



FreeStyle

Navigator II

Continuous Glucose Monitoring System



User's Manual



Table of Contents

Indications for Use	1	Glucose Alarms	20
Warnings	1	Alarm Tones	20
Cautions	2	Day/Night Glucose Alarms	21
System-Related Information	3	Audio/Vibrate Settings	22
Getting To Know Your FreeStyle Navigator II System	3	Mute/Un-Mute Alarms	22
System Kit	3	Alarm Snooze Setup	23
Sensor Kit	4	Responding to Alarms	23
Receiver Features	5	Troubleshooting	24
Receiver Home Screen	6	Living with Your FreeStyle Navigator II System	24
Initial Setup	7	Reconnecting to a Sensor if Signal is Interrupted	24
Charging the Receiver	7	Wireless Transmission Range	24
Setting Time and Date	7	Bathing, Showering and Swimming	24
Setting Time and Date Format	8	Sleeping	24
Display Preferences	9	Visibility	24
Prepare to Insert a Sensor	9	Travelling	25
Inserting a New Sensor	10	How to Clean your Transmitter	25
Attaching the Transmitter	12	How to Clean your Receiver	25
Connecting to a New Sensor	12	How to Clean your Receiver Skin	26
Checking your Blood Glucose	13	Disposal	26
Calibrating	16	System Specifications	27
Removing a Sensor and Transmitter	17	Glossary of Symbols	28
Setting Glucose Targets and Alarms	18	Receiver Screens	29
Glucose Targets	18	Receiver Icons	30
Glucose Alarms Settings	19	Electromagnetic Compatibility	31

Indications for Use

The FreeStyle Navigator II Continuous Glucose Monitoring System is a glucose monitoring device indicated for continually measuring interstitial fluid glucose levels in people (age 6 and older) with diabetes mellitus. The indication for children (age 6 - 17) is limited to those who are supervised by a caregiver who is at least 18 years of age. The caregiver is responsible for managing or assisting the child to manage the FreeStyle Navigator II System and also for interpreting or assisting the child to interpret FreeStyle Navigator II readings.

The FreeStyle Navigator II Continuous Glucose Monitoring System is designed to replace blood glucose testing in the self-management of diabetes with the exceptions listed below. Under the following circumstances, use a blood glucose meter to check the current glucose readings from the FreeStyle Navigator II Continuous Glucose Monitoring System Sensor:

- During times of rapidly changing glucose levels, interstitial glucose levels as measured by the Sensor and reported as current may not accurately reflect blood glucose levels. When glucose levels are falling rapidly, glucose readings from the Sensor may be higher than blood glucose levels. Conversely when glucose levels are rising rapidly, glucose readings from the Sensor may be lower than blood glucose levels.
- In order to confirm hypoglycaemia or impending hypoglycaemia as reported by the Sensor.
- If symptoms do not match the FreeStyle Navigator II Continuous

Glucose Monitoring System reading. Do not ignore symptoms that may be due to low blood glucose or high blood glucose.

For more detailed information on the FreeStyle Navigator II system, see the Expert Guide. The Expert Guide can be found on a CD-ROM inside your system kit. For a printed copy of the Expert Guide, please contact Customer Care.

Warnings

- During times of rapidly changing glucose (more than 120 mg/dL per hour or 6.7 mmol/L per hour), continuously reported interstitial glucose levels as measured by the FreeStyle Navigator II Sensor may not accurately reflect blood glucose levels. Under these circumstances, use the built-in FreeStyle Lite Blood Glucose (BG) Meter to conduct finger-stick testing to check the continuous glucose results from the FreeStyle Navigator II Sensor.
- In order to confirm hypoglycaemia or impending hypoglycaemia as reported by the FreeStyle Navigator II Continuous Glucose Sensor, use the built-in FreeStyle Lite Blood Glucose Meter to conduct finger-stick testing to check the FreeStyle Navigator II reading.
- Do not ignore symptoms that may be due to low blood glucose or high blood glucose. If you have symptoms that do not match the FreeStyle Navigator II reading, use the built-in FreeStyle Lite Blood Glucose Meter to conduct finger-stick testing to check the FreeStyle Navigator II Continuous Glucose reading. If you are experiencing symptoms that are not consistent with your glucose readings, consult your healthcare team.
- 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 Sensor

Support Mount to the skin and cause the Sensor to dislodge. If the Sensor dislodges due to the Sensor Support Mount adhesive failing to adhere to the skin, you may get unreliable results or no results without a warning. Choose the correct Sensor insertion site when inserting the Sensor and prepare the site by following the instructions for site preparation.

- Severe dehydration and excessive water loss may cause false results. If you believe you are suffering from dehydration, consult your physician immediately.

Cautions

- To ensure accuracy and correct performance, the FreeStyle Navigator II System includes built-in self-checks to detect some conditions that may cause the Sensor to not function correctly. On rare occasions, the system may not be able to detect all conditions that affect Sensor function and you may get inaccurate continuous monitoring results. If the problem continues, discard the current Sensor and insert a new one.
- If you have hypoglycaemia or hypoglycaemia unawareness, then perform blood glucose checks ONLY on your fingers. Changes in glucose levels may be observed in finger blood samples sooner than in samples from approved alternate sites. If an alternate site must be used, vigorous rubbing of the alternate site before lancing can help minimise this difference.
- Performance of the FreeStyle Navigator II System has not been evaluated in pregnant women.
- The system should not be used in environments that are oxygen-rich or that contain a combustible gas.
- Performance of the system under conditions of fluctuating hydration levels, such as during renal dialysis, has not been evaluated.
- The Receiver and Transmitter of your FreeStyle Navigator II System operate on a frequency that may be used by other communications devices, including amateur "HAM" radio transmitters (which may be fixed, mobile or handheld "walkie-talkie" type units). The communication between your Transmitter and Receiver may occasionally be lost when you are near HAM radio equipment. If your FreeStyle Navigator II System loses wireless communication, move away from the HAM radio to re-establish wireless communication.
- If you have a medical appointment that includes strong magnetic or electromagnetic fields, such as an X-ray, MRI (Magnetic Resonance Imaging), CT (Computed Tomography) scan or another type of exposure to radiation, keep your Receiver and Transmitter/Sensor Unit 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.
- Changes or modification to the device not expressly approved by Abbott Diabetes Care Inc. could void the user's authority to operate this equipment.

