

FortisCare R13N
Self-Monitoring Blood Glucose System

User's Manual

**Please read this User's Manual thoroughly
before using your blood glucose meter.**

Dear FortisCare R13N SMBG System Owner,

Thank you for using the **FortisCare R13N** Self-Monitoring Blood Glucose (SMBG) System. We designed this system to be dependable, easy-to-use, compact, lightweight and portable to help you monitor your blood glucose on a regular basis.

Please read this manual thoroughly before you begin testing. This manual provides you and your diabetes care team with important information and step-by-step direction to use the **FortisCare R13N** Self-Monitoring Blood Glucose System.

Thanks again for choosing the **FortisCare R13N** SMBG System.

Intended Use

The **FortisCare R13N Self Monitoring Blood Glucose Test System** is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips, palm or forearm. Testing is done outside the body (In Vitro diagnostic use). It is indicated for use at home (over the counter [OTC]) by persons with diabetes, or in clinical settings by healthcare professionals, as an aid to monitor the effectiveness of diabetes control.

Standard Accessories

Your new **FortisCare R13N** Blood Glucose meter and accessories work together to measure the amount of glucose in your blood. The system includes:

- **Blood Glucose Meter**
- **Test Strip x 10 ct.**
- **Normal Control Solution**
- **Carrying Case**
- **Control Solution Instructions**
- **Self-Test Log Book**
- **Lancet x 5 ct.**
- **Lancing device**
- **AST Lancing Device Cap**
- **CR2032 Lithium Battery x 1 ct.**
- **User's Manual**
- **Test Strip Instructions**

Optional Accessories

- **High Control Solution**
- **Low Control Solution**

Note:

1. Normal control solution is included with the system.
2. High and Low control solutions are available. For purchase, please call the Customer Care Service toll-free at 1-866-994-3345.

Why is it so important to test blood glucose regularly?

Testing your blood glucose regularly can make a big difference in how you manage your diabetes every day. We've made this SMBG system as simple as possible to help you to use the meter regularly. Your meter is easy to use, and you can adjust the lancing device for your comfort.

Do you need Help?

If you have questions or need assistance, please call the Customer Care Service toll-free at 1-866-994-3345 (Eastern Standard Time, Mon-Fri 8:00AM-6:00PM) or E-mail: info@oaktreeint.com. You can also visit www.oaktreeint.com for diabetes management tools and product demonstrations.

Note:

Although the FortisCare R13N SMBG System is easy to use, you may need to consult your healthcare professional (this may be your doctor, pharmacist or diabetes nurse educator) for instructions on how to use the system. Only the correct use of the system will ensure accurate results.

Important Information About Your New Meter

- **FortisCare R13N** blood glucose meter is designed and approved for testing fresh capillary blood from fingertip, palm and forearm. The meter is for outside the body (in vitro) use. It should not be used to diagnose diabetes.
- Only use **FortisCare R13N** blood glucose meter with **EasyPlus mini R13N** Blood Glucose Test Strips. Other test strips will give inaccurate results.
- Testing is not valid for neonatal blood specimen.
- Do not disassemble the meter as this may cause damage to the components resulting in incorrect reading. Disassembling the meter will also void the warranty.
- Always keep the meter clean and store it in a safe place. Protect the meter from direct sunlight to ensure a longer lifespan.
- You should not store the meter and test strips in a car, a bathroom or a refrigerator.
- Keep the meter, test strips and lancing device away from children and pets.
- You should not test critically ill patients with home-use blood glucose meters.
- Elevated levels of acetaminophen, uric acid, gentisic acid, levodopa, dopamine, ascorbic acid and methyldopa may affect results.

- Incorrect results may occur when performing the test. If you believe you are not feeling well, please contact your healthcare professional.
- Remove batteries if the meter will not be used for one month or more.
- Warning for potential biohazard: Healthcare professionals using this system on multiple patients should be aware that all products or objects that come in contact with human blood, even after cleaning, should be handled as if capable of transmitting viral disease.
- Consult with your healthcare professional before testing on your palm or forearm.
- Do not touch the strips with wet hands.
- Do not use expired strips (the expiration date is shown on the bottle.)
- Do not bend, cut or twist the strips.
- Up to the altitude of 10,000 feet has effect on readings.

Health-Related Information

- If you are very dehydrated, urinating frequently, low blood pressure, shock or hyperosmolar hyperglycemic nonketotic coma (HHNKC), you may get a test result that is lower than what your blood glucose really is. If you think you are dehydrated, call your doctor right away.
- If you have followed the steps in the user's manual, but still have symptoms that don't seem to match your test results, or if you have questions, please talk to your doctor.
- Please read your test strip instructions carefully for additional health-related information.

Warning for potential biohazard:

Healthcare professionals using this system on multiple patients should handle all products or objects in contact with human blood carefully to avoid transmitting viral disease, even after cleaning.

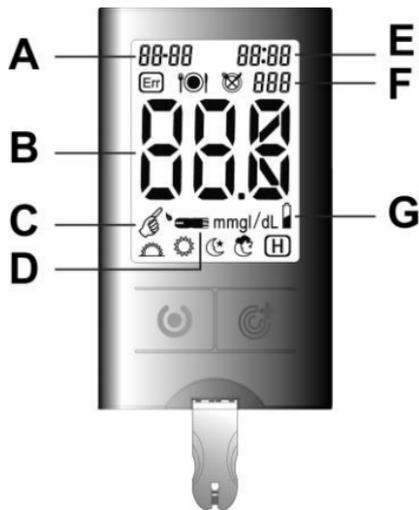
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Chapter 1: Understanding Your Meter

The FortisCare R13N Blood Glucose Meter



- A.** Month and date
- B.** Test result
- C.** Application of blood or control solution

