



EMMU Self-Monitoring Blood Glucose System

User's Manual

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

Introduction

Welcome to the **FortisCare[®] EMMU** Self-Monitoring Blood Glucose (SMBG) System. This system is dependable & easy-to-use, utilizing a compact, lightweight and portable meter that will aide you in monitoring your patients' blood glucose levels.

Please read this manual thoroughly before you begin testing. It provides you and your diabetes care team important information and step-by-step directions for use of the **FortisCare[®] EMMU** Self-Monitoring Blood Glucose System.

Intended Use

The **FortisCare[®] EMMU Self Monitoring Blood Glucose Test System** is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertip. Testing is done outside the body (In Vitro diagnostic use). The **FortisCare[®] EMMU** Blood Glucose System is intended for multiple-patient use in professional healthcare settings, as an aid to monitor the effectiveness of diabetes control. The system must be used with safety lancets, and **FortisCare[®] EMMU** Safety Lancets are a part of the system. A new safety lancet should be used every time you perform a test. The system is not to be used on neonates, nor for the diagnosis of, or screening for, diabetes mellitus.

Important Safety Instructions

Only single-use safety lancets (such as **FortisCare[®] EMMU Safety Lancets**) should be used, & a new safety lancet should be used for each test.

All parts of the kit are considered biohazardous and may transmit infection, even if you have performed cleaning and disinfection. Wash hands thoroughly with soap and water after handling the meter. Follow Standard Precautions when using the meter and obtaining a sample. A new pair of gloves should be worn by the user before testing each patient.

The meter should be disinfected after each use. The **FortisCare[®] EMMU Self Monitoring Blood Glucose Test System** may be used for testing multiple patients when Standard Precautions and the disinfection procedures included in this manual are followed.

Included with each **FortisCare[®] EMMU Blood Glucose Meter**:

- **FortisCare[®] Control Solution (Normal)**
- **2 AAA batteries**
- **User's Manual**

Available separately:

- **FortisCare[®] Blood Glucose Test Strips**
- **FortisCare[®] Safety Lancet**
- **FortisCare[®] Control Solution (Low) & (High)**

For further information, please see:

"Biosafety in Microbiological and Biomedical Laboratories (BMBL)"

<http://www.cdc.gov/biosafety/publications/bmbl5/>

"Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline--Third Edition " Clinical and Laboratory Standards Institute (CLSI) M29-A3.

"Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings 2007", <http://www.cdc.gov/hicpac/2007ip/2007isolationprecautions.html>.

"FDA Public Health Notification: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication" (2010)

<http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm>

"CDC Clinical Reminder: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens" (2010)

<http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html>

Important Information about your new FortisCare[®] EMMU Meter

- The **FortisCare[®] EMMU** Blood Glucose Meter is designed and approved for testing fresh capillary whole blood samples from the fingertip, palm and forearm. The meter is for in vitro use ONLY (for testing outside the body). It should not be used to diagnose diabetes.
- Remove batteries if the meter will not be used for one month or more.
- The **FortisCare[®] EMMU** Blood Glucose Meter can only be used with **FortisCare[®]** Blood Glucose Test Strips. Other test strips will give inaccurate results. **FortisCare[®]** Blood Glucose Test Strips feature a unique glucose dehydrogenase chemistry system.
- Testing is not valid for neonatal blood specimens.
- Do not disassemble the meter as this may cause damage to the components resulting in incorrect readings. 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 safety lancets away from children and pets.
- You should not test critically ill patients with home-use blood glucose meters.
- Critically ill patients should not be tested with blood glucose meters. See page 9 for more explanation.
- 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.

Note:

- Do not touch the strips with wet hands.
- Do not use expired strips (the expiration date is shown on the vial.)
- Do not bend, cut or twist the strips.
- Altitude up to 10,000 feet above sea level has no effect on readings.

Why is it so important to test blood glucose regularly?

Testing blood glucose regularly can make a big difference in how you manage your patients' day to day diabetic care. We've made the **FortisCare[®] EMMU** Self-Monitoring Blood Glucose System as simple as possible to help you use it regularly.

Do you need Help?

If you have questions or need assistance, please call the Customer Care Service toll-free at 866-922-6033 (Eastern Standard Time, Mon-Fri 8:00AM~6:00PM).

Health-Related Information

- If the patient is experiencing dehydration, frequent urination, low blood pressure, shock or hyperosmolar hyperglycemic nonketotic coma (HHNKC), you may get a test result that is lower than the actual blood glucose level. We recommend confirming the result on such patients via a clinical laboratory.
- 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 call the Customer Care Service toll-free at 866-922-6033 (Eastern Standard Time, Mon-Fri 8:00AM~6:00PM).
- Healthcare personnel should wash hands & change gloves between patients, even if patient-dedicated testing devices and single-use lancing devices are used.