Customer Care: + 8000 - 2255 - 232 (+ 8000 - CALL - ADC)

System-Related Information

- The FreeStyle Navigator II System is designed as a complete system. Use only the FreeStyle Navigator II Sensor, FreeStyle Navigator II Transmitter, FreeStyle Navigator II Receiver, FreeStyle Control Solution and FreeStyle Lite Test Strips.
- Do NOT share your system with others.
- Avoid getting dust, dirt, blood, control solution, water or other substances in the Receiver's USB and test strip ports.
- **Interfering Substances:** Testing suggests that usual levels of ascorbic acid (Vitamin C) have no effect on the function of the system but salicylic acid has a small effect. Testing suggests that normal levels of uric acid, lipids and bilirubin do not affect system function. The impact of oral hypoglycaemic agents and other potential interfering substances has not been studied.

Getting To Know Your FreeStyle Navigator II System

Thank you for selecting the **FreeStyle Navigator II Continuous Glucose Monitoring System** to help you manage your diabetes. The FreeStyle Navigator II System is a continuous glucose monitor (CGM) and blood glucose (BG) meter, which is designed to be safe and easy to use. The FreeStyle Navigator II System consists of two kits; a System Kit and a Sensor Kit.

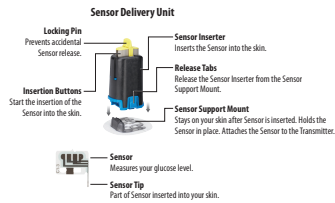
System Kit



- **Receiver** – The handheld controller that wirelessly communicates with the Transmitter and displays glucose measurements. The Receiver also has a built-in FreeStyle Lite Blood Glucose Meter. The Receiver uses a rechargeable battery. Your Receiver serial number is listed on the back of your Receiver.

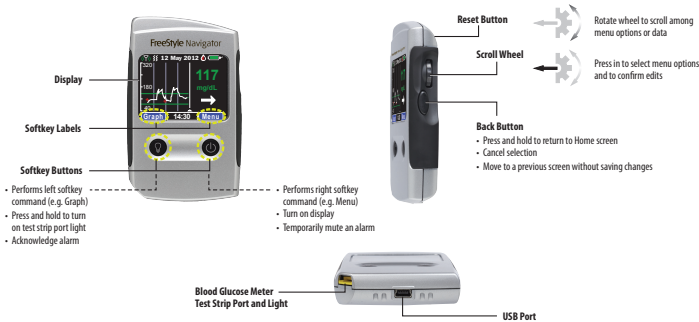
- **Transmitter** – When correctly worn on the body along with the Sensor and Sensor Support Mount (see Sensor Kit), the Transmitter measures continuous glucose and communicates data to the Receiver. The Transmitter serial number is printed on the bottom surface of the Transmitter or can be accessed from the Receiver.
 - **A/C Wall Charger** – A charger that plugs into a standard wall outlet to provide power to the Receiver via a USB Port.
 - **Charging Cable** – A cable that connects the Receiver to the A/C Wall Charger or another powered USB Port for charging.
 - **Adapters** – The plugs used with your A/C Wall Charger in order to use your A/C Wall Charger in your geographic region.
 - **Receiver Skin** – The Receiver's silicone skin is an optional accessory, not required for use. Does not contain latex.
- Contact your healthcare team or Customer Care if you need to replace your Transmitter or Receiver. They can suggest the correct way to dispose of old parts.

Sensor Kit



- **Sensor Delivery Unit** – The combination of 2 parts that you put together: the Sensor Support Mount and the Sensor Insertor (with pre-installed Sensor). The Sensor Delivery Unit inserts the FreeStyle Navigator II Sensor about 5 mm under your skin.
- **Sensor Insertor** – A single-use device that guides the Sensor into the skin.
- **Sensor Support Mount** – A single-use component that attaches to your skin with an adhesive pad. Designed to hold the Transmitter and Sensor on your body for up to 5 days. The combination of the Sensor Support Mount (with Sensor) and the Transmitter that is worn on your body is known as the Transmitter/Sensor Unit.

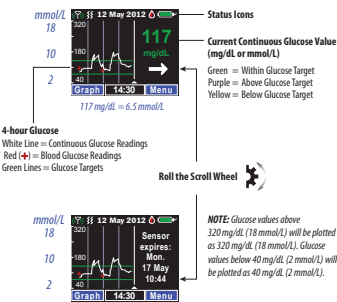
Receiver Features



Note: Pressure or force applied to the screen of the Receiver can cause permanent damage to the screen. Use the same precautions you would use with other personal electronic devices.

Receiver Home Screen

To turn the Receiver On, press the Power button. Your Receiver displays the Home screen when turned on.



Rolling the Scroll Wheel shows when the Sensor is scheduled to expire. If there is no active Sensor, the Receiver displays instructions to "Insert and Connect to a new Sensor."

Current Continuous Glucose Value – The Home Screen shows your current continuous glucose reading and a trend arrow that indicates how fast your glucose is changing and in what direction (increasing or decreasing).

Trend arrow	What it means
→	Glucose is changing gradually (less than 60 mg/dL per hour or 3.3 mmol/L per hour)
↘	Glucose is decreasing moderately (between 60 and 120 mg/dL per hour or between 3.3 and 6.7 mmol/L per hour)
↓	Glucose is decreasing rapidly (more than 120 mg/dL per hour or 6.7 mmol/L per hour)
↗	Glucose is increasing moderately (between 60 and 120 mg/dL per hour or between 3.3 and 6.7 mmol/L per hour)
↑	Glucose is increasing rapidly (more than 120 mg/dL per hour or 6.7 mmol/L per hour)

Graph Softkey – To display a more detailed Timeline Graph, press the Graph softkey button.

Menu Softkey – To go to the Main Menu, press Menu. **Status Icons** – Visual symbols indicating the status of your FreeStyle Navigator II System. See Receiver Icons table on the last page of this User's Manual.

Initial Setup

Charging the Receiver

Before using your FreeStyle Navigator II System for the first time, you MUST fully charge the Receiver's battery for at least 6 hours. Do not disconnect the Charging Cable from your Receiver until it is fully charged. = fully charged = not fully charged = completely depleted

CAUTION: Do NOT check your blood glucose while charging your Receiver.

Connect one end of your Charging Cable to an electrical outlet with the A/C Wall Charger or to a powered USB Port, such as on a computer. Connect the other end of the Charging Cable to your Receiver. To fully charge the battery, charge the Receiver for at least 6 hours.

A fully charged Receiver battery typically lasts approximately 3 days. Battery life may be shortened if you activate the display frequently. The number of alarms you receive may also shorten battery life.

