Glucertain™

Blood Glucose Monitoring System

User's Manual

Glucertain™

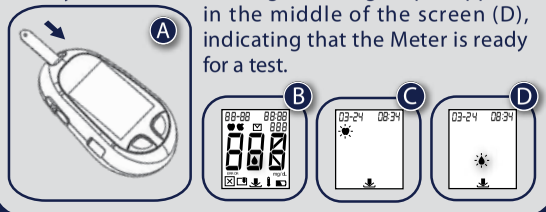
Blood Glucose Monitoring System

Quick Start Guide

No Code | Glucose Dehydrogenase Technology | 5 Sec. Result | Mini 0.6ul Sample

Glucertain™ Blood Glucose System Quick Start Guide

1 **Insert Glucertain Test Strip into Meter** (see picture A). The Meter turns on automatically, and the backlight briefly illuminates all the display elements (B). Then blank screen with date & time and flashing apple appears, indicating the "before meal" setting (C). Use the left button to adjust to "after meal" or CS (control solution) if necessary, and confirm the setting by pressing the right button. Once you confirm the setting, a flashing droplet appears in the middle of the screen (D), indicating that the Meter is ready for a test.



2 **Obtain blood sample and apply to Glucertain Test Strip.** Use Glucertain Safety Lancet (A) to obtain a small droplet of blood (only 0.6 microliter needed). Touch the tip of the Test Strip (holding the Meter) to the droplet (B). Capillary action will pull the sample into the Strip (C), and when enough blood is detected the Meter beeps and the test begins (D).

3 **Read the result.** The Meter counts down from 5 seconds and displays the result. If error code or inappropriate result is obtained, consult the User's Manual.

4 **Discard the Test Strip and the Lancet into an appropriate sharps or biohazard container.** Hold the Meter over the container and slide the ejection button to eject the Strip. The Meter shuts off automatically once the Strip is removed.

For more detailed information, consult the complete Glucertain User's Guide.

Glucertain™

Blood Glucose Monitoring System

5 Sec. Result | Mini 0.6ul Sample | Glucose Dehydrogenase Technology | No Code

User's Manual

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

1.

Introduction

Welcome to the **Glucertain™ Blood Glucose 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. Think about these important features:

No Code: Time-saving & much easier than code systems

Glucose Dehydrogenase Technology: Eliminates incorrect readings on patients receiving Oxygen therapy

Quick: Test Results in 5 seconds

Mini Sample Size: 0.6 uL

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 **Glucertain Blood Glucose System**.

2.

Intended Use

The **Glucertain Blood Glucose 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 **Glucertain 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 **Glucertain 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 **Glucertain 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 **Glucertain Blood Glucose System** may be used for testing multiple patients when Standard Precautions and the disinfection procedures included in this manual are followed.

3.

Included with each Glucertain Blood Glucose Meter:

- **Glucertain Control Solution (High)**
- **2 AAA batteries**
- **User's Manual**

Available separately:

- **Glucertain Blood Glucose Test Strips**
- **Glucertain Safety Lancets**
- **Glucertain Control Solution (Low)**

For further information, please see:

"Biosafety in Microbiological and Biomedical Laboatories (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

4.

Important Information about your new Glucertain Meter

- The **Glucertain 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.
- The **Glucertain Blood Glucose Meter** can only be used with **Glucertain Blood Glucose Test Strips**. Other test strips will give inaccurate results. **Glucertain 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.
- Critically ill patients should not be tested with blood glucose meters. See page 7 for more explanation.
- 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.

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 of 10,000 or more feet may have an 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 **Glucertain Blood Glucose System** as simple as possible to help you use it regularly.

Do you need help?

For technical assistance, call toll-free 866-203-2761 (Eastern Time, Mon-Fri 8:00AM-5:00PM).

For customer service, call CellEra, LLC toll-free 800-892-2391, or your medical supply distributor.

