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IPR2023-01409

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5,262,035; 5,264,104; 5,264,105; 5,593,852; 5,899,855; 5,918,603; 5,965,380; 6,071,391; 6,103,033; 6,120,676; 6,121,009; 6,134,461; 6,143,164; 6,162,611; 6,175,752; 6,284,478; 6,299,757; 6,329,161; 6,338,790; 6,461,496; 6,484,046; 6,503,381; 6,514,718; 6,560,471; 6,565,509; 6,591,125; 6,592,745; 6,605,200; 6,605,201; 6,616,819; 6,618,934; 6,676,816; 6,749,740; 6,893,545; 6,932,894; 6,942,518; 6,973,706; 6,990,366; 7,003,340; 7,003,341; 7,074,308; 7,090,756; 7,299,082.

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ART16072 Rev. A 05/08

Abbott

FreeStyle Navigator®

Continuous Glucose Monitoring System



User's Guide

R_x *Only* **CAUTION:** Federal law restricts this device to sale by or on the order of a physician.

Abbott

Indications for Use

The FreeStyle Navigator® Continuous Glucose Monitoring System is indicated for continually recording interstitial fluid glucose levels in people (ages 18 and older) with diabetes mellitus for the purpose of improving diabetes management. Readings and alarms about glucose levels from FreeStyle Navigator® Continuous Glucose Monitoring System are not intended to replace traditional blood glucose monitoring. Before adjusting therapy for diabetes management based on the results and alarms from the FreeStyle Navigator® Continuous Glucose Monitoring System, traditional blood glucose tests must be performed. The FreeStyle Navigator® Continuous Glucose Monitoring System provides a built-in blood glucose meter to confirm the continuous glucose result.

The FreeStyle Navigator® Continuous Glucose Monitoring System provides real-time readings, graphs, trends, and glucose alarms directly to the user. The FreeStyle Navigator® Continuous Glucose Monitoring System is intended to be used in home settings to aid people with diabetes in predicting and detecting episodes of hypoglycemia and hyperglycemia and in clinical settings to aid health care professionals in evaluating glucose control. The FreeStyle Navigator® Continuous Glucose Monitoring System is available only by prescription.

Contraindications

The FreeStyle Navigator® Continuous Glucose Monitoring System must be removed prior to Magnetic Resonance Imaging (MRI).

How to Use this Guide?

This guide has many Sections arranged in a logical sequence that will be useful for the first time use and every use thereafter. Most Sections begin with a purpose for that Section, when to perform the steps in that Section, materials required to perform the steps in that Section and important cautions, warnings and helpful information. The first page of each Section will be very useful when you are getting familiar with the system. Once you are familiar with the system and the typical precautions, you may find yourself relying less on the first page of the individual Sections.

The remainder of each Section describes the steps to perform the tasks. The steps are organized in a simple manner to allow you to see what to do based on what you experience and based on where you are in that particular Section. It is important that you go through the steps in the order that they have been presented. Every Section also indicates if you have reached the end of the Section. If you find it difficult to use the guide or if you seem lost or confused, use the table of contents, index, glossary and appendices to help you. The table of contents provides a list of Sections you will find in this guide and what each Section contains. The appendices have useful information that you may want to refer to. The glossary provides a list of terms and what they mean. The index is a tool you could use to quickly find terms and items that you are looking for.

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Glossary of Symbols

	Do not re-use		Temperature limitation
$R_{x\ Only}$	Rx only. For use by prescription only		Manufactured by
STERILE	Sterile		Consult operating instructions
	Use by	LOT	Batch code
SN	Serial number	REF	Catalog number

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1 Getting Acquainted

Section 1

Section 1 – Key Terms

- **Alarms**
- **Blood Glucose Mode**
- **Continuous Monitoring Mode**
- **FreeStyle Navigator Continuous Glucose Monitoring System**
- **FreeStyle Test Strips**
- ***in vitro***
- **Interstitial Fluid**
- **LEFT/RIGHT Option Buttons**
- **Receiver**
- **Receiver Display Screen**
- **Receiver Test Strip Port**
- **Reports**
- **Sensor**
- **Sensor Delivery Unit**
- **Sensor Inserter**
- **Sensor Insertion Button**
- **Sensor Locking Pin**
- **Sensor Release Tabs**
- **Sensor Support Mount**
- **Transmitter**
- **Transmitter Tabs**
- **UP/DOWN Arrow Buttons**

1 Getting Acquainted

Introduction

Important: *Read all of the instructions in this User's Guide and the FreeStyle® Test Strip package insert before using your FreeStyle Navigator® Continuous Glucose Monitoring System. Adjustments to your treatment should be done under the guidance of your healthcare team.*

Your FreeStyle Navigator system continuously reads, displays, and records the glucose levels in the fluids found between the cells under your skin (interstitial fluids). It does this by using a small, thin, plastic sensor inserted just under the skin.

Your FreeStyle Navigator system provides you with continuous glucose readings in real time. By having access to more frequent glucose measurements, you can monitor your glucose levels and gain an understanding of patterns in your glucose levels. This will help you and your healthcare team see how factors such as your diet, insulin, exercise, and diabetes medication affect your glucose levels, and to adjust your treatment plan accordingly.

Your FreeStyle Navigator system has a number of helpful features.

- Wireless communication between the transmitter and receiver.
- Disposable sensor that can be worn up to 5 days.
- Alarms to alert you to low or high glucose levels (hypoglycemia or hyperglycemia) ***before*** reaching those low and high glucose levels and ***when*** reaching those glucose levels.
- Graphs and statistics that show your glucose results in easy-to-understand formats.
- Directional glucose trend arrows that show if your glucose values are rising or falling and how fast.
- Memory to hold up to 60 days worth of data.
- Wireless communication capabilities to a personal computer.
- Built-in FreeStyle® Blood Glucose Meter for performing blood glucose measurements.
- Event entry capabilities (like meals, exercise, insulin and other).
- Backlit display.

Important: *Keep this User's Guide for future reference. It will come in handy when you have to do procedures that you do not do often enough to remember.*

How are the parts packaged?

Your FreeStyle Navigator system comes with two kits:

- A System kit.
- A Sensor kit.

The System Kit

- *1 FreeStyle Navigator Receiver in a Receiver Skin*
- *2 AAA Alkaline Batteries (for the receiver)*
- *1 FreeStyle Navigator Transmitter*
- *1 Silver Oxide 357 HC Battery (for the transmitter)*
- *1 Belt Clip (for the receiver)*
- *1 FreeStyle Lancing Device*
- *1 Finger Cap (for the lancing device)*
- *1 User's Guide*
- *1 Getting Started Guide*
- *1 Quick Reference Card*
- *1 Welcome Card*
- *6 Overbandages*
- *12 Alcohol Prep Pads*
- *30 Sterile Lancets*
- *1 Vial of FreeStyle Control Solution and Insert*
- *1 Vial of 50 FreeStyle Strips and Strip Insert*
- *1 Warranty Registration Card*

The Sensor Kit

- *6 Sterile Sensor Delivery Units (each containing a sensor) and Product Insert*
- *1 Silver Oxide 357 HC Replacement Battery (for the transmitter)*

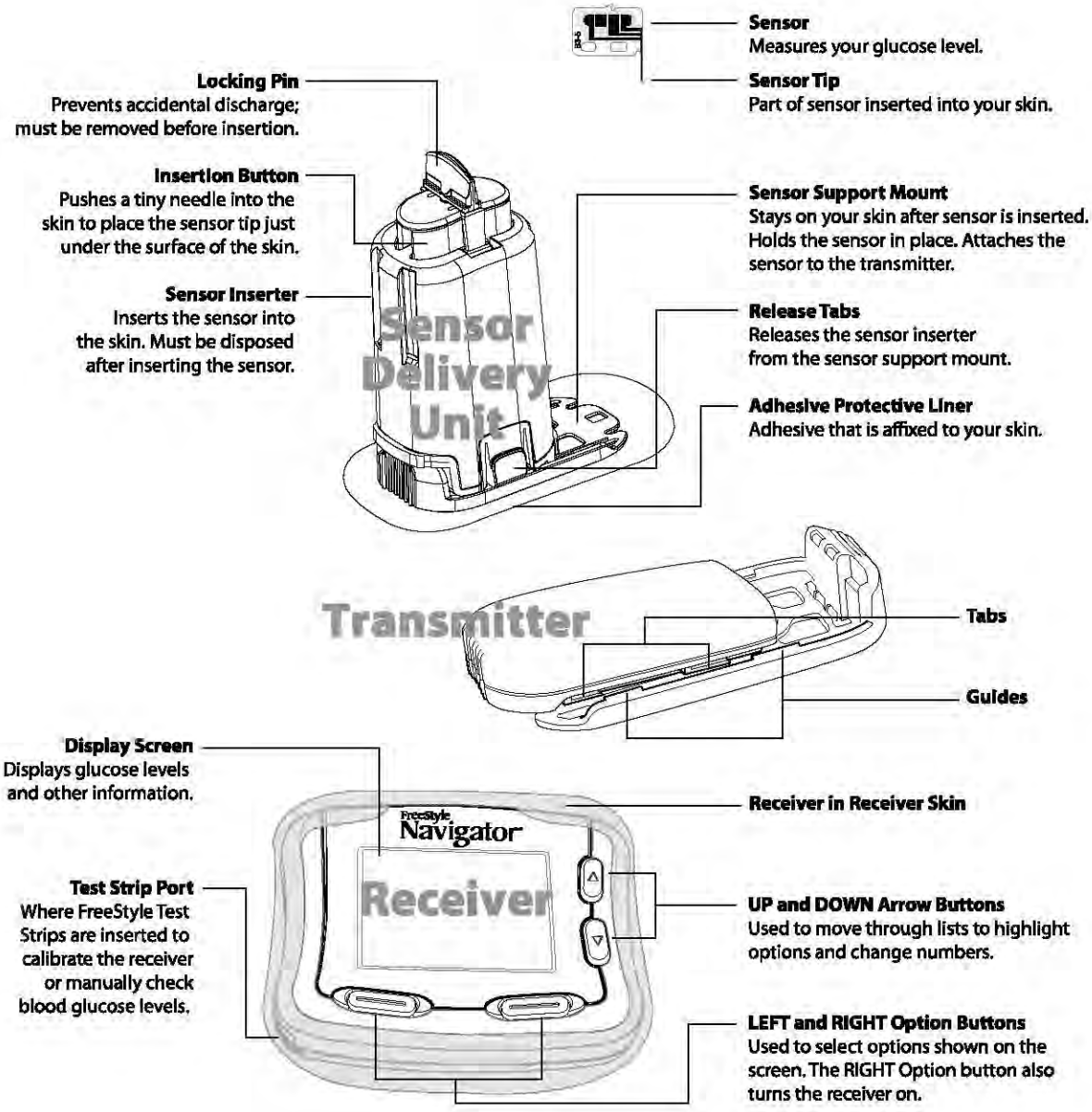
- In addition, the FreeStyle Navigator system can transfer data to a computer wirelessly using Bluetooth® technology.

Important Notes:

- The FreeStyle Navigator® Continuous Glucose Monitoring System is designed as a complete system. Use only the FreeStyle Navigator Sensor, the FreeStyle Navigator Transmitter, the FreeStyle Navigator Receiver and FreeStyle Test Strips.
- The system is intended for your personal use; do **NOT** share your system with others.

What are the key parts of my system?

Your FreeStyle Navigator system includes the following major parts:



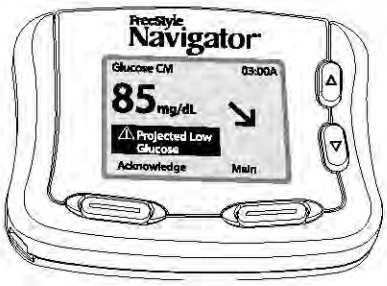
a. A FreeStyle Navigator Sensor that you insert about 5 mm under your skin. Each inserted sensor is intended to remain in place and provide a continuous glucose reading for up to 5 days. The sensor is contained in the Sensor Delivery Unit.

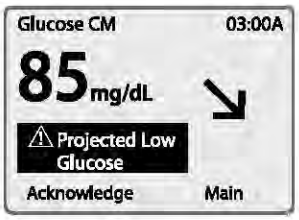
b. A wireless FreeStyle Navigator Transmitter (Tx), a small electronic device that connects to the sensor and sends glucose values to the receiver once every minute.

c. A wireless FreeStyle Navigator Receiver (Rx) that captures and displays glucose measurements. With the press of a button, the receiver displays the glucose measurement taken from the sensor.

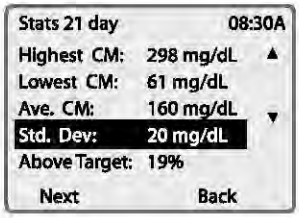
Note: The receiver also has a built-in FreeStyle Blood Glucose Meter that can be used for blood glucose testing. The receiver should always be kept with you on a belt, in a pocket, or in a purse.

Key features of the System

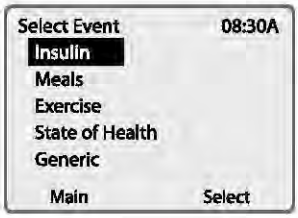




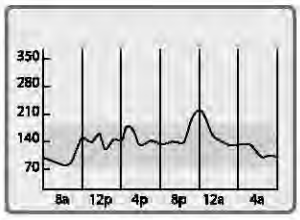
Alarms



Statistics



Event Log



Line Graph

Your receiver comes with backlight capability to see the screen in dark environments. The backlight can be turned on by pressing and releasing the DOWN Arrow button and then pressing and releasing the RIGHT Option button.

For more details on the different symbols and icons on the screen, see Section 9 on "Daily Use".

Using your system

For Daily Activities

You will be wearing a sensor and a transmitter at all times while you are using the system. Keep the following in mind as you go about your normal routine.

- Only wear the sensor and transmitter on a flat surface of either your abdomen or the back of your upper arm.
- ***Sleeping*** – The sensor and transmitter should not interfere with your normal sleeping patterns. As you get ready to go to sleep, place the receiver within 10 feet to maintain the transmitter-to-receiver connection.
- ***Bathing*** – Do **NOT** wear the receiver while bathing or showering. Do **NOT** allow the receiver to get wet. However, you can wear the sensor and transmitter while bathing or showering.
- ***Swimming*** – You may swim while wearing the sensor and transmitter. Do **NOT** go deeper than 1 meter (approximately 3 feet).

Note: The connection between the transmitter and receiver is **NOT** maintained when the transmitter is underwater; thus, you will **NOT** receive continuous glucose readings. However, when you take the sensor and transmitter out of the water, the continuous glucose readings will resume.

When Traveling by Plane

Note: Do **NOT** perform the upload data feature when you are on a commercial aircraft.

Follow the guidelines below when traveling. Always check with local authorities prior to departure as rules and regulations may change without notice.

At the airport:
Notify the security personnel of the presence of the device when going through the security systems.

On the plane:
Check with your airline before departure whether the device will be permitted aboard the aircraft. The airline companies set policies regarding the use of medical devices on board their flights.

If you want to disable the transmit function of the transmitter, follow these steps:

1. If you are currently wearing a sensor, remove the sensor.
2. Detach the transmitter from the sensor support mount and remove the battery from the transmitter.
3. Program into the receiver that you have ended a sensor session.
4. By removing the battery from the transmitter, you have broken the connection between the transmitter and receiver. You can set the data loss alarms and system alarms to a short vibration mode in order to prevent the device from sounding alarms. Once you put a new battery into the transmitter, make sure to set the alarms to the original setting.

Note: Insert a fresh battery into the transmitter after travel before inserting a new sensor.

You can always use your receiver to check your blood glucose manually in the Blood Glucose mode.

How do I prepare my system for the first time?

When you are setting up your receiver for the first time, perform all of the procedures listed below ***in the order that they are listed***. Check each procedure off when you complete it.

- ❑ Install batteries in the transmitter first and then in the receiver (***see Section 2***).
- ❑ Set the time and date (***see Section 3***).
- ❑ Perform a control solution test (***see Section 4***).
- ❑ Insert your sensor (***see Section 5***).
- ❑ Attach your transmitter (***see Section 6***).
- ❑ Calibrate your receiver when prompted (***see Section 7***).
- ❑ Set the alarms in the receiver (***see Section 8***). **Note:** This can be done while waiting to perform the first calibration.

Result: *Your system is operational.*

Warnings, Cautions And Important Notes

Important Notes About System Performance

The following items describe situations that could lead to inaccurate or unreliable continuous glucose results.

Cautions:

- *Movement of the sensor support mount or excessive perspiration at the sensor insertion site due to activities like vigorous exercise or bumping against objects may lead to poor adhesion of the support mount to the skin and cause the sensor to dislodge. If the sensor dislodges due to the sensor support adhesive failing to adhere to the skin, you may get unreliable results or no results. The system may not provide a warning in such circumstances. Choose the proper sensor insertion site when inserting the sensor and prepare the site by following the instructions for site preparation.*
- *If your results from the Continuous Monitoring mode seem erroneous, check and make sure that the sensor has not dislodged. If you notice the sensor is dislodged from the skin, or if you see that the adhesive on your overbandage or the sensor support mount is coming loose, discard the old sensor and insert a new sensor.*
- *The FreeStyle Navigator system includes built-in self-checks to detect conditions that may cause the sensor to not function properly. On rare occasions the system may not be able to detect all such conditions (for example if the adhesive peels up from your skin), and you may get inaccurate results in the Continuous Monitoring mode. If you believe your results are not reliable, or are inconsistent with how you feel, perform a Blood Glucose mode test to measure your glucose. If the problem continues, discard the old sensor and insert a new sensor.*
- *You should never reset your user settings when you are wearing a sensor. This will reset parameters that may affect your system performance.*
- *If you accept an incorrect transmitter ID when linking your Transmitter and Receiver, your glucose readings will be incorrect.*
- *Do **NOT** use the sensor delivery unit if the sterile package is open or damaged.*

Important:

- *Once the code has been entered and you have hit the Set button, you will not be able to change the sensor code number. If you have entered the code incorrectly, you will have to replace the sensor and enter the right sensor code. If you choose the wrong sensor code, you may get erroneous results from the sensor. The code numbers MUST match to ensure accurate test results.*
- *Do **NOT** remove or replace the transmitter from the sensor support mount while wearing a sensor. If you notice that the transmitter is not properly attached, replace the sensor with a new sensor and then reattach the transmitter.*

Important Things to Remember About System Calibration

***Caution:** Always calibrate the system using only a finger-stick blood sample. Do **NOT** use alternate site blood glucose measurements to calibrate the system. The receiver contains a built-in FreeStyle® Blood Glucose Meter for performing calibration tests.*

***Important:** Your blood glucose level must be between 60 and 300 mg/dL (3.3 and 16.7 mmol/L) to be able to perform calibration tests. If your blood glucose level is changing rapidly, you may not be able to calibrate the system. For example, during a meal or exercise, your glucose levels may vary rapidly. Try to time your sensor insertion so that your calibration times do not coincide with your regular meal or exercise activities.*

Important Things to Remember About System Calibration *(con't)*

Important: *In clinical trials, we observed that the sensor signal sometimes temporarily decreases from the true value. This typically happens at night during sleep, and recovers rapidly when the user moves or is awakened. However, in order to avoid being affected by this phenomenon the system should not be calibrated when the wearer is asleep.*

- You may not be able to calibrate the system if your glucose levels are changing rapidly. (e.g. during or after exercise, meals or insulin dosing). Under such conditions, the system may not ask you to calibrate; instead, it will delay its request until conditions are acceptable.
- You **MUST** successfully complete 4 calibration tests. You will calibrate at approximately 10, 12, 24 and 72 hours after sensor insertion. If you do not complete calibration tests successfully in the allotted time periods, your glucose readings will NOT be displayed and alarms will be inactive. The system may ask you to perform additional calibrations between 2nd and 3rd calibrations depending on the sensor signal. In such cases, you will be prompted with a message to do additional BG tests.
- The receiver will beep (or vibrate) to prompt you to do a calibration. The receiver will display a blood drop icon and the message "Do BG Test." The system will prompt you with alarm messages when your calibrations are unsuccessful.
- You will not have continuous monitoring until you have successfully completed the first calibration (at least for the first ten hours after sensor insertion).
- If you get a request for a calibration or expect additional calibration requests during a time when you do not want to be disturbed (e.g. sleep time), you can choose to wait to perform additional BG tests at a later point in time. If you choose to wait and the allotted time window for calibration has expired, please note that you will not get glucose results until you have performed a successful calibration. You can turn off the System Alarms (or set to vibrate) if you do not want to be disturbed by frequent requests for calibration. In order to silence the alarms that warn you when the allotted time window for a calibration has expired, you must turn off the data loss alarms and all the four glucose alarms (Low Glucose, High Glucose, Projected Low Glucose and Projected High Glucose).

Before You Get Started

Installation and operation of the FreeStyle Navigator® Continuous Glucose Monitoring System requires using a specialized introducer needle to insert the glucose sensor into the skin. Infection, inflammation, or bleeding at the glucose sensor insertion site are possible risks of inserting a sensor into your skin. The glucose sensor should be removed if redness, pain, tenderness, or swelling develops at the sensor insertion site.

Cautions:

- *Before adjusting treatment for diabetes management based on the continuous glucose results from your FreeStyle Navigator system, perform a Blood Glucose mode test to confirm the continuous result.*
- *Performance of the FreeStyle Navigator system has not been evaluated in pregnant women.*
- *Performance of the system under conditions of fluctuating hydration levels such as during renal dialysis has not been evaluated.*

Before You Get Started *(con't)*

Cautions:

- *Low or high glucose measurements can indicate a potentially serious medical condition.*
- *If you have hypoglycemia, or hypoglycemia unawareness, then test ONLY on your fingers.*
- *The high and low alarms are intended to assist you in managing your diabetes and should not be exclusively used to detect hypoglycemia or hyperglycemia. The alarms should always be used in conjunction with other indications of glycemic state such as your glucose level, trend, line graph etc.*
- *High and low glucose alarms are DIFFERENT from your glucose targets. Low and high glucose alarms alert you when you've crossed a certain low or high value. Glucose targets allow the reports and line graphs to show how your glucose levels have been performing compared to your set targets.*
- *The Low Glucose alarm cannot be set below 60 mg/dL (3.3 mmol/L). Therefore, it is not intended to notify you of severe hypoglycemia.*
- *The High Glucose alarm cannot be set above 300 mg/dL (16.7 mmol/L). Therefore, it is not intended to notify you of severe hyperglycemia.*
- *It is important to use the correct type of batteries in the receiver, otherwise the battery life may not be accurately monitored.*
- *Do NOT immerse the receiver in water or in any other liquid. Avoid getting water or any other liquid in the test strip port.*
- *Changes or modifications not expressly approved by Abbott Diabetes Care, Inc. could void the user's authority to operate the equipment.*
- *The system should not be used in environments that are oxygen-rich or that contain a combustible gas.*
- *The radio receiver and transmitter of your FreeStyle Navigator system operate on the frequency of 433.6 MHz. Primary users of this frequency band include amateur "HAM" radio transmitters. Because of the coexistence of the FreeStyle Navigator radio connection and HAM transmitters, there may be instances where the connection between your transmitter and receiver may be lost when in proximity to HAM radio equipment. The FreeStyle Navigator system is designed to sense and notify you about a lost connection. If your FreeStyle Navigator system loses the radio connection, increase the separation distance between yourself and the transmitter by moving away from the HAM radio. The FreeStyle Navigator radio connection should re-establish itself. You should note that HAM radio products can be fixed, mobile or portable handheld ("walkie talkie" type) units.*

Important: *Because you must insert a new sensor after each battery replacement, you should replace the batteries just before you insert a new sensor. For example, if you drop your receiver and the batteries fall out, you will have to insert a new sensor.*

Warnings:

Keep your system and its components away from young children because:

- There are small parts that may be dangerous if swallowed.
- The control solution caps are choking hazards.
- The test strip vial and sensor delivery unit packaging may contain a drying agent that could be harmful if inhaled or swallowed and may cause skin and eye irritation.

NEVER point a pre-cocked sensor inserter toward the eyes, face, or any other body part where sensor insertion is not desired.

Before You Get Started *(con't)*

- If your results from the continuous monitoring mode do not reflect how you feel, test your glucose using the Blood Glucose mode.
- If you observe a significant change in your continuous glucose readings that you think is erroneous, or if you feel the blood glucose measurement in the Blood Glucose mode is erroneous and you are close to an electromagnetic interference source, move away from the source of interference and check to see if the condition fades away.
- If you have a medical appointment that includes X-ray, MRI (Magnetic Resonance Imaging), CT (Computed Tomography) scan, or another type of exposure to radiation, keep your system and sensor away from the area. Before exposure to such radiation, discard any sensor you are wearing and insert a new sensor after the radiation session. The effect of these types of radiation on the performance of the system has not been evaluated.

Helpful health related information:

The following pertain to your health and should always be kept in mind:

- The system is intended to assist you in better managing your diabetes by allowing you to know your glucose levels throughout the day.
- Test results below 60 mg/dL (3.3 mmol/L) mean your glucose levels are low.
- Test results above 240 mg/dL (13.3 mmol/L) mean your glucose levels are high.
- Severe dehydration and excessive water loss may cause false low results. If you believe you are experiencing severe dehydration, consult your healthcare team immediately.
- If you get results below 60 mg/dL (3.3 mmol/L) or above 240 mg/dL (13.3 mmol/L) and do not have symptoms of hypoglycemia or hyperglycemia, 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 240 mg/dL (13.3 mmol/L), consult your healthcare team.
- If you are experiencing symptoms that are not consistent with your glucose test results, consult your healthcare team. Physiologic differences between the interstitial fluid and capillary blood may result in differences in glucose measurements. Differences in glucose measurement between interstitial fluid and your finger may be observed during times of rapid change in blood glucose, e.g. after eating, dosing insulin, or exercising.
  - Interstitial fluid (ISF) is the fluid between cells in the body. Movement of nutrients, oxygen and glucose from the blood into the cells happen across the ISF. Therefore, if the glucose in the bloodstream rises (e.g. during meals), that rise is not seen in the ISF until later. Similarly, if glucose levels in the ISF drop (for example during exercise, the cells consume glucose rapidly) that drop is not seen in the bloodstream until later.
- 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, or calf) may result in different glucose readings. Differences in blood glucose readings between your finger or palm (at the base of your thumb) and other test sites (forearm, upper arm, hand, thigh, or calf) may be observed after eating, taking insulin, diabetes medication, or exercising.
- Test your finger if you are testing for hypoglycemia or if you have hypoglycemia unawareness (see next page for definition of hypoglycemia unawareness). Changes in glucose levels may be observed in finger blood samples sooner than in samples from alternate sites (forearm, upper arm, hand, thigh, or calf). If an alternate site must be used, vigorous rubbing of the alternate site before lancing can help minimize this difference.
- Do not use the FreeStyle Navigator system for diagnosing diabetes, testing newborns, or testing arterial or venous blood.

What is Hypoglycemia Unawareness?

Hypoglycemia unawareness is a condition where you are having hypoglycemia but you do not have any of the usual warning symptoms (such as rapid heartbeat, sweating, shakiness, anxiety, or a tingling sensation in your fingers or toes). Those warning symptoms are either absent or greatly reduced. Instead, the first sign may be confusion or impaired thinking, which makes it even more difficult to know if you are experiencing low blood glucose. You could find yourself in the midst of a severe hypoglycemic episode without any warning at all.

Symptoms of Hypoglycemia Unawareness:
Because you would have missed the early warning signs of hypoglycemia, the only signs or symptoms you may have would be due to the effects of low blood glucose on the brain:

- Irritability
- Tiredness
- Confusion
- Forgetfulness
- Pale skin
- Slurred speech
- Loss of consciousness

This condition is potentially dangerous because hypoglycemia confusion can occur without warning.