Upon disconnecting from the Charging Cable, the Receiver completes a sequence of self-checks. If the display is turned on, the Receiver emits tones, vibrates and flashes screen checks during this time. If the Receiver



Charging Cable, Receiver, and A/C Wall Charger

7

Setting Time and Date

can detect that any portion of the self-test fails, the Receiver displays a message on the screen to contact Customer Care.

To turn the Receiver On, press the Power button .

TIME / DATE

09 : 28

Accept

CURRENT DATE

Month = --

Day = --

Year = --

Accept

CURRENT TIME

Hour = --

Minute = --

Accept

CURRENT TIME

Hour = 09

Minute = --

Accept

CURRENT TIME

Hour = 09

Minute = 28

Accept

Push scroll wheel to set time

Push scroll wheel to select "Month"

Scroll up or down to select month

Push scroll wheel to confirm and repeat for "Day" and "Year"

Push scroll wheel to select "Hour"

Scroll up or down to select hour

Push scroll wheel to confirm and repeat for "Minute"

8

Setting Time and Date Format

If you need to change your time and date format settings, follow the instructions below:

Menu → Settings → Time & Date → Format

12 May 2012

Graph 16.52 Menu

MAIN MENU

Add Event

Status

Settings

Manual Cal

Home Select

SETTINGS

Time & Date

Display

Glucose Targets

Self Test

Home Select

TIME & DATE

16:14

18 May 2012

Format Done

FORMAT

Time = 24 Hour

Date = Day / Month

Accept

Push scroll wheel to select "Month"

Scroll up or down to select month

Push scroll wheel to confirm and repeat for "Day" and "Year"

8

Display Preferences

DISPLAY

Language ▾ English

Timeout ▾ 15 Seconds

Decimal Format ▾ x.x

Accept

Menu → Settings → Display Preferences

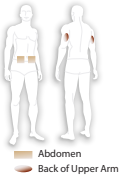
Display	Options	Comments
Language	English, Svenska, Deutsch, Nederlands, Français, Italiano, Español, Dansk, Suomi, Norsk, Português	
Timeout	15 - 120 Seconds	How long the Receiver can remain idle before the display turns off.
Decimal Format	X,X or X.X	

Prepare to Insert a Sensor

Before inserting your first Sensor please read this entire section to understand how to attach and detach the Transmitter from the Sensor Support Mount. This will help ensure your first Sensor insertion is successful.

CAUTION: Do NOT use the Sensor Inserter or Sensor Support Mount if their sterile packages have been opened or otherwise damaged.

- Insert Sensors only in the abdomen or back of the upper arm.
- 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).
- Always change the insertion site for each new Sensor.
- Site rotation helps prevent discomfort, irritation, bruising, skin rashes and sensitivity reactions to adhesives.
- Choose a site that is at least 2.5 cm (1 inch) away from an insulin infusion site and/or previous insertion site.
- It might help to develop a routine in which you rotate the sites in the same order (for example, left arm, right arm, left abdomen, right abdomen and then repeat).



CAUTION: Do NOT reuse FreeStyle Navigator II Sensors due to risk of infection. Not suitable for re-sterilisation.

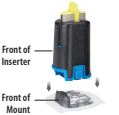
Inserting a New Sensor

WARNINGS:

- The Sensor Inserter packaging may contain a drying agent that could be harmful if inhaled or swallowed and may cause skin and eye irritation.
- Never point the pre-cocked Sensor Inserter towards the eyes, face or any other body part where Sensor insertion is not desired.

1. Prepare your selected insertion site by cleaning it with soap and water first and then wiping it with an alcohol prep pad.
Note: The insertion area **MUST** be clean and dry; otherwise, an infection could occur or the Sensor Support Mount may not stick to the site.
2. Remove the Sensor Inserter and Sensor Support Mount from their sterile packages. Save the package of the Sensor Inserter; it contains the Sensor Code number. You need to enter this code number into the Receiver at a later step.
Note: Make note of the Sensor Code found on the Sensor Inserter packaging. You will need to enter this code after insertion.

3. Assemble the Sensor Inserter onto the Sensor Support Mount by fitting the front of the Sensor Inserter over the raised portion of the Sensor Support Mount and pressing downwards. You should hear or feel a slight click as the pieces engage.



4. Remove the adhesive protective liner from the bottom of the Sensor Support Mount. Be careful not to fold the adhesive back on itself.



5. Place the Sensor Support Mount, adhesive side down, on the cleaned area of skin at the insertion site. Smooth the adhesive pad against your skin with your fingers. Hold it firmly in place to make sure it sticks to the skin. If inserting the Sensor on the back of your arm, place the Sensor Support Mount lengthwise down your arm with the front of the Sensor Support Mount towards your shoulder. If inserting the Sensor on your abdomen, position the Sensor Support Mount horizontally, parallel to your waist.



Note: Apply Sensor Support Mount directly onto skin. Do NOT apply Sensor Support Mount on any materials (clothing, bandages, etc.).

6. Use your thumb and index finger to twist the locking pin, on top, one-quarter turn. Pull the locking pin to remove it.
- 
- CAUTION:** Once the locking pin has been removed and the Insertion Buttons are pressed, a needle quickly goes just under your skin to place the Sensor. Do NOT press the buttons until you are ready to insert the Sensor.
7. Hold the black part of the Sensor Inserter, avoiding the blue release tabs. Press down firmly on both grey Insertion Buttons on the top of the Sensor Inserter. Try not to press the Sensor Inserter assembly down into the skin when pressing the buttons. You may feel a slight pinch as the Sensor is placed under your skin.
- 
- Note:** Both buttons must be fully depressed for the Sensor to be correctly inserted. The buttons are fully depressed when they are even with the top of the Sensor Inserter.

8. Hold the Sensor Inserter and firmly squeeze the 2 blue release tabs at its base. Lift the Sensor Inserter straight up and away from the Sensor Support Mount. Be careful not to pull the Sensor Support Mount off of your skin during removal.
- 
- Note:** Do NOT try to remove the Sensor Inserter without squeezing the blue release tabs as this may dislodge the Sensor Support Mount.
9. After removing the Sensor Inserter, the Sensor is visible with its tip inserted into your skin and the top of the Sensor even with the top edge of the Sensor Support Mount. You may see a small amount of bleeding at the insertion site. If there is continuous bleeding that does not stop, remove the Sensor Support Mount and Sensor and repeat the Sensor insertion procedure with a new Sensor at a new insertion site.
- 
10. Discard the Sensor Inserter safely. We recommend a sharps container or a puncture-proof container with a tight lid.

