

AgaMatrix®

 WaveSense **JAZZ™**
WIRELESS

 [®] AUTOMATICALLY SYNCs VIA
Bluetooth® technology



Advanced Blood Glucose Monitoring System

OWNER'S GUIDE

Welcome to Your New AgaMatrix WaveSense JAZZ™ Wireless Blood Glucose Monitoring System

The AgaMatrix WaveSense JAZZ Wireless Blood Glucose Meter is designed to work with the AgaMatrix Diabetes Manager, an iOS or Android™ application (app) installed on a supported device. Data is transmitted between the AgaMatrix WaveSense JAZZ Wireless Meter and the AgaMatrix Diabetes Manager App via *Bluetooth*® wireless technology.

Key Features in the AgaMatrix WaveSense JAZZ Wireless Meter

Convenient Connection – The AgaMatrix WaveSense JAZZ Wireless uses *Bluetooth*® *Smart* wireless technology–for an easy to use, low energy connection to supported devices.

Seamlessly Sync Results to App – Use the AgaMatrix WaveSense JAZZ Wireless Meter with the AgaMatrix Diabetes Manager App to sync glucose results directly to your iOS or Android device. The App can be used to conveniently store and manage your diabetes information, review trends, or share with your healthcare team. It can be downloaded from the App StoreSM or on Google Play™.

Small size – The AgaMatrix WaveSense Jazz Wireless Meter is small and portable, for easy testing on the go.

System Requirements (Meter and App)

A compatible iOS or Android device. Visit our website for more information: www.agamatrix.co.uk



Customer Care: 0800 093 1812 (Landline Freephone) or 01235 838588 (Mobile Freephone*).

*If free minutes included in contract.

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

By using the AgaMatrix WaveSense JAZZ Wireless Blood Glucose Monitoring System (Meter) with the AgaMatrix Diabetes Manager (the App).

You agree that the use of this software together with an iPod, iPhone or iPad ("Apple Product") shall only be as a personal organization or supplemental data display tool and not as a source of medical advice. You agree that this software will never be used to replace the advice of a doctor, or your own common sense and independent judgment, and that you will not at any time rely on any information presented on your Apple Product as the basis for health care, medical or other decisions that may result in injury or other ill effects. You agree to take sole responsibility for your health care decisions, including contacting a physician or other health care professional regarding all medical conditions, tests, diagnoses and treatment options and agree that Apple shall have no liability for any action you or anyone using the software may take, regardless of the information received, displayed, calculated or transmitted by your Apple Product. Apple assumes no risk for your use of the software and makes no warranties whatsoever, express or implied, regarding the accuracy, completeness or usefulness of any information presented on your Apple Product as a result of using the software.



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1 Important Information About Your AgaMatrix WaveSense JAZZ Wireless System

This Owner's Guide is intended to instruct the user on how to use the meter.

Your meter is ready to use right out of the box. Unpack your system. Check that all system kit contents are included—there is a list of kit contents in this Owner's Guide. Ensure that the retail carton has not been damaged.

You should sync your meter to the AgaMatrix Diabetes Manager App (the App) to set your meter's time and date before testing. This will ensure that results from meter are sent wirelessly to the App. See Chapter 5 for more information.

CAUTION: Please read all the instructions provided in this Owner's Guide and practice the testing procedures before using the AgaMatrix WaveSense JAZZ Wireless Blood Glucose Monitoring System. Blood glucose monitoring should be done under the guidance of a healthcare professional (HCP).

Important Safety Instructions:

The lancing device and lancets should only be used by one person. Never share lancing devices or lancets. Used test strips, lancets, and lancing devices may be considered bio-hazardous or medical waste in your city or town. Follow your healthcare professional's instructions for disposal.

To ensure accurate results and reduce chance of infection and disease spread by blood:

- Wash your hands and the test site with warm, soapy water, rinse and dry thoroughly before every test. Unwashed hands and test sites may lead to inaccurate results.
- Make sure there is no grease, oil or lotion on the test site.
- Use lancets only once.
- Do not use any lancing device or lancet that has been used by another person.
- Always keep your meter and lancing device clean.

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

Keep the meter and testing supplies away from young children. Small items such as test strips, lancets, protective covers on the lancets, and control solution vial cap are choking hazards. Do not ingest or swallow any items.

AgaMatrix WaveSense JAZZ Wireless Blood Glucose Monitoring System Test Principle:

The AgaMatrix WaveSense JAZZ Wireless blood glucose monitoring system measures a glucose concentration in a sample of fresh capillary whole blood.

WaveSense™ is the technology used in AgaMatrix Meters. After insertion of a test strip into the AgaMatrix WaveSense

JAZZ Wireless Meter, a sample of blood obtained by fingerstick is applied to the test strip. The blood sample size for the meter is a minimum of 0.5 μ L.

The blood reacts with a reagent on the test strip that contains glucose oxidase, an electron mediator, and other materials. The chemical reaction with glucose that takes place on the strip generates an electrical signal that is measured and processed by the meter.

The meter computes a glucose concentration and displays the result. The measurement range of the system is 1.1 to 33.3 mmol/L glucose. Capillary whole blood samples with a haematocrit range of 20% to 60% can be measured.

The AgaMatrix WaveSense JAZZ Wireless Meter is calibrated to provide a glucose concentration for a capillary whole blood sample that is equivalent to the plasma glucose concentration of that sample.

AgaMatrix WaveSense JAZZ Wireless Blood Glucose Monitoring System Intended Use:

[1] For the quantitative measurement of blood glucose levels in fresh capillary whole blood samples drawn from the fingertip, palms (at the base of the thumb), or forearms.

[2] For self testing outside the body (*In vitro* diagnostic use), by people with diabetes at home (over the counter (OTC)), or in a clinical setting by healthcare professionals, as an aid to monitor the effectiveness of diabetes control.

[3] With AgaMatrix WaveSense JAZZ Test Strips and AgaMatrix

Control Solution only. Do not use other brands of test strips and control solution with this meter. This may produce inaccurate results.

IMPORTANT: The AgaMatrix WaveSense JAZZ Wireless Meter is intended to be carried in the carrying case provided and not directly in a pocket. If the meter is carried in a pocket it could be damaged.

