



**Owner's Booklet**



# FreeStyle

## InsuLinX

Blood Glucose Monitoring System



 **Abbott**

## FreeStyle InsuLinx at a Glance

### Touch screen

Displays your test results and other important information. Use touch screen buttons to work with your meter.

### USB port

Plug in your micro USB cable here to download test results.

### Test strip port and light

Insert a test strip here. The meter powers on when you insert a test strip.

### Meter Home button

This button is used to turn the meter on and off, control the backlight and to go back to the Home screen.

### Test strip

Insert strip into the meter with printed side up.

### Sample areas

Apply blood or control solution to one sample area only.















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# Symbols

Symbol	What It Means
	Settings
	Extras
	Strip light on/off switch
	Reminders
	Logbook
	Insulin marker
	Weekly messages (not read and read)
	Insulin log feature
	Meter out of temperature range

Symbol	What It Means
	View blood glucose results in chart form when weekly messages option is turned on
	Drop down menu for sorting results in logbook chart view
	Meal marker: Before meal result
	Meal marker: After meal result
	Meal marker: Other time/no mark
	Indicates a control solution test result
	Low battery
	Caution

## Important Information About Your Blood Glucose Monitoring System

When removing your new FreeStyle InsuLinx system from its packaging, check that the contents are undamaged and that you have all parts listed below. If any parts are missing or damaged, contact Customer Service.

Your kit contains the following contents:

- 1 FreeStyle InsuLinx Meter
- 1 Micro USB Cable
- 1 Owner's Booklet
- 1 Carrying Case
- 1 FreeStyle Lancing Device II
- 10 Lancets
- 10 FreeStyle InsuLinx Test Strips (may be sold separately)
- 1 FreeStyle Control Solution - Normal (may be provided separately)

FreeStyle Control Solution is available in three ranges - Low, Normal and High. For additional supplies, please contact Customer Service at 1-800-222-3100 or your distributor or retail pharmacy.

### Intended Use

The FreeStyle InsuLinx Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertip. The FreeStyle InsuLinx Blood Glucose Monitoring System is intended to be used by a single person and should not be shared.

The FreeStyle InsuLinx Blood Glucose Monitoring System is intended for self testing outside the body (*in vitro* diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The FreeStyle InsuLinx Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes or for neonatal use.

The FreeStyle InsuLinx Blood Glucose Test Strips are for use with the FreeStyle InsuLinx Blood Glucose Meter to quantitatively measure glucose in capillary whole blood samples drawn from the fingertip.

**IMPORTANT:**

The device must not be used on more than one person including other family members due to the risk of spreading infection. All parts of the device and its accessories are considered biohazardous and can potentially transmit infectious diseases, even after performing the cleaning and disinfection procedure.<sup>1,2</sup>

If the meter is being operated by a second person who is providing testing assistance to the user, the meter and lancing device should be cleaned and disinfected prior to use by the second person.

Use only FreeStyle InsuLinx test strips and FreeStyle® control solution with this meter. Other products can produce inaccurate results.

- The meter displays results from 20 mg/dL to 500 mg/dL. Low or high blood glucose results can indicate a potentially serious medical condition. Contact your health care professional before taking any action based on an unclear message or result.
- The expected glucose level for a non-diabetic, non-pregnant fasting adult is under 100 mg/dL.<sup>3</sup>
- Two hours after meals, levels should be less than 140 mg/dL.<sup>3</sup>
- Consult your healthcare professional to determine the range that is appropriate for you.

**WARNING:**

- Test on your fingers if you are testing for low blood glucose (hypoglycemia) or if you suffer from hypoglycemia unawareness.
- This system contains small parts that may be dangerous if swallowed.

**CAUTION:**

- Please read all the instructions provided in this Owner's Booklet and practice the testing procedures before using the FreeStyle InsuLinx system. Before setting up and using your meter, work with your health care professional to determine which meter features are most appropriate for you and your diabetes management.


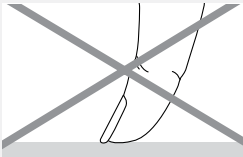
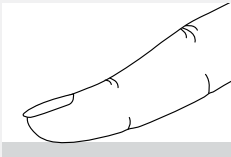



## Limitations:

- For in-vitro diagnostic use only (external use only).
- Not for diagnosis of or screening for diabetes.
- Not for testing of neonates.
- The test strips are for single use only. Do not reuse test strips.
- The system can give false results greater than 10,000 feet (3,048 meters) above sea level.
- The system can give false results outside the hematocrit range: 15% to 65%.
- Individuals experiencing a hypoxia state may yield falsely low results.
- In situations of decreased peripheral blood flow, capillary blood testing may not be appropriate as it may not represent the true physiological state. Examples would include but are not limited to: severe dehydration caused by diabetic ketoacidosis or the hyperosmolar non-ketotic state, hypotension, shock, or peripheral vascular disease.<sup>4, 5, 6</sup>
- This device should not be used to test critically ill patients.
- For single patient use at home by a lay user.
- Severe dehydration or excessive water loss may cause false low results. If you believe you are suffering from severe dehydration, consult your physician immediately.
- Cholesterol up to 500 mg/dL or triglycerides up to 3,000 mg/dL do not significantly affect test results. However, glucose values in specimens beyond these levels, should be interpreted with caution.

# Set up Your Meter for the First Time

Set the language, current date, and time.

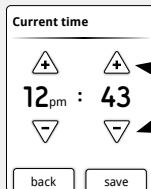
Step	Action
1	<p>Press the meter Home button.</p> 
2	<p>Tap the language you want the meter to use.</p> <div></div> <p>Use the pad of your finger.</p> <p>Do not use your fingernail or any other object to tap the screen</p> <p><b>Note:</b> The <b>OK</b> button will appear when you select the language. Tap the <b>OK</b> button to move to the next screen.</p>

3



Tap the **arrow buttons** to change the date. Then tap **save**.

