

ReliOn™ PREMIER

VOICE

Blood Glucose Monitoring System



User Manual

For single user / home use only
For use with ReliOn™ Premier Test Strips only.
Test strips sold separately.

Welcome to the ReliOn™ Premier Voice Blood Glucose Monitoring System

Thank you for choosing the ReliOn™ Premier Voice Blood Glucose Monitoring System. The system provides you with safe, fast and convenient blood glucose *in vitro* (i.e., outside the body) monitoring. The bilingual talking function of ReliOn™ Premier Voice Meter can be used as an aid for using the meter.

The ReliOn™ Premier Voice Meter is also designed to minimize code related errors in monitoring by using the auto coding function. You'll receive an accurate result in five seconds with a small 0.5 µL blood sample.

This booklet contains important information about the ReliOn™ Premier Voice Blood Glucose Monitoring System.

Please read it carefully before testing your blood glucose.

DISTRIBUTED BY:

Walmart Inc.,
Bentonville, AR 72716
www.ReliOnBGM.com

Customer Service

1-855-776-0662
7a.m.–7p.m. Central time,
7 days a week

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

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Important Information: Read This First

To receive safe and optimum system benefits, please read the entire manual contents before using the system. Please note the following information.

- **Do not** use the system for diagnosis or screening of diabetes.
- Use only fresh capillary whole blood samples for testing.
- Alternate site and fingertip test results may differ significantly due to rapid changes in the blood glucose level after eating, insulin injection or exercise.

Intended Use

- The ReliOn™ Premier Voice Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips and alternate sites such as the forearm, palm, thigh, and calf. Alternate site testing should be used only during steady-state blood glucose conditions.
- The ReliOn™ Premier Voice Blood Glucose Monitoring System is intended for at-home *in vitro* (outside the body) self-testing by people with diabetes as an aid in monitoring the effectiveness of diabetes control.
- The system is intended to be used by a single person and should not be shared.
- The system is not intended for use on neonates, and is not for the diagnosis or screening of diabetes.

- ReliOn™ Premier Blood Glucose Test Strips are for use with the ReliOn™ Premier Voice Blood Glucose Meter to quantitatively measure glucose in fresh capillary whole blood samples drawn from the fingertips and alternate sites.
- ReliOn™ Premier Control Solutions are for use with the ReliOn™ Premier Voice Meter and ReliOn™ Premier Test Strips to check that the meter and test strips are working together properly, and that the test is performing correctly.

Important Health-related Information

- The ReliOn™ Premier Voice Blood Glucose Monitoring System is intended for *in vitro* (outside the body) diagnostic use only and for the quantitative measurement of glucose in capillary whole blood.
- The ReliOn™ Premier Voice Blood Glucose Monitoring System is intended for use by a single user only. Do not share the meter and lancing device with another person.
- The ReliOn™ Premier Voice Blood Glucose Meter is designed to minimize code-related errors in monitoring by using the no-coding function.
- Glucose in blood samples reacts with the chemical in the test strip to produce a small electrical current. The ReliOn™ Premier Voice Meter converts this electrical current to glucose concentration.
- The ReliOn™ Premier Voice Blood Glucose Meter should be used only with the ReliOn™ Premier Test Strips.
- An abnormally high or low red blood cell count (hematocrit level over 60 % or below 20 %) may produce inaccurate results.

- Inaccurate results may occur in severely hypotensive (having low blood pressure) individuals or patients in shock.
- Inaccurate low results may occur for individuals experiencing a hyperglycemic-hyperosmolar state, with or without ketosis.
- Inaccurate results may occur in patients undergoing oxygen therapy.
- Critically ill patients should not be tested with the ReliOn™ Premier Voice Blood Glucose Monitoring System.
- All parts of this kit are considered biohazardous and can potentially transmit infectious diseases, even after you have performed pre-cleaning and disinfection.
- For questions or concerns, contact Customer Service: 1-855-776-0662, 7 a.m. to 7 p.m. Central time, 7 days a week. At all other times or in case of emergency, please contact your healthcare professional or emergency medical response.

This device is not intended for use in healthcare or assisted-use setting such as hospitals, physician offices or long-term care facilities because it has not been cleared by the FDA for use in these settings, including for routine assisted testing or as part of glycemic control procedures.

Use of this device on multiple patients may lead to the transmission of Human Immunodeficiency Virus (HIV), Hepatitis C Virus (HCV), Hepatitis B Virus (HBV), or other bloodborne pathogens.

Specifications

Product specifications	
Measurement range	20–600 mg/dL
Sample size	Minimum 0.5 µL
Test time	5 seconds
Sample type	Fresh capillary whole blood
Calibration	Plasma-equivalent
Assay method	Electrochemical
Battery life	1,000 tests
Power	Two alkaline AAA batteries
Memory	500 test results
Size	3.90 x 2.21 x 0.75 inches (100 x 56 x 19 mm)
Weight	2.47 oz (70 g) with batteries

Operating ranges	
Temperature	50–104 °F (10–40 °C)
Relative humidity	10–90 %
Hematocrit	20–60 %

Storage/Transport conditions		
Temperature	Glucose Meter (with batteries)	32–122 °F (0–50 °C)
	Test strip	34–86 °F (1–30 °C)
	Control solution	46–86 °F (8–30 °C)
Relative humidity	Test strip	20–80 %

ReliOn™ Premier Voice Blood Glucose Monitoring System


ReliOn™ Premier Voice Blood Glucose Monitoring System includes the following items:

- ① ReliOn™ Premier Voice Blood Glucose Meter
 - ② User Manual
 - ③ Quick Reference Guide
 - ④ Batteries
 - ⑤ Logbook
 - ⑥ Carry Case
- Check all the components after opening the ReliOn™ Premier Voice Blood Glucose Monitoring System package.
 - ReliOn™ Premier Test Strips and Control Solutions are necessary but not included.
 - ReliOn™ Premier Test Strips, Control Solutions and data cable for the diabetes management system can be ordered separately by contacting Customer Service: 1-855-776-0662, 7 a.m. to 7 p.m. Central time, 7 days a week.

CAUTION

- The meter and lancing device are for single-patient use.
- **DO NOT** share them with anyone including other family members.
- **DO NOT** use on multiple patients.

Inserting or Replacing the Batteries

- The ReliOn™ Premier Voice Meter uses two AAA alkaline batteries.
- **Do not** mix old and new batteries.
- **Do not** mix alkaline, standard (carbon-zinc) or rechargeable (ni-cad, ni-mh, etc.) batteries.
- Before using the meter, check the battery compartment and insert batteries if empty.
- When the  symbol appears on the display while the meter is in use, the batteries should be replaced as soon as possible.
- Test results may not be saved if the batteries run out completely.