Do Not Use the AgaMatrix WaveSense JAZZ Wireless Blood Glucose Monitoring System for:

- [1] The diagnosis of or screening of diabetes.
 - [2] Testing the glucose levels of neonates (children under 4 weeks).
 - [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.
 - [5] Alternative site results should never be used to calibrate a continuous glucose monitor (CGM).
 - [6] Alternative site results should never be used in insulin dose calculations.
-

AgaMatrix WaveSense JAZZ Test Strips

AgaMatrix WaveSense JAZZ Test Strips are for use with the AgaMatrix WaveSense JAZZ Wireless Blood Glucose Meter to

quantitatively measure glucose in fresh capillary whole blood samples drawn from the fingertip, palm (at the base of the thumb), or forearm.

AgaMatrix Control Solutions

AgaMatrix Control Solutions are for use with the AgaMatrix WaveSense JAZZ Wireless Blood Glucose Meter and AgaMatrix WaveSense JAZZ Test Strips to check that the meter and test strips are working together properly and that the test is performing correctly.

Bluetooth® Smart

Bluetooth® Smart is a type of wireless RF (Radio Frequency) communication. Cell phones use Bluetooth® wireless technology as do many other devices. Your meter uses Bluetooth® Smart to pair with compatible iOS and Android devices to send results to the AgaMatrix Diabetes Manager (the App).

Note: You should sync your meter to the App to set your meter's time and date before testing. This will ensure that results from meter are sent wirelessly to the App. See Chapter 5 for more information.

Supported Devices

The AgaMatrix Diabetes Manager, “the App”, is an application that allows users to add, modify, and view health data, including glucose, insulin, carbs, and weight. The App works on a variety of iOS and Android devices. To see an updated list,

visit your meter manufacturer's website.

When the App is paired with your meter the data from your meter will automatically sync with your App whenever the two devices are in range.

CHAPTER

2 The AgaMatrix WaveSense JAZZ Wireless System Kit

The System Kit Contains:

- AgaMatrix WaveSense JAZZ Wireless Blood Glucose Meter
- Two Pre-installed CR2032, 3 Volt, Lithium Batteries
- Lancing Device with Cap
- Clear AST Lancing Device Cap
- 30 Sterile Lancets
- Compact Carrying Case
- 1 Vial of 25 AgaMatrix WaveSense JAZZ Test Strips
- AgaMatrix WaveSense JAZZ Test Strip Insert
- AgaMatrix Control Solution
- AgaMatrix Control Solution Insert
- AgaMatrix WaveSense JAZZ Wireless Owner's Guide
- AgaMatrix WaveSense JAZZ Wireless Quick Start Guide
- Prescription Card
- Registration Card
- Two Replacement CR2032, 3 Volt, Lithium Batteries
- AgaMatrix Log Book

About the AgaMatrix WaveSense JAZZ Wireless Meter

Please note the correct orientation of the device in the sample image below.



(1) Display Area: Glucose test results, symbols, and messages appear here.

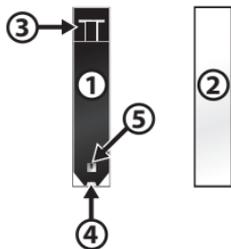
Inspect the display for damage by viewing the Intro Animation. You will see the Intro Animation every time you insert a test strip or press the meter button. If you see a significant portion of the display not lighting up appropriately, do not use the meter and call Customer Care.

(2) Meter Button: The button is the circle on the front of the meter. It is on the opposite side of the meter's strip port. It is used to turn on the meter and view past glucose test results.

(3) Test Strip Port: Insert the AgaMatrix WaveSense JAZZ Test Strip, with the contact bars facing up, into the test strip port.

About the AgaMatrix WaveSense JAZZ Test Strips

With your system, you can test your blood glucose on your fingertips. Testing with the system requires a small sample size, 0.5µL of blood, about the size of a pinhead.



(1) Front of the Test Strip: The front of the test strip is black in color. Ensure that the front (black-colored) side of the test strip is facing towards you when inserting a test strip into the meter's test strip port.

(2) Back of the Test Strip: The back of the test strip is white in color. Ensure that the back (white-colored) side of the test strip is facing away from you when inserting a test strip into the meter's test strip port.

(3) Contact Bars: This end is inserted, front of the test strip facing towards you, into the meter's test strip port.

(4) Sample Area: Blood or control solution should be applied to the tip of the test strip here.

(5) Visual Fill Window: This window will turn red when enough blood has been applied or blue when enough control solution has been applied.

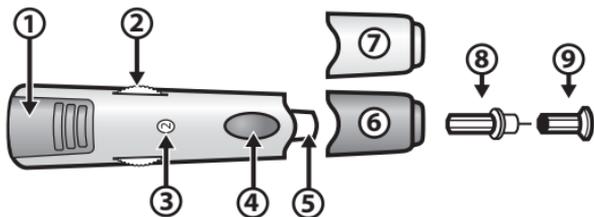
Important Test Strip Information:

- Store the AgaMatrix WaveSense JAZZ Blood Glucose Test Strip vial in a cool, dry place at 8°C to 30°C.
- Use the AgaMatrix WaveSense JAZZ Blood Glucose Test Strips only within the system operating temperature range of 10°C to 40°C.
- Keep away from direct sunlight and heat.
- Store your AgaMatrix WaveSense JAZZ Blood Glucose Test Strips in their original vial only; never store them in another vial, any other container or outside the vial.
- With clean, dry hands you may gently handle the AgaMatrix WaveSense JAZZ Blood Glucose Test Strip when removing it from the vial or inserting it into the meter.
- After removing an AgaMatrix WaveSense JAZZ Blood Glucose Test Strip from the vial, immediately close the vial cap tightly.
- Do not use AgaMatrix WaveSense JAZZ Blood Glucose Test Strips beyond the expiration date or 180 days after first opening the vial. This may cause inaccurate results. Write the discard date (180 days from the first opening) on the test strip vial.
- Do not bend, cut or alter AgaMatrix WaveSense JAZZ Blood Glucose Test Strips.
- Apply only fresh capillary blood or control solution to the sample area of the AgaMatrix WaveSense JAZZ Blood

Glucose Test Strip.

- Use AgaMatrix WaveSense JAZZ Blood Glucose Test Strips only once.
- Only use AgaMatrix WaveSense JAZZ Blood Glucose Test Strips with the AgaMatrix WaveSense JAZZ and AgaMatrix WaveSense JAZZ Wireless Meters.
- Dispose of used test strips properly.