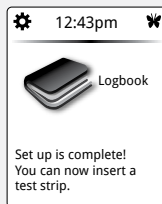
4



Tap the **arrow buttons** to set the time. Then tap **save**.

**Notes:**

- You will see the Home screen when you complete this step.



- If you don't complete these steps, the meter will continue to prompt you to set the language when you turn it on.

**IMPORTANT:** If the date and time are not set correctly, some meter functions may not work properly. If the meter loses time, the home screen will display --:-- until it is reset.

## Getting to Know Your Meter

Learn how to turn your meter on and off, find the Home screen, use the ? Help button, and use the backlight and strip light.

### Turn Your Meter On and Off



To turn the meter on:

- Press the meter Home button, or
- Insert a test strip.

To turn the meter off:

- If you're on the home screen, press the meter Home button, or
- Remove a test strip, or
- Do nothing for **2 minutes**.

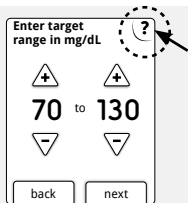
### Find the Home Screen



Most of your meter activities will begin at the Home screen.

Press the meter Home button anytime to return to the Home screen **except** when a test strip is inserted.

## Use the “?” Help Button



Tap the ? Help button anytime you see it and want more information.

## Turn the Backlight On and Off

The backlight can help you view the screen in low light.

To turn the backlight on:

- Press and hold the meter Home button for **3 seconds**.


To turn the backlight off:

- Wait for 15 seconds, or
- Press and hold the meter Home button for **3 seconds**.


## Turn the Strip Light On and Off



To turn the strip light on:

- If a test strip is inserted, press and hold the meter Home button for **3 seconds**.
- If a test strip is not inserted, turn the backlight on, then tap the strip light symbol  on the home screen.

To turn the strip light off:


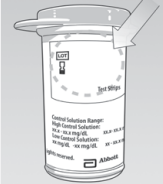
- Tap the strip light symbol .

# Test Your Blood Glucose

Get a blood glucose test result.

You will need:

- FreeStyle InsuLinx test strips that are not expired.
- Lancing device and new lancets to obtain a blood sample.

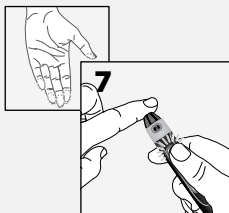
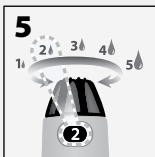
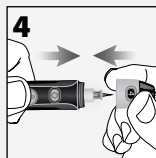
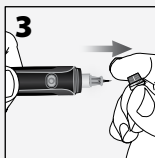
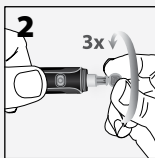
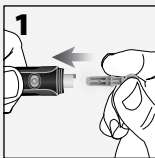
Step	Action	
1		<p>Wash your hands with soap and warm water. Rinse and dry thoroughly.</p> <ul style="list-style-type: none"><li>• Do <b>not</b> use lotion or cream on the test site.</li></ul>
2		<p>Check the test strip expiration date.</p> <ul style="list-style-type: none"><li>• Do <b>not</b> use expired test strips; they may cause inaccurate results.</li></ul>

**3**



Perform the test.

- a. Insert a test strip and close the test strip vial.
- b. Use your lancing device loaded with a lancet to obtain a blood drop from your fingertip.

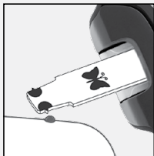


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### 3

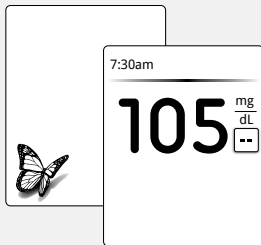
(Continued)



- c. Apply blood to the test strip as shown in the picture.
- d. The meter will beep once to let you know that you have applied enough blood.

**Notes:**

- Once you start applying blood, you have 60 seconds to fill the test strip on the same side of the test strip only. The time you have left is shown as a countdown on the screen.
- The time that the meter takes to display a result depends on your blood glucose level. The higher your blood glucose level, the longer it takes to get a result.
- The meter turns off after 2 minutes of inactivity. Remove and reinsert the unused test strip to restart the meter.



View the test result.

- A butterfly will appear on the screen while you wait for your result. The meter will beep twice when your result is ready.
- Remove and properly discard the test strip and lancet. Discard your used lancet properly in a puncture resistant container.

Refer to the *Your Test Results* section to learn how to understand and mark your test results.

**Notes:**



- Your result is now stored in your logbook.
- You should clean and disinfect your meter at least once per week. Refer to the *Cleaning and Disinfecting Your Meter* section for instructions.

**IMPORTANT:** After performing a blood glucose test, wash your hands with soap and water. Thoroughly dry your hands.

## Your Test Results

View, understand, and mark your test results; know what to do if you receive an error message.

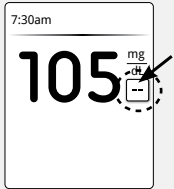

### Low and High Blood Glucose Results

Display	What To Do
<div> <b>Low glucose</b></div> <p>Appears when result is: lower than 70 mg/dL</p>	Follow your health care professional's advice to treat low blood glucose.
<div> <b>High glucose</b></div> <p>Appears when result is: higher than 240 mg/dL</p>	Follow your health care professional's advice to treat high blood glucose.