Attaching the Transmitter

Before attaching a new Transmitter to the Sensor Support Mount for the first time, write down the Transmitter serial number (located on the bottom surface of the Transmitter).

Write down your serial number _____

1. After the Sensor has been inserted, position the Transmitter over the Sensor Support Mount so that the contact points face the Sensor.
2. Lower the Transmitter onto the Sensor Support Mount directly over the round part of the "keyhole".
3. Hold the Transmitter between your index finger and thumb and slide the Transmitter until it clicks into place.

Note: Do NOT remove or replace the Transmitter from the Sensor Support Mount while wearing the Sensor. Doing so may end your Sensor life.



Connecting to a New Sensor

1. On your Receiver, select **Menu → Connect to Sensor**. The Receiver instructs you to, "Hold Receiver next to Sensor." Hold the Receiver next to the Transmitter/Sensor Unit. The Receiver searches for the wireless signal from the Transmitter.



When the Receiver connects with the Transmitter, the Receiver emits the Success tone (if Progress Tones are On).

Note: If the Receiver cannot connect to the Transmitter, it notifies you with a screen message and the Failure tone (if Progress Tones are On). Check that the Transmitter is correctly attached to the Sensor Support Mount and that the Receiver is directly on top of the Transmitter. Press **Yes** to try connecting again.

2. The first time you connect a new Transmitter to the Receiver a "New Transmitter Found" message is displayed on the screen.

- Verify that the Transmitter ID displayed on the screen is the same as your Transmitter serial number that you wrote down (located on the bottom surface of the Transmitter).
- If this number does not match, press **No**.
- If this number matches, press **Yes** to continue to the Sensor Code screen.



Only Displayed for New Transmitters

CAUTION: If you accept an incorrect Transmitter serial number, your glucose readings will be incorrect or not available.

After you accept the new Transmitter serial number, you will only see this screen again when you connect to a new Transmitter.

3. When the Receiver has accepted a Transmitter serial number, the Sensor Code screen is displayed.



4. Using the Scroll Wheel, enter the 3 digit Sensor Code from the Sensor Inserter packaging.



CAUTION: The code numbers MUST match to ensure accurate glucose results.

Note: Once the Sensor Code has been entered and you have pressed **Accept**, you cannot change the Sensor Code number. Be careful: If you enter the code incorrectly, you have to replace the Sensor. If you enter the wrong Sensor Code, you may get incorrect continuous glucose results.

5. Press **Accept** to start the Sensor.

The Receiver automatically displays the Home screen. An  icon is displayed at the top while the system waits for the first calibration time (approximately 1 hour). The system displays "—" before continuous glucose monitoring is available.



When the system is ready to be calibrated, a  icon is displayed. To calibrate, perform a blood glucose check.

Checking your Blood Glucose

You can use the built-in FreeStyle Lite Blood Glucose Meter at any time to check your blood glucose, whether wearing a Sensor or not. You can perform the blood glucose check on your fingertip or approved alternative site on the body. When calibrating, perform a blood glucose check only on your fingers.

Note: Use ONLY the FreeStyle Lite Test Strips with the FreeStyle Navigator II System. Using other strips can produce inaccurate results. For important test strip information, including storage and usage details, refer to the FreeStyle Lite Test Strip package insert.

WARNING: The FreeStyle Lite Test Strips and lancets are small parts that may be dangerous if swallowed.

CAUTION: Do NOT check your blood glucose while charging your Receiver.

Prepare the FreeStyle Lite Test Strip

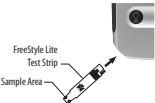
1. Locate the expiry date on the vial of FreeStyle Lite Test Strips. If the test strips have expired, discard them and obtain a new vial of test strips.



2. Remove a single test strip from the vial and close the vial tightly.

Insert the FreeStyle Lite Test Strip into the Receiver's test strip port

Note: To use the test strip port light, press and hold the Left Softkey button  for 2 seconds when the display is on.



1. Make sure that the Receiver Display is on the Home screen or the display is turned off.
2. Turn the test strip so the  faces up.
3. Grasp the test strip by the end with the sample areas.

4. Insert the other end of the test strip into the Receiver's test strip port until it stops. The Receiver displays "Apply Blood Sample" along with a blood drop and test strip.

Note: If you do not apply your blood within 2 minutes of inserting a test strip, the display turns off. To resume testing, remove and reinsert the unused test strip.



Prepare your test site

CAUTION: Perform blood glucose checks ONLY on your fingers if you have hypoglycaemia or hypoglycaemia unawareness or when you are calibrating your system.

Note: Vary the sites from test to test to avoid tenderness and to avoid creating calluses. Avoid moles, veins, bones and tendons.

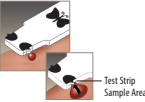
1. Wash your hands and the test site with soap and water and dry thoroughly. Make sure there is no lotion on the test site.
2. If testing a site other than the finger, rub the test site vigorously until you feel it getting warm (3 to 5 seconds).

Lance your test site to get a blood sample

1. Wait until you see "Apply Blood Sample" appear on the Receiver's display before lancing your finger. Set the Receiver aside and proceed to the next step.

- Notes:**
- Use a new sterile lancet each time. NEVER use a lancet or lancing device for more than one person.
 - Follow instructions for your lancing device.

Apply blood sample and wait for results

1. Gently apply blood to ONLY ONE sample area of the test strip. Only a very tiny drop of blood is needed.
Note: Do NOT apply blood to both sample areas of the test strip. If this happens, discard the test strip.

2. Watch the Receiver Display. When enough blood is applied, the Receiver shows a circle of 4 arrows while it measures the blood glucose. If Progress Tones are on, you also hear a two-note Progress Tone.
Note: If needed, you have up to 60 seconds to add blood to the same sample area of the test strip.


The Receiver displays your blood glucose results when the check is complete. If Progress Tones are on, you also hear a chime-like Progress Tone when results appear.

This screen displays your blood glucose result. Press Home to return to the Home screen.
Note: Measurements are accurate between 5 ° to 40 °C (40 ° to 104 °F). If the temperature is out of range, the Receiver displays the  symbol with your glucose reading.

Discard the test strip and lancet

- Test strips may be used only once. Discard used test strips in a sealable container such as a sharps container to avoid contact with biohazards.

Your blood glucose results

Work with your healthcare team to determine the low and high values for your blood glucose target range. If you get results below or above your target range and do NOT have symptoms of hypoglycaemia or hyperglycaemia, repeat the test. If you have symptoms or continue to get results that are low or high, follow the treatment recommended by your healthcare team.