Step 1

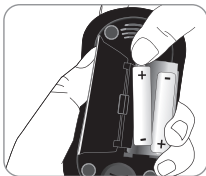
Make sure the meter is turned off. Press firmly on the battery cover and slide in the direction of the arrow. Then swing it open.



Step 2

Remove the used batteries and insert the two new batteries.

Close the battery cover firmly.

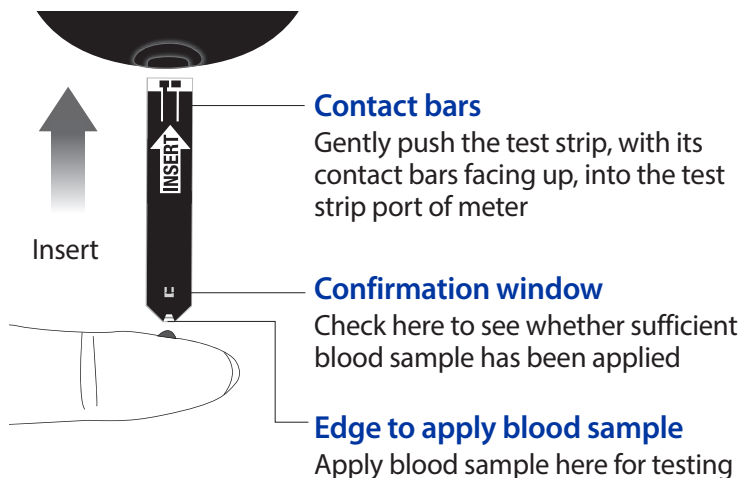


NOTE

- Removing the meter batteries will not affect your stored results. However, meter setting may need to be reset, see page 16.

ReliOn™ Premier Blood Glucose Test Strip

The ReliOn™ Premier Voice Blood Glucose Monitoring System measures blood glucose quickly and accurately. It automatically absorbs the small blood sample applied to the narrow edge of the test strip.



Important Safety Instructions

- All components that come into contact with blood samples should be considered to be biohazardous and capable of transmitting viral diseases, even after disinfection.
- **Do not** share the meter or lancing device with another person.
- The ReliOn™ Premier Test Strips should be used only with fresh capillary whole blood samples.
- **Do not** reuse test strips.

- **Do not** use ReliOn™ Premier Test Strips beyond the expiration date. This may cause inaccurate results.
- When test strips are used and stored according to correct storage and handling methods, both new, unopened vials and vials that have been opened can be used until the expiration date printed on the test strip box and vial label.
- Store test strips in a cool and dry place at a temperature between 34–86 °F (1–30 °C) and 20–80 % relative humidity.
- Keep test strips away from direct sunlight or heat, and do not freeze.
- Store test strips only in their original vial.
- Close the vial tightly after taking out a test strip for testing and use the test strip immediately.
- Avoid getting any liquid or moisture in the test strip vial. This can affect the test strips and cause inaccurate test results.
- **Do not** apply samples other than capillary whole blood or control solution to the test strip.
- Handle test strips only with clean, dry hands.
- **Do not** bend, cut or alter test strips in any way.
- For detailed storage and usage information, refer to the ReliOn™ Premier Test Strips package insert.
- Keep meter and testing supplies away from young children.

CAUTION

Do not allow any foreign substances or liquid substances, such as dirt, blood, or water, enter into the meter. The meter may be damaged or may malfunction. Follow the warning information provided below to prevent possible damage to the meter.

- Do not apply the blood or control solution samples directly to the test strip port.
- Do not apply the blood or control solution samples to the test strip while holding the meter in a way that the tip of the test strip faces upwards. The blood or control solution samples may run down the surface of the test strip and flow into the test strip port.
- Do not store your meter in unsanitary or contaminated sites.
- Make sure to follow the Pre-cleaning and Disinfection Procedures found in the Caring for the ReliOn™ Premier Voice System section of this user manual.

NOTE

- You can get more safety information at FDA Public Health Notification (<http://wayback.archive-it.org/7993/20170111013014/http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm>) or at CDC Clinical Reminder (www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html).

ReliOn™ Premier Voice Blood Glucose Meter

Data Port

Used to transfer data from the meter to a computer with a data cable



Speaker

Announces each step

< Button

Selects or changes information

Display

Shows results and messages

ⓘ Button

Turns the meter on/off, confirms menu selections

> Button

Selects or changes information

Test Strip Port

Insert test strip here



Test Strip Ejector

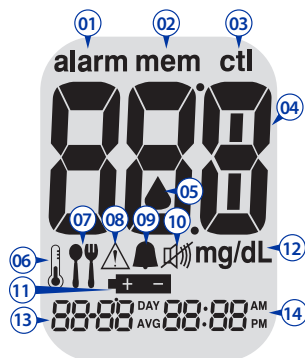
Slide down to discard used strips



NOTE

- The data cable for the data management software can be ordered separately. Please contact Customer Service: 1-855-776-0662, 7 a.m. to 7 p.m. Central time, 7 days a week.

ReliOn™ Premier Voice Blood Glucose Meter Display



① **alarm:** appears when the time alarm has been set

② **mem:** appears when test results stored in the memory are displayed

③ **ctl:** appears when the control solution test results are displayed

④ **Test results**

⑤ **Blood insertion symbol:** indicates meter is ready for the application of a drop of blood or control solution

⑥ **Temperature symbol**

⑦ **Post-meal test flag:** appears during post-meal testing and when post-meal test results are displayed

⑧ **Hypoglycemia (low blood sugar) symbol:** appears when the test result is below the hypoglycemic level

⑨ **Post-meal alarm symbol:** appears when the post-meal alarm has been set

⑩ **Mute symbol:** appears only when the sound is set to 'OFF'

⑪ **Battery symbol:** indicates meter batteries are running low and need to be replaced

⑫ **mg/dL:** unit for measuring blood glucose

⑬ **Date / temperature** ⑭ **Time**

NOTE

- It is recommended to check if the display screen on the meter matches the illustration above every time the meter turns on.
- Do not use the meter if the display screen does not exactly match the illustration as the meter may show incorrect results.

Setting Up the ReliOn™ Premier Voice System

Meter settings, such as time and date, should be checked and updated before using the meter or after changing the meter batteries.

Press and hold the ① button for 3 seconds to enter the 'SET' mode. While setting up the meter, current settings will appear on the display. The meter will also announce each function when the talking function is on. Press and hold the < or > button to scroll faster. To complete the settings and exit from the 'SET' mode, press and hold the ① button for 3 seconds again.

Adjusting Language, Date, Time and Sound

Step 1 Entering the 'SET' Mode

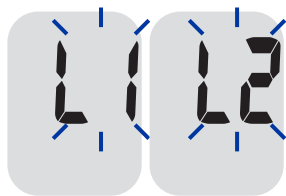
Press and hold the ① button for 3 seconds. After all the segments flash across the screen, 'SET' is displayed on the screen. If the talking function is on, the meter will say "Set meter." Press the ① button again to go to the next step.



