

ReliOn™ Premier COMPACT Blood Glucose Monitoring System

User Manual

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ReliOn™ Premier COMPACT Blood Glucose Monitoring System is waived under CLIA.

01 - 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 instructions:

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

Intended Use

- The ReliOn™ Premier COMPACT Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips and alternate sites such as the forearm, palm, thigh and calf.
- Alternate site testing should be used only during steady-state blood glucose conditions.
- The ReliOn™ Premier COMPACT Blood Glucose Monitoring System is intended for use 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.
- ReliOn™ Premier Blood Glucose Test Strips are for use with the ReliOn™ Premier family of blood glucose meters to quantitatively measure glucose in fresh capillary whole blood samples drawn from the fingertips and alternate sites.
- ReliOn™ Premier Control Solutions are for use with the ReliOn™ Premier family of blood glucose meters and ReliOn™ Premier Test Strips to check that the meter and the test strips are working together properly and that the test is performing correctly.

Important Information

- The ReliOn™ Premier COMPACT Blood Glucose Monitoring System is intended for *in vitro* (outside the body) diagnostic use only and for the quantitative measurement of glucose in capillary whole blood.
- The ReliOn™ Premier COMPACT Blood Glucose Monitoring System is intended for use by a single user only. Do not share the meter and lancing device with anyone including other family members. Never use on multiple users.
- The ReliOn™ Premier COMPACT Blood Glucose Meter is designed to minimize code related errors in monitoring by using the no coding function.
- The ReliOn™ Premier COMPACT Blood Glucose Meter should be used only with ReliOn™ Premier Blood Glucose Test Strips.

- An abnormally high or low red blood cell count (hematocrit level over 60 % or below 20 %) may produce inaccurate results.
- Inaccurate results may occur in severely hypotensive individuals or patients in shock.
- Inaccurate low results may occur for individuals experiencing a hyperglycemic-hyperosmolar state, with or without ketosis.
- Critically ill patients should not be tested with blood glucose meters.
- All parts of the kit are considered biohazardous and can potentially transmit infectious diseases, even after you have performed pre-cleaning and disinfection.
- For questions or concerns, contact Customer Service: 1-855-776-0662, 7 a.m. to 7 p.m. Central time, 7 days a week. At all other times or in case of emergency, contact your healthcare professional or emergency medical response.

02 - ReliOn™ Premier COMPACT Blood Glucose Monitoring System

ReliOn™ Premier COMPACT Components

Verify that all these components are included in the system box.

- ReliOn™ Premier COMPACT Blood Glucose Meter
- ReliOn™ Premier Blood Glucose Test Strips (50)
- User Manual / Quick Reference Guide
- Test Strip Insert
- Carry Case
- Logbook
- Lancing Device
- Battery (1)
- Lancets (10)

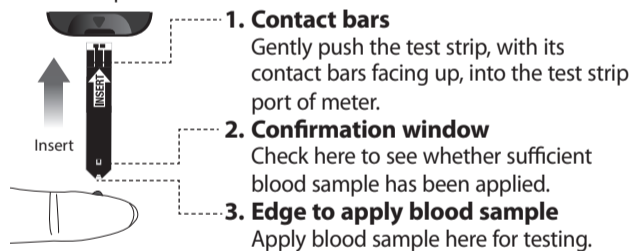
- Check all the components after opening the ReliOn™ Premier COMPACT Blood Glucose Monitoring System package.
- ReliOn™ Premier Control Solutions are necessary but not included.
- ReliOn™ Premier Control Solutions can be ordered separately by contacting Customer Service: 1-855-776-0662, 7 a.m. to 7 p.m. Central time, 7 days a week. At all other times, contact your healthcare professional.

Specifications

- Measurement range: 20–600 mg/dL
- Sample size: Minimum 0.5 µL
- Test time: 5 seconds
- Sample type: Fresh capillary whole blood
- Calibration: Plasma-equivalent
- Battery life: 1,000 tests
- Assay method: Electrochemical
- Power: One 3.0 V lithium battery (type CR2032)
- Operating range Temperature: 50–104 °F (10–40 °C)
- Relative humidity: 10–90 %
- Hematocrit: 20–60 %

03 - ReliOn™ Premier Blood Glucose Test Strip

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



Important Safety Instruction

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

CAUTION

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

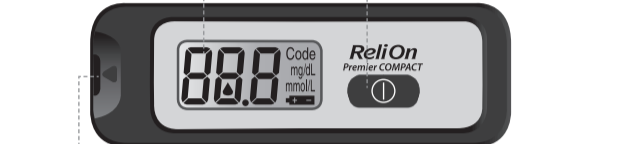
- Do not apply the blood or control solution samples directly to the test strip port.
- Do not apply the blood or control solution samples to the test strip while holding the meter in a way that the tip of the test strip faces upwards. The blood or control solution samples may run down the surface of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

