ONETOUCH Vibe™ *Plus*

Insulin Pump and CGM System

Actual Size

Owner's booklet

Get to know your system

Dexcom | G5® mobile

Welcome

Thank you for choosing OneTouch Vibe™ Plus. Your OneTouch Vibe™ Plus System can play an integral part in the glucose management and continuous insulin delivery regimen that you have established with your health care professional (HCP).

Your OneTouch Vibe™ Plus System is comprised of an OneTouch Vibe™ Plus Insulin Pump that delivers insulin, and a separate Dexcom G5® Sensor and Transmitter that obtain glucose readings from below your skin every five minutes. Glucose readings are sent wirelessly to the pump display where you are alerted if your readings are trending low or high, and can be used to help you make decisions for managing your diabetes. The frequent measuring of glucose levels from below the skin is called continuous glucose monitoring, or CGM for short.

Your Owner's Booklet will provide you with a thorough understanding of OneTouch Vibe™ Plus and how to get the most from it. The Owner's Booklet is designed to provide the information that you are looking for when you need it, and is organized in an easy-to-find style that places the information at your fingertips. Visit www.onetouch.com to find additional information about educational programs in your area and other information about diabetes management.

Your Owner's Booklet is organized into 3 main sections. The introduction section provides important information before you begin using the System. *Section I* covers instructions for using the OneTouch Vibe™ Plus Insulin Pump. *Section II* covers instructions for using the Dexcom G5® Sensor and Transmitter with your pump.

Of course, you may still have questions. If you do, Customer Service at 1 877 937-7867 will be happy to answer your call.

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SECTION II DEXCOM G5® MOBILE CGM SYSTEM

Check with your HCP regarding your individual training needs. **DO NOT** attempt to connect to your pump before you have been trained on your pump.

As part of your training, your HCP will assist you in making the appropriate selections for your insulin pump and continuous glucose monitoring (CGM) settings. Your insulin pump must be programmed for your own personal use as your insulin pump settings impact the calculations for proper insulin delivery. Users should be familiar with the insulin delivery features of the pump (basal and bolus delivery and the suspend/resume feature), as described in *Section I* of your Owner's Booklet before you begin using the continuous glucose monitoring (CGM) features on your pump.

Reading the Owner's Booklet and viewing information on the System display

- Take special note of Warnings and Precautions, along with Safety Information throughout the Owner's Booklet, which are identified with ⚠.
- Refer to *Chapter 11 Section I*, and *Chapter 10 Section II*, for information on warnings, alarms, and alerts that sound/display on the OneTouch Vibe™ Plus System.
- Display screens throughout the Owner's Booklet are examples only. They should not be considered suggestions for individual programming and may not be representative of your current health status.
- The System uses a color display screen, however display screens throughout the Owner's Booklet are always shown in black and white.
- Your OneTouch Vibe™ Plus System consists of an OneTouch Vibe™ Plus Insulin Pump that provides continuous insulin delivery, and a Dexcom G5® Sensor and Transmitter, which provide continuous glucose monitoring (CGM). Throughout the Owner's Booklet there are references to the individual devices that make up the System. For simplicity, the OneTouch Vibe™ Plus Insulin Pump will often be referred to as "your Pump". The Dexcom G5® Sensor will often be referred to as "your Sensor". The Dexcom G5® Transmitter will often be referred to as "your Transmitter".
- "HCP" refers to any health care professional that you may be in contact with regarding your diabetes and its treatment. This includes doctors and nurses.

- "Blood Glucose" is often abbreviated as "BG" on the pump display, and throughout the Owner's Booklet. Blood glucose is the amount of glucose (or sugar) in your blood.
- "Continuous Glucose Monitoring" is often abbreviated as "CGM" on the pump display and throughout the Owner's Booklet. CGM is the ongoing measurement of glucose from fluid below your skin (called interstitial fluid). The level of glucose in your blood (as measured by a fingerstick test taken with a BG meter) may differ from the level of glucose in your interstitial fluid (as measured by CGM).
- "Bolus stacking" refers to programming/delivering a bolus dose before a previous bolus has finished working. This can lead to hypoglycemia.
- "Insulin on Board" will often appear in an abbreviated form as "IOB" on the pump display and throughout the Owner's Booklet. Insulin on Board is a feature on your pump that keeps track of how much insulin may still be left in your body from a previous bolus. Accounting for any Insulin on Board can help you calculate the right insulin amount when it is time to deliver another bolus and prevent an overcorrection from "bolus stacking".
- "Insulin to Carb" ratio is often abbreviated as "I:C" ratio on the pump display and throughout the Owner's Booklet. Your Insulin to Carb Ratio is how many carbohydrates you can cover with 1 unit of insulin.
- "Insulin Sensitivity Factor" is often abbreviated as "ISF" on the pump display and throughout the Owner's Booklet. Your Insulin Sensitivity Factor is how much you can reduce your blood glucose with 1 unit of insulin.
- "Carbohydrates" is often abbreviated as "carbs" on the pump display and throughout the Owner's Booklet. Foods that contain carbohydrates raise blood glucose. You will need to know how many carbohydrates are in the foods you eat to make accurate decisions on how much insulin to bolus to cover meals or snacks.
- "ezBG" appears on the pump display and throughout the Owner's Booklet. ezBG is a pump feature that lets you calculate a suggested bolus amount to cover a high blood glucose.
- "ezCarb" appears on the pump display and throughout the Owner's Booklet. ezCarb is a pump feature that lets you calculate a suggested bolus amount to cover the carbohydrates in a meal or snack.

- "ezBolus" appears throughout the Owner's Booklet. ezBolus is a pump feature that lets you use the Audio Bolus button as a shortcut to deliver a Normal Bolus. This lets you bypass all the pump screens you would normally use to deliver a Normal Bolus and is only operational if the Audio Bolus feature is turned OFF.
- When "fingerstick" appears on the pump display and throughout the Owner's Booklet, it refers to glucose values obtained with a BG meter using a fingertip blood sample. Fingerstick tests give a different type of glucose measurement than the glucose readings provided by the System, and are necessary to calibrate the System.
- All mentions of screen displays, menus, buttons, etc. in *Section II* refer to the OneTouch Vibe™ Plus Insulin Pump unless specifically stated otherwise.
- *Bluetooth®* Smart is abbreviated to BLE throughout the Owner's Booklet.

Intended Use of System

The OneTouch Vibe™ Plus System consists of the OneTouch Vibe™ Plus Insulin Pump paired with the Dexcom G5® Sensor and Transmitter.

The OneTouch Vibe™ Plus Insulin Pump is indicated for continuous subcutaneous insulin infusion for the management of insulin-requiring diabetes. It can be used solely for continuous insulin delivery and as part of the OneTouch Vibe™ Plus System to receive and display continuous glucose measurements from the Dexcom G5® Sensor and Transmitter.

The OneTouch Vibe™ Plus System's continuous glucose monitoring (CGM) is indicated for detecting trends and tracking patterns in persons **(age 2 and older)** with diabetes, and is intended to complement, not replace, information obtained from standard home glucose monitoring devices. CGM aids in the detection of episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments, which may minimize these excursions. Interpretation of results from the Dexcom G5® Sensor and Transmitter should be based on the trends and patterns seen with several sequential readings over time.

The System is intended for single patient use and requires a prescription.

Pediatric Use (2-17 years old)

Consider the following for pediatric use of the OneTouch Vibe™ Plus System.

Younger Children (2-7 years old)	Older Children (8-17 years old)
• Younger children may inadvertently press the pump buttons and deliver insulin, which can lead to hypoglycemic events. For younger children, enable the auto-lock feature on the pump. The pump will lock when the pump enters into sleep mode to prevent inadvertent button pushing. Adults may unlock the pump as needed. *To unlock the pump:* wake up your pump and press and hold the ▲ and ▼ buttons at the same time until the screen is unlocked. • Inadvertent dislodgement of the insulin tubing from the infusion site may occur more frequently with children. Consider adequately securing the infusion site and tubing. • Securing the pump in either a tamper resistant case or beyond the reach of the child may help prevent tampering and inadvertent button pushing by the child.	• The lock feature may be used to prevent inadvertent delivery of insulin. *To lock the pump:* wake up your pump and press and hold the ▲ and ▼ buttons at the same time until the screen reads "(LOCKED)". *To unlock the pump:* wake up your pump and press and hold the ▲ and ▼ buttons at the same time until the screen is unlocked. • We recommend adult supervision with any handling of the pump. • Be aware that the Insulin on Board feature reverts to 0 during a pump battery change.

Younger Children (2-7 years old)	Older Children (8-17 years old)
• Minimum dosing of the OneTouch Vibe™ Plus System ◦ Basal 0.025 units ± 5% ◦ Bolus 0.05 units ± 5% • Be aware that the Insulin on Board feature reverts to 0 during a pump battery change. • Be aware to achieve optimum performance and battery longevity we recommend an Energizer® Lithium L91 AA battery (1.5V). Use of other batteries may affect the timing of the Low Battery Warning message and Replace Battery alarm notifications. When an Energizer® Lithium L91 AA battery (1.5V) is used, the Low Battery Warning message will be displayed for a minimum of 30 minutes before the battery is empty and the Replace Battery alarm will sound/display a minimum of 3 minutes before the battery is empty.	• Be aware to achieve optimum performance and battery longevity we recommend an Energizer® Lithium L91 AA battery (1.5V). Use of other batteries may affect the timing of the Low Battery Warning message and Replace Battery alarm notifications. When an Energizer® Lithium L91 AA battery (1.5V) is used, the Low Battery Warning message will be displayed a minimum of 30 minutes before the battery is empty and the Replace Battery alarm will sound/display a minimum of 3 minutes before the battery is empty.

Refer to the *Caregiver Warnings* in this section for more information.

Description of System

The OneTouch Vibe™ Plus System consists of the OneTouch Vibe™ Plus Insulin Pump and the Dexcom G5® Sensor and Transmitter. The pump is used to deliver insulin continuously throughout the day and night (basal insulin), and to deliver a single amount (bolus insulin) at meal times to cover carbs in the foods you eat. Bolus insulin is also used to lower a high BG. An insulin cartridge up to 200 units of insulin is inserted into the pump. The pump connects to your body with a disposable infusion set that you replace every few days when you refill the pump cartridge with insulin.

The Dexcom G5® Sensor and Transmitter automatically collect glucose readings every 5 minutes from fluid below your skin. The Sensor sits below your skin and is connected to the Transmitter. Readings are sent wirelessly to the pump display where you are alerted if your glucose readings are trending low or high, and can be used to help you make decisions for managing your diabetes.

While using the OneTouch Vibe™ Plus System, you will continue to use a BG meter to obtain periodic glucose test results from a blood sample from your fingertips. Measurements from a BG meter are used to calibrate the OneTouch Vibe™ Plus System on a regular basis, to help ensure the accuracy of glucose readings from the Dexcom G5® Sensor and Transmitter.

The OneTouch Vibe™ Plus Insulin Pump may be used with or without the Dexcom G5® Sensor and Transmitter. If the Dexcom G5® Sensor and Transmitter are not used, you will not be able to automatically collect and receive glucose readings every 5 minutes from fluid below your skin. You can simply use the pump for insulin delivery.

Potential benefits from using the OneTouch Vibe™ Plus System

- Your OneTouch Vibe™ Plus Insulin Pump provides an automated way to deliver basal and bolus insulin. The pump also provides an automated way to store personal diabetes and insulin health profile data that you can use to fine tune insulin delivery. This includes being able to store up to 12 ISFs, 12 I:C Ratios and 12 BG Targets, for different times of the day. Up to 4 basal programs can be stored in the pump to meet varying daily insulin needs. You can always use the TEMP Basal feature on your pump to temporarily adjust basal rates for a selected period of time.
- When delivering a bolus on your OneTouch Vibe™ Plus Insulin Pump, you have the option to deliver it all at once (Normal Bolus), or program the pump to deliver some initially and the rest later (Combo Bolus). You can even adjust the speed of bolus insulin delivery. A built-in bolus calculator feature helps you calculate the right bolus amount for any situation.
- The calculator feature on your OneTouch Vibe™ Plus Insulin Pump helps take the guesswork out of calculating the right bolus amount to cover carbs (ezCarb Bolus) or to lower a high BG (ezBG Bolus). A pre-programmed Food Database in the pump gives you access to carb amounts for many common foods when using the calculator feature.
- The IOB feature on your pump automatically keeps track of insulin that may still be in your body from a previous bolus and factors that amount in when using the calculator feature. This helps prevent stacking of boluses and can stop you from bolusing too much insulin.
- Several safety features are built into the OneTouch Vibe™ Plus Insulin Pump such as a notification if you exceed the basal or bolus insulin limits that you set. You can set personal reminders on the pump for you to check your BG, and also to store specific guidelines on sick days. If needed, the Suspend feature lets you stop all insulin delivery while still allowing you to stay connected to the pump.
- Your OneTouch Vibe™ Plus Insulin Pump automatically stores specific insulin and pump profile data. This includes records of bolus delivery, changes in basal rates, how many times you suspended insulin delivery, and pump priming. You can access these records at any time.

Potential benefits from using the OneTouch Vibe™ Plus System *(continued)*

- When you enable CGM on your OneTouch Vibe™ Plus System, you will be able to continuously monitor your glucose levels measured from fluid below your skin (interstitial fluid). CGM Sensor readings are continually displayed on your pump. When you are unable to test and track your BG with a BG meter, such as when sleeping, CGM provides a way to keep track of glucose levels. CGM will let you know if your CGM Sensor readings are holding steady, or trending low or high. CGM is designed to complement regular testing of your BG with a BG meter and does not replace regular BG testing. If CGM Sensor readings are not consistent with the way you feel or they are trending high or low, you should test your BG with a BG meter and use that value to make any necessary treatment decisions. With pump and CGM integration you will be able to review therapy decisions and how those decision impacted your CGM Sensor reading to learn and better manage your diabetes.

Contraindications for using the OneTouch Vibe™ Plus Insulin Pump

Insulin pump therapy is not recommended for people with diabetes who are unwilling or unable to:

- Test their BG levels four to six times per day or as recommended by their HCP.
- See their HCP regularly.
- Respond to pump alerts, warnings, and alarms because they are visually or hearing impaired.

Not following these guidelines will make it difficult for you to determine the proper amount of insulin you need based on your current health status and the foods you eat. Not seeing your HCP on a regular basis will not allow them to make proper adjustments to your pump settings and diabetes treatment plan that would be beneficial to your health. Not being able to respond to pump notifications means you may not be aware of certain health conditions or problems with your pump that require your attention.

Contraindications for using the Dexcom G5® Sensor and Transmitter

Contraindications let you know when not to use the Dexcom G5® Transmitter and Sensor; you may hurt yourself or damage the system.

- MRI/CT/Diathermy: Remove the Dexcom G5® Sensor and Transmitter before Magnetic Resonance Imaging (MRI), Computed Tomography (CT) scan, or high-frequency electrical heat (diathermy) treatment. The Dexcom G5® Sensor and Transmitter have not been tested during MRI or CT scans or with diathermy treatment. The magnetic fields and heat could damage the Sensor and Transmitter, which may cause it to display inaccurate glucose readings or may prevent alerts.
- Medications: Taking medications with acetaminophen while wearing the Sensor may falsely raise your Sensor glucose readings. The level of inaccuracy depends on the amount of acetaminophen active in your body and is different for each person.
- The pump and any type of metallic infusion set must be removed prior to an MRI, and left outside the room during the procedure.

Possible risks associated with using the OneTouch Vibe™ Plus System

As with any medical device, there are risks associated with using the OneTouch Vibe™ Plus System. While some of the risks are the same as with multiple daily injections of insulin, there are additional risks associated with continuous insulin delivery and continuous glucose monitoring. Review these risks with your HCP before you begin using the OneTouch Vibe™ Plus System.

- Not reading the Owner's Booklet or following the *Instructions for Use* poses a major risk for using the OneTouch Vibe™ Plus System. It is important to follow the proper procedures for setting up and using your System. Not following the proper procedures can lead to user error and result in serious injury to your health, or damage to the System.
- Other risks associated with OneTouch Vibe™ Plus System include the possible dangers of over and under delivery of insulin. Over delivery of insulin can result in very low BG levels (hypoglycemia). Under delivery of insulin can result in very high BG levels (hyperglycemia). Over or under delivery of insulin may be caused by problems with the pump or problems with the infusion set. It may also be the result of a malfunction or user not making the proper decisions on the quantity of insulin to take.

Possible risks associated with using the OneTouch Vibe™ Plus System *(continued)*

- Any malfunction or damage to the System can result in over or under delivery of insulin. It can also leave the user without any primary means of delivering insulin. Make sure to follow the safety information throughout the Owner's Booklet, such as what to do with your System when undergoing certain medical procedures.
- Risks associated with infusion sets include occlusions or air bubbles in the tubing which can affect the delivery of insulin. Bruising and infection may also occur at the infusion site.
- If you enable CGM on your OneTouch Vibe™ Plus System, there is a risk of relying on CGM Sensor readings for making treatment decisions. CGM Sensor readings from interstitial fluid are different than BG values from a BG meter and should not be used for making treatment decisions, specifically regarding the quantity of insulin to take. Relying on CGM Sensor readings for treatment decisions may result in over or under delivery of insulin. There is also a risk of bruising or infection at the Sensor insertion site.
- Refer to the Warnings and Precautions in the *Before You Begin* section for information on risks associated with infusion set and Sensor insertion sites. For risks associated with diabetic ketoacidosis (DKA) such as nausea and vomiting, refer to the *Diabetic Ketoacidosis (DKA)* section in *Chapter 15 Section I*.

Insulin

Your OneTouch Vibe™ Plus Insulin Pump is designed and calibrated to deliver U100 rapid-acting insulin. The following rapid-acting insulins have been tested by Animas® and found to be safe for use in the System: Humalog® and NovoLog®. The use of any other insulin with your System has not been tested.

NOTE: **DO NOT** exceed the insulin manufacturer's recommended temperature and humidity ranges when operating the OneTouch Vibe™ Plus Insulin Pump.

Wireless Co-existence, Quality of Service (QoS), and Data Security

Your OneTouch Vibe™ Plus System is designed to work safely and effectively in the presence of nearby wireless devices, and will not affect their performance. The OneTouch Vibe™ Plus System is designed to communicate only with the Dexcom G5® Transmitter via *Bluetooth®* Smart capabilities. See *Chapter 13 Section II* for complete information.

Electromagnetic and electrostatic interference

Your OneTouch Vibe™ Plus Insulin Pump has been designed to operate in the presence of common sources of electrostatic and electromagnetic interference, such as store security systems. However, your pump should not be exposed to very strong electromagnetic fields, such as Magnetic Resonance Imaging (MRI), Radiofrequency (RF) welders, magnets used to lift automobiles, and some "free-fall" amusement park rides. Very strong magnetic fields, such as those in an MRI, can damage the System.

Environmental conditions and factors

Your System is designed to work safely and effectively when used within the operating guidelines covered in the Owner's Booklet. These include the temperature, humidity, altitude and air pressure limitations noted in the *Technical Specifications* sections in *Chapter 17 Section I* and *Chapter 13 Section II*. Some environmental factors such as high gravity forces (e.g., when riding a roller coaster) or flying in aircraft without cabin pressurization can interfere with insulin delivery but will not damage the pump. Other environmental factors such as entering an area where there might be explosive gases can damage the pump. The Owner's Booklet will provide information on those known environmental conditions and factors that can impact the safety and performance of the System. If you are unsure of a certain environmental condition or factor that may impact the System or your health, please contact your HCP and/or Customer Service.

⚠ Important Safety Information about your OneTouch Vibe™ Plus System

Carefully read all Contraindications, Warnings and Precautions before using your OneTouch Vibe™ Plus Insulin System. If you do not understand something or have any questions, please consult your HCP and/or Customer Service.

⚠ **CAUTION:** There are risks inherent in using a pump and Sensor. Refer to the possible risks earlier in this section if you experience any rash, swelling, redness, infection, bruising, or irritation around the infusion site or Sensor insertion site. Refer to *Chapter 15 Section I*, if you experience any fever, vomiting, nausea, or other discomfort. If such conditions persist, you should contact your HCP.

⚠ Warnings – OneTouch Vibe™ Plus Insulin Pump

Warnings are potential hazards that can damage the device, can cause over or under delivery of insulin, or create other situations that can result in serious injury to your health, including death.

⚠ **WARNINGS**

- **DO NOT** begin using your pump until you have read the Owner's Booklet. Not following the instructions or troubleshooting techniques can damage the pump and/or result in over or under delivery of insulin. This could lead to very low (hypoglycemia) or very high (hyperglycemia) BG levels.
- **CHECK** with your HCP regarding your individual training needs. **DO NOT** attempt to connect to your pump before you have been trained on your pump. Failure to consult with your HCP or using your pump without the necessary training could result in serious injury or death.
- **DO NOT** use any other insulin with your pump other than the U100 rapid-acting insulins (Humalog® or NovoLog®) listed in the Owner's Booklet. Use of incorrect insulin, or insulin with a greater or lesser concentration, may result in over or under delivery of insulin. This could lead to very low (hypoglycemia) or very high (hyperglycemia) BG levels. Very high BG levels may also lead to diabetic ketoacidosis (DKA).
- **DO NOT** put any other medication or substance inside the pump. The pump is only indicated for use with rapid-acting insulin. The use of other medications or substances can damage the pump, and result in injury if infused.

⚠ **WARNINGS** *(continued)*

- **ALWAYS** have an alternative method of administering insulin if delivery is interrupted on your pump for any reason. Because this pump uses only rapid-acting insulin, you will not have any long-acting insulin in your body. To avoid the risk of a very high BG level or a build up of ketones in the blood (ketoacidosis), you must be prepared to give yourself an injection of insulin.
- **DO NOT** allow small children (either pump users or non-users) to come in contact with or ingest small pump, sensor, or transmitter component pieces. Small component pieces could pose a choking hazard. If ingested or swallowed, these small component pieces may cause internal injury or infection. For example, the batteries alone contain chemicals that may be especially harmful to children.
- **DO NOT** begin using the pump until your HCP has confirmed certain pump settings and Advanced Features on your pump that are correct for you. Many personal settings for the pump, such as your Basal Rates, Insulin to Carb (I:C) ratios, Insulin Sensitivity Factors (ISF), BG Targets, and Insulin on Board (IOB) duration, should be determined only with input from your HCP. Advanced Features, such as Extended Bolus, Combo Bolus, Insulin on Board, and the Carb and BG Bolus Calculators, require a greater knowledge of insulin pumping and advanced self-care skills, with input from your HCP. Failure to have the correct settings or not following the Advanced Features instructions can result in over or under delivery of insulin.
- **DO NOT** program or deliver a bolus on your pump unless you know how much insulin may be remaining from a previous bolus. Delivering a new bolus on top of a previous bolus is called “bolus stacking”. Bolus stacking can result in over delivery of insulin, which can lead to serious injury or death. Discuss bolus stacking with your HCP before you begin using the bolus features on your pump.
- **ALWAYS** review changes in your pump settings with your HCP to make sure they are correct. Incorrect settings can result in under delivery or over delivery of insulin.
- **DO NOT** reuse cartridges or infusion sets. They should be discarded after each use to avoid contamination or infection. **ALWAYS** discard used cartridges and infusion sets according to local regulations for the safe disposal of medical waste. Contact your HCP or local waste collection agency for more information. Failure to follow these guidelines can pose health hazards.

⚠ **WARNINGS** *(continued)*

- **DO NOT** deliver a suggested bolus amount based on the bolus calculator if you have already administered a manual injection by syringe or pen. The bolus calculator does not account for insulin amounts from manual injections and could prompt more insulin to be delivered than needed, and result in hypoglycemia. Contact your HCP to know how long to wait after administering a manual injection before relying on the bolus calculator.
- **DO NOT** deliver a "suggested" bolus amount from bolus calculations on your pump until you have reviewed the amount on the pump display. If you dose an insulin amount that is too high or too low, this could lead to a very low (hypoglycemia) or very high (hyperglycemia) BG level. You can always adjust the insulin units up or down before you decide to administer your bolus. Discuss the bolus calculator feature and all relevant personal settings with your HCP before using the calculator for the first time.
- **NEVER** start any part of the Prime/Rewind sequence on your pump while the infusion set is connected to your body. Always disconnect before you begin the sequence. The Prime/Rewind sequence includes steps for rewinding the pump motor, loading an insulin cartridge, and priming the infusion set tubing. Failure to disconnect your infusion set from your body before performing these steps can result in over delivery of insulin. If your pump sustains internal damage, the amount of unintended insulin delivery could be significant. This could result in serious injury or death from hypoglycemia.
- **NEVER** tighten the cartridge cap when your infusion set is attached to your body. Tightening the cartridge cap while your infusion set is attached to your body may disrupt the flow of insulin through the tubing that is threaded through the cap.
- **MAKE SURE** to twist the Luer connector an extra quarter of a turn to ensure a secure connection between the cartridge and infusion set tubing. If the connection is not secure, insulin may leak around the cartridge, resulting in under delivery of insulin.
- **CHECK** the battery cap vent and primary vent below the cartridge cap to make sure they are not clogged whenever you replace the battery, cartridge or infusion set. **DO NOT** use the pump if the vents are clogged. The vents allow air to flow in and out of the pump, and have a membrane on the inside that helps keep your pump waterproof. Remove any debris from the vents using your fingers and a soft cloth.

⚠ **WARNINGS** *(continued)*

- **DO NOT** remove the Audio Bolus/ezBolus™ button from the right side of your pump. Removing the button can damage the pump, compromise the waterproof feature of your pump, and result in over or under delivery of insulin. This can lead to very low (hypoglycemia) or very high (hyperglycemia) BG levels.
- **DO NOT** use a sharp object to clean the vents or you may puncture the vents/membrane and compromise the waterproof feature of your pump. Replace the battery cap if you are unable to remove the debris from the battery cap vent. See *Chapter 12 Section I*.
- **DO NOT** use excessive force to tighten the battery cap. This can cause your pump case to crack. Cracks, chips, or damage to your pump can impact the battery contact/and or waterproof feature of your pump.
- **DO NOT** use any batteries in your pump other than what is recommended in this Owner's Booklet. Other batteries do not have the necessary characteristics to power your pump, and can damage the pump and/or result in over or under delivery of insulin. This can lead to very low (hypoglycemia) or very high (hyperglycemia) BG levels. Use of other batteries may void the pump warranty and can damage the device. See *Chapter 3 Section I*.
- **AVOID** infusion sites on skin areas with tattoos, or areas with rough patches or scarring from your pump or insulin injections. These skin areas can cause redness, irritation, swelling, infection, and will interfere with the intended amount of insulin delivery.
- **DO NOT** expose the pump to very strong electromagnetic fields. **ALWAYS** remove the pump before entering an area where there are very strong magnets. If you plan to undergo an MRI, remove your pump and keep it outside the room during the procedure. These types of energy fields can damage the System and lead to over or under delivery of insulin. This could lead to very low (hypoglycemia) or very high (hyperglycemia) BG levels.
- **DO NOT** expose the pump to any medical procedure that involves the use of energy fields (for example, ionizing radiation or magnetic radiation). **ALWAYS** remove the OneTouch Vibe™ Plus System (pump, Sensor and Transmitter) before entering the room where one of these procedures will be performed. These types of energy fields can damage the System and lead to over or under delivery of insulin. This could lead to very low (hypoglycemia) or very high (hyperglycemia) BG levels.

⚠ **WARNINGS** *(continued)*

Caregivers are responsible for helping to ensure safe and effective delivery of insulin to people in their care. To assist Caregivers, there are a number of safety features on the OneTouch Vibe™ Plus System to help prevent injury to those receiving insulin therapy.

- **ENABLE** the auto-lock feature to avoid inadvertent button pushes that may lead to hypoglycemic events.
- **CHECK** to ensure that maximum insulin delivery limits in the pump have been set. Contact the HCP to determine the appropriate limits for basal rate, and bolus, over a 2-hour period and over a 24-hour period.
- **DISABLE** the Audio Bolus feature to prevent an inadvertent bolus delivery.
- **SET** high and low CGM Warnings to receive notifications when CGM Sensor readings fall out of range or when CGM Sensor readings are rising or falling faster than the limits you set in the pump. Contact the HCP to determine appropriate CGM Warning settings.
- **CONFIRM** audio Alerts, Warnings, and Alarm volume settings are appropriately set so any notifications will be heard and can be addressed.
- **ALWAYS** lock the pump when not in use to avoid inadvertent button presses that may lead to inadvertent bolus delivery or a change to pump settings that may affect insulin delivery.
- **IT IS RECOMMENDED** for patients ages 7 and under to use a tamper resistant case that shields the buttons from accidental button pushing that can lead to incorrect insulin delivery.
- **CONTINUE** to reinforce with children the proper use of the pump and associated risks.

⚠ The OneTouch Vibe™ Plus System and Medical Procedures

The following warnings cover the pump, Transmitter/Sensor, infusion sets, and also apply to the patient and/or HCP administering the procedure.

Medical Procedure	Warnings
• CARDIAC CATHETERIZATION • CT SCANS • ELECTRO-CAUTERY • MRI • NUCLEAR STRESS TEST (myocardial perfusion imaging) • PACEMAKER/AICD Reprogramming • THERAPEUTIC RADIATION/ ONCOLOGY (cancer treatment radiation) • X-RAY, DENTAL • X-RAY, MAMMOGRAM • DIATHERMY	• **DO NOT** bring pump or Transmitter/Sensor into the same room where the procedure is being performed. • Teflon/plastic infusion set can remain in, as long as the pump is disconnected and removed. Other types of infusion sets must be removed.

The pump, infusion set and Transmitter/Sensor can remain on/in during these medical procedures:

- COLONOSCOPY
- EKG
- LASER SURGERY
- ULTRASOUND

Medical Procedure	Warnings
• X-RAY, BODY FLUOROSCOPY (chest, neck, abdomen, torso, etc.)	• **DO NOT** bring pump or Transmitter/Sensor into the same room where the procedure is being performed, unless a lead apron that completely covers pump is worn during the procedure. The person administering the procedure (if they are wearing a pump) must proceed to a designated safety area during the procedure. • Teflon/plastic infusion set can remain in, as long as the pump is disconnected and removed. Other types of infusion sets must be removed.
• X-RAY, BONE DENSITOMETRY	• **DO NOT** bring pump or Transmitter/Sensor into the same room where the procedure is being performed, unless a lead apron that completely covers pump and Transmitter is worn during the procedure. The person administering the procedure (if they are wearing a pump or Transmitter) must proceed to a designated safety area during the procedure. • Teflon/plastic infusion set can remain in, as long as the pump is disconnected and removed. Other types of infusion sets must be removed.

⚠ Precautions – OneTouch Vibe™ Plus Insulin Pump

Precautions indicate potential hazards that can damage the device and cause moderate to mild injury to your health.

⚠ PRECAUTIONS

- **DO NOT** open the pump other than to replace the battery or insulin cartridge. Your pump is a sealed device that should be opened ONLY by the manufacturer. If your pump seal is broken by anyone other than an authorized Animas® factory technician, or if the back label on your pump is removed, your pump is no longer waterproof and the warranty is voided.
- **DO NOT** place your pump more than 12 vertical inches (30 centimeters) above your infusion site, as it may lead to over delivery of insulin. If you place your pump within 12 vertical inches (30 centimeters) of the infusion site, or at a vertically lower position than the infusion site, this condition is eliminated.
- **CHECK** the infusion site daily for proper placement, air bubbles and leaks. **DO NOT** use an infusion set that is not properly placed, has air bubbles or has leaks. Improperly placed infusion sites, air bubbles or leaks can result in under delivery of insulin.
- **CHECK** the infusion set tubing daily for any damage, leaks or kinks. **DO NOT** use infusion set tubing that is damaged, has leaks or is kinked. Damaged, leaking or kinked tubing can restrict or stop insulin delivery and result in under delivery of insulin.
- **CHANGE** your infusion set every 2 to 3 days as recommended by your HCP to avoid infection. Use clean hands when handling infusion sets. Clean the skin area near the intended insertion site. Contact your HCP if you have signs or symptoms of infection at your insulin infusion site or Sensor insertion site.
- **CHECK** the cartridge for leaks, cracks, or other damage each time you change it. To avoid leakage, make sure to securely tighten the Luer connection between the cartridge and infusion set. You can check for leaks by wrapping a tissue around the Luer connection to see if it gets wet.
- **CHECK** the insulin cartridge o-rings for damage (breaks, cracks or fraying) prior to inserting a new cartridge into your pump. **DO NOT** use a cartridge that has damaged o-rings. If the o-rings are damaged, replace the cartridge with a new one. Damaged cartridge o-rings can result in under delivery or over delivery of insulin.

⚠ **PRECAUTIONS** *(continued)*

- **CHECK** the battery cap o-ring for damage (breaks, cracks or fraying) whenever you replace the pump battery. **DO NOT** use a battery cap that has a damaged o-ring or does not fit securely. If the o-ring is damaged or not securely attached, replace the battery cap with a new one. A damaged battery cap o-ring, or one that does not fit securely, can impact the battery contact and/or the waterproof feature of your pump. See *Chapter 3 Section I*.
- **CHECK** your pump personal settings whenever you change the pump battery to make sure they were saved. It is important that your pump is set correctly for your insulin delivery needs and current health status. Not having the correct settings can result in over or under delivery of insulin. Consult your HCP as needed.
- **CONFIRM** that you can feel the pump vibrate and you can hear audible tones whenever you change the pump battery. This is a built-in safety check every time you replace the pump battery. It is important that these two features are working correctly as they are used to confirm certain pump operations and to alert you to conditions that require your attention.
- **KEEP** the communication window on the pump free of obstructions, if you use the download feature. Solid objects between the window and the wireless download cable can interfere with transmission. Refer to the *Instructions for Use* included with the wireless download cable. Contact Customer Service for information regarding compatible diabetes management software that you can use to track, review and analyze pump data on your computer.
- **CONFIRM** Alerts, Warnings, and Alarms on your pump as soon as possible since the pump uses battery power to display, sound and vibrate each notification. If you do not confirm notifications, your pump will continue to use battery power as the notifications repeat and progress. This will result in reduced battery life.
- **ALWAYS** look at the pump display for confirmation that an intended Audio Bolus amount is correct, when you first begin using the Audio Bolus feature. This will ensure that you are correctly using the audio/vibration prompts and button pushes to deliver the intended bolus amount. See *Chapter 9 Section I*.

⚠ **PRECAUTIONS** *(continued)*

- **CONTACT** your HCP about lifestyle changes such as starting or stopping your exercise program or if you experience significant weight loss/gain. These changes can affect the way your body uses insulin. Your basal rates may need to be modified. Failure to adjust your basal rates accordingly may result in serious injury.
- **DO NOT** stop using your pump if you are ill, unless instructed to do so by your HCP. Even when you are sick, your body still needs insulin. Contact your HCP for further instructions as insulin needs may change during this time. See *Chapter 15 Section I*.
- **DISCONNECT** from your pump when undertaking activities that involve rapid changes in altitude or gravitational force. Although such changes will not cause damage to the pump, they can interfere with proper insulin delivery and result in injury.

  Examples of the type of activities during which disconnection is indicated include:
  - Flying in aircraft without proper cabin pressurization if aircraft warning system indicates problems with cabin pressure;
  - Skydiving;
  - Riding on roller coasters and other amusement park rides that involve rapid changes in gravity;
  - Deep-sea diving.

  If you are unsure whether the activity is likely to interfere with your pump's delivery of insulin, then temporarily disconnect the pump during the activity.
- **MAKE SURE** to have someone around you (family, friends, etc.) who understands diabetes, insulin and pump therapy. In the event of an emergency, they can help you. Make sure they are familiar with any information given to you by your HCP. Users should always contact their HCP or call 911 for help in the case of emergency.
- **ALWAYS** check your BG levels one to two hours after changing your infusion set. Plan infusion set changes at meals or one to two hours before bedtime to ensure that the infusion set is inserted correctly and delivering insulin appropriately. This way you will be able to respond to problems with your infusion set in a timely manner and while you are awake.

⚠ **PRECAUTIONS** *(continued)*

- **SET** pump Alerts, Warnings and Alarms to high volume before going to sleep, unless otherwise recommended by your HCP. This way you will have a better chance of waking up if there is a situation that requires immediate action.
- **ALWAYS** check that you have enough insulin in your pump to last through the night, before going to bed. Your body needs basal insulin even while you sleep. If you are sleeping, you may not be aware that your pump is no longer delivering insulin.
- **ALWAYS** remove the air bubbles from the cartridge and tubing before beginning insulin delivery. Air bubbles represent space where insulin should be and can compromise delivery accuracy. Make sure the insulin is at room temperature, fill the cartridge slowly, and tap the cartridge in order to remove all air bubbles. Refer to the *Instructions for Use* included with your cartridge packaging for additional information.
- **DO NOT** expose your pump to temperatures outside the range 40° F to 98° F. Your pump is not designed to operate in temperatures outside this range. Extreme temperatures can affect the safety and performance of the pump. **DO NOT** exceed the insulin manufacturer's recommended temperature and humidity ranges when operating the OneTouch Vibe™ Plus Insulin Pump.
- **DO NOT** use your pump if you suspect it might be damaged or not working properly. You can damage your pump by dropping it, hitting it with something hard, or not using it as intended. You should disconnect the pump or suspend insulin delivery if you think the damage might result in over or under delivery of insulin. Make sure to have an alternate method for administering insulin such as pens and syringes if you are unable to use your pump. Before you start using your pump again, check for any visible damage to the pump, such as cracks or chips that can impact the battery contact and/or the waterproof feature of your pump. Check that the cartridge cap, battery cap and infusion set are properly in place. Check for insulin leaks around the cartridge by wrapping a piece of tissue around the connection area to see if it gets wet. Turn the pump on to see if the pump display is clear. Contact Customer Service if you identify or suspect damage.
- **DO NOT** bring your pump into areas where there may be explosive gases. There is a risk of explosion if you use your pump in these areas. Remove your pump if you need to enter these areas.

⚠ **PRECAUTIONS** *(continued)*

- **DO NOT** use household cleaners, chemicals, bleach, alcohol wipes, skin prep, scouring pads or sharp instruments to clean your pump. Cleaning your pump with these materials can damage the pump. Clean your pump with a soft, lint free cloth dampened with water or a mild detergent such as liquid soap. Never put your pump in the dishwasher or use scalding hot water to clean it. See *Chapter 12 Section I*.
- **NEVER** use a hair or hand dryer, microwave oven or baking oven to dry your pump if it gets wet. The use of these appliances can damage the pump. Use a soft towel or cloth.
- **NEVER** clean the inside of the battery or insulin cartridge compartments.
- **DO NOT** reset the Low Cartridge Warning if the alert has already sounded/displayed, until you have loaded a new cartridge. The alert will only sound/display once for each cartridge change. If you deliver a bolus amount which reduces your remaining insulin below the Low Cartridge Warning threshold, a Low Cartridge Warning will display/sound after the bolus is delivered. The amount remaining may be lower than the Low Cartridge Warning threshold.
- **MAKE SURE** to select the correct Battery Type on the Verify screen when you change the battery. This will ensure accuracy of the Low and Replace Battery Warnings.
- It is possible that nearby devices, such as a cell phone or other wireless device, can interfere with CGM Sensor readings or alerts received by the pump. If *Bluetooth®* communication is lost or interrupted, try increasing the distance between your pump and the interfering device to see if communication is re-established. If needed, remove or turn off the nearby device. Refer to *Chapter 12 Section II* for more information on conditions that may cause *Bluetooth®* communication problems.

⚠ Warnings – Using the Dexcom G5® Sensor and Transmitter with your OneTouch Vibe™ Plus Insulin Pump

⚠ WARNINGS

- **ONLY** use your OneTouch Vibe™ Plus Insulin Pump with the Dexcom G5® Sensor and Transmitter. The pump is not compatible and will not work with the Dexcom G4® Transmitter, or any other versions of Dexcom Sensors and Transmitters.
- **DO NOT** use the Dexcom G5® Sensor and Transmitter if you are pregnant (or planning to get pregnant) or on dialysis.
- **DO NOT** use glucose readings from the Dexcom G5® Sensor and Transmitter to make treatment decisions, such as how much insulin you should take. The Sensor and Transmitter do not replace a BG meter and BG values may differ from Sensor glucose readings. Using glucose readings from the Sensor and Transmitter to make treatment decisions can result in serious injury or death.
- **DO NOT** ignore symptoms of high and low BG levels, even if your Sensor glucose readings indicate you are in control. If your Sensor glucose readings do not fit with your symptoms, you should always measure your BG level with a BG meter. Relying on Sensor glucose readings to treat symptoms may lead to inappropriate treatment decisions and result in serious injury or death.
- **CALIBRATE** your Sensor with a BG value from a BG meter at least once every 12 hours. Periodic BG values from a BG meter adjust the Sensor so that it more accurately reflects your body's health status. The accuracy of your Sensor glucose readings may be compromised unless you calibrate at least once every 12 hours. Calibrating more than once every 12 hours is okay and will not affect the accuracy of your Sensor glucose readings.
- **DO NOT** calibrate your CGM if your glucose level is changing at a significant speed, typically more than 2 mg/dL per minute. Calibrating during a significant rise or fall in glucose levels may affect the accuracy of Sensor glucose readings. See *Chapter 6 Section II* for more information on how the pump displays changes in CGM glucose readings.

⚠ **WARNINGS** *(continued)*

- **DO NOT** use alternative BG site testing (blood from your palm or forearm, etc.) for CGM calibration. Alternate site blood glucose values may be different than those taken from a fingerstick blood glucose value and may not represent the timeliest blood glucose value. Use a blood glucose value taken only from a fingerstick for calibration. Alternative site BG values might affect Sensor accuracy and result in your missing severe hypoglycemia (low blood glucose) or hyperglycemia (high blood glucose) events.
- **DO NOT** use a broken Sensor or attempt to remove the broken Sensor if no portion of it is visible above the skin. Sensors can fracture on rare occasions. You may not be able to obtain glucose readings from a broken Sensor or the readings may be inaccurate. Consult your HCP about removing it, especially if you have symptoms of infection or inflammation (redness, swelling or pain) at the insertion site. Report the broken Sensor to Customer Service.
- **DO NOT** place the Sensor on any other sites other than under the skin of the belly (abdomen), or, in the case of patients between the ages of 2 and 17, the belly or upper buttocks. Sensor placement has not been tested and **IS NOT APPROVED** for other sites. Sensors placed on other sites may provide inaccurate glucose readings and lead to inappropriate treatment decisions. This can result in serious injury or death.
- **DO NOT** use your Transmitter if the outer case is damaged or cracked. This could create an electrical safety hazard or malfunction, and result in serious injury or death. Always inspect your Transmitter for damage prior to use.
- **DO NOT** enter Sensor glucose readings as BG values in pump bolus calculations. Always use a BG value from a BG meter. Using a Sensor glucose reading in bolus calculations may lead to inaccurate suggested bolus amounts, and may result in under or over delivery of insulin if you choose to bolus that amount.
- **MAKE SURE** to replace the pump battery when prompted with the Replace Battery Alarm to continue recording and displaying CGM Sensor readings. The Replace Battery Alarm will stop all CGM functions, and no further CGM Sensor readings will be displayed until the battery is replaced.

⚠ Precautions – Using the Dexcom G5® Sensor and Transmitter with your OneTouch Vibe™ Plus Insulin Pump

⚠ PRECAUTIONS

Expiration Date

- **DO NOT** use expired Sensors. Before inserting, always check the package label for the expiration date using the YYYY-MM-DD format.
- If past the expiration date, don't use because the Sensor glucose readings might not be accurate, resulting in you missing a severe low or high glucose event.

Sensor Package

- **DO NOT** use Sensor if its sterile package has been damaged or opened. Using a non-sterile Sensor might cause infection.

Clean and Dry Before Using

- Before opening the Sensor package, wash your hands with soap and water, then dry. If your hands are dirty while inserting the Sensor, you may contaminate the insertion site and get an infection.
- Before Sensor insertion, clean the skin with alcohol wipes to prevent infections. **DO NOT** insert the Sensor until the cleaned insertion site is dry, and free from any lotions or perfumes.
- If your insertion site is not clean and completely dry, you run the risk of infection or the Sensor pod not sticking and falling off.

Sensor Placement

- **CHANGE** the site where you place the Sensor with each new insertion. Using the same site too often might not allow the skin to heal, causing scarring or skin irritation.
- Sensor placement is important. **MAKE SURE** the area you place your Sensor won't:
  - Be bumped, pushed, or squeezed
  - Have scars, tattoos, or irritation
- Insertion in these areas might affect Sensor performance, resulting in you missing a severe low or high glucose event.

⚠ **PRECAUTIONS** *(continued)*

- **AVOID** injecting insulin or placing an insulin pump infusion set within three inches of the Sensor. The insulin might affect Sensor performance, resulting in you missing a severe low or high glucose event.
- **STORE** Sensors at temperatures between 36° F to 77° F for as long as the Sensor packaging/insert indicates. Sensors stored at temperatures outside this range may be damaged and lead to inaccurate glucose readings. You may store your Sensors in the refrigerator if it is within this temperature range. **DO NOT** store Sensors in a freezer.
- **DO NOT** use the Suspend delivery feature on your pump if you want to temporarily suspend insulin delivery and still view CGM Sensor readings and CGM warnings. Your pump will not receive CGM Sensor readings when you suspend delivery. While Temp Basal is set to OFF, CGM Sensor readings will continue to be available, although insulin delivery will be temporarily suspended.
- **BEWARE** that if insulin delivery is suspended on your pump because the **AUTO-OFF ALARM** (no button presses for a user-defined number of hours) has sounded/displayed, your CGM session (see *Section II*) will remain active, but CGM Sensor readings will not be recorded or displayed. As soon as insulin delivery resumes, CGM Sensor readings will start recording and displaying again.
- If you are using the Dexcom G5® Sensor and Transmitter with your pump, suspending your pump affects the recording and displaying of CGM Sensor readings.
- While insulin delivery is suspended, your CGM session (see *Section II*) will remain active, but CGM Sensor readings will not be recorded or displayed. As soon as insulin delivery resumes, CGM Sensor readings will start recording and displaying again.
- If you are using the Dexcom G5® Sensor and Transmitter with your pump, you can disconnect from the session by turning Bluetooth off, however, the session will remain active.

⚠ **WARNING:** Any changes or modifications to the OneTouch Vibe™ Plus Insulin Pump or Dexcom G5® Sensor and Transmitter not expressly approved by Animas Corporation or Dexcom, Inc. may void the warranty and can damage the device.

Emergency Kit

Keep an emergency kit with you at all times to make sure you have necessary supplies.

