ReliOn PREMIER

BLU

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 BLU Blood Glucose Monitoring System

Thank you for choosing the ReliOn™ Premier BLU Blood Glucose Monitoring System. The system provides you with rapid and convenient blood glucose *in vitro* (i.e., outside the body) diagnostic monitoring. You can obtain accurate results in just five seconds with a small (0.5 µL) blood sample.

Test results can be sent to a smartphone through Bluetooth® wireless connection.

Bluetooth® wireless technology

Bluetooth® wireless technology is used by some smartphones and many other devices. ReliOn™ Premier BLU Blood Glucose Meter uses Bluetooth® wireless technology to pair* and send your blood glucose test results to a smartphone.

When using the ReliOn™ Premier BLU Blood Glucose Monitoring System, we suggest you pair your ReliOn™ Premier BLU Blood Glucose Meter with your smartphone and track your blood glucose test results.

- No part of this document may be reproduced in any form or by any means without the prior written consent of the manufacturer.
- The information in this manual is correct at the time of printing. However, the manufacturer reserves the right to make any necessary changes at any time without notice as our policy is one of continuous improvement.
- *The process of creating a connection between two Bluetooth® devices. An autogenerated passkey has to be exchanged between the two devices. Once the devices are paired (connected), they will automatically communicate with each other when the Bluetooth® feature is activated.

DISTRIBUTED BY:

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7 a.m. to 7 p.m. Central time, 7 days a week

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



Turn off the Bluetooth® feature in areas where the use of wireless devices is restricted, such as hospitals, airplanes, and some healthcare professional offices.

Trademarks

The Bluetooth® word mark and logos are registered trademarks owned by Bluetooth® SIG, Inc. and any use of such marks by the manufacturer is under license. All other trademarks and trade names are those of their respective owners.

FCC Radiation Exposure Statement

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment.

This equipment should be installed and operated with minimum distance of eight inches (20 cm) between the radiator and your body.

Any changes or modifications not expressly approved by the manufacturer could void the user's authority to operate this equipment.

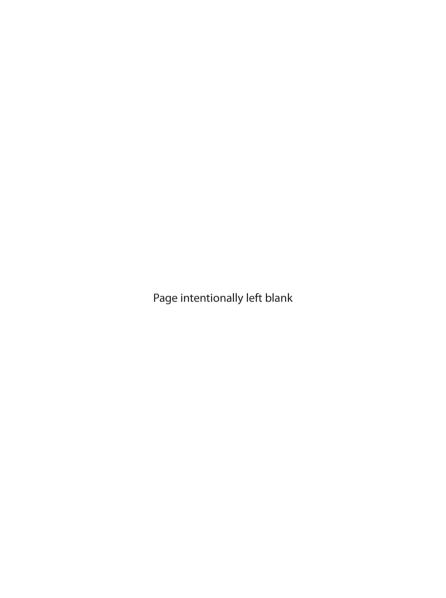


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Important Information: Read This First

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.

Intended use

- The ReliOn™ Premier BLU Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips.
- The ReliOn™ Premier BLU Blood Glucose Monitoring System is intended for self-testing outside the body (in vitro) by people with diabetes at home as an aid to monitor 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.
- The ReliOn™ Premier Blood Glucose Test Strips are for use with the ReliOn™ Premier BLU Blood Glucose Meter to quantitatively measure glucose in fresh capillary whole blood samples drawn from the fingertip.

Important Safety Information

- The ReliOn™ Premier Control Solutions are for use with the ReliOn™ Premier BLU Blood Glucose 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.
- Please use this device only for the intended use described in this user manual.
- Please follow the suggested cleaning and disinfection procedures described in this user manual.
- ReliOn™ Premier Blood Glucose Test Strips are intended for single use only. They should be disposed of in an appropriate container immediately after use.
- The ReliOn™ Premier BLU Blood Glucose Meter is designed to minimize code related errors in monitoring by using the no-coding function.
- Glucose in blood samples react with the chemical in the test strip to produce a small electrical current. The ReliOn™ Premier BLU Blood Glucose Meter detects this electrical current and measures the amount of glucose in the blood sample.
- If your test result is below 60 mg/dL or above 240 mg/dL, consult a healthcare professional immediately.

