ReliOn

PLATINUM

Wireless Blood Glucose Monitoring System



ENGLISH

User's Manual for Single Patient Use Only

Wireless Blood Glucose Meter

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The ReliOn Platinum System

The ReliOn Platinum Blood Glucose Monitoring System is comprised of the ReliOn Platinum meter and ReliOn Platinum test strips.

The ReliOn Platinum Blood Glucose Monitoring System is intended to quantitatively measure glucose in fresh capillary whole blood from the fingertip as an aid in monitoring the effectiveness of glucose control.

The ReliOn Platinum Blood Glucose Monitoring System is intended for in vitro diagnostic single patient use by people with diabetes at home.

The ReliOn Platinum Blood Glucose Monitoring System is intended to be used by a single person and should not be shared.

This system is not for use in diagnosis or screening of diabetes mellitus, nor for neonatal use.

ReliOn Platinum control solutions are for use with the ReliOn Platinum Blood Glucose Monitoring System to check that the meters and test strips are working together properly and that the test is performing correctly.

The system includes: ReliOn Platinum meter with batteries, ReliOn Platinum test strips*, and control solutions*

Alternative Site Testing Limitations

The ReliOn Platinum Blood Glucose Monitoring System is not indicated for Alternative Site Testing (AST). *Some items may not be included in the kit. They are a separate purchase.

WARNING



- Choking hazard. Small parts. Keep away from children under the age of 3 years.
- Keep new and used batteries away from children. Ingestion or insertion into the body may cause chemical burns, perforation of soft tissues, and death. Severe burns may occur within 2 hours of swallowing. If you think a battery might have been swallowed or placed inside any part of the body, seek medical attention immediately.
- If the battery compartment does not close securely, stop using the product and keep it away from children. Contact Customer Service at 1-800-819-1097.

NOTE

- The term "blood glucose" is used when referring to blood sugar.
- Sample data screens are shown throughout the manual. Your data will differ.

Limitations

- Do not use the meter at high hematocrit levels above 65 % or low hematocrit levels below 10 %.
- Not for use in diagnosis or screening of diabetes mellitus.
- Not for neonatal use.

- Abnormally high concentrations (greater than 5 mg/dL) of ascorbic acid (vitamin C) may cause inaccurate results. High-dose vitamin C therapy that would result in abnormally high concentrations is typically prescribed by your healthcare professional. If you are not sure if this applies to you, please check with your healthcare professional.
- Do not use the meter system to measure blood glucose in people who are experiencing cardiovascular collapse (severe shock) or decreased peripheral blood flow.
- Do not use during or soon after xylose absorption testing since xylose may cause inaccurate results. Xylose absorption testing is performed under the supervision of a doctor. Ask your doctor how long to wait after xylose testing before performing a blood glucose test.
- Not for use on critically ill patients, patients in shock, dehydrated patients, or hyperosmolar patients with or without ketosis.
- This system has not been tested at altitudes higher than 10,150 feet. Do not use the system at altitudes above 10,150 feet.

Need Help?

For questions, contact Customer Service at 1-800-819-1097. Phone support is available from 8:00 AM - 8:00 PM ET, Monday - Friday. For questions at all other times, or in case of emergency, contact your healthcare professional or emergency medical response.

About Testing Yourself or Others

WARNING

- DO NOT CHANGE YOUR THERAPY BASED ON A TEST RESULT THAT DOES NOT MATCH HOW YOU FEEL OR IF YOU BELIEVE THAT YOUR TEST RESULT COULD BE INCORRECT.
- It is strongly recommended to have a back-up testing method available.
 Failure to test could cause a delay in therapy decisions and lead to a serious medical condition. Examples of back-up testing methods include a back-up meter and test strips. Ask your healthcare professional or pharmacist about other possible back-up methods.
- If your blood glucose result does not match how you feel and you have followed the instructions in this User's Manual, follow your healthcare professional's instructions, or contact your healthcare professional.

WARNING

- During normal testing, any blood glucose meter may come in contact with blood. All parts of the kit are considered biohazardous and can potentially transmit infectious diseases from bloodborne pathogens, even after you have performed cleaning and disinfecting.^{1,2}
- The meter should never be used by more than one person. Do not share the meter with anyone, including family members, due to the risk of infection from bloodborne

- pathogens.^{1,2} Do not use on multiple patients!
- Use of this device on multiple patients may lead to transmission of Human Immunodeficiency Virus (HIV), Hepatitis C Virus (HCV), Hepatitis B Virus (HBV), or other bloodborne pathogens.
- Cleaning and disinfecting the meter destroys most, but not necessarily all, bloodborne pathogens.³
- If the meter is being operated by a second person who is providing testing assistance to the user, the meter should be cleaned and disinfected prior to use by the second person.
- Disinfect the meter before allowing anyone else to handle it. Do not allow anyone else to test with the meter.
- It is important to keep the meter clean and disinfected. For instructions on how to clean and disinfect the meter, see the chapter Meter Cleaning and Disinfecting.
- Wash hands and dry thoroughly before and after handling the meter or test strips.

NOTE

 Perform a control test when you open a new test strip box or if you think that a test result is incorrect.
 Performing a control test lets you

- know that the meter and test strips are working properly.
- Refer to the test strip and control solution package inserts for additional health-related information.
- Blood glucose and BG are interchangeable and mean the same thing.

Special Information for Caregivers

- Consult your healthcare professional to determine if it is appropriate for your child to be taught how to use the meter system or any other medical products.
- Some people with diabetes do not experience symptoms of low blood glucose (hypoglycemia). Others, such as children or people who are unconscious or have certain disabilities, may not be able to communicate their symptoms to caregivers. For these reasons, do not change any therapy without first talking to a healthcare professional.