Step 2 Selecting a Language

The meter has a bilingual, talking function that can be used as a verbal aid for using the meter and hearing test results.

When entering the language selection mode for the first time, 'L1' will be blinking and the meter will announce "Language Selection" in the default language, English.



To select another language (L2, Spanish), press the < or > button. Press the ① button to confirm the language and progress to the next step.

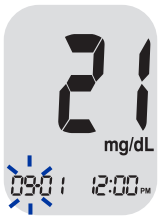
Step 3 Setting the Year

The meter will say “Set year” if the talking function is on. Press the < or > button until correct year appears. Press and hold the < or > button to scroll faster. After setting the year, press the ① button to confirm the selection and progress to the next step.



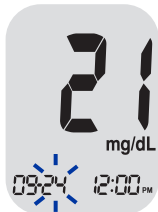
Step 4 Setting the Month

A number indicating the month will blink on the bottom left corner of the screen. If the talking function is on, the meter will say “Set month.” Press the < or > button until the correct month appears. Press the ① button to confirm the selection and progress to the next step.



Step 5 Setting the Date

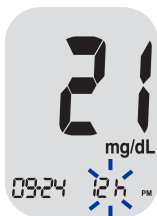
The meter will say “Set date” when the talking function is on. Press the < or > button until blinking number shows the correct date. Press the ① button to confirm the date and progress to the next step.



Step 6 Setting the Time Format

The meter can be set in the 12-hour (AM/PM) or the 24-hour clock format.

If the talking function is on, the meter will say “Set time 12-hour / 24-hour.” Press the < or > button to select a format. The AM/PM is not displayed in the 24-hour format. After selecting the format, press the Ⓜ button to progress to the next step.



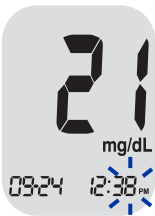
Step 7 Setting the Hour

If the talking function is on, the meter will say “Set hour.” Press the < or > button until the correct hour appears. Press the Ⓜ button to confirm the hour and progress to the next step.



Step 8 Setting the Minute

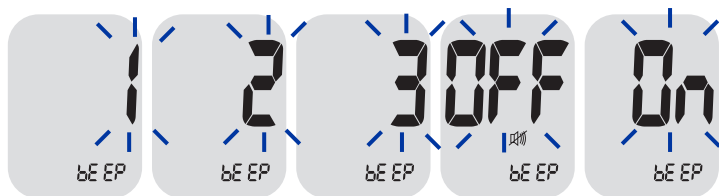
If the talking function is on, the meter will say “Set minute.” Press the < or > button until the correct minute appears. After setting the minute, press the Ⓜ button to progress to the next step.



Step 9 Turning the Sound On/Off

A number showing the sound volume will blink and the meter will say “Set volume.” Press the < or > button to adjust the volume from 1 (lowest) to 3 (highest), or to turn the beep sound ‘OFF’ or ‘On’.

When ‘beep On’ is selected, the meter will beep instead of announcing messages. To turn off the sound, press the ⓘ button when ‘OFF’ blinks on the display. Then the 🚫 symbol will appear on the display and the meter will be muted. Press the ⓘ button to save the setting and progress to the next step.





NOTE

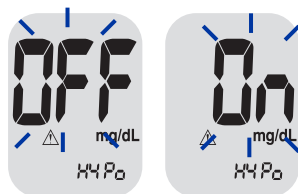
- 🚫 symbol is displayed only when the sound is set to ‘OFF.’

Setting the Hypoglycemia (low blood sugar) Indicator

The meter can indicate a possible low blood glucose test result (hypoglycemia). The hypoglycemia level can be selected from a level of 60 to 20 mg/dL.

Step 10 Turning on the Hypoglycemia Indicator


When entering the hypoglycemia indicator setting mode, the  symbol and 'HYPO' will blink. If the talking function is on, the meter will say "Set hypoglycemia indicator." On pressing the < or > button, the screen will display 'On' or 'OFF.' Press  button to set the hypoglycemia level if 'On' is selected. The screen will return to step 2, language selection mode, if 'OFF' is selected.

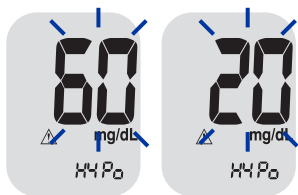


CAUTION


- Ask your healthcare professional to help you decide what your hypoglycemia level is before setting your hypoglycemic level.

Step 11 Setting Your Hypoglycemic Level

The hypoglycemic level can be set from 60 to 20 mg/dL. To set your hypoglycemic level, press the < or > button until the level you want appears. Press the  button to confirm. Then the screen will return to step 2, language selection mode (See page 16).



Step 12 Exiting from Set Mode

After completing the meter settings, press and hold the  button for 3 seconds to confirm all settings and exit the 'SET' mode. If the talking function is on, the meter will announce the set date and time for confirmation.

Checking the System



ReliOn™ Premier Voice Meter and Test Strips should be checked using ReliOn™ Premier Control Solutions, available in two levels (Level 1 and 2). ReliOn™ Premier Control Solutions contain known amounts of glucose and are used to check that the meter and test strips are working properly.

The test strip vials have ReliOn™ Premier Control Solution ranges printed on their labels. Compare the result displayed on the meter to the control solution range printed on the test strip vial.

Before using a new meter or a new vial of test strips, you should conduct a control solution test following the procedure on pages 22–24 with ReliOn™ Premier Control Solutions.

NOTE

- Use ReliOn™ Premier Control Solutions only.
- Check the expiration dates printed on the bottle. When the control solution bottle is first opened, record the discard date (date opened plus three (3) months) in the space provided on the label.
- Make sure the meter, test strips and control solutions are at room temperature before testing. Control solution tests must be done at room temperature, 68–77 °F (20–25 °C).
- Before using the control solution, shake the bottle, discard the first 1 or 2 drops and wipe the tip clean.
- Close the control solution bottle tightly and store at a temperature between 46–86 °F (8–30 °C).

Use ReliOn™ Premier Control Solution when:

- You want to practice the test procedure, instead of using blood
- You use the meter for the first time
- You begin using a new vial of test strips
- You suspect that the meter or the strips are not working properly
- You think your test results are inaccurate or they do not reflect how you feel
- The meter is dropped or damaged

Control Solution Testing

Step 1

Insert a test strip into the meter's test strip port, with the contact bars facing upwards. Gently push the test strip into the test strip port until the meter automatically turns on and the ▲ symbol appears. If the talking function is on, the meter will say "Blood glucose test. Please apply blood onto the test strip."



Step 2

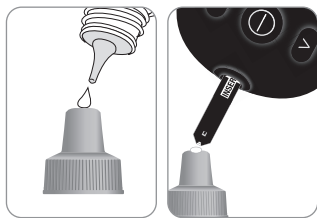
While the ▲ symbol blinks, press and hold the < button for 3 seconds until 'ctl' appears on the display. If the talking function is on, the meter will say "Control solution test. Please apply control solution onto the test strip."



