



Continuous Glucose Monitoring System

User's Guide

The FreeStyle Navigator™ Continuous Glucose Monitoring System (the “System”) continually reads, displays, and records interstitial fluid glucose levels in people with diabetes as an alternative to traditional blood glucose monitoring. It provides readings directly to the user in real time. It also provides alarms for the detection and assessment of episodes of hypoglycemia or hyperglycemia. It is intended for everyday use in the home to aid people with diabetes, and for use in clinical settings to aid healthcare professionals in evaluating glucose control. It is intended for prescription use only.

CAUTION: Read all the instructions provided in this User’s Guide before using the System. Glucose management (therapy adjustment) should be done only under the guidance of your healthcare team.

IMPORTANT INFORMATION

System-Related Information

- The FreeStyle Navigator™ Continuous Glucose Monitoring System is designed as a complete System. Use only the FreeStyle Navigator™ Sensor, FreeStyle Navigator™ Transmitter, and FreeStyle Navigator™ Receiver.
- The System is intended for your own personal use; do NOT share your System.
- If you are unsure about the meaning of any Receiver messages or results, consult your healthcare team or call the Clinical Trial Support Line at **1-888-971-4766**.

System-Related Warnings and Cautions

- WARNING: Keep the System and its components away from young children, as there are small parts that may be dangerous if swallowed. The caps are choking hazards. The Test Strip cap or vial may contain a drying agent that could be harmful if inhaled or swallowed and may cause skin and eye irritation.
- WARNING: Never point the pre-cocked Sensor Inserter toward the eyes, face, or any other body part where Sensor insertion is not desired.
- Changes or modifications not expressly approved by Abbott Diabetes Care could void the user's authority to operate the equipment.
- The System should not be used in an oxygen-rich environment or one related to anesthetic gas.
- To reduce the chance of infection, do NOT leave a Sensor inserted for more than 3 days.
- Once the Locking Pin has been removed from the Sensor Delivery Unit, the Sensor will be released if the button is pressed (see page 48). Do NOT press the button until you are ready to insert the Sensor.

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- The Sensor should be removed if redness, pain, tenderness, or swelling develops at the insertion site.
 - The Sensor Support Mount and Transmitter are water resistant and may be worn while bathing, showering, or swimming. While swimming, make sure you do not go deeper than 1 meter (roughly 3 feet) or the Sensor gasket might leak, causing the Transmitter to stop working properly. When the Transmitter is underwater, the Transmitter/Receiver connection will be broken and you will not receive continuous glucose readings.
 - Do NOT immerse the Receiver in water or any other liquid. Avoid getting water or any other liquid in the Receiver's Test Strip Port.
 - The Transmitter should be removed from the Sensor Support Mount and cleaned (see page 141) each time you remove a used Sensor (every 3 days).
 - If the Sensor Support Mount fails to adhere to the skin, the Sensor will not work and you will need to insert a new Sensor.
 - Do NOT drop the Receiver.
 - When using the System in the Blood Glucose Mode, use *only* FreeStyle Test Strips and FreeStyle Control Solution. Other brands of test strips or control solution can give you inaccurate results.
 - Do NOT use FreeStyle Control Solution for calibration.
 - If you get a Control Solution test result that falls outside the range printed on the Test Strip vial, repeat the test with a new Test Strip. If the test result is still outside the range on the vial, the System may not be working properly. Do NOT use the System to test your glucose levels unless you get a Control Solution test result within the range printed on the Test Strip vial.

Health-Related Information

- The System is intended to assist you in better managing your diabetes by allowing you to know your glucose levels throughout the day.

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- The System is not intended to be used for diagnosing diabetes, testing newborns, or testing arterial blood.
 - Test results below 60 mg/dL (3.3 mmol/L) mean your glucose levels are too low.
 - Test results above 300 mg/dL (16.7 mmol/L) mean your glucose levels are too high.
 - Severe dehydration and excessive water loss may cause false low results. If you believe you are suffering from severe dehydration, consult your healthcare team immediately.
 - If your results do not reflect how you feel, wait at least 1 minute and review the new data from the Continuous Monitoring Mode or test your glucose using the Blood Glucose Mode.
 - If you get results below 60 mg/dL (3.3 mmol/L) or above 300 mg/dL (16.7 mmol/L) and do not have symptoms of hypoglycemia or hyperglycemia, wait at least 1 minute and review the new data from the Continuous Monitoring Mode or test your glucose using the Blood Glucose Mode.
 - If you have symptoms of hypoglycemia or hyperglycemia, or continue to get results below 60 mg/dL (3.3 mmol/L) or above 300 mg/dL (16.7 mmol/L), consult your healthcare team.
 - If you are experiencing symptoms that are not consistent with your glucose test results, consult your healthcare team.
 - When testing your glucose levels in the Blood Glucose Mode, differences in the blood circulation in your finger or palm at the base of your thumb* and other test sites (forearm, upper arm, hand, thigh, calf) may result in different glucose readings. Differences in blood glucose readings between your finger or palm and other test sites may be observed after eating, taking insulin medication, or exercising.

* Palm testing at the base of your thumb is the same as finger testing; see Appendix A.

- It is recommended that you test your finger or palm at the base of your thumb if you are testing for hypoglycemia or if you suffer from hypoglycemia unawareness (see Table below). Changes in glucose levels may be observed in finger or palm blood samples sooner than in samples from alternate sites (forearm, upper arm, hand, thigh, calf). Vigorous rubbing of alternate sites before lancing can help minimize this difference.

How Would I Know if I Have Hypoglycemia Unawareness?

	<u>Yes</u>	<u>No</u>
1. Do you often get blood glucose readings below 55 mg/dL (3.1 mmol/L) without any of the usual symptoms of hypoglycemia (sweating, tremors, rapid heartbeat, nervousness, extreme hunger)?	<input type="checkbox"/>	<input type="checkbox"/>
2. Have you had episodes of impaired thinking?	<input type="checkbox"/>	<input type="checkbox"/>
3. Have there been times when other people told you that you appeared pale, tired, confused, or acted as if in "slow motion?"	<input type="checkbox"/>	<input type="checkbox"/>
4. Have you been irritable or forgetful, even though you physically felt fine?	<input type="checkbox"/>	<input type="checkbox"/>
5. Have you had difficulty managing a hypoglycemic episode alone, and needed others to help you?	<input type="checkbox"/>	<input type="checkbox"/>
6. Have you ever had a seizure or loss of consciousness without any warning signs?	<input type="checkbox"/>	<input type="checkbox"/>
7. Do you try to maintain a very tightly controlled blood glucose level (often running below 90 mg/dL [5 mmol/L])?	<input type="checkbox"/>	<input type="checkbox"/>
8. Have you had frequent episodes of hypoglycemia?	<input type="checkbox"/>	<input type="checkbox"/>
9. Have you had diabetes for more than 20 years?	<input type="checkbox"/>	<input type="checkbox"/>
10. Have you had a recent episode of severe hypoglycemia?	<input type="checkbox"/>	<input type="checkbox"/>

If you answered Yes to any of these questions, consult your healthcare team.

Health-Related Cautions

- The Low and High Glucose Alarms are not intended to indicate severe hypoglycemia or hyperglycemia because the Low Glucose Alarm can not be set below 60 mg/dL (3.3 mmol/L) and the High Glucose Alarm can not be set above 300 mg/dL (16.7 mmol/L).
- Therapy adjustment should be done only with guidance of a healthcare professional.
- Physiologic differences between interstitial fluid (used to determine glucose levels in the Continuous Monitoring Mode) and capillary blood (used to determine glucose levels in the Blood Glucose Mode) may result in different glucose readings. These differences may be seen after eating, taking insulin, or exercising. This is a normal physiologic difference and does not reflect on the accuracy of the System.

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INTRODUCTION

The FreeStyle Navigator™ Continuous Glucose Monitoring System (the “System”) is designed to give people with diabetes an accurate *continual* reading of their glucose levels in *real time*. It does this by measuring glucose levels in the interstitial fluid—the fluid in the tiny spaces between your tissues—via a small, thin, plastic Sensor inserted just under the skin. The System is designed to be used *instead of* traditional meters that use blood to measure glucose levels.

By having access to more frequent glucose measurements, you can monitor your glucose levels and gain an understanding of glucose trends. This will help you and your healthcare team see how diet, insulin, exercise, and medication affect your glucose levels, and to adjust your treatment plan accordingly.

In addition to its ability to provide continuous glucose readings, the System has a number of other helpful features, including alarms to alert you to low or high glucose levels (hypoglycemia or hyperglycemia), and reports that show your glucose information in easy-to-understand ways. The System is intended for everyday use in the home and is available by prescription only. It is also intended for use in clinical settings to help healthcare professionals evaluate glucose test results.

CAUTION: Read the entire User’s Guide before using the System. Adjustments to your treatment plan should be done under the guidance of your healthcare team.

The System includes:

- A FreeStyle Navigator™ Sensor that you insert under your skin. Each inserted Sensor is intended to remain in place and provide a continuous glucose reading for up to 3 days.
- A wireless FreeStyle Navigator™ Transmitter, a small electronic device that makes an electrical connection to the portion of the Sensor that extends

above the skin. The Transmitter processes the very low current signals it receives from the Sensor and sends the glucose values to the Receiver once every minute.

- A wireless FreeStyle Navigator™ Receiver that captures and displays glucose measurements. With the press of a button, the Receiver displays the glucose measurements taken from the Sensor. The Receiver also has a built-in FreeStyle Blood Glucose Meter that can be used for blood glucose testing. The Receiver should always be kept with you on a belt, in a pocket, or in a purse.

How to Use This Guide

Although you should read this *entire* User's Guide before using your System, it is also designed to serve as an easy-to-use reference manual. Sections 1 –4 (*The System, Getting Started, Using the Receiver, and Maintaining the Transmitter/Receiver Connection*) provide the information you need to get your System up and running. Section 5 (*Advanced Features*) can help you get the most out of your System. Sections 6 and 7 (*Maintenance, Alarms, Error Codes and Troubleshooting*) can be of help if you have any problems. Finally, a Glossary and Index are included to help you understand unfamiliar words and locate the information you need.

Where to Get Help

Help is available 24 hours a day, 7 days a week.

If you have any questions about your System, call the Clinical Trial Support Line at **1-888-971-4766**.

If you have any questions about your glucose levels, glucose target goals, treatment plan, or diabetes management, consult your healthcare team.

1. THE SYSTEM

THE SYSTEM

This section introduces you to the different parts (components) of your FreeStyle Navigator™ Continuous Glucose Monitoring System, and explains the difference between the Continuous Monitoring Mode and the Blood Glucose Mode. Tips on sleeping, bathing, swimming, and traveling by plane with your System are also included.

Components

Your System comes in two kits: a System Kit and a Sensor Kit.

The System Kit contains:

- One FreeStyle Navigator™ Receiver
- Two AAA alkaline batteries for the Receiver
- One FreeStyle Navigator™ Transmitter
- One 357 (silver oxide) battery for the Transmitter
- One protective carrying case for the Receiver (with belt clip)
- One FreeStyle Lancing Device
- One finger cap (for lancing device)
- One *User's Guide*
- One *Getting Started Guide*

The Sensor Kit contains:

- Ten Sterile Sensor Delivery Units (each containing a Sensor)
- One vial of 50 FreeStyle Test Strips
- One vial of FreeStyle Control Solution
- Thirty sterile lancets
- Ten adhesive remover application pads
- Ten IV Prep wipes
- One 357 (silver oxide) replacement battery for the Transmitter

This User's Guide contains detailed information on the use of these components. Please see "Getting Started" (Section 2) for the basic information you'll need to start using your System.

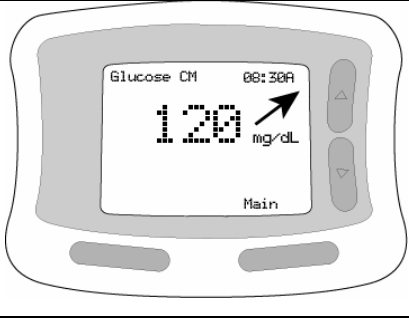
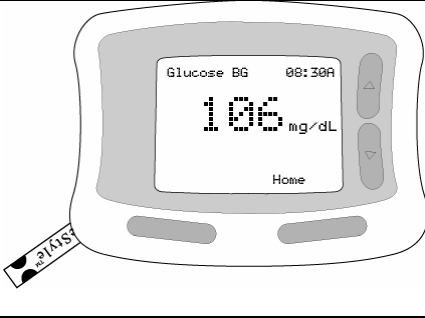
Continuous Monitoring Mode vs Blood Glucose Mode

The System operates in two separate modes: Continuous Monitoring Mode and Blood Glucose Mode. The Continuous Monitoring Mode is the mode you will use most of the time. It continuously displays the glucose level in your interstitial fluid (the fluid in the tiny spaces between your tissues). This glucose reading comes from the Sensor you will place just beneath your skin and is updated every minute. In the Blood Glucose Mode, you can perform traditional blood glucose testing manually, using a FreeStyle Test Strip and a drop of blood. Although you can use the Blood Glucose Mode whenever you wish, its main use is for calibrating the System.

IMPORTANT: Blood glucose testing is REQUIRED for calibration each time you insert a new Sensor. You will be prompted to perform a blood glucose test for calibration at approximately 1, 3, and 24 hours after Sensor insertion. If you do not perform these calibrations within the allowable time period, the Continuous Monitoring Mode will not operate, your glucose readings will not be displayed, and alarms will not be active.

Table 1.1 highlights some of the differences between the Continuous Monitoring Mode and the Blood Glucose Mode.

Table 1.1. Continuous Monitoring Mode vs Blood Glucose Mode

Continuous Monitoring Mode	Blood Glucose Mode
 <p>The image shows the FreeStyle Receiver in Continuous Monitoring Mode. The screen displays 'Glucose CM' at the top left, '08:30A' at the top right, and a large '120' with 'mg/dL' below it. An arrow points to the right above the '120'. The word 'Main' is at the bottom of the screen.</p>	 <p>The image shows the FreeStyle Receiver in Blood Glucose Mode. The screen displays 'Glucose BG' at the top left, '08:30A' at the top right, and a large '106' with 'mg/dL' below it. The word 'Home' is at the bottom of the screen. A FreeStyle Test Strip is inserted into the port on the left side of the device.</p>
<p>“Glucose CM” is seen at the top left of the Display Screen.</p>	<p>“Glucose BG” is seen at the top left of the Display Screen.</p>
<p>Most frequently used mode.</p>	<p>Built-in FreeStyle Blood Glucose Meter. Used mainly to calibrate the System.</p>
<p>Measures glucose from interstitial fluid detected by a Sensor in your skin.</p>	<p>Measures glucose from a blood sample that you supply.</p>
<p>Uses a Sensor to measure glucose levels. A Transmitter sends the glucose reading to the Receiver.</p>	<p>Uses a FreeStyle Test Strip to measure blood glucose levels.</p>
<p>Should only be used with FreeStyle Navigator™ Transmitters and Sensors.</p>	<p>Should only be used with FreeStyle Test Strips and FreeStyle Control Solution.</p>

The System automatically works in the Continuous Monitoring Mode. To switch to the Blood Glucose Mode, simply insert a FreeStyle Test Strip into the Receiver’s Test Strip Port. Use *only* FreeStyle Test Strips. When the Test Strip is removed, the Receiver will automatically switch back to the Continuous Monitoring Mode.

Daily Living

When using the System, you will be wearing a Sensor and Transmitter at all times (day and night). Only wear the Sensor/Transmitter on your abdomen or on the back of your upper arm. Keep these things in mind as you go about your normal routine.

- *Sleeping*—The Sensor and Transmitter should not interfere with your normal sleeping patterns. As you get ready to go to sleep, you should place the Receiver close by (within 10 feet) in order to maintain the Transmitter/Receiver connection (see page 87).
- *Bathing*—You can bathe or shower while wearing the Sensor/Transmitter. Do not wear the Receiver while bathing or allow it to get wet.
- *Swimming*—You can swim while wearing the Sensor/Transmitter. Do not go deeper than 1 meter (roughly 3 feet) or the Sensor gasket might leak, causing the Transmitter to stop working properly. The Transmitter/Receiver connection is not maintained when the Transmitter is underwater and thus you will not receive continuous glucose readings during this period. As soon as you take the Sensor/Transmitter out of the water, continuous glucose readings will resume.
- *Traveling by Plane*—Federal Aviation Administration (FAA) regulations may prohibit the use of the Transmitter on commercial aircraft (visit www.faa.gov for the most up-to-date information). Since signals from the Transmitter may interfere with aircraft communications, you may not be able to wear the Sensor and Transmitter during flight. However, you can check your blood glucose levels manually in the Blood Glucose Mode except during takeoff and landing.

Before going through airport security, you should:

1. Remove your Sensor and disconnect the Transmitter from the Sensor Support Mount (see page 51).
2. Remove and discard the Transmitter battery (see page 142).
3. Unlink the Transmitter and Receiver (see page 92) to stop the Receiver from sending or receiving signals. Alarms associated with the Continuous Monitoring Mode will also be turned off.

After your flight:

1. Insert a *new* battery into the Transmitter (see page 28). If you reinsert the old battery, the battery life timer will not be accurate, and the battery may stop working without warning.
2. Relink the Transmitter to the Receiver (see page 93).
3. Insert a new Sensor (see page 45) and attach the Transmitter (see page 57).

Now that you know a little more about the System, it's time to start using it!

2. GETTING STARTED

This section contains everything you need to know to begin using your FreeStyle Navigator™ Continuous Glucose Monitoring System. You may also want to use the separate “Getting Started Guide” while going through these steps.

The Receiver: Initial Set-up

The Receiver: Initial Set-up

This section contains information on installing the Receiver's batteries, using the Receiver's buttons, and setting the date and time. Step-by-step instructions for performing a Control Solution test (to ensure that the Receiver is working properly) are also included.

The FreeStyle Navigator™ Receiver (see below) looks and feels much like a traditional blood glucose meter. However, unlike traditional blood glucose meters, the Receiver can provide you with *continuous* glucose readings from the Sensor. The Receiver also has a built-in FreeStyle Blood Glucose Meter that works as a traditional blood glucose meter when a FreeStyle Test Strip is inserted into the Test Strip Port. You can wear the Receiver on your belt or carry it in your pocket or purse.

The Receiver (Front)



The Receiver (Back)



Installing the Batteries

The receiver is designed to operate for 90 days with 2 AAA alkaline batteries.

To install the batteries:

1. Press down on the ridged part of the Battery Door on the back of the Receiver and slide the Battery Door out.
2. Insert 2 new AAA alkaline batteries into the compartment. Line up the batteries with the +/- inside the compartment.
3. Close the Battery Door by sliding it into place. Push the Battery Door until it clicks.

CAUTION: Use only AAA alkaline batteries. Do NOT use lithium, nickel cadmium (NiCad), nickel hydride (NiMH), carbon zinc (heavy duty), or rechargeable batteries. They will not power the Receiver properly and the Receiver will not show the correct remaining battery life.

NOTE: To avoid draining the batteries, be careful not to accidentally press and hold the Receiver's buttons for a long period of time. When changing batteries, be sure to finish within 10 minutes to preserve your date/time settings.

Battery life may be shorter than 90 days if your Receiver's alarms are set to vibrate (see page 112), if you use backlighting frequently, or if the Transmitter/Receiver connection is broken often. If you will not be using your Receiver for an extended period of time, you can unlink it from the Transmitter (see page 92) or remove the batteries from the Receiver to preserve their life.

IMPORTANT: An alarm will sound and a Battery Icon will appear on the screen when your Receiver batteries are running low. This alarm means you have approximately 1 week of battery power remaining. Because you must insert a new Sensor after each battery replacement, you should replace the batteries just before you insert a new Sensor. If your batteries are low and you fail to replace them, they may run out and the Receiver will not display your glucose levels or sound alarms.

Turning the Receiver Display Screen On

To turn the Receiver display screen on, press the *Right Option Button* (see below).



The Receiver display screen automatically turns off after 12 seconds to save battery power. You cannot turn the screen off manually. In addition, the Receiver cannot be turned off because it runs continuously (unless you remove the batteries).

The Receiver has a backlight that can be used to light up the screen (for use in the dark). Once the backlight is turned on, it will stay on as long as the display screen is in use. It will turn off automatically when the screen goes blank after 12 seconds of no activity.

To turn the Receiver display screen on with backlighting:

1. Press the *Down Arrow Button* (see below).
2. Then press the *Right Option Button* (see below). The Receiver will turn on with the backlight illuminated.

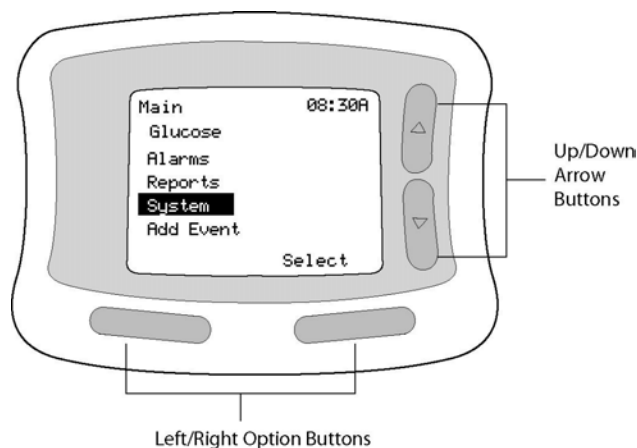


Setting the Date and Time

You must set the correct date and time when you first install new batteries, and to adjust for Daylight Savings Time. When changing your batteries, be sure to finish within 10 minutes to preserve your date/time settings.

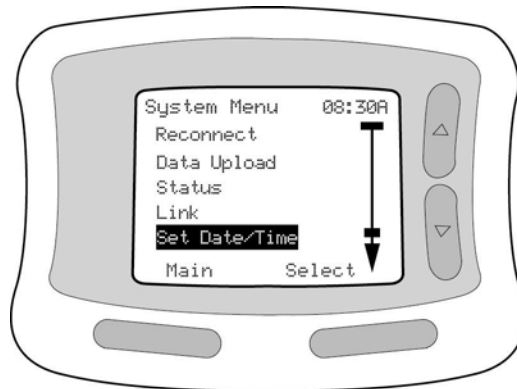
To set the date and time:

1. Press the *Right Option Button* once to turn the Receiver on. Press it again to see the *Main Menu*.

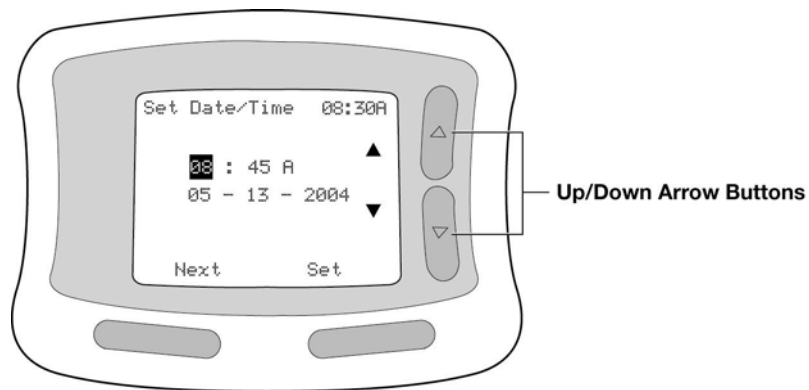


3. Use the *Up/Down Arrow Buttons* to highlight **System**. Press the *Right Option Button* to **Select**.

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- Use the *Up/Down Arrow Buttons* to highlight **Set Date/Time**. Press the *Right Option Button* to **Select** (see below).



- Press the *Left Option Button* to move from one field to the next.
- Use the *Up/Down Arrow Buttons* to increase or decrease the numbers (see below).



- When you are done, press the *Right Option Button* to **Set** the date and time. Press the *Left Option Button* to return to the *Main Menu* (or wait 12 seconds and the display screen will automatically turn off).