NOTE

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

04 - ReliOn™ Premier COMPACT Blood Glucose Meter

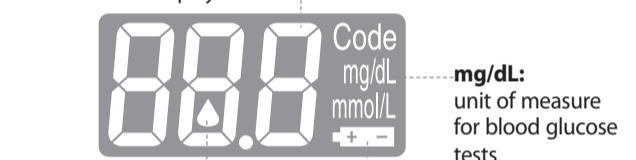
Display Shows results, messages
Button Turns the meter on/off and checks the memory



Test Strip Port Insert test strip here

ReliOn™ Premier COMPACT Blood Glucose Meter Display

Test results: test results are displayed here



- **Blood insertion symbol:** ▲ indicates meter is ready for the application of a drop of blood or control solution
- **Battery symbol:** 🔋 indicates meter battery is running low and needs to be replaced

NOTE
The unit of measurement for your ReliOn™ Premier COMPACT Meter is preset and fixed in mg/dL.

05 - Checking the System

- ReliOn™ Premier COMPACT Blood Glucose Meter and Test Strips should be checked using ReliOn™ Premier Control Solutions, available in two levels (Level 1 and 2). The ReliOn™ Premier Control Solutions contain known amounts of glucose and are used to check that the meter and the 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 ReliOn™ Premier 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 page 7 with ReliOn™ Premier Control Solutions.

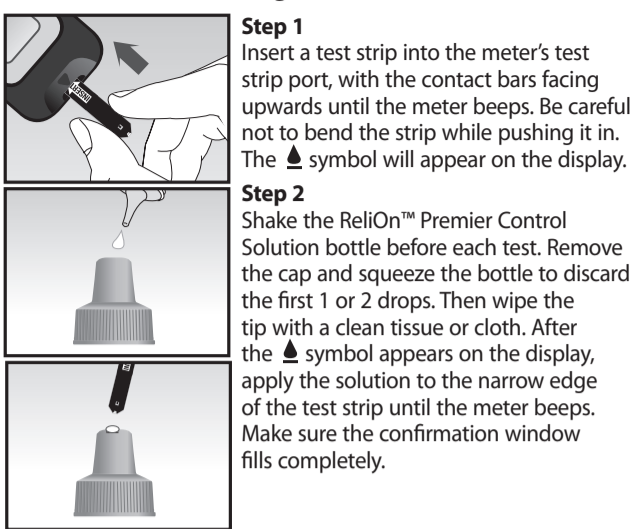
NOTE

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

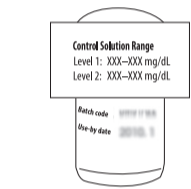


NOTE

- The meter will switch off if the control solution sample is not applied within 2 minutes of the ▲ symbol appearing on the screen.
- If the meter turns off, remove the strip, reinsert it. Then start from step 1.

Step 3

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



Step 4

Compare the result displayed on the meter to the range printed on the test strip vial. The result should fall within that range. Used test strips should be discarded safely in disposable containers.

CAUTION

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

Comparing the Control Solution Test Results

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

Situations	Actions
<ul style="list-style-type: none"> • When the control solution bottle was not shaken well. • When the meter, test strip, or the control solution were exposed to high or low temperatures. • When the first drop of the 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 6.
<ul style="list-style-type: none"> • When the control solution is past the expiration date printed on the bottle. • When the control solution is past its discard date (the date the bottle was opened plus three (3) months). • When the control solution is contaminated. 	Discard the used control solution and repeat the test using a new bottle of control solution.

CAUTION

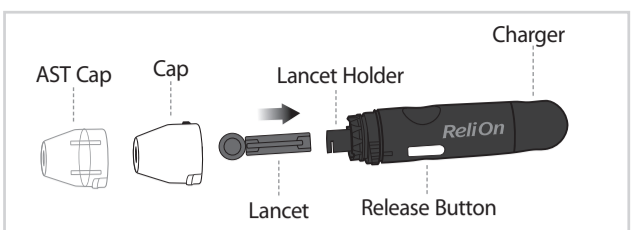
- If results continue to fall outside the range printed on the test strip vial, the meter and test strip may not be working properly. Do not use your system and contact Customer Service: 1-855-776-0662, 7 a.m. to 7 p.m. Central time, 7 days a week.

NOTE

- The ReliOn™ Premier Control Solution can be purchased separately. Contact Customer Service: 1-855-776-0662, 7 a.m. to 7 p.m. Central time, 7 days a week.

06 - Using the Lancing Device

You will need a lancing device in order to collect a blood sample. You may use the lancing device contained in the ReliOn™ Premier COMPACT Blood Glucose Monitoring System or any other medically approved lancing device.