Step 3

Shake the ReliOn™ Premier Control Solution bottle well before each test. Remove the cap and squeeze the bottle to discard the first 1 or 2 drops.

Then wipe the tip with a clean tissue or cloth. While the ▲ symbol blinks, apply the control solution to the narrow edge of the test strip until the meter beeps. Make sure the confirmation window of test strip fills completely.



NOTE

- The meter may switch off if the control solution is not applied within 2 minutes of the ▲ symbol appearing on the screen.
- If the meter turns off, remove the strip, reinsert and start from step 2.

Step 4

A test result will appear after the meter counts down from 5 to 1. If the talking function is on, test result will be announced.

If step 2 is missed, the test result can be marked as a control solution test result by pressing and holding the < button for 3 seconds until 'ctl' appears on the display.

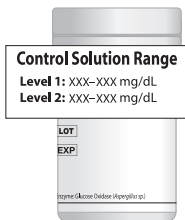
When 'ctl' is displayed, the result is stored in the meter's memory but is not included in the averages.



Step 5

Compare the result displayed on the meter to the range printed on the test strip vial. The result should fall within that range.

Example range shown. Please see your current vial of test strips for the actual range.



Step 6

Slide the test strip ejector button to discard the used test strip safely in a disposable container.



CAUTION

- The ranges printed on the test strip vial are for ReliOn™ Premier Control Solutions only.
- They do not have any connection to your blood glucose level.

Comparing the Control Solution Test Results

The test result of each control solution should be within the range printed on the label of test strip vial. Repeat the control solution test if the test result falls outside of this range.

Out of range results may occur due to the following factors.

Situations	Actions
<ul style="list-style-type: none">• When the control solution bottle was not shaken well• When the meter, test strip or the control solution were exposed to high or low temperatures• When the first one or two drops of the control solution were not discarded or the tip of the bottle was not wiped clean• When the meter is not functioning properly	Repeat the control solution test by referring to the ' NOTE ' on page 21.
<ul style="list-style-type: none">• When the control solution is past the expiration date printed on the bottle• When the control solution is past its discard date (the date the bottle was opened plus three (3) months)• When the control solution is contaminated	Discard the used control solution and repeat the test using a new bottle of control solution.

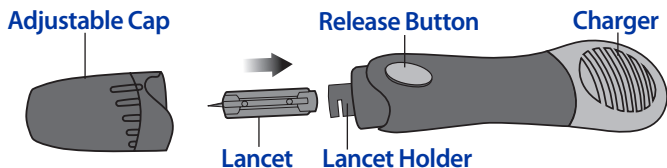
If results continue to fall outside the range printed on the test strip vial, the ReliOn™ Premier Voice Meter and ReliOn™ Premier Test Strips may NOT be working properly. Do not use your system and contact Customer Service: 1-855-776-0662, 7 a.m. to 7 p.m. Central time, 7 days a week. At all other times or in case of emergency, please contact your healthcare professional or emergency medical response.

NOTE

- The ReliOn™ Premier Control Solutions can be purchased separately. Contact Customer Service: 1-855-776-0662.

Using the Lancing Device (sold separately)

A lancing device, such as the ReliOn™ Lancing Device (sold separately), is needed in order to collect a blood sample.



- The lancing device is for use by a single user only and should not be shared with anyone including other family members.

CAUTION

To reduce the chance of infection

- All components that come into contact with blood samples should be considered to be biohazardous and capable of transmitting viral diseases, even after disinfection.
- Do not use a lancet that has been used by another person and never share your meter and lancing device with anyone.
- Wash your hands thoroughly with soap and water after handling your meter, lancing device or test strips.
- Keep your meter and lancing device clean. See the pre-cleaning and disinfection section on page 46.

NOTE

- Repeated puncturing at the same sample site may cause pain or skin calluses (thick hard skin).
- Choose a different site each time you test.

Preparing the Lancing Device

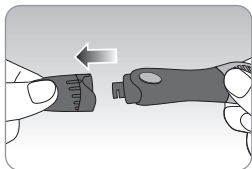
Step 1

Wash hands and the sample site with soap and warm water. Rinse and dry thoroughly.



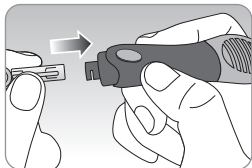
Step 2

Pull the adjustable cap sideways to remove.



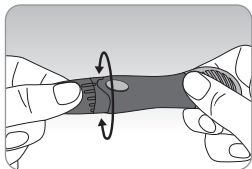
Step 3

Insert a new disposable lancet firmly into the lancet holder. Twist off the protective cover of the lancet and set it aside, then replace the adjustable tip. Keep the protective cover to replace on top of the used lancet after testing.



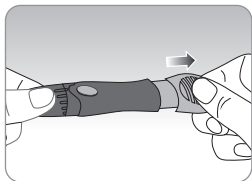
Step 4

The lancing device has five puncture depth settings. The shorter lines are for a shallower puncture and the longer lines are for a deeper puncture. Adjust the depth of puncture as necessary.



Step 5

Cock the lancing device by holding the body in one hand and pulling on the charger. A click may be heard.



NOTE

- The skin depth to retrieve samples will vary for various people at different sample sites.
- The lancing device's adjustable tip allows the best depth of skin penetration for an adequate sample size.
- A beginning setting of three (3) is recommended.

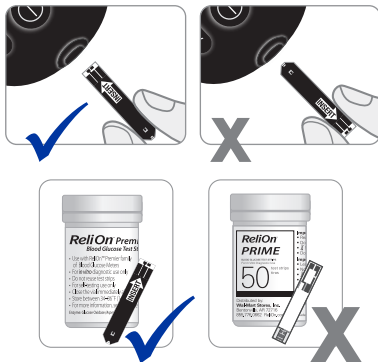
Preparing the Meter and Test Strip

Step 6

Insert a test strip with the contact bars facing up into the meter's test strip port.

Push the test strip gently into the test strip port until the meter automatically turns on and the ▲ symbol appears.

If the talking function is on, the meter will say "Blood glucose test. Please apply blood onto the test strip."



Flagging Post-meal Test Results

ReliOn™ Premier Voice Meter allows post-meal test to be flagged with 🍴 symbol.

The post-meal flag (🍴) can be attached and deleted just before applying the blood sample or when the test result is displayed just after testing.

Once the test result is saved with the post-meal flag (🍴), it cannot be deleted.

Step 7

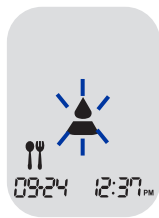
To attach a post-meal flag (🍴) to a test result, press and hold the > button for 3 seconds after inserting the test strip.

