
	Arm	93.7%	91.7%	96.7%	93.4%	97.3%	96.7%
12.2	Buttock	92.9%	90.7%	98.7%	96.4%	98.7%	97.8%
	Arm	90.7%	89.8%	96.6%	94.9%	96.6%	95.3%
13.9	Buttock	88.3%	88.3%	95.3%	93.0%	95.9%	94.2%
	Arm	86.9%	85.8%	95.6%	94.0%	95.6%	95.1%
16.7	Buttock	91.8%	91.8%	95.9%	93.8%	95.9%	94.8%
	Arm	82.1%	81.3%	89.3%	84.8%	90.2%	88.4%

Glucose Missed Detection Rate

The Missed Detection Rate is the rate that the device did not alert when it should have. For example, the BG was at or below the hypoglycemic threshold, or at 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 glucose is low or high, so that they can correct the low or high glucose. A low missed detection rate indicates that users can have confidence that they will be notified by the device if their glucose is low or high.

For example, per the following table, the threshold alert, predictive alert, or both alerts (threshold and predictive) for adults did not sound 17.8%, 6.6% or 6.6% of the time within 30 minutes (or 17.8%, 10.5% or 8.6% within 15 minutes) when the user had a BG at or less than 3.9 mmol/L for a sensor inserted in the arm.

Table 53. Glucose MISSED Detection Performance, Adults

Glucose Missed Detection Rate							
mmol/L	Insertion Site	Threshold Only		Predictive Only		Threshold and Predictive	
		30 min	15 min	30 min	15 min	30 min	15 min
2.8	Arm	58.8%	58.8%	14.7%	14.7%	14.7%	14.7%
3.0	Arm	52.4%	52.4%	9.5%	19.0%	9.5%	19.0%
3.3	Arm	34.5%	35.3%	9.5%	18.1%	9.5%	17.2%
3.9	Arm	17.8%	17.8%	6.6%	10.5%	6.6%	8.6%
4.4	Arm	13.2%	15.1%	6.1%	9.0%	5.7%	9.0%
5.0	Arm	15.1%	15.4%	9.1%	15.4%	8.8%	11.9%

Table 53. Glucose MISSED Detection Performance, Adults (continued)

Glucose Missed Detection Rate							
mmol/L	Insertion Site	Threshold Only		Predictive Only		Threshold and Predictive	
		30 min	15 min	30 min	15 min	30 min	15 min
10.0	Arm	9.8%	11.7%	1.6%	4.9%	1.4%	4.2%
12.2	Arm	14.1%	14.4%	4.2%	6.7%	3.9%	6.0%
13.9	Arm	19.7%	19.7%	6.4%	9.4%	6.4%	8.4%
16.7	Arm	25.4%	26.3%	5.1%	11.0%	5.1%	10.2%

Table 54. Glucose MISSED Detection Performance, Pediatrics (7-17 Years of Age)

Glucose MISSED Detection Rate							
mmol/L	Insertion Site	Threshold Only		Predictive Only		Threshold and Predictive	
		30 min	15 min	30 min	15 min	30 min	15 min
2.8	Buttock	48.0%	48.0%	8.0%	32.0%	8.0%	28.0%
	Arm	57.7%	57.7%	15.4%	34.6%	15.4%	34.6%
3.0	Buttock	46.5%	46.5%	11.6%	32.6%	11.6%	30.2%
	Arm	48.8%	48.8%	20.9%	32.6%	20.9%	30.2%
3.3	Buttock	42.5%	42.5%	13.8%	20.0%	13.8%	18.8%
	Arm	38.3%	40.7%	13.6%	22.2%	13.6%	19.8%
3.9	Buttock	19.6%	20.7%	3.3%	7.6%	3.3%	5.4%
	Arm	20.0%	21.0%	5.0%	8.0%	5.0%	7.0%
4.4	Buttock	8.6%	9.5%	0.9%	6.0%	0.9%	4.3%
	Arm	8.0%	8.8%	2.4%	4.0%	2.4%	3.2%
5.0	Buttock	9.0%	9.0%	3.5%	6.9%	3.5%	5.6%
	Arm	12.6%	13.2%	3.1%	6.3%	3.1%	4.4%
10.0	Buttock	5.6%	6.6%	1.7%	4.5%	1.7%	2.1%
	Arm	6.3%	8.3%	3.3%	6.6%	2.7%	3.3%
12.2	Buttock	7.1%	9.3%	1.3%	3.6%	1.3%	2.2%
	Arm	9.3%	10.2%	3.4%	5.1%	3.4%	4.7%
13.9	Buttock	11.7%	11.7%	4.7%	7.0%	4.1%	5.8%
	Arm	13.1%	14.2%	4.4%	6.0%	4.4%	4.9%
16.7	Buttock	8.2%	8.2%	4.1%	6.2%	4.1%	5.2%
	Arm	17.9%	18.8%	10.7%	15.2%	9.8%	11.6%