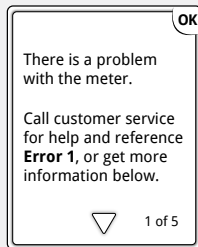
Display	What To Do
<p><b>LO</b></p> <p>Appears when result is: lower than 20 mg/dL</p>	<ol style="list-style-type: none"> <li>1. LO may indicate that your blood glucose is very low. Follow your health care professional's advice immediately and then repeat the test.</li> <li>2. If your blood glucose results do not match how you feel, perform a control solution test to confirm that your meter and strips are working properly.</li> </ol>
<p><b>HI</b></p> <p>Appears when result is: higher than 500 mg/dL</p>	<ol style="list-style-type: none"> <li>1. HI may indicate that your blood glucose is very high. Wash your hands and then repeat the test. If the result is HI again, follow your health care professional's advice immediately.</li> <li>2. If your blood glucose results do not match how you feel, perform a control solution test to confirm that your meter and strips are working properly.</li> </ol>

## Use Meal Markers

Mark your blood glucose test result as 'Before meal' or 'After meal', or as another time. Meal markers are used to provide additional information for Weekly Messages and in the FreeStyle Auto-Assist reports.

Step	Action
1	<div data-bbox="257 274 463 499"></div> <p data-bbox="488 274 1281 303">When viewing your blood glucose test result, tap the <b>dashes</b> -- .</p>
2	<div data-bbox="257 554 477 806"></div> <p data-bbox="488 554 1153 583">Tap your selection. Tap <b>OK</b> to return to the result screen.</p> <p data-bbox="488 595 573 621"><b>Notes:</b></p> <ul data-bbox="518 626 1263 850" style="list-style-type: none"><li>• If you mark as <b>Before meal</b>, you can choose to set a test reminder for 1 or 2 hours after your meal.</li><li>• You can select <b>Other time</b> if you are testing at times other than before or after a meal.</li><li>• If you need to, you can change a meal marker for the current result by tapping the meal marker button from the result screen.</li></ul>

## Error Messages



Example of an Error Message

Your meter will explain what an error message means, its possible causes, and what to do about it.

### Notes:

- Remember to tap the arrow button to see all of the important information.
- Tap **OK** to return to the Home screen.

## Temperature Warning



This symbol may appear after inserting a test strip. It will include a message saying the meter is either too hot or too cold to use right now. Blood glucose tests taken outside of the operating temperature range may not be accurate.

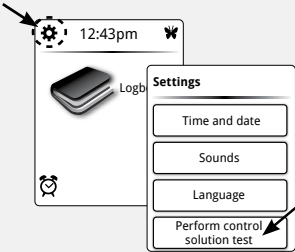

Tap **OK** to clear the screen and test again later.

## Control Solution Test

A control solution test should be performed when you are not sure of your results and want to confirm that your meter and test strips are working properly.

### IMPORTANT:


- Control solution results should fall within the control solution range printed on the test strip vial.
- Do **not** use control solution past its expiration date. Discard control solution 3 months after opening or on the expiration date printed on the bottle, whichever comes first. (Example: open April 15, discard July 15; write the discard date on the side of the bottle.)
- The control solution range is a target range for control solution only, not for your blood glucose level.
- Use only FreeStyle control solution with this meter.
- Replace the cap securely on the bottle immediately after use.
- Do not add water or other liquid to control solution.
- Contact Customer Service for information on how to obtain control solution.

Step	Action
1	<p>At the Home screen, tap <b>Settings</b> ⚙️. Then tap <b>Perform control solution test</b>.</p> 
2	<p>Perform the control solution test.</p> <ol style="list-style-type: none"> <li>Insert a test strip and close the test strip vial.</li> <li>Apply control solution to the test strip as shown in the picture.</li> <li>The meter will beep once to let you know that you have applied enough control solution.</li> <li>A butterfly will appear on the screen while you wait for the result. The meter will beep twice when the result is ready.</li> </ol> 



Compare the control solution result to the range printed on the test strip vial. The result should fall within the range.

**Notes:**


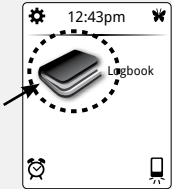
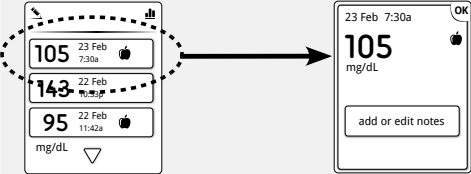
- If you see an error message on the screen, your meter will explain what it means, its possible causes, and what to do next.
- The result will be marked as a control solution test in your logbook. It will **not** be included in your charts and reports.
- You may also mark a control solution test after it is performed by following these steps:
  - a. At the Home screen, tap **Logbook** .
  - b. Tap your most recent test. You can only modify this result.
  - c. Tap the down arrow. Then tap **add or edit notes**.
  - d. Tap the option for **control solution test**. Then tap **OK**.
  - e. You can now see your most recent result marked as a control solution test.

Out of Range Control Solution Results

- Repeat the test if control solution results are outside the range printed on the test strip vial.
- Stop using the meter if control solution results are consistently outside the range printed on the test strip vial. Contact Customer Service.



# View Logbook

Review blood glucose history; review and log meals, insulin doses, notes about your test results, and control solution tests.

Step	Action
1	<p>At the Home screen, tap <b>Logbook</b> .</p> 
2	<p>Review your results.</p> <p><b>Notes:</b></p> <ul style="list-style-type: none"><li>• Use the down arrow to scroll through logbook entries.</li><li>• Tap any entry to see details of results and notes, if any.</li></ul> 

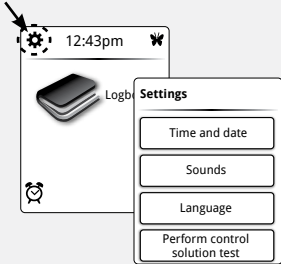
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**Notes (Continued):**

- If you turned on the Notes feature through FreeStyle Auto-Assist, you can tap the **add or edit notes** button to add or edit notes to your most recent result. Refer to the FreeStyle Auto-Assist *Set up Advanced Features for Your Meter Logbook* section for how to set up this feature.
- You can tap the  at the top left of the screen to use the Insulin Log feature and enter your insulin dose. Refer to the FreeStyle Auto-Assist *Set up Advanced Features for Your Meter Logbook* section for how to turn off this feature.
- If you turned on Weekly Messages, you will see the chart symbol  at the top right of the screen. Tap it to review your results for up to 14 days. To learn more about weekly messages, refer to the *Set up and Use Weekly Messages* section.
- A LO result (under 20 mg/dL) is included in the memory as LO.
- A HI result (over 500 mg/dL) is included in the memory as HI.