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

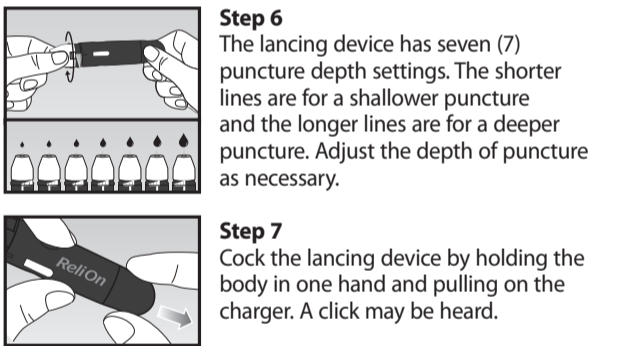
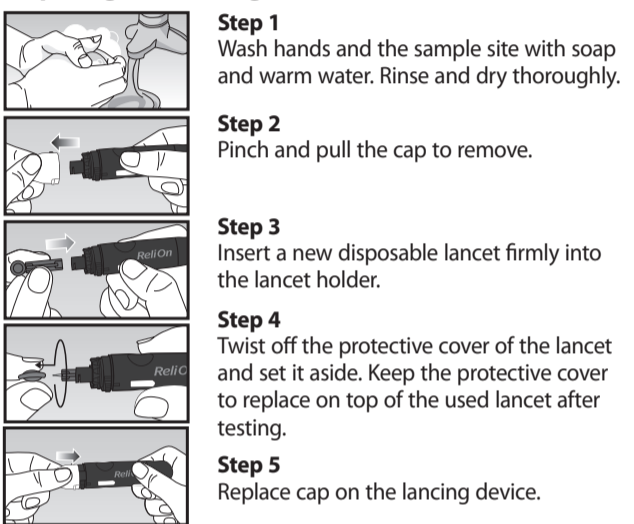
CAUTION

- To reduce the chance of infection
- All components that come into contact with blood samples should be considered 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 and test strips.
- Keep your meter and lancing device clean. See the pre-cleaning and disinfection section on page 16.

NOTE

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

Preparing the Lancing Device



NOTE

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

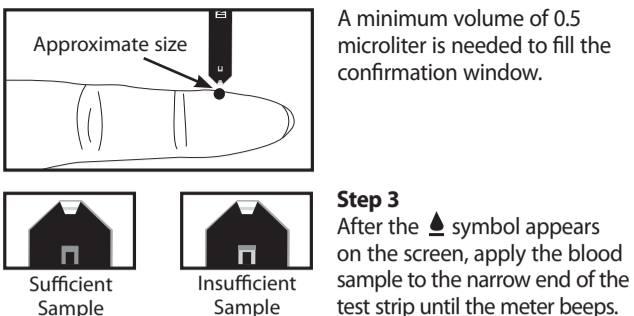
07 - Testing Your Blood Glucose Level

Step 1
Insert a test strip with the contact bars facing upwards into the meter's test strip port. Push the test strip gently into the test strip port until the power automatically turns on and the ▲ symbol appears.



Step 2

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.

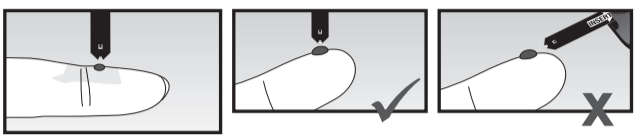


A minimum volume of 0.5 microliter is needed to fill the confirmation window.

Step 3

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 abnormally high viscosity (thickness or stickiness) or insufficient volume, an 'Er4' message may appear. It is recommended that the application of blood sample to the test strip be performed virtually vertical to the sample site as shown in the diagram below.



Step 4

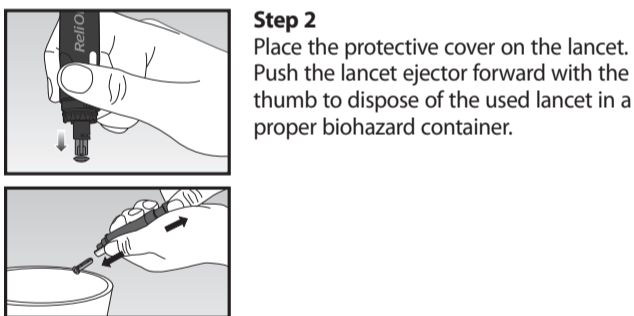
The test result will appear after the meter counts down from '5' to '1'. The result will be automatically stored in the meter's memory.

If the test strip is removed after the test result is displayed, the meter will automatically switch off after three (3) seconds. Discard used test strip safely in a disposable container.

NOTE

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

Discarding Used Lancets



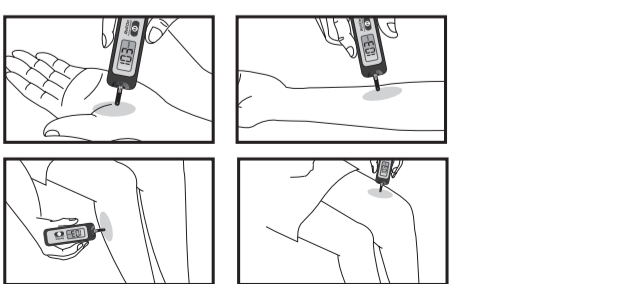
CAUTION

- Check for damages before using the lancet. If they have been damaged, please discard it and use other 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.

08 - Alternate Site Testing

What is AST (Alternate Site Testing)?
When someone tests their glucose, they take the blood sample from the tip of the finger. However, since there are many nerve endings distributed there, it can be painful.