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

If **Low** appears on your Receiver, your result is lower than 20 mg/dL (1.1 mmol/L). If you have symptoms of low blood glucose (for example: weakness, sweating, nervousness, headache or confusion), follow your healthcare team's recommendations for treating severe hypoglycaemia. If you do not have any symptoms, wash and dry your hands and repeat the blood glucose check on your finger with a new test strip. If you receive a second **Low** result, follow your healthcare team's recommendations for treating severe hypoglycaemia.


If **High** appears on your Receiver, your result is higher than 500 mg/dL (27.8 mmol/L). If you have symptoms of high blood glucose (for example: fatigue, thirst, excess urination or blurry vision), follow your healthcare team's recommendations for treating hyperglycaemia. If you do not have any symptoms, wash and dry your hands and repeat the blood glucose check on your finger with a new test strip. If you receive a second **High** result, follow your healthcare team's recommendations for treating severe hyperglycaemia.

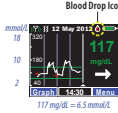

Calibrating

Calibrating is the process the FreeStyle Navigator II System uses to match your interstitial fluid glucose readings with your blood glucose readings. You need to calibrate the system by checking your blood glucose at approximately 1, 2, 10, 24 and 72 hours after Sensor insertion.

- When the system is ready to be calibrated, it prompts you to "Check your BG to calibrate" and emits an audible alarm based on your settings. You will also see a blood drop  icon on the Home screen. To calibrate the system, perform a blood glucose check.

Note: If your system alarms are turned off, you will not see the "Check your BG to calibrate" screen or hear audible alarms.

- See the Expert Guide for more information on performing and troubleshooting calibrations.
- There is a time window in which each calibration needs to be completed called a **grace period**. If you do not calibrate before the grace period ends, the continuous glucose results are no longer displayed and the glucose alarms become inactive. Your Sensor remains active. If you missed the grace period, simply perform a blood glucose check at any time you see the blood drop  icon to continue the calibration process; this resumes continuous glucose monitoring.



Calibration	Time After Starting The Sensor	Grace Period
1st	1 hour	No grace period
2nd	2 hours	30 minutes
3rd	10 hours	2 hours
4th	24 hours	8 hours
5th	72 hours	8 hours

CAUTIONS:

- Always calibrate the system using a finger-stick blood sample. Do NOT use alternative site blood glucose measurements to calibrate the system.
- Do NOT use FreeStyle Control Solution for calibration. Do NOT perform the control solution test when the system prompts you to calibrate.
- In clinical trials, the continuous glucose readings were sometimes temporarily lower than the blood glucose readings. This typically happened during sleep and recovered rapidly when the wearer moved or awakened. In order to reduce the effects of this phenomenon, the system should not be calibrated when the wearer is asleep.

Removing a Sensor and Transmitter

The Sensor must be changed:

- At least every 5 days. The system automatically ends the Sensor session after 5 days. You can check your remaining Sensor life on the Home screen or by selecting **Menu** → **Status**. See the Expert Guide for more information about changing a Sensor.
- If you notice any irritation or discomfort at the Sensor insertion site. Taking action at the first sign of irritation or discomfort keeps small issues from turning into larger ones.
- If a Receiver alarm instructs you to replace the Sensor.

WARNING: 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 Sensor Support Mount to the skin and cause the Sensor to dislodge. If the Sensor dislodges due to the Sensor Support Mount adhesive failing to adhere to the skin, you may get unreliable results or no results without a warning. Choose the proper Sensor insertion site when inserting the Sensor and prepare the site by following the instructions for site preparation.

CAUTION: If your continuous monitoring results seem incorrect, check to see if the Sensor has dislodged. If you notice the Sensor is dislodged from the skin, or if you see that the adhesive on your Sensor Support Mount is coming loose, discard the current Sensor and insert a new Sensor.

1. Pull up one edge of the adhesive and slowly peel it off your skin in one continuous motion. Avoid folding the adhesive back on itself as this will make it more difficult to remove the Transmitter from the Sensor Support Mount.



2. After the Transmitter/Sensor Unit is off your skin, pull down on the adhesive at the bottom of the Sensor Support Mount while you are holding onto the Transmitter (the end furthest from the Sensor). You may hear a click as the Transmitter separates from the Sensor Support Mount. Slide the Transmitter off the used Sensor Support Mount.



Note: Do not attempt to pry the Transmitter from Sensor Support Mount. If you have difficulty, call Customer Care for assistance.

Shortly after separating the Transmitter (within approximately 1 minute), you may get a screen which reads "TX DETACHED. Transmitter has detached from Sensor. CGM is not available. Replace the Sensor to continue CGM." If this screen is displayed, press **OK**.

If you don't separate the Transmitter from the Sensor Support Mount, the Receiver displays a screen which reads "Did you remove the Sensor? Select "Yes" to end CGM." Press **Yes**.

3. Discard the Sensor Support Mount (with the Sensor attached). The Transmitter should be cleaned each time you remove a used Sensor.



Note: Do Not discard the Transmitter. NEVER attempt to reuse the Sensor Support Mount or Sensor.

Setting Glucose Targets and Alarms

See the Expert Guide for more information on alarms and settings.

Glucose Targets

Glucose Targets are the low and high glucose levels you would like your glucose to stay between.

Note: These targets are different from your glucose alarms settings. Changing your Glucose Targets will not change your alarms settings.



1. Select **Menu** → **Settings** → **Glucose Targets**.

$80 \text{ mg/dL} = 4.4 \text{ mmol/L}$
 $160 \text{ mg/dL} = 8.9 \text{ mmol/L}$
2. Use the Scroll Wheel to select, adjust and set your preferences for:
 - **Low Target** – Set 60 – 248 mg/dL (3.3 – 13.8 mmol/L) for the low glucose target
 - **High Target** – Set 62 – 250 mg/dL (3.4 – 13.9 mmol/L) for the high glucose target
3. Press **Accept** to save the setting and exit.

