WaveSense KEYNOTE™
Blood Glucose Monitoring System

OWNER'S GUIDE

Powered by WaveSense™

Manufacturer:
AgaMatrix, Inc.
10 Manor Parkway
Salem, NH 03079 USA

8100-01821 Rev F

24-Hour Customer Service:
+1 (866) 906 4197

In case of emergency, contact your healthcare professional or emergency response.

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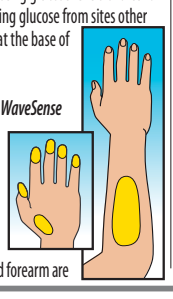
1 Important Information About Your WaveSense KeyNote System

The WaveSense KeyNote System should be used: [1] For measuring blood glucose levels from fresh capillary whole blood samples taken from the fingertips, palms (at the base of the thumb), or forearms. **[2]** With WaveSense KeyNote Test Strips and WaveSense Control Solution only. Use with other unapproved test strips or control solution will void the manufacturer's warranty and will lead to inaccurate results. **[3]** Outside of the body (i.e., *in vitro* diagnostic use only).

Do not use the WaveSense KeyNote System for: [1] The diagnosis of diabetes. **[2]** Testing the glucose levels of neonates. **[3]** Testing glucose levels of arterial or venous blood. **[4]** Testing glucose from sites other than the fingertip, palm (at the base of the thumb), or forearm.



Possible test sites: ***The WaveSense KeyNote System requires only 0.5 µL of blood to perform a glucose test.*** For the best results, test glucose from the tips of any finger. The palm (at the base of the thumb) and forearm are alternate, but less accurate, test sites. Only select soft and fleshy areas to lance. Avoid lancing any bony areas, obvious veins and moles. Physiological differences in circulation between the fingertip, palm (at the base of the thumb), and forearm may result in differences in blood glucose measurements between these sites. Differences in glucose concentrations may be observed after eating, taking insulin medication, or exercise. Changes in blood glucose may be detected in the fingertips before the palm (at the base of the thumb) and forearm.

It is recommended that you use a fingertip sample if: [1] You are testing for hypoglycemia or if you suffer from hypoglycemia unawareness, **[2]** You are testing your blood glucose within 2 hours of eating, taking insulin, diabetes pills, exercise, or **[3]** Your blood glucose results obtained from the palm (at the base of the thumb) or forearm are not consistent with the way you feel.

CAUTION: Please read all the instructions provided in this owner's guide and practice the testing procedures before using the WaveSense KeyNote Blood Glucose Monitoring System. Blood glucose monitoring should be done under the guidance of a healthcare professional.

2 Getting Started

Unpack your WaveSense KeyNote System Kit. Dispose of the packing material properly.

IMPORTANT: To ensure accurate use of meter, verify the time, date and units of measure.

For step-by-step instructions on setting the time and date settings, please refer to section 14 "Setting Time and Date."

3 Symbols

The following symbols may appear on the equipment packages or in the documents:

Serial Number: SN
Manufacturer:
In Vitro Diagnostic Medical Device: IVD
Batch Code: LOT
Consult Instructions For Use:
Do Not Reuse:
Temperature Limitation: 46°F 8°C – 86°F 30°C
Use By:
Catalogue Number: REF

4 Meter Basics

METER SYSTEM CHECK
Each time your meter is activated, the meter will perform a meter system check. All display segments and the backlight will briefly flash ON.

IMPORTANT: If all the display segments DO NOT flash ON (each time your meter is activated), do not use the meter. Call customer service immediately.

HOW TO ACTIVATE THE METER AND View Individual Results: [1] When your meter is deactivated, press any button once. The display shows the most recent test result with time and date. **[2]** Press the LEFT arrow button repeatedly to scroll thru every test result, starting from the most recent and ending with the oldest.

View Time-of- Day Averages: [1] When your meter is deactivated, press any button once. The display shows the most recent test result with time and date. **[2]** Press the RIGHT arrow button repeatedly to scroll thru your Breakfast, Lunch, Dinner, and Bedtime Averages.

Enter MENU Mode: [1] When your meter is deactivated, press and hold any button for 2 seconds to enter the MENU mode. **[2]** Press the RIGHT or LEFT arrow buttons to view the options: MEM (14, 30 and 90 Day Averages and Graphs), SET (meter settings), and AL1 to AL6 (reminder alarms 1 thru 6).

Enter MEM (Memory) Mode *to view 14, 30 and 90 Day Averages and Graphs*: [1] Enter the MENU mode. **[2]** Press the RIGHT or LEFT arrow buttons until the MEM symbol is displayed. **[3]** When the MEM symbol is displayed, press the CENTER button.

Enter SET (Settings) Mode: [1] Enter the MENU mode. **[2]** Press the RIGHT or LEFT arrow buttons until the SET symbol is displayed. **[3]** When the SET symbol is displayed, press the CENTER button.

HOW TO DEACTIVATE THE METER
To deactivate the meter, press and hold the CENTER button for 2 seconds. If left inactive for 3 minutes, the meter will be deactivated automatically.

HOW TO ACCELERATE THROUGH OPTIONS
Hold down the RIGHT or LEFT arrow buttons to accelerate through options or results.

5 Performing a Control Solution Test

The WaveSense KeyNote system has 2 levels of control solution: normal and high. Select the level of control solution you want to use.

The control solution is used to: [1] Ensure that your WaveSense KeyNote Meter and Test Strips are working together properly. **[2]** Practice testing without having to use your own blood.

Control solution tests should be performed when you: [1] First get your WaveSense KeyNote Meter. **[2]** Begin using a new vial of WaveSense KeyNote Test Strips. **[3]** Suspect that your WaveSense KeyNote Meter or Test Strips are not working properly. **[4]** Think your test results are not accurate. **[5]** Have dropped or damaged your meter or exposed your meter to liquids other than blood samples. **[6]** Are advised by your healthcare professional to do so.

