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Customer Care: 1-800-992-3612 Call toll-free 24 hours a day, 7 days a week. Visit us at www.relion.com

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User's Guide For *in vitro* diagnostic use



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Welcome

Thank you for choosing the ReliOn[®] Ultima Blood Glucose Monitoring System.

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Important steps for using the System are inside this guide. Please read it carefully.

Your new Blood Glucose Monitoring System is an important tool that can help you better manage your diabetes. Blood glucose results can help you understand your diabetes and what happens with:

• Food

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- Exercise
- Stress and illness
- Diabetes medications

Always monitor your blood glucose according to your healthcare professional's recommendations.





CHAPTER 1

Important Things to Know about Your Blood Glucose Monitoring System

Intended Use Your System:

- Is indicated for home (lay user) or professional use in the management of patients with diabetes.
- Is for use outside the body (*in vitro* diagnostic use).
- Is for monitoring glucose in fresh whole blood (for example, from the fingertip).



Potential Infection Risk:

Healthcare professionals performing blood tests with this system on multiple patients must always wear gloves and should follow the infection control policies and procedures approved by their facility.



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Questions?

Call Customer Care:

24 hours a day, 7 days a week

1-800-992-3612

IMPORTANT:

Observe caution when using around children. Small parts may constitute a choking hazard.

Important Information

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How Your Blood Glucose Monitoring System Works

When you insert a test strip into your monitor, the Apply Sample message shows on your monitor's display window. When a blood sample or control solution sample is applied to the test strip, the glucose reacts with the chemicals on the test strip. This reaction produces a small electrical current that is measured. The result shows on your monitor's display window.

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Blood Glucose Monitoring System Kit Contents Blood Glucose Monitor User's Guide

- Contains system information and directions.

Carrying Case

 Use this to store and carry your monitor and other monitoring supplies.

Logbook

 Use this to record your test results, activities and medications.

Lancing Device, Lancets and Instructions for Use – Use this to obtain a blood drop.

Blood Glucose Test Strips and Instructions for Use **Items not included:**

Solartek or MediSense Control Solutions Data Management System



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Important Information

Getting to Know Your Monitor's Features

Important Information

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Display Window

This shows:

- Blood glucose results.
- Glucose LOT numbers.
- Previous test results and error messages.
- Blood glucose averages.



IMPORTANT:



Each time you turn your monitor on, a full display shows. This is called a Display Check. Look at the Display Check each time it appears on your monitor's display window, especially before you check your blood glucose. The Display Check shows on the display window briefly.

Display Check

Do not use the monitor if the monitor Display Check does not exactly match the picture here (for example, if you see a "3" instead of an "8"). The monitor may show an incorrect result when you use it. Please call Customer Care for assistance.





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Set Time Format

In "Set Time Format", you choose how the time shows on the monitor's display window.

Set Date Format

In "Set Date Format", you choose how the month and day show on the monitor's display window.

Measurement Unit

Blood glucose measurement unit is factory-set in mg/dL.

How to Set the Beeper, Date, Time, & View Measurement Unit

Before you start, please note: "Press and Hold" means that you press the button in for at least 2 seconds. "Press and Release" means that you press the button and let it go quickly. Press and Hold the ① button to turn the monitor off and save your settings at any time. The monitor automatically turns off after 30 seconds of no action.

If you like the setting that you see on your monitor and do not want to change it, Press and Release the ① button to move to the next setup option.

Set Beeper

The \checkmark means the beeper is ON. The X means the beeper is OFF.



Setting Up Your Monitor

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Beeper OFF



- \bigcirc Press and Release the 0 button
- 5 to save the beeper setting and to move to Set Time (Hour).



Set Time

Hour:

Setting Up Your Monitor

The Hour flashes on and off.

Press and Release the ▶ button to move the hour forward.

2 If you go past the correct hour, Press and Release the ◀ button to move the hour back.

Press and Release the ① button to save the hour and to move to Set Minutes.



Minutes:

The Minutes flash on and off.

- Press and Release the ▶ button to move the minutes forward.
- 2 If you go past the correct minute, Press and Release the ◀ button to move the minutes back.



Setting Up Your Monitor

Press and Release the ① button to
 save the minutes and to move to Set
 Date

Set Date

Year:

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The Year flashes on and off.

Press and Release the ▶ button to move the year forward.

) If you go past the correct year, Press

 \angle and Release the \triangleleft button to move the year back.

3 Press and Release the ① button to save the year and to move to Set Month.



Month:

Setting Up Your Monitor

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The Month flashes on and off.