When doing a glucose test, using different parts of the body, such as the forearms, palms, thighs and calves, can reduce the pain during testing. This method of testing with different parts of the body is called Alternate Site Testing. While AST may reduce the pain during testing, it may not be simple for everyone and the following precautions should be observed during testing.



Alternate Site Blood Sampling (forearm, palm, thigh, calf)
Select a clean, soft and fleshy sample site area free of visible veins and hair and away from bones. Gently massage the sample site to help blood circulation to minimize result differences between fingertip and alternate site sampling. Firmly press and hold the lancing device against site. Wait until the skin surface under the lancing device changes color. Then press the release button while continuing to apply pressure. Keep holding the lancing device against your skin until sufficient (at least 0.5 µL) blood is drawn. Carefully lift the lancing device away from your skin.

CAUTION

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

Things to know when using AST

Please read the following before testing at alternate sites (forearms, palms, thighs, and calves). The capillary whole blood of the fingertips reflects changes in glucose levels more rapidly than in alternate sites. The test results from the fingertip testing and AST may differ due to factors such as lifestyle and eating food which affect glucose levels.

Acceptable situations for AST
<ul style="list-style-type: none"> • Fasting period • Before a meal
Situations requiring fingertip test
<ul style="list-style-type: none"> • When the glucose levels are rapidly increasing, such as during two (2) hours after a meal or exercise. • When sick or when glucose levels seem quite lower than test value. • When hypoglycemia is not well recognized. • When insulin has the biggest effect. • Two (2) hours after an insulin injection.

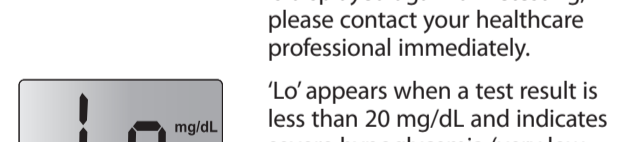
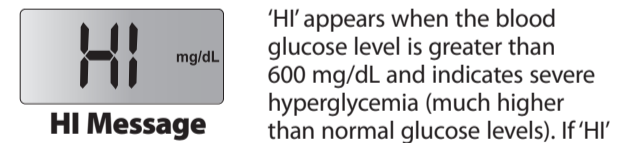
AST Precautions

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

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

09 - 'HI' and 'Lo' Messages

The ReliOn™ Premier COMPACT Meter displays test results between 20 to 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 on retesting, please contact your healthcare professional immediately.

'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 on 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.

10 - Viewing Test Results in Meter Memory

Step 1
The meter memory can store up to ten (10) results at one time. The results will be saved in the order it was measured and you can view stored results by pushing the ⏪ button.

Step 2
When the button is pushed, number '1' will appear on the screen for one (1) second and then the result will be shown. This is the most recent test result that is saved in the memory. To go on to the second recent result, press the button again. Now number '2' will appear for one (1) second and the next result will be displayed. By repeating this process, you can go through to result number 10 which is the oldest data saved in the memory. To exit from the memory mode, press and hold down the button for about two (2) seconds. The meter will turn off.

11 - Understanding Error Messages

E-r-1
A used test strip was inserted.
-> Remove the strip and reinsert a new test strip.

E-r-2
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.

E-r-3
The temperature during the test was above or below the operating range.
-> Move to an area where the temperature is within the operating range 50-104 °F (10-40 °C) and repeat the test after the meter and test strips have reached a temperature within the operating range.

E-r-4
The blood sample is of insufficient volume or blood is too thick.
-> Repeat the test after inserting a new test strip.

E-r-5
This error message may appear when the wrong blood glucose test strip is used instead of the ReliOn™ Premier Blood Glucose Test Strip.
-> Repeat the test with a ReliOn™ Premier Blood Glucose Test Strip.

E-r-6
There is a problem with the meter.
-> Do not use the meter. Contact Customer Service: 1-855-776-0662.

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E-r-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.

12 - Caring for the ReliOn™ Premier COMPACT System

- To minimize the risk of transmission of bloodborne 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 bloodborne pathogens.

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

NOTE
• The life span of a ReliOn™ Premier COMPACT Meter is 5 years. We recommend disinfecting both the meter and lancing device at least once per week. We have validated a total of 260 cleaning and disinfecting cycles (260 pre-cleaning and 260 disinfection cycles) to represent weekly cleaning and disinfecting over the use life of 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.

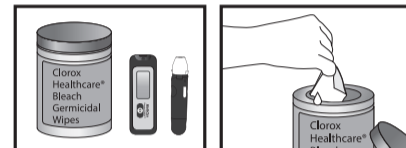
16

We have validated **Clorox Healthcare Bleach Germicidal Wipes** with 0.55 % sodium hypochlorite as the active ingredient for disinfecting the ReliOn™ Premier COMPACT 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 COMPACT User Manual, please read the instructions provided by the manufacturer of **Clorox Healthcare Bleach Germicidal Wipes** before using it.