Control solution should only be used for 90 days after first opening the bottle or until the expiration date printed on the label, whichever comes first.

IMPORTANT: Count forward 90 days from the date you open a new bottle of WaveSense Control Solution. This is your discard date.

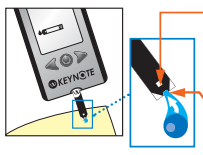
Write the discard date on the WaveSense Control Solution bottle.

Important WaveSense Control Solution information: [1] Use only WaveSense Control Solution with your WaveSense KeyNote System. **[2]** Always replace the cap on the control solution bottle immediately after using. **[3]** Do not add water or any other liquid to control solution. **[4]** Control solution tests should be performed within the system operating temperature range of 50 °F to 104 °F (10 °C to 40 °C).

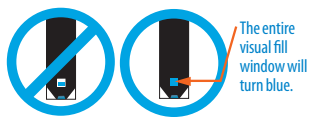
[1] Inserting a WaveSense KeyNote Test Strip: Insert a new WaveSense KeyNote Test Strip into the meter. The meter will be activated.

[2] Adjusting Code Number: The meter will display a test strip code number. If this is not the same as the code number printed on the test strip vial, press the LEFT or RIGHT buttons until the meter displays the same code number as printed on the test strip vial.

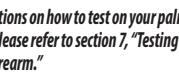
[3] Applying Control Solution: Shake the control solution bottle. Discard the first drop of control solution and wipe the bottle tip clean using a clean tissue or paper towel. Dispense a second drop onto a clean surface, such as an unused resealable plastic bag. Bring the tip of the test strip to the control solution sample. The WaveSense KeyNote System will automatically detect if a test is performed with WaveSense Control Solution.



When control solution is applied, the visual fill window on the WaveSense KeyNote Test Strip turns blue.



On the WaveSense KeyNote Meter display, droplet symbols appear on the test strip symbol to indicate that the control solution is filling the WaveSense KeyNote Test Strip.



Your meter will beep once indicating that you should remove the tip of the WaveSense KeyNote Test Strip from the control solution sample.

[4] Viewing Control Solution Test Result: The result will appear on the display screen and, if the volume is enabled, your meter will beep once. The word "control" will also appear on the display screen.

Compare the result of your control solution test to the range printed on the WaveSense KeyNote Test Strip vial label for the control solution level (normal or high) that you used. Your control solution result should fall within this range. The control solution test result is stored in memory.

Normal: 80-120 mg/dL
High: 220-320 mg/dL

To deactivate the meter, remove the used WaveSense KeyNote Test Strip. Dispose of used materials properly.

If your control solution test results are out of the range, repeat the test. If the results from the control solution tests continue to fall outside that range, do not use the WaveSense KeyNote System to test your blood glucose. Call customer service.

IMPORTANT: Out-of-range test results may be caused by: [1] Expired or defective control solution. **[2]** Expired or defective test strip. **[3]** Error in performing test. **[4]** Watered-down control solution. **[5]** Code number on WaveSense KeyNote Test Strip vial not matching code number set in the meter. **[6]** Meter malfunction. **[7]** Control solution test done outside the operating temperature of 50 °F to 104 °F (10 °C to 40 °C). **[8]** Failure to shake the control solution bottle vigorously. **[9]** Failure to discard the first drop of control solution and to wipe the bottle tip clean.

CAUTION: Results from control solution tests do not reflect your blood glucose level. The control solution range is a target range for control solution only. It is not a target range for your blood glucose level.

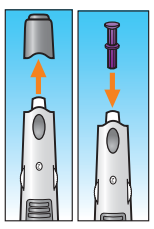
6 How to Test Your Blood Glucose Level

CAUTION: To ensure accurate results, wash your hands with warm, soapy water and dry before every test. Make sure there is no grease, oil or lotion on the test site. Use lancets only once. Do not use any lancet that has been used by another person. Interfering substances (see test strip insert sheet for interfering substances) on unwashed hands may lead to inaccurate results.

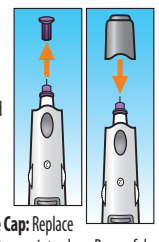
[1] Preparing the WaveSense Lancing Device: ***Use the gray cap for testing on a fingertip and the clear cap for testing on the palm (at the base of the thumb) or forearm.***

– Remove Lancing Device Cap: Pull the cap off the lancing device.

– Insert New Lancet: Insert a new WaveSense Lancet firmly into the lancet holder cup. Pushing the lancet into the lancet holder cup may cock the device; this is OK.

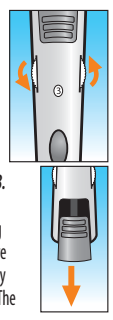


– Pull the Lancet Top Off: Hold the lancet firmly in place with one hand and use your other hand to pull off the lancet top. Do not discard the lancet top. It should be used when discarding your used lancet.



– Replace Lancing Device Cap: Replace the lancing device cap until it snaps into place. Be careful not to touch the exposed needle on the lancet.

– Set the Lancing Level: The WaveSense Lancing Device offers 8 depth settings. Rotate the dial to the desired setting as shown in the depth indicator window. Level 1 is the most shallow; level 8 is the deepest. ***If you have never lanced before, it is recommended that you start at level 3.***



– Cock the Handle: Pull the cocking handle out until it clicks. You may have already cocked the handle accidentally while inserting the lancet; this is OK. The lancing device is now ready for use.

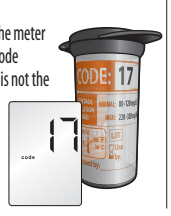
[2] Calibrating Your WaveSense KeyNote Meter

– Insert a WaveSense KeyNote Test Strip: Insert a new WaveSense KeyNote Test Strip into the meter.