The post-meal flag (🍴) and the 🍴 symbol will appear on the screen.

If the talking function is on, the meter will say "Post-meal test. Please apply blood onto the test strip."

The test result will also be displayed with the post-meal flag (🍴).

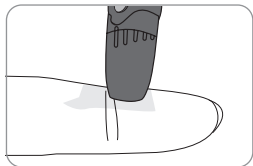
If you do not want to save the result as a post-meal test, move on to Step 8 after Step 6. If you want to delete the post-meal flag (🍴) that has been attached, press and hold the > button for 3 seconds again before applying the blood sample or when the test result is displayed just after testing.



Applying the Blood Sample

Step 8

Obtain a blood sample using the lancing device. Place the device against the pad of the finger. The best puncture sites are on the middle or ring fingers.



Press the release button. Remove the lancing device from the finger. Wait a few seconds for a blood drop to form.

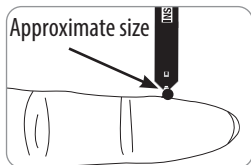
A minimum volume of 0.5 microliter is needed to fill the confirmation window.

Step 9

After the ▲ symbol appears on the screen, apply the blood sample to the narrow end of the test strip until the meter beeps.

If the blood sample does not fill the confirmation window completely, an 'Er4' message may appear because of abnormal viscosity or insufficient volume.

If the talking function is on, the meter will say "Error four. The sample was not enough or too thick."



Good
Sample

Insufficient
Sample

Then discard the test strip, insert a new one and apply the blood sample again after ▲ symbol appears on the screen.

NOTE

- The meter may switch off if the blood sample is not applied within 2 minutes of the ▲ symbol appearing on the screen.
- If the meter turns off, remove the strip, reinsert and start from step 7.

Step 10

The test result will appear after the meter counts down from 5 to 1.

If the talking function is on, the result will be announced.

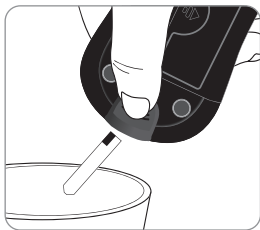
The result will be automatically stored in the meter memory.



Step 11

Discard the used test strip safely in a disposable container by pushing up the test strip ejector.

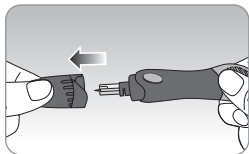
If the test strip is removed after the test result is displayed, the meter will automatically turn off after 3 seconds.



Discarding Used Lancets

Step 1

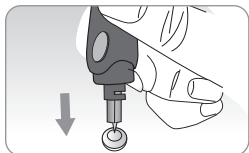
Pull the adjustable cap sideways to remove.



Step 2

Place the protective cover on the lancet.

Remove lancet and dispose of the used lancet in a proper biohazard container.



CAUTION

- Check for damage before using the lancet. If it has been damaged, please discard it and use another lancet.
- The lancet is very sharp. Please keep away from children.
- Keep the lancets in a cool and dry place.
- The lancet is for single use only. Never share or reuse a lancet. Always dispose of lancets properly.

Alternate Site Testing

What is AST (Alternate Site Testing)?

When someone tests their glucose, they usually take the blood sample from the tip of the finger. However, since there are many nerve endings in the fingertip, it can be quite painful. When doing a glucose test, using different parts of the body, such as the forearms, palms, thighs, and calves, can reduce the pain during testing. This method of testing with different parts of the body is called Alternate Site Testing. While AST may reduce the pain during testing, it may not be simple for everyone and the following precautions should be observed during testing.

Alternate Sites for Testing



Alternate Site Blood Sampling (forearm, palm, thigh, calf)

Select a clean, soft and fleshy sample site area free of visible veins and hair and away from bones. Gently massage the sample site to help blood circulation to minimize result differences between fingertip and alternate site sampling.

Firmly press and hold the lancing device against site. Wait until the skin surface under the lancing device changes color.

Then press the release button while continuing to apply pressure. Keep holding the lancing device against your skin until sufficient (at least 0.5 μ L) blood is drawn. Carefully lift the lancing device away from your skin.

CAUTION

AST results should never be used to calibrate Continuous Glucose Monitoring Systems nor entered into an insulin dosing calculator or pump for dosing recommendations.

Things to Know When Using AST

Please read the following before testing at alternate sites (forearms, palms, thighs, and calves).

The capillary whole blood of the fingertips reflects changes in glucose levels more rapidly than in alternate sites. The test results from the fingertip testing and AST may differ due to factors such as lifestyle and ingested food which affect glucose levels.

Acceptable Situations for AST

- Fasting period
- Before a meal

Situations Requiring Fingertip Test

- When the glucose levels are rapidly increasing, such as during the two hours after a meal or exercise
- When sick or when glucose levels seem quite lower than test value
- When hypoglycemia is not well recognized
- When insulin has the biggest effect
- Two hours after an insulin injection

AST Precautions

- Do not ignore the symptoms of hyperglycemia or hypoglycemia.
- When the results of the test do not reflect the way you feel, retest using the fingertip. If the fingertip result still does not reflect the way you feel on retesting, please consult your healthcare professional.
- Do not rely on the AST results for changing your treatment method.
- The amount of glucose in alternate sites differs from person to person.
- Before using AST, please consult your healthcare professional.

NOTE

- Results from alternate site and fingertip samples may differ from each other, as there is a time lag for the glucose levels to reach the same value. Use a fingertip sample if you suffer from hypoglycemia or have experienced hypoglycemic shock or symptoms.
- If the sample drop of blood runs or spreads due to contact with hair or with lines on your palm, do not use that sample. Try puncturing again in a smoother area.

'HI' and 'Lo' Messages

'HI' Message

The meter displays results between 20–600 mg/dL.

'HI' appears when the blood glucose level is greater than 600 mg/dL and indicates severe hyperglycemia (much higher than normal glucose levels).

If the talking function is on, the meter will say "Your blood glucose reading is above 600 mg/dL."

If 'HI' is displayed again upon retesting, please contact your healthcare professional immediately.



'Lo' Message

'Lo' appears when a test result is less than 20 mg/dL and indicates severe hypoglycemia (very low glucose levels).

If the talking function is on, the meter will say "Your blood glucose reading is below 20 mg/dL."

If 'Lo' is displayed again upon retesting, please contact your healthcare professional immediately.



NOTE

- If messages for hyperglycemia or hypoglycemia are displayed, even if you do not have these conditions, please contact Customer Service: 1-855-776-0662, 7 a.m. to 7 p.m. Central time, 7 days a week. At all other times or in case of emergency, please contact your healthcare professional or emergency medical response.

Target Blood Glucose Ranges

Reminders	Your target ranges
<i>Time of day</i>	<i>from your healthcare professional</i>
Before breakfast	
Before lunch or dinner	
1 hour after meals	
2 hours after meals	
Between 2 a.m. and 4 a.m.	

