FreeStyle
Optium Neo
Blood Glucose and Ketone Monitoring System

Owner's Setup Guide
User's Manual

Abbott

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1 FreeStyle Optium Neo At-A-Glance

Display Window
- Displays meter Home screen (shown here)
- Displays your test results and other important information

Logbook

Up Button

USB Port
- Insert a data cable here for uploading test results to a computer (data management system required)

Power Button
- Turns meter on and off and returns to the Home screen

Strip Port
- Insert a test strip here

Down Button

Test Strip
- Insert the test strip into the meter

Target Area
- Apply blood or control solution to the white target area at the end of the test strip

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2 Meter Symbols

Symbol	What It Means	Symbol	What It Means
	Logbook		Breakfast insulin dose
	Meter ready for sample application		Lunch insulin dose
CtL	Control solution result		Dinner insulin dose
U	Units of insulin		Fasting test
	Insulin	KET	Ketone
	Morning long-acting insulin dose		Low battery
	Evening long-acting insulin dose	PC	Connected to computer
SEt	Insulin dose setup		Setup mode
↓	Low blood glucose or pattern	↑	High blood glucose or pattern

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3 Quick Start – Testing Your Blood Glucose

1. **Wash and dry hands before and after testing.**
   Note: Check test strip expiry date.

2. **Insert strip.**

3. **Lance test site and apply blood.**

4. **View result.**
   For more information on how to perform a test, see Section 7.

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4 Intended Use

The FreeStyle Optium Neo Blood Glucose and Ketone Monitoring System is for use outside the body only (*in vitro* diagnostic use) for self testing or professional use as an aid in the management of diabetes.

Use for measuring glucose in fresh whole blood samples taken from fingers, forearm, upper arm or the base of the thumb. Use for measuring ketone (β-hydroxybutyrate) in fresh whole blood samples from fingers only.

The system may also aid in the management of diabetes by providing the user with suggested recommendations to insulin dose(s) based on healthcare professional entered data.

IMPORTANT:
- Use only FreeStyle Optium blood glucose test strips and FreeStyle Optium blood β-Ketone test strips. Other test strips may produce inaccurate results.
- See test strip instructions for use for more information about sample types.
- Read the instructions in this Owner's Setup Guide. Failure to follow instructions may cause incorrect results. Practice the testing procedures before using the meter.
- Follow your healthcare professional's advice when testing blood glucose levels and blood ketone levels.
- Observe caution when using around children. Small parts may constitute a choking hazard.

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5 Getting to Know Your Meter

Turning Your Meter On and Off

To turn your meter on:
- Press the ✎, or
- Insert a strip

To turn your meter off:
- Press and hold the ✎ for 3 seconds, or
- Do nothing for 2 minutes

Checking Your Meter Screen Every Time You Turn It On

Meter Off Screen

Start-up Test Screen

Your meter screen should be fully black when powered off. Each time you turn on your meter, a white start-up test screen will appear for 1 second.

If you see any *white* segments in the black off screen, or any *black* segments in the white test screen, there may be a problem with the meter. Contact Customer Care.

Note: If the meter battery is low, the ▯◘◙ *will appear in both the meter off screen and start-up test screen.*

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6 Setting Up the Meter

To confirm that the date and time are set correctly, follow the steps below.

Set Time

1. Start with meter off (no test strip inserted)
   - Press ✎ to turn on the meter
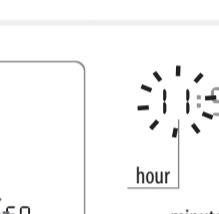
2. Press and hold the time (11:50) on the screen for 3 seconds until the screen changes.

3. Set Time Format (12 hour or 24 hour clock)
   - Press ⌄ or ⌃ to change
   - Press ✎ to continue
   Note: Your meter can display either a 12 h (1:23 PM) or 24 h (13:23) time format. If you prefer the 12 h format, there is no "AM". If setting a PM time, continue to press ⌃ until you see the "PM".
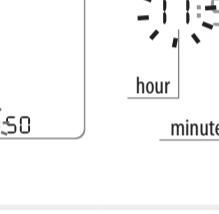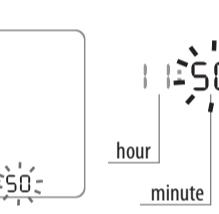
4. Set Hour
   - The hour blinks. Press ⌄ or ⌃ to set the hour
   - Press ✎ to continue
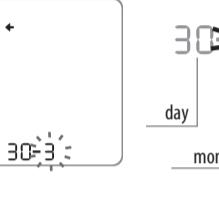
5. Set Minutes
   - The minutes blink. Press ⌄ or ⌃ to set the minutes
   - Press ✎ to continue

12 h (e.g. 1:23 PM)
24 h (e.g. 13:23)

Set Date

6. Set Month
   - The month blinks. Press ⌄ or ⌃ to set the month
   - Press ✎ to continue

7. Set Day
   - The day blinks. Press ⌄ or ⌃ to set the day
   - Press ✎ to continue

8. Set Year
   - Press ⌄ or ⌃ to set the year
   - Press ✎ to save. Setup complete

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7 Testing Your Blood Glucose or Blood Ketone

IMPORTANT:
- Only use a test strip once.
- Read the test strip instructions for use before performing your first blood glucose or ketone test. It contains important information and will tell you how to store and handle the test strips.
- The meter and its accessories are for use by a single person.
- Refer to the lancing device insert for detailed instructions on how to use the lancing device.
- Do not put urine on the test strip.

Check your ketone:
- When you have an illness
- When your blood glucose is above 13.3 mmol/L
- When you and your healthcare professional feel it is necessary

Prepare to Test

1. **Select your test site.**
   Test site choices for blood glucose testing are fingers, forearm, upper arm, or base of the thumb. Use only fingertip blood samples for blood ketone testing.
   Note: Avoid moles, veins, bones, and tendons. Bruising may occur at the test site. If bruising occurs, consider selecting another site.