This kit should include but is not limited to:

- Quick-acting glucose tablets or gel
- BG monitoring supplies including meter, test strips, lancing device, lancets, meter batteries
- Blood or urine ketone testing supplies
- Rapid-acting and other insulin as recommended by your HCP
- Extra infusion sets and Animas® 2.0 mL Cartridges (200 unit/2mL)
- Dressing and adhesive, if used
- An extra Energizer® Ultimate Lithium AA battery (1.5V) for your pump
- An extra pump battery cap
- An extra pump cartridge cap
- Glucagon Emergency Kit®
- Emergency contact phone numbers
- A backup plan for obtaining and delivering insulin when you are unable to use your pump, such as insulin pens or syringes

Be sure to inform a family member, co-worker, and/or friend where this emergency kit is kept.

Supply Reordering

You can place orders for cartridges, infusion sets, skin prep, batteries, replacement battery caps, and many pump accessories by contacting Customer Service or Customer Support at 1 877 937-7867 or your distributor.

To place orders for Dexcom G5® Sensor and Transmitter supplies, contact Dexcom.

Section I

OneTouch Vibe™ Plus Insulin Pump

Section I of this Owner's Booklet contains information about how to use, program, and maintain your new pump. It is important to read it carefully. Even if you are an experienced pumper, keep your Owner's Booklet handy for reference. Any reference to CGM refers to the optional Dexcom G5® Sensor and Transmitter that are reviewed in *Section II*.

You have begun a new way of life with your OneTouch Vibe™ Plus Insulin Pump.

Your choice to begin pump therapy is a sign that you are committed to taking excellent care of yourself. Your pump has been specially designed to help you manage your diabetes, using sophisticated safety systems.

Your pump is used for insulin therapy to help maintain your blood glucose (BG) targets as recommended by your HCP. You program it to deliver two ways: 1) a continuous, 24-hour "basal" rate and 2) "bolus" insulin deliveries to accommodate for immediate doses to cover foods eaten and high BG. It is important to remember that successful pump therapy is a partnership of advanced technology and responsible self-care.

Please take a moment to look at the back of your pump and write down the serial number (SN).

My pump serial number/SN is: _____

Technical Help

If there is anything you do not understand in the Owner's Booklet or if you have a question or need assistance with your pump, please contact Customer Service.

We understand that you may have questions and concerns when using a new product. Please do not hesitate to call for assistance!

If you are having problems with your diabetes management, please contact your HCP.

Important Note

DO NOT Remove the Factory-Installed Plastic Display Lens Protection Film.

Your pump now comes with a new factory-installed transparent plastic lens protection film covering the display lens. This protective film is highly durable and is designed to protect your pump display lens from incidental damage. **DO NOT attempt to remove this film. This protective film must remain in place at all times to fully protect your pump display lens from scratches and other cosmetic damage.** This film will not protect your pump display lens from extreme abuse.

Should the pre-installed lens protection film become damaged or separate from the display, the film should be replaced. Replacement films can be purchased by contacting Customer Service.

Please note that the OneTouch Vibe™ Plus Insulin Pump limited warranty does not cover damage resulting from normal wear and tear, accidents, negligence or misuse, and abuse, including scratched display lenses. We urge you to protect your pump screen from damage and use a lens protection film at all times.

OneTouch Vibe™ Plus Insulin Pump Kit Contents

Your OneTouch Vibe™ Plus Insulin Pump Kit includes your insulin pump and other accessories you will need to begin insulin delivery. Check the contents of your kit to make sure all items are included. If any items are missing, contact Customer Service.

Your OneTouch Vibe™ Plus Insulin Pump Kit includes:

a. OneTouch Vibe™ Plus Insulin Pump

b. One Energizer® Lithium L91 AA battery (1.5V) for your pump

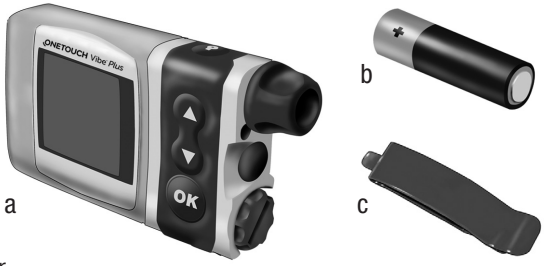
c. Low Profile Clip

d. Owner's Booklet*

e. Quick Start Guide*

NOTE: A Tamper Resistant Case* will be provided to pediatric patients ages 7 and under.

** not pictured*



Explanation of symbols

Shown below are symbols you will find on your OneTouch Vibe™ Plus Insulin Pump or its packaging.

On the front of your pump:

Up Arrow button

Down Arrow button

OK button

On the top of your pump:

Contrast button/CGM shortcut

On the back of your pump:

S/N	Serial Number
	Manufacturer
	Date of Manufacture
IPX8	Protected against water submersion – Pump tested to 12 feet for 24 hours
	Shock Protection Type BF Medical Equipment
REF	Catalog Number
	Consult Owner's Booklet
MR	MR (Magnetic Resonance) Unsafe
CE 0086	Marking certifies that the device meets the European Council Directive 93/42/EEC
Rx only	Prescription Use Only – United States federal law restricts this device to sale by or on the order of a physician

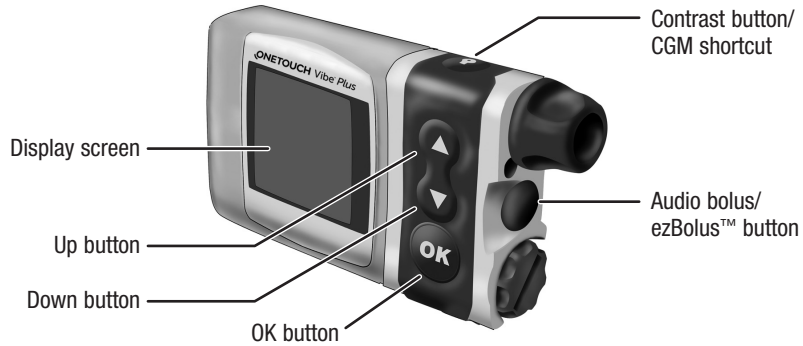
On your pump kit packaging:

	Do Not Reuse
	Fragile
	Keep Dry
	Caution (Consult Owner's Booklet)
	Bluetooth® Smart capabilities
106 kPa 50	Pressure Limitations
100% RH 10% RH	Relative Humidity Limitations
+60°C -20°C	Temperature Limitations
	Hazardous waste – Dispose of in accordance with local regulations

An insulin pump is a tool to allow you to better manage your diabetes. When connected to a properly-inserted infusion set, your pump delivers insulin at a continuous level (basal rate), 24 hours a day. You program delivery of an immediate dose (bolus) of insulin to cover food eaten or to correct high BG.

Your pump is engineered and manufactured to the highest standards of quality.

Get to know your OneTouch Vibe™ Plus Insulin Pump



Main Function Buttons

There are 4 buttons for main programming functions. The ▲ and ▼ buttons allow you to move through screen selections and to scroll up and down to enter values such as a bolus amount. The OK button allows you to select an item or activate a function. The Audio bolus/ezBolus™ button allows you to program a bolus using audible tones (or vibrate pulses) to confirm programming and delivery.

Programming Basics

- Use the ▲/▼ buttons to scroll to the desired selection and then press the OK button to select. If the cursor is flashing, it means your pump is in Edit mode and by scrolling with the ▲/▼ buttons, you can edit the flashing field.
- Once you have finished editing, press the OK button to confirm your entry and to exit the Edit mode.
- If your pump display turns off before you have had a chance to confirm your entry, that entry may not be saved. Be sure to check your edits/entries the next time you turn your pump display on.

Display Screen

All programming, operations, warnings and alarms are shown on the display screen.

Contrast Button/CGM Shortcut

Pressing the button on your pump (see image of pump on previous page) adjusts the contrast of your display. There are three contrast levels: Dim, Default and Bright. To preserve battery life, your pump display will Auto-dim when no pump function button (any button other than the Contrast or Audio Bolus buttons) has been pressed for half the period you set for the display to time out under Advanced Features. While in **Auto-dim** mode, you can restore the default contrast level you have set by pressing the button on top of your pump. Pressing a function button while in Auto-dim mode will restore the default contrast level as well as perform the function of the button. To adjust contrast during a Call Service alarm, you must use the button. See *Chapter 9 Section I*.

If you are not using the Dexcom G5® Sensor and Transmitter with your pump, CGM functions and data will not be operational on your pump display. However, pressing the button while the pump is in sleep mode will awaken the pump to one of the CGM Trend graphs or the CGM Data screen, even though the CGM functions are not operational. In this case, the CGM trend or Data screens will not have any information, and you will need to return to the MAIN MENU screen. Press OK on your pump to return to the CGM Menu screen and then press OK again with "Main Menu" highlighted to return to the MAIN MENU screen.

If you are using the Dexcom G5® Sensor and Transmitter with your pump, pressing the button while the pump is in sleep mode will awaken the pump to one of the CGM Trend graphs or the CGM Data screen. See *Chapter 6 Section II*.

NOTE:

- If your pump is locked, you will be required to unlock the pump after pressing the contrast button to view one of the CGM trend graphs or CGM data screen.
- When viewing your pump display in bright sunlight, it is recommended you shade the screen or move to a shady area for best visibility.
- If your pump goes to sleep and an error has not been cleared, pressing the button will awaken the pump to the error screen. This will continue until the error condition has been cleared.

Audio Bolus/ezBolus™

This button allows you to program a bolus without looking at your pump. It uses audible tones (or vibrate pulses) to confirm programming and delivery. If you choose not to activate the Audio Bolus feature, this button provides a shortcut to the Normal Bolus screen. See *Chapter 10 Section I* for more information.

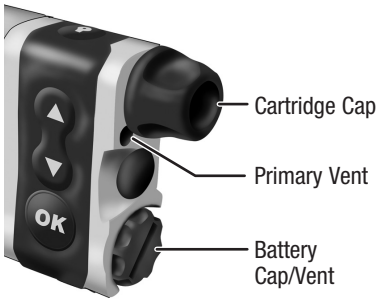
NOTE:

- If your pump is locked the Audio Bolus feature is activated by pressing the Audio Bolus button; however, the user will be required to unlock the pump to initiate the Audio Bolus sequence.
- When you first use the Audio Bolus feature, you should always look at the screen to confirm correct programming until you are comfortable with using audio or vibration feedback to program a bolus. See *Chapter 9 Section I*.

⚠ **WARNING: DO NOT** remove the Audio Bolus/ezBolus™ button from the right side of your pump. Removing the button can damage the pump, compromise the waterproof feature of your pump, and result in over or under delivery of insulin. This can lead to very low (hypoglycemia) or very high (hyperglycemia) BG levels.

Battery Cap/Vent

This cap unscrews easily with a coin to replace and secure your battery. There is an o-ring around the cap, which prevents water from entering the pump. The battery cap also is equipped with a built-in vent to allow air to enter your pump to maintain pressurization but prevent water from entering. Be careful not to over tighten the battery cap. See *Chapter 3 Section I*.



Primary Vent

This vent is part of the redundant vent safety system that allows air inside your pump to maintain equalized pressure but prevents water from getting inside. It is acceptable to place the pump under clothing, as this will not block the vents.

⚠ **WARNING: CHECK** the battery cap vent and primary vent below the cartridge cap to make sure they are not clogged whenever you replace the battery, cartridge or infusion set. **DO NOT** use the pump if the vents are clogged. The vents allow air to flow in and out of the pump, and have a membrane on the inside that helps keep your pump waterproof. Remove any debris from the vents using your fingers and a soft cloth. **DO NOT** use a sharp object to clean the vents or you may puncture the vents/membrane and compromise the waterproof feature of your pump. Replace the battery cap if you are unable to remove the debris from the battery cap vent. See *Chapter 12 Section I*.

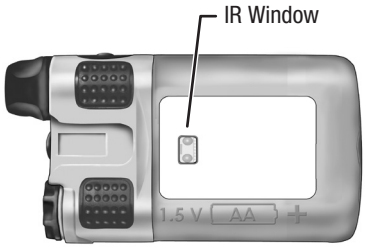
Cartridge Compartment Cap

This cap secures your cartridge and infusion set in your pump. See *Chapter 3* in this section for more information about the insulin cartridge and infusion set, including when and how to change them.

⚠ **WARNING: NEVER** tighten the cartridge cap when your infusion set is attached to your body. Tightening the cartridge cap while your infusion set is attached to your body may disrupt the flow of insulin through the tubing that is threaded through the cap.

IR Window

The IR window is framed in blue. This is the infrared communication window. Refer to the *Instructions for Use* included with the wireless download cable for more information about downloading using the infrared communication window. Contact Customer Service for information regarding compatible diabetes management software that you can use to track, review and analyze pump data on your computer.



Sounds

Your pump allows you to customize the volume level or use the vibrate function to notify you of warnings and alarms and to confirm certain insulin deliveries. If you are using the Dexcom G5® Sensor and Transmitter with your pump, you have the option to set CGM-related alarms and alerts in the CGM Setup Menu (see *Chapter 2 Section II*).

Auto-Lock Feature

You can use the auto-lock feature to prevent accidental button pressing.

1. An auto-lock feature can be enabled or disabled. See *Chapter 9 Section I* on how to configure the auto-lock feature.

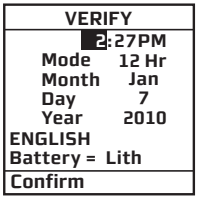
2. To unlock your pump, wake up your pump so the screen reads "(LOCKED) Press & hold both arrow buttons to unlock" and press and hold the ▲ and ▼ buttons at the same time until the screen display wakes up.

NOTE: For Pediatric patients or those patients whose therapy is administered by a caregiver it is recommended the auto-lock feature is turned ON.

⚠ **WARNING:** For patients whose insulin pump settings and insulin administration are managed by a caregiver, it is recommended the caregiver enables the auto-lock feature on the pump to avoid inadvertent button pushing. Inadvertent button pushing or tampering with the insulin pump can result in changes to pump settings. Changes to pump settings can cause a change to insulin delivery therapy thus potentially causing a hypoglycemic or hyperglycemia event. It is also recommended for patients whose insulin pump settings and insulin administration are managed by a caregiver to put the pump in a tamper resistant case for an additional layer of security.

Basic Display Screens

Verify Screen

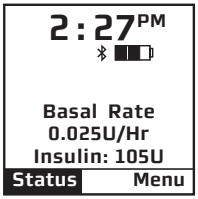


When you insert a battery, this is the first screen you see after the hourglass appears on the display. From here, you should verify the settings for time, date, language and battery type. With "Confirm" highlighted, press OK to confirm the settings and go to the Home screen.

If you do not confirm the settings on the VERIFY screen, you will be notified with an alarm beep sequence on your pump. If not confirmed, the pump will play 4 long tones/vib every 3 minutes until the screen is confirmed.

It is important to have the correct (current) date and time set in your pump. If the pump loses the date and time setting due to the battery being removed, you will not be able to go to the Home screen (see next page) until you edit and confirm the settings on the Verify screen.

Home Screen



Once you have your pump set up, the Home screen is the first screen that is displayed when you "wake up" your pump. Press the ▲, ▼ or OK button to wake up your pump. (The Home screen shows the time of day, an approximate battery life indicator, if you have an extended bolus or temp basal currently active, current basal rate, and how much insulin remains in your cartridge.) You can access the MAIN MENU from here or you can take a shortcut to the STATUS screen. The battery life indicator is shaded to show approximate battery life remaining.

Bluetooth Indicator

Bluetooth symbol will be present indicating that your Bluetooth is on. The symbol will not be present when Bluetooth is off. Patient can turn on/off Bluetooth through your CGM menu screen.

Battery life indicator


Full battery power remaining


About 2/3 battery power remaining

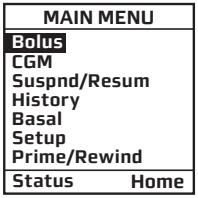

About 1/3 battery power remaining


Little or no battery power remaining

NOTE: Battery life varies by type of battery, storage conditions, and how long the battery has been in use. Expect actual battery life to be less than what is shown by the battery life indicator if you access pump features on a regular basis. Be prepared to replace the battery whenever the battery icon shows that it is less than completely (shaded) full.

After a set amount of time with no button presses, your pump display screen will “time out” to conserve battery life. When your pump times out, the screen display is blank.

MAIN MENU Screen



This screen shows all MAIN MENU options.

Bolus

This selection takes you to the Normal Bolus screen. If you have activated Advanced Bolus features, the BOLUS MENU will be displayed. From the BOLUS MENU you can select the bolus type, program and deliver the bolus dose.

Suspend/Resume

This selection stops all basal delivery and stops/cancels all bolus deliveries. Selecting Resume restarts basal delivery but any programmed bolus deliveries would need to be re-set.

History

This selection allows you to review history of boluses, total daily dose (TDD), alarms, primes, suspend and basal information.

Basal

This selection allows you to access and program your basal rate. This continuous rate maintains your BG between meals. This rate will be determined by your HCP. The default Basal Menu will display one basal program and the Temp Basal option. You can activate additional basal program options with the Setup Advanced menu.

Setup

This selection allows you to personalize the settings and features of your pump, as well as add advanced features to the menu. Your HCP will advise you on which features are best suited for your plan of treatment, as well as train you to achieve the best results.

Prime/Rewind

This selection prepares the pump for the insertion of a new filled insulin cartridge, and fills your infusion set tubing and cannula or needle with a few drops of insulin before delivery can begin. Refer to *Priming your Pump and Infusion Set* in *Chapter 3 Section I*.

Status

This selection allows you to quickly see your current/most recent settings and pump deliveries.

CGM (see Section II)

If you are using the Dexcom G5® Sensor and Transmitter with your pump, this selection takes you to the CGM Menu where you can access all CGM functions available on your pump. In addition, you have the option to set BG limits, alarms, sound levels, etc. If you are not using the Dexcom G5® Sensor and Transmitter with your OneTouch Vibe™ Plus Insulin Pump, CGM functions and data will not be operational on your pump display.

To complete this section, you will need the following items:

- OneTouch Vibe™ Plus Insulin Pump
- Energizer® Lithium L91 AA battery (1.5V)
- Coin
- Infusion set with standard Luer connector
- Animas® 2.0 mL Cartridge (200 unit/2mL)
- Alcohol wipe (to clean top of insulin vial)
- Vial of U100 insulin (rapid-acting) at room temperature (see allowed insulin types in the *Before You Begin* section)
- Skin prep such as IV PREP (to clean and prepare site for infusion set insertion)

Battery Type

Your pump is designed to achieve optimum performance and battery longevity with an Energizer® Lithium L91 AA battery (1.5V). Use of other lithium batteries may affect the Low Battery and Replace Battery alarm notifications. Check to be sure you have the correct lithium battery type before inserting the battery.

⚠ CAUTION:

- You can safely power your pump with a conventional AA alkaline battery (1.5V), but battery life is significantly reduced and the Low Battery and Replace Battery alarm notifications may be affected.
- **MAKE SURE** to select the correct Battery Type on the Verify screen when you change the battery. This will ensure accuracy of the Low and Replace Battery Warnings.

If you must use an AA alkaline battery, the following is recommended:

- Energizer® E91

> ⚠ **WARNING:**
> - **DO NOT** use rechargeable batteries or Carbon-Zinc batteries with your pump. They do not have the necessary characteristics to power your pump, and can damage the pump and/or result in over delivery or under delivery of insulin. Use of rechargeable or Carbon-Zinc batteries may void the pump warranty and can damage the device.
> - **DO NOT** use AA batteries with voltages higher than 1.5V with your pump. Use of any battery other than 1.5V can damage your pump.

NOTE: Your pump uses battery power to notify you of alerts, warnings, and alarms. If you do not confirm the notification, your pump will continue to use battery power as the notifications repeat and progress. This will result in reduced battery life and the Replace Battery Alarm screen appearing sooner than expected.

Changing the Battery

Always disconnect from infusion site prior to changing the battery.

After you replace the battery:

- A full rewind and prime sequence is required. See *Priming your Pump and Infusion Set* in this chapter.
- The Insulin on Board (IOB) calculation will be reset to zero (0.00U) every time you change the battery. When bolusing after a battery change, you will need to take into account any insulin that you may still have on board from a previous bolus, even if the Bolus Calculator displays 0.00U IOB.
- All bolus deliveries are canceled at the time of a battery change (Audio Bolus, Combo Bolus, and Normal Bolus). For more information regarding the types of bolus delivery, including Combo Bolus, refer to *Chapter 10 Section I*.
- The Combo bolus returns to the factory set default duration and split settings.

- You should review your basal program settings to make sure they have been saved in the pump.
- Basal program delivery will automatically resume.
- Any Temp Basal in effect before the battery change will be canceled.
- To resume your Temp Basal program, you will need to re-enter and initiate your Temp Basal settings.
- Any active CGM session in effect before the battery change will automatically resume.

⚠ WARNING:

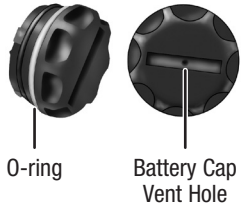
- **MAKE SURE** you understand and are prepared for what actions you might need to take when there is little or no battery power remaining in your pump. Make sure to have an alternate method for administering insulin, such as pens and syringes if you are likely to be disconnected for an extended period of time. Contact your HCP for making insulin adjustments with a pen or syringe when disconnected for an extended period of time.
- Low Battery Warning will appear when the remaining battery life approaches 30 minutes. Upon receiving this warning, the user should replace the battery to avoid an interruption in insulin delivery.
- You can remove the pump battery for up to 12 hours without having to reset the time and date. Once you re-insert the battery, after the 12-hour period, the pump will prompt you to enter the time and date. You must reset time and date to continue using the pump.
- If you are using the Dexcom G5® Sensor and Transmitter with your pump, the Replace Battery alarm will stop all CGM communications with the pump, as such no further CGM Sensor readings will be displayed until the battery is replaced. See *Section II*.

Changing the Battery *(continued)*

1. Disconnect from infusion site.

2. Use a coin to unscrew the battery cap with a counter-clockwise motion.

3. Check your battery cap for damage such as cracks or missing threads, and be sure the colored o-ring fits securely and is not torn or damaged.



4. Check the vent hole on the top of the battery cap to be sure it is clear of debris. This vent maintains pressurization while preventing water from entering the compartment.

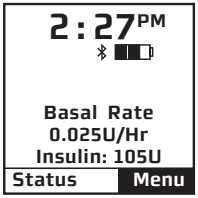
5. Insert the Energizer® Lithium L91 AA (1.5V) battery into the battery compartment with the positive (+) end going in first.

6. Replace the cap, and then use a coin to slowly tighten the cap by turning clockwise until you cannot see the o-ring and the cap is flush with pump body.

⚠ **WARNING: DO NOT** over tighten the battery cap. Once the o-ring is no longer visible and the cap is flush with the pump body, the cap is properly tightened. If you over tighten the cap, you may not be able to remove it and you can damage the pump. Cracks, chips, or damage to your pump can impact the battery contact/and or waterproof feature of your pump.

7. Each time you change the battery, your pump will run a series of self-tests which will last a few seconds. An all black screen with an hourglass symbol will appear followed by the VERIFY screen. Your pump will give a beep to alert you to verify (or change) the time/date, language and battery type.

8. Check the displayed time/date, battery type and language. If correct, scroll down to highlight "Confirm" and press the OK button. The Home screen will be displayed. For more details on changing the time and date, see *Setup – Basics, Setting/Changing Time and Date* in this chapter.



NOTE: The time and date must be programmed to confirm the VERIFY screen.

9. To change the battery type, highlight the "Battery" field and press OK to activate Edit mode (indicated by flashing cursor).

10. Use the ▲/▼ buttons to change battery type and press OK to confirm and exit Edit mode.

NOTE:

- The correct battery type must be selected in order for your battery life indicator to be accurate. "Lith" = Lithium, "Alkl" = Alkaline.
- It is important to have the correct (current) date and time set in your pump. If the pump loses the date and time setting due to the battery being removed for an extended period, you will not be able to go to the Home screen until you edit and confirm the settings on the Verify screen.

11. Scroll to "Confirm" and press OK. The Home screen is displayed.

NOTE: Until you have programmed a basal rate, the Alert screen shown here will appear when your pump is awakened. Simply scroll to "Confirm" and press OK to move past this Alert screen.

12. Each time you change the battery, a full Prime/Rewind sequence is required (see *Priming your Pump and Infusion Set* in this chapter). Disconnect the pump from your infusion set prior to starting the Prime/Rewind sequence and when priming.

Setup

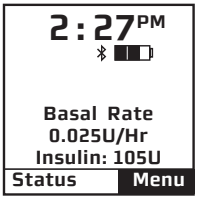
Setting/Changing the Time and Date

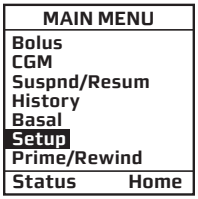
When you change your battery, the Verify screen allows you to edit the time and date.

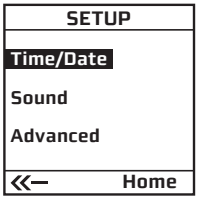
You can also access the Time/Date SETUP screen by selecting “Setup” from the MAIN MENU.

1. From the Home screen, press OK to select “Menu”. Scroll to “Setup” on the MAIN MENU. Press OK.

2. Scroll to “Time/Date” on the Setup Menu. Press OK.



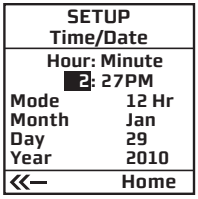




3. Press the OK button to activate Edit mode (indicated by flashing cursor).

4. Use the ▲/▼ buttons to change to your desired settings. Press the OK button to confirm your setting and exit Edit mode.

5. Use the ▲/▼ buttons to select the next field. Repeat the above process. Scroll to highlight “Main Menu” and press OK button when finished. The MAIN MENU will be displayed.



NOTE:

- It is important to have the correct (current) date and time set in your pump. Be sure to confirm the date and time before saving them in your pump.
- If you select the 12-hour time format, the AM/PM indicators will change as you scroll to set the time. Be sure the desired AM or PM selection is correctly displayed when setting the time.

Seasonal time adjustments (may apply to certain countries or regions)

You may need to adjust the time in your pump to reflect seasonal time changes in your local area or when traveling between time zones. Please contact your HCP prior to traveling for advice on how to manage insulin delivery.

If you advance the hour on your pump clock after **11pm but before midnight,** you must also manually forward the date by one day. If you change your pump clock **after midnight,** your pump date will have changed automatically to the appropriate date.

It is recommended that you set your clock back **before midnight on Saturday or after 1am on Sunday.** This keeps your pump set to the correct date. Your pump will register an additional hour in the Daily Totals History because the day has essentially been altered to consist of 25 hours. If you change the clock between midnight and 1am, you must also change the date. This will result in a duplicate date entry in your history. (This duplicate entry will contain up to one hour's worth of insulin delivered.)

Sounds – Setting/Changing

The sound menu only adjusts sounds for pump-related functions. It does not activate the feature. For example, Audio Bolus Sound is adjusted in this menu, but to turn the Audio Bolus feature on, go to the Setup Advanced menu. See *Chapter 9 Section I*. If you are using the Dexcom G5® Sensor and Transmitter with your pump, refer to *Chapter 2 Section II* to set CGM-related sounds.

Your pump comes pre-loaded with a tune for most Alerts, Reminders and Alarms on medium and high volume settings. This tune plays only for the initial audible notification. If you do not confirm the initial notification, the next sound will be the factory default. If not confirmed, Warnings and Alarms will automatically progress to high volume and vibrate within one hour. Refer to *Chapter 11 Section I* and *Chapter 10 Section II* for a complete description of alarms, alerts and warnings.

The options from the first SETUP SOUND menu are listed below. Normal Bolus Sound and Temp Basal Sound can be set to one of the following: Vibrate (Vib), Low volume (L) , Medium volume (M) , High volume (H) or can be shut off (OFF) completely.

For safety reasons, the Audio Bolus sound **cannot** be turned off.

Normal Bolus Sound – A single beep at the beginning and end of bolus delivery.

Audio Bolus Sound – A single beep at the beginning and end of bolus delivery to confirm delivery of an Audio Bolus. Refer to *Chapter 10 Section I* for a description of Audio Bolus beeps. (OFF is not an option for this sound setting).

Temp Basal Sound – A single beep once every 30 minutes to remind the user that a Temp basal is in effect.

The options from the second SETUP SOUND menu are listed below. They can be set to one of the following: Vibrate (Vib), Low volume (L), Medium volume (M), High volume (H) or can be shut off (OFF).

For safety reasons, the Reminder, Warning and Alarm sounds **cannot** be turned off.

NOTE: Some CGM warnings do not have sounds.

Reminder Sound – A single beep at the time of the Reminder. (OFF is not an option for this sound setting).

Warning Sound – A tune will play when the Warning is displayed. (OFF is not an option for this sound setting).

Alert Sound – A single beep when the Alert is displayed.

Alarm Sound – A tune will play when the Alarm is displayed. (OFF is not an option for this sound setting).

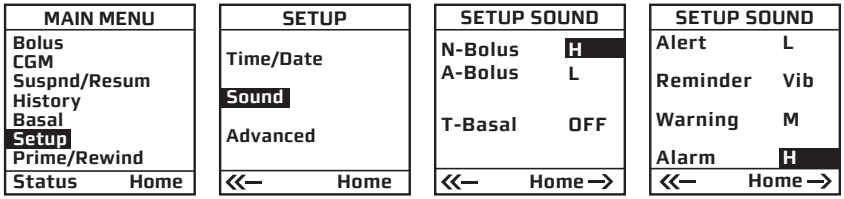
⚠ **CAUTION: SET** pump Alerts, Warnings and Alarms to high volume before going to sleep, unless otherwise recommended by your HCP. This way you will have a better chance of waking up if there is a situation that requires immediate action.

1. From the MAIN MENU, scroll to “Setup”. Press the OK button.

2. Scroll to “Sound”. Press the OK button to go to the SETUP SOUND screen.

3. Use the ▲/▼ buttons to scroll to your selection. Press the OK button.

4. The cursor will flash to indicate you can edit the selection. Use ▲/▼ buttons to change to desired setting. Press the OK button to confirm.



5. Repeat for remaining selections.

6. Scroll to “→” to access second SETUP SOUND menu or scroll to “Home” when finished to return to the Home screen.

The Cartridge

Filling the Cartridge

Refer to the *Instructions for Use* included with your cartridges.

Connecting the Tubing to the Cartridge

To complete this section, you will need the following:

- Filled Animas® 2.0 mL Cartridge (200 unit/2mL)
- Infusion set compatible (standard Luer lock and insulin-compatible tubing) with your OneTouch Vibe™ Plus Insulin Pump

NOTE: The pump is not designed to alert you as to when to change your infusion set. Consult with your HCP on how often to change your infusion set.

⚠ WARNING:

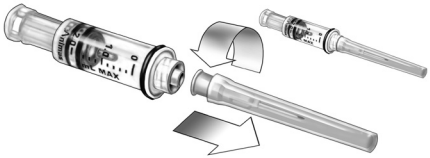
- The performance of your pump cannot be guaranteed if cartridges other than those manufactured by Animas Corporation are used.
- **DO NOT** use any infusion set other than those marketed for use with insulin infusion pumps using insulin-compatible tubing and with a standard Luer lock with your OneTouch Vibe™ Plus Insulin Pump. The efficacy of your pump cannot be guaranteed if other types of infusion sets are used. If you are unsure about whether your infusion set can be used with your OneTouch Vibe™ Plus Insulin Pump, consult your HCP.
- **NEVER** start any part of the Prime/Rewind sequence on your pump while the infusion set is connected to your body. Always disconnect before you begin the sequence. The Prime/Rewind sequence includes steps for rewinding the pump motor, loading an insulin cartridge, and priming the infusion set tubing. Failure to disconnect your infusion set from your body before performing these steps can result in over delivery of insulin.

1. Clean the workspace where you will be connecting the infusion set to the cartridge. Wash your hands thoroughly with soap and water, and then dry them completely before you handle the infusion set.

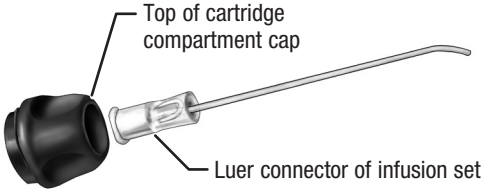
2. Open the sterile infusion set package and remove its contents. If the package is damaged or opened, use another set and contact your supplier.

3. Completely remove the cartridge compartment cap from your pump by unscrewing it, using a counter-clockwise motion.

4. Remove the infusion set tubing protective cap from the Luer connector. (Not all infusion sets have these caps.)



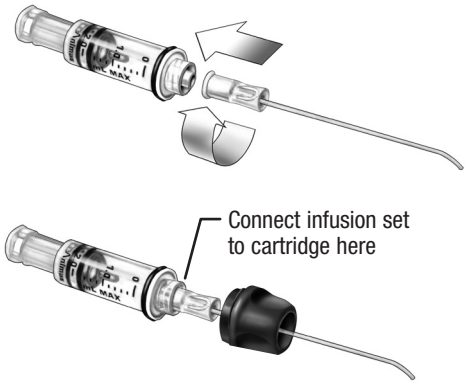
5. After removing protective cap, thread the Luer connector of the infusion set through the top (smaller) opening of the cartridge compartment cap, being careful not to touch Luer tip with hands or work surface.



Correctly threaded through cap

6. Remove cap from the filled cartridge tip.

7. Attach the infusion set Luer connector to cartridge tip using a clockwise motion to tighten the cap until it is snug. **Then twist another quarter of a turn.** To avoid insulin spillage and introduction of air in the cartridge, it should never be filled beyond the 2.0 mL mark. The plunger is properly positioned for maximum fill when the black o-ring nearest to the plunger tip is centered on the 2.0 mL mark.



⚠ **WARNING:**

- **MAKE SURE** to twist the Luer connector an extra quarter of a turn to ensure a secure connection between the cartridge and infusion set tubing. If the connection is not secure, insulin may leak around the cartridge, resulting in under delivery of insulin.
- When handling the cartridge, take care not to twist or turn the plunger in the cartridge body. Maintaining straight alignment of the plunger keeps the o-rings properly seated, which minimizes the possibility of introducing air into the cartridge and insulin spillage.

8. Put cartridge/tubing assembly aside.

⚠ **CAUTION:** Check for leaks, cracks or damage each time you change your cartridge and infusion set. To avoid leakage, be sure to tighten the Luer connection securely. You can check for moisture periodically by wrapping a tissue around the Luer connection between the cartridge and infusion set.

Changing the Cartridge

1. Disconnect infusion set from your body.

2. Unscrew the cartridge cap, leaving tubing connected to the cartridge.

3. With the tubing connected to the cartridge, pull cartridge straight out of your pump.

4. Disconnect tubing from cartridge and discard. Proceed with filling the new cartridge as outlined in previous sections in this chapter.

NOTE: Check your BG with a BG meter each time you change your infusion set or insulin cartridge.

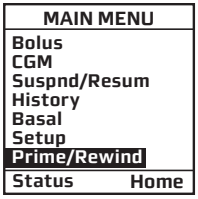
Priming your Pump and Infusion Set

NOTE: As each step is completed, the check box on the ezPrime menu will be shaded.

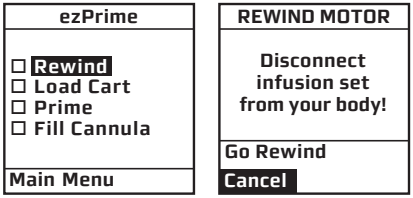
⚠ **WARNING: NEVER** start any part of the Prime/Rewind sequence on your pump while the infusion set is connected to your body. Always disconnect before you begin the sequence. The Prime/Rewind sequence includes steps for rewinding the pump motor, loading an insulin cartridge, and priming the infusion set tubing. Failure to disconnect your infusion set from your body before performing these steps can result in over delivery of insulin.

1. Make sure you are disconnected from your pump.

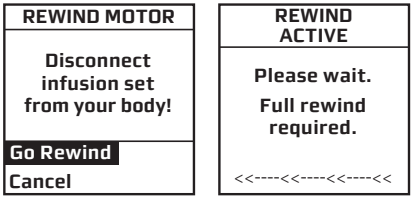
2. From the MAIN MENU, select “Prime/Rewind” to display the ezPrime screen. “Rewind” is highlighted. You must rewind the pump motor before you load an insulin cartridge.



3. Press OK with "Rewind" highlighted on the ezPrime screen to display the REWIND MOTOR screen. "Cancel" is highlighted.



4. Scroll up to "Go Rewind" on the REWIND MOTOR screen and press OK.



5. The pump will vibrate as it performs a self-test and then start to rewind. As the rewind continues, the REWIND ACTIVE screen will show the position of the rewind rod. When the rewind is complete, the pump displays the REWIND COMPLETE screen. The pump will beep once to let you know the rewind is complete.

NOTE: If using a partially filled cartridge, you can select "Stop" on the REWIND ACTIVE screen to stop the rewind at the position desired. You can do this at any time before the REWIND COMPLETE screen appears. After every third rewind, your pump is required to do a Full Prime/Rewind and will not offer the option of selecting the "Stop" position. A Full Prime/Rewind is always required when a battery is inserted.

6. Insert your filled cartridge.

7. Secure cartridge compartment cap to pump by turning in a clockwise motion until snug but **DO NOT** over tighten.

⚠ **WARNING: NEVER** start any part of the Prime/Rewind sequence on your pump while the infusion set is connected to your body. Always disconnect before you begin the sequence. The Prime/Rewind sequence includes steps for rewinding the pump motor, loading an insulin cartridge, and priming the infusion set tubing. Failure to disconnect your infusion set from your body before performing these steps can result in over delivery of insulin.

NOTE:

- If screen display has timed out while loading your cartridge, select "Prime/Rewind" from the MAIN MENU and highlight "Load Cart" from the ezPrime menu. Press OK to display the REWIND COMPLETE screen. Continue with step 8.
- You can only highlight "Load Cart" from the ezPrime menu after the rewind action is complete. This is true for all ezPrime menu options: you can only proceed to the next action once the previous action is complete.

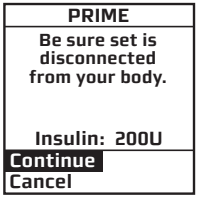
ezPrime
■ Rewind ☐ Load Cart ☐ Prime ☐ Fill Cannula
Main Menu

8. On the REWIND COMPLETE screen, "Continue" is highlighted. Press OK. Your pump will align the piston rod with the cartridge. The LOAD CARTRIDGE ACTIVE screen is displayed, followed by the PRIME screen. Your pump will beep once to let you know the cartridge is aligned with the piston rod.

REWIND COMPLETE
Disconnect set. Load U100 cartridge. Attach cap.
Continue Cancel

LOAD CARTRIDGE ACTIVE
Please wait.
>>---->>---->>---->>

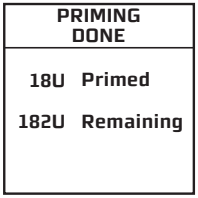
9. On the PRIME screen, "Continue" is highlighted. Press OK to display the DELIVER PRIME screen.



10. With "Go Prime" highlighted on the DELIVER PRIME screen, press and **hold** OK to display the PRIMING ACTIVE screen and begin priming.

⚠ **WARNING: NEVER** start any part of the Prime/Rewind sequence on your pump while the infusion set is connected to your body. Always disconnect before you begin the sequence. The Prime/Rewind sequence includes steps for rewinding the pump motor, loading an insulin cartridge, and priming the infusion set tubing. Failure to disconnect your infusion set from your body before performing these steps can result in over delivery of insulin.

11. Release the OK button to display the PRIMING DONE screen. After a few seconds, the ezPrime screen will appear and "Fill Cannula" is highlighted.



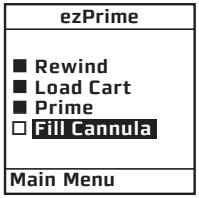
MAKE SURE your infusion set is properly primed by confirming that you have seen 5 drops of insulin come out the end of your infusion set. The amount of Prime insulin displayed on the PRIMING DONE screen may differ from the amount displayed during the Priming procedure by ±2U. If additional priming is required, select "Prime" a second time from the ezPrime screen and repeat steps for priming until you are sure 5 drops of insulin come out the end of your infusion set.

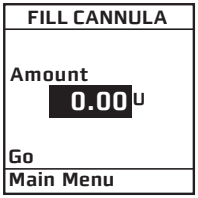
The maximum Prime amount is 20U at a time. The amount of Prime insulin displayed on the PRIMING DONE screen may differ from the amount displayed during the Priming procedure by ±2U. If additional priming is required, select "Prime" a second time from the ezPrime screen and repeat the steps for priming until you are sure 5 drops of insulin come out the end of your infusion set.

Refer to the *Instructions for Use* included with your infusion set for proper insertion guidelines. See *Selecting the Infusion Site* and *Inserting the Infusion Set* in this chapter.

12. Press the OK button to display the FILL CANNULA screen.

NOTE: This step is not necessary for needle sets.



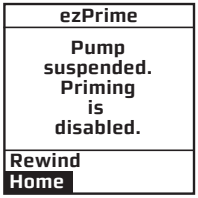


13. Use the ▲/▼ buttons to enter the amount of insulin needed to fill the cannula. Refer to the *Instructions for Use* included with your infusion set for details on how much insulin is required to fill the cannula. Press OK so that "Go" is highlighted.

14. Press OK to fill the cannula.

NOTE: The maximum Fill Cannula amount is 1U at a time.

Be sure the infusion set is not connected to your body until the prime is complete.



If your pump is suspended, the screen will alert you with the ezPrime "Pump suspended" screen. You must resume delivery of your pump in order to complete the Priming function. Scroll to "Home" on the ezPrime screen and press OK to display the MAIN MENU. Select "Suspnd/Resum" and follow the steps for resuming insulin delivery. See *Chapter 6 Section I*.

NOTE: The Fill Cannula step is not required for your pump to operate. For example, when you prime your pump after a battery change and you are not inserting a new infusion set, this step is not necessary. Filling the cannula when not necessary can result in unwanted delivery of insulin.

Selecting the Infusion Site and Inserting the Infusion Set

Your HCP will review appropriate site selections and techniques for insertion based on your body type. Refer to the *Instructions for Use* included with your infusion set for proper insertion guidelines.

⚠ **WARNING: AVOID** infusion sites on skin areas with tattoos, or areas with rough patches or scarring from your pump or insulin injections. These skin areas can cause redness, irritation, swelling, infection, and can interfere with the intended amount of insulin delivery.

⚠ **CAUTION:** If you are using the Dexcom G5® Sensor and Transmitter with your pump, **AVOID** injecting insulin or placing an insulin pump infusion set within 3 inches (7.5 centimeters) of the Sensor. Insulin delivery within 3 inches (7.5 centimeters) of the Sensor can cause inaccurate Sensor glucose readings.

Changing the Cartridge and Infusion Set

Cartridges and infusion sets require replacement and are not to be reused. Cartridges and infusion sets should be changed every 2 to 3 days as recommended by your HCP to avoid infection.

⚠ **WARNING: DO NOT** reuse cartridges or infusion sets. They should be discarded after each use to avoid contamination or infection. **ALWAYS** discard used cartridges and infusion sets according to local regulations for the safe disposal of medical waste. Contact your HCP or local waste collection agency for more information. Failure to follow these guidelines can pose health hazards.

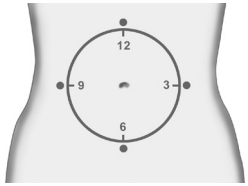
⚠ **CAUTION:**

- **CHECK** the infusion set tubing daily for any damage, leaks or kinks. **DO NOT** use infusion set tubing that is damaged, has leaks or is kinked. Damaged, leaking or kinked tubing can restrict or stop insulin delivery and result in under delivery of insulin.
- Change your infusion set every 2 to 3 days as recommended by your HCP to avoid infusion set occlusion or site infection.
- Rotate (alternate) the infusion set insertion sites giving time for healing. You should establish a routine for rotation and visual examination of the infusion set insertion sites to ensure that the sites remain healthy and free of redness, irritation, swelling, or infection.

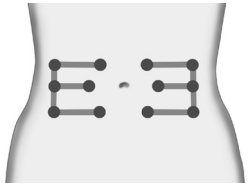
You should establish a routine for rotation and visual examination of the infusion set insertion sites to ensure that the sites remain healthy and free of redness, irritation, swelling, or infection.

Two commonly used methods for rotating infusion sites:

1. Visualize a clock drawn on your abdomen encircling your belly button. Start with your first infusion site at the 12 o'clock position and then move to the 3 o'clock, 6 o'clock and 9 o'clock positions, and back to the 12 o'clock position. Repeat in a circular fashion.



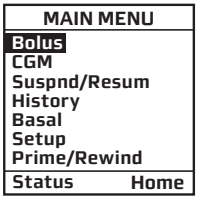
2. Visualize the letter "E" (or a backwards "E") drawn on either side of your belly button. Start with your first infusion site at one end of a letter and then move to the next point on the letter. Continue until you have covered all points on the letter, and then switch to other side of your belly button.



This chapter covers the basics of a Normal bolus. A Normal Bolus is a one-time infusion of insulin usually administered before a meal or when BG is high. It is used to cover your insulin needs. You should consult with your HCP to determine bolus insulin needs. Always check BG levels with a fingerstick test from your BG meter prior to making bolus decisions.

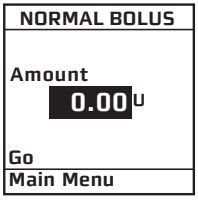
Your pump provides Normal Bolus and Advanced Bolus features (Audio Bolus, Combo Bolus, ezBG Bolus and ezCarb Bolus). A Normal Bolus is an infusion of insulin all at once, usually before a meal or when BG is high. See *Chapter 9 Section I* for a description of Advanced Bolus features.

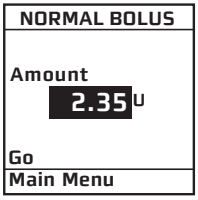
1. From the MAIN MENU, select "Bolus". If Advanced Features is not turned on, the Normal Bolus screen will be displayed and the cursor will flash over the amount field to indicate that it can be edited.



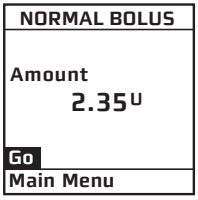
NOTE: ezBolus™ is a one-button shortcut to the Normal Bolus screen whenever the Audio Bolus feature is not activated. Press the black button on the right side of your pump. The Normal Bolus screen is displayed. Program a Normal Bolus as usual.

2. Use the ▲/▼ buttons to enter desired bolus amount.





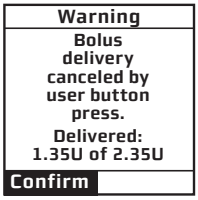
3. Press OK so that "Go" is highlighted. Press OK to deliver the bolus.



4. The Delivering bolus screen is displayed. If you have activated the Normal Bolus sound in the SETUP SOUND menu, your pump will beep to confirm start of delivery, as well as when delivery is complete.