Note: 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.

Explanation of Meter Symbols



	Date (on the left side)		Medical Record No. (patient number)
	Time (on the right side)		Apply Control Solution
AM	AM (Before Noon)		Apply blood
PM	PM (After Noon)	mg/dL	Unit
	Result / Message		Battery
	Insert a strip		Temperature

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Chapter 1: Understanding Your Meter

FortisCare[®] EMMU Blood Glucose Meter

Test Strip Slot-

Insert a test strip here.

Display-

Shows results, patient numbers, and messages.

Power Button-

Press to turn on/off the meter, and to confirm the setting.

Left (←) Button-

Press to enter memory, adjust setting, and scroll through results.

Strip Ejector-

Push the Strip Ejector to remove the strip.

Battery Door-

Flip open the battery door by pushing the tab in the direction of the arrow and pulling the door up.

Right (→) Button-

Press to enter memories, adjust setting, and scroll through results.



The FortisCare[®] EMMU Accessories

Blood Glucose Test Strip

Electrode

Strip Insert Direction

Hand Hold Area

Reaction area

Blood collection area



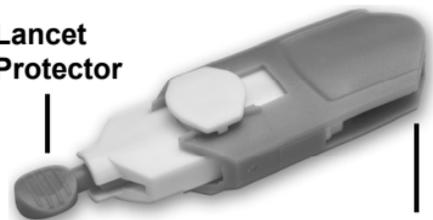
Test Strip Bottle Control Solution Bottle



Expiration Date

Safety Lancet

Lancet
Protector



Lancet Holder

Note: The used lancet cannot be reloaded.

Inserting Batteries



1. Open the battery door on the back of the meter by pushing the tab in the direction of the arrow and pulling the door up.
2. Insert two batteries. The meter will beep to confirm the batteries are inserted correctly.
3. Put the battery door back in place and snap it closed.

Setting the Time, Date and Medical record — First Time Use

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



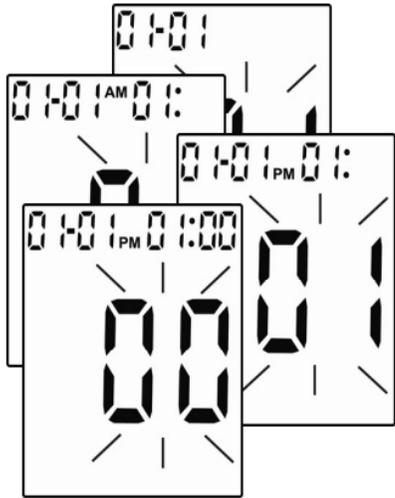
1. Press  (Power Button) to turn the meter on.



2. Press  (Right button) for 2 seconds to get into the setting mode.



3. The large display shows the last 2-digit of the year that flashes at the top of the display as well. Press  (Left button) or  (Right button) to adjust the year and press  (Power Button) to confirm the setting.



4. Repeat step 2 to set the date and time. The flashing field is the one you are currently setting.

5. Press ← (Left button) or → (Right button) to turn on/off the function of medical record number and press  (Power Button) to confirm the setting.

Note: When the function of  turns on, it allows you to identify different testing objectives by marking them from 001-999 so the testing results can be reviewed by the medical record numbers you mark them.

Using FortisCare[®] Blood Glucose Test Strips

- Use only with **FortisCare[®]** Blood Glucose Meters.
- **FortisCare[®] EMMU** Self-Monitoring Blood Glucose System is a “no code” system and does not require test strip calibration.
- **FortisCare[®] EMMU** Self-Monitoring Blood Glucose System utilizes glucose dehydrogenase chemistry to avoid incorrect readings on patients receiving Oxygen therapy.
- Run a control solution test every time you open a new box of strips (See Chapter 2 “Control Solution Testing.”)
- After you take a test strip out of the vial, tightly close the vial immediately to keep the test strips dry.
- Use the test strip within three minutes after taking it out of the vial.
- The strip is for single use only. Do not reuse it.
- When you open a new test strip vial, check the expiration date. The test strips are good for the six months from the initial date the vial is opened or until the expiration date, whichever comes first. Record the date you initially open the test strip vial in the designated spot on the vial.
- Store the test strip vial and your meter in a cool dry place, between 35.6°F - 86°F (2°C-30°C). Do not freeze.
- Insert the test strip into the meter before applying blood or control solution.
- Do not touch the test strip with wet hands. Do not bend, cut, or twist the test strips.