Limitations of ReliOn™ Premier BLU Blood Glucose Monitoring System

- An abnormally high or low red blood cell count (hematocrit level over 65 % or below 15 %) may produce inaccurate results.
- Inaccurate results may occur in severely hypotensive individuals or patients in shock.
- Inaccurate low results may occur for individuals experiencing a hypoglycemic hyperosmolar state, with or without ketosis.
- Severe dehydration (excessive water loss) may cause false low results. If you believe you are suffering from severe dehydration, consult your healthcare professional immediately.
- Altitudes higher than 10,000 ft. (3,048 m) above sea level may have an effect on the performance of the test strip.
- This system is for single-patient use only and should not be shared.
- Not for neonatal use.
- Not for use on critically ill patients.
- Not for use in anyone undergoing oxygen therapy.
- For in vitro diagnostic use only.
- Do not use for the diagnosis of or screening of diabetes mellitus.
- The ReliOn™ Premier BLU Blood Glucose Meter should only be used with ReliOn™Premier Blood Glucose Test Strips.
- 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	Five seconds	
Sample type	Fresh capillary whole blood	
Calibration	Plasma-equivalent	
Assay method	Electrochemical	
Battery life	1,000 tests	
Power	Two 3.0 V lithium batteries (disposable, type CR2032)	
Memory	1,000 test results	
Size	4.06 x 2.23 x 0.67 inches (103 x 54 x 17 mm)	
Weight	2.53 oz (71.7 g) with batteries	
Bluetooth® technology	 Frequency range: 2.4–2.4835 GHz Operating range distance: maximum 32 feet (10 m) unobstructed Operating channels: 40 channels Security encryption: 128-bit AES (Advanced encryption standard) 	

Operating ranges	
Temperature	42.8–111.2 °F (6–44 °C)
Relative humidity	10–90 %
Hematocrit	15–65 %

Specifications

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 BLU Blood Glucose Monitoring System

ReliOn[™] Premier BLU Blood Glucose Monitoring System includes the following items:

- ReliOn™ Premier BLU Blood Glucose Meter
- User Manual
- · Ouick Reference Guide
- Bluetooth® Pairing Quick Guide
- Logbook
- · Carrying Case
- Batteries (2)

Check all the components after opening the ReliOn™ Premier BLU Blood Glucose Monitoring System package.

ReliOn™ Premier Test Strips and Control Solutions are necessary but not included.

ReliOn™ Premier 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. At all other times, contact your healthcare professional.

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 BLU Blood Glucose Meter uses two 3.0 V lithium 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.
- The test results may not be saved if the batteries run out.

Step 1

Make sure the meter is turned off. Push the cover in the direction of the arrow to open the battery compartment.



Step 2

Remove the used batteries and insert two new batteries with the '+' side facing up. Make sure the batteries are inserted firmly.





Step 3

Place the cover on the battery compartment. Close the battery cover firmly. A click may be heard.

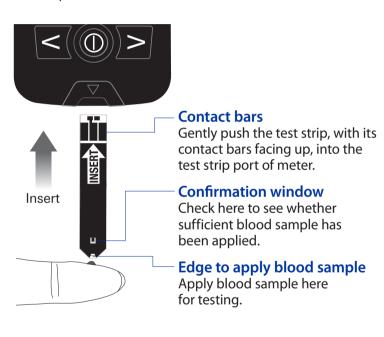


NOTE

• Removing the meter batteries will not affect your stored results. However, meter setting may need to be reset, see page 18.

ReliOn™ Premier Blood Glucose Test Strip

The ReliOn™ Premier BLU 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.



Warning

- ReliOn[™] Premier Blood Glucose Test Strips should only be used with fresh capillary whole blood samples.
- Do not reuse test strips.
- Do not use test strips past the expiration date.
- 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 $^{\circ}$ F (1–30 $^{\circ}$ C) and 20–80 $^{\circ}$ 8 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 and dry hands.
- Do not bend, cut or alter test strips in any way.
- For detailed storage and usage information, refer to the ReliOn™ Premier Blood Glucose Test Strip package insert.