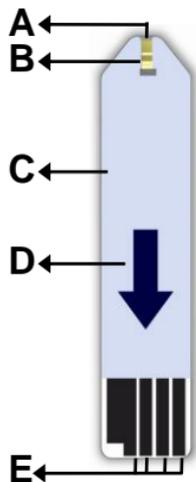
- D.** Insert test strip
- E.** Time
- F.** Test records
- G.** Battery status

Explanation of Meter Symbols

	Left button
	System fault
	PC, after meals
	Noon, from 10:00 am to 04:00 pm
	Night: from 10:00 pm to 04:00 am
	Right button
	AC, before meals
	Morning, from 4:00 am to 10:00 am
	Evening, from 04:00 pm to 10:00 pm
	Hypoglycemia 20~60 mg/dL

The FortisCare Blood Glucose Test Strip and Accessories

Blood Glucose Test Strip



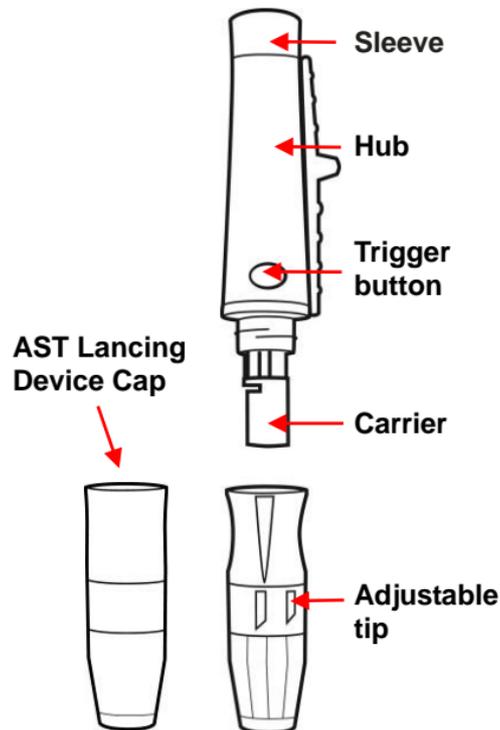
- A. Blood collection area
- B. Reaction area
- C. Hand hold area
- D. Strip insert direction
- E. Electrode

Test Strip Bottle Control Solution Bottle



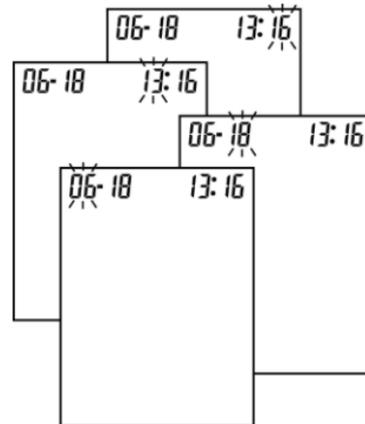
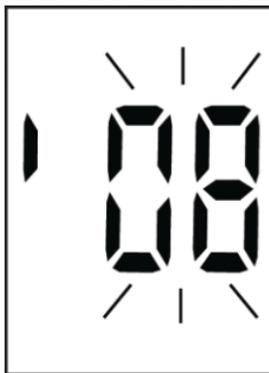
Expiration
Date

Lancing Device



Setting The Time and Date—First Time Use

Setting the current time and date in your meter is important if you intend to use the meter memory.



1. Put a battery into the slot and the meter turns on automatically.
2. The last 2-digits of the year flash at the center of the display. Press  to adjust the year and Press  to confirm the setting.
3. Repeat step 2 to set the date and time. The flashing field is the one you are currently setting.

Note:

The unit of Blood Glucose Meter is set at mg/dL without any modification function.

Using EasyPlus mini R13N Blood Glucose Test Strip

- Use only with FortisCare R13N Blood Glucose Meter.
- Run a control solution test every time you open a new box of test strips (See Chapter 2 "Control Solution Testing.")
- Keep the test strips in their original bottle.
- Close the bottle tightly right away, after you take a test strip out. This keeps the test strip dry.
- Use the test strip within three minutes after you take it out of the bottle.
- The strip is for single use only. Do not reuse it.
- Record the date you open the test strip bottle. Be sure to check the "Expiration date" on the test strip bottle. The test strip is good for three months from the date the bottle is opened or until the expiration date on the bottle, whichever comes first.
- Store the test strip bottle and your meter in a cool dry place.
- Store the test strips between 35.6° F - 86° F (2° C - 30° C). Do not freeze.
- Do not apply blood or control solution to the test strip until you insert it into the meter.
- Do not touch the test strip with wet hands. Do not bend, cut, or twist the test strips.

Chapter 2: Control Solution Testing

Why Run A Control Solution Test

We recommend that you run the **FortisCare** normal control test because it lets you know that your meter and test strips are working properly to give you reliable results. You should run the control solution test when:

- You use the **FortisCare R13N** Blood Glucose Meter for the first time.
- You open a new bottle of test strips.
- You think the meter or test strips may be working incorrectly.
- You drop the meter.
- You have repeated a test and the test results are still lower or higher than expected.
- You are practicing the test procedure.

Note:

Professional users are instructed to follow federal, state, and local guidelines.

About The Control Solution

- Use only with **EasyPlus mini R13N** test strips.
- Write the date you opened the bottle on the bottle label. The control solution is good for three months from the date the bottle is opened or until the expiration date on the bottle, whichever comes first.
- Do not use a control solution that is past the expiration date.
- The control solution can stain clothing. If you spill it, wash your clothes with soap and water.
- Close the bottle tightly after every use.
- Left over control solution should not be added back into the control bottle.
- Store the bottle of control solution at room temperature, between 35.6° F - 86° F (2° C - 30° C). Do not freeze.

Running A Control Solution Test

You need the meter, a test strip, and control solution.