   Do **not** use blood samples from alternative sites when:
   - You think your blood glucose is low or changing rapidly
   - You have been diagnosed with hypoglycaemic unawareness
   - Alternative site results do not match the way you feel
   - You are within two hours of eating a meal, taking insulin, or exercising

2. **Wash your hands** and the test site with soap and warm water.
   - Rinse and dry thoroughly.
   - Do **not** use lotion or cream on the test site.

3. **Check test strip expiry date.**
   Do **not** use expired test strips; they may cause inaccurate results.

Performing a Blood Glucose or Blood Ketone Test

1. **Open the foil test strip packet** at the notch and tear down to remove the test strip.

2. **Insert the test strip** into the meter until it stops. This will turn on the meter.
   Notes:
   - Be sure to check that your meter screen is working properly each time you turn your meter on. If you see any white segments in the black off screen, or any black segments in the white test screen, there may be a problem with the meter. (See Section 5, Getting to Know Your Meter, for more details)
   - The meter turns off after 3 minutes of inactivity. Remove and reinsert the unused test strip to restart the meter.

   The ◉ blinks, indicating the meter is ready for you to apply a sample to the test strip.
   Note: KET will appear on the screen if you have inserted a purple blood ketone strip.

3. **Obtain a blood sample.**
   Use the lancing device to obtain a blood sample. (See lancing device instructions for use for more information.)

4. **Apply blood to the test strip.**
   Bring the blood drop to the white area at the end of the test strip. The blood is drawn into the test strip.
   Hold blood to test strip until you see 3 short lines on the meter screen. This means you have applied enough blood.
   Notes:
   - If you are testing blood glucose, you will see a 5-second countdown. If you are testing blood ketone, you will see a 10-second countdown.
   - Do **not** remove the test strip from the meter during the countdown.
   - If the countdown does not start, you may not have applied enough blood to the test strip. See test strip instructions for use for re-application instructions. If the countdown still does not start, remove the used strip and discard it correctly. Start a new test with a new test strip.

   Blood Glucose Result example
   Blood Ketone Result example

5. **View the result.**
   The test is complete when the result appears on the meter screen (examples shown). The result is stored in memory.
   Note: If you see a ✓ this means the meter can suggest a new meal insulin dose. Ignore this if you're not about to eat a meal and take your meal insulin dose.

6. Press and hold ✎ to turn off the meter. Discard the used test strip correctly.

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8 Understanding Blood Glucose Test Results and Patterns

The meter displays blood glucose results in mmol/L. The unit of measurement is preset. You cannot change this setting.

IMPORTANT: The meter displays results from 1.1 - 27.8 mmol/L. Low or high blood glucose results can indicate a potentially serious medical condition.

Low Blood Glucose Results

If You See . . .	What It Means	What To Do
A solid red arrow / A blinking red arrow	Appears when result is lower than 3.9 mmol/L or the target set on the meter by your healthcare professional.	Follow your healthcare professional's advice to treat low blood glucose.
	A pattern of low glucose has developed. If 2 low results occur within the past 5 days AND both are within the same 3-hour time period, the meter will display a blinking ↓.	Follow your healthcare professional's advice to treat low blood glucose.
LO Appears when result is lower than 1.1 mmol/L	Severe low blood glucose **or** There may be a problem with the test strip.	Repeat the test with a new test strip. If the result is LO, contact your healthcare professional **immediately**.
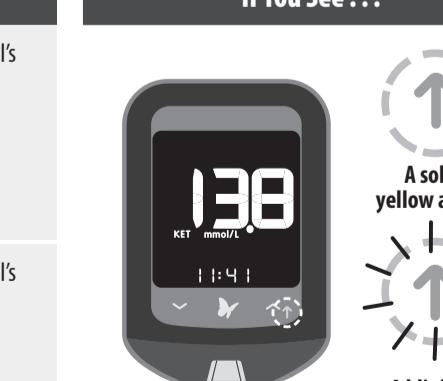
Note: If you see the error messages E-3 or E-4, consult the Error Messages section in this Owner's Setup Guide.

IMPORTANT: Contact your healthcare professional if you have symptoms do **not** match your test result, and you have followed the instructions in this Owner's Setup Guide.

High Blood Glucose Results

If You See . . .	What It Means	What To Do
A solid yellow arrow / A blinking yellow arrow	Appears when result is higher than 13.3 mmol/L or the target set on the meter by your healthcare professional.	Follow your healthcare professional's advice to treat high blood glucose.
	A pattern of high glucose has developed. If 3 high results occur within the past 5 days AND all are within the same 3-hour time period, the meter will display a blinking ↑.	Follow your healthcare professional's advice to treat high blood glucose.
	Blood glucose level is higher than or equal to 13.3 mmol/L.	Check blood ketone if checking ketones is part of your diabetes management program.
HI Appears when result is higher than 27.8 mmol/L	Severe high blood glucose **or** There may be a problem with the test strip.	Repeat the test with a new test strip. If the result is HI, contact your healthcare professional **immediately**.
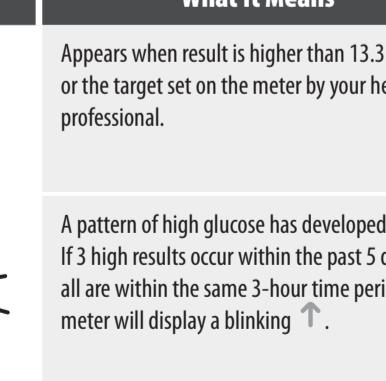
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9 Understanding Blood Ketone Test Results

The meter displays ketone results in mmol/L, from 0.0 - 8.0 mmol/L. The unit of measurement is preset. You cannot change this setting.

IMPORTANT: Follow your healthcare professional's advice before you make any changes to your diabetes management program.