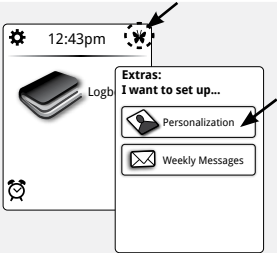

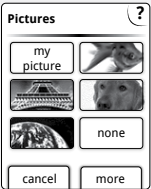
# Change Your Meter Settings

Change time and date, sounds, or language.

Step	Action
1	<div data-bbox="198 233 532 549"></div> <p data-bbox="578 233 1070 295">At the Home screen, tap <b>Settings</b> ⚙️. Then tap the setting you want to change.</p> <p data-bbox="578 305 1207 367"><b>Note:</b> Tap <b>Sounds</b> to change Notification and Button sounds.</p> <ul data-bbox="607 383 1227 543" style="list-style-type: none"><li>• Notification sound <b>On</b>: Meter will beep when the test strip is filled, the result appears on the screen, an error occurs, and when you get a reminder.</li><li>• Button sound <b>On</b>: Meter will beep each time you tap a button.</li></ul>
2	<p data-bbox="196 631 902 657">Press the meter Home button to return to the Home screen.</p> <p data-bbox="196 663 1127 694"><b>Note:</b> You can change your meter settings anytime by simply repeating Step 1.</p>

## Personalize Your Meter

Change the picture you see when you perform a blood glucose test.

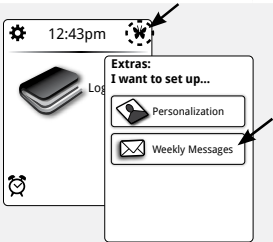

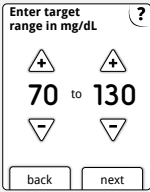
Step	Action
1	<div></div> <p>At the Home screen, tap <b>Extras</b>  . Then tap <b>Personalization</b>.</p>
2	<div></div> <p>Select your picture and tap <b>yes</b> to confirm the change.</p> <p><b>Notes:</b></p> <ul style="list-style-type: none"><li>You can also use <b>my picture</b> to select a personal picture such as a family member or pet. Refer to the <i>FreeStyle Auto-Assist Set up Your Meter Personalization</i> section for how to upload your picture.</li><li>You can change your picture anytime by simply repeating Steps 1 and 2.</li></ul>

# Set up and Use Weekly Messages

Turn on and use weekly messages. This feature will help you identify patterns in your blood glucose results.

**IMPORTANT:** Ask your health care professional for your blood glucose target range.

## Set up Weekly Messages

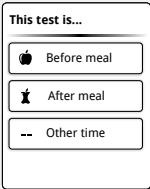



Step	Action
1	<div></div> <p>At the Home screen, tap <b>Extras</b> .</p> <p>Then tap <b>Weekly Messages</b>.</p>
2	<div></div> <p>Enter your target range. This is the desired target range for blood glucose values. This target range will only be used to determine Weekly Messages. Tap <b>next</b> to save.</p> <p><b>Notes:</b></p> <ul style="list-style-type: none"><li>• Target values cannot be set below 70 mg/dL or above 180 mg/dL.</li><li>• Tap the <b>?</b> Help button for more information.</li></ul>

**3**

Tap **done** to return to the Home screen.

**Note:** You can change your weekly messages settings anytime by simply repeating the setup procedure.

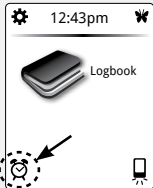

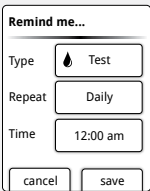
## Use Weekly Messages

Step	Action
1	Perform a blood glucose test.
2	<p>Mark your meal during the blood glucose test.</p> <p>If you have set up weekly messages, you will see this screen while you wait for your blood glucose test result. Tap your selection.</p> 
3	<p>Tap  Message to read weekly messages from the results screen. Then tap <b>OK</b> to get back to your blood glucose test result.</p> <p><b>Notes:</b></p> <ul style="list-style-type: none"> <li>• Weekly messages will also be stored in your logbook.</li> <li>•  is displayed after the message is read.</li> </ul> 

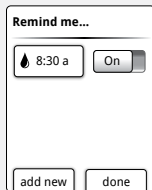
# Set up and Use Reminders

Set your meter to remind you when to test, when to take your insulin, or for other alarms.

## Set up Reminders

Step	Action
1	<div data-bbox="230 280 412 505"></div> <p data-bbox="463 280 1215 350">At the Home screen, tap the <b>Clock</b> .</p> <p data-bbox="463 322 1215 350">You will see the 'Remind me' screen with your menu of options.</p>
2	<div data-bbox="230 619 408 847"></div> <p data-bbox="463 619 1254 677">a. Tap <b>Type</b> of reminder button to select which reminder you want to set (Test, Take Insulin, or Alarm).</p> <p data-bbox="463 692 1208 750">b. Tap <b>Repeat</b> button to set how often you want the reminders (Daily, Once, Countdown Timer).</p> <p data-bbox="463 764 1218 843">c. Tap <b>Time</b> and tap the arrow buttons to set the reminder time. Tap <b>save</b>.</p>





You can now:

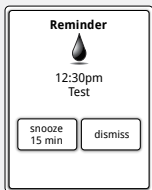
- Tap the **On/Off** button to turn a reminder on or off.
- Tap **add new** to set more reminders.