1. Put a test strip into the meter in the direction of the arrow and the icon of  shows itself.
2. Press  twice to set “CtL” and press  to confirm the setting.
3. Place the meter on a flat surface, like a table.
4. Remove the control solution bottle cap and wipe the tip of the bottle with a tissue.

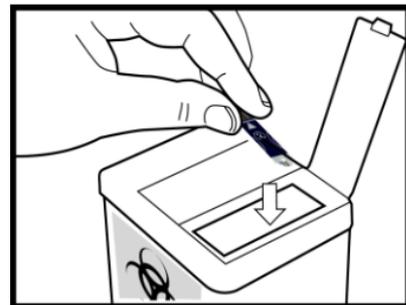
- If display stays at  or  and no any setting is made, the test results will always in  or .
- If you do not choose “CtL”, the test results will be included in the memory of blood test.



5. Squeeze the bottle until a tiny drop forms at the tip of the control solution cap.
6. Touch the drop to the Blood collection area at the end of the test strip.
7. Do not put control solution on top of the test strip.



8. When you hear the beeper, you have enough control solution in the test strip.
The meter starts to count down from 5 seconds and will show the results.
9. A result appears on the display.
Don't remove the test strip yet.
Check if the reading falls within the range printed on the test strip bottle.



10. Remove the test strip and throw it away after you have compared the reading to the range printed on the test strip bottle.

Understanding Control Solution Test Results

The label on your test strip bottle shows the acceptable ranges for the Control Solutions. The result you get should be inside this range. Make sure you compare the result to the correct level of control.

When the control solution result is inside the range on the test strip bottle, your test strips and your meter are working properly.

If your control solution result is not inside the acceptable range (printed on your test strip bottle), here are some things you can do to solve the problem:

Note:

Control Solution values will be included in the memory and averages. Refer to the section “Viewing & Deleting Test Results” to delete the control solution values before averaging your test results.

Troubleshooting Checks

Action

✓ Was the test strip exposed to open air for a long period of time?	If yes, repeat the control test with properly stored strips.
✓ Was the test strip bottle capped tightly?	If no, this will humidify strips inside. Replace the test strips.
✓ Was the meter functioning well?	You can use the control solutions to verify the meter's functions.
✓ Is the control solution expired or contaminated?	If yes, replace with a new control solution to check the performance of SMBG system.
✓ Were test strips and control solutions stored in cool, dry places?	If no, repeat the control test with properly stored strips or control solutions.
✓ Did you follow the testing steps properly?	Read Chapter 2 "Control Solution Testing" and test again. Stop using the meter if you continue to obtain the inaccurate results. Call Consumer Services Toll-Free: 866-994-3345 (Eastern Standard Time, Mon-Fri 8:00AM-6:00PM) or E-mail: info@oaktreeint.com

Chapter 3: Testing Your Blood Glucose

Using The Lancing Device

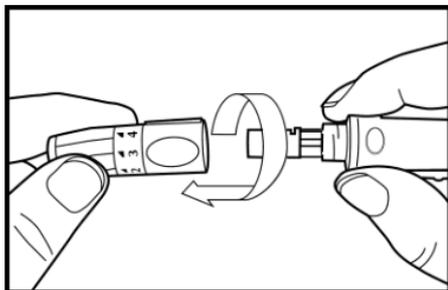
- The best depth setting is the lowest number that draws enough blood for a test. Try different settings to find the one that's right for you.
- Please do not share your lancing device with anyone. And always use a new, sterile lancet. Lancets are for one time use only.

Note:

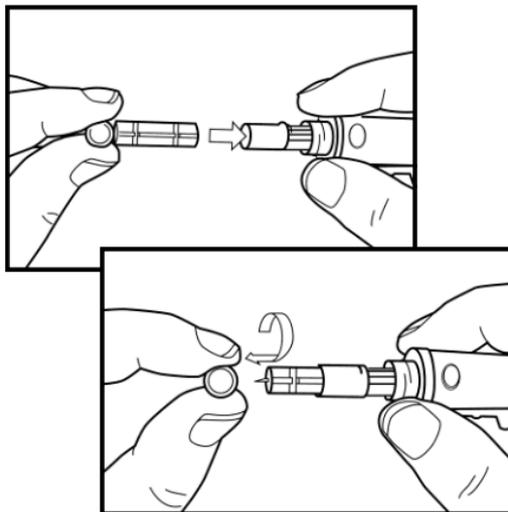
Used test strips and lancets are considered bio-hazardous waste in accordance with local regulations and should be handled as if capable of transmitting infection. The users may discuss methods for disposing of used test strips and lancets with their doctor.

Inserting A Lancet Into The Lancing Device

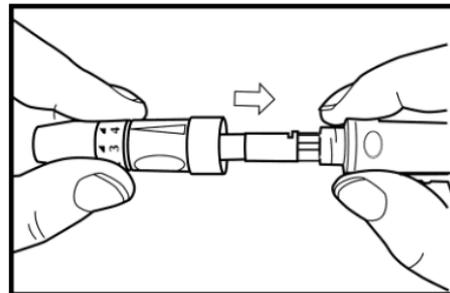
You must first load the lancet into the lancing device to get it ready for use.



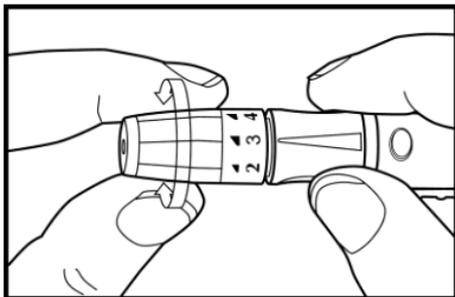
1. Unscrew the Cap.