Make sure you insert the test strip, with the contact bars facing up, into the strip port. The meter will be activated automatically.

Note: ***If you do not start the test within 3 minutes, the meter deactivates. To reactivate your meter, take out the unused WaveSense KeyNote Test Strip and reinsert it into the meter.***

– Adjust Code Number: The meter displays a pre-set test strip code number for 2 seconds. If this is not the same as the code number printed on the test strip vial, press the LEFT or RIGHT buttons until the meter displays the same code number as printed on the test strip vial. The meter now displays the blood drop and test strip symbols. The WaveSense KeyNote System is now ready for you to apply blood.



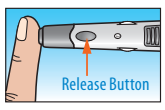
Note: ***You can still change the code number as long as you have not applied blood to the WaveSense KeyNote Test Strip by pressing the LEFT and RIGHT arrow buttons.***

[3] Lancing
– Lance Test Site: To ensure accurate results, wash hands with warm, soapy water and dry before every glucose test. ***For details on possible test sites, refer to section 1, "Important Information About Your WaveSense KeyNote System."***

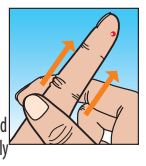
For instructions on how to test on your palm or forearm, please refer to section 7, "Testing On Your Palm or Forearm."

Note: ***Keep your hand warm or gently massage the site you are lancing to stimulate blood flow.***

Press the lancing device against the site to be lanced. Press the release button.



– Express Blood Drop: Wipe away the first blood drop that appears using a clean tissue or paper towel. Squeeze from the base of your finger up towards the tip, until a second small blood drop forms. Do not squeeze directly around the lanced area.

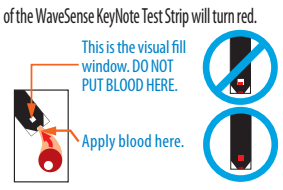


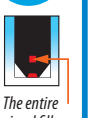
[4] Applying Blood Sample

CAUTION: Be sure not to press the RIGHT or LEFT arrow buttons while applying blood. You might accidentally change the calibration code number.

– Bring Test Strip to Blood Sample: The meter now displays the blood drop and test strip symbols. This means your WaveSense KeyNote System is now ready for you to apply blood. Immediately bring the WaveSense KeyNote Test Strip to the blood sample. ***The test strip fills from the tip. Do not try to smear blood on the top surface.***

The WaveSense KeyNote Test Strip acts like a sponge and draws the blood into the test strip through the sample area. The visual fill window of the WaveSense KeyNote Test Strip will turn red.

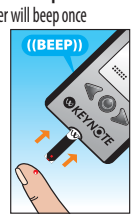




IMPORTANT: [1] Remove the test strip from the blood sample as soon as you hear the beep. **[2]** Do not press the WaveSense KeyNote Test Strip against the test site. **[3]** Do not scrape blood onto the WaveSense KeyNote Test Strip. **[4]** Do not apply blood to the top side of the WaveSense KeyNote Test Strip. **[5]** Do not apply blood to the WaveSense KeyNote Test Strip when the test strip is out of the meter. **[6]** Do not put blood or foreign objects into the WaveSense KeyNote strip port. **[7]** Do not apply more blood after beep. **[8]** Carefully read the test results on the screen before making any treatment decisions.

On the display, blood drop symbols appear on the test strip symbol to indicate that blood is filling the WaveSense KeyNote Test Strip.

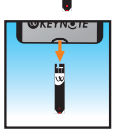
– Remove Test Strip from Blood Sample When You Hear The Beep: Your meter will beep once indicating that you should remove the tip of the WaveSense KeyNote Test Strip from the blood sample.



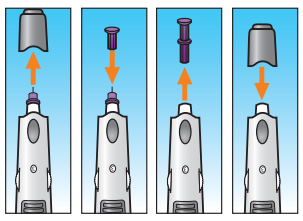
The moving dot bar indicates that your blood glucose test is in progress.

Your test is completed when your blood glucose test result with time and date is shown on the display. If the volume is enabled in SET Options, you will hear a beep. Your test result is now stored in the memory.

[5] Final Steps
– Remove the Test Strip: Remove the used WaveSense KeyNote Test Strip. The WaveSense KeyNote Meter will automatically deactivate.



– Remove the Lancet: When you have finished testing, pull off the cap from the lancing device. Replace the lancet top. Extract the lancet from the lancet holder cup by pulling on the plastic collar of the lancet (near the middle of the lancet). Replace the lancing device cap until it snaps or clicks into place.



Discard the used WaveSense KeyNote Test Strip and Lancet properly.

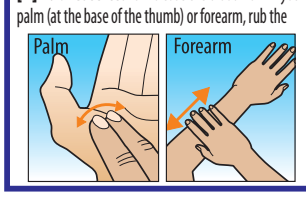
WARNING: The lancing device should only be used by one patient. Do not re-use lancets.

7 Testing on Your Palm or Forearm

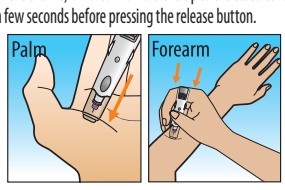
Testing glucose levels with blood obtained from the palm (at the base of the thumb) or forearm may reduce the pain of testing. The technique for testing on the palm and forearm is slightly different than testing on the finger. Always discuss changes to your testing habits with your healthcare professional.

IMPORTANT: When testing on the palm (at the base of the thumb) or forearm, you may need to set the lancing device to a deeper setting or use a larger lancet to obtain enough blood to perform a test. Consult your healthcare professional for a recommendation.

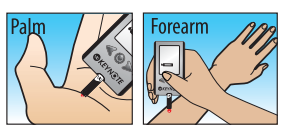
[1] Prepare the Lancing Device: Replace the gray lancing device cap with the clear cap.
[2] Rub Test Site: To increase the blood flow in your palm (at the base of the thumb) or forearm, rub the area that you will be testing. Ensure that your palm or forearm is facing up and held level.