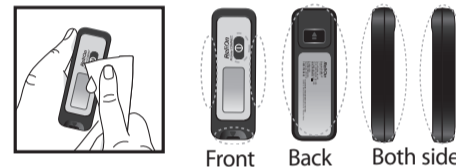
Name	Clorox Healthcare® Bleach Germicidal Wipes
Manufacturer	Clorox Professional Products Company Phone: 1-800-537-1415 Website: www.cloroxprofessional.com
EPA registration number	67619-12
Active ingredients	Sodium Hypochlorite: 0.55 %

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

Pre-Cleaning and Disinfection Procedure



1 **Open the cap of the Clorox Healthcare Bleach Germicidal Wipes container** and pull out one (1) towelette and close the cap.



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

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- Dispose of the used towelette in a trash bin.
- Pull out one (1) new towelette and wipe the entire surface of the meter three (3) times horizontally and three (3) times vertically using a new towelette to remove bloodborne pathogens.
- Dispose of the used towelette in a trash bin.
- Allow exteriors to remain wet for one (1) 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 with 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 7 for how to do 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 or battery compartment. Never immerse the meter or hold it under running water because this will damage the meter.

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CAUTION
Storage and Handling
• Keep the meter in a cool and airy place.
• Do not expose the meter to direct sunlight or heat for extended periods of time.
• Do not let dirt, dust, blood or water enter into the meter's test strip port.
• Do not drop the meter or subject it to strong shocks.
• Do not try to fix or alter the meter in any way.
• Store all meter components in the carrying case to prevent loss.
• The ReliOn™ Premier COMPACT Meter should be used only with ReliOn™ Premier Test Strips.
• Avoid getting any liquid or moisture in the test strip vial. This can affect the test strips and cause inaccurate test results.
• Do not apply samples other than capillary whole blood or control solution to the test strip.

CAUTION
Do not allow any foreign substances or liquid substances, such as dirt, blood, or water, enter into the meter. The meter may be damaged or may malfunction. Follow the warning information provided below to prevent possible damage to the meter.
• Do not apply the blood or control solution samples directly to the test strip port.
• Do not apply the blood or control solution samples to the test strip while holding the meter in a way that the tip of the test strip faces upwards. The blood or control solution samples may run down the surface of the test strip and flow into the test strip port.
• Do not store your meter in unsanitary or contaminated sites.
• Make sure to follow the Pre-cleaning and Disinfection Procedures found in the Caring for the ReliOn™ Premier COMPACT System section of this user manual.

NOTE
• For additional information or technical assistance contact Customer Service: 1-855-776-0662, 7 a.m. to 7 p.m. Central time, 7 days a week.

13 - Replacing the Battery

The ReliOn™ Premier COMPACT Meter uses one 3.0 V lithium battery (non-rechargeable, replaceable, type CR2032). Before using the meter, check the battery compartment and insert battery if empty.
If blinks when the meter is turned on or a test strip is inserted, it means there is not enough power for tests. So, the battery needs to be changed.
The test results might not be saved if the battery runs out.

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Step 1
Make sure that the meter is turned off. Push the cover down slightly and in the direction of the arrow to open the battery compartment.

Step 2
Remove the used battery and insert a new battery with the '+' side facing up. Make sure the battery is inserted firmly.
- The meter will not operate if the battery is inserted upside down.

Step 3
Place the cover on the battery compartment. Push cover in the direction of the arrow to close. A click may be heard.

CAUTION
• There is a risk of explosion if the battery is replaced with an incorrect type. Please dispose of the used battery according to your local regulations.

14 - Performance Characteristics

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

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

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

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• Accuracy results for glucose concentration < 75 mg/dL

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

• Accuracy results for glucose concentration ≥ 75 mg/dL

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

Precision: Precision studies were performed in a laboratory using the ReliOn™ Premier COMPACT System.

Within Run Precision

Blood avg.	38 mg/dL	SD = 1.9 mg/dL
Blood avg.	86 mg/dL	SD = 3.2 mg/dL
Blood avg.	125 mg/dL	CV = 4.1 %
Blood avg.	189 mg/dL	CV = 2.6 %
Blood avg.	334 mg/dL	CV = 2.8 %

Total Precision

Control avg.	35 mg/dL	SD = 1.2 mg/dL
Control avg.	116 mg/dL	CV = 2.4 %
Control avg.	324 mg/dL	CV = 2.3 %

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

Alternate Site Testing Evaluation
Comparison of various AST with respect to the results of YSI measurements.

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

	Within ± 5 mg/dL	Within ±10 mg/dL	Within ±15 mg/dL
Fingertip	1/2 (50 %)	2/2 (100 %)	2/2 (100 %)
Forearm	1/2 (50 %)	2/2 (100 %)	2/2 (100 %)
Palm	2/2 (100 %)	2/2 (100 %)	2/2 (100 %)
Thigh	1/2 (50 %)	2/2 (100 %)	2/2 (100 %)
Calf	1/2 (50 %)	2/2 (100 %)	2/2 (100 %)

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• Alternate site test results for glucose concentration ≥ 75 mg/dL

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

15 - Warranty Information

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

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

Any claim must be made within the warranty period.