About the AgaMatrix Lancing Device



(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 Holder Cup: Holds the lancet into place inside the lancing device.

(6) Lancing Device Cap: Covers the lancet when in lancing device.

(7) Alternate Site Testing Cap: An AST clear lancing device cap used for obtaining a blood sample on the palm (at the base of the thumb) or forearm.

(8) Lancet: Lances the skin to produce a drop of blood.

(9) Lancet Cover: Covers the lancet for safety. Remove after inserting into the lancet holder cup.

Meter Basics

[1] Battery Installation: The batteries are pre-installed in the AgaMatrix WaveSense JAZZ Wireless Meter.

[2] To Pair with a Secondary Device (iOS/Android): The meter is ready to be used right out of the box, however, if you want to sync readings from your meter to the App and set your meter's time and date, you must pair your meter with the App. See Chapter 5 for details on pairing and syncing.

Test results without a set time and date will be saved to the meter in chronological order, but will not sync to the App when paired.

Test results taken prior to the time and date being set will not have a time and date associated with them on the meter. You

can manually add these readings to the App to include them in your statistics.

[3] Review Mode: While the meter is off enter review mode by pressing the Meter Button. The most recent glucose test result will display.

Each time the Meter Button is pressed the display will scroll to the next result in history.

Example Result:

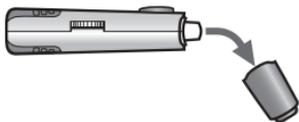


[4] Turning Off: The meter will automatically turn off after 30 seconds of being inactive.

Preparing the Lancing Device for Use

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.

[1] Remove Lancing Device Cap: Snap off the cap from the lancing device.



[2] Insert New Lancet: Insert a new lancet firmly into the lancet holder cup as shown in the picture below. Pushing the

lancet into the lancet holder cup may cock device; this is OK.



[3] Twist the Lancet Cover Off: Hold the lancet firmly in place with one hand and use your other hand to twist off the lancet cover. Keep the lancet cover. It should be used when discarding your used lancet.



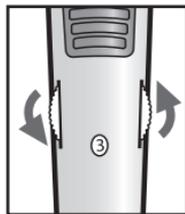
[4] Replace Lancing Device Cap: Replace the lancing device cap until it snaps into place. Be careful not to touch the exposed needle on the lancet.



[5] Set the Lancing Level: The AgaMatrix Lancing Device offers 8 depth settings.

Rotate the dial to the desired setting as shown in the depth indicator window.

Level 1 is the shallowest; level 8 is the deepest. If you have never lanced before, it is recommended that you start at level 3.



[6] Cock the Handle: Pull the cocking handle out until it clicks. You may have already cocked the handle while inserting the

lancet; this is OK.



The lancing device is now ready for use.

CHAPTER

5 Pairing and Syncing Your Meter with the App

The AgaMatrix Diabetes Manager (“the App”) is an application that allows users to add, modify, and view health data, including glucose, insulin, carbs, and weight.

The app works on a variety of iOS and Android devices. To see an updated list, visit your meter manufacturer’s website.

When the App is paired with your meter, the data from your meter will automatically sync with your app whenever the two devices are in range, about 10 meters.

The App can be downloaded for free from the App StoreSM on your iPhone® or iPod touch® or on Google Play™ on your Android™ device.

IMPORTANT: Please note that the App stores sensitive health-related information on your supported device. We recommend keeping your supported device up-to-date with the latest security software. For more information on keeping your supported device and information safe, please contact the manufacturer of your supported device.

Pair Versus Sync

All devices that communicate via Bluetooth® wireless technology need to first “pair” with each other so they can establish a connection and get authorized to communicate with each other. You will only have to pair your meter to another device one time.

After your meter is paired with your device, it will “sync”, or transfer data, every time it is within close proximity (10 meters) of your paired device.

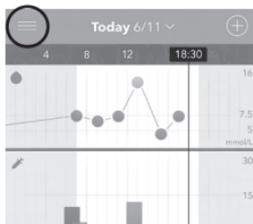
Pairing for the First Time

Before pairing your meter with the App for the first time, the App must be installed on your supported device. Ensure that the date and time on your supported device is correct.

[1] Launch the App: Tap on the App icon on your supported device.



[2] Navigate to the Menu: Tap on the icon made of three lines.



[3] Tap on “Meters”

[4] Tap “Add a new meter”

[5] On your meter, press and hold the Meter Button.

[6] Select your meter when it appears in the App. A 6-digit passkey will appear on the meter.

Example image of a passkey:



[7] Type the number into the App.

Both the meter and the App will indicate that pairing was successful. The meter will have a check symbol and the App will show a message.

Example image of a check symbol:



The meter and the App must be within 10 meters of each other in order to pair and transfer data.

WARNING: Do not pair the meter with an App on a device used by another person. Data synced from the meter cannot be deleted from the App. If you pair with another person’s meter, the data from each meter will be combined in the App and may give you incorrect reports.

How to Pair an Additional Meter

You can pair your meter with up to 8 supported devices. Follow the same steps above to pair additional meters.

How to Un-pair the App from the Meter

[1] In the App, tap on the Menu icon, then tap on “Meters.”

[2] Find the meter you wish to disassociate with your App by matching the serial number shown in the App to the number shown on the serial number label. You can find this label under the meter battery door.

[3] Swipe left on the selected meter. Tap on “forget.” The meter will no longer transfer data to the App.

Automatic Data Transfer (Sync)

The first time your meter pairs with your supported device it will set the date and time on your meter.

Every time your meter and supported device are within 10 meters of each other, and the meter is turned on, any recent data will be transferred to the App and the date and time will be set to match the date and time on your supported device.

Time and Date

The time and date settings on the meter are configured to match the supported device’s time and date settings.

For example: if your supported device is set to 12 hour time, the meter's time will be set to 12 hour time. If your device is set to 24 hour time, you will see an "a" or "p" next to the time.

Example of 12 hour time:

A digital display with a black background and white text. On the left, the number "7.0" is shown in a large, bold font. To its right, the time "12:20p" is displayed in a smaller font.