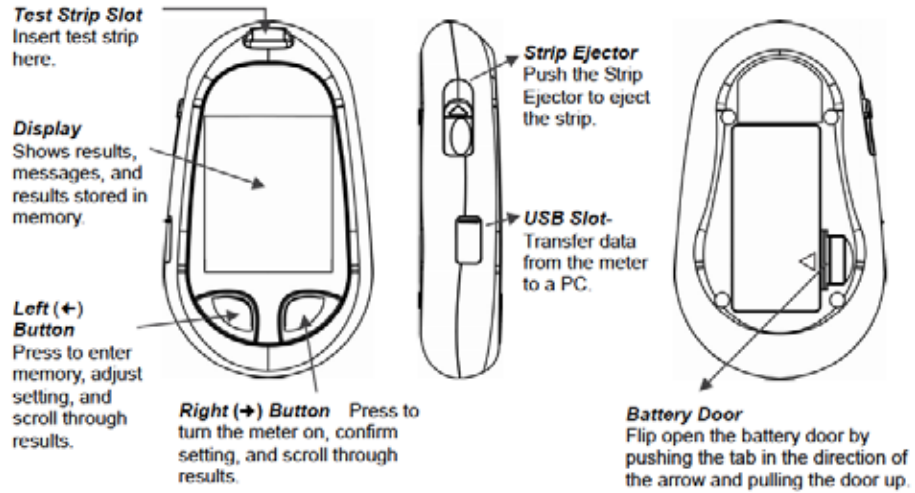
Health-Related Information

- 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 Technical Service toll-free at 866-203-2761 (Eastern Time, Mon-Fri 8:00AM-5:00PM).
- 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.

Table of Contents

Chapter 1: Understanding the Glucertain Blood Glucose System

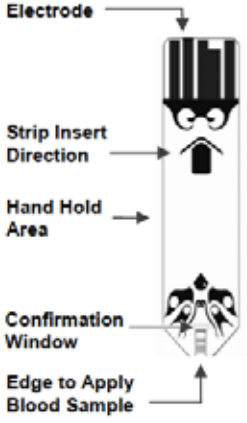


Glucertain Blood Glucose Meter Display

88-88	Date (on left)		Before meal
88:88	Time (on right)		After meal
88.8	Result		Insert strip
888	Record/Average display		Temperature
CS	Control solution (appears as result)		Error
A	AM (appears as result)		Upload Data
P	PM (appears as result)	M	Memory
	Battery		Apply blood to test strip

Glucertain Blood Glucose Test Strips

Glucertain Test Strip



Glucertain Test Strip Vial

Glucertain Safety Lancets

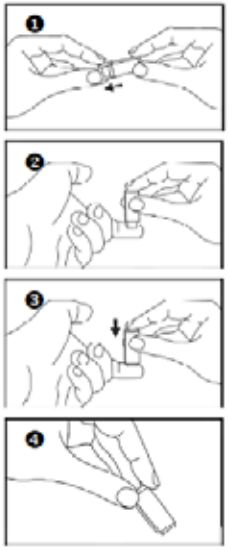
Cat #	Size	Color-code
30226	26 gauge	Pink
30228	28 gauge	Purple

Note:
28 gauge is the most comfortable. 26 gauge works better on thicker skin.

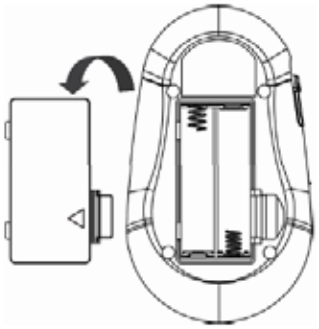
Instructions for use

Clean test site prior to use.

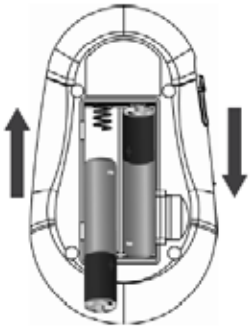
1. Pull off protective cap. Sterility of lancet tip is maintained until protective cap is removed.
2. Position Glucertain Lancet onto test site.
3. Push firmly against test site. Sharp Lancet tip is actuated and punctures skin.
4. After use dispose into appropriate "sharps" container.



Installing Batteries



1. Open the battery door on the back of the meter by pushing the tab to the left and pulling the door up.



2. Insert two batteries. The meter will beep to confirm the batteries are inserted correctly.

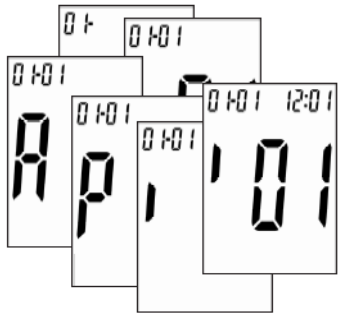
3. Put the battery door back in place and snap it closed. The meter turns on automatically.

Setting The Time and Date - First Time Use

Set the current time and date in your meter.

1. Press → (right button) to turn the meter on.

2. The large display shows the last 2-digits of the year that flashes at the top of the display as well. Press ← (left button) to adjust the year and press → (right button) to confirm the setting.