[3] Lance Test Site: Press the tip of the clear cap against your skin on the palm of your hand (at the base of the thumb) or forearm. Hold the tip to the test site for a few seconds before pressing the release button.



[4] Express Blood Drop: After lancing, hold the lancing device against your skin until a blood droplet forms. Do not squeeze directly around the lanced area. Make sure the blood drop is large enough to completely fill the visual fill window of the test strip. Pull the lancing device directly off your palm or forearm to ensure that you do not smear the blood drop. Return to section 6, step 4 to continue with testing instructions.



8 Meter Specifications

Assay Method: Dynamic Electrochemistry
Maximum Altitude: 10,000 ft
Calibration: Plasma equivalent
Sample: Whole blood, capillary
Sample Size: 0.5 microliters
Average Glucose Test Time: 6 seconds
Measurement Units: mg/dL
Alarms: 6 programmable alarms
Result Range: 20 to 600 mg/dL
Hematocrit: 20% to 60%
Operating Relative Humidity: Up to 90%
Operating Temperature: 50 °F to 104 °F (10 °C to 40 °C)
Test Strip Storage Temperature: 46 °F to 86 °F (8 °C to 30 °C)
Memory: 300 blood glucose and control solution test results with date, time, and averaging (14, 30 and 90 days and time-of-day)
Power Source: Two CR2032, 3 volt, lithium batteries, replaceable
Automatic Shutoff: 3 minutes after last user action
Size: Width 1.6" x Length 2.8" x Height 0.6" (4.4 cm x 7.7 cm x 1.6 cm)
Weight: 44.1 g (including batteries)

9 Caring for Your Meter and Lancing Device

When using your meter, avoid getting dirt, dust, blood, control solution, water or any other liquid into the strip port and battery compartment. Clean the outside of the meter or the lancing device using a cloth dampened with mild detergent or mild soap. If you wish to clean the lancing device cap only, remove the cap, wash it in warm water, rinse well, and dry.

CAUTION: Never immerse the meter or the body of the lancing device in water or any other liquid solution.

Display Messages

CAUTION: Low or high blood glucose test results can indicate a potentially serious medical condition. Follow your healthcare professional's recommendations.

The ADA (American Diabetes Association) recommends the following target ranges for adults with Diabetes: Pre-Prandial Plasma Glucose 90-130 mg/dL and Post-Prandial Plasma Glucose < 180 mg/dL. Always consult your healthcare professional for your recommended target ranges.

LO MESSAGE: Lo *Flashing message, with double beep (if volume is enabled in SET Options)* **MEANING:** Glucose test result is lower than 20 mg/dL. This Lo result may indicate hypoglycemia (low blood glucose). The Lo result is stored in the memory with time and date. **ACTIONS:** If you feel symptoms such as weakness, sweating, nervousness, headache or confusion, follow your healthcare professional's recommendations. *If you get a Lo glucose test result but have no symptoms of low blood glucose, then retest with a new WaveSense KeyNote Test Strip. If you still get a Lo test result, follow your healthcare professional's recommendations.*

HI MESSAGE: Hi *Flashing message, with double beep (if volume is enabled in SET Options)* **MEANING:** Glucose test result is above 600 mg/dL. This Hi result may indicate hyperglycemia (high blood glucose). The Hi result is stored in the memory with time and date. **ACTIONS:** If you feel symptoms such as fatigue, thirst, excessive urination, or blurry vision, follow your healthcare professional's recommendations. *If you get a Hi glucose test result but have no symptoms of high blood glucose, then retest with a new WaveSense KeyNote Test Strip. If you still get a Hi glucose test result, follow your healthcare professional's recommendations. Checking ketones may be advisable.*

HYPOGLYCEMIC WARNING ALARM: HY PO *Test result flashes, with double beep (if volume is enabled in SET Options)* **MEANING:** If the Hypoglycemic Warning Alarm is set, your glucose test result is lower than the pre-set limit.

HYPERGLYCEMIC WARNING ALARM: HY Pr *Test result flashes, with double beep (if volume is enabled in SET Options)* **MEANING:** If the Hyperglycemic Warning Alarm is set, your glucose test result is higher than the pre-set limit.

KETONE MESSAGE: Ketone *Flashing message, with double beep (if volume is enabled in SET Options)* **MEANING:** The result of the glucose test is higher than 240 mg/dL. **ACTIONS:** You should check ketones. Follow your healthcare professional's recommendations.

TEMPERATURE MESSAGE: *Flashing message, with double beep (if volume is enabled in SET Options)* **MEANING:** The test has been performed outside the operating temperature range. **ACTIONS:** Move to an area with an ambient temperature of 50 °F to 104 °F (10 °C to 40 °C). Wait for the meter and test strips to reach the new temperature (usually 10-20 minutes) and retest.

LOW BATTERY MESSAGE: *Flashing message* **MEANING:** The battery in your meter is low. **ACTIONS:** If the battery symbol appears, the batteries must be replaced. If the battery symbol appears, the backlight will be disabled in all modes.

Troubleshooting #1

Troubleshooting Situation #1: ***Meter does not enter the TEST Mode after inserting a WaveSense KeyNote Test Strip.***

[1] CAUSE: The batteries have insufficient power. **ACTION:** Replace the batteries, set time and date, and test.