Before You Start Testing

WARNING

- Carefully read and follow the instructions in the User's Manual and package inserts for the test strips and control solutions. It is very important to follow the instructions in order to avoid an incorrect test result that may lead to improper therapy.
- The meter, test strips, and control solution are only for use outside the body (in vitro). Do not eat the test

strips. Do not swallow or inject the control solution or use the control solution for any purpose other than testing the ReliOn Platinum system.

NOTE

Set the time and date on the meter before you begin testing.

The ReliOn Platinum Meter



Front View

Up Button ▲ and Down Button ▼

Press to turn the meter on and off, adjust settings, and scroll through test results.

2. Display

Right Side View

Shows results, messages, and test results stored in memory.

3. Target Range Indicator

Indicates whether your blood glucose result falls above, within, or below a pre-set range of values.

4. Micro USB Port

Transfers data from the meter to a computer (PC).

Left Side View

5. Test Strip Ejector

Press to remove test strip.







Underside View

Battery DoorOpen to replace batteries.

Test Strip Slot Insert test strip here.



- 8. Test Strip Container* (for example)
- Test Strip Metallic End Insert this end into the meter.
- Test Strip Yellow Edge
 Touch blood drop or control solution here.
- 11. Control Solution Bottle*
- 12. Batteries

*Some items may not be included in the kit. They are a separate purchase.

Using the Meter Buttons

When instructed to press a meter button, press it briefly and release it.

When instructed to press and **hold** a meter button, press and hold it for 3 or more seconds.

Button Functions

Here are the functions of the Up button and Down button on the meter. These functions are used throughout this manual.

| Button | Function | Action |
|---------------|---|--------------------|
| A | Turn the meter on. | Press and release. |
| [Up button] | Increase an option. | |
| [op sation] | Move forward through test results in memory. | |
| | Set time and date selections. | Press and hold. |
| | Turn meter off. | |
| _ | Decrease an option. | Press and release. |
| [Down button] | Move back through test results in memory. | |
| | | |
| | Enter set-up mode. | Press and hold. |
| | Enter Bluetooth wireless technology pairing mode. | |

Target Range

WARNING

This function is no substitute for hypoglycemia training by your healthcare professional.

Consult your healthcare professional for the blood glucose range appropriate for you. It is very important to stay within your target range.

The target range is set by default at 70–180 mg/dL. The target range can be

set from a lower limit of 60–140 mg/dL to an upper limit of 90–300 mg/dL. Consult your healthcare professional before changing the target range.

To change the target range, pair the meter to a mobile device, or connect it to a PC with diabetes management software installed. Then follow the diabetes management software or mobile app instructions. Functionality may vary by software or mobile app. For questions, contact Customer Service at 1-800-819-1097.

Symbols

| Symbol | Description |
|-----------------------|---|
| Ti day I ave | 7-day average symbol. This indicates that you are viewing the 7-day average of your blood glucose results. |
| II_I day I I ave | 14-day average symbol. This indicates that you are viewing the 14-day average of your blood glucose results. |
| III day | 30-day average symbol. This indicates that you are viewing the 30-day average of your blood glucose results. |
| ijiji day Jiji ave | 90-day average symbol. This indicates that you are viewing the 90-day average of your blood glucose results. |
| 8 | Bluetooth symbol |
| Ĉ | Control bottle symbol |
| 1 | Drop symbol |
| X | Hourglass symbol |
| | Low battery symbol |
| | No data to display |
| @ | Pairing symbol. A flashing symbol indicates the meter is attempting to pair with a device. A solid symbol indicates the meter pairing was successful. |
| | Target range indicator arrow. When flashing, your blood glucose result is outside the target range. |
| [] | Temperature warning symbol |
| | Test strip symbol. A flashing symbol indicates the meter is ready for you to insert a test strip. |
| 1)) | Wireless symbol. A flashing symbol indicates the meter is attempting to connect to the paired device. A solid symbol indicates the meter is connected to a paired device. |

Setting the Time and Date



Press A to turn the meter on.

The flashing test strip symbol appears on the display.



Press and hold \(\bar{\psi}\) until set-up appears on the display. The hour flashes

Press A to increase

the hour or press T to decrease the hour.

3



Press and hold A to set the hour and move to the next field. The minutes flash.

Press A to increase

the minutes or press \blacktriangledown to decrease the minutes.

4



Repeat step 3 to adjust each field. After setting the year, press and hold **v** until the flashing test strip

symbol appears to save your settings.

NOTE

- The meter prompts you to set the time and date the first time you turn the meter on or if an error occurs.
- Press and hold at any time until the flashing test strip symbol appears to perform a test.
- . The time and date on the meter may synchronize to the time and date on the paired device each time the meter sends data to the paired device. See the chapter Wireless Communication and Meter Pairing

WARNING

- The meter should never be used by more than one person. Do not share the meter with anyone, including family members, due to the risk of infection from bloodborne pathogens. ^{1,2} Do not use on multiple patients!
- · Blood glucose results can be displayed in either mg/dL or mmol/L. The back label of the meter shows the unit of measurement. This meter is set to ma/dL. If the meter shows the wrong unit, contact Customer Service at 1-800-819-1097. The correct unit of measurement in the US is ma/dL. If you do not know which unit of measurement is correct for you, contact your healthcare professional. Using the wrong unit of measurement may cause misinterpretation of your actual blood glucose level and may lead to improper therapy.



Using the ReliOn Platinum System

WARNING

To prevent inaccurate results:

- If you drop the meter or drop the meter with a test strip inserted, the meter and/ or test strip could be damaged. Discard the test strip and perform a control test with control solution and a new, unused test strip to ensure the meter and test strips are both working properly. Then repeat the blood glucose test with a new test strip.
- DO NOT remove test strips from the test strip container and put them into another container, such as a plastic bag, pocket, purse, wallet, etc. Storing test strips outside of the test strip container can damage the test strips and lead to inaccurate results. It is important that the test strips remain in their original container until the time of use
- DO NOT expose test strips to heat, moisture, or humidity. Temperatures outside the required range, as well as moisture and humidity, can damage the test strips and lead to inaccurate results.
- DO NOT bend, cut, or alter the test strips.
- DO NOT get dirt, food, or other material on the test strip.
- When performing a blood glucose test, remove your finger from the test strip after the test strip is dosed and the flashing hourglass symbol appears on the meter. Failure to move your finger away from the test strip during measurement could give inaccurate results.