NOTE: If you make a mistake or want to exit from the *Set Date/Time* screen, simply leave the Receiver alone for 12 seconds. It will automatically turn off, and any changes you made will be cancelled or cleared.

IMPORTANT: Be sure to set the date and time correctly. The accuracy of Line Graph and Statistical Reports depends on accurate date/time settings.

Performing a Control Solution Test

FreeStyle Control Solution is a red liquid that contains a fixed amount of glucose and can be used:

- To ensure that your Receiver and Test Strips are working properly prior to calibration or blood glucose testing.
- To check that you are following the correct testing procedure.
- To practice Blood Glucose Mode testing without having to use your own blood.

The best way to check your Receiver is to perform a test using FreeStyle Control Solution. A Control Solution test follows the same procedure as a blood glucose test, except that you use a sample of Control Solution instead of a drop of blood. If the Receiver reading is within the Control Solution acceptable range, the Receiver is working properly.

You'll want to perform a Control Solution test:

- When you first get your Receiver, before performing a calibration.
- When you open and begin using a new vial of Test Strips.
- When you suspect that your Receiver or Test Strips are not working properly.
- When you think your glucose test results are not accurate, or if your test results are not consistent with how you feel.

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- When your Receiver is dropped, damaged, or exposed to liquids.
 - When your healthcare team advises you to do so.

CAUTION: Do NOT use FreeStyle Control Solution for calibration.

FreeStyle Control Solution is good for 3 months after opening the bottle, or until the expiration date printed on the label, whichever comes first. Count forward 3 months from the date you open a new bottle of Control Solution. This is your discard date. Write this date on the side of the Control Solution bottle. For example, if you open the Control Solution on January 15th, count forward 3 months to April 15th. This is the discard date that you record on the bottle.

Ensuring accurate Control Solution results:

- Use only FreeStyle Control Solution with your Test Strips. The use of other brands of Control Solution may produce inaccurate results.
- Replace the cap on the Control Solution bottle immediately after using.
- Do NOT use Control Solution past the expiration date or you may get inaccurate results.
- Do NOT add water or any liquid to Control Solution.
- Control Solution tests are specified to be accurate only when performed between 59° and 104°F (15° and 40°C).

CAUTION: Results from Control Solution tests do NOT reflect your blood glucose level.

The Control Solution test results should fall within the range printed on the Test Strip vial label. If Control Solution test results are out of this range, **repeat the test**. Out-of-range Control Solution test results may be caused by:

- Expired or bad Control Solution.
- Expired or bad Test Strips.

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- Error in performing test.
 - Watered-down Control Solution.
 - Code on Test Strip vial does not match code set in Receiver.
 - Receiver malfunction.
 - Control Solution test done outside 59° to 104°F (15° to 40°C).

IMPORTANT: The Control Solution range is a target range for Control Solution only. It is NOT a target range for your blood glucose levels.

If your Control Solution test results continue to fall outside the range printed on the Test Strip vial, the Receiver may not be working properly. Do NOT use the System to test your glucose levels. Call the Clinical Trial Support Line at **1-888-971-4766**.

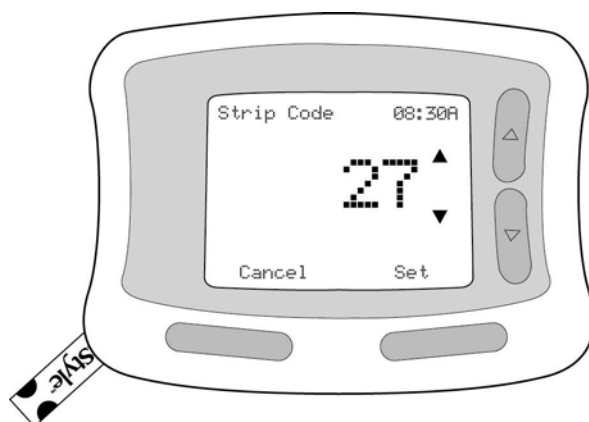
Important Test Strip Information:

- The System has an operating range of 40 to 104 F (5 to 40 C).
- Use the Test Strips only within the System operating temperature range.
- Store the Test Strip package in a cool, dry place between 37 to 86F (3 to 30 C).
- Keep Test Strip package away from direct sunlight and heat.
- Store your Test Strips in their original vial only; never transfer them to another vial or any other container or carrying case.
- Never store individual Test Strips outside the vial.
- After removing a Test Strip from the vial, immediately replace the vial cap and close tightly.
- With clean, dry hands, you may gently touch the Test Strip anywhere when removing it from the vial or inserting it into the Receiver.
- Do NOT use Test Strips beyond the expiration date printed on the package as this may cause inaccurate results.
- Do not bend, cut, or alter Test Strips in any way.

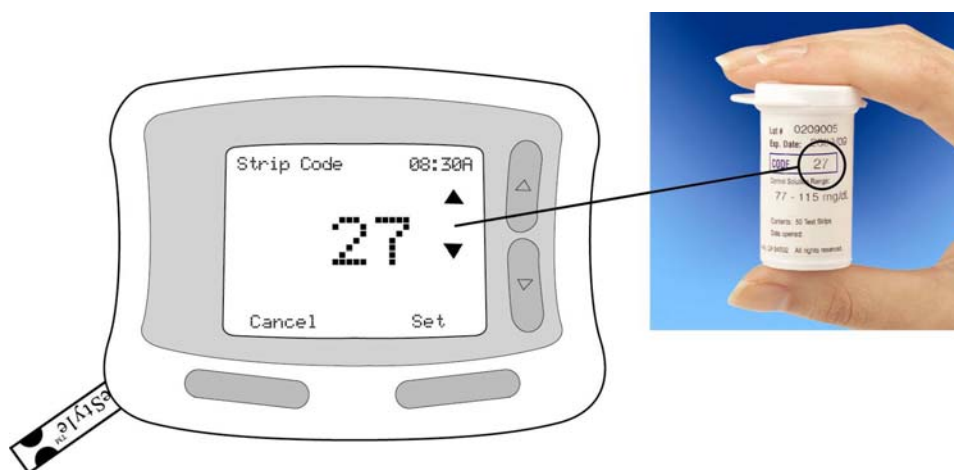
For detailed storage and usage information, refer to the FreeStyle Test Strip package insert.

To perform a Control Solution test:

1. Insert only the **top** end of the Test Strip into the Receiver (with the dark-colored rectangle going into the Receiver; see below). Grasp the bottom of the Test Strip with the name “FreeStyle” on the Test Strip facing up. Insert the top of the Test Strip into your Receiver until it stops. This will turn on the Receiver. (See above Table for important Test Strip information.)

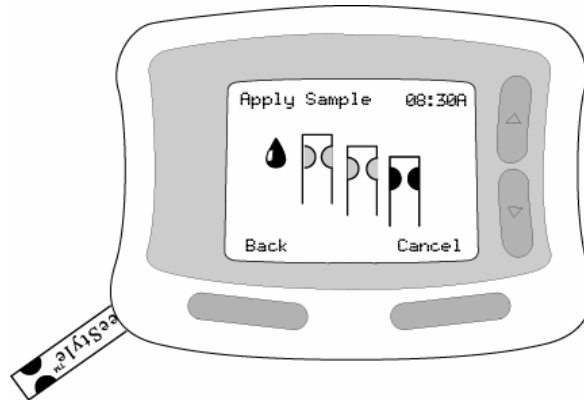


2. The code number on the Receiver display screen should match the code number on the side of your Test Strip vial (see below). They must always match or your results will be inaccurate. If the code numbers match, press the *Right Option Button* to select **Set**. If the code numbers do not match, use the *Up/Down Arrow Buttons* to change the code. Once the code on the screen matches the code on the Test Strip vial, press the *Right Option Button* to select **Set**.



NOTE: If you do not change or set the Test Strip code number within 3 seconds, the Receiver automatically moves on to the next step and will accept a Control Solution using the existing Test Strip code number. If you need to change the Test Strip code number, press the *Left Option Button* to go **Back** to the previous screen, or simply remove the Test Strip and reinsert it. Then carefully select the correct Test Strip code number as described in Step 2.

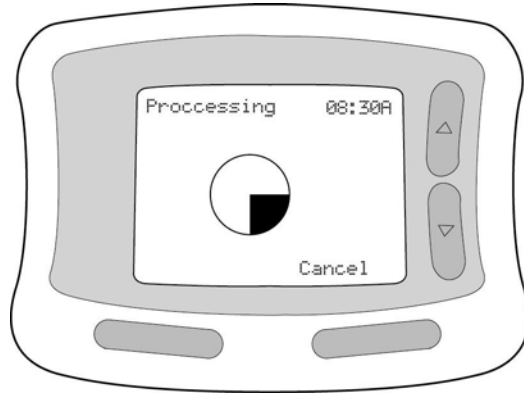
3. The Receiver will prompt you to **Apply Sample** (see below).



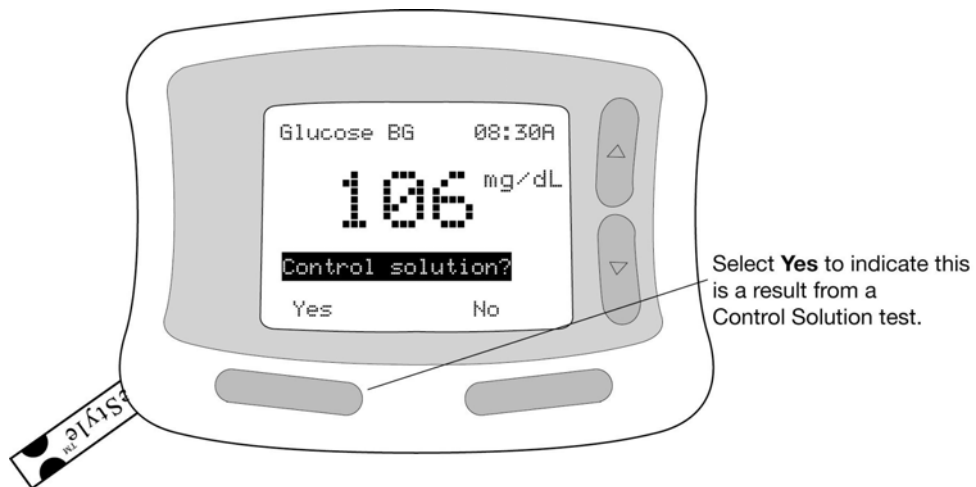
4. Gently touch only **one edge** of the Test Strip to the Control Solution. Specifically, apply the Control Solution to the Test Strip edge next to one of the dark-colored half-circles. If Progress Tones are turned on (see page 111), the Receiver will beep once to indicate that enough Control Solution was applied.

IMPORTANT: Do NOT apply Control Solution to both edges of the Test Strip.

-
5. A stopwatch will appear on the Display Screen while the Receiver is measuring the Control Solution glucose level (see below). The Receiver will beep twice when the Control Solution test result appears.



6. The Receiver will ask you if the result is from a Control Solution test. Select **Yes** by pressing the *Left Option Button* (see below). If you do not select **Yes**, the System will record the result *not* as a Control Solution result but as a blood glucose result.



-
7. Compare your Control Solution test result to the range printed on your Test Strip vial label (see below). Your Control Solution result should fall within the range printed on the side of your Test Strip vial. If your test result does not fall within the range, repeat the Control Solution test with a new Test Strip.



8. Remove and discard the Test Strip. (Test Strips may be used only once.)
9. Clean the Receiver after any Control Solution test (see page 141).

You are now ready to insert the Sensor.

The Sensor

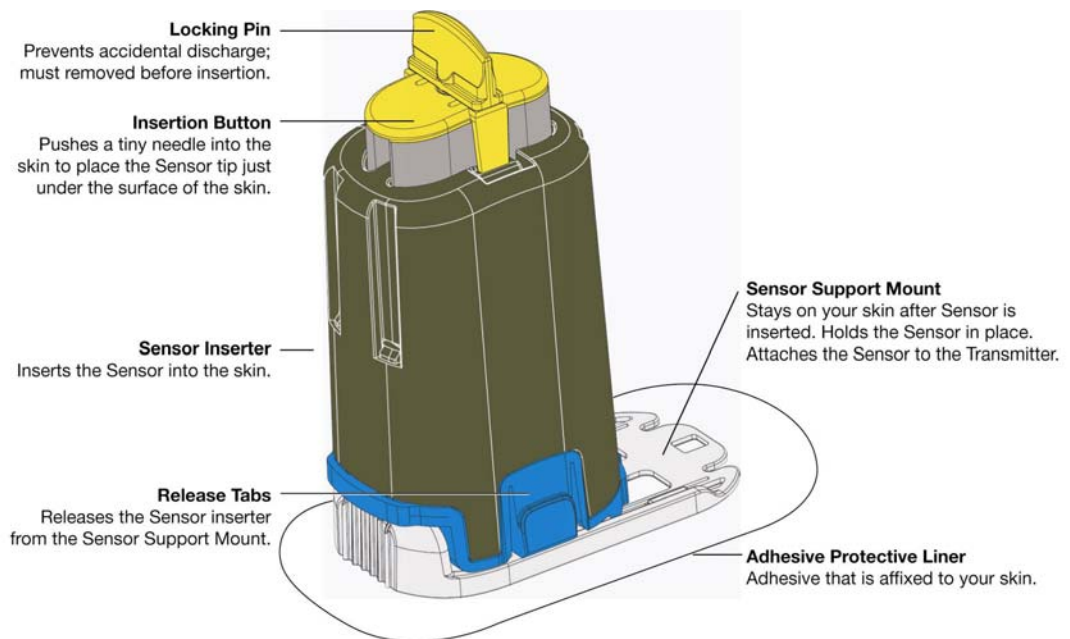
The Sensor

To measure glucose levels, you must insert the tip of a small thin plastic FreeStyle Navigator™ Sensor (see below) under your skin. The Sensor Delivery Unit (see below) is designed and packaged to enable safe insertion of the sterile electrochemical glucose Sensor into your skin. Each inserted Sensor is intended to remain in place and provide a continuous glucose reading for up to 3 days. The Sensor Delivery Unit has 2 parts packaged together: the Sensor Inserter with pre-installed Sensor (which puts the tip of the Sensor under your skin) and the Sensor Support Mount (which stays on your skin to hold the Sensor in place and also attaches the Sensor to the Transmitter; see below).

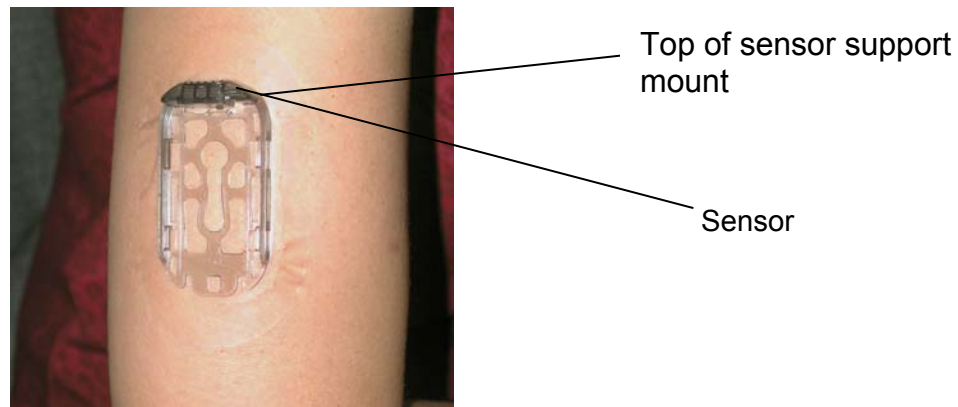
The Sensor



The Sensor Delivery Unit



The Sensor Support Mount



The Sensor Inserter is a plastic-cased device that is cylindrical-shaped. A pre-cocked, coiled spring is connected to a needle, used to guide the Sensor for insertion. With a single push of the Insertion Button, the needle guides the Sensor into the skin and is quickly withdrawn from the skin. The Locking Pin is designed to avoid accidental discharge of the Sensor Inserter. Do not remove the Locking Pin until the Sensor Support Mount is adhered to the skin.

The Sensor Support Mount is designed to stay on your skin to hold the Sensor in place and attach the Sensor to the Transmitter. The blue Release Tabs release the inserter from the Support Mount after the Sensor is inserted into the skin. The Adhesive Protective Liner surrounding the Sensor Support Mount is designed to hold the Support Mount and Transmitter onto the body for up to 3 days of normal use.

When to Insert the Sensor

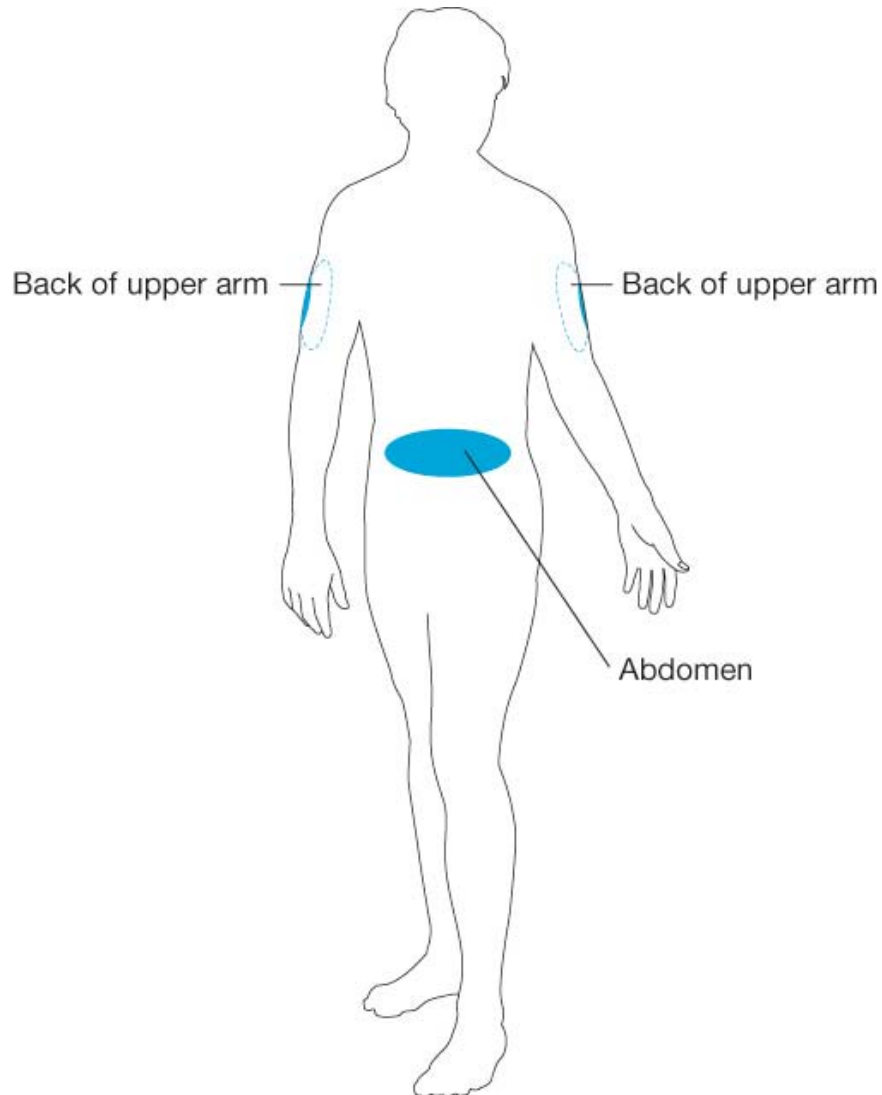
It's best to insert the Sensor when your glucose levels are stable, because you will not have continuous monitoring data during the hour after insertion and you will not be able to calibrate the System if your glucose levels are changing rapidly. If you eat before you are due to calibrate, you may not be able to perform the calibration until your glucose levels stabilize. In addition, because you will need to calibrate at approximately 1, 3, and 24 hours after Sensor insertion, it is best not to insert the Sensor just before you go to bed.

What You'll Need to Insert the Sensor

- Soap and water
- IV Prep wipes
- Sensor Delivery Unit (in its unopened package)
- Transmitter (reusable)
- Receiver (reusable)

Selecting the Insertion Site

Wear the Sensor and Transmitter only on your abdomen or the back of your upper arm (see below).



NOTE: Avoid areas where the edges of clothing may catch or rub against the Sensor. Do NOT insert the Sensor in the same place it was just inserted. Avoid areas with scars, stretch marks, or lumps. Select an area of skin that stays flat during your normal daily activities (no bending or creasing). Avoid areas with excess hair, or consider shaving the area. Insertion of a Sensor on the abdomen or back of upper arm are the only sites studied in clinical trials.

CAUTION: You cannot rely on obtaining glucose results if the Sensor Support adhesive Mount fails to adhere to the skin because of improper site selection.

Preparing the Insertion Site

1. Wash your hands thoroughly with soap and water.
2. Clean the selected area with soap and water. Be sure to rinse and pat the area dry.
3. After the area is dry, you may also wipe the area with an IV Prep wipe to promote adhesion.

NOTE: The insertion area must be clean and dry. If the area is not clean, an infection may occur. If the area is not dry, the Sensor Support Mount adhesive may not stick.

Inserting the Sensor

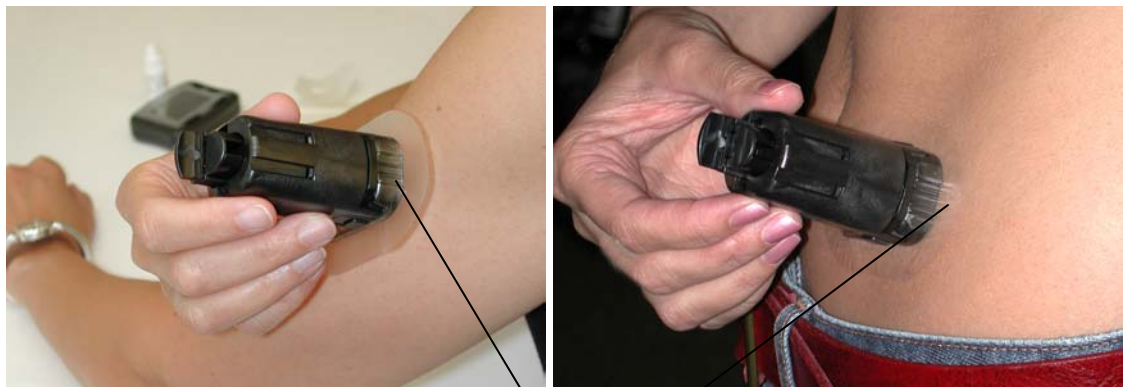
1. Remove the Sensor Delivery Unit from its sterile package. **Save this package; it contains the Sensor code number.** Later, you will need to enter this code number into the Receiver.

NOTE: Do NOT use the Sensor Delivery Unit if the sterile package has been opened or otherwise damaged.

-
2. Remove the adhesive protective liner from the bottom of the Sensor Support Mount. The adhesive protective liner has two sections. Bend it slightly so you can see the seam. Peel away the smaller section first. Then remove the larger section (see below).



3. Place the Sensor Support Mount, adhesive side down, on the cleaned area of skin at the insertion site (see below). If inserting the Sensor on the back of your arm, place the Sensor Support Mount lengthwise down your arm with the top of the Sensor Support Mount facing up. Having the top of the Sensor Support Mount facing up will allow fluids to drain away from the Sensor Contact Points (for example, when you bathe). If inserting the Sensor on your abdomen, position the Sensor Support Mount horizontally. The top of the Sensor Support Mount **MUST** be pointing to your *left* to allow fluids to drain away from the Sensor Contact Points.



Top of Sensor Support Mount

-
4. Smooth the adhesive pad against your skin with your fingers. Hold it firmly in place to make sure it sticks to the skin.

NOTE: Do NOT place a bandage under the Sensor. If you use a bandage, the Sensor may not penetrate the skin and the System will not work.