CAUTION

- Keep the meter and testing supplies away from young children.
- Drying agents in the vial cap may be harmful if inhaled or swallowed, and may cause skin or eye irritation.

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 BLU
 System section of this user manual.

NOTE

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

ReliOn™ Premier BLU Blood Glucose Meter

ReliOn

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Data Port

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

<,>Button

Turns the meter on, selects or changes information.

Display Shows re

Shows results and messages.

① Button

Turns the meter on/off, confirms menu selections, and changes information.



Test Strip Port

Insert test strip here.

Test Strip Ejector

Slide down to discard used test strips.

- 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.
- The unit of measurement is fixed and cannot be changed by the user.

ReliOn™ Premier BLU Blood Glucose Meter Display



- Memory recall mode: appears when test results stored in the memory are displayed
- 2 PP2 alarm: appears when the postmeal alarm has been set
- 3 Bluetooth® symbol: appears when Bluetooth® is turned on
- 4 Mute symbol: appears only when the sound is set to OFF
- (5) Control Solution flag: appears when the control solution test results are saved or displayed
- 6 Test results: test results display panel
- 7 alarm: appears when the time alarm has been set
- 8 mg/dL: unit for measuring blood glucose
- Battery symbol: indicates meter battery is running low and needs to be replaced
- ® Blood insertion symbol: indicates meter is ready for the application of a drop of blood or control solution
- 1 Pre-meal test flag: used for tests done before eating
- Post-meal test flag: used for tests done after eating
- (3) Fasting test flag: used for tests done after fasting for at least 8 hours
- 14 Month/Day/Hour/Minute

- 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 BLU 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 three seconds to enter 'SET' mode. After all settings are finished, press and hold the ① button for three seconds to turn off the meter.

Press the < or > button to change values. Press and hold the < or > button to scroll faster.

Step 1 Entering the SET Mode

Press and hold the ① button for three seconds. After all the segments flash across the screen, 'SET' is displayed on the screen.

Press the < or > button to select 'YES' and press the \bigcirc button to go to the next step.



- Follow steps 2–3 to pair your meter and smartphone.
- Pairing allows the meter to communicate wirelessly with your smartphone.
- Ensure that devices are within the maximum Bluetooth® range of 32 feet (10 meters).
- Before pairing your meter and smartphone, download the compatible app to your smartphone.
 Visit relionbgm.com/app to find the compatible app.

Setting Up Bluetooth®

Step 2 Bluetooth® Pairing

 Download Mobile App: Download the data management mobile app by visiting relionbgm.com/app and following the instructions to download the compatible mobile app.



Initiate your meter's Bluetooth® pairing mode by one of **(2)** the following two methods:

- 1. On your smartphone, open the app you have downloaded from the section above, titled Download Mobile App.
- 2. With your meter, take a blood glucose reading. Upon removal of the test strip, the meter will automatically go into Bluetooth® pairing mode.

Or, press and hold down your meter's right arrow button for three seconds. This will place your meter into Bluetooth® pairing mode.

The Bluetooth® (*) will blink, indicating your meter is in Bluetooth® pairing mode.

- 3. Then follow the directions on the smartphone's app screen to complete the pairing.
- 4. If the smartphone displays 'Unable to Sync', follow the steps listed on the app screen.

NOTE

- the screen when the Bluetooth® feature is on.
- When the ** symbol is not present on the screen, the Bluetooth®





• When you need to turn the Bluetooth® feature on or off, press the ① button when 'On' or 'OFF' blinks on the screen.

NOTE

 Some smartphones, especially those that are not tested or approved by the manufacturer may **NOT** be compatible with your meter.

Adjusting the Date and Time

Step 3 Setting the Year

Press the < or > button until the correct year appears. After setting the year, press the ① button to confirm your selection and to go to the next step.



Step 4 Setting the Month

A number indicating the month will blink on the screen.

Press the < or > button until the correct month appears. Press the ① button to confirm your selection and to go to the next step.



Step 5 Setting the Date

Press the < or > button until the blinking number shows the correct date. Press the ① button to confirm the date and to go 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.