3. Repeat step 2 to set the month, date and time. The flashing field is the one you are currently setting. (A=AM, P=PM)

Using Glucertain Blood Glucose Test Strips

- Use only with Glucertain Blood Glucose Meters.
- Glucertain Blood Glucose Test System is a "no code" system and does not require test strip calibration.
- Glucertain Blood Glucose Test 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 test strips (See Chapter 2 "Control Solution Testing.")
- Keep the test strips in their original vial.
- 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.
- When you open a new test strip vial, check the expiration date. The test strips are good for three 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°F - 85°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 Glucertain 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 Glucertain Blood Glucose Meter.
- When you open a new vial of Glucertain test strips.
- If you think the meter or test strips may be working incorrectly.
- If the meter is dropped.
- If test results are lower or higher than expected, you have repeated the test with similar results.
- When you practice the test procedure.

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

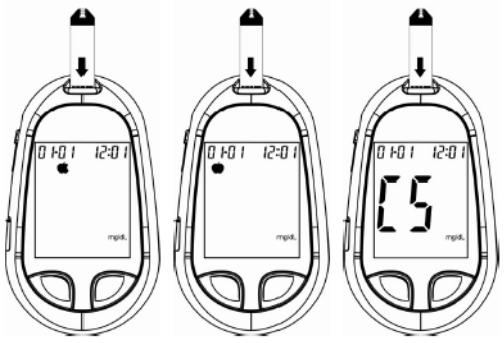
About Glucertain Control Solutions

- Use only with **Glucertain Blood Glucose 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 control solution that is past the expiration date.
- The control solution can stain clothing. If you spill, wash your clothes promptly with soap and water.
- Close the control solution 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°F - 85°F(2°C - 30°C). Do not freeze.
- Glucertain Control Solutions are available in Level 1 (Low) and Level 3 (High). To purchase, contact your medical supply distributor or CellEra, LLC.

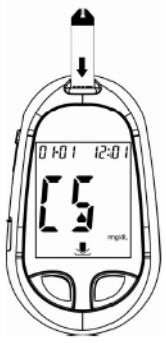
Running a Control Solution Test

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

1. Put a test trip into the meter per the direction of the arrow on the test strip. The meter turns on automatically.



2. Press ← (left button) to cycle through Before meal, After Meal & stop at Control Solution Mode (CS), then press → (right button) to confirm the setting.



3. The icons and appear.

4. Place the meter on a flat, level surface. Shake the control solution bottle well or roll between your palms.

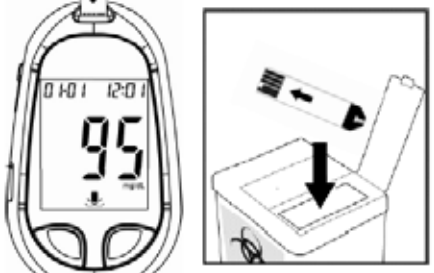
5. Remove the control solution bottle cap and wipe the tip of the bottle with a tissue.

6. Squeeze the bottle until a tiny drop forms at the tip of the bottle.

7. Touch the drop at the tip of the test strip (see above for proper technique).

8. The meter starts to count down from 5 seconds and then shows the test result.

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



10. Push the Strip Ejector to eject the test strip.

11. Dispose properly.

Understanding Control Solution Test Results

The label on your test strip vial shows the acceptable ranges for the Control Solutions. The result you get should be within this range. Make sure you compare the result to the correct level (High or Low) of control solution.

When the control result is within 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 that begin in Chapter 5, page 28.

21.

Chapter 3: Testing For Blood Glucose

Using the Glucertain Lancets

- Only single-use safety lancets should be used with this system.
- Instructions for Use for Glucertain Clinical Safety Lancets are printed on the side of the Lancet box and on page 14 of this manual.

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.

22.

23.

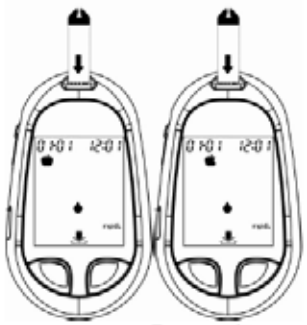
Obtain a Blood Sample from the Fingertip to Run a Blood Glucose Test

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. Put a test strip into the meter in the direction of the arrow on the strip. The meter turns on automatically & backlight turns on.

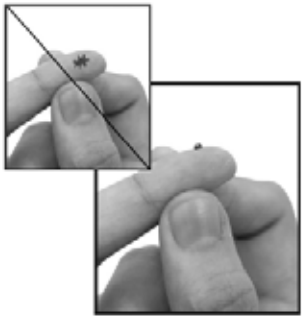
3. Press ← (left button) to set Before Meal or After Meal Mode, then press → (right button) to confirm the setting.

24.



4. The icons and appear.
When the blood drop flashes on the display, you are ready to use the Glucertain Safety Lancet to obtain a blood sample.