5. Remove the Locking Pin by using your thumb and index finger to twist it a quarter turn (see below). Pull it away to remove. The Sensor Support Mount adhesive will help to keep the Sensor Support Mount in place.



6. Press the button on the top of the Sensor Inserter (see below). You will feel a slight pinch as the Sensor is placed just under your skin.

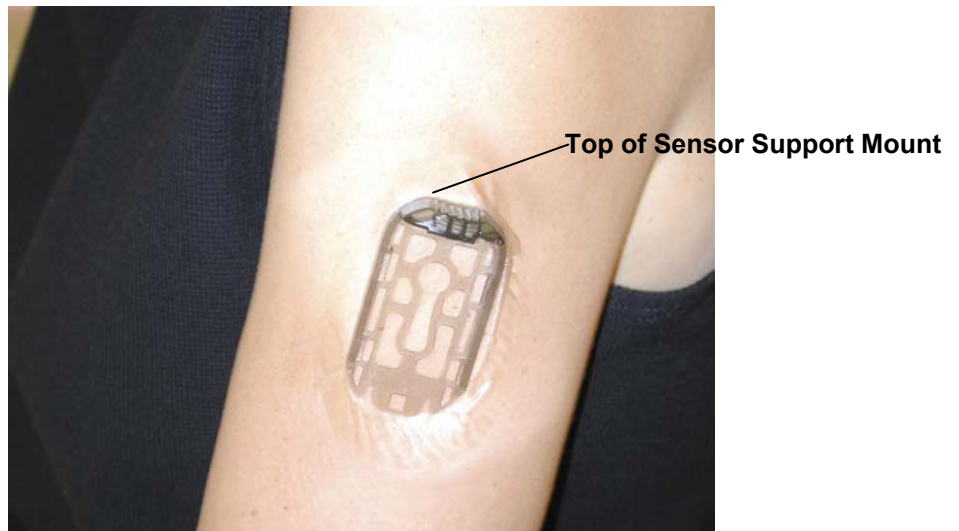


CAUTION: Once the Locking Pin has been removed and the button is pressed, a needle will quickly go just under your skin to place the Sensor. **Do NOT press the button until you are ready to insert the Sensor.**

7. Hold the Sensor Inserter and firmly squeeze the two blue Release Tabs at its base (see below). Lift the Sensor Inserter straight up and away from the Sensor Support Mount. Make sure the Sensor Support Mount remains on your skin.



8. Check that the Sensor has been properly placed (see below). On your abdomen, the top of the mount should always point to your left. The Sensor should be visible, with its tip inserted into your skin. A small drop of blood may be visible.



NOTE: If there is more than a small drop of blood at the Sensor insertion site, it may interfere with the Transmitter connection and you will not receive continuous glucose

readings. If the drop of blood is larger than the example shown below, remove the Sensor, clean the site, and cover with a bandage. Select a new Sensor insertion site and insert a fresh Sensor.

Example: 

9. Discard the Sensor Inserter in a sharps container or other puncture-proof container with a lid.

When to Change the Sensor

The Sensor MUST be changed at least every 3 days. You should change your Sensor if you notice ANY irritation or discomfort at the Sensor insertion site, or if the Receiver reports a problem with the inserted Sensor. Taking action at the first sign of irritation or discomfort will keep small issues from turning into larger or ongoing ones.

It is recommended that you do not change your Sensor at the same time you change your insulin pump infusion set, as you will not get continuous glucose readings for at least 1 hour after Sensor insertion (until after the first calibration).

Site Rotation

To prevent discomfort, irritation, bruising, skin rashes, or sensitivity to adhesives, it is important to rotate across several sites and to insert Sensors only in the abdomen or back of the upper arm. Always change the insertion site each time a new Sensor is used.

Rotating the sites in a predictable pattern may help you remember to rotate them evenly. For example, you may want to start in the upper-right corner of your abdomen, and then move one inch to the left when you insert a new Sensor, continuing in a circular direction. Or, start on the right arm at a high position, move to a low position on the right arm, then repeat on the left arm.

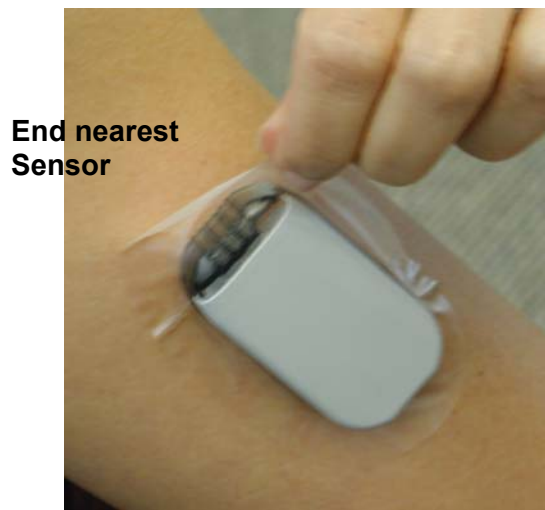
Site Maintenance

Careful site preparation and maintenance can help to lower the risk of infection and improve Sensor adhesion. A number of helpful products are available:

- *Antiseptics*—If you tend to develop infections at the Sensor insertion site, consider prepping the skin with an antiseptic. Ask your healthcare team which antiseptic is best for you.
- *Dressings and Skins*—If you are having trouble with the Sensor Support Mount sticking to your skin, consider applying a bandage over the Transmitter. A variety of such bandages are available at your local pharmacy. Ask your healthcare team which type of bandage is best for you.
- *Adhesive Enhancers*—If you're having trouble getting the Sensor Support Mount to stick to your skin, you may want to try an adhesive enhancer, which will help the adhesive pad on the Sensor Support Mount stick to your skin better. IV Prep wipes are adhesive enhancers included in your Sensor Kit. After applying this type of product, be sure that the Sensor insertion site is thoroughly dry before placing the Sensor Support Mount on your skin. Ask your healthcare team which adhesive enhancer is best for you.
- *Skin Barriers*—If you experience sensitivity to adhesives, there are products that may help prevent irritation or sensitivity by placing a barrier between your skin and the Sensor Support Mount's adhesive pad. These products may also help the adhesive stick better. Be sure to allow the skin to dry thoroughly before inserting the Sensor or applying another tape or dressing. Ask your healthcare team which skin barrier product is best for you.

Removing the Sensor

1. If needed, use an adhesive remover application pad to wipe a small amount of adhesive remover around the edges of the Sensor Support Mount. Or, moisten a cotton ball with adhesive remover and dab it around the edges of the Sensor Support Mount.
2. With the Transmitter still attached to the Sensor Support Mount, grasp the top end of the adhesive and slowly peel it off your skin in one continuous motion (see below).



-
3. Unhook the latch on the bottom of the Transmitter and slide the Transmitter off the Sensor Support Mount (see below). Discard the Sensor Support Mount (with the Sensor attached). The Sensor Support Mount and Sensor cannot be reused. **Do NOT discard the Transmitter.**



4. Gently wash the Transmitter with soap and water (see page 141). Rinse thoroughly. Dry thoroughly with a clean, soft, lint-free cloth.
5. If necessary, use an adhesive remover, baby oil, or a wet, soapy washcloth to remove any adhesive residue left on your skin.

The Transmitter

The Transmitter

The FreeStyle Navigator Transmitter is a small electronic device that makes an electrical connection to the portion of the Sensor that extends above the skin (see below). The Transmitter processes the very low current signals it receives from the Sensor and sends the glucose values to the Receiver once every minute. The Transmitter contains a replaceable battery (silver oxide 357) that is designed to provide one month of service. When you first receive your System, the Transmitter and Receiver will already be linked—that is, the Receiver will be preset to receive glucose information from the specific Transmitter included with your System.

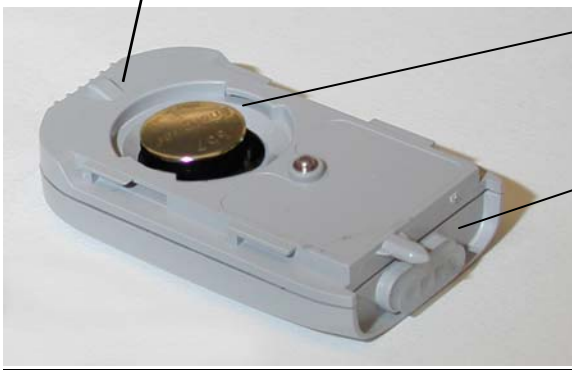
The Transmitter (Front)



Transmitter Tabs—Provide a secure connection to the Sensor Support Mount

The Transmitter (Back)

Sensor Support Mount Latch—Secures the Transmitter to the Sensor Support Mount



Battery

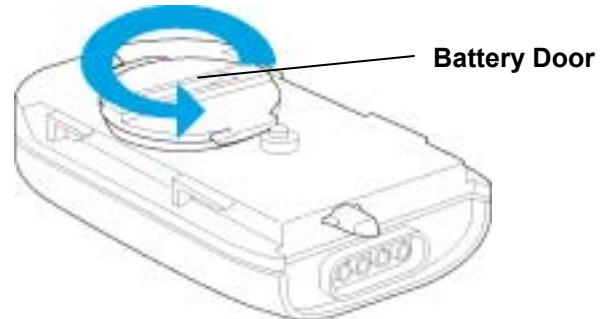
Contact Points—Connect the Transmitter to the Sensor Support Mount.

Installing the Transmitter Battery

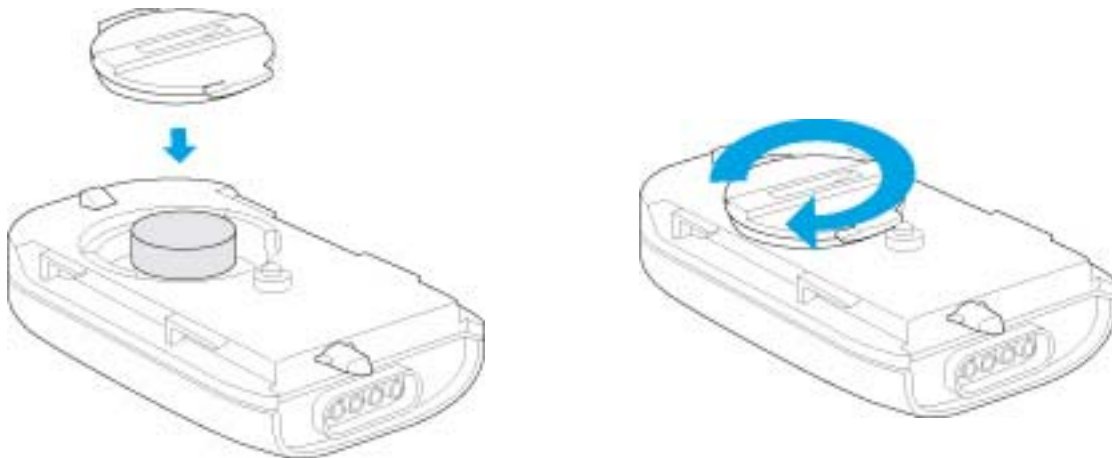
The Transmitter is designed to operate for 30 days with a single silver oxide 357 battery (small coin cell battery).

To insert the Transmitter battery:

1. Using a coin or fingernail, rotate the small circular Battery Door on the back of the Transmitter counterclockwise. Remove the Battery Door carefully.



2. Insert a new silver oxide 357 battery.
3. Replace the Battery Door and rotate clockwise (see below). Be sure the battery door is closed securely to create a seal.

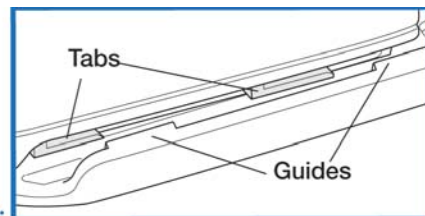


NOTE: When changing the battery, always insert a *new* battery into the Transmitter. If you insert an old battery, the battery life timer will not be accurate and the battery may stop working without warning.

IMPORTANT: The Receiver will sound an alarm and display a "Replace TX Battery with New Sensor" message 4 days before the Transmitter battery needs to be changed. Replace the Transmitter battery just before you insert a new Sensor.

Attaching the Transmitter to the Sensor

1. After the Sensor has been inserted, place the Transmitter partway over the Sensor Support Mount with the front facing away from the Sensor Support Mount.
2. Slide the Transmitter until it clicks into place (see below). The Transmitter Tabs slide into the Sensor Support Mount Guides for a tight connection. Check that there is no space between the Sensor Support Mount and the Transmitter.



NOTE: Because of differences in skin type, exercise, weather, and other factors, adhesion of the Sensor/Transmitter unit may vary. You may want to use an over-bandage in certain conditions (see page 49).

Once the Transmitter is attached to the Sensor, it will begin transmitting data to the Receiver. After entering the Sensor code and performing the first calibration (see next sub-section) you will be receiving continuous glucose readings.

The Receiver: Calibration and the Blood Glucose Mode

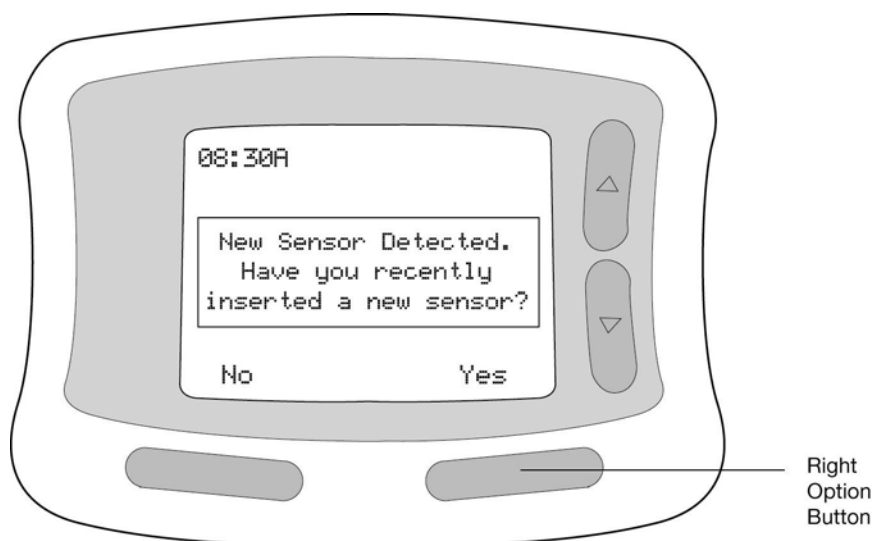
The Receiver: Calibration and the Blood Glucose Mode

Once you insert the Sensor and attach the Transmitter, you need to complete just 2 more steps before beginning to receive continuous glucose readings: 1) enter the Sensor code into the Receiver and 2) calibrate the Receiver.

Entering the Sensor Code Into the Receiver

1. Within 2 minutes of attaching the Transmitter to the Sensor, the Receiver will beep once to let you know that it recognizes a new Sensor. Press the *Right Option Button* once to turn the Receiver display on. The following message will appear on the screen: "New Sensor Detected. Have you recently inserted a new Sensor?" (see below). Select **Yes** by pressing the *Right Option Button*.

NOTE: If at any time you get this message and you have not just connected a Transmitter to a newly inserted Sensor, select **No**. You may get this message, for example, during the cleaning of the Transmitter or if the Transmitter is bumped while connected to the Sensor.

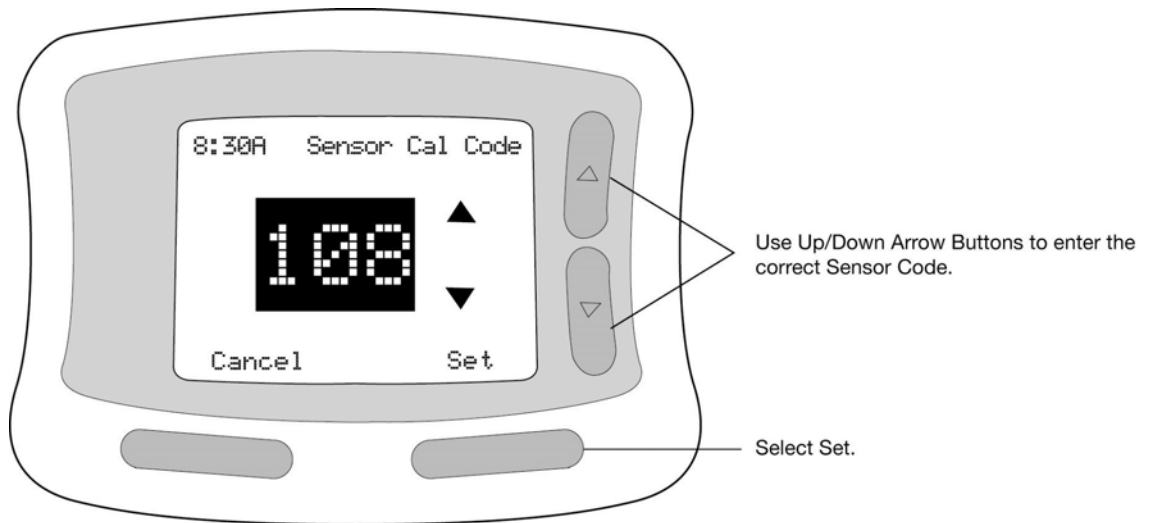


- The Receiver will ask you to select the Sensor code number (see below).

Sensor Code — **Code 106**

Continuous Glucose Monitoring System
Sterile Sensor Delivery System
PRT04873-001 **Single Use**
LOT 0419543 **Exp. 2005/01**
E-Beam
S/N
TheraSense, Inc
Alameda, CA 94502
CAUTION: INVESTIGATIONAL DEVICE. LIMITED BY FEDERAL (OR
UNITED STATES) LAW TO INVESTIGATIONAL USE.

- Use the *Up/Down Arrow Buttons* to change the number on the Receiver Screen to match the number on the packaging (see below). Press the *Right Option Button* to **Set**.



Calibrating the Receiver and Using the Blood Glucose Mode

Your last step in setting up the System is to calibrate the Receiver. You do this by measuring the glucose level in a drop of capillary blood using the Blood Glucose Mode. The Receiver compares the reading it gets from the capillary blood to the reading the Sensor takes from the interstitial fluid (where glucose levels are measured in the Continuous Monitoring Mode). The Receiver can then calculate accurate, real-time glucose readings.

When to Calibrate

Blood glucose testing is required for calibration each time you insert a new Sensor. You will be prompted to perform a blood glucose test approximately 1, 3, and 24 hours after Sensor insertion.

NOTE: You must perform all 3 calibration tests. If you do not complete all 3 calibration tests in the allowed time periods, your glucose readings will not be displayed, and alarms will be inactive. See Table 2.1 for details regarding each calibration test. If a calibration failure occurs, see Table 7.2 on page 152 for detailed instructions.

IMPORTANT: Your blood glucose level must be between 60 and 400 mg/dL (3.3 and 22.2 mmol/L) to be able to perform calibration tests. If your blood glucose level is outside this range or if it is changing rapidly, the System will not be calibrated, continuous glucose readings will not be available, and alarms will not function. Under such conditions, the System may not ask you to calibrate; instead, it will delay its request until conditions are acceptable.

Table 2.1: Calibration Test Details

Calibration	When to Perform	What Happens if Calibration is Missed	What to do if Calibration is Missed
First Calibration	<p>Approximately 1 hour after Sensor insertion.</p> <p>An alarm will sound and the Receiver display screen will show “Do BG Test”. A blood drop icon will also appear.</p>	<p>Continuous glucose levels will not be displayed until this calibration is performed. The Receiver display screen will show “— — —”.</p>	<p>Do the calibration test as soon as possible; continuous glucose levels will then begin to be displayed and alarms will function.</p>
Second Calibration	<p>Between 2 and 4 hours after the first successful calibration (approximately 3 to 5 hours after Sensor insertion).</p> <p>An alarm will sound and the Receiver display screen will show “Do BG Test”. A blood drop icon will also appear.</p>	<p>Continuous glucose levels will no longer be displayed and alarms will not function. The Receiver display screen will show “Do BG Test— Alarms Inactive”.</p>	<p>Do the calibration test as soon as possible (even if more than 4 hours have passed); continuous glucose levels will then be displayed and alarms will resume.</p>
Third Calibration	<p>Between 21 and 29 hours after the second calibration (approximately 24 to 32 hours after Sensor insertion).</p> <p>An alarm will sound and the Receiver display screen will show “Do BG Test”. A blood drop icon will also appear.</p>	<p>Continuous glucose levels will no longer be displayed and alarms will not function. The Receiver display screen will show “Do BG Test— Alarms Inactive”.</p>	<p>Do the calibration test as soon as possible (even if more than 29 hours have passed); continuous glucose levels will then be displayed and alarms will resume.</p>

NOTE: During the first hour after the Sensor is inserted, or until you successfully complete your first calibration, the Receiver does NOT calculate glucose levels. During this time, you can perform glucose tests in the Blood Glucose Mode if needed. The Blood Glucose Mode testing can be done at any time.

Here is a sample calibration schedule:

Day 1

8:00 AM: Insert new Sensor.

9:00 AM: Perform First Calibration (1 hour after insertion).

11:00 AM: Perform Second Calibration (2 hours after first successful calibration).

Day 2

8:00 AM: Perform Third Calibration (21 hours after second successful calibration).

Supplies Needed for Calibration

Before performing a blood glucose test for calibration, be sure you have the following materials nearby:

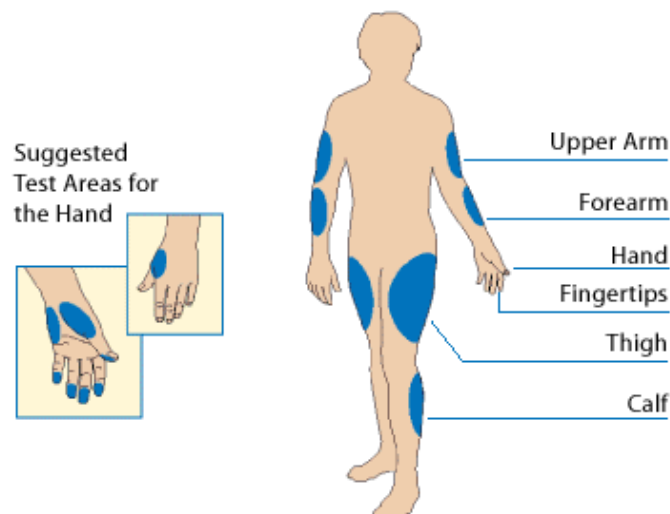
- Soap, water, towel
- FreeStyle lancing device
- Sterile lancets
- FreeStyle Test Strip
- Receiver
- Sharps container or other puncture-proof container with lid

Switching to the Blood Glucose Mode

To switch to the Blood Glucose Mode for blood glucose testing for calibration or other purposes, simply insert a FreeStyle Test Strip into the Test Strip Port. You will know you are in the Blood Glucose Mode because the Display Screen will show Glucose **BG** in the upper left corner (not Glucose **CM**). To switch back to the Continuous Monitoring Mode, remove the Test Strip. Or, if you do not touch any buttons on the Receiver for 12 seconds, the screen will go blank, and when you turn the Receiver on, you will be back in the Continuous Monitoring Mode.

Blood Glucose Testing Sites

To calibrate the System, only use a blood sample from your finger or forearm. You can use a blood sample taken from a number of different areas on your body to check your blood glucose levels in the Blood Glucose Mode. You may take a blood sample from your forearm, upper arm, hand, thigh, or calf, as well as from your fingers or your palm at the base of your thumb (see below). When blood glucose is changing rapidly, blood from the fingertips or palm may show these changes sooner than blood from other sites. When selecting a site, be sure to avoid moles, veins, bones, and tendons.