Tap **done** to return to the Home screen. When any reminders are turned On, the time of your next reminder will appear on your home screen next to the ⌚.

#### Notes:

- You can change your reminders anytime by simply repeating the setup procedure.
- To add a reminder such as when to exercise, refer to the FreeStyle Auto-Assist *Set up Meter Reminders* section.

## Use Reminders



Your reminder will appear even if the meter is turned off.

Tap your selection to **snooze** or **dismiss** your reminder.

#### Notes:

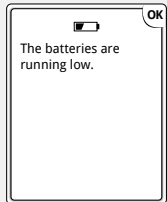
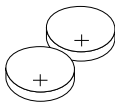
- Missed reminders will remain on the screen until dismissed.
- If you have set an insulin reminder, you will be able to log a dose after tapping **dismiss** when the reminder appears. This will not work if you turn the Insulin Log feature off. If you enter a rapid-acting insulin dose here, it will be stored as "meal" insulin when you print reports through FreeStyle Auto-Assist.

## Taking Care of Your Meter

Take care of your meter and keep it operating safely.

### Changing Batteries

**Note:** The meter uses **2** replaceable CR 2032 coin cell batteries.

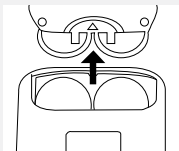


You will see this screen when your batteries are low.

**Note:** Your meter settings and logbook information will be saved when you change the batteries.

**IMPORTANT:** After you first see this warning, you can perform approximately 28 tests before you need to change the batteries.

Step	Action
1	<p>Change your batteries.</p> <ol style="list-style-type: none"><li>Slide open the battery door on the back of the meter.</li><li>Remove the old batteries.</li><li>Install new batteries with (+) facing up.</li><li>Slide the door back into place until it clicks.</li></ol> <p><b>Note:</b> The next time you turn your meter on, it will ask you to confirm the time and date.</p>



*Used batteries should be removed and disposed as required by local regulations.*

## **Cleaning and Disinfecting Your Meter and Lancing Device**

Cleaning and disinfecting your meter and lancing device is important to prevent the spread of infectious diseases. It is recommended that you clean and disinfect your meter and lancing device a minimum of once per week. The meter has a use life of 5 years, which is 522 cleaning and 522 disinfection cycles (2 cycles per week for 5 years). The lancing device has a use life of 2 years, which is 210 cleaning and 210 disinfection cycles (2 cycles per week for 2 years).

If the meter is being operated by a second person who is providing testing assistance to the user, the meter and lancing device should be cleaned and disinfected prior to use by the second person.

Cleaning is the physical removal of organic soil from the meter and lancing device surfaces. By keeping your meter and lancing device clean, you help ensure that it is working properly and that no dirt gets in the device. Cleaning allows for successful, subsequent disinfection.

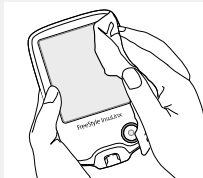
Disinfection is a process that destroys pathogens, such as viruses and other microorganisms on the meter and lancing device surfaces. By disinfecting your meter and lancing device, you help ensure that no infection is passed when you or others come in contact with your meter and lancing device.

<b>Step</b>	<b>Action</b>
<b>1</b>	Assemble cleaning and disinfecting supplies: Clorox Healthcare Bleach Germicidal Wipes, EPA Reg. #67619-12. These disinfectant wipes contain a 0.55% Sodium Hypochlorite (NaOCl) solution and have been shown to be safe for use with the meter and lancing device. They may be purchased at major online retailers, such as Walmart.com, Amazon.com, and OfficeDepot.com.

**IMPORTANT:** Do **not** place the meter or lancing device in water or other liquids. Avoid getting dust, dirt, blood, control solution, water, or any other substance in the meter's test strip port and USB port.

For cleaning, wipe all outside surfaces of the meter and lancing device thoroughly with the bleach wipes until they are visibly clean. Clean the strip port, data port and battery compartment with caution and do not force liquids into sensitive meter electronic openings. Clean your meter at least once a week. Clean your lancing device when visibly dirty (at least once a week).

For disinfection, wipe all outside surfaces of your meter and the lancing device until they are wet in order to disinfect the meter or the lancing device. Clean the strip port, data port and battery compartment with caution and do not force liquids into sensitive meter electronic openings. Surfaces must remain wet for a full one (1) minute. After 1 full minute, immediately dry with drying towel to remove any residual moisture. Disinfect your meter at least once a week. Disinfect your lancing device when visibly dirty (at least once a week).



**Note:** Squeeze bleach wipe to remove excess solution before wiping the meter or lancing device.

**3**

Allow the meter or lancing device to air dry completely before performing a blood glucose test.

**Note:** If you notice any signs of deterioration on the meter or lancing device (such as clouding or crazing on the display of the meter, corroding or eroding of the plastic housing or button, or cracking of plastic housing, display, or button) or if the meter does not turn on or if the lancing device does not work after cleaning and disinfection, discontinue use of the meter or lancing device and contact Customer Service.

**4**

When finished, thoroughly wash your hands with soap and water. If you require assistance or see signs of deterioration on your meter or lancing device (such as clouding or crazing on the display of the meter, corroding or eroding of the plastic housing or button, or cracking of plastic housing, display, or button), contact Customer Service at 1-800-222-3100.

## Troubleshooting

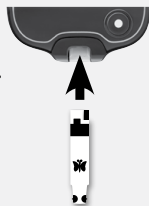
### 1. Test strip is inserted in the port and nothing happens.