If you were driving a car or operating heavy machinery, confusion or delayed reaction could cause an accident.

Hypoglycemia unawareness can develop for several reasons:

a. Having frequent hypoglycemic episodes.

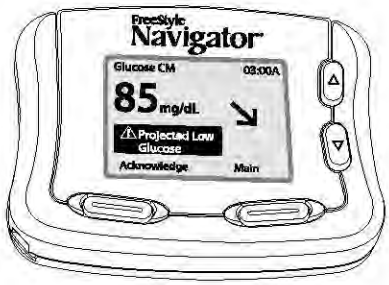
b. Having long standing diabetes and autonomic neuropathy (a form of diabetic neuropathy in which your body does not release its usual hormones to warn you of low blood glucose and to tell your liver to release glucose as a protective mechanism).

If you think you have hypoglycemia unawareness, talk to your healthcare team.

What are the Continuous Monitoring mode and Blood Glucose mode?

Your FreeStyle Navigator system operates in two modes:

- Continuous Monitoring mode (Glucose CM).
- Blood Glucose mode (Glucose BG).



Continuous Monitoring Mode (Glucose CM)

The Continuous Monitoring mode is the mode you will use most of the time. It continuously displays the glucose level in the fluid in the tiny spaces between your tissues (interstitial fluid). This glucose reading comes from the sensor you will place just beneath your skin and is updated every minute.

- "Glucose CM" at the top left of the display.
- The glucose reading is typically accompanied by a directional trend arrow that indicates how fast your glucose is changing and in what direction.
- Most frequently used mode.
- Measures glucose from interstitial fluid detected by a sensor in your skin.
  - Uses a sensor to measure glucose levels.
  - A transmitter sends the glucose readings to the receiver.
  - Should only be used with FreeStyle Navigator system Transmitters and FreeStyle Navigator Sensors.



Blood Glucose Mode (Glucose BG)

You will perform traditional blood glucose testing (BG testing) in the Blood Glucose mode using a FreeStyle Test Strip and a drop of blood. You can use the Blood Glucose mode whenever you wish to perform a traditional blood glucose test. It is also used for calibrating the system. Blood Glucose mode tests used for calibrating the system can also be relied on like traditional blood glucose tests.

- "Glucose BG" at the top left of the display.
  - Built-in FreeStyle Blood Glucose Meter.
- Measures glucose from a blood sample that you supply.
- Uses a FreeStyle Test Strip to measure blood glucose levels.

Note: Use **ONLY** FreeStyle Test Strips and Control Solution. FreeStyle Lite Test Strips will not work in the receiver. Other brands of test strips or control solution can give you inaccurate results.

The system typically works in the Continuous Monitoring mode. It switches to the Blood Glucose mode when you insert a FreeStyle Test Strip into the receiver's test strip port. In order to turn the Blood Glucose mode on, you have to insert the test strip when the receiver is either turned off or when it displays the glucose screen.

END OF Section 1

2 Install or Replace Transmitter and Receiver Batteries

Section 2

Section 2 – Key Terms

- **Alarm**
- **Icon**
- **Receiver**
- **Transmitter**
- **Battery Life**
- **Alkaline Batteries**
- **357 HC Silver Oxide Battery**
- **Reconnect**

2 Install or Replace Transmitter and Receiver Batteries

Purpose To ensure that your FreeStyle Navigator system has power to operate properly.

Start Do this procedure:

- The first time you use your FreeStyle Navigator system.
- When the receiver displays the Low Battery message and alarm and the battery icon appears on the screen.
- When the receiver sounds an alarm and displays the "Replace TX Battery with Next Sensor" message.

Materials Gather these materials before you begin:

- 2 new AAA alkaline batteries for the receiver. We recommend Energizer® Max®, Energizer® e2® Titanium®, and Energizer® Industrial batteries. Other batteries may not provide expected battery life.
- 1 Silver Oxide 357 HC battery for the transmitter.
- A coin.
- Your FreeStyle Navigator Receiver.
- Your FreeStyle Navigator Transmitter.

Helpful Information

Caution: *It is important to use the correct type of batteries in the receiver, otherwise the battery life may not be accurately monitored.*

Important:

- *An alarm will sound and a battery icon will appear on the screen when your receiver batteries are running low. You must replace your receiver batteries the next time you replace your sensor. Make sure to replace batteries before inserting your next sensor.*
- *An alarm will sound and a message will appear on the screen when your transmitter battery is running low. You have approximately 4 days of battery power remaining when this first happens.*
- *Because you must insert a new sensor after each battery replacement, you should replace the batteries just before you insert a new sensor. For example, if you drop your receiver and the batteries fall out, you will have to insert a new sensor.*
- *After installing the transmitter or receiver batteries, allow a couple of minutes for the system to recognize new batteries. You may then access the status of the battery life from the System menu in your receiver (see Status Information in Section 10). If the batteries are new, the status screen will show 75-100% as remaining battery life.*

- **If your receiver batteries are low and you fail to replace them, they may run out without a warning and the receiver will neither display your glucose levels nor sound alarms.**
- The transmitter's battery life is estimated to be up to 30 days.
- The receiver's battery life is estimated to be 60 days. However, battery life may be shorter than 60 days if your receiver's alarms are set to vibrate, 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, remove the batteries from the receiver to preserve battery life.
- To avoid draining the receiver's batteries, be careful not to accidentally press and hold the receiver's buttons for a long period of time.
- After changing the batteries, make sure that you reconnect the transmitter and receiver to establish communication between them.
- If you are replacing batteries on both the transmitter and receiver, replace the battery in the transmitter first.

Install or Replace the Transmitter Battery



Fig. 1

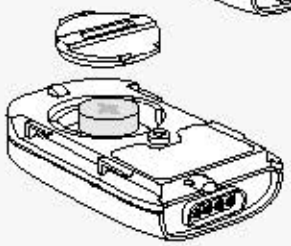


Fig. 2

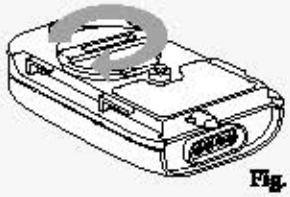


Fig. 3

a. Turn the circular battery door counterclockwise with either a coin or your fingernail. (Fig. 1)

b. Carefully remove the battery door.

c. Remove the old battery, if any, and discard it properly.

d. Insert a NEW silver oxide 357 HC battery with the plus sign (+) facing you. (Fig. 2)

***Important:** When inserting the battery in the transmitter, pay special attention to placing the battery straight in rather than at an angle. Do not rock the battery back and forth as this can shorten the battery life.*

e. Replace the battery door and secure it in place by rotating clockwise. (Fig. 3)

Note: The battery door must be closed securely to create a seal. Do not apply excessive force when closing. Excessive force can damage the plastic material of the battery door and the transmitter case. If you are not changing the receiver batteries at this time, reconnect the transmitter and receiver, then go to 'Check your work' at the end of this Section.

Install or Replace the Receiver Batteries



Battery door





Note: The receiver skin must be removed in order to access the receiver's battery door.

a. Locate the battery door on the back of the receiver.

b. Press down on the ridged part of the battery door to slide the battery door completely out.

c. Remove old batteries, if any, and discard them properly.

Note: Be sure to finish within 5 minutes to prevent losing the date and time settings.

d. Insert the new batteries with the positive (+) as shown. Align the + and - signs of the batteries with the signs as shown in the battery compartment.

e. Press each battery into its channel making sure the battery fits tightly.

Note: The receiver will not operate if the batteries are not inserted in the proper direction.

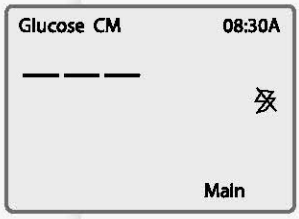
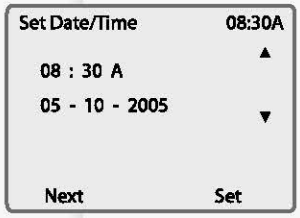
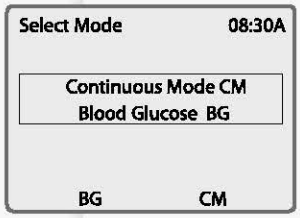
f. Replace the battery door with the tab facing the receiver.

g. Align the edges of the door with the channel in the battery compartment.

h. Slide the door into the receiver until it clicks.

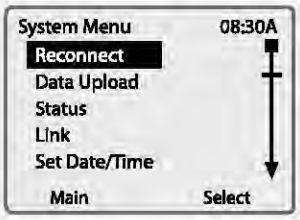
i. Match the screen on your receiver with ONE of the screens in the next table and perform the corresponding step.

Match what you see on your Receiver with ONE of the screen shots shown below.

If the display is	*Then*
	• Press the RIGHT Option button to see if the screen turns on. • If screen turns on, compare with the screens below and perform the matching steps. • If screen does **NOT** turn on, then repeat this procedure ensuring that the batteries are: – New. – Oriented properly in the battery compartment. – If the problem persists see Section 10 on troubleshooting.
	• The receiver is working properly. Go to "Check your work". You may not see the icon if you have connection between the transmitter and receiver. Reconnect the transmitter and receiver if you see the icon.
	• The time and date need to be set. Go to Step 4 of Section 3. • Set the Time and Date. After setting the time and date, reconnect the transmitter and receiver. Then, "Check your work".
	• Select the mode that you want the system to operate in. • Go to Section 14 to link the transmitter and receiver. • Go to "Check your work".

OVER

Reconnect the Receiver to the Transmitter.



a. Place the receiver within 10 feet of the transmitter.

b. Press the RIGHT Option button twice to display the Main Menu screen.

c. Use the UP or DOWN Arrow button to highlight System.

d. Press the RIGHT Option button (Select) to display the System menu with Reconnect highlighted.

e. Press the RIGHT Option button (Select).

f. Wait for the receiver to beep. If it beeps:

- Twice – The system is connected.
- Three times – The system is not connected. Make sure the battery in the transmitter is new and ensure that the receiver and transmitter are linked (see Section 14).

Note: If the transmitter and receiver are connected properly, the disconnect icon will not appear on the screen.

Check your work.

***Result:** An operational system.*

You have done this procedure correctly when:

- ❑ The batteries have been installed and the battery doors have been closed securely.
- ❑ The old batteries have been disposed of properly.
- ❑ The transmitter and receiver have been reconnected.

3 Set the Time and Date

Section 3

Section 3 – Key Terms

- **LEFT/RIGHT Option Buttons**
- **Main Menu**
- **Receiver**
- **System Menu**
- **Transmitter**
- **UP/DOWN Arrow Buttons**

3 Set the Time and Date

Purpose To ensure the correct time and date are associated with your data.

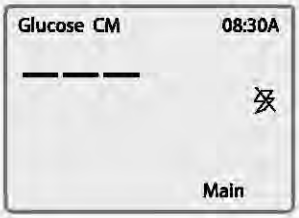
Start Do this procedure:
- The first time you use your FreeStyle Navigator system.
- When you install new batteries.

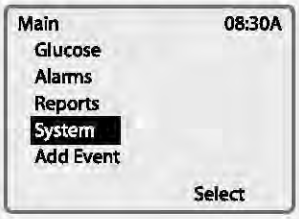
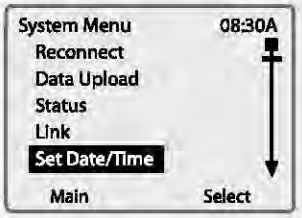
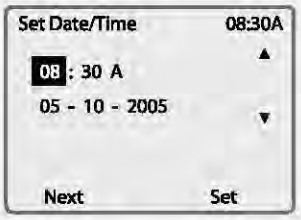
Materials Your FreeStyle Navigator Receiver.

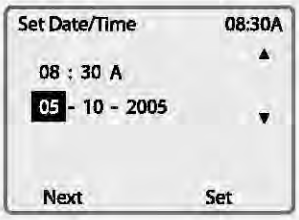
Helpful Information

Important: *Be sure to set the date and time correctly. The correctness of the line graph and statistical reports depends upon the date and the time being correct.*

- The receiver is on whenever batteries with sufficient charge are in the receiver.
- If the batteries are discharged or removed for 5 minutes or more, you must reset the date and time.
- 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.
- If you change the time and/or date in the receiver, the line graphs and statistical reports will be affected. For example, if you travel from one time zone to another and change the time to match the local time zone, the appearance of your graph will be affected.

Steps	Do This
1. Go to the Main screen. 	**Note:** When setting the time and date after inserting the batteries, start from Step 4. **a.** Turn the display on. **b.** Press the RIGHT Option button a second time to display the Main screen. If your transmitter and receiver are connected, you will not see the icon.

Steps	Do This
2. Go to the System screen. 	a. Press the DOWN Arrow button to highlight System. b. Press the RIGHT Option button (Select) to go to the System Menu screen.
3. Select Set Date/Time from the System Menu screen. 	a. Use the UP/DOWN Arrow buttons to highlight Set Date/Time on the System Menu screen. b. Press the RIGHT Option button (Select) to display the Set Date/Time screen.
4. Set the time. 	a. Use the UP/DOWN Arrow buttons to set the current hour. b. Press the LEFT Option button (Next) to move to the minutes digits. c. Use the UP/DOWN Arrow buttons to set the current minutes. d. Press the LEFT Option button (Next) to move to the AM or PM field. e. Use the UP/DOWN Arrow buttons to select A (AM) or P (PM). f. To set the date, go to Step 5.

Steps	Do This
5. Set the date.  	**a.** Press the LEFT Option button (Next) to move to the Month field. **b.** Use the UP/DOWN Arrow buttons to set the current month. **c.** Press the LEFT Option button (Next) to move to the Date field. **d.** Use the UP/DOWN Arrow buttons to set the current date. **e.** Press the LEFT Option button (Next) to move to the Year field. **f.** Use the UP/DOWN Arrow buttons to set the current year. **g.** Confirm that your selections are correct: • If **NO**, press the LEFT Option button (Next) and repeat this procedure from Step 5a. • If **YES**, press the RIGHT Option button (Set) to accept your changes. ***Result:*** *The screen displays the System menu.* **h.** Press the LEFT Option button (Main) to return to the Main screen.
6. Check your work.	***Result:*** *Your FreeStyle Navigator Receiver is operating with the correct time and date.* You have done this procedure correctly when: ❑ The time is correct. ❑ The date is correct.

4 Perform a Control Solution Test

Section 4

Section 4 – Key Terms

- **Control Solution Test**
- **FreeStyle Control Solution**
- **FreeStyle Test Strips**
- **LEFT/RIGHT Option Buttons**
- **Receiver**
- **UP/DOWN Arrow Buttons**

4 Perform a Control Solution Test

Purpose

The purpose of the control solution test is to:

- Ensure that your receiver and test strips are working properly prior to calibration or blood glucose testing.
- Check that you are following the correct testing procedure.
- Practice Blood Glucose mode testing without having to use your own blood. A Control Solution test is not the same as a calibration. See Section 7 for calibrating the system.

Start

Do this procedure when you:

- Set up your receiver for the first time.
- Open and begin using a new vial of test strips.
- Suspect that your receiver or test strips are not working properly.
- Suspect that your glucose test results are not accurate.
- Suspect that your test results are not consistent with how you feel.
- Drop, damage, or expose the receiver to liquids.
- Are advised by your healthcare team to do so.

Materials

Gather these materials before you begin:

- FreeStyle Navigator Receiver.
- FreeStyle Control Solution.
- FreeStyle Test Strips.

Helpful Information

Caution:

- ***Do NOT** use FreeStyle Control Solution for calibration. Do **NOT** perform the control solution test when the system asks you to 'Do BG Test' for calibration.*
- *Results from Control Solution tests do **NOT** reflect your blood glucose level.*

***Important:** The control solution range is a target range for the control solution only. It is **NOT** a target range for your blood glucose levels.*

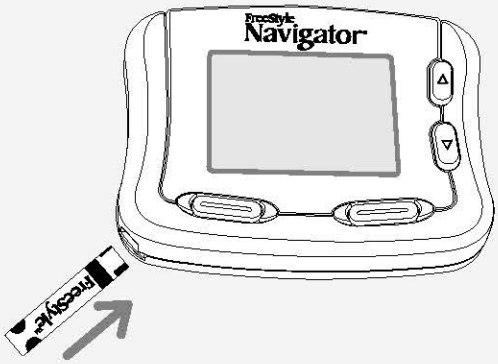
***Important:** If your control solution test results continue to fall outside of the range printed on the test strip vial, the receiver may not be working properly. Do **NOT** use the system to test your glucose levels. Call Customer Care.*

Ensure accurate control solution results by doing the following:

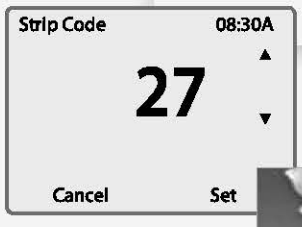
- Use **ONLY** FreeStyle Control Solution and FreeStyle Test Strips.
- Replace the cap on the control solution vial immediately after using.
- Do **NOT** use your control solution past the expiration date or the discard date.
- Do **NOT** add water or any liquid to the control solution.
- Perform control solution tests only between 59° and 104° F (15° and 40° C).

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

Steps	Do This
1. Verify that your FreeStyle Control Solution is current. 	**Note:** FreeStyle Control Solution is good for three months after opening the bottle, or until the expiration date printed on the label, whichever comes first. Count forward three 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. ***Example:*** *You open the control solution on January 15th. Count forward three months to April 15th. This is the discard date that you record on the bottle.*
2. Prepare test strip. 	**a.** Locate the expiration date on the vial of FreeStyle Test Strips. ***If strips are expired, obtain a new vial of strips.***
	**b.** Locate the code number (you'll need it in a minute). **c.** Remove a single test strip from the vial. **d.** Close the vial tightly before continuing but do **NOT** put the vial away.

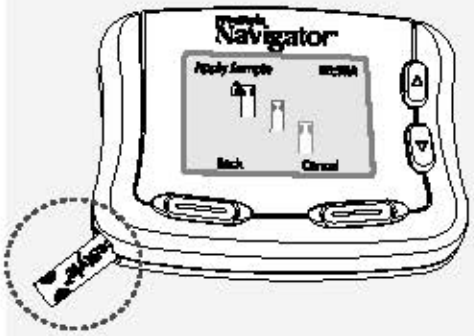
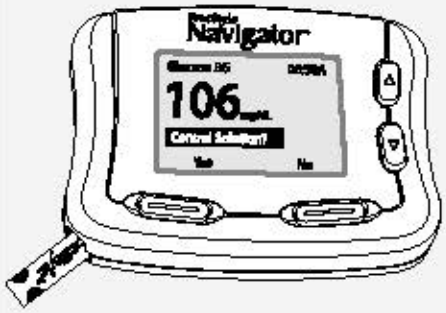
Steps	Do This
3. Insert test strip into the receiver. 	**a.** Turn the test strip so "FreeStyle" text faces up. **b.** Grasp the test strip by the end with the two half circles. **c.** Insert the end with the dark rectangle into the receiver at the lower left corner of the receiver. ***Result:*** *The receiver display screen turns on and displays the Strip Code screen.* **Note:** If the screen does not turn on, refer to Section 10 on troubleshooting.
4. Compare code numbers.	Compare the code number on the display with the code number on the vial of test strips.

If	*Then*
• The numbers match.	**a.** Press the RIGHT Option button (Set). **b.** Go to Step 5.
• The numbers do **NOT** match.	**a.** Use the UP/DOWN Arrow buttons to change the code to match. **b.** Press the RIGHT Option button (Set). **c.** Go to Step 5.
• The screen changes to the Apply Sample screen.	If the numbers did **NOT** match: **a.** Press the LEFT Option button (Back). **b.** Repeat Step 4. If the numbers match, go to Step 5.



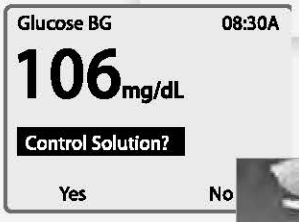


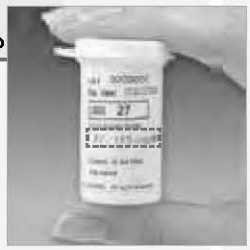
OVER

Steps	Do This
5. Apply control solution.  	***Important:*** *Do NOT apply control solution to both edges of the test strip.* **Notes:** • Gently touch **ONLY ONE EDGE** of the test strip to the control solution next to one of the dark half-circles. • If progress tones are turned on, the receiver will beep to indicate that enough control solution was applied. ***Result:*** *A stopwatch will appear on the display screen while the receiver measures the control solution.* • The receiver will beep twice when the test results appear.
6. Confirm that you used a control solution. 	Press the LEFT Option button (Yes) to alert the receiver that you used a control solution for this test. **Note:** If you do **NOT** select yes, the system will record the result as a blood glucose result instead of a control solution result, which can result in an incorrect statistical report. ***Go to the next step.***

Steps	Do This
7. Evaluate the test results.	Compare the test results displayed on the screen to the range printed on the vial of test strips.

If the result	*And*	*Then*
• Falls **WITHIN** the range.	→	Go to Step 8.
• Falls **OUTSIDE** of the range.	You've repeated the test.	Call Customer Care.
	You've **NOT** repeated the test.	Repeat the test from Step 1 with a NEW test strip.
• Is an error message.	→	Go to Section 10 on troubleshooting.





77 – 115 mg/dL

8. Check your work.	***Result:*** *Control solution test results displayed on the receiver screen.* You have done this procedure correctly when: ❑ The results are within the normal control solution range. ❑ The used test strips have been discarded properly. ❑ The control solution tests are marked as control solution tests.

END OF Section 4

5 Insert or Remove Your Sensor

Section 5

Section 5 – Key Terms

- **Calibration**
- **Reconnect**
- **Sensor**
- **Sensor Delivery Unit**
- **Sensor Inserter**
- **Sensor Insertion Button**
- **Sensor Insertion Site**
- **Sensor Locking Pin**
- **Sensor Release Tabs**
- **Sensor Support Mount**
- **Sharps Container**
- **Transmitter Receiver Connection**

Now that you are ready to insert a sensor, here are a few helpful tips.

- Reconnect your transmitter and receiver **BEFORE** inserting a new sensor.
- **BEFORE** inserting a new sensor, program into the receiver that the old sensor has been removed.
- Make sure there are no messages or icons related to low battery conditions on the receiver **BEFORE** inserting a sensor.
- When attaching the transmitter, you may not always hear a click. Place the transmitter about halfway over the sensor support mount and slide the transmitter back and forth to make sure it moves freely before you attach it. You will feel a click as you slide it into place.
- After attaching the transmitter to a new sensor, allow the system a few minutes to recognize a new sensor. Reconnect the receiver and transmitter to make sure they are communicating.
- When responding to messages about sensor insertion and sensor removal, choose the appropriate answer ('Yes' or 'No').
- Do **NOT** use the Link/Unlink feature unless you have received a new transmitter or receiver from the manufacturer. To establish communication between them, **ALWAYS** use the 'Reconnect' feature. {**Note:** Link is **NOT** the same as Reconnect}
- Avoid errors and messages related to calibration by following a few simple guidelines:
  - Do **NOT** calibrate if your blood glucose is higher than 300 mg/dL (16.7 mmol/L) or lower than 60 mg/dL (3.3 mmol/L).
  - If you have just exercised, eaten or taken insulin, your glucose levels may be changing rapidly. Allow about an hour for the glucose levels to reach a relatively steady state before calibrating.
  - The system automatically detects conditions that may not be suitable for calibration. It may delay calibration requests in such instances. Wait for the system to prompt you and **LOOK** for the icon on the screen.
- It is normal during typical usage to get multiple messages about failed calibrations ("Cal Failed") or additional calibration requirements ("Cal Required"). The system automatically evaluates conditions for calibration and displays appropriate messages if those conditions are not met or if the calibrations fail. This helps maintain system accuracy. When you get these messages, simply follow the prompts on the screen or guidelines in the *User's Guide*. If you get too many messages, please call Customer Care.
- Do **NOT** change batteries during a sensor wear. Changing the batteries resets the system and will force you to remove the sensor.

If you need assistance, please call Customer Care.

5 Insert or Remove Your Sensor

Purpose

To insert, remove, or replace a small, thin, plastic sensor under your skin so that your FreeStyle Navigator system can continuously monitor your glucose level.

Start

Do this procedure:

- The first time you use your FreeStyle Navigator system.
- Every 5 days after that.
- Replace your sensor sooner than 5 days when:
  - There is any redness, pain, tenderness, or swelling at the insertion site.
  - An error code displays on your receiver indicating a sensor problem.
- When replacing batteries.

Materials

Gather these materials before you begin:

- Soap and water.
- Alcohol prep pads.
- A sensor delivery unit in its **UNOPENED** package.
- Your transmitter.
- Your receiver.

Helpful Information

Important: *Keep the following in mind when inserting your sensor.*

- *You will not have continuous monitoring data until you have successfully completed the first calibration (at least for the first ten hours after sensor insertion).*
- *You may not be able to calibrate the system if your glucose levels are changing rapidly. For example, during a meal or exercise, your glucose levels may vary rapidly. Try to time your insertion so that your calibration times do not coincide with your regular meal or exercise activities.*

Note: You should ***keep your sensor inserted for 5 days***. See the exceptions listed above under **Start**.

- The system will ask you to perform 4 calibrations at approximately -10, 12, 24 and 72 hours after inserting a new sensor (See Section 7).
- You **MUST** change your sensor every 5 days, to reduce the chance of infection. The system automatically terminates a sensor session after 5 days. Do **NOT** leave the sensor inserted for more than 5 days.
- Taking action at the first sign of irritation or discomfort will keep small issues from turning into larger or ongoing ones.
- You may not be able to perform the calibration after you eat until your glucose levels stabilize.
- See Appendix A: Site Maintenance for additional helpful suggestions.
- Before inserting a new sensor make sure that there are no low battery messages displayed on the receiver. This will help avoid data loss after the insertion if the batteries are running low.

Interferents: *In vitro* and *in vivo* testing suggest 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.

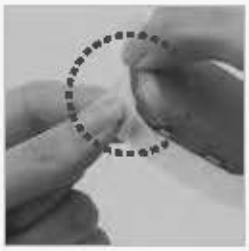
Important Things to Know About Getting Reliable Results

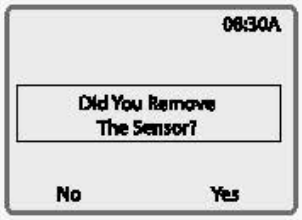
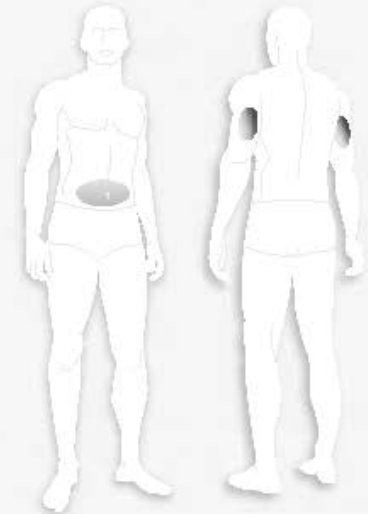
Caution: *Movement of the sensor support mount or excessive perspiration at the sensor insertion site due to activities like vigorous exercise or bumping against objects may lead to poor adhesion of the support mount to the skin and then cause the sensor to dislodge. If the sensor dislodges due to the sensor support adhesive failing to adhere to the skin, you may get unreliable results or no results. The system may not provide a warning in such circumstances. Choose the proper sensor insertion site when inserting the sensor and prepare the site by following the instructions for site preparation.*

Caution: *If your results from the Continuous Monitoring mode seem erroneous, check and make sure that the sensor has not dislodged. If you notice the sensor is dislodged from the skin, or if you see that the adhesive on your overbandage or the sensor support mount is coming loose, discard the old sensor and insert a new sensor.*

Steps	Do This
1. Decide what to do.	