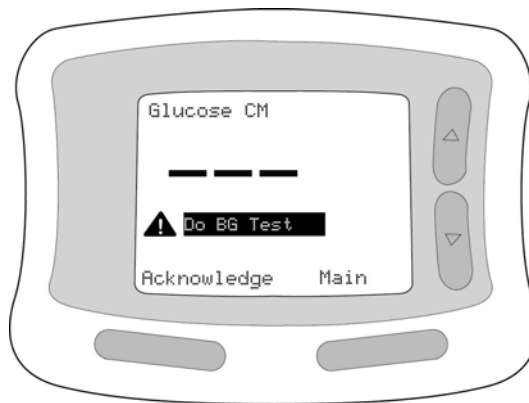


CAUTION: It is recommended that you test on your fingers or palm at the base of your thumb if you are testing for hypoglycemia or if you suffer from hypoglycemia unawareness (see page 6).

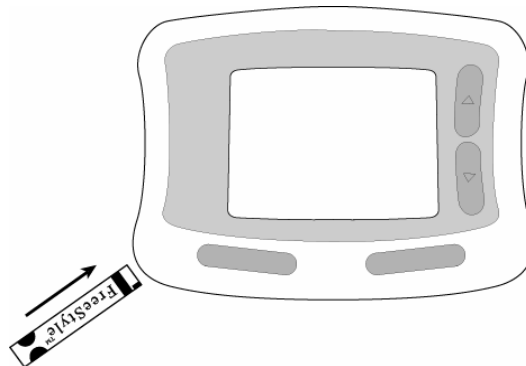
Calibrating

Follow these steps to calibrate the System:

1. Approximately 1, 3, and 24 hours after you insert a Sensor, the Receiver will alarm and prompt you to **Do BG Test** (see below).



2. Insert a FreeStyle Test Strip into the Receiver's Test Strip Port (see below). Insert the end with the dark rectangle. Push until the Test Strip stops.

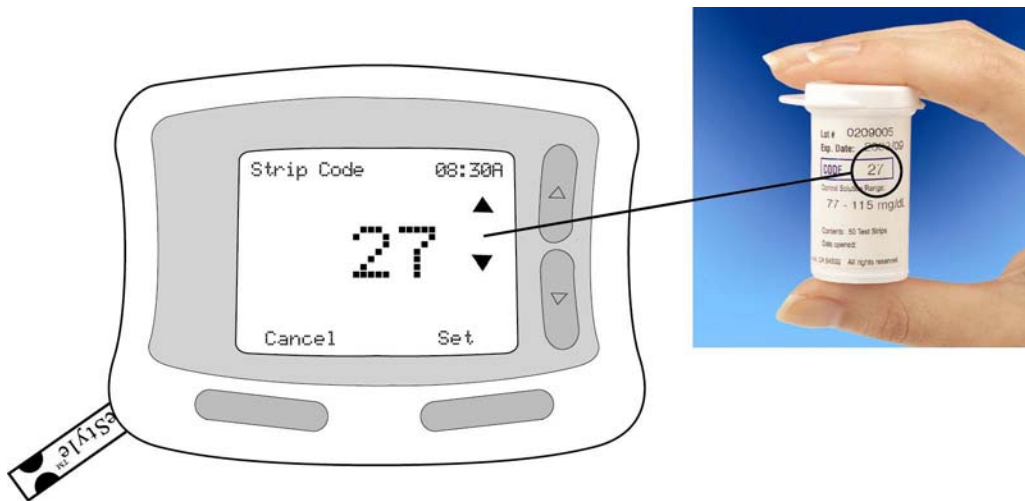


NOTE: If you do not start the test within 2 minutes of inserting the Test Strip, the Receiver will display an "Er4" message. To start the test again, simply remove the old Test Strip and insert an unused Test Strip.

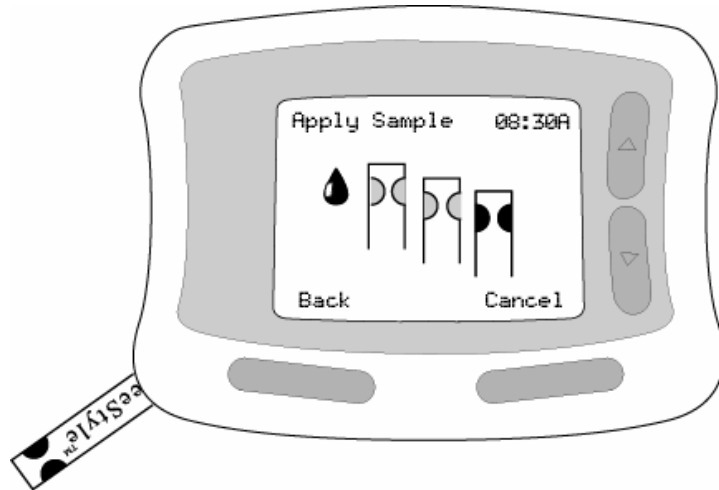
-
3. Once the Test Strip is inserted, the Receiver will automatically display the most recently used Test Strip code number. Compare the code number on the Screen to the code number on the Test Strip vial. If the code numbers match, press the *Right Option Button* to select **Set**. If the code numbers do not match, use the *Up/Down Arrow Buttons* to change the code, and, once the code on the screen matches the code on the Test Strip vial, press the *Right Option Button* to select **Set**.

NOTE: If you do not change or set the Test Strip code number within 3 seconds, the Receiver will accept a blood sample using the existing Test Strip code number and automatically move on to the next step. If you need to change the Test Strip code number, press the *Left Option Button* to go **Back** to the previous screen, or simply remove the Test Strip and reinsert it. Then carefully select the correct Test Strip code number as described in Step 3.

NOTE: To ensure accurate test results, **MAKE SURE** the code number on the Receiver matches the code number on the Test Strip vial.



-
4. The Receiver will prompt you to **Apply Sample** (see below).



5. Lance the test site to get a blood sample. The lancing device, which is included as part of the System kit, is pictured below.

Lancing Device



To use the lancing device

I. Wash your hands and the selected test site with soap and water. Make sure there is no lotion on the test site. Thoroughly dry your hands and the test site.



II. Snap the clear cap off the lancing device.

III. Insert a new FreeStyle lancet firmly into the white lancet cup holder. Pushing the lancet into the cup may cock the device; this is OK.



IMPORTANT: Use a new sterile lancet for every test. Never use a lancet for more than one person.

IV. Hold the lancet firmly in place with one hand and use your other hand to twist off the rounded top.



V. Replace the cap until it snaps or clicks into place. Be careful not to touch the exposed needle on the lancet.



IMPORTANT: Use the grey cap for finger tests. Lancing with the clear cap may be completed at the following sites: forearm, upper arm, hand, thigh, and calf.

VI. The lancing device offers 4 different depth settings. Move the dial to the desired setting as shown in the depth indicator window. Level 1 is the shallowest depth; level 4 is the deepest. To lance parts of the body other than the finger, start at level 2 and use the clear cap. To lance your finger, set the depth setting to its shallowest depth (1) and use the grey cap.



VII. Pull the dark grey Cocking Handle out until it clicks. You may have already cocked the device in Step III; this is OK.




VIII. To lance your forearm, upper arm, hand, thigh, or calf:
a. Bring fresh blood to the surface by rubbing the test site vigorously for a few seconds until you feel it getting warm.




b. Hold the clear cap down against the top of your test site. Depress the release button. Do not lift up.



c. Continue to hold the lancing device and gradually increase pressure for several seconds. While holding the lancing device on your test site, look through the clear cap; the blood sample should be about the size of a pinhead (example: ).

d. Lift the lancing device straight up; be careful not to smear the blood sample on your test site.

To lance your finger:

- a. Stimulate blood flow by keeping your hand warm or by lowering your hand to waist level and by gently massaging your finger.
- b. Lightly touch the lancing device (with the grey cap) against the side of your fingertip.
- c. Press the release button, and then place the lancing device on to the table or desk near you. Gently squeeze your finger, if needed, until a blood drop the size of a pinhead forms (example: ).

IX. When you have finished testing, snap off the cap from the lancing device. Hold the lancet over a sharps container or other puncture-proof container with a lid. Pinch the white clip that holds the lancet until the lancet falls out.



-
6. With the Test Strip in the Receiver, apply blood to the Test Strip by bringing the edge of the Test Strip to the blood sample at a slight angle and by gently touching the Test Strip—at the half-circle, and at a slight angle—to the blood sample (see below). Blood will be absorbed into the Test Strip.



When Using FreeStyle Test Strips:

- Do NOT press the Test Strip down hard against the test site.
- Do NOT scrape the blood.
- Do NOT apply blood to the flat side of the Test Strip.
- Do NOT apply blood to the Test Strip when the Test Strip is out of the Receiver.
- Do NOT apply blood to both edges of the Test Strip.
- Do NOT put blood or foreign objects into the Receiver's Test Strip Port.

IMPORTANT: Test Strips may be used only once. Discard used Test Strips.

7. A Stopwatch Icon will appear while the Receiver is measuring the blood glucose level. If Progress Tones are turned on (see page 111), the Receiver will beep once to let you know enough blood was used. The Receiver will beep twice when the blood glucose result appears. Blood glucose levels take about 7 seconds to calculate. The higher the blood glucose level, the longer the calculation time.

NOTE: If after 5 seconds you don't see the Stopwatch Icon on the Receiver display screen, the blood sample may be too small. You can continue to add blood to the Test Strip for up to 60 seconds as long as you apply blood to the same edge of the Test Strip.

Low and High Glucose Results

The Receiver displays results from 20 to 500 mg/dL (1.1 to 27.8 mmol/L).

CAUTION: Low or high glucose measurements can indicate a potentially serious medical condition.

LO Readings

If your test result is below 20 mg/dL (1.1 mmol/L), "LO" appears on the Receiver display screen. This indicates that you may be experiencing severe hypoglycemia (low blood glucose levels).

- If you get a "LO" reading and have symptoms such as weakness, sweating, nervousness, headache, or confusion, follow your healthcare team's recommendations for treating hypoglycemia.
- If you have a "LO" reading but have no low blood glucose level symptoms, retest with a new Test Strip.
- If you still get a "LO" reading with a repeated test, follow your healthcare team's recommendations for treating hypoglycemia.

You may want to check for low blood glucose levels when you:

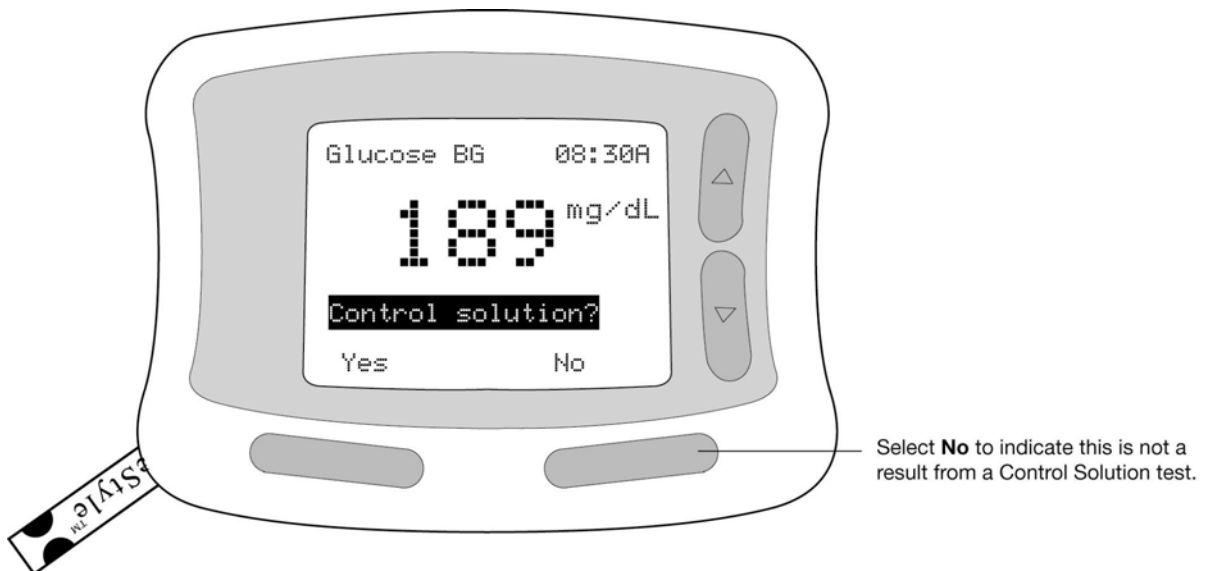
- Are feeling symptoms such as weakness, sweating, nervousness, headache, or confusion.
- Have delayed a meal after taking insulin.
- Have been advised to test by your healthcare team.

HI Readings

If your test result is above 500 mg/dL (27.8 mmol/L), “HI” appears on the Receiver display screen. This reading indicates severe hyperglycemia (high blood glucose levels).

- If you get a “HI” reading and have symptoms such as fatigue, thirst, excess urination, or blurry vision, follow your healthcare team’s recommendations for treating hyperglycemia.
- If you get a “HI” reading but have no high blood glucose level symptoms, retest with a new Test Strip.
- If you still get a “HI” reading with a repeated test, follow your healthcare team’s recommendations for treating hyperglycemia.

8. Once your blood glucose result is displayed, the Receiver will ask if the result is from a Control Solution test (see below). Press the *Right Option Button* to select **No**. (For more information about Control Solution tests, see page 32.) If you ignore this prompt, the System will default to **No**.



9. Remove and discard the Test Strip.

You are now ready to start using your System!

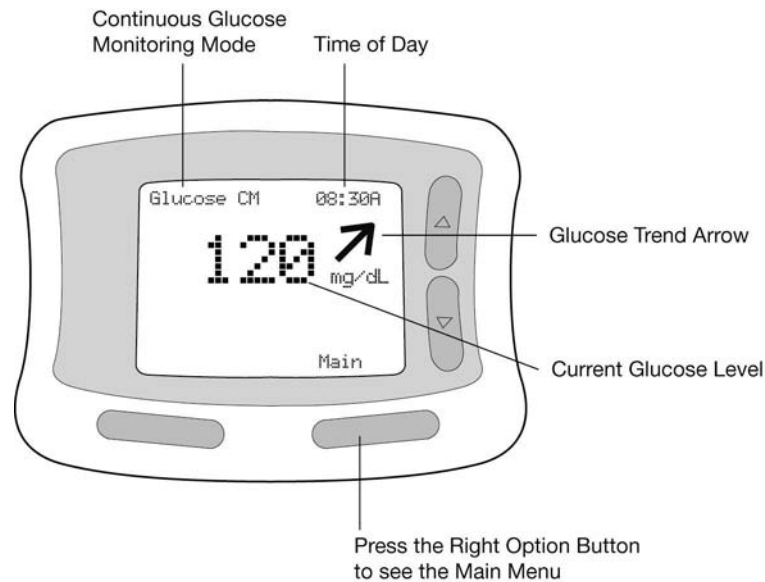
3. USING THE RECEIVER

USING THE RECEIVER

Once you've inserted the Sensor, attached the Transmitter, and calibrated the Receiver (see Section 2), you are ready to start using your FreeStyle Navigator™ Continuous Glucose Monitoring System. This section introduces you to the Receiver's basic functions.






The Glucose (Initial) Display Screen

The first screen you see when you turn your Receiver on displays your current glucose level (updated every minute) and a Glucose Trend Arrow (see below).



Glucose Trend Arrows let you know the direction that your glucose levels are moving—whether they are stable, increasing, or decreasing—and how quickly they are changing. There are 5 types of Glucose Trend Arrows (Table 3.1).

Table 3.1. Glucose Trend Arrows

Glucose Trend Arrow	Description
	Relatively Stable A horizontal Glucose Trend Arrow means your glucose is relatively stable (changing at a rate of less than 60 mg/dL/hr [3.3 mmol/L/hr]).
	Moderate Rise A Glucose Trend Arrow angled upward means your glucose is increasing moderately (at a rate of greater than 60 mg/dL/hr [3.3 mmol/L/hr] but less than 120 mg/dL/hr [6.7 mmol/L/hr]).
	Moderate Fall A Glucose Trend Arrow angled downward means your glucose is decreasing moderately (at a rate of greater than 60 mg/dL/hr [3.3 mmol/L/hr] but less than 120 mg/dL/hr [6.7 mmol/L/hr]).
	Rapid Rise A Glucose Trend Arrow pointing straight up means your glucose is increasing rapidly (at a rate of greater than 120 mg/dL/hr [6.7 mmol/L/hr]).
	Rapid Fall A Glucose Trend Arrow pointing straight down means your glucose is decreasing rapidly (at a rate of more than 120 mg/dL/hr [6.7 mmol/L/hr]).

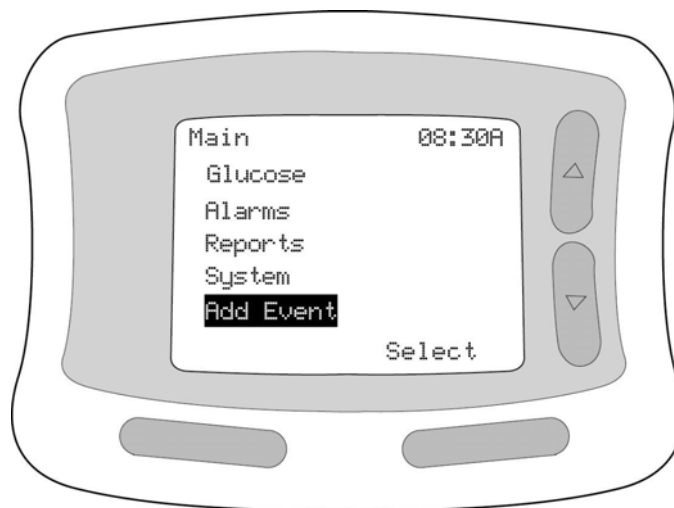
The letters **CM** in the display screen's upper left corner indicate the Receiver is operating in the Continuous Monitoring Mode. This means the glucose reading that you see comes from the Sensor inserted under your skin, not from a drop of blood on a Test Strip.

The current time of day can be seen in the display screen's upper right corner. See page 30 for instructions on how to change the date and time.

NOTE: To save on battery power, the Receiver display screen goes blank after 12 seconds of no activity. To turn the Receiver display screen back on, simply press the *Right Option Button*.

Main Menu

The Receiver's *Main Menu* displays a list of options that allow you to perform many functions and view specific information (see below).



To use the *Main Menu*:

1. Press the *Right Option Button* once to turn the Receiver on.
2. Press the *Right Option Button* again and the *Main Menu* will appear.
3. Use the *Up/Down Arrow Buttons* to find and highlight the option you want.
4. Press the *Right Option Button* to **Select** the option you want and advance to the next screen.

Table 3.2 contains a list of *Main Menu* options; each of these options is explained in detail in Section 5 (page 97).






Table 3.2. Main Menu Options

Main Menu Options	Description
Glucose	Allows you to see your current continuous glucose level and Glucose Trend Arrow.
Alarms	Allows you to set and activate different types of alarms.
Reports	Allows you to view past and current glucose readings and other information in order to evaluate glucose trends and recent therapy decisions (insulin doses, carbohydrate ratio calculations, etc.)
System	Allows you to view the <i>System Menu</i> .
Add Event	Allows you to record the time, date and other information for specific activities and events. Activities and events that you may want to add (or your healthcare team may ask you to add) including insulin doses, meals, exercise, illness, and low blood glucose symptoms.

Icons

Icons (graphic symbols) may appear on the Receiver's Glucose (initial) screen or *Main Menu* screen. These icons alert you to non-urgent system conditions or required actions. Icons are listed in the Table 3.3.

Table 3.3. Icons

Icons	Description
	A stopwatch icon appears when the System is processing a Control Solution or blood glucose sample in the Blood Glucose Mode. This icon goes away when the test result appears.
	A blood drop icon means it is time to do a calibration. Calibration needs to be done approximately 1, 3, and 24 hours after inserting a new Sensor. For more information on calibration, see page 61.
	An hourglass icon appears when the System is waiting. For example, it will appear for the first hour after a new Sensor has been inserted, while the System is waiting to do the first calibration. You don't need to do anything when you see this icon.
	The connection icon appears where there is a problem with the Transmitter/Receiver connection. For more information about maintaining or restoring this connection, see page 88.
	The battery icon means it is time to replace the batteries in the Receiver. New batteries should be installed just before a new Sensor is inserted. For more information on replacing the Receiver batteries, see page 142.

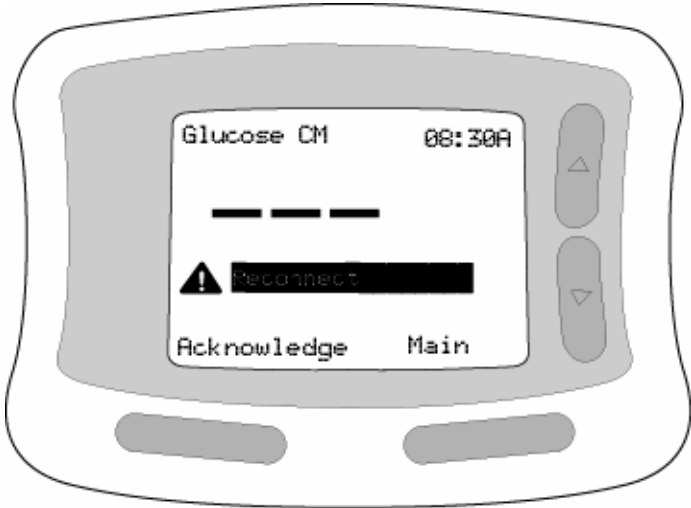
For other information on Receiver options and functions not discussed in the section, see "Getting Started" (Section 2) or "Advanced Features" (Section 5).

4. MAINTAINING THE TRANSMITTER/RECEIVER CONNECTION

MAINTAINING THE TRANSMITTER/RECEIVER CONNECTION

The Transmitter sends glucose measurements to the Receiver once every minute using radio frequency transmission. The Transmitter and Receiver must be within 10 feet of each other to maintain a consistent connection. If the Transmitter is more than 10 feet from the Receiver, the connection may be broken and you will not receive continuous glucose readings. An alarm will sound to remind you to keep the Receiver and the Transmitter within 10 feet of each other (Table 4.1).

Table 4.1. Breaking the Transmitter/Receiver Connection

Amount of Time Connection Has Been Broken	What Will Happen
3 Minutes	The System will no longer show glucose readings and you will not receive glucose alarms.
5 Minutes	<p>The Receiver will sound an alarm. You will also see an alert on the screen (see below).</p> 
8 or More Minutes	The Receiver will sound a more urgent, repeating alarm.

Refer to Table 7.2 on page 152 for more information about connection-specific alarms.

To temporarily silence the alarms without reconnecting, press the *Left Option Button* to **Acknowledge** the alarms.

In addition to distance, there are other factors that can affect the Transmitter/Receiver connection:

- *Receiver Location*—In some cases, where the Receiver is located relative to the Transmitter can affect the connection. For example, having the Transmitter on your abdomen and the Receiver in your back pocket may result in a broken connection.
- *Nearby Objects*—Large metal objects (for example, filing cabinets) and large containers of water (for example, waterbeds) can sometimes interfere with the connection.
- *Interfering Signals*—The System is designed to work in the presence of most electronics (for example, cell phones and computers). Electronics that produce radio frequencies (for example, some computers and computer displays) *may* cause the connection to be broken.

Tips for Maintaining the Connection

Follow these tips to help maintain the Transmitter/Receiver connection:

- Keep the Receiver with you at all times. If you leave it somewhere and walk away, the Transmitter/Receiver connection will be broken.
- When you sleep, place the Receiver on a high headboard or nearby dresser, rather than in bed or clipped to your clothing.
- If a Connection Alarm sounds, adjust the placement of the Transmitter and/or Receiver to restore the connection.