Expected Values: Normal blood glucose levels for an adult without diabetes are below 100 mg/dL before meals and fasting* and are less than 140 mg/dL two hours after meals.¹

*Fasting is defined as no caloric intake for at least eight hours.

Reference

1. American Diabetes Association (Standards of Medical Care in Diabetes - 2021. *Diabetes Care*), January 2021, vol 44 (Supplement 1): S15-S33.

Transferring Test Results

Test results stored in ReliOn™ Premier VOICE Blood Glucose Meter can be transferred from the meter to a compatible desktop data management application via cable.

For more information, visit relionbgm.com/app or contact Customer Service: 1-855-776-0662, 7 a.m. to 7 p.m. Central time, 7 days a week.



Meter Memory

The ReliOn™ Premier Voice Meter can save up to 500 test results with time, date and temperature. If the memory is full, the oldest test result will be deleted and the latest test result will be stored.

The ReliOn™ Premier Voice Meter calculates and displays the averages of total test results, pre-meal test (Pr) results, and post-meal test (P) results from the last 1, 7, 14, 30 and 90 days.

Viewing Past Test Averages

Step 1

Press the Ⓢ or < button to turn on the meter.

If the talking function is on, the meter will say "Memory recall."

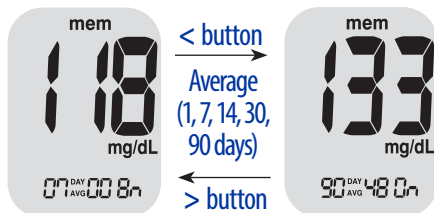
The current date and time will be displayed at the bottom of the screen followed by the 1 day average value and the number of the test results saved within the current day.

The number of tests within the current day



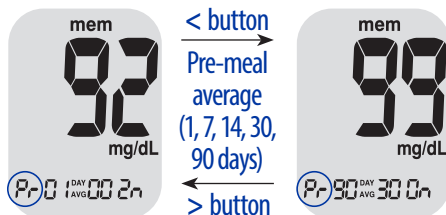
Step 2

Press the < button to view the 7-, 14-, 30- and 90-day average values and the number of tests performed for the test period.




Step 3

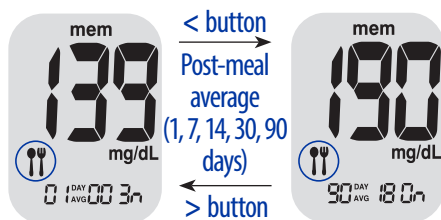
Continue to press the < button to view the 1-, 7-, 14-, 30- and 90-day pre-meal average values and the number of tests performed pre-meals for the test period.




The pre-meal test averages appear with the 'Pr' symbol.

Step 4

Continue to repeatedly press the < button; the 1-, 7-, 14-, 30- and 90-day post-meal average values and the number of tests performed post-meals with the  symbol for the test period will appear on the screen.



Step 5

Use the > button to scroll back through the averages seen previously. To turn off the meter, press the  button.

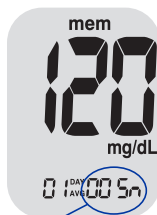
Viewing Test Results

Step 1

Press the ① or < button to turn the meter on.

The current date and time will be displayed on the bottom of the screen followed by the 1 day average value and the number of the test results saved within the current day.

The number of tests within the current day



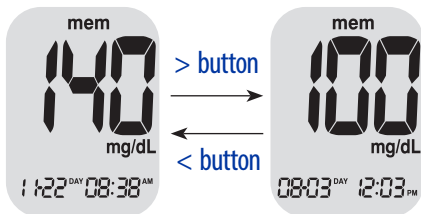
Step 2

Use the > button to scroll through the stored test results, starting from the most recent and ending with the oldest.

Press the < button to return to the result seen previously.

The test date and the recorded temperature will display alternately.

After checking the stored test results, press the ① button to turn off the meter.



Setting the Alarm Function

Four types of alarms can be set in the ReliOn™ Premier Voice Meter. One post-meal alarm (PP2 alarm) and three time set alarms (alarm 1–3).

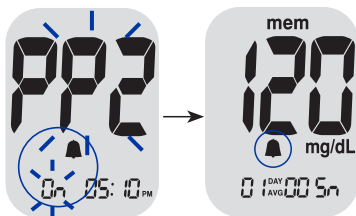
- The 'PP2' alarm goes off 2 hours after setting the alarm
- The alarms ring for 15 seconds and can be silenced by pressing the <, > or ⓐ button, or by inserting a test strip

Setting the Post-meal Alarm (PP2 Alarm)

Step 1 Setting the PP2 Alarm On

Without inserting a test strip, press and hold the < button for 3 seconds to set the post-meal alarm. 'PP2,' the 📢 symbol and 'On' will be displayed. If the talking function is on, the meter will say "Post-meal alarm is on."

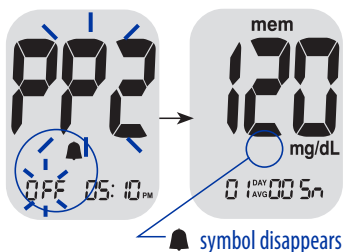
The screen will then automatically change to the memory check mode. At this time, the 📢 symbol, indicating that the 'PP2' alarm has been set, will be displayed on the screen.



Step 2 Setting the PP2 Alarm OFF

To turn off the 'PP2' alarm, press and hold the < button for 3 seconds. 'PP2,' the 📢 symbol and 'OFF' will appear on the screen.

If the talking function is on, the meter will say "Post-meal alarm is off."



Then the screen will change automatically to the memory check mode without 📢 symbol displayed.

Setting the Time Alarms (Alarm 1–3)

Step 1

Without inserting a test strip, press the < and ① buttons simultaneously for 3 seconds to enter the time alarm mode.

While 'OFF' blinks on the screen, alarm 1 will be displayed.

If the talking function is on, the meter will say "Set alarm one."



Step 2

On pressing the > button, alarm 1 is set and 'On' is displayed on the screen.

Press the > button again to cancel alarm 1 and 'OFF' will blink on the screen.



Step 3

Press the < button to adjust the time of alarm 1.

A number indicating the time will blink on the screen.

Press the > button to set the hour.



Step 4

On pressing the < button, the number indicating the minute will start blinking.

Press the > button to set the minute.



Step 5

Press the ① button to finish and to enter the alarm 2 mode.

Repeat steps 2 to 5 to set the remaining time alarms (alarm 2 and 3).



Step 6

Press and hold the ① button for 3 seconds to finish and turn the meter off.

Caring for the ReliOn™ Premier Voice System

- To minimize the risk of transmission of blood-borne pathogens, the pre-cleaning and disinfection procedure should be performed as recommended in the instructions below.
- Wash your hands thoroughly with soap and water after handling the meter, lancing device or test strips.
- If the meter is being operated by a second person who is providing testing assistance to the user, the meter and lancing device should be disinfected prior to use by the second person.