Press the < or > button to select a format. The AM•PM symbol is not displayed in the 24-hour format. After selecting the format, press the ① button to go to the next step.



Step 7 Setting the Hour

Press the < or > button until the correct hour appears. Press the ① button to confirm the hour and go to the next step.



Step 8 Setting the Minute

Press the < or > button until the correct minute appears. After setting the minute, press the ① button to go to the next step.



Turning the Sound On/OFF

Step 9

On pressing the < or > button, the screen will display 'On' or 'OFF'. Press the ① button to confirm the selection.



The meter will beep in the following instances if set to 'On'.

- · When a button is pressed to turn on the meter
- · When the test strip is inserted in the meter
- When the blood sample is absorbed by the test strip and the test starts
- · When the test result is displayed
- When the < button is pressed to set the post-meal (PP2) alarm
- When it is time for a preset blood glucose test



If the sound is set to 'OFF', none of the sound functions will work.

After setting the sound, press the ① button to go to the next step.

NOTE

 The 側 symbol is displayed only when the sound is set to 'OFF'.

Turning on the Test Strip Expiration Date Indicator

Step 10

This setting allows you to turn the test strip expiration date indicator 'On' or 'OFF'. This setting turns the function 'On' or 'OFF' **only**. See page 26 to set the test strip expiration date.

When 'EP' appears on the screen, press the < or > button. The screen will display 'On' or 'OFF'. Press the ① button to confirm the setting.

If you do not want to set the indicator, press the \bigcirc button while the screen displays 'OFF'.



- If the preset expiration date expires, the meter will display 'EP' when the test strip is inserted.
- The display will alternate between 'EP', and date and time when the test result is displayed right after the test
- If the expiration date is set to October of 2023, the meter will display EP at the start of November, 2023.

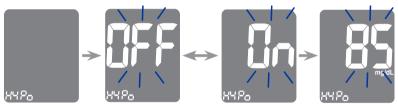


Turning on the Hypoglycemia Indicator

This setting allows you to turn the hypoglycemia indicator (possible low blood sugar) 'On' or 'OFF' and select the desired level for the indicator. You will be alerted any time your test result is lower than the selected level.

Step 11

On pressing the < or > button, the screen will display 'On' or 'OFF'. Press the ① button when 'On' appears to enter the setting. Press the < or > button until the desired hypoglycemia level between 20 and 90 mg/dL appears. Then, press and hold the ① button for three seconds to confirm the level, save all setting and turn off the meter.



NOTE

 If the test result is lower than the pre-set hypoglycemia level, the meter will display the following.



CAUTION

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

Setting the Test Strip Expiration Date Indicator

Step 1 Entering the Expiration Date Setting

Press and hold the < and > buttons at the same time for three seconds to enter the expiration date settings. After all segments flash across the screen, 'EP' will appear on the display.

NOTE

• The test strip expiration date is printed on the test strip vial.

Step 2 Setting the Expiration Year

A number indicating the year will blink in the left corner of the screen. Press the < or > button until the correct year appears.

Press the ① button to confirm the year and go to the next step.



Step 3 Setting the Expiration Month

A number indicating the month will blink at the bottom of the screen. Press the < or > button until the correct month appears.

After setting the month, press the ① button for three seconds to save your setting and turn off the meter.



Checking the System



ReliOn™ Premier BLU Blood Glucose Meter and Test Strips should be checked using ReliOn™ Premier Control Solutions, available in two levels (Level 1 and Level 2). ReliOn™ Premier Control Solutions contain a known amount 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 28–30 with ReliOn™ Premier Control Solutions.

- Use ReliOn™ Premier Control Solutions only (available for purchase separately).
- Check the expiration date printed on the bottle. When the control solution bottle is first opened record the discard date (date opened plus three 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 one or two 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 using the control solution, instead of blood
- · You use the meter for the first time
- · You begin using a new vial of test strips
- You suspect that the meter or test 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 port until the meter beeps. Be careful not to bend the test strip while pushing it in.

The symbol will show up.



Step 2

You can flag the control solution test result by pressing the > button for three seconds. To undo the control solution flag, press the > button for three seconds again.