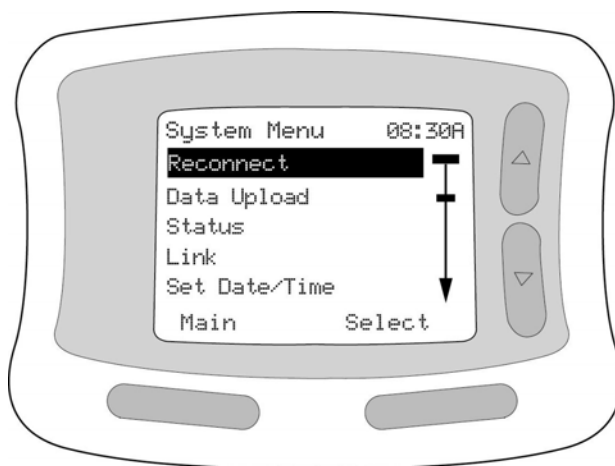
Reconnecting Automatically

If the Transmitter/Receiver connection is broken, the Receiver will continually try to reconnect with the Transmitter. To reconnect, move the Receiver to within 10 feet of the Transmitter. Wait for the connection icon to disappear from the display to confirm reconnection.

Reconnecting Manually

If the Receiver has not been connected to the Transmitter for 30 minutes or more, you will need to follow these steps to manually reconnect:

1. Bring the Receiver to within 10 feet of the Transmitter.
2. Press the Receiver's *Right Option Button* once to turn the Receiver on. Press it again to see the *Main Menu*.
3. Use the *Up/Down Arrow Buttons* to highlight **System**. Press the *Right Option Button* to **Select**.
4. Use the *Up/Down Arrow Buttons* to highlight **Reconnect** (see below). Press the *Right Option Button* to **Select**.



5. Wait for the Transmitter to automatically send a signal to reconnect with the Receiver. The Receiver will beep twice if reconnection is successful. It will beep 3 times if the reconnection is unsuccessful. If the reconnection is unsuccessful,

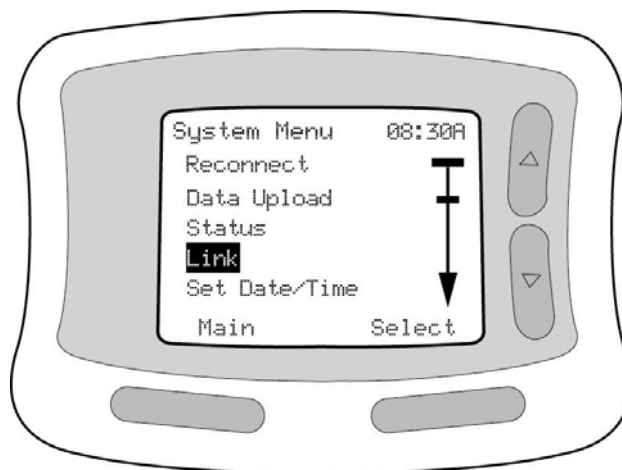
review the information at the beginning of this section, or refer to “Troubleshooting” (Section 7).

Linking the Receiver to a New Transmitter

When you first receive your System, the Transmitter and Receiver will already be linked. If you replace the Transmitter, you must unlink the old Transmitter from the Receiver, and then link the new Transmitter. You should do this *just before* inserting a new Sensor. If you link a new Transmitter to your Receiver while a Sensor is inserted, you will need to insert a new Sensor.

To link to a new Transmitter, follow these steps:

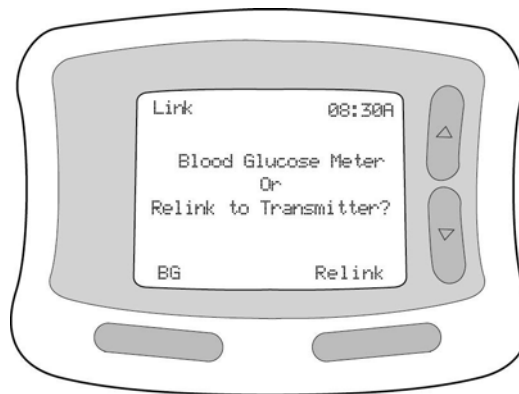
1. Place the Receiver within 10 feet of the new Transmitter.
2. Press the Receiver’s *Right Option Button* once to turn the Receiver on. Press it again to see the *Main Menu*.
3. Use the *Up/Down Arrow Buttons* to highlight **System**. Press the *Right Option Button* to **Select**.
4. Use the *Up/Down Arrow Buttons* to highlight **Link** (see below). Press the *Right Option Button* to **Select**.



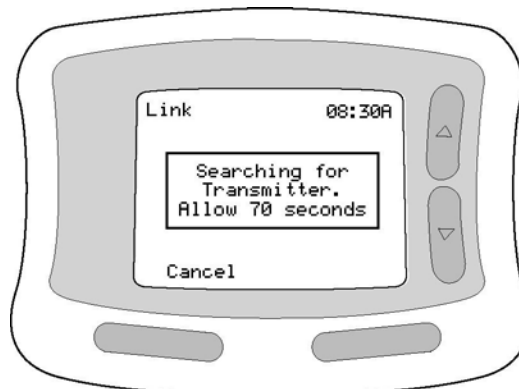
-
5. The Display Screen will show the current Transmitter ID. Press the *Left Option Button* to select **Unlink** (see below). This will unlink/disconnect the old Transmitter.



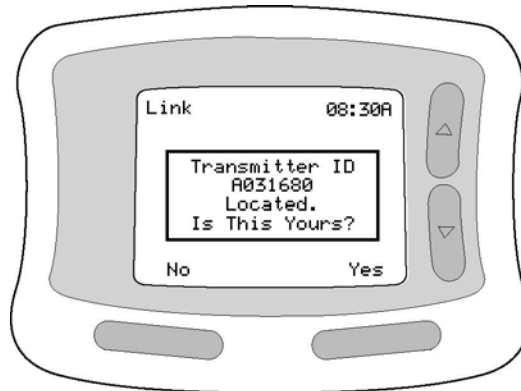
6. The display screen will next ask if you want to perform a blood glucose test (BG) or to relink to a Transmitter (see below). Press the *Right Option Button* to select **Relink** (see below).



7. Wait for the Receiver to detect the Transmitter and display the Transmitter serial number (ID). This may take up to 70 seconds.



-
8. Once the Receiver has detected the new Transmitter, the display screen will show the following:



9. Check the ID on the bottom of your Transmitter. If it matches the ID that appears on the display screen, press the *Right Option Button* to select **Yes**.

CAUTION: If you accept an incorrect Transmitter ID, your glucose readings will be incorrect.

Your Transmitter and Receiver are now linked. Unless you unlink the Transmitter and Receiver, you will not have to relink again until you replace the Transmitter.

Unlinking the Transmitter and Receiver

You can unlink the Transmitter and Receiver to stop the Receiver from sending or receiving signals and to turn off all alarms associated with the Continuous Monitoring Mode (for example, if you will be flying on a commercial aircraft). Note that you will NOT receive continuous glucose data while the Transmitter and Receiver are unlinked.

Follow these steps to unlink the Transmitter and Receiver:

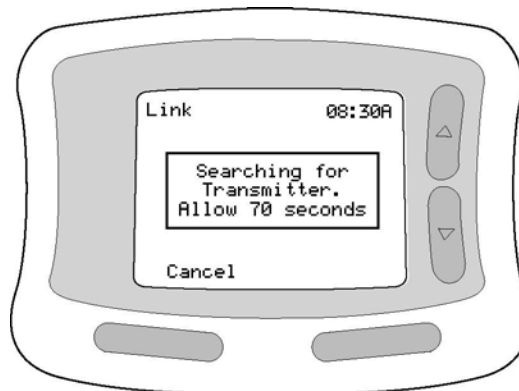
1. Press the Receiver's *Right Option Button* once to turn the Receiver on. Press it again to see the *Main Menu*.
2. Use the *Up/Down Arrow Buttons* to highlight **System**. Press the *Right Option Button* to **Select**.

-
3. Use the *Up/Down Arrow Buttons* to highlight **Link**. Press the *Right Option Button* to **Select**.
 4. Press the *Left Option Button* to select **Unlink**.
 5. Press the *Left Option Button* to select **BG**.

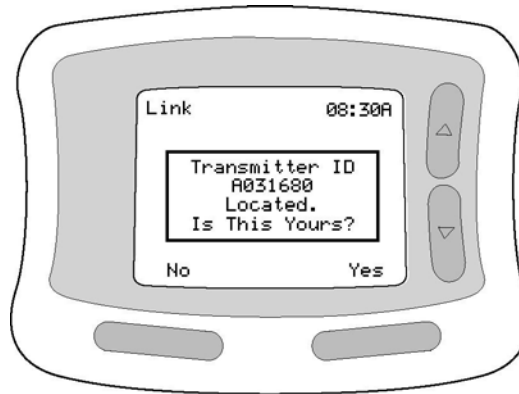
NOTE: You can still perform blood glucose measurements in Blood Glucose Mode while the Transmitter and Receiver are unlinked.

Relinking after Unlinking

1. Place the Transmitter within 10 feet of the Receiver.
2. Press the Receiver's *Right Option Button* once to turn the Receiver on. Press it again to see the *Main Menu*.
3. Use the *Up/Down Arrow Buttons* to highlight **System**. Press the *Right Option Button* to **Select**.
4. Use the *Up/Down Arrow Buttons* to highlight **Link**. Press the *Right Option Button* to **Select**.
5. Wait for the Receiver to detect the Transmitter and display the Transmitter serial number (ID; see below). This may take up to 70 seconds.



-
6. Once the Receiver has detected the new Transmitter, the display screen will show the following:



7. Check the ID at the bottom of your Transmitter. If it matches the ID that appears on the screen, press the *Right Option Button* to select **Yes**.

5. ADVANCED FEATURES

ADVANCED FEATURES

This section explains the use of the FreeStyle Navigator™ Continuous Glucose Monitoring System's more advanced features—*Alarms, Reports, System, and Add Events*—which can be accessed through the *Main Menu*.

NOTE: The *Main Menu* also includes a *Glucose* option; for more information about this option, see page 79.

Alarms

Alarms

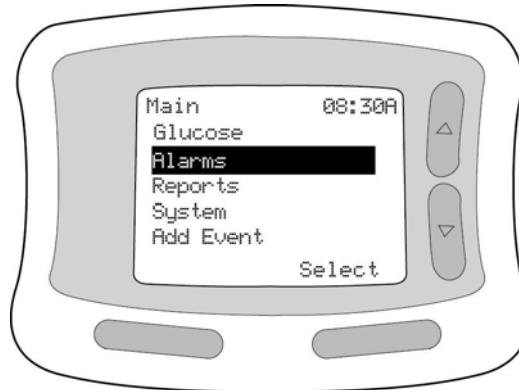
The Receiver has seven different alarms—four to alert you to glucose conditions, two for System features, and one for Progress Tones. Alarms are listed in Table 5.1.

Table 5.1. Alarms

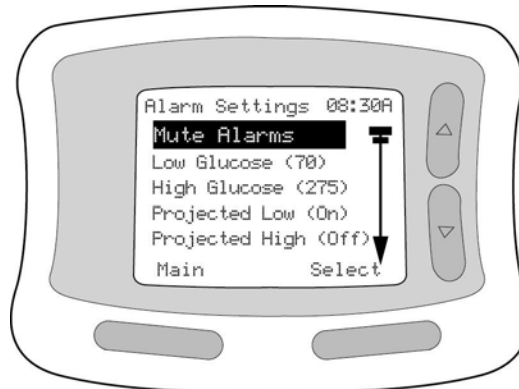
Alarm	Description
Low Glucose	Notifies you when you are at your low glucose threshold (a number you and your healthcare team will set).
High Glucose	Notifies you when you are at your high glucose threshold (a number you and your healthcare team will set).
Projected Low	Provides an early warning when you are approaching your low glucose threshold.
Projected High	Provides an early warning when you are approaching your high glucose threshold.
Data Loss	Notifies you when your glucose data will be lost and the alarms will not be working. Data Loss Alarms sound when the Transmitter/Receiver connection is broken or when you are overdue to change the Sensor.
System	Non-urgent System notifications. Examples include low battery life and time for calibration.
Progress Tones	Communicate progress, errors, and successful completion of System activities such as Blood Glucose Mode Testing.

Accessing the Alarms Menu

1. Select **Alarms** from the *Main Menu* (see below).



2. The *Alarms Menu* will appear (see below).



3. Use the *Up/Down Arrow Buttons* to select the alarm you want to view or modify.
Press the *Right Option Button* and the specified alarm screen will appear.

NOTE: You can cancel out of any alarm screen by waiting 12 seconds without making a selection. If you don't press any buttons for 12 seconds, the Receiver screen will go blank. Or, if you've made changes but changed your mind, before you pressed Select, you can wait 12 seconds and allow the Receiver screen to go blank, and the changes will be cleared or cancelled.

NOTE: Be careful to avoid making unintentional changes to System settings when setting or turning off Alarms.

Setting Low and High Glucose Alarms

Low and High Glucose Alarms can be set to notify you when your glucose levels reach a certain low or high threshold. Your healthcare team should help you determine appropriate thresholds. Low Glucose Alarms can be set to anywhere between 60 and 139 mg/dL (3.3 and 7.7 mmol/L). High Glucose Alarms can be set anywhere between 140 and 300 mg/dL (7.8 and 16.7 mmol/L).

CAUTION: The Low and High Glucose Alarms are not intended to indicate severe hypoglycemia or hyperglycemia because the Low Glucose Alarm can not be set below 60 mg/dL (3.3 mmol/L) and the High Glucose Alarm can not be set above 300 mg/dL (16.7 mmol/L).

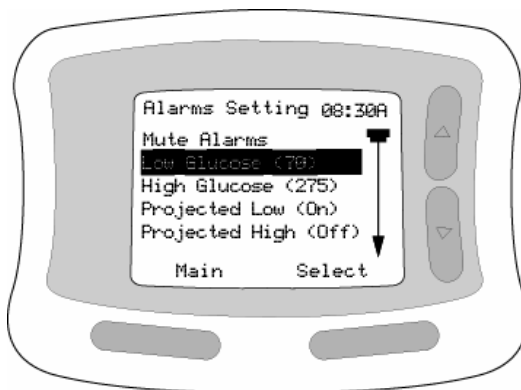
NOTE: High and Low Glucose Alarms are DIFFERENT from your Glucose Targets. For information about Glucose Targets, see page 117.

From the Low/High Glucose Alarm screens you can:

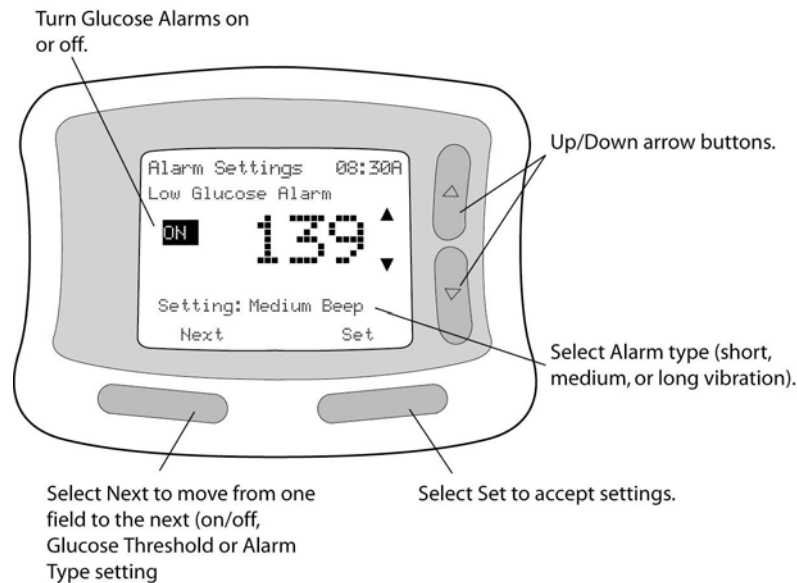
- Turn the Glucose Alarms on or off.
- Set your low and high glucose thresholds.
- Select Alarm types (low, medium, or high beep or short, medium, or long vibration).

To change Low or High Glucose Alarms:

1. Select **Low Glucose** or **High Glucose** from the *Alarms Menu* (see below).



-
- The first setting on the Low/High Glucose alarm screen is **on/off**. To move to another option (low or high glucose threshold, type of alarm), press the *Left Option Button* to select **Next**.
 - To change the settings, use the *Up/Down Arrow Buttons* to increase/decrease numbers or move between selections in a field (see below).



- Press **Next** (*Left Option Button*) to move from one field to the next.
- Press **Set** (*Right Option Button*) to accept the settings and return to the *Alarms Menu*.

After making an adjustment or reviewing settings, the Receiver will play back a brief example of the alarm you selected. If the alarm is turned off, you will not receive an audible playback of the setting, but a message will display on the screen.

Setting Projected Low and Projected High Glucose Alarms

Projected Low and Projected High Alarms are early warning alarms that tell you your glucose is changing and is approaching your low or high glucose threshold. Both the level of your glucose thresholds and how fast your glucose is changing will affect when your Projected Alarms are triggered. You can select the sensitivity of the early

warning alarms (which determines how far in advance you are alerted) from the Projected Alarm screens.

NOTE: The System uses your low and high glucose thresholds as a basis for triggering Projected Alarms, regardless of whether or not the Low or High Glucose Alarms are turned on.

From the Projected Low and Projected High Alarm screens you can:

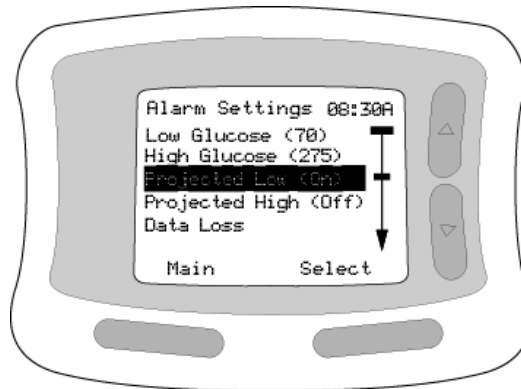
- Turn the Projected Alarms on or off.
- Set or change alarm sensitivities (see Table 5.2 and/or consult your healthcare team to determine which sensitivity level is best for you).
- Select alarm type (low, medium, or high beep or short, medium, or long vibration).

Table 5.2. Alarm Sensitivity (Projected High/Low Glucose Alarms)

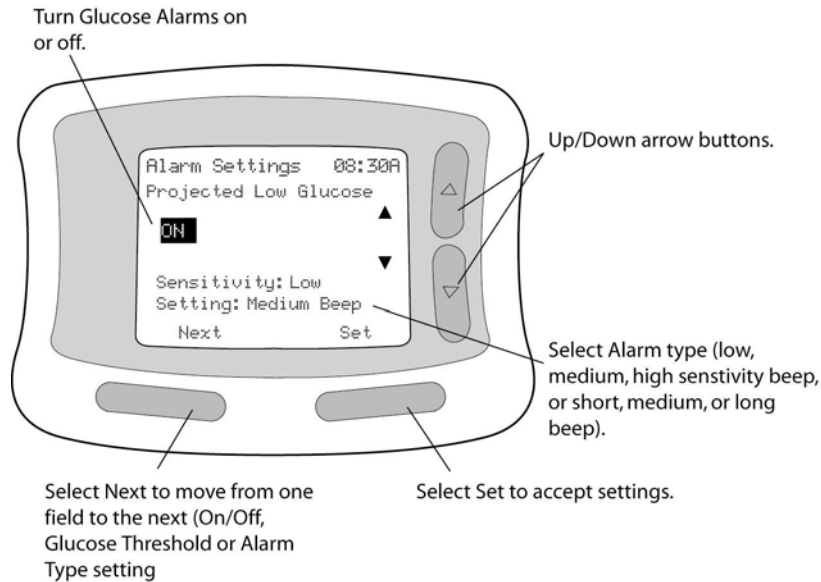
Sensitivity	Estimated Time Before Glucose Level Reaches High or Low Threshold	When to Use
High	30 minutes	If you want to be warned <i>far in advance</i> if your glucose level approaches your high or low glucose threshold, set the sensitivity to High and you will be warned approximately 30 minutes ahead of when the System thinks you will reach the threshold.
Medium	20 minutes	If you want <i>a little bit of advanced warning</i> when your glucose level approaches your high or low glucose threshold, set the sensitivity to Medium and you will be warned approximately 20 minutes ahead of when the System thinks you will reach the threshold.
Low	10 minutes	If you want to be warned <i>just before</i> your glucose level reaches your high or low glucose threshold, set the sensitivity to Low and you will be warned 10 minutes ahead of when the System thinks you will reach the threshold.

To set or change Projected Alarms:

1. Select **Projected Low** or **Projected High** from the *Alarms Menu* (see below).



2. The first setting option on the Projected Low or Projected High Alarm Screen is **on/off**. To move to another option (sensitivity, alarm type), press the *Left Option Button* to select **Next**.
3. To change the settings use the *Up/Down Arrow Buttons* to move between selections in a field (see below).



4. Press **Next** (*Left Option Button*) to move from one field to the next.
5. Press **Set** (*Right Option Button*) to accept the settings and return to the *Alarms Menu*.

After making an adjustment or reviewing settings, the Receiver will play back a brief example of the alarm you selected. If the alarm is turned off, you will not receive an audible playback of the setting but a message will display on the screen.

Setting Data Loss Alarms

Data Loss Alarms notify you when:

- The Sensor is expired.
- The Transmitter/Receiver connection is broken.

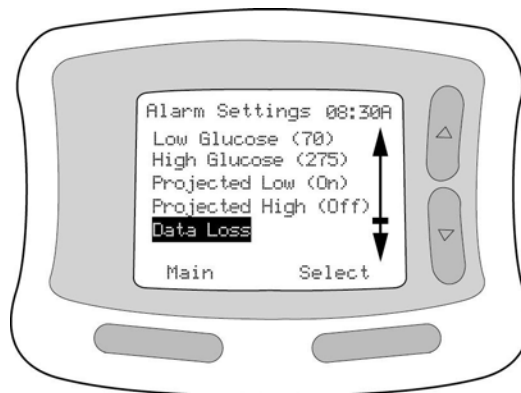
From the Data Loss Alarm Screen you can:

- Turn Data Loss Alarms on or off.
- Select alarm type (low, medium, or high beep or short, medium, or long vibration).

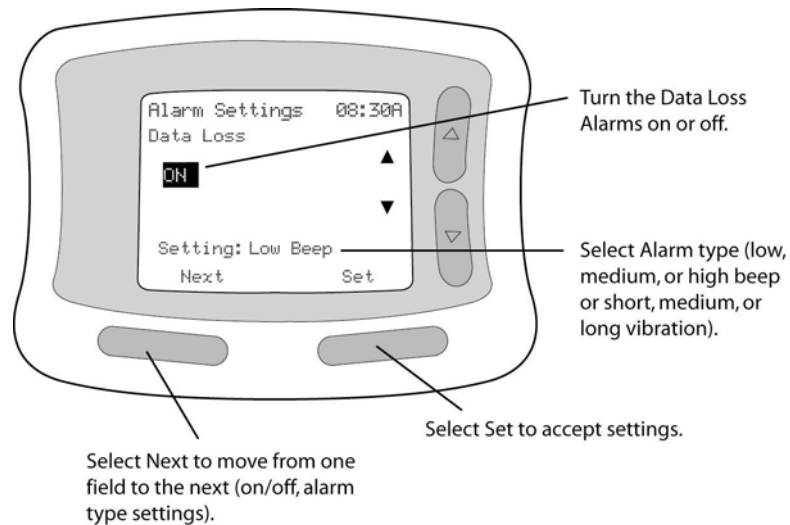
IMPORTANT: If you want to turn off your Data Loss Alarms, you will also need to turn off all of your Glucose Alarms.

To set or change Data Loss Alarm:

1. Select **Data Loss** from the *Alarms Menu* (see below).



-
- The first setting option on the Data Loss alarm screen is **on/off**. To move to alarm type, press the *Left Option Button* to select **Next** (see below).