Chapter 2: Control Solution Testing

When to Run a Control Solution Test

Running the **FortisCare**[®] Control Solution Test will let you know that your meter and test strips are working properly. You should run control solution tests:

- If you are using a new **FortisCare**[®] **EMMU** Blood Glucose Meter.
- When you open a new vial of **FortisCare**[®] test strips.
- If you think the meter or test strips may be working incorrectly.
- If the meter is dropped.
- If the results are lower or higher than expected, you have repeated the test with similar results.
- When you practice the test procedure.

About Control Solution

- Use only with **FortisCare**[®] test strips.
- Write the date you initially opened the Control Solution bottle on the 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 returned to the control solution bottle.
- Store the bottle of control solution at room temperature, between 35.6°F - 86°F (2°C- 30°C). Do not freeze.
- **FortisCare**[®] Control Solutions are available in Level 1 (Low), Level 2 (Normal), and Level 3 (High). To purchase, contact your medical supply distributor or Oak Tree Health.

Running A Control Solution Test

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



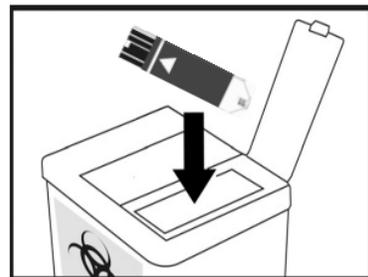
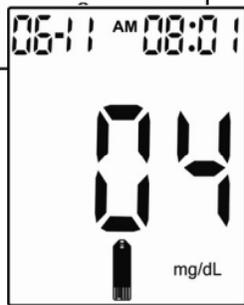
1. Put a test strip into the meter in the direction of the arrow.



2. Press ← (Left button) to select the mode of Control Solution, and the icon of  flashes.



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.
5. Squeeze the bottle until a tiny drop forms at the tip of the bottle and place solution on top of bottle cap.



6. Touch the drop to the Blood collection area at the tip of the test strip. **Do not put control solution on the top of test strip** The meter starts to count down from 5 seconds and will show the results.

7. Do not remove the test strip until you confirm that the reading falls within the range printed on the test strip vial.

8. Push the Strip Ejector to eject the test strip.
9. Dispose properly.

Understanding Control Solution Test Results

The label on your test strip vial shows the acceptable ranges for the Control Solutions – normal, high, and low. The result you get should be inside the acceptable range for the appropriate control solution level. Make sure you compare the result to the correct level of control.

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

If your control solution result is not within the acceptable range printed on your test strip vial, look at the troubleshooting checks on next page.

Troubleshooting Checks

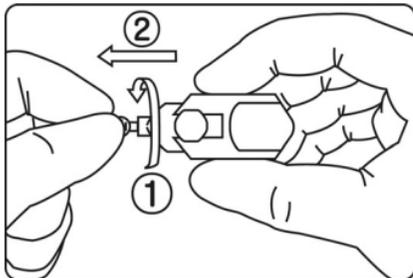
Action

✓ Was the test strip exposed to open air for a long period of time?	Repeat the control test with properly stored strips.
✓ Was the test strip vial capped tightly?	This will humidify strips inside. Replace the test strips.
✓ Was the meter functioning well?	You can use control solution to verify the meter's functions. (Chapter 2)
✓ Is the control solution expired or contaminated?	Replace with new control solution to check the performance of FortisCare[®] Self-Monitoring Blood Glucose System.
✓ Were test strips and control solutions stored in cool, dry places?	Repeat the control test with properly stored strips and/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 inaccurate results. Please contact the FortisCare[®] Customer Care Service line at 866-922-6033 for further troubleshooting.

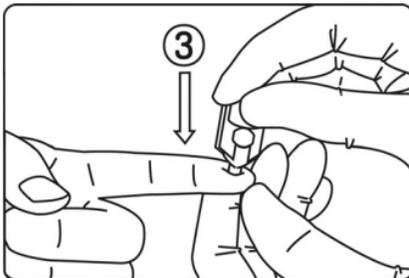
Chapter 3: Testing For Blood Glucose

Instructions for Using the FortisCare[®] Safety Lancets

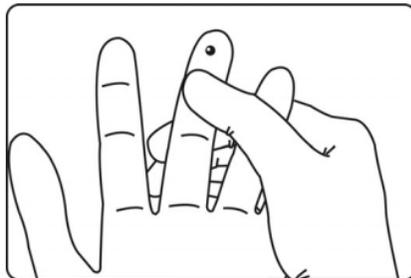
Only single-use safety lancets should be used with this system. Clean test site prior to use.