- Inspect the test strip container before using the test strips for the first time. If you see any damage to the container, or if anything prevents the cap from closing properly, do not use the test strips. Do not perform a control test. Contact Customer Support at 1-800-819-1097.
- The ReliOn Platinum test strips are for testing fresh capillary whole blood.
- · Use only ReliOn Platinum test strips.
- Use the test strip immediately after removing it from the test strip container.
- Do not apply blood or control solution to the test strip before inserting it into the meter. If you applied blood or control solution before inserting the test strip into the meter, retest with a new test strip. If a result appears before applying blood or control solution, do not act on that result.
- Close the test strip container tightly immediately after removing a test strip.
 Moisture can damage the test strips and produce incorrect results.
- Store the unused test strips in their original test strip container with the cap tightly closed.
- Discard the test strips if they are past the Use By date printed on the test strip container. If the Use By date is missing or cannot be read, do not use the test strips. Contact Customer Service at 1-800-819-1097.
- Refer to the test strip package insert for test strip storage and system operating conditions.
- Do not reuse test strips. Once control solution or blood has been applied to a

- test strip, discard it. If a retest is necessary, use a new test strip.
- Perform a control test every time you open a new test strip box.

Performing a Blood Glucose Test with Blood from Your Fingertip

Refer to the Important Safety Information section at the beginning of this manual.

NOTE

- You need the meter, a test strip, and a lancing device with a lancet inserted to perform a blood glucose test.
- A blood glucose test cannot be performed while the meter is connected to a PC with a USB cable.



Wash your hands with warm soapy water and dry thoroughly. Dirty or wet hands could affect test results.

Prepare the lancing device.



Check the **Use By** date on the test strip container.

Do not use test strips past the **Use By** date.

Blood Glucose Tests

3



Remove a test strip from the test strip container.

Close the cap tightly.



Gently squeeze your finger to assist the blood flow. This helps vou get a blood drop.

4



Insert the metallic end of the test strip into the meter. The meter turns on.

8



Touch the vellow edge of the test strip to the blood drop.

Do not put blood on top of the test strip.

5



When a flashing drop symbol appears. perform a fingerstick with the lancing device.

9



9:38am (2.11 - 🕱

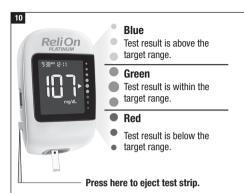
Remove your finger from the test strip when the flashing hourglass symbol appears. Failure to move your finger away from the test strip could give inaccurate test results.

6



Press the lancing device firmly against the side of your fingertip to prick your finger.

2 Blood Glucose Tests



Your test result appears with an arrow. This arrow shows if your test result falls above, within, or below the target range.* The target range is represented by the green region of the target range indicator. The arrow will flash if your test result falls above or below this range.

*The target range is set by default at 70–180 mg/dL. Consult your healthcare professional before changing the target range. To change the target range, pair the meter to a mobile device or connect it to a PC with diabetes management software installed. Then follow the diabetes management software or mobile app instructions. Functionality may vary by software or mobile app. For questions, contact Customer Service at 1-800-819-1097.

NOTE

When performing a **blood glucose test**: If the control bottle symbol and the flashing L1 or L2 appear on the display with your blood glucose result, an error has occurred.

- · Do not act on the blood glucose result.
- Discard the test strip and repeat the blood glucose test with a new test strip.

11

Remove and discard the used test strip by pulling the test strip out of the meter or by pressing the test strip ejector on the side of the meter.

12



Wash your hands with warm soapy water and dry thoroughly.

Unusual Blood Glucose Results

If your blood glucose result does not match how you feel, follow these steps:

- Perform a control test. See the chapter Control Tests.
- 2. Repeat the blood glucose test.

If your blood glucose result still does not match how you feel, follow your healthcare professional's instructions or contact your healthcare professional immediately.

NOTE

Always follow your healthcare professional's instructions. For example, if your healthcare professional has advised you to immediately treat a low blood glucose result (such as by eating something), then do that first.

WARNING

- Do not change your treatment because of one blood glucose result.
- NEVER ignore symptoms of low or high blood glucose.

Symptoms of Low or High Blood Glucose

WARNING

- The meter is designed to provide a numerical value for blood glucose in the range of 20–600 mg/dL.
- Being aware of the symptoms of low or high blood glucose can help you understand your test results and decide what to do if they seem unusual
- Low blood glucose (hypoglycemia): Symptoms of hypoglycemia may include, but are not limited to, anxiety, shakiness, sweating, headache, increased hunger, dizziness, pale skin color, sudden change in mood or irritability, fatigue, difficulty concentrating, clumsiness, palpitations, and/or confusion.
- High blood glucose (hyperglycemia): Symptoms of hyperglycemia may include, but are not limited to, increased thirst, frequent urination, blurred vision, drowsiness, and/or unexplained weight loss.
- If you are experiencing any of these symptoms, or other unusual symptoms, test your blood glucose from the fingertip. If your blood glucose result is displayed as LO or HI, follow your healthcare professional's instructions or contact your healthcare professional immediately. If your blood glucose result does not match how you feel, follow the steps in the Unusual Blood Glucose Results section of this chapter.

2

Comparing Your Meter Result to a Laboratory Result

A common question is how the blood glucose results on the meter compare to the laboratory results. Your blood glucose can change quickly, especially after eating, taking medication, or physical activity. If you test yourself in the morning, then go to your healthcare professional's office for a blood glucose test, your test results will probably not match, even if you are fasting. This is typically not a problem with the meter, it just means that time has elapsed and your blood glucose level has changed.