[2] CAUSE: The batteries are installed incorrectly or there are no batteries in the meter. **ACTION:** Check that both batteries are installed correctly, with the positive (+) sign facing up towards you.
[3] CAUSE: WaveSense KeyNote Test Strip has been inserted upside down, wrong end in, or incompletely inserted into the meter. **ACTION:** Insert the WaveSense KeyNote Test Strip with the black side up and the contact bars of the test strip in the meter. Ensure that the test strip is fully inserted.
[4] CAUSE: Defective meter or defective WaveSense KeyNote Test Strips. **ACTION:** Call customer service.
[5] CAUSE: Blood or foreign objects put into the WaveSense KeyNote Meter strip port. **ACTION:** Call customer service.

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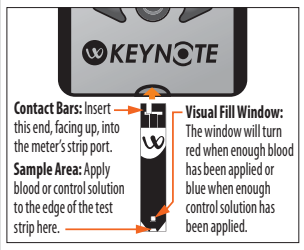
10 About the WaveSense KeyNote System

Your WaveSense KeyNote System includes:
- WaveSense KeyNote Blood Glucose Meter
- Two Pre-installed CR2032, 3 volt, Lithium Batteries
- Lancing Device with Cap
- Clear AST Lancing Device Cap
- 10 Sterile Lancets
- Compact Carrying Case
- Control Solution
- Owner's Guide

About the WaveSense KeyNote Test Strip:
With your WaveSense KeyNote System, you can test your blood glucose on your fingertips, palms (at the base of the thumb) and forearms. Testing with the WaveSense KeyNote System requires a small sample size, 0.5 µL of blood, about the size of a pinhead.

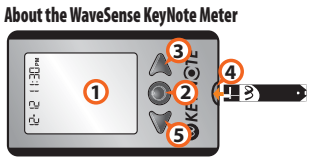


CAUTION: Discard used test strips properly.

IMPORTANT: Use WaveSense KeyNote Test Strips only once. Only use WaveSense KeyNote Test Strips with the WaveSense KeyNote System.

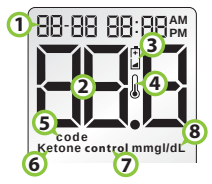
Important Test Strip Information:
[1] Store the WaveSense KeyNote Test Strip vial in a cool, dry place at 46 °F to 86 °F (8 °C to 30 °C). **[2]** Use WaveSense KeyNote Test Strips only within the system operating temperature range of 50 °F to 104 °F (10 °C to 40 °C). **[3]** Keep away from direct sunlight and heat. **[4]** Store your WaveSense KeyNote Test Strips in their original vial only; never store them in another vial, any other container or outside the vial. **[5]** After removing a WaveSense KeyNote Test Strip from the vial, immediately close the vial cap tightly. **[6]** With clean, dry hands you may gently handle the WaveSense KeyNote Test Strip when removing it from the vial or inserting it into the meter. **[7]** Do not use WaveSense KeyNote Test Strips beyond the expiration date or 90 days after first opening the vial. This may cause inaccurate results. Write the discard date (90 days from the first opening) on the test strip vial. **[8]** Do not bend, cut or alter WaveSense KeyNote Test Strips. **[9]** Apply only fresh capillary blood or control solution to the sample area of the WaveSense KeyNote Test Strip.

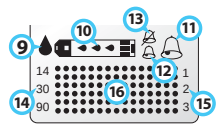
About the WaveSense KeyNote Meter



(1) Display: Glucose test results, symbols, messages, and graphs appear here. **(2) CENTER Button:** Use the CENTER button to confirm an option or make a selection in a menu. **(3) RIGHT Arrow Button:** Use the RIGHT arrow button to scroll forward through options. **(4) Strip Port:** Insert the WaveSense KeyNote Test Strip, with the contact bars facing up, into the strip port. **(5) LEFT Arrow Button:** Use the LEFT arrow button to scroll backward through options.

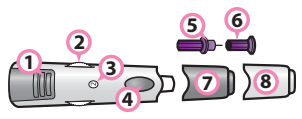
About the WaveSense KeyNote Meter Display Segments
(1) Date and Time: Appears here, including when the meter is deactivated. **(2) Glucose Test Results (3) Low Battery:** Appears when the batteries in your meter are running low. **(4) Temperature Symbol:** Appears when the meter is outside its operating temperature range of 50 °F to 104 °F (10 °C to 40 °C). **(5) Code Symbol:** Appears when displaying the code number of the test strip. **(6) Ketone Symbol:** Appears when your glucose test results are higher than 240 mg/dL. **(7) Control Solution Symbol:** Appears after you have performed a control solution test. **(8) Units of Measurement:** Results will be displayed in mg/dL.





(9) Apply Sample to Test Strip: The test strip symbol and flashing droplet symbol will signal you to apply sample to the test strip. **(10) Sample Entering Test Strip:** The three droplet symbols will appear within the test strip symbol when blood or control solution enters the test strip. **(11) High Volume:** large bell indicates high volume. **(12) Low Volume:** small bell indicates low volume. **(13) Volume OFF:** small bell with a line across it indicates mute. **(14) 14, 30 and 90 Day Indicators:** The appropriate number of days will appear when viewing graphical averages. **(15) 1,2,3 Countdown:** The 1, 2 and 3 symbols will appear during a test. **(16) Graphing Area:** Areas of the dot matrix will appear during a test and when displaying graphs.

About the WaveSense Lancing System



(1) Cocking Handle: Cocks the device so it is ready to lance. **(2) Depth Adjustment Dial:** Adjusts how deep the lancet will lance the skin. **(3) Depth Indicator Window:** Displays the depth setting of the lancing device. **(4) Release Button:** Fires the lancet. **(5) Lancet:** Lances the skin to produce a drop of blood. **(6) Lancet Cap:** Covers the lancet for safety. **(7) Lancing Device Cap:** Covers the lancet when in lancing device. Remove after inserting into the lancet holder cup. **(8) Alternate Site Testing Cap:** Used for obtaining a blood sample on the palm (at the base of the thumb) or forearm.