1. Twist off the protective lancet cap.



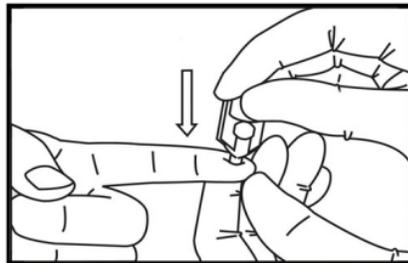
2. Position the lancet and press it firmly against the puncture site.



3. Gently apply intermittent pressure on the puncture site to obtain sufficient blood.

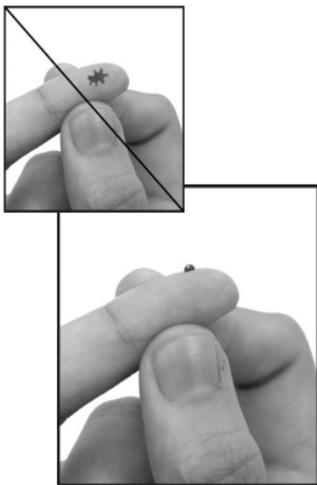
Note: Used test strips and lancets are considered bio-hazardous waste in accordance with U.S. & local regulations and should be handled as if capable of transmitting infection. Follow your healthcare facility's policies for the proper handling of bio-hazardous materials and sharps disposal.

Running a Blood Glucose Test with Blood from Your Fingertip



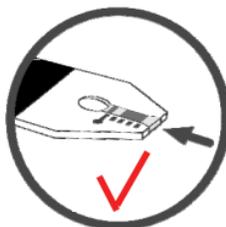
1. Wash your hands with soap and warm water. Rinse and dry thoroughly. A new pair of clean gloves should be worn by the user before testing each patient.
2. Insert a test strip into the meter in the direction of the arrow. The meter turns on and the icon  shows automatically.
3. Press  (Left button) or  (Right button) to set a Patient number and press  to confirm the setting.
4. Swab the blood collection area on a patient's finger with an alcohol swab.
Please wait at least 5 seconds until the intended area is dry and clean before using the Lancet.
5. Twist off the protective lancet cap.
6. Position the lancet and press it firmly against the puncture site.

Note: If the function of  is on, but without marking any medical record number before applying blood, the test result will be recorded under .

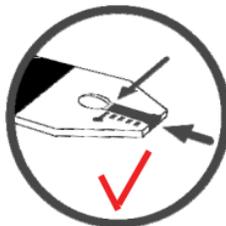


7. Gently squeeze and/or massage your fingertip until a round drop of blood on your fingertip.

Apply blood to the edge of the test strip.



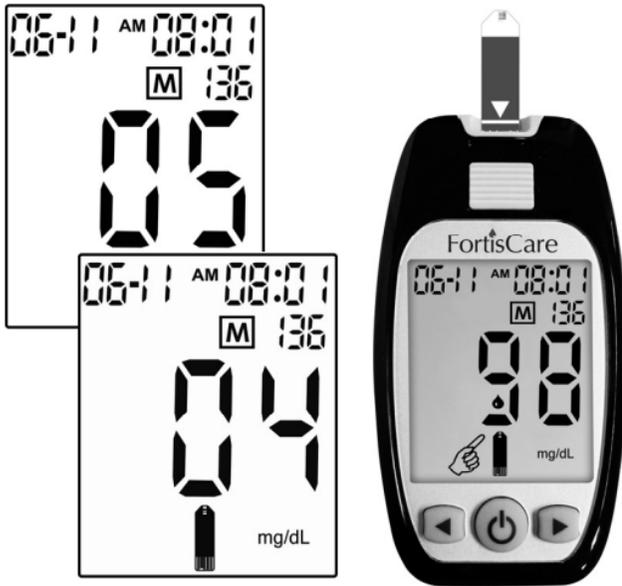
Do not apply blood on top of the test strip.



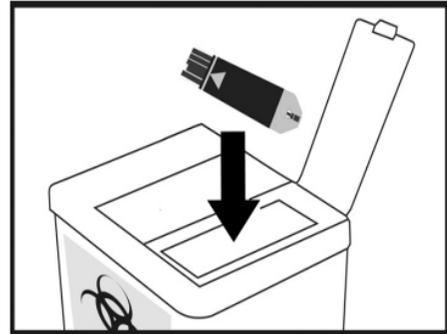
Be sure to get enough blood on strip to make it to the confirmation window.

Not enough blood on strip to get a test result.

8. Touch the blood drop at 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.



9. The meter starts to count down from 5 seconds and then displays the test result.



10. Push the Strip Ejector to eject the test strip & dispose of both strip & lancet properly.
11. After discarding, wash hands thoroughly with soap and water. Rinse and dry thoroughly.
12. Clean and disinfect the meter following the instruction in Chapter 5.
13. Change gloves between patients.