5. 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.
6. Pull off the protective cap.
7. Place Glucertain Lancet onto test site. Push against site to actuate and puncture skin.



8. Gently squeeze and/or massage your fingertip until a round drop of blood on your fingertip.
9. Wipe away the first drop with a tissue and use the second drop.

10. Touch the drop to the tip of the transparent window of the test strip.
Do not put blood on top of the strip.
When there is enough blood in the strip's confirmation window, the meter will begin to take a reading.

11. The meter counts down from 5 seconds and then displays the test result.

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

Expected Values

The Glucertain 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*.

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 relative humidity (above 90%) may cause inaccurate results.**
2. **Hematocrit below 20% or above 60% may not allow accurate results.**

Chapter 4: Meter Memory & Data Transmission

Memory, Storing Test Results

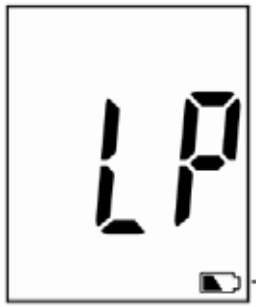
Your meter stores a maximum of 480 test results with the time and date of the test. You can review them at any time. When the memory is full, the oldest result is dropped as the newest is added, so it is very important to have the correct time and date set in the meter.

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.

The average data function should not be used when meters are moved between patients.

Chapter 5: Maintenance and Troubleshooting

When to Install Batteries



Low battery symbol

The meter uses two alkaline AAA batteries. Batteries will normally last for more than 2000 tests. Other types of AAA batteries are acceptable, but in-use life may vary. 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 not turn on the first time batteries are installed. Press and hold "➔" Right Button or insert the test strip to turn your meter on.
The meter turns off automatically. Or you can press and hold "➔" Right Button to turn your meter off.

Notes re Battery Replacement:
1. **The meter won't delete earlier records when you replace the batteries.**
2. **You should reset the time and date after you replace the batteries.**
3. **AAA batteries are required. Alkaline batteries are recommended.**
4. **Remove batteries when you will not be using the meter for one month or more.**

Cleaning and Disinfecting the Glucertain Blood Glucose Meter

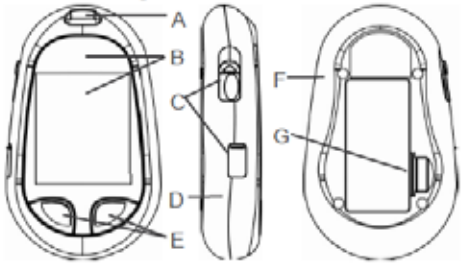
Choosing the disinfectant

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	High
C	Side Button	High
D	Side Case	High
E	Front Buttons	High
F	Back Case	Medium
G	Battery Cover	Medium

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

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.

Glucertain™ Blood Glucose Meter Cleaning & Disinfection Procedure

Choosing the Disinfectant Wipes

According to Guideline for Disinfection and Sterilization in Healthcare Facilities in 2008, we recommend that you 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 Instructions

Keep the meter free of dirt, dust, bloodstains, and water stains. The meter must be properly cleaned and disinfected after every use.
Using two wipes, follow the cleaning instruction first & the disinfection instruction second.

1. Cleaning: Do the cleaning step first to remove heavy soil and touch contaminants left on the surface of the meter. Open, unfold and use first disinfectant wipe. All blood and other body fluids must be thoroughly cleaned from surfaces and objects using the first wipe.

2. Disinfection: After cleaning, unfold a second wipe and thoroughly wet all the surfaces of the meter, including the ports. Treated area must remain visibly wet for a full 2 minutes to effectively kill blood-borne pathogens (such as viral hepatitis) and to prevent cross-contamination. Use additional wipe(s) as needed to keep the meter continuously wet for 2 minutes. Air dry the meter for at least 30 seconds.

Do:

– Make sure the meter is turned off during cleaning and disinfection.

– Keep the test strip vial tightly closed when performing the cleaning and disinfection procedures because the fumes from the disinfectant may affect the performance of the strip.

– After cleaning and disinfection, please perform the physical appearance and performance check of devices.

– Please wear gloves when doing the following physical and performance check steps.

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.

Physical Appearance check of the meter after each cleaning or disinfection:

Check item	Accept Result
Is the display transparency clear?	Yes
Is there NO erosion on the strip slot or other parts?	Yes
Action: If any of the results is "No" the user should call the Technical Support line toll-free at 866-994-3345 (Eastern Time, Mon-Fri 9:00AM-6:00PM).	

