

PROCEDURE MANUAL



Lab Name:

Procedure #:

Procedure: CLIA Complexity: WAIVED

Prepared By	Date Adopted	Supersedes Procedure #

Review Date	Revision Date	Signature

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This Procedural Bulletin is intended to provide a ready outline reference for performance of the assay. It is the obligation of every manufacturer of medical devices labeled FOR *IN VITRO* DIAGNOSTIC USE to provide a complete package insert in accordance with FDA labeling regulation (21 CFR 809.10). Prepared in accordance with the guidelines recommended by the Clinical and Laboratory Standards Institute, Wayne, PA 19087; CLSI Document GP2-A2.

Clarity Diagnostics provides CLSI procedures for your use. The procedures are required to include the same information as listed in the package insert. Any modifications to this document are the sole responsibility of the Laboratory.

CLIA Complexity: WAIVED

Intended Use:

Clarity BG1000 Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood drawn from fingertip, palm, and forearm of diabetic patients by healthcare professionals as an aid in the management of diabetes, and may be used for testing multiple patients in clinical setting.

It is intended for use outside the body (in-vitro diagnostic use) and not for the diagnosis of or screening for diabetes or for neonatal use. The alternative site testing (palm or forearm) should be done only during steady state times (when glucose is not changing rapidly). Only auto-disabling, single use lancing devices (safety lancet) should be used with this system.

Application:

Clarity BG1000 Blood Glucose Test Strips are for in-vitro diagnostic use.

The Clarity BG1000 Blood Glucose Meter is not a substitute for the physician or healthcare professional. Use the Clarity BG1000 Blood Glucose Meter in conjunction with patients healthcare program.

Test Principle:

Glucose in the blood sample reacts with glucose oxidase on the test strip and a harmless electrical current is produced. The strength of these currents change with the amount of glucose in the blood sample and the Clarity BG1000 Blood Glucose Meter automatically interprets this reaction. Glucose measurements are reported as plasma equivalents. This system uses a plasma equivalent method. Results that use a plasma equivalent method are approximately 11% higher than those obtained with whole-blood equivalent test strips.

Special Features:

- Accurate result in 5 seconds using only 0.5µl blood sample.
- The Clarity BG1000 Blood Glucose Meter identifies the test strip code automatically.
- Stores up to 300 test results.
- Blood glucose measurement units are pre-set in mg/dl.

Usage and Storage:

- Before using your monitoring system, please place it in the environment of the system's normal operating temperature range of 50-104°F for about twenty (20) minutes.
- Do not allow dirt or dust in the test strip port in order to avoid affecting the monitoring system's accuracy .
- Do not attempt to repair or alter your monitoring system.
- Handle your monitoring system with care.
- Avoid leaving the meter in extremely hot or cold places, such as near a heat source or in an extremely hot or cold car.
- Do not store or use the meter or test strips at high humidity levels, such as in the bathroom or kitchen .
- Always close the cap of the test strip bottle immediately after removing a test strip. Make sure the cap is tightly closed.
- Do not use a corrosive product (e.g. Benzene, Acetone) to clean your monitoring system)

Important Information:

- Before using the Clarity BG1000 Blood Glucose Monitoring System, please read this manual carefully.
- The Clarity BG1000 Blood Glucose Monitoring System is for testing outside of the body (in-vitro diagnostic use).
- This product is not for neonatal use or severely dehydrated individuals or patients.
- Use this system only for blood glucose test.
- Make sure to use your test strip immediately after retrieving it from the vial, be sure to keep the test strip vial closed tightly at all times.
- For the most accurate results, make sure your hands are clean and dry before removing the test strips from the vial. Do not touch test strip slit.
- Do not use test strips that have expired, using expired test strips may cause inaccurate test results.
- Do not reuse test strips. This test strip is for single use only.
- Before the test you must make sure that the code number displayed on the meter matches the code number on the test strip vial.
- Be sure to check the glucose measurement unit on the meter before the test.
 - This meter is preset to mg/dl.
 - mg/dl is the unit of measurement used in the US.
- Make sure the test strip vial is closed tightly and stored at 39.2-86°F. Do not freeze.
- Keep test strips away from direct sunlight and heat.
- The meter and test strips should be handled at the same temperature.
- For accurate test results, keep the Clarity BG1000 Blood Glucose Monitoring System operating temperature at a range between 50-104°F for more than twenty (20) minutes before testing.
- You may use this system at altitude up to 10,000 feet.
- Keep your Clarity BG1000 Blood Glucose Meter, lancing device, and control solutions out of reach of children.
- Clean and disinfect your Clarity BG1000 Blood Glucose Meter before testing each patient.
- Dispose of used test strips and lancing device according to local regulations. Inaccurate results may occur for individuals or patient in shock.
- Inaccurate results may occur for individuals experiencing a hyperglycemic- hypervolemic state with or without ketosis . Critically ill patients should not be tested with this blood glucose meter.
- Interferences: Acetaminophen, salicylates, uric acid, ascorbic acid (vitamin C) and other interferent substances in normal blood or normal therapeutic concentrations do not significantly affect results, however abnormally high concentrations in blood may cause inaccurate results.
- Patients undergoing oxygen therapy may yield false low results.
- Lipemic samples (triglycerides) in excess of 1,500 mg/dl may produce elevated results.
- Hematocrit is the percentage of red blood cells in the blood. HGT levels of 30-55% do not affect glucose measurements with this meter.
- This test strip is not for use with arterial, venous, neonatal, serum or plasma samples.
- Testing outside of HGT level range of (30-55%) and recommended storage conditions may cause inaccurate results.
- Testing under out of the specification range may cause inaccurate results.