If you want to	*Then*
• Change or remove your sensor.	Go to Step 2.
• Insert your sensor.	Go to Step 4.

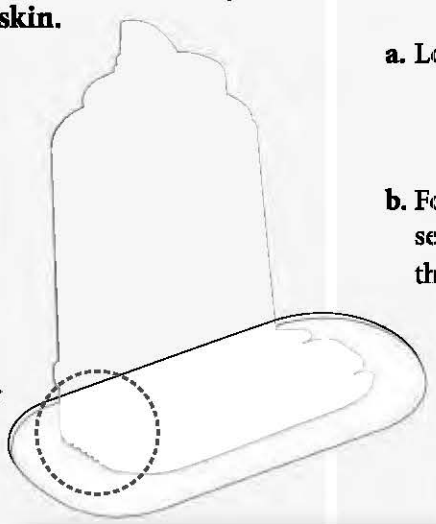
Steps	Do This
2. Remove the sensor.	
 Fig. 1	a. Wipe a small amount of isopropyl alcohol around the edges of the sensor support mount. **Note:** You can use a regular alcohol prep pad from your local drugstore.
 Fig. 2	b. Grasp the top end of the adhesive (the end nearest the sensor, see Fig.1) and slowly peel it off your skin in one continuous motion. c. Pull down on the adhesive at the bottom of the support mount (the end farthest from the sensor, see Fig.2). You will hear a click as the transmitter separates from the support mount. d. Discard the sensor support mount (with the sensor attached). ***Important:*** • *Do NOT discard the transmitter.* • *NEVER reuse the sensor support mount and sensor.* e. Gently wash the transmitter with soap and water. f. Dry the transmitter thoroughly with a clean, soft, lint-free cloth. Be sure that you blot the sensor connector on the end of the transmitter. g. If necessary, use an alcohol wipe prep pad, baby oil, or a wet, soapy washcloth to remove any adhesive left on your arm. h. Dry your arm with a clean dry towel before continuing. ***Important:*** *Do NOT use adhesive remover wipes containing ether or ether-containing components to remove adhesive residue from the transmitter. Adhesive remover solutions such as Uni-Solve® and others that contain ether components can damage the transmitter case. We recommend using regular alcohol pads for cleaning adhesive residues.* i. Proceed to next step to end sensor session.

Steps	Do This
3. End sensor session. 	a. Press the RIGHT Option button twice to get to the Main menu. b. Press the UP/DOWN Arrow button to highlight System. c. Press the RIGHT Option button to select System. d. Press the UP/DOWN Arrow button to highlight Status. e. Press the RIGHT Option button to select Status. f. Press the RIGHT Option button to select Removed Sensor. g. Press the RIGHT Option button to select Yes. The system now knows you have removed the sensor. If you are going to replace your sensor now, continue to Step 4.
4. Reconnect the receiver to the transmitter. 	a. Place the receiver within 10 feet of the transmitter. b. Press the RIGHT Option button twice to display the Main Menu screen. c. Use the UP/DOWN Arrow button to highlight System. d. Press the RIGHT Option button (Select) to display the System menu with Reconnect highlighted. e. Press the RIGHT Option button (Select). f. Wait for the receiver to beep. If it beeps: • Twice – The system is connected. • Three times – The system is not connected. Make sure the battery in the transmitter is new and ensure that the receiver and transmitter are linked (see Section 14). **Note:** If the transmitter and receiver are connected properly, the disconnect icon will not appear on the screen.
5. Select an insertion site. 	***Caution:** If the sensor dislodges due to the sensor support adhesive failing to adhere to the skin, you may get unreliable or no results. Improper site selection and improper site preparation may cause poor adherence to the skin.* **Notes:** • Select a site ONLY on the back of the upper right arm, on the back of the upper left arm, or on your abdomen. • Do **NOT** insert the sensor where another sensor was just removed (See "Site Selection" in Appendix A). • Rotate where you insert your sensor across several sites. • Avoid areas where the edges of clothing may catch or rub against the sensor. • Avoid areas with scars, moles, 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. • Choose a site that is at least 1 inch away from an insulin infusion site.

Steps	Do This
6. Prepare the insertion site.	**a.** Wash your hands thoroughly with soap and water. **b.** Clean the selected insertion site area with soap and water. **c.** Rinse the area thoroughly and pat dry. **d.** Wipe the area with an alcohol prep pad. **Note 1:** The insertion area **MUST** be clean and dry. Otherwise: • An infection could occur. • The sensor support mount may not stick to the site. **Note 2:** Do **NOT** place a bandage on the insertion site before inserting the sensor. The sensor may not penetrate the skin and the system will not work with a bandage under the sensor.
7. Remove the sensor delivery unit from package.	***Caution:*** *Do **NOT** use the sensor delivery unit if the sterile package is open or damaged.* **a.** Remove the sensor delivery unit from its sterile package by peeling off the foil on the back of the package. **b.** Save the package. **Note:** You will need the sensor code number on the back of the package, later. ***Important:*** *We recommend that you save the sensor kit carton or the sensor sterile package until the last sensor from your sensor kit has been used and discarded. Saving the package will help you to have sensor lot information, expiration dates and sensor code etc. accessible when you need them.*
8. Remove the protective liner from the sensor support mount. 	**a.** Bend the two-piece protective liner slightly so you can see the seam between the two pieces. **b.** Peel away the smaller section. **c.** Peel away the larger section.

OVER

Steps	Do This
9. Attach the sensor delivery unit to your skin.	

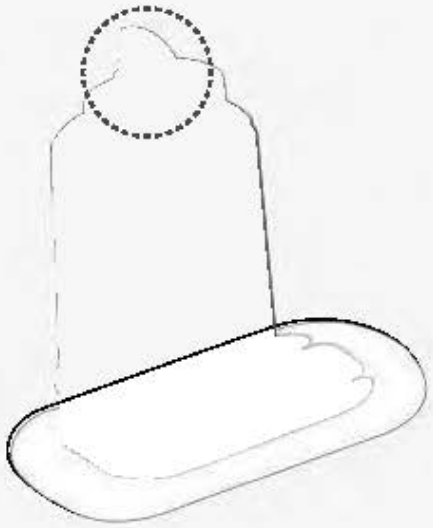


a. Locate the top of the sensor support mount.

b. Follow the instructions below as you place the sensor support mount, adhesive-side down, on the insertion site:

If you are	*Then*
• Inserting the sensor on the back of your arm.	Place the sensor support mount lengthwise on your arm with the top of the sensor support mount facing your shoulder. 
• Inserting the sensor on your abdomen.	Place the sensor support mount horizontally on your abdomen. 

10. Ensure that the adhesive pad is adhered to your skin.	**a.** Hold the sensor delivery unit firmly in place. **b.** Smooth the adhesive pad against your skin.

Steps	Do This
11. Remove the locking pin. 	a. Grasp the top of the locking pin with your thumb and index finger. b. Twist the locking pin a 1/4 turn in either direction until the locking pin clicks.  c. Pull the locking pin away to remove it. **Note:** The sensor support mount adhesive will help keep the sensor support mount in place.
12. Insert sensor. 	***Caution:*** *Do **NOT** press the button until you are ready to insert the sensor. Doing so may cause unintended results or injury.* a. Hold the sensor inserter as shown and press down on both sides of the button at the same time. ***Important:*** *Do **NOT** press on the blue release tabs while pressing the button on the top of the inserter.* **Note:** You will feel a slight pinch as the sensor is placed just under your skin.
13. Remove inserter  	a. Hold the sensor inserter and firmly squeeze the two blue release tabs at the inserter's base, as you lift the inserter away from the sensor support mount. **Note:** Do **NOT** lift the inserter without squeezing the blue release tabs as this may dislodge the sensor support mount.

OVER

Steps	Do This
14. Check the sensor support mount.	**a.** Confirm the sensor support mount remains tightly adhered to your skin by sliding your finger along the edges of the adhesive pad and examine for any gaps in adhesion. **b.** Examine the area for a drop of blood. You may see some blood from the insertion site. If there is continuous bleeding that does not stop in a few minutes even after blotting with a clean cloth or swab, repeat the procedure from Step 2 to remove the sensor support mount, select a new site and insert a **NEW** sensor. **c.** Use a mirror to check that sensor is correctly placed.



If	*Then*
	Sensor is ***correctly*** placed. You will see the tip of the sensor is inserted under the skin and the sensor is flush against the top edge of the sensor support mount.
	Sensor is missing. **1.** Remove sensor support mount. **2.** Go to Step 1 to insert a **new** sensor.

Steps	Do This
15. Discard the sensor inserter safely.	We recommend a sharps container or a puncture-proof container with a tight lid.
16. Check your work.	***Result:*** *An inserted sensor, a removed sensor, or a replaced sensor.* You have done this procedure correctly when: ❑ The system successfully recognized that you removed a sensor (if you removed a sensor). ❑ The site was selected and prepared according to the guidelines given in this procedure. ❑ The receiver and transmitter were reconnected successfully. ❑ The sensor support mount is tightly adhered to either your abdomen or the back of your upper arm. ❑ The sensor is inserted in a site that is different from the site that was used for the last sensor. ❑ The sensor is visible with the tip inserted into your skin. ❑ The sensor inserter is disposed safely.

END OF Section 5

6 Attach Your Transmitter

Section 6

Section 6 – Key Terms

- **LEFT/RIGHT Option Buttons**
- **Receiver**
- **Sensor Code**
- **Sensor Support Mount**
- **System**
- **Transmitter**
- **UP/DOWN Arrow Buttons**

6 Attach Your Transmitter

Purpose To enable the transmitter to send glucose data to the receiver.

Start Do this procedure after inserting a new sensor.

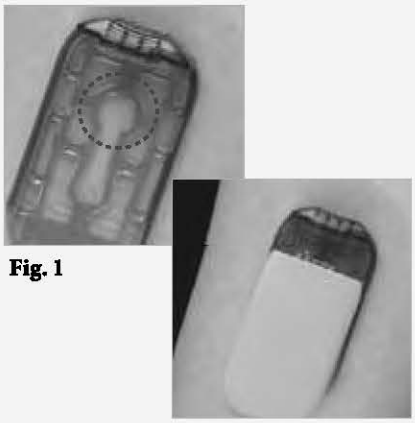
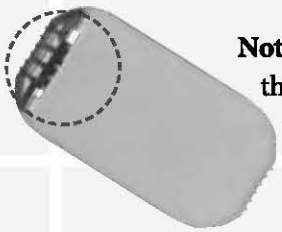
Materials Your FreeStyle Navigator Transmitter with battery installed.



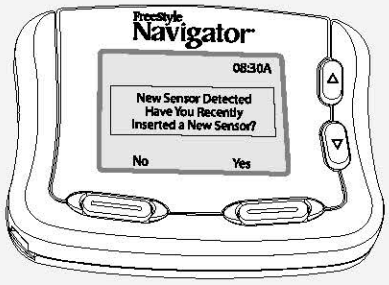
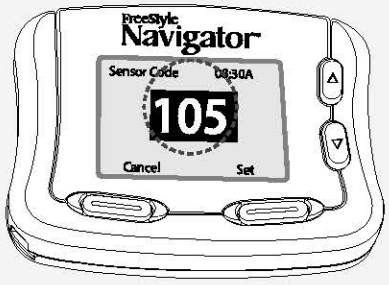
Helpful Information

Important: *Do **NOT** remove or replace the transmitter from the sensor support mount while wearing a sensor. If you notice that the transmitter is not properly attached, replace the sensor with a new sensor and then re-attach the transmitter.*

- Make sure that you establish communication between the receiver and transmitter by reconnecting them if necessary.
- After you attach your transmitter, you must keep your receiver within 10 feet of the transmitter to maintain a consistent connection. If the connection between the transmitter and receiver is broken you will not receive continuous glucose readings.
- The connection can also be affected by objects getting between the transmitter and receiver, by nearby large metal objects, and by some electronic devices that produce radio frequencies.
- If a connection alarm sounds, move the transmitter closer to the receiver to restore the connection. If you have trouble with the connection between the transmitter and receiver, see Section 10 on troubleshooting.

Steps	Do This
1. Attach the transmitter to the sensor support mount.	
 Fig. 1	**a.** Position the transmitter over the sensor support mount so that the battery side faces the mount. **b.** Lower the transmitter onto the mount. **Note:** It helps to position the transmitter's connector directly over the ***round part of the "keyhole"*** (Fig. 1) as you lower the transmitter. ***Result:*** *The transmitter fits flush against the mount and slides smoothly back and forth on the guide rails.*
 Fig. 2	**c.** Hold the transmitter between your forefinger and thumb and slide the transmitter until it clicks into place. Apply firm pressure as you slide the transmitter into place. (Fig. 2)
	 **Note:** It is normal to see a gap between the transmitter and the support mount towards the top.
2. Confirm the transmitter is correctly attached to the sensor support mount.	
	**a.** Look at the side of the transmitter where the bottom sits on the guide rails. **b.** Is there a space between the bottom edge of the transmitter and the top edge of the guide rails?
	

If	*Then*
• No	The transmitter is correctly attached. Go to Step 3.
• Yes	**1.** Go to Section 5 to replace your sensor. **2.** Repeat this procedure to attach your transmitter.

Steps	Do This
3. Apply an over-bandage (Optional). 	Apply an over-bandage to hold down the transmitter and sensor support mount. Use an over-bandage if you find that the sensor support mount is not adhering well during daily activities. ***Caution:*** *If your results from the Continuous Monitoring mode seem erroneous, check and make sure that the sensor has not dislodged. If you notice the sensor is dislodged from the skin, or if you see that the adhesive on your overbandage or the sensor support mount is coming loose, discard the old sensor and insert a new sensor.* ***Go to the next step.***
4. Enter the sensor code into your receiver.  **Fig. 1**  **Fig. 2** ***Caution:*** *The code numbers **MUST** match to ensure accurate test results.*	**a.** When you hear the receiver beep, press the RIGHT Option button **once** to turn the receiver on. ***Result:*** *The receiver screen says, "New Sensor Detected Have You Recently Inserted a New Sensor?"* (Fig. 1) **Note:** Typically, it may take up to 3 minutes after attaching the transmitter before the receiver beeps. See Section 10 to troubleshoot if you do not get the sensor detection message. **b.** Press the RIGHT Option button (Yes). **Note:** If you ever see this message at any other time, press the LEFT Option button (No). **c.** Press the UP or DOWN Arrow button to change the number on the receiver screen to the number on the packaging. (Fig. 2).  ***Important:*** *Once the code has been entered and you have hit the Set button as instructed below, you will not be able to change the sensor code number. If you have entered the code incorrectly, you will have to replace the sensor and enter the right sensor code. If you choose the wrong sensor code, you may get erroneous results from the sensor.* **d.** Press the RIGHT Option button (Set) to accept the number on the screen.

OVER

Steps	Do This
5. Check your work.	***Result:*** *A transmitter ready to send glucose data.* You have done this procedure correctly when: ❑ The transmitter is securely attached to the sensor support mount. ❑ You have applied an over-bandage as necessary to hold down the transmitter and the sensor support mount. ❑ The sensor code has been correctly entered into the receiver. ❑ You see an  icon on the top right hand corner of the screen.

End Of Section 6

7 Calibrate Your System/Test Blood Glucose Manually

Section 7

Section 7 – Key Terms

- BG Mode
- Calibrate
- Calibration BG
- Control Solution
- FreeStyle Test Strips
- Icon
- Lancet
- Lancing Device
- Lancing Device Cocking Handle
- Lancing Device Depth Indicator Window
- Lancing Device Depth Setting
- Lancing Device Lancet Cup Holder
- LEFT/RIGHT Option Buttons
- Receiver Test Strip Port
- Sharps Container
- UP/DOWN Arrow Buttons

7 Calibrate Your System/Test Blood Glucose Manually

Purpose To ensure the receiver will calculate your glucose readings accurately.

Start Do this procedure:

- **Each time** the receiver prompts you with the message, "Do BG Test." You will see a blood drop icon on the screen and you will also hear the system beep (or vibrate).
- When you need to measure your blood glucose manually using the built-in FreeStyle Meter.

Materials

- Soap, water, and a clean towel.
- A FreeStyle Lancing Device.
- Sterile lancets.
- FreeStyle Test Strips.
- Your FreeStyle Navigator Receiver.
- A sharps container.

Helpful Information

Important Things to Remember About System Calibration

- The system is calibrated using a capillary whole blood glucose measurement (performed in the Blood Glucose mode using the built-in FreeStyle Blood Glucose Meter). In order to calibrate, 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 glucose readings.
- Do not use venous blood for calibrating the system.

> ***Caution:*** *Always calibrate the system only using a finger-stick blood sample. Do* ***NOT*** *use alternate site blood glucose measurements to calibrate the system. The receiver contains a built-in FreeStyle® Blood Glucose Meter for performing calibration tests.*

Important: *Your blood glucose level must be between 60 and 300 mg/dL (3.3 and 16.7 mmol/L) to be able to perform calibration tests. If your blood glucose level is changing rapidly, you may not be able to calibrate the system. For example, during a meal or exercise, your glucose levels may vary rapidly. Try to time your sensor insertion so that your calibration times do not coincide with your regular meal or exercise activities.*

Important: *In clinical trials, we observed that the sensor signal sometimes temporarily decreases from the true value. This typically happens at night during sleep, and recovers rapidly when the user moves or is awakened. However, in order to avoid being affected by this phenomenon the system should not be calibrated when the wearer is asleep.*

- You may not be able to calibrate the system if your glucose levels are changing rapidly (e.g. during or after exercise, meals or insulin dosing). Under such conditions, the system may not ask you to calibrate; instead, it will delay its request until conditions are acceptable.

Helpful Information *(con't)*

- You **MUST** successfully complete 4 calibration tests. You will calibrate at approximately 10, 12, 24 and 72 hours after sensor insertion. If you do not complete calibration tests successfully in the allotted time periods, your glucose readings will NOT be displayed and alarms will be inactive. The system may ask you to perform additional calibrations between 2nd and 3rd calibrations depending on the sensor signal. In such cases, you will be prompted with a message to do additional BG tests.
- The receiver will beep (or vibrate) to prompt you to do a calibration. The receiver will display a blood drop icon and the message "Do BG Test." The system will prompt you with alarm messages when your calibrations are unsuccessful.
- You will not have continuous monitoring until you have successfully completed the first calibration (at least for the first ten hours after sensor insertion).
- If you get a request for a calibration or expect additional calibration requests during a time when you do not want to be disturbed (e.g. sleep time), you can choose to wait to perform additional BG tests at a later point in time. If you choose to wait and the allotted time window for calibration has expired, please note that you will not get glucose results until you have performed a successful calibration. You can turn off the System Alarms (or set to vibrate) if you do not want to be disturbed by frequent requests for calibration. In order to silence the alarms that warn you when the allotted time window for a calibration has expired, you must turn off the data loss alarms and all the four glucose alarms (Low Glucose, High Glucose, Projected Low Glucose and Projected High Glucose).

When to calibrate the system?

You will calibrate the system at approximately 10, 12, 24 and 72 hours after sensor insertion.

For example:

Insertion at night

If you insert the sensor at 9:00 pm on Day 1,
the first calibration would be at 7:00 am on Day 2,
the second calibration would be at 9:00 am on Day 2,
the third calibration would be at 9:00 pm on Day 2,
the fourth calibration would be at 9:00 pm on Day 4.
Sensor removal would be at 9:00 pm on Day 6.

What happens in the example if the first calibration does not occur until 9 am on Day 2?

The 2 hour delay will add on to the second, third and fourth calibration. Second calibration will now happen at 11 am on day 2 and so on. However, sensor removal will still happen at 9 pm on Day 6.

Although a typical calibration sequence will occur as shown, each calibration has to be performed in a specific window of time.

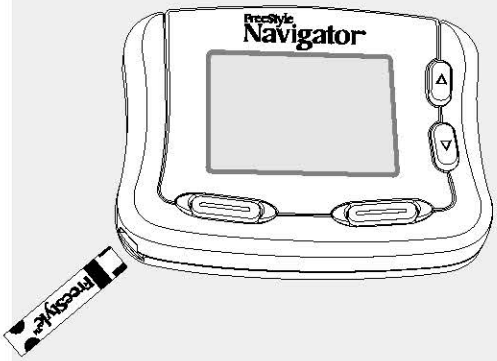
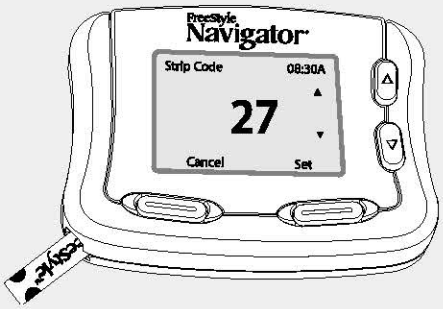
- 1st calibration: Must be performed at approximately 10 hours after a new sensor has been inserted. The first calibration can be performed after the 10 hours. Continuous glucose readings will NOT be reported until the 1st calibration is performed successfully.
- 2nd calibration: Must be performed between 2 and 4 hours after the 1st calibration or continuous glucose will not be reported. The 2nd calibration can be performed after 4 hours; continuous glucose reporting will resume after completing the 2nd calibration successfully.
- 3rd calibration: Must be performed between 12 and 20 hours after the 2nd calibration or continuous glucose will not be reported. The 3rd calibration can be performed after 20 hours; continuous glucose reporting will resume after completing the 3rd calibration successfully.
- 4th calibration: Must be performed between 48 and 56 hours after the third calibration or continuous glucose will not be reported. The fourth calibration can be performed after 56 hours; continuous glucose reporting will resume after completing the 4th calibration successfully.

Helpful Information *(con't)*

Some common reasons for unsuccessful calibrations

- Your BG test result is below 60 mg/dL (3.3 mmol/L) or above 300 mg/dL (16.7 mmol/L). Perform the calibration test when your blood glucose is within the above range.
- Your blood glucose is changing too rapidly. This can happen during a meal or exercise activities or if you have taken insulin. Give yourself an hour before you try to perform a calibration test again. Do not perform a Blood Glucose mode test for calibration if you do not see the blood drop icon on the screen.
- The skin temperature may be out of range (the skin temperature has to be between 77° F (25° C) and 104° F (40° C).
- The sensor signal may be out of range or has changed relative to the last successful calibration.
- Improper Blood Glucose mode testing. Carefully follow the instructions in this Section to perform a BG test (keep your hands clean, enter the right strip code and choose finger for calibration tests) to avoid errors from the Blood Glucose mode test.

The system will prompt you with alarm messages when your calibrations are unsuccessful. See Section 10 for more information or call Customer Care. You will have to perform additional Blood Glucose mode tests (BG tests) if your calibrations are unsuccessful.

Steps	Do This
1. Insert a FreeStyle Test Strip into the receiver's test strip port. 	**a.** Insert the end with the dark rectangle. **b.** Gently push until the test strip stops. ***Result:*** *The receiver will display the most recently used test strip code number.*
2. Ensure that the code number on the screen matches the code number on the test strip vial.  	***Caution:*** *The code numbers **MUST** match to ensure accurate test results.* Compare the code number on the display with the code number on the vial of test strips.

If	*Then*
• The numbers match.	**a.** Press the RIGHT Option button (Set). **b.** Go to Step 3.
• The numbers do **NOT** match.	**a.** Use the UP/DOWN Arrow buttons to change the code to match. **b.** Press the RIGHT Option button (Set). **c.** Go to Step 3.
• The screen changes to the Apply Sample screen.	*If the numbers do **NOT** match:* **a.** Press the LEFT Option button (Back). **b.** Repeat Step 2. *If the numbers match, go to Step 3.*

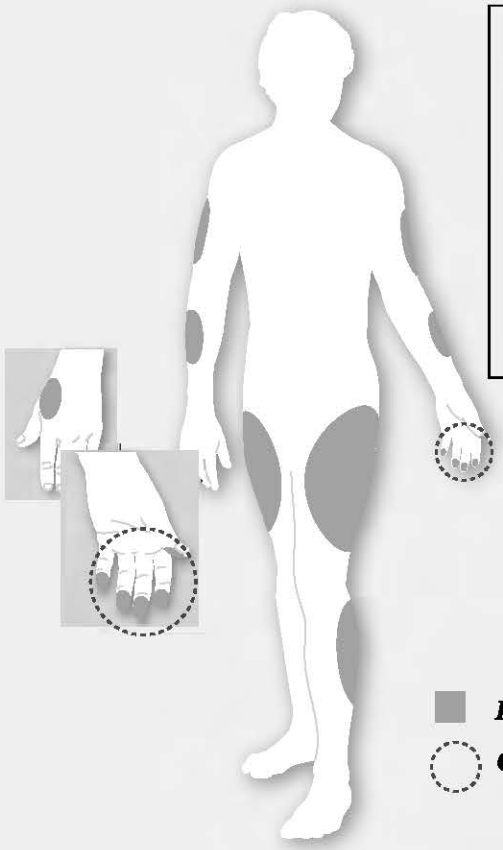
Result: *The receiver will prompt you to "Apply Sample."*

Steps	Do This
3. Select a test site.	

Caution: *If you have hypoglycemia, or hypoglycemia unawareness, then test* **ONLY** *on your fingers.*

Note 1: Vary the sites from test to test to avoid tenderness and to avoid creating calluses.

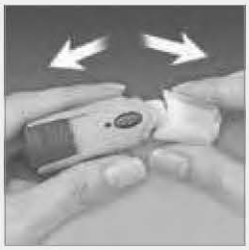
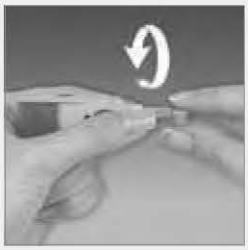
Note 2: Avoid moles, veins, bones, and tendons.



Caution: *Always calibrate the system using only a finger-stick blood sample. Do* **NOT** *use alternate site blood glucose measurements to calibrate the system. The receiver contains a built-in FreeStyle® Blood Glucose Meter for performing calibration tests.*

If	*Then*
• You are calibrating the system.	Select **ONLY** a finger for testing (see red circles).
• You are simply doing a manual glucose test and **NOT** calibrating.	Select from among the sites shown including the circled areas.

OVER

Steps	Do This
4. Prepare for lancing. 	**a.** Wash your hands and the selected test site with soap and water. Make sure there is no lotion on the test site. **b.** Thoroughly dry your hands and the test site. **c.** Snap the cap off the lancing device. ***Important:*** *Use a new sterile lancet for every test.* ***NEVER*** *use a lancet for more than one person.*
	**d.** Insert a new FreeStyle Lancet firmly into the white lancet cup holder. ***Important:*** *Do not touch the exposed needle on the lancet.*
	**e.** Hold the lancet firmly in place with one hand and use your other hand to twist off the rounded top.
	f. Replace the cap until it snaps or clicks into place.

If your test site is	*Then*
• A finger.	Use the grey cap.
• Your forearm or a test site other than the finger.	Use the clear cap.



Steps	Do This
4. Prepare for lancing. ***(con't)***	**g.** Select the lancing device depth setting.

If you are lancing	*Then*
• A finger.	Set the depth setting to its shallowest depth (1).
• Your forearm.	Start at Level (2) or higher if your experience with setting 2 does not produce a usable sample.



- The FreeStyle® Lancing Device offers four 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, we recommend that you start at Level (2) and use the clear cap.

  To lance your finger, we recommend that you set the depth setting to its shallowest depth (1) and use the grey cap.



h. Pull the dark grey cocking handle out until it clicks.

Note: You may have already cocked the device in Step 4d.

i. Prepare the site:

If you are using	*Then to stimulate blood flow*
• A finger.	Warm your hand, lower it to waist level, and gently massage the finger.
• Your forearm.	Rub the test site vigorously until you feel it getting warm (three to five seconds).