Although you always apply fresh capillary whole blood to the test strip, the system has been calibrated to deliver plasma-like values for easier comparison to laboratory results.

If you want to compare your meter result to the laboratory result, you must be fasting. Take the meter to your healthcare professional's office and test yourself by fingerstick within 5 minutes of having blood drawn from your arm by a healthcare professional. Keep in mind that the laboratory uses different technology than the meter.

When to Perform a Control Test

Performing a control test lets you know the meter and test strips are working properly. You should perform a control test when:

- · you open a new test strip box.
- you left the test strip container open.
- · you think the test strips are damaged.
- you want to check the meter and test strips.
- the test strips were stored in extreme temperatures, humidity, or both.
- · you dropped the meter.
- your test result does not match how you feel
- you want to check if you are performing the test correctly.

About the Control Solutions

- Refer to the control solution package insert for detailed use instructions and control solution storage conditions.
- Use only control solutions compatible with the ReliOn Platinum system.
- Close the control solution bottle tightly after use.
- Write the date you open the control solution bottle on the bottle label. The control solution must be discarded 3 months from the date the control solution bottle was opened (discard date) or on the **Use By** date on the bottle label, whichever comes first.
- Do not use control solution that is past the Use By or discard date.
- The meter automatically recognizes the difference between the control solution and blood.

- The control solution can stain fabric.
 Remove stains by washing with soap and water
- The control results are not displayed in memory.
- Control solution can be ordered separately by contacting Customer Service at 1-800-819-1097

Performing a Control Test

NOTE

- The ranges for Level 1 and Level 2 controls are printed on the test strip container label.
- The meter turns off 90 seconds after a successful test or 15 seconds after the test strip is removed, provided no other action is taken

You need the meter, a test strip, and control solution Level 1 or Level 2.



Check the **Use By** date on the test strip container. Do not use test strips past the **Use By** date.



Remove a test strip from the test strip container.

Close the cap tightly.

Control Tests

3





Insert the metallic end of the test strip into the meter. Place the meter on a flat surface. The meter turns on

A flashing drop symbol appears.

4



Select the control solution to test. You will confirm the level later in the test

5



Remove the bottle cap. Wipe the tip of the bottle with a tissue. Squeeze the bottle until a tiny drop forms at the tip.





Touch the drop to the vellow edge of the test strip. Do not put control solution on top of the test strip.

A flashing hourglass symbol appears when there is enough control solution in the test strip.

7



or



(example)

(example)

The control result, the bottle symbol, and the flashing L1 or L2 appear on the display. Press and hold ∇ to confirm the control level you tested.

Press A or T to alternate between I 1 and 12

NOTE

When performing a control test: If the control bottle symbol and the flashing L1 or L2 D0 N0T appear on the display with your control result, an error has occurred

- Do not act on the control result.
- Discard the test strip and repeat the control test with a new test strip.

3 Control Tests



OK appears if the control result is within range.

Err appears if the control result is out of range.



Wipe the tip of the bottle with a tissue. Cap the bottle tightly.

Remove and discard the used test strip.

Understanding Out-of-Range Control Results

WARNING

- The control range applies only to a control result. It only indicates that the test strips and meter are working properly. Do not use a control result to interpret blood glucose results.
- If the control result is out of range, do not use the meter until you solve the problem.
 Check the following list to help solve the problem.

| Troubleshooting Checks | Action |
|--|--|
| Were the test strips or control solutions expired? | Discard the test strips or control solution if either is past the Use By date. If the control solution was opened more than 3 months ago, discard it. Repeat the control test with an unexpired test strip and an unexpired control solution. |

Control Tests

| Troubleshooting Checks | Action |
|--|---|
| Did you wipe the tip of the control solution bottle before use? | Wipe the tip of the bottle with a tissue. Repeat the control test with a new test strip and a fresh drop of control solution. |
| Were the caps on the test strip container and the control solution bottle always closed tightly? | Replace the test strips or control solution if you think either was uncapped for some time. Repeat the control test. |
| Was the test strip used immediately after it was removed from the test strip container? | Repeat the control test with a new test strip and a fresh drop of control solution. |
| Were the test strips and control solutions stored in a cool, dry place? | Repeat the control test with a properly stored test strip or control solution. |
| Did you follow the directions? | Read the chapter Control Tests and repeat the control test. |
| Did you choose the correct control solution level, either 1 or 2, when you performed the control test? | If you chose the wrong control solution level, you can still compare the control result to the range printed on the test strip container. |
| Are you still unsure of the problem? | Contact Customer Service at 1-800-819-1097. |

Overview

- The meter automatically stores at least 720 blood glucose results in memory with the time and date of the test
- Once 720 blood glucose results are in memory, adding a new blood glucose result deletes the oldest blood glucose result.
- If more than 720 blood glucose tests are performed within a 90-day period, only the 720 most recent test results are included in the 90-day average.
- The meter automatically stores at least 30 control results in memory, but only the current control result can be viewed on the meter. To view stored control results, transfer them to a compatible software application.
- Once 30 control results are in memory, adding a new control result deletes the oldest control result.
- Control results are not viewable in memory and are not included in the 7, 14, 30, or 90-day averages.

WARNING

Do not change your therapy based on an individual test result in memory. Talk to your healthcare professional before changing therapy based on test results in memory.

NOTE

The meter may have time and date auto-sync capability when paired with a mobile device that may update the meter time and date automatically. Even if you use your meter in multiple time zones, results are stored from newest to oldest and not by time and date.

Reviewing Blood Glucose Results in Memory



With the meter off, press ▼ to view the most recent blood glucose result with its time and date at the top of the display.



Continue to press

▼ to view previous test results from newest to oldest.

NOTE

Press **a** to move back through oldest to newest test result.