CAUTION: Use only Clarity BG1000 Test Strips with your Clarity BG1000 Blood Glucose Meter.

Healthcare Professional Information:

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

- When using the Clarity BG1000 Blood Glucose Monitoring System always follow the recognized procedures for handling objects that are potentially contaminated with human material. Practice the health and safety policy of your laboratory or institution.
- A drop of blood is required to perform a blood glucose test. Only fresh capillary blood can be used.

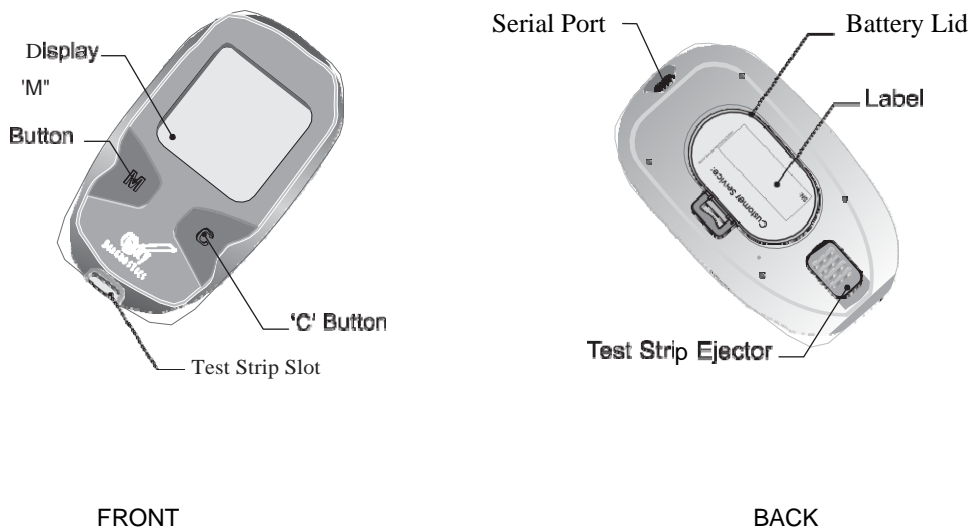
The Complete Medisign BG1000 Blood Glucose Monitoring System:

The Clarity BG1000 Blood Glucose Monitoring System includes the Clarity BG1000 Meter, Carrying Bag, User Manual, Warranty Card and (2) 3.0 Volt CR2032 Lithium Batteries.

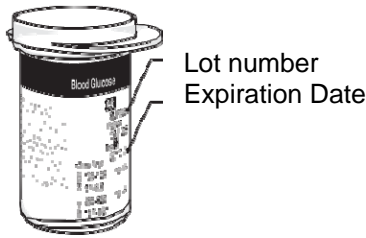
Clarity BG1000 Test Strips, Clarity BG1000 Glucose Control Solutions are required but not included and must be purchased separately.

Auto-disabling single-use lancing device, Clarity BG1000 Test Strips and Clarity BG1000 Glucose Control Solutions (Level 2, Level3), Clarity BG1000 Diabetes Management Software and Clarity BG1000 Data Transfer Cable can be purchased by contacting your distributor, or for additional information you can contact Clarity Diagnostics Customer Service at 1-877-722-6339.

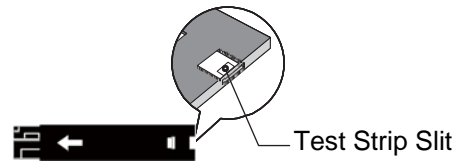
Clarity BG1000 Blood Glucose Meter:



Clarity BG1000 Blood Glucose Test Strip:



Test Strip Vial



Clarity BG1000 Blood Glucose Test Strip

- Use Clarity BG1000 Blood Glucose Test Strips with the Clarity BG1000 Blood Glucose Meter.
- Check the expiration date of your test strips before using.
- Write the opening date of the new test strip vial in order to avoid using any expired products.