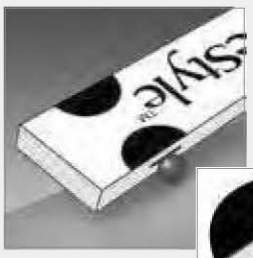
OVER

Steps	Do This
5. Lance the site.   	**To lance your finger (grey cap):** **a.** Lightly touch the lancing device against the side of your fingertip. **b.** Press the release button. **c.** Put the lancing device down. **d.** Gently squeeze your finger, if needed, until a drop of blood the size of a pinhead forms.
  	**To lance your forearm (clear cap):** **a.** Hold the lancing device against the test site. **b.** Press the release button. **c.** Continue to hold the lancing device against the test site as you: **i)** Inspect the test site through the clear cap. **ii)** Gradually increase pressure until the sample is the size of this dot: • ***Important:*** *Do **NOT** smear the sample as you do the next step.* **d.** Lift the lancing device ***straight up***.

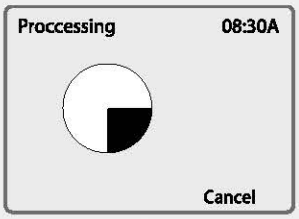
Steps

6. Test the sample.









Do This

Do Not:

- Use test strips more than once. Discard used test strips.
- Scrape the blood.
- Apply blood to the flat side of the test strip.
- Apply blood to the test strip when the test strip is out of the receiver.
- Apply blood to both edges of the test strip.
- Put blood or foreign objects into the receiver's test strip port.

a. Holding the receiver at a slight angle to the sample, gently touch the half-circle on the test strip to the sample.

Important: Your blood glucose level must be between 60 and 300 mg/dL (3.3 and 16.7 mmol/L) to be able to perform calibration tests. If your blood glucose level is changing rapidly, you may not be able to calibrate the system.

b. Observe the receiver:

If	*Then*
• The stopwatch icon does **NOT** appear within 5 seconds.	Continue adding blood sample to the **SAME** half-circle for up to 60 seconds.
• The receiver **BEEPS ONCE** (only if Progress Tones are turned on).	Enough blood has been used.
• The stopwatch icon appears.	The receiver is measuring your blood glucose level.
• The receiver **BEEPS TWICE** (only if Progress Tones are turned on).	The test is done. Go to Step 7.
• Your blood glucose results appear in the display (takes an average of 7 seconds).	
• The receiver beeps three times.	The test has failed. Repeat the test. Refer to Section 10 for error messages and troubleshooting.
• You get an error message.	

OVER

Steps	Do This

7. Interpret the blood glucose results.

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

If	*And*	*Then*
• Lo appears in the display. Lo appears when the measured glucose result is less than 20 mg/dL (1.1 mmol/L).	You do **NOT** have low blood glucose symptoms.	Repeat the test from Step 3 using: • Your finger. • A new test strip.
	You have any of these symptoms: • Weakness • Headache • Sweating • Confusion • Nervousness	Follow your healthcare team's recommendations for treating hypoglycemia.
	This is your second test.	
• Hi appears in the display. Hi appears when the measured glucose result is more than 500 mg/dL (27.8 mmol/L).	You do **NOT** have high blood glucose symptoms.	Repeat the test from Step 3 with a new test strip.
	You have any of these symptoms: • Fatigue • Excess urination • Thirst • Blurry vision	Follow your healthcare team's recommendations for treating hyperglycemia.
	This is your second test.	
• The receiver displays results from 20 to 500 mg/dL (1.1 mmol/L to 27.8 mmol/L).		Continue to Step 8.

8. Confirm you did NOT use Control Solution.



Press the RIGHT Option button to indicate that you did **NOT** use a Control Solution.

Press the RIGHT Option button to select 'No' and press the RIGHT Option button again to view the continuous glucose results. See Section 10 to respond to alarm messages if there are any.

Note: *If you do not select 'No' for the "Control Solution?" question in this step within two minutes, the system automatically considers it a blood test.*

Steps	Do This
9. Remove and discard the test strip.	***Important:** Test strips may be used only once. Discard used test strips.*
10. Discard the lancet. 	**Note:** Use a sealed container such as a sharps container to avoid biohazards. a. Snap off the cap from the lancing device. b. Hold the lancet over a sharps container or other puncture-proof container with a lid. c. Pinch the white clip that holds the lancet until the lancet falls into the container.
11. Check your work.	***Result:** A properly calibrated receiver. You have done this procedure correctly when:* ❑ Your hands and the test site have been cleaned with soap and water and thoroughly dried with a clean towel. ❑ The code number in the receiver matches the code number for the test strips. ❑ The test site for calibration was a finger. ❑ The test site for manual blood glucose testing was selected from any of the other test sites shown in Step 3 of this Section. ❑ You used your finger, if you have hypoglycemia unawareness. ❑ You used the grey cap on the lancing device for a finger site. Or, you used the clear cap on the lancing device for a forearm site. ❑ The lancing produced an adequate amount of blood without smearing. ❑ You followed all of the notes in Step 6 when testing the blood. ❑ You interpreted the test results according to Step 7. ❑ You selected NO in response to the receiver's inquiry, "Control Solution?" ❑ You disposed the lancet in a sharps container or in a puncture-proof sealed container. END OF Section 7

8 Set, Review, or Change the Alarm Settings

Section 8

Section 8 – Key Terms

- Alarm Menu
- Alarm Sensitivity
- Alarm Type
- Data Loss
- High Glucose Alarm
- High Glucose Threshold
- LEFT/RIGHT Option Buttons
- Low Glucose Alarm
- Low Glucose Threshold
- Main Menu
- Progress Tones
- Projected High Alarm
- Projected Low Alarm
- Receiver
- System
- System Alarms
- UP/DOWN Arrow Buttons

8 Set, Review, or Change the Alarm Settings

Purpose

To set the receiver to:

- Alert you when your glucose conditions change.
- Notify you when the receiver needs attention.
- Notify you when the receiver begins or completes certain activities.

Start

Do this task:

- Immediately after you finish the first set up of your FreeStyle Navigator system.
- When your healthcare team gives you new glucose threshold numbers.
- Anytime you get a "Preferences Lost Reconfigure" alarm message on the receiver.
- Anytime you replace your receiver.
- Anytime you want to change your alarm settings.
- Anytime you want to review your alarm settings.

Materials

- Your FreeStyle Navigator Receiver.
- Low and high glucose threshold values (from your healthcare team).

Helpful Information

Caution: *The high and low alarms are intended to assist you in managing your diabetes and should not be exclusively used to detect hypoglycemia or hyperglycemia. The alarms should always be used in conjunction with other indications of glycemic state such as your glucose level, trend, line graph etc.*

Caution: *High and low glucose alarms are* ***DIFFERENT*** *from your glucose targets. Low and high glucose alarms alert you when you've crossed a certain low or high value. Glucose targets allow the reports and line graphs to show how your glucose levels have been performing compared to your set targets.*

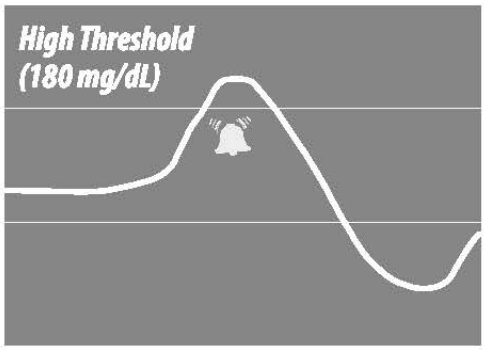
Caution: *Before adjusting treatment for diabetes management based on the continuous glucose results from your FreeStyle Navigator system, perform a Blood Glucose mode test to confirm the continuous result.*

- ***High and low glucose alarms*** let you know when your glucose levels are above or below your low and high glucose ***threshold*** values. You will decide the low and high glucose threshold values based on input from your healthcare team. If there is no glucose data, you will not get glucose alarms.
- A ***projected alarm*** is an alarm that provides an ***early warning*** of an event that is likely to occur if the current trend continues. Projected alarms use the low and high glucose ***threshold*** values regardless of whether or not the low and high glucose alarms are turned on.

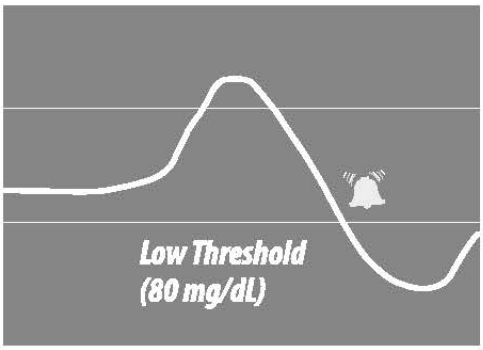
  For example, a projected low alarm lets you know when you are approaching your low glucose ***threshold*** *value. You will decide the amount of notice required (whether you should be notified approximately 10 minutes, 20 minutes or 30 minutes in advance of reaching your* ***threshold*** *value) based on the input from your healthcare team.*
- A data loss alarm warns you when glucose results are no longer available. They occur when the sensor has expired, when the transmitter-receiver connection is broken, when a calibration has expired or when the sensor is not working properly. The data loss alarm cannot be turned off without turning off the glucose alarms (Low Glucose, High Glucose, Projected Low Glucose and Projected High Glucose).
- ***System alarms*** notify you of events like low battery or time to calibrate.
- ***Progress tones*** notify you of errors, results, and successful completion of steps in activities like Blood Glucose mode testing.

About Glucose Alarms

The FreeStyle Navigator® system is designed to alert you when your glucose levels reach preset low or high values. These values or 'threshold values' can be programmed in the receiver for any individual. These high and low glucose alarms or the threshold alarms are designed to alert you ***when*** your glucose levels cross these threshold values.

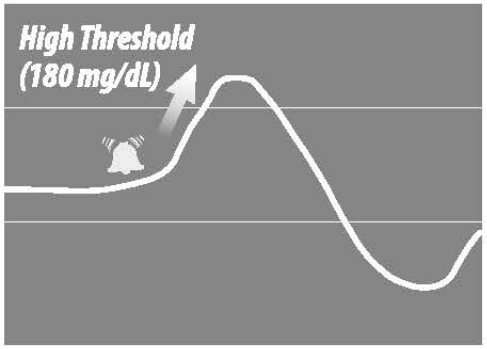


Example of a High Glucose Threshold Alarm - The alarm sounds ***when*** the glucose level crosses the preset threshold value.

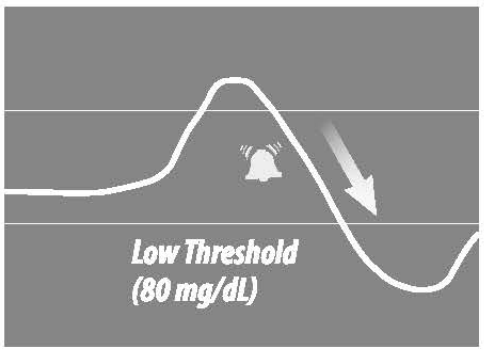


Example of a Low Glucose Threshold Alarm - The alarm sounds ***when*** the glucose level crosses the preset threshold value.

In addition to alerting you of a high or low glucose condition, the system can also alert you ***before*** you reach such a high or low glucose condition. These alarms are called the projected high and projected low glucose alarms. They can be set at low, medium and high sensitivities to alert you approximately 10, 20 or 30 minutes before your glucose levels reach the high or low threshold values, assuming your glucose keeps changing at the same rate. You can turn all glucose alarms ON or OFF. If the alarms are turned OFF, you will not get any alarms.



Example of a Projected High Glucose Alarm - The alarm sounds ***before*** the glucose level reaches the preset threshold value.



Example of a Projected Low Glucose Alarm - The alarm sounds ***before*** the glucose level reaches the preset threshold value.

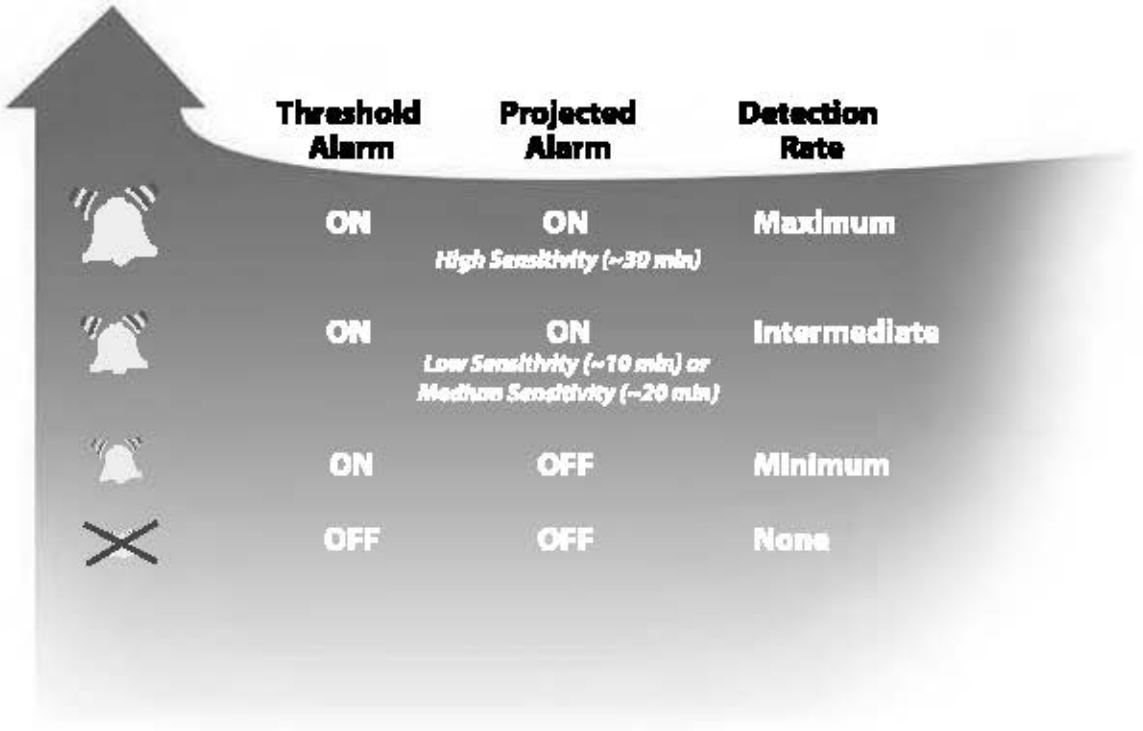
These alarms are designed to help you take action as soon as you are notified. Projected low and projected high glucose alarms increase the overall ability to detect a condition of low or high glucose. However, they cannot be relied on exclusively for notification of all low and high glucose conditions.

High and low glucose threshold alarms can detect a low or high glucose condition more often than projected high and projected low glucose alarms (see alarm performance under performance characteristics for more information). Therefore, do **NOT** turn off the low and high glucose threshold alarms to rely just on the projected high and projected low glucose alarms.

In order to get maximum notification of low and high glucose conditions, use both the low and high glucose threshold alarms ***AND*** the projected low and projected high glucose alarms.

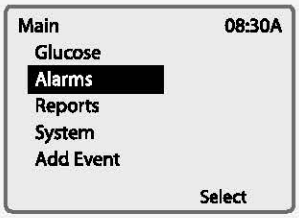
About Glucose Alarms *(con't)*

Follow the guidelines below when selecting your alarm settings for detection of high and low glucose conditions. When the detection rate is maximum, you will get the greatest number of alarms. When the detection rate is minimum, you will get the fewest number of alarms.



***Caution:** Do **NOT** rely solely on the projected glucose alarms for detection of low or high glucose conditions. Always use both the low glucose and high glucose threshold alarms **AND** the projected low and projected high glucose alarms for maximum notification of low or high glucose conditions.*

OVER

Steps	Do This
1. Access the Alarms menu from the Main menu. 	**Note:** If you don't press any buttons within 12 seconds, the receiver screen will go blank and the last change will be lost if you haven't pressed the Select button. **a.** Press the UP Arrow button or the DOWN Arrow button to highlight Alarms. **b.** Press the RIGHT Option button (Select) to go to the Alarms Setting screen.
2. Decide what to do.	

If you want to	*Then*
• Set, review or change the Low glucose alarm.	Go to Step 3.
• Set, review or change the High glucose alarm.	Go to Step 4.
• Set, review or change the PROJECTED Low glucose alarm.	Go to Step 5.
• Set, review or change the PROJECTED High glucose alarm.	Go to Step 6.
• Set, review or change the Data loss alarms.	Go to Step 7.
• Set, review or change the System alarms.	Go to Step 8.
• Set Progress tones.	Go to Step 9.
• Mute all audible alarms.	Go to Step 10.

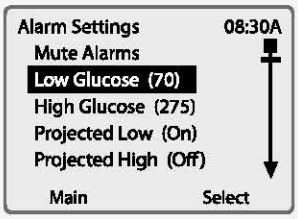
Note: In all the subsequent steps choosing the Next button will allow you to go from one field to another. For example, you can go from the ON/OFF field to the Glucose threshold field to the alarm setting field. Choosing the UP/DOWN Arrow button will allow you to choose the value you want for the field.

For example, choose ON or OFF for the alarm, choose a number for the threshold like 70 mg/dL or choose medium beep or long beep for the alarm setting.

Review the alarm performance data in Section 18 for a detailed analysis of the effectiveness of the glucose alarms.

Steps	Do This

3. Set, review, or change the Low Glucose alarm.



Decide what settings you want:

- Alarm on or off.
- Your threshold value.

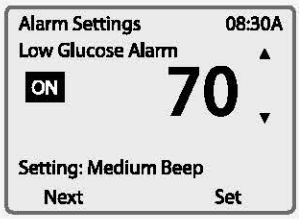
Note: The alarm can only be set between 60 and 139 mg/dL (3.3 mmol/L and 7.7 mmol/L).

- Alarm type (Setting).
  - Low, medium, or high beep.
  - Short, medium, or long vibration.

Caution: *The Low Glucose alarm cannot be set below 60 mg/dL (3.3 mmol/L). Therefore, it is not intended to notify you of severe hypoglycemia.*

a. Select Low Glucose from the Alarms menu.

- Use the UP/DOWN Arrow buttons to highlight Low Glucose.
- Press the RIGHT Option button to select Low Glucose.



b. Review or change your settings.

- Press the LEFT Option button (Next) to move from one field to the next.
- Use the UP/DOWN Arrow buttons to change the setting in any field.
- Press the RIGHT Option button (Set) to accept the settings and return to the Alarms menu.

  Note: The receiver will respond with a brief sample of the alarm you selected.

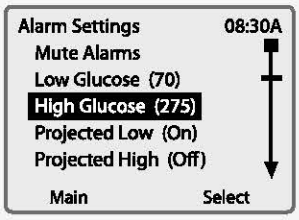
c. Decide what to do next.

If	*Then*
• You are setting, reviewing, or changing all alarms.	Continue to the next step.
• You are finished setting, reviewing, and changing alarms.	Go to Step 11.

OVER

Steps	Do This

4. Set, review, or change the High Glucose alarm.



Decide what settings you want:

- Alarm on or off.
- Your threshold value.

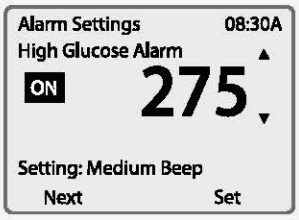
Note: The alarm can only be set between 140 and 300 mg/dL (7.8 mmol/L and 16.7 mmol/L).

- Alarm type (Setting).
  - Low, medium, or high beep.
  - Short, medium, or long vibration.

Caution: *The High Glucose alarm cannot be set above 300 mg/dL (16.7 mmol/L). Therefore, it is not intended to notify you of severe hyperglycemia.*

a. Select High Glucose from the Alarms menu.

- Use the UP/DOWN Arrow buttons to highlight High Glucose.
- Press the RIGHT Option button to select High Glucose.



b. Review or change your settings.

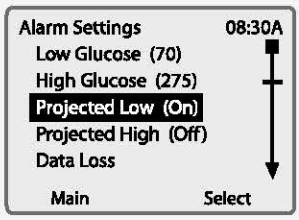
- Press the LEFT Option button (Next) to move from one field to the next.
- Use the UP/DOWN Arrow buttons to change the setting in any field.
- Press the RIGHT Option button (Set) to accept the settings and return to the Alarms menu.

  Note: The receiver will respond with a brief sample of the alarm you selected.

c. Decide what to do next.

If	*Then*
• You are setting, reviewing, or changing all alarms.	Continue to the next step.
• You are finished setting, reviewing, and changing alarms.	Go to Step 11.

Steps	Do This
5. Set, review, or change your Projected Low glucose alarm.	

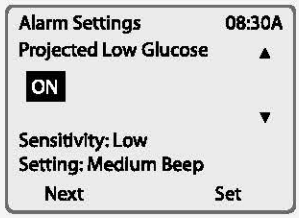


Decide what settings you want:

- Alarm on or off.
- Sensitivity.
- Alarm type (Setting).
  - Low, medium, or high beep.
  - Short, medium, or long vibration.

a. Select Projected Low from the Alarms menu.

- Use the UP/DOWN Arrow buttons to highlight Projected Low.
- Press the RIGHT Option button to select Projected Low.



If you want this much notice before reaching your Low glucose level:	Then set the **Sensitivity** to:
• Maximum detection (most alarms, approximately 30 minutes in advance of events)	**High**
• Intermediate detection (intermediate alarms, approximately 20 minutes in advance of events)	**Medium**
• Low detection (fewest alarms, approximately 10 minutes in advance of events)	**Low**

b. Review or change your settings.

- Press the LEFT Option button (Next) to move from one field to the next.
- Use the UP/DOWN Arrow buttons to change the setting in any field.
- Press the RIGHT Option button (Set) to accept the settings and return to the Alarms menu.

  Note: The receiver will respond with a brief sample of the alarm you selected.

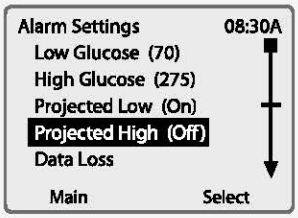
c. Decide what to do next.

If	*Then*
• You are setting, reviewing, or changing all alarms.	Continue to the next step.
• You are finished setting, reviewing, and changing alarms.	Go to Step 11.

OVER

Steps	Do This

6. Set, review, or change your Projected High glucose alarm.

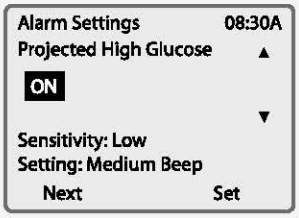


Decide what settings you want:

- Alarm on or off.
- Sensitivity.
- Alarm type (Setting).
  - Low, medium, or high beep.
  - Short, medium, or long vibration.

a. Select Projected High from the Alarms menu.

- Use the UP/DOWN Arrow buttons to highlight Projected High.
- Press the RIGHT Option button to select Projected High.



If you want this much notice before reaching your High glucose level:	Then set the **Sensitivity** to:
• Maximum detection (most alarms, approximately 30 minutes in advance of events)	**High**
• Intermediate detection (intermediate alarms, approximately 20 minutes in advance of events)	**Medium**
•Low detection (fewest alarms, approximately 10 minutes in advance of events)	**Low**

b. Review or change your settings.

- Press the LEFT Option button (Next) to move from one field to the next.
- Use the UP/DOWN Arrow buttons to change the setting in any field.
- Press the RIGHT Option button (Set) to accept the settings and return to the Alarms menu.

  Note: The receiver will respond with a brief sample of the alarm you selected.

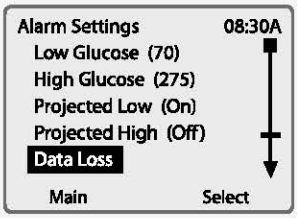
c. Decide what to do next.

If	*Then*
• You are setting, reviewing, or changing all alarms.	Continue to the next step.
• You are finished setting, reviewing, and changing alarms.	Go to Step 11.

Steps

Do This

7. Set, review, or change the Data Loss alarms.



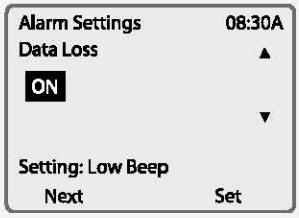
Decide what settings you want:

- Alarm on or off.
- Alarm type (Setting).
  - Low, medium, or high beep.
  - Short, medium, or long vibration.

Important: *If you turn off your Data Loss alarms, you must also turn off your Low Glucose, High Glucose, Projected Low and Projected High alarms.*

a. Select Data Loss from the Alarms menu.

- Use the UP/DOWN Arrow buttons to highlight Data Loss.
- Press the RIGHT Option button to select Data Loss.



b. Review or change your settings.

- Press the LEFT Option button (Next) to move from one field to the next.
- Use the UP/DOWN Arrow buttons to change the setting in any field.
- Press the RIGHT Option button (Set) to accept the settings and return to the Alarms menu.

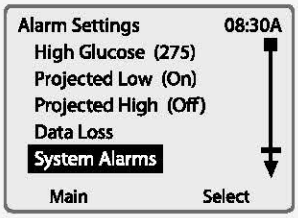
  Note: The receiver will respond with a brief sample of the alarm you selected.

c. Decide what to do next.

If	*Then*
• You are setting, reviewing, or changing all alarms.	Continue to the next step.
• You are finished setting, reviewing, and changing alarms.	Go to Step 11.

Steps	Do This

8. Set System Alarms.

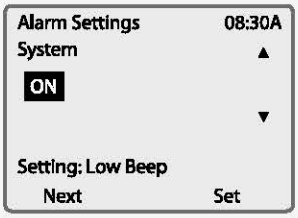


Decide what settings you want:

- Alarm on or off.
- Alarm type (Setting).
  - Low, medium, or high beep.
  - Short, medium, or long vibration.

Important: *If you turn off the System Alarms, the receiver will* ***NOT*** *prompt you to do the calibration tests after you insert a new sensor.*

a. Select System Alarms from the Alarms menu.



b. Review or change your settings.

- Press the LEFT Option button (Next) to move from one field to the next.
- Use the UP/DOWN Arrow buttons to change the setting in any field.
- Press the RIGHT Option button (Set) to accept the settings and return to the Alarms menu.

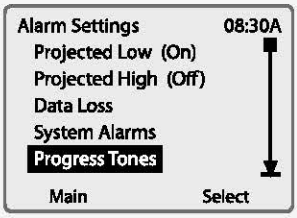
  Note: The receiver will respond with a brief sample of the alarm you selected.

c. Decide what to do next.

If	*Then*
• You are setting, reviewing, or changing all alarms.	Continue to the next step.
• You are finished setting, reviewing, and changing alarms.	Go to Step 11.

Steps

9. Set Progress Tones.

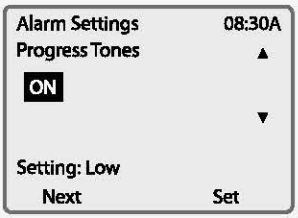


Decide what settings you want:

- Turn progress tones on or off.
- Set progress tones volume low or high.

Do This

a. Select Progress Tones from the Alarms menu.



b. Review or change your settings.

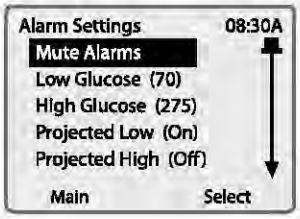
- Press the LEFT Option button (Next) to move from one field to the next.
- Use the UP/DOWN Arrow buttons to change the setting in either field.
- Press the RIGHT Option button (Set) to accept the settings and return to the Alarms menu.

  Note: The receiver will respond with a brief sample of the alarm you selected.

c. Decide what to do next.

If	*Then*
• You want to mute alarms.	Go to Step 10.
• You are finished setting, reviewing, and changing alarms.	Go to Step 11.