Reviewing Your Test Result Averages

The meter uses all of your blood glucose results from the past 7, 14, 30, or 90 days to calculate a single number. This number is called the average, and helps you to understand your blood glucose results over a given period of time.



With the meter off, press ▼ to turn the meter on. The most recent blood glucose result appears on the display.

90-day average

Press ▲ to see the 7-day average. Continue to press ▲ to move through your 7, 14, 30, and 90-day averages.

The number of test results in the average = n.

NOTE

- Press to move back through averages to the most recent blood glucose result.
- If the memory contains a blood glucose test result that is HI or LO, or is corrupt, then the time period and day/ave will flash to alert you that those test results are not included in the average.

Wireless Communication and Meter Pairing

Overview

The process of creating a connection between the meter and the mobile device is called pairing. You will need an application on your mobile device that can accept the meter data. You can use this application to wirelessly and automatically synchronize your diabetes information between the meter and the mobile device.

Pairing

The meter can only pair with 1 device at a time. Pairing with a second device overwrites the first pairing.

The meter and the device to be paired should be within 3 feet of each other.

1

On Your Mobile Device

Open the app and select **Pair Meter**. If prompted, turn on Bluetooth wireless technology.

2

On Your Meter



With the meter off, press and hold ▼ until the Bluetooth symbol appears. The pairing symbol and wireless symbol both appear and flash.

3

On Your Mobile Device

Within the app, select your meter from the list of found meters. When prompted, enter the 6-digit PIN located on the back of your meter.

The meter times out after 30 seconds once you are prompted to enter the PIN.



4

On Your Meter





OK appears if pairing is successful. **Err** appears if pairing is unsuccessful.

NOTE

The meter may have time and date auto-sync capability when paired with a mobile device that may update the meter time and date automatically. Even if you use your meter in multiple time zones, results are stored from newest to oldest and not by time and date.

Transferring Data Wirelessly

If the meter is paired with a mobile device and Bluetooth wireless technology is on, your test results will be sent to the paired device automatically.

Turning Bluetooth Wireless Technology Off

Turn Bluetooth wireless technology off to disable wireless communication (flight mode). Turning Bluetooth wireless technology off will not unpair your meter.



With the meter off, press ▼ to turn the meter on. The last test result appears.



Press and hold ▼ until the Bluetooth symbol disappears.

Turning Bluetooth Wireless Technology On

If you have turned Bluetooth wireless technology off, follow these steps to turn it back on. This will enable wireless communication with your mobile device.



With the meter off, press ▼ to turn the meter on. The last test result appears.



6 Connecting to a PC

Connecting the Meter to a PC Using a USB Cable

Follow these steps to access diabetes management software on a PC. You can use this software to view stored results, set the meter time and date, and change the target range. Functionality may vary by software. For questions, contact Customer Service at 1-800-819-1097.



Plug the small end of a USB cable into the meter.



Plug the large end of a USB cable into a USB port on the PC.

If the meter is off, it turns on.



Start the diabetes management software and initiate a data transfer.



The meter transfers the data to the software.

NOTE

The USB cable does not charge the meter batteries. Remove the USB cable after you have finished.

7 Meter Cleaning and Disinfecting

What is the difference between cleaning and disinfecting?

Cleaning is the removal of dirt from the meter 3

Disinfecting is the removal of most, but not all, disease-causing and other types of microorganisms (bloodborne pathogens) from the meter.³

Approved Cleaning and Disinfecting Product

The following product has been approved for cleaning and disinfecting the meter:

Super Sani-Cloth (EPA* reg. no. 9480-4)

Super Sani-Cloth can be purchased from Walmart.com.

- Do not use any other cleaning or disinfecting solutions. Using solutions other than the Super Sani-Cloth could result in damage to the meter.
- The effect of using more than one product interchangeably to clean and disinfect the meter has not been tested.
 Always use Super Sani-Cloth to clean and disinfect the meter.
- The manufacturer has demonstrated that the product is good for 5-year use, after testing in a total of 260 disinfection cycles (equal to cleaning and disinfecting once per week for 5 years).

NOTE

For technical assistance or questions on cleaning and disinfecting, contact Customer Service at 1-800-819-1097.

Cleaning and Disinfecting the Meter

WARNING

If the meter is being operated by a second person who is providing testing assistance to the user, the meter should be cleaned and disinfected prior to use by the second person.

To clean and disinfect without damaging the meter, follow these procedures carefully.

When to Clean and Disinfect the Meter

- Clean the meter to remove visible dirt or other material prior to disinfecting.
- Clean and disinfect the meter at least once per week and when blood is present on the surface of the meter.
- Clean and disinfect the meter before allowing anyone else to handle the meter. Do not allow anyone else to use the meter on themselves for testing purposes.

^{*}Environmental Protection Agency

7

Meter Cleaning and Disinfecting

NOTE

Using cleaning and disinfecting products could result in damage to the meter. If you notice any of the following signs of deterioration after cleaning and disinfecting your meter, stop using your meter and contact Customer Service at 1-800-819-1097: residue around buttons, clouding of display, button malfunction, out-of-range control results.

What to Clean and Disinfect

The following parts of the meter should be cleaned and disinfected:

- The area around slots and openings (do not get any moisture in slots or openings)
- · The meter display
- · The entire meter surface

How to Clean and Disinfect the Meter

WARNING

Failure to follow these instructions will damage the meter and stop it from working properly.

- DO NOT clean or disinfect the meter while performing a blood glucose or control test.
- DO NOT get any moisture in slots or openings.
- DO NOT spray anything onto the meter.
- DO NOT immerse the meter in liquid.
- Always use the same product for both cleaning and disinfecting.







Wash hands with soap and water and dry thoroughly.



Turn the meter off and wipe the entire meter surface with a Super Sani-Cloth. Carefully wipe around

the test strip slot and other openings.

Make sure that no liquid enters any slot or opening.