Example of 24 hour time:

A digital display with a black background and white text. On the left, the number "7.0" is shown in a large, bold font. To its right, the time "12:20" is displayed in a smaller font.

For example: a date of "10/12" will mean Oct 12 if your supported device set to MM/DD, and it will mean Dec 10 if your supported device is set to DD/MM.

A digital display with a black background and white text. On the left, the number "7.0" is shown in a large, bold font. To its right, the date "10/12" is displayed in a smaller font.

Airplane Mode

You can keep your meter paired with your supported device while flying, just turn Bluetooth on while the device is in Airplane mode.

Force Data Transfer (Sync)

If you suspect that data is not being transferred from the meter to the App, you can force the two to sync.

[1] In the App, navigate to the “Meters” section of the menu.

[2] You should see your meter listed. If there are no meters listed, you must pair your meter to your App. See pairing instructions at the start of this chapter.

[3] If you see your meter listed, tap on the “Sync” button.

[4] Press the Meter Button on your meter to activate the screen.

All new data will transfer to the App and the meter will be set with the time and date of your supported device.

All test result scorecards in the App that have been synced from the meter cannot be deleted.

CHAPTER

6

Important Information about Performing Control Solution Tests

The AgaMatrix WaveSense JAZZ Wireless Blood Glucose Monitoring System should only be used with AgaMatrix Control Solution.

The Control Solution is Used to:

[1] Ensure that your 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 meter.
 - [2]** Suspect that your meter or test strips are not working properly.
 - [3]** Think your test results are not accurate.
 - [4]** Have dropped or damaged your meter or exposed your meter to liquids.
 - [5]** Are advised by your healthcare professional to do so.
-

Important AgaMatrix Control Solution Information:

- [1]** Use only AgaMatrix Control Solution with your AgaMatrix WaveSense JAZZ Wireless Meter.
 - [2]** Always shake the control solution bottle before use.
 - [3]** Always discard the first drop of control solution and wipe the bottle tip clean using a clean tissue or paper towel.
 - [4]** Replace the cap on the control solution bottle immediately after use.
 - [5]** Do not add water or any other liquid to control solution.
 - [6]** Control solution tests should be performed within the system operating temperature range of 10°C to 40°C (50°F to 104°F).
-

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]** Meter malfunction.
- [6]** Control solution test done outside the system operating temperature of 10°C to 40°C (50°F to 104°F).
- [7]** Failure to shake the control solution bottle vigorously before using.
- [8]** Failure to discard the first drop of control solution and to wipe the bottle tip clean.

IMPORTANT: 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.

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.

[1] Inserting a Test Strip: Insert a test strip into the meter's test strip port. Make sure you insert the test strip into the strip port with the contact bars facing towards you.



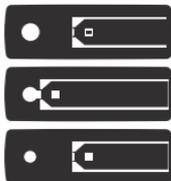
The meter will turn on when the test strip is inserted.



[2] Meter Ready for Test: The meter will then display the Apply Sample to Test Strip Animation, indicating it is now ready for you to apply control solution. You do not need to set a calibration code for this meter.

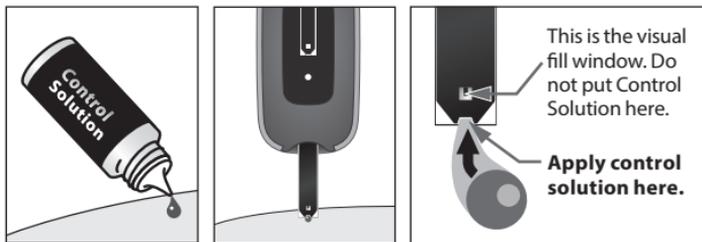


Apply Sample to Test Strip Animation:



[3] Applying Control Solution:

1. Shake the control solution bottle.
2. Discard the first drop of control solution.
3. Wipe the bottle tip clean using a clean tissue or paper towel.
4. Dispense a second drop onto a clean surface, such as an unused resealable plastic bag.
5. Avoid handling the test strip's sample area (where control solution should be applied).
6. Bring the tip of the test strip to the control solution sample at a 90 degree angle immediately so that the control solution does not evaporate.



The meter will automatically detect if a test is performed with control solution.

[4] Remove the Test Strip from Control Solution Sample When the Test Strip's Visual Fill Window Completely Turns Blue:



The sample applied symbol will appear on the meter's screen and will beep when the meter recognizes the control solution and has enough to calculate a result.

Sample Applied Symbol:



The calculating animation will begin on the meter display. This animation indicates that a sample has been applied to the test strip and the meter is calculating the test result.

Calculating Animation:



[5] Viewing Control Solution Test Result: The control solution test result will appear on the meter display.

The unit of measure (mmol/L) will appear to the right of the control solution test result. The control solution bottle symbol will appear next to the test result.

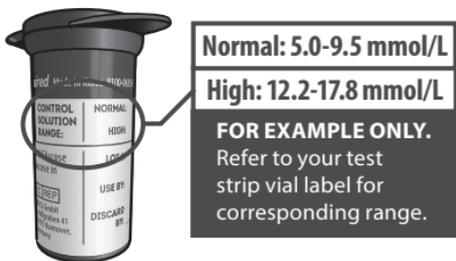
The control solution test result is stored in the meter's memory but will not transfer to the App during syncing.

Example Result:

7.2  **mmol/L**

Compare the result of your control solution test to the range printed on your test strip vial label for the control solution level that you used. Your control solution result should fall within this range.

Example Result:



If Your Control Solution Test Results Are Out of the Range:

- [1]** Repeat the test and refer to Chapter 14 of this guide to see potential causes of error.
- [2]** If the results from the control solution tests continue to fall outside that range, do not use the meter to test your blood glucose.
- [3]** Call Customer Care. The phone number is printed at the start of this guide and also printed on the back of your meter.

[6] Remove the Used Test Strip From the Strip Port:

Control solution test results will not be sent to the App on your supported device.



Removing the used test strip will turn off your meter.

[7] Dispose of Used Materials Properly: Follow your healthcare professional's instructions for disposal.

CHAPTER

8

**Before you Test your Blood –
Important Health-Related Information**

[1] Inaccurate results may occur in severely hypotensive individuals or patients in shock. Inaccurate low results may occur for individuals experiencing a hyperglycaemic-hyperosmolar state, with or without ketosis. Critically ill patients should not be tested with blood glucose meters.