Press and Release the button to move the month forward.

2 Press and Release the 4 button to If you go past the correct month, move the month back.

Press and Release the ${f O}$ button to save 3 the month and to move to Set Day.



Day:

The Day flashes on and off.

Press and Release the button to move the day forward.

If you go past the correct day, Press

2 and Release the ◀ button to move the day back.

 $3\,$ Press and Release the \odot button to save the day and to move to Set Time Format.



Set Time Format

You have two choices:

Choice #1: For the 12-hour format, AM or PM shows.

Choice #2: For the 24-hour format, AM or PM does not show.

To change the Time Format, Press and Release the ◀ button or the ▶ button once.

2 Press and Release the ① button to save the Time Format and to move to Set Date Format.

Set Date Format

You have two choices:

Choice #1: For the month-day format, "-" shows with the date.

Example: "25 May" shows as "5-25"

Choice #2: For the day.month format, "•" shows with the date.

Example: "25 May" shows as "25.5"

To change the Date Format, Press and Release the button or the
 ▶ button once.

Press and Release the ① button to save the Date Format and to move to Measurement Unit.

Choice #1



Setting Up Your Monitor

Choice #2







CHAPTER 3

Ouestions? Call Customer Care: 1-800-992-3612 24 hours a day, 7 days a week

Calibrating Your Monitor

Why Calibrate Your Monitor?

Your monitor must be calibrated so that it can recognize the test strip you are using. Calibration ensures that your results are accurate.

When to Calibrate Your Monitor

- When you use the monitor for the first time.
- EACH time you open and use a new box of blood glucose test strips.

What You Will Need

- Blood Glucose Monitor
- For glucose calibration:
 - Blood glucose test strip
 - Blood glucose test strip instructions for use
 - Blood glucose test strip calibrator

How to Calibrate Your Monitor

When you insert a test strip for the first time, the display window shows:

This means the monitor is **not** calibrated for blood glucose monitoring.

IMPORTANT:

- Use only the calibrator that is packaged in the box of test strips you are using.
- **Do not** use test strips that have expired. Check the expiration date on the test strip foil packet and test strip box. If only the year and month are shown, the expiration date is the last day of the month.



Calibrating Your Monitor

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When the LOT number on the monitor display window and test strip calibrator both read LOT 00000:

What It Means:

Calibration is complete.

What to Do:

You may now monitor your blood glucose.

When the LOT number on the monitor display window and calibrator DO NOT match:

What It Means:

Your monitor may not be calibrated correctly.

What to Do:

- Check that the calibrator is labeled LOT 00000.
- Try to calibrate again.

IMPORTANT: If the LOT numbers on the monitor display window and calibrator still do not match, contact Customer Care. **Do not** attempt to monitor your blood glucose. Your monitor may show an incorrect result.

6 Remove the calibrator from the monitor and store it in your monitor's carrying case.

IMPORTANT: Do not throw the calibrator away until you have used all of the test strips in the box.

If you have any trouble calibrating your system, please contact Customer Care.

Calibrating Your Monitor

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CHAPTER 4

Questions? Call Customer Care: 1-800-992-3612 24 hours a day, 7 days a week

Monitoring Your Blood Glucose

► What You Will Need

- Blood glucose test strip with its instructions for use
- Blood glucose monitor
- Lancing device and a new, sterile lancet

Important Information about Monitoring Your Blood Glucose

- **Do not** use out-of-date test strips. Check the expiration date printed on the test strip box and on each test strip foil packet. If only the month and year are printed on the test strip, then the expiration date is the last day of that month.
- For more detailed information about your test strip, please read its instructions for use before monitoring.
- Use the test strip **immediately** when you take it out of its foil packet.



Example: Expiration date March 31, 2011

- **Do not** use a wet, bent, scratched, or damaged test strip.
- **Do not** use the test strip if its foil packet has a puncture or tear in it.

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Monitoring Blood Glucose









Important:

If the countdown does not start:

What It Means:

You might not have applied enough blood to the test strip.

What to Do:

Apply a second drop of blood to the test strip. Refer to your test strip instructions for use for the number of seconds you have to apply a second drop.

 If the countdown still does not start, or if the number of seconds you have to apply a second drop have passed, discard the test strip, turn off your monitor, and try again with a new test strip.

> At the end of the countdown:

- If the beeper is ON, listen for the beeper.
 - The blood glucose result shows on the display window.
 - The result is stored in your monitor's memory. You may also write the result in your logbook.