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

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

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

Returns
For instruction 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.

DISTRIBUTED BY:
Walmart Inc.,
Bentonville, AR 72716
www.ReliOnBGM.com

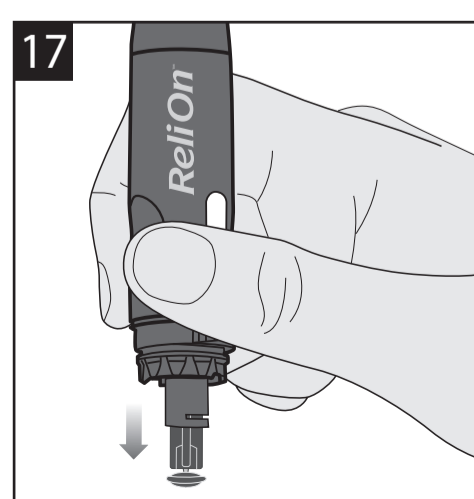
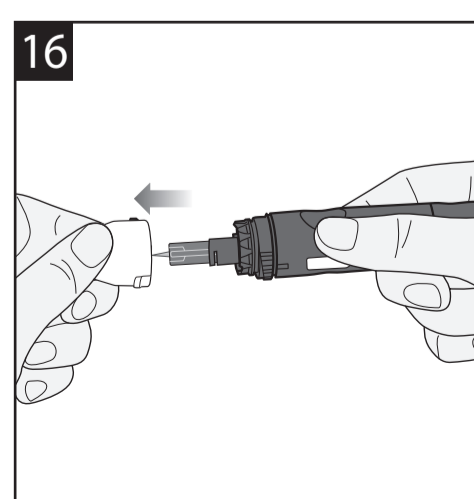
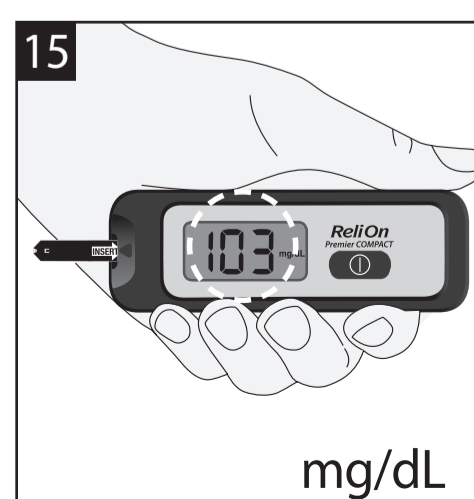