Glossary

Glossary

active insulin	Active insulin is bolus insulin delivered by the insulin pump that continues to lower BG levels. Active insulin is not necessarily reflective of the pharmacokinetics and pharmacodynamics of rapid acting insulins.
active insulin time	Affects the length of time that bolus insulin is tracked as active insulin.
activity guard	An attachment that secures the reservoir during activity or when the insulin pump is worn by a child.
alarm	An audible beep or vibration with a message that requires immediate attention.
alarm history	A feature that stores information about recent alarms and alerts.
alert	An audible beep or vibration with a message to inform of a situation that may require attention.
alert before low	An alert that occurs when the low SG reading is being approached.
alert limits	The settings that determine when low and high SG alerts are triggered.
alert on low	An alert that occurs when the SG reading reaches or falls below the low limit.
auto basal	The automatically adjusted basal insulin delivered by the SmartGuard feature based on the current SG readings.
Auto correction	A correction bolus automatically delivered by the MiniMed 780G system to maximize time in range. Auto correction only occurs when using the SmartGuard feature.

auto suspend	A feature that suspends insulin delivery and triggers an alarm if no buttons are pressed for the specified period of time. Insulin delivery resumes when the alarm is cleared.
awake mode	A state in which the pump screen is on. The Home screen appears unless another screen is being used.
basal insulin	Insulin that is continuously delivered by the insulin pump to meet 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 setting for the amount of continuous basal insulin to be delivered per hour.
BG	The acronym for blood glucose. For more information, see blood glucose (BG) .
BG meter	A device that measures glucose levels in the blood.
BG targets	The high and low BG readings used for BG correction when using the Bolus Wizard feature in Manual mode.
Block mode	A feature that restricts the ability to change all settings. Certain functions can still be performed, such as suspend insulin delivery or clear alarms and alerts.
blood glucose (BG)	Glucose that is present in the blood, commonly measured by a BG meter.
bolus BG check reminder	A reminder for a BG check after programming a bolus. The reminder appears when the specified time period has passed.
bolus insulin	Insulin used to cover an expected rise in BG levels due to carbohydrates, or to lower a high BG reading down to the BG target range.
bolus speed	The delivery speed for bolus insulin.

Bolus Wizard feature	In Manual mode, a feature that uses individual Bolus Wizard settings to calculate an estimated bolus amount based on the BG value and the entered carbs. These settings include carb ratio, insulin sensitivity factor, BG target range, and active insulin time.
calibrate	The process of using a blood glucose (BG) meter reading to help the sensor glucose (SG) readings more closely match the glucose measured in your blood.
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	The acronym for continuous glucose monitoring. For more information, see continuous glucose monitoring (CGM) .
continuous glucose monitoring (CGM)	A monitoring tool that uses a glucose sensor placed below the skin to continuously measure the amount of glucose in the interstitial fluid.
correction bolus	Insulin used to lower a high BG or SG reading down to a target value.
CT scan	The acronym for computed tomography scan.
daily history	Details of the events entered or actions performed using the insulin pump.
diabetic ketoacidosis	A serious condition that occurs when insulin levels are low, BG levels are elevated, and the body uses fat for energy. This process produces ketones, which upset the acid-base balance in the body, 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 delivers a normal bolus in preset increments using sound or vibrate confirmation.
EMC	The acronym for electromagnetic compatibility.
ESD	The acronym for electrostatic discharge.
food bolus	A dose of insulin given to cover an expected rise in glucose levels from carbohydrates.
GPS	The acronym for global positioning system.
high limit	The setting the insulin pump uses to determine when to alert for a high SG condition.
infusion set	Tubing that connects to the reservoir on one end, and has a needle or cannula on the other end, that is inserted into the body. Insulin travels from the insulin pump through the infusion set into the body.
infusion site	The location on the body where the infusion set is inserted.
insulin sensitivity factor	The amount that BG is reduced by one unit of insulin. The insulin sensitivity factor is used to calculate correction bolus amounts.
insulin stacking	Occurs when a bolus is delivered while active insulin from a previous bolus is still lowering glucose levels. Insulin stacking can result in hypoglycemia.
interstitial fluid	The fluid that surrounds the cells in the body.
IV	The acronym for intravenous.
lock	A feature that prevents accidental button presses.
low limit	The setting the insulin pump uses to determine when to alert for a low SG condition and suspend insulin delivery.