OVER

Steps	Do This
10. Mute all audible alarms for 1 hour.	**Note 1:** You will still get vibration, visual alarms will still be displayed and you will continue to get Low Glucose alarms. **Note 2:** If you want to turn off all alarms for more than one hour, you should turn off each alarm individually. Exercise caution when turning off or muting alarms. For example, if you turn off the low and high glucose alarms, you will **NOT** get low and high glucose alarms.
	**a.** Select Mute Alarms from the Alarms menu.
	**b.** Press the RIGHT Option button (Select) to mute alarms for 1 hour. **Note:** If you change your mind before you press the RIGHT Option button (Select), press the LEFT Option button (Cancel) to return to the Alarm screen without muting the alarms. If the alarms are muted, you will see a symbol indicating that the alarms are muted. Once the alarms have been muted, they cannot be turned on before the 1 hour expires. ***Important:*** *Muting the alarms is not recommended during times when you are unable to interact with your receiver (for instance, when you are asleep). Interacting with your receiver includes activities such as pressing the buttons, viewing the screen, or inserting a strip to do a BG test.* *If no buttons are pressed during the 1 hour muting period during which an alarm is active, the alarm response period will elapse during the mute time and no further alarms will sound until the display has been activated.*
11. Return to the main menu.	Press the LEFT Option button (Main) on the Alarms menu to return to the main menu.
12. Check your work.	***Result:*** *The result will be a receiver set up to alert you to your glucose conditions, to system events, and to activity progress in a way that you prefer.* You will have done this procedure correctly when the receiver provides alarms as you want it to.

9 Daily Use

Section 9

Section 9 – Key Terms

- **BG Mode**
- **CM Mode**
- **Directional Glucose Trend Arrows**
- **Icon**
- **Receiver**
- **Transmitter**
- **Transmitter Receiver Connection**

9 Daily Use

Purpose To read and understand your display screen.

Start Do this procedure:
- Anytime you are using your system in the Continuous Monitoring mode.

Materials Your receiver.

Helpful Information

- Your receiver and transmitter must be linked, connected, and calibrated in order to use the system in the Continuous Monitoring mode.
- When you sleep, place the receiver on a high headboard or on a nearby dresser rather than clipping it to your bed clothing or taking it to bed. Be aware that if the receiver is set to vibrate and if you place it too far from you, you may not hear it vibrate.
- You must keep your receiver within 10 feet of the transmitter to maintain a consistent connection. If the connection between the transmitter and receiver is broken you will not receive continuous glucose readings.
- The connection can also be affected by objects getting between the transmitter and receiver, like nearby large metal objects, and by some electronic devices that produce radio frequencies.
- As a periodic check, turn your receiver on a few times everyday to make sure that it is still producing glucose results.
- As a periodic check, turn on the low glucose alarm everyday to make sure that it sounds an alarm (or vibrates) based on your settings.
- If a connection alarm sounds, adjust the placement of the receiver, to restore the connection. Step 2 of this Section describes how to maintain connection between the receiver and transmitter. For general troubleshooting, refer to Section 10 as well.
- If the display turns off, press the RIGHT Option button to turn it back on.

Steps	Do This

1. Decide what to do.

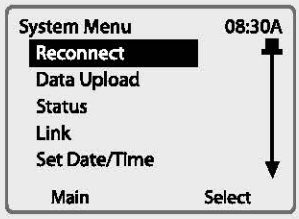
If you want to	*Then go to this Step*
• Connect your receiver and transmitter.	2
• Reconnect your receiver and transmitter.	2
• Interpret the CM screen.	3
• Interpret icons on the CM screen.	4
• Interpret icons on the Main screen.	4
• Turn the receiver backlight on.	5

2. Reconnect the receiver to the transmitter.

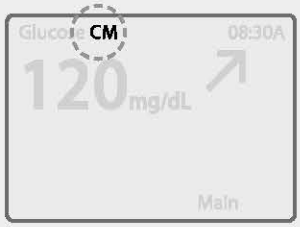
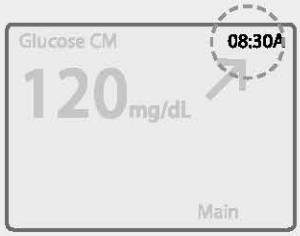
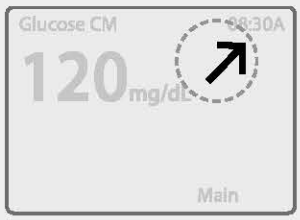
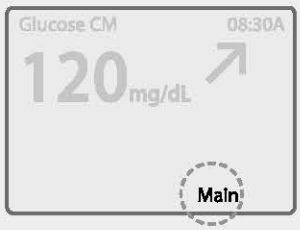
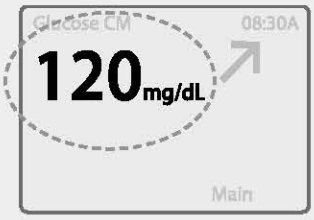
a. Place the receiver within 10 feet of the transmitter.

b. Decide what to do next.

If the receiver has lost connection	*Then*
• For less than 30 minutes.	**1.** Wait for the connection icon to disappear automatically from the display to confirm connection. **2.** Go back to Step 1 of Section 9.
• For 30 minutes or more.	**1.** Press the RIGHT Option button twice to display the Main Menu screen. **2.** Use the UP/DOWN Arrow button to highlight System. **3.** Press the RIGHT Option button (Select) to display the System menu with Reconnect highlighted. **4.** Press the RIGHT Option button (Select). **5.** Wait for the receiver to beep. If it beeps: • Twice – the system is connected. Go back to Step 1 of Section 9. • Three times – the system is not connected. Make sure the battery in the transmitter is new and ensure that the receiver and transmitter are linked (see Section 14).



Steps	Do This
3. Interpret the CM screen.	Press the RIGHT Option button to turn the display on. ***Result:*** *The Glucose CM screen is displayed.*

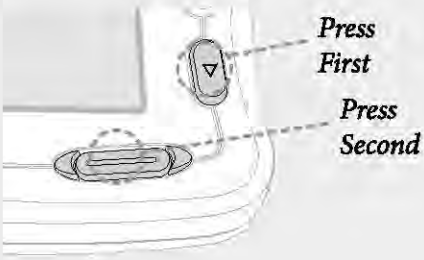
Location	*Description*
	If CM appears here, the receiver is operating in the Continuous Monitoring mode. If BG appears here, the receiver is operating in the Blood Glucose mode.
	The current time of day.
	The directional glucose trend arrow tells you the direction that your glucose levels are trending and how fast (see Step 4). The system uses 15 minutes of continuous glucose data to display the arrow. Occasionally, the arrow may not be displayed temporarily. Refer to the Line Graph for recent glucose history.
	Tells you what pressing the RIGHT Option button will do – in this case, it takes you to the Main screen.
	Your current glucose level. Follow the recommendations of your healthcare team to treat low glucose (hypoglycemic) and high glucose (hyperglycemic) episodes.

Caution: *Before adjusting treatment for diabetes management based on the continuous glucose results from your FreeStyle Navigator system, perform a Blood Glucose mode test to confirm the continuous result.*

OVER

Steps	Do This
4. Interpret the icons.	**Note:** The directional trend arrows are different from the projected glucose alarms (Section 8). For example, you can have a projected low glucose alarm and still have a relatively stable trend arrow.

This Icon	*Means*
	Your glucose is changing gradually, changing at a rate of less than 60 mg/dL/hr (3.3 mmol/L/hr).
	Your glucose is increasing moderately, at a rate between 60 mg/dL/hr and 120 mg/dL/hr (3.3 mmol/L/hr and 6.7 mmol/L/hr).
	Your glucose is decreasing moderately, at a rate between 60 mg/dL/hr and 120 mg/dL/hr (3.3 mmol/L/hr and 6.7 mmol/L/hr).
	Your glucose is increasing rapidly, at a rate of greater than 120 mg/dL/hr (6.7 mmol/L/hr).
	Your glucose is decreasing rapidly, at a rate of greater than 120 mg/dL/hr (6.7 mmol/L/hr).
	The system is processing a control solution or blood glucose sample in the Blood Glucose mode.
	It is time to do a calibration. See Section 7.
	The system is waiting until it is time to do something (for example, waiting to do the 1st calibration after inserting a sensor). You don't need to do anything.
	There is a problem with the transmitter-receiver connection. See Step 2.
	The alarm is muted.
	It is time to replace the batteries in the receiver. Install the new batteries just before you insert a new sensor. See Section 2.
	This icon shows up for Blood Glucose mode test results that happened when the operating temperature was beyond the system's specified operating temperature range and may be less accurate. Discard the test and repeat another test within the operating temperature range of the system.

Steps	Do This
5. Turn the Backlight on.  	**a.** In order to turn the backlight on, your receiver has to be turned off. If the receiver is on, wait for 12 seconds to allow the receiver to turn off. **b.** Press and release the **DOWN** Arrow button. Then immediately press and release the **RIGHT** option button. Your receiver will turn on with a backlight.
6. Check your work.	***Result:*** *You are aware of your glucose levels and trends. You have done this procedure correctly when:* ❑ You correctly interpret the directional glucose trend arrows. ❑ You can tell your current glucose level at a glance. ❑ You maintain the connection between your transmitter and receiver or can reconnect the transmitter and receiver when the connection is lost. ❑ You can correctly interpret the icons that appear on the receiver screen.

END OF Section 9

10 Respond to Alarms, Errors, and Problems

Section 10

Section 10 – Key Terms

- Alarms Menu
- Calibration BG
- CM Status
- Calibration
- High Glucose Alarm
- Icon
- Low Glucose Alarm
- Projected High Alarm
- Projected Low Alarm
- Receiver Status
- Sensor
- Sensor Support Mount
- Status Information
- Transmitter
- Transmitter Receiver Connection
- Transmitter Status

10 Respond to Alarms, Errors, and Problems

Purpose To resolve alarm messages, error codes, or problems.

Start Do this any time you:

- Receive either an alarm or an error code in the Continuous Monitoring mode or the Blood Glucose mode.
- Experience problems with your FreeStyle Navigator system.

Materials Your FreeStyle Navigator system.

Helpful Information

Caution: *For ALL alarms, if you do not turn on the display of the receiver within the first hour of the notification of an alarm, the receiver will stop beeping (or vibrating). No further alarms will sound (beep or vibrate) until the display has been activated.*

Important: *Muting the alarms is not recommended during times when you are unable to interact with your receiver (for instance, when you are asleep). Interacting with your receiver includes activities such as pressing the buttons, viewing the screen, or inserting a strip to do a BG test.*

If no buttons are pressed during the 1 hour muting period during which an alarm is active, the alarm response period will elapse during the mute time and no further alarms will sound until the display has been activated.

- Press the RIGHT Option button to respond to a vibration or audio alarm.
- Press the LEFT Option button to turn off a text display message.
- See Section 8, Step 10 to mute all audible alarms for 1 hour.
- Alarms are given a level of urgency based on how soon you must respond. Alarms act differently depending upon the level of urgency:

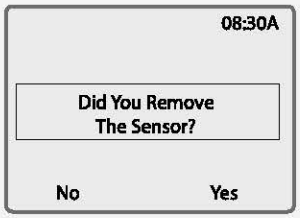
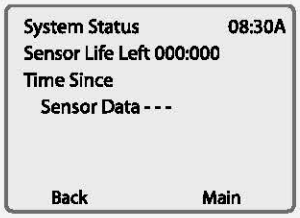
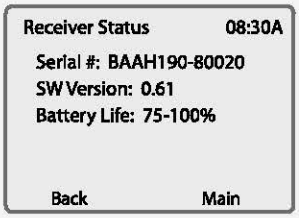
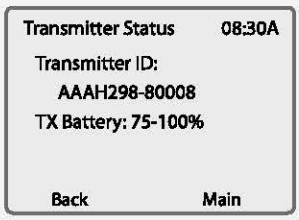
If the level of urgency is	*Then the alarm*
High – **H**	• **Must <u>never</u> be ignored.** • Cannot be muted. • Is the same as a medium urgency alarm in all other respects.
Medium – **M**	• Can be muted. • Sounds three short beeps every 6 seconds for 1 minute or until you activate the display. • Repeats every 5 minutes until acknowledged or fixed. • Repeats every 15 minutes after acknowledged until fixed.
Intermediate – **I**	• Is the same as the medium urgency alarm except the intermediate alarm will stop and will not sound again: – After 1 hour. – When acknowledged. – Can be muted.
Low – **L**	• Does not need to be addressed right away. • It is a single beep that does not repeat. Can be muted. • Is turned off when acknowledged.

- The level of urgency is indicated in some of the following tables with H for high, M for medium, I for intermediate, and L for low.
- The alarms are alphabetized in the following tables.
- If you cannot find the information you need, call Customer Care.

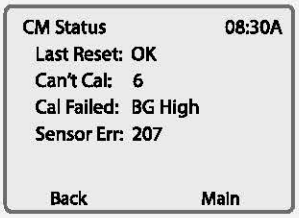
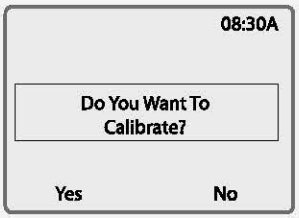
OVER

Status Information

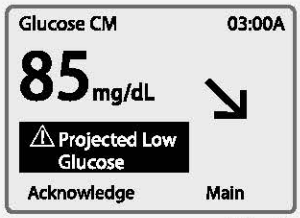
The receiver can provide you with a number of different types of Status Information. Available Status Information is listed in the following table. To access the Status information, press the RIGHT option button twice to get to the Main menu and use the UP or DOWN arrow button to highlight System. Select System by pressing the RIGHT option button. Highlight and select Status from the System menu.

Status Information	*Description*
Removed Sensor 	Allows you to indicate you are removing a Sensor so the Data Loss Alarm will not set off. Use this only if you are removing a sensor. **Note:** Once you select this option, the system will terminate any active sensor.
System Status 	Shows information about the System, including Sensor life remaining (in hours) and time since valid data was transmitted (in hours).
Receiver Status 	Shows information about the receiver, including serial number and software version (may be useful when calling Customer Care), as well as battery life remaining.
Transmitter Status 	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 the transmitter the receiver is linked to. It also shows battery life remaining. After replacing the battery, once the system has recognized the new battery, it will display battery life as 75-100%. If there is no connection between the transmitter and receiver, you will see 3 dashes, "- - -", instead of the battery life.

Status Information *(con't)*

Status Information	*Description*
CM Status. 	Stores recent error codes related to the Continuous Monitoring mode (may be useful when calling Customer Care). **Note:** The CM Status screen shows information about calibration and sensor errors. You can get information about why the system did not prompt you to perform a calibration ("Can't Cal: xxx") or why a calibration failed ("Cal Failed: xxx") or why continuous glucose readings are not displayed ("Sen Err: xxx"). These numbers and information help troubleshoot your system performance. The Customer Care representative may ask you to access the CM Status information.
Calibration BG. 	Allows you to add a new blood glucose reading used for calibration. Use this selection **ONLY** at the request of a Customer Care representative. **Note:** Once you use this feature to successfully perform an additional calibration, the system discards the parameters from the previous calibrations. It begins to calculate glucose results based on this calibration. When using the Calibration BG feature, always perform an additional Blood Glucose mode test to confirm the first test. This feature cannot be used in the first ten hours after sensor insertion. Using this feature does not change the regular scheduled times for calibration.

Alarms and Errors

Display	*Description*
 Fig. 1	The system will notify you of any conditions that may need your attention through messages that will be displayed on your receiver screen. You can find out what those messages mean and how to respond to them. For example, see Fig. 1. The messages are arranged alphabetically in the table titled "Respond to alarm message".
 Fig. 2	When you use your built in FreeStyle Meter to make measurements, you may receive error codes on the receiver. You can find out how to respond when you get those codes. For example, see Fig. 2.

OVER

Respond to alarm message:

Alarm Message	Urgency	What It Means	What to Do
— — —	N/A	• System is not producing continuous 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. • Problem with the connection between the receiver and transmitter. • Sensor problem (or sensor no longer in your skin). • Transmitter failure. • Sensor is expired.	Wait for the receiver to prompt you with an alarm message.
"_____" A Flashing line on the bottom of the screen.	N/A	You are in one of the menu items and a new alarm message has just been triggered.	By using the RIGHT and LEFT option and UP/DOWN buttons on the receiver go to the Glucose screen and read your alarm.
Flashing light at the test strip port.	N/A	Receiver has reset.	Call Customer Care.
⚠ Alarms Inactive Insert New Sensor.	I	Alarms are not operating because the 5-day life of the sensor has ended.	Remove the sensor and insert a new one (see Section 5).
⚠ Alarms Inactive Replace Receiver.	I	Receiver malfunction. Problem has persisted for an hour.	Call Customer Care.
⚠ 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 Section 5).
⚠ Alarms Inactive Replace Transmitter.	I	Transmitter problem for an hour. Alarms are not active.	Replace the transmitter, and insert a new sensor.

High – **H**, Medium – **M**, Intermediate – **I**, Low – **L**

Respond to alarm message: *(con't)*

Alarm Message	Urgency	What It Means	What to Do
⚠ 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 one hour. The alarms are not working.	Remove the sensor and insert a new one (see Section 5). If problem persists, then replace transmitter.
⚠ 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 300 mg/dL (3.3 and 16.7 mmol/L) for proper calibration.	If your glucose level is high, follow your healthcare professional's advice for a high glucose level (hyperglycemic) episode. Perform another Blood Glucose mode test for calibration.
⚠ 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 300 mg/dL (3.3 and 16.7 mmol/L) for proper calibration.	If your glucose level is low, follow your healthcare professional's advice for a low glucose level (hypoglycemic) episode. Perform another Blood Glucose mode test for calibration.
⚠ 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 for calibration.
⚠ 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 perform a Blood Glucose mode test for calibration.
⚠ Cal Failed: Redo BG Later.	I	Calibration failed because the information from the transmitter was incomplete or there is no connection between the transmitter and receiver or your glucose levels have been changing rapidly.	Make sure that the receiver and transmitter are connected. Wait 1 hour and perform a Blood Glucose mode test for calibration.
⚠ Cal Failed: Redo BG Test.	I	Calibration test was very different from the previous calibration.	Perform another Blood Glucose mode test for calibration.

High – **H**, Medium – **M**, Intermediate – **I**, Low – **L**

Respond to alarm message: *(con't)*

Alarm Message	Urgency	What It Means	What to Do
⚠ Cal Required: Redo BG in 2 hrs.	I	Sensor signal is settling. The system requires another calibration in 2 hours. You will continue to get glucose results during that time.	Wait for the "Do BG test" prompt and perform another Blood Glucose mode test for calibration. You will have half hour to perform the calibration after which you will not get glucose results or alarms until the calibration is completed successfully.
⚠ Cool Down Skin.	L	Unable to calibrate the system because the skin temperature is too warm.	Cool the skin at the insertion site and wait for the "Do BG Test" prompt and perform another Blood Glucose mode test for calibration. You can cool down your skin temperature by moving to a cooler environment. If you are wearing warm clothing (like a sweater or jacket), try taking them off.
⚠ Cool Down Skin Redo BG Later.	I	Calibration failed because your skin temperature is too warm.	Cool the skin at the insertion site. Wait for half an hour and perform another Blood Glucose mode test for calibration. You can cool down your skin temperature by moving to a cooler environment. If you are wearing warm clothing (like a sweater or jacket), try taking them off.
⚠ Did You Remove The Sensor?	L	• 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.	• If you did not just remove the sensor, select No. • Ensure that the transmitter is attached firmly to the sensor support mount. • Ensure that the sensor support mount is attached firmly to the skin. • If the alarm persists, remove the sensor and insert a new one (see Section 5).

High – **H**, Medium – **M**, Intermediate – **I**, Low – **L**

Respond to alarm message: *(con't)*

Alarm Message	Urgency	What It Means	What to Do
Do BG Test.	M	A Blood Glucose mode test is needed for calibration. The receiver will prompt you to perform this test approximately 10 hours after the sensor insertion, 2 to 4 hours after the first successful calibration, 12 to 20 hours after the second successful calibration and 48 to 56 hours after the third successful calibration.	Perform a Blood Glucose mode test for calibration See Section 7.
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 for calibration.
High Glucose.	M	Your glucose has reached your preset high glucose threshold.	Follow the recommendations of your healthcare team for treating a high glucose level (hyperglycemic) episode.†
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 Main menu, then select Link. If the transmitter ID that appears on the display screen is correct, select Yes. See Section 14.
Log Cleared.	L	History log has been successfully cleared.	Acknowledge the alarm.
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, call Customer Care.

† ***Caution:*** *Before adjusting treatment for diabetes management based on the continuous glucose results from your FreeStyle Navigator system, perform a Blood Glucose mode test to confirm the continuous result.*

High – **H**, Medium – **M**, Intermediate – **I**, Low – **L**

Respond to alarm message: *(con't)*

Alarm Message	Urgency	What It Means	What to Do
⚠ Low Glucose.	H	Your glucose has reached your preset low glucose threshold.	Follow the recommendations of your healthcare team for treating a low glucose level (hypoglycemic) episode.†
⚠ New Sensor Detected Have You Recently Inserted a New Sensor?	L	• 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.	If you just inserted a new sensor, select Yes. If you did not insert a new sensor, select No. Ensure that the transmitter is attached firmly to the sensor support mount. If the alarm persists, the sensor may have failed. Remove the sensor and insert a new one (see Section 5). This message can appear during or after cleaning the transmitter. Ensure that the transmitter is thoroughly dry before inserting a new sensor (see Section 13).
⚠ 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 and other user-settable items like the country settings.
⚠ Projected High Glucose.	M	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. When set to **High** sensitivity, you have approximately 30 minutes before reaching your high glucose threshold. When set to **Medium** sensitivity, you have approximately 20 minutes before reaching your high glucose threshold. When set to **Low** sensitivity, you have approximately 10 minutes before reaching your high glucose threshold.	Follow the recommendation of your healthcare team for treating or stopping the rise in glucose that you are experiencing.†

† ***Caution:*** *Before adjusting treatment for diabetes management based on the continuous glucose results from your FreeStyle Navigator system, perform a Blood Glucose mode test to confirm the continuous result.*

High – **H**, Medium – **M**, Intermediate – **I**, Low – **L**

Respond to alarm message: *(con't)*

Alarm Message	Urgency	What It Means	What to Do
Projected Low Glucose.	M	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. When set to **High** sensitivity, you have approximately 30 minutes before reaching your low glucose threshold. When set to **Medium** sensitivity, you have approximately 20 minutes before reaching your low glucose threshold. When set to **Low** sensitivity, you have approximately 10 minutes before reaching your low glucose threshold.	Follow the recommendations of your healthcare team for treating or stopping the drop in glucose that you are experiencing.†
Receiver Error Alarms Inactive.	I	Receiver error.	The problem could go away in 50 minutes or less. If problem persists, call Customer Care.
Reconnect.	L	The receiver has not been receiving signals sent by the transmitter for 5 minutes. 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 Main menu, then select Reconnect. See Section 9, Step 2.
Reconnect–Alarms Inactive.	M	The receiver has not been receiving signals sent by the transmitter for 8 minutes. 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 Main menu, then select Reconnect. See Section 9, Step 2.
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 Section 5). Ignore the message if there is no sensor inserted.

† ***Caution:*** *Before adjusting treatment for diabetes management based on the continuous glucose results from your FreeStyle Navigator system, perform a Blood Glucose mode test to confirm the continuous result.*

High – **H**, Medium – **M**, Intermediate – **I**, Low – **L**

Respond to alarm message: *(con't)*

Alarm Message	Urgency	What It Means	What to Do
⚠ Replace Receiver Battery Within 1 Week.	L	The batteries in your receiver will lose power in approximately 1 week.	Replace the receiver batteries before you insert a new sensor (see Section 2). Replacing the batteries before a sensor has expired will require you to insert a new sensor.
⚠ 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 Section 5).
⚠ Replace TX Batt With Next Sensor.	L	The transmitter battery monitor indicates there are only 4 days of battery left.	Replace the transmitter battery prior to inserting the next sensor. Be sure to reconnect the transmitter and receiver. Replacing the batteries before a sensor has expired will require you to insert a new sensor.
⚠ Sensor Error Alarms Inactive.	I	Unstable sensor signal. Unable to calculate glucose. Alarms are not working.	Wait for 50 minutes for the problem to go away. Ensure that the sensor is firmly attached and that the transmitter and the sensor support mount are not loose. If the problem persists, remove sensor and insert new one.
⚠ Sensor Error Replace Sensor.	I	Sensor failure. No more BG alarms will occur.	Remove and insert a new sensor (see Section 5) if this message appears within the first 10 hours after sensor insertion. Otherwise, please call Customer Care before removing the sensor.
⚠ Skin Temp Range Alarms Inactive.	I	Skin temp out of range (too warm or too cold). Condition has been persistent for 10 minutes. Alarms are not working.	Bring skin temperature within range. Ensure that the sensor support mount is firmly attached to the skin. If the problem persists after 50 minutes, remove the sensor and insert a new one (see Section 5). If the problem still persists, replace transmitter.

High – **H**, Medium – **M**, Intermediate – **I**, Low – **L**

Respond to alarm message: *(con't)*

Alarm Message	Urgency	What It Means	What to Do
⚠ Transmitter Error Alarms Inactive.	I	Transmitter problem. Alarms are not working.	Wait for the problem to go away. If the problem persists after 50 minutes, you will get the alarm. "Alarms Inactive. Replace Transmitter".
⚠ 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.
⚠ Warm Up Skin.	L	Unable to calibrate the System because the skin temperature is too cold.	Warm the skin at the insertion site and wait for the "Do BG Test" prompt and perform another Blood Glucose mode test for calibration. You can warm up the skin temperature by moving to a warmer environment or by putting on some warm clothing.
⚠ Warm Up Skin Redo BG Later.	I	Calibration failed because your skin temperature is too cold.	Warm the skin at the insertion site. Wait for the blood drop icon to appear in about half an hour and perform another Blood Glucose mode test for calibration. You can warm up the skin temperature by moving to a warmer environment or by putting on some warm clothing.

High – **H**, Medium – **M**, Intermediate – **I**, Low – **L**

Respond to Blood Glucose Mode error codes. *(Note: There is no Error 5)*

If error code is	And you have any of these symptoms	Then
Er1	• Weakness • Sweating • Nervousness • Headache • 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 the test strip vial, retest your blood using a new test strip. • If the test does not work or if the error persists, call Customer Care.
Er2	• Thirst • Fatigue • Excess urination • 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 the test strip vial, retest your blood using a new test strip. • If the test does not work or if the error persists, call Customer Care
Er3	→	Be sure you see Apply Sample 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 the test strip vial, retest your blood using a new test strip. • If the test does not work or if the error persists, call Customer Care.
Er4	→	Perform a control solution test using a new test strip: • If results are within the range printed on the test strip vial, retest your blood using a new test strip. • If the test does not work or if the error persists, call Customer Care.
Er6	→	**Note:** Do **NOT** touch the RIGHT Option button while applying blood or control solution to the test strip. 1. Retest using a new test strip. 2. If error persists, call Customer Care.

OVER

Troubleshoot problems

The problems you can troubleshoot in this Section are listed below and are arranged in the order of appearance.

Receiver

- The receiver will not turn on.
- The blood glucose test won't start after you apply a sample.
- Unexpected characters on the receiver display screen, unusual or unexpected receiver screen appearance.
- There is no glucose value on the screen.

Sensor Insertion

- There is skin irritation at the sensor insertion site.
- The sensor support mount is not sticking to your skin.
- Discomfort when inserting the sensor.
- The system does not recognize a new sensor after attaching the transmitter to the sensor support mount.

  Note: Also see Appendix A on Site Maintenance.