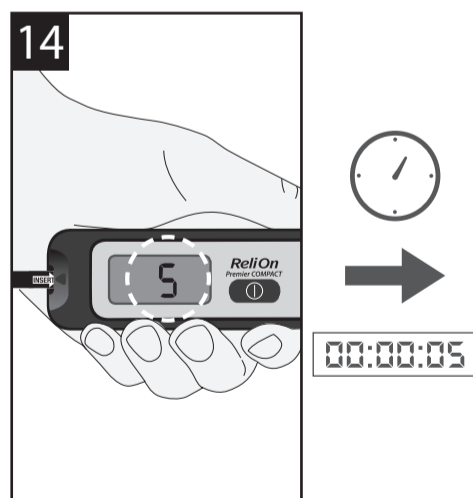
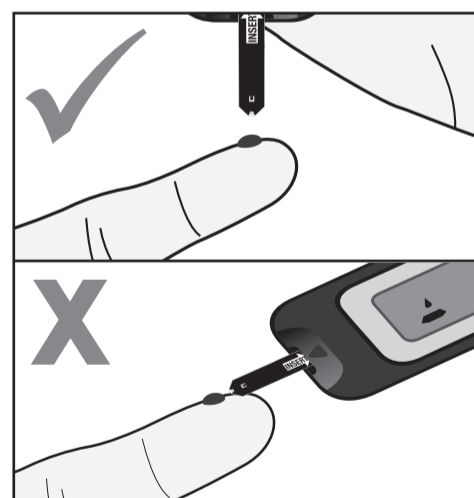
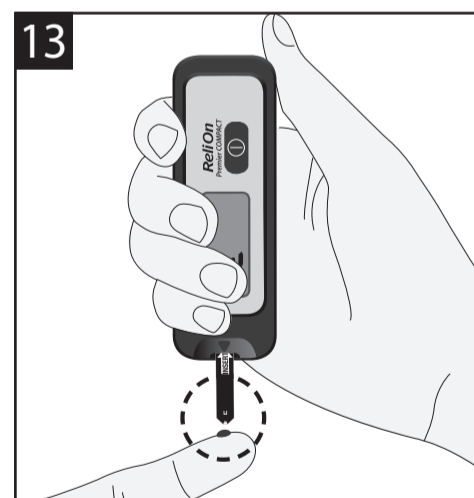
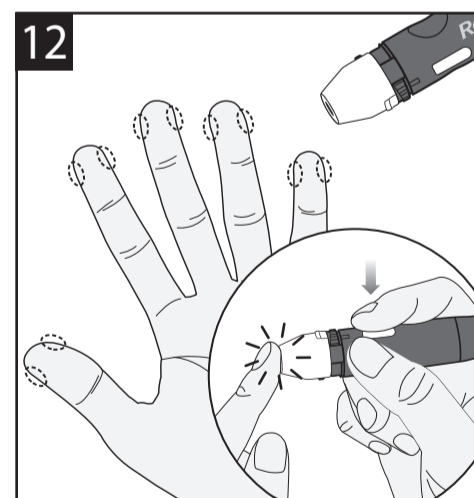
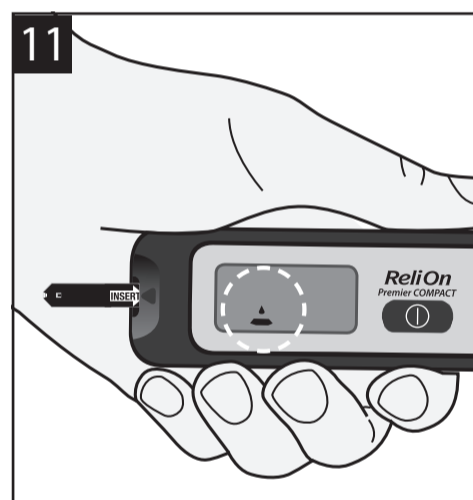
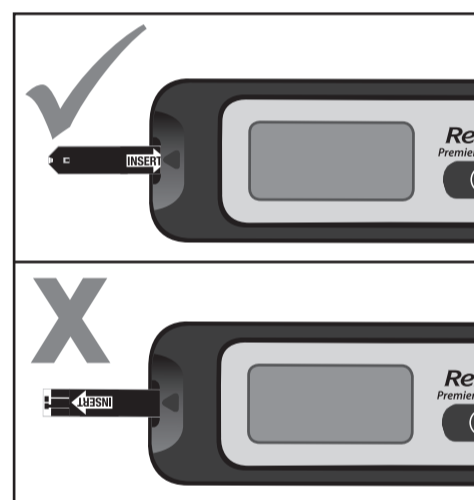
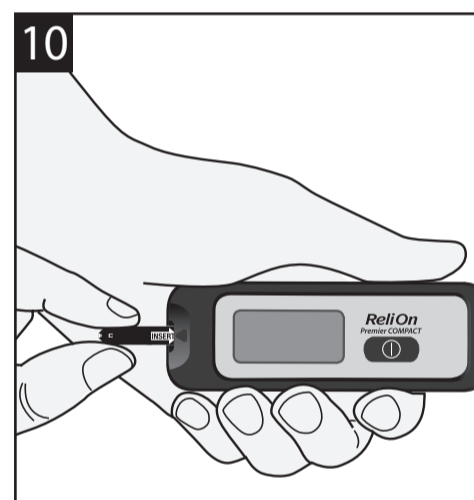
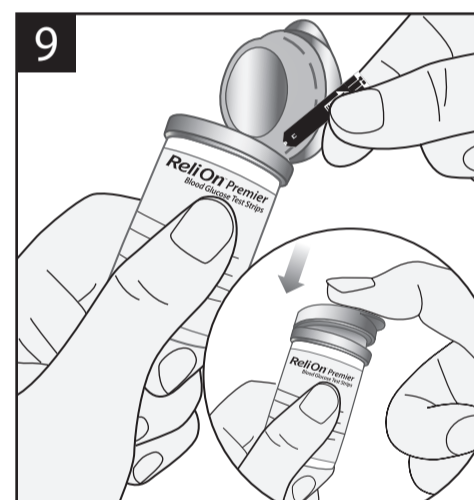
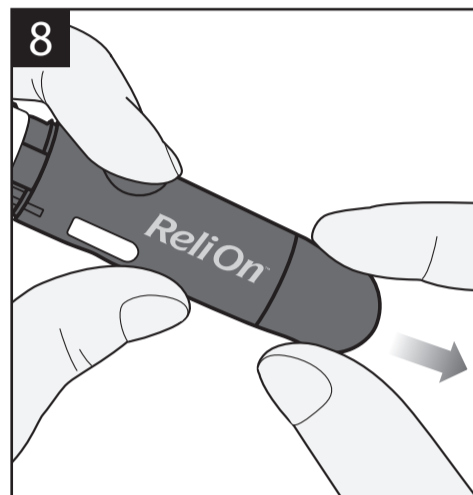
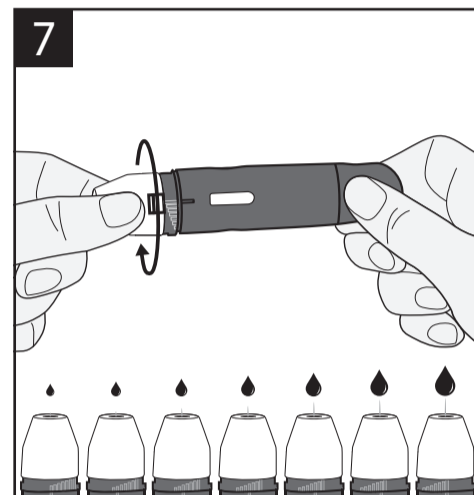
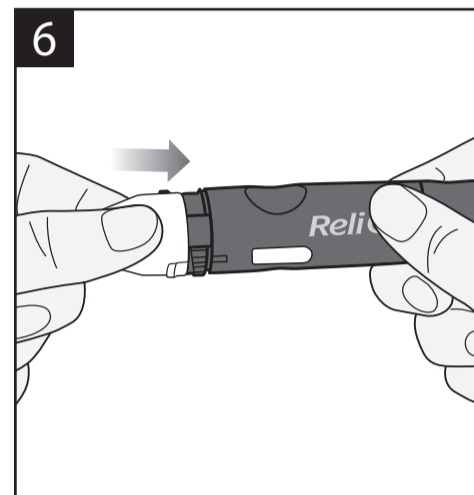