Step 3

Shake the ReliOn™ Premier Control Solution bottle before each test.

Remove the cap and squeeze the bottle to discard the first one or two drops.





Wipe the tip with a clean tissue or cloth. Dispense a drop of control solution onto a clean non-absorbent surface. It helps to squeeze a drop onto the top of the cap as shown.

After the symbol appears on the display, apply the solution to the narrow edge of the test strip until the meter beeps. Make sure the confirmation window fills completely.

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

Step 4

The display segments will rotate clockwise and a test result will appear after the meter counts down from '5' to '1'.

When flagged, the result is stored in the meter's memory but it 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 the range.



CAUTION

The range printed on the test strip vial is for the ReliOn™
 Premier Control Solutions only. It has nothing to do with
 your blood glucose level.

NOTE

 ReliOn[™] Premier Control Solutions 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.

Comparing the Control Solution Test Results

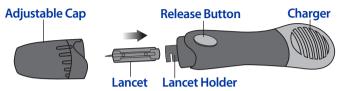
The test result of each control solution should be within the range printed on the label of the test strip vial. Repeat the control solution test if the test result falls outside of the range. Out-of-range results may occur in the following situations:

Situations	Do This
 When the control solution bottle was not shaken well. When the meter, test strip or control solution was exposed to high or low temperatures. When the first one or two drops of control solution was 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 27.
 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 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 Test Strips and ReliOn™ Premier BLU Blood Glucose Meter 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.

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.

Use a soft cloth or tissue to wipe the lancing device. If necessary, a small amount of alcohol on a soft cloth or tissue may be used.

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 52.

- 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

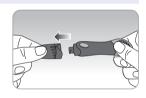
Wash hands and sample site with soap and warm water.

Rinse and dry thoroughly.



Step 2

Pull the adjustable cap sideways to remove.



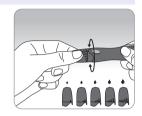
Step 3

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.



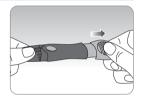
Step 4

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.



- 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 '3' is recommended.

Preparing the Meter and Test Strip

Step 6

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

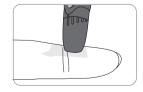
Push the test strip in gently until the meter beeps. Be careful not to bend the test strip. The symbol will appear on the screen.



Applying Blood Sample

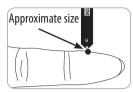
Step 7

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 device from the finger. Wait a few seconds for a blood drop to form.

A minimum volume of $0.5 \mu L$ is needed to fill the confirmation window.



Step 8

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 confirmation window is not filled in time because of abnormal viscosity (thickness and stickiness) or insufficient volume, the **Er4** message may appear.

It is recommended to place the test strip vertically into the blood sample site as shown below.







NOTE

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

Step 9

At this time, the display segments will rotate clockwise while the blood sample is going into the test strip.

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

The result will be automatically stored in the meter's memory.

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

Discard used test strips safely in disposable containers.

If the Bluetooth® feature is activated, the meter will send the test result to the connected smartphone.



NOTE

To transmit glucose data using the Bluetooth® feature:

- The Bluetooth® feature on the meter must be turned on
- The meter and a smartphone must be paired
- The paired smartphone app must be launched

The meter will transmit data in the following cases:

- When the test strip is ejected after measuring
- When the meter is turned on (when untransmitted data exists)



Step 10

You can attach a flag to a result to indicate particular situations while the test strip is still in the meter.

When the result is displayed right after a test, press the < or > button to select a pre-meal flag (), a post-meal flag (), a fasting flag () or a control solution flag ().

When you remove the test strip while the desired flag is blinking, the test result is stored with the flag.

If you do not want to add any flags on the test result, remove the test strip after the test result is displayed.



No flag



Pre-meal flag



Post-meal flag



Fasting flag

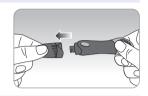


Control solution flag

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.

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



NOTE

 If the messages persist, 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, contact your healthcare professional or emergency medical response.

Target Blood Glucose Ranges

Reminders Time of day	Your target ranges from your healthcare professional
Before breakfast	
Before lunch or dinner	
One hour after meals	
Two hours after meals	
Between 2 a.m. and 4 a.m	n.