[2] Severe dehydration and excessive water loss may yield inaccurate results. If you believe you are suffering from severe dehydration, consult your healthcare professional immediately.

[3] Patients undergoing oxygen therapy may receive

inaccurate results.

[4] Results below 3.9 mmol/L may mean low blood glucose levels (hypoglycaemia).

[5] Results over 13.3 mmol/L may mean high blood glucose levels (hyperglycaemia). Checking ketones may be advisable.

[6] If you get results below 3.9 mmol/L or above 13.3 mmol/L and do not have symptoms of hypoglycaemia or hyperglycaemia, repeat the test. If you have symptoms, or continue to get results that fall below 3.9 mmol/L or rise above 13.3 mmol/L, follow the treatment plan recommended by your healthcare team or contact your healthcare professional immediately.

[7] If you are experiencing symptoms that are not consistent with your blood glucose test and you have followed all instructions described in this Guide, follow your healthcare professional's recommendations.

[8] If you get repeated error messages and are experiencing symptoms of hypo or hyperglycaemia, contact your healthcare professional immediately as this may indicate low or high glucose. If this error code persists on retesting, consult your healthcare professional (see Chapter 14: Error Messages).

[9] Do not use test strips that are expired or appear to be damaged as they may return inaccurate results.

[10] Healthcare professionals should follow their institution's infection control protocols.

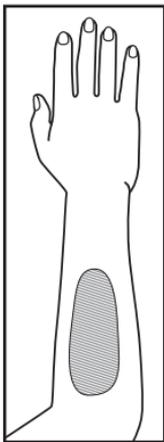
[11] Always follow your healthcare professional's recommendations.

[12] Treatment goals are individualized for each patient. Speak with your healthcare professional about the target blood glucose ranges that are right for you.

[13] Prior to performing a blood glucose measurement be sure the testing environment is between the operating temperature range of your system (found at the back of this guide).

Possible test sites:

The meter only requires a small droplet of blood (0.5 μ L), about the size of a pinhead, 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 alternative, but less accurate, test sites. Only select soft and fleshy areas to lance. Avoid lancing any bony areas, obvious veins or 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, or exercise. Changes in blood glucose may be detected in the fingertips, before the palm (at the base of the thumb) and forearm.

Alternative site testing should be done only during steady-state times (when glucose is not changing rapidly).

It is recommended that you use a fingertip sample if:

[1] You are testing for hypoglycaemia or if you suffer from hypoglycaemia unawareness.

[2] You are testing your blood glucose within 2 hours of eating, taking insulin, medication, exercise.

[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: To ensure accurate results and reduce chance of infection and disease spread by blood, wash your hands and the test site with warm, soapy water, rinse and dry thoroughly before every test. Unwashed hands and test sites may lead to inaccurate results. Make sure there is no grease, oil or lotion on the test site. Use lancets only once. Do not use any lancing device or lancet that has been used by another person. Always keep your meter and lancing device clean.

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

9 How to Test Your Blood Glucose Level

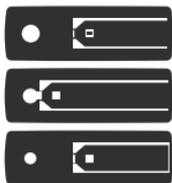
IMPORTANT: You must pair your meter to the App to be able to sync readings from your meter to the App and set your meter's time and date. For instructions on how to pair refer to Chapter 5. Test results without a set time and date will be saved to the meter in chronological order, but will not sync to the App. Test results without a set time and date will only show unit of measure (mmol/L).

[1] Insert a Test Strip: Insert a new test strip into the meter's test strip port. Make sure you insert the test strip, with the contact bars facing towards you, into the test strip port. The meter will turn on.



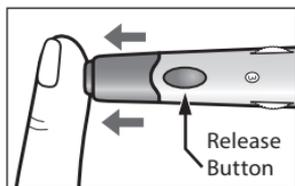
[2] Meter Ready For Test: The meter now displays the apply sample to test strip animation, indicating it is now ready for you to apply blood. You do not need to set a calibration code for this meter.

Apply Sample to Test Strip Animation:



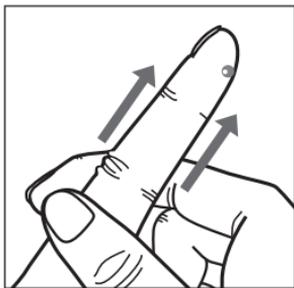
[3] Lance the Test Site: Press the lancing device against the site to be lanced. Press the release button.

For instructions on how to test on your palm or forearm, please refer to Chapter 10.



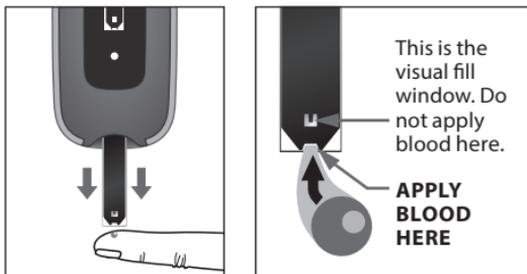
[4] Obtain a Drop of Blood: Squeeze from the base of your finger up towards the tip, milking your finger, until a small blood drop forms.

Do not squeeze directly around the lanced area!

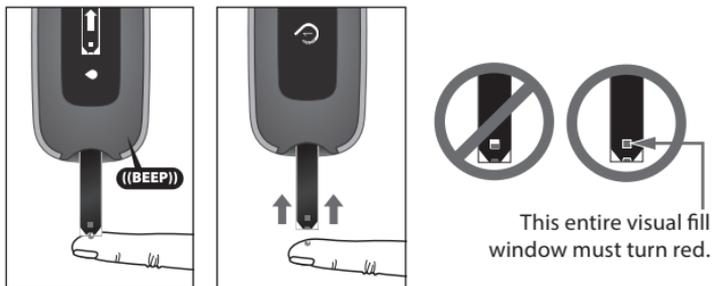


[5] Bring Test Strip to Blood Sample: Immediately bring the meter with the inserted test strip to the blood sample at a 90 degree angle. The test strip fills from the tip. Do not try to smear blood on the top surface.

The test strip acts like a sponge and draws the blood into the test strip through the sample area. The visual fill window of the test strip will turn red indicating blood has been absorbed in the test strip.