Blood ketone is expected to be below 0.6 mmol/L.[2] High blood ketone may be caused by illness, fasting, vigorous exercise, or uncontrolled blood glucose levels.[1-3]

Repeat a blood ketone test using a new blood ketone test strip when:
- HI appears on the display
- Your result is unusually high
- You question your result
- Your blood ketone result is 0.0 mmol/L, but your blood glucose is higher than 16.7 mmol/L

Display	What It Means	What To Do
Result is between 0.6 – 1.5 mmol/L.	High blood ketone. A problem requiring medical assistance may be occurring.	Follow your healthcare professional's advice.
Result is higher than 1.5 mmol/L.	You may be at risk of developing diabetic ketoacidosis (DKA).[2-6]	Contact your healthcare professional **immediately**.
HI Appears when result is higher than 8.0 mmol/L.	Very high blood ketone or There may be a problem with the test strip.	Repeat the test with a new test strip. If the result is HI, contact your healthcare professional **immediately**.

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10 View Logbook

Your meter logbook can store up to 1,000 events – including blood glucose, ketone, and control solution results, insulin doses, and other meter information.

Viewing Your Logbook Events

1. While on the Home screen, press ✎ to view your logbook events.

2. Press ⌄ to scroll through to view your logbook events.

Examples:

Blood Glucose Result

Insulin Dose — Units of Insulin

Fasting Result

Control Solution Result

Viewing Your Blood Glucose Averages

1. While on the Home screen, press ✎ to open the logbook.

2. While in the logbook, press ✎ any time to view your 7-day average. [7-dAY]
   - Press ⌄ to view 14-day average. [14-dAY]
   - Press ⌄ to view 30-day average. [30-dAY]
   - Press ✎ to return to your logbook events.

Your average

Number of tests in this average

Press ⌄ or ⌃ to scroll through 7-, 14- and 30-day averages.

Notes:
- Averages do not include glucose control solution results.
- Control solution results not marked as control solution tests may cause averages to be inaccurate.
- ---- appear on the meter screen when there are no current events or averages to view.
- LO blood glucose test results are included as 1.1 mmol/L when calculating averages.
- HI blood glucose test results are included as 27.8 mmol/L when calculating averages.

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:

- Use only MediSense glucose and ketone control solutions with the meter.
- Control solution results should fall within the control solution range printed on the test strip instructions for use.
- Check that the LOT number printed on the test strip foil packet and instructions for use match.
- Do not use control solution past its expiry date. Discard control solution 3 months after opening or on the expiry 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 blood glucose levels.
- Replace the cap securely on the bottle immediately after use.
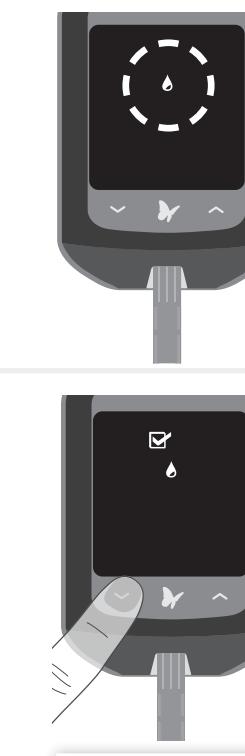
IMPORTANT: *(continued)*

- Do not add water or other liquid to control solution.
- Control solution results do not reflect your blood glucose.
- Contact Customer Care for information on how to obtain control solution.
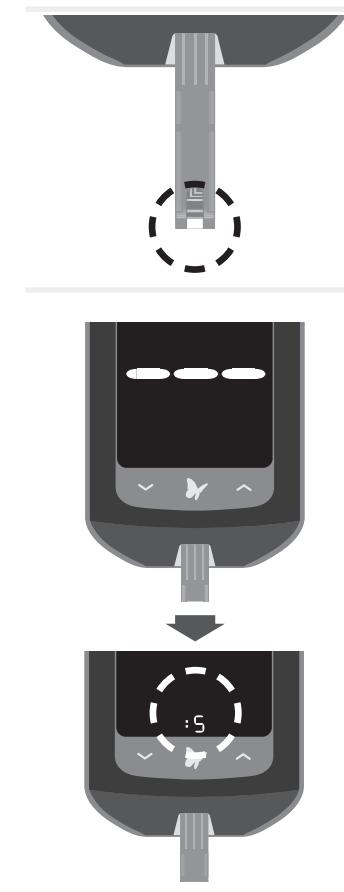
Performing a Control Solution Test

1. **Open the foil test strip packet** at the notch and tear down to remove the test strip.

2. **Insert the test strip** until the meter turns on.

   Notes:
   - *Be sure to check that your meter screen is working properly each time you turn your meter on. If you see any white segments in the black off screen, or any black segments in the white test screen, there may be a problem with the meter. (See Section 5, Getting to Know Your Meter, for more details.)*
   - *The meter turns off after 3 minutes of inactivity. Remove and reinsert the unused test strip to restart the meter.*

The 💧 blinks, indicating the meter is ready for you to apply a sample to the test strip.

Note: KET will appear on the screen if you have inserted a purple blood ketone strip.

3. Press and hold the down arrow for 3 seconds to **mark the test as a control solution test**. The ☑ appears. The meter is now ready for you to apply control solution to the test strip.

IMPORTANT: The test result will be saved to memory as a blood result if not marked as a control solution test. This may affect your blood glucose averages.

4. **Apply control solution to the test strip.**
   Shake the control solution bottle to mix the solution. Apply a drop of control solution to the white area at the end of the test strip in the area shown. The control solution is drawn into the test strip.

5. **Hold the control solution to the test strip until:**
   - You see 3 short lines on the meter screen. This means you have applied enough control solution and the meter is reading the control solution test.