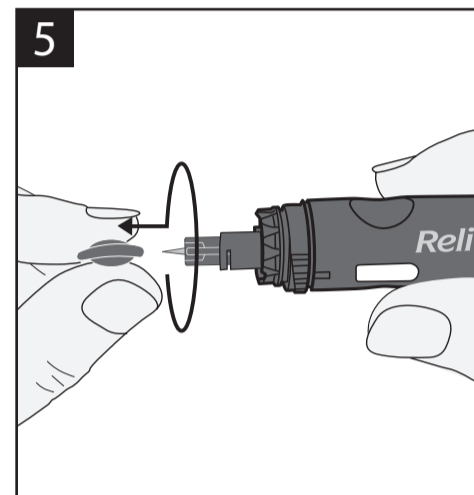
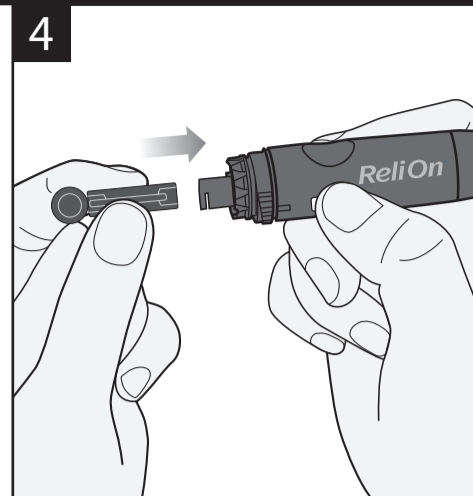
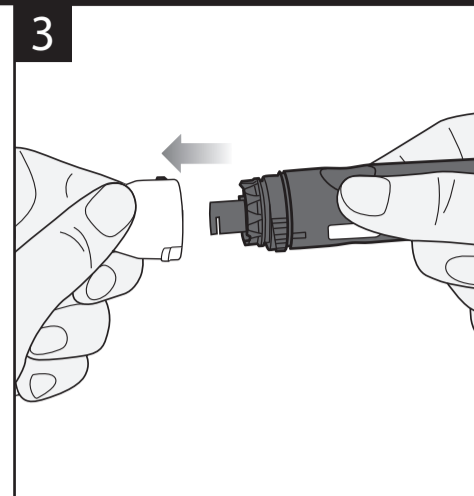
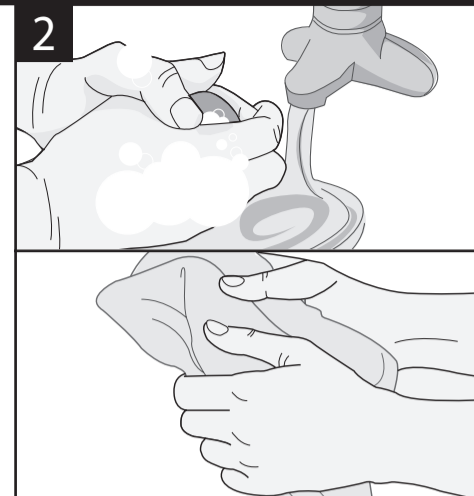
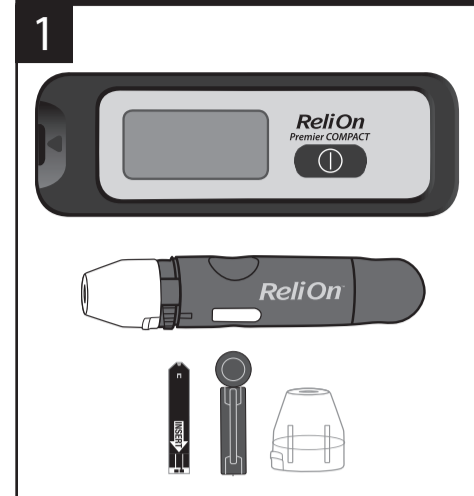
Customer Service
1-855-776-0662
7 a.m. to 7 p.m. Central time,
7 days a week.

At all other times or in case of emergency, contact your healthcare professional or emergency medical response.

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