#### What It Means

- Test strip is inserted incorrectly or not fully inserted into the meter

#### What To Do

Insert the test strip as shown.



- No batteries are installed
- Batteries are installed incorrectly

Install batteries with (+) facing up.

- Dead batteries

1. Change batteries. Reset date and time, if needed.
2. If problem continues, contact Customer Service.

- Meter may be plugged into a computer

Unplug the meter from the computer.

- Problem with test strip

Try a new test strip.

- Problem with meter
- Blood or foreign objects put in the test strip port

Contact Customer Service.

**2. The test does not start after applying the blood drop.**

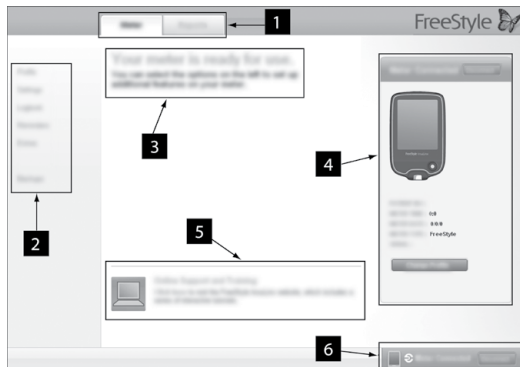
<b>What It Means</b>	<b>What To Do</b>
<ul style="list-style-type: none"><li>• Blood drop is too small</li></ul>	Add blood to the same sample area within 60 seconds, or repeat the test using a new test strip and a larger blood drop.
<ul style="list-style-type: none"><li>• Problem with test strip</li><li>• Sample applied after meter turns off</li></ul>	<ol style="list-style-type: none"><li>1. Repeat the test using a new test strip. Wait for 'apply blood to strip' message to appear before applying blood (or 'apply control solution to strip' message if you are applying control solution).</li><li>2. If problem continues, contact Customer Service.</li></ol>
<ul style="list-style-type: none"><li>• Problem with meter</li></ul>	Contact Customer Service.

# FreeStyle Auto-Assist: Progress Reporting Software

## Getting to Know Your FreeStyle Auto-Assist Software

Welcome to FreeStyle Auto-Assist. This software tool allows you to take a more informed role in managing your diabetes. It can help you and your health care professional evaluate needs and options for your diabetes management program.

**Note:** Your meter must be connected to the computer in order to modify settings or view reports. Reports will be created based on the current data saved on your meter. No data from the meter logbook is saved to your computer.



1. **Meter and Report tabs:** Provide access to meter setup features or report options.
2. **Submenu:** Provides access to additional features within each tab.
3. **Message box:** Keeps you posted on software status and any next steps (if needed).
4. **Meter information:** Shows meter details such as time, date, serial number, and patient name/ID.

5. **Online Support and Training:** Provides a link to online training and support.
6. **Meter Status Bar:** Displays meter connection status.



## Install the FreeStyle Auto-Assist Software

**Note:** FreeStyle Auto-Assist is compatible with both PC and Mac operating systems.

Step	Action
1	With your meter off, use the provided micro USB cable to connect your meter's USB port to your computer. If you do not have the micro USB cable provided with the meter, you may use other micro USB cables.
2	The software will start automatically for installation or use. Follow the InstallShield Wizard prompts. Click <b>Next</b> after each entry. Note that you may be asked to supply an administrator password.
3	Click <b>Finish</b> or <b>Close</b> once installation is complete. The program will automatically launch whenever you connect the meter to your computer.

**WARNING:** To avoid the possibility of electric shock, never perform a blood glucose test while the meter is connected to the computer.

If the installation does not automatically start, follow the steps below to install the software.

### **Windows Computer Systems (includes Windows 7, Windows Vista and Windows XP)**

<b>Step</b>	<b>Action</b>
<b>1</b>	Locate “My Computer” on your desktop. Double-click “My Computer” to open.
<b>2</b>	Locate the “FreeStyle Auto-Assist” icon. Double-click on this icon to open.
<b>3</b>	Locate the “Windows” folder. Double-click on this folder to open.
<b>4</b>	Locate the “Disk1” folder. Double-click on this folder to open.
<b>5</b>	Locate the “Setup application” icon. Double-click on this icon to begin the installation.

### **Macintosh Computer Systems (OS X, includes Leopard, Snow Leopard and Lion)**

<b>Step</b>	<b>Action</b>
<b>1</b>	In the Finder window, select the Device called “FreeStyle Auto-Assist” in the Devices section.
<b>2</b>	Within the FreeStyle Auto-Assist Device, select “Mac”.
<b>3</b>	Double-click on the “FreeStyle Auto-Assist.pkg” file.

For additional questions, please contact Customer Service.

## FreeStyle Auto-Assist System Requirements

- At minimum, a computer with a USB 2.0 compliant hub running Windows with a single-core 1GHz processor and 512MB RAM or running Mac OS X Leopard with an Intel dual-core 1.83GHz processor and 512MB RAM.
- Compatible operating systems:
  - Windows 7 (32 and 64 bit)
  - Windows Vista (32 and 64 bit)
  - Windows XP (Service Pack 3)
  - Macintosh Leopard, Snow Leopard and Lion (Intel processor)

## Change Your Meter Settings

Change clock style, language, or sound preferences.

Step	Action
1	Go to the <b>Meter</b> tab. On the left side of the screen, click <b>Settings</b> .
2	Make your selections: <ul style="list-style-type: none"><li>a. <b>Clock style</b>, click your choice.</li><li>b. <b>Language</b>, select your choice.</li><li>c. <b>Sound</b>, click On or Off to change your Notification or Button sounds.</li></ul>
3	Click <b>Save to meter</b> .



## Set up Advanced Features for Your Meter Logbook

Set up additional meter logbook features such as the ability to log all your insulin doses and add up to 11 custom notes that can be logged with your blood glucose test results.