Understanding Your Test Results

Expected Values*

The **FortisCare**[®] Blood Glucose test strips are whole-blood referenced and calibrated for easier comparison to lab results. The American Diabetes Association recommends a post-meal glucose level of less than 180 mg/dL and a pre-meal glucose of 70–130 mg/dL*.

* Reference: American Diabetes Association. Standards of medical care in diabetes-Table 10. Diabetes care. 2011; Vol. 34, Suppl 1, S21.

Unusual Test Results

If the results are inconsistent with the patient's symptoms, 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. After running the quality control and retesting the patient, if there are still concerns about the performance of the meter, inform the Nursing Supervisor and follow your facility's procedure for cross-checking results with the Laboratory or another glucose test method (not another meter).
4. For accuracy and precision data and for important information on limitations, see the instructions that come with your test strips.

Note: 1. Extremely high humidity may affect the test results. A relative humidity above 90% may cause inaccurate results.
2. Hematocrit below 20% may cause higher results. Hematocrit above 60% may cause lower results.

Chapter 4: Meter Memory, Setup

Memory, Storing Test Results

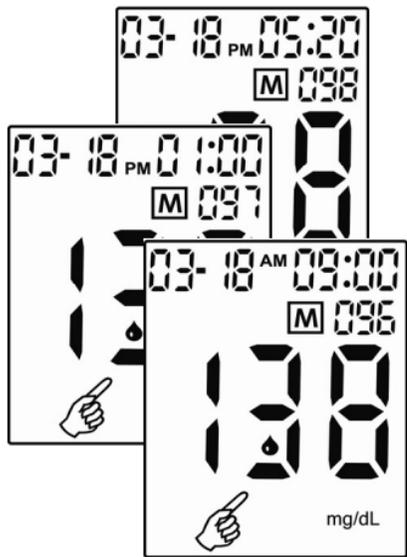
Your meter stores a maximum of 480 test results with the time and date of the test. You can review them at any time. When the memory is full, the oldest result is dropped as the newest is added, so it is very important to have the correct time and date set in the meter.

The memory function is necessary in order to transmit data to a central location (separate software & instructions are available), and should not be used as a substitute for proper charting of patient data.

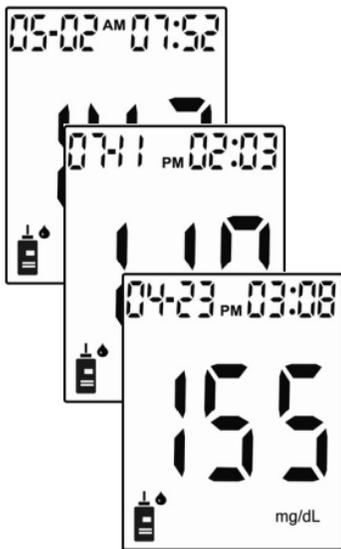
Note:

- 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 480 results are in memory, adding a new result causes the oldest one to be deleted.**

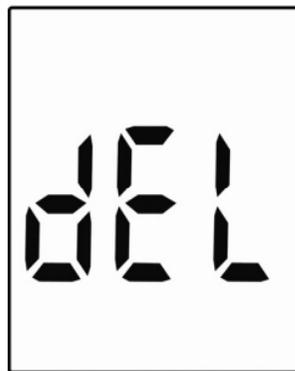
Viewing and Deleting Test Results



1. Press ← (Left button) or → (Right button) to view the test results of each patient's number.



2. The test results of control solution shows without Patient's numbers.



3. To delete a test result, press ← (Left button) for more than 2 seconds and display shows "dEL", press ⏻ to confirm deletion.
4. Press ← (Left button) or → (Right button) to keep reviewing the results.

Running With Your Computer

To Transfer data, the meter has to be at the status of hibernation.



1. Use the USB cable to connect to the meter and your computer. The display shows "PC".



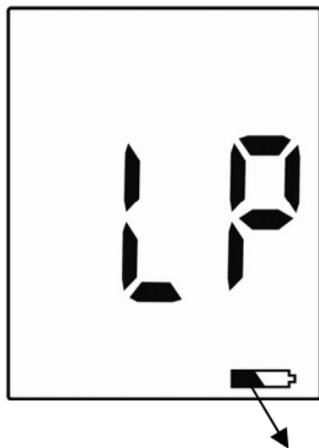
2. The meter starts to transfer data to the "GlucoManager™".



3. When all data are uploaded from the meter to the PC, the meter shows "OK" and beeps.

Chapter 5: Maintenance and Troubleshooting

Inserting Battery



Low battery symbol

The meter uses two alkaline 1.5V (AAA) batteries. Batteries will normally last for more than 2000 tests. Other types of 1.5V (AAA) batteries 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.