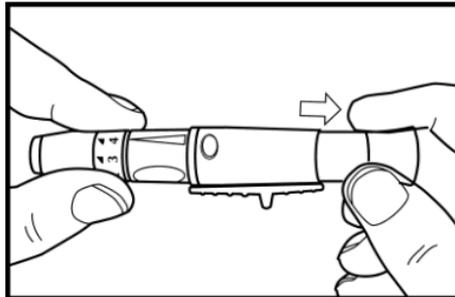
2. Insert the lancet into the lancing device firmly then twist off the protective cover.



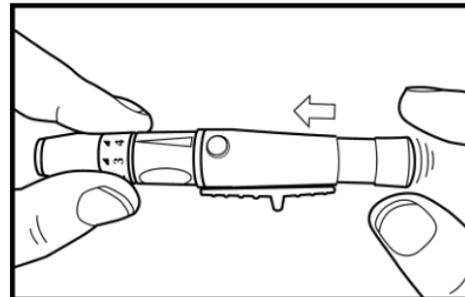
3. Recap the front cap.



4. Select the desired penetration depth.



5. Pull on the sliding barrel of the lancing device until it clicks and then release.
Now the lancing device is ready.
Do not prick your finger until your meter and strip are prepared.



6. Set the lancing device aside until later in the test.

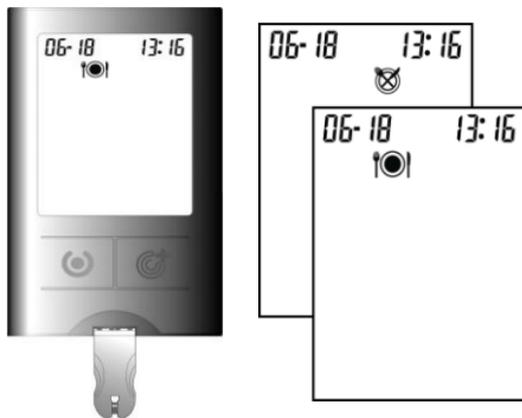
Note:

Select 1-2 for soft or thin skin, 3-4 for average, and 5-6 for thick or calloused skin.

Running A Blood Glucose Test With Blood From Your Fingertip



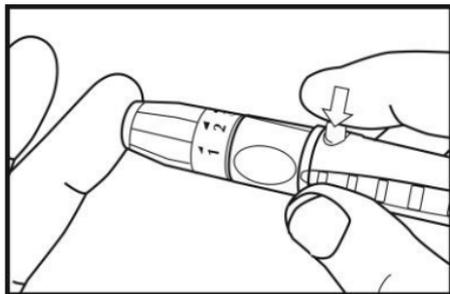
1. Wash your hands with soap and warm water. Rinse and dry thoroughly.



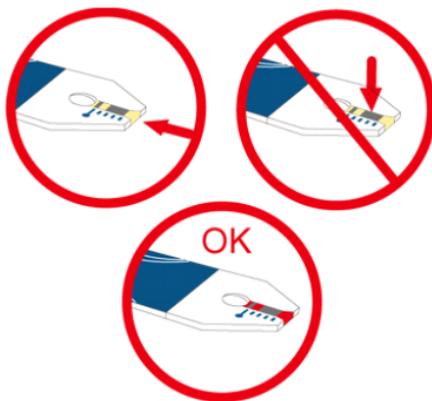
2. Insert a test strip into the meter in the direction of the arrow and the icon  will appear.
3. Press  to set  or  and press  to confirm the setting.



4. When the blood drop flashes on the display, obtain a drop of blood from your fingertip.
5. Gently squeeze your finger to assist the flow of blood.



6. Place the lancing device against the tip or side of your finger; press the trigger button to activate the lancing device.



7. Gently squeeze your finger to assist the flow of blood. This helps you get a blood drop. Touch the blood drop to the tip of the transparent window of the test strip. **Do not put blood on top of the strip.** Be sure to get enough blood on the strip's reaction zone. Otherwise, an inaccurate reading may result.



8. The meter will beep when enough blood has entered the strip's reaction zone. The result will appear on the display after 5 seconds.

Alternate Site Testing (AST)

Understanding Alternate Site Testing

What is AST?

Besides the fingertip, you can test the palm or forearm.

What is the advantage of AST?

You have the option of testing other places on your body besides the fingertip.

Consult your health care professional before you begin using the palm or forearm for testing. Blood glucose test results obtained from your palm and forearm may differ significantly from fingertip samples.

We strongly recommend that you:

Do AST ONLY in the following intervals:

- In a pre-meal or fasting state (more than 2 hours since the last meal).
- Two hours or more after taking insulin.
- Two hours or more after exercise.

Do NOT use AST if:

- You think your blood glucose is low.
- You are unaware of hypoglycemia.
- Your AST results do not match the way you feel.
- You are testing for hyperglycemia.
- Your routine glucose results are often fluctuating.
- If you are pregnant.

Fingertip test only:

- If sick
- If blood glucose is low
- After exercising
- Two hours or less after eating
- When basal insulin is most active
- After injecting rapid-acting insulin (two hours or less)

What to do:

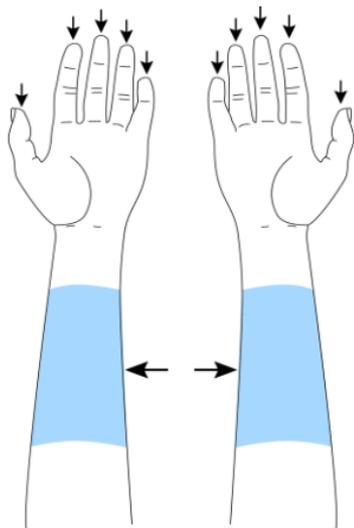
- If the blood glucose test result does not match how you feel, do a fingertip test to confirm the result again.
- If you often do not notice when your blood glucose is low, do a fingertip test.