[6] Remove Your Finger From the Test Strip When the Test Strip's Visual Fill Window Completely Turns Red and the Meter Beeps: During testing, the sample applied symbol will appear on the meter's screen and the meter will beep when you should remove the test strip from the blood sample.



CAUTION: If the visual fill window does not completely fill, you may get an inaccurate result. Retest and ensure that the

visual fill window is completely full.

The calculating animation will begin on the meter display. This animation indicates that a sample has been applied to the test strip and the meter is calculating the test result.

Calculating
Animation:



IMPORTANT:

- Remove the test strip from the blood sample as soon as the test strip's visual fill window completely turns red (you will also hear a beep).
 - Do not press the test strip against the test site.
 - Do not scrape blood onto the test strip.
 - Do not apply blood to the top side of the test strip.
 - Do not apply blood to the test strip when the test strip is out of the meter.
 - Do not put blood or foreign objects into the test strip port.
 - Do not apply more blood after the test strip's visual fill window completely turns red and the calculating animation begins on the meter's display.
-

[7] Viewing Blood Glucose Test Result: The blood glucose test result will appear on the meter display. Results will be displayed in mmol/L.

Example Result:



The test result is stored in the meter's memory.

Carefully read the test results on the meter screen before making any treatment decisions.

Glucose Display Messages

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

LOW MESSAGE:



Glucose test result is lower than 1.1 mmol/L. This low result may indicate hypoglycaemia (low blood glucose). The low result is stored in the meter. On the App it will be saved as a test result of <1.1 mmol/L with time and date. The value will be represented as 1.1 mmol/L in the statistics in the App.

ACTIONS: If you feel symptoms such as weakness, sweating, nervousness, headache or confusion, follow your healthcare professional's recommendations. If you get a low glucose test result but have no symptoms of low blood glucose, then retest with a new test strip. If you still get a low test result,

follow the treatment plan recommended by your healthcare team or contact your healthcare professional immediately.

HIGH MESSAGE:



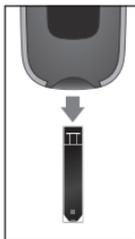
Glucose test result is above 33.3 mmol/L. This high result may indicate hyperglycaemia (high blood glucose). The high result is stored in the meter. On the App it will be saved as a test result of >33.3 mmol/L with time and date. The value will be represented as 33.3 mmol/L in the statistics in the App.

ACTIONS: If you feel symptoms such as fatigue, thirst, excessive urination, or blurry vision, follow your healthcare professional's recommendations. If you get a high glucose test result but have no symptoms of high blood glucose, then retest with a new test strip. If you still get a high glucose test result, follow your healthcare professional's recommendations. Checking ketones may be advisable.

If you feel that your results do not match with how you are feeling contact your doctor or nurse.

[8] Remove the Used Test Strip From the Meter Test Strip

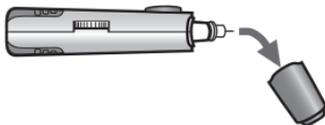
Port: Avoid touching the test strip's sample area (where blood was applied).



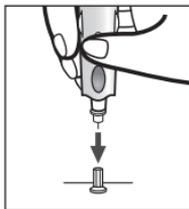
Removing the used test strip will turn off your meter. If you leave the test strip in your meter, it will time out after 90 seconds.

[9] Final Steps:

Remove the Lancet: When you have finished testing, snap off the cap from the lancing device. Be careful not to touch the lancet tip.



Place the lancet cover onto a hard, even surface (such as a tabletop) with the open end facing up. While the lancet is still in the lancing device, bring the lancet tip to the lancet cover to recover the used lancet. You can then safely handle the used lancet.



Extract the lancet from the lancet holder cup by pulling and twisting on the plastic collar of the lancet (near the middle of the lancet).



Replace the lancing device cap onto the lancing device until it

snaps or clicks into place.



Discard the used lancet properly. Follow your healthcare professional's instructions for disposal.



WARNING: The information from the App should only be used as a reference. Do not make treatment decisions based solely on the information provided by the App. All health-related decisions should be made in conjunction with the advice of a qualified healthcare professional (HCP). It is important that you and your HCP understand how the statistics are calculated before making any adjustments to treatment. This information can be found in the App User's Guide (accessible from the App).

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.

When testing on alternative sites always use the clear lancing device cap that has been specially designed for this purpose. The clear plastic allows you to see a blood drop form without removing the lancing device and the concave tip aids in the collection of a blood sample.

WARNING: Alternative Site Testing (AST)
Physiological differences in circulation between the fingertip, palm (at the base of the thumb), or 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) or forearm.

Alternative site testing should be done only during steady - state times (when glucose is not changing rapidly).

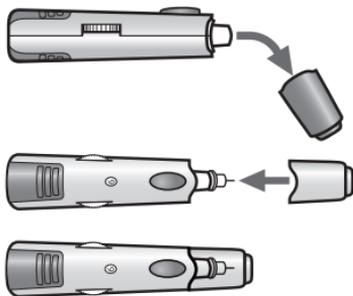
Alternative site results should never be used to calibrate a continuous glucose monitor (CGM). Alternative site results should never be used in insulin dose calculations.

It is recommended that you use a fingertip sample if:

- You are checking for hypoglycaemia or if you suffer from hypoglycaemia unawareness,
- You are checking your blood glucose within 2 hours of eating, taking insulin, medication, exercise, or
- 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: To ensure accurate results, wash your hands with warm, soapy water, rinse and dry thoroughly before every test. Clean and make sure there is no grease, oil or lotion on the test site.

[1] Prepare Lancing Device: Follow Chapter 4 to prepare lancing device. Replace the gray lancing device cap with the clear cap.



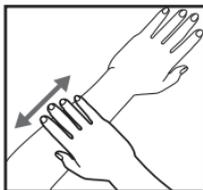
[2] Follow Chapter 9 to prepare for glucose testing.

[3] 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.

Palm:

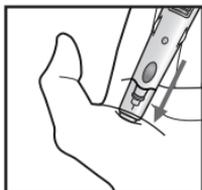


Forearm:

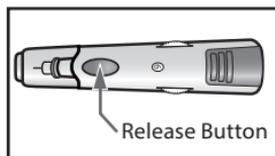
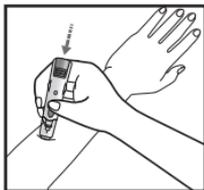


[4] Lance Test Site: Press the tip of the clear cap against your skin on the palm of your hand (at the base of the thumb) or forearm. Hold the tip to the test site for a few seconds. Then press the release button.