NOTE:

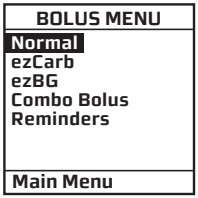
- During a bolus delivery, you can stop delivery at any time by pressing any button on the front panel of your pump. This action stops delivery and cancels the remaining amount. The Warning screen shown here will be displayed, providing you with the original amount of the bolus and the amount that has been delivered. Confirm the Warning by pressing OK and return to the Home screen. The amount delivered will be added to your Bolus History. Once a bolus is stopped it cannot be resumed. A new bolus amount must be programmed using the same steps for delivering a Normal Bolus. Stopping a Normal Bolus before the full amount has been delivered does not impact the bolus calculator settings that provide the inputs for calculating a suggested bolus amount.



- You can check when you last gave a bolus by looking in History or Status. These features are covered later. See *Chapter 7* and *Chapter 8 Section I*.

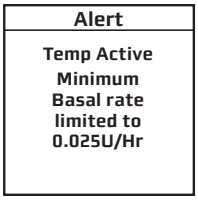
⚠ **WARNING: DO NOT** deliver a suggested bolus amount based on the bolus calculator if you have administered a manual injection by syringe or pen. The bolus calculator does not account for manual injections and could prompt more insulin to be delivered than needed, which could result in hypoglycemia. Contact your HCP to know how long to wait after administering the manual injection before relying on the bolus calculator.

NOTE: If you have Advanced Bolus and Reminders features turned on, the BOLUS MENU shown on the right will be displayed when you select "Bolus" from the MAIN MENU. Select "Normal" and press OK. Follow steps 2 through 4 in this chapter.



You can program your pump to display either 1 or 4 basal program options. Basal insulin is delivered continuously to help keep your BG in target between meals. Having more than one pre-set basal program makes it easy for you to switch programs for weekends, weekdays, shift work, menstruation and sick days. If you are new to pumping, your HCP may suggest you first become comfortable with one program before programming multiple basal programs. Consult with your HCP about basal insulin needs and what to do if you become ill.

NOTE: When you set a negative temporary basal rate, your pump will vibrate, beep and display an Alert screen to remind you of the minimum delivery limit. The screen (see the Alert screen below) will display once for 4 seconds, and the pump will vibrate and give one audible alert (if you turn on Alert sounds in Setup).

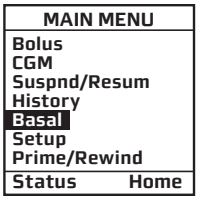


Setting a Basal Program

Each basal program can be set with up to 12 different basal rates (doses) in a 24-hour period. These 12 basal rates can be set to accommodate your changing basal needs throughout the day. For example, your body may need more insulin in the early hours of sleeping to compensate for the "dawn phenomenon." You can program time segments to begin at any hour or half hour.

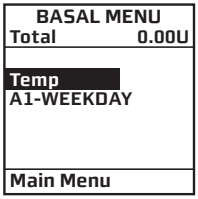
NOTE: The ▲/▼ buttons will move the cursor through pump display entries (fields) when not in Edit mode. When in Edit mode, the ▲/▼ buttons will change the value of the entry (field). If the cursor is flashing, that means you can edit the entry. Use the OK button to start/stop Edit mode.

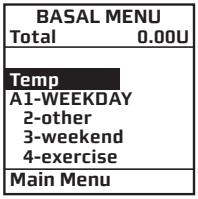
1. From the MAIN MENU, select "Basal". Press OK.



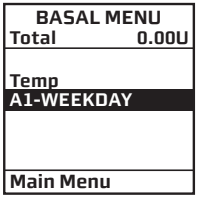
The BASAL MENU displays the following:

- Total basal insulin programmed for the 24-hour period
- Temp (if you wish to program a Temporary Basal rate)
- The active basal program, designated by number and by name, as well as an "A" to indicate the active program. (If you have activated multiple basal programs in the Setup Advanced menu, all 4 basal program options will be displayed as shown on the far right.)

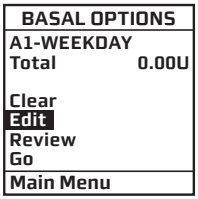




2. To set up a basal program (in this example the 1-WEEKDAY program) scroll to "1-WEEKDAY" and press OK to display the BASAL OPTIONS screen. On the BASAL OPTIONS screen, "Total" refers to the expected amount of insulin to be delivered in 24 hours with this basal program.



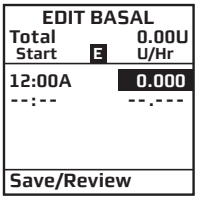
NOTE: You do not have to Suspend your pump to edit an active program. When you select "Edit" from the BASAL OPTIONS screen, your pump automatically suspends delivery. When you exit the Edit mode, the active program delivery automatically resumes.

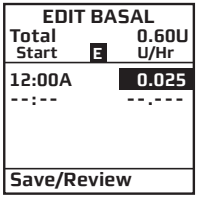


3. To edit the selected basal program, press the OK button. From the EDIT BASAL screen, you can edit the basal segments of the selected program (in this example the 1-WEEKDAY program).

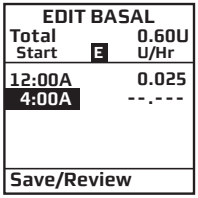
4. Scroll to the desired "U/Hr" field. Press OK to activate Edit mode (indicated by flashing cursor). The highlighted "E" indicates you are in the Edit mode.

5. Use ▲/▼ buttons to set desired basal rate for the first start time (12 AM in this example). Press OK to confirm and exit Edit mode for this field.



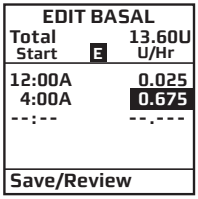


6. Scroll down to select the next "Start" time field. Press the OK button to activate Edit mode (indicated by flashing cursor).



NOTE: The next available empty basal segment will appear automatically as you program the previous segment. If the next empty basal segment does not appear, you have programmed all 12 possible segments.

7. To change the next "Start" time field as desired, press the OK button to exit Edit mode. Segments can start on the hour or half hour. The end time of the current time segment is always assumed to be midnight.



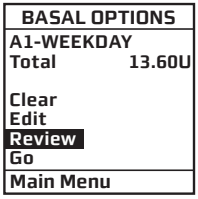
NOTE: The 24-hour Total changes automatically as you change U/Hr settings.

8. Continue until basal segments have been set as recommended by your HCP.

9. When finished, scroll to "Save/Review" and press OK. *If you have edited the active program, it is now resumed automatically.* The BASAL OPTIONS screen is displayed and "Review" is highlighted.

NOTE: If your screen display has timed out (gone to sleep) or if an Alarm/Warning appears before you have selected "Save/Review" while editing, a Warning screen will remind you the basal edit has not been saved and basal delivery has been suspended. See *Chapter 11 Section I*.

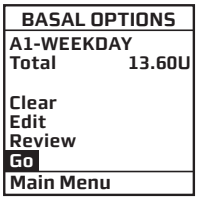
10. Press OK to review your entries for accuracy. Your basal segment settings are displayed, 5 per screen, depending on how many of the possible segments you have programmed. If you have more than 5 segments programmed, scroll to "Next" on the bottom of the first or second screen to see the second and third screens as desired.



11. When finished reviewing the basal segment screens, press OK with "Options" highlighted or any of the basal program review screens. The BASAL OPTIONS screen is displayed.

a. If you have edited and saved/reviewed the active program, it is resumed automatically. You can also select "Go" and the Home screen is displayed, which shows the current rate of delivery for the program that is active.

b. If you have edited an inactive program and wish to activate it, select "Go" from the BASAL OPTIONS screen. When you select "Go", the Home screen is displayed, which shows the current rate of delivery for the program that is active.



Adding/Changing Segments in an Existing Basal Program

1. From the BASAL MENU, select desired program and press OK. The BASAL OPTIONS screen is displayed and "Edit" is highlighted.

2. Press OK to display the EDIT BASAL screen and begin editing basal segments.

3. Scroll to highlight the field you wish to change or to next available blank line to add a segment. Press OK to activate Edit mode. (The cursor will flash to indicate Edit mode.)

4. Use ▲/▼ buttons to set Start times and U/Hr amounts.

5. Check that the AM/PM settings are correct.

NOTE:

- If you program a segment to start at the same time as an existing segment, the previously entered segment is replaced.
- If you program a segment to start at a time that precedes an existing segment, the new segment is automatically inserted in the correct place. You must then scroll to the new segment, highlight the corresponding U/Hr field and enter or change amount, if desired.

6. When finished, scroll to “Save/Review” and press OK. If you have edited the active program, it is now resumed automatically. The BASAL OPTIONS screen is displayed.

a. Select “Review” from the BASAL OPTIONS screen to review your entries for accuracy. Your basal segment settings are shown (5 on first screen, 5 on second screen and 2 on last screen). If you have more than 5 segments programmed, scroll to “Next” to see second and third screens as desired.

b. If you have edited an inactive program, select the program from the BASAL MENU. Press OK. Select “Go” from the BASAL OPTIONS screen to activate the program you have selected.

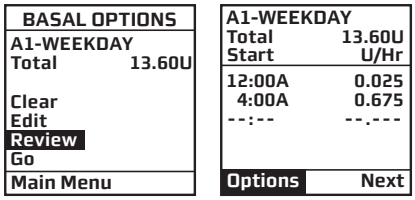
When you select “Go”, the Home screen is displayed, which shows the current rate of delivery for the program that is active. (Or you can simply wait for your pump display to time out. When you press any button, your active basal program rate information is displayed on the Home screen.)

⚠ **CAUTION: ALWAYS** review changes in your pump settings with your HCP to make sure they are correct. Incorrect settings can result in under delivery or over delivery of insulin.

Reviewing Basal Programs

1. From the BASAL MENU, scroll to highlight desired program. Press OK.

2. Scroll to "Review" from the BASAL OPTIONS screen. Press OK. Your basal segment settings are displayed, 5 per screen, depending on how many of the possible segments you have programmed. If you have more than 5 segments programmed, scroll to "Next" on the bottom of the first or second screen to see the second and third screens as desired.



3. When finished reviewing the basal segment screens, press OK with "Options" highlighted or any basal program review screens. The BASAL OPTIONS screen is displayed.

4. Scroll to "Main Menu" and press OK. The MAIN MENU is displayed. *The active basal program continues.*

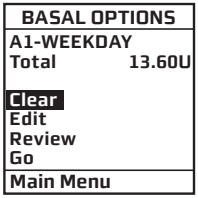
5. If reviewing an inactive program and you wish to activate it, select the program you wish to activate from the BASAL MENU screen. Press OK.

6. Select "Go" from the BASAL OPTIONS screen to activate the program. The Home screen is displayed to show the current rate per hour of the program you have activated.

Clearing Basal Programs

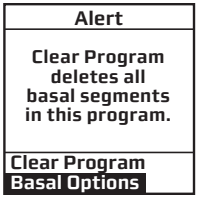
This feature allows you to clear all information from a basal program.

1. From the BASAL MENU, scroll to desired program.



2. From the BASAL OPTIONS screen, scroll to "Clear". Press OK.

If you press OK to select "Clear", your pump will check to be sure you want to clear all the segments of the basal program selected. The Alert screen shown here is displayed. If you do wish to clear all the basal segments of the selected program, scroll to "Clear Program" and press OK.



If you do not wish to clear all the basal segments, scroll to "Basal Options" and press OK. The BASAL OPTIONS screen will be displayed.

If all segments of your active basal program are set to 0.000 U/Hr your pump will not deliver any basal insulin. Each time you wake up your pump, the Alert screen shown here is displayed. If you have turned on the sound for Alerts, you will also be notified by a beep or vibrate. This Alert screen does not progress to higher audible alarms. You have the option to either select "Confirm" to quickly go to the MAIN MENU or select "Basal Menu" to reset rates in your active program. For more information see *Chapter 11 Section I*.

Temporary Basal Feature

This feature allows you to temporarily increase or decrease your basal delivery rate for a set duration to cover events such as sick days or exercise. Once the set duration expires, the pump will resume your active basal delivery program/rate. You can decrease your basal rate by up to 90% (in 10% decrements) or increase your basal rate by up to 200% (in 10% increments). You can also set to OFF.

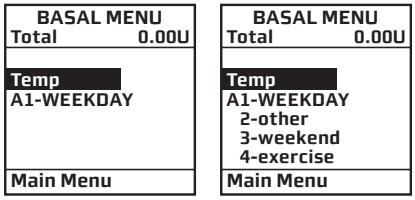
You can set duration for up to 24 hours in half-hour increments. (If you have activated multiple basal programs in the Setup Advanced menu, all 4 basal program options will be displayed as shown on screen example in step 1 that follows.)

With a battery change, cartridge change, priming your infusion set, suspending insulin delivery, or warnings, alarms, and alerts that stop insulin delivery, any Temp Basal is canceled. Once insulin delivery resumes, your active basal program/rate for the current time set in the pump will resume. If you wish to return to Temp Basal mode, you will need to re-set your desired percentage and duration.

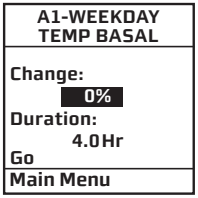
As an example, let's say you are about to play tennis and would like to decrease your basal rate by 40% for the next 2 hours.

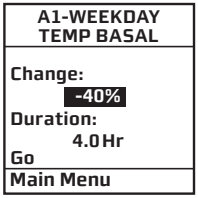
If your current active basal rate is 1.000 U/Hr, your Temp Basal rate setting will adjust the rate to 0.600 U/Hr (1.000 U/Hr to 0.400 U/Hr) for the next 2 hours. After the 2 hour period, your active basal program/rate will resume to 1.000 U/Hr. See steps 1 through 4 that follow to set a Temp Basal.

1. From the BASAL MENU, scroll to "Temp". Press OK.

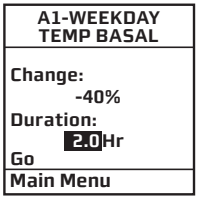


2. The "Change" % field will flash to indicate Edit mode. Use the ▲/▼ buttons to enter the percentage change desired. Press the OK button to exit Edit mode.





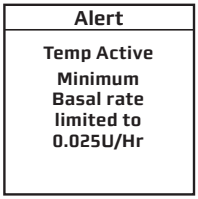
3. The "Duration" field is highlighted. Press OK to activate Edit mode.



4. Use the ▲/▼ buttons to enter the duration desired. Press OK to exit Edit mode.

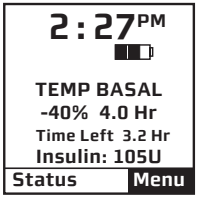
NOTE:

- The lowest basal delivery amount possible is 0.025 U/Hr. When you set a negative temporary basal rate, your pump will vibrate, beep and display an Alert screen to remind you of the minimum delivery limit. The screen will display once for 4 seconds, and the pump will vibrate and give one audible alert (if you turn on Alert sounds in Setup).
- If you would like to deliver a temp basal amount less than 0.025 U/Hr, you can select "OFF" in the "Change" % field in the screen above. This will set the temp basal rate to 0.0 U/Hr for the duration selected.



5. "Go" is highlighted. Press OK to activate Temp Basal.

6. The Home screen is displayed and shows your Temp Basal is active, the percentage change, the duration and how much time is left. When the duration of time is complete, your pump will automatically resume the active basal program.

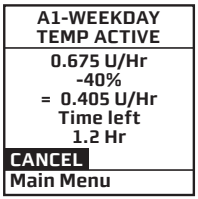


NOTE: If you turned on the Temp Basal sound in Setup, your pump will beep once every 30 minutes to remind you of Temp Basal status.

Canceling a Temporary Basal Program

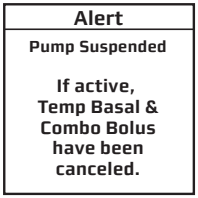
1. From the BASAL MENU, select "TEMP BASAL". Press OK.

2. Details of the current active Temp Basal program will be displayed. Scroll up to "CANCEL" and press OK.



Your previously active basal program will be activated and the Home screen will be displayed to show the current rate per hour of the active basal program.

NOTE: If you Suspend your pump while a Temp Basal program is active, the Temp Basal will be canceled and an Alert screen will notify you that the Temp Basal program has been canceled. Your active basal program/rate will resume once insulin delivery resumes. This Alert is displayed once and gives an audible tone once (if you turned on Alert sounds in Setup). Temp Basal is also canceled when you change the battery and/or prime.



As an example, let's say you set a Temp Basal that would reduce your basal rate by 40% for the next 2 hours.

If your current active basal rate is 1.000 U/Hr, your Temp Basal rate setting will adjust the rate to 0.600 U/Hr (1.000 U/Hr to 0.400 U/Hr).

During the 2 hour period you decide to suspend your pump at which time all insulin delivery will stop, and the Temp Basal in effect will be canceled. Upon resuming insulin delivery, your basal rate will resume to your active basal program/rate of 1.000 U/Hr.

⚠ **WARNING:**

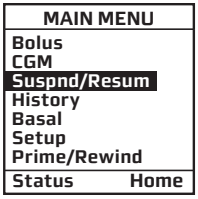
- **ALWAYS** review changes in your pump settings with your HCP to make sure they are correct. Incorrect settings can result in under or over delivery of insulin.
- **ALWAYS** use a fingerstick BG for treatment decisions, in regards to how much insulin you should take. The Sensor and Transmitter do not replace a BG meter and BG values may differ from Sensor glucose readings. Using glucose readings from the Sensor and Transmitter to make treatment decisions can result in serious injury or death.

This feature allows you to stop and restart delivery quickly and easily.

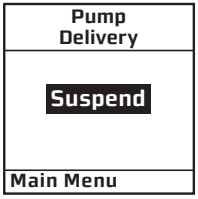
It also cancels delivery of any Temp Basal or Bolus, including any Combo Bolus that may be currently active. The Combo Bolus feature is covered in *Chapter 9 Section I*. You will not be able to deliver any insulin while the pump is suspended, including any bolus amount suggested by the bolus calculator.

Suspending Delivery

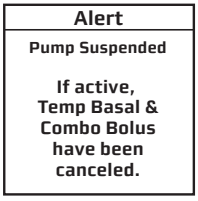
1. From the MAIN MENU, scroll to "Suspnd/Resum" and press OK.



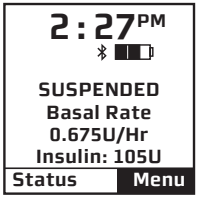
2. "Suspend" is highlighted. Press OK.



The screen will display a message reminding you that this mode not only suspends your active basal delivery but also *cancels* any Temp Basal or Combo Bolus that may be active. It also cancels delivery of any Temp Basal or Bolus, including any bolus initiated using the bolus calculator, and any Combo Bolus that may currently be active. The Combo Bolus feature is covered in *Chapter 9 Section I*. You will not be able to deliver any insulin while the pump is suspended, including any bolus amount suggested by the bolus calculator. Once you resume delivery, you will need to re-enter values if you want to use the bolus calculator to suggest and deliver another bolus.



3. The Home screen is then displayed, showing that pump deliveries are suspended.

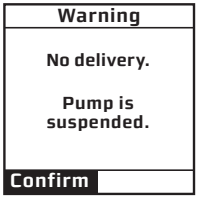


⚠ CAUTION:

- If you are using the Dexcom G5® Sensor and Transmitter with your pump, suspending your pump affects the recording and displaying of CGM Sensor readings.
- While insulin delivery is suspended, your CGM session (*see Section II*) will remain active, but CGM Sensor readings will not be recorded or displayed. As soon as insulin delivery resumes, CGM Sensor readings will start recording and displaying again.
- If you want to temporarily suspend insulin delivery but still view CGM Sensor readings, do not use the suspend delivery feature. Instead, you can set Temp Basal to OFF for the time period you want basal delivery suspended.

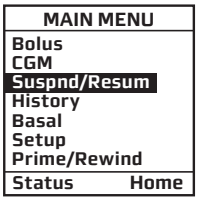
NOTE:

- Periodically, your pump will beep (or vibrate if that is the setting you selected) to remind you of the Suspend status. If not confirmed, the beeps will progress to high volume in one hour. You can confirm the Warning to reset the audible sequence. See *Chapter 11 Section I*.
- If you are using the Dexcom G5® Sensor and Transmitter with your pump and you suspend insulin delivery during the 2-hour CGM Calibration Startup period, the calibration sequence will continue and the CGM session will remain active even though insulin delivery is suspended.
- See *Section II* for information on CGM functions.

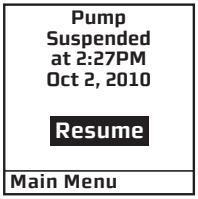


Resuming Delivery

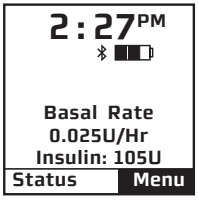
1. From the MAIN MENU, scroll down to “Suspnd/Resum” and press OK.



2. “Resume” is highlighted. Press OK.



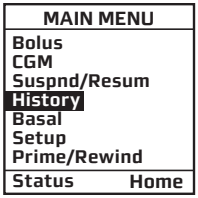
3. The Home screen is displayed to show you that your pump is no longer in Suspend mode. Your previously active basal program is automatically resumed.



Your pump stores important records for your review. You can access your pump's history and view it directly on your pump screen. Or you can use compatible diabetes management software to track, review and analyze pump history on your computer. If you are using the Dexcom G5® Sensor and Transmitter with your pump, and want to view CGM History, see *Chapter 7 Section II*.

Your pump stores basal rates, boluses, alarms and settings. Your pump stores these records indefinitely, even when batteries are removed.

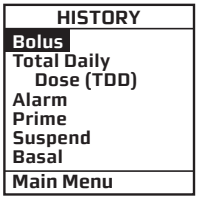
From the MAIN MENU, select "History". The HISTORY menu is displayed.

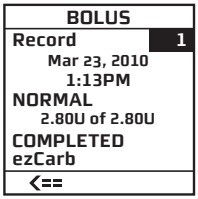


Bolus History

Your pump displays the last 500 Bolus records.

1. From the HISTORY menu, select "Bolus".





The screen displays the following:

- Bolus Record number
- Date of bolus
- Time of bolus
- Type of bolus delivered
  - Normal
  - Combo
  - Audio
- Amount of bolus programmed and delivered
- Status of bolus
  - ACTIVE
  - COMPLETED
  - CANCELED
- If ezBG or ezCarb was used

2. To view other Bolus records first scroll up to highlight the record field. Press OK to activate Review mode (indicated by flashing cursor).

3. Record 1 indicates the most recent record. Use the ▲/▼ buttons to scroll to other records.

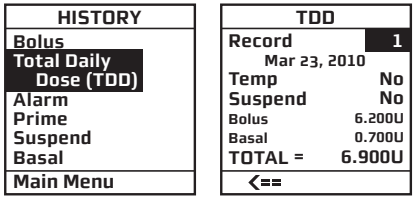
4. When finished reviewing, press OK to exit Review Mode.

5. "<==" is highlighted. Press OK to return to the HISTORY menu.

Total Daily Dose (TDD) History

Your pump displays the last 120 TDD records.

1. From the HISTORY menu, select "Total Daily Dose (TDD)".



This screen displays the following:

- Record number
- Date of record
- If Temp Basal was active on that date
- If Suspend was activated on that date
- Total Bolus for the date
- Total Basal for the date
- Total dose for the date

NOTE: Each daily total is the total delivered since midnight.

2. Scroll up to highlight the record field. Press OK to activate Review Mode (indicated by flashing cursor).

3. Record 1 indicates the most recent record. Use the ▲/▼ buttons to scroll to other records.

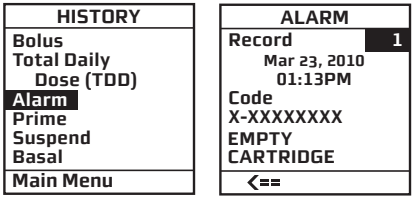
4. When finished reviewing, press OK to exit Review Mode.

5. "<<==" is highlighted. Press OK to return to the HISTORY menu.

Alarm History

Your pump HISTORY menu displays the last 30 alarm records related to insulin delivery. If you are using the Dexcom G5® Sensor and Transmitter with your pump, alarms related to CGM functions can be displayed under the CGM Menu options (see *Chapter 7 Section II*).

1. From the HISTORY menu, select "Alarm".



The screen displays the following:

- Record number
- Date of alarm
- Time of alarm
- Alarm code
- Alarm type

2. Scroll up to highlight the record field. Press OK to activate Review Mode (indicated by flashing cursor).

3. Record 1 indicates the most recent record. Use the ▲/▼ buttons to scroll to other records.

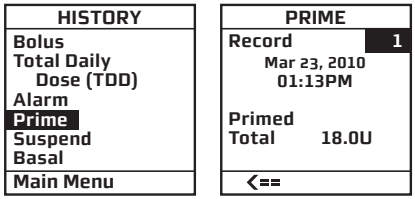
4. When finished reviewing, press OK to exit Review Mode.

5. "<==" is highlighted. Press OK to return to the HISTORY menu.

Prime History

Your pump displays the last 60 Prime and Fill Cannula records. Prime and Fill Cannula records are stored as separate records.

1. From the HISTORY menu, select "Prime".

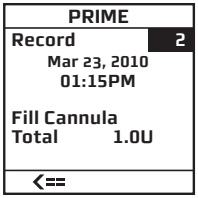


The screen displays the following:

- Record number
- Date of prime
- Time of prime
- Amount of prime

2. Scroll up to highlight the record field. Press OK to activate Review Mode (indicated by flashing cursor).

3. Record 1 indicates the most recent record. Use the ▲/▼ buttons to scroll to other records.



The screen displays the following:

- Record number
- Date of cannula fill
- Time of cannula fill
- Amount of cannula fill

4. When finished reviewing, press OK to exit Review Mode.

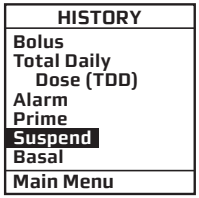
5. "<==" is highlighted. Press OK to return to the HISTORY menu.

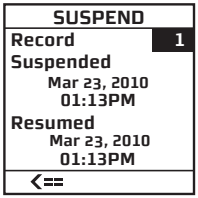
Suspend History

Your pump displays the last 30 Suspend records.

1. From the HISTORY menu, select “Suspend”. The screen displays the following:

- Record number
- Date and time pump delivery was suspended
- Date and time pump delivery was resumed





2. Scroll up to highlight the record field. Press OK to activate Review Mode (indicated by flashing cursor).

3. Record 1 indicates the most recent record. Use the ▲/▼ buttons to scroll to other records.

4. When finished reviewing, press OK to exit Review Mode.

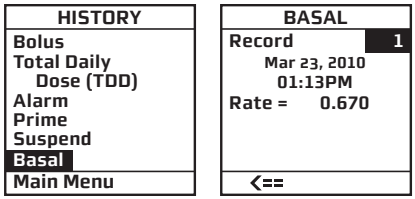
5. “<==” is highlighted. Press OK to return to the HISTORY menu.

Basal History

Your pump keeps track of whenever there has been a change in a basal rate and will display the last 270 basal "rate change" records.

1. From the HISTORY menu, select "Basal". The screen displays the following:

- Record number
- Date and time basal rate was adjusted
- Basal rate adjustment



2. Scroll up to highlight the record field. Press OK to activate Review Mode (indicated by flashing cursor).

3. Record 1 indicates the most recent record. Use the ▲/▼ buttons to scroll to other records.

4. When finished reviewing, press OK to exit Review Mode.

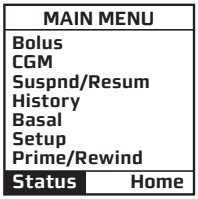
5. "<==" is highlighted. Press OK to return to the HISTORY menu.

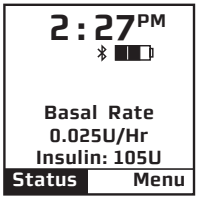
NOTE: Basal History records each basal rate change. When no basal is being delivered, the Basal History Record will show 0 units delivered. This can happen for the following reasons:

- Cartridge change
- Battery change
- Suspend
- Alarm
- Basal segment set to 0.00
- Basal edit screen accessed
- Prime menu accessed
- Loss of prime

This feature gives you easy access to a summary of information about your pump's current programming and performance. There are eight Status screens. The Status screen number represents the order in which the screens can be viewed.

1. From the MAIN MENU or from the Home screen, scroll to "Status" and press OK.

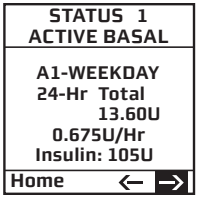




Status Screen 1 – Active Basal

The screen displays the following information:

- Which basal program is currently active
- The 24-hour total for the active basal program
- Units per hour currently being delivered
- Insulin currently remaining in cartridge



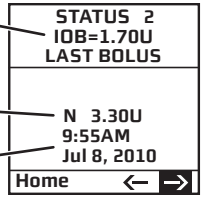
To move to the next STATUS screen, press OK with "→" highlighted at the bottom of the screen.

To return to the Home screen, highlight "Home" and press OK.

Status Screen 2 – Insulin on Board, Last Bolus

The screen displays the following information:

- Amount of insulin currently "on board" (indicated by "IOB" on the screen). For more information on this feature, see *Chapter 9 Section I*.
- Type and amount of last completed bolus
  - N = Normal
  - C = Combo (normal portion only)
  - A = Audio
- Time and date of last bolus



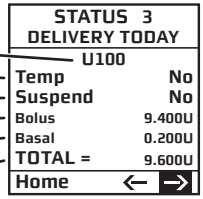
To move to the next STATUS screen, press OK with "→" highlighted at the bottom of the screen.

To return to the Home screen, highlight "Home" and press OK.

Status Screen 3 – Delivery Today

The screen displays the following information since midnight and up to the current time stored in the pump:

- Insulin type
- If Temp Basal has been active
- If Suspend has been active
- Total bolus amount delivered
- Total basal amount delivered
- Total insulin delivered (*excluding* prime amounts)



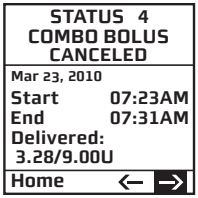
To move to the next STATUS screen, press OK with "→" highlighted at the bottom of the screen.

To return to the Home screen, highlight "Home" and press OK.

Status Screen 4 – Combo Bolus

The screen displays the following information:

- Most recent Combo Bolus status
  - Active or Completed or Canceled
  - Start date
  - Start time
  - End time
  - Amount delivered (if active, shows amount delivered as of current time stored in the pump)



For more information on Combo Bolus, see *Chapter 10 Section I*.

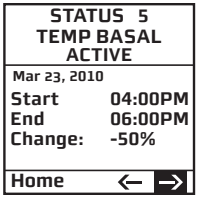
To move to the next STATUS screen, press OK with "→" highlighted at the bottom of the screen.

To return to the Home screen, highlight "Home" and press OK.

Status Screen 5 – Temp Basal

The screen displays the following information:

- Most recent Temp Basal status
  - Active/Inactive
  - Start date
  - Start time
  - End time
  - % adjustment



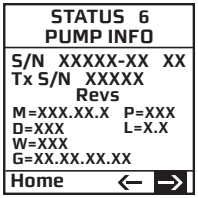
To move to the next STATUS screen, press OK with "→" highlighted at the bottom of the screen.

To return to the Home screen, highlight "Home" and press OK.

Status Screen 6 – Pump Information

The screen displays the following information:

- Pump serial number
- Transmitter ID (see *Chapter 2 Section II*).
- Software versions

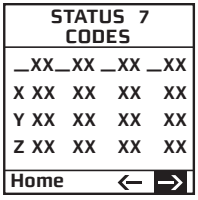


To move to the next STATUS screen, press OK with "→" highlighted at the bottom of the screen.

To return to the Home screen, highlight "Home" and press OK.

Status Screen 7 – Additional Pump Codes

The screen contains a series of alphanumeric codes that Customer Service can use to troubleshoot problems with your pump.

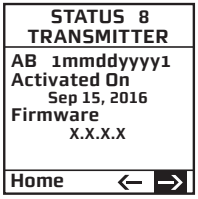


To move to the next STATUS screen, press OK with "→" highlighted at the bottom of the screen.

To return to the Home screen, highlight "Home" and press OK.

Status Screen 8 – Transmitter Information

The screen contains Transmitter information that may be required upon calling customer service to help troubleshoot problems with your Transmitter.



To move to the next STATUS screen, press OK with "→" highlighted at the bottom of the screen.

To return to the Home screen, highlight "Home" and press OK.

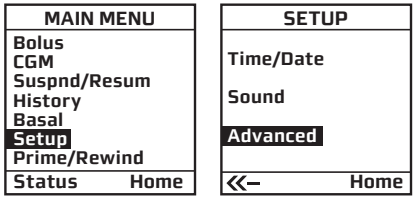
Now you have made it through the basics! Your pump offers many advanced features that you may find helpful in managing your diabetes. Consult with your HCP to determine which advanced features and settings are appropriate for you.

⚠ **WARNING: ALWAYS** review changes in your pump settings with your health care professional to make sure they are correct. Incorrect settings can result in under or over delivery of insulin.

This chapter tells you how to set up and turn on the advanced features. *Chapter 10 Section I* covers how to use each advanced feature.

From the MAIN MENU, select "Setup". Then select "Advanced" from the SETUP screen and press OK.

Selecting "Advanced" gives you access to series of Advanced Feature setup screens (SETUP ADV 1 – SETUP ADV 9) where you can make your selections to activate and personalize Advanced Feature settings.

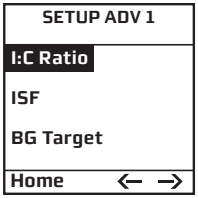


The SETUP ADV 1 screens allow you to program personal settings that will be used with the ezCarb and ezBG features.

Setup Advanced Screen 1 – Personal Settings - Insulin to Carb (I:C) Ratios

An Insulin to Carb (I:C) ratio is the amount of carbs you can cover with one unit of insulin. Your HCP may recommend that you use different Insulin to Carb (I:C) ratios for different times of the day. When you use the ezCarb feature, your pump will automatically select the I:C ratio for the current time stored in the pump.

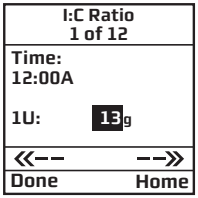
This screen allows you to set different I:C ratios for 12 different time slots.



NOTE: If you set only one Insulin to Carb Ratio, it will be used for the entire 24-hour period.

1. From the SETUP ADV 1 screen, scroll up to "I:C Ratio". Press OK.

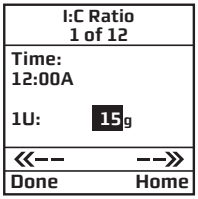
2. The first segment always starts at midnight. The last time slot available is 11:30pm. Use the ▲/▼ buttons to scroll to the "1U:" (grams) field.

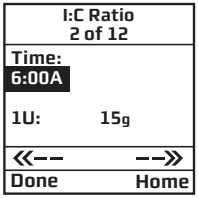


3. Press OK to change to flashing cursor for Edit mode.

4. Use the ▲/▼ buttons to change to desired setting.

5. Press OK when setting is made.





6. To move to the next I:C Ratio screen, scroll to "––»" and press OK.

7. Scroll up to the "Time" field and press OK to change to flashing cursor for Edit mode.

8. Use the ▲/▼ buttons to change the segment start time. Press OK.

9. Scroll to the "1U:" (grams) field and press OK to change to flashing cursor for Edit mode.

10. Use the ▲/▼ buttons to change the "1U:" (grams) field as desired. Press OK. Repeat to set remaining segments per your HCP's recommendations.

To review your settings, highlight "––»" and press OK to scroll through each segment. Confirm the times and setting values are correct.

When finished, scroll to "Done" and press OK to return to the SETUP ADV 1 screen.

To return to the Home screen, scroll to "Home" and press OK.

⚠ **WARNING: DO NOT** set your I:C ratios without first consulting your HCP. Failure to have the correct I:C ratios can result in over or under delivery of insulin.

Setup Advanced Screen 1 – Personal Settings - Insulin Sensitivity Factor (ISF)

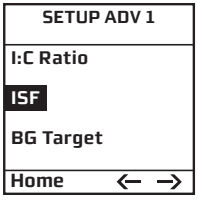
An Insulin Sensitivity Factor (ISF) is the amount you can expect to lower your BG with one unit of insulin. Your HCP may recommend that you use different Insulin Sensitivity Factors (ISFs) for different times of the day. When you use the ezCarb or ezBG feature, your pump will automatically select the ISF for the current time stored in the pump.

This screen allows you to set different ISFs for 12 different time slots.

NOTE: If you set only one Insulin Sensitivity Factor, it will be used for the entire 24-hour period.

⚠ **WARNING: ALWAYS** review changes in your pump settings with your HCP to make sure they are correct. Incorrect settings can result in under or over delivery of insulin and result in serious injury or death.

1. From the SETUP ADV 1 screen, scroll up to "ISF". Press OK.

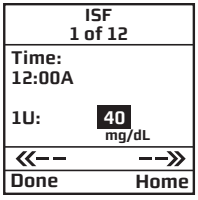


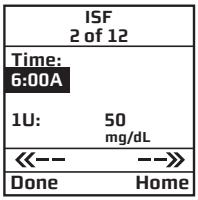
2. The first segment always starts at midnight. The last time slot available is 11:30pm. Use the ▲/▼ buttons to scroll to the "1U:" (mg/dL) field.

3. Press OK to change to flashing cursor for Edit mode.

4. Use the ▲/▼ buttons to change to desired setting.

5. Press OK when setting is made.





6. To move to the next ISF screen, scroll to "--»" and press OK.

7. Scroll up to the "Time" field and press OK to change to flashing cursor for Edit mode.

8. Use the ▲/▼ buttons to change the segment start time. Press OK.

9. Scroll to the "1U:" (mg/dL units) field and press OK to change to flashing cursor for Edit mode.

10. Use the ▲/▼ buttons to change the "1U:" (mg/dL units) field as desired. Press OK. Repeat to set remaining segments per your HCP's recommendations.

To review your settings, highlight "--»" and press OK to scroll through each segment. Confirm the times and setting values are correct.

When finished, scroll to "Done" and press OK to return to the SETUP ADV 1 screen.

To return to the Home screen, scroll to "Home" and press OK.

Setup Advanced Screen 1 – Personal Settings - BG Target Ranges

A BG Target is your personal goal for keeping your BG levels under control. A BG Target may be set as an actual range (with a minimum and maximum value), or a single value. Your HCP may recommend you use different BG Target ranges (or values) for different times of the day.

The BG Targets (ranges or values) that you set in the pump are important as they are used in calculating suggested BG correction bolus amounts when using the ezBG and ezCarb features on your pump (see *Chapter 10 Section I*). When the pump calculates a suggested BG correction bolus, it begins the calculation by determining the difference between your current BG and the BG Target range/value for the current time of day stored in the pump. That number, along with your ISF, is then used to calculate a BG correction bolus amount that would bring your current BG in line with your BG Target range/value.

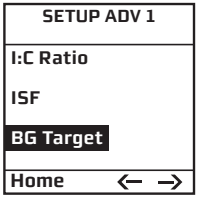
In addition to the BG correction bolus amount, there are other factors that are used in calculating suggested insulin bolus amounts when using the ezBG and ezCarb features on your pump. These include the amount of Insulin on Board from a previous bolus, your ISF, and your I:C Ratio. For more information about Insulin on Board including activation of the feature on your pump, refer to *Setup Advanced Screen 8 – Insulin on Board* in this chapter. See *Chapter 10 Section I* for information on using the ezBG and ezCarb features on your pump.

NOTE: The BG Targets discussed here are different than the Low and High Glucose Alerts that apply only to CGM Sensor readings when using the Dexcom G5® Sensor and Transmitter with your pump. See *Chapter 2 Section II* for more information on CGM Alerts.

The SETUP ADV 1 (BG Target) screen allows you to set different BG Target (ranges or values) for 12 different time slots. Each BG Target (range or value) is set by first selecting a BG Target and then a +/- amount that will define the minimum and maximum of the range. For example, a BG Target of 120 mg/dL and a +/- amount of 10 mg/dL means the Target range will be set to 110 to 130 mg/dL. If you prefer to correct your BG to one target value rather than a range, set the +/- amount to 0.

NOTE: If you set only one BG Target, it will be used for the entire 24-hour period.

1. From the SETUP ADV 1 screen, scroll up to “BG Target”. Press OK.

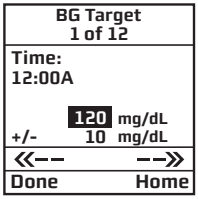


2. The first segment always starts at midnight. The last time slot available is 11:30pm. Use the ▲/▼ buttons to scroll to the BG Target field.

3. Press OK to change to flashing cursor for Edit mode.

4. Use the ▲/▼ buttons to change to desired setting.

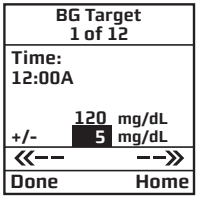
5. Press OK when setting is made.



6. Scroll to the “+/-”(range) field. Press OK to change to flashing cursor for Edit mode.

7. Use the ▲/▼ buttons to change the range as desired. Press OK.

8. To move to the next BG Target screen, scroll to “--»” and press OK.



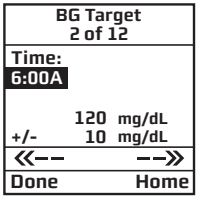
9. Scroll up to the “Time” field and press OK to change to flashing cursor for Edit mode.

10. Use the ▲/▼ buttons to change the segment start time. Press OK.

11. Scroll to the BG Target field. Press OK to change to flashing cursor for Edit mode.

12. Use the ▲/▼ buttons to change to desired setting.

13. Press OK when setting is made.



14. Scroll to the "+/-"(range) field. Press OK to change to flashing cursor for Edit mode.

15. Use the ▲/▼ buttons to change the range as desired. Press OK. Repeat to set remaining segments per your HCP's recommendations.

To review your settings, highlight "⟶⟶" and press OK to scroll through each segment. Confirm that the times and setting values are correct.

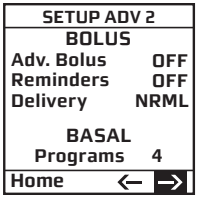
When finished, scroll to "Done" and press OK to return to the SETUP ADV 1 screen.

To return to the Home screen, scroll to "Home" and press OK.

Setup Advanced Screen 2 – Advanced Bolus Features and Multiple Basal Programs

You can program your pump to increase the number of bolus types and basal program options available to you. You can also program the speed of bolus insulin delivery, and choose to turn the personal Reminders feature on or off.

This screen allows you to:



- Turn Advanced Bolus Features (ezCarb, ezBG, Combo Bolus) on or off
- Turn personal Reminders feature on or off
- Select bolus delivery speed
  - NRML (normal): 1U every second
  - SLOW: 1U every 5 seconds

NOTE: Users may experience a slight stinging sensation with normal bolus delivery. If this occurs changing the bolus delivery speed to "SLOW" may reduce the stinging sensation, particularly with very large boluses.

- Select either 1 basal program or 4 basal programs to be displayed in the BASAL MENU. Users find this feature beneficial if their activity level is different during the week than on weekends. Switching work shifts is another reason to use multiple basal programs. Some people use a different basal program during menstruation. An "A" will appear to the left of the Basal Program that is currently active when displaying the BASAL MENU screen.

NOTE: On the SETUP ADV 2 screen you can only set your basal programs to 1 if your 1-Weekday program is active. The Alert screen shown here will be displayed to remind you. If a basal program other than the "1-Weekday" program is currently active on your pump, you cannot change the number of basal programs on the SETUP ADV 2 screen from 4 to 1. This is because you have already activated a second basal program. The Alert screen shown here will be displayed to remind you.

1. From the SETUP ADV 2 screen, scroll to the desired field.

2. Press OK to change to flashing cursor for Edit mode.

3. Use the ▲/▼ buttons to change to desired setting.

4. Press OK when setting is made.

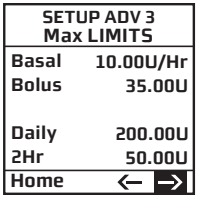
5. Scroll to "→", "←", or "Home" at the bottom of the screen. Select "→" or "←" to go to other Advanced Setup screens, or "Home" to go to the Home screen.

6. Press OK.

Setup Advanced Screen 3 – Insulin Limits

You can program your pump to control the maximum amount of basal, bolus, daily insulin, and insulin delivered in a 2-hour period. Your pump will alert you when you exceed these amounts.

This screen allows you to:



- Set maximum basal delivery per hour
- Set maximum bolus amount
- Set maximum daily (24-hour) delivery amount. Your pump checks that total insulin delivery each 24-hour period (running from midnight of the previous day to midnight of the current day) does not exceed this limit.
- Set maximum 2-hour delivery amount. Your pump checks that total insulin delivery over each rolling 2-hour period does not exceed this limit.

NOTE: The maximum bolus amount you can deliver for any type of bolus (including Audio Bolus) is 35U.

⚠ WARNING:

- Use caution when bolusing amounts greater than 25 units. Bolusing very large amounts of insulin can result in over delivery of insulin.
- Insulin delivery limits should be determined in consultation with your HCP.
- Caregivers should speak with the patient's HCP regarding maximum pump settings as a layer of security against inadvertent button pushing resulting in insulin delivery.

1. From the SETUP ADV 3 screen, scroll to the desired field.

2. Press OK to change to flashing cursor for Edit mode.

3. Use the ▲/▼ buttons to change to desired setting.

4. Press OK when setting is made.

5. Scroll to "→", "←", or "Home" at the bottom of the screen. Select "→" or "←" to go to other Advanced Setup screens, or "Home" to go to the Home screen.

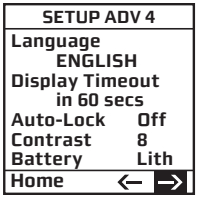
6. Press OK.

NOTE: Should you attempt a delivery that exceeds the limits you have set, your pump will alert you and display a text message. See *Chapter 11 Section I* for additional information.

Setup Advanced Screen 4 – Language Setup, Display Timeout, Auto-Lock, Contrast and Battery Type

You can customize how information will be displayed on your pump, and what type of battery you will use.

This screen allows you to:



- Select a different language
- Set the length of time your display stays on before timing out (sleep mode)
  - 15, 30, 45 or 60 seconds
- Select Auto-Lock feature ON or OFF

  NOTE:
  - If auto-lock is enabled your pump will lock after entering sleep mode.
  - For pediatric patients or those patients whose therapy is administered by a caregiver it is recommended the auto-lock is turned ON.
- Select a contrast setting
- Select Lithium (recommended) or Alkaline battery type. If you select the wrong battery type, the alarm screens may not function properly. You can also change the battery type on the VERIFY screen when you insert a new battery.

1. From the SETUP ADV 4 screen, scroll to the desired field.

2. Press OK to change to flashing cursor for Edit mode.

3. Use the ▲/▼ buttons to change to desired setting.

4. Press OK when setting is made.

5. Scroll to "→", "←", or "Home" at the bottom of the screen. Select "→" or "←" to go to other Advanced Setup screens, or "Home" to go to the Home screen.

