



FreeStyle
Precision Neo

Blood Glucose Monitoring System

Owner's Setup Guide User's Manual

Abbott

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5 Intended Use

The FreeStyle Precision Neo Blood Glucose Monitoring System is for use outside the body only (in vitro diagnostic use) in the quantitative measurement of glucose in whole blood only. It is not intended to be used on the fingers, or it is not intended to be used for testing neonatal blood samples or for the diagnosis or screening of diabetes.

The FreeStyle Precision Neo System is indicated for the home (lay) user in the management of patients with diabetes. It is intended to be used by one person and should not be used more than once per day.

The FreeStyle Precision Neo Blood Glucose Test Strips, for use with the FreeStyle Precision Neo Blood Glucose Meter, to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips.

IMPORTANT:

- Use only FreeStyle Precision Neo blood glucose test strips. Other test strips may produce inaccurate results.
- See test strip instructions for information about sample types.
- The meter and its accessories are for use by a single person. They must not be used more than once per day. It is recommended that family members share the meter and lancing device. All parts of the meter and its accessories are considered biohazardous and can potentially transmit infectious diseases, even after performing the cleaning and disinfection procedures.
- 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.
- Read the instructions in this Owner's Setup Guide. Failure to follow instructions may cause inaccurate results. Practice the testing procedures before using the meter.
- Follow your healthcare professional's advice when testing blood glucose levels.
- Observe caution when using around children. Small parts may constitute a choking hazard.
- This device should not be used to treat critically ill patients.
- Not for use on patients who are dehydrated, hypotensive, in shock, or for individuals in hyperglycemic/hypoglycemic states, with, or without ketones.

We're here to help! Monday through Friday, 8AM to 8PM Eastern Standard Time. If you have any questions about any of our FreeStyle products, please contact Customer Care toll-free at 1-800-527-3339.

8 Testing Your Blood Glucose

Performing a Blood Glucose Test

1. Open the full 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. Note: Be sure to check that your meter screen is working properly each time you turn your meter on. If you see any error messages on the meter screen, or any blue segments in the meter screen, there may be a problem with the meter. (See Section 6, Getting to Know Your Meter, for more details.)
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 or top of the test strip. The blood is drawn into the test strip.

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

If you see any white segments on the black strip, or any blue segments in the meter screen, there may be a problem with the meter. Contact Customer Care.

Note: If the meter battery is low, the will appear on both the meter off screen and start-up screen.

If you see any white segments on the black strip, or any blue segments in the meter screen, there may be a problem with the meter. Contact Customer Care.

Preparing Your Meter On and Off

To Turn Your Meter On and Off

- Press the or to turn on the meter.
- Turn your meter off:
 - Press and hold the for 3 seconds, or
 - Do nothing for 2 minutes

To Check 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.

If you see any white segments on the black strip, or any blue segments in the meter screen, there may be a problem with the meter. Contact Customer Care.

Note: If the meter battery is low, the will appear on both the meter off screen and start-up screen.

If you see any white segments on the black strip, or any blue segments in the meter screen, there may be a problem with the meter. Contact Customer Care.

To Set Time Format (12 hour or 24 hour clock)

- Press or to change.
- Press to continue.

Note: If you are using the meter for the first time, the time format is set to 12:00 (12:23 PM or 12:23 AM). If you prefer the 12:00 format, there is an "AM" setting. If you prefer the 24:00 format, there is a "PM" setting. To change the time format, press until you see the "PM" or "AM".

If you see any white segments on the black strip, or any blue segments in the meter screen, there may be a problem with the meter. Contact Customer Care.

To Set Date

- Set Month:
 - The month blinks. Press or to set the month.
 - Press to continue

Note: If the month is set to "00", the month is set to January.

If you see any white segments on the black strip, or any blue segments in the meter screen, there may be a problem with the meter. Contact Customer Care.

To Set Day

- Set Day:
 - The day blinks. Press or to set the day.
 - Press to continue

Note: If the day is set to "00", the day is set to Sunday.

If you see any white segments on the black strip, or any blue segments in the meter screen, there may be a problem with the meter. Contact Customer Care.

To Set Year

- Press or to set the year.
- Press to save. Set complete

Note: If you see any white segments on the black strip, or any blue segments in the meter screen, there may be a problem with the meter. Contact Customer Care.