7 Meter Cleaning and Disinfecting

3

A separate Super Sani-Cloth should be used for cleaning and disinfection. For disinfecting the meter, get a new cloth and repeat step 2, making sure the surface stays wet for 2 minutes. Let air dry.

Make sure that no solution is seen in any slot or opening.





Wash hands with soap and water and dry thoroughly.

Meter Maintenance

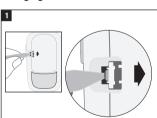
The meter automatically tests its own systems every time you turn it on and lets you know if something is wrong. See the Error Messages section of this chapter.

If you have problems with the meter, drop the meter, or think the results are not accurate, perform a control test with an unexpired test strip and control solution. If the control result is not within the acceptable range, contact Customer Service at 1-800-819-1097

WARNING

Keep new and used batteries away from children. See the warning in the Important Safety Information section at the beginning of this manual for additional information.

Changing the Batteries



Open the child-resistant battery door by inserting a narrow object, such as a pen, into the slot (see image above). Push the tab in the direction of the arrow and lift the battery door up.

2



Remove the old batteries. Press and hold **\(\rightarrow \)** for at least 2 seconds.

3



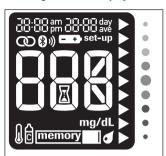
Slide the new batteries under the tabs with the (+) side facing up. Put the battery door back

in place and snap it closed. Immediately discard the old batteries

NOTE

- · Always have a spare set of batteries.
- Battery life may vary due to factors such as temperature and battery manufacturer
- The meter uses two 3-volt lithium batteries, coin cell type CR2032. This type of battery can be found in many stores.
- Always replace both batteries at the same time and with the same brand.
- Meter data is not lost when you replace the batteries.

Checking the Meter Display



With the meter off, press and hold until all display segments appear. Check the meter display for missing segments. All segments should look like the picture above. If any segments are missing from the display, contact Customer Service at 1-800-819-1097, as there may be a problem with the meter.

Error Messages

WARNING

- Never make therapy decisions based on an error message.
- If you have any concerns or see any other error message, contact Customer Service at 1-800-819-1097.

NOTE

The error code and **Err** will alternate on the display for all coded error messages (E-1 through E 14).



The meter will not turn on or the display is blank.

· Batteries are dead.

Insert new batteries.

 Display is damaged. / Meter is defective.

Contact Customer Service at 1-800-819-1097.

Extreme temperatures.

Move the meter to a location with a more moderate temperature.



The meter is connected to a PC and a blood glucose or control test cannot be performed.

EITHER remove the USB cable and perform a blood glucose or control test OR remove the test strip and start a data transfer.



The meter was unable to pair with a mobile device.

Retry the pairing.



The batteries are almost out of power.

Change the batteries now. If the symbol reappears after the batteries have been replaced, remove the batteries again, press and hold either meter button for at least 2 seconds, then reinsert the batteries.



(The error code and **Err** will alternate on the display.)

The test strip may be damaged, not properly inserted, or was previously used.

Remove and reinsert the test strip, or replace it if damaged or previously used



(The error code and Err will alternate on the display.)

A meter or test strip error has occurred.

This error message could appear if the cap on the test strip container was not closed tightly. The test strips may have been damaged due to improper storage or handling.

Never make therapy decisions based on an error message.

Repeat the blood glucose test. If a second E-3 error message appears, perform a control test with the control solution and a new test strip. See the Performing a Control Test section in the chapter Control Tests. If you continue to receive an E-3 error message, use an alternate method for testing your blood glucose, such as a back-up meter and test strip. If the alternate method gives an extremely high blood glucose result, or if an alternate method is not available, contact your healthcare professional immediately.

In rare cases, an E-3 error message may indicate that your blood glucose is extremely high and above the system's measuring range. See the Unusual Blood Glucose Results section in the chapter Blood Glucose Tests for other possible causes of the error message.



(The error code and Err will alternate on the display.)

Not enough blood or control solution was drawn into the test strip for measurement or was applied after the test had started.

Discard the test strip and repeat the blood glucose or control test.



(The error code and **Err** will alternate on the display.)

Blood or control solution was applied to the test strip before the flashing drop symbol appeared on the display.

Discard the test strip and repeat the blood glucose or control test.



(The error code and **Err** will alternate on the display.)

An electronic error occurred.

Remove the batteries, press and hold either meter button for at least 2 seconds, and reinsert the batteries. Perform a blood glucose or control test.



(The error code and **Err** will alternate on the display.)

The temperature is above or below the proper range for the system.

Refer to the test strip package insert for system operating conditions. Move to an area with the appropriate conditions and repeat the blood glucose or control test. Do not artificially heat or cool the meter.



(The error code and **Err** will alternate on the display.)

The batteries may be out of power.

Turn the meter back on. If you are in a cold environment, move to a location with a more moderate temperature and retest. If the message continues to appear after several attempts, replace the batteries. If the message reappears after the batteries have been replaced, remove the batteries, press and hold either meter button for at least 2 seconds, then reinsert the batteries.



(The error code and **Err** will alternate on the display.)

The time and date setting may be incorrect

A flashing wireless symbol appears while the meter attempts to synchronize the time and date with the paired device. When the wireless symbol no longer appears, press the Up button to turn the meter off. Press the Up button a second time until the flashing test strip symbol appears. If time and date sync was not successful the meter prompts you to set them the next time you turn it on. See the Setting the Time and Date section in the chapter Your New System.



(The error code and Err will alternate on the display.)

The test strip may be damaged.

Repeat the blood glucose or control test with a new test strip.



(The error code and Err will alternate on the display.)

Your blood sample may contain a high level of ascorbate.

Contact your healthcare professional.



(The error code and Err will alternate on the display.)

Fluid or foreign material may be present in the test strip slot.

Remove and reinsert the test strip or repeat the blood glucose or control test with a new test strip. If the error persists, contact Customer Service at 1-800-819-1097



(The error code and Err will alternate on the display.)