Palm:



Forearm:



The meter will store up to 300 of the most recent blood glucose and control solution test results. When the meter reaches the 300 test result capacity, the oldest test result will be deleted and a new test result will be saved.

Note: If the meter has been synced with the App, glucose test results can be reviewed in the App even after they have been deleted from the meter.

[1] Viewing the Most Recent Test Result:

Press the Meter Button to display the most recent test result. The unit of measure, date and time will scroll to the right of the test result.

Example Result:

A black rectangular display showing the number 5.6 in large white font, followed by the unit mmol/L in smaller white font.A black rectangular display showing the number 5.6 in large white font, followed by the date 10/12 in smaller white font.A black rectangular display showing the number 5.6 in large white font, followed by the time 12:20 in smaller white font.

If it was a control solution test result, the control solution icon will appear to the right of the test result.

Example Result:

A black rectangular display showing the number 7.2 in large white font, followed by a small white icon of a control solution vial, and then the unit mmol/L in smaller white font.

[2] Viewing All Stored Test Results: Continue pressing the Meter Button to view every test result, starting from the most

recent and ending with the oldest. When you reach the oldest reading stored on the device, you will see a brief animation before the most recent reading is displayed again.



[3] Turning Off Your Meter: The meter will turn off (time out) automatically after 30 seconds.

CHAPTER

12 Caring For Your Meter and Lancing Device

When using your meter, avoid getting dirt, dust, blood, control solution, water or any other foreign substance into the test 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. Be careful when cleaning your meter to avoid getting liquid into the test strip port.

13 Batteries

Your meter comes with two pre-installed CR2032, 3 volt, lithium batteries.



Two replacement CR2032, 3 volt, lithium batteries are included in the pocket of your meter's carrying case.

Batteries are harmful if swallowed. Keep away from small children.

LOW BATTERY MESSAGE:

(This message appears for 2 seconds.)



You can still perform a test when you see a low battery message, but you should replace your batteries as soon as possible. Use only CR2032 or DL2032 batteries.

DEAD BATTERY MESSAGE:



The batteries in your meter do not have enough power to activate your meter and perform a test; batteries must be replaced.

IMPORTANT: When the batteries are replaced, the time and date will be erased from your meter. You must sync your meter with your supported device to ensure your readings have time

and date. To sync your meter, see instructions in Chapter 5. Removing the batteries does not affect the stored glucose records.

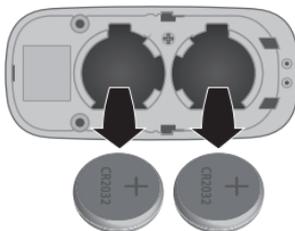
NOTE: Dispose of used batteries according to your local environmental regulations. Your meter is also an electronic device. When disposing of your meter, follow all local environmental regulations.

How to Replace the Batteries:

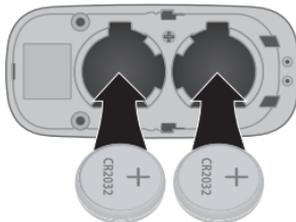
[1] Open Battery Door: Make sure the meter is off. Turn the meter so you are looking at the battery door. Slide the battery door off the meter.



[2] Remove the Old Batteries: To remove the used batteries, use a non metallic tool.



[3] Install the New Batteries: Install the new batteries with the positive (+) sign facing up towards you.



[4] Close Battery Door: Slide the battery door onto the meter. Make sure that the battery door is completely closed before using the meter.



The AgaMatrix WaveSense JAZZ Wireless Meter is designed to work accurately under most usual conditions. On rare occasions, the meter will display an error message instead of a glucose result.

The meter 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 possible problems related to each message listed in this chapter.

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.

CAUTION: If you get repeated error messages and are experiencing symptoms of hypo or hyperglycaemia, contact your healthcare professional immediately as this may indicate low or high glucose. If this error code persists on retesting, consult your healthcare professional.

Error 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. Retest using a new test strip.
[3] If this message appears after the 1-2-3 countdown instead of a result, it may indicate that you applied more blood after testing began.

Error 2:  **Err2**

The meter has detected an irregularity with the sample.

[1] The test strip may be partially filled. Retest using a new test strip. Ensure that enough blood is applied to the test strip when retesting.

[2] The sample may not be blood or control solution. Retest using a new test strip. Ensure that the test site is clean prior to performing a blood glucose test or that the control solution bottle tip is wiped clean prior to performing a control solution test.

Error 3:  **Err3**

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. Check the test strip vial for the expiration date. Do not use test strips beyond the expiration date or 180 days after first opening the vial. You may need to retest using a new test strip from a new vial of test strips.

[2] The test strip may have been mishandled by vigorous bending or shaking. Retest using a new test strip.

[3] Parts of the test strip may have become covered in grease, oil, or lotion. Retest using a new test strip.

[4] The test strip port on your meter may be dirty. Call Customer Care for assistance. The phone number is printed on the back of your meter.

Error 4:  **Err4**

The meter was unable to produce a result or unusual test strip problems have occurred that may be related to extreme conditions.

[1] This error may be caused by extremely high glucose. If you are experiencing symptoms of hyperglycaemia, contact your healthcare professional immediately. If this error code persists on retesting, call Customer Care or consult your healthcare professional.

[2] Retest where it is closer to a room temperature of 21°C to 24°C (70°F to 75°F).

Error 5:  **Err5**

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, call Customer Care or consult your healthcare professional.

Error 6:  **Err6**

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 haematocrit levels. Retest in a warmer location.

[2] If this error code persists on retesting, call Customer Care. The phone number is printed on the back of your meter.

Error 7:  **Err7**

Meter problems have occurred that are beyond your control.

Contact Customer Care for assistance. The phone number is printed on the back of your meter.

Error 8:  **Err8**

A problem has occurred related to the meter hardware.

Contact Customer Care for assistance. The phone number is printed on the back of your meter.

If there is a temperature warning or error, the thermometer symbol is displayed for 5 seconds and then the meter turns off.

LOW TEMPERATURE MESSAGE:



The meter is below its operating temperature range of 10°C to 40°C (50°F to 104°F).