Receiver and Transmitter

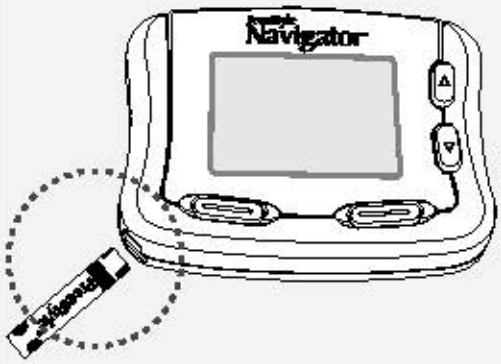
Connection

- You are not sure whether your receiver and transmitter are connected.

Calibration

- The receiver does not prompt you to do a BG test for calibration.

The receiver will not turn on.





a. Was the test strip inserted correctly (the "FreeStyle" side was up as you inserted the end with the dark rectangle)?

   If **YES**, go to Step c.

   If **NO**, repeat the test with a new strip taking care that the "FreeStyle" side is up as you insert the end with the dark rectangle until it stops.

b. Did this solve your problem?

   If **YES**, stop.

   If **NO**, continue with Step c.

c. Are the batteries installed correctly?

   If **YES**, go to Step d.

   If **NO**, Install the batteries correctly and reset time and date.

d. The batteries may be dead, replace existing batteries and reset time and date.

e. Repeat the test with a new test strip.

   If this did not resolve your problem call Customer Care.

   Note: Whenever batteries are removed and replaced or re-installed in the receiver, you will have to reconnect the transmitter and receiver and insert a new sensor.

The Blood Glucose test won't start after you apply a sample.

Note: Ensure that you apply your sample when the Apply Sample message appears on the display.

a. Repeat the test using a LARGER sample on a new test strip.

b. If this did not resolve your problem call Customer Care.

Unexpected characters on the receiver display screen, unusual or unexpected receiver screen appearance.

If	*Then*
The batteries are installed correctly.	If you are close to a source of electromagnetic interference (see Appendix C for further details), move away from the interfering source and see if the problem goes away. If there is consistent interference from a source, contact the manufacturer of the source or a certified electrician for help. The batteries may have to be replaced. Replace batteries with fresh ones and reset date and time.
The batteries are installed incorrectly.	Install batteries correctly and reset date and time.

a. Reconnect the transmitter and receiver.

b. Insert a new sensor.

c. If this did not solve the problem, call Customer Care.

OVER

There is no glucose value on the screen.

If	*And*	*Then*
You are waiting for the first calibration.	It has been less than 10 hours after the insertion of the sensor.	You will see an icon on the screen. Wait for the system to prompt you to do a BG test for calibration.
It has been more than 10 hours after insertion of the sensor.	You see an icon on the screen.	Allow the system up to 2 hours to prompt you to do a BG Test for calibration.
It has been more than 10 hours after insertion of the sensor.	You receive alarms (for example, skin temperature related alarms or connection alarms).	Acknowledge the alarm, take appropriate action (for example, bring the skin temperature within range or establish connection between the transmitter and receiver) and allow the system up to 2 hours to prompt you to do a BG test for calibration.
The time window for calibration (for example, you have 2 hours to perform the second calibration, see Section 7) has expired.	You have not performed a BG Test for calibration.	Perform a BG test for calibration. (see Section 7).
You have performed all the appropriate calibrations successfully.	You see an icon on the screen.	Follow the guidelines for trouble-shooting connection between the transmitter and receiver.
You have performed all the appropriate calibrations successfully.	→	Allow the system up to 1 hour to start displaying the glucose values on the screen.

If none of the above helps solve the problem, replace the sensor (Section 5) or call Customer Care.

Skin irritation at sensor insertion site.

a. Ensure that seams, waistbands, or other constrictive clothing or accessories do not cover the site causing friction.

b. Inspect the site.

If the irritation is	*Then*
Around the edges of the adhesive or tape.	Lift the edges slightly all around the dressing.
Wherever the adhesive touches skin.	You may be sensitive to the adhesive or material, consult your healthcare team to identify the best solution.

c. If none of the above works, consult your healthcare team for other suggestions.

The sensor support mount is not sticking to your skin.

Note: Do Step a through Step c **BEFORE** placing the sensor support mount on your skin.

a. Clean the insertion site by washing with soap and water.

b. Dry the site thoroughly with a clean towel.

c. Wipe the area with an alcohol prep pad.

d. If your skin-type requires more adhesive than provided on the sensor support mount, or if you anticipate an activity level that may require more adhesive, place an over-bandage over the transmitter **AFTER** connecting the transmitter to the sensor support mount.

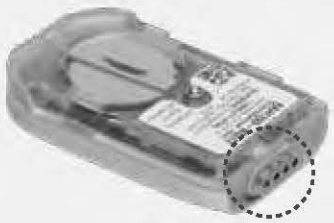
OVER

Discomfort when inserting the sensor.

a. Rub the insertion site with ice before inserting the sensor.

b. If that doesn't work, call Customer Care.

The system does not recognize a new sensor after attaching the transmitter to the sensor support mount.

If	*Then*
Your transmitter and receiver are not connected.	You will see the icon on the screen. Try establishing connection between the receiver and transmitter. If the system still does not recognize a new sensor in about 3 minutes, remove the sensor and insert a new sensor (Section 5).
Your receiver and transmitter are connected.  Contact Points	**a.** Make sure that the transmitter is firmly attached to the sensor support mount and wait for 3 minutes to allow the system to recognize the sensor. **b.** If the system still does not recognize the sensor, remove the sensor (Section 5), establish connection between the transmitter and receiver (Section 9), insert a new sensor, and attach the transmitter to the sensor support mount (Section 6). Make sure that the contact points on the transmitter are dry, clean, and not excessively worn.
Your system is not linked and you see the "Link" message on your screen.	Your system may not be linked. Perform the steps to link the system (Section 14). Make sure you reconnect the system after linking (Section 9). Remove and insert a new sensor.

If none of the above solves the problem, there may be something wrong with your transmitter. Call Customer Care.

You are not sure whether your receiver and transmitter are connected.

If	*Then*
You do not see the icon on the screen.	Your system is connected.
You see the icon.	There is no connection between the receiver and transmitter. Reconnect the transmitter and receiver, see Section 9.
You see the icon and the reconnect procedure was unsuccessful.	Check and make sure that the transmitter battery is not old or exhausted. If the battery is old or exhausted, then **a.** Remove the sensor. **b.** Change the battery. **c.** Establish connection between transmitter and receiver. **d.** Insert a new sensor.
You continue to see the icon even after replacing the battery in the transmitter.	Wait for a couple of minutes after inserting the new battery to allow the system to recognize the new battery. If after two minutes, the system still does not recognize the new battery, there is probably something wrong with your transmitter. Call Customer Care.
You see the "Link" message on the screen.	Your system is not linked. Perform the steps to link the system (Section 14). Make sure you reconnect the system after linking (Section 9).

OVER

The system does not prompt you with a message to do BG test for calibration.

If	*And*	*Then*
The system did not prompt you with a message recognizing a new sensor after you attached the transmitter to the sensor support mount.	→	Follow the troubleshooting guidelines on sensor recognition.
It has been less than 10 hours after insertion of the sensor.	→	Wait for the 10 hour time period to end and allow the system to prompt you to do a BG Test for calibration.
It has been more than 10 hours after the insertion of the sensor.	There is a icon on the screen.	Reconnect the transmitter and receiver (Section 9) and allow the system up to 2 hours to prompt you to do a BG Test for calibration.
It has been more than 10 hours after the insertion of the sensor.	You have received alarm messages on the receiver.	Acknowledge the alarm message, take appropriate action and allow the system up to 2 hours to prompt you to do a BG Test for calibration.

If none of the above helps solve the problem, replace the sensor (Section 5) or call Customer Care.

Check your work.

Result: *Information on what to do in the event of alarm messages, error codes, or other common problems.*

You will have done this task correctly when you have resolved the problem or contacted either your healthcare team or Customer Care for additional suggestions or help.

END OF Section 10

11 Add Events

Section 11

Section 11 – Key Terms

- Events
- Exercise Event
- Generic Event
- Insulin Event
- LEFT/RIGHT Option Buttons
- Meal Event
- State Of Health Event
- UP/DOWN Arrow Buttons

11 Add Events

Purpose To create a record of events that may affect your glucose levels.

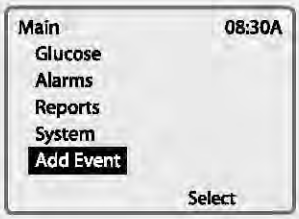
Start Do this procedure any time you observe anything that may affect your glucose levels, including your state of health and daily activities such as meals, exercise, and insulin dosages.

Materials
- Your FreeStyle Navigator Receiver.
- Data and details about the event that you want to record.

Helpful Information

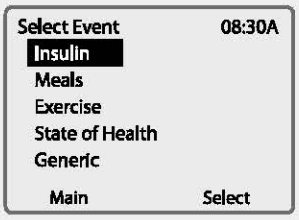
Important: *To edit an event, go to Section 12, Review Your Reports and Edit Events.*

- Pressing the RIGHT Option button (Set) completes the entry of your event regardless of how much or how little detail you have provided.
- The current date and time are automatically recorded when you enter an event. If you enter the event at a later time, you must change the date and time of the event to when it actually occurred before you press the RIGHT Option button (Set) to save the event.
- If you change your mind about saving the event, use the UP/DOWN Arrow button to change **SAVE** to **CANCEL** before you press the RIGHT Option button (Set).

Steps	Do This
1. Access the Add Event screen from the Main menu. 	**Note:** If you don't press any buttons for 12 seconds, the receiver screen will go blank and the last change will be lost if you haven't pressed the Select button. **a.** Press the UP Arrow button or the DOWN Arrow button to highlight Add Event. **b.** Press the RIGHT Option button (Select) to go to the Select Event screen.

Steps	Do This

2. Select the type of event you want to record.

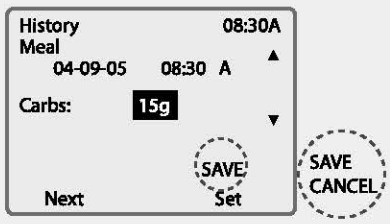


Use the UP Arrow button or the DOWN Arrow button to highlight the type of event:

If the event deals with	*Then*
• Meals or snacks.	1. Highlight Meals. 2. Press the RIGHT Option button (Select). 3. Go to Step 3.
• Details of an insulin dose. (injection or pump)	1. Highlight Insulin. 2. Press the RIGHT Option button (Select). 3. Go to Step 4.
• Exercise.	1. Highlight Exercise. 2. Press the RIGHT Option button (Select). 3. Go to Step 5.
• Your state of health. • Symptoms. • Other health related observations.	1. Highlight State of Health. 2. Press the RIGHT Option button (Select). 3. Go to Step 6.
• Other events.	1. Highlight Generic. 2. Press the RIGHT Option button (Select). 3. Go to Step 7.

Note: For all the steps below, make sure that you have entered the correct date and time.

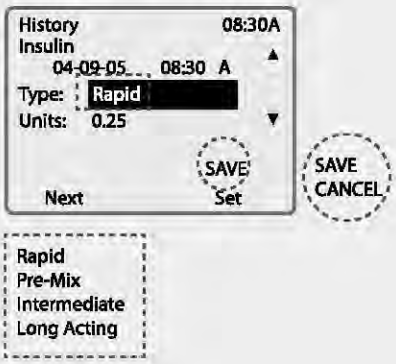
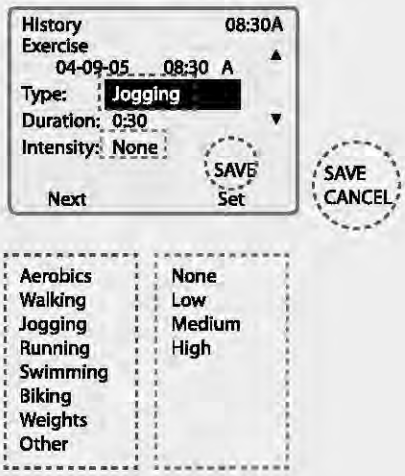
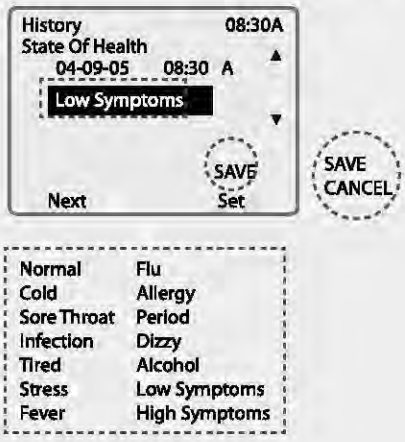
3. Record meal events.



a. Use the LEFT Option button (Next) to select which item to enter or change (Carbohydrate grams, SAVE/CANCEL, Date, Time).

b. Use the UP Arrow button or the DOWN Arrow button to change the selected item.
Note: You can change the carbohydrate grams from 0 to 350 grams in 1 gram increments.

c. When you are done, press the RIGHT Option button (Set) to save (or cancel) the event.

Steps	Do This
4. Record insulin events.	
	**a.** Use the LEFT Option button (Next) to select which item to enter or change (Type, Units, SAVE/CANCEL, Date, Time). **b.** Use the UP Arrow button or the DOWN Arrow button to change the selected item. **Note:** Your insulin choices are Rapid, Intermediate, Long Acting, or Pre-mix. **c.** When you are done, press the RIGHT Option button (Set) to save (or cancel) the event.
5. Record exercise events.	
	**a.** Use the LEFT Option button (Next) to select which item to enter or change (Type, Duration, Intensity, SAVE/CANCEL, Date, Time). **b.** Use the UP Arrow button or the DOWN Arrow button to change the selected item. **Note:** Your exercise choices are: • **Type:** Aerobics, Walking, Jogging, Running, Swimming, Biking, Weights, or Other. • **Duration:** 0:00 to 2:30 (hrs:minutes) in 15 minute increments. • **Intensity:** None, Low, Medium, or High. **c.** When you are done, press the RIGHT Option button (Set) to save (or cancel) the event.
6. Record state of health events.	
	**a.** Use the LEFT Option button (Next) to select which item to enter or change (State of health, SAVE/CANCEL, Date, Time). **b.** Use the UP Arrow button or the DOWN Arrow button to change the selected item. **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. **c.** When you are done, press the RIGHT Option button (Set) to save (or cancel) the event.

Steps	Do This
7. Record generic events. 	**a.** Use the LEFT Option button (Next) to select which item to enter or change (Event, SAVE/CANCEL, Date, Time). **b.** Use the UP Arrow button or the DOWN Arrow button to change the selected item. **Note 1:** There are eight generic event numbers that you 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.) **Note 2:** Write down the meanings for each number as you assign them so you don't forget what they represent (you don't have to assign meanings to all the numbers). **c.** When you are done, press the RIGHT Option button (Set) to save (or cancel) the event.
8. Check your work.	***Result:*** *An electronic record of all events that may affect your glucose levels.* You have done this procedure correctly when the event records are complete and accurate.

12 Review Reports and Edit Events

Section 12

Section 12 – Key Terms

- Event History Reports
- Events
- Exercise Event
- Generic Event
- Glucose Targets
- Insulin Event
- LEFT/RIGHT Option Buttons
- Line Graph
- Main Menu
- Meal Event
- Multi-Day Statistics
- Reports
- Single-Day Statistics
- State Of Health Event
- Statistical Reports
- UP/DOWN Arrow Buttons

12 Review Reports and Edit Events

Purpose

- To review your glucose levels.
- To help you and your healthcare team detect patterns in your glucose levels relative to your targets.
- To review a history of events that are important to your treatment plan.
- To edit event history.

Start

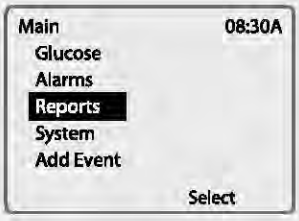
- When you or your healthcare team want to know about your glucose levels or about events that may either explain your glucose levels or influence your treatment plan.
- When you need to make changes to your event history.

Materials Gather these materials before you begin:

- Your glucose targets (your healthcare team can help determine these).
- Your receiver.

Helpful Information

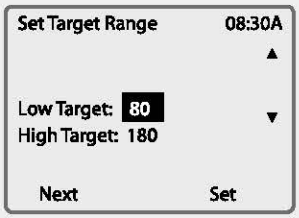
- Your healthcare team will usually give you glucose targets. Compare your actual glucose levels with these targets to see how you are doing. Ask your healthcare team to tell you how your levels should compare to each target.
- Glucose targets are **DIFFERENT** from the thresholds for low and high glucose alarms. Low and high glucose alarms alert you when you've reached the low or high threshold value. Glucose targets allow the reports and line graphs to show how your glucose levels have been performing compared to your set targets.

Steps	Do This
1. Access the Reports menu from the Main menu. 	**a.** Press the UP Arrow button or the DOWN Arrow button to highlight Reports. **b.** Press the RIGHT Option button (Select) to go to the Select Reports screen.

Steps	Do This
2. Decide what you want to do.	**Note:** Your reports will be more meaningful if you set glucose targets. Glucose targets give you something to compare your actual glucose levels with. Decide what to do:

If you want to	*Then*
• Set glucose targets.	Go to Step 3.
• See a line graph showing a history of your glucose levels.	Go to Step 4.
• See a statistical summary of your glucose levels over time.	Go to Step 5.
• Review or edit the events you have recorded in your receiver.	Go to Step 7.
• Quit and return to the Main menu.	Press the LEFT Option button (Main) on the Reports menu.

3. Set your glucose targets.



a. Select Glucose Targets from the Select Report menu.

i) Press the UP Arrow button or DOWN Arrow button to highlight Glucose Targets.

ii) Press the RIGHT Option button (Select) to go to the Glucose Targets screen.

b. Enter your low glucose target using the UP or DOWN arrows.

c. Press the LEFT Option button (Next) to move to the High Glucose target setting.

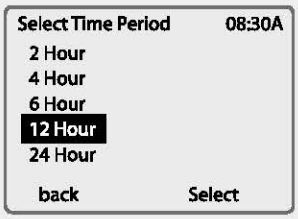
d. Enter your high glucose target using the UP or DOWN arrows.

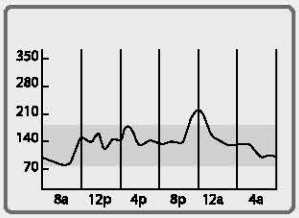
e. Press the RIGHT Option button (Set) to save the settings.

Result: *The settings are saved and the Select Report screen appears.*

f. Return to Step 2 to decide what to do next.

Steps	Do This
4. View a line graph of your glucose level history.	





Note: The line graph display range is between 20 mg/dL (1.1 mmol/L) and 350 mg/dL (19.4 mmol/L).

Glucose values exceeding 350 mg/dL (19.4 mmol/L) will be plotted as 350 mg/dL (19.4 mmol/L).

Glucose values ***falling below*** 20 mg/dL (1.1 mmol/L) will be plotted as 20 mg/dL (1.1 mmol/L).

a. Select Line Graphs from the Select Report menu.
  i) Use the UP Arrow button or DOWN Arrow button to highlight Line Graph.
  ii) Press the RIGHT Option button (Select) to go to the Select Time Period screen.

b. Select the time period (2, 4, 6, 12, or 24 hours) using the UP Arrow button or the DOWN Arrow button.

c. Interpret the graph:
- Notice your glucose target range (the shaded horizontal band).
- Notice your glucose level (in mg/dL along the left hand side) at different times (bottom line).
- Notice the trends and the times that your glucose level is outside of your target range.
- Notice how different events that you entered are located in relation to your glucose profile. Events entered will be shown on the line graph with letters indicating the event - "I" for Insulin, "M" for meals, "E" for exercise, "H" for state of health and the number (1 thru 8) for a generic event.

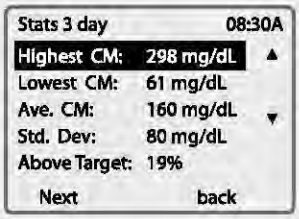
Note: The line shows both your continuous readings (plotted every 10 minutes) and your blood glucose readings (the "+" symbols on the line graph).

When viewing the line graph, you can scroll forward on the time axis by pressing the UP Arrow button and you can scroll backward on the time axis by pressing the DOWN Arrow button. You will not be able to see the date on the time axis.

d. Decide what to do next.

If you want to	*Then*
• View a line graph for another time period.	**1.** Press the RIGHT Option button to return to the Select Time Period screen. **2.** Go to Step 4b.
• End viewing line graphs.	**1.** Press the RIGHT Option button to return to the Select Time Period screen. **2.** Press the LEFT Option button (Back) to return to the Select Reports screen. **3.** Go to Step 2 to decide what to do next.

OVER

Steps	Do This
5. View a statistical summary of your glucose levels. 	**a.** Select Statistics from the Select Reports menu. i) Use the UP Arrow button or DOWN Arrow button to highlight Statistics. ii) Press the RIGHT Option button (Select) to go to the Statistics screen. **Note:** The Stats screen shows you a summary of glucose results relative to your glucose targets. **b.** Press the LEFT Option button (Next) to advance to the desired period. **Note:** You can view statistical reports for 1, 3, 7, 14, 21, or 28 day periods, in that order. (Continue to Step 6)

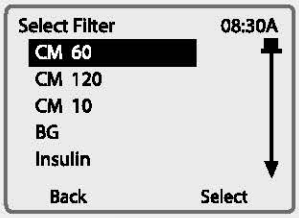
Steps	Do This
6. Select the desired statistical reading.	**Note:** Statistics include **ONLY** continuous glucose results. Glucose readings that were taken in the Blood Glucose mode are **NOT** included in the statistics. **a.** Use the UP Arrow button or DOWN Arrow button to highlight the statistic you want to review ***for the selected period.***

If you want to know	*Then highlight*
• Your highest glucose reading.	Highest CM.
• Your lowest glucose reading.	Lowest CM.
• Your average glucose reading.	Ave. CM.
• How well you are maintaining your levels near the average value.	Std. Dev. **Note:** A **small** number indicates that most of your glucose readings are close to your average value. A **large** number indicates that many of your glucose levels vary considerably from your average value.
• The percentage of readings that are above your high glucose target.	Above Target.
• The percentage of readings that are within your glucose targets (between the high and low targets).	Within Target.
• The percentage of readings that are below your low glucose target.	Below Target.
• The average number of low glucose alarm events per day.	Low/Day.
• The average number of high glucose alarm events per day.	High/Day.
• The average number of projected low alarm events per day (early warnings).	Proj Low/Day.
• The average number of projected high alarm events per day (early warnings).	Proj High/Day.

b. Press the LEFT Option button (Next) to view other periods.
Note: You can view reports for 1, 3, 7, 14, 21, or 28 day periods, in that order.
c. Press the RIGHT Option button (Back) to return to the Select Reports screen.
d. Go to Step 2 to determine what to do next.

OVER

Steps	Do This
7. Review or change your event history.	



a. Select Event History from the Select Reports menu.

b. Use the UP or DOWN Arrow button to highlight the event you want to review or edit.

If you want to review/edit your	*At*	*Then highlight*
• Continuous glucose measurements.*	10 minute intervals	CM 10
	60 minute intervals	CM 60
	120 minute intervals	CM 120
• Blood glucose readings.*	→	BG
• Insulin events.	→	Insulin
• Meal events.	→	Meals
• Exercise events.	→	Exercise
• State of health.	→	State of Health
• Miscellaneous events.	→	Generic
• Alarms history.*	→	Alarm history
• All events.	→	User Events

(* = Cannot be edited)

c. Use the RIGHT Option button (Select) to go to the highlighted report.

d. Decide what to do next.

If you want to	*Then*
• Edit the event.	Go to Step 9.
• Interpret the event.	Go to Step 8.
• Review other events.	1. Select the LEFT Option button (Back) to go to the Select Filter screen. 2. Go to Step 7b.
• Stop reviewing events.	1. Select the LEFT Option button (Back) to go to the Select Filter screen. 2. Select the LEFT Option button to go to the Select Report screen. 3. Go to Step 2 to decide what to do.

Steps	Do This
8. Interpret your events.	**a.** Interpret the events using the notes about each type of event in the table below:

Event	*Notes*
CM (CM 60, CM 120, and CM 10)	• Each recorded measure is displayed on one screen with its date and time. • Displays actual measures at the indicated intervals. • Does **NOT** display averaged measures. • Use the RIGHT Option button (Next) to move to the next recorded CM reading.
BG	• Each BG measure is displayed on one screen with its date and time. • All BG measures are displayed. • A check mark ✓ indicates that the measure was marked as a control. • Use the RIGHT Option button (Next) to move to the next recorded BG screen.
Insulin	Each recorded insulin event is displayed with type, dosage in units, date, and time.
Meals	Each recorded meal event is displayed with its carbohydrate value in grams, date, and time.
Exercise	Each recorded exercise event is displayed with its description, duration in hours and minutes, intensity, date, and time.
State of Health Generic Alarm History User Events	• Each recorded event is displayed with its description, date, and time. **Note:** Generic events do **NOT** include a description, just a number that represents the event.

b. Go to Step 7d.

OVER

Steps	Do This
9. Edit the event.	**Note:** You **CANNOT** edit your glucose measurements. **a.** Press the RIGHT Option button (Edit). **b.** Use the LEFT Option button (Next) to select the item you want to change. **c.** Use the UP or DOWN Arrow button to change the selected item. **d.** Repeat this process from Step 9b until you've changed every item that you wanted to change. **Note:** If you change your mind about saving your edits, change SAVE to CANCEL. **e.** Press the RIGHT Option button to save or cancel your edits.
10. Check your work.	***Result:*** *The result will be an increased awareness of your glucose level history, glucose level patterns, and events that could affect your treatment plan.* You will have done this procedure correctly when: ❑ Your glucose targets are set correctly. ❑ You view and correctly interpret line graphs for any available period. ❑ You correctly select and view any desired statistical summary for any of the available time periods. ❑ You can review any of the available event history reports. ❑ Your events have been edited to your satisfaction.

END OF Section 11

13 Clean Your System

Section 13

Section 13 – Key Terms

- **Receiver**
- **Transmitter**
- **Contact Points**

13 Clean Your System

Purpose To maintain the appearance of your system.

Start Do this procedure:

- Every time you change your sensor (transmitter).
- Any time the system needs cleaning.

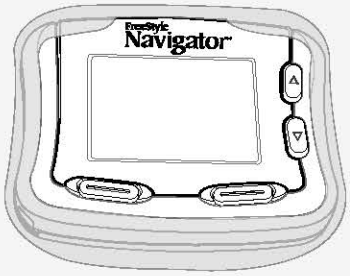
Materials Make sure you have access to these materials before you begin:

- Mild soap.
- Running water.
- A clean, soft, lint-free towel for cleaning and drying. For example, a dish towel.
- 70% isopropyl alcohol.

Helpful Information

- Your FreeStyle Navigator system needs minimal maintenance aside from cleaning and battery replacement.
- Avoid getting dust, dirt, blood, control solution, water, or any other substance in the receiver's test strip port.
- Keep your receiver in its protective carrying case when you are not using it.

  Note: Your transmitter and receiver cannot be repaired when broken.
- The transmitter should be removed from the sensor support mount and cleaned each time you remove a used sensor (every 5 days).
- Contact your healthcare team or Customer Care when you need to replace your transmitter or receiver. They will suggest a proper way to dispose of the old parts.
- Your transmitter has a life of 2 years from the date of first use. Replace the transmitter after that time period.
- Do **NOT** use adhesive remover wipes or solutions containing ether or ether-containing components for cleaning or removing residual adhesive from the transmitter or receiver. These solutions can damage the casing of the receiver and transmitter.