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Monitoring Blood Glucose

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Result 300 mg/dL or Higher

When your blood glucose result is 300 mg/dL or higher, **KETONES?** flashes on and off on the display window.

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What to Do:

Monitor your blood glucose again with a new test strip. If the message appears again, follow your healthcare professional's instructions.

"HI" Result

What It Means:

Your monitor has determined that your blood glucose result is higher than 500 mg/dL or there may be a problem with the test strip.

What to Do:

Monitor your blood glucose again with a new test strip. If **HI** shows on the display window again, contact your healthcare professional **immediately**.



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"E-4" Result

What It Means:

Your blood glucose may be too high to be read by the system, or there may be a problem with the test strip.

What to Do:

Monitor your blood glucose again with a new test strip. If **E-4** shows on the display window again, contact your healthcare professional **immediately**.



Important:

It is recommended that you repeat the blood glucose test with a new test strip when:

- LO shows on the display window.
- You obtain a low blood glucose result, but you do not have symptoms of low blood glucose.
- Your monitor displays a blood glucose result that is unusually low, lower than 50 mg/dL.
- HI shows on the display window.
- You obtain a high blood glucose result, but you do not have symptoms of high blood glucose.
- Your monitor displays a result that is unusually high, higher than 300 mg/dL.
- You question your result.

Important:

A result that is incorrect may have a serious medical outcome. Consult your healthcare professional before changing your diabetes medication program.

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Blood Glucose

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Monitoring



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• **Do not** inject the control solution or use the control solution as eye drops.

For Healthcare Professionals:

- Use two levels of Solartek or MediSense Control Solution to do control solution tests with each new box of test strips.
- Ensure that quality control is performed in accordance with Federal, state and local guidelines.

What You Will Need

- Blood Glucose Monitor
- Blood glucose test strip and its instructions for use
- Solartek or MediSense Control Solutions and instructions for use

How to Do Control Solution Testing Getting Started

Wash your hands using warm soapy water and dry them completely.



- Check that the LOT number on the test strip
- instructions for use matches the test strip foil packet.
- 3 Remove the test strip from its foil packet.

Solution Testing

Control

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Note: Do not remove the test strip from the monitor or disturb it during the countdown.

Important: If the countdown does not start:

What It Means:

You might not have applied enough control solution to the test strip.

What to Do:

Apply a second drop of control solution to the test strip. Refer to your test strip instructions for use for the number of seconds you have to apply a second drop.



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 If the countdown still does not start, or if the number of seconds you have to apply a second drop have passed, discard the test strip, turn off your monitor, and try again with a new test strip.

At the end of the countdown:

- If the beeper is ON, listen for the beeper.
 - The control result shows on the display window.
 - The result is stored in your monitor's memory as a control result. In your logbook, record the result as a control result.

Shutting Off Your Monitor

Removing the test strip from the strip port turns off the monitor. You can use the opened foil packet to remove and discard your used test strip.

Control Solution

Testing



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What Can Your Monitor Show You? Memory

Your monitor has a memory that stores up to 450 events. This is a combination of control results, your personal blood glucose results, and other monitor information.

You can review up to 450 of your most recent events on your monitor's display window.

Glucose Averages

You can view the average of all your blood glucose results from the last 7, 14, or 30 days. If you marked your control solution tests, the averages do not include control solution results. (For more information on marking control solution tests, see Chapter 5.)

Important:

- To review blood glucose averages, you **must** set the date and time before monitoring.
- If you **do not** mark control solution tests, this may affect your glucose averages.
- Blood glucose averages **do not** include glucose control results, or results that do not show the time, month, and day.

• When there are no previous results or blood glucose averages to review, the display window shows three dashes.

Reviewing Results

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Press and Release the ① button at any time to return to Memory.

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5 Press and Hold the ① button to turn off your monitor. Otherwise, the monitor turns off after 30 seconds.

Transferring Your Results to a Computer

Download of test results to a computer requires a compatible data management system. For more information, please go to our website or call Customer Care.



Reviewing Results



Questions? Call Customer Care: 1-800-992-3612 24 hours a day, 7 days a week

CHAPTER 7

Understanding & Troubleshooting Error Messages

There are times when error messages may show on your monitor's display window.

In the next few pages, we describe the error messages that may show on your monitor's display window, what they mean, and what you need to do.