To Press to Turn Off the Meter

- Press to turn off the meter. Discard the used test strip properly.

If you see any white segments on the black strip, or any blue segments in the meter screen, there may be a problem with the meter. Contact Customer Care.

To Press to Turn On the Meter

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11 MediSense Glucose and Ketone Control Solution

IMPORTANT:
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.

Performing a Control Solution Test

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



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



Note:
• Be sure to check that your meter screen is working properly each time you turn your meter on. If you see any other settings on the black off screen, or any other settings in the meter screen, there may be a problem with the meter. (See Section 6, Getting to Know Your Meter.)
• If the meter turns off after 5 minutes of inactivity, remove and reinsert the unused test strip to restart the meter.

The **A** blinks, indicating the meter is ready to apply control solution to the test strip.

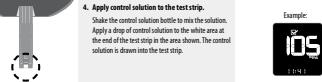


3. Press and hold the control solution arrow for 2 seconds to start the test or a control solution test. The **✓** appears. The meter is now ready to apply control solution to the test strip.



IMPORTANT: The test result will be saved to memory as a blood result if not marked as a control solution test. This will 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 first 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.

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

6. View the result.
The test is complete (example shown) when the result appears on the meter screen. The result is stored in memory as a blood result.



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

12 Transferring Meter Data to a Computer

Transferring meter data to a computer requires a compatible data management program. You will also need a micro USB cable to connect your meter's USB port to your computer (available separately). For more information, 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.

13 View Logbook

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

Viewing Your Logbook Events



1. While on the Home screen, press **⇨** to open the Meter for today's results; only the time will be displayed at the bottom of the screen. For previous day's results, the date will alternate with the time.

2. Press **↶** to scroll through to view your logbook events.

Viewing Your Blood Glucose Averages



1. While on the Home screen, press **⇨** to open the Meter for today's results; only the time will be displayed at the bottom of the screen. For previous day's results, the date will alternate with the time.

2. While in the logbook, press **⇨** any time to view your 1-day average. [**1-00-00-00**]

• Press **⇨** to view 1-day average. [**1-00-00-00**]

• Press **⇨** to return to your logbook events.

Note: Averages do not include glucose control solution results.

• Control solution results are marked as control solution tests may cause results to be inaccurate.

— appear on the meter screen when there are no control solution results to view.

• **L-0** Blood glucose test results are included as 20 mg/dL when calculating averages.

• **H-1** Blood glucose test results are included as 500 mg/dL when calculating averages.

14 Error Messages

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 are within the meter's operating range. (See test strip instructions for use in the appropriate range.)
2. Wait for the meter and test strips to adjust to ambient 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.

E-3 Blood 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.

E-4 The blood glucose test strip is 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 Meter error

1. Check that you are using the correct strip for this meter. (See test strip instructions for use in the appropriate range.)
2. Repeat the test using a new test strip. If the error reappears, contact Customer Care.

E-6 Meter error

1. Check that you are using the correct strip for this meter. (See test strip instructions for use in the appropriate range.)
2. Repeat the test using a new test strip. If the error reappears, contact Customer Care.

E-7 No coding required or Test strip may be damaged, used, or the meter does not recognize it

1. Check that you are using the correct strip for this meter. (See test strip instructions for use in the appropriate range.)
2. Repeat the test using a new test strip. If the error reappears, contact Customer Care.

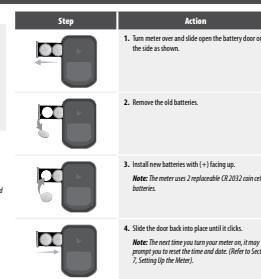
E-8 Meter error

1. Turn off the meter.
2. Repeat the test using a new test strip.
3. If the error reappears, contact Customer Care.

15 Taking Care of Your Meter and Lancing Device

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.



Cleaning and Disinfecting the Meter and Lancing Device

This section describes the cleaning and disinfection tasks for the Freestyle Precision Neo Meter and the Freestyle Lancing Device.

Cleaning and disinfecting your meter and lancing device is important to prevent the spread of infectious diseases. The meter has a mean life of 5 years, which is S22 cleaning and S22 disinfection cycles (2 cycles per week for 2 years). The lancing device has a mean life of 2 years, which is 210 cleaning and 210 disinfection cycles (2 cycles per week for 2 years).