Steps	Do This
1. Clean your transmitter.  Contact Points	**a.** Wash the transmitter with mild soap and water. **b.** Rinse the transmitter thoroughly under running water. **c.** Dry the transmitter thoroughly with a clean, soft, lint-free towel. **d.** Shake any water out of the transmitter's contact points and blot on a clean, dry, lint-free towel. **e.** Make sure that the contact points are clean, dry, and not excessively worn.
2. Clean your receiver skin. 	Before cleaning the receiver skin, remove it from the receiver. Wash the receiver skin in mild soap and water.
3. Clean your receiver. 	***Caution:*** *Do **NOT** immerse the receiver in water or in any other liquid. Avoid getting water or any other liquid in the test strip port.* Wipe the outside of your receiver with a clean, soft, lint-free towel dampened with either a mild soapy solution or 70% isopropyl alcohol.
4. Check your work.	***Result:*** *A clean transmitter, receiver and receiver skin.* You have done this procedure correctly when: ❑ All visible dust, dirt, grime, and other foreign substances have been removed. ❑ The transmitter is thoroughly dry, including the contact points.

END OF Section 13

14 Link and Unlink Your Transmitter and Receiver

Section 14

Section 14 – Key Terms

- **BG Mode**
- **CM Mode**
- **Link/Unlink**
- **Receiver**
- **Transmitter**

14 Link and Unlink Your Transmitter and Receiver

Purpose To enable secure communication between your transmitter and your receiver.

Start Do this procedure:

- When you replace either your transmitter or your receiver.

Materials Gather these materials before you begin:

- Your receiver.
- Your transmitter.

Note: Your system may need fresh batteries if it cannot establish communication.

Helpful Information

Important: *You will **NOT** receive continuous glucose data while the transmitter and receiver are unlinked and all alarms associated with the Continuous Monitoring mode will be turned off.*

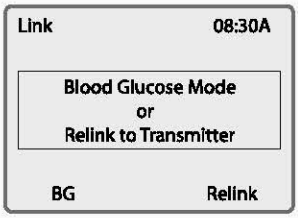
- You **MUST** unlink your receiver from your old transmitter and link your receiver to your new transmitter whenever you replace your transmitter.
- Once the transmitter and receiver are linked, they don't have to be re-linked or unlinked unless you want to link the receiver to a new transmitter. If you attempt to link your receiver to a new transmitter, you must replace the current sensor with a new sensor.
- You can still perform blood glucose measurements in the blood glucose mode while the transmitter and receiver are unlinked.
- Link is **NOT** the same as Reconnect. Typically, when you receive the system kit, your receiver and transmitter are already linked – your receiver knows which transmitter it is paired with. The receiver will then accept data only from that transmitter. Once your receiver and transmitter are linked, you do not need to link them again unless you have had to unlink them (if changing transmitter). "Reconnect" (see Section 9 Step 2) establishes connection if your receiver and transmitter have been temporarily moved beyond the normal range of communication (10 feet).

Steps	Do This

1. Decide what you want to do.

If you want to	*Then go to Step*
• Unlink your receiver from your transmitter.	2
• Link your receiver to your transmitter.	3
• Check your work.	4

2. Unlink your receiver from your transmitter.



a. Press the RIGHT Option button twice to display the Main menu.

b. Use the UP or DOWN Arrow button to highlight System.

c. Press the RIGHT Option button (Select) to display the System menu.

d. Use the UP or DOWN Arrow button to highlight Link.

e. Press the RIGHT Option button (Select) to display the Link screen.

f. Press the LEFT Option button (Unlink) to unlink your transmitter from your receiver.

Note: Unlinking your receiver from your transmitter will terminate your sensor. If you proceed, you will need to insert a new sensor after linking to your new transmitter. A warning screen is displayed if you have a sensor in progress. Press the button labeled "Yes" to continue unlinking.

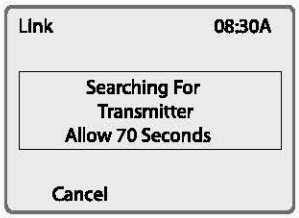
g. Press the LEFT Option key (BG) to operate your system in the Blood Glucose mode. By choosing this option, you have shut off the Continuous Monitoring mode.

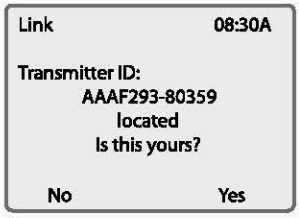
Note: You can now use your receiver to perform blood glucose measurements (See Section 7).

h. Go to Step 1 to decide what to do next.

Steps	Do This

3. Link your receiver to your transmitter.





a. Place the receiver within 10 feet of the transmitter.
b. Press the RIGHT Option button twice to display the Main menu.
c. Use the UP or DOWN Arrow button to highlight System.
d. Press the RIGHT Option button (Select) to display the System menu.
e. Use the UP or DOWN Arrow button to highlight Link.
f. Wait while the receiver searches for the transmitter.

Note: It may take the receiver up to 70 seconds to find the transmitter.

Result: *The receiver displays the transmitter's ID number.*



Verify that the ID number displayed on the screen is the same as the ID number on the bottom of your transmitter.

If the ID numbers	*And this is your*	*Then*
• Are the same.	→	1. Press the RIGHT Option button (Yes). ***Result:*** *The Main menu is displayed.* 2. Go to Step 4.
• Are **NOT** the same.	1st attempt	Press the Left Option button (No). The receiver will continue to search for another transmitter in the vicinity.
	2nd attempt	Call Customer Care.

Caution: *If you accept an incorrect transmitter ID when linking your Transmitter and Receiver, your glucose readings will be incorrect.*

4. Check your work.

Result: *A linked or unlinked transmitter and receiver. You have done this procedure correctly when:*

- ❑ Your system is linked when you wanted it linked.
- ❑ Your system is unlinked when you wanted it unlinked.
- ❑ You called Customer Care after your 2nd attempt to link failed.
- ❑ The ID number of the transmitter displayed by the receiver (under the Transmitter Status menu item) matches the ID on the transmitter label.

END OF Section 14

15 Reset User Settings

Section 15

15 Reset User Settings

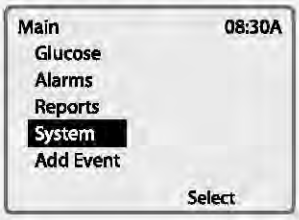
Purpose To reset the user settings to the default values.

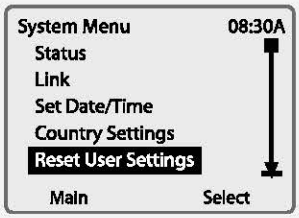
Start Do this procedure anytime you feel a need to return your settings to the factory defaults.

Materials Your FreeStyle Navigator Receiver.

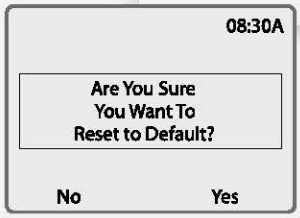
Helpful Information

- If you don't press any button within 12 seconds, the receiver screen will go blank and the last change will be lost if you haven't pressed the Select button.
- Be careful to avoid making unintentional changes to the system settings and configuration.
- Resetting user settings resets the following items to their default. **Note:** The units of glucose cannot be changed. [*The default values are shown in brackets*]:
  - High Glucose Target. *[180 mg/dL (10 mmol/L)]*
  - Low Glucose Target. *[80 mg/dL (4.4 mmol/L)]*
  - Alarm Settings: *[Med Beep]*
    - On/Off
    - Low beep
    - Medium beep
    - High beep
    - Short vibe
    - Medium vibe
    - Long vibe
    - Alarm Thresholds
  - Country Settings: *[Local settings]*
    - Date format
    - Time format
    - Language
    - Decimal format
  - Displays for the items in the Add Event menu:
    - Insulin type *[Rapid]*
    - Insulin dose *[1 unit]*
    - Exercise type *[Walking]*
    - Exercise duration *[30 min.]*
    - Exercise intensity *[Medium]*
    - State of Health *[Normal]*
    - Generic Event *[1]*
  - Strip Cal code. *[18]*
  - Sensor Code. *[109]*
  - Low Glucose Alarm. *[65 mg/dL (3.6 mmol/L)]*
  - High Glucose Alarm. *[300 mg/dL (16.7 mmol/L)]*

Steps	Do This
1. Access the System menu from the Main menu. 	**a.** Press the UP or DOWN Arrow button to highlight System. **b.** Press the RIGHT Option button (Select) to go to the System Menu screen.

Steps	Do This
2. Access the Reset User Settings screen. 	**a.** Press the UP or DOWN Arrow button to highlight Reset User Settings. **b.** Press the RIGHT Option button (Select) to go to the Reset User Settings Screen.
3. Reset your settings.	Confirm what you want to do:

If you want to	*Then*
• Return your system to its default settings.	Press the RIGHT Option button (Yes). **Note:** You will lose your personal settings.
• Change your mind.	Press the LEFT Option button (No). **Note:** Your personal settings will be retained.



Caution: *You should never reset your user settings when you are wearing a sensor. This will reset parameters that may affect your system performance.*

4. Check your work.	***Result:*** *Your receiver with the settings you want.* You have done this procedure correctly when the receiver's settings match your desired settings: ❑ Default settings OR, ❑ Your personal settings (if you changed your mind).

END OF Section 15

16 Change Country Settings

Section 16

Section 16 – Key Terms

- **LEFT/RIGHT Option Buttons**
- **Receiver**
- **System Menu**
- **UP/DOWN Arrow Buttons**

16 Change Country Settings

Purpose To set the date and time formats, the language, and the decimal format.

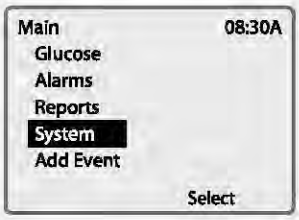
Start Do this procedure when your requirements differ from the country setting currently being used by the system.

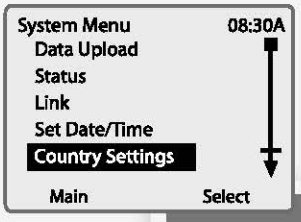
Materials Gather these materials before you begin:

- Your requirements for displaying date, time format and the other items mentioned in the purpose statement.
- Your FreeStyle Navigator Receiver.

Helpful Information

- Check with your healthcare team if you have any questions about your requirements.
- If you don't press any button within 12 seconds the receiver screen will go blank and the last change will be lost if you haven't pressed the RIGHT Option button (Select).

Steps	Do This
1. Access the System menu from the Main menu 	**a.** Press the UP or DOWN Arrow button to highlight System. **b.** Press the RIGHT Option button (Select) to go to the Select System screen.

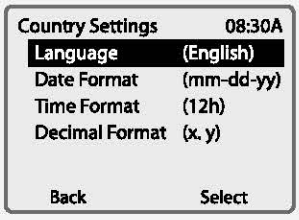
Steps	Do This
2. Access the Country Settings menu. 	**a.** Press the UP or DOWN Arrow button to highlight Country Settings. **b.** Press the RIGHT Option button (Select) to go to the Country Settings screen. **c.** Decide what you want to do:

If you want to change how this is displayed	*Then go to Step*
• Language.	**3**
• Date.	**4**
• Time.	**5**
• Decimals.	**6**
• None of the above. (you are done changing the country settings.)	**2d**

d. Press the LEFT Option button (Back) twice to return to the Main menu.

e. Go to Step 7 to check your work.

3. Change the Language.



a. Use the UP or DOWN Arrow button to highlight Language.

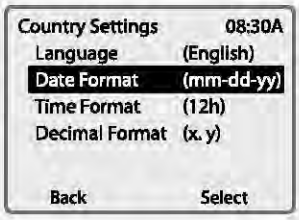
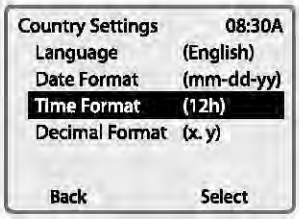
b. Press the RIGHT Option button (Select) to go to the Select Language screen.

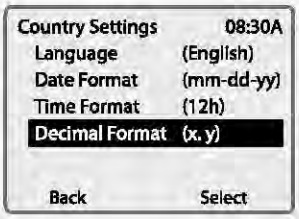
c. Use the UP or DOWN Arrow button to highlight the language that you want to use.

d. Press the RIGHT Option button (Set) to accept your selection.

Result: *The Country Settings screen is displayed.*

e. Go to Step 2c to decide what to do next.

Steps	Do This
4. Change the Date Format.  	a. Use the UP or DOWN Arrow button to highlight Date Format. b. Press the RIGHT Option button (Select) to go to the Select Date Format screen. c. Use the UP or DOWN Arrow button to select either the mm-dd-yy or the dd-mm-yy format. d. Press the RIGHT Option button (Set) to accept your choice. ***Result:*** *The Country Settings screen is displayed.* e. Go to Step 2c to decide what to do next.
5. Change the Time Format.  	a. Use the UP or DOWN Arrow button to highlight Time Format. b. Press the RIGHT Option button (Select) to go to the Select Time Format screen. c. Use the UP or DOWN Arrow button to select either the 12h or the 24h format. d. Press the RIGHT Option button (Set) to accept your choice. ***Result:*** *The Country Settings screen is displayed.* e. Go to Step 2c to decide what to do next.

Steps	Do This
6. Change the Decimal Format.  	**a.** Use the UP or DOWN Arrow button to highlight Decimal Format. **b.** Press the RIGHT Option button (Select) to go to the Select Decimal Format screen. **c.** Use the UP or DOWN Arrow button to select either the x.y or the x,y format. **d.** Press the RIGHT Option button (Set) to accept your choice. ***Result:*** *The Country Settings screen is displayed.* **e.** Go to Step 2c to decide what to do next.
7. Check your work.	***Result:*** *A display that presents information in the format that you prefer.* You have done this procedure correctly when you are satisfied with the format the system uses to display information.

17 Appendix A: Site Maintenance

Appendix A

Section 17 – Appendix A

- Adhesive Enhancers
- Antiseptics
- Dressings
- Site Rotation
- Skin Barriers

17 Appendix A: Site Maintenance

Introduction

Careful site selection, preparation, and maintenance can help to lower the risk of infection and improve sensor adhesion. In addition to site selection, a number of helpful products are available.

Site Selection

Site rotation helps prevent discomfort, irritation, bruising, skin rashes, and sensitivity to adhesives. It is important for you to rotate across several sites and to insert sensors only in the abdomen or in the 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, you may want to start on the right arm at a high position, move to a low position on the right arm, then repeat on the left arm.

Helpful products

Choose from the list of products below as needed.

- Antiseptics – If you tend to develop infections at the sensor insertion site, consider prepping the skin with an antiseptic. Ask your healthcare team to recommend which antiseptic is best for you.
- Dressings – 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 to recommend 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. Adhesive enhancers help the adhesive pad on the sensor support mount stick to your skin. 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 to recommend 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 to recommend which skin barrier product is best for you.

END OF Section 17

18 Appendix B: Specifications

Appendix B

Section 18 – Appendix B

- Calibration
- Hematocrit
- Interstitial Fluid
- Receiver
- Transmitter

18 Appendix B: Specifications

System Specifications

Your FreeStyle Navigator system specifications are listed in the following table:

Operating Temperature	40° F to 104° F (4° C to 40° C).
Storage Temperature	Store the transmitter and receiver between 14° F (-10° C) and 113° F (45° C). Store the test strips and sensor delivery units between 37° F (3° C) and 86° F (30° C). Control solution should be stored between 50° F (10° C) and 86° F (30° C).
Operating Humidity (Receiver)	5% to 90% (non-condensing).
Operating and Storage Altitude	Sea level to 10,000 feet (3,048 meters).
Operating Pressure	14.7 psia (sea level) to 10.1 psia (10,000 feet).
Sensor Life	Up to 5 days.
Sensor Operating Skin Surface Temperature	77° F (25° C) to 104° F (40° C).
Glucose Result Range	20 to 500 mg/dL (1.1 to 27.8 mmol/L).
Glucose Assay Method (for CM mode)	Amperometric electrochemical sensor using WIRED ENZYME™ technology. Continuous subcutaneous measurement of glucose in interstitial fluid by a sensor inserted approximately 5mm under the skin.
Power Source	Transmitter: One silver oxide 357 HC battery (small coin cell battery), replaceable (battery life is ~ 30 days). Receiver: Two AAA alkaline batteries, replaceable (battery life is ~ 60 days). We recommend Energizer® MAX®, Energizer® e2® Titanium®, and Energizer® Industrial batteries. Other batteries may not provide expected battery life.
Transmitter Size	Height: 2.05 in. (5.2 cm). Width: 1.23 in. (3.1 cm). Depth: 0.43 in. (1.1 cm).
Transmitter Weight	0.48 oz. (13.61 grams) – including battery.
Transmitter Battery Life	Up to 30 days.
Wearing Transmitter Under Water	Up to 1 meter under water for no more than 30 minutes.

18 Appendix B: Specifications *(con't)*

Receiver Size	Height: 2.5 in. (6.3 cm). Width: 3.24 in. (8.2 cm). Depth: 0.88 in. (2.2 cm).
Receiver Weight	3.5 oz. (99.2 grams) – including batteries.
Receiver Battery Life	Up to 60 days.
Automatic Shutoff	Built-in blood glucose meter: 2 minutes after last user action. Receiver: 12 seconds after last user action.
Receiver Memory	• 60 days of normal use including continuous glucose readings (stored every 10 minutes) and daily blood glucose readings. • Date/time will be remembered for 5 minutes after receiver battery removal.
Calibration	Plasma equivalent.
Calibration Time	• 1st calibration: Must be performed at approximately 10 hours after a new sensor has been inserted. The first calibration can be performed after the 10 hours. Continuous glucose readings will NOT be reported until the 1st calibration is performed successfully. • 2nd calibration: Must be performed between 2 and 4 hours after the 1st calibration or continuous glucose will not be reported. The 2nd calibration can be performed after 4 hours; continuous glucose reporting will resume after completing the 2nd calibration successfully. • 3rd calibration: Must be performed between 12 and 20 hours after the 2nd calibration or continuous glucose will not be reported. The 3rd calibration can be performed after 20 hours; continuous glucose reporting will resume after completing the 3rd calibration successfully. • 4th calibration: Must be performed between 48 and 56 hours after the third calibration or continuous glucose will not be reported. The fourth calibration can be performed after 56 hours; continuous glucose reporting will resume after completing the 4th calibration successfully.
Blood Glucose Test Time (for BG mode)	Average of 7 seconds.
Blood Glucose Assay Method (for BG mode)	Coulometric electrochemical sensor.
Blood Sample Type (for BG mode)	Whole blood, capillary.
Hematocrit (for BG mode)	15% to 65%.

18 Appendix B: Specifications *(con't)*

Performance Characteristics

Note: Please consult your healthcare team on how to use the information in this section.

Performance of the FreeStyle Navigator® Continuous Glucose Monitoring System was evaluated in a controlled clinical study. The study was conducted in 3 centers and included a total of 58 subjects with diabetes. Each subject wore two FreeStyle Navigator Sensors over a 5-day period. The subjects wore one sensor on the back of the upper arm and one on their abdomen. The FreeStyle Navigator system was calibrated with capillary fingerstick measurements using the built-in FreeStyle Blood Glucose Meter at approximately 10, 12, 24 and 72 hours after insertion of the sensor.All measurements were performed by a trained clinic study staff or the subject.

During the study, subjects came to the clinical center for frequent glucose samples measured once every 15 minutes on the YSI (Yellow Springs Instrument) STAT Plus™ Glucose Analyzer. YSI measurements were performed in duplicate on venous whole blood and the FreeStyle measurements were performed in duplicate on capillary blood from the finger. All YSI whole blood measurements were adjusted by applying a +12% correction factor (based on a normal hematocrit value of 45%).

Users and healthcare providers should consider that performance in this study might be idealized. Participants enrolled in the clinical study and certain conditions of the study tend to result in above average glucose control. This, in turn, may result in the appearance that the FreeStyle Navigator Continuous Glucose Monitoring System agrees with blood glucose levels better than it does under typical conditions. Monitors that measure glucose in interstitial fluid often show better agreement to blood glucose levels when glucose levels are not changing rapidly or when glucose levels are not extremely low or high. The following are some examples of why performance of the FreeStyle Navigator Continuous Glucose Monitoring System may be idealized.

- Subjects saw, on average, 15 fingerstick results per day in the clinic and 8 fingerstick results per day at home. This enables subjects to control their glucose levels better.
- While subjects participated in the clinic portion of the study, they were more limited in their activities than someone at home. They were also provided with all their meals. Subjects who are more active, or with poor eating habits, may create more challenging conditions for the FreeStyle Navigator Continuous Glucose Monitoring System.
- The built-in FreeStyle glucose meters used in the study were well maintained. Because the built-in FreeStyle meter is used to calibrate the FreeStyle Navigator Continuous Glucose Monitoring System, performance may be poorer if the system is not well maintained. It is important to carry out quality-control checks on the system and code the system according to the manufacturer's instructions to optimize performance of the FreeStyle Navigator Continuous Glucose Monitoring System.

18 Appendix B: Specifications *(con't)*

Accuracy

Table 1 below shows the distribution of all the data from the In-Clinic study on the Clarke Error Grid. Accuracy was assessed by comparing the differences between the FreeStyle Navigator system and the YSI laboratory reference. The Clarke Error Grid Analysis evaluates the clinical relevance of the differences by dividing a correlation plot (Figure 1) into five zones as described in Table 1. The YSI results and the corresponding glucose results from the FreeStyle Navigator system together (called a 'data pair' or 'matched data points') determine what zone of the error grid the results fall into. Table 1 also shows that glucose data measured by FreeStyle Navigator system on the arm and on the abdomen have similar distribution on the error grid. This demonstrates that there is no difference in the performance of the system when worn on the abdomen or on the back of the upper arm.

Table 1. Clarke Error Grid Analysis. Continuous glucose results from FreeStyle Navigator System (mg/dL) vs. the YSI (mg/dL)

Zone in the Clarke Error Grid	N (pairs of data)	Percentage in the different zones (%)	Sensor Insertion Site	
			Abdomen %	Arm %
A	16627	81.7	81.5	81.8
B	3398	16.7	16.8	16.6
C	19	0.1	0.1	0.1
D	316	1.6	1.6	1.5
E	2	0.0	0.0	0.0
Total	20362	There is no difference between the performance of the system on the arm and the performance of the system on the abdomen.		

Error Grid Explanation

A – Clinically accurate; would lead to correct and safe treatment

B – Benign; would lead to benign decisions or no treatment decisions

C – Overcorrection; would lead to over-correction of normal glucose levels

D – Failure to detect; would lead to failure to detect and treat high or low glucose levels

E – Erroneous readings; would lead to erroneous treatment decisions

18 Appendix B: Specifications *(con't)*

Table 2 is a summary of the statistics that describe how well data from the FreeStyle Navigator system correlates to the results from the reference method. Glucose results from the FreeStyle Navigator system and the corresponding results from the YSI (a total 20362 pairs of data points) in the In-Clinic study were used to determine the correlation.

Figure 1.

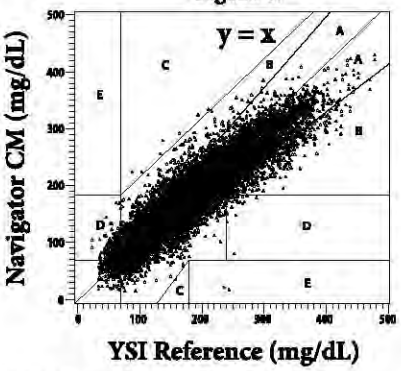


Table 2. Regression Analysis. FreeStyle Navigator System (mg/dL) vs the YSI (mg/dL)

Slope	0.92
Intercept	14.3 mg/dL
Correlation Coefficient (r)	0.93
N	20362
Range	25 – 533 mg/dL
Overall mean bias	+0.8 mg/dL

Table 3a displays the distribution of all the data from the In-Clinic study on the Clarke Error Grid. It breaks the data set into smaller groups based on the glucose value reported by the YSI. For each of these smaller groups, the table shows what percentage of data fall into different zones of the grid.

Table 3a. Accuracy performance at different glucose levels using the Clarke Error Grid Analysis

Reference Glucose Level (mg/dL)	Number of Paired Readings	A and B (%)	A (%)	B (%)	C (%)	D (%)	E (%)
20-40	22	54.5	54.5	N/A*	N/A*	45.5	0.0
41-80	1295	77.7	55.2	22.5	0.0	22.3	0.0
81-120	3820	99.9	69.5	30.4	0.1	N/A*	N/A*
121-240	11430	99.9	85.4	14.4	0.1	N/A*	0.0
241+	3795	99.5	91.7	7.8	0.0	0.4	0.1
Overall	**20362**	98.3	**81.7**	**16.7**	**0.1**	**1.6**	**0.0**

*N/A means that the Clarke Error Grid does not consider the possibility of these zones in that concentration range.

Table 3b displays the same data as in table 3a on the Continuous Glucose-Error Grid. This is a modified error grid that is designed to evaluate the clinical accuracy of continuous glucose monitoring systems based on both glucose data points in time and the rate of change of glucose.

Table 3b. Accuracy performance at different glucose levels using the Continuous Glucose-Error Grid Analysis

Zone	YSI ≤ 70 mg/dL		70 mg/dL < YSI ≤180 mg/dL		YSI > 180 mg/dL		All	
	N	%	N	%	N	%	N	%
Accurate Readings	369	59.5	10407	98.9	8364	98.6	19140	97.5
Benign Errors	5	0.8	99	0.9	74	0.9	178	0.9
Erroneous Readings	246	39.7	22	0.2	41	0.5	309	1.6
ALL	620	100.0	10528	100.0	8479	100.0	19627	100.0

18 Appendix B: Specifications *(con't)*

Performance Relative to the Reference (YSI)

Error grid analysis (like the Clarke Error Grid Analysis and Continuous Glucose-Error Grid Analysis) is one way to evaluate the accuracy of the FreeStyle Navigator system. The accuracy can also be assessed by analyzing the difference in the glucose results from the FreeStyle Navigator system when compared to the results from the YSI. Table 4a shows an analysis of the measure of closeness of the FreeStyle Navigator system to the YSI. It breaks the data into smaller groups based on the glucose value reported by the YSI. The table reports the mean absolute difference for the data pairs in each of the smaller groups. Table 4b shows the same data at different levels of glucose and further groups them by the amount of difference from the YSI. Table 5 breaks out the overall performance relative to the YSI for the two sites of sensor insertion.

The overall median absolute relative difference for all the data pairs is **9.3%.**

Table 4a. Performance relative to YSI at different glucose levels

Glucose (mg/dL)	Performance
20-40	Mean Absolute Difference = 32.3 mg/dL
41-80	Mean Absolute Difference = 18.1 mg/dL
81-120	Mean Absolute Difference = 16.3 mg/dL
121-240	Mean Absolute Relative Difference = 11.0%
>240	Mean Absolute Relative Difference = 9.5%

Table 4b. Performance relative to YSI at different levels of glucose – grouped by amount of difference from the YSI

Glucose Range (mg/dL)	Number of Paired Readings	Percent Within 20% of the YSI	Percent Within 30% of the YSI	Percent Within 40% of the YSI
20-40*	22	31.8	54.5	72.7
41-80*	1295	65.9	82.0	90.7
81-120	3820	69.5	85.2	92.7
121-240	11430	85.4	95.1	98.3
>241	3795	91.7	98.8	99.9
Overall	20362	82.3	93.1	97.0

*The absolute difference from the YSI reading is measured in mg/dL if the YSI reading is 20-80 mg/dL.