6. Press OK.

Contrast Button/CGM Shortcut

Pressing the button on the top of your pump adjusts the contrast of your display. There are three contrast levels: Dim, Default and Bright. To preserve battery life, your pump display will **Auto-dim** when no pump function button (any button other than the Contrast or Audio Bolus buttons) has been pressed for half the time period you set for the display to time out under Advanced Setup screen 4. For example, if you set the display time out for 60 seconds, the pump will Auto-dim with no button pushes in a 30 second period. While in Auto-dim mode, you can restore the default contrast level you have set by pressing the button on top of your pump. Pressing a function button while in Auto-dim mode will restore the default contrast level as well as perform the function of the button. **If in Call Service Alarm mode, you must use the button to restore the default contrast level.**

To return contrast setting to original factory default, press the button and button at the same time. When the word "Contrast" is displayed on the screen, press any button to return to the default contrast setting.

If you are not using the Dexcom G5® Sensor and Transmitter with your pump, CGM functions and data will not be operational on your pump display. However, pressing the button while the pump is in sleep mode will awaken the pump to one of the CGM Trend graphs or the CGM Data screen, even though the CGM functions are not operational. If your pump is locked, you will be required to unlock the pump after pressing the button to view one of the CGM trend graphs or CGM data screen. In this case, the CGM trend or Data screens will not have any information, and you will need to return to the MAIN MENU. Press OK on your pump to return to the CGM Menu and then press OK again with "Main Menu" highlighted to return to the MAIN MENU.

If you are using the Dexcom G5® Sensor and Transmitter with your pump, pressing the button while the pump is in sleep mode will awaken the pump to one of the CGM Trend graphs or the CGM Data screen. See *Chapter 6 Section II*.

NOTE: When viewing your pump display in bright sunlight, it is recommended you shade the screen or move to a shady area for best visibility.

Setup Advanced Screen 5 – Auto-OFF Feature

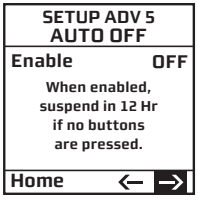
You may program your pump to automatically suspend basal delivery and sound an alarm if no pump buttons are pressed in a user-selected number of hours. This feature can be used as a safeguard in case the user thinks there is some possibility that they might not be able to stop insulin delivery on their own, or to alert someone nearby that they need help.

If the alarm is displayed/sounds, it means all insulin delivery has stopped, and you will need to press OK to confirm, disconnect and re-prime before resuming insulin delivery.

In addition to suspending the current basal program, the suspension of insulin delivery also results in the cancellation of any temp basal and bolus, including Combo Bolus settings that were previously in effect. Once you re-prime the pump, the basal program that would be in effect at the current time set in the pump will resume. You will need to re-set any bolus, any temp or Combo Bolus that had been in effect. See *Chapter 11 Section I* for more information on the AUTO-OFF Alarm.

⚠ **CAUTION: BEWARE** that if insulin delivery is suspended on your pump because the AUTO-OFF ALARM (no button presses for a user-defined number of hours) has sounded/displayed, your CGM session (see *Section II*) will remain active, but CGM Sensor readings will not be recorded or displayed. As soon as insulin delivery resumes, CGM Sensor readings will start recording and displaying again.

This screen allows you to turn the feature on and set the time period for checking if there have been button presses.



1. From the SETUP ADV 5 screen, scroll to the desired field.
2. Press OK to change to flashing cursor for Edit mode.
3. Use the ▲/▼ buttons to change to desired setting.
4. Press OK when setting is made.
5. Scroll to "→", "←", or "Home" at the bottom of the screen. Select "→" or "←" to go to other Advanced Setup screens, or "Home" to go to the Home screen.
6. Press OK.

Setup Advanced Screen 6 – Low Cartridge Warning Setting and Occlusion Sensitivity Setting

You can program your pump to alert you when your insulin cartridge is running low. The occlusion detection is automatic. A blockage may restrict the flow of insulin into your body.

This screen allows you to:

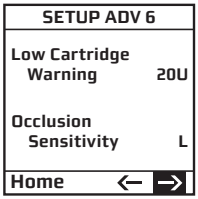
- Set your low cartridge warning to alert you when you have 10, 20, 30, 40 or 50 units remaining in the cartridge.
- Set your pump to detect a blockage with high sensitivity (H) or low sensitivity (L). The sensitivity level refers to how quickly the pump will sense back pressure from an occlusion in the infusion line, with H meaning "more sensitive" and L meaning "less sensitive". Review the Occlusion Sensitivity setting with your HCP and see *Chapter 17 Section I* for more information.

1. From the SETUP ADV 6 screen, scroll to the desired field.

2. Press OK to change to flashing cursor for Edit mode.

3. Use the ▲/▼ buttons to change to desired setting.

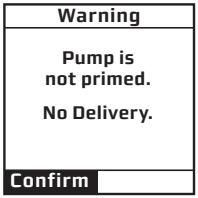
4. Press OK when setting is made.



5. Scroll to "→", "←", or "Home" at the bottom of the screen. Select "→" or "←" to go to other Advanced Setup screens, or "Home" to go to the Home screen.

6. Press OK.

NOTE: Any time you change the Occlusion Sensitivity level setting you must re-prime your pump. Once the occlusion setting has been changed, your pump will display a warning screen, reminding you that your pump is not primed. You will not be able to deliver insulin until you complete the steps for priming your pump. Refer to *Priming your Pump and Infusion Set* in *Chapter 3 Section I* for completing the steps on priming your pump.



The Low Cartridge Warning only alerts you one time for each cartridge. For example, if you have it set to 30U and receive an alert, and then change the setting to 20U, it will not alert at 20U until after the next cartridge has been primed.

If a bolus is delivered which causes a Low Cartridge Warning, the amount of remaining insulin may be lower than the Low Cartridge Warning threshold. See *Chapter 11 Section I* for more information about the Warning.

Setup Advanced Screen 7 – Audio Bolus Feature

You can set your pump to bolus without having to look at the screen display. This is done through button presses and audio/vibration prompts, using the small black button below the cartridge cap on the right side of your pump. All boluses delivered this way with the Audio Bolus feature will be delivered as Normal Boluses.

This screen allows you to:

- Turn the Audio Bolus feature on or off
- Select the Audio Bolus delivery step size
  - 0.1, 0.5, 1.0, 5.0 Units

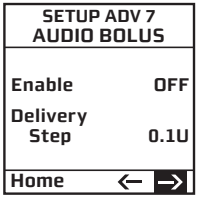
⚠ **WARNING:** If you are a Caregiver or a user who requires supervision for their insulin delivery, it is **RECOMMENDED** that you disable the Audio Bolus feature (turn it off). Disabling the feature means pressing the Audio Bolus Button will not deliver a bolus. Instead, pressing the button will take the user to the Normal Bolus screen where they must actively set and choose to deliver a bolus. Disabling the Audio Bolus feature along with using the Auto-Lock feature will prevent unintended button pushes by the user that might result in over delivery of insulin. Over delivery of insulin may lead to serious injury.

1. From the SETUP ADV 7 screen, scroll to the desired field.

2. Press OK to change to flashing cursor for Edit mode.

3. Use the ▲/▼ buttons to change to desired setting.

4. Press OK when setting is made.



NOTE: If Audio Bolus is activated, you cannot use the side button as a shortcut to Normal Bolus. You can still give a Normal Bolus via the Main Menu.

5. Scroll to "→", "←", or "Home" at the bottom of the screen. Select "→" or "←" to go to other Advanced Setup screens, or "Home" to go to the Home screen.

6. Press OK.

Setup Advanced Screen 8 – Insulin on Board Setting

The Insulin on Board feature activated and set by you helps you calculate how much insulin might still be active in your body from a previous bolus dose. The actual amount of insulin left in your body is determined by the rate at which your body uses insulin, your infusion site, your activity level, and other factors. Your pump uses a curvilinear algorithm that mimics the way insulin is metabolized to track Insulin on Board. Accounting for any Insulin on Board can help you calculate the right insulin amount when it is time to deliver another bolus and may prevent an overcorrection from "bolus stacking".

The Insulin on Board setting is important as Insulin on Board amounts are taken into consideration when using the ezBG and ezCarb features on your pump to calculate suggested bolus amounts (see *Chapter 10 Section I*). Insulin on Board will appear in abbreviated form as "IOB" on the pump display. Insulin on Board amounts apply only if the feature has been activated on your pump, and you are using either the ezBG or ezCarb features to calculate a suggested bolus amount. In certain situations, your pump will calculate a reduced suggested total bolus amount to account for any Insulin on Board.

Insulin on Board when using the ezCarb feature:

The ezCarb Bolus Total screen will display a carb correction amount, a BG correction amount, your Insulin on Board amount (if the feature is activated), and a suggested total bolus amount.

NOTE: The displayed carb correction, BG correction, and Insulin on Board amounts (if the feature is activated), and the resulting total bolus amount are for reference only. They do not represent the actual calculation performed on the pump.

Accounting for any Insulin on Board can help you calculate the right insulin amount when it is time to deliver another bolus and may prevent an overcorrection from "bolus stacking". If the Insulin on Board feature is activated, your Insulin on Board amount will always be displayed for reference, but may not always be applied to the suggested total bolus amount. Insulin on Board will appear in abbreviated form as "IOB" on the pump display.

Refer to *Chapter 10 Section I* for an example of ezCarb when the Insulin on Board feature on your pump is activated.

Insulin on Board when using the ezBG feature:

The ezBG Total screen will display a BG correction amount, your Insulin on Board amount (if the feature is activated), and a suggested total bolus amount.

NOTE: The displayed BG correction and Insulin on Board amounts, and the resulting total bolus amount are for reference only. They do not represent the actual calculation performed on the pump.

If the Insulin on Board feature is activated, your Insulin on Board amount will always be displayed for reference, but may not always be applied to the suggested total bolus amount. For instance, when Insulin on Board is enough to cover the amount required to bring a high BG back into target range, no additional insulin amount will be suggested to cover the high BG.

Refer to *Chapter 10 Section I* for an example of ezBG when the Insulin on Board feature on your pump is activated.

DO NOT use any other insulin with your pump other than the U100 rapid-acting NovoLog® and Humalog® insulin listed in the Owner's Booklet. Use of incorrect insulin, or insulin with a greater or lesser concentration, may result in over or under delivery of insulin. This could lead to very low (hypoglycemia) or very high (hyperglycemia) BG levels. Very high BG levels may also lead to diabetic ketoacidosis (DKA).

Then SETUP ADV 8 screen allows you to:

- Turn the Insulin on Board (indicated by "IOB-2" on the screen) feature on or off.
- Select the duration from 1.5 to 6.5 hours in half-hour increments.

1. From the SETUP ADV 8 screen, scroll to the desired field.

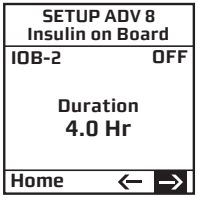
2. Press OK to change to flashing cursor for Edit mode.

3. Use the ▲/▼ buttons to change to desired setting.

4. Press OK when setting is made.

5. Scroll to "→", "←", or "Home" at the bottom of the screen. Select "→" or "←" to go to other Advanced Setup screens, or "Home" to go to the Home screen.

6. Press OK.



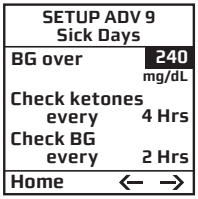
NOTE: Your pump is constantly tracking Insulin on Board, so when you turn on the feature, your pump will immediately take into account the current amount remaining from previous bolus doses within the time frame you have selected during set up of the feature.

Setup Advanced Screen 9 – Sick Day Guidelines

Your HCP may recommend guidelines to use when you are sick, such as when to test your BG or ketones. Your pump provides a convenient way to store some of these guidelines. For more information on sick day guidelines, refer to *Chapter 15 Section I* and contact your HCP.

This screen allows you to:

- Set a BG limit as a reminder for testing when sick
- Set the frequency of checking for ketones when sick
- Set the frequency of checking your BG when sick



1. From the SETUP ADV 9 screen, scroll to the desired field.

2. Press OK to change to flashing cursor for Edit mode.

3. Use the ▲/▼ buttons to change to desired setting.

4. Press OK when setting is made.

5. Scroll to "→", "←", or "Home" at the bottom of the screen. Select "→" or "←" to go to other Advanced Setup screens, or "Home" to go to the Home screen.

6. Press OK.

NOTE:

- This screen is intended as a reference only. Alerts are NOT triggered based on values displayed on this screen.
- The BG limit you set on the SETUP ADV 9 screen is different than the Low and High Glucose Alerts that apply only to CGM Sensor readings when using the Dexcom G5® Sensor and Transmitter with your pump. See *Chapter 2 Section II* for more information on CGM Alerts.

⚠ **CAUTION: DO NOT** begin using the pump until your HCP has confirmed which pump settings and Advanced Features on your pump are right for you. Many pump personal settings, such as your Basal Rates, Insulin to Carb (I:C) ratios, Insulin Sensitivity Factors (ISF), BG Target (ranges or values), and Insulin on Board (IOB) duration, should be determined only with input from your HCP. Advanced Features, such as Extended Bolus, Combo Bolus, Insulin on Board, and the Carb and BG Bolus Calculators, require a greater knowledge of insulin pumping and advanced self-care skills, and input from your HCP. Failure to have the correct settings or not following the correct instructions for using the Advanced Features can result in over or under delivery of insulin.

NOTE: Before using these features, you must turn them on in the Setup Advanced menu. See *Chapter 9 Section I*.

Audio Bolus/ezBolus™ Button

The Audio Bolus/ezBolus™ button on the right side of your pump serves two purposes. If you activate the Audio Bolus feature, it allows you to bolus without looking at the screen display. This is convenient if you wear your pump under your clothing. When first using the Audio Bolus feature, also check the display screen until you are comfortable with the programming steps. If you do not wish to use the Audio Bolus feature, this button serves as a shortcut to the Normal Bolus screen. See *ezBolus™* in this chapter.

⚠ **CAUTION: ALWAYS** look at the pump display for confirmation that an intended Audio Bolus amount is correct, when you first begin using the Audio Bolus feature. This will ensure you are correctly using the audio/vibration prompts and button pushes to deliver the intended bolus amount. See *Chapter 9 Section I*.

1. Turn on Audio Bolus in the Setup Advanced menu and select your preferred step size. See *Setup Advanced Screen 7 – Audio Bolus Feature* in *Chapter 9 Section I*.

2. The Audio Bolus button is the soft rubber button on the end of your pump. Press it once. Your pump will beep (or vibrate) to indicate you have accessed Audio Bolus mode as well as indicate the step size you have set up.

The number of beeps (or vibrate pulses) reminds you of the step size you have set.

- 1 beep (or vibration pulse) indicates 0.1U step size
- 2 beeps (or vibration pulses) indicates 0.5U step size
- 3 beeps (or vibration pulses) indicates 1.0U step size
- 4 beeps (or vibration pulses) indicates 5.0U step size

3. Press the Audio Bolus button once for each step size you have programmed to reach the desired total amount. For example, if you are using 1.0U step size and you wish to bolus 4 units, press the button 4 times. You will hear a beep tone or vibrate for each button press. If you are using 0.5U step size and you wish to bolus 4 units, press the button 8 times.

4. Within 5 seconds, your pump will respond with a number of confirmation beeps/vibration pulses equal to the number of times you pressed the Audio Bolus button.

DO NOT press any of the function buttons until the confirmation beep sequence is complete. Once the confirmation beep sequence is complete, you can press any function button other than the Audio Bolus button or Contrast button to cancel.

5. Within 5 seconds, your pump will beep/vibrate twice to "ask" you to confirm that you wish to activate delivery and "Confirm" is displayed on the Audio Bolus screen.

NOTE: You can press any function button other than the Audio Bolus button or Contrast button to cancel.

6. Within 5 seconds, press the button again to activate delivery. Your pump will beep/vibrate twice to confirm your delivery command. The Delivering bolus screen is displayed and your pump will beep/vibrate once to signal the start of delivery and once to signal end of delivery (if you turned on Normal Bolus Sounds in Setup).

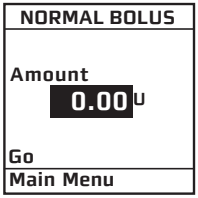
NOTE: You can press any function button other than the Audio Bolus button or Contrast button to cancel.

If you cancel a bolus delivery after you have activated it, the screen at right will be displayed. See *Chapter 11 Section I*.

NOTE: If during a bolus delivery your low cartridge level is reached, your pump will not display the warning until after the bolus is completed. So you could possibly have less insulin available than your low cartridge setting after the bolus is delivered.

The maximum number of Audio Bolus button presses is 20. Therefore, if you have set the step size to 0.1U, the maximum audio bolus amount is 2U. If you have set the step size at 0.5U, the maximum audio bolus amount is 10U and if your step size is 1.0U, the maximum audio bolus amount is 20U. With a 5.0U step size, the maximum audio bolus amount cannot be greater than 35U, which is the maximum amount for any type of bolus. You will be alerted on the display if you try to deliver any bolus amount that exceeds 35U.

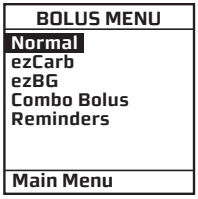
ezBolus™



ezBolus™ is a one-button shortcut to the Normal Bolus screen whenever the Audio Bolus feature is not activated.

1. Press the black button on the right side of your pump once. The Normal Bolus screen is displayed. Program a Normal Bolus as usual.

Advanced Bolus Features



- ezCarb
- ezBG
- Combo Bolus
- Reminders

All Advanced Bolus features are activated in the Setup Advanced Menu. See *Setup Advanced Screen 2 – Advanced Bolus Features and Multiple Basal Programs* in *Chapter 9 Section I*. When the Advanced Bolus features and Reminders are activated, the full BOLUS MENU is displayed.

⚠ **WARNING: DO NOT** deliver a "suggested" bolus amount from bolus calculations on your pump until you have reviewed the amount on the pump display. If you dose an insulin amount that is too high or too low, this could lead to a very low or very high BG level. You can always adjust the insulin units up or down before you decide to administer your bolus. Discuss the bolus calculator feature and all relevant personal settings with your HCP before using the calculator for the first time.

NOTE: When using the ezCarb or ezBG feature to calculate a "suggested" total bolus amount, that amount will be set to 0.00U whenever the calculation results in a negative number.

Before you begin using the ezBG and ezCarb features on your pump, take note how your pump determines the difference between your current BG and the BG Target range/value.

If you set a BG Target range, then the difference between your current BG and your BG Target range is determined as follows:

- If your current BG is above your BG Target range, your pump subtracts the midpoint of your BG Target range from your current BG.

  For example, if you set a BG Target range of 100 to 140 mg/dL (midpoint is 120 mg/dL) and your current BG is 160 mg/dL, then the resulting difference is 160 mg/dL – 120 mg/dL = 40 mg/dL.

- If your current BG is below your BG Target range, your pump subtracts the midpoint of your BG Target range from your current BG. The resulting difference will be a negative number.

  For example, if you set a BG Target range of 100 to 140 mg/dL (midpoint is 120 mg/dL) and your current BG is 80 mg/dL, then the resulting difference is 80 mg/dL – 120 mg/dL = – 40 mg/dL.

- If your current BG is within your BG Target range, then the resulting difference is automatically set to 0 mg/dL.

  For example, if you set a BG Target range of 80 to 110 mg/dL (midpoint is 95 mg/dL) and your current BG is 90 mg/dL, then the resulting difference is set to 0 mg/dL.

If you set a single BG Target value, then the difference between your current BG and your BG Target value is determined as follows:

- If your current BG is above your BG Target value, the pump subtracts your BG Target value from your current BG.

  For example, if you set a BG Target value of 105 mg/dL and your current BG is 110 mg/dL, then the resulting difference is 110 mg/dL – 105 mg/dL = 5 mg/dL.

- If your current BG is below your BG Target value, the pump subtracts your BG Target value from your current BG. The resulting difference will be a negative number.

  For example, if you set a BG Target value of 105 mg/dL and your current BG is 100 mg/dL, then the resulting difference is 100 mg/dL – 105 mg/dL = – 5 mg/dL.

- If your current BG is exactly equal to your BG Target value, then the resulting difference is automatically set to 0 mg/dL.

  For example, if you set a BG Target value of 90 mg/dL and your current BG is 90 mg/dL, then the resulting difference is set to 0 mg/dL.

ezCarb

This feature allows you to enter the number of carbs eaten, either manually, or by selecting items from a Food Database. Your pump will then automatically calculate your bolus dose, based on your I:C ratio, ISF and BG Target for the current time stored in the pump. Consult your HCP for your personal I:C ratios, ISFs and BG Target ranges. See *Setup Advanced Screen 1* in *Chapter 9 Section I*.

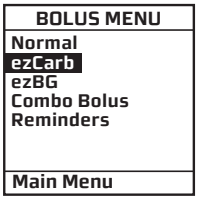
If the Insulin on Board feature is activated, your pump will take Insulin on Board amounts into consideration when calculating a suggested bolus amount. If the feature is not activated on your pump, dashes (----) will appear instead of a number in the "IOB" field.

The following pages provide examples of how to use the ezCarb feature to calculate a suggested bolus amount to cover a set number of carbs and reduce a high BG. The first example shows how to manually enter a carb, and the second example shows how to select carb amounts from the ezCarb Food Database. The third example shows how to add a BG correction bolus to a carb bolus.

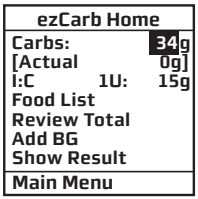
NOTE: Carb amounts you enter with the ezCarb feature will be stored in the pump along with insulin delivery data. You can use compatible diabetes management software to track, review and analyze pump carb and insulin data on your computer.

Calculating an ezCarb Bolus by Entering Carbs Manually

1. From the BOLUS MENU, scroll to "ezCarb". Press OK. The ezCarb Home screen is displayed.



2. The cursor will flash on the "Carbs" field to indicate that you can edit the total number of carbs eaten. Use the ▲/▼ buttons to enter the number of carbs. Press OK. "Add BG" is highlighted in the event you need to add a BG Correction Bolus to the ezCarb Bolus. (See *Adding a BG Correction Bolus to ezCarb* in this chapter.)



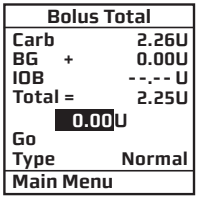
NOTE:

- The maximum limit for carb totals that are used in the bolus calculator is 999g.
- The "Actual" field below the "Carbs" field reflects the carb amount entered from the Food Database and will be set to 0g (grams) for any carb amounts you entered manually.

3. Check that the grams of carbs entered and your I:C ratio are correct. The I:C ratio is the Insulin to Carb ratio for the current time set in the pump. If they are not correct, scroll up to highlight the fields and press OK to enter Edit mode. Then use the ▲/▼ buttons to correct them.

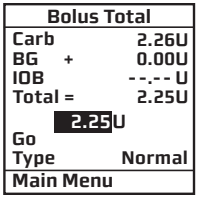
4. Scroll down to "Show Result".

5. Press OK to display the Bolus Total screen. The suggested (calculated) bolus amount from your ezCarb Bolus appears in the "Total" field. Above the "Total" field are the three parts that are used in calculating the suggested "Total" amount. **Carb** refers to the carb correction amount that was calculated to cover the carbs you manually entered. **BG** refers to any BG correction bolus you may have added. In this example, you did not add a BG correction so the BG amount is set to 0.00U. **IOB** refers to the Insulin on Board amount from a previous bolus. In this example, the Insulin on Board feature is not turned on so dashes appear instead of a number.



Below the suggested "Total" amount is the bolus amount entry field where you can choose to deliver the suggested amount or adjust the amount as needed. This field will display 0.00U, and will be highlighted and flashing.

6. Press the ▲ button once to change the amount to match the suggested bolus amount. Then use the ▲/▼ buttons to adjust the amount if necessary. When you have the desired delivery amount displayed, press OK. "Go" is highlighted.

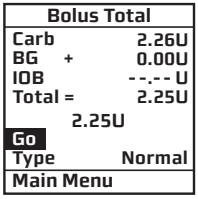


NOTE:

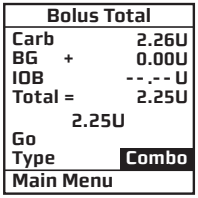
- Calculated total units will be rounded to the nearest .05 units.
- If the maximum bolus limit you set in Advanced Features is less than the suggested "Total" bolus amount on the Bolus Total screen, the bolus amount entry field will change to that limit (rather than the suggested "Total" amount) when you press the ▲ button once.

7. Decide whether to give a Normal Bolus or a Combo Bolus.

8. For a Normal Bolus, press OK with "Go" highlighted to deliver it. Your display will indicate that the bolus is being delivered.



9. If you wish to give a Combo Bolus, scroll to the "Type" field and press OK to edit.



10. Use the ▲/▼ buttons to select bolus type: "Normal" (default) or "Combo". Press OK.

11. "Go" is highlighted. Press OK.

NOTE: If you select the Combo Bolus option, the Combo Bolus screen will be displayed. See *Combo Bolus* in this chapter for instructions on delivering the Combo Bolus.

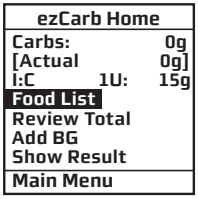
Calculating an ezCarb Bolus by Entering Carbs Using the Food Database

The Food Database provides you with an easy and accurate way to obtain carb totals when using the bolus calculator in the ezCarb Bolus screen. A special "Favorites" selection in the Food Database lets you create a separate library of food items and carb amounts for your most preferred or frequently consumed food items.

NOTE: The Food Database on your pump contains a limited list of basic food items. Before calculating a suggested bolus amount, refer to calorieking.com for a more comprehensive list of foods, food varieties, and their carb amounts.

1. From the BOLUS MENU, scroll to "ezCarb". Press OK.

2. On the ezCarb Home screen, press OK to exit Edit mode. "Food List" is highlighted. Press OK.

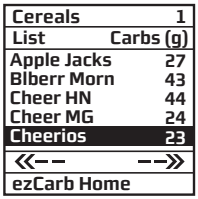


3. The Food List screen will appear where you can access 16 food categories. The first six food categories appear on the Food List screen. Scroll to "«––" or "––»" and press OK to display the other food categories.

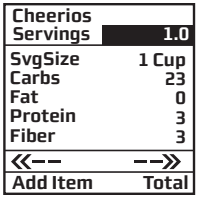
4. Scroll to desired food category and press OK.

5. An additional menu of food items (brand choices) appears along with the carb totals for a typical serving size. Scroll up to the desired brand choice and press OK. To display additional brand choices for this food category, scroll to "«––" or "––»" and press OK.

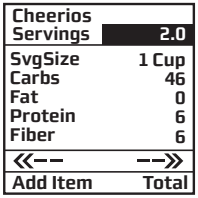
NOTE: To return to the Food List to select a different category, scroll up and highlight "List" and press OK.



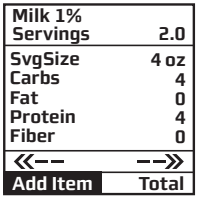
6. Nutritional information is displayed for the standard serving size of that brand choice. The "Servings" field is highlighted and flashing.



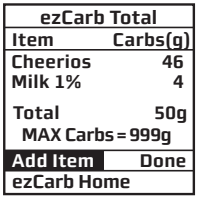
7. Use the ▲/▼ buttons to adjust the serving size as needed and press OK. As you adjust the serving size, the nutritional units will automatically be re-calculated.



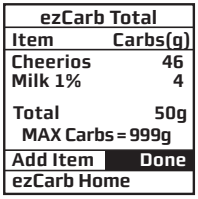
8. "Add Item" will be highlighted. Up to nine food items may be selected for use with the bolus calculator. Repeat steps 2-6 to add additional food items. When you are finished adding food items, use the ▲/▼ buttons to scroll to "Total" and press OK.



9. The ezCarb Total screen will appear and will list all your food items and their specific carb amounts. "Done" will be highlighted. If you have entered more than 5 food items, scroll to "«--" or "--»" and press OK to review your other selected food items.



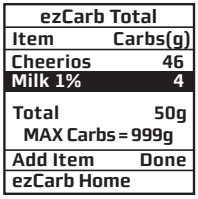
NOTE: The max limit for carb totals that are used in the bolus calculator is 999g. If your carb total from total Food Database items is more than 999g, the display will show the actual total you selected in the "Total" field. "MAX Carbs = 999(g)" will appear to let you know that the max carb limit (999g) will be used in the bolus calculator.



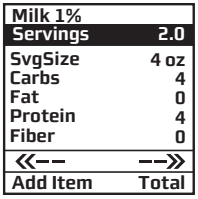
10. Review the food items and carb amounts on the ezCarb Total screen.

a. If the food items and carb amounts are both *correct*, press OK with "Done" highlighted. The ezCarb Home screen will be displayed, with the total carb amount displayed in the "Carbs" field. The "Actual" field below the "Carbs" field also reflects the carb amount entered using the Food Database. Proceed to *Adding a BG Correction Bolus to ezCarb* section that follows to add a BG correction, or highlight "Show Result" and press OK to calculate the ezCarb bolus.

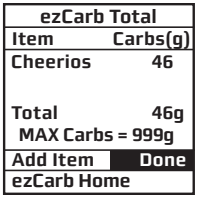
b. If the food items and carb amounts are not correct, scroll up to the food item you wish to edit and press OK.



Nutritional information is displayed for that food item. The "Servings" field is highlighted and flashing. Use the ▲/▼ buttons to adjust the serving size as needed. To delete a food item, change the serving size to 0. When you are finished, press OK with "Total" highlighted. You will return to the ezCarb Total screen and your adjusted carb amounts and total will be displayed. When all entries are completed, highlight "Done" and press OK to return to the ezCarb Home screen.



NOTE: You may also review carb amounts for food items selected from the Food Database by highlighting "Review Total" on the ezCarb Home screen and pressing OK. The ezCarb Total screen discussed in step 9 will appear where you adjust serving sizes or change food items as needed.

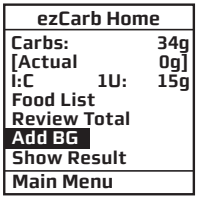


Adding a BG Correction Bolus to ezCarb

The following example shows how to add a BG correction bolus (to lower a high BG) to a carb bolus.

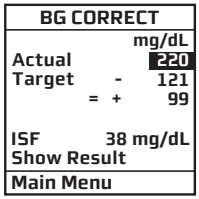
1. On the ezCarb Home screen, enter the number of carbs. Press OK.

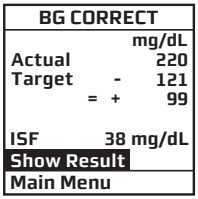
2. "Add BG" is highlighted. Press OK. The BG CORRECT screen is displayed.



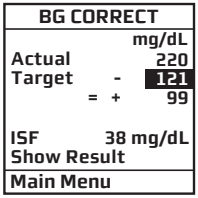
⚠ **WARNING:** If you are using the Dexcom G5® Sensor and Transmitter with your pump, **DO NOT** enter CGM Sensor readings as BG values. **DO NOT** use glucose readings from the Dexcom G5® Sensor and Transmitter to make treatment decisions, such as how much insulin you should take. The Sensor and Transmitter do not replace a BG meter and BG values may differ from Sensor glucose readings. Using glucose readings from the Sensor and Transmitter to make treatment decisions can result in serious injury or death. See *Section II*.

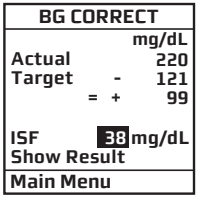
3. The "Actual" field is highlighted and flashing to indicate Edit mode. Use the ▲/▼ buttons to enter your current (Actual) BG value. Press OK. "Show Result" is highlighted.





4. Check that the BG Target and ISF are correct. The "Target" field is your BG Target for the current time set in the pump. The ISF is your Insulin Sensitivity Factor for the current time set in the pump. The number below the BG Target is the difference between your current (Actual) BG and your target BG. In this example, it is +100 mg/dL.

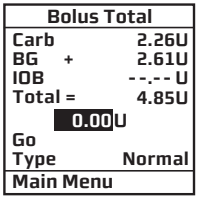




a. If they are *correct*, press OK with "Show Result" highlighted.

b. If they are *not correct*, scroll up to highlight the fields and press OK. Use the ▲/▼ buttons to adjust the values. Press OK to exit Edit mode. Scroll down to "Show Result". Press OK.

5. The Bolus Total screen is displayed and the suggested (calculated) bolus amount from your ezCarb Bolus appears in the "Total" field. Above the "Total" field are the three parts that are used in calculating the "Total" suggested amount. **Carb** refers to the carb correction amount. **BG** refers to the BG correction amount calculated from the BG CORRECT screen. **IOB** refers to the Insulin on Board amount from previous bolus. In this example, the Insulin on Board feature is not turned on.

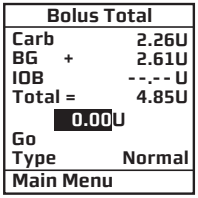


Below the suggested "Total" amount is the bolus amount entry field where you can choose to deliver the suggested amount or adjust the amount as needed. This field will display 0.00U, and will be highlighted and flashing. Press the ▲ button once to change the amount to match the suggested bolus amount. Then use the ▲/▼ buttons to adjust the amount if necessary. When you have the desired delivery amount displayed, press OK.

NOTE:

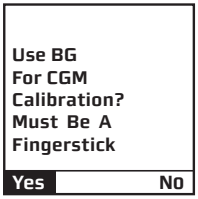
- Calculated total units will be rounded to the nearest .05 units.
- If the maximum bolus limit you set in Advanced Features is less than the suggested "Total" bolus amount on the Bolus Total screen, the bolus amount entry field will change to that limit (rather than the suggested "Total" amount) when you press the ▲ button once.

6. "Go" is highlighted. Press OK to deliver as a Normal Bolus or scroll to the "Type" field to select Combo Bolus, then select "Go".



If you selected the Combo Bolus option, you will begin the steps for delivering the ezCarb units as a Combo Bolus (see *Combo Bolus* in this chapter). The bolus amount you entered on the Bolus Total screen in step 6 will appear in the "Total" field on the first Combo Bolus screen.

7. If you are using the Dexcom G5® Sensor and Transmitter with your pump, you will be prompted on the display after the bolus is delivered to decide if the BG value you just entered should be used to calibrate your CGM (see *Chapter 5 Section II*). Select "Yes" and press OK to use this BG value for CGM calibration.



NOTE:

- This screen will appear only if you are in an active CGM session. If you decide to use the BG value for CGM calibration, the value must be within 40 to 400 mg/dL, must be from a fingerstick BG test, and must have been taken within the last 5 minutes.
- The pump display may time out before you have had a chance to confirm the use of the BG value for CGM calibration. In this case, the BG value will **not** be used for CGM calibration.

⚠ **WARNING: DO NOT** use a BG test result from an alternative sampling site (for example, your palm or forearm) for CGM calibration. Alternative site BG values might affect Sensor accuracy and result in your missing severe hypoglycemia (low blood glucose) or hyperglycemia (high blood glucose) events.

ezCarb Examples with the Insulin on Board Feature Activated

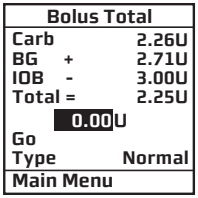
If the Insulin on Board feature is activated, your Insulin on Board amount will be displayed for reference on the ezCarb Bolus Total screen.

With the Insulin on Board feature activated, your suggested ezCarb total bolus amount will be as follows:

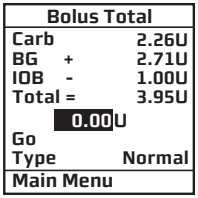
- If your current BG is above your target range, and your Insulin on Board amount is greater than your BG correction amount, then your suggested total bolus amount will be your Carb Correction amount. This is illustrated in example 1 that follows.
- If your current BG is within your target range, or equal to your target value, your suggested total bolus amount will be your Carb correction.
- If your current BG is above your target range, and your BG correction amount is greater than your Insulin on Board amount, then your suggested total bolus amount will be your Carb correction amount plus your BG correction amount minus your Insulin on Board amount. This is illustrated in example 2 that follows.
- If your current BG is below your target range, your suggested total bolus amount will be your Carb correction amount plus your BG correction amount minus your Insulin on Board amount. The suggested total bolus amount will be 0.00U whenever the calculation results in a negative number. A negative number implies that any additional insulin bolus amount would potentially result in over delivery of insulin and hypoglycemia. Discuss the calculator feature with your HCP so you have a thorough understanding of how it works before you begin using it.

The following examples illustrate typical screens you may encounter when using the ezCarb feature with Insulin on Board activated. Insulin on Board amounts appear in the "IOB" field.

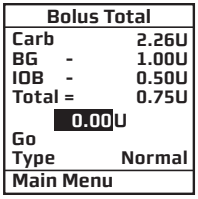
In Example 1, the Insulin on Board amount is displayed for reference but is not applied to the suggested total bolus amount. In this case, even though your current BG level is above the target range, there is sufficient Insulin on Board to cover the high BG. Therefore, the only insulin amount suggested is to cover the carbs being consumed.



In Example 2, the Insulin on Board amount is displayed for reference and is applied to the suggested total bolus amount. In this case, your current BG is above your target range, and your BG correction amount is greater than your Insulin on Board amount. Therefore, the insulin amount suggested is to cover the carbs being consumed, and any BG correction amount not already covered by your Insulin on Board.

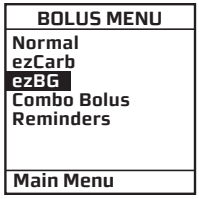


In Example 3, your current BG is below your target range, resulting in a negative BG correction amount. In this case, your carb amount needs to be offset by your BG correction amount since you are already below your target range. Therefore, the insulin amount suggested is to cover only the carb amount not already covered by your Insulin on Board amount and the negative BG correction amount.



ezBG

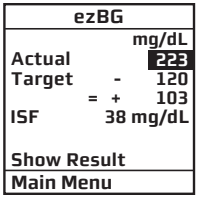
This feature allows you to calculate a BG correction bolus based on your ISF and BG Target range for the current time stored in the pump. To use this feature, you must enter your current (Actual) BG value. If the Insulin on Board feature is activated, your pump will subtract your Insulin on Board amount from the BG correction amount before calculating and displaying the suggested bolus amount.

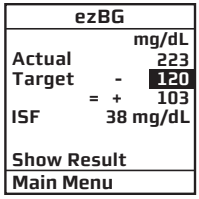


1. Obtain a BG value using a fingerstick sample.

2. From the BOLUS MENU, select "ezBG". Press the OK button.

3. The "Actual" field will be highlighted and flashing to indicate Edit mode. Use the ▲/▼ buttons to enter your actual BG value. Press the OK button to confirm the entry and exit Edit mode.





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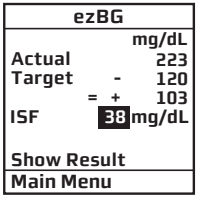
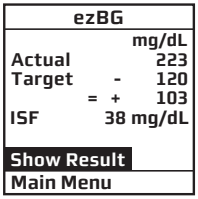
The difference between your current (Actual) BG and BG Target appears below the "Target" field. The difference is calculated according to whether your current (Actual) BG is within, below, or above your BG Target. Refer to *Setup Advanced Screen1 – BG Target Ranges* in *Chapter 9*, and in *Chapter 10 Section I* for information on how your BG Target settings impact the calculation of a BG correction bolus.

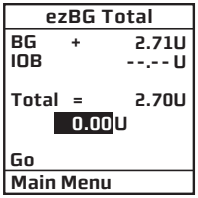
4. Check to be sure that both the BG Target and Insulin Sensitivity Factor (ISF) are correct. Your HCP will give you these values. If you need to edit these fields, scroll up to highlight the field and press OK to activate Edit mode. Use ▲/▼ buttons to change target. Press OK to confirm and to exit Edit mode.



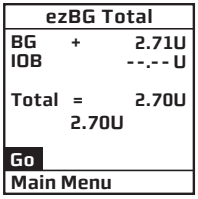
5. "Show Result" is highlighted. Press OK.



6. The ezBG Total screen is displayed and the suggested bolus amount from your ezBG Bolus appears in the "Total" field. Above the "Total" field are the two parts that are used in calculating the suggested "Total" amount. **BG** refers to the BG correction amount calculated from the previous ezBG screen. **IOB** refers to the Insulin on Board amount from a previous bolus.



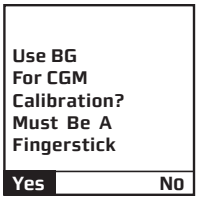
Below the suggested amount "Total" is the bolus amount entry field where you can choose to deliver the suggested amount or adjust the amount as needed. This field will display 0.00U, and will be highlighted and flashing. Press the ▲ button once to change the amount to match the suggested bolus amount. Then use the ▲/▼ buttons to adjust the amount if necessary. When you have the desired delivery amount displayed, press OK. With "Go" highlighted, press OK to deliver the bolus.



NOTE:

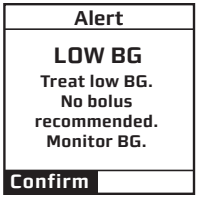
- If the BG amount on the ezBG Total screen is a negative number, the suggested "Total" amount will be set to 0.00U.
- Calculated total units will be rounded to the nearest .05 units.
- If the maximum bolus limit you set in Advanced Features is less than the suggested "Total" bolus amount on the Bolus Total screen, the bolus amount entry field will change to that limit (rather than the suggested "Total" amount) when you press the ▲ button once.

7. If you are using the Dexcom G5® Sensor and Transmitter with your pump, you will be prompted on the display after the bolus is delivered to decide if the BG value you just entered should be used to calibrate your CGM (see *Chapter 5 Section II*). Select "Yes" and press OK to use this BG value for CGM calibration. If the pump display times out before you select "Yes", the BG value will **not** be used for CGM calibration.



NOTE:

- If you enter a BG amount below 70 mg/dL or above 250 mg/dL, your pump will alert you that you have entered an out of range BG. To confirm the Alert, press OK. Your pump will still use the out of range BG value in ezCarb and ezBG bolus calculations, but treat the out of range BG as prescribed by your HCP.



- The LOW BG and HIGH BG Alerts discussed here are different than the Low and High Glucose Alerts that apply only to CGM Sensor readings when using the Dexcom G5® Sensor and Transmitter with your pump. See *Chapter 2 Section II* for more information on CGM Alerts.

ezBG Examples with the Insulin on Board Feature Activated

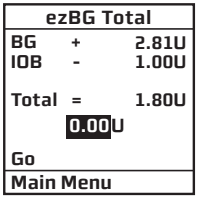
If the Insulin on Board feature is activated, your Insulin on Board amount will be displayed for reference on the ezBG Total screen.

With the feature activated, your suggested ezBG total bolus amount will be as follows:

- If your current BG is above your target range, and your BG correction amount is greater than your Insulin on Board amount, the suggested total bolus will be your BG correction amount minus your Insulin on Board amount. This is illustrated in example 1 below.
- In all other situations, your suggested total bolus will be 0.00U.

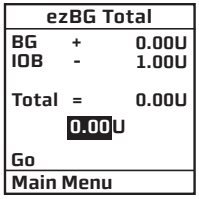
The following examples illustrate typical screens you may encounter when using the ezBG feature with Insulin on Board activated. Insulin on Board amounts appear in the "IOB" field.

In Example 1, the Insulin on Board amount is displayed for reference and is applied to the suggested total bolus amount.

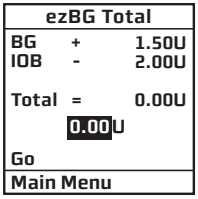


Example 1

In Examples 2 and 3, the Insulin on Board amount is displayed for reference but is not applied to the suggested total bolus amount. In Example 3, even though your current BG level is above the target range, there is sufficient Insulin on Board to cover the high BG. Therefore, no insulin amount is suggested to cover the high BG. In Example 2, your BG level is low. Therefore, no insulin amount is suggested.



Example 2

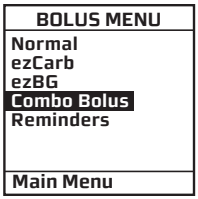


Example 3

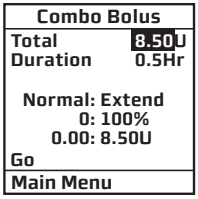
Combo Bolus

The Combo Bolus feature is used to "split" your bolus into a Normal and Extended Bolus. This feature is useful for consumption of high carb/high fat meals such as pizza, that have prolonged carb absorption. It is also useful if you will be eating ("grazing") over a few hours or if you have gastroparesis, where food remains in the stomach for a longer period than normal. You can program part of your bolus amount to be delivered immediately (Normal portion) and part of it to be delivered slowly over the course of up to 12 hours (Extended portion). Your HCP can help you determine the "split" of Normal to Extended insulin amounts, as well as the duration that is most appropriate for you.

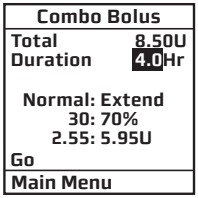
1. From the BOLUS MENU, select "Combo Bolus". If you used the ezCarb Bolus option to calculate a bolus and chose to deliver it as a Combo Bolus, you will begin at the Combo Bolus screen in step 2.



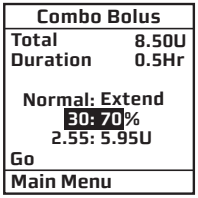
2. Use the ▲/▼ buttons to enter the Total bolus amount. Press OK. "Go" is highlighted. The factory default setting for Duration is 30 minutes, and the default Ratios are 0% Normal and 100% Extended. If these settings are appropriate, press OK to deliver.



3. To change either the Duration or Ratio, scroll up to the desired field and press OK to activate Edit mode.



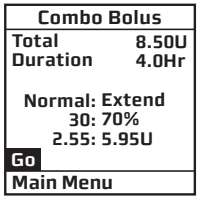
4. Use the ▲/▼ buttons to change settings. As you change the Ratio by percentage, the amount in units is automatically changed. *You cannot change the ratio by units, only by percentage.*

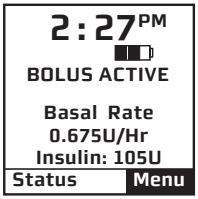


5. When settings are correct, press OK to confirm and exit Edit mode.

NOTE: Your pump is "smart"; it will remember your last duration and the ratio (as percentages) that you programmed. So if you use the same duration and ratio for certain types of meals, you need only change the total bolus amount the next time you use this feature. However, the last programmed Combo Bolus settings will be cleared each time you change the battery.

6. Scroll to "Go" and press OK to activate. The Home screen shows Combo Bolus Active.

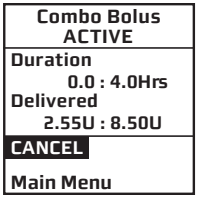




To *cancel* an active Combo Bolus from the BOLUS MENU, select "Combo Bolus". Details of the active Combo Bolus will be displayed.

Scroll to "CANCEL" and press OK to cancel the Combo Bolus.

NOTE: If you Suspend your pump, any active Combo Bolus will also be canceled and the screen display will alert you. Combo Bolus is also canceled when you change the battery and/or prime your pump.