- To change the settings use the *Up/Down Arrow Buttons* to move between selections within a field.
- Press **Next** (*Left Option Button*) to move from one field to the next.
- Press **Set** (*Right Option Button*) to accept the settings and return to the *Alarms Menu*.

After making an adjustment or reviewing settings, the Receiver will play back a brief example of the alarm you selected. If the alarm is turned off, you will not receive an audible playback of the setting but a message will display on the screen.

Setting System Alarms

System Alarms notify you when:

- The Receiver batteries are low.
- The Transmitter batteries are low.
- A Blood Glucose Mode Test is needed for calibration.

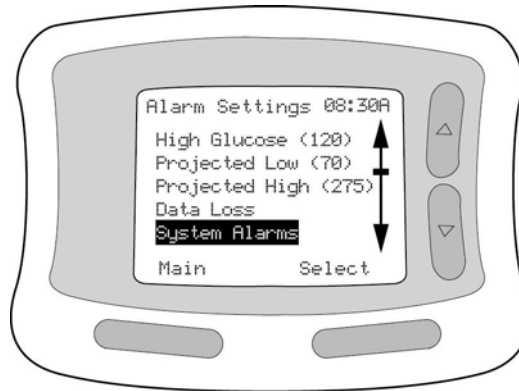
From the System Alarm screen you can:

- Turn System Alarms on or off.
- Select alarm type (low, medium, or high beep or short, medium, or long vibration).

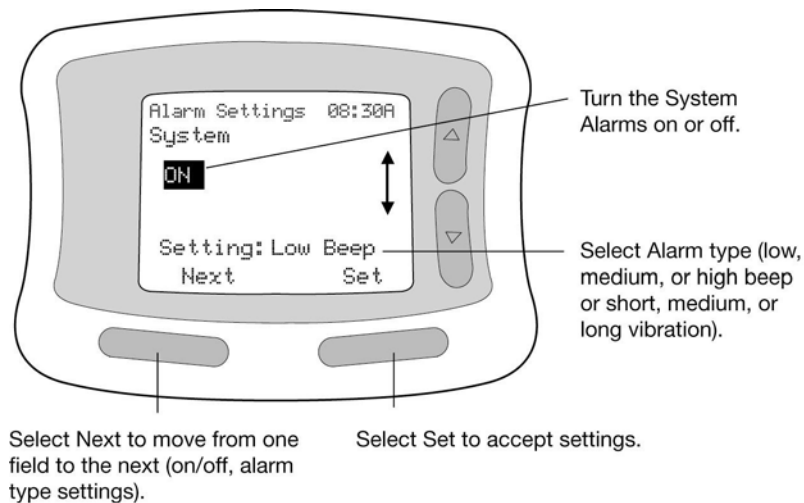
IMPORTANT: If you turn off System Alarms, you will not get the calibration prompts after you insert a new Sensor.

To set or change System Alarms:

1. Select **System** from the *Alarms Menu* (see below).



2. The first setting option on the System Alarm screen is **on/off**. To move to alarm type, press the *Left Option Button* to select **Next**.



-
3. Change the desired settings (on/off, alarm type) by using the *Up/Down Arrow Buttons* to move between selections within a field (see above).
 4. Press **Next** (*Left Option Button*) to move from one field to the next.
 5. Press **Set** (*Right Option Button*) to accept the settings and return to the *Alarms Menu*.

After making an adjustment or reviewing settings, the Receiver will play back a brief example of the alarm you selected. If the alarm is turned off, you will not receive an audible playback of the setting but a message will display on the screen.

Setting Progress Tones

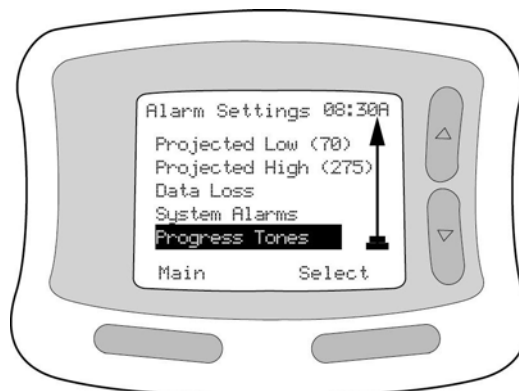
Routine System activities such as Blood Glucose Mode testing use sounds to notify you of errors, results, and successful completion of steps. These sounds are known as Progress Tones.

From the Progress Tones Screen you can:

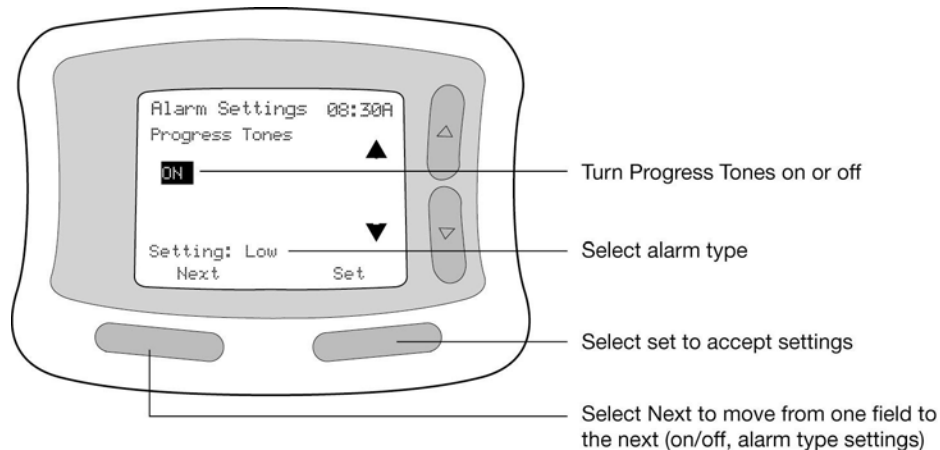
- Turn Progress Tones on or off.
- Select Progress Tone volume (low or high).

To set or change Progress Tones:

1. Select **Progress Tones** from the *Alarms Menu* (see below).



-
- The first setting option in the Progress Tones screen is **on/off**. To move to tone option, press the *Left Option Button* to select **Next**.
 - To change the settings use the *Up/Down Arrow Buttons* to move between selections in a field.



- Press **Next** (*Left Option Button*) to move from one field to the next.
- Press **Set** (*Right Option Button*) to accept the settings and return to the Alarms Menu.

After making an adjustment or reviewing settings, the Receiver will play back a brief example of the alarm you selected. If the alarm is turned off, you will not receive an audible playback of the setting but a message will display on the screen.

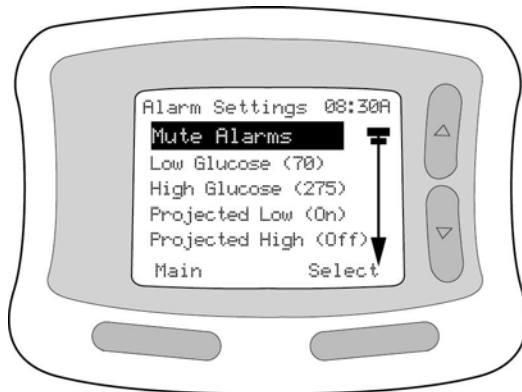
Muting Audible Alarms

The Mute Alarms feature allows you to turn off all audible alarms for 1 hour. Even when alarms are muted, you will still get vibration and visual alarms. After 1 hour, alarms will sound again. If you want to turn off alarms for extended periods of time, you should turn off each alarm individually.

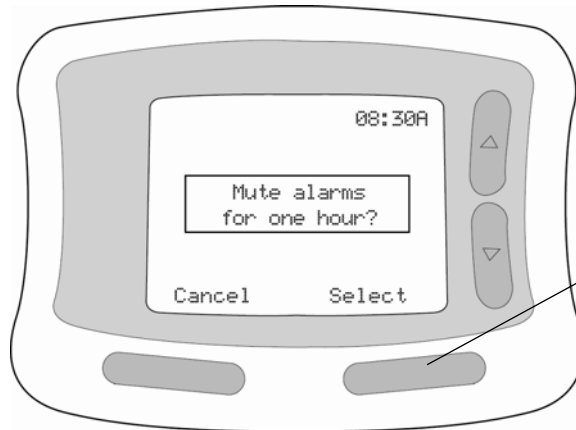
NOTE: When alarms are muted, you will not be able to hear any alarms and will need to rely on vibrations and visual displays only.

To Mute Alarms:

1. Select **Mute Alarms** from the *Alarms Menu* (see below).



2. Press **Select** (*Right Option Button*) to mute alarms (see below).



Press **Select** to turn off alarms for 1 hour.

Reports

Reports

Your Receiver can provide you with a number of reports, including Line Graphs, Statistical Reports, and Event Histories.

IMPORTANT: Be sure to set the date and time correctly (see page 30). The accuracy of Line Graph and Statistical Reports depends on accurate date and time settings.

Setting Glucose Targets

Your reports will be more meaningful if you set Glucose Targets. Glucose Targets give you something to compare your actual glucose levels with. Your healthcare team can help you determine your Glucose Targets.

NOTE: Glucose Targets are DIFFERENT from High and Low Glucose Alarms. For information about High and Low Glucose Alarms, see page 103.

To set Glucose Targets:

1. Select **Reports** from the *Main Menu*. Then select **Glucose Targets**.

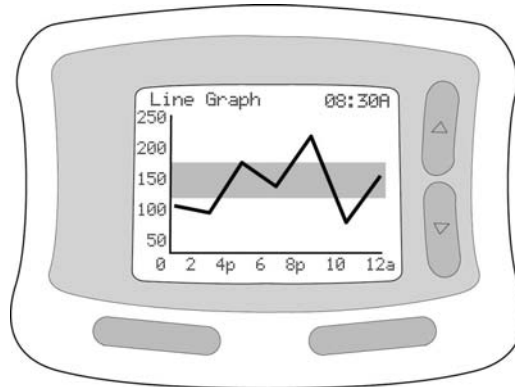


2. Enter Low and High Glucose Targets using the *Up/Down Arrow Buttons*. Default values are 80 mg/dL (4.4 mmol/L; low) and 180 mg/dL (10 mmol/L; high).

-
3. Press **Next** (*Left Option Button*) to move to the next field. Repeat Step 2.
 4. Press **Set** (*Right Option Button*) to save the settings.

Line Graphs

Line Graph Reports show continuous glucose lines (plotted at 10-minute intervals) for several different time periods (2, 4, 6, 12, or 24 hours; see below).



Line Graph Reports let you see how your glucose levels change over time. Your Glucose Target range is represented by a shaded horizontal band. The selected time period is plotted on the horizontal axis. Glucose levels (in mg/dL) are plotted on the vertical axis. Line Graph Reports display both continuous readings (a continuous line graph) and blood glucose readings (plotted as “+” symbols on the line graph).

NOTE: The line graph scale does not go below 20 mg/dL (1.1 mmol/L) or above 350 mg/dL (19.4 mmol/L). If any of your glucose values fall below 20 mg/dL (1.1 mmol/L), they will be plotted as 20 mg/dL (1.1 mmol/L). If any of your glucose values fall above 350 mg/dL (19.4 mmol/L), they will be plotted as 350 mg/dL (19.4 mmol/L).

To set a time period for a Line Graph Report:

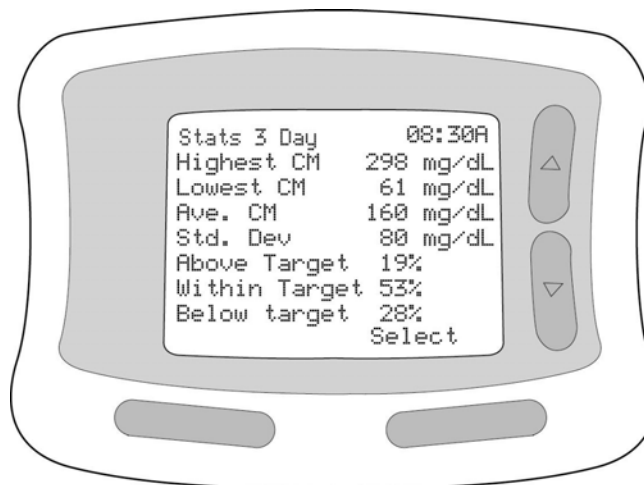
1. Select **Reports** from the Receiver's *Main Menu*.
2. Select **Line Graphs** from the list of Reports (see below).



3. Select the time period you want using the *Up/Down Arrow Buttons*.
4. Press the *Right Option Button* to **Select** and return to the previous screen.

Statistics

The System's statistics screen shows a comprehensive summary of glucose results relative to your Glucose Targets (see below).



You can view Statistical Reports for 1-, 3-, 7-, 14-, 21-, or 28-day time periods. Viewing this sort of information may help you see patterns in your glucose levels.

To select the time periods for your Statistical Reports:

1. Select **Report** from the Receiver's *Main Menu*.
2. Select **Statistics** from the list of Reports.



3. Use the *Up/Down Arrow Buttons* to highlight the statistic you want.
4. Press **Next** (*Left Option Button*) to advance to the next time period. Press **Back** to return to the *Reports Menu*.

NOTE: Statistics include ONLY continuous glucose results. Glucose readings that were taken in the Blood Glucose Mode are not included in the calculations.

Available Statistical Reports are outlined in Table 5.3.

Table 5.3. Statistical Reports

Statistic	Description
Highest CM	The highest continuous glucose reading over the selected time period.
Lowest CM	The lowest continuous glucose reading over the selected time period.
Ave. CM	The average continuous glucose reading over the selected time period.
Std. Dev.	This number is related to the average glucose level. For example, a small number indicates that most of your glucose readings during the day are close to the average value and that you are maintaining your glucose levels near that value. A large number indicates that many of your glucose levels during the day vary considerably from the average value and that you are not maintaining your levels near the average value.
Above Target	The percentage of readings over the selected time period that are above your High Glucose Target.
Within Target	The percentage of readings over the selected time period that are within your Glucose Targets (between the high and low glucose targets).
Below Target	The percentage of readings over the selected time period that are below your Low Glucose Target.
Low/Day	The average number of Low Glucose Alarm events per day for the selected time period.
High/Day	The average number of High Glucose Alarm events per day for the selected time period.
Proj Low/Day	The average number of Projected Low Alarm (early warning) events per day for the selected time period.
Proj High/Day	The average number of Projected High Alarm (early warning) events per day for the selected time period.

Event Histories

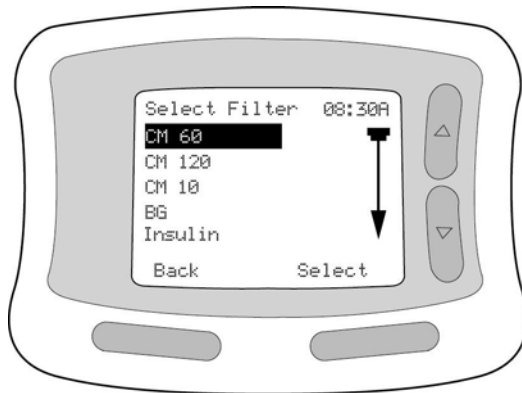
Event Histories are another type of report that you can select. These reports detail the Events that you have recorded in your Receiver (see page 135 for information about Adding Events).

To access Event Histories:

1. Select **Reports** from the Receiver's *Main Menu*.
2. Select **Event History** (see below).



3. In the Event History menu you will see a list of choices, or filters, through which you can view the events (see below).



Types of Event History Reports are listed in Table 5.4.

Table 5.4. Event History Reports

Event History Report	Description
CM 60	Recorded glucose readings (60-minute intervals). Not averaged values. Each CM 60 reading is displayed on a single screen with its date/time.
CM 120	Recorded glucose readings (120-minute intervals). Not averaged values. Each CM 120 reading is displayed on a single screen with its date/time.
CM 10	Recorded glucose readings (10-minute intervals). Not averaged values. Each CM 10 reading is displayed on a single screen with its date/time. This is the most frequent glucose data available.
BG	Recorded Blood Glucose (BG) readings. Each BG reading is displayed on a single screen with its date/time. All BG readings are displayed. A check mark appears next to BG readings that were marked as control.
Insulin	Recorded Insulin Events. Each Insulin Event entered is displayed on a single screen with type (rapid, intermediate, basal, or mixed), dosage (in units), and date/time.
Meals	Recorded Meal Events. Each Meal Event entered is displayed on a single screen with its carbohydrate value (in grams) and date/time.
Exercise	Recorded Exercise Events. Each Exercise Event entered is displayed on a single screen with its description (running, swimming, walking, biking, for example), duration (hours and minutes), intensity, and date/time.

Event History Report	Description
State of Health	Recorded State of Health. Each State of Health Event entered is displayed with its description (normal, cold, sore throat, infection, for example) and date/time.
Generic	Recorded Generic Events. Each Generic Event entered is displayed with its description and date/time.
Alarm History	Recorded Glucose Alarm Events. Each Glucose Alarm Event is displayed with its description (Low Glucose, High Glucose, Projected Low, and Projected High) and date/time.
User Events	Recorded User Events. Each User Event (includes Insulin, Meal, Exercise, State of Health, and Generic Events, described above) is displayed with its description and date/time.

Uploading Data

The System is designed to allow your healthcare team to upload data to a computer in the clinic. To upload data, your healthcare team will select **System** from your Receiver's *Main Menu* and then select **Data Upload** from the *System Menu*.

System

System

The *Main Menu's System* option gives you access to features needed for proper System functioning. *System Menu* options are listed in Table 5.5.

Table 5.5. System Menu Options

Menu Option	Where to Go for More Information
Reconnect	See page 89.
Data Upload	See page 124.
Status	See below.
Link	See page 90.
Set Date/Time	See page 30.

Status Information

The Receiver can provide you with a number of different types of Status Information. Available Status Information is listed in the Table 5.6.

Table 5.6. Status Information

Status Information	Description
Removed Sensor	Allows you to indicate you are removing a Sensor so Data Loss Alarms will not be set off.
System Status	Shows information about the System, including Sensor life remaining and time since valid data was transmitted.
Receiver Status	Shows information about the Receiver, including serial number and software version (may be useful when calling Clinical Trial Support), as well as battery life remaining.
Transmitter ID	Shows the Transmitter's serial number. You may need to verify the serial number after linking to a new Transmitter. This unique value is used by the Receiver to accept data from only your Transmitter. It also shows battery life remaining.
CM Status	Stores recent error codes related to the Continuous Monitoring Mode (may be useful when calling Clinical Trial Support).
Calibration BG	Allows you to add a new blood glucose reading used for calibration. Use this selection ONLY at the request of a Clinical Trial Support representative.

Removed Sensor

Removed Sensor is an optional feature that can be activated when you manually remove a Sensor. Activating the Removed Sensor feature:

- Keeps the Data Loss Alarm from sounding when you remove the Sensor.
- Electronically records the time and date of Sensor removal.

To activate the Removed Sensor feature:

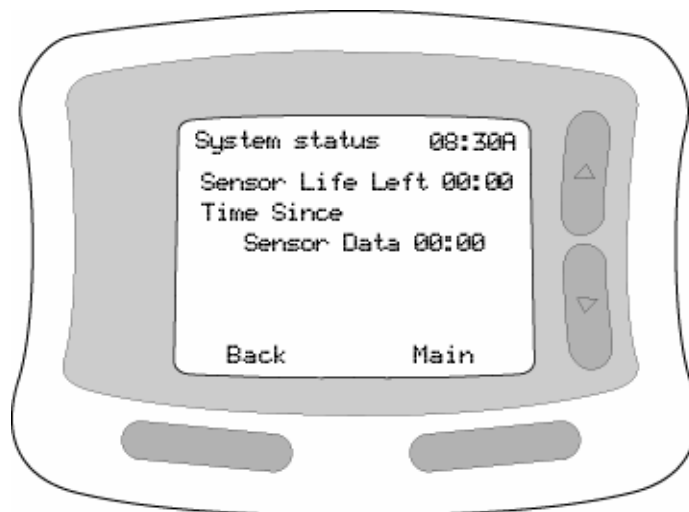
1. Select **System** from the *Main Menu*.
2. Select **Status** from the *System Menu*.
3. **Select Removed Sensor** from the **Status Menu**. Press the **Right Option Button** to activate.

System Status

System Status allows you to view information about the Sensor. *Sensor Life Left* will tell you how much Sensor time remains (total Sensor lifespan is 3 days displayed in hours). If the Transmitter/Receiver connection has been broken or if there is a problem with the System, *Time Since Sensor Data* will tell you how long it has been since the Receiver has received valid data.

To view System Status (see below):

1. Select **System** from the *Main Menu*.
2. Select **Status** from the *System Menu*.
3. Select **System Status** from the *Status Menu*.



Receiver Status

Receiver Status provides you with information regarding the Receiver, including serial number, software version, and battery life remaining (Table 5.7). To view Receiver Status (see below):

1. Select **System** from the *Main Menu*.
2. Select **Status** from the *System Menu*.
3. Select **Receiver Status** from the *Status Menu*.

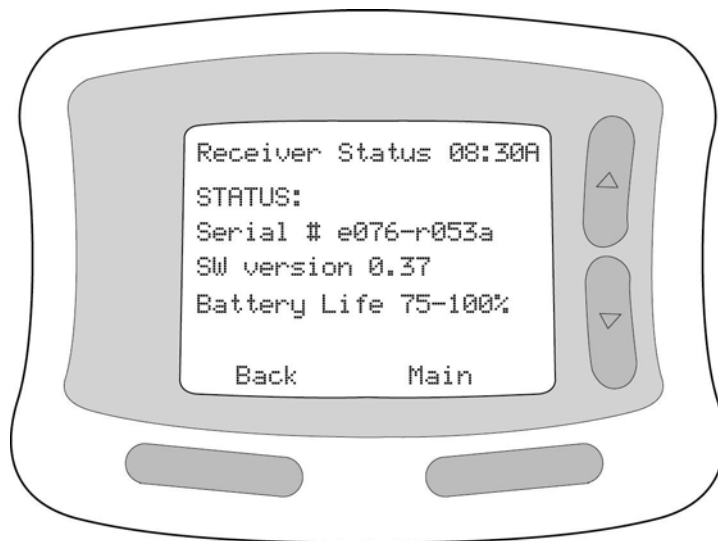


Table 5.7. Receiver Status

Field	Description
Serial #	Shows the Receiver's serial number.
SW Version	Shows the Receiver's software version.
Battery Life	Shows the charge that remains in the Receiver's battery. During typical use of the Receiver, the batteries should last about 3 months.

Transmitter Status

Transmitter Status allows you to view the Transmitter serial ID number and battery life remaining (Table 5.8). To view Transmitter Status (see below):

1. Select **System** from the *Main Menu*.
2. Select **Status** from the *System Menu*.
3. Select **Transmitter Status** from the *Status Menu*.

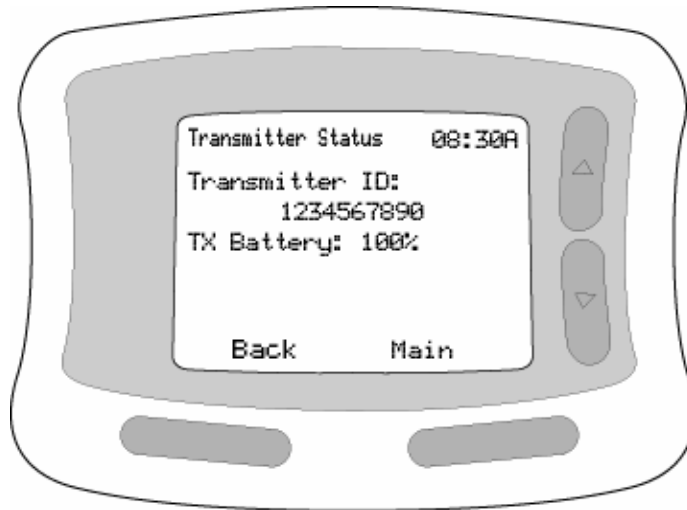


Table 5.8. Transmitter Status

Field	Description
Transmitter ID	Shows the Transmitter's serial number. You may need to verify the serial number after linking to a new Transmitter. This unique value is used by the Receiver to accept data only from your Transmitter.
TX Battery	Shows the life that remains in the Transmitter's battery. During typical use of the Transmitter, the battery should last about 30 days.