Pre-cleaning and Disinfection

Pre-cleaning procedure is needed to clean dirt as well as blood and other body fluids on the exterior of the meter and lancing device before performing the disinfection procedure.

The disinfection procedure is needed to prevent transmission of bloodborne pathogens.


- For the meter and lancing device, this pre-cleaning and disinfection procedure should be performed **once per week**.

NOTE

- The life span of a ReliOn™ Premier Voice Meter is 5 years. We recommend disinfecting both the meter and lancing device at least once per week. We have validated a total of 260 cleaning and disinfecting cycles (260 pre-cleaning and 260 disinfection cycles) to represent weekly cleaning and disinfecting over the use life of the meter and lancing device.
- 1 pre-cleaning and 1 disinfection cycle per week X 52 weeks per year X 5 years = 260 pre-cleaning and 260 disinfection cycles.

- We have validated **Clorox Healthcare Bleach Germicidal Wipes** with 0.55 % sodium hypochlorite as the active ingredient for disinfecting the ReliOn™ Premier Voice Meter and lancing device. It has been shown to be safe for use with the meter and lancing device.

This disinfectant is available commercially in towelette form. In addition to ReliOn™ Premier Voice Blood Glucose Monitoring System instruction, **please read the instructions provided by the manufacturer of Clorox Healthcare Bleach Germicidal Wipes before using it.**

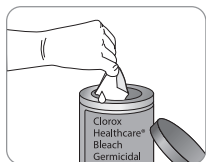
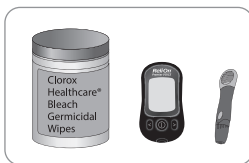
Name	Clorox Healthcare® Bleach Germicidal Wipes	
Manufacturer	Clorox Professional Products Company Phone: 1-800-537-1415 Website: www.cloroxprofessional.com	
EPA registration number	67619-12	
Active ingredients	Sodium Hypochlorite: 0.55 %	

NOTE

- The disinfectant products can be purchased by online retailers (e.g. Walmart.com) or by telephone at the manufacturer.
- To find out where to purchase the disinfectant product, please contact the manufacturer or visit their website as listed above.

Pre-cleaning and Disinfection Procedures

- ① Open the cap of the Clorox Healthcare Bleach Germicidal Wipes container and pull out 1 towelette and close the cap.



- ② Wipe the entire surface of the meter 3 times horizontally and 3 times vertically using one towelette to pre-clean blood and other body fluids.



Front



Back

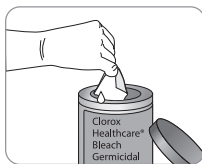


Both sides

- ③ Dispose of the used towelette in a trash bin.



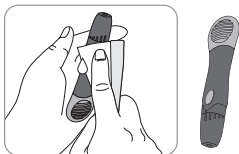
- ④ Pull out 1 new towelette and wipe the entire surface of the meter 3 times horizontally and 3 times vertically using the new towelette to remove bloodborne pathogens.



⑤ Dispose of the used towelette in a trash bin.

⑥ Allow exteriors to remain wet for 1 minute.

⑦ Repeat the same procedure for the lancing device (step ① to step ⑥).



NOTE

- After the pre-cleaning and disinfection procedure, the control solution should be tested to confirm that the meter works properly before using the meter.
- Control solution tests should be performed using ReliOn™ Premier Control Solutions.
- Verify that the test results are within the range printed on the test strip vial.
- See page 21 for how to do a control solution test.

NOTE

If any of the following deterioration signs appears after pre-cleaning or disinfecting, please stop using the system and contact Customer Service: 1-855-776-0662, 7 a.m. to 7 p.m. Central time, 7 days a week. At all other times or in case of emergency, please contact your healthcare professional or emergency medical response.

- The inscriptions on the exterior of the ReliOn™ Premier Voice Meter or ReliOn™ Lancing Device have been removed
- The color of the ReliOn™ Premier Voice Meter or ReliOn™ Lancing Device has changed or faded
- Cracks or roughness develop on the ReliOn™ Premier Voice Meter or ReliOn™ Lancing Device
- A segment of the meter display does not flash when powered on
- Control solution test results do not fall within the stated range on the test strip vial

CAUTION

- **Do Not** use other cleaners or disinfectants because other chemicals have not been validated and may damage the meter.
- **Do Not** get fluids inside the meter through the test strip port, data port or battery compartment. Never immerse the meter or hold it under running water because this will damage the meter.

CAUTION

Storage and Handling Caution

- Store the meter in a cool, dry place between 32–122 °F (0–50 °C)
- **Do not** expose the meter to direct sunlight or heat for extended periods of time
- **Do not** let dirt, dust, blood or water enter into the meter's test strip port
- **Do not** drop the meter or subject it to strong shock
- **Do not** try to fix or alter the meter in any way
- Keep the meter in a cool and airy place
- The ReliOn™ Premier Voice Meter should be used only with ReliOn™ Premier Test strips
- Store all meter components in the carry case to prevent loss
- Avoid getting any liquid or moisture in the test strip vial. This can affect the test strips and cause inaccurate test results.
- **Do not** apply samples other than capillary whole blood or control solution to the test strip.

CAUTION





Do not allow any foreign substances or liquid substances, such as dirt, blood, or water, enter into the meter. The meter may be damaged or may malfunction. Follow the warning information provided below to prevent possible damage to the meter.




- Do not apply the blood or control solution samples directly to the test strip port.
- Do not apply the blood or control solution samples to the test strip while holding the meter in a way that the tip of the test strip faces upwards. The blood or control solution samples may run down the surface of the test strip and flow into the test strip port.
- Do not store your meter in unsanitary or contaminated sites.
- Make sure to follow the Pre-cleaning and Disinfection Procedures found in the Caring for the ReliOn™ Premier Voice System section of this user manual.





NOTE

- For additional information or technical assistance contact Customer Service: 1-855-776-0662, 7 a.m. to 7 p.m. Central time, 7 days a week. At all other times or in case of emergency, please contact your healthcare professional or emergency medical response.

Understanding Error Messages

Message	What is said	What it means	What to do
	"Error 1. Used test strip."	A used test strip was inserted.	Remove the strip and insert a new test strip.
	"Error 2. The sample has been applied before the blood symbol appeared."	The blood or control solution sample was applied before the ▲ symbol appeared.	Repeat the test with a new test strip and wait until the ▲ symbol appears before applying the blood or control solution sample.
	N/A	The thermometer of meter is not stabilized yet.	Retry the test after about 30 minutes for the thermometer to be stabilized.
	"Error 4. The sample was not enough or too thick."	The blood sample is of insufficient volume or blood is too thick.	Repeat the test using a new test strip.