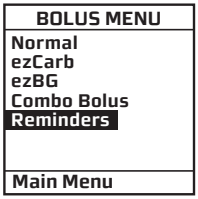


Reminders

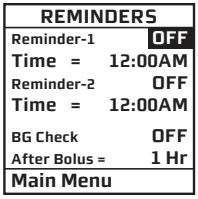
This feature allows you to set personal reminders if you have activated the Reminders feature (see *Setup Advanced Screen 2 – Advanced Bolus Features and Multiple Basal Programs* in *Chapter 9 Section I*). You can set two separate reminders to prompt you at two designated times during the day, and one reminder to check BG at a certain time after a bolus. Confirm the Reminder by pressing OK. Once you have confirmed the Reminder, you will not be alerted again.

Bolus Reminders for Time of Day

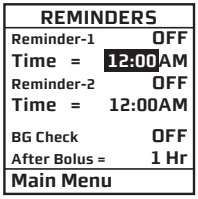
1. From the BOLUS MENU, select "Reminders". Press OK.



2. The "Reminder-1" field will be highlighted. Press OK to enter Edit mode. Use the ▲/▼ buttons to turn on or off. Press OK to confirm and exit Edit mode.



3. The "Time" field for this reminder will be highlighted. Press OK to activate Edit mode. Use the ▲/▼ buttons to enter the time you wish a reminder to sound (or vibrate, if that is the setting you selected in the SETUP SOUND menu). Press OK to confirm your setting and exit Edit mode.

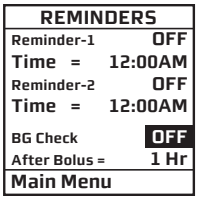


When the feature is turned on, your pump will display the “Reminder” screen on the right at the selected time of day.

4. Repeat for Reminder 2.

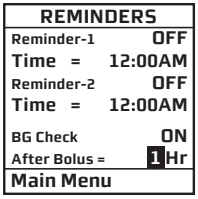
BG Check Reminder

1. From the REMINDERS menu, select “BG Check” to remind you to check your BG. Press OK to activate Edit mode to turn this reminder on or off. Press OK to confirm and exit Edit mode.

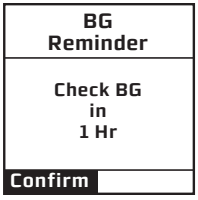


NOTE: The BG Check reminder you set here is independent of the “Enter BG” prompts you will see when using the Dexcom G5® Sensor and Transmitter with your pump.

2. Scroll down to highlight the “After Bolus” field. Press OK to select the field and activate Edit mode. Use the ▲/▼ buttons to enter how long after a Normal Bolus you wish your pump to sound (or vibrate) to remind you to check your BG. You can select a reminder time of 1, 2, 3 or 4 hours.



When this feature is turned on, your pump will display the BG Reminder screen immediately after a bolus. On this screen you can use the ▲/▼ buttons to select a different reminder time (1, 2, 3, or 4 hours), or choose not to be reminded by entering 0. For example, if you have given a bolus in the evening, you may not wish to have the Reminder sound while you are sleeping. If the Reminder is not confirmed, battery life will be reduced and the Replace Battery Alarm will appear sooner than expected.



NOTE: The BG Reminder screen is not displayed when you use the Audio Bolus feature.

NOTE: When you enter a time, your pump will sound a reminder and display this screen at that time after any Normal Bolus or Audio Bolus is delivered, including the Normal portion of a Combo Bolus. If you program an Extended Bolus only, the reminder will sound at the default time you have set.

3. When finished setting reminders, scroll to "Main Menu" and press OK to display the MAIN MENU.

Alerts, Warnings and Alarms

Your pump has a “progressive” warnings and alarms safety system. This means if you do not confirm the warning or alarm, it will get progressively louder and change to a sweep tone with vibration within one hour. At the high volume stage, if you do not confirm the warning or alarm, the sweep tone will begin and will not stop until appropriate action is taken.

Your pump uses battery power to notify you of alerts, warnings, and alarms. If you do not confirm the notification, your pump will continue to use battery power as the notifications repeat and progress. This will result in reduced battery life and the Replace Battery Alarm screen appearing sooner than expected.

Additionally, there are certain warnings (e.g., Low Cartridge Warning, Occlusion Alarm) that take precedence over less critical ones (e.g., Low Battery Warning). This means if you do not confirm the more critical warning, battery life will be reduced and your pump may skip the Low Battery Warning and go directly to the Replace Battery Alarm.

If multiple alerts, warnings, or alarms occur simultaneously, the pump will display the most critical one first. After confirming the condition with the highest priority (the one currently displayed), the alert, alarm, or warning with the next highest priority will be displayed until confirmed. Each alert, alarm, and/or warning must be confirmed separately until all simultaneous conditions have been confirmed.

Take special note of alerts, alarms and/or warnings that include messages about insulin delivery continuing or stopping, particularly when they occur simultaneously on the pump. It is possible to see a “Deliveries continue” message followed by a “No delivery” message. “Deliveries continue” means insulin delivery is not impacted by the alert, alarm and/or warning that prompted the message. “No delivery” means insulin delivery has stopped and will remain stopped until the problem that caused the alert, alarm and/or warning to appear is resolved.

Alerts are automatically displayed to remind you of a function that you have set or a condition that exists. Warnings are triggered for a variety of reasons. They require you to confirm the warning by pressing OK and/or taking action to address the warning. Alarms are triggered by several conditions. All require you to address the alarm by taking appropriate action in order to clear the alarm condition.

♪ – Indicates that this alert, warning or alarm can play a tune as the initial notification for medium and high volume settings. The pump default for sounds at the low volume setting is a factory-set sound.

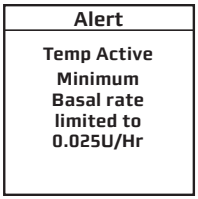
There is an additional list of warnings, alarms and alerts that will display/sound on your pump related to the use of CGM functions when you begin using your Dexcom G5® Sensor and Transmitter with your pump. See *Chapter 10 Section II* for more information on this list. Certain CGM warnings, alarms and alerts may display/sound on your pump if you enter CGM information without the intention of initiating a valid CGM session. An example is entering a valid Transmitter ID without actually inserting a Transmitter/Sensor.

Alarms, warnings and alerts will display actual insulin units during pump operation, rather than the "XX" or "XXX" units displayed on some of the screens in this list.

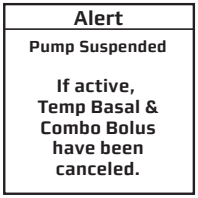
Alert: Active Basal Program Empty	
Cause	Active basal program is empty.
Effect	No basal deliveries.
Message	Displayed once **until confirmed or until pump goes to sleep** and each time manually awakened.
Action	None required but can confirm or select "Basal Menu".
Beeps/Vib	User selected, one time and each time manually awakened. No progression.

Alerts, Warnings and Alarms *(continued)*

Alert: Temp Basal Minimum Rate	
Cause	Negative Temp Basal activated.
Effect	Basal delivery will not go below 0.025 U/Hr.
Message	Displayed once for 4 seconds.
Action	None required.
Beeps/Vib	User selected, one time. No progression.



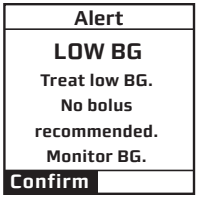
Alert: Suspend (Temp Basal/Combo Bolus Canceled)	
Cause	Pump suspended.
Effect	Any active Temp Basal/Combo Bolus canceled.
Message	Displayed once for 4 seconds.
Action	None required.
Beeps/Vib	User selected, one time. No progression.



Alerts, Warnings and Alarms *(continued)*

Alert: Low BG ♪	
Cause	BG entry below 70 mg/dL.
Effect	Requires user confirmation to continue.
Message	Displayed until confirmed or until pump goes to sleep.
Action	Press OK to confirm.
Beeps/Vib	User selected, one time. No progression.

NOTE: The LOW BG Alert is different than the Low Glucose Alert that applies only to CGM Sensor readings when using the Dexcom G5® Sensor and Transmitter with your pump. Refer to *Chapter 2 Section II* for information on CGM-related alerts.

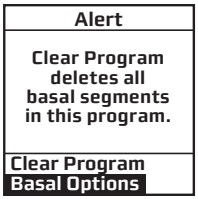


Alert: High BG ♪	
Cause	BG entry above 250 mg/dL.
Effect	Requires user confirmation to continue.
Message	Displayed until confirmed or until pump goes to sleep.
Action	Press OK to confirm.
Beeps/Vib	User selected, one time. No progression.

NOTE: The HIGH BG alert is different than the High Glucose alert that applies only to CGM Sensor readings when using the Dexcom G5® Sensor and Transmitter with your pump. Refer to *Chapter 2 Section II* for information on CGM-related alerts.

Alerts, Warnings and Alarms *(continued)*

Alert: Clear Program Basal Segments ♪	
Cause	Clear command selected from BASAL OPTIONS screen.
Effect	Requires user confirmation to continue.
Message	Displayed until one of the two options is selected or until pump goes to sleep.
Action	Select “Clear Program” or “Basal Options”.
Beeps/Vib	User selected, one time. No progression.

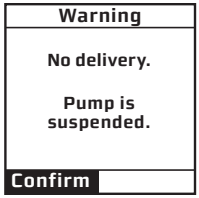


Alert: Basal Program Display Change ♪	
Cause	Changing display of basal programs from 4 to 1 but program 1 is not currently active.
Effect	Requires user confirmation to continue.
Message	Displayed until confirmed or until pump goes to sleep.
Action	Press OK to confirm.
Beeps/Vib	User selected, one time. No progression.

Alerts, Warnings and Alarms *(continued)*

Warning: Basal Delivery Suspended ♪	
Cause	Basal Edit was not saved.
Effect	Basal delivery stopped.
Message	Displayed when manually awakened until confirmed.
Action	Press OK to select "Edit Basal". Review basal edits and select "Save/Review".
Beeps/Vib	User selected, every 3 minutes until confirmed. If not confirmed, progresses to sweep/vib within one hour.

Warning: Suspend ♪	
Cause	Pump suspended manually.
Effect	All insulin deliveries stop.
Message	Displayed each time pump is awakened. Then displayed once every 3 minutes upon confirmation, and once every 15 minutes if not confirmed, until action is taken.
Action	Press OK to confirm. Resume delivery.
Beeps/Vib	User selected, once every 3 minutes if confirmed, once every 15 minutes if not. No progression. Sweep/vib within one hour only if bolus or basal delivery was in progress when pump was suspended.



Alerts, Warnings and Alarms *(continued)*

Warning: No Cartridge Detected, Deliveries Disabled ♪	
Cause	No cartridge detected after "Load cartridge" step during Prime/Rewind.
Effect	No insulin deliveries.
Message	Displayed when manually awakened until confirmed.
Action	Press OK to confirm. Be sure Prime/Rewind sequence is completed with cartridge properly in place.
Beeps/Vib	User selected, once every 3 minutes. No progression if confirmed each time displayed. Sweep/vib within one hour if not confirmed.

Warning: Low Battery ♪	
Cause	Battery life will last a minimum of 30 minutes.
Effect	Insulin deliveries continue.
Message	Displays when pump is awake until confirmed. Displays when triggered by event (such as bolus) and when manually awakened.
Action	Press OK to confirm. Insert new Battery.
Beeps/Vib	User selected, every 3 minutes until confirmed. If not confirmed, progresses to sweep/vib within one hour.

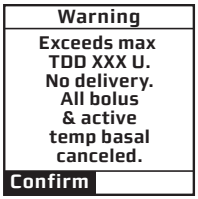
Alerts, Warnings and Alarms *(continued)*

Warning: Low Cartridge ♪	
Cause	Low insulin level reached.
Effect	Insulin deliveries may continue until Empty Cartridge alarm is triggered.
Message	Displayed when manually awakened until confirmed.
Action	Press OK to confirm. Replace with filled cartridge.
Beeps/Vib	User selected, every 3 minutes until confirmed. If not confirmed, progresses to sweep/vib within one hour.

Warning: Exceeds Max Bolus ♪	
Cause	Audio bolus delivery exceeds user-set maximum.
Effect	Bolus delivery stops.
Message	Displayed when manually awakened until confirmed.
Action	Press OK to confirm. Reprogram max bolus amount in the Setup Advanced menu.
Beeps/Vib	User selected, every 3 minutes until confirmed. If not confirmed, progresses to sweep/vib within one hour.

Alerts, Warnings and Alarms *(continued)*

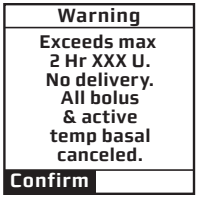
Warning: Exceeds Max TDD ♪	
Cause	Bolus delivery exceeds user-set maximum Total Daily Dose (TDD).
Effect	All insulin deliveries stop. Any Combo Bolus or Temp Basal is canceled.
Message	Displayed when manually awakened until confirmed.
Action	Press OK to confirm. Reprogram max TDD amount in the Setup Advanced menu. If the Warning is not confirmed by the time your pump clock passes midnight, the message will continue to be displayed.
Beeps/Vib	User selected, every 3 minutes until confirmed. If not confirmed, progresses to sweep/vib within one hour.



Alerts, Warnings and Alarms *(continued)*

Warning: Exceeds Max 2-hour Delivery ♪	
Cause	Combined basal and bolus delivery exceeds user-set 2-hour maximum.
Effect	Insulin delivery stops when 2-hour maximum is reached. Any Combo Bolus or Temp Basal is canceled.
Message	Displayed when manually awakened until confirmed.
Action	Press OK to confirm. Reprogram Max 2-Hr amount in the Setup Advanced menu.
Beeps/Vib	User selected, every 3 minutes until confirmed. If not confirmed, progresses to sweep/vib within one hour.

NOTE: If the Exceeds Max TDD or the Exceeds Max 2-hour Delivery warning appears and is not confirmed, the warning will re-appear every 3 minutes. Basal deliveries will stop until either the warning is confirmed or that time period is complete. For the Exceeds Max TDD warning, Basal deliveries will resume the following day (beginning at midnight). For the Exceeds Max 2-hour Delivery warning, Basal deliveries will resume the next 2-hour time period.



Alerts, Warnings and Alarms *(continued)*

Warning: Exceeds Max Basal ♪	
Cause	Basal delivery rate (or Temp Basal delivery) exceeds user-set maximum.
Effect	Basal delivery stops.
Message	Displayed when awakened (by basal delivery attempt every 3 minutes or manually) until confirmed.
Action	Press OK to confirm. Reprogram Max Basal amount in the Setup Advanced menu (or reprogram Temp Basal).
Beeps/Vib	User selected, every 3 minutes until confirmed. If not confirmed, progresses to sweep/vib within one hour.

Warning: Delivery Canceled due to Low Cartridge ♪	
Cause	Basal or Bolus delivery exceeds insulin remaining in cartridge.
Effect	Basal or Bolus delivery stopped.
Message	Once per occurrence and each time awakened until confirmed.
Action	Press OK to confirm. Replace with full cartridge.
Beeps/Vib	User selected, every 3 minutes until confirmed. If not confirmed, progresses to sweep/vib within one hour.

Alerts, Warnings and Alarms *(continued)*

Warning: No Prime, No Delivery ♪	
Cause	Pump is not primed.
Effect	All insulin deliveries stop.
Message	Every 3 minutes or when awakened manually.
Action	Press OK to confirm. Disconnect, reprime.
Beeps/Vib	User selected, every 3 minutes until confirmed. If not confirmed, progresses to sweep/vib within one hour.

Warning: Bolus Delivery Canceled ♪	
Cause	User pressed function button on pump during bolus delivery.
Effect	Bolus delivery stopped.
Message	Every 3 minutes or when awakened manually.
Action	Press OK to confirm. If button was pressed accidentally, repeat steps (see *Chapter 4 Section I*) to deliver remaining insulin units.
Beeps/Vib	User selected, every 3 minutes until confirmed. If not confirmed, progresses to sweep/vib within one hour.

Alerts, Warnings and Alarms *(continued)*

Alarm: Occlusion ♪	
Cause	Occlusion/blockage detected in the insulin delivery path.
Effect	All insulin deliveries stop.
Message	Continuous until confirmed.
Action	Press OK to confirm. Disconnect and prime to clear occlusion. Option to select "Suspend" (see *Suspend Warning* screen in this chapter).
Beeps/Vib	User selected, every 3 minutes until confirmed. If not confirmed, progresses to sweep/vib within one hour. (Once confirmed, No Prime warning triggered, see *No Prime Warning* screen in this chapter.)

Alarm: Empty Cartridge ♪	
Cause	Cartridge empty.
Effect	All insulin deliveries stop.
Message	Continuous until confirmed.
Action	Press OK to confirm. Replace with full cartridge. Option to select "Suspend" (see *Suspend Warning* screen in this chapter).
Beeps/Vib	User selected, every 3 minutes until confirmed. If not confirmed, progresses to sweep/vib within one hour. (Once confirmed, No Prime warning triggered, see *No Prime Warning* screen in this chapter.)

Alerts, Warnings and Alarms *(continued)*

Alarm: Replace Battery	
Cause	Battery life has a minimum of 3 minutes remaining.
Effect	All insulin deliveries stop.
Message	Continuous until battery is removed or has no power remaining.
Action	Remove battery to silence alarm. Insert new battery.
Beeps/Vib	MAX volume every 3 minutes until action taken. If not confirmed, will progress to 4 long tones.

Alarm: Call Service	
Cause	Hardware or software problem detected.
Effect	All insulin deliveries suspended.
Message	Continuous until battery is removed.
Action	Remove pump battery to silence the alarm, or press OK to silence alarm for 30 minutes (alarm can only be silenced once). Contact Customer Service.
Beeps/Vib	Fixed beep/vib tone. If not confirmed, progresses to sweep/vib within one hour.

NOTE: Some Call Service Alarms have a unique sound/vibration sequence and cannot be silenced by pressing OK.

For these Alarms the usual progression is replaced by 3 chirps/vib repeated every 9 minutes for the first half hour. This is followed by 4 long tones/vib after that.

Alerts, Warnings and Alarms *(continued)*

Alarm: Auto-Off ♪	
Cause	Pump suspended because there were no button presses on the pump in the time period set by the user for the AUTO-OFF Alarm feature.
Effect	All insulin deliveries stop.
Message	Continuous until confirmed.
Action	Press OK to confirm. Adjust time period in the Setup Advanced menu.
Beeps/Vib	User-selected, every 3 minutes until confirmed. If not confirmed, progresses to sweep/vib within one hour. (Once confirmed, No Prime warning triggered, see *No Prime Warning* screen in this chapter.)

Section I of this Owner's Booklet covers safety, maintenance, troubleshooting, lifestyle, and technical information about your OneTouch Vibe™ Plus Insulin Pump.

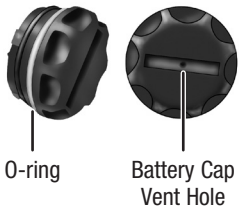
Care and Maintenance of your OneTouch Vibe™ Plus Insulin Pump

The Vents

Your pump has two vents. Vents serve two purposes. First, they allow air to enter and exit your pump so that pressure is equalized under a variety of environmental circumstances, such as changes in altitude. Second, the vents are backed by a special membrane, which keeps water from entering your pump.

Battery Cap with O-ring and Vent

Your battery cap contains an o-ring and vent. The vent is a tiny hole backed by a membrane, which allows air to pass through but prevents water from entering. The o-ring helps to keep your pump waterproof. It is recommended that you change the battery cap/vent every six months. If you work in a dusty environment such as a construction site, mill, cement factory, etc., or if you are a frequent swimmer, you should change your battery cap every 3 months. This is because your battery cap will wear out more quickly from repeated exposure to dirt, debris or water. You can contact Customer Service to order an extra battery cap.



⚠ **WARNING: CHECK** the battery cap vent and primary vent below the cartridge cap to make sure they are not clogged whenever you replace the battery, cartridge or infusion set. **DO NOT** use the pump if the vents are clogged. The vents allow air to flow in and out of the pump, and have a membrane on the inside that helps keep your pump waterproof. Remove any debris from the vents using your fingers and a soft cloth. **DO NOT** use a sharp object to clean the vents or you may puncture the vents/membrane and compromise the waterproof feature of your pump. Replace the battery cap if you are unable to remove the debris from the battery cap vent.

Cleaning

⚠ CAUTION:

- **DO NOT** use household cleaners, chemicals, bleach, alcohol wipes, skin prep, scouring pads or sharp instruments to clean your pump. Cleaning your pump with these materials can damage the pump. Clean your pump with a soft, lint free cloth dampened with water or a mild detergent such as liquid soap. Never put your pump in the dishwasher or use scalding hot water to clean it.
- **NEVER** clean the inside of the battery or insulin cartridge compartments.
- **NEVER** use a hair or hand dryer, microwave oven or baking oven to dry your pump if it gets wet. The use of these appliances can damage the pump. Use a soft towel or cloth.

General Wear and Tear

If you drop your pump or it has been hit against something hard, inspect it to be sure it is still working properly. Check that the display screen is working and clear, that the cartridge cap, battery cap and infusion set are properly in place. Check for leaks around the cartridge by wrapping a piece of tissue around the connection area. Cracks, chips or damage to your pump may impact the battery contact and/or the waterproof feature of your pump. Contact Customer Service if you identify or suspect your pump is damaged. They will help determine if your pump should be replaced.

Disposal

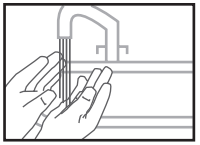
Local regulations require controlled disposal of devices such as insulin pumps. Contact Customer Service for disposal instructions.

Dispose of batteries according to your local environmental regulations.

Your pump display Lens Protection Film Kit contains 3 lens protection films, the film application solution (901-002-01) and a rubber squeegee.

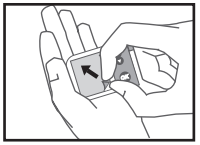
Follow the instructions below for proper application.

1. Wash your hands thoroughly with mild soap and water.



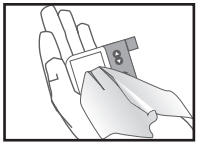
2. Slowly remove existing lens protection film.

- **DO NOT** use heat or metal instruments.



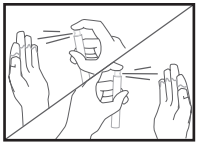
3. Clean lens with a dry lint free cloth.

- Film can be applied without disconnecting the pump.



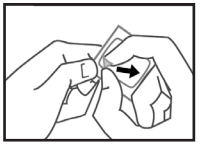
4. Spray fingers with film application solution, 901-002-01.

- Solution contains isopropyl alcohol.
- Shake before use.
- **DO NOT** ingest.

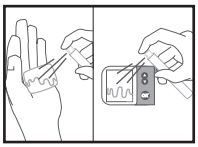


5. Remove lens film from paper backing.

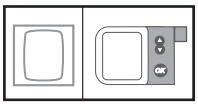
- Touch with wet fingers only.
- Hold adhesive side up.
- **DO NOT** let film adhere to itself.



6. Spray entire film adhesive area and lens with solution.

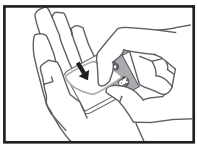


NOTE: Before proceeding, make sure the film orientation matches the frame orientation of the lens.



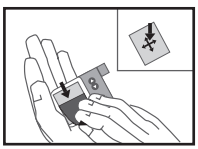
7. Place film onto lens.

- Place adhesive side down, facing lens.
- **DO NOT** press into place.
- If needed, remove film, reapply solution, and reposition film to align all edges.



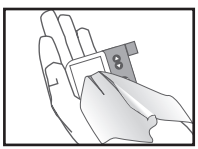
8. Pull squeegee firmly across film.

- Start from center of lens and pull in all directions, to remove moisture and bubbles from under the surface.
- Pull squeegee across all corners and edges to adhere film.



9. Remove excess moisture with a lint free cloth.

- If necessary, apply direct pressure to film edges until film is adhered to lens.
- Your pump can be used immediately after film application.
- Wash hands thoroughly after film application.



IMPORTANT INFORMATION: The viewing area of the pump display should be visually clear after film application. If air or moisture bubbles are visible after the film is installed, peel the film up from one edge at least to the location of the bubbles. Re-spray the film adhesive and the pump surface with solution, and re-apply the film with the squeegee. If this does not remove the bubbles, reinstall a new film.

It is a good idea to set up a troubleshooting procedure to use anytime you suspect something might be wrong. Work with your HCP to establish guidelines in the event of a problem.

Hypoglycemia

⚠ **WARNING:** Low BG is a risk for anyone using insulin therapy. You may experience one or more of the following symptoms:

- Shakiness; rapid heart rate; anxiety; perspiration; cold, clammy skin; weakness; blurred or double vision; sudden hunger; tingling in your hands, lips, or tongue; headache and confusion.

- If you experience symptoms of hypoglycemia, you should immediately eat a quick-acting carbohydrate (glucose tablets, juice, or hard candy).
- If your BG is abnormally low, **DO NOT** attempt to program your pump yourself. Get help.
- Treat hypoglycemia immediately.
- If you are using the Dexcom G5® Sensor and Transmitter with your pump, **DO NOT** rely on CGM Sensor readings if you experience symptoms of hypoglycemia. If you suspect hypoglycemia, obtain a fingerstick value with your BG meter. See *Section II*.

Treatment for Hypoglycemia*

1. Eat or drink 15-20 grams of carbohydrate (glucose is the best treatment for lows).

2. Retest your BG in 15 minutes.

3. If still hypoglycemic, repeat steps 1 and 2.

** 2014 ADA Standards of Care in Diabetes (Diabetes Care Volume 37, Supplement 1, January 2014)*

Troubleshooting hypoglycemia:

INSULIN PUMP

POSSIBLE CAUSE OF LOW BG	SUGGESTED SOLUTION
Basal rate programmed incorrectly	Check times and rates, remember to review basal programs when making any changes.
Clock time incorrect	Reset clock to current time, being careful to check AM and PM.
Pump exposed to MRI	Disconnect from pump. Contact Customer Service.

FOOD INTAKE

POSSIBLE CAUSE OF LOW BG	SUGGESTED SOLUTION
Bolus too large	Check bolus amounts and times. Bolus only enough to lower your BG to normal level.
Low carbohydrate intake for bolus	Measure carbohydrates accurately. See dietitian for carb counting review. May need recalculation of I:C ratio; consult with HCP.
Improper timing of bolus	Match timing of bolus with intake of food. Check BG prior to meal bolus and adjust accordingly.
Alcohol consumption	May cause hypoglycemia (or may cause hyperglycemia). Eat food when drinking alcohol. Be cautious with bedtime bolus. Always check BG before going to bed. Consult HCP.

Troubleshooting hypoglycemia: *(continued)*

ACTIVITY

POSSIBLE CAUSE OF LOW BG	SUGGESTED SOLUTION
Did not Suspend pump or activate Temp Basal	Consult HCP for guidelines for use of Temp Basal rate during exercise.
Low carbohydrate intake prior to exercise	If not decreasing insulin prior to or during exercise, may need to eat foods containing carbohydrate prior to exercise.
Unplanned activity (shopping)	If BG is below 100 mg/dL, eat snack prior to exercise. Frequent BG testing before, during and after any activity.
Long or intensive exercise	Effects of exercise can be present for hours after activity has stopped. Consult with HCP for specific guidelines.
Insulin infusion site is too close to the Sensor insertion site when using the Dexcom G5® Sensor and Transmitter with your pump	Make sure the sites are at least 3 inches (7.5 centimeters) away from each other.

Always check BG levels with a fingerstick test from your BG meter.

Preventing hypoglycemia:

- Check BG a minimum of four times a day, and more frequently with exercise.
- Keep accurate track of carbohydrates in the foods you eat.
- Consult your HCP if you are experiencing frequent hypoglycemia or have a severe low that may require the help of another person.

It may be necessary to adjust your basal rates, bolus doses, or review your BG Target goals, along with your daily regimen of food and exercise. If you have a low BG level (hypoglycemia), follow the routine established for you by your HCP.

- It is important to monitor your BG frequently, including periodic checks overnight.
- Investigate the cause of hypoglycemia.
- If you are using the Dexcom G5® Sensor and Transmitter with your pump, check your BG frequently if your CGM Sensor readings suggest possible hypoglycemia or hyperglycemia.

Hyperglycemia

Because your pump uses only rapid-acting insulin, you will not have a reserve of long-acting insulin in your body. This means that any interruption in the delivery of insulin by your pump can quickly result in a sharp rise of your BG levels.

Hyperglycemia (high BG) can occur within two to four hours after insulin delivery stops, and diabetic ketoacidosis (DKA) can develop within four to ten hours.

Several things can cause a high BG value. The most common problems and causes of high BG are listed in the tables below, as are some suggested solutions.

Diabetic Ketoacidosis (DKA)

Hyperglycemia can lead to DKA. If your BG is above 250 mg/dL, **check blood or urine ketones per your HCP**. **Remember, the first signs of DKA are often nausea and vomiting**. Also remember that because you no longer have long-acting insulin in your System, DKA can develop quickly if you ignore and/or fail to troubleshoot potential problems.

Troubleshooting hyperglycemia:

INFUSION SET

POSSIBLE CAUSE OF HIGH BG	SUGGESTED SOLUTION
Redness, irritation, inflammation, swelling, discharge or discomfort	Change infusion set tubing and site. Contact HCP.
Bump or nodule at infusion site	Change infusion set and rotate sites. Avoid this area for site selection.
Scar tissue	Avoid this area for site selection.
Catheter inserted in area of friction	Avoid waistline and friction areas.
Kink in tubing/catheter	Change infusion set tubing and site.
Infusion set not primed (air in tubing)	Disconnect tubing from body. Prime tubing completely.
Cannula not filled	Verify filling volume from manufacturer's instructions, and program that amount when prompted on the FILL CANNULA screen as needed.
Tubing not tightly attached to cartridge	Tighten tubing attachment to cartridge.

Troubleshooting hyperglycemia: *(continued)*

INSULIN

POSSIBLE CAUSE OF HIGH BG	SUGGESTED SOLUTION
Cloudy, clumpy, crystallized, and expired insulin, or insulin exposed to extreme temperatures	Remove infusion set then cartridge and discard. Use new vial of insulin.

FOOD INTAKE

POSSIBLE CAUSE OF HIGH BG	SUGGESTED SOLUTION
Bolus insufficient or omitted	Review carbohydrate counting and I:C ratio settings.
High protein or fat intake	Consult dietitian; may need to count protein and fat.
Long meal, continuous snacking, slowly-absorbed food (high fiber), delayed digestion (gastroparesis)	Consult HCP. May need to use extended bolus or combination bolus option.
Improper bolus timing	Consult HCP.

ACTIVITY

POSSIBLE CAUSE OF HIGH BG	SUGGESTED SOLUTION
Less activity	Use Temp Basal increase. Consult HCP.
Overuse of Temp Basal reduction	Record amount of time for changes. Frequent BG testing to document changes.
BG higher than 250 mg/dL with ketones before exercise	**BG will increase with exercise when ketones are present. DO NOT exercise when ketones are present. Consult HCP for exercise guidelines.**

Troubleshooting hyperglycemia: *(continued)*

⚠ **CAUTION: CHANGE** your infusion set every 2 to 3 days as recommended by your HCP to avoid infection. Use clean hands when handling infusion sets. Clean the skin area near the intended insertion site. Contact your HCP if you have signs or symptoms of infection at your insulin infusion site or Sensor insertion site.

OTHER

POSSIBLE CAUSE OF HIGH BG	SUGGESTED SOLUTION
Medications (steroids, terbutaline, acetaminophen and other hormone treatments)	Inform HCP of all medication changes or additions.
Infection, illness, virus	Refer to *Sick Day Management Guidelines* in *Chapter 15 Section I*.
Pre-menstrual cycle	Consult HCP. May need to use Temp Basal or set additional Basal Program.
Pregnancy	Insulin requirements may increase in later trimesters. Consult HCP.
Weight changes	May need recalculation of basal or bolus doses. Consult HCP.

⚠ **WARNING: ALWAYS** review changes in your pump settings with your HCP to make sure they are correct. Incorrect settings can result in under or over delivery of insulin.

When in doubt, change it out! 1. Follow guidelines provided by your HCP. 2. Change infusion set. 3. Check for ketones. 4. Take rapid-acting insulin by injection.

Problems with Infusion Sets, Sites and Cartridge

A number of problems can occur with infusion sets and sites, the most common of which are listed in the following table, along with some suggested solutions.

POSSIBLE PROBLEMS	SUGGESTED SOLUTION
Air bubbles in tubing	Always fill your pump cartridge with room temperature insulin. Check Luer lock connection and tubing; change infusion set if needed. If using a disconnect set, remove the set from your infusion site and prime the bubbles out. Check that cartridge plunger is straight (plunger rod is not bent or leaning to one side) and the cartridge is not filled with more than 2.0 mL of insulin.
Kinked tubing	Straighten tubing if needed; replace infusion set if needed.
Dislodged needle or cannula	Change infusion set and site. Consider using different tape, dressing or infusion set. A cannula cannot be pushed back into skin successfully.
Blood in tubing (insulin looks pink or red)	Change infusion set and site. Check needle/cannula angle at new infusion site.
Insulin leak	Check Luer lock connection by wrapping a tissue around it to check for moisture; tighten or change cartridge and infusion set if needed. Check that cartridge is not filled with more than 2.0 mL of insulin. **DO NOT** tighten cartridge cap while the infusion set is connected to your body.
Redness, tenderness, lumps, itching, warmth, discharge	Change infusion set and site; use clean technique. Treat old site for infection if necessary. Consult HCP.
Cartridge Reused	**DO NOT reuse cartridge. Cartridge is for single use only.**

Troubleshooting Pump Operation Problems

Changing insulin delivery settings

If a basal delivery occurs while you are changing any of the pump settings that affect basal delivery (specifically, Battery Type, IOB, Low Cartridge Warning Level, Temp Basal Alert Sound Type or any of the delivery limit settings), but you have not confirmed the setting changes by pressing OK, the new settings will be used temporarily only for the basal delivery that was in process at the time the changes were entered. If you do not confirm your setting changes by pressing OK when you enter the changes, the changes will be lost, and the pump will revert to the last confirmed settings for the next basal delivery.

The same situation will occur, if the pump enters into sleep mode while you are changing the pump settings but before you confirm the changes by pressing OK. The change that went into effect temporarily will not be saved, and, when you awaken the pump, the setting will revert to the last confirmed settings saved in the pump.

Once confirmed by pressing OK, new settings will be saved and stored in the pump and utilized for the next basal delivery.

Remember to confirm your settings. You can also suspend the pump while you are changing settings and then resume insulin delivery after all changes have been confirmed.

Basal History Record

If your basal rate is greater than 20 U/Hr and you receive a Call Service Alarm, this may result in a single incorrect Basal History record. This does not impact the programmed basal rate or the calculation of the actual amount delivered; your programmed basal rate will remain unchanged, and your Total Daily Dose will reflect the actual amount of insulin delivered.

Contact 24-hour Customer Service for assistance if you receive a Call Service Alarm.

Temp Basal Indicator

When reviewing your TDD History, if the duration for a Temp Basal runs across a calendar day (e.g., 11PM to 11AM), the Temp Basal indicator will only display "Yes" on the day the Temp Basal was initiated.

Make sure your HCP is aware of the behavior of the Temp Basal indicator when reviewing your records and evaluating discrepancies between programmed Basal Rate and TDD. Contact Customer Service for support, if you have any questions as to the functioning of the Temp Basal Indicator.

Contact Customer Service if you are unable to resolve a pump operational issue. If you have any concerns regarding your therapy, or are experiencing any of the signs of hypoglycemia, hyperglycemia, DKA, or other medical issues, contact your HCP immediately.

CGM Warning "229-963B Periodic Communication Error"

When you navigate to the CGM trend graph screen, if you see that every other data point is missing, or if you notice "**229-963B Periodic Comm Error**" occurring every 10 minutes in the CGM Warnings History screen, you can follow the actions described below to resolve the issue:

1. Turn off Bluetooth (refer to *Chapter 5* Bluetooth on/off), wait 20 minutes, turn on Bluetooth and rejoin the CGM session. Wait another 20 minutes, then check your CGM trend graph screen to see if the issue has been resolved. If the issue still persists, proceed to step 2.

2. Restart the pump (refer to *Chapter 3* to restart and prime). The pump will automatically rejoin the CGM session. Wait 20 minutes, then check your CGM trend graph screen to see if the issue has been resolved. If the issue still persists, call customer service.

During periods of minor illness, it may be more difficult to maintain good control of your diabetes. Examples of minor illness are: dental surgery, colds, nausea/vomiting, sore throat, mild infections, diarrhea, fever. However, you should call your HCP if:

- Illness persists without improvement for 24-48 hours.
- Temperature rises above 100° F.
- Vomiting or diarrhea continues longer than 4 hours.
- A ketone strip indicates there are moderate to large amounts of ketones in your urine.
- BG levels continue to run less than 60 mg/dL or above 250 mg/dL (above 130 mg/dL during pregnancy) after taking extra bolus doses as prearranged by your HCP.
- You show signs of diabetic ketoacidosis (DKA), dehydration or other serious problems such as: increased drowsiness, abdominal or chest pain, difficulty breathing, fruity odor to the breath, dry cracked lips, mouth or tongue.
- Any uncertainty as to what to do to take care of yourself.

Never omit your insulin! If you are ill and cannot eat, your need for insulin continues and may also increase.

- Continue your usual basal dose of insulin along with bolus insulin to cover food eaten or to correct high BG as prearranged with your HCP.
- You may need to temporarily increase or decrease your basal rate by using the Temp Basal feature as prearranged with your HCP.

Medication

Always let your HCP know ALL medications that you are taking. Even medications you are taking for other reasons may impact your diabetes management, so it is important that you always let your HCP know all the medications you are taking.

⚠ **CONTRAINDICATION:** Taking medications containing acetaminophen while wearing the Sensor may inaccurately raise your Sensor glucose readings. The level of inaccuracy depends upon the amount of acetaminophen active in your body and may be different for each person. **DO NOT** rely on Sensor glucose readings if you have recently taken acetaminophen.

Blood and Urine Testing

- Check your BG before your usual mealtime and every 2-4 hours if indicated.
- **Test your blood or urine for ketones at least 4 times a day, or according to instructions from your HCP.**

Fluids and Diet

Always follow your HCP's sick day guidelines. Fluid intake is essential with any illness. Consume 8.3 ounces (240 mL) of fluid per hour. Every third hour consume 8.3 ounces (240 mL) of a sodium-rich liquid, such as bouillon. You need to consume 150-200 grams of carbohydrates daily. If ketones are moderate, contact your HCP. Develop a sick plan with your HCP prior to illness.

Exercise and Sports

There are many options for wearing your pump during exercise and sports activities. During "low-contact" sport activities, such as walking, biking or aerobics, your pump can be clipped to the waistband, or for added security, placed in a "sport case." During "contact" sports such as baseball, basketball or hockey, your pump can be disconnected for up to one hour. Always follow your HCP's individual guidelines when disconnecting your pump because you may need to compensate for missed basal insulin. Before and after you disconnect for any length of time, remember to check your BG levels.

Swimming

Your pump is tested for immersion in water to a depth of 12 feet for 24 hours under normal swimming conditions. You should not wear your pump while scuba diving or when using high diving boards. Your pump should not be taken into hot tubs, as the extreme temperature can adversely affect insulin quality.

If your pump has been dropped, examine it carefully for cracks or signs of damage. If the back label of your pump is not securely affixed or if you suspect your pump may have been damaged or otherwise had its waterproof integrity compromised, **DO NOT** use in water. Contact Customer Service.

If you are using the Dexcom G5® Sensor and Transmitter with your pump, the Dexcom G5® Sensor and Transmitter are tested at IP28 (water resistant when submerged for up to 8 feet for a maximum of 24 hours).

⚠ **CAUTION:** Wireless communication does not work well through water so the range is much less if you are in a pool, bathtub, or waterbed.

High Altitude Activities (Skiing, Hiking, etc.)

Your pump is tested at altitudes up to 10,000 feet at standard operating temperatures. Extreme altitude, temperature or atmospheric conditions may affect pump performance. Refer to *Chapter 17 Section I* for more information on pump operating conditions. Your Dexcom G5® Sensor and Transmitter components are tested at altitudes up to 11,998 feet. Refer to *Chapter 13 Section II* for more information on CGM operating conditions. Check the instructions that come with your BG meter for more information on meter operating conditions.

Traveling

With a pump, traveling becomes less complicated and more enjoyable. However, traveling still requires preparation. Remember to order your pump supplies in advance and pack the following items:

- A letter from your HCP that explains the necessity of carrying insulin supplies and wearing a pump.
- A prescription for insulin, both rapid-acting for your pump and the type recommended by your HCP in case you need to take insulin by injection. (Remember, your pump is designed and calibrated to use U100 concentration insulin only. Use of any insulin with lesser or greater concentration can result in serious injury or death.)
- Emergency supplies listed in the *Before You Begin* section.
- Accessible snacks.
- Bottled water to prevent dehydration while flying. (Remember to check your BG frequently to distinguish between high BG dehydration and normal flight dehydration.)
- The name of a referral HCP at your final destination in case of an emergency.

Also to consider when traveling:

- Pack your insulin carefully so that it is not exposed to extreme temperatures or temperature changes. (Refer to the instructions that came with your insulin for appropriate storage conditions.)
- Pack your pump supplies in carry-on luggage when traveling by air or train. **DO NOT** pack your supplies in checked luggage. Contact your local airport administration or security office before traveling by air to obtain prescription/medical supply carry-on regulations.
- Your pump may set off the metal detector at airport security check-in. Additionally, airport security systems, such as X-rays, may damage the pump, so it may be necessary to disconnect and remove the pump prior to going through security. Contact your local airport administration or security office before traveling by air to obtain information about bringing your pump through airport security check-in.
- Delays through customs may occur if you have a pump malfunction and need a pump replacement. Contact Customer Service for information about obtaining a pump replacement.
- Adjust your pump's clock when crossing time zones.

For more information on traveling with pumps, visit the American Diabetes Association (ADA) website (www.diabetes.org) or call your local airport for security guidelines that may apply.

Intimacy

Your pump need not interfere with intimacy. You can disconnect most infusion sets. Always follow your HCP's guidelines when disconnecting from your pump. You may need to compensate for missed basal insulin. Also, before and after you disconnect for any length of time, remember to check your BG levels.

ONETOUCH VIBE™ PLUS INSULIN PUMP WARRANTY

Animas® warrants that the OneTouch Vibe™ Plus Insulin Pump will be free from defects in material and workmanship, for a period of four (4) years from the date of purchase by the original purchaser. This limited warranty extends only to the original retail purchaser.

If, during the warranty period, the pump should fail because of a defect in material or workmanship, it may be returned to Animas®. Animas® may repair or replace your pump with a new or recertified pump, without charge to the purchaser. In certain circumstances and at its sole discretion, Animas® may instead elect to refund all or a portion of the purchase price of the pump to the purchaser. Freight and transportation charges, where applicable, incurred in shipping a pump to be repaired or replaced under this limited warranty will be paid by Animas®. In the event a pump is replaced or repaired under this warranty, the warranty period shall not be extended. Once you have received your repaired or replaced pump, you must return your original pump to Animas®. In the event it is not returned, this warranty shall be void and the user will not be entitled to future pump replacement or repairs.

This limited warranty is valid only if the OneTouch Vibe™ Plus Insulin Pump is used under normal use and conditions and in accordance with the manufacturer's instructions as detailed in the Owner's Booklet provided to you at time of purchase. This limited warranty does not extend to any damage resulting from the following:

- changes or modifications to the pump by the user or any other third person after the date of manufacture;
- service or repairs performed by any person or entity other than an Animas®-authorized service person;
- a force majeure or other event beyond the control of Animas®;
- accidents, negligence, misuse, or abuse of the pump by the user or any other third person, including, but not limited to, improper storage of or physical abuse such as dropping or otherwise incurred damage to the OneTouch Vibe™ Plus Insulin Pump; or
- normal "wear and tear," including but not limited to cosmetic damage such as scratched display lenses and/or scratched paint.

This warranty will not apply:

- If damage results from use of non-Animas cartridges and/or infusion sets.

This limited warranty only covers the pump and does not cover batteries, infusion sets, cartridges, battery caps, or other accessories of the insulin pump. Animas® cannot guarantee the availability of any third party components or accessories compatible with the pump, including but not limited to those manufactured by Dexcom, Inc. related to the continuous glucose monitoring functionality of the pump.

Except as expressly set forth in this limited warranty, all other warranties are expressly disclaimed and excluded, including, without limitation, any warranties of merchantability or fitness for a particular purpose.

The remedies provided for in this warranty are the exclusive remedies available in the event of any breach hereof. Except for such remedies, Animas®, its suppliers, and its distributors shall not be liable for any losses, liabilities, claims, or damages of any kind or nature whatsoever, including, without limitation, any indirect, consequential, incidental, or special damages caused by or arising from a defect of the insulin pump.

ONETOUCH VIBE™ PLUS INSULIN PUMP ACCESSORY WARRANTY

Limited Product Warranty for Insulin Pump Accessories (Cases, Clips, Skins, etc.)

Your OneTouch Vibe™ Plus Insulin Pump accessory is warranted against defects in materials and workmanship for a period of THREE (3) MONTHS from the date of original retail purchase. If a defect exists, Animas Corporation, at its option and to the extent permitted by law will (1) exchange the product with a functionally equivalent product or (2) refund the original purchase price. This warranty is available only to the original retail purchaser and excludes damage resulting from abuse, accident, modifications or other causes that are not defects in materials and workmanship. TO THE EXTENT PERMITTED BY APPLICABLE LAW ANIMAS® IS NOT LIABLE FOR ANY DIRECT, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES ARISING OUT OF THE USE OR SERVICE OF THE PRODUCT. THE WARRANTY AND REMEDIES DESCRIBED ABOVE ARE EXCLUSIVE AND IN LIEU OF ALL OTHER WARRANTIES, REMEDIES, AND CONDITIONS, WHETHER ORAL, WRITTEN, EXPRESS, STATUTORY OR IMPLIED. TO THE EXTENT PERMITTED BY APPLICABLE LAW ANIMAS® DISCLAIMS ALL IMPLIED AND STATUTORY WARRANTIES, INCLUDING, WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. IF IMPLIED WARRANTIES CANNOT BE DISCLAIMED, THEN SUCH WARRANTIES ARE LIMITED IN DURATION TO THE DURATION OF THIS WARRANTY. Any recovery is limited to the original purchase price. No other person is authorized to modify this limited warranty.

OneTouch Vibe™ Plus INSULIN PUMP MAINTENANCE PARTS WARRANTY

Limited Product Warranty for Insulin Pump Maintenance Parts (Battery Caps, Cartridge Caps, etc.)