   Notes:
   - *If you are testing with a blood glucose strip, you will see a 5-second countdown. If you are testing with a blood ketone strip, you will see a 10-second countdown.*
   - *Do not remove the test strip from the meter during the countdown.*
   - *If the countdown does not start, remove and discard the used test strip, turn off the meter and try again with a new strip.*

Examples:

6. **View the result.**
   The test is complete (examples shown) when the result appears on the meter screen. The result is stored in memory as a control solution result.

   Compare the control solution result to the range printed on the blood glucose or blood ketone test strip instructions for use. The result should fall within the range.

   Note: KET appears with the result if performing a ketone 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 instructions for use.
   - Stop using the meter if control solution results are consistently outside the range printed on the test strip instructions for use. Contact Customer Care.

Transferring meter data to a computer requires a compatible data management system. You will also need a micro USB cable to connect your meter's USB port to your computer.
For more information, please contact Customer Care.

WARNING: To avoid the possibility of electric shock, never perform a blood glucose test while the meter is connected to the computer.
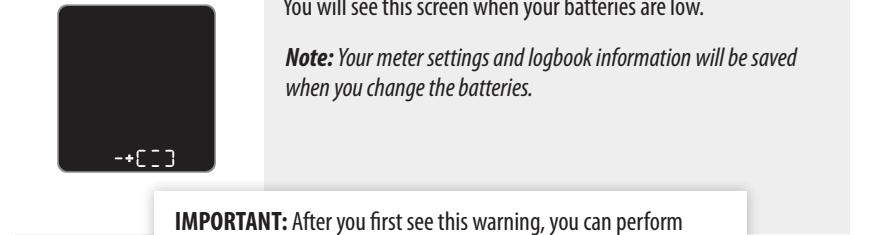
Message	What It Means	What To Do
E-1	The temperature is too hot or too cold for the meter to work properly	1. Move the meter and test strips to a location where the temperature is within the test strip operating range. (See test strip instructions for use for the appropriate range.) 2. Wait for the meter and test strips to adjust to the new temperature. 3. Repeat the test using a new test strip. 4. If the error reappears, contact Customer Care.
E-2	Meter error	1. Turn off the meter. 2. Repeat the test using a new test strip. 3. If the error reappears, contact Customer Care.

Message	What It Means	What To Do
E-3	Blood drop is too small or Incorrect test procedure or There may be a problem with the test strip	1. Review the testing instructions. 2. Repeat the test using a new test strip. 3. If the error reappears, contact Customer Care.
E-4	The blood glucose level may be too high to be read by the system or There may be a problem with the test strip	1. Repeat the test using a new test strip. 2. If the error reappears, contact Customer Care.
E-5	Blood was applied to the test strip too soon	1. Review the testing instructions. 2. Repeat the test using a new test strip. 3. If the error reappears, contact Customer Care.

Message	What It Means	What To Do
E-6	Meter error	1. Check that you are using the correct strip for this meter. (See test strip instructions for use to verify your strip is compatible with this meter.) 2. Repeat the test using a test strip for use with your meter. 3. If the error reappears, contact Customer Care.
E-7	No coding required or Test strip may be damaged, used, or the meter does not recognise it	1. Check that you are using the correct test strip for this meter. (See test strip instructions for use to verify your strip is compatible with this meter.) 2. Repeat the test using a test strip for use with your meter. 3. If the error reappears, contact Customer Care.
E-9	Meter error	1. Turn off the meter. 2. Repeat the test using a new test strip. 3. If the error reappears, contact Customer Care.

Changing Batteries
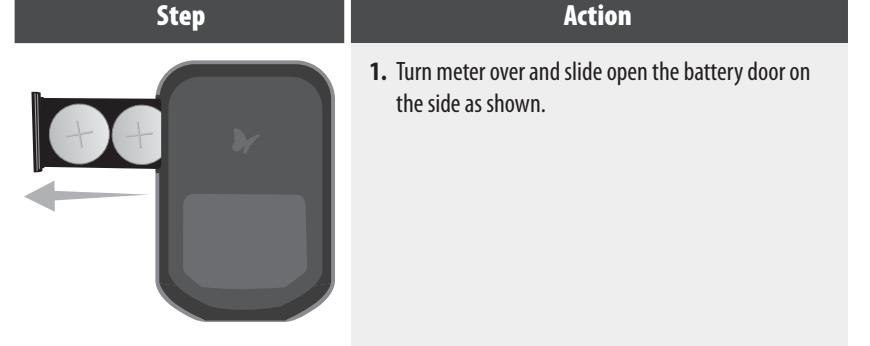
You will see this screen when your batteries are low.