Tan off the meter prior to cleaning and disinfection. Users should wash hands thoroughly with soap and water after handling the meter, lancing device, or test strips.

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.

CAUTION: Do not place the meter in water or other liquid. Avoid getting dirt, dirt, blood, control solution, water, bleach, or any other substance in the meter's test strip port, USP port and battery compartment.

Note: Cleaning and disinfecting the meter and lancing device helps ensure that no infection is passed when you or others come in contact with the meter and lancing device. The meter and lancing device should be cleaned with a separate bleach wipe prior to use.

Clean and disinfect your meter at least once a week. Clean and 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.

Cleaning and disinfection should be performed using Clorox Healthcare Bleach Germicidal Wipes at least once per week.

The meter has a mean life of 5 years and has been validated for S22 cleaning and S22 disinfection cycles (the equivalent of 2 cycles per week for 5 years).

The lancing device has a mean life of 2 years and has been validated for 210 cleaning and 210 disinfection cycles (2 cycles per week for 2 years). The meter and lancing device are made of plastic and do not contain any metal parts.

Cleaning and disinfecting the meter is important to prevent the spread of infectious diseases.

Cleaning is the physical removal of organic soil from the meter and lancing device surfaces.

Keeping the meter and lancing device clean helps ensure that they are working properly and that no dirt gets in the device. Cleaning allows for successful, safe, and effective disinfection.

Disinfection is a process that destroys, such as viruses and other microorganisms, on the meter and lancing device surfaces. Disinfecting the meter and lancing device helps ensure that no infection is passed when you or others come in contact with the meter and lancing device. The meter and lancing device should be cleaned with a separate bleach wipe prior to use.

Clean and disinfect your meter at least once a week. Clean and 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.

Cleaning and disinfection should be performed using Clorox Healthcare Bleach Germicidal Wipes at least once per week.

IMPORTANT: If you require assistance or if you notice any signs of deterioration on the meter or lancing device (such as clouding or cracking on the display of the meter, corroding or eroding of the plastic housing, or cracking of the plastic housing or display) or if the meter does not turn on or if the lancing device does not work after cleaning and disinfection, discontinue the use of the meter or lancing device and contact Customer Care (1-800-527-3339).

16 Troubleshooting

What It Means

What To Do

1. 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.

1. Change batteries. Reset date and time, if needed.

Meter may be plugged into a computer (PC appears on meter screen)

1. Unplug the meter from the computer.

Problem with the test strip

1. Try a new test strip.

Problem with the meter

1. Contact Customer Care.

Blood sample is too small

1. Repeat the test using a new test strip.
2. If the test still does not start, contact Customer Care.

2. The test does not start after applying the blood sample.

1. Repeat the test using a new test strip.
2. If the test still does not start, contact Customer Care.

17 Meter Specifications

Assay method

Amperometry

Size

2.25 in (w) x 4.32 in (d) x 0.34 in (h)
5.72 cm (w) x 10.86 cm (d) x 0.87 cm (h)

Storage temperature

-4°F to 140°F (-20°C to 60°C)

System altitude

See test strip instructions for use

Measurement range

For blood glucose testing: 20–500 mg/dL

Memory

Up to 1000 events, including blood glucose and control solution results, 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

59°F to 104°F (15°C to 40°C)

Power source

Two CR2032 lithium (coin cell) batteries

Lancing device

The lancing device has a mean life of 2 years, which is 210 cleaning and 210 disinfection cycles (2 cycles per week for 2 years).

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

Electromagnetic Compatibility (EMC): Freestyle Precision Neo meter has been tested for both electrostatic discharge and radio frequency interference. Emissions are low and unlikely to interfere with nearby electronic equipment. To test radio frequency interference do not use the Freestyle Precision Neo meter near cellular or cordless phones, radio transmitters or other electronic devices. If you experience interference, move the meter away from the source of the interference. Avoid use of the meter in very dry environments, as electrostatic discharges from synthetic materials (e.g., carpet) could damage the meter.

18 References

References:

1. "FDA Public Health Notification: Use of Fingertip Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication" (2010) <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm24053.htm>
2. CDC Clinical Consideration: Use of Fingertip Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens" (2010) <http://www.cdc.gov/injectionSafety/fingertipDeviceFAQ.html>
3. American Diabetes Association. Standards of Medical Care in Diabetes—2013. Diabetes Care 2013;36(Suppl.1):S61-S66.

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