Caution:

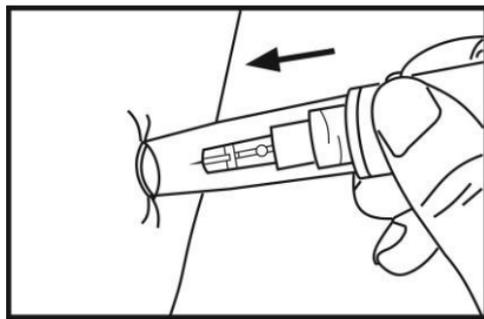
- Talk with your healthcare professional before you test forearm.
- Do NOT ignore symptoms of high or low blood glucose.
- Fingertip samples are able to show the rapid change of glucose faster than forearm samples.
- Do NOT change your treatment just because of a result.

Running A Blood Glucose Test With Blood From Your Forearm

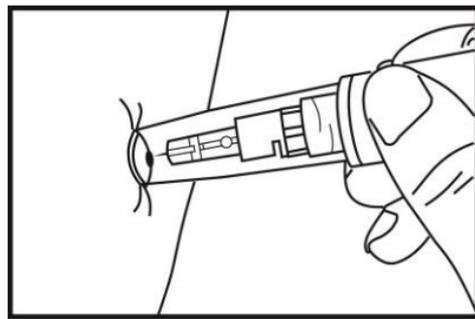
Please use the clear cap with the lancing device for AST testing.



1. Massage the puncture area of forearm for a few seconds.

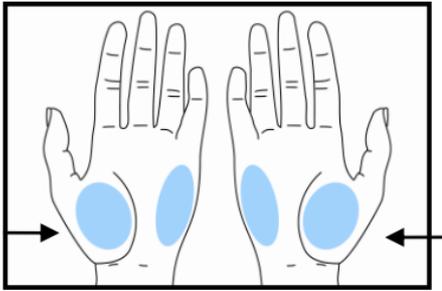


2. Press and hold the device with clear adjustable tip against the forearm.

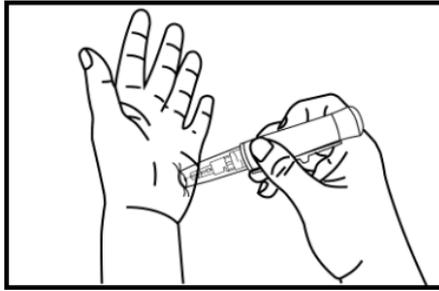


3. Press the trigger button to activate the lancing device. Hold the device against forearm and increase pressure until the blood sample size is sufficient.

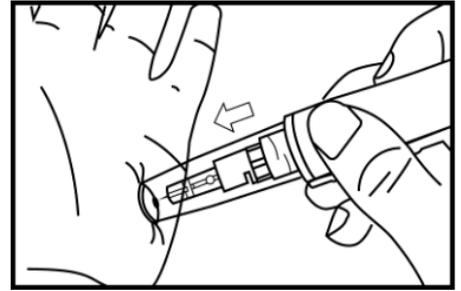
Running A Blood Glucose Test With Blood From Your Palm



1. Massage the puncture area of forearm for a few seconds.



2 .Press and hold the device with one clear adjustable tip against the palm

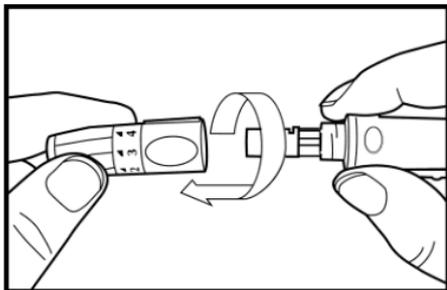


3 .Press the trigger button to activate the lancing device.
4 .Hold the device against palm and increase pressure until the blood sample size is sufficient.

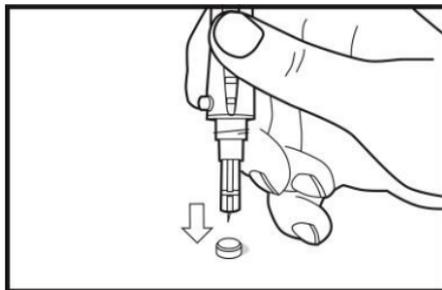
Note:

- Check with your healthcare professional before test other sites than fingertip.
- Please do NOT use the first drop of blood sample.

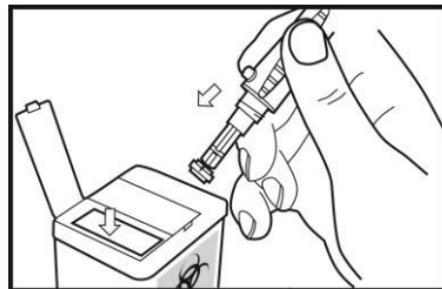
Discarding Used Lancets



1. Unscrew and remove the cap.



2. Without touching the used lancet, stick the lancet tip into its protective cover.



3. Pointing the lancing device toward a container for sharp or biohazard material, slide the ejection button up to release the covered lancet into the container.

Understanding Your Test Results

The **EasyPlus mini R13N** Blood Glucose test strips are plasma referenced and calibrated for easier comparison to lab results. The normal fasting blood glucose range for an adult without diabetes is 70-110 mg/dL. Two hours after meals, the blood glucose range for an adult without diabetes is less than 120 mg/dL. For people with diabetes: please consult your doctor for the blood glucose range appropriate for you.

Unusual Test Results

If your test result doesn't match the way you feel, please follow these steps:

1. Run a control solution test, Chapter 2 "Control Solution Testing."
2. Repeat a blood glucose test, Chapter 3 "Testing Your Blood glucose."
3. If your test results still don't reflect the way you feel, call your doctor immediately.