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.
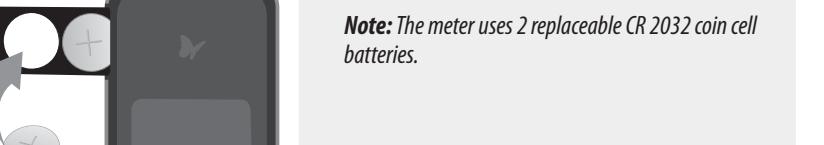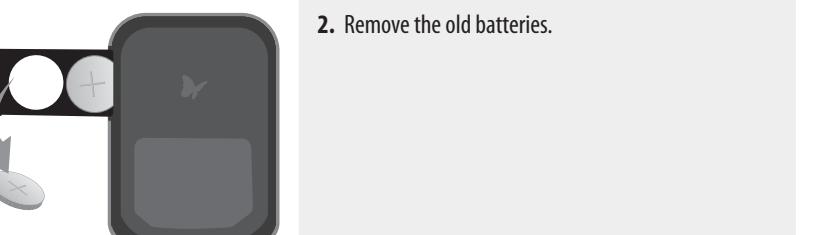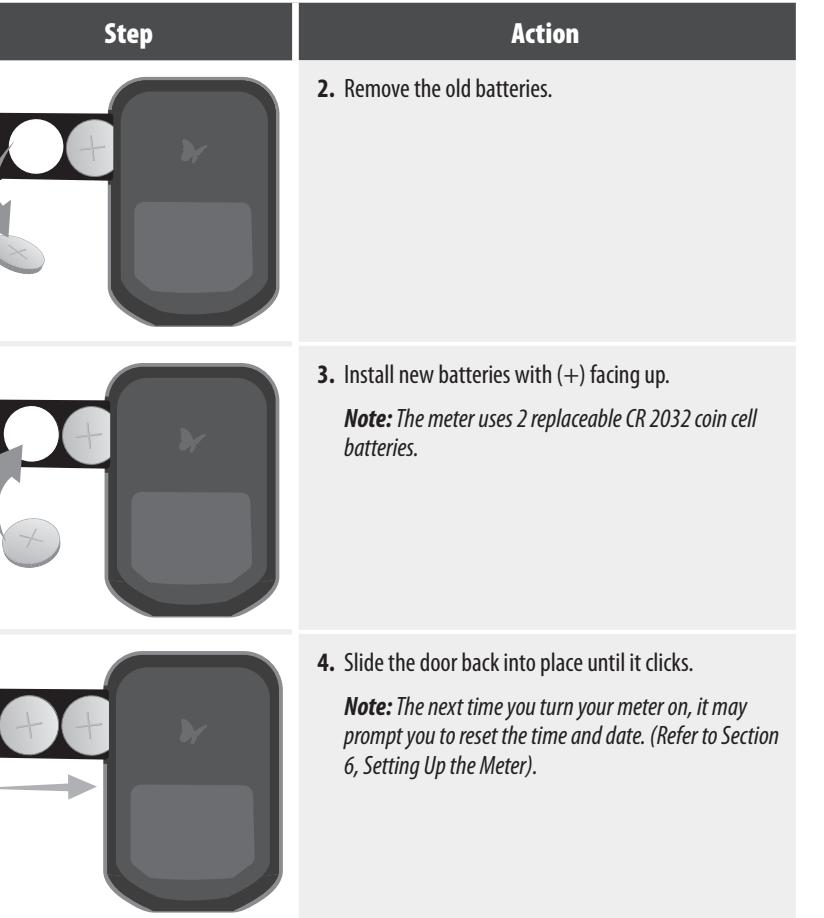
WARNING: Batteries should be kept away from small children. If swallowed, contact a healthcare professional immediately.

Step	Action
	1. Turn meter over and slide open the battery door on the side as shown.
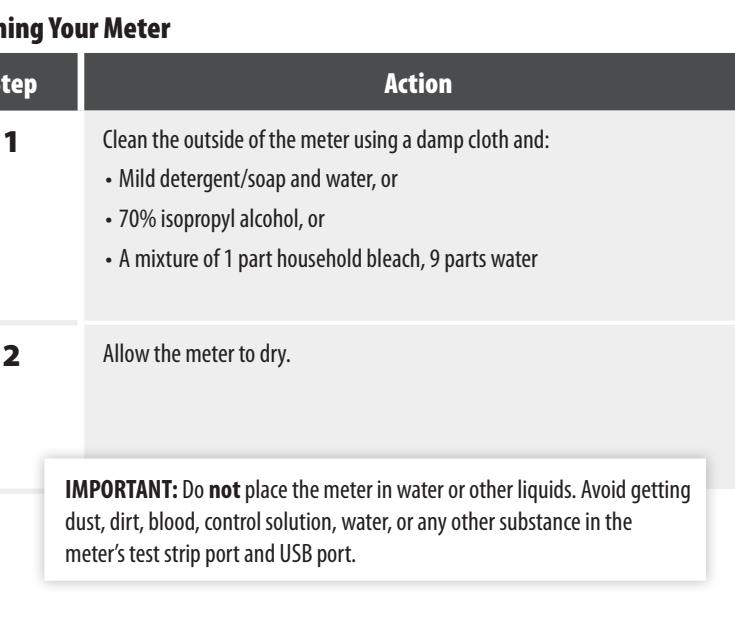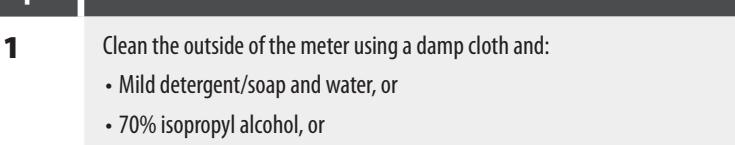
Step	Action
	2. Remove the old batteries.
	3. Install new batteries with (+) facing up. *Note: The meter uses 2 replaceable CR 2032 coin cell batteries.*
	4. Slide the door back into place until it clicks. *Note: The next time you turn your meter on, it may prompt you to reset the time and date. (Refer to Section 6, Setting Up the Meter).*

Note: When you no longer need the meter, remove the batteries and dispose of the batteries and meter in accordance with your local government regulations.

The European Battery Directive requires separate collection of spent batteries, aiming to facilitate recycling and to protect the environment. The batteries in this product should be removed and disposed in accordance with local regulations for separate collection of spent batteries.

Cleaning Your Meter
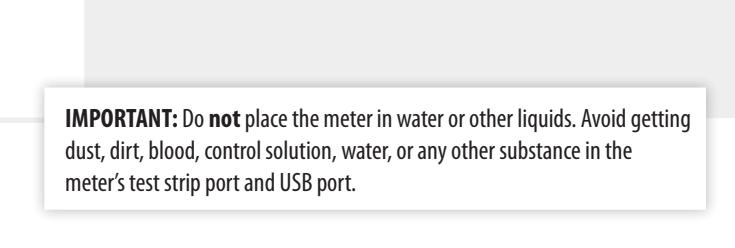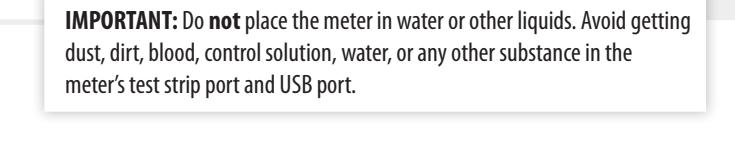
Step	Action
1	Clean the outside of the meter using a damp cloth and: • Mild detergent/soap and water, or • 70% isopropyl alcohol, or • A mixture of 1 part household bleach, 9 parts water
2	Allow the meter to dry.