Glucose Alarms Settings

Type	What It Is	Settings Available
LOW GLUCOSE	The low glucose alarm notifies you when your glucose level is below your Low Glucose Threshold value.	• Threshold Range: 60 – 119 mg/dL (3.3 – 6.6 mmol/L) • Snooze time: 15 – 60 min • Alarm Tones, Vibrate or Off
HIGH GLUCOSE	The high glucose alarm notifies you when your glucose level is above your High Glucose Threshold value.	• Threshold Range: 120 – 300 mg/dL (6.7 – 16.7 mmol/L) • Snooze time: 15 – 240 min • Alarm Tones, Vibrate or Off
PROJECTED LOW	The projected low glucose alarm provides an early warning of an event that is likely to occur if the current trend continues. You select how early you want to be notified (approximately 10, 20 or 30 minutes) before your glucose level is predicted to reach the threshold value.	• Advance Notice: 10, 20 or 30 minutes • Alarm Tones, Vibrate or Off
PROJECTED HIGH	The projected high glucose alarm provides an early warning of an event that is likely to occur if the current trend continues. You select how early you want to be notified (approximately 10, 20 or 30 minutes) before your glucose level is predicted to reach the threshold value.	• Advance Notice: 10, 20 or 30 minutes • Alarm Tones, Vibrate or Off
Data Loss Alarm	Notification that continuous data is no longer available.	Alarm Tones, Vibrate or Off
System Alarm	Notification for events like low battery and time to calibrate.	Alarm Tones, Vibrate or Off
Progress Tones	Sounds to assist you regarding the progress and status of specific steps, like performing a blood glucose check.	Volume: Low, High or Off

Glucose Alarms

Glucose alarms are notifications related to your continuous glucose readings. Work with your healthcare team to determine your glucose alarm settings. Alarms are displayed on your Receiver as a message. You may be alerted to an alarm by sound or vibration depending on your alarm settings.

If you are not receiving continuous glucose data, you do not get glucose alarms.

- CAUTIONS:**
- The Low and High Glucose Alarms should not be used exclusively to detect low or high glucose conditions. The alarms should always be used with other indications of glycaemic state such as your glucose level, trend, Timeline Graph, etc.
 - Do NOT rely solely on the projected glucose alarms for detection of low or high glucose conditions. Always use both the Low and High Glucose Threshold alarms AND the Projected Low and High Glucose Alarms for maximum notification of low or high glucose conditions.
 - 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 hypoglycaemia.
 - 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 hyperglycaemia.
 - Low and High Glucose Alarm thresholds are different from your **Glucose Targets**. Low and High Glucose Alarms alert you when you have passed your pre-set value. Glucose Targets allow the reports and Timeline Graphs to show how your glucose levels have been performing compared to your set targets.

Alarm Tones

You can turn on each alarm individually in the Tones screens. To turn On an alarm, select the Tone you would like to hear when the alarm occurs.



Menu → Alarms → Tones

Low Glucose	Beep
High Glucose	Pulse
Projected Low	Harp
Projected High	Zing
(Press Next to show page 2 of tones)	Delight
Data Loss	Rhythm
System	Vibe (vibrate)
	Off

Note: Exercise caution when turning off alarms. For example, if you turn off the Low Glucose Alarms, you do NOT receive text, audible nor vibratory notification for low glucose events.

Day/Night Glucose Alarms

GLUCOSE ALARMS

Day Start = 07:00

Night Start = 21:00

Next

Glucose Alarms	Options	Comments
Day Start	00:00 - 24:00	Day and Night Alarm settings allow you to define different glucose alarm thresholds for different times of the day.
Night Start	00:00 - 24:00	Day and Night Alarm settings allow you to define different glucose alarm thresholds for different times of the day.
	Off	If you only want to use one set of glucose alarms settings for the entire day, set Night Start = Off. The system will use the Day Alarms settings for the entire day.

Note: The system will not allow you to select the same time for Day Start and Night Start.

DAY ALARMS

Low Glucose = 80 mg/dL

High Glucose = 200 mg/dL

Projected Low = 20 min

Projected High = 20 min

Next

DAY AND NIGHT GLUCOSE ALARM TIMELINE IN 24-HOUR PERIOD

01:00

07:00

21:00

00:59

Legend

Uses Day Alarm settings

Uses Night Alarm settings

Menu → Alarms → Day/Night Alarms

Low Glucose	60 - 119 mg/dL (3.3 - 6.6 mmol/L)	Your Low Glucose Threshold; you will receive an alarm when your continuous glucose reading falls below this level
High Glucose	120 - 300 mg/dL (6.7 - 16.7 mmol/L)	Your High Glucose Threshold; you will receive an alarm when your continuous glucose reading exceeds this level
Projected Low	10, 20 or 30 minutes	Before your glucose level is predicted to reach the Low Glucose value
Projected High	10, 20 or 30 minutes	Before your glucose level is predicted to reach the High Glucose value

Audio/Vibrate Settings

The **Audio/Vibrate** screen allows you to set your alarms to audible or vibrate. For example, you may not want to hear your alarms during a meeting. You can also adjust the volume of your Progress Tones in this screen.

AUDIO / VIBRATE

Alarms = Audio

Volume = Medium

Progress Tones = Low

Accept

Menu → Alarms → Audio/Vibrate		
Alarms	Audio	If you select Audio, you will hear notifications based on your Tones settings
	Vibe	If you select Vibe, all alarm notifications are vibratory only
	Audio + Vibe	If you select Audio+Vibe, alarm notifications are both vibratory and audible according to your Tones settings
Volume	Low, Medium, High	Audio volume level for audible alarm notifications
Progress Tones	Low, High, Off	Audio volume level for Progress Tones

Note: Be aware that if the Receiver is set to vibrate and you place it too far from you, you may not hear it vibrate.

Mute/Un-Mute Alarms

You can temporarily mute the audio alarms on your Receiver for 1 to 12 hours. After the time has elapsed, the alarms automatically return to their original settings. Example, if you are going to the cinema to watch a film, you can set Mute Time to 2 hours before the film starts. After the film, you can expect to hear your alarms again.

MUTE ALARMS

Mute Time = 8 hours

Accept

Menu → Alarms → Mute/Un-Mute		
Mute Time	1-12 hours	How long you want to temporarily disable audible alarms

Note: Muting silences all audible notifications except for Low Glucose Alarms. Any alarms set to Vibe will continue to generate vibratory and onscreen text notifications. While alarms are muted, you will see a  on the Home screen. To turn off alarms for more than 12 hours, you must select **Menu → Alarms → Tones** and turn off alarms one at a time.

Alarm Snooze Setup

The FreeStyle Navigator II System includes a **Low Glucose Snooze** and **High Glucose Snooze** feature that allows you to set how frequently a Low Glucose or High Glucose Alarm repeats after you have already cleared the alarm.

SNOOZE SETUP

Low Glucose = 30 min

High Glucose = 60 min

Accept

Menu → Alarms → Snooze Setup		
Low Glucose	15 - 60 minutes	How soon you want to temporarily disable Low Glucose Alarms after you have cleared one
High Glucose	15 - 240 minutes	How soon you want to temporarily disable High Glucose Alarms after you have cleared one

Note: If it typically takes one to two hours for your glucose levels to fall after a correction bolus or injection, you may want to set the High Glucose snooze time to 60 min or 120 min to avoid unnecessary alarms.