Your OneTouch Vibe™ Plus Insulin Pump maintenance part is warranted against defects in materials and workmanship for a period of SIX (6) MONTHS from the date of original retail purchase. If a defect exists, Animas Corporation, at its option and to the extent permitted by law will (1) exchange the product with a functionally equivalent product or (2) refund the original purchase price. This warranty is available only to the original retail purchaser and excludes damage resulting from abuse, accident, modifications or other causes that are not defects in materials and workmanship. TO THE EXTENT PERMITTED BY APPLICABLE LAW ANIMAS® IS NOT LIABLE FOR ANY DIRECT, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES ARISING OUT OF THE USE OR SERVICE OF THE PRODUCT. THE WARRANTY AND REMEDIES DESCRIBED ABOVE ARE EXCLUSIVE AND IN LIEU OF ALL OTHER WARRANTIES, REMEDIES, AND CONDITIONS, WHETHER ORAL, WRITTEN, EXPRESS, STATUTORY OR IMPLIED. TO THE EXTENT PERMITTED BY APPLICABLE LAW ANIMAS® DISCLAIMS ALL IMPLIED AND STATUTORY WARRANTIES, INCLUDING, WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. IF IMPLIED WARRANTIES CANNOT BE DISCLAIMED, THEN SUCH WARRANTIES ARE LIMITED IN DURATION TO THE DURATION OF THIS WARRANTY. Any recovery is limited to the original purchase price. No other person is authorized to modify this limited warranty. Some states do not allow limitations on how long an implied warranty lasts, or exclusions of incidental or consequential damages, so the above limitations may not apply to you. This warranty gives you specific legal rights, and you may have other rights, which vary from state to state.

Technical Specifications – OneTouch Vibe™ Plus Insulin Pump

NOTE: When applicable, testing used 23" Comfort™ infusion set and temperature of 73° F ± 2° F.

Dimensions	3.25 x 2.00 x 0.86 inches (8.26 x 5.08 x 2.18 centimeters)
Weight	approximately 3.70 ounces (105 grams)
Number of Basal Segments	12 per Program
Number of Basal Programs	4
Basal Delivery Frequency (Basal rates of 0.2 U/Hr or higher)	every 3 minutes
Temp Basal Range	-90% to +200%, in 10% increments, OFF
Temp Basal Duration	0.0 hr to 24 hrs in 0.5 hr increments
Extended Bolus Duration	0.1 hr to 12 hrs, with 0.5 hr increments for 0.5 hr to 12 hrs
Battery Type	Energizer® Lithium L91 AA (1.5V) (recommended) or Energizer® E91 Alkaline AA (1.5V) (optional)
Number of Batteries	1
Battery Life, Typical Use	approximately 3 to 4 weeks for an Energizer® Lithium L91 AA battery (1.5V)

Technical Specifications – OneTouch Vibe™ Plus Insulin Pump *(continued)*

Maximum Volume Infused Under Single Fault Condition	Max 2.0U
Cartridge Capacity	up to 2.0 mL or 200 units
Storage Conditions	-4° F to +140° F 10% to 100% relative humidity, including condensation 500 Hpa to 1060 Hpa Batteries must be removed during storage periods exceeding 2 weeks
Operating Conditions	+40° F to +98° F Outside these temperatures, the flow accuracy and time to occlusion could be compromised 700 Hpa to 1060 Hpa 20% to 90% relative humidity, including condensation up to 10,000 feet **DO NOT** exceed the insulin manufacturer's recommended temperature and humidity ranges when operating the OneTouch Vibe™ Plus Insulin Pump.
Critical Audible Alarms	50 dB(A) at 1m min., per IEC 60601-2-24
Pump Disposal	Contact Customer Service for pump disposal information
Audio Bolus Range	0.1 to 2.0U in 0.1U step 0.5 to 10.0U in 0.5U step 1.0 to 20.0U in 1.0U step 5.0 to 35.0U in 5.0U step

Performance Characteristics

Flow Rate Accuracy

Delivery Mode	Accuracy
Bolus	+/- 5%
Basal	+/- 5%

Maximum Time to Occlusion Alarm*

Basal/Bolus Delivery	Low Occlusion Sensitivity Setting	High Occlusion Sensitivity Setting
0.025 U/Hr basal	120 hours	72 hours
1.0 U/Hr basal	3 hours	1.5 hours
3U or more bolus	30 seconds	8 seconds

** Maximum Time to Occlusion will vary based upon user-selected delivery rates. Certain factors, such as the presence of air in the infusion set or the cartridge and/or ambient temperature changes, can delay an occlusion alarm.*

Bolus Volume After Occlusion Release (1.0 U/Hr basal)	• 1.5U max with occlusion sensitivity set to high • 3.0U max with occlusion sensitivity set to low
Delivery Rates	• Bolus, under 1U: 1.1 to 2.2 U/sec • Bolus, 1U or more (normal delivery speed): 0.5 to 0.9 U/sec • Bolus, 1U or more (slow delivery speed): 0.2 to 0.4 U/sec • Prime: 1.7 to 3.3 U/sec
Insulin Types Used	Rapid-acting U100 insulin
Basal Rate Range	0.025 to 25 U/Hr in 0.025 U/Hr steps
Bolus Range	0.05 to 35U in 0.05U steps
Protection From Equipment Error	More than 1.5 million redundant safety cross-checks per day for both hardware and software functionality
Bluetooth Capabilities Specifications: (when using the Dexcom G5® Sensor and Transmitter with your pump)	• Range between pump and Sensor/Transmitter: 12 feet • Frequency: 2.4 GHz • Pump Mode: Receive only

Continuous Operation, Internally Powered Device

Type BF Medical Equipment (Patient isolated, not defibrillator protected)

Waterproof Equipment, IPX8 (protected against the effects of submersion, tested at 12 feet for 24 hours)

Infrared communication port

Patient's Bill of Rights and Responsibilities

It is the intent of Animas Corporation to address and respect patients' rights in providing care and services. It is the policy of Animas Corporation to provide services to all patients without regard to race, color, national origin, religion, sex, age or disability. No person shall be excluded from participation in or be denied the benefits of any service, or be subject to discrimination because of race, color, national origin, religion, sex, age or disability.

It is the responsibility of all Animas® employees involved in interaction with the patient through sales, education programs, customer service or any other means to understand and promote this policy. It is the responsibility of patients of Animas Corporation to actively participate in his or her own care.

- The patient is given information to allow decision making regarding care or services. The patient is responsible for providing accurate and complete information about his or her health and medical conditions.
- The patient is involved in conflict resolution. The patient should inform Animas® about his or her expectations and satisfaction with care.
- Patient complaints will be heard, reviewed and resolved to the best of our ability. The patient should ask questions when they do not understand his or her own care, treatment, services, or what they are expected to do.
- The patient should follow the treatment plan or contact his or her HCP if unable to do so. The patient should also express any concerns about his or her ability to follow the instructions and should report changes in his or her condition as appropriate. If they do not follow the instructions, the patient should accept shared responsibility for the outcomes of care, treatment, services, or what they are expected to do.
- The patient is involved in resolving ethical issues.
- The patient has a right to confidentiality and privacy with regards to his or her medical information. The patient should notify Animas® Customer Support with concerns related to product or safety issues.

- The patient has a right to have his or her property respected. The patient should be considerate and respectful of Animas® employees.
- The patient should meet any financial obligation agreed to with Animas®. The Animas® Inside Sales Department will discuss billing of co-pays and deductibles, including whether the patient has the ongoing ability to pay for supplies. Animas® will also address patients who lose insurance coverage.
- The patient has a right to have his or her communication needs met. Animas® will work with the patient to ensure that any language requirements, including sign language and any additional educational needs, are met.

If the patient believes that they have been denied a benefit of service because of race, color, national origin, religion, sex, age or disability, patient may file a Complaint of Discrimination with the Manager of Animas®' Customer Service Department, either verbally or in writing.

If the complaint is filed in writing, it should include a name, address, phone number and a brief description of what occurred leading to the belief that the individual was discriminated against. In this way the appropriate person may respond to the complaint. The complaint may also be filed with external agencies such as the State Department of Social Services, or the State Department of Health and Human Services.

Please contact Animas Corporation if there are any questions or concerns regarding this information.

The Joint Commission

Animas® is committed to the safety and care of its patients. As part of this commitment, Animas® is accredited by The Joint Commission, which sets the standards for quality of care in the health care community. If you would like to contact The Joint Commission regarding an issue, you may do so by fax (630-792-5636) or mail (Office of Quality Monitoring, The Joint Commission, One Renaissance Boulevard, Oakbrook Terrace, IL 60181). You will need to complete a Quality Incidence Report Form, which is available from The Joint Commission.

MEDICARE DMEPOS SUPPLIER STANDARDS

NOTE: **This is an abbreviated version of the supplier standards Medicare DMEPOS suppliers must meet. These standards are listed in their entirety in the Code of Federal Regulations – 42 C.F.R. 424.57(c). The full text of these standards can be obtained at http://ecfr.gpoaccess.gov. Upon request we will furnish you a written copy of the standards.**

1. A supplier must be in compliance with all applicable Federal and State licensure and regulatory requirements and cannot contract with an individual or entity to provide licensed services.
2. A supplier must provide complete and accurate information on the DMEPOS supplier application. Any changes to this information must be reported to the National Supplier Clearinghouse within 30 days.
3. An authorized individual (one whose signature is binding) must sign the application for billing privileges.
4. A supplier must fill orders from its own inventory, or must contract with other companies for the purchase of items necessary to fill the order. A supplier may not contract with any entity that is currently excluded from the Medicare program, any State health care programs, or from any other Federal procurement or nonprocurement programs.
5. A supplier must advise beneficiaries that they may rent or purchase inexpensive or routinely purchased durable medical equipment, and also make them aware of the purchase option for capped rental equipment.
6. A supplier must notify beneficiaries of warranty coverage and honor all warranties under applicable State law, and repair or replace free of charge Medicare-covered items that are under warranty.
7. A supplier must maintain a physical facility on an appropriate site. This standard requires that the location is accessible to the public and staffed during posted hours of business. The location must be at least 200 square feet and contain space for storing records.
8. A supplier must permit CMS or its agents to conduct on-site inspections to ascertain the supplier's compliance with these standards. The supplier location must be accessible to beneficiaries during reasonable business hours, and must maintain a visible sign including posted hours of operation.

9. A supplier must maintain a primary business telephone listed under the name of the business in a local directory or a toll free number available through directory assistance. The exclusive use of a beeper, answering machine, answering service or cell phone during posted business hours is prohibited.
10. A supplier must have comprehensive liability insurance in the amount of at least $300,000 that covers both the supplier's place of business and all customers and employees of the supplier. If the supplier manufactures its own items, this insurance must also cover product liability and completed operations.
11. A supplier must agree not to initiate telephone contact with beneficiaries, with a few exceptions allowed. This standard prohibits suppliers from contacting a Medicare beneficiary based on a physician's oral order unless an exception applies.
12. A supplier is responsible for delivery and must instruct beneficiaries on use of Medicare-covered items, and maintain proof of delivery.
13. A supplier must answer questions and respond to complaints of beneficiaries, and maintain documentation of such contacts.
14. A supplier must maintain and replace at no charge or repair directly, or through a service contract with another company, the Medicare-covered items it has rented to beneficiaries.
15. A supplier must accept returns of substandard (less than full quality for the particular item) or unsuitable items (inappropriate for the beneficiary at the time it was fitted and rented or sold) from beneficiaries.
16. A supplier must disclose these supplier standards to each beneficiary to whom it supplies a Medicare-covered item.
17. A supplier must disclose to the government any person having ownership, financial, or control interest in the supplier.
18. A supplier must not convey or reassign a supplier number; i.e., the supplier may not sell or allow another entity to use its Medicare billing number.
19. A supplier must have a complaint resolution protocol established to address beneficiary complaints that relate to these standards. A record of these complaints must be maintained at the physical facility.

20. Complaint records must include: the name, address, telephone number and health insurance claim number of the beneficiary, a summary of the complaint, and any actions taken to resolve it.
21. A supplier must agree to furnish CMS any information required by the Medicare statute and implementing regulations.
22. All suppliers must be accredited by a CMS-approved accreditation organization in order to receive and retain a supplier billing number. The accreditation must indicate the specific products and services, for which the supplier is accredited in order for the supplier to receive payment of those specific products and services (except for certain exempt pharmaceuticals). Implementation Date - October 1, 2009
23. All suppliers must notify their accreditation organization when a new DMEPOS location is opened.
24. All supplier locations, whether owned or subcontracted, must meet the DMEPOS quality standards and be separately accredited in order to bill Medicare.
25. All suppliers must disclose upon enrollment all products and services, including the addition of new product lines for which they are seeking accreditation.
26. All suppliers must meet the surety bond requirements specified in 42 C.F.R. 424.57 (c). Implementation Date - May 4, 2009
27. A supplier must obtain oxygen from a state- licensed oxygen supplier.
28. A supplier must maintain ordering and referring documentation consistent with provisions found in 42 C.F.R. 424.516(f).
29. DMEPOS suppliers are prohibited from sharing a practice location with certain other Medicare providers and suppliers.
30. DMEPOS suppliers must remain open to the public for a minimum of 30 hours per week with certain exceptions.

NOTE: **Medicare defines an insulin pump as a capped rental.**

- Medicare will pay a monthly rental fee for a period not to exceed 13 months, after which ownership of the equipment is transferred to the Medicare beneficiary.
- After ownership of the equipment is transferred to the Medicare beneficiary, it is the beneficiary's responsibility to arrange for any required service or repair.

Section II

Dexcom G5® Mobile CGM System

Section II of this Owner's Booklet covers instructions for using the Dexcom G5® Sensor and Transmitter in conjunction with your OneTouch Vibe™ Plus Insulin Pump. In addition to providing continuous insulin delivery, your OneTouch Vibe™ Plus System is designed to perform continuous glucose monitoring (CGM) when used in conjunction with the Dexcom G5® Sensor and Transmitter. The Dexcom G5® Sensor and Transmitter are packaged and shipped separately. Once you have activated the *Bluetooth* communication link between them, your OneTouch Vibe™ Plus System can provide an integrated approach to managing your glucose levels.

The Sensor is a disposable unit that you insert under the skin of your belly (abdomen) to continuously monitor your glucose levels for up to 7 days. Glucose is measured from fluid below the skin surface (interstitial fluid). The Transmitter is a reusable device that snaps into your Sensor pod.

Together, the Sensor and Transmitter wirelessly send CGM Sensor readings every 5 minutes to your OneTouch Vibe™ Plus Insulin Pump where the data can be viewed and analyzed on the pump's color display. You can also set your pump to alert you when your CGM Sensor readings are too high or too low, or are rising or falling too quickly. Certain historical CGM data records are also available for review on your pump (see *Chapter 7* in *Section II* for more information). You can use compatible diabetes management software (DMS) to track, review and analyze CGM data (from your pump) on your computer.

While a fingerstick test with a BG meter gives you a glucose measurement at one point in time (like a still picture), CGM information displayed on your pump will help you understand the speed and direction of your glucose changes over time (like a video camera).

Knowing when your CGM Sensor readings are trending low or high, and by how much, can provide a better understanding of your glucose cycles throughout the day, and during sleeping hours when it is hard to test with a BG meter.

There are differences in how glucose is measured in the blood versus how it is measured in the fluid below the skin. And there is a lag time between when glucose is absorbed into the blood versus when it is absorbed into fluid below the skin. This is why there may be a difference between your BG meter readings and CGM Sensor readings. You will still need to use your BG meter for calibrations and to make treatment decisions.

You will need to calibrate the Sensor and Transmitter on a regular basis with fingerstick values from a BG meter. Any commercially-available BG meter can be used for obtaining fingerstick calibration values.

Dexcom G5® Sensor and Transmitter

Dexcom G5® Transmitter
(Reusable)

Dexcom G5® Sensor and Applicator
(Single Use)

Symbols on Dexcom G5® Sensor and Transmitter package labels

The following symbols may be found on the Dexcom G5® Sensor and Transmitter package labels. These symbols tell you about the proper and safe use of the Sensor and Transmitter. This table shows what each symbol means.


"Use By" Date


Caution


DO NOT Reuse

Serial Number

Sterile by Radiation

Lot Number

Part Number, Catalog Number


Type BF Applied Part


European Union WEEE Directive 2006-66-EC

Contact Customer Service regarding recycling of the Dexcom G5® Transmitter.


Two-sided Temperature Limits

Temporary Submersion


Follow Operating Instructions


Date of Manufacture


Manufacturer


Two-Sided Humidity Limitation


DO NOT Use if Package is Damaged

Ship By Date

Marking certifies that the device meets the European Council Directive 93/42/EEC


Bluetooth® Smart capabilities

About *Bluetooth®* (BLE) Communication

Your pump and Dexcom G5® Sensor and Transmitter have built-in BLE capabilities. BLE is a type of wireless communication. Cell phones use BLE technology, as do many other devices. BLE capability is how your pump and CGM communicate and share CGM data.

The BLE feature on your pump will be turned off when you first receive it. In order to begin using your pump and Sensor/Transmitter together as a system, you must enter the ID of your Transmitter into your pump to enable BLE communication.

BLE communication between your pump and Sensor/Transmitter will work up to a distance of about 12 feet and will transmit through clothing. Direct line of sight is not required for BLE communication. As long as you have a good BLE signal and are within range, you can use your pump to display CGM data. Exposing your pump and Sensor/Transmitter to water, lying in a waterbed, and certain objects in between the two devices may interfere with BLE communication. Nearby metallic objects and electric blankets may also interfere with BLE communication.

When conditions or distance cause BLE communication to be lost or interrupted, data transfer between the pump and Sensor/Transmitter devices will stop temporarily. This means that you will not be able to use your pump to display most recent CGM data or future CGM Sensor readings until the BLE communication is restored. As soon as the problem is resolved, BLE communication will resume. Refer to *Chapter 12* in *Section II* for more information on conditions that may cause BLE communication problems.

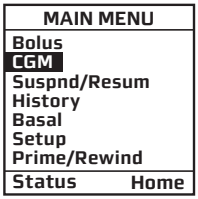
Setting your Transmitter ID

Your Sensor/Transmitter and pump communicate using BLE communication. After BLE is enabled, BLE communication will be activated when you enter the unique Transmitter ID into the pump and start/join your CGM session. This will ensure that communication takes place only between this pump and this Transmitter. Any time you replace the Transmitter, you will need to enter the new Transmitter ID into the pump. Similarly, if your pump is replaced, you will need to enter the current Transmitter ID into the new pump.

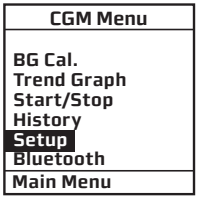
CGM menu options are not available while the pump is suspended. **DO NOT** remove the Transmitter from the box until you are ready to use it. Since the Transmitter is reusable, you do not need a new one every time you start a sensor session. Keep your current session's Transmitter box.

1. For the initial setup, remove the Transmitter from the box.

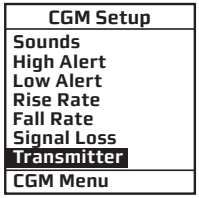
2. From the MAIN MENU, scroll to "CGM" and press OK.

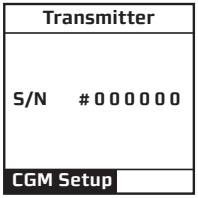


3. Scroll to "Setup" on the CGM Menu and press OK.

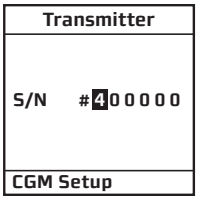


4. Scroll to "Transmitter" and press OK. The Transmitter screen will be displayed and "CGM Setup" will be highlighted.





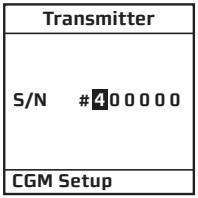
5. Scroll to the "S/N#" field. The last digit will be highlighted. Scroll to the first digit and then press OK so that the first digit is flashing.



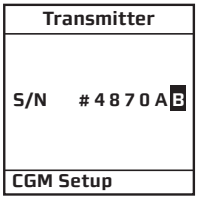
NOTE:

- If this is the first time you are entering a Transmitter ID, all zeros (000000) will appear in the "S/N#" field.
- The Transmitter ID appears on the underside of the Transmitter.
- The Transmitter ID should begin with 4.

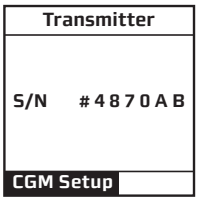
6. Use the ▲/▼ buttons to enter the first number/letter of the Transmitter ID. Press OK to move to the next digit and press OK again so that the second digit is flashing.



7. Repeat these steps until you have correctly entered all 6 numbers/letters from your Transmitter ID. Press OK when the last digit is highlighted.



8. "CGM Setup" will be highlighted. If you need to edit the Transmitter ID you just entered, scroll to the "S/N#" field and re-enter the correct Transmitter ID. With "CGM Setup" highlighted, press OK to return to the CGM Setup screen.



NOTE:

- You can join an active CGM session through entering the Transmitter ID.

NOTE:

- A Dexcom CGM receiver cannot be used when using a Dexcom G5® Transmitter with a pump. Turn off the receiver to prevent any interruptions in communication between your pump and the Transmitter.
- Entering a valid Transmitter ID but not inserting a Transmitter/Sensor may trigger certain CGM warnings, alarms and alerts to display/sound on your pump.

Setting CGM Alerts on your Pump

You can set your pump to display and sound (beep/vibrate) an alert when:

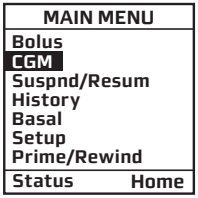
- Your CGM Sensor readings are outside your target range.
- Your CGM Sensor readings may be rising or falling too quickly.
- Your Transmitter is not within BLE range of your pump.
- There are other CGM problems that require your attention.

On a few CGM settings, you can also select a "snooze time." The snooze time tells your pump to display/sound the alert again at a set amount of time after first confirming the alert, if the condition causing the original alert has not been resolved. Consult with your HCP on the settings that are most appropriate for you.

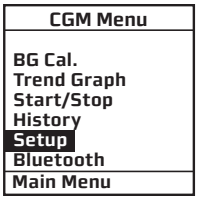
CGM settings affect how and when your pump displays/sounds an alert, and how information is displayed on the CGM Data and CGM Trend screens.

NOTE: Your pump does not have the same "progressive" warnings and alarms safety system for CGM functions as it does for insulin delivery functions.

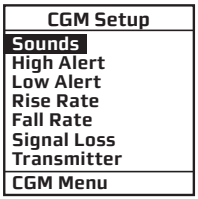
1. From the MAIN MENU, scroll to "CGM" and press OK.



2. Scroll to "Setup" and press OK.



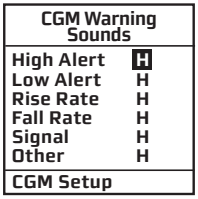
3. Scroll to "Sounds" on the CGM Setup screen and press OK.



You can set pump sounds for:

- High Alert
- Low Alert
- Rise Rate
- Fall Rate
- (Transmitter) Signal Loss
- Other (alerts)

4. The "High Alert" field will be highlighted on the CGM Warning Sounds screen. Press OK so that the highlight is flashing. Use the ▲ and ▼ buttons to select the desired sound for this alert. Press OK.



Pump sounds may be set to:

- Vibrate (Vib) only
- Low Volume (L) beep and vibrate
- Medium Volume (M) beep and vibrate
- High Volume (H) beep and vibrate (default setting)

5. Repeat step 4 for the remaining alerts (Low Alert, Rise Rate, Fall Rate, Signal Loss, Other).

6. When you are finished, scroll to "CGM Setup" and press OK to return to the CGM Setup screen.

Setting CGM Alert Values/Limits

You can enable/disable alerts and set CGM values/limits for:

- High Alert
- Low Alert
- Rise Rate
- Fall Rate

You can also set a "snooze time" for the High and Low Alert limits and the (Transmitter) Signal Loss Alert. See the pages that follow for more information on CGM Alerts.

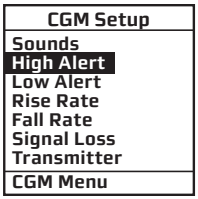
NOTE:

- If you disable an Alert, it will not display/sound on the pump.
- You cannot disable the CGM Warning that displays/sounds when your most recent CGM Sensor reading is at or below 55 mg/dL.

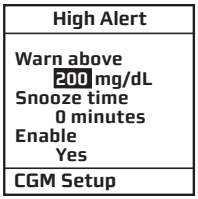
High and Low Glucose Alerts

The High and Low (Glucose) Alerts will display/sound on your pump if the last CGM Sensor reading is at the limit or falls above or below these limits.

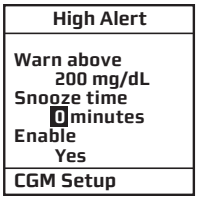
1. From the CGM Setup screen, scroll to "High Alert". Press OK.



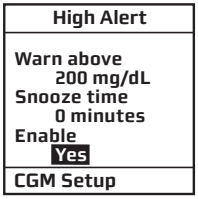
2. With the "Warn above" field highlighted on the High Alert screen, press OK so that the highlight is flashing. Use the ▲/▼ buttons to select the desired level for the High Alert and press OK. You may set the High Alert from 120 mg/dL to 400 mg/dL (default is 200 mg/dL) in 10 mg/dL increments.



3. The "Snooze Time" field will be highlighted. Use the ▲/▼ buttons to select the desired snooze time for the High Alert and press OK. The snooze time lets you set a time for the High Alert to display/sound again on your pump after you first confirm the alert, if the condition causing the original alert has not been resolved. You may set a snooze time from 0 to 300 minutes (default is 0 minutes – no re-alert) in 30 minute increments.

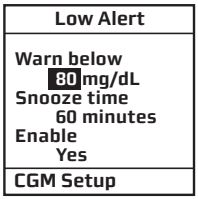


4. Scroll to the "Enable" field and press OK to enter edit mode. The Enable setting gives you the option to display/sound the High Alert on your pump whenever the last CGM Sensor reading falls at or above this level. When you select "No", this feature is disabled so that High Alerts will not display/sound on your pump. The default setting is "Yes" – enable.



5. When you are finished, scroll to "CGM Setup" and press OK to return to the CGM Setup screen.

6. Scroll to "Low Alert" on the CGM Setup screen and repeat these steps for the Low (Glucose) Alert. You may set the Low Alert from 60 mg/dL to 100 mg/dL (default is 80 mg/dL) in 5 mg/dL increments, the snooze time from 0 to 300 minutes (default is 0 minutes – no re-alert) in 30 minute increments, and either enable or disable (default is "Yes" – enable) the Low Alert.



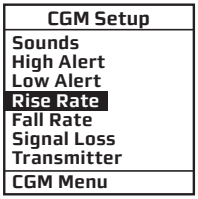
7. When you are finished, scroll to "CGM Setup" and press OK to return to the CGM Setup screen.

NOTE: The High and Low (Glucose) Alert levels that are set here will appear as horizontal lines on the graphs included in the CGM Trend screens. These levels will also affect the color coding of the Trend Arrows that appear in the CGM Data and CGM Trend screens. If you choose to disable these alerts, the horizontal lines will not appear on the Trend graph and the alerts will not display/sound on the pump; however, a line indicating the fixed low glucose level of 55 mg/dL will then appear. See *Chapter 6* in S*ection II* for more information on the CGM Data and CGM Trend screens.

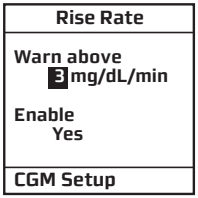
Rise and Fall Rate Alerts

The Rise and Fall Rate Alerts will display/sound on your pump if your CGM Sensor readings begin to rise or fall at or faster than these limits.

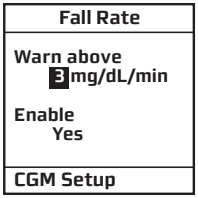
1. From the CGM Setup screen scroll to "Rise Rate". Press OK.



2. With the "Rise Rate" field highlighted on the Rise Rate screen, press OK to activate the edit mode (flashing highlight). Use the ▲/▼ buttons to select the desired value for the Rise Rate Alert and press OK to return to the CGM Setup screen. You may set the Rise Rate limit at either 2 mg/dL per minute or the default rate limit of 3 mg/dL per minute.



3. Scroll to "Fall Rate" on the CGM Setup screen and repeat these steps for the Fall Rate Alert. When you are finished, scroll to "CGM Setup" and press OK to return to the CGM Setup screen. You may set the Fall Rate limit at either 2 mg/dL per minute or the default rate limit of 3 mg/dL per minute.

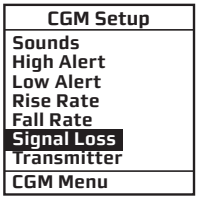


NOTE: You can enable or disable (default is "Yes" – enable) the Rise and Fall Rate Alerts. If this feature is disabled, the Rise and Fall Rate Alerts will not display/sound on the pump.

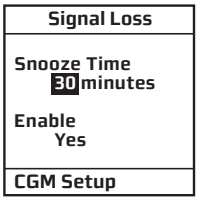
(Transmitter) Signal Loss Alert

The (Transmitter) Signal Loss Alert will display/sound on your pump if your Transmitter is not within BLE range of your pump (12 feet). The (Transmitter) Signal Loss Alert will display/sound on your pump if your pump loses communication with your Transmitter.

1. From the CGM Setup screen, scroll to "Signal Loss". Press OK.



2. With the "Snooze Time" field highlighted on the Signal Loss screen, press OK to activate the edit mode (flashing highlight). Use the ▲/▼ buttons to select the desired snooze time for the alert and press OK. The snooze time lets you set a time for the Signal Loss Alert to display/sound again on your pump after you first confirm the alert, if the condition causing the original alert has not been resolved. You may set a snooze time from 21 to 201 minutes (default value is 30 minutes) in 3 minute increments.



3. When you are finished, scroll to "CGM Setup" and press OK to return to the CGM Setup screen.

NOTE: You can enable or disable (default is "Yes" – enable) the Signal Loss Alert. If this feature is disabled, the Signal Loss Alert will not display/sound on the pump.

To use the OneTouch Vibe™ Plus System, you will need your OneTouch Vibe™ Plus Insulin Pump and a Dexcom G5® Sensor and Transmitter. You will also need a BG meter and test strips for calibration and to make all treatment decisions. Once inserted and calibrated, the Sensor will continuously measure and display your glucose readings for up to 7 days (166 hours after the 2-hour startup period). This chapter will show you how to insert the Sensor and attach the Transmitter.

Sensor Overview

The Sensor is a device that continuously measures your glucose levels from fluid below your skin. You will use a BG meter periodically to calibrate your Sensor. Calibrating the Sensor helps keep the CGM Sensor accurate over the 7-day life of the Sensor.

Transmitter Overview

⚠ **WARNING: DO NOT** dispose of your Transmitter. It is reusable. The same Transmitter is used for each Sensor session until you have reached the end of the Transmitter battery life.

The Transmitter collects the Sensor readings and sends them to the pump using wireless *Bluetooth* (BLE) technology. This happens every 5 minutes for up to 7 days. The Transmitter and Sensor are water resistant when properly connected.

The transmission range from the Transmitter to the pump is up to 12 feet without obstruction. *Bluetooth* wireless communication does not work well through water so the range may be much less if you are in a pool, bathtub, or waterbed. Nearby metallic objects and electric blankets may also interfere with wireless communication.

Remember your Transmitter is reusable. With a battery life of 90 days, use the same Transmitter over a number of Sensor sessions. You will receive prompts as you near the end of its battery life. When you take a Sensor off after the 7-day session, remember to take the Transmitter out of the Sensor and clean it before reusing it for the next Sensor session.

Before You Start

⚠ CONTRAINDICATION:
Contraindications let you know when not to use the Dexcom G5® Transmitter and Sensor; you may hurt yourself or damage the system. Remember, if used during certain situations, the risk of use may clearly outweigh any potential benefit.

- **MRI/CT/Diathermy:** Remove the Dexcom G5® Sensor and Transmitter before Magnetic Resonance Imaging (MRI), Computed Tomography (CT) scan, or high-frequency electrical heat (diathermy) treatment. The Dexcom G5® Sensor and Transmitter have not been tested during MRI or CT scans or with diathermy treatment. The magnetic fields and heat could damage the Sensor and Transmitter, which may cause it to display inaccurate glucose readings or may prevent alerts.
- **Medications:** Taking medications with acetaminophen while wearing the Sensor may falsely raise your Sensor glucose readings. The level of inaccuracy depends on the amount of acetaminophen active in your body and is different for each person.
- The pump and any type of metallic infusion set must be removed prior to an MRI, and left outside the room during the procedure.

General CGM System Warnings

Warnings outline important hazard information, describing any serious and/or life threatening situations, their consequences, how to avoid danger while using the system and how to protect the Dexcom G5® Mobile CGM System from harm.

⚠ WARNING:

Review Training Materials

- Thoroughly review this User Guide materials before using your Dexcom G5® Transmitter and Sensor.
- Incorrect use could lead you to misunderstand system information or might affect its performance and you might miss a severe low or high glucose event.

Treatment Decisions

- The Dexcom G5® Transmitter and Sensor does not replace your BG meter.
- When making treatment decisions, such as the amount of insulin you need, only use your BG value. Don't use the Dexcom G5® Sensor glucose readings because readings can be different from your BG value. If Sensor glucose readings are used in determining treatments, it could result in you missing a severe low or high glucose event.

Don't Ignore Low/High Symptoms

- If your Sensor glucose readings don't match your symptoms, measure your BG with a fingerstick. You may miss a severe low or high glucose event.

Who Shouldn't Use

- The Dexcom G5® Transmitter and Sensor were **not evaluated** for the following persons:
  - Pregnant women
  - Persons on dialysis
  - Critically ill patients
- The system's accuracy hasn't been tested in people falling into these groups and Sensor glucose readings may be inaccurate, resulting in missing a severe low or high glucose event.

Calibration Warning and Precautions

Calibration is the process of making sure your Sensor continues to be accurate. Your Sensor doesn't automatically know what your glucose levels are – you have to teach your system what a given BG value is by entering in a KNOWN glucose value from your BG meter.

⚠ WARNING:
Calibrate on Schedule
Calibrate at least once every 12 hours. Calibrating less often than every 12 hours might cause Sensor glucose readings to be inaccurate, resulting in you missing a severe low or high glucose event.

⚠ PRECAUTION:
Be Accurate, Be Quick
- Enter the exact BG value displayed on your BG meter within five minutes of a fingerstick.
- Entering the wrong BG values, or waiting more than five minutes before entry, might affect Sensor performance, resulting in you missing a severe low or high glucose event.

Significant Glucose Rate Changes
- Don't calibrate when your BG is changing at a significant rate: more than 2 mg/dL per minute.
- Look for rate change arrows on your display device screen and don't calibrate when you see:
  - A single arrow, pointing up
    - Rising 2-3 mg/dL each minute
  - Two arrows pointing up
    - Rising more than 3 mg/dL each minute
  - A single arrow, pointing down
    - Falling 2-3 mg/dL each minute
  - Two arrows pointing down
    - Falling more than 3 mg/dL each minute
- Calibrating during a significant rise/fall of your BG may affect accuracy of Sensor glucose readings, resulting in you missing a severe low or high glucose event.

⚠ **PRECAUTION:** *(Continued)*

Fingerstick Only

- Only use fingerstick measurements from your BG meter for calibration.
- Alternative site BG values from your arms, palm of your hand, etc., may be different and less accurate than your fingerstick BG values. Using alternative sites for calibration might affect Sensor performance, resulting in you missing a severe low or high glucose event.

Prior to Initial Calibration: Data/Alarm/Alert

- After starting a new Sensor session, prior to your initial calibrations and during the 2-hour startup period, you won't receive any Sensor information such as readings, Alarms or Alerts. Without these, you may miss a severe low or high glucose event.
- Continue to take fingerstick measurements during a new Sensor 2-hour startup period.

System/Hardware/Software Warnings and Precautions

In this section, you will learn how to safely use the Dexcom G5® Transmitter and Sensor with your OneTouch Vibe™ Plus Pump. Some sections have either Precautions or Warnings, others will have both.

⚠ WARNING:

Sensor Breaking Off

- On rare occasions, the Sensor wire may break or detach from the Sensor pod.
- Within 24 hours of experiencing a broken Sensor wire, please call our 24/7 Technical Support department, toll free at 1.877.339.2664 or toll at 1.858.200.0200.
- If a Sensor wire breaks under the skin with no portion of it visible, don't remove it. Contact your healthcare professional if you have redness, swelling, or pain at the insertion site.

Placement

- Do not insert the Sensor component of the Dexcom G5® CGM System in a site other than the belly/abdomen (ages 2 years and older) or the upper buttocks (ages 2 to 17 years). The placement and insertion of the Sensor component of the Dexcom G5® CGM System is not approved for other sites.
- If placed in other areas, the Dexcom G5® CGM System may not function properly.

Storage

- During a Sensor's shelf life, store it between 36° F to 77° F. While you don't need to keep your Sensor in a refrigerator, you can as long as the refrigerator is between 36° F and 77° F.
- Never store Sensors and/or Sensor packages in a freezer.
- Storing the Sensor incorrectly might cause the Sensor glucose readings to be incorrect, resulting in you missing a severe low or high glucose event.

⚠ PRECAUTION:

Expiration Date

- Don't use expired Sensors. Before inserting, always check the package label for the expiration date using the YYYY-MM-DD format. If past the expiration date, the Sensor glucose readings might not be accurate, resulting in you missing a severe low or high glucose event.

Sensor Package

- Don't use a Sensor if its sterile package has been damaged or opened. Using a non-sterile Sensor might cause infection.

Clean and Dry Before Using

- Before opening the Sensor package, wash your hands with soap and water, then dry. If your hands are dirty while inserting the Sensor, you may contaminate the insertion site and get an infection.
- Before Sensor insertion, clean the skin with alcohol wipes to prevent infections. Don't insert the Sensor until the cleaned insertion site is dry, and free from any lotions or perfumes.
- If your insertion site is not clean and completely dry, you run the risk of infection or the Sensor pod not sticking and falling off.

Sensor Placement

- Change the site where you place the Sensor with each new insertion. Using the same site too often might not allow the skin to heal, causing scarring or skin irritation.
- Sensor placement is important. Make sure the area you place your Sensor won't:
  - Be bumped, pushed, or squeezed
  - Have scars, tattoos, or irritation
- Insertion in these areas might affect Sensor performance, resulting in you missing a severe low or high glucose event.
- Avoid injecting insulin or placing an insulin pump infusion set within three inches of the Sensor. The insulin might affect Sensor performance, resulting in you missing a severe low or high glucose event.

Transmitter Warnings and Precautions

⚠ WARNING:

Inspect Transmitter

If your Transmitter is damaged or cracked in any way, don't use it. Damaged components could create an electrical safety hazard or malfunction, which might cause electrical shocks.

Choking

The Transmitter is small and may pose a choking hazard. Don't put it in your mouth or allow children to play with it.

⚠ PRECAUTION:

Reusable: Don't Throw Away

- When ending a session, *don't throw away the Transmitter.*
- The Transmitter is reusable and can be used in multiple Sensor sessions. Keep using it until the system notifies you the Transmitter battery is about to expire.

Don't Share Your Transmitter

- Never share your Transmitter with another person. The Dexcom G5® Transmitter and Sensor are prescription-only medical devices and are meant, or indicated, for your use only.
- Your Transmitter is tied to your readings. If used by someone else, your reports, Alarms and Alerts, etc., would be wrong, possibly resulting in you missing a severe low or high glucose event.

System Precautions

Next are precautions for the Transmitter and Sensor.

⚠ PRECAUTION:

Use Correct Transmitter and Sensor

- Different generations' Transmitters and Sensors are not interchangeable with each other.
- The Dexcom G5® Transmitter is not compatible with the Dexcom G4® PLATINUM Transmitter. The Dexcom G5® Transmitter won't work if you mix the Transmitter from different generations, possibly resulting in you missing a severe low or high glucose event.
- You can use a Dexcom G4® PLATINUM Sensor with the Dexcom G5® Transmitter. Before using the Sensor, make sure the Sensor label says "Dexcom G5® Mobile/G4® PLATINUM Sensor," or "Dexcom G4® PLATINUM Sensor."

System Accuracy

- System accuracy may be affected when your glucose is changing at a significant rate such as during exercise or after a meal.
- Significant glucose rise/fall rates:
  - Rising 2-3 mg/dL each minute
  - Rising more than 3 mg/dL each minute
  - Falling 2-3 mg/dL each minute
  - Falling more than 3 mg/dL each minute

⚠ CAUTION: U.S. law restricts the sale of the Dexcom G5® Transmitter and Sensor to sale by or on order of a physician.

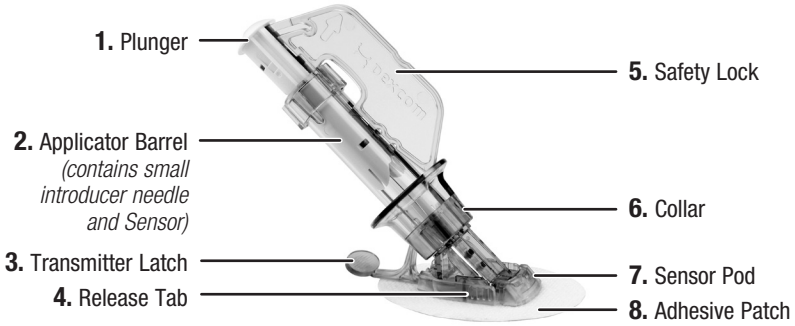
Inserting a new Sensor and Transmitter

Review the Sensor Applicator Pouch

The sterilized Sensor Pouch contains the Sensor and the single use Sensor Applicator. Important label information is on the outside of the Pouch. Make sure the expiration date on the Sensor Pouch has not passed and **DO NOT** use if it has. Before removing the Sensor Applicator out of its sterile Pouch, you will need to determine the best place to insert your Sensor.

Single use Sensor Applicator

Review the Sensor Applicator

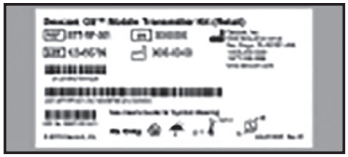


What it is		What it does
1	Plunger	Inserts Sensor wire into your body.
2	Applicator Barrel	Contains small Insertion Needle and Sensor wire. Disposable, for single use only.
3	Transmitter Latch	Locks Transmitter into Sensor Pod.
4	Release Tab	Allows you to remove Applicator Barrel from Sensor Pod.
5	Safety Lock	Prevents Plunger from inserting Sensor until you are ready.
6	Collar	Removes Insertion Needle. Helps remove Applicator Barrel once Sensor wire is inserted.
7	Sensor Pod	Holds Sensor wire in place under skin. Holds Transmitter.
8	Adhesive Patch	Adhesive Patch Holds the Sensor/Transmitter in place on your skin.

Review the Transmitter Box

The Transmitter Box contains the Transmitter. On the bottom of the Box is important label information. Keep the Box until the Transmitter battery dies and you have to replace the Transmitter.

Reusable Transmitter*



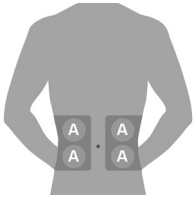
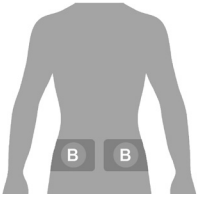
Label on bottom of box

**The Transmitter in your Box may look different than this picture.*

Choose and Prepare the Insertion site

Choose a place on your belly (or the upper buttocks if you are between the ages of 2 and 17) to insert the Sensor. The site should be either above or below your belt line. The best areas are usually flat, "pinchable", and free from where rubbing can occur (such as along the waist band, seat belt strap or where you lay when sleeping.) For more help on Sensor insertion sites, consult with your HCP.

Insertion Sites

Where they are		Who can use these sites
	Front of body (belly area)	Ages 2 and above
	Back of body (upper buttocks)	Ages 2 to 17

Optional Skin Adhesive Site Preparation

Use optional skin adhesives (for example, Mastisol™ or Skin Tac™) as part of your insertion site preparation to help keep your Sensor Pod attached. Apply the skin adhesive after you selected and cleaned your insertion site. Use circular motions and create an oval, making sure you do not get any skin adhesive in the middle. Let the oval dry based on the adhesive manufacturer's instructions. Once dry,your skin may feel slightly sticky. See *step 1c* that follows for instructions.

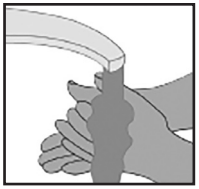
NOTE: Contact your HCP for specific questions regarding the use of medical tape, barrier wipes and/or other adhesives as it relates to your use of the Dexcom G5® Sensor and Transmitter.

Insert the Sensor

You have collected and reviewed all of the items needed to begin a Sensor session, and prepared the Sensor site. You are now ready to insert your Sensor.

1. Prepare the site, Sensor and Applicator

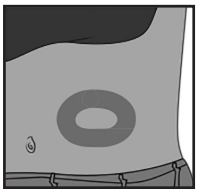
a. Wash and dry your hands.



b. Clean insertion site with alcohol wipe.

Let dry.

c. *Optional step* for applying skin adhesive to insertion site.



Create an oval on the skin

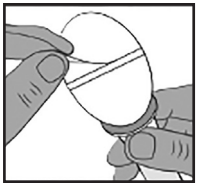
- **DO NOT** get any skin adhesive inside the circle.
- Let skin adhesive dry.
- Sensor should be inserted on clean skin at the center of the circle.

d. Remove Sensor and Applicator from Pouch and check for damage.

If the Pouch is damaged or already open, or the Sensor or Applicator are damaged, **DO NOT** use. Keep Sensor Pouch until Sensor session is complete.

2. Attach Sensor Pod

a. Pull adhesive backing tabs.



DO NOT touch sticky adhesive patch.

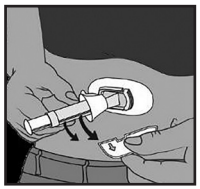
b. Place Sensor horizontally (not vertically) on skin.

Move fingers around the top of the adhesive patch several times to secure tape.

3. Insert Sensor wire

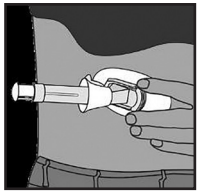
a. Hold Applicator Barrel.

Pull Safety Lock out.



b. Place fingers of one hand on the edges of the adhesive patch.

Pinch up your skin at the tips of the white adhesive.



c. Place two fingers directly above the Collar and your thumb on the white Plunger, and push the Plunger completely down the Applicator Barrel.

You should hear 2 clicks.

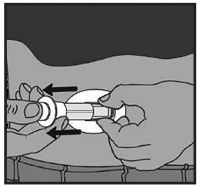
NOTE: Finger placement is important for correct insertion

4. Remove Applicator Barrel and Collar

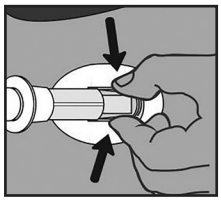
a. Keeping your thumb on the Plunger, move your two fingers from above to below the collar, and pull the Collar all the way back towards your thumb.