Message	What is said	What it means	What to do
	"Error 5. Strip insertion error. Please insert test strip properly."	This error message may appear when the wrong blood glucose test strip is used instead of the ReliOn™ Premier Test Strip.	Repeat the test with a ReliOn™ Premier Test Strip. Insert the strip with the contact bars facing up, and push in gently until the meter turns on.
	"Error 6. Meter failure."	There is a problem with the meter.	Do not use the meter. Contact Customer Service: 1-855-776-0662.
	"Error 7. Meter failure."	There is a problem with the meter. This error message may appear when the wrong blood glucose test strip is used instead of the ReliOn™ Premier Test Strip.	Repeat the test with a ReliOn™ Premier Test Strip. If the correct test strip is inserted, the meter will automatically turn on and enter test mode. If the error message persists even after inserting the correct test strip, do not use the meter and contact Customer Service: 1-855-776-0662.

Message	What is said	What it means	What to do
 	<p>"Error 8/ Error 9. Meter failure."</p>	<p>There is a problem with the meter.</p>	<p>Do not use the meter. Contact Customer Service: 1-855-776-0662.</p>
	<p>"The room temperature is too low."</p>	<p>The temperature during the test is below the operating range.</p>	<p>Move to an area where the temperature is within the operating range of (50–104 °F/10–40 °C) and repeat the test after the meter and test strips have reached a temperature within the operating range.</p>
	<p>"The room temperature is too high."</p>	<p>The temperature during the test is above the operating range.</p>	

NOTE

- If the error messages persist, contact Customer Service: 1-855-776-0662, 7 a.m. to 7 p.m. Central time, 7 days a week. At all other times or in case of emergency, please contact your healthcare professional or emergency medical response.

General Troubleshooting

Problem	Troubleshooting
The display is blank even after inserting a test strip.	<ul style="list-style-type: none">• Check whether the test strip is inserted with the contact bars facing up. Check if the test strip has been inserted completely into the test strip port.• Check if the appropriate test strip was used.• Check if the batteries are inserted correctly.• Replace the batteries.
The test does not start even after applying the blood sample on the test strip.	<ul style="list-style-type: none">• Check if the confirmation window is filled adequately.• Repeat the test after inserting a new test strip.
The test result does not match the way you feel.	<ul style="list-style-type: none">• Repeat the test after inserting a new test strip.• Check the validity period of the test strip.• Perform control solution test.

NOTE

- If the problem is not resolved, please contact Customer Service: 1-855-776-0662, 7 a.m. to 7 p.m. Central time, 7 days a week. At all other times or in case of emergency, please contact your healthcare professional or emergency medical response.

Performance Characteristics

The performance of ReliOn™ Premier Voice Blood Glucose Monitoring System has been evaluated in laboratory and clinical tests.

Accuracy: The ReliOn™ Premier Voice Blood Glucose Monitoring System is calibrated to yield results equivalent to plasma glucose concentrations. The accuracy of the ReliOn™ Premier Voice System (Model GM505UAA) was tested by comparing blood glucose results obtained by patients with those obtained using a YSI Model 2300 Glucose Analyzer, a lab instrument. The results below were obtained by diabetic patients at clinic centers.

	Obtained by healthcare professionals	Obtained by lay users
Slope	1.023	1.032
Y-intercept	-1.86 mg/dL	-3.63 mg/dL
Correlation coefficient(r)	0.995	0.985
Number of samples	110	105
Range tested	30–485 mg/dL	67–413 mg/dL

- Accuracy results for glucose concentration < 75 mg/dL

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
14/17 (82 %)	17/17 (100 %)	17/17 (100 %)

- Accuracy results for glucose concentration ≥ 75 mg/dL

Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20 %
54/93 (58 %)	82/93 (88 %)	93/93 (100 %)	93/93 (100 %)

Precision: Precision studies were performed in a laboratory using the ReliOn™ Premier Voice Blood Glucose Monitoring System.

<i>Within Run Precision</i>		
Blood avg.	38 mg/dL	SD = 1.9 mg/dL
Blood avg.	86 mg/dL	SD = 3.2 mg/dL
Blood avg.	125 mg/dL	CV = 4.1 %
Blood avg.	189 mg/dL	CV = 2.6 %
Blood avg.	334 mg/dL	CV = 2.8 %

<i>Between Run Precision</i>		
Control avg.	35 mg/dL	SD = 1.2 mg/dL
Control avg.	116 mg/dL	CV = 2.4 %
Control avg.	324 mg/dL	CV = 2.3 %

This study shows that there could be variation of up to 4.1 %.

Alternate Sites Testing Evaluation

Comparison of results using various AST sites with the results of YSI measurements.

- Alternate site test results for glucose concentration < 75 mg/dL

	Within \pm 5 mg/dL	Within \pm 10 mg/dL	Within \pm 15 mg/dL
Fingertip	1/2 (50.0 %)	2/2 (100 %)	2/2 (100 %)
Forearm	1/2 (50.0 %)	2/2 (100 %)	2/2 (100 %)
Palm	2/2 (100 %)	2/2 (100 %)	2/2 (100 %)
Thigh	1/2 (50.0 %)	2/2 (100 %)	2/2 (100 %)
Calf	1/2 (50.0 %)	2/2 (100 %)	2/2 (100 %)

- Alternate site test results for glucose concentration \geq 75 mg/dL

	Within \pm 5 %	Within \pm 10 %	Within \pm 15 %	Within \pm 20 %
Fingertip	27/48 (56.3 %)	46/48 (95.8 %)	48/48 (100 %)	48/48 (100 %)
Forearm	19/48 (39.6 %)	42/48 (87.5 %)	47/48 (97.9 %)	48/48 (100 %)
Palm	28/48 (58.3 %)	38/48 (79.2 %)	46/48 (95.8 %)	48/48 (100 %)
Thigh	17/48 (35.4 %)	36/48 (75.0 %)	46/48 (95.8 %)	48/48 (100 %)
Calf	27/48 (56.3 %)	46/48 (95.8 %)	48/48 (100 %)	48/48 (100 %)

Warranty Information

Warranty

The manufacturer warrants that the ReliOn™ Premier Voice Meter shall be free of defects in material and workmanship in normal use for a period of 5 years.

The meter must have been subjected to normal use. The warranty does not cover improper handling, tampering, use or service of the meter.

Any claim must be made within the warranty period.

The manufacturer will, at its discretion, repair or replace a defective meter, or meter part that is covered by this warranty.

As a matter of warranty policy, the manufacturer will not reimburse the consumer's purchase price.

Obtaining Warranty Service

To obtain warranty service, you must return the defective meter or meter part along with proof of purchase.

Returns

For instructions on how to return your meter, contact Customer Service: 1-855-776-0662, 7a.m.–7p.m. Central time, 7 days a week.

Meters returned without this authorization will not be accepted.