IMPORTANT: Do **not** place the meter 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.
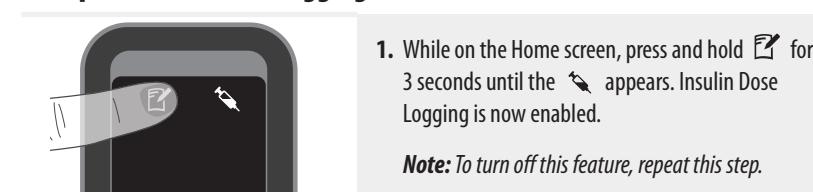
	What It Means	What To Do
1. Test strip is inserted in the strip port and nothing happens.	Test strip is not inserted properly or fully into the meter	1. With the contact bars (3 black lines) facing up, insert the test strip into the meter until it stops. This turns on the meter. 2. If the meter still does not turn on, contact Customer Care.
	No batteries are installed; Batteries installed incorrectly	Refer to Section 14, Taking Care of Your Meter, on how to properly install batteries.
	Dead batteries	Change batteries. Reset date and time, if needed.
	Meter may be plugged into a computer (PC appears on meter screen)	Unplug the meter from the computer.
	Problem with the test strip	Try a new test strip.
	Problem with the meter	Contact Customer Care.
2. The test does not start after applying the blood sample.	Blood sample is too small	1. See test strip instructions for use for re-application instructions. 2. Repeat the test using a new test strip. 3. If the test still does not start, contact Customer Care.
	Sample applied after meter turns off	1. Review the testing instructions. 2. Repeat the test using a new test strip. 3. If the test still does not start, contact Customer Care.
	Problem with meter or test strip	1. Repeat the test using a new test strip. 2. If the test still does not start, contact Customer Care.

Introduction
This feature allows you to log insulin doses so they are recorded in the logbook. You can enable this feature at any time.

Set Up for Insulin Dose Logging
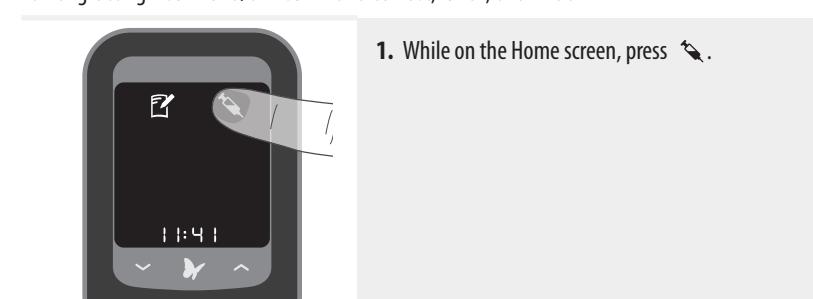
1. While on the Home screen, press and hold 📝 for 3 seconds until the 💉 appears. Insulin Dose Logging is now enabled.
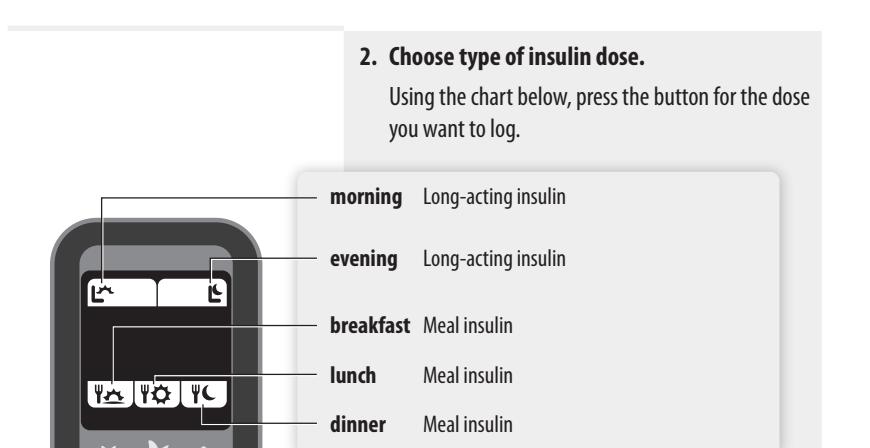
   Note: To turn off this feature, repeat this step.