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

Reference

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

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

Transferring Test Results Using the Data Cable

Test results stored in ReliOn™ Premier BLU 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 BLU Blood Glucose Meter can save up to 1,000 blood glucose test results with time and date. If the memory is full, the oldest test result will be deleted and the latest test result will be stored.

The meter calculates and displays the averages of total test results, pre-meal () test results, post-meal test () and fasting test results () from the last 1, 7, 14, 30 and 90 days.

Viewing Past Test Averages

Step 1

Press the <, > or \bigcirc button to turn on the meter.

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

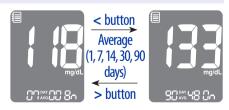
The number of tests

The number of tests within the current day -



Step 2 Viewing Averages

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



Step 3 Viewing Pre-meal Averages

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





Step 4 Viewing Post-meal Averages

Press the < button to view 1-, 7-, 14-, 30- and 90-day average values and the number of tests performed post-meals with the **X** symbol for the last test period.



buttonPost-mealAverage(1, 7, 14, 30, 90days)button



Step 5 Viewing Fasting Averages

Press the < button to view 1-, 7-, 14-, 30- and 90-day average values and the number of tests performed during fasting with the (3) symbol for the last test period.







Step 6 Viewing Pre-meal Averages

Use the > button to scroll through the averages seen previously.

Press the (1) button to turn off the meter.

NOTE

• The control solution test results saved with the **G** symbol are **not included** in the averages.

Viewing Test Results

Step 1

Press the <, > or \bigcirc button to turn the meter on.

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

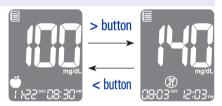
The number of tests

played on y the one-day e test results

The number of tests within the current day

Step 2

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



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

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

NOTE

• The control solution test results saved with the symbol will be displayed with symbol when you review the stored test results.

Setting the Alarm Function

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

- The PP2 alarm goes off two 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 Turning the PP2 Alarm On

Without inserting a test strip, press and hold the < button for three seconds to set the post-meal alarm.

'PP2', the symbol and 'On' will be displayed. The screen will then automatically change to the memory recall mode.



At this time, the **a** symbol, indicating that the PP2 alarm has been set, will be displayed on the screen.

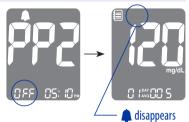
NOTE

 The PP2 alarm will automatically turn off if the meter's time setting is adjusted to more than two hours before or just past the currently activated PP2 alarm time.

Step 2 Turning the PP2 Alarm OFF

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

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



Setting the Time Alarms (Alarm 1–3)

Step 1

Without inserting a test strip, press the < and ⊕ buttons simultaneously for three seconds to enter the time alarm setting.

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



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'. 'OFF' will blink on the screen.



Step 3

Press the < button to adjust the time of 'alarm 1'. A number indicating the hour 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 go to 'alarm 2' setting.

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



Step 6

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

Caring for the ReliOn™ Premier BLU 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

The 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 blood-borne 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 BLU Blood Glucose Meter is five 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 your 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 BLU 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 BLU Blood Glucose Monitoring System instructions, 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	ROLL COLLEGE BOOK CONTROL OF THE COLLEGE COLLEGE OF THE COLLEGE
Active ingredients	Sodium Hypochlorite: 0.55 %	

NOTE

- The disinfectant products can be purchased through 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 one towelette and close the cap.
- ② Wipe the entire surface of the meter three times horizontally and three 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 one new towelette and wipe the entire surface of the meter three times horizontally and three times vertically using a new towelette to disinfect the meter.





- ⑤ Dispose of the used towelette in a trash bin.
- ⑥ Allow exteriors to remain wet for one minute.



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 two different levels of ReliOn™ Premier Control Solutions (Level 1 and/or Level 2).
- Verify that the test results are within the range printed on the test strip vial.
- See page 29-31 for how to perform a control solution test.

NOTE

If any of the following deterioration signs appear 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.