### Set up the Insulin Log Feature


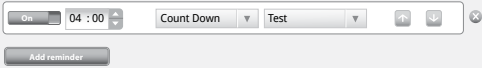
Step	Action
1	Go to the <b>Meter</b> tab. On the left side of the screen, click <b>Logbook</b> .
2	Make your selections: a. The feature is on when you receive the meter. If you want to turn it off, click the button to <b>Off</b> . If you want to turn it back on, click the button to <b>On</b> to record your insulin doses. b. Check the appropriate boxes for the types of insulin you take.
3	Click <b>Save to meter</b> . For more information about adding insulin doses to your meter logbook, refer to the <i>View Logbook</i> section.

## Set up Notes for Your Meter Logbook

Step	Action
1	Go to the <b>Meter</b> tab. On the left side of the screen, click <b>Logbook</b> .
2	Click <b>Notes</b> on the Logbook submenu.
3	<p>Make your selections:</p> <ol style="list-style-type: none"><li>Click the button to <b>On</b> to use Notes.</li><li>The first four notes are: Exercise, Felt ill, Medication, and Felt low. You can choose to accept these; or</li><li>Edit, change order, delete, or add up to 11 custom notes.<ul style="list-style-type: none"><li>Click <b>Edit note</b> to change the name of a note. Then click <b>Done</b>.</li><li>Change the order of the notes by using the up and down arrows (this will change the order they appear on the meter).</li><li>Click the  button next to the note you want to delete.</li><li>Click <b>Add note</b> to add a custom note.</li></ul></li></ol> 
4	<p>Click <b>Save to meter</b>.</p> <p>For more information about adding notes to results in your meter logbook, refer to the <i>View Logbook</i> section.</p>


## Set up Meter Reminders

Set your meter to remind you when to test, when to take your insulin, or for other alarms. The software allows you to set up to 12 different personal reminders.

Step	Action
1	Go to the <b>Meter</b> tab. On the left side of the screen, click <b>Reminders</b> .
2	Set up to 12 reminders by clicking <b>Add reminder</b> .
3	<p>Set up your reminders:</p> <ol style="list-style-type: none"><li>Click the <b>On/Off</b> button to turn a reminder On or Off.</li><li>Use the up and down arrows to select the time.</li><li>Use the drop down menus to select when you want the reminder repeated and the type of reminder. You can also add a custom type of reminder.</li><li>Click <b>Add</b> to add the reminder.</li><li>Change the order of the reminders by using the up and down arrows (this will change the order they appear on the meter).</li><li>Click the  button next to the reminder you want to delete.</li></ol> 
4	<p>Click <b>Save to meter</b>.</p> <p>For more information about reminders on your meter, refer to the <i>Set up and Use Reminders</i> section.</p>

## Set up Your Meter Personalization

Change the picture you see when you perform a blood glucose test.

Step	Action
1	Go to the <b>Meter</b> tab. On the left side of the screen, click <b>Extras</b> .
2	Make your selection: <ul style="list-style-type: none"><li>Click on one of the available pictures to select it. Click <b>Save to meter</b>. You will now see this picture each time you perform a blood glucose test.</li><li>If you would like to use a personal picture from your computer, go to Step 3.</li></ul>
3	Click <b>My Picture</b> .
4	<p>Upload a personal picture from your computer.</p> <p>a. Click <b>Choose</b>.</p> <p>b. Select your picture. Click <b>Open</b>.</p> <p>c. Adjust your picture so that it fits inside the borders of the box. To change the size, use the slider bar.</p>  <p>d. Click <b>Set Picture</b>.</p> <p>e. Click <b>Save to meter</b>.</p> <p>For more information about personalizing your meter, refer to the <i>Personalize Your Meter</i> section.</p>



Example  
personal picture

## Change Rapid-acting Insulin Dose Increments

Set your insulin dose increments to either 1.0 or 0.5 units for use with the Insulin Log feature.

**IMPORTANT:** It is strongly recommended that you work with your health care professional to determine which insulin dose increment is best for you.

Step	Action
1	Go to the <b>Meter</b> tab. On the left side of the screen, click <b>Extras</b> .
2	Click <b>Dose Increments</b> .
3	Click your choice, <b>1.0</b> unit or <b>0.5</b> unit.
4	Click <b>Save to meter</b> .



## Set up Weekly Messages on Your Meter




Turn on weekly messages. This feature will help you identify patterns in your blood glucose results.

**IMPORTANT:** Ask your health care professional for your blood glucose target ranges.

Step	Action
1	Go to the <b>Meter</b> tab. On the left side of the screen, click <b>Extras</b> .
2	Turn on Weekly Messages. a. Click <b>Weekly Messages</b> . b. Click the button to <b>On</b> to use this feature. c. Enter your target range.
3	Click <b>Save to meter</b> . For more information about weekly messages on your meter, refer to the <i>Set up and Use Weekly Messages</i> section.

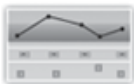
# FreeStyle Auto-Assist Reports

The FreeStyle Auto-Assist software allows you to choose from six reports:

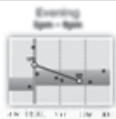
Report	What It Does
	<p><b>The Snapshot report</b> is a general summary of data for the specified date range. It also includes notes that inform you and your health care professional about important trends in blood glucose data by putting the data into words. Up to six notes will be displayed at one time, in order of clinical significance.</p>
	<p><b>The Modal Day Report</b> shows the daily pattern of blood glucose levels over the specified date range.</p>
	<p><b>The Logbook Report</b> is a table of blood glucose and insulin values for each day in the specified date range.</p>

## Report

## What It Does



**The Daily Statistics Report** provides an overview of blood glucose and insulin data over the date range and displays it in a series of easy-to-read tables.