Manual bolus	A feature to manually enter and deliver a dose of insulin.
Manual mode	Manual mode refers to system functions that are used when the SmartGuard feature is not active.
Max basal rate	The maximum amount of basal insulin that can be programmed by the user per hour in Manual mode.
Max bolus	The maximum bolus amount that can be programmed by the user in one dose.
meter	A term for any BG meter.
missed meal bolus reminder	A reminder when a bolus is not delivered during the specified time period, which is often around meal times.
MRI	The acronym for magnetic resonance imaging.
NiMH	The acronym for nickel-metal hydride.
normal bolus	A type of bolus that provides an entire dose of insulin immediately.
notifications	All notifications are designed to get 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 the insulin pump is fully functional, but the screen goes dark to save power.
preset bolus	A feature to set up and save a bolus for specific meals or snacks that are frequently consumed.
preset temp basal	A feature to set up and save temporary basal rates for repeated use.
reminder	A type of notification to help remember an action.

reservoir	The small container that is filled with insulin and inserted into the insulin pump.
Resume basal alert	An alert that occurs when the insulin pump has automatically resumed basal insulin delivery after a Suspend before low or Suspend on low event because the SG readings have met the necessary criteria. This alert always occurs if basal insulin delivery has resumed because the two-hour maximum suspend time has elapsed.
rewind	A feature that returns the piston to its start position to place a new reservoir into the insulin pump.
RF	The acronym for radio frequency.
rise alert	An alert that occurs if the SG reading is rising rapidly.
sensitivity	For more information, see insulin sensitivity factor .
sensor (glucose sensor)	The small part of the CGM system that is inserted just below the skin to measure glucose levels in the interstitial fluid and collect the sensor data. The sensor wirelessly sends the collected sensor data to the pump or other compatible mobile device.
sensor glucose (SG)	Glucose that is present in the interstitial fluid and is measured by a glucose sensor.
set change reminder	A reminder to change the infusion set.
SG	The acronym for sensor glucose. For more information, see sensor glucose (SG) .
Sleep mode	A state in which the insulin pump is fully functional, but the screen is dark. The insulin pump automatically enters Sleep mode when no buttons are pressed for about two minutes.

SmartGuard bolus feature	A feature that assists to calculate a recommended bolus amount based on optional carbohydrate intake and optional BG or SG measurement. One or both of the two optional values may be entered.
SmartGuard feature	An insulin delivery feature that automatically controls basal insulin delivery to regulate BG levels to a target SG value.
SN	The acronym for serial number.
Square Wave bolus	A bolus delivered evenly over the specified time period.
suspend	Suspend features include the Suspend before low feature and the Suspend on low feature.
Suspend before low	A feature that suspends insulin delivery when the sensor predicts the SG reading is approaching the low limit.
suspend delivery	A feature that stops all insulin delivery until it is resumed. Only the basal insulin restarts when delivery is resumed.
Suspend on low	A feature that suspends insulin delivery when the SG reading reaches or falls below the low limit.
TDD	The acronym for total daily dose.
temp basal rate (temporary basal rate)	A feature that temporarily increases or decreases the current basal rate for the specified duration of time.
transfer guard	The plastic piece that comes attached to the reservoir. It is used to connect the reservoir to the insulin vial while the reservoir fills with insulin.

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