11 Time-of-Day Averages and Individual Results

This section covers the steps on how to view your:
– Most Recent Glucose Test Result
– 300 Past Glucose Test Results, with time and date
– Breakfast, Lunch, Dinner and Bedtime Averages

The WaveSense KeyNote Meter calculates averages of all the test results during breakfast, lunch, dinner and bedtime. Control solution, Hi and Lo test results, out-of-temperature-range results, and results without a valid date / time are not included in the averages. Averages are composed of results only within the last 14 days. Breakfast averages include glucose measurements between 4:00 AM and 10:00 AM, lunch averages are between 10:00 AM and 4:00 PM, dinner averages are between 4:00 PM and 10:00 PM, and bedtime averages are between 10:00 PM and 4:00 AM.

[1] Viewing Time-of-Day Averages
Press any button once when the meter is deactivated. The display shows the most recent glucose test result with the time and date. Press the RIGHT arrow button. The display now shows your breakfast average.

Press the RIGHT arrow button. The display now shows your lunch average.

Press the RIGHT arrow button. The display now shows your dinner average.

Press the RIGHT arrow button. The display now shows your bedtime average.

Note: ***To return to the most recent test result, press CENTER button.***

[2] Viewing Individual Results
Press and release the CENTER button. The display will show the most recent glucose test result with the time and date. Use the LEFT arrow button to view every test result, starting from the most recent and ending with the oldest.

Note: ***At any point, press CENTER button to return to the most recent test result.***

12 View 14, 30 and 90 Day Averages and Graphs

This section covers the steps on how to view your:
– 14 Day Numerical Average and Trend Graph
– 30 Day Numerical Average and Trend Graph
– 90 Day Numerical Average and Trend Graph
– 14, 30 and 90 Day Averages Comparison Graph

The WaveSense KeyNote Meter calculates the averages from the last 14, 30 and 90 days, starting from the current time and date shown on the meter. Control solution, Hi and Lo test results, out-of-temperature-range results, and results without a valid time / date are not included in the averages.

IMPORTANT: Results, averages, and graphs stored in memory should only be used as a reference. Do not make treatment decisions based solely on stored results, averages, and graphs. Consult with your healthcare professional regarding treatment options.

[1] Enter MENU Mode
Press and hold any button for 2 seconds to enter the MENU mode.

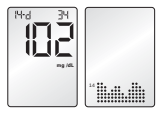
[2] Enter Memory Option
When the MEM symbol appears, press the CENTER button to enter the Memory option.

Note: ***Use the RIGHT or LEFT arrow buttons to scroll through the MENU Mode options.***

The number of glucose test results saved (within the time period) is displayed in the top right corner.

[3] Viewing MEMORY Test Results
– View 14 Day Averages and Graphs: The display shows your 14 day numerical average. Press the RIGHT or LEFT arrow buttons to view your 14 day trend graph.

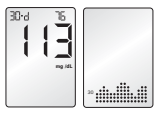
You can move from the 14 day trend graph to the 14 day numerical average by pressing the RIGHT or LEFT arrow buttons.



– View 30 Day Averages and Graphs: Press the CENTER button to view your 30 day numerical average.

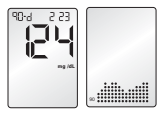
Press the RIGHT or LEFT arrow buttons to view your 30 day trend graph.

You can move from the 30 day trend graph to the 30 day numerical average by pressing the RIGHT or LEFT arrow buttons.



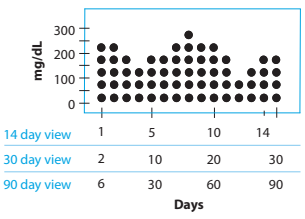
– View 90 Day Averages and Graphs:
Press the CENTER button to view your 90 day numerical average. Press the RIGHT or LEFT arrow buttons to view your 90 day trend graph.

You can move from the 90 day trend graph to the 90 day numerical average by pressing the RIGHT or LEFT arrow buttons.

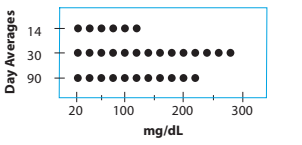


– View 14, 30 and 90 Day Average Comparison Graph: Press CENTER button to view your 14, 30 and 90 day average comparison graph. The display shows an overview with three trend bars comparing the 14, 30 and 90 days averages.

One dot represents 50 mg/dL.



One dot represents 20 mg/dL.



13 Setting Meter Volume and Backlight

[1] Enter MENU Mode: When your meter is deactivated, press and hold any button for 2 seconds to enter the MENU mode.

[2] Enter SET Option: The MEM symbol will appear. Press the RIGHT arrow button until the SET symbol is displayed. Press the CENTER button.

[3] Setting Meter Volume: There are three beep volume options. The default setting is "high." Select the preferred volume setting with the RIGHT or LEFT arrow buttons. Your selection will be highlighted by the blinking of the symbol. Press the CENTER button to confirm your selection. Continue to set the MENU Mode Backlight option.

Note: ***The meter will always produce a beeping sound after you have applied blood or control solution to a test strip. This sound lets you know when to take your blood sample or control solution away from the test strip. You will hear this sound if the volume is set to ON or OFF in the SET Options.***

[4] Setting Backlight Option: You can enable or disable the backlight. The default setting for the backlight is enabled. The changed status of the backlight will be activated immediately.

Select the preferred setting with the RIGHT or LEFT arrow buttons. Press the CENTER button to confirm and continue on to set the Time Format and Time.

Note: ***Disabling the backlight in the SET menu also disables backlight for alarms.***

14 Setting Time and Date

[1] Enter MENU Mode: When your meter is deactivated, press and hold any button for 2 seconds to enter the MENU mode.

[2] Enter SET Option: The MEM symbol will appear. Press the RIGHT arrow button until the SET symbol is displayed. Press the CENTER button.