Continuous Monitoring (CM) Status

Continuous Monitoring (CM) Status lets you view recent error codes related to the Continuous Monitoring Mode (Table 5.9). These codes appear only when the System is not functioning properly. Use this option only under the direction of a Clinical Trial Support representative.



Table 5.9. Continuous Monitoring (CM) Status

Field	Description
Last Reset	Stores the reason for the last System reset.
Can't Cal	Stores a code for the most recent delayed calibration.
Cal Failed	Stores a code for the most recent unsuccessful calibration.
Sensor Err	Stores a code for the most recent Sensor error.

Calibration BG

Calibration BG allows you to add a new blood glucose measurement to the average used for Sensor calibration. Use this feature only under the direction of a Clinical Trial Support representative.

Add Event

Add Event

The Add Event option allows you to electronically record a variety of activities and observations that may affect your glucose levels. This information may help you evaluate patterns in your glucose control and diabetes management. Once entered, events may be viewed in several ways:

- As part of Event History reports (see page 122).
- As part of Line Graph reports (indicated by small letters stacked on the horizontal time axis; see page 118).
- Events may also be uploaded to a valid software application by your healthcare team.

For many events, you can simply record the time and date. Or, you can take additional steps to record events in more detail. Pressing the *Right Option Button* completes the entry of your event regardless of how much detail you have provided. Events are listed in Table 5.10.

NOTE: The date and time are automatically recorded when you enter an event. If you enter the event at a later time, you must enter the date and time the event occurred.

Table 5.10. Events

Event	Description
Meal Event	Records details of a meal or snack. A Meal Event may be recorded as carbohydrate grams. This information may help you in carbohydrate counting or determining insulin/carbohydrate ratios. It can also help you recognize glucose patterns.
Insulin Event	Logs details of an insulin dose (injection or pump) to aid in evaluating dosing decisions. Insulin Events are always recorded with a time and date notation and may also include type of insulin and dose amount (units).
Exercise Event	Records the time and date and a description of many popular forms of exercise. You may also specify the intensity and duration of each exercise event.
State of Health Event	Records events, symptoms, and other observations that may aid in recognizing glucose patterns.
Generic Event	Records any other event you and your healthcare team decide is useful in evaluating glucose patterns. You may assign up to eight Generic Events for observations of your choosing.

To add Events:

1. Select **Add Event** from the *Main Menu*.
2. Select the Event you wish to enter. Then, follow the instructions for that Event (see below).

Meal Event

1. Use the *Left Option Button* to select which item to enter (Date, Time, Carbohydrate Grams) and to move from one item to the next.
2. Use the *Up/Down Arrow Buttons* to select each item.
3. When you are done, press the *Right Option Button* to **Save** the Meal Event.

Insulin Event



1. Use the *Left Option Button* to select each item (Date, Time, Type of Insulin, Units) and to move from one item to the next.
2. Use the *Up/Down Arrow Buttons* to select each item.
3. When you are done, press the *Right Option Button* to **Save** the Insulin Event.

NOTE: Your Insulin Type choices are Rapid, Intermediate, Long Acting, or Pre-mix.

Exercise Event

1. Use the *Left Option Button* to select each item (Date, Time, Type of Exercise, Intensity, Duration) and to move from one item to the next.
2. Use the *Up/Down Arrow Buttons* to select each item.
3. When you are done, press the *Right Option Button* to **Save** the Exercise Event.

NOTE: Your type of Exercise choices are Aerobics, Walking, Jogging, Running, Swimming, Biking, Weights, or Other. Duration can be increased or decreased by 15-minute increments. Your Intensity choices are None, Low, Medium, or High. You can record each Exercise Event in 15-minute segments, up to 2.5 hours.

State of Health Event



1. Use the *Left Option Button* to choose each item (Date, Time, State of Health) and to move from one item to the next.
2. Use the *Up/Down Arrow Buttons* to select each item.
3. When you are done, press the *Right Option Button* to **Save** the State of Health Event.

NOTE: Your State of Health choices are Normal, Cold, Sore Throat, Infection, Tired, Stress, Fever, Flu, Allergy, Period, Dizzy, Alcohol, Low Symptoms, or High Symptoms.

Generic Event

1. There are eight Generic Event numbers that you and/or your healthcare team can assign to specific events (for example, #1 can refer to "Dining Out", #2 to "Shopping", #3 to "Inactive Day", #4 to "Party", etc.). Decide what you want your Generic Event numbers to represent (you don't have to assign meanings to all of the numbers at once), and write down your choices.
2. Use the *Left Option Button* to select which item to change (Date, Time, Generic Event) and to move from one item to the next.
3. Use the *Up/Down Arrow Buttons* to change each item (including choosing the number that corresponds to the Generic Event you are recording).
4. When you are done, press the *Right Option Button* to **Save** the Generic Event.

6. MAINTENANCE

MAINTENANCE

The FreeStyle Navigator™ Continuous Glucose Monitoring System requires minimal maintenance aside from cleaning and battery replacement. You should, however, avoid getting dirt, dust, blood, control solution, water, or any other substance in the Receiver's Test Strip Port. The Receiver should be stored in its protective carrying case when not in use.

NOTE: The Transmitter and Receiver CANNOT be repaired when broken. There are no replacement parts for these devices except for batteries. Contact your healthcare team if you need to replace your Transmitter or Receiver.

Cleaning the Transmitter

You should clean the Transmitter each time you change the Sensor. Follow these steps:

1. Wash the Transmitter with mild soap and water.
2. Rinse the Transmitter thoroughly under running water.
3. Shake any water out of the Transmitter Contact Points.
4. Dry the Transmitter thoroughly using a clean, soft, lint-free cloth. Make sure that the Contact Points are dry.

Cleaning the Receiver

CAUTION: Do NOT immerse the Receiver in water or any other liquid. Avoid getting water or any other liquid into the Test Strip Port.

To clean the Receiver, wipe the outside with a cloth dampened with either mild soapy water or 70% isopropyl alcohol.

Changing the Transmitter Battery

The Transmitter is designed to operate for approximately 30 days with 1 silver oxide 357 battery (small coin cell battery). The Receiver will sound an alarm and display the "Replace TX Battery with new Sensor" message 4 days before the Transmitter battery needs to be changed. You should wait to change the Transmitter battery until just before you insert a new Sensor.

For instructions on changing the Transmitter battery, see page 56.

NOTE: One Transmitter battery comes with each Sensor Kit.

Changing the Receiver Batteries

The Receiver is designed to operate for approximately 90 days with 2 AAA batteries. When the Receiver Batteries run low, the Receiver will sound an alarm and display the "Replace Receiver Battery within 1 week" message 1 week before the Receiver batteries need to be changed. A battery icon will also appear on the Receiver.

IMPORTANT: After the Receiver Battery Alarm sounds, wait to replace the Receiver's batteries until just before the next time you insert a new Sensor.

For instructions on installing the Receiver's batteries, see page 28.

NOTE: Once you take the old batteries out, you have 10 minutes to install the new batteries. If you do not install the new batteries within this 10-minute time frame, you may have to reset the date and time (see page 30).

Disposal of Components

- Used Sensor Inserters and lancets should be disposed of in a sharps container or other puncture-proof container with a lid.
- Used Transmitter and Receiver batteries should be disposed of according to local regulations.
- Should your Transmitter or Receiver need to be replaced, first contact the Clinical Trial Support Line. If they advise you to dispose of either or both of these items, follow your local regulations for disposal of electronic equipment.

7. Alarms, Error Codes, and Troubleshooting

Alarms, Error Codes, and Troubleshooting

Use this section to identify Alarms and Error Codes associated with the Continuous Glucose Monitoring and Blood Glucose Modes. Solutions to problems that may occur are also provided. If you can't find the information you need, call the Clinical Trial Support Line at 1-888-971-4766.

Alarms

Alarms

Continuous Monitoring Alarms alert you to issues related to the Continuous Monitoring Mode. These Alarms are given an Urgency rating based on how soon you need to address the alarm (for example, Low Urgency alarms do not need to be addressed right away, while High Urgency alarms should be addressed immediately; see Table 7.1)

Table 7.1: Levels of Alarm Urgency

Urgency Level	Type of Alarm
Low Urgency	A single beep. This type of alarm can be muted (see page 112), and will be turned off when you acknowledge the alert.
Intermediate Urgency	A series of three short beeps. These beeps will repeat every 6 seconds for 1 minute or until you activate the display. If the alarm is not acknowledged and the condition remains the same, it will sound again in 5 minutes. The Intermediate Urgency Alarm will not sound again after 5 minutes if the alarm is acknowledged, or if the situation is fixed (for example, moving the Transmitter and Receiver closer if the alarm is connection-related). It will stop completely after an hour. The Intermediate Urgency Alarm can be muted (see page 112).
Medium Urgency	A series of three short beeps. These beeps will repeat every 6 seconds for 1 minute or until you activate the display. The alarm will repeat every 5 minutes until the situation is fixed, except when it is acknowledged—then it will repeat every 15 minutes until the situation is fixed. The Medium Urgency Alarm can be muted (see page 112).
High Urgency	The High Urgency alarm is the same as the Medium Urgency alarm except that it cannot be muted.

To acknowledge alarms:

- Press the *Right Option Button* to turn off a vibration or audio alarm.
- Press the *Left Option Button* to turn off a text display message.

Table 7.2 provides a complete listing of Continuous Monitoring Mode alarm messages.

Table 7.2: Continuous Monitoring Mode Alarm Messages

Alarm Message	Urgency*	What It Means	What To Do
Calibration Alarms			
Do BG Test	M	A Blood Glucose Mode test is needed for calibration. The Receiver will prompt you to perform this test approximately 1, 3, and 24 hours after a new Sensor is inserted.	Perform a Blood Glucose Mode test (see page 63).
Cal Failed: Receiver Temp Redo BG Later	I	Calibration failed because the Receiver was too warm or too cold.	Bring the Receiver to room temperature, and then perform another Blood Glucose Mode test. If calibration fails 3 times, remove the Sensor and insert a new one (see page 43).
Cal Failed Redo BG Test	I	Calibration result was very different from the previous calibration. Another Blood Glucose Mode test is needed.	Perform another Blood Glucose Mode test.
Cool Down Skin Redo BG Later	I	Calibration failed because your skin temperature is too high.	Cool the skin at the insertion site. Perform another Blood Glucose Mode test. If calibration fails 3 times, remove the Sensor and insert a new one (see page 43).

* Urgency is defined as: L = Low, I = Intermediate, M = Medium, H = High

Alarm Message	Urgency*	What It Means	What To Do
Do BG Test Alarms Inactive	I	Calibration was not performed within the required time; therefore, readings will not be displayed and the alarms are not working.	Perform a Blood Glucose Mode test. If the alarm persists, remove the Sensor and insert a new one (see page 43).
Cal Failed: High BG Redo BG Later	I	Calibration failed because the Blood Glucose Mode test reading was too high. The System needs a blood glucose level between 60 and 400 mg/dL (3.3 and 22.2 mmol/L) for proper calibration.	Perform another Blood Glucose Mode test. If your glucose level is still high, follow your healthcare professional's advice for a high glucose (hyperglycemic) episode.
Cal Failed: Low BG Redo BG Later	I	Calibration failed because the Blood Glucose Mode test reading was too low. The System needs a blood glucose level between 60 and 400 mg/dL (3.3 and 22.2 mmol/L) for proper calibration.	Perform another Blood Glucose Mode test. If your glucose level is still low, follow your healthcare professional's advice for a low glucose (hypoglycemic) episode.
Cal Failed: Redo BG in 1 HR	I	The Blood Glucose Mode test showed the Sensor may not be working properly.	Wait 1 hour and try again.
Cal Failed: Redo BG Later	I	Calibration failed.	Perform another Blood Glucose Mode test. If calibration fails three times, remove the Sensor and insert a new one (see page 43).
Warm Up Skin Redo BG Later	I	Calibration failed because your skin temperature is too low.	Warm the skin at the insertion site. Perform another Blood Glucose Mode test. If calibration fails 3 times, remove the Sensor and insert a new one (see page 43).

* Urgency is defined as: L = Low, I = Intermediate, M = Medium, H = High

Alarm Message	Urgency*	What It Means	What To Do
Cool Down Skin	L	Unable to calibrate the System because the skin temperature is too high.	Cool the skin at the insertion site. Wait for the “Do BG Test” prompt.
Warm Up Skin	L	Unable to calibrate the System because the skin temperature is too low.	Warm the skin at the insertion site. Wait for the “Do BG Test” prompt.
Connection Alarms			
Reconnect Alarms Inactive	M	The Receiver has not been receiving signals sent by the Transmitter for 8 minutes. Five minutes of data have been lost. The Receiver is either too far from the Transmitter or there are materials or signals causing interference.	Be sure the Receiver and Transmitter are within 10 feet of one another. If the alarm persists, select System from the <i>Main Menu</i> , then select Reconnect (see page 89).
Link	L	The Receiver is not linked to the Transmitter. The link is necessary for the System to operate in the Continuous Monitoring Mode.	Place the Receiver within 10 feet of the Transmitter. Select System from the Receiver’s <i>Main Menu</i> , then select Link . If the Transmitter ID that appears on the display screen is correct, select Yes (see page 92).
Reconnect	L	The Receiver has not been receiving signals sent by the Transmitter for 5 minutes. Two minutes of data have been lost. The Receiver is either too far from the Transmitter or there are materials or signals causing interference.	Be sure the Receiver and Transmitter are within 10 feet of one another. If the Alarm persists, select System from the <i>Main Menu</i> , then select Reconnect (see page 89).

* Urgency is defined as: L = Low, I = Intermediate, M = Medium, H = High

Alarm Message	Urgency*	What It Means	What To Do
Glucose Level Alarms			
— — — —	N/A	<ul style="list-style-type: none"> • Continuous monitor is not producing glucose results. This is normal for new Sensors before the first calibration (Blood Glucose Mode test) is performed. Low and High Glucose Alarms cannot function while this appears on the display. • Connection between the Transmitter and Receiver is bad. • Sensor failure (or Sensor no longer in your skin). • Transmitter failure. • Sensor is expired. 	<ul style="list-style-type: none"> • If you see this alarm message more than 3 hours after a new Sensor is inserted and the Receiver does not request a blood glucose measurement, the Sensor is not functioning correctly. Remove the Sensor and insert a new one (see page 43). • If you see this alarm message after you have been getting continuous glucose results, check the Transmitter/Receiver connection. • Check the insertion site to make sure the adhesive is holding the Sensor in your skin. If the Sensor is no longer in your skin, insert a new Sensor.
Low Glucose	H	Your glucose has reached your preset low glucose threshold.	Follow the recommendation of your healthcare team for treating a low glucose (hypoglycemic) episode.
High Glucose	M	Your glucose has reached your preset high glucose threshold.	Follow the recommendations of your healthcare team for treating a high glucose (hyperglycemic) episode.

* Urgency is defined as: L = Low, I = Intermediate, M = Medium, H = High

Alarm Message	Urgency*	What It Means	What To Do
Projected High Glucose	M	<p>This is an early warning that your glucose level and the rate at which it is changing indicate that you may soon reach your high glucose threshold.</p> <p>When set to High sensitivity, you probably have about 30 minutes before reaching your high glucose threshold.</p> <p>When set to Medium sensitivity, you probably have about 20 minutes before reaching your high glucose threshold.</p> <p>When set to Low sensitivity, you probably have about 10 minutes before reaching your high glucose threshold.</p>	Follow the recommendations of your healthcare team for treating or stopping the rise in glucose that you are experiencing.

* Urgency is defined as: L = Low, I = Intermediate, M = Medium, H = High

Alarm Message	Urgency*	What It Means	What To Do
Projected Low Glucose	M	<p>This is an early warning that your glucose level and the rate at which it is changing indicate that you may soon reach your Low Glucose Threshold.</p> <p>When set to High sensitivity, you probably have about 30 minutes before reaching your Low Glucose Threshold.</p> <p>When set to Medium sensitivity, you probably have about 20 minutes before reaching your Low Glucose Threshold.</p> <p>When set to Low sensitivity, you probably have about 10 minutes before reaching your Low Glucose Threshold.</p>	Follow the recommendations of your healthcare team for treating or stopping the drop in glucose that you are experiencing.
Receiver-related Alarms			
Alarms Inactive Replace Receiver	I	Receiver malfunction. Problem has persisted for 1 hr.	Call the Clinical Trial Support.
Receiver Error Alarms Inactive	I	Receiver error.	Wait 50 minutes for the problem to go away. If problem persists, call Clinical Trial Support.
Log Cleared	L	History log has been successfully cleared.	Acknowledge the alarm.

* Urgency is defined as: L = Low, I = Intermediate, M = Medium, H = High

Alarm Message	Urgency*	What It Means	What To Do
Log Corrupted Some Data Lost	L	History log is corrupt.	The Receiver detected a corrupt sector in the log and erased it. The data in this sector is lost. Your reports will not contain this lost data. If the error occurs again, call Clinical Trial Support.
Preferences Lost Reconfigure	L	An error occurred with the Receiver configuration. The Receiver has reset. Your stored preferences may be lost.	Review your alarm settings.
Replace Receiver Battery Within 1 Week	L	The batteries in your Receiver will lose power in approximately 1 week.	Replace the Receiver batteries (see page 28) before you insert a new Sensor. Then reset the time and date (see page 30). Replacing the batteries before a Sensor has expired will require you to insert a new Sensor.
Replace TX Battery With Next Sensor	L	The Transmitter battery monitor indicates there are only 4 days of battery power left.	Replace the Transmitter battery prior to inserting the next Sensor. Be sure to reconnect the Transmitter and Receiver.
TX Battery Exhausted Replace Battery	L	Transmitter battery power loss is imminent.	Remove Sensor, replace Transmitter battery, reconnect Transmitter and Receiver, and insert a new Sensor.
Sensor-related Alarms			
Alarms Inactive Insert New Sensor	I	Alarms are not operating because the 3-day life of the Sensor has ended.	Remove the Sensor and insert a new one (see page 43).

* Urgency is defined as: L = Low, I = Intermediate, M = Medium, H = High

Alarm Message	Urgency*	What It Means	What To Do
Alarms Inactive Replace Sensor	I	The Sensor is not functioning properly. The alarms are not working.	Remove the Sensor and insert a new one (see page 43).
Alarms Inactive Skin Temp Range	I	Skin temperature at the insertion site is either too low or too high for the System to produce correct readings. Condition has been persistent for up to 60 minutes. The alarms are not working.	Remove the Sensor and insert a new one (see page 43).
Remove Any Sensor Alarms Inactive	I	Alarms are not operating. The Receiver thought the Sensor was inserted when the Receiver was reset.	Remove the Sensor and insert a new one (see page 43). Ignore the message if there is no Sensor inserted.
Did You Remove the Sensor?	L	<ul style="list-style-type: none"> The System has detected that the Sensor was just removed. If this message appears and you did not remove the Sensor, there may be a faulty connection between the Sensor and the Transmitter. 	<p>If you just removed the Sensor, select Yes.</p> <p>If you did not just remove the Sensor, select No.</p> <p>If the alarm persists, the Sensor may have failed. Remove the Sensor and insert a new one (see page 43).</p>
New Sensor Detected. Did you recently Insert new Sensor?	L	<ul style="list-style-type: none"> The System has detected a new Sensor. If this message appears and you did not insert a new Sensor, there may be a faulty connection between the Sensor and the Transmitter. 	<p>If you just inserted a new Sensor, select Yes.</p> <p>If you did not insert a new Sensor, select No. If the alarm persists, the Sensor may have failed. Remove the Sensor and insert a new one (see page 43).</p>

* Urgency is defined as: L = Low, I = Intermediate, M = Medium, H = High

Alarm Message	Urgency*	What It Means	What To Do
Replace Sensor Soon	L	The Sensor will reach the end of its life within 2 hours.	Replace the Sensor within the next 2 hours (see page 43).
Transmitter-related Alarms			
Transmitter Error Alarms Inactive	I	Transmitter problem. Alarms are not working.	Wait for the problem to go away. If problem persists for 50 more minutes, you will get the alarm "Alarms Inactive Replace Transmitter."
Alarms Inactive Replace Transmitter	I	Transmitter problem for an hour. Alarms are not working.	Replace the Transmitter, and insert a new Sensor.

* Urgency is defined as: L = Low, I = Intermediate, M = Medium, H = High

Error Codes

Error Codes

A complete listing of the Blood Glucose Mode Error Codes can be found in Table 7.3.

Table 7.3: Blood Glucose Mode Error Codes

Error Code	What It Means	What To Do
Er1	<ul style="list-style-type: none">• Not enough blood was applied to Test Strip.• Problem with Test Strip.• Problem with Receiver.• Very low blood glucose (less than 20 mg/dL [1.1 mmol/L]).	<ul style="list-style-type: none">• If you have symptoms such as weakness, sweating, nervousness, headache, or confusion, follow your healthcare team's advice for treating a low glucose level (hypoglycemic) episode.• Perform a Control Solution test using a new Test Strip. If results are within the range printed on Test Strip vial, retest your blood using a new Test Strip.• If Control Solution test does not work or error code persists, call Clinical Trial Support.
Er2	<ul style="list-style-type: none">• Problem with the Test Strip.• Problem with Receiver.• Very high blood glucose (greater than 500 mg/dL [27.8 mmol/L]).• High Control Solution applied when temperature is too cold. (This applies only to Control Solution labeled High.)	<ul style="list-style-type: none">• If you have symptoms such as thirst, fatigue, excess urination, or blurry vision, follow your healthcare team's advice for treating a high glucose level (hyperglycemic) episode.• Perform a Control Solution test using a new Test Strip. If results are within the range printed on Test Strip vial, retest your blood using a new Test Strip.• If Control Solution test does not work or error code persists, call Clinical Trial Support.

Error Code	What It Means	What To Do
Er3	<ul style="list-style-type: none"> • Incorrect procedure (for example, blood was applied to Test Strip before Test Strip was inserted into Receiver). • Problem with the Test Strip. • Problem with the Receiver. 	<ul style="list-style-type: none"> • Be sure you see <i>Apply Sample</i> on the Receiver screen before you apply blood or Control Solution. • Perform a Control Solution test using a new Test Strip. If results are within the range printed on Test Strip vial, retest your blood using a new Test Strip. • If Control Solution Test does not work or error code persists, call Clinical Trial Support.
Er4	<ul style="list-style-type: none"> • Problem with Test Strip. • Problem with Receiver. 	<ul style="list-style-type: none"> • Perform a Control Solution Test using a new Test Strip. If results are within the range printed on Test Strip vial, retest your blood using a new Test Strip. • If Control Solution Test does not work or error code persists, call Clinical Trial Support.
Er5	N/A	This error code not currently in use.
Er6	Button on Receiver was pressed while you were applying blood or Control Solution.	Retest using a new Test Strip. Do NOT touch the <i>Right Option Button</i> while applying blood or Control Solution to the Test Strip. If error code persists, call Clinical Trial Support.

Troubleshooting

Troubleshooting

A list of problems that may occur as you use your System—along with suggested solutions—is presented in Table 7.4.