You should hear 2 clicks.

NOTE: Finger placement is important for correct Needle removal.

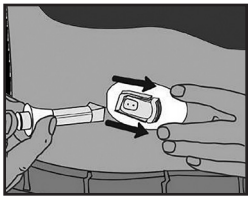


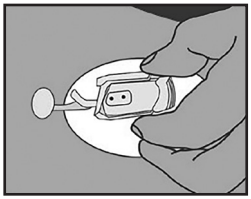
b. Hold the Transmitter Latch down against your body, and squeeze the ribbed release tabs on the sides of the Sensor Pod.



c. Move Applicator Barrel forward and out, away from your body.

The Sensor Pod and Transmitter Latch remain attached to your body.





NOTE: Follow local regulations for Applicator disposal.

If this is the first time inserting a Sensor, you may have questions or need help. If you do, consult with your HCP or contact Customer Service.

Attach the Transmitter

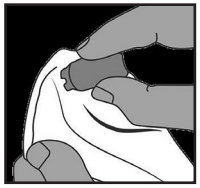
Now that you have inserted your Sensor, you need to attach your Transmitter. Since the Transmitter is reusable, you do not need a new one every time you start a Sensor session. Keep the Transmitter Box from your current Sensor session. The bottom label has important information you may need after you have inserted the Transmitter. Before inserting your Transmitter, check that you have entered the correct Transmitter ID into your pump. Once the Transmitter has been attached, if you remove it, it will stop the current CGM session.

1. Remove the Transmitter from the Transmitter Box.

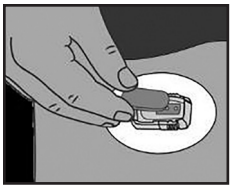
Save Box and Safety Lock from Sensor Applicator (this helps remove Transmitter once Sensor session is over).

a. Wipe the back of the Transmitter with an alcohol wipe and let dry for 2-3 minutes.

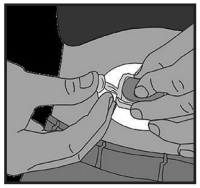
- **DO NOT** let the back of the Transmitter touch your skin.
- **DO NOT** scratch the back of the Transmitter as this can harm the waterproof seal.
- **DO NOT** touch the metal dots on the bottom of the Transmitter.



b. With the flat side of the Transmitter facing down toward the Sensor Pod, slide the smaller end of the Transmitter under the Sensor Pod lip located in front of the Pod's ribbed tabs, away from the Transmitter Latch.

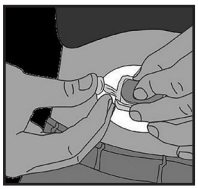


c. With one hand holding the Transmitter in place, use your other hand to push the Transmitter Latch up and forward over the wide end of the Transmitter.



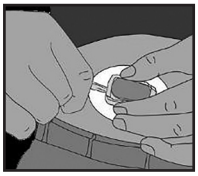
d. Verify the Transmitter is securely in place before removing the Transmitter Latch.

Make sure none of the sides of the Transmitter popped out of the Sensor Pod. If the Transmitter is not completely snapped in, you might have a bad connection, and it will not be watertight.



e. Holding the sides of the Sensor Pod with one hand, use your other hand to twist the Transmitter Latch away from your body so that it completely detaches.

DO NOT remove the Transmitter while the Sensor Pod is attached to your skin.



Loose Sensor Pod

The Sensor Pod should stay on your skin using its own adhesive. If the patch peels up, use medical tape (such as Blenderm™, Tegaderm™, Smith & Nephew IV3000®, 3M™ tape) for extra support.

- Tape over the white adhesive patch on all sides for even support.
- **DO NOT** tape over the Transmitter or any plastic parts of the Sensor Pod.
- **DO NOT** tape under the Sensor Pod.
- **DO NOT** leave any substance on the skin where you insert the Sensor.

The Right Way to Use Tape for Extra Support

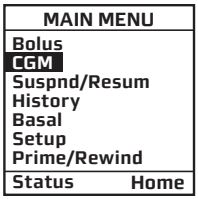
The Sensor/Transmitter and Water

The Sensor is water resistant when showering, bathing or swimming if the Transmitter is fully snapped in. The Sensor has been tested to be water resistant when submerged up to 8 feet for a maximum of 24 hours.

2-Hour CGM Startup Period

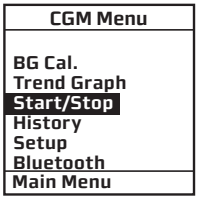
Once your Sensor is inserted, your Transmitter is attached, and your Transmitter ID is entered into your pump and Bluetooth is turned on, you are ready to begin a CGM session. Each CGM session will last up to 7 days (166 hours after the 2-hour startup period), after which you will need to replace the Sensor and start a new CGM session. During the 2-hour startup period, your CGM will make adjustments so that it adapts to your body's biological environment.

1. From the MAIN MENU, scroll to "CGM" and press OK. The CGM Menu appears.



2. Scroll to "Start/Stop" and press OK. The Start/Join CGM screen appears.

NOTE: If your pump is currently in a CGM session and "Start/Stop" is selected, you will go to the CGM Stop Session screen. See later section *Ending a CGM Session Before the 7-Day Expiration Time*.

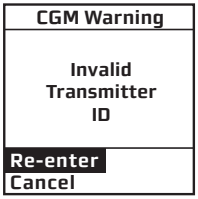


3. To begin the 2-hour startup period, select “GO” on the Start/Join screen. When you select “GO”, a series of CGM Warning screens will appear. These screens will appear every time you begin a new 2-hour CGM startup period. If you need to cancel the start of the CGM session, scroll to “CANCEL” and press OK to return to the CGM Menu.

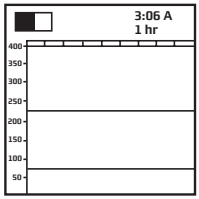
A warning screen will remind you to always use fingerstick BG values to make treatment decisions. With “Confirm” highlighted, press OK to continue.

NOTE: You must confirm this CGM Warning screen to calibrate the CGM at the end of the 2-hour startup period.

NOTE: A CGM Warning screen will appear if you start a CGM session and have left the Transmitter ID as the default “000000”. Press OK to re-enter the correct Transmitter ID.



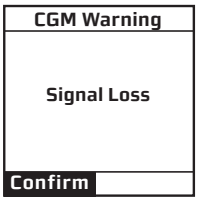
Once you start a CGM session, initially ANT will appear until the pump and Transmitter are paired and a secure communication link has been established. Once paired the display will provide a shaded box both on the CGM home screen and CGM Trend screen that provides status of the warm-up session. The shaded area of the box will gradually diminish over the 2 hour startup period.



Keep your pump within 12 feet of your Sensor/Transmitter during the 2-hour startup period for best communication. You can check that your devices are communicating by pressing the contrast button/CGM shortcut on your pump while the pump is in sleep mode to display one of the CGM Information screens (see *Chapter 6 Section II*). If your pump is locked, you will be required to unlock the pump after pressing the button to view one of the CGM trend graphs or CGM data screen.

If the ANT symbol appears on the CGM Data or Trend screen and/or if your pump displays the Signal Loss Warning screen, then your devices are not communicating. Press OK to confirm the Signal Loss warning if present. See next page for troubleshooting.

To troubleshoot CGM communication:



- Check that your pump and the Sensor/Transmitter are within 12 feet of each other. If not, move them closer. Wait about 5-10 minutes to see if the **shaded box** appears on the CGM Data or Trend screen (ANT will disappear).
- The pump and Sensor/Transmitter may lose communication when they are near other metallic objects, or while you are in a pool or bathtub, lying on a waterbed or using an electric blanket.
- If the Warning screen appears again, verify that you have entered the correct Transmitter ID into your pump.
- Refer to *Chapter 12* in *Section II* for troubleshooting problems with CGM communication.
- Check on pump Status Screen 6 that you entered the Transmitter ID correctly. If the correct ID has been entered, and the Warning screen continues to re-appear, contact Customer Service.

NOTE: After starting a new Sensor session, you will not receive Sensor glucose readings until your 2-hour startup period has ended, and you have completed your initial calibrations (see following page).

In order for your CGM to work properly, you will be prompted to calibrate your CGM with fingerstick BG test results at various times during a CGM session. More specifically, you will need to be prepared to take a fingerstick test(s) with your commercially-available BG meter, and enter the BG results into your pump within 5 minutes of being prompted. The purpose of calibration is to correlate Sensor readings to the reference BG meter to maintain Sensor performance.

These are the required times for calibration:

- Startup Calibration – two at the end of the 2-hour CGM startup period.
- Calibration Update – at least once every 12 hours during a CGM session.
- Recalibration – is required if one of the fingerstick BG values entered for Startup Calibration or Calibration Update is not accepted by the CGM, or if the CGM determines that it requires recalibration.

NOTE: You may see a few second delay in screen display immediately after entering a CGM calibration value. This is normal as the calibration value is processed.

⚠ **CONTRAINDICATION:** Taking medications containing acetaminophen while wearing the Sensor may inaccurately raise your Sensor glucose readings. The level of inaccuracy depends on the amount of acetaminophen active in your body and may be different for each person. **DO NOT** rely on Sensor glucose readings if you have recently taken acetaminophen.

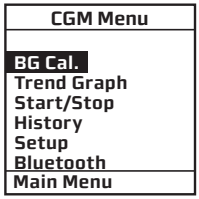
⚠ **WARNING:**

- **CALIBRATE** your Sensor with a BG value from a BG meter at least once every 12 hours. Periodic BG values from a BG meter adjust the Sensor so that it more accurately reflects your body's health status. The accuracy of your Sensor glucose readings may be compromised unless you calibrate at least once every 12 hours. Calibrating more than once every 12 hours is okay and will not affect the accuracy of your Sensor glucose readings.
- **DO NOT** use a BG value for CGM calibration unless it is from a fingerstick test taken with a BG meter within the last 5 minutes, and is within 40 to 400 mg/dL. Failure to follow these instructions can result in inaccurate Sensor glucose readings.
- When using your BG meter to obtain CGM calibration values, it is important to follow these instructions to ensure the accuracy of the BG values used for CGM calibration.
  - Always use a fingerstick test.
  - **DO NOT** use alternative sampling sites (e.g., palm or forearm).
  - Always use the same BG meter for all calibrations within a CGM session.
  - **DO NOT** switch your BG meter in the middle of a CGM session.
  - Follow your BG meter instructions for BG testing.
  - Follow proper BG testing techniques, such as washing your hands prior to doing a fingerstick, to ensure accurate calibration values and CGM performance.

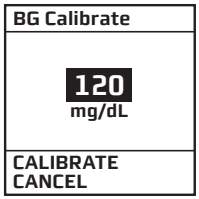
2-Hour CGM Startup Period Calibration

When the 2-hour CGM startup period ends, you will be prompted to enter 2 separate fingerstick BG values into your pump. Press OK to confirm the Warning.

1. Scroll to "BG Cal." on the CGM Menu screen and press OK.



2. The "BG value" field will be highlighted and flashing on the BG Calibrate screen. Use the ▲/▼ buttons to enter the first of 2 fingerstick BG values. Press OK. "CANCEL" will be highlighted. Scroll to "CALIBRATE" and press OK. If you need to cancel the BG value, scroll to "CANCEL" and press OK. In either case, you will return to the CGM Menu.



NOTE: The default value on the BG Calibrate screen is 120 mg/dL the first time you calibrate.

3. Repeat step 2 to enter the second, new BG value. The second BG value must be from a new fingerstick test from a BG meter. **DO NOT** re-enter the first BG value again as this may impact the accuracy of your Sensor glucose readings. If you do not enter the second BG value within a few minutes, you will see a second CGM Warning screen.

NOTE: Suspending insulin delivery during the 2-hour CGM Startup period will not affect the initial calibration sequence, and the CGM session will remain active.

12-hour CGM Calibration Update

Your CGM requires that you perform a calibration update at least once every 12 hours with a fingerstick BG value that you enter into the pump. Calibration updates are necessary to make sure Sensor readings remain accurate. Follow the steps under the preceding section *2-Hour CGM Startup Period Calibration* for entering a BG value at any time. Any fingerstick BG value you may have entered in your pump during ezCarb and ezBG Bolus calculations may serve as a BG value for the calibration update (see *Chapter 10* in *Section I*). **You only need to enter 1 fingerstick BG value for each 12-hour CGM calibration update. Unless the CGM determines that it requires recalibration.**

If you forget to enter a BG value during each 12-hour period, you will be prompted to enter one. Press OK to confirm the Warning and follow the steps for entering a BG value. The CGM Warning screen will re-appear until you enter a new BG fingerstick value that is accepted for calibration.

CGM Recalibration

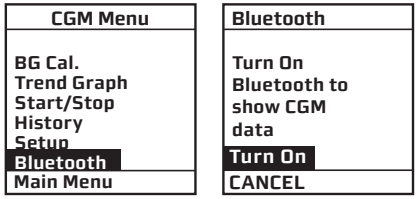
When you enter a fingerstick BG value for calibration update, the CGM checks how well it is functioning compared to BG meter results. During each calibration update, you may be prompted for another fingerstick BG value. You may also be prompted for another fingerstick BG value during the 2-hour startup period, or at any other time that the CGM determines that it needs recalibration.

When prompted, press OK to confirm the Warning and follow the steps for entering a BG value. You will continue to be reminded to enter a valid BG value until the BG value is accepted for recalibration. BG will appear on the CGM Data and CGM Trend screens in place of your current CGM Sensor reading until the BG value is accepted. You may also choose to end the CGM session (see *Chapter 8* in *Section II*) after repeated unsuccessful attempts at recalibration.

DO NOT enter a BG value for CGM calibration if you see the ANT or ??? on the CGM Data or CGM Trend screens on your pump (see *Chapter 6* in *Section II*). This means the pump and Transmitter/ Sensor are not communicating. Your BG value will not be accepted if either of these symbols appear. Refer to *Chapter 12* in *Section II* for troubleshooting problems with CGM calibration. Any BG value you enter when using the ezBG or ezCarb feature on your pump can be used for CGM calibration update/ recalibration. When prompted to choose if you want the BG value used for CGM calibration, select "Yes" and press OK.

Bluetooth On/Off

There may be occasions where you have an active CGM session and want to temporarily disconnect from the session without stopping the session. You can continue your active CGM session and disconnect without stopping the session by turning Bluetooth off from your CGM menu screen. To re-establish communications with your Transmitter simply turn your Bluetooth on and rejoin the session from the CGM Start/Join screen. Within 5-minutes a new CGM Sensor reading will be provided.



NOTE: The Bluetooth symbol only appears on the home screen when Bluetooth is On. Bluetooth must be on to calibrate your CGM for all CGM-related operations.

During an active session, CGM Sensor readings will be sent from your Transmitter to your pump every 5 minutes. You may use your pump to view and analyze CGM data using the CGM Data and CGM Trend screens. CGM Sensor readings between 40 and 400 mg/dL will be displayed as the actual value on CGM Data and CGM Trend screens. CGM Sensor readings above 400 mg/dL will display as HIGH, and CGM Sensor readings below 40 mg/dL will display as LOW, on CGM Data and CGM Trend screens.

The screens provide important information about your current and previous CGM Sensor readings, whether your CGM Sensor readings fall above or below High and Low (Glucose) Alert levels, and whether your CGM Sensor readings may be rising or falling too fast. It is important that you focus on the CGM trends and rate change on your pump, rather than a single CGM Sensor reading. See *Chapter 2* in *Section II* for CGM settings that impact how information is displayed on the CGM Data and CGM Trend screens.

⚠ **WARNING:**

- **DO NOT** use glucose readings from the Dexcom G5® Sensor and Transmitter to make treatment decisions, such as how much insulin you should take. The Sensor and Transmitter do not replace a BG meter and BG values may differ from Sensor glucose readings. The BG value from your BG meter should be used for treatment decisions. Using glucose readings from the Sensor and Transmitter to make treatment decisions can result in serious injury or death. The direction, speed that glucose is changing, and trend graph from your Sensor and Transmitter and displayed on your pump provide additional information to help with your diabetes management decisions.
- **DO NOT** ignore symptoms of high and low BG levels, even if your Sensor glucose readings indicate you are in control. If your Sensor glucose readings do not fit with your symptoms, you should always measure your BG level with a BG meter. Relying on Sensor glucose readings to treat symptoms may lead to inappropriate treatment decisions and result in serious injury or death.

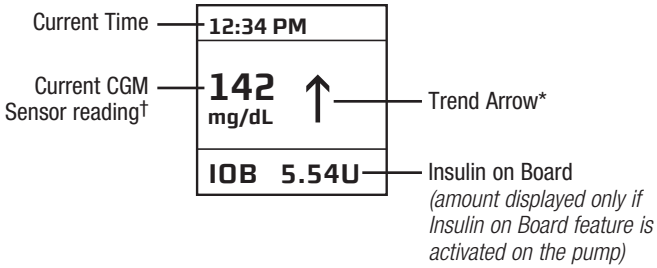
⚠ **CAUTION:** While insulin delivery is suspended, your CGM session will remain active, but CGM Sensor readings will not be recorded or displayed. As soon as insulin delivery resumes, CGM Sensor readings will start recording and displaying again. If you want to temporarily suspend insulin delivery but still view CGM Sensor readings, **DO NOT** use the suspend delivery feature. Instead, you can set pump Basal to OFF or use Temp Basal with a negative adjustment for the time period you want basal delivery suspended.

CGM Data Screen

The CGM Data screen provides a snapshot of your current CGM Sensor readings. Each CGM Data screen displays the current time on your pump, your current CGM Sensor reading, any Insulin on Board (indicated by "IOB" on the screen), and Trend Arrows that represent how fast your CGM Sensor readings may be rising or falling.

See the charts on the following pages for the meaning of the various symbols that might appear on the CGM Data screen.

Example CGM Data Screen



When the pump is in sleep mode, pressing the Contrast button/CGM shortcut will awaken the pump to the CGM Data or Trend screen last displayed when the pump went to sleep. If your pump is locked, you will be required to unlock the pump after pressing the button to view one of the CGM trend graphs or CGM data screen.

** Trend Arrows (on CGM Data and CGM Trend screens) and CGM data points (readings) on the CGM Trend screen are color coded. An explanation of the Trend Arrows and the color coding appears on the following pages.*

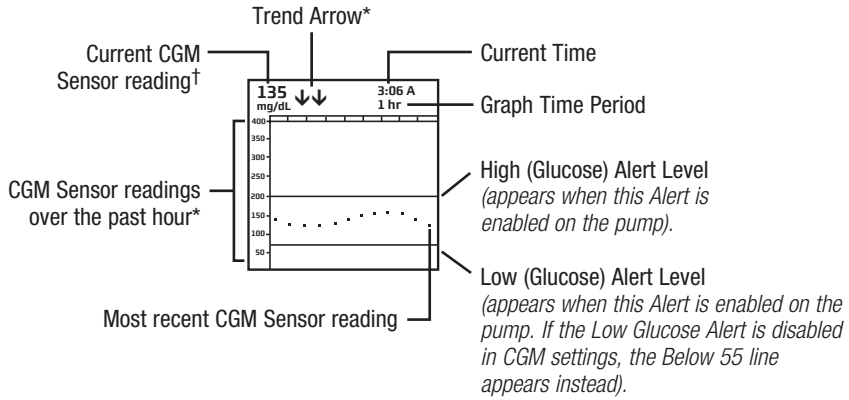
† A symbol may appear in place of your current CGM Sensor reading on CGM Data and CGM Trend screens. An explanation of these symbols appears on the following pages.

CGM Trend Screen

The CGM Trend screen provides a more detailed view of your glucose status, and includes a graphical display of your CGM Sensor readings over a time period you select (1, 3, 6, 12, or 24 hours). Each CGM Trend screen also includes the current time on your pump, your most recent CGM Sensor reading, High (Glucose) and Low (Glucose) Alert settings, and Trend Arrows that represent how fast your CGM Sensor readings may be rising or falling.

See the charts on the following pages for the meaning of the various symbols that might appear on the CGM Trend screen. During an active CGM session, you can access the CGM Trend screen by pressing the Contrast button/CGM shortcut to wake up the pump. If your pump is locked, you will be required to unlock the pump after pressing the button to view one of the CGM trend screens.

Example
CGM Trend Screen



When the pump is in sleep mode, pressing the Contrast button/CGM shortcut will awaken the pump to the CGM Data or Trend screen last displayed when the pump went to sleep.

** Trend Arrows (on CGM Data and CGM Trend screens) and CGM data points (readings) on the CGM Trend screen are color coded. An explanation of the Trend Arrows and the color coding appears on the following pages.*

† A symbol may appear in place of your current CGM Sensor reading on CGM Data and CGM Trend screens. An explanation of these symbols appears on the following pages.

CGM Data and CGM Trend Screen Arrows and Color Key

NOTE: The color key applies to the Trend Arrows on the CGM Data and CGM Trend screens, and CGM data points (readings) on the CGM Trend screens.

Trend Arrows

These arrows indicate whether your CGM Sensor readings is rising or falling and at what rate.

Symbol	Condition
↑↑	**Rapidly rising:** Your CGM glucose readings are rising more than 3 mg/dL each minute.
↑	**Rising:** Your CGM glucose readings are rising 2 – 3 mg/dL each minute.
↗	**Slowly rising:** Your CGM glucose readings are rising 1 – 2 mg/dL each minute.
→	**Constant:** Your CGM glucose readings are steady (not increasing/decreasing more than 1 mg/dL each minute).
↘	**Slowly falling:** Your CGM glucose readings are falling 1 – 2 mg/dL each minute.
↓	**Falling:** Your CGM glucose readings are falling 2 – 3 mg/dL each minute.
↓↓	**Rapidly falling:** Your CGM glucose readings are falling more than 3 mg/dL each minute.
No arrow(s)	**No Rate Change Information:** The CGM cannot always calculate how fast your CGM glucose readings are rising or falling.

NOTE:

- Trend Arrows do not appear when CGM Sensor readings are "missing" on the CGM Data and CGM Trend screens (see *Missing CGM Sensor readings* in this chapter).
- Always review Trend Arrow information with the other information on CGM Trend screen graphs so you have a more complete picture of how your CGM Sensor readings are trending.

⚠ **WARNING: DO NOT** use glucose readings from the Dexcom G5® Sensor and Transmitter to make treatment decisions, such as how much insulin you should take. The Sensor and Transmitter do not replace a BG meter and BG values may differ from Sensor glucose readings. Using glucose readings from the Sensor and Transmitter to make treatment decisions can result in serious injury or death.

Color Key
Red arrows (or red CGM data points on the CGM Trend screens) indicate your most recent CGM Sensor reading was at or above the High (Glucose) Alert level you set in your pump.
Green arrows (or green CGM data points on the CGM Trend screens) indicate your most recent CGM Sensor reading was between the High and Low (Glucose) Alert levels you set in your pump.
Blue arrows (or blue CGM data points on the CGM Trend screens) indicate your most recent CGM Sensor reading was at or below the Low (Glucose) Alert level you set in your pump.

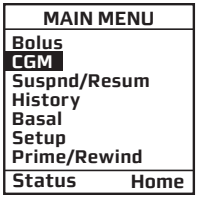
Symbols That Might Appear in Place of your Current CGM Sensor reading

These symbols may appear in place of your current CGM Sensor reading on the CGM Data and CGM Trend screens.

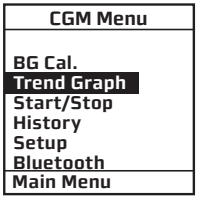
Symbol	Condition
	There is no active CGM session.
	A Sensor was inserted within the last 30 minutes. No CGM Sensor readings are available.
	A Sensor was inserted between 30 and 60 minutes ago. No CGM Sensor readings are available.
	A Sensor was inserted between 60 and 90 minutes ago. No CGM Sensor readings are available.
	A Sensor was inserted between 90 and 120 minutes ago. No CGM Sensor readings are available.
	Fingerstick BG values needed for calibration.
	The CGM Sensor reading cannot be displayed at this time.
	There was no communication between the pump and Transmitter within the last 5 minutes.
	Most recent CGM Sensor reading was higher than 400 mg/dL.
	Most recent CGM Sensor reading was lower than 40 mg/dL.
	Bluetooth is turned OFF.

Accessing the CGM Data and CGM Trend screens from the CGM Menu

1. From the MAIN MENU, scroll to "CGM" and press OK. The CGM Menu will appear.

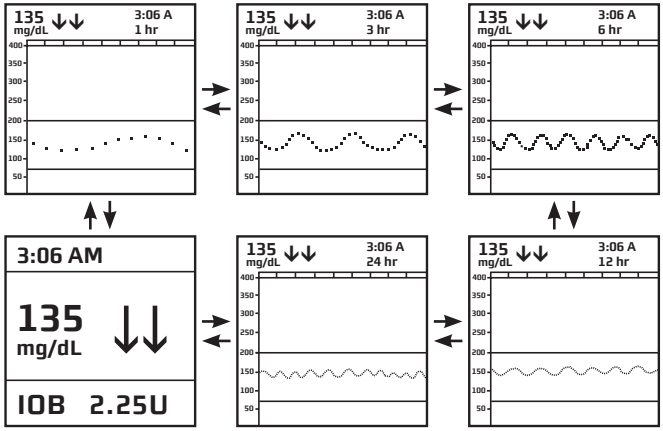


2. Scroll to "Trend Graph" and press OK. The last CGM Trend or Data screen (if you have just awakened the pump) will be displayed.



3. Use the ▲/▼ buttons to scroll through the 1-hr, 3-hr, 6-hr, 12-hr, and 24-hr CGM Trend screens, and then the CGM Data screen.

CGM Sensor readings (data points) on CGM Trend screens track from right (most recent) to left (oldest) for the time period covered. The CGM Trend screens show you where your CGM Sensor readings have been and where your CGM Sensor readings are headed. To return to the CGM Menu, press OK while viewing the CGM Data screen or any CGM Trend screen.



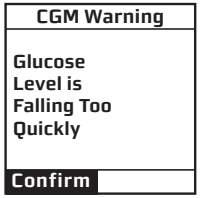
CGM High/Low and Rise/Fall Rate Alerts

The High and Low (Glucose) Alerts let you know when your CGM Sensor readings fall outside the levels you set in the pump. The Rise and Fall Rate Alerts let you know when your CGM Sensor readings are rising or falling faster than the limits you set in the pump. You have the option to enable or disable these alerts, and customize the levels/limits based on your HCP's recommendations (see *Chapter 2* in *Section II*). In addition to the information on CGM Data and CGM Trend screens, these alerts are another way of letting you know when your CGM Sensor readings may be getting dangerously high or low.

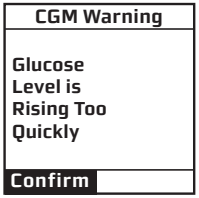
⚠ WARNING:

- **DO NOT** use glucose readings from the Dexcom G5® Sensor and Transmitter to make treatment decisions, such as how much insulin you should take. The Sensor and Transmitter do not replace a BG meter and BG values may differ from Sensor glucose readings. The BG value from your BG meter should be used for treatment decisions. Using glucose readings from the Sensor and Transmitter to make treatment decisions can result in serious injury or death. The direction, speed that glucose is changing, and trend graph from your Sensor and Transmitter and displayed on your pump provide additional information to help with your diabetes management decisions.
- **DO NOT** ignore symptoms of high and low BG levels, even if your Sensor glucose readings indicate you are in control. If your Sensor glucose readings do not fit with your symptoms, you should always measure your BG level with a BG meter. Relying on Sensor glucose readings to treat symptoms may lead to inappropriate treatment decisions and result in serious injury or death.

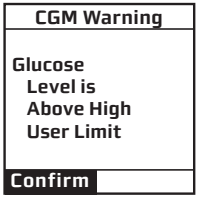
NOTE: The CGM Alerts discussed here are separate from the LOW BG and HIGH BG Alerts that display/sound on your pump when you enter a BG value below 70 mg/dL or above 250 mg/dL.



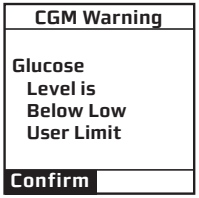
Fall Rate Alert



Rise Rate Alert



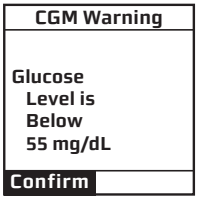
High (Glucose) Alert



Low (Glucose) Alert

In these 4 instances, insulin deliveries and your CGM session will continue. Press OK to continue but be prepared to treat High or Low BG according to your HCP's recommendations.

An additional CGM Alarm will display/sound on your pump when your most recent CGM Sensor reading is at or below 55 mg/dL. This Alarm limit is fixed, and cannot be changed or disabled. You will be re-alerted every 30 minutes if your current CGM Sensor reading remains at or below 55 mg/dL.



Refer to *Chapter 10* in *Section II* for additional information about CGM Warnings that display/sound on your pump.

Missing CGM Sensor readings

Periodically you may notice you are “missing” CGM Sensor readings on the CGM Data and CGM Trend screens. “Missing” means one or more CGM Sensor readings have not been received or were not understood by your pump, and are not available for display. You can identify “missing” data by a symbol appearing instead of your most recent CGM Sensor reading and trend arrow(s), or that there are gaps (no data) when displaying CGM Trend graphs.

This can happen when:

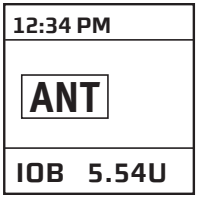
- Your pump and Sensor/Transmitter are not communicating.
- Your pump does not recognize the Sensor/Transmitter signal.
- Your pump is waiting for you to enter a fingerstick BG value to recalibrate the CGM.
- The CGM Sensor reading cannot be displayed.

⚠ WARNING:

- **DO NOT** use glucose readings from the Dexcom G5® Sensor and Transmitter to make treatment decisions, such as how much insulin you should take. The Sensor and Transmitter do not replace a BG meter and BG values may differ from Sensor glucose readings. The BG value from your BG meter should be used for treatment decisions. Using glucose readings from the Sensor and Transmitter to make treatment decisions can result in serious injury or death. The direction, speed that glucose is changing, and trend graph from your Sensor and Transmitter and displayed on your pump provide additional information to help with your diabetes management decisions.
- **DO NOT** ignore symptoms of high and low BG levels, even if your Sensor glucose readings indicate you are in control. If your Sensor glucose readings do not fit with your symptoms, you should always measure your BG level with a BG meter. Relying on Sensor glucose readings to treat symptoms may lead to inappropriate treatment decisions and result in serious injury or death.

Missing CGM Sensor readings – ANT symbol appears in place of current CGM Sensor reading

When the ANT symbol appears on either the CGM Data or CGM Trend screens, your pump did not receive the last CGM Sensor reading from your Sensor/Transmitter. This is most likely due to your pump and Sensor/Transmitter not being in range.

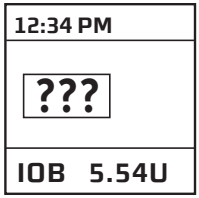


Try moving your pump and Sensor/Transmitter closer to each other and wait at least 10 minutes for the next CGM Sensor reading to be received. Also verify on pump Status Screen 6 that the correct Transmitter ID has been entered into the pump. Your pump and Sensor/Transmitter may lose communication when you are in a pool or bathtub, lying on a waterbed, using a electric blanket, or have other metallic objects nearby. If the ANT symbol remains on the display, there is still a problem with your pump receiving CGM Sensor readings. Contact Customer Service for assistance.

NOTE: When you see ANT instead of a CGM Sensor reading, taking additional fingerstick BG tests and entering the values into your pump will not result in further CGM Sensor readings appearing on the display. Any fingerstick BG values entered into your pump while the ANT is displayed will be ignored.

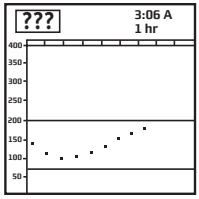
Missing CGM Sensor readings – [???] appears in place of current CGM Sensor reading

Any time you see the [???] symbol on either the CGM Data or CGM Trend screens, your pump did not understand a CGM Sensor reading that it received from your Sensor/Transmitter.



Check that your Sensor is still sticking well to your skin and that nothing else is rubbing against the Sensor Pod, such as seat belts. Check that the Transmitter is snapped in on both sides of the Sensor Pod.

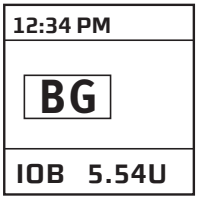
Contact Customer Service for assistance if [???] continues to appear for more than an hour. When you see [???] instead of a CGM Sensor reading, taking additional fingerstick BG tests and entering the values into your pump will not result in further CGM Sensor readings appearing on the display. Any fingerstick BG values entered into your pump while the [???] is displayed will be ignored.



The [???] problem will usually resolve by itself within a short period of time and your CGM session will continue to provide CGM Sensor readings. Other problems may be serious enough to result in a Sensor failure, and your CGM session will terminate. Your pump will notify you on the display if that happens. **Your pump will continue to deliver insulin if there is a Sensor failure**. After pressing OK to confirm the Warning, contact Customer Service for assistance.

Missing CGM Sensor readings – BG appears in place of current CGM Sensor reading

Any time you see the BG symbol on either the CGM Data or CGM Trend screens, your pump requires that you enter a fingerstick BG value for a calibration update or recalibration. This is because the Sensor needs to recalibrate based on your current BG level.



A CGM Warning screen will also appear to remind you to enter a fingerstick BG value.

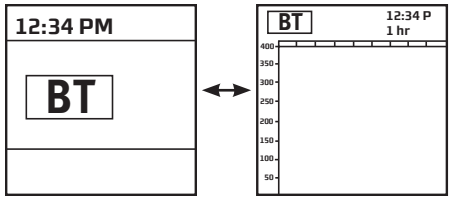
Follow the steps for entering a fingerstick BG value (see *Chapter 5* in *Section II*). After entering a fingerstick BG value, a CGM Sensor reading should immediately appear on the display, and CGM Sensor readings should resume being updated every 5 minutes. If a CGM Sensor reading does not immediately appear, follow any display prompts and refer to *Chapter 10* in *Section II* to troubleshoot any warnings, alarms, or alerts.

The BG symbol will remain on CGM Data and CGM Trend screens until the calibration update/ recalibration was successful. Your pump will then begin/resume displaying CGM Sensor readings.

Missing CGM Data

Any time you see a BT symbol on either the CGM Data or CGM Trend screens, it is because the pump's Bluetooth is turned OFF. CGM data are not available when Bluetooth is turned OFF.

Follow the steps (See *Chapter 5* in *Bluetooth ON/OFF Section*) to turn on the Bluetooth to view active CGM data.



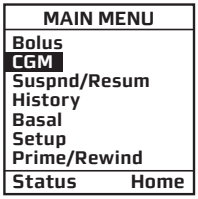
You can review certain historical CGM records on your pump. Or you can use compatible diabetes management software to track, review and analyze pump CGM history on your computer.

CGM Session Start History

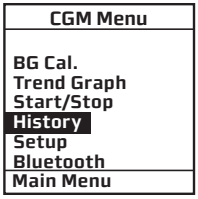
This selection displays the start date and time of your current CGM session.

NOTE: CGM Session Start history is only available if a CGM session is currently active.

1. From the MAIN MENU, scroll to "CGM" and press OK. The CGM Menu appears.

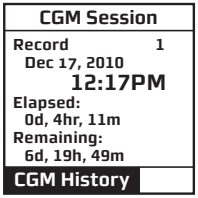


2. Scroll to "History" and press OK.



3. With "Session Start" highlighted on the CGM History screen, press OK. The CGM History screen appears.

The start date and time of your current CGM session will appear on the display. Only your last (current) CGM Session Start record is available for viewing. To return to the CGM History screen, highlight “CGM History” on any Session Start record screen and press OK.



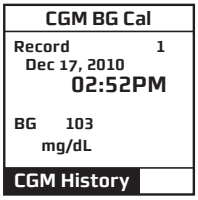
If there is no active CGM session, a CGM Warning screen will appear to remind you.

Last BG Calibration History

This selection displays the date, time and value of the last BG calibration entered in your pump or other device.

1. From the CGM History screen, scroll to “Last BG Cal”. Press OK.

The BG value, date and time of your last BG calibration will appear on the display. Only your last (current) BG calibration record is available for viewing. To return to the CGM History screen, highlight “CGM History” on any BG Calibration record screen and press OK.

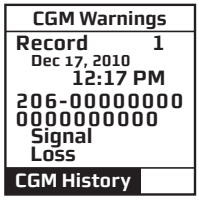


CGM Alert History

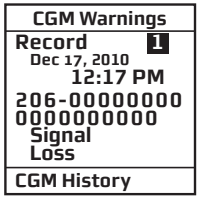
This selection displays the date, time, alert code and description of at least 300 of your last CGM alerts.

1. From the CGM History screen, scroll to "Warnings". Press OK.

The CGM Warnings screen will be displayed, and "CGM History" will be highlighted. The most recent CGM Alert record will be displayed, along with the date, time, code, and description of the alert. Prior CGM Alert will be kept until storage space is filled, then the oldest data will be overwritten and permanently lost as new data is recorded.



2. To go to other Alarm records, first scroll to the "Record" field at the top of the screen and press OK so that the highlight over the record number is flashing. Then use the ▲/▼ buttons to scroll to other CGM Alarm records.



To return to the CGM History screen, highlight "CGM History" on any Alert record screen and press OK.

Each CGM session may be worn up to 7 days (168 hours including a 2-hour startup period), after which you will need to replace the Sensor and start a new CGM session. You can also choose to end the CGM session early, or the CGM session might end earlier than the 7 days due to a Sensor failure.

Sensor Expiration

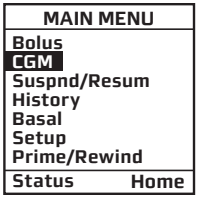
When you are within six hours of the expiration time, your pump will begin prompting you with a series of reminders that your session will be expiring shortly. You will be reminded with 6 hours remaining, 2 hours remaining, and 30 minutes remaining. Press OK to confirm the Warning at any of the reminder times.

During this time your pump will continue to receive CGM Sensor readings. Once the final 30 minutes ends, you will be prompted that your CGM session has ended. Press OK to confirm the CGM Warning and return to the CGM Menu. You will no longer receive CGM Sensor readings on your pump until you replace the Sensor, begin a new CGM session, and complete the 2-hour startup period (see *Chapter 4* in *Section II*).

Ending a CGM Session Before the 7-Day Expiration Time

At any point during the CGM session, you may also choose to end the session before its intended expiration time.

1. From the MAIN MENU, scroll to "CGM" and press OK. The CGM Menu appears.



2. Scroll to "Start/Stop" and press OK.

3. With "STOP" highlighted on the Stop CGM screen, press OK.

You will be notified on your pump display that you have stopped the CGM session. After a few seconds, you will return to the CGM Menu screen.

Early Sensor Expiration

In some cases, the CGM session may end before you have completed a full 7-day period. See *Chapter 10* in *Section II* for more information on the Sensor Failure Warnings that may be displayed on your pump.

⚠ WARNING:

- **DO NOT** use a broken Sensor or attempt to remove the broken Sensor if no portion of it is visible above the skin. Sensors can fracture on rare occasions. You may not be able to obtain glucose readings from a broken Sensor or the readings may be inaccurate. Consult your HCP about removing it, especially if you have symptoms of infection or inflammation (redness, swelling or pain) at the insertion site. Report the broken Sensor to Customer Service.
- For patients undergoing an MRI with a retained wire broken off from a Sensor, in-vitro MRI testing did not detect any safety hazards. There was no significant migration or heating of the wire and imaging artifacts were limited to the area around the wire.
- The pump and any type of metallic infusion set must be removed prior to an MRI, and left outside the room during the procedure.

At the end of every CGM session, you will need to remove your Transmitter and Sensor.

⚠ WARNING:

- **DO NOT** use a broken Sensor or attempt to remove the broken Sensor if no portion of it is visible above the skin. Sensors can fracture on rare occasions. You may not be able to obtain glucose readings from a broken Sensor or the readings may be inaccurate. Consult your HCP about removing it, especially if you have symptoms of infection or inflammation (redness, swelling or pain) at the insertion site. Report the broken Sensor to Customer Service.
- For patients undergoing an MRI with a retained wire broken off from a Sensor, in-vitro MRI testing did not detect any safety hazards. There was no significant migration or heating of the wire and imaging artifacts were limited to the area around the wire.
- The pump and any type of metallic infusion set must be removed prior to an MRI, and left outside the room during the procedure.
- **DO NOT** use a Sensor beyond the intended 7-day wear period. Stopping a CGM session will not extend the Sensor life beyond the 7 days. Your Sensor session will end 7 days after you start a CGM session.
- **DO NOT** remove the Transmitter from the Sensor Pod while Sensor Pod is attached to your skin. This may cause the Sensor to break off under the skin. If you need to remove the Transmitter, you will need to remove the Sensor Pod with it.
- **DO NOT** dispose of your Transmitter. It is reusable. The same Transmitter is used for each Sensor session until you have reached the end of the Transmitter battery life.
- Consult your local waste management authorities for instructions to dispose of devices containing electronic waste (Transmitter) and blood contacting parts (Sensor and Applicator).

Removing the Sensor Pod and Transmitter

Removing the Sensor

Think of the Transmitter as being part of the Sensor Pod. **DO NOT** remove the Transmitter before removing the Sensor Pod from your body.

1. Gently peel the Sensor Pod adhesive patch from your skin.

The Sensor wire comes out with the Sensor Pod.

2. Remove the Transmitter from the Sensor Pod.

3. Discard the Sensor Pod and Sensor Applicator following your local waste management regulations for disposing items that come in contact with blood.

Removing the Transmitter from the Sensor Pod

Remember your Transmitter is reusable. With a battery life of 90 days, use the same Transmitter over a number of Sensor sessions. You will receive prompts as you near the end of its battery life.

When you take a Sensor off after the 7-day session, remember to take the Transmitter out of the Sensor and clean it before reusing it for the next Sensor session.

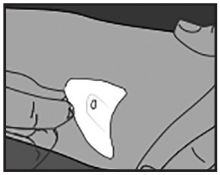
You can detach the Transmitter two ways:

1. Using the Safety Lock you removed from the Applicator Barrel at the beginning of the Sensor session.

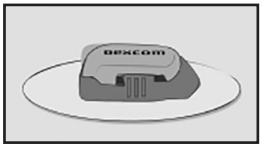
2. Without the Safety Lock by using the tabs holding the Transmitter in the Sensor Pod.

Method 1 - Transmitter removal using the Safety Lock

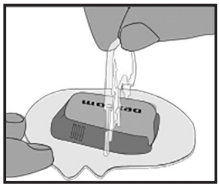
1. Grasp the end of the adhesive patch and peel it up and away from your body to remove the Sensor Pod and Transmitter.



2. Put the Sensor Pod on a flat surface.



3. Place the jagged edge of the Safety Lock over the wide edge of the Transmitter and in between the open slots on the sides of the Sensor Pod.



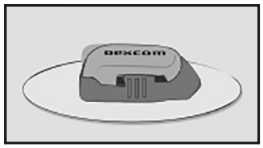
4. Lift the Safety Lock up.

Method 2 – Manually removing the Transmitter without the Safety Lock

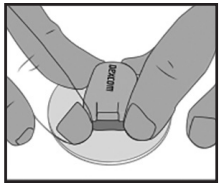
If you no longer have the Safety Lock, do not worry. You can use your fingers to remove the Transmitter from the old Sensor Pod.

1. Grasp the end of the adhesive patch and peel it up and away from your body to remove the Sensor Pod and Transmitter.

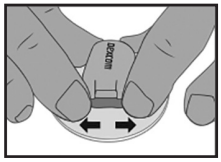
2. Put the Sensor Pod on a flat surface.



3. Grasp the wide end of the Sensor Pod with two hands and place fingers in the open slots on the sides.



4. Pull the tabs away from the Transmitter.



Your pump **DOES NOT** have the same "progressive" warnings and alarms safety system for CGM functions as it does for insulin delivery functions. Refer to *Chapter 11* in *Section I* for more information on the progressive warnings and alarms safety system for pump alarms not related to CGM functions.

This chapter reviews the warnings and alerts that appear and sound on your pump regarding CGM functions. See *Chapter 11* in *Section I* for information on warnings, alarms, and alerts associated with insulin delivery on your pump.

If multiple CGM alerts, warnings, or alarms occur simultaneously, the pump will display the most critical one first. After confirming the condition with the highest priority (the one currently displayed), the alert, alarm, or warning with the next highest priority will be displayed until confirmed. Each alert, alarm, and/or warning must be confirmed separately until all simultaneous conditions have been confirmed.

The CGM warnings and alerts that are described in this chapter apply only to the Dexcom G5® Sensor and Transmitter part of your OneTouch Vibe™ Plus System. They do not apply to any other Dexcom Sensor and Transmitter.

CGM Warning: Enter 2 Startup BGs	
Cause	No BG values have been entered in the pump following the 2-hour CGM startup session.
Effect	Insulin deliveries continue. CGM Sensor readings do not start.
Message	Displayed each time pump is awakened until confirmed, and action is taken.
Action	Press OK to confirm. You must enter 2 BG values for startup calibration. Take 2 fingerstick BG tests and enter values in pump. **DO NOT** enter a fingerstick BG value if ANT or ??? appear on the CGM Trend or Data screen, as it will not be accepted for calibration. See *Chapter 5* in *Section II* for more information.
Beeps/Vib	User selected (under CGM Setup Menu options), every 3 minutes until confirmed. If confirmed, snooze for 15 minutes. No progression.

CGM Warning: Session Failed to start	
Cause	Communication error between the pump and Transmitter.
Effect	Pump is not able to establish session with the Transmitter
Message	Displayed each time pump is awakened until confirmed or maximum are display exceeded.
Action	Press OK to confirm and try again to establish a session.
Beeps/Vib	User selected (under CGM Setup Menu options), every 3 minutes up to 3 time or until confirmed. No progression.

CGM Warning: Enter 1 more of 2 Startup BGs	
Cause	Only 1 of the 2 required BG values has been entered in the pump following the 2-hour CGM startup session.
Effect	Insulin deliveries continue. CGM Sensor readings do not start.
Message	Displayed each time pump is awakened until confirmed, and action is taken.
Action	Press OK to confirm. Take fingerstick BG test and enter value in pump. **DO NOT** enter a fingerstick BG value if ANT or ??? appear on the CGM Trend or Data screen.
Beeps/Vib	User selected (under CGM Setup Menu options), every 3 minutes until confirmed. If confirmed, snooze for 15 minutes. No progression.

CGM Warning: Enter BG	
Cause	No BG values have been entered in the pump in the last 12 hours.
Effect	Insulin deliveries continue. CGM continues.
Message	Displayed each time pump is awakened until confirmed, and action is taken.
Action	Press OK to confirm. Take fingerstick BG test and enter value in pump. **DO NOT** enter a fingerstick BG value if ANT or ??? appear on the CGM Trend or Data screen.
Beeps/Vib	Silent (no Beeps/Vib). If confirmed, snooze for 15 minutes. No progression.