The meter will turn on the first time batteries are installed. Please press and hold power button or insert the test strip to turn your meter on.

The meter will turn off automatically. Or you can press and hold power button to turn your meter off.

Note:

- 1. The meter won't delete earlier records after you replace the battery.**
- 2. You should reset the time and date again after you replace the battery.**
- 3. 1.5V (AAA) x 2 batteries are available at most stores. You may take the old battery with you for replacement.**
- 4. Remove the battery when you will not be using the meter for one month or more.**

Cleaning and Disinfecting the FortisCare[®] Blood Glucose Meter

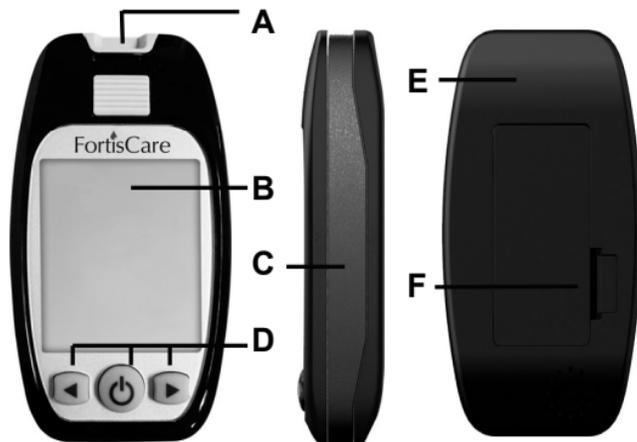
Choosing the disinfectant

According to Guideline for Disinfection and Sterilization in Healthcare Facilities in 2008, you should clean your glucose meter after every use to prevent any possibility of cross infection. Wipes used should be EPA-registered as a disinfectant. Many EPA-registered disinfectant wipes have "2-minute" claims. If your wipes have higher or lower dwell times, you should adjust your technique accordingly.

Cleaning and Disinfection Instruction

Please keep the meter free of dirt, dust, bloodstain, and water stains. After every use, follow both the cleaning & disinfection instructions below, using the EPA-registered wipes.

Meter cleaning area



Code	Name	Possibility of contact with blood
A	Strip Slot	High
B	Front Case	Medium
C	Side Case	High
D	Front Buttons	High
E	Back Case	Low
F	Battery Cover	Medium

Step 1: Cleaning Instruction: Clean first to remove any heavy soil left on the surface of the meter. All blood and body fluids must be thoroughly cleaned from surfaces and objects before disinfection with a germicidal wipe. Open, unfold and use the first germicidal wipe to remove heavy soil.

Step 2: Disinfection Instruction: After cleaning, & before using the meter again, unfold a new wipe and thoroughly wet all the surface of the meter, including the strip port and the other connection port. Treated area must remain visibly wet for a full 2 minutes. Use additional wipe(s) if needed to assure continuous 2 minute wet contact time. Let the device air dry for 30 seconds.

Do:

- Make sure the meter is turned off during cleaning and disinfection.
- Keep test strip vial(s) tightly closed when performing cleaning and disinfection procedures; the fumes from the disinfectant may affect the performance of the strips.
- After cleaning and disinfection, please perform a physical appearance and performance check of devices.
- Always wear gloves when cleaning & testing.

Do Not:

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

Note:

After disinfection, users' gloves should be removed and hands should be thoroughly washed with soap and water before proceeding to the next patient.

Performance check of the meter

Steps	Check item	Accept Result
<i>After each cleaning</i>		
1. Press and hold power button for 3 sec.	Is meter powered on?	Yes
	Does meter make beep sound?	Yes
2. Press and release left or right button.	Does data indicate as stored in the memory?	Yes
	Is the display clear? Can you read the result?	Yes
<i>After each disinfection</i>		
1. Insert test strip	Is meter powered on?	Yes
2. Run control solution test	Any reading?	Yes
	Is the reading within control range?	Yes
3. Eject test strip	Does meter power off?	Yes
4. Press and hold power button for 3 sec.	Is meter powered on?	Yes
	Does meter make beep sound?	Yes
5. Press and release left or right button.	Does data indicate as stored in the memory?	Yes
	Is the display clear? Can you read the result?	Yes
Action: If any of the results are “No” the user should call the Customer Care Service toll-free at 866-922-6033 (Eastern Standard Time, Mon-Fri 8:00AM~6:00PM) for assistance.		

Physical Appearance check of the meter after each cleaning or disinfection

Check item	Accept Result
Is the display clear to read? Is the transparency clear?	Yes
Are the strip slot & other parts free of corrosion?	Yes
Action: If any of the results are "No" the user should call the Customer Care Service toll-free at 866-922-6033 (Eastern Standard Time, Mon-Fri 8:00AM~6:00PM) for assistance.	