An electronic error has occurred.

Contact Customer Service at 1-800-819-1097.



Blood glucose may be higher than the measuring range of the system (higher than 600 mg/dL).

See the Unusual Blood Glucose Results section in the chapter Blood Glucose Tests.



Blood glucose may be lower than the measuring range of the system (lower than 20 mg/dL).

See the Unusual Blood Glucose Results section in the chapter Blood Glucose Tests.

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Technical Information

Product Limitations

See the literature packaged with the test strips and control solutions for the latest information on product specifications and limitations.

| Specifications | |
|---|---|
| Blood volume Sample type Measuring time Measuring range Test strip storage conditions System operating conditions | Refer to the test strip package insert. |
| Meter storage conditions | Temperature: -13–158 °F |
| Memory capacity | At least 720 blood glucose results and at least 30 control results with time and date; and 7, 14, 30, and 90-day averages. |
| Automatic off | 90 seconds; or 15 seconds after a test strip is removed. |
| Power supply | Two 3-volt lithium batteries (coin cell type CR2032) |
| Display | LCD |
| Dimensions | 77.3 × 48.6 × 16.0 mm (LWH) |
| Weight | Approx. 43 g (with batteries) |
| Construction | Hand-held |
| Protection class | III |
| Meter type | The ReliOn Platinum meter is suitable for continuous operation. |
| Control solution storage conditions | Refer to the control solution package insert. |
| Continua Interfaces | USB: micro-B connector; Bluetooth low energy technology; Continua Certified® to a Continua Certified manager. |
| Radio frequency connectivity | Bluetooth low energy technology operating in the frequency band of 2,402 MHz to 2,480 MHz with a maximum transmitted power of 0 dBm (1 mW). |

Representation of Accuracy for Home Use

Your ReliOn Platinum meter result may vary slightly from your actual blood glucose value. This is due to slight differences in technique and the natural variation in the test technology. See the table below with performance study data that shows the ReliOn Platinum system achieved 96 % of results within ±15 % of the laboratory. In this study, the meter gave results within ±15 % of their true blood glucose level 336 out of 350 times.

The data in the following table was collected from a typical user study to demonstrate the ReliOn Platinum meter accuracy.

ReliOn Platinum Accuracy Results compared to Laboratory Results

| (within ±20 % of laboratory) | (99 %) 346 of 350 results |
|--|---------------------------|
| Accurate Results (within ±15 % of laboratory) | (96 %) 336 of 350 results |
| More Accurate Results (within ±10 % of laboratory) | (88 %) 307 of 350 results |
| Most Accurate Results (within ±5 % of laboratory) | (63 %) 220 of 350 results |

Bluetooth Wireless Technology — The meter uses Bluetooth low energy wireless technology to communicate and transfer information. Bluetooth wireless technology is a form of radio frequency (RF) technology that operates in the unlicensed industrial, scientific, and medical band at 2.4 to 2.485 GHz. The RF channel utilized for communication between the meter and other devices, such as a smartphone, is not an open channel. The meter can only communicate with the device that

- utilizes Bluetooth low energy technology,
- 2. it is paired with, and
- has an application that can accept the meter's data.

Electromagnetic Compatibility – The meter meets the electromagnetic emission requirements as per EN ISO 15197. The chosen basis for electrostatic discharge immunity testing was basic standard IEC 61000-4-2. In addition, the meter meets the electromagnetic emissions

requirements as per EN 61326-2-6 / EN 60601-1-2. Its electromagnetic emission is thus low. Interference from the meter to other electrically-driven equipment is not anticipated.

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

- This device may not cause harmful interference, and
- this device must accept any interference received, including interference that may cause undesired operation.

In the event there is interference from another device, it is recommended that you increase the distance between the meter and that device. You can also turn off the interfering device. In addition, you can turn off Bluetooth low energy wireless technology on the meter.

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

uncontrolled environment. This equipment is in direct contact with the body of the user under normal operating conditions. This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation

This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna
- Increase the separation between the equipment and receiver.

Changes or modifications not expressly approved by the party responsible for compliance (i.e., the manufacturer) could void the user's authority to operate the equipment.

Performance Analysis – Refer to the test strip package insert.

Test Principle – Refer to the test strip package insert.

Communication Protocol – The ReliOn Platinum blood glucose meter is Continua

Certified. Continua Certified signifies that this product complies with applicable IEEE 11073-10417 standards and that it has been tested and certified against the 2016 Continua Design Guidelines which include the Blood Glucose specification for Bluetooth low energy technology, Bluetooth SIG, Glucose Profile, Version 1.0 and Bluetooth SIG, Glucose Service, Version 1.0

Product Safety Information

WARNING

- This meter meets IEC 61010-1 and IEC 61010-2-101 safety standards.
- Strong electromagnetic fields may interfere with the proper operation of the meter. Do not use the meter close to sources of strong electromagnetic radiation.
- To avoid electrostatic discharge, do not use the meter in a very dry environment, especially one in which synthetic materials are present.

Discarding the Meter, Test Strips, and Batteries

WARNING

- Any product coming in contact with blood is considered contaminated (potentially infectious).*
- During normal testing, any blood glucose meter may come in contact with blood.
- Dispose of sharps according to local regulations.

Comply with any laws or ordinances relating to the disposal of sharps and/or contaminated products. Contact your local health department or other appropriate authorities for proper handling and disposal of used meters, used test strips, used lancets, and used batteries. Follow the instructions provided by your healthcare professional.

Consider the following points when discarding used testing materials: Consider recycling the meters and batteries at an appropriate facility. Be aware the meter is potentially hazardous electronics scrap (e-scrap) and should be disposed of accordingly. The batteries are potentially hazardous also and should be discarded accordingly.

Disinfect the meter before recycling or discarding.