How to Use Insulin Dose Logging
For long-acting insulin and/or insulin for breakfast, lunch, or dinner.
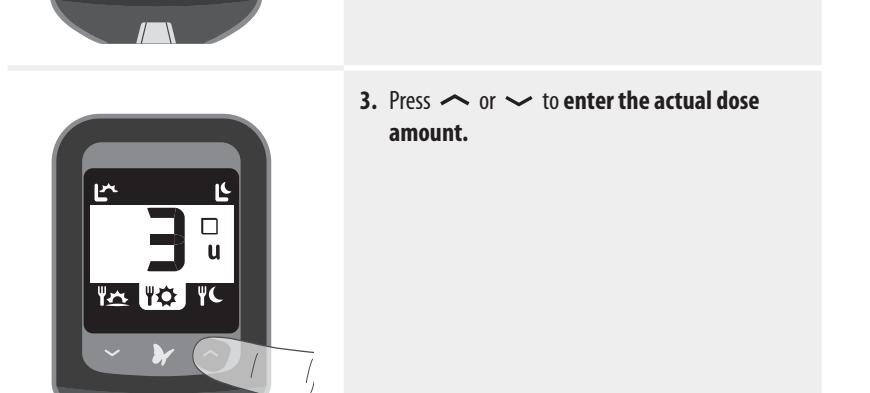
1. While on the Home screen, press 💉.
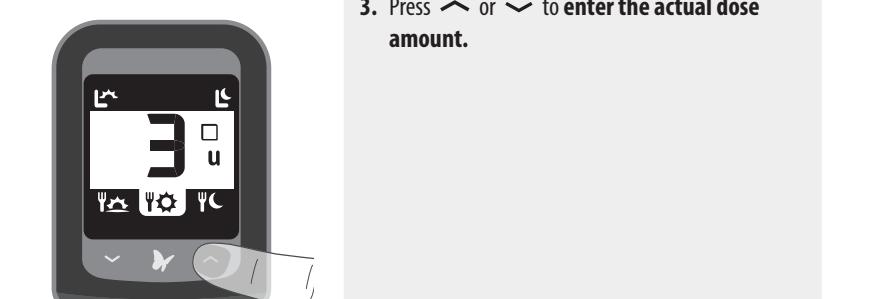
2. **Choose type of insulin dose.**
   Using the chart below, press the button for the dose you want to log.

morning	Long-acting insulin
evening	Long-acting insulin
breakfast	Meal insulin
lunch	Meal insulin
dinner	Meal insulin
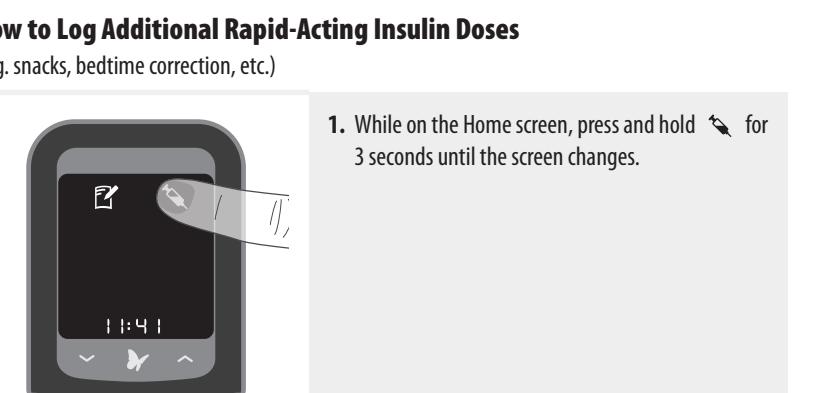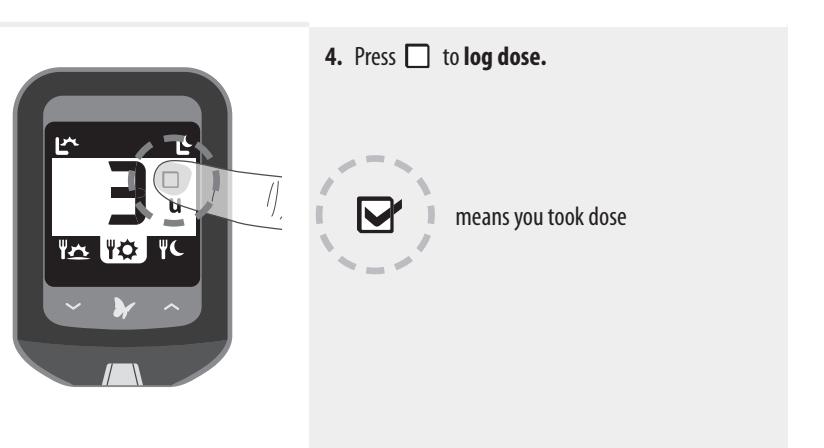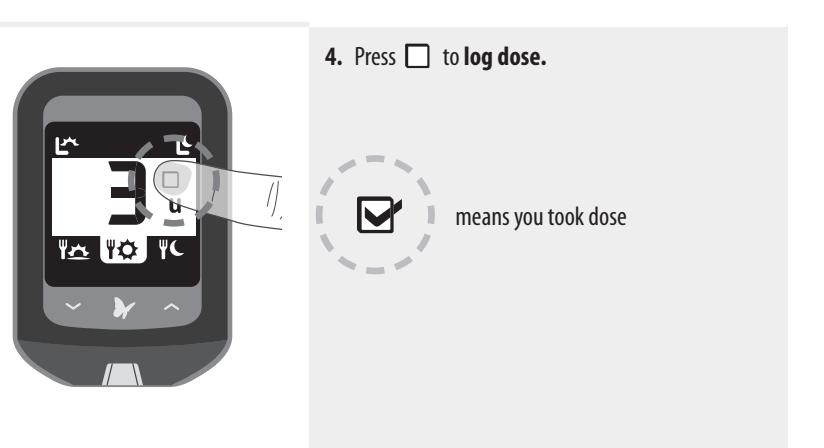
3. Press ⌃ or ⌄ to **enter the actual dose amount.**
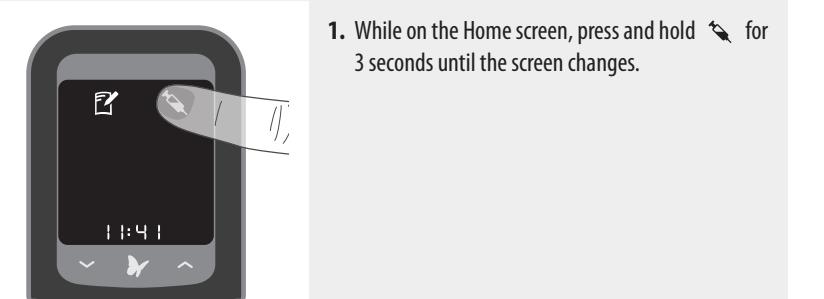
4. Press □ to **log dose.**