Meter Life when Cleaned and Disinfected

The meter has been tested through 20,000 validated cycles (10,000 cycles of cleaning and 10,000 cycles of disinfection). If the meter is used for 9 cycles of cleaning and 9 cycles of disinfection per day, it will last in professional use for 3 years.

Cleaning And Disinfection Frequency

At least **9** cycles of cleaning per day and **1** cycle of disinfection per week with allow the user to use the device for **4** years. The meter can sustain 20,000 cycles of cleaning and disinfection and the lancing device can sustain 14,600 cycles of cleaning and disinfection.

Cleaning Frequency: 9 cycles/day X 365 days/year X **4** year product life = 13,140 cycles of cleaning

Disinfection Frequency: 1 cycle/week X 52 weeks/year X **4** year product life = 208 cycles of disinfections

< 20,000 validated cycles of cleaning and disinfection for the meter

< 14,600 validated cycles of cleaning and disinfection for the lancing device

4 year product life is for properly cleaning and disinfection. After 4 years, the meter must be replaced with a new 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 power button to see the complete display. All the indicators should be clear and look exactly like the picture to the left. If not, please contact your local dealer.

Screen Messages And Troubleshooting

Never make treatment decisions based on an error message. If you have any concerns, call the Customer Care Service toll-free at 866-922-6033 (Eastern Standard Time, Mon-Fri 8:00AM~6:00PM).

Message

What it means?

What to do?

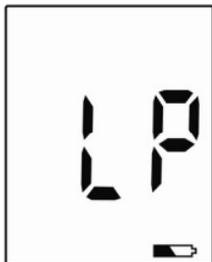


Humidified / Used strips

The meter has detected a problem with the test strip.

Repeat the test with a new strip.

Refer to pages 24-26 for information on sample application.



Low power

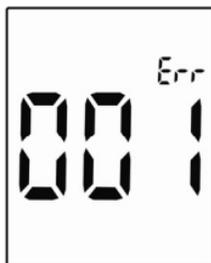
The meter batteries do not have enough power to perform a test.

Replace the new batteries.

Message

What it means?

What to do?



System error

There may be a problem with the meter.

Repeat the test with a new test strip.

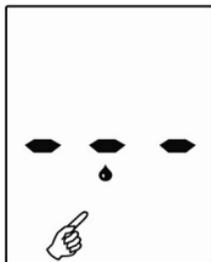
Refer to pages 24-26. If this error message appears again, please contact your local dealer.



Memory Error

Replace the batteries first.

If **ERROR 005** appears again, please contact your local dealer.



No result in memory.

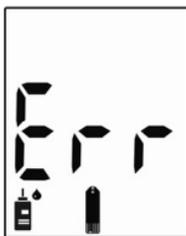
The test proceeds incompletely.
The meter was unable to recall this result.

You can still perform a blood glucose test and get an accurate test result.

Message

What it means?

What to do?

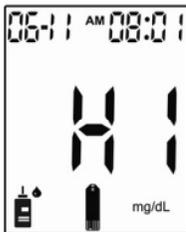
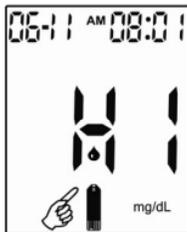


Volume detector error

The volume of blood or control solution is NOT enough.

Replace the batteries first.

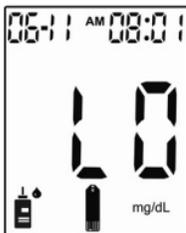
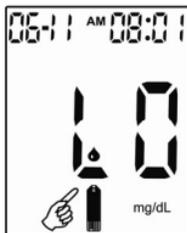
If **Err** appears again, please contact your local dealer.



Test result is higher than 600 mg/dL (33.3 mmol/L).

Re-check your glucose level.

If the result is HI again, obtain and follow instructions from your healthcare professional without delay.



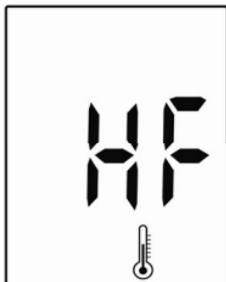
The test result is lower than 20 mg/dL (1.1 mmol/L).

This may require immediate treatment according to your healthcare professional's recommendations. Although this message could be due to a test error, it is safer to treat first and then do another test.

Message

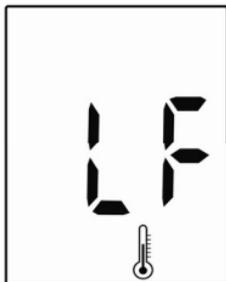
What it means?

What to do?



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.

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.