**The Meal Event Averages Report** compares the before meal and after meal blood glucose levels for the morning, midday, and evening times over the specified date range. This report also shows before and after meal averages, and insulin intake for meals.



**The Meter Settings Report** shows current meter and insulin settings.

## Set up or Change Report Preferences


The FreeStyle Auto-Assist software allows you to set the following report preferences:

- Report set
- Time frame
- Glucose Targets  
(includes hypoglycemia threshold)
- Auto-save options
- Print color
- Quick print

**IMPORTANT:** Work with your health care professional to understand your report data.

**Note:** Your blood glucose targets and hypoglycemia threshold preferences will only be used in the reports and will not change any meter settings.

**Note to health care professionals:** These preferences will be stored on your computer and will be used when creating reports from any meter.

Step	Action
1	Go to the <b>Reports</b> tab. If this is the first time you are creating reports, click  to be guided through the report preferences setup.
2	If you wish to change your report preferences, click <b>Report Preferences</b> on the left side of the screen. Use the submenus to change your report preferences.

## Create, View, Save, and Print Reports

Step	Action
1	<p>Go to the <b>Reports</b> tab. On the left side of the screen, click <b>Create Reports</b>.</p> <p><b>Note:</b> You can change report settings from this screen by clicking <b>Edit</b> on the setting you wish to change. Click <b>Done</b> to save changes. These changes are not stored in Report Preferences.</p>
2	<p>If you would like to preview the reports, click <b>View on Screen</b>. Use the arrows to view the next/previous report page.</p> <p>To save the report as a PDF, click <b>Save</b>.</p> <p><b>Note:</b> The Adobe Acrobat Reader program must be installed on your computer to save files in Adobe Acrobat PDF format. Go to <b>www.Adobe.com</b> for instructions on downloading this program free over the Internet.</p> <p>Click <b>Print</b> to print your selected reports.</p>

## Additional FreeStyle Auto-Assist Features

Feature	What It Does	How To Access
<b>First time Meter Setup</b>	Sets your meter's language, date, and time.	If you have not yet set up your meter, plug it into your computer and click <b>Set up Meter</b> from the Welcome screen.
<b>Export Data</b>	Exports meter data to a text file.	From the menu bar at the top of the screen, click <b>File</b> . From the drop down, click <b>Export data</b> .
<b>Update Software</b>	Installs updates to your FreeStyle Auto-Assist software and meter.	Your FreeStyle Auto-Assist software will alert you when updates are ready.
<b>Backup Meter Files</b>	Saves a backup file containing your current meter settings and preferences.	Go to the <b>Meter</b> tab. On the left side of the screen, click <b>Backups</b> . Click <b>Save backup file</b> .
<b>Restore Meter Files</b>	Replaces your current meter settings with settings from a backup file.	Go to the <b>Meter</b> tab. On the left side of the screen, click <b>Backups</b> . Click <b>Restore Settings</b> .

**IMPORTANT:** Make sure you choose the proper file to restore. If the incorrect file is chosen, the meter may be set with the wrong settings (such as insulin settings or blood glucose targets).

## Meter Specifications




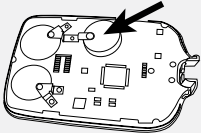
<b>Altitude</b>	Up to 10,000 feet (3,048 meters) above sea level
<b>Assay method</b>	Coulometric electrochemical sensor
<b>Automatic shutoff</b>	Two minutes of inactivity
<b>Battery life</b>	Up to 3000 tests
<b>Calibration</b>	Plasma equivalent glucose values
<b>Meter cleaning and disinfection:</b>	The meter has a use life of 5 years, which is 522 cleaning and 522 disinfection cycles (2 cycles per week for 5 years).
<b>Lancing device cleaning and disinfection:</b>	The lancing device has a use life of 2 years, which is 210 cleaning and 210 disinfection cycles (2 cycles per week for 2 years).
<b>Hematocrit</b>	15% to 65%
<b>Service Life</b>	5 years
<b>Measurement unit</b>	mg/dL
<b>Meter storage temperature</b>	-4 °F to 140 °F (-20 °C to 60 °C)

<b>Memory</b>	Up to 165 days based on an average of 3 tests and 3 insulin logs per day
<b>Minimum Computer Requirements</b>	System must only be used with EN60950-1 rated computers. Use a USB certified cable.
<b>Operating relative humidity</b>	5% to 90% (non-condensing)
<b>Operating temperature</b>	40 °F to 104 °F (4 °C to 40 °C)
<b>Power source</b>	Three CR 2032 3V lithium batteries, two of which are replaceable
<b>Result range</b>	20 mg/dL to 500 mg/dL
<b>Sample</b>	Fresh capillary whole blood samples
<b>Sample size</b>	0.3 microliter (300 nanoliters)
<b>Size</b>	2.4 in (w) x 3.8 in (l) x 0.6 in (d)      6.0 cm (w) x 9.5 cm (l) x 1.5 cm (d)
<b>Weight</b>	2.1 to 2.3 oz. (59.4 to 65.6 g) including batteries



## Appendix — End of Meter Life/ Backup Battery Removal

**Note:** Carry out this process only when you no longer intend to use the meter. The meter will no longer operate once opened to remove the backup battery.

Step	Action	
1		Remove battery door.
2		Insert small screwdriver blade between case above the USB port.
3		Pry case open with screwdriver. Continue prying around the case until the case separates.
4		Remove backup battery and dispose of battery and meter properly.

## References:

- <sup>1</sup> "FDA Public Health Notification: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication" (2010) <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm>
- <sup>2</sup> "CDC Clinical Reminder: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens" (2010) <http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html>
- <sup>3</sup> American Diabetes Association. (2015). 2. Classification and Diagnosis of Diabetes. Diabetes Care, 38(Supplement 1), S8-S16.
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