*29 CFR 1910.1030 – Bloodborne pathogens

Explanation of Symbols

These symbols may appear on the packaging, on the meter, and in the instructions for the ReliOn Platinum meter.

| <u> </u> | Caution, refer to safety-related notes in the instructions for use accompanying this product. |
|--------------------|---|
| FCC ID: WX3-415 | This device complies with Part 15 of the FCC Rules. |

| GTIN | Global Trade Item Number |
|------|---|
| SN | Serial number |
| + | 3-volt coin cell type CR2032 |
| * | Keep new and used batteries away from children. |

Additional Supplies

Test Strips: ReliOn Platinum test strips

Control Solutions: Control solutions compatible with the ReliOn Platinum system

References

- ¹ FDA Public Health Notification: "Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication, (2010). Update 11/29/2010." https://downloads.regulations.gov/FDA-2016-M-0035-0003/content.pdf Accessed December 13, 2021.
- ² Klonoff DC. Improving the safety of blood glucose monitoring. J Diabetes Sci Technol. 2011 Nov 1;5(6):1307-11. doi: 10.1177/193229681100500601. PMID: 22226247; PMCID: PMC3262696.
- ³ Healthcare Infection Control Practices Advisory Committee (HICPAC), William A. Rutala, Ph.D., M.P.H., and David J. Weber, M.D., M.P.H. Centers for Disease Control and Prevention, 2019. "Guideline for Disinfection and Sterilization in Healthcare Facilities." Atlanta. https:// www.cdc.gov/infectioncontrol/guidelines/ disinfection/. Accessed July 23, 2021.

Warranty

ReliOn Platinum Meter Limited 3-Year Warranty

The manufacturer warrants to the original purchaser of the meter that your ReliOn Platinum meter will be free from defects in materials and workmanship for three years from the date of purchase. If, during this 3-year period, the meter does not work properly because of a defect in materials or workmanship, the manufacturer will replace it with a new ReliOn Platinum meter or equivalent product free of charge. The warranty on the replacement meter will expire on the date of the original warranty expiration or 90 days after the shipment of a replacement system, whichever period is longer. The purchaser's exclusive remedy with respect to the ReliOn Platinum meter shall be replacement.

This warranty does not apply to the performance of a ReliOn Platinum meter that has been damaged by accident or has been altered, misused, tampered with, or abused in any way. The manufacturer will handle meters that show damage or abuse according to its Non-Warranty Service Policy described in the next section.

THE ABOVE WARRANTY IS EXCLUSIVE OF ALL OTHER WARRANTIES, AND THE MANUFACTURER MAKES NO OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION, THE IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. IN NO EVENT SHALL THE MANUFACTURER BE LIABLE TO THE PURCHASER OR ANY OTHER PERSON FOR ANY INCIDENTAL, CONSEQUENTIAL,

INDIRECT, SPECIAL, OR PUNITIVE DAMAGES ARISING FROM OR IN ANY WAY CONNECTED WITH THE PURCHASE OR OPERATION OF THE METER OR ITS PARTS. NO WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, IF ANY IS IMPLIED FROM THE SALE OF THE METER, SHALL EXTEND FOR A LONGER DURATION THAN THREE YEARS FROM THE DATE OF PIIRCHASE

Some states do not allow limitations on how long an implied warranty will last or the exclusion of incidental or consequential damages, so the above limitation and exclusion may not apply to you. This warranty gives you specific legal rights, which vary from state to state.

Non-Warranty Service Policy

The manufacturer's Non-Warranty Service Policy applies to meters where the above warranty has not become effective, has become inapplicable, or has expired. The manufacturer will replace, at its option, meters returned to it for a service charge (not to exceed \$35).

Replacement will be with the same or similar product. Replacement meters will be warranted for a period of 90 days from shipment under a limited warranty providing for replacement of parts and labor at no charge.

Warranty and Service Instructions

All requests for return of Relion Platinum meters under the above warranty or service policy must be made to Customer Service at 1-800-819-1097. You will be

10 License and Warranty

mailed a return authorization label, which must be affixed to your carton for shipping the system to the manufacturer. Cartons received without this label will be returned to you at your expense.

Customers experiencing difficulties should review the troubleshooting information in Meter Maintenance and Troubleshooting of this manual. Further inquiries should be directed to Customer Service at 1-800-819-1097.

Limited License

CAUTION

A restricted license limits use of the ReliOn Platinum system (meter and test strips) in the United States. Carefully read the User's Manual before use.

The ReliOn Platinum system (meter and test strips) and its use are protected by U.S. Patent Nos. 7.276.146 (expires 4-October-2022): 7.276.147 (expires 4-October-2022); 8,298,401 (expires 4-October-2022): 8.303.801 (expires 4-October-2022): 8.329.026 (expires 4-October-2022); 7,452,457 (expires 2-May-2026): 7.488.601 (expires 1-February-2026): 7.569.126 (expires 28-December-2026); and 7.604.721 (expires 12-August-2026). A license to use the ReliOn Platinum system is required until the expiration of the last-to-expire patent listed above and is only granted when the ReliOn Platinum meter is used with the ReliOn Platinum test strips.

ReliOn Platinum test strips are specifically

manufactured for operation with the ReliOn Platinum meter. Use of other test strips supplied by another manufacturer may prevent or impair the proper function of the ReliOn Platinum system.

Using the ReliOn Platinum system indicates your acceptance of the restricted license to use the ReliOn Platinum system only with ReliOn Platinum test strips. If you do not agree to the terms and conditions of the restricted license, you may return, to the manufacturer, the unused ReliOn Platinum system for a full refund. If you have any questions, please call Customer Service at 1-800-819-1097.

Except where prohibited by statute, all warranties covering the ReliOn Platinum system are voided by use of the ReliOn Platinum meter with any test strips other than ReliOn Platinum test strips.

Patent Information

U.S. Pat.: http://www.roche-diagnostics.us/patents

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