Performance check of the meter when/if there is a problem after cleaning:

Steps	Check item	Accept Result
	After each cleaning & disinfection	
1. Insert test strip	Does meter power on?	Yes
2. Apply Control solution	Do you get a reading? Is the reading within control range?	Yes Yes
3. Remove test strip	Does meter power off?	Yes
4. Press/hold right button for 3 sec.	Does meter power on? Does meter beep?	Yes Yes
5. Press and release left button.	Do memory readings appear? Can they be read clearly?	Yes Yes

Action: If any of the results is "No", please call the Technical Support toll-free at 866-994-3345 (EasternTime, Mon-Fri 9:00AM~6:00PM) for replacement 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 "➔" Right Button to see the complete display. All the indicators should be clear and look exactly like the picture to the left. If not, please call Technical Service toll-free at 866-203-2761 (Eastern Time, Mon-Fri 8:00AM-5:00PM).

Troubleshooting the Glucertain Blood Glucose System

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.
✓ Is the cap on the test strip vial kept tight to prevent moisture or humidity from affecting strips?	If the cap was not tight, or the vial was left uncapped, open a new vial of test strips. Do not reuse the strips from the affected vial.
✓ Was the meter functioning well?	If not. 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 Glucertain Blood Glucose system.
✓ Were test strips and control solutions stored in cool, dry places?	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 inaccurate results, please contact technical service toll-free at 866-203-2761 or CellEra, LLC at 800-892-2391.

Screen Messages and Troubleshooting

Never make treatment decisions based on an error message.

Humidified/Used strips
Action: Replace with a new strip.

Humidified/Used strips
Action: Replace with a new strip.

System fault
Action: Replace the batteries first. If **ERROR 001** appears again, please call the Technical Service.

Note: Technical Service toll-free at 866-203-2761 (Eastern Time, Mon-Fri 8:00AM-5:00PM).

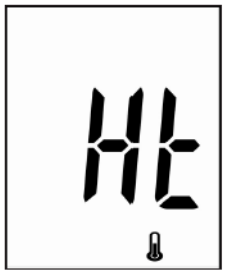
System fault
Action: Replace the batteries first. If the above or Err appears, please call the Technical Service.

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, please call the Technical Service.

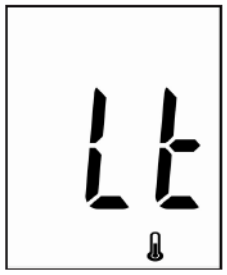
The test result is lower than 20 mg/dL.
Action: Test again. If the result is still the same, try a control solution test and if the control solution test falls within the correct range, please call the Technical Service.

Note: Technical Service toll-free at 866-203-2761 (Eastern Time, Mon-Fri 8:00AM-5:00PM).

Err message. Not enough sample was drawn into the test strip for measurement.
Action: Discard the test strip and repeat the test..



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		Glucertain Blood Glucose Meter
Chemistry system		Glucose Dehydrogenase
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.	35°F - 85°F (2°C -30°C)
	Relative Humidity	40-85 % RH
Blood sample		0.6 µL Fresh blood from fingertip, palm, or forearm
Hematocrit (Hct)		20~60%
Power		2 Alkaline 1.5V (AAA)
Battery life		Over 2000 tests
Display dimension		35.0 × 43.0 mm
Device dimension H × W × D		98 x 57 x 22 mm
Weight		43.2 grams w/o battery
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 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: Hematocrit values 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 of 10,000 feet or more may have an effect on readings.

Healthcare Professionals – Please note these additional Limitations

7. If the patient has the following conditions, the result may be inaccurate:
   - Severe dehydration
   - Severe hypotension (low blood pressure)
   - Shock
   - A state of hyperglycemic-hyperosmolar state (with or without ketosis)
8. 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 Glucertain Glucose Meter.
9. Critically ill patients should not be tested with Glucertain Blood Glucose Meters.

10. 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

A more extensive list of drugs and other substances that do not interfere with Glucertain test results may be found at www.celleralIc.com.

Warranty

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

Please read this Glucertain User's Manual before operation. If you have any questions and/or need assistance, please contact us as follows:

Technical Service, within the USA, call toll-free: 866-203-2761 (Eastern Time, Mon-Fri 8:00AM -- 5:00 PM)

Customer Service, within the USA, call toll-free: 800-892-2391 (Eastern Time, Mon-Fri 8:00 AM – 4:00 PM)

Device Information

Glucertain™ Blood Glucose System
Glucertain™ Blood Glucose Test Strips
Glucertain™ Blood Glucose Meter
Glucertain™ Safety Lancets
Glucertain™ Control Solution

Reference:

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

Manufactured for:

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