CGM Warning: Enter BG	
Cause	The BG value entered has not been accepted for startup calibration or calibration update.
Effect	Insulin deliveries continue. CGM continues but with a possible CGM data gap.
Message	Displayed each time pump is awakened until confirmed, and action is taken.
Action	Press OK to confirm. Take another fingerstick BG test and enter value in pump. You will continue to be reminded to enter a valid BG value until the BG value is accepted for recalibration. **DO NOT** enter a fingerstick BG value if ANT or ??? appear on the CGM Trend or Data screen.
Beeps/Vib	User selected (under CGM Setup Menu options), every 3 minutes up to 3 times or until confirmed. No progression.

CGM Warning: Outlier Calibration request by Transmitter	
Cause	Sensor unable to calibrate now, user must wait 15 minutes from original warning.
Effect	Insulin deliveries continue. CGM continues.
Message	Displayed each time pump is awakened until confirmed, and action is taken.
Action	Press OK to confirm. After 15 minutes take fingerstick BG test and enter value in pump. **DO NOT** enter a fingerstick BG value if ANT or ??? appear on the CGM Trend or Data screen.
Beeps/Vib	Silent (no Beeps/Vib). If confirmed, snooze for 15 minutes. No progression.

CGM Warning: Calibration required by Transmitter	
Cause	System did not accept recent calibration, user must enter new calibration.
Effect	Insulin deliveries continue. CGM continues but with a possible CGM data gap.
Message	Displayed each time pump is awakened until confirmed, and action is taken.
Action	Press OK to confirm. Take fingerstick BG test and enter value in pump. **DO NOT** enter a fingerstick BG value if ANT or ??? appear on the CGM Trend or Data screen.
Beeps/Vib	User selected (under CGM Setup Menu options), every 3 minutes until confirmed. If confirmed, snooze for 15 minutes. No progression.

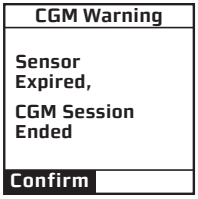
CGM Warning: Always use Fingerstick BG for Treatment Decisions and CGM Calibration	
Cause	Appears at start of every CGM session.
Effect	Insulin deliveries continue. CGM continues.
Message	Displayed each time pump is awakened until confirmed.
Action	Press OK to confirm. Never use a CGM Sensor reading to make treatment decisions or to calibrate the CGM. Take fingerstick BG test before adjusting insulin dose, eating, exercising, or making any other treatment decisions. Using CGM Sensor readings to make treatment decisions can result in under delivery or over delivery of insulin. Using CGM Sensor readings to calibrate the CGM can result in inaccurate CGM Sensor readings.
Beeps/Vib	User selected (under CGM Setup Menu options), one time. No progression.

CGM Warning: CGM Session Expires In 06:00	
Cause	Current CGM Session has 6 hours left until 7-day period ends.
Effect	Insulin deliveries continue. CGM continues.
Message	Displayed each time pump is awakened until confirmed. Each time the pump is awakened, the screen will display the actual time remaining rather than the original 6 hours displayed when the Warning first appeared.
Action	Press OK to confirm. Replace Sensor in 6 hours and start new CGM session.
Beeps/Vib	Silent (no Beeps/Vib), one time. No progression.

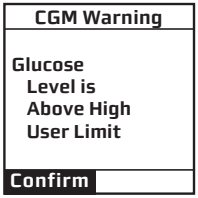
CGM Warning: CGM Session Expires In 02:00	
Cause	Current CGM Session has 2 hours left until 7-day period ends.
Effect	Insulin deliveries continue. CGM continues.
Message	Displayed each time pump is awakened until confirmed. Each time the pump is awakened, the screen will display the actual time remaining rather than the original 2 hours displayed when the Warning first appeared.
Action	Press OK to confirm. Replace Sensor in 2 hours and start new CGM session.
Beeps/Vib	Silent (no Beeps/Vib), one time. No progression.

CGM Warning: CGM Session Expires In 00:30	
Cause	Current CGM Session has 30 minutes left until 7-day period ends.
Effect	Insulin deliveries continue. CGM continues.
Message	Displayed each time pump is awakened until confirmed. Each time the pump is awakened, the screen will display the actual time remaining rather than the original 30 minutes displayed when the Warning first appeared.
Action	Press OK to confirm. Replace Sensor in 30 minutes and start new CGM session.
Beeps/Vib	User selected (under CGM Setup Menu options), every 3 minutes up to 3 times, or until confirmed. No progression.

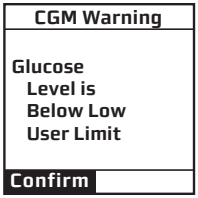
CGM Warning: Sensor Expired, CGM Session Ended	
Cause	Current CGM Session has expired.
Effect	Insulin deliveries continue. CGM session ends.
Message	Displayed each time pump is awakened until confirmed.
Action	Press OK to confirm. Replace Sensor and start new session.
Beeps/Vib	User selected (under CGM Setup Menu options), every 3 minutes up to 3 times, or until confirmed. No progression.



CGM Warning: Glucose Level is Above High User Limit	
Cause	Last CGM Sensor reading at or above limit set in pump.
Effect	Insulin deliveries continue. CGM continues.
Message	Displayed each time pump is awakened until confirmed.
Action	Press OK to confirm. Check BG with fingerstick test.
Beeps/Vib	User selected (under CGM Setup Menu options), every 3 minutes until confirmed. If confirmed, snooze for user selected snooze time. No progression.

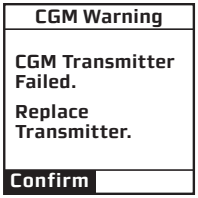


CGM Warning: Glucose Level is Below Low User Limit	
Cause	Last CGM Sensor reading at or below limit set in pump.
Effect	Insulin deliveries continue. CGM continues.
Message	Displayed each time pump is awakened until confirmed.
Action	Press OK to confirm. Check BG with fingerstick test.
Beeps/Vib	User selected (under CGM Setup Menu options), every 3 minutes until confirmed. If confirmed, snooze for user selected snooze time. No progression.

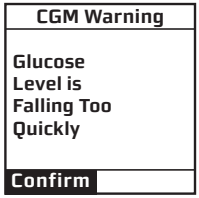


CGM Warning: CGM Transmitter Expired	
Cause	No Transmitter battery power to continue a new session.
Effect	Insulin deliveries continue. CGM session ends.
Message	Displayed each time pump is awakened until confirmed or maximum re display exceeded.
Action	Press OK to confirm. Replace Transmitter and start new session.
Beeps/Vib	User selected (under CGM Setup Menu options), every 3 minutes up to 3 time or until confirmed. No progression.

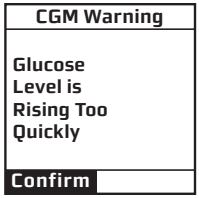
CGM Warning: CGM Transmitter Failed	
Cause	Transmitter error indicating that the Transmitter is not functioning properly.
Effect	Insulin deliveries continue. CGM session ends.
Message	Displayed each time pump is awakened until confirmed or maximum re display exceeded.
Action	Press OK to confirm. Replace Transmitter and start new session.
Beeps/Vib	User selected (under CGM Setup Menu options), every 3 minutes up to 3 time or until confirmed. No progression.



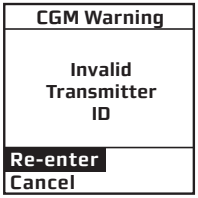
CGM Warning: Glucose Level is Falling Too Quickly	
Cause	CGM Sensor readings are falling at or faster than Fall Rate limit (2 or 3 mg/dL/min) set in pump.
Effect	Insulin deliveries continue. CGM continues.
Message	Displayed each time pump is awakened until confirmed.
Action	Press OK to confirm. Check BG with fingerstick test.
Beeps/Vib	User selected (under CGM Setup Menu options), every 3 minutes up to 3 times, or until confirmed. No progression.



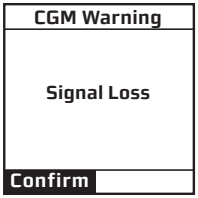
CGM Warning: Glucose Level is Rising Too Quickly	
Cause	CGM Sensor readings are rising at or faster than Rise Rate limit (2 or 3 mg/dL/min) set in pump.
Effect	Insulin deliveries continue. CGM continues.
Message	Displayed each time pump is awakened until confirmed.
Action	Press OK to confirm. Check BG with fingerstick test.
Beeps/Vib	User selected (under CGM Setup Menu options), every 3 minutes up to 3 times, or until confirmed. No progression.



CGM Warning: Invalid Transmitter ID	
Cause	Transmitter ID entered in pump is not valid.
Effect	Insulin deliveries continue. CGM session does not start.
Message	Displayed until confirmed or until pump goes into sleep mode.
Action	Press OK to re-enter the correct ID or select "Cancel" and press OK to return to the CGM Menu. Refer to *Chapter 2* in *Section II* for information on entering the Transmitter ID.
Beeps/Vib	User selected (under CGM Setup Menu options), one time. No progression.



CGM Warning: Transmitter Signal Loss	
Cause	Pump and Sensor/Transmitter are not within 12 feet of each other or other possible obstruction. Pump is unable to receive CGM Sensor readings and Sensor/Transmitter is unable to receive BG values for calibration.
Effect	Insulin deliveries continue. CGM data gap for time period devices were not within BLE range.
Message	Displayed each time pump is awakened until confirmed.
Action	Press OK to confirm. Move devices closer and wait 10 minutes.
Beeps/Vib	User selected (under CGM Setup Menu options), every 3 minutes until confirmed. If confirmed, snooze for user selected snooze time. No progression.



CGM Warning: Transmitter Not Found	
Cause	Pump and Sensor/Transmitter are not within 12 feet of each other or other possible obstruction. Pump is unable to establish connection with the Transmitter during pairing.
Effect	Insulin deliveries continue. Pump is not able to establish connection with the Transmitter.
Message	Displayed each time pump is awakened until confirmed.
Action	Press OK to confirm. Move devices closer and wait 10 minutes.
Beeps/Vib	User selected (under CGM Setup Menu options), every 3 minutes until confirmed. If confirmed, snooze for user selected snooze time. No progression.

CGM Warning: CGM Session Stopped	
Cause	CGM session stopped due to a problem with the Sensor or Transmitter.
Effect	Insulin deliveries continue. CGM session stops.
Message	Displayed each time pump is awakened until confirmed.
Action	Press OK to confirm. Replace Sensor and start new CGM session.
Beeps/Vib	User selected (under CGM Setup Menu options), every 3 minutes up to 3 times or until confirmed. No progression.

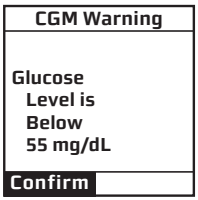
CGM Warning: CGM Sensor Failure, Insulin Delivery Continues	
Cause	Sensor error indicating that Sensor is not functioning properly.
Effect	Insulin deliveries continue. CGM session ends.
Message	Displayed each time pump is awakened until confirmed.
Action	Press OK to confirm. Contact Customer Service for assistance.
Beeps/Vib	User selected (under CGM Setup Menu options), every 3 minutes up to 3 times or until confirmed. No progression.

CGM Warning: CGM Failure, Insulin Delivery Continues, Call Service	
Cause	Sensor/Transmitter and pump are not communicating.
Effect	Insulin deliveries continue. CGM session stops.
Message	Displayed each time pump is awakened until confirmed.
Action	Press OK to confirm. Contact Customer Service for assistance.
Beeps/Vib	User selected (under CGM Setup Menu options), every 3 minutes until confirmed. No progression.

CGM Warning: Replace CGM Transmitter, Low Battery	
Cause	Transmitter battery power is low.
Effect	Insulin deliveries continue. CGM continues but with possible data gaps.
Message	Displayed each time the pump is awakened until confirmed.
Action	Press OK to confirm. You must replace the entire Transmitter. See *Chapter 9* in *Section II* for more information.
Beeps/Vib	User selected (under CGM Setup Menu options), every 3 minutes until confirmed. No progression.

CGM Warning: CGM Transmitter Battery Low	
Cause	Transmitter nearing end of life.
Effect	Insulin deliveries continue.
Message	Displayed once per week for the last three weeks.
Action	Press OK to confirm. The warning will not reoccur after user confirms the warning until after a new session has been started. Order a new Transmitter.
Beeps/Vib	User selected (under CGM Setup Menu options), every 3 minutes until confirmed. No progression.

CGM Warning: Glucose Level is Below 55 mg/dL	
Cause	Last CGM Sensor reading at or below 55 mg/dL (fixed limit set in pump – not user selected).
Effect	Insulin deliveries continue. CGM continues.
Message	Displayed each time pump is awakened until confirmed.
Action	Press OK to confirm. Check BG with fingerstick test.
Beeps/Vib	Every 3 minutes until confirmed. If confirmed, snooze for 30 minutes. No progression.

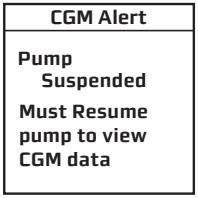


CGM Alert: CGM Session Stopped By User	
Cause	User stopped current CGM session.
Effect	Insulin deliveries continue. CGM session ends.
Message	Displayed once for 4 seconds.
Action	None required.
Beeps/Vib	User selected (under CGM Setup Menu options), one time. No progression.

CGM Alert: CGM Session Active	
Cause	Transmitter ID cannot be entered if CGM session is active.
Effect	Insulin deliveries continue. CGM continues.
Message	Displayed once for 4 seconds.
Action	None required.
Beeps/Vib	User selected (under CGM Setup Menu options), one time. No progression.

CGM Alert: CGM Session Not Active	
Cause	You are trying to enter a BG Calibration value on the pump CGM Menu but no CGM session is active.
Effect	Insulin deliveries continue. No CGM.
Message	Displayed once for 4 seconds.
Action	Start new CGM session if desired.
Beeps/Vib	User selected (under CGM Setup Menu options), one time. No progression.

CGM Alert: Pump Suspended. Must Resume pump to view CGM data	
Cause	CGM Menu options not available on pump while it is suspended.
Effect	Insulin delivery currently suspended. Active CGM session continues but CGM data not available on pump. If you want to temporarily suspend insulin delivery but still view CGM Sensor readings, do not use the suspend delivery feature. Instead, you can set Temp Basal to OFF for the time period you want basal delivery suspended, and still be able to view CGM Sensor readings.
Message	Displayed once for 4 seconds.
Action	Resume pump operation.
Beeps/Vib	User selected (under CGM Setup Menu options), one time. No progression.



CGM Alert: Session in Progress	
Cause	Accessing Transmitter ID, BG Cal. or CGM session history under CGM Menu when a session has just began.
Effect	Insulin deliveries continue. Cannot access Transmitter ID, BG Cal. or CGM session history when session in progress.
Message	Displayed once for 4 seconds.
Action	Wait up to 10 minutes after start of session.
Beeps/Vib	Beep, one time. No progression.

CGM Alert: CGM Session Stop in Progress	
Cause	Accessing Transmitter ID, BG Cal. or CGM session history under CGM Menu after the user stopped the session.
Effect	Insulin deliveries continue. Cannot access Transmitter ID, BG Cal. or CGM session history when session in progress
Message	Displayed once for 4 seconds.
Action	Wait up to 10 minutes after stop of session.
Beeps/Vib	Beep, one time. No progression.

CGM Warning: CGM Session Disconnected	
Cause	Pump disconnects from an existing CGM session. For example when Bluetooth is turned off.
Effect	Insulin deliveries continue. Pump disconnects from session.
Message	Displayed each time pump is awakened, until confirmed or maximum re-display exceeded.
Action	Press OK to confirm. Start/Join the session.
Beeps/Vib	User selected (under CGM Setup Menu options), every 3 minutes up to 3 times, or until confirmed. No progression.

CGM Warning: Join active session	
Cause	During an active session Pump detects a new session started in Transmitter.
Effect	Insulin deliveries continue. Join or disconnect session.
Message	Displayed each time pump is awakened, until confirmed or maximum re display exceeded.
Action	Press Yes or No to join active session.
Beeps/Vib	User selected (under CGM Setup Menu options), every 3 minutes up to 3 times, or until confirmed. No progression.

Care and Maintenance of your Dexcom G5® Sensor and Transmitter

Only use Dexcom-supplied parts (Dexcom G4®/G5® Sensor and Transmitter) with your OneTouch Vibe™ Plus System. **DO NOT** use Sensors and Transmitters from other companies.

The pump is not compatible with any other versions of Dexcom Sensors and Transmitters.

Cleaning the Transmitter

1. Wipe the outside of the Transmitter with a wrung-out, slightly water-dampened cloth or isopropyl alcohol wipe.
2. The Transmitter is water resistant when snapped into the Sensor pod, but **DO NOT** soak the Transmitter by itself in liquid.
3. **DO NOT** use soap, nail polish remover, or paint thinner. Only use isopropyl alcohol and water.
4. **DO NOT** use wipes that contain adhesives (e.g., IV PREP) that could damage the Transmitter.
5. Place the Transmitter on a clean, dry cloth and air dry for 2-3 minutes.

Storage

Sensor

- Keep the Sensor in its sterile packaging until you are ready to use it.
- **DO NOT** insert Sensors past the Use By Date printed on the Sensor package label. The Use By Date format is YYYY-MM-DD. Sensors must be inserted on or before the end of the calendar day printed on the Sensor package label.
- Storage temperature should be 36° F to 77° F. You may store your Sensors in the refrigerator if it is within this temperature range. **DO NOT** store Sensors in a freezer.
- Store at humidity levels between 15% to 85% relative humidity.

Transmitter

- Keep the Transmitter clean and away from areas where it might be damaged when not in use.
- Storage temperature should be 32° F to 113° F.
- Store at humidity levels between 10% to 95% relative humidity.

Disposal

Consult your local waste management authorities for instructions to dispose of devices containing electronic waste (Transmitter) and blood contacting parts (Sensor and Applicator).

Problems with Sensor Insertion

Problems can occur during Sensor insertion, and in keeping the Sensor Pod attached to your body. Common problems seen with patient use and suggested solutions are listed in the following table.

Possible problems	Suggested Solution
Safety Lock will not detach from the Applicator	• Make sure to pull straight out using the arrows on the Safety Lock as a guide. • **DO NOT** wiggle the Safety Lock back and forth or you may snap off/break the Safety Lock and damage the Applicator.
Applicator Collar will not pull up	• Make sure the white plunger is completely pressed down before pulling the collar up. • Firmly pull up on the collar.
Applicator will not detach from the Sensor Pod	• Pull the Collar all the way up. It should be very close to the top of the Applicator. • Make sure the Transmitter Latch is down before squeezing the Release Tabs. • Then squeeze the center part of the ribbed Release Tabs on the side of the Sensor Pod, and lift the Applicator away from your body.
Transmitter Latch will not remove easily	• Hold the Sensor Pod down with one hand and twist the Latch with the other hand to remove it. • **DO NOT** try to snap it straight off.

Problems with Sensor Insertion *(continued)*

Sensor Pod does not remain stuck on body	• **DO NOT** use any cream or lotion on your skin where you attach the Sensor Pod. • Clean the skin with alcohol and make sure it is dry before you attach the Sensor Pod. **DO NOT** leave any substance on the skin where the Needle inserts. • You may use medical tape (such as Blenderm™) over the white adhesive patch of the Sensor Pod.
	⚠ **WARNING: DO NOT** place the tape over the Transmitter or the plastic parts of the Sensor Pod.

Problems with CGM Calibration/Recalibration

Your CGM requires calibration with fingerstick BG values at various times. After entering a BG value(s) into your pump, you may still be prompted to enter another BG value(s) if the BG value is not consistent with current CGM Sensor readings.

CGM CALIBRATION ISSUE	SUGGESTED SOLUTION
Repeat prompts to enter BG values during startup calibration	• You must enter 2 separate fingerstick BG values when prompted at the end of the 2-hour startup period. • BG values must be within 40 to 400 mg/dL and must have been taken within the last 5 minutes. If there is a delay in entering the BG values, it may impact the accuracy of your CGM Sensor readings. • You may continue to be reminded to enter another BG value(s) if one or both of the BG values you have entered is/are not accepted. The reminder will re-appear until both BG values are accepted and startup calibration is successful.

Problems with CGM Calibration/Recalibration *(continued)*

Repeat prompts to enter BG values during calibration update/ recalibration	• You must enter at least one fingerstick BG value every 12 hours for the calibration update. • BG values must be within 40 to 400 mg/dL and must have been taken within the last 5 minutes. • You may continue to be reminded to enter another BG value(s) if the one you entered is not accepted. The reminder will re-appear until the BG value is accepted and calibration update/recalibration is successful.
Continued prompts to enter BG values even after following all instructions	• Your pump and Sensor/Transmitter may not be communicating. Make sure the devices are within BLE range. Check to see if the **[???]** or **[ANT]** symbol appears in place of your current CGM Sensor reading on the CGM Data or Trend screen. **DO NOT** enter fingerstick BG values for startup calibration or calibration update/recalibration if **[???]** or **[ANT]** appears. If you were out of BLE range, it may take about 10 minutes for your pump and Sensor/Transmitter to resume communication. Wait 10 minutes to see if the devices start communicating and then enter a new fingerstick BG value. • BG values must be within 40 to 400 mg/dL and must have been taken within the last 5 minutes. • If your pump and Sensor/Transmitter are communicating, and you continue to be prompted for additional fingerstick BG values, contact Customer Service for assistance.

Problems with *Bluetooth* communication

Certain conditions may cause BLE communication between your pump and Sensor/Transmitter to be lost or interrupted. When BLE communication is lost or interrupted, **???** or **ANT** will appear instead of your current CGM Sensor reading on the CGM Data and Trend screens. If your pump and Sensor/Transmitter are not within BLE range, the Signal Loss Warning may also display/sound (see *Chapter 10* in *Section II*). Common causes for BLE communication to be lost or interrupted seen with patient use and suggested solutions are listed in the following table. You will need to wait 10 minutes once BLE communication resumes for CGM Sensor readings to begin appearing again on your pump.

POSSIBLE CAUSE OF BLE COMMUNICATION PROBLEMS	SUGGESTED SOLUTION
Your pump and Sensor/Transmitter are not within allowable BLE range	Make sure your pump and Sensor/Transmitter are within 12 feet of each other.
Damp clothing	Change to dry clothing.
Electric blankets	Remove the blanket.
Water in pool or bathtub	Get out of the water.
Waterbeds	Switch to regular bed.
Nearby metallic objects	Remove or move away from metallic objects.
High levels of noise/energy/static from nearby electrical devices	Move away from the source of the noise.

Sensor Failures/Errors

Your CGM session may be interrupted or stopped before the end of a full 7-day period due to Sensor failure or error.

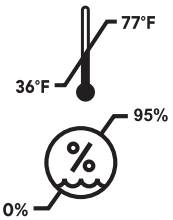
Sensor Failures – The Sensor Failure Warning or CGM Failure Warning (see *Chapter 10* in *Section II*) will display/sound, and the CGM session will stop. Contact Customer Service for assistance before inserting a new Sensor and starting a new CGM session.

Follow the guidelines below to have the best result with your Sensors.

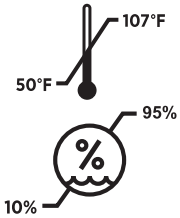
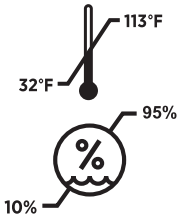
POSSIBLE PROBLEMS	SUGGESTED SOLUTION
Expired/damaged Sensors, or Transmitter/Sensor not attached/secured properly	• **DO NOT** use expired Sensors. • Store Sensors at 36° F to 77° F. See *Chapter 11* in *Section II* for maintenance and storage of your Sensors. • Make sure your Transmitter is snapped in fully. • Make sure your Sensor Pod is not dislodged or peeling up.

Technical Specifications

Dexcom G5® Sensor

Displayed Glucose Range	40 to 400 mg/dL	
Sensor Life	Up to 7 days	
Calibration	Fingerstick test with commercially-available BG meter	
Calibration Range	40 to 400 mg/dL	
Storage Conditions	Temperature: 36° F to 77° F Humidity: 0% to 95% RH	
Sterilization	Sterile by radiation	STERILE R

Dexcom G5® Transmitter

Dimensions (including Sensor Pod)	Refer to the Dexcom G5® Mobile CGM System User's Guide	
Weight (including Sensor Pod)	Refer to the Dexcom G5® Mobile CGM System User's Guide	
Power Supply	Silver oxide batteries (not replaceable)	
Operational Conditions	Temperature: 50° F to 107.6° F Humidity: 10% to 95% RH	
Storage Conditions	Temperature: 32° F to 113° F Humidity: 10% to 95% RH	
Operating Altitude	-1300 to 13,800 feet	
Limited Warranty	3 months	
Moisture Protection	IP28: Protection against insertion of large objects and immersion in water up to 8 feet for 24 hours	
Protection Against Electrical Shock	Type BF applied part	

Dexcom G5® Transmitter Performance Characteristics

PARAMETER	PERFORMANCE CHARACTERISTICS
Transmitter Frequency Range	2.402 – 2.480 GHz
Bandwidth	1.02 MHz
Maximum Output Power	1.0 mW EIRP
Data Rate	1 Mbps
Data Communication Range	12 feet

OneTouch Vibe™ Plus System Wireless Co-existence, Quality of Service (QoS), and Data Security

Wireless Co-existence and Quality of Service (QoS)

Wireless testing including wireless co-existence was conducted on the System. Testing indicated that the System can operate in the presence of *Bluetooth* interference and co-exists with other wireless devices operating in the same vicinity. No nearby wireless products or devices were found to affect the performance of the OneTouch Vibe™ Plus System, nor was any product or device found to be affected by the OneTouch Vibe™ Plus System.

Data security

The OneTouch Vibe™ Plus System is designed to only accept *Bluetooth* communications from recognized and linked Dexcom G5® Transmitters. A unique Dexcom G5® 6-digit Transmitter Identification Number (ID) must be manually entered by the user into the pump to establish a secure unidirectional communication link. The only way to create a wireless communication link with the pump is by using the Dexcom G5® Transmitter identification number.

The OneTouch Vibe™ Plus System with the Dexcom G5® Transmitter incorporates proprietary *Bluetooth* encryption technology to protect users against potential cyber security threats. Users should be mindful of potential cyber security breaches. If you believe a cyber security breach may have occurred please contact Animas Customer Service immediately.

Electromagnetic Emissions:

The information contained in this section is intended to provide guidance on the proper operation of the OneTouch Vibe™ Plus System with respect to electromagnetic compatibility (EMC). Following this guidance will not guarantee faultless operation but should provide reasonable assurance of such. The tables in this section are required by the EMC standard, IEC 60601-1-2.

Medical electrical systems need special precautions regarding electromagnetic compatibility (EMC) and need to be installed and put into service according to the EMC information provided in this Owner's Booklet.

The System is intended for use in an electromagnetic environment in which radiated *Bluetooth* disturbances are controlled. The user of the System can help prevent electromagnetic interference by maintaining a minimum distance between portable/mobile *Bluetooth* communications equipment (transmitters) and the System as recommended in *Chapter 13* in *Section II*.

Cables and accessories not specified for use with the OneTouch Vibe™ Plus System by Animas® are not authorized. Use of such unauthorized cables or accessories may adversely impact safety, performance and EMC (increased emissions or decreased immunity).

Care should be taken if the OneTouch Vibe™ Plus System is adjacent to or stacked upon other electrical equipment. If such use is unavoidable, it should be verified through observation that neither product is affected by the proximate use.

Guidance and Manufacturer's Declaration on Electromagnetic Emissions The OneTouch Vibe™ Plus System is intended for use in the electromagnetic environment specified below. The customer or the user of the OneTouch Vibe™ Plus System should assure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic Environment – Guidance
Bluetooth emissions CISPR 11	Group 1	The OneTouch Vibe™ Plus System uses *Bluetooth* energy only for its internal function. Therefore, its *Bluetooth* emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Bluetooth emissions CISPR 11	Class B	The OneTouch Vibe™ Plus System complies with the limits specified by CISPR11 Group 1, Class B.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The OneTouch Vibe™ Plus System is intended for use in the electromagnetic environment specified below. The customer or the user of the OneTouch Vibe™ Plus System should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 8 kV contact ± 15 kV air (pump, IEC 60601-2-24) ± 8 kV contact ± 15 kV air (Transmitter)	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/ output lines	Not applicable	Not applicable
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Not applicable	Not applicable

Guidance and Manufacturer's Declaration – Electromagnetic Immunity *(continued)*
The OneTouch Vibe™ Plus System is intended for use in the electromagnetic environment specified below. The customer or the user of the OneTouch Vibe™ Plus System should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	Not applicable	Not applicable
Power Frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	30 A/m (pump, IEC 60601-2-24) 3 A/m (Transmitter)	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Conducted *Bluetooth* IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	Not applicable	

NOTE: U_T is the a.c. mains voltage prior to application of the test level.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity *(continued)*

The OneTouch Vibe™ Plus System is intended for use in the electromagnetic environment specified below. The customer or the user of the OneTouch Vibe™ Plus System should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Radiated *Bluetooth* IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	10 V/m	Portable and mobile *Bluetooth* communications equipment should be used no closer to any part of the OneTouch Vibe™ Plus Insulin Pump, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the Transmitter. **Recommended separation distance:** $d = 0.35 \sqrt{P}$ 80 MHz to 800 MHz $d = 0.7 \sqrt{P}$ 800 MHz to 2,5 GHz where *P* is the maximum output power rating of the Transmitter in watts (W) according to the Transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed *Bluetooth* transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] *Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to Bluetooth transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the OneTouch Vibe™ Plus System is used exceeds the applicable Bluetooth compliance level above, the OneTouch Vibe™ Plus System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the OneTouch Vibe™ Plus System.*

[b] *Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.*

Recommended separation distances between portable and mobile *Bluetooth* communications equipment and the OneTouch Vibe™ Plus Insulin Pump

The OneTouch Vibe™ Plus System is intended for use in the electromagnetic environment in which *Bluetooth* disturbances are controlled. The customer or user of the OneTouch Vibe™ Plus System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile *Bluetooth* communications equipment (transmitters) and the OneTouch Vibe™ Plus System as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d = [\frac{3,5}{V1}] \sqrt{P}$	80 MHz to 800 MHz $d = 0.35 \sqrt{P}$	800 MHz to 2,5 GHz $d = 0.7 \sqrt{P}$
0.01	not applicable	0.035	0.070
0.1	not applicable	0.11	0.22
1	not applicable	0.35	0.70
10	not applicable	1.11	2.2
100	not applicable	3.5	7.0

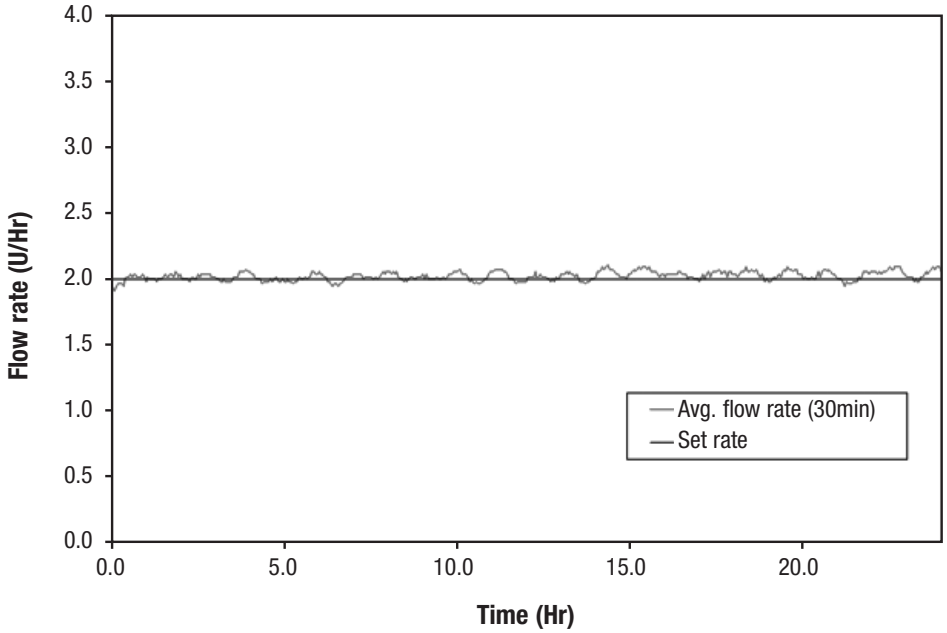
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

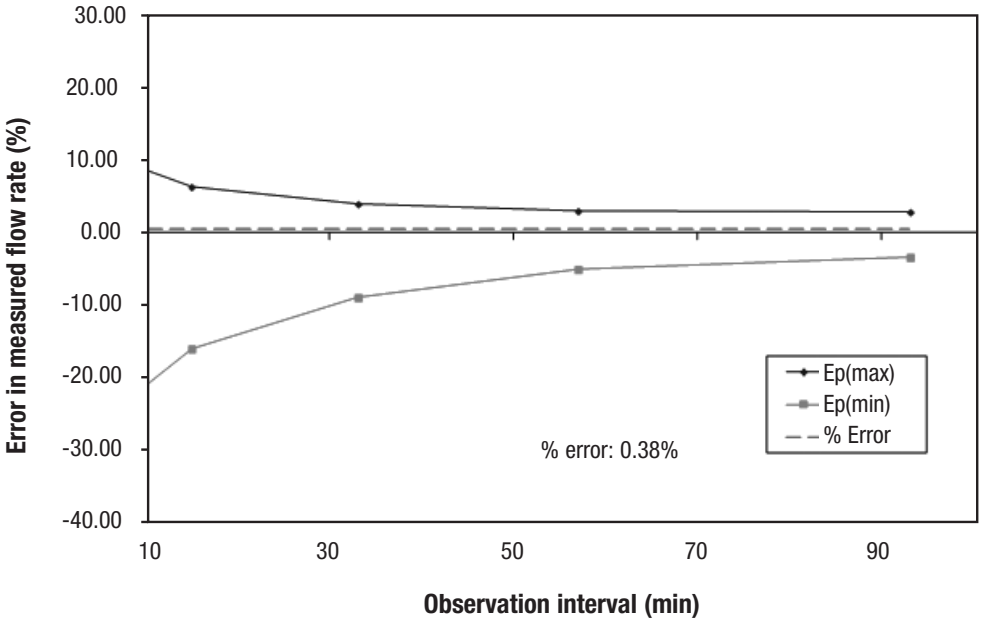
Pump flow accuracy upon initial start up

Average flow rate during a 24 hour delivery period. The measurements were taken at an intermediate basal rate of 2.0 U/Hr at room temperature.



Pump flow accuracy after initial stabilization period

The Trumpet curve shows the accuracy of the flow rate as a function of an averaging window. The reported percent error deviation is calculated over a 5 hour delivery period (100 deliveries).



(The above pump flow test indicates that the insulin pump delivered with an accuracy of 0.38%).

Appendix A: Glossary

alpha cells - Alpha cells are found in the pancreas. They produce a hormone called glucagon, which raises BG levels.

alternative site (BG) testing - This is when you obtain BG values from somewhere on your body other than your fingertip. **DO NOT** use BG values from alternative site testing for CGM calibration.

applicator - See *CGM Sensor applicator*.

audio bolus - Your pump has a special feature that lets you deliver a bolus without having to look at the screen display. This feature is convenient if you wear your pump under your clothing. Once you activate and program this feature, you can use the soft rubber button on the right side of your pump to deliver a bolus.

basal rate - The basal rate is the amount of insulin that is continuously delivered by an insulin pump. It is measured in units per hour (U/Hr). The basal rate usually provides about 40% to 60% of the daily total delivery of insulin.

beta cells - Beta cells are found in the pancreas. They produce insulin, which lowers BG levels. In type 1 diabetes mellitus, the beta cells are destroyed, so the body can no longer produce insulin.

blood glucose (BG) levels - BG levels are the measure of how much glucose (sugar) is in the blood. The normal level is about 70 to 110 mg/dL.

blood glucose (BG) meter - Any commercially-available BG meter can be used with your OneTouch Vibe™ Plus System.

blood glucose (BG) value - A fingerstick BG test result taken with your commercially-available BG meter.

Bluetooth (BLE) - How CGM Sensor readings are sent from the Transmitter to the pump.

BLE range - The allowable distance between the pump and Sensor/Transmitter for them to be able to communicate.

bolus - A bolus is the amount of insulin delivered at one time, usually before a meal or when BG is high.

cannula - A cannula is a small tube that is inserted into the body. Some infusion sets are designed so that only the cannula remains in the body and the needle used for insertion is removed.

calibration - See *CGM calibration*.

CGM calibration - This is when you enter fingerstick BG values into the pump for initial startup period and at least once every 12 hours thereafter. Calibrations are needed for your OneTouch Vibe™ Plus System to display continuous glucose readings and trend information. (**DO NOT** use alternative site testing for CGM calibration.)

CGM components - The Sensor, Transmitter, and other components used to insert/remove the Sensor.

CGM data gaps - This can happen when the pump does not display a CGM Sensor reading that is sent from the Transmitter. Symbols may appear instead of a CGM Sensor reading to let you know that the pump cannot display a reading.

CGM Sensor reading - The continuous glucose monitoring value sent to your pump every 5 minutes.

CGM rise and fall rate alerts - Alerts based on how fast your CGM Sensor readings rise/fall.

CGM safety lock - The Safety Lock keeps the Needle inside the Applicator before you are ready to insert. It also helps you snap the Transmitter out of the Sensor Pod after your CGM session has ended.

CGM Sensor applicator - A disposable piece that comes attached to the Sensor Pod, and inserts the Sensor Probe under the skin. There is a Needle inside the Applicator that you remove once you have inserted the Sensor Probe.

CGM Sensor pod - The small base of the Sensor attached to your belly that holds the Transmitter and Sensor Probe in place. The Sensor Pod and Transmitter are all that remain on your skin during each Sensor use.

CGM Sensor probe - The part of the Sensor that is inserted under your skin with the Applicator. It measures the glucose levels in your surrounding tissue fluid.

CGM startup period - The 2-hour startup period after you tell the pump you have inserted a new Sensor (CGM Sensor readings cannot be provided during this time).

CGM Transmitter - The CGM component that snaps into the Sensor Pod and wirelessly sends CGM Sensor readings to your pump.

CGM Transmitter ID - Transmitter ID that is entered into your pump to talk to the Transmitter.

CGM Transmitter latch - The small disposable piece that snaps the Transmitter into the Sensor Pod. It is removed after the Transmitter is snapped in.

CGM trends - Trends let you see the pattern of your CGM Sensor readings over time; you can see where your CGM Sensor readings have been and where your CGM Sensor readings are headed. The pump displays five glucose Trend Graphs: the 1-Hour, 3-Hour, 6-Hour, 12-Hour, and 24-Hour Graphs. Each Trend Graph shows trends over the amount of time shown on the screen.

CGM trend rate arrows - Arrows on CGM Data and Trend screens that indicate how fast your CGM Sensor readings are changing. Seven different arrows show you when the speed and direction of your CGM Sensor readings change.

combo bolus - Your pump lets you split a bolus amount into 2 parts, a Normal portion and an Extended portion. The Normal portion is delivered all at once and the Extended portion is delivered over an extended period of time that you set. A combo bolus is useful when eating foods that contain carbs that are absorbed more slowly over time.

continuous glucose monitoring (CGM) - The automatic measurement of glucose levels every few minutes using a method/device other than a traditional BG meter.

dawn phenomenon - More insulin may be required in the early hours of normal sleep to counteract the release of several hormones that act to increase BG levels. This increased need for insulin is known as dawn phenomenon and may cause a person with diabetes to have a high BG level upon waking. Basal rate delivery by the OneTouch Vibe™ Plus Insulin Pump can be programmed to compensate for dawn phenomenon.

default - A pump setting that is selected automatically unless another option is chosen.

diabetes - Diabetes is a complex disease in which the body cannot maintain healthy BG levels because either enough insulin cannot be produced or the body cannot appropriately use insulin. In type 1 diabetes, the body no longer produces insulin and in type 2 diabetes, the body cannot use insulin properly.

diabetic ketoacidosis (DKA) - DKA results when there is not enough insulin available to help glucose enter the cells where it is used for energy. The body, in turn, burns muscle and fat for energy. A waste product of fat burning is ketones. Ketones accumulate in the blood and then pass through the urine and lungs. This condition can be identified by urine and/or blood tests. DKA usually requires hospitalization and can be fatal if not promptly treated.

fingerstick - A blood glucose test taken with a blood glucose meter using a blood sample obtained from the fingertip.

gastroparesis - Gastroparesis is a complication of diabetes that causes delayed emptying of the stomach, resulting in unpredictable swings in BG levels.

glucagon - Glucagon is a hormone produced by the alpha cells in the pancreas. It causes BG levels to rise.

glucose - Glucose is a carbohydrate and the body's most important source of energy. It is produced from digested food, by the normal action of the liver, and is carried by the blood and other fluids throughout the body.

hyperglycemia - Hyperglycemia is also known as high blood glucose (BG). It occurs when BG levels rise above 180 mg/dL, and the body does not have enough or cannot use insulin to process food. Symptoms of hyperglycemia include nausea, vomiting, muscle and joint aches, blurred vision, excessive thirst, and frequent urination. Over time, weight loss can result. Hyperglycemia can occur even while using an insulin pump and can lead to diabetic ketoacidosis (DKA) if untreated.

hypoglycemia - Hypoglycemia is also known as low blood glucose (BG). It occurs when BG levels drop to below 70 mg/dL. This can happen if a person with diabetes has taken too much insulin or has exercised more than usual. Symptoms of hypoglycemia include dizziness, shakiness, rapid heartbeat, sudden hunger, cold or clammy skin, fuzzy vision, confusion, mood changes, and tingling or numbness in the hands, arms, tongue, or lips. Hypoglycemia can occur even while using an insulin pump, and if left untreated, can lead to unconsciousness and diabetic coma.

infrared - Infrared is a wireless means by which the OneTouch Vibe™ Plus Insulin Pump communicates with external devices using an optical signal which is invisible to the human eye.

infusion set - An infusion set consists of a length of thin plastic tubing (available in various lengths) with a Luer-lock connector at one end, and at the other end, a very small cannula that is placed under the skin. It is connected to the insulin pump and used to deliver insulin to the body.

infusion site - The infusion site is the place on the body where the infusion set needle is inserted under the skin.

insulin - Insulin is a hormone produced by the beta cells in the pancreas. Insulin is needed by the body to regulate the production and use of glucose.

insulin limits - Insulin limits are a programmable feature of the OneTouch Vibe™ Plus Insulin Pump. After consulting with your HCP, you can use the Advanced Setup Menu to program maximum limits for basal rate delivery, bolus delivery, 2-hour, and total daily delivery.

insulin on board - Refers to how much insulin remains in your body from a previous bolus. Knowing how much insulin remains allows you to adjust your next bolus amount accordingly to avoid delivering too much insulin. You can use the Insulin on Board feature on your pump to account for any remaining insulin when calculating suggested bolus amounts. “Insulin on Board” will often appear in an abbreviated form as “IOB” on the pump display as well as in example display screens.

insulin pump - An insulin pump is a small, battery-powered device that mechanically pumps measured amounts of insulin through an infusion set into the body. THE PUMP IS NOT AUTOMATIC. You program and control it, and you must perform four to six BG tests daily to ensure delivery of appropriate amounts of insulin by the pump.

insulin sensitivity factor (ISF) - Refers to how much you can lower your BG (in mg/dL) with 1 unit of insulin. Your ISF is one of several factors you use in calculating the amount of insulin you should deliver to cover for a high BG. Your pump will use the ISF(s) you have programmed into your pump when calculating suggested bolus amounts.

insulin to carb (I:C) ratio - Refers to how many carbs you can cover with 1 unit of insulin. Your I:C ratio is one of several factors you use in calculating the amount of insulin you should deliver to cover a carb amount. Your pump will use the I:C ratio(s) you have programmed into your pump when calculating suggested bolus amounts.

ketones - Ketones, or ketone bodies, are substances produced by normal liver activity, and used by muscle tissue. In uncontrolled diabetes, the process becomes unbalanced and ketones can accumulate in the blood, pass through the urine and ultimately result in diabetic ketoacidosis (DKA).

Luer-lock - A Luer-lock, or Luer connection, is a standardized, specially threaded fitting used to connect the infusion set to the pump’s insulin cartridge.

maximum total daily dose (TDD) delivery warning - You can program your pump to alert you when combined basal and bolus insulin delivery will exceed a maximum daily amount you have set in your pump.

maximum two-hour (2hr) delivery warning - You can program your pump to alert you when combined basal and bolus insulin delivery will exceed a maximum 2-hour amount you have set in your pump.

mg/dL - mg/dL is the unit used to measure glucose levels. It is the abbreviation for milligrams of glucose per deciliter of blood. To convert mg/dL to mmol/L, divide by 18.02 or multiply by 0.055.

occlusion - Occlusion means "blockage." The OneTouch Vibe™ Plus Insulin Pump is designed to be able to sense when delivery of the insulin is being blocked for some reason. The pump will automatically stop delivering insulin and give an alarm to alert you to clear the occlusion and re-start the pump.

o-ring - Both the cartridge and the battery cap contain an "o" shaped ring made of a soft material that functions as a seal when compressed. O-rings operate properly only if the surface is free of defects (cuts, scratches, abrasion).

pancreas - The pancreas is a glandular organ just behind the stomach, next to the liver. It produces digestive enzymes used to break down proteins in food. It contains alpha cells, which produce glucagon, and beta cells, which produce insulin.

rise and fall alerts - See *CGM rise and fall alerts*.

safety lock - See *CGM safety lock*.

sensor pod - See *CGM Sensor pod*.

sensor probe - See *CGM Sensor probe*.

startup period - See *CGM startup period*.

stress hormones - Stress hormones (or "counter-regulatory" hormones) are released by the body in times of intense physical or emotional stress. These hormones cause the body to release glucose. If the glucose is not used as energy, hyperglycemia and ketoacidosis can result.

subcutaneous - Subcutaneous means beneath the skin. The infusion set needle is placed subcutaneously.

temporary (or temp) basal - Setting a temporary basal lets you increase or decrease your current basal program rate for a desired period of time. Your current basal rate is based on the basal program that is currently active in your pump. When you set a temporary basal, you select a percentage increase or decrease, and then set the desired time period the increase or decrease will stay in effect.

transmitter - See *CGM Transmitter*.

transmitter ID - *See CGM Transmitter ID*.

transmitter latch - See *CGM Transmitter latch*.

trend arrow - See *CGM trend arrow*.

type 1 diabetes - Type 1 diabetes results from destruction of the beta cells in the pancreas. People with type 1 diabetes mellitus must use insulin to regulate their BG levels.

type 2 diabetes - Type 2 diabetes usually occurs in people 40 years or older. People with type 2 diabetes have a progressive loss of beta cells over time. They can sometimes regulate their BG levels by following an individual meal plan, exercising and taking antidiabetic pills. They frequently require insulin for optimal BG control.

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