Note:

1. **Extremely high humidity may affect the test results. A relative humidity greater than 90% may cause inaccurate results.**
2. **A red blood cell count (Hematocrit) that is either very high (above 55%) or very low (below 30%) may not provide accurate results.**
3. **Some studies have shown that electromagnetic fields may affect results. Do not test near an operating microwave oven.**

Symptoms Of High Or Low Blood Glucose

Being aware of the symptoms of high or low blood glucose can help you understand your test results and decide what to do if they seem unusual. Here are the most common symptoms:

Greater than 240 mg/dL

What It Means:

The test result is higher than reference normal range. (70-110 mg/dL)

Symptoms:

fatigue, increased appetite or thirst, frequent urination, blurred vision, headache, general aching, or vomiting.

What to Do:

- If you are experiencing any of these symptoms, test your blood glucose.
- If the result displayed is greater than 240 mg/dL and you have symptoms of high blood glucose, contact your healthcare professional instantly.
- If the result does not match how you feel, follow the steps under "Unusual Test Results."

Below 60 mg/dL

What It Means:

The test result is lower than reference normal range. (70-110 mg/dL)

Symptoms:

sweating, trembling, blurred vision, rapid heartbeat, tingling, or numbness around mouth or fingertips.

What to Do:

- If you are experiencing any of these symptoms, test your blood glucose.
- If the result displayed is below 60 mg/dL and you have symptoms of low blood glucose, contact your healthcare professional instantly.
- If the result does not match how you feel, follow the steps under "Unusual Test Results."

Comparing Your Meter Result To A Lab Result

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

If you want to compare your meter result to the lab result, you must be fasting. Bring your meter to the doctor's office, and test yourself by fingertip within five minutes of having blood drawn from your arm by a healthcare professional. Keep in mind that the lab could use different technology than FortisCare R13N blood glucose meter, and that blood glucose meters for self testing generally read somewhat lower or higher than the lab result.

For accuracy and precision data and for important information on limitations, see the instructions that come with your test strips.

Chapter 4: Meter Memory, Setup

Memory, Storing Test Results

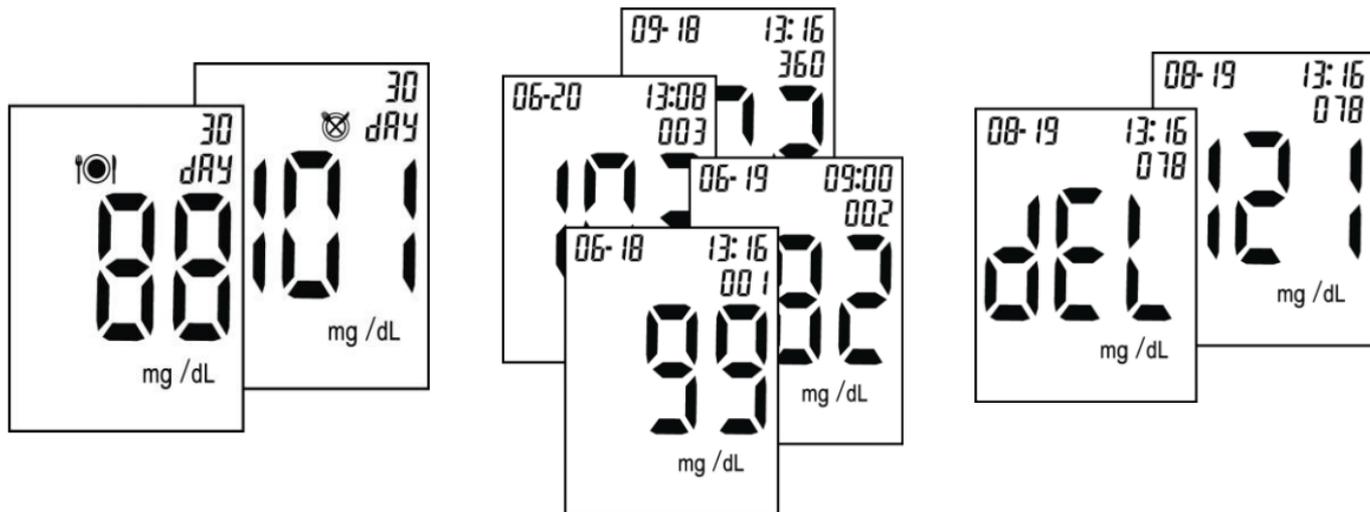
Your meter stores a maximum of 360 test results with the time and date of the test. You can review them at any time. When the memory is full, the oldest result is dropped as the newest is added, so it is very important to have the correct time and date set in the meter.

Note:

- 1. Do not change your therapy based on one individual result in memory.**
- 2. The memory is not lost when you replace the battery. You do need to check that the time and date are still correct. See Section "Setting the time and date" in Chapter 1.**
- 3. Once 360 results are in memory, adding a new result causes the oldest one to be deleted.**
- 4. Control Solution values will be included in the memory and averages. Refer to the section "Viewing & Deleting Test Results" to delete the control solution values before averaging your test results.**

Viewing & Deleting Test Results

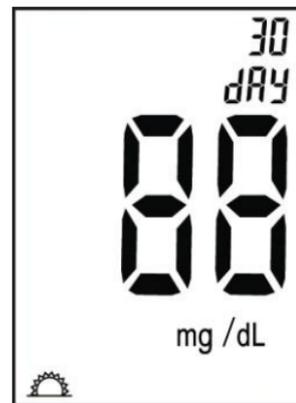
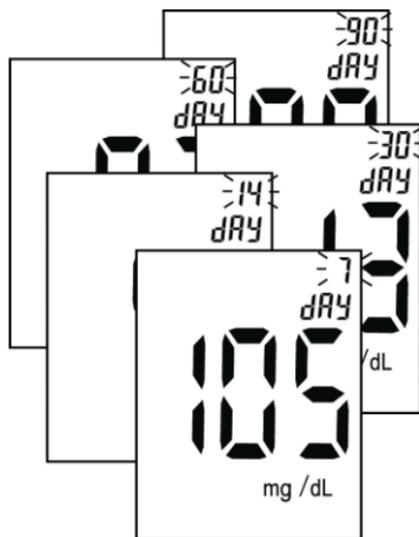
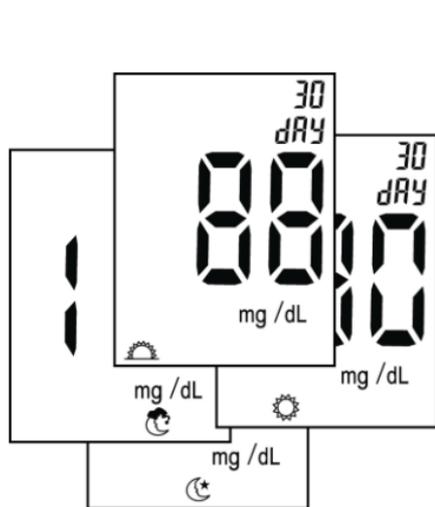
You can review them at any time without inserting a test strip.