[3] Setting Time: Press CENTER repeatedly until you see a screen with the message 12H or 24H, you are ready to set the meter's time.

Select a 12 or 24 hour clock format with the RIGHT or LEFT arrow buttons.

The 12 hour clock display option is indicated by a 12H. The 24 hour clock display option is indicated by a 24H. Your selection will be highlighted by the blinking of the symbol.

Press the CENTER button to confirm your selection and move on to the hour setting.

Set the hour (flashing) with the RIGHT or LEFT arrow buttons. Press the CENTER button to confirm and continue on to set the minute.

Hour: 5:34 PM

Set the minute (flashing) with the RIGHT or LEFT arrow buttons. Press the CENTER button to confirm and continue on to set the date.

Minute: 6:34 PM

[4] Setting Date: Set the month (flashing) with the RIGHT or LEFT arrow buttons. Press the CENTER button to confirm and continue on to the day setting.

Month: 08-26 20 08

Set the day (flashing) with the RIGHT or LEFT arrow buttons. Press the CENTER button to confirm and move on the year setting.

Day: 08-26 20 08

Set the year (flashing) with the RIGHT or LEFT arrow buttons. Press the CENTER button to confirm and continue on to set the Hypo Limit.

Year: 08-26 20 08

15 Setting Hypoglycemic and Hyperglycemic Warning Alarms

[1] Enter MENU Mode: When your meter is deactivated, press and hold any button for 2 seconds to enter the MENU mode.

[2] Enter SET Option: The MEM symbol will appear. Press the RIGHT arrow button until the SET symbol is displayed. Press the CENTER button.

[3] Setting Your Hypoglycemic Warning Alarm: Press CENTER repeatedly until you see the HYPO symbol in the top right corner of the screen. You are ready to set the Hypoglycemic Warning Alarm.

WARNING: Your healthcare professional should recommend what your hypoglycemic limit is.

The Hypoglycemic Warning Alarm alerts you when your glucose test results are below the hypoglycemic limit that you have set. The meter is pre-set to a hypoglycemic limit of 70 mg/dL. Always consult your healthcare professional for your recommended target ranges. When your glucose test results are below your set hypoglycemic limit, the date, time and result will flash on the display.

Set the Hypoglycemic Limit ON or OFF with the RIGHT or LEFT arrow buttons. Your selection will be highlighted by the blinking of the symbol. Press the CENTER button to confirm your selection.

Set the Hypoglycemic Limit (flashing) with the RIGHT or LEFT arrow buttons. Press CENTER button to confirm and continue on to set the Hyper Limit.

[4] Setting Your Hyperglycemic Warning Alarm:

WARNING: Your healthcare professional should recommend what your hyperglycemic limit is.

The Hyperglycemic Warning Alarm alerts you when your glucose test results are above the hyperglycemic limit that you have set. The meter is pre-set to a hyperglycemic limit of 240 mg/dL. Always consult your healthcare professional for your recommended target ranges. When your glucose test results are above your set hyperglycemic limit, the date, time and result will flash on the display.

Set the Hyperglycemic Limit ON or OFF with the RIGHT or LEFT arrow buttons. Your selection will be highlighted by the blinking of the symbol. Press CENTER button to confirm your selection.

Set the Hyperglycemic Limit (flashing) with the RIGHT or LEFT arrow buttons. Press CENTER button to confirm. This will bring you back to MENU Mode at the SET options.

16 Setting Alarms

There are 6 alarms you can set to remind you when to test your glucose levels.

When alarms are activated: [1] If an alarm is set and the WaveSense KeyNote Meter is deactivated, the alarm will activate the meter. "AL1" thru "AL6" (depending which alarm is set) is displayed. The display backlight flashes, and the meter will beep repeatedly for 15 seconds. **[2]** You can turn the alarm OFF by pressing any button. **[3]** The alarms will not appear during Menu and Test Modes. If an alarm is set to sound or flash while using these modes, it will appear after the meter is deactivated.

CAUTION: Follow your healthcare professional's recommendations on when and how often to test your glucose.

[1] Enter MENU Mode: When your meter is deactivated, press and hold any button for 2 seconds to enter the MENU mode.

[2] Enter Alarm Option: The MEM symbol appears. Press the RIGHT or LEFT arrow buttons until the alarm you want to set is displayed (AL1 to AL6). If this is your first time setting an alarm, use AL1. Press CENTER to select an alarm to set.

[3] Turning Alarms ON or OFF: Press the RIGHT or LEFT arrow buttons to enable (ON) or disable (OFF) the alarm. The default setting is OFF. Confirm your selection by pressing CENTER button. Your selections will be highlighted by a blinking symbol.

[4] Setting Alarm Times: You can now set the time. First, set the flashing numbers (hour) with the RIGHT or LEFT arrow buttons. Accelerated change is possible by holding down the arrow buttons. Press CENTER to confirm and to move on to set the minute.

Set (minute) with the RIGHT or LEFT arrow buttons. Press the CENTER button to confirm the alarm time and to move on to set the alarm volume.

[5] Setting Alarm Volumes: There are three volume options. A silent alarm will only flash the meter's screen. The default setting is "high". Select your preferred setting with the RIGHT or LEFT arrow buttons. Confirm by pressing the CENTER button. This will bring you back to MENU Mode.

Note: ***The volume of an alarm will be affected by the meter's volume setting, which can be changed in the meter's settings (SET) option. If your meter is set to silent mode, then the alarm will not sound, regardless of the individual alarm setting. Also, if your meter is set to low volume mode, then an alarm set for high volume will default to low volume mode.***

[6] Setting Multiple Alarms: To set other alarms, press the RIGHT or LEFT arrow buttons until the alarm you want to set (AL1 to AL6) is displayed. Follow the previous steps in this section 16, "Setting Alarms."

17 Batteries

CAUTION: When the battery symbol appears, you should replace the batteries immediately. Only use CR2032 batteries.