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[®] EMMU Blood Glucose Meter	
Range	20~600 mg/dL	
Response time	5 seconds	
Memory sets	480 test results	
Operating condition	Temp.	50°F ~104°F (10°C ~40°C)
	Relative Humidity	R.H. ≤ 90%
Storage and transportation condition	Temp.	-4F - 122°F (-20°C - 50°C)
	Relative Humidity	R.H. ≤ 90%
Blood sample	0.6 µL	
	Fresh blood from fingertip	
Hematocrit (Hct)	20~60%	
Power	Alkaline Battery (2 ct.)	
Battery life	Over 2000 tests	
Display dimension	1.4 x 1.7 inches (35.0 x 43.0 mm)	
Device dimension H x W x D	3.7 x 2.0 x 0.8 inches (94 x 50 x 19.5 mm)	
Weight	1.68 oz. without batteries (47.7±1 gram)	
Principles	Electrochemical biosensor technology	
Software via USB	GlucoManager [™]	

Limitations

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 temperatures between 50°F and 104°F (10°C and 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 hematocrit between 20% and 60% will not affect the results. Hematocrit below 20% may cause higher results. Hematocrit above 60% may cause lower results.
6. Altitude up to 10,000 feet above sea level has no effect on readings.

Healthcare Professionals – Please note these additional Limitations

1. If the patient has the following conditions, the result may fail:
 - ◆ Severe dehydration
 - ◆ Severe hypotension (low blood pressure)
 - ◆ Shock
 - ◆ A state of hyperglycemic-hyperosmolar state (with or without ketosis)
2. 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[®] EMMU** Blood Glucose Meter.
3. Critically ill patients should not be tested with home-use blood glucose meters.
4. DO NOT use during xylose absorption testing. Xylose in the blood will interfere Self-Monitoring Blood Glucose System.

5. Interfering Substances depend on the concentration. The below substances up to the test concentration will not affect the test results.

Exogenous Interference data				
Exogenous Substances	highest Conc. tested	interference or no	Bias @ blood glucose Conc.	Note
Acetaminophen	8 mg/dL	Yes	14.2%@80 mg/dL 14.9%@120 mg/dL	The highest no interference concentration is 7 mg/dL
Ascorbic Acid	4 mg/dL	No	NA	
Dopamine	5.2 mg/dL	Yes	31.0%@80 mg/dL 18.2%@120 mg/dL	The highest no interference concentration is 2.6 mg/dL
Gentisic Acid	6 mg/dL	No	NA	
Ibuprofen	50 mg/dL	No	NA	
L-Dopa	4 mg/dL	Yes	16.3%@80 mg/dL 11.4%@120 mg/dL	The highest no interference concentration is 2 mg/dL
Methyldopa	2 mg/dL	No	NA	
Sodium Salicylate	50 mg/dL	No	NA	
Tetracycline	1.5 mg/dL	No	NA	
Tolbutamide	100 mg/dL	No	NA	
Galactose	20 mg/dL	No	NA	
Maltose	20 mg/dL	No	NA	
Xylose	8 mg/dL	Yes	10.1%@80 mg/dL	The highest no interference concentration is 6 mg/dL
Fructose	30 mg/dL	No	NA	
Manose	10 mg/dL	No	NA	
Sucrose	50 mg/dL	No	NA	

Endogenous Interference data				
Endogenous Substances	highest Conc. tested	interference or no	Bias @ blood glucose Conc.	Note
Xylitol	200 mg/dL	No	NA	
Glipizide	8 mg/dL	No	NA	
Bilirubin- unconjugated	25 mg/dL	No	NA	
Cholesterol	500 mg/dL	No	NA	
Creatinine	30 mg/dL	No	NA	
Triglycerides	1000 mg/dL	No	NA	
Uric Acid	15.9 mg/dL	Yes	14.3% @ 80 mg/dL 17.5% @ 120 mg/dL	The highest no interference concentration is 11.9 mg/dL

Device Information

FortisCare[®] EMMU SMBG System

FortisCare[®] EMMU Blood Glucose Meter

FortisCare[®] High Control Solution

FortisCare[®] Blood Glucose Test Strip

FortisCare[®] Normal Control Solution

FortisCare[®] Low Control Solution

Manufacturer: EPS BIO TECHNOLOGY CORP.

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

Oak Tree Health warrants

This means during the warranty period if your **FortisCare**[®] **EMMU** Self-Monitoring Blood Glucose System does not work for any reason (other than obvious abuse), Oak Tree Health will replace it with a new system or an equivalent product free of charge.

Safety Lancets

Manufacturer:

GMMC

768-1, Wonsi-Dong, Danwon-Ku, Ansan-Si, Gyeonggi-Do, Korea

P/N: 718063724 Rev.A01