1. Press  to review test results of 30 days in  or .
2. Press  to review all results in order from records of 360 to 001.
3. To delete a test result, press  for 3 seconds and display shows "dEL".
4. Press  to keep reviewing test results.
5. The meter will turn off in 1 minute automatically.

Meter Memory

You can review them at any time without inserting a test strip.



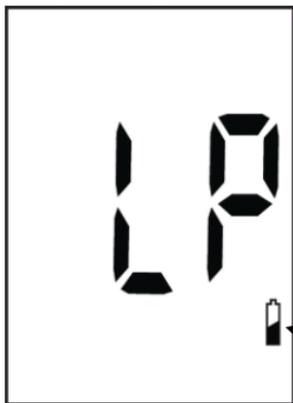
1. Press  to review test results of 30 days in , , , or .

2. Press  to review results of 7, 14, 30, 60 or 90 days.

3. Press  to go back the display of .
4. Meter will turn off in 1 minute automatically.

Chapter 5: Maintenance and Troubleshooting

Installing Batteries



The meter uses one CR2032 Lithium Battery. Batteries will normally last for more than 2000 tests. Other types of CR2032 Lithium Battery are also acceptable, but the capacity of test times may differ. Install the batteries when you first use the meter or replace with new batteries when the "LP" (low power) message and the low battery symbol appear on the display.

Low battery symbol

Note:

- 1. The meter won't delete earlier records after you replace batteries.**
- 2. You should reset the time and date again after you replace the batteries.**
- 3. CR2032 Lithium Battery is available at most stores. You may take the old batteries with you for replacement.**
- 4. Remove batteries when you will not be using the meter for one month or more.**

Cleaning Your Meter

Caring for your **FortisCare R13N** SMBG system does not require special cleaning. Please keep the meter free of dirt, dust, bloodstain, and water stains. Follow these guidelines carefully to help you get the best performance possible:

Do:

- Make sure the meter is turned off.
- Gently wipe the meter's surface with a soft cloth slightly dampened.

Do Not:

- Get any moisture in the test strip slot.
- Spray any cleaning solution directly onto the meter.
- Put the meter under water or liquid.
- Pour liquid into the meter.

Maintenance And Testing



Your meter needs little or no maintenance with normal use. It automatically tests its own systems every time you turn it on and lets you know if something is wrong. (See "Screen Messages" and what to do about them.)

To make sure the display is working properly, turn off the meter. Press and hold  to see the complete display. All the indicators should be clear and look exactly like the picture to the left. If not, call the Customer Care Service Center toll-free: 1-866-994-3345. (Eastern Standard Time, Mon-Fri 8:00AM-6:00PM) or E-mail: info@oaktreeint.com

Cleaning Your Lancing Device

- To clean the lancing device, wipe with a soft cloth dampened with water and mild detergent. **DO NOT** place the entire device under water.
- To disinfect the cap after cleaning. Place it in 70%-75% rubbing alcohol for 10 minutes at least once a week. Allow the cap to air-dry after disinfecting.

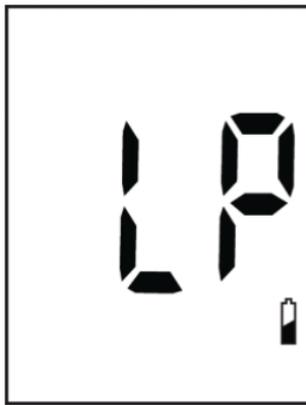
Screen Messages And Troubleshooting

Never make treatment decisions based on an error message. If you have any concerns, please contact your local dealer.



Humidified/Used strips

Action: Replace with a new strip.



Low power

Action: Replace with new batteries.



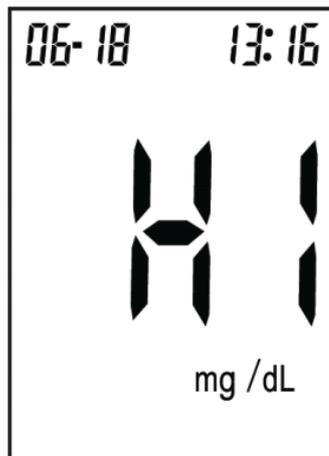
System fault

Action: Replace the batteries first. If 001 ERROR appears again, please call Customer Service toll-free **1-866-994-3345** or E-mail: info@oaktreeint.com.



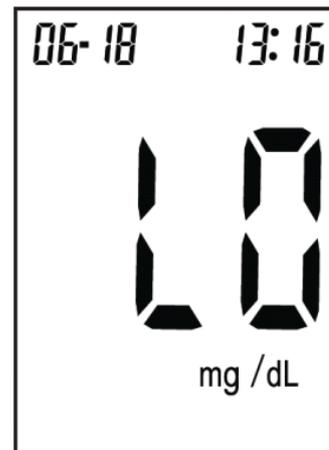
The test result is among
20~60 mg/dL. (H)

Action: Please call your
healthcare professional.