Table 7.4: Troubleshooting

Problem	Possible Cause	What To Do
Receiver does not turn on when you press the <i>Right Option Button</i> or insert a Test Strip.	<ul style="list-style-type: none"> Batteries are dead. 	<ul style="list-style-type: none"> Change batteries, then reset time and date (see page 30).
	<ul style="list-style-type: none"> Batteries were installed incorrectly. 	<ul style="list-style-type: none"> Make sure batteries are oriented correctly (see page 142). If batteries were installed incorrectly or removed, reset the time and date (see page 30). Whenever the batteries are taken out and put back in, you will also need to insert a new Sensor and reconnect the Transmitter (see page 89).
	<ul style="list-style-type: none"> Test Strip was inserted incorrectly or incompletely. 	<ul style="list-style-type: none"> Always insert the Test Strip end with the dark rectangle (see page 67). Make sure “FreeStyle” is facing up.
	<ul style="list-style-type: none"> Defective Receiver or Test Strips. 	<ul style="list-style-type: none"> Repeat test with a new Test Strip.
	<ul style="list-style-type: none"> Defective Receiver. Blood or foreign object in Test Strip Port. 	<ul style="list-style-type: none"> Call Clinical Trial Support.

Problem	Possible Cause	What To Do
Blood glucose test does not start after you apply the sample.	<ul style="list-style-type: none"> • Sample was too small. 	<ul style="list-style-type: none"> • Repeat the test with a new Test Strip and larger sample.
	<ul style="list-style-type: none"> • Sample was applied after Receiver automatically shut off. 	<ul style="list-style-type: none"> • Repeat the test with a new Test Strip. Apply sample when Apply Sample appears on the display.
	<ul style="list-style-type: none"> • Defective Test Strip. 	<ul style="list-style-type: none"> • Call Clinical Trial Support.
	<ul style="list-style-type: none"> • Defective Receiver. 	
Unexpected characters on the Receiver screen, unusual screen appearance, or unexpected screen appearance.	<ul style="list-style-type: none"> • Batteries failing. 	<ul style="list-style-type: none"> • Change batteries, then reset time and date (see page 30). • Make sure batteries are oriented correctly (see page 142). If batteries were installed incorrectly or removed, reset the time and date (see page 30). • Whenever the batteries are taken out and put back in, you will also need to insert a new Sensor and reconnect the Transmitter (see pages 89).
	<ul style="list-style-type: none"> • Damaged or defective screen. 	<ul style="list-style-type: none"> • If the unusual or unexpected screen appearance continues, call Clinical Trial Support.
Discomfort during Sensor insertion.	<ul style="list-style-type: none"> • Sensitivity to pain. 	<ul style="list-style-type: none"> • At next insertion rub the Sensor insertion site with ice before inserting Sensor. • Call Clinical Trial Support if problem persists.

Problem	Possible Cause	What To Do
Sensor Support Mount is not sticking to your skin.	<ul style="list-style-type: none"> • Dirty or wet skin at insertion site. • Lotion at insertion site. • Your skin or activity level may require more adhesive than that provided on the Sensor Support Mount. 	<ul style="list-style-type: none"> • Clean the Sensor insertion site by washing with soap and water. Make sure your skin is clean and thoroughly dry before placing Sensor Support Mount on skin. • Wipe the skin with an IV Prep wipe before inserting the Sensor. • Place an over-bandage over the Transmitter after connecting the Transmitter to the Sensor Support Mount.
Skin irritation at Sensor insertion site.	<ul style="list-style-type: none"> • Sensitivity to the Sensor adhesive. • Friction from the Sensor. 	<ul style="list-style-type: none"> • If irritation is around the edges of the adhesive or tape, lift the edges slightly all around the dressing. • If irritation is wherever the adhesive touches skin, you may be sensitive to the tape's adhesive or material. • Avoid wearing seams or waistbands over the site. • Consult your healthcare team to identify the best solution.

APPENDICES

Appendix A: Clinical Study for Palm and Finger Test

A clinical study was conducted to compare glucose readings using blood from the finger and blood from the palm at the base of the thumb. Forty-one subjects with type 1 diabetes were given a glucose challenge to raise glucose to a hyperglycemic state and then given subcutaneous insulin to reduce glucose to a normal or hypoglycemic state. The differences between readings from the finger and palm at the base of the thumb sites for all glucose levels and for low glucose levels are summarized below.

Table A.1. Clinical Trial Glucose Readings

	Range	Number of Test Pairs	Average Difference	Standard Deviation
All Tests	43-477 mg/dL (2.4-26.5 mmol/L)	1309	-2.1%	12.7%
Low Glucose	43-69 mg/dL (2.4-3.8 mmol/L)	72	1.9 mg/dL (0.3 mmol/L)	9.0 mg/dL (0.5 mmol/L)

Appendix B: Performance Characteristics

Description

The FreeStyle Navigator™ System is designed to continuously monitor glucose levels in subcutaneous tissue fluid in the range 20 to 500 mg/dL (1.1 to 27.8 mmol/L). Clinical studies have shown that subcutaneous tissue fluid glucose measurements by the System generally agree with fingerstick or alternate site blood glucose values and with venous laboratory values.

In Vivo Performance

The *in vivo* performance of the system was evaluated in a multi-center clinical trial that involved 85 subjects who used the system at home for an average of 17.8 days. Each subject used an average of 12 Sensors. Subjects took an average of 8 blood glucose measurements each day using the built-in FreeStyle blood glucose meter. System performance was assessed by comparing the Blood Glucose Mode readings with the Continuous Monitoring Mode readings. The data from the study were used to calculate the mean difference, mean absolute difference (MAD), and absolute relative error (ARE) between the Continuous Monitoring Mode and Blood Glucose Mode test results.

Estimated Mean Difference

The mean difference and mean percent difference were estimated using a mixed model repeated measures ANOVA (ANalysis Of VAriance). The mean difference between the glucose Sensor and the reference Receiver was 7.2 mg/dL (0.4 mmol/L)(std err = 0.78) at glucose concentrations <100 mg/dL (5.6 mmol/L) and the mean percent difference was -1.72% (std err = 0.36%) at glucose concentrations = 100 mg/dL (5.6 mmol/L).

Mean Absolute Difference (MAD) and Mean Absolute Relative Error (ARE)

The MAD between the Continuous Monitoring Mode and the Blood Glucose Mode glucose measurements was 17.4 mg/dL (0.4 mmol/L) (for measurements <100 mg/dL (5.6 mmol/L)). The ARE was 13.7% for glucose measurements = 100 mg/dL (5.6 mmol/L).

Linear Regression Analysis

Linear regression analysis of the Continuous Monitoring Mode compared to the Blood Glucose Mode yielded the following results over a glucose range of 20 to 464 mg/dL (1.1 to 25.8 mmol/L):

$$y = 0.943x + 6.8$$

$$\text{Slope} = 0.943$$

$$\text{Intercept} = 6.8$$

$$r = 0.893$$

Accuracy

Accuracy of the System was evaluated in a clinical study (N = 28) by comparing System readings to the glucose concentration of venous samples collected every 15 minutes for 72 hours and measured using a Yellow Springs Instruments (YSI) Glucose Analyzer. This testing yielded the following results over a glucose range of 20 to 500 mg/dL (1.1 to 27.8 mmol/L):

$$y = 1.00x + 5.7$$

$$\text{Slope} = 1.00$$

$$\text{Intercept} = 5.7$$

$$r = 0.914$$

Clarke Error Grid Analysis

Table 1 shows the distribution of the System/YSI data pairs within the zones of the Clarke Error Grid. Overall, 98.2% of the pairs were within the clinically accurate A Zone or the clinically acceptable B Zone of the error grid.

Table B.1: Clarke Error Grid Analysis of Data from FreeStyle Navigator™ System Accuracy Study

Clarke Error Grid Zone	Number of Pairs	Percent	Cumulative Percent
A	7865	70.7	70.7
B	3056	27.5	98.2
C	36	0.3	98.5
D	165	1.5	100.0
E	0	0.0	100.0

Interferents

In vitro and *in vivo* testing suggests that usual pharmacologic levels of ascorbic acid have no effect on the function of the System but salicylic acid has minimal effect. *In vitro* testing suggests that normal physiologic levels of uric acid, lipids, and bilirubin do not affect System function. The impact of oral hypoglycemic agents and other potential interfering substances has not been studied.

Limitations

Inaccuracy in glucose values obtained using the BG mode during calibration of the System will affect the accuracy of the System.

Appendix C: Specifications

Table C.1: FreeStyle Navigator™ System Specifications

Operating and storage temperature	40° to 104°F (4° to 40°C)
Operating and storage relative humidity	5% to 90%
Operating and storage altitude	Sea level to 10,000 feet (3,048 meters)
Operating pressure	14.1 psia (sea level) to 10.1 psia (10,000 feet)
Sensor life	Up to 3 days
Glucose result range	20 to 500 mg/dL (1.1 to 27.8 mmol/L)
Glucose assay method	Wired enzyme
Power source	Transmitter: One silver oxide 357 battery (small coin cell battery), replaceable (battery life is ~ 30 days) Receiver: Two AAA alkaline batteries, replaceable (battery life is ~ 3 months)
Transmitter size	Height 2.05 in. (5.2 cm)
	Width 1.23 in. (3.1 cm)
Transmitter weight	.48 oz
Transmitter battery life	Up to 30 days
Receiver size	Height 2.50 in. (6.3 cm)
	Width 3.25 in. (8.1 cm)
	Depth 0.88 in. (2.2 cm)
Receiver weight	3.5 oz. (including batteries; 99.2 grams)
Receiver battery life	Up to 3 months
Automatic shutoff	<i>Built-in blood glucose meter: 2 minutes after last user action</i>

	<i>Receiver: 12 seconds after last user action</i>
Receiver memory	<ul style="list-style-type: none"> • 60 days of normal use including continuous glucose readings (stored every 10 minutes) and daily blood glucose readings • Date/time will be remembered for 10 minutes after Receiver battery removal
Calibration	<ul style="list-style-type: none"> • Plasma equivalent
Calibration time	<ul style="list-style-type: none"> • First Calibration: This should be done approximately one hour after a new Sensor has been inserted. There is no maximum time allowed for this. Data CANNOT begin to be calculated until this first calibration is done. • Second Calibration: This must be done between 2 and 4 hours after the first calibration or glucose will no longer be calculated. The second calibration can still be performed after 4 hours, and glucose calculation will then resume. • Third Calibration: This must be done between 21 and 29 hours after the second calibration or glucose will no longer be calculated. The third calibration can still be performed after 29 hours, and glucose calculation will then resume.
Blood glucose test time	Average of 7 seconds
Blood glucose assay method	Coulometric electrochemical sensor
Blood sample type	Whole blood, capillary
Hematocrit	15% to 65%.

Classification

The Transmitter and Receiver are classified as follows:

-
- Internally-powered equipment
 - Type B equipment
 - Mode of operation for the Receiver is “continuous operation”
 - Mode of operation for the Transmitter is “continuous operation with intermittent loading”

FCC Compliance Information

Transmitter

Model Number: PRT01809-001

FCC Rules: Tested to comply with FCC Part 15, Class B, Security/Remote Control Transmitter

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

- This device may not cause harmful interference.
- This device must accept any interference received, including interference that may cause undesired operation.

NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or locate the receiving antenna.

-
- Increase the separation between the equipment and Transmitter.
 - Consult the dealer or an experienced radio/TV technician for help.

CAUTION: Changes or modification to the device not expressly approved by Abbott Diabetes Care could void the user's authority to operate the equipment.

Receiver

Model Number: PRT01845-001

Operating Environment: For Home or Office Use

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

- This device may not cause harmful interference.
- This device must accept any interference received, including interference that may cause undesired operation.

NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or locate the receiving antenna.
- Increase the separation between the equipment and Receiver.
- Consult the dealer or an experienced radio/TV technician for help.

CAUTION: Changes or modification to the device not expressly approved by Abbott Diabetes Care could void the user's authority to operate the equipment.

GLOSSARY

GLOSSARY

Adhesive Enhancers—Products that can help the adhesive pad on the Sensor Support Mount stick better to your skin.

Alarms—Sounds, vibrations, or text that the Receiver uses to notify you of certain conditions.

Alarms Menu—A menu you can access from the *Main Menu*. From the *Alarms Menu* you can turn an alarm on or off, set its sensitivity, and select alarm type.

Alarm Sensitivity—Can be adjusted to trigger the Projected Low/High Glucose Alarms (early warning alarms) sooner or later. The higher the sensitivity, the sooner the alarm will sound.

Alarm Type—Refers to the sound or vibration of the alarm. Alarm types include low, medium, or high beeps and short, medium, or long vibrations.

Antiseptics—Products that can be used at the Sensor insertion site if you tend to develop infections.

Backlighting—A light inside the Receiver that lets you see the display screen in the dark (at night, for example).

Blood Glucose Mode—One of two modes in which the System functions (the other is Continuous Monitoring Mode). In the Blood Glucose Mode, you can perform traditional blood glucose testing manually using a FreeStyle Test Strip and a drop of blood. Although you can use the Blood Glucose Mode whenever you wish, its main use is for calibrating the System.

Calibration—The System must be calibrated approximately 1, 3, and 24 hours after inserting a new Sensor. The System is calibrated using a blood glucose measurement (performed in the Blood Glucose Mode using the built-in FreeStyle Blood Glucose Meter). The Receiver compares the reading it gets from the blood to the reading the Sensor takes from the interstitial fluid. Based on the calibration, the Receiver calculates the most accurate real-time glucose readings.

Calibration BG—Allows you to add a new blood glucose measurement to the average used for Sensor calibration. Use this feature only under the direction of a Clinical Trial Support representative.

Capillary Blood—Blood from the tiny blood vessels in your body (such as in the tip of your finger or alternate sites) used to measure glucose levels in the Blood Glucose Mode. Capillary blood is also used for measuring glucose levels with traditional glucose meters.

CM Status—Lets you view recent error codes related to the Continuous Monitoring Mode. These codes appear only when the System is not functioning properly. Use this option only under the direction of a Clinical Trial Support representative.

Continuous Monitoring Mode—One of two modes in which the System functions (the other is Blood Glucose Mode). This is the mode you will use most of the time. It displays the glucose level in your interstitial fluid continuously, as measured by the Sensor you place just beneath your skin.

Control Solution Test—A test done with FreeStyle Control Solution in the Blood Glucose Mode using the built-in FreeStyle Blood Glucose Meter to ensure that the System is working properly.

Data Loss Alarm—An alarm that tells you when you are about to lose data, or when your alarms are about to stop working. Data Loss Alarms sound when the Transmitter/Receiver connection is broken or when the Sensor has expired.

Data Upload—The act of transferring data from the System to a computer.

Dressings and Skins—Products that can be used as over-bandages to cover the Transmitter. These can help the Sensor Support Mount adhesive stick to your skin.

Events—Activities and observations that can affect your glucose levels that you record in your System. Reviewing Events may help you see patterns in your glucose levels and how you manage your diabetes. Once entered into the System, Events may be viewed in several ways, including Event History Reports or Line Graph Reports.

Event History Reports—A type of report that incorporates the Event information you enter (for example, histories of recent glucose results, insulin doses, carbohydrate content of meals, exercise, state of health, etc.).

Exercise Event—A record of many popular forms of exercise. You may also specify the intensity and duration of each Exercise Event.

FreeStyle Control Solution—A solution containing a known amount of glucose. Used to perform Control Solution tests to make sure the System is working properly.

FreeStyle NavigatorTM Continuous Glucose Monitoring System—Also referred to as the “System”, this device is designed to give people with diabetes a continual reading of their glucose levels in real time.

FreeStyle Test Strips—A small strip into which you place a drop of blood to perform Blood Glucose Mode tests. You must use ONLY FreeStyle Test Strips with the System.

Generic Event—A record of any event that you or your healthcare team think is useful in evaluating glucose patterns. You may assign up to eight Generic Events to observations of your choosing.

Glucose Targets—The high and low levels that you would like your glucose to stay between. Used to make reports more meaningful. Glucose Targets are separate from—and independent of—the levels you may be using for High and Low Glucose Alarms.

Glucose Trend Arrows—Arrows shown on the Receiver that let you know whether your glucose levels are stable, increasing, or decreasing, and how quickly they are changing.

Hematocrit—A measure of the amount of red blood cells in your body.

High Glucose Alarm—Notifies you when you are at your high glucose threshold (a number you and your healthcare team will set).

High Glucose Threshold—The level you do not want your glucose level to rise above. You and your healthcare team choose the level that is right for you, and you set in the System. The high glucose threshold is used by the High Glucose Alarm and the Projected High Glucose Alarm.

Icons—Simple graphic symbols that appear on the Receiver display screen to alert you to non-urgent System conditions or actions required.

Insulin Event—A record of insulin doses (injection or pump) that you enter in the System to help you evaluate current therapy. The time and date of an Insulin Event are always recorded, and you may also enter the type of insulin and dose amount (units).

Interstitial Fluid—The fluid in the tiny spaces between your tissues. This is what the System uses to continually measure your glucose levels.

In vivo—The measuring of something *in* the body.

In vitro—The measuring of something *out of* the body, for example, in a test tube.

Lancet—A tiny, sharp-pointed, disposable component used with the lancing device to obtain a drop of blood for a Blood Glucose Mode test.

Lancing Device—A handheld piece of equipment that is used with a lancet to obtain a drop of blood for a Blood Glucose Mode test.

Lancing Device Cocking Handle—A part of the lancing device that you pull to position the lancet for pricking the test site.

Lancing Device Depth Setting—A part of the lancing device that lets you to adjust how deep the lancet pricks your skin.

Lancing Device Depth Indicator Window—A window on the lancing device that shows you the depth setting you have chosen.

Lancing Device Lancet Cup Holder—A part of the lancing device that holds the lancet in place when pricking your skin.

Left/Right Option Buttons—Buttons on the bottom of the Receiver face that allow you to select options shown on the display screen. The Right Option Button also turns the Receiver display screen on.

Line Graph Reports—Show continuous glucose lines (plotted at 10-minute intervals) for several different time periods (2, 4, 6, 12, or 24 hours).

Low Glucose Alarm—An alarm that tells you when you are at your low glucose threshold (a number you and your healthcare team will set).

Low Glucose Threshold—The level that you do not want your glucose level to fall below. You and your healthcare team choose the level that is right for you, and you set it in the System. The low glucose threshold is used by the Low Glucose Alarm and the Projected Low Glucose Alarm.

Main Menu—Displays a list of options that allow you to perform many functions and view specific information.

Meal Event—A record of a meal and snack that you enter in the System to help you see patterns in your glucose levels. The time and date are always recorded. You may also record carbohydrate grams to help you count carbohydrates or determine insulin/carbohydrate ratios.

Multi-day Statistics—A type of Statistical Report that shows a summary of glucose results in relation to your Glucose Targets over a specified number of days. You can choose 3-, 7-, 14-, 21-, or 28-day time periods.

Projected High Alarm—Provides an early warning when you are approaching your high glucose threshold.

Projected Low Alarm— Provides an early warning when you are approaching

your low glucose threshold.

Progress Tones—Communicate progress, errors, and successful completion of System activities such as Blood Glucose Mode testing.

Receiver—A wireless component of the System that looks and feels much like a traditional blood glucose meter. However, unlike traditional blood glucose meters, the Receiver can provide you with *continuous* glucose readings from the Sensor. The Receiver also has a built-in FreeStyle Blood Glucose Meter that works as a traditional blood glucose meter when a FreeStyle Test Strip is inserted into the Test Strip Port. You can wear the Receiver on your belt or carry it in your pocket or purse.

Receiver Display Screen—The rectangular window on the center of the Receiver that displays glucose levels and other important information.

Receiver Status—Provides you with information regarding the Receiver, including serial number, software version, and battery life remaining.

Receiver Test Strip Port—The slot on the lower left edge of the Receiver where you insert the FreeStyle Test Strips to calibrate the System or perform Blood Glucose Mode tests.

Reports—Information about your glucose levels shown in a way to help you and your healthcare team analyze changes in your glucose levels and your treatment plan (such as changes in insulin doses, carbohydrate intake, etc.) Several types of reports are available.

Sensor—The part of the System that you insert under your skin. Each inserted Sensor is intended to remain in place and provide a continuous glucose reading for up to 3 days.

Sensor Code Number—A number between 106 and 113 that you will find on the Sensor Delivery Unit packaging. This code number must be entered into the Receiver after you insert a new Sensor and before you complete the System calibration.

Sensor Delivery Unit—The Sensor Delivery Unit is designed and packaged to enable safe insertion of the electrochemical glucose Sensor into your skin. The Sensor Delivery Unit has 2 parts assembled and packaged together: the Sensor Inserter with pre-installed Sensor (which puts the tip of the Sensor under your skin) and the Sensor Support Mount (which stays on your skin to hold the Sensor in place and also attaches the Sensor to the Transmitter).

Sensor Inserter—The Sensor Inserter is a cylindrical-shaped, plastic-cased device. A pre-cocked, coiled spring is connected to a stainless steel needle, used to guide the Sensor for insertion. With a single push of the Insertion Button, the needle guides the Sensor into the skin and is quickly withdrawn from the skin. The Locking Pin is designed to avoid accidental discharge of the Sensor Inserter. Do not remove the Locking Pin until the Sensor Support Mount is adhered to the skin.

Sensor Insertion Button—With a single push of the Insertion Button, the needle guides the Sensor into the skin and is quickly withdrawn from the skin.

Sensor Insertion Site—The place on your body where you insert a Sensor, either on the abdomen or the back of the upper arm. Always change the Sensor insertion site each time a new Sensor is used. The Sensor should be inserted at least 1 inch from the previous site.

Sensor Locking Pin—A pin on the Sensor Delivery Unit that was designed to prevent accidental release of the Sensor. This must be removed before the Sensor can be inserted.

Sensor Release Tabs—Parts of the Sensor Delivery Unit that release the Sensor Inserter from the Sensor Support Mount.

Sensor Support Mount—The Sensor Support Mount is designed to stay on your skin to hold the Sensor in place and attach the Sensor to the Transmitter. The blue Release Tabs release the Sensor Inserter from the Sensor Support Mount after the Sensor is inserted into the skin. The Adhesive Protective Liner surrounding the Sensor Support Mount is designed to hold the Support Mount and Transmitter onto the body for up to 3 days of normal use.

Sharps Container—A safe place for disposal of Sensor Inserters and lancets.

Single-day Statistics—A type of Statistical Report that shows a summary of glucose results in relation to your Glucose Targets over a one-day period.

Site Rotation—The practice of using a different location on the body each time you insert a new Sensor. The new Sensor should be inserted at least 1 inch from the previous site.

Skin Barriers—Products that can help prevent irritation or sensitivity problems at the Sensor insertion site.

State of Health Event—A record of health-related events, symptoms, and other observations that may help you see patterns in your glucose levels.

Statistical Reports—A comprehensive summary of glucose results relative to your Glucose Targets. You can view Statistical Reports for 1-, 3-, 7-, 14-, 21-, or 28-day time periods. Viewing this kind of information can help you see patterns in your glucose levels.

Status Information—Information about the System and how it is working, such as Sensor time or battery life remaining.

System—A short name for the FreeStyle Navigator™ Continuous Glucose Monitoring System.

System Alarms—Non-urgent System messages (for example, low battery life, time for calibration).

System Menu—A menu available from the *Main Menu* that is used to access Status information and other functions.

Transmitter—A small electronic device that makes an electrical connection to the portion of the Sensor that extends above the skin. The Transmitter processes the very low current signals it receives from the Sensor and sends the glucose values to the Receiver once every minute.

Transmitter Contact Points—Conductive points that connect the Transmitter to the Sensor Support Mount.

Transmitter/Receiver Connection—The wireless connection needed for the System to function. The Transmitter and the Receiver must be within 10 feet of each other for the connection to be valid.

Transmitter Sensor Support Mount Latch—A connector that helps secure the Transmitter to the Sensor Support Mount.

Transmitter Status—Allows you to view the Transmitter serial ID number and battery life remaining.

Transmitter Tabs—Connectors that help secure the Transmitter to the Sensor Support Mount.

Up/Down Arrow Buttons—Buttons on the right face of the Receiver that allow you to move through lists to highlight options. Also used to change numbers.

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