- The inscriptions on the exterior of the meter or lancing device have been removed.
- The color of the meter or lancing device has changed or faded.
- Cracks or roughness develop on the meter or lancing device.
- · A part of the segment on the meter display does not flash.
- 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 transmission port or battery compartment. Never immerse the meter or hold it under running water because this will damage the meter.

Storage and Handling Caution

- Store the meter in a cool and dry place between 32-122 °F.
- **Do not** expose the meter to direct sunlight, heat or excessive humidity for an extended period 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.
- Store all meter components in the carrying case to prevent loss and help keep the meter clean.
- 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.

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.

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 BLU
 System section of this user manual.

Understanding Error Messages

Message	What it Means	What to Do
Eri	A used test strip was inserted.	Repeat the test with a new test strip.
Erd	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.
Er3	The temperature during the test was above or below the operating range.	Move to an area where the temperature is within the operating range 42.8–111.2 °F (6–44 °C). Repeat the test after the meter and test strips have reached a temperature within the operating range.
Ery	The blood sample is of insufficient volume or blood is too thick.	Repeat the test after inserting a new test strip.

Message	What it Means	What to Do
E-5	This error message may appear when the wrong blood glucose test strip is used instead of a ReliOn™ Premier Blood Glucose Test Strip.	Repeat the test with a ReliOn™ Premier Blood Glucose Test Strip.
E-8	There is a problem with the meter.	Do not use the meter. Contact Customer Service: 1-855-776-0662.
	There is a problem with the Bluetooth® communication.	Contact Customer Service: 1-855-776-0662.
E-8	An electronic error occurred during the test.	Repeat the test with a new test strip. If the error message persists, contact Customer Service: 1-855-776-0662.

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.

General Troubleshooting

Problem	Troubleshooting
The display is blank even after inserting a test strip.	 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 whether the batteries are inserted with the '+' side facing up. Replace the batteries.
The test does not start even after applying the blood sample on the test strip.	 Check if the confirmation window is filled completely. Repeat the test after inserting a new test strip.
The test result does not match the way you feel.	 Repeat the test after inserting a new test strip. Check the expiration date 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.

Performance Characteristics

Performance of the ReliOn™ Premier BLU Blood Glucose Monitoring System has been evaluated in laboratory and clinical tests.

Accuracy

The accuracy of the ReliOn™ Premier BLU Blood Glucose Monitoring System was assessed by comparing blood glucose results obtained by patients with those obtained using a YSI Model 2300 Glucose Analyzer, a laboratory instrument. The following results were obtained by diabetic patients at clinic centers.

Slope	1.0223
Y-Intercept	-1.3686
Correlation coefficient (r)	0.9934
Number of subjects	371
Range tested	48-553 mg/dL

Accuracy results for glucose concentration < 75 mg/dL

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
25/41 (61 %)	40/41 (97.6 %)	41/41 (100 %)

Accuracy results for glucose concentration ≥ 75 mg/dL

Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20 %
231/330 (70 %)	317/330 (96.1 %)	330/330 (100 %)	330/330 (100 %)

User performance results for glucose concentrations between 48 mg/dL and 553 mg/dL.

Within \pm 15 mg/dL and Within \pm 20 %
371/371 (100 %)

Precision

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

Within Run Precision			
Blood average	43 mg/dL	SD = 1.9 mg/dL	CV = 4.3 %
	71 mg/dL	SD = 2.1 mg/dL	CV = 2.9 %
	135 mg/dL	SD = 3.8 mg/dL	CV = 2.8 %
	203 mg/dL	SD = 5.2 mg/dL	CV = 2.6 %
	343 mg/dL	SD = 11 mg/dL	CV = 3.2 %

Between Run Precision			
	36 mg/dL	SD = 1.4 mg/dL	CV = 3.8 %
Control average	114 mg/dL	SD = 3.4 mg/dL	CV = 3.0 %
	135 mg/dL	SD = 8.2 mg/dL	CV = 2.4 %

Warranty Information

Warranty

The manufacturer warrants that the ReliOn™ Premier BLU Blood Glucose Meter shall be free of defects in material and workmanship in normal use for a period of five 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, 7 a.m. to 7 p.m. Central time, 7 days a week.

Meters returned without this authorization will not be accepted.

N	IOTES