Test result is higher than
600 mg/dL.

Action: Test again. If the result
is still the same, try a control
solution test and if the control
solution test falls within the
correct range, then please
contact your healthcare
professional.



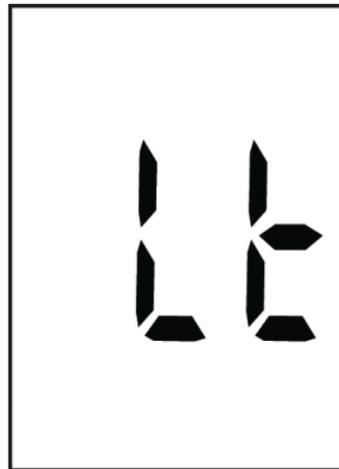
The test result is lower than
20 mg/dL.

Action: Test again. If the result is
still the same, try a control
solution test and if the control
solution test falls within the
correct range, then please
contact your healthcare
professional.



The "Ht" and thermometer icon appears. Temperature is too high, outside the required range of 50°F - 104°F (10°C - 40°C). This alerts users that an incorrect result may occur if the test continues.

Action: Relocate the meter to a location with temperature between 50°F - 104°F (10°C - 40°C).



The "Lt" and thermometer icon appears. Temperature is too low, outside the required range of 50°F - 104°F (10°C - 40°C). This alerts users that an incorrect result may occur if the test continues.

Action: Relocate the meter to a location with temperature between 50°F - 104°F (10°C - 40°C).

Chapter 6: Technical Information

Specifications

Brand name	FortisCare R13N Blood Glucose Meter	
Range	20 - 600 mg/dL	
Test time	5 seconds	
Memory sets	360 test results	
Operating condition	Temp.	50°F - 104°F (10°C - 40°C)
	Relative Humidity	R.H. \leq 90%
Blood sample	0.6 μ L	
	Fresh blood from fingertip, palm or forearm	
Hematocrit (Hct)	30-55%	
Power	CR2032 Lithium Battery	
Battery life	Over 2000 tests	
Display dimension	1.65" x 1.26" (42.0 x 32.0 mm)	
Device dimension H x W x D (mm)	2.95" x 1.73" x 0.39" (75.0 x 44.0 x 10.0 mm)	
Weight	1.06 oz (30.0 grams) w/o batteries	
Principles	Electrochemical biosensor technology	

Limitation

The test strips are used for fresh capillary whole blood samples.

1. DO NOT use neonate blood sample.
2. Extreme humidity may affect the results. A relative humidity greater than 90% may cause incorrect results.
3. The system should be used at a temperature between 50°F - 104°F (10°C - 40°C). Outside this range, the system may get incorrect results.
4. DO NOT reuse the test strips. The test strips are for single use only.
5. Hematocrit: The hematocrits between 30% and 55% will not significantly affect the results. Hematocrit below 30% may cause higher results. Hematocrit above 55% may cause lower results. If you do not know your hematocrit level, please consult with your healthcare professional.
6. Up to the altitude of 10000 feet has effect on readings.

Healthcare Professionals – Please note these additional Limitations

7. Patients undergoing oxygen therapy may have inaccurate results.
8. If the patient has the following conditions, the result may fail:
 - ◆ Severe dehydration
 - ◆ Severe hypotension (low blood pressure)
 - ◆ Shock
 - ◆ A state of hypoglycemic-hyperosmolar state (with or without ketosis)

9. Lipemic samples: Cholesterol level up to 500 mg/dL and triglycerides up to 3,000 mg/dL do not affect the results. Grossly lipemic patient samples have not been tested and are not recommended for testing with **FortisCare R13N** Glucose Meter.
10. Critically ill patients should not be tested with home-use blood glucose meters.
11. Interfering Substances depend on the concentration. The below substances up to the test concentration will not affect the test results.

Interfering , Substance	Test Concentration mg/dL	Bias at 50±5 mg/dL	% Bias at 250±5 mg/dL	% Bias at 500±5 mg/dL
Acetaminophen	8	10.2	6.5	3.8
Ascorbic Acid	2.5	11.8	-6.8	5.3
Dopamine	2	4.3	12.9	6.3
Gentisic Acid	6	7.8	2.8	-4.3
L-Dopa	2	3.8	-1.2	-1.8
Methyldopa	2	5.2	-2.3	4.1
Uric Acid	13	7.6	3.9	3.8

Device Information

FortisCare R13N SMBG System,
EasyPlus mini R13N Blood Glucose Test Strips,
FortisCare R13N Blood Glucose Meter,
FortisCare Low Control Solution,
FortisCare Normal Control Solution,
FortisCare High Control Solution.

Reference:

* American Diabetes Association: Standards of Medical Care for Patients with Diabetes Mellitus, Diabetes Care, 25(2002), p.S37

Manufacturer:

No.8, R&D RD III, Hsinchu Science Park, Hsinchu, Taiwan 30077

Lancing Device

Meets the requirements of MDD 93/42/EEC

Manufacturer:

STERILANCE MEDICAL (SuZhou) INC.

68# LiTangHe RD, XiangCheng, Suzhou, China 215131

Tel : +86 512 65799308 Fax : +86 512 67217663

Lancet

Meets the requirements of MDD 93/42/EEC

Manufacturer:

SAE HAN MEDICAL CORP.

700-113 PUB GOT-DONG, IL SAN-GU, GOYANG-CITY, KYUNGGI-DO, KOREA

TEL : 82-31-923-4330 FAX : 82-31-923-4331

E-mail : saehan@saehanmed.com

Warranty

EPS warrants the original purchaser for a period of 3 years from the date of purchase. This means during the warranty period if your Self-Monitoring Blood Glucose System does not work for any reason (other than obvious abuse), EPS will replace it with a new system or an equivalent product free of charge.