Message	What It Means	What You Need to Do
	Temperature is too hot or too cold for the system to work properly.	 Move your monitor and test strips to a location where the temperature is appropriate and monitor again with a new test strip. You may have to wait for your monitor to adjust to the new temperature. Refer to your test strip instructions for use for the appropriate operating temperature range. If the error message appears again, contact Customer Care.
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1/12/10 3:38:56 PM

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Message	What It Means	What You Need to Do
	Monitor error.	 Turn the monitor off, then repeat previous monitoring steps. If the error message appears again, contact Customer Care.
	There may be a problem with the test strip.	 Review the monitoring instructions. Monitor again with a new test strip. If the error message appears again, contact Customer Care.
Error Messages	Blood glucose result may be too high to be read by the system. OR There may be a problem with the blood glucose test strip.	 Monitor again with a new test strip. If the error message appears again, contact your healthcare professional immediately.

Message	What It Means	What You Need to Do
	Blood applied to test strip too soon.	 Review the monitoring instructions. Monitor again with a new test strip. If the error message appears again, contact Customer Care.
	Calibration/Test strip error.	 Repeat the calibration using the calibrator bar that came with the test strip you are using. Check the date setting on your monitor. Check the expiration date on the test strip foil packet. If the error message appears again, contact Customer Care.
	Test strip error. Test trip may be damaged, used, or the monitor does not recognize it.	 Monitor again using a test strip designed for use with the ReliOn® Ultima monitor. If the error message appears again, contact Customer Care.

Message	What It Means	What You Need to Do
	Monitor error.	 Remove test strip, turn monitor off, and try to monitor again. If the error message appears again, contact Customer Care.
Error Messages	Monitor error.	 Remove test strip, turn monitor off, and try to monitor again. If the error message appears again, contact Customer Care.

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Questions? Call Customer Care: 1-800-992-3612 24 hours a day, 7 days a week

CHAPTER 8 Your Monitor's Specifications & Limitations

	2.94" (7.47 cm) 2.10" (5.33 cm) (top) 1.70" (4.32 cm) (bottom) 0.64" (1.63 cm)	
Weight	1.41-1.62 ounces (40-46 grams)	
Power Source	One CR 2032 Lithium (coin cell) battery	
Battery Life	Approximately 1,000 tests	
Memory	Up to 450 events including control results, personal blood glucose results, and other monitor information	
Storage Temperature		
	-13° to 131°F (-25° to 55°C) See test strip instructions for use See control solution instructions for use	
Blood Glucose Assay Range	See blood glucose test strip instructions for use	
Control Solution Range	See blood glucose test strip instructions for use	

Specifications & Limitations ۲

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Functions	- Blood glucose monitoring
	- Memory 450 events
	- Glucose averaging: 7-Day, 14-Day, and 30-Day Averages
	- Control solution marking and testing
	- Backlight: If ON – Stays ON during countdown; turns OFF 30 seconds after result is displayed. If OFF – Stays OFF during countdown; stays OFF during data upload
	- Beeper: If ON – Beeps when countdown starts and finishes
Data port	Yes
Monitor	
Operating Range Temperature:	50° to 122°F (10° to 50°C)
Relative Humidity:	````
System Operating	
Range	
Temperature:	The system operating range is the operating range of the test strip you are using. See "Limitations of Procedure" section in test strip instructions for use.
Relative Humidity:	10% to 90%, non-condensing



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CHAPTER 9

Caring For Your Monitor

Questions? Call Customer Care: 1-800-992-3612 24 hours a day, 7 days a week

Cleaning Your Monitor

Store your monitor in its carrying case. If the surface of your monitor gets dirty, you may clean it. Use a damp cloth and mild soap.

Healthcare professionals: Acceptable cleaning solutions include 10% Bleach, 70% Alcohol, or 10% Ammonia.

IMPORTANT:

Do not try to clean the strip port. **Do not** pour liquid into the strip port or buttons. **Do not** place your monitor in water or any other bath.

Replacing Your Monitor's Battery

When your monitor needs its batteries replaced, the display window shows one of two things:

This means the battery is low.

You may still use your monitor and the results will be accurate. However, the backlight is not usable. It is recommended that you replace the battery at this time.

This means the battery must be **replaced.** The monitor is not usable. The monitor turns off automatically.

IMPORTANT:

Do not remove the old battery until you have a new battery to install. It may be necessary to reset the time and date once you install a new battery.





Caring for Your Monitor

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CHAPTER 10

Support

Questions? Call Customer Care: 1-800-992-3612 24 hours a day, 7 days a week

Support

We are committed to providing you with support. If you have any questions and/or need assistance, call Customer Care: 1-800-992-3612, 24 hours a day, 7 days a week.



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