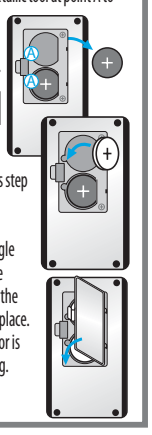
Your WaveSense KeyNote Meter comes with two pre-installed, CR2032, 3 volt, lithium batteries. If your batteries run low, the battery symbol flashes until you change the batteries. The backlight is disabled in all modes when the battery symbol is on. When changing batteries the current time and date settings will be reset. The time and date will automatically be set to 01-01 12:00. Correct time and date settings are needed to get correct averages. Removing the batteries does not affect the meter's memory or previously stored user settings, such as those set in SET Options (e.g. calibration code, alarms, etc.). If a battery is installed incorrectly it will damage the other battery in the meter. If this happens discard both batteries.

Replacing the Batteries
[1] Open Battery Door: Make sure the meter is deactivated. Turn the meter so you are looking at the battery door. Press the battery door clip to the right to open. Remove the battery door. Be careful not to misplace the battery door.

[2] Remove and Install 1st Battery: To remove the used battery, use a non-metallic tool at point A to pop out the battery. Install the new battery with the positive (+) sign facing up towards you.

Used: ⊕ New: ⊕

[3] Remove and Install 2nd Battery: Repeat previous step for the 2nd battery.



[4] Close Battery Door: Angle the battery door back onto the meter. Swing down and press the door until it snaps gently into place. Make sure that the battery door is completely closed before using.

18 Important Health-Related Information

Please Read the Following: [1] Severe dehydration and excessive water loss may yield inaccurate results. If you believe you are suffering from severe dehydration, consult your healthcare professional immediately. **[2]** The ADA (American Diabetes Association) recommends the following target ranges for adults with Diabetes: Pre-Prandial Plasma Glucose 90-130 mg/dL and Post-Prandial Plasma Glucose < 180 mg/dL. Always consult your healthcare professional for your recommended target ranges. **[3]** Results below 70 mg/dL may mean low blood glucose levels (hypoglycemia). **[4]** Results over 240 mg/dL may mean high blood glucose levels (hyperglycemia). Checking ketones may be advisable. **[5]** If you get results below 70 mg/dL or above 240 mg/dL and do not have symptoms of hypoglycemia or hyperglycemia, repeat the test. If you have symptoms, or continue to get results that fall below 70 mg/dL or rise above 240 mg/dL, follow your healthcare professional's recommendations. **[6]** If you are experiencing symptoms that are not consistent with your blood glucose test and you have followed all instructions described in the WaveSense KeyNote Owner's Guide, follow your healthcare professional's recommendations. **[7]** Patients undergoing oxygen therapy may receive inaccurate results. **[8]** Always follow your healthcare professional's recommendations.

Error Messages

The WaveSense KeyNote Blood Glucose Monitoring System has been designed to work accurately under most usual conditions. On rare occasions, the meter will display an error message instead of a glucose result. The WaveSense KeyNote system is able to detect specific problems which may allow you to determine the cause of the error without wasting valuable test strips. When you are presented with an error message, check for common problems that may explain the source of the error.

CAUTION: In certain cases, the meter may return an error code or provide an inaccurate result if it is being used near electrical equipment, like a power generator or a computer monitor.

Error 1: Er 1 ***Problems have occurred that are related to test strip use.***
[1] If this message appears the moment the test strip is inserted, the test strip may be wet or damaged. **[2]** If the message appears during a test, the test strip may have been removed too early. **[3]** If this message appears after the last progress bar instead of a result, it may indicate that you applied more blood after testing began.

Error 2: Er 2 ***The meter has detected an irregularity with the sample.***
[1] The test strip may be partially filled; you should check the window of the test strip to confirm that it is full. **[2]** The sample may not be blood or control solution. **[3]** You may have entered the wrong calibration code.

Error 3: Er 3 ***The meter has detected that the test strip is in poor condition.***
[1] The test strip may have been improperly stored (e.g. hot, humid conditions) or may be expired. **[2]** The test strip may have been mishandled by vigorous bending or shaking. **[3]** Parts of the test strip may have become covered in grease, oil or lotion. **[4]** The strip port connector may be dirty.

Error 4: Er 4 ***Unusual test strip problems have occurred that may be related to extreme conditions.***
[1] Retest where it is closer to a room temperature of 70 °F to 75 °F (21 °C to 24 °C).

Error 5: Er 5 ***The meter was unable to produce a reliable result.***
[1] This may be caused by a non-blood sample or a combination of high glucose and other medical conditions. **[2]** If this error code persists on retesting, consult your healthcare professional.

Error 6: Er 6 ***The test strip has taken too long to generate a signal.***
[1] This may be caused by a combination of cold operating temperature and high hematocrit levels. Retest in a warmer location. **[2]** If this error code persists on retesting, consult your healthcare professional.

Error 7 with Battery Icon: Er 7 ***Replace batteries immediately before testing.***

Error 7: Er 7
Meter problems have occurred that are beyond your control. Contact customer service for assistance.

Troubleshooting #2

Troubleshooting Situation #2: ***The glucose test sequence does not start after applying the blood sample.***

[1] CAUSE: Defective test strip. **ACTION:** Repeat the test with a new WaveSense KeyNote Test Strip. If this does not work, call customer service.
[2] CAUSE: Sample applied after meter times out and deactivates. **ACTION:** Repeat the test using a new WaveSense KeyNote Test Strip. Wait until you see the blood and test strip symbols on the display screen before you apply the blood sample.
[3] CAUSE: Defective meter. **ACTION:** Call customer service.

24-Hour Customer Service:
+1 (866) 906 4197

In case of emergency, contact your healthcare professional or emergency response.