ACTIONS: Move to an area with an ambient temperature of 10°C to 40°C (50°F to 104°F). Wait for the meter and test strips

to reach the new temperature (usually 10-20 minutes) before using the meter or performing a test.

HIGH TEMPERATURE MESSAGE:



The meter is above its operating temperature range of 10°C to 40°C (50°F to 104°F).

ACTIONS: Move to an area with an ambient temperature of 10°C to 40°C (50°F to 104°F). Wait for the meter and test strips to reach the new temperature (usually 10-20 minutes) before using the meter or performing a test.

CHAPTER

15 Troubleshooting

Troubleshooting Situation #1: Meter does not display the Apply Sample to Test Strip Animation after inserting a test strip.

[1] CAUSE: The meter's batteries have insufficient power.
ACTION: The meter's batteries must be changed immediately.

[2] CAUSE: The test strip has been inserted upside down, wrong end in, or incompletely inserted into the meter.
ACTION: Remove the test strip from the meter's test strip port. Reinsert the test strip with the black side up and the end of the test strip with contact bars inserted up into the meter's test strip port. Ensure that the test strip is fully inserted.

[3] CAUSE: Defective meter or defective test strips.
ACTION: Call Customer Care. The phone number is printed on

the back of your meter.

[4] CAUSE: Blood or foreign objects put into the meter test strip port.

ACTION: Call Customer Care. The phone number is printed on the back of your meter.

Troubleshooting Situation #2: After applying the blood sample, the meter doesn't begin the Calculating Animation and no test result is displayed.

[1] CAUSE: Defective test strip.

ACTION: Repeat the test with a new test strip. If this does not work, call Customer Care. The phone number is printed on the back of your meter.

[2] CAUSE: Sample was applied after 90 seconds of inserting a test strip.

ACTION: Repeat the test using a new test strip. Wait until you see the Apply Sample to Test Strip Animation appear on the meter display screen before you apply the blood sample.

[3] CAUSE: Defective meter.

ACTION: Call Customer Care. The phone number is printed on the back of your meter.

Troubleshooting Situation #3: Meter results are not syncing to the supported device.

[1] CAUSE: The meter and supported device are not properly paired or were not initially synced.

ACTION: See Chapter 5 to pair your meter with your supported

device. If the meter is already paired, but not syncing, follow the instructions in that chapter to force sync your devices.

[2] CAUSE: Bluetooth on supported device is not on.

ACTION: Go to the settings menu in your supported device and ensure that Bluetooth is turned on. If you continue to experience issues, check your supported device's instructions for more information.

[3] CAUSE: The meter and supported device are not within 10 meters of each other.

ACTION: Bring your meter and supported device next to each other and attempt to force sync the two devices.

16 AgaMatrix WaveSense JAZZ Wireless Meter Specifications

Assay Method: Dynamic Electrochemistry

Maximum Altitude: 3,048 meters

Calibration: Plasma equivalent

Coding: No Code

Control Solution Storage Temperature: 2°C to 30°C
(36°F to 86°F)

Sample: Whole blood, capillary

Blood Sample Size: 0.5 microliters

Average Glucose Test Time: 5 seconds

Measurement Units: mmol/L

Result Range: 1.1 to 33.3 mmol/L

Haematocrit: 20% to 60%

Operating Relative Humidity: 25% to 90%

Operating Temperature: 10°C to 40°C (50°F to 104°F)

Memory: 300 blood glucose and control solution test results with date, time

Power Source: two CR2032 3 volt lithium batteries

Automatic Shutoff: 30 seconds after last user action

Size: Width 30 mm x Length 65 mm x Height 10 mm
(1.18" x 2.56" x 0.39")

Test Strip Storage Temperature: 8°C to 30°C (46°F to 86°F)

Weight: 18.4 g

Wireless Frequency: 2.4 GHz worldwide ISM band
(Instrumentation, Scientific and Medical)

Equipment not suitable for use in the presence of flammable mixtures.

When disposing of your meter follow all local environmental regulations.

In locations where cell phone use is not permitted, such as some hospitals and some healthcare professional offices, the meter should be off.

The meter has been tested and found to be appropriate for use at home. In most cases, it should not interfere with other home electronic devices if used as instructed. However, the meter gives off radio frequency (RF) energy from the Bluetooth feature. If not used correctly, the meter may interfere with your TV, radio, or other electronic devices that receive or transmit RF signals.

With the exception of your iOS or Android device, other electronic wireless devices that are in use nearby, such as another cell phone or a wireless network, may prevent or delay the transmission of data from your meter to the app. Moving away from or turning off these electronic devices may allow communication.

If you experience meter interference problems, try moving your meter away from the source of the interference. You can also move the electronic device or its antenna to another location to solve the problem. If you continue to experience interference, contact Customer Care.

The AgaMatrix WaveSense JAZZ Wireless Meter complies with U.S. federal guidelines, Part 15 of the FCC rules. These rules state two conditions specific to the operation of the device:

This device may not cause harmful interference.

This device must accept any interference received, including interference that may cause undesirable operation.

FCC guidelines help ensure that the AgaMatrix WaveSense JAZZ Wireless Meter will not affect the operation of other nearby electronic devices. Additionally, other electronic devices should not affect the use of your meter.

This meter complies with CISPR 11: 2009, Class B (Radiated Only). Emissions of the energy used are low and not likely to cause interference in nearby electronic equipment.

This meter meets the requirements for immunity to electrical interference at the frequency range and test levels specified in international standard ISO 15197:2013 which include:

Electromagnetic immunity requirements as per EN 61326-2-6 and EN ISO 15197 Annex A. The meter has been tested for immunity to Level 3 electrostatic discharge as specified IEC 61000-4-2.

This meter has been tested for immunity to radio frequency interference over the frequency range 80MHz to 2.5GHz at 3V/m as specified in IEC 61000-4-3.

Electromagnetic emissions requirements as per EN 61326-2-6 and EN ISO 15197 Annex A. Its electromagnetic emission is therefore low.

Serial Number: 

Manufacturer: 

In Vitro Diagnostic Medical Device: 

Batch Code: 

Consult Instructions For Use: 

Do Not Reuse: 

Temperature Limitation: 

Use By: 

Catalogue Number: 

Sterile: 

European Authorised Representative: 



8100-10145 Rev B