Responding to Alarms

The title of alarm messages describes the cause of the alarm. Details on what the alarm means and what you can do are provided in the Receiver message. See Section 8 in the Expert Guide for a table listing other alarm messages that you may see on your Receiver. The possible cause(s) and recommended action for each alarm is provided.

Note: If you have tried the recommended actions and need additional help or have questions, call your healthcare team or Customer Care.

Softkey Buttons

If You Wish To ...	Action
... temporarily mute the alarm	Press the Right Softkey button to temporarily mute the alarm. The alarm will repeat every 5 minutes until it is cleared.
... clear the alarm	Press the Right Softkey button to turn on the display, then press the Left Softkey button to clear the alarm. Note that the receiver alarm may sound again after 15 minutes if your glucose remains above or below your High or Low Glucose Thresholds.

If an alarm occurs while the Receiver is displaying a screen besides the Home screen, you receive a flashing Pending Alarm symbol in the upper right corner of your Receiver screen. You also receive a Pending Alarm symbol if multiple alarms occur at the same time.

Troubleshooting

For troubleshooting information, see Section 11 in the Expert Guide. Call your healthcare professional or Customer Care for additional information.

Living with Your FreeStyle Navigator II System

Reconnecting to a Sensor if Signal is Interrupted

- If your Receiver and Transmitter become disconnected for any reason (as indicated by the icon), you can reconnect them by following the steps below.
1. Make sure that the Transmitter is firmly attached to the Sensor.
 2. The Receiver will automatically try to reconnect with the Transmitter within the first 30 minutes of being disconnected. If it has been more than 30 minutes, or if you want to re-establish connection immediately, select **Menu → Connect to Sensor**.
 3. Hold the Receiver directly on top of the Transmitter. When reconnection is successful, you will see the icon on the Home screen.
- Your FreeStyle Navigator II System can be used during a wide variety of indoor and outdoor activities. Depending on the activity, there are some considerations to be aware of:

Wireless Transmission Range

Your Transmitter and Receiver can maintain a connection at distances up to 30 metres (100 feet) in open air without obstructions. Individual experiences may vary depending upon the line of sight, walls, trees or other obstructions within the area.

Note: Be aware that if you are out of audible range of the Receiver, you will not hear any alarms if they occur. The Transmitter has no alarms.

Bathing, Showering and Swimming

The Receiver has exposed ports and should NEVER be submerged in liquids, however, your Sensor and Transmitter are water resistant. You can wear the Transmitter/Sensor Unit while bathing or showering. You may also swim while wearing the Transmitter/Sensor Unit. Do NOT go deeper than 1 metre (3 feet).

Sleeping

The Transmitter/Sensor Unit should not interfere with your normal sleeping patterns. As you get ready to go to sleep, place the Receiver nearby to hear any alarms that may occur. It is recommended to charge your Receiver overnight to avoid data interruption.

Visibility

The Receiver Display may be less visible in direct sunlight.

Travelling

Check with local authorities prior to departure as rules and regulations may change without notice. Follow these guidelines when travelling:

- Notify security personnel of the presence of the device when going through security systems.
- If you need to disable your Transmitter:

1. Select **Menu → Settings → Airplane Mode → Wireless = Off** and hold the Receiver directly on top of your Transmitter.

When your Transmitter is disabled, you will see the  icon and "In Airplane Mode" on the Home screen.

- To re-enable your Transmitter:

1. Select **Menu → Settings → Airplane Mode → Wireless = On** and hold the Receiver directly on top of your Transmitter.

You will see the  icon when the wireless communication of your Transmitter is re-enabled.

Note: If you are changing time zones, you can manually change the time and date settings on your Receiver by selecting **Menu → Settings → Time & Date**. Changing the time and date affects the Timeline Graph and statistical results.

How to Clean your Transmitter

The Transmitter should be removed from the Sensor Support Mount and cleaned each time you remove a used Sensor (every 5 days).

1. Wash the Transmitter with mild soap and water.
2. Rinse the Transmitter thoroughly under running water.
3. Dry the Transmitter thoroughly with a clean, soft, lint-free cloth or paper towel.
 - Shake and blot any water out of the Transmitter's contact points.
4. Make sure that the contact points are dry and clean. Check for apparent signs of damage such as bent contact points.



How to Clean your Receiver

1. Wipe the outside of your Receiver with a clean, soft, lint-free cloth or paper towel lightly dampened with either a mild soapy solution or 70% isopropyl alcohol. Always be careful not to get water or any other substance in the USB or test strip ports.
2. Use a clean, soft, lint-free cloth or paper towel to remove any remaining soap or alcohol.



CAUTIONS:

- Do NOT immerse the Receiver in water or any other liquid. Avoid getting water or any other substance in the USB and test strip ports.
- Do NOT clean your Receiver with steam.
- 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 casings of the Transmitter and Receiver.

How to Clean your Receiver Skin

1. Remove the Receiver Skin.
2. Wash the skin in mild soap and water and dry thoroughly.
3. Check to make sure the inside of the skin is completely dry before putting it back on the Receiver.



Disposal

This product should be disposed of in accordance with all applicable local regulations related to the disposal of electronic equipment, batteries, sharps and potentially biologically contaminated materials.

Contact Customer Care for further information on the appropriate disposal of system components.



The Transmitter must not be disposed of via standard waste collection. Separate collection for electrical and electronic equipment waste per Directive 2002/96/EC in the European Union is required.