   ☑ means you took dose
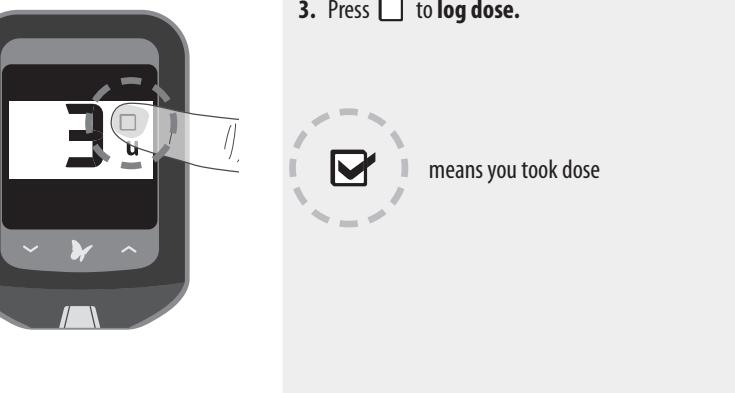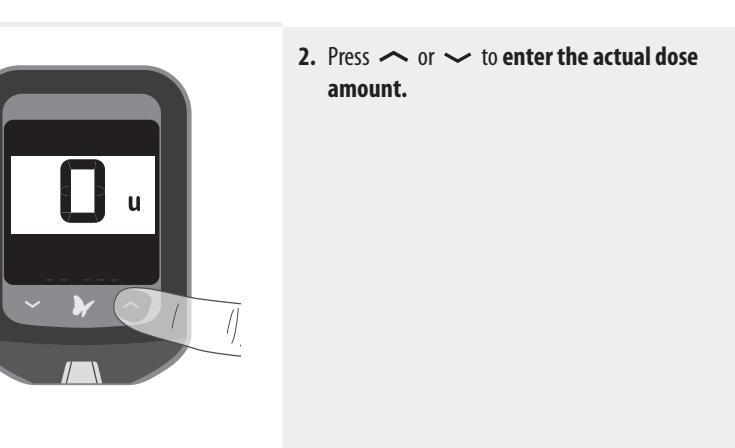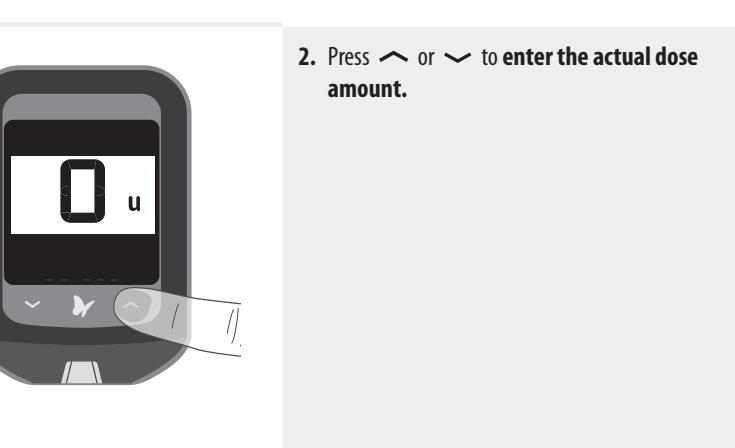
How to Log Additional Rapid-Acting Insulin Doses
(e.g. snacks, bedtime correction, etc.)

1. While on the Home screen, press and hold 💉 for 3 seconds until the screen changes.

2. Press ⌃ or ⌄ to **enter the actual dose amount.**

3. Press □ to **log dose.**

   ☑ means you took dose

Assay method	AmperometrCy
Automatic shutoff	At least two minutes of inactivity
Battery life	Up to 3000 tests
Measurement range	For blood glucose testing 1.1 - 27.8 mmol/L For blood ketone testing 0.0 - 8.0 mmol/L
Memory	Up to 1000 events, including blood glucose, blood ketone, and control solution results, insulin doses, and other meter information
Minimum computer requirements	System must only be used with EN60950-1 rated computers. Use a USB certified cable
Operating relative humidity	10% to 90% (non-condensing)
Operating temperature	Meter: 10 °C to 50 °C (50 °F to 122 °F) System: See test strip instructions for use

Power source	Two CR 2032 lithium (coin cell) batteries
Size	5.97 cm (w) x 8.68 cm (l) x 0.87 cm (d) 2.35 in (w) x 3.42 in (l) x 0.34 in (d)
Storage temperature	-20 °C to 60 °C (-4 °F to 140 °F)
System altitude	See test strip instructions for use
Weight	33 to 37 g (1.2 to 1.3 oz.) including batteries

Note: For test strip specifications, see test strip instructions for use.

Electromagnetic Compatibility (EMC): FreeStyle Optium Neo meter has been tested for both electrostatic discharge and radio frequency interference. Emissions are low and unlikely to interfere with other nearby electronic equipment. To limit radio frequency interference do not use the FreeStyle Optium Neo meter near cellular or cordless telephones, radio transmitters or other electrical or electronic equipment that are sources of electromagnetic radiation, as these may interfere with the proper operation of the meter. Avoid use of the device in very dry environments, as electrostatic discharges from synthetic materials (e.g., carpets) could cause damage.

Symbol	What It Means	Symbol	What It Means
📖	Consult instructions for use	⚠	Caution
🌡	Temperature limit	🔲	Use-by date
🏭	Manufacturer	IVD	In vitro diagnostic medical device
LOT	Batch code	REF	Catalogue number
⊘	Do not re-use	♻	Recycle
📅	Date of manufacture	SN	Serial number
🚱	Do not drink	STERILE R	Sterilised using irradiation (lancets only)
CE	CE Mark		

The European Battery Directive requires separate collection of spent batteries, aiming to facilitate recycling and to protect the environment. The batteries in this product should be removed and disposed in accordance with local regulations for separate collection of spent batteries.

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