Table 5. Performance relative to YSI at different insertion sites

Overall MeanAbsolute RelativeDifference	MARD by Insertion Site	
	Abdomen	Arm
12.8% (Std. Dev. = 13.6%)	13.1%	12.6%

18 Appendix B: Specifications *(con't)*

Performance Over the Duration of Wear

This section presents the performance data in a variety of ways to demonstrate the performance of the system over time during the entire sensor wear period. The sensor is worn on the body for up to 5 days, during which time the system has to be calibrated 4 times. Typically, the system has to be calibrated at 10, 12, 24 and 72 hours after sensor insertion. Data presented in this section demonstrates how the sensor performs as a function of time.

Sensor Stability

Tables 6a-6b show there is little difference in accuracy over the five days of sensor wear according to the Clarke Error Grid Analysis (Table 6a) and the Continuous Glucose-Error Grid Analysis (Table 6b).

Table 6a. Clarke Error Grid Analysis by day of wear

Zone	Day 1	Day 2	Day 3	Day 4	Day 5
	%	%	%	%	%
A	82.5	82.4	79.4	84.0	80.9
B	16.4	16.6	18.3	14.2	16.9
C	0.2	0.1	0.0	0.0	0.0
D	0.9	0.9	2.2	1.8	2.1
E	0.0	0.1	0.0	0.0	0.0
Overall Mean Absolute Relative Difference (%) MARD0	12.6	12.3	14.1	11.9	13.0

Table 6b. Continuous Error Grid Analysis by day of wear

Zone	Day 1	Day 2	Day 3	Day 4	Day 5
	%	%	%	%	%
Accurate Readings	97.9	97.8	97.1	97.4	97.3
Benign Errors	1.0	1.2	0.7	0.8	0.8
Erroneous Readings	1.1	1.0	2.2	1.8	1.9

Table 6c groups the difference between glucose results from the FreeStyle Navigator system and the YSI into different blocks (within 20%, within 30% and within 40% from the YSI). It shows there is little change in the difference from YSI over time, thus demonstrating sensor stability.

Table 6c. Difference from the YSI at different times after sensor insertion

Time After Insertion (hours)	Percent Readings Within 20% of the YSI*	Percent Readings Within 30% of the YSI*	Percent Readings Within 40% of the YSI*
10-12	86	92	96
12-24	82	93	97
24-72	81	92	97
72-122	82	93	97

*The absolute difference from the YSI reading is measured in mg/dL if the YSI reading is at or below 75 mg/dL.

18 Appendix B: Specifications *(con't)*

Stability of Sensor Calibration

FreeStyle Navigator system typically requires a calibration at 10, 12, 24 and 72 hours after insertion of the sensor. This section presents information about the performance of the system by the 4 calibration periods. The table (Table 6d) breaks each calibration period into smaller slots and summarizes the difference from YSI in each slot. The data below demonstrates that there is little change in the system performance within each period.

Table 6d. Distribution of the difference from the YSI in the different calibration windows

Calibration Period		Percent Readings Within 20%* of the YSI	Percent Readings Within 30%* of the YSI	Percent Readings Within 40%* of the YSI
Cal 1 (typically occurs 10 hrs after sensor insertion)	First Calibration Period	80	88	94
Cal 2 (typically occurs 12 hours after sensor insertion)	First Third of Second Calibration Period	83	94	98
	Second Third of Second Calibration Period	83	94	98
	Final Third of Second Calibration Period	84	95	98
Cal 3 (typically occurs 24 hours after sensor insertion)	First Third of Third Calibration Period	84	94	98
	Second Third of Third Calibration Period	80	92	97
	Final Third of Third Calibration Period	80	91	95
Cal 4 (typically occurs 72 hours after sensor insertion)	First Quarter of Final Calibration Period	86	93	96
	Second Quarter of Final Calibration Period	84	92	96
	Third Quarter of Final Calibration Period	80	93	98
	Final Quarter of Final Calibration Period	82	93	97

* The absolute difference from the YSI reading is measured in mg/dL if the YSI reading is at or below 75 mg/dL.

Sample Glucose Traces

The following figures show examples of glucose traces from the In-Clinic study. These traces are representative examples of excellent, average and poor performance of the system. These traces show an overlay of the continuous glucose readings from the FreeStyle Navigator system and the blood glucose measurements made using the laboratory YSI reference. The blood glucose measurements that were used to calibrate the system are marked with 'x' in the traces. Glucose results from the FreeStyle Navigator system are shown using circles and the glucose results from the laboratory reference (YSI) are shown using triangles. Time (hours since sensor insertion) is on the horizontal axis, and glucose value in mg/dL is on the vertical axis.

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Figure 2. Sample of a Representative 'Excellent' Glucose Trace

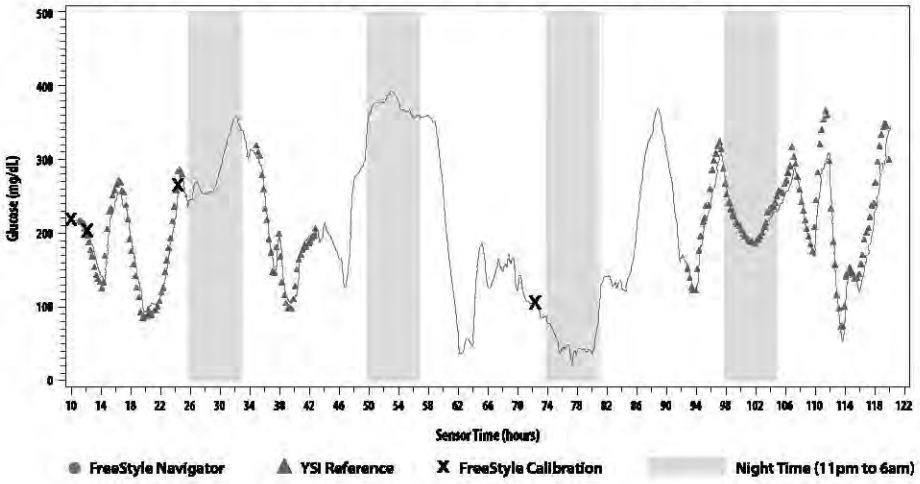


Figure 3. Sample of a Representative 'Average' Glucose Trace

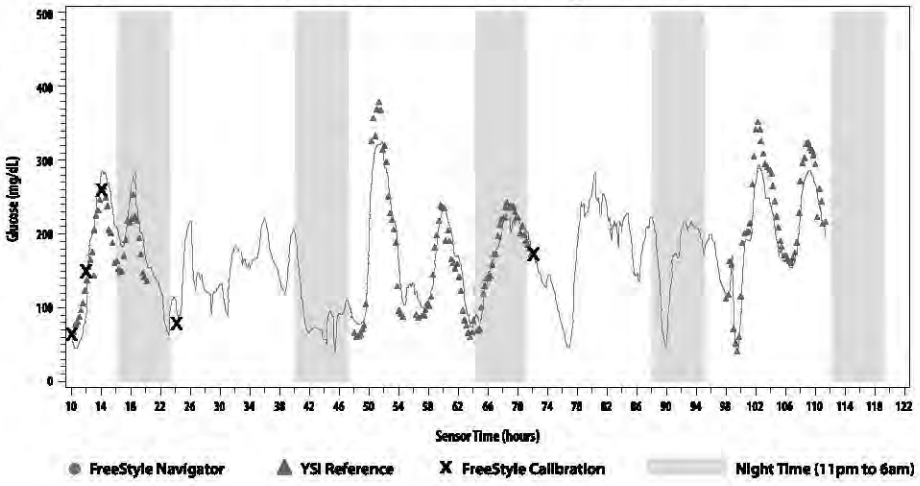
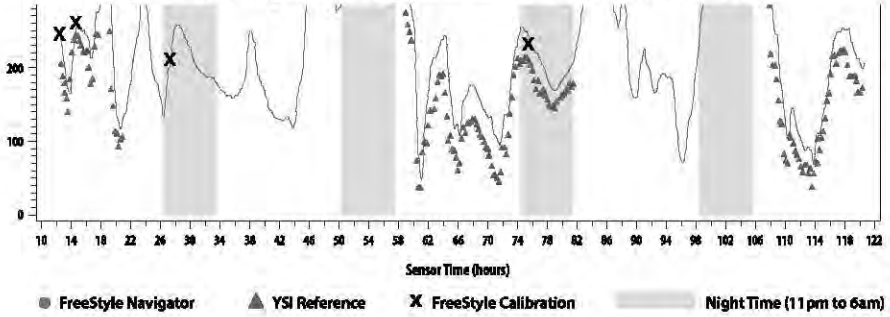


Figure 4. Sample of a Representative 'Poor' Glucose Trace



OVER

18 Appendix B: Specifications *(con't)*

Determination of Alarm Performance

The threshold alarm is characterized below. The projected alarm performance has not been established.

The performance of low and high glucose alarms was assessed in an in-clinic study using 58 subjects with type 1 diabetes wearing one FreeStyle Navigator sensor on the arm and one sensor on the abdomen. FreeStyle Navigator continuous data were masked from the subjects and investigators and the alarms were not turned on. During 50 hours the subjects' venous glucose was tested with a YSI 2300 Stat Plus glucose analyzer at 15 minute intervals. Arm and abdomen data were pooled in the alarm analysis. Alarm performance was evaluated in a retrospective analysis of the study data. As alarm performance was developed retrospectively, your results may vary from those reported below.

Definitions:

Hypoglycemic event – two or more successive YSI measurements below the alarm threshold or one YSI measurement 6 mg/dL below the alarm threshold.

Hyperglycemic event – two or more successive YSI measurements above the alarm threshold or one YSI measurement 6% above the alarm threshold.

True Threshold Alarm – a threshold alarm that occurred ± 30 minutes from the start of a hypoglycemic or hyperglycemic event

True Alarm Rate – the percentage of time the glucose level was beyond the threshold and an alarm was activated

$$\frac{\textit{Events Detected by True Threshold Alarms}}{\textit{Total Events}} \textit{ X 100}$$

Missed Alarm Rate – the percentage of time the glucose level was beyond the threshold and an alarm was not activated

$$\frac{\textit{Events Not Detected by True Threshold Alarms}}{\textit{Total Events}} \textit{ X 100}$$

False Threshold Alarm – a threshold alarm that occurred when a YSI measurement within ± 30 minutes was not beyond the threshold setting

False Alarm Rate – the percentage of time an alarm occurred when glucose level was not beyond the threshold setting

$$\frac{\textit{False Threshold Alarms}}{\textit{Total Threshold Alarms}} \textit{ X 100}$$

18 Appendix B: Specifications *(con't)*

Detection of Low Glucose

See Table 7 below for detection of low glucose. As an example, when the threshold alarm was set at 70 mg/dL (during the day), 56 % of the low glucose events were detected by FreeStyle Navigator.

Table 7. Low Glucose Detection

	DAY			NIGHT		
Low Alarm Setting (mg/dL)	Day True Alarms*	Day Missed Alarms**	Day False Alarms***	Night True Alarms*	Night Missed Alarms**	Night False Alarms***
	% (n/N†)	% (n/N)	% (n/N)	% (n/N)	% (n/N)	% (n/N)
65	46 (56/121)	54 (65/121)	19 (18/95)	80 (12/15)	20 (3/15)	41 (11/27)
70	56 (98/176)	44 (78/176)	16 (21/132)	79 (19/24)	21 (5/24)	40 (14/35)
75	59 (130/219)	41 (89/219)	9 (15/161)	72 (23/32)	28 (9/32)	37 (14/38)
85	61 (189/308)	39 (119/308)	7 (17/228)	65 (22/34)	35 (12/34)	33 (14/43)

* True Alarms are the percentage of time the glucose level was below the threshold and an alarm was activated.

** Missed Alarms are the percentage of time the glucose level was below the threshold and an alarm was not activated.

*** False Alarms are the percentage of time an alarm occurred but the glucose level was not below the threshold setting.

†n/N is the (n)umber of observations divided by the total (N)umber.

Detection of High Glucose

See Table 8 for detection of high glucose. As an example, when the threshold alarm was set at 240 mg/dL (during the day), 78 % of the high glucose events were detected by FreeStyle Navigator.

Table 8. High Glucose Detection

	DAY			NIGHT		
High Alarm Setting (mg/dL	Day True Alarms*	Day Missed Alarms**	Day False Alarms*	Night True Alarms**	Night Missed Alarms***	Night False Alarms***
	% (n/N†)	% (n/N)	% (n/N)	% (n/N)	% (n/N)	% (n/N)
180	89 (561/630)	11 (69/630)	11 (68/628)	69 (29/42)	31 (13/42)	7 (3/44)
240	78 (295/376)	22 (81/376)	12 (47/393)	41 (12/29)	59 (17/29)	25 (7/28)
270	70 (193/274)	30 (81/274)	12 (32/265)	21 (3/14)	79 (11/14)	36 (5/14)
300	61 (117/192)	39 (75/192)	12 (20/161)	12 (1/8)	88 (7/8)	33 (1/3)

* True Alarms are the percentage of time the glucose level was above the threshold and an alarm was activated.

** Missed Alarms are the percentage of time the glucose level was above the threshold and an alarm was not activated.

*** False Alarms are the percentage of time an alarm occurred but the glucose level was not above the threshold setting.

†n/N is the (n)umber of observations divided by the total (N)umber.

18 Appendix B: Specifications *(con't)*

Measuring Glucose in Interstitial Fluid

FreeStyle Navigator system measures glucose in the interstitial fluid (ISF) by means of a sensor that is inserted about 5 mm under the skin. Interstitial fluid is the fluid between the body's cells. Physiologic differences between the interstitial fluid and capillary blood may result in differences in glucose measurements. Differences in glucose measurement between interstitial fluid and your finger may be observed during times of rapid change in blood glucose, e.g. after eating, dosing insulin, or exercising. Movement of nutrients, oxygen and glucose from the blood into the cells happen across the ISF.

Therefore, if the glucose in the bloodstream rises (e.g. during meals), that rise is not seen in the ISF until later. Similarly, if glucose levels in the ISF drop (for example during exercise, the cells consume glucose rapidly) that drop is not seen in the bloodstream until later.

On average, glucose levels in the ISF lag the glucose levels in capillary blood by 14 minutes. This is a physiological phenomenon that can vary from one person to another.

Precision

Data from two sensors inserted at different insertion sites was used to calculate the between sensor reproducibility. Based on 312953 pairs of data sets, the average between sensor reproducibility was 10%.

Sensor Insertion, Calibration and Sensor Wear

Home Use Study: Sensor insertion, calibration and sensor wear were evaluated in a Home Use Study where 137 participants used the product on their own in a home environment. The participants wore 8 sensors during the study period of 40 days. They wore the sensors either on the arm or abdomen. During the first 20 days of the study, continuous glucose results were not visible to the participants. During the following 20 days, participants had access to the glucose measurements. In addition to required calibration tests, the participants performed 4 finger stick measurements a day using the built-in FreeStyle meter. The following information is based on the findings from this study.

When used as directed, 96.8% of the total sensor insertions were successful. 92.6% of the sensors were calibrated successfully and began producing glucose results within 12 hours after sensor insertion. The median time for a successful first calibration was 10.1 hours. The median duration of wear of calibrated sensors was 120 hours. 83% of sensor wears lasted at least 108.3 hours. The median wear time for sensors inserted on the arm was 0.4 hours longer than for sensors inserted on the abdomen.

Skin Interaction

Based on the examination of 124 study participants at a 21-day follow up, the following incidence of skin issues were observed in 304 site exams.
Moderate to severe itching – 1.6% of the time
Moderate bruising – 0.3% of the time
Moderate erythema – 1.0% of the time
Moderate pain – 0.3% of the time
Rate of mild incidences for any individual category of skin issues above including edema, rash, induration, bleeding and others was less than 5%.

19 Appendix C: FCC Compliance Information

Appendix C

19 Appendix C: FCC Compliance Information

Electromagnetic Interference and Your FreeStyle Navigator® Continuous Glucose Monitoring System

Important Information about Electromagnetic Interference

The FreeStyle Navigator® Transmitter and Receiver communicate using radio frequency waves. The FreeStyle Navigator system has been designed to be reliable and immune to common electromagnetic interference so that it is not influenced by such interference. However, under rare circumstances, if you happen to be in an environment of strong electromagnetic radiation, there may be some interference. Examples of possible sources of interference are: store doorways, store checkout counters, metal detectors like those used in airport security systems or electronic surveillance devices, and radio transmitting devices such as cellular phones, 2-way radio and cordless phones.

Interference may occur in the vicinity of equipment marked with  symbol.

If such interference happens, it tends to be temporary. This makes it unlikely that you will experience any noticeable difference in the performance of the system. In the event of electromagnetic interference, you may experience loss of communication between the receiver and transmitter, you may see unrecognizable characters on the receiver display screen, or you may not see continuous glucose results. The system is designed to alert you of these conditions through audio (beep or vibrate) or visual (icons, unrecognizable characters on the screen or lack of glucose results) means.

If you observe a significant change in your continuous glucose readings that you think is erroneous, or if you feel the blood glucose measurement in the Blood Glucose mode is erroneous and you are close to an electromagnetic interference source, move away from the source of interference and check to see if the condition fades away. Always maintain a minimum separation distance from potential sources of electromagnetic interference (see Tables 3 and 4 in this section for guidance).

Depending on your distance from the source of interference, the strength of the interfering signal, and the relative orientation between you and the source of interference, you may or may not see or experience these conditions. ***When in doubt, move away from any likely source of electromagnetic interference.*** If you experience consistent interference from any source, contact the manufacturer or dealer for that source and have a trained technician assess the situation. In addition, please report any consistent interference issues to Abbott Diabetes Care Customer Care.

If you have a medical appointment that includes X-ray, MRI (Magnetic resonance Imaging), CT (Computed Tomography) scan, or another type of exposure to radiation, keep your system and sensor away from the area. Before exposure to such radiation, discard any sensor you are wearing and insert a new sensor after the radiation session. The effect of these types of radiation on the performance of the system has not been evaluated.

19 Appendix C: FCC Compliance Information *(con't)*

Guidance and Manufacturer's Declaration – Electromagnetic Emissions

Table 1. The FreeStyle Navigator system is intended for use in the electromagnetic environment specified below. The customer or the user of the FreeStyle Navigator system should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF Emissions CISPR 11	Group 1	The FreeStyle Navigator system uses RF Energy only for its Intended function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	The FreeStyle Navigator system is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not Applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not Applicable	

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

Table 2. The FreeStyle Navigator system is intended for use in the electromagnetic environment specified below. The customer or user of the FreeStyle Navigator system should assure that it is used in such an environment.

Immunity test	Test Level	FreeStyle Navigator System Compliance Level	Electromagnetic Environment– Guidance
Tx/Rx Electrostatic Discharge (ESD) IEC60601-1-2	±8 kV Contact Discharge ±15 kV Air Discharge	±8 kV Contact Discharge ±15 kV Air Discharge	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Tx/Rx Electrostatic Discharge (ESD) EN 300 489-3	±4 kV Contact Discharge ±8 kV Air Discharge	±4 kV Contact Discharge ±8 kV Air Discharge	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Magnetic Field Immunity IEC 60601-1-2	3A/m @ 50Hz and 60Hz 5 min dwell time	3A/m @ 50Hz and 60Hz 5 min dwell time	Power frequency magnetic fields should be at a level characteristic of a typical location in a typical commercial or hospital environment.
Transmitter Radiated Emissions FCC CFR 47 Part 15.231(e)	Must be below 72.9 dBuV/m @433.56MHz	67.9 dBuV/m @ 433.56MHz	

Guidance and Manufacturer's Declaration - Electromagnetic Immunity. *(con't)*

Transmitter Radiated Emissions for EN EN 300 220-3	Must be below 107.5 dBuV/m @433.56MHz	83.1 dBuV/m @ 433.56MHz	
Transmitter Intentional Radiation Occupied Bandwidth for FCC EN 300 220-3	Less than 1084 kHz @433.56MHz	253 kHz @ 433.56MHz	
Transmitter Unintentional Radiation CISPR 11 Class B	Less than 30 dBuV/m @ 203.48MHz	12.6 dBuV/m @ 203.48MHz	
Receiver Unintentional Radiation CISPR 11 Class B Sec 5	Below 30 dBuV/m (30-230Mhz 37dBuV/m) (230Mhz -1GHz)	21.1 dBuV/m @ 429.79MHz	
Tx/Rx Radiated Immunity IEC 60601-1-2	80Mhz-3000MHz 10V/m @ 80% 1kHz AM Modulation 108 second dwell time	80Mhz-3000MHz 10V/m @ 80% 1kHz AM Modulation 108 second dwell time	
Tx Radiated Immunity IEC 60601-1-2 EN 300 220-3	80Mhz-2500MHz 3V/m @ 80% 1kHz AM Modulation 2.874 msec dwell time	80Mhz - 2500MHz 3V/m @ 80% 1kHz AM Modulation 2.874 msec dwell time	
Tx Frequency Stability EN 300 220-3	80Mhz-2500MHz 3V/m @ 80% 1kHz AM Modulation 2.874 msec dwell time	Within 433.05-434.79MHz operating range and < 100ppm Frequency Error	
Electrical Fast Transient / Burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input / output lines	Not Applicable Battery Operated	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV for Differential mode ±2 kV for common mode	Not Applicable Battery Operated	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips on Power Supply input lines IEC 61000-4-11	<5% for 0.5 cycle 40% Ut* for 5 cycles 70% Ut* for 25 cycles < 5% Ut* for 5 sec	Not Applicable Battery Operated	Mains power quality should be that of a typical commericial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or battery pack.

* Ut is the a.c. mains voltage prior to application of the test level.

19 Appendix C: FCC Compliance Information *(con't)*

Recommended separation distance between portable and mobile RF Communications equipment and the FreeStyle Navigator system.

Table 3. The FreeStyle Navigator system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the FreeStyle Navigator system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the FreeStyle Navigator system as recommended below, according to the maximum output power of the communications equipment.

Radiated maximum power of Transmitter W	**Separation distance according to frequency of transmitter (m)**	
	80 – 800MHz $d = 1.2\sqrt{P}$	**800MHz - 3GHz** $d = 2.3\sqrt{P}$
0.01	0.12	0.23
0.1	0.38	0.73
1	1.20	2.30
10	3.79	7.27
100	12.00	23.00

For Transmitters rated a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800MHz the separation distance for the higher frequency range applies.
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
Note 3: 1 meter = 3.28 feet.

Guidance and Manufacturers' Declaration – Electromagnetic Immunity.

Table 4. The FreeStyle Navigator system is intended for use in the electromagnetic environment specified below. The Customer or the user of the FreeStyle Navigator system should assure that it is used in such an environment.

Immunity Test	Test Level	Compliance Level	Electromagnetic Environment – Guidance
Tx/Rx Radiated Immunity Test	80MHz -3000MHz 10V/m @ 89% 1kHz AM Modulation 108 second dwell Time	80MHz -3000MHz 10V/m @ 89% 1kHz AM Modulation 108 second dwell Time	Portable and mobile RF Communications equipment should be used no closer to any part of the FreeStyle Navigator, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended Separation Distance $d = 1.2\sqrt{P}$ (m) @ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ (m) @ 800 MHz to 2.5GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from RF transmitters, as determined by an electromagnetic site survey[a] should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol: 

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular /cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measurement field strength in the location in which the FreeStyle Navigator system is used exceeds the applicable RF compliance level above the FreeStyle Navigator system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the FreeStyle Navigator system.

[b] Over the frequency range 150kHz to 80 MHz, field strengths should be less than 3 V/m.

19 Appendix C: FCC Compliance Information *(con't)*

Caution: *The radio receiver and transmitter of your FreeStyle Navigator system operate on the frequency of 433.6 MHz. Primary users of this frequency band include amateur "HAM" radio transmitters. Because of the coexistence of the FreeStyle Navigator radio connection and HAM transmitters, there may be instances where the connection between your transmitter and receiver may be lost when in proximity to HAM radio equipment.*

The FreeStyle Navigator system is designed to sense and notify you about a lost connection. If your FreeStyle Navigator system loses the radio connection, increase the separation distance between yourself and the transmitter by moving away from the HAM radio. The FreeStyle Navigator radio connection should re-establish itself. You should note that HAM radio products can be fixed, mobile or portable handheld ("walkie talkie" type) units.

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: PRT03831-xxx.

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:

1. This device may not cause harmful interference.
2. 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 Inc. could void the user's authority to operate this equipment.*

19 Appendix C: FCC Compliance Information *(con't)*

Receiver

Model Number: PRT03410-xxx.

Operating Environment: For Home or Office Use.

DECLARATION OF CONFORMITY

We, Abbott Diabetes Care Inc.

1360 South Loop Road
Alameda, California 94502
510-749-5400

Declare under our sole responsibility that the product
FreeStyle Navigator Receiver

Part Number: PRT03410-xxx

Complies with Part 15 of FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

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 Inc. could void the user's authority to operate this equipment.*

END OF Section 19

20 Glossary

Glossary

20 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 are used by the receiver 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	A setting that you can adjust 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 you can use 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.
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 at approximately 10, 12, 24 and 72 hours after sensor insertion. 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 real-time glucose readings.
Calibration BG	Allows you to add a new blood glucose measurement that is used for sensor calibration. Use this feature only under the direction of a Customer Care representative or your healthcare team. Use of this feature will discard all the earlier calibrations. The sensor life will not be reset.
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 Customer Care representative or your healthcare team.
Contact Points	Conductive points that connect the transmitter to the sensor support mount.

20 Glossary *(con't)*

Continuous Monitoring Mode	One of two modes in which the system functions (the other is Blood Glucose mode). You will use this mode 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. Along with the glucose numbers, this mode also displays a directional glucose trend arrow.
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 in the Blood Glucose mode.
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 your FreeStyle Navigator system to a computer.
Dressings	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 to 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 your receiver and test strips are working properly prior to calibration or blood glucose testing.
FreeStyle Navigator® Continuous Glucose Monitoring System	Also referred to as the system, this device is designed to give people with diabetes a continuous 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 thinks 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.

20 Glossary *(con't)*

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 go above 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 alarm and the Projected High Glucose alarm use the high glucose threshold.
Icons	Simple graphic symbols that appear on the receiver display screen to alert you to 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. You may also enter the type of insulin and dose amount (units).
Interstitial Fluid	The fluid in the tiny spaces between the cells in your body. The system uses this fluid to measure your glucose levels.
in vitro	The measuring of something out of the body. For example, in a test tube.
in vivo	The measuring of something in the body.
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 Indicator Window	A window on the lancing device that shows you the depth setting you have chosen.
Lancing Device Depth Setting	A part of the lancing device that lets you to adjust how deep the lancet pricks your skin. A higher number means a deeper penetration of the lancet.
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.

20 Glossary *(con't)*

Line Graph Reports	Show continuous glucose lines (plotted at 10-minute intervals) for several different periods (2, 4, 6, 12, or 24 hours).
Link	This procedure is performed so that the receiver can be paired with a transmitter. Once linked, the receiver would know to accept information from that transmitter alone. When shipped out of the factory, the receiver and transmitter are already linked.
Low Glucose Alarm	An alarm that tells you when you go below 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 alarm and the Projected Low Glucose alarm use the low glucose threshold.
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 periods.
Progress Tones	Communicate progress, errors, and successful completion of system activities such as Blood Glucose mode testing.
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.
Receiver (Rx)	Also called Rx. 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 Skin	The receiver skin is an optional accessory for use with your FreeStyle Navigator Receiver.
Receiver Status	Provides you with information regarding the receiver, including serial number, software version, and remaining battery life. This information can be accessed from your System menu item in the Main menu.
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.

20 Glossary *(con't)*

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 5 days.
Sensor Code	A number 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 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 which 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, on either 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 pin 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.
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.

20 Glossary *(con't)*

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 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	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 (Tx)	Also called Tx. 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 data to the receiver once every minute.
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.
Unlink	The process of removing the transmitter ID from the receiver. Once unlinked, the receiver will no longer be paired with a specific transmitter. Before beginning to use the system, the receiver and transmitter have to be linked.
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.

END OF Section 20

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