System Specifications

Your FreeStyle Navigator II System specifications are listed in the following table:

Operating Temperature	4 °C to 40 °C (41 °F to 104 °F)
Storage Temperature	Store the Transmitter and Receiver between -10 °C (14 °F) and 45 °C (113 °F). Store Sensor Inserters and Sensor Support Mounts between 3 °C (37 °F) and 30 °C (86 °F). Store test strips between 4 °C (40 °F) and 30 °C (86 °F). Control solution should be stored between 2 °C (36 °F) and 30 °C (86 °F)
Operating Humidity (Receiver)	10% to 93% (non-condensing)
Operating and Storage Altitude	Sea level to 3,048 metres (10,000 feet)
Operating Pressure	1.0 bar (14.7 psia, sea level) to 0.7 bar (10.1 psia, 3,048 metres (10,000 feet))
Sensor Life	Up to 5 days
Sensor Operating Skin Surface Temperature	25 °C to 40 °C (77 °F to 104 °F)
Glucose Result Range	20 to 500 mg/dL (1.1 to 27.8 mmol/L)
Receiver Memory	60 days of normal use including continuous glucose readings (stored every 10 minutes) and daily blood glucose readings
Transmitter Battery and Battery Life	CR2032 Lithium Coin Cell, non-replaceable; up to 1 year of daily use under typical conditions
Receiver Battery and Battery Life	One Lithium-ion rechargeable, non-replaceable; Maximum voltage 4.1Volts. Typical capacity of 830mAhrs. Battery is UL 1642 Compliant. Charge sufficient for up to at least 3 days of typical use.
Wearing Transmitter Under Water	Up to 1 metre (3 feet) under water for no more than 45 minutes
Haematocrit (checking your Blood Glucose)	15% to 65%
Transmitter Skin Contact Material	The Transmitter has a temperature probe made of stainless steel that contacts the skin during wear. Surgical stainless steel contains 8 –14% nickel
Radio Frequency	Transmission range: Up to 3 metres (10 feet) through RF transparent materials; up to 30 metres (100 feet) in the absence of RF reflective materials Transmitter transmission frequency and power: less than 100uW (-10dBm) at 433.6MHz from at least 3 metres Receiver bandwidth: 102.4kHz bandwidth at 433.6MHz

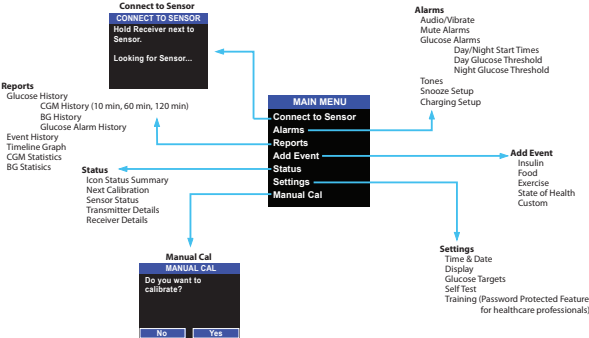
AC Adapter 5W USB	Abbott Diabetes Care PRT20992
Plug Kit AC adapter OUS	Abbott Diabetes Care PRT20993
Cable	Abbott Diabetes Care PRT23557-001 (ADC)

Ensure that you are using a personal computer that complies with the requirements of EN60950-1.

Glossary of Symbols

	Do Not Re-Use		Manufacturer
	Sterile		Consult Operating Instructions
	Use By		Batch Code
	Serial Number		Catalogue Number
	Caution		Authorised Representative in the European Community
	Temperature Limitation		CE Mark
	Do not use if package is damaged		Transmitter can withstand immersion into one metre of water for up to 30 minutes
	Type BF applied part		Keep dry
	Non-ionising radiation		

Receiver Screens



Receiver Icons

	Icon	Status	Display Indicators
Receiver		Not Charging	The battery icon contains 1 to 4 bars. Each bar represents 25% of battery charge. An icon without a plug indicates that the battery is not currently being charged.
		Charging	An icon with a plug indicates the battery is charging.
		Charged	If the entire icon is green, this indicates the Receiver is completely charged.
Audio/Vibrate		Audio and Vibrate	The audio and vibratory settings for your Receiver. The settings apply to glucose, data loss and system alarms, but not to your Progress Tones.
		Audio only	
		Vibrate only	
		Mute	
Wireless		Connected	The status of the wireless connection between the Transmitter and your Receiver.
		Not Connected	The system shows the Not Connected icon when the Transmitter and Receiver are not communicating.
Calibration		Hourglass	The Hourglass icon is displayed when calibration is needed but the system is not ready to be calibrated or when glucose results are temporarily unavailable. You may still check your blood glucose.
		Blood Drop	The Blood Drop icon indicates that it is time to calibrate.

More information on the status of your FreeStyle Navigator II System can be accessed by selecting **Menu → Status**.

Electromagnetic Compatibility

- The System needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this manual.
- Portable and mobile RF communications equipment can affect the System.
- The use of accessories, transducers and cables other than those specified by Abbott Diabetes Care may result in increased EMISSIONS or decreased IMMUNITY of the System.
- The System should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the System should be observed to verify normal operation in the configuration in which it will be used.

Guidance and manufacturer's declaration – electromagnetic emissions

The System is intended for use in the electromagnetic environment specified below. The customer or the user of the System should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The System uses RF energy only for its internal 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	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity

The System is intended for use in the electromagnetic environment specified below. The customer or the user of the System should assure that it is used in such an environment.

IMMUNITY test	IEC 60601 test level	Compliance Level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical domestic, commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical domestic, commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% <i>U</i> ¹ (>95% dip in <i>U</i> ¹) for 0.5 cycle 40% <i>U</i> ¹ (60% dip in <i>U</i> ¹) for 5 cycles 70% <i>U</i> ¹ (30% dip in <i>U</i> ¹) for 25 cycles <5% <i>U</i> ¹ (>95% dip in <i>U</i> ¹) for 5 seconds	<5% <i>U</i> ¹ (>95% dip in <i>U</i> ¹) for 0.5 cycle 40% <i>U</i> ¹ (60% dip in <i>U</i> ¹) for 5 cycles 70% <i>U</i> ¹ (30% dip in <i>U</i> ¹) for 25 cycles <5% <i>U</i> ¹ (>95% dip in <i>U</i> ¹) for 5 seconds	Mains power quality should be that of a typical domestic, commercial or hospital environment. If the user of the System requires continued operation during power mains interruptions, it is recommended that the System be powered from an uninterruptible power supply or a battery.

Note: *U*¹ is the a.c. mains voltage prior to application of the test level.

IMMUNITY test	IEC 60601 test level	Compliance Level	Electromagnetic environment – guidance
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical domestic, commercial or hospital environment.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2 \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	Recommended separation distance $d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz

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 metres (m).

Field strengths from fixed 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 (mobile/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the System is used exceeds the applicable RF compliance level above, the System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorientating or relocating the System.

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

Recommended separation distances between portable and mobile RF communications equipment and the System

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

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in metres (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 800 MHz, the separation distance for the higher frequency range applies.

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



Abbott Diabetes Care Ltd
Range Road
Witney, Oxon
OX29 0YL, UK



Abbott Diabetes Care Inc.
1360 South Loop Road
Alameda, CA 94502 USA



PRT22683-101

©2011-2013 ART22683-101 Rev. B 01/15

. in various jurisdictions.