Explanation of Display:

1		Low Battery Warning
2	MEM	Stored Test Results
3	888	Test Results
4	mg/dL	Unit of Measure
5		Temperature Error
6		Beeping Sound Muted
7		Pre Meal/Post Meal Tags
8		Ready to Test
9		Control Solution
10	AVG	Average Result
11	88.88	Month/Date
12	88:88	Time

Testing Your Blood Glucose:

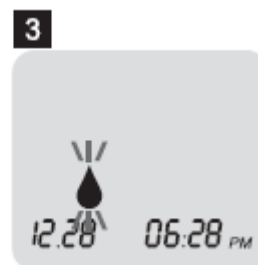
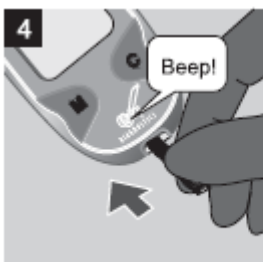
Disinfect Before Testing:



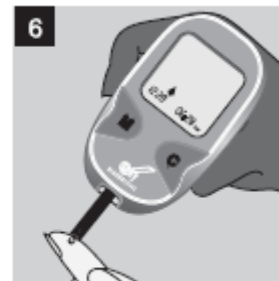
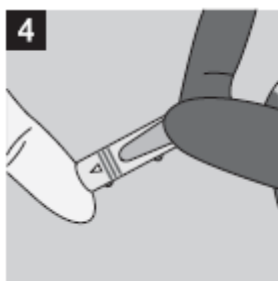
- Before testing, let patients wash hands with soap and water and dry thoroughly.
- Use an alcohol prep pad to wipe the area before testing.

- Wait until the alcohol dries completely.

Performing a Blood Glucose Test:



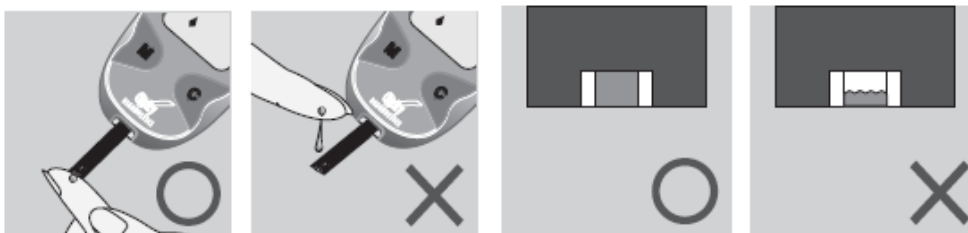
1. Insert a test strip to turn on the meter. Make sure it is inserted completely without bending the test strip.
2. The meter identifies the code number automatically. Compare the code number displayed on the LCD with the code number shown on the test strip vial. If they do not match try again with an another test strip. If the problem persists contact Clarity Diagnostics Customer Support at 1-877-722-6339.
3. When the blood symbol appears, you can proceed with the test.



4. Choose a sample site on the outer edge of one finger, but try to avoid the index finger or thumb. Place the sampling device's platform against the finger and take the sample. Always choose a different finger each time to avoid soreness.
5. Gently squeeze the patients finger to assist the flow of blood. Do not squeeze excessively on the puncture site.
6. Hold the tip of the test strip to the drop of blood, the test strip will automatically draw the blood into the test strip. When the test strip has enough blood the meter will beep.

NOTICE:

When the blood sample is not sufficient, the display screen will show the message of 'Er4'. (Please refer to error message in this manual.)



CAUTION:

Do not drop the blood directly on the end of the test strip.
 The sample channel at the end of the test strip should show full. When you hear a beeping sound, you have enough blood in the test strip.
 Inaccurate results may occur for individuals or patient in shock.
 Inaccurate results may occur for individuals experiencing a hyperglycemic-hypersmolar state, with or without ketosis. Critically ill patients should not be tested with a blood glucose meter.

NOTICE:

If the test result is abnormal, please retest with a new test strip. If the test result also has a problem, please refer to the Troubleshooting section in this manual.



7. The test result will appear after the meter counts down from five (5) seconds. Do not shake the meter while the meter is counting down.

8. After five seconds you will hear a second beep and the test result will be displayed. You can remove the test strip by pushing the test strip ejector on the back of the meter. The meter will automatically power off.

CAUTION:

- Do not leave the auto-disabling, single use lancing devices after use, be sure to dispose of properly.
- Only an auto-disabling, single use lancing devices should be used.
- Always dispose of the used auto-disabling, single use lancing devices in a biohazard container.
- Keep your Glucose Meter, test strips, control solution and auto-disabling, single use lancing devices out of reach of pet or children at all times.
- Do not reuse auto-disabling, single use lancing devices. Those are for single use only.
- The user needs to adhere to the Standard Precautions when handling or using this device.
- All parts of the glucose monitoring system should be considered potentially infectious and are capable of transmitting blood-borne pathogens between patients and healthcare professionals.
- For more information, refer to 'Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings 2007'.
<http://www.cdc.gov/hicpac/2007ip/2007isolationprecautions.html>
- The meter should be disinfected after use on each patient. This Blood Glucose Monitoring System may only be used for testing multiple patients when Standard Precautions and the manufacturer's disinfection procedures are followed.
- A new pair of clean gloves should be worn by the user before testing each patient.
- Refer to the following practice guidelines:
 - Bio safety in Microbiological and Biomedical Laboratories (BMBL) found at <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.

Flagging Test Results:



If you want to flag pre-meal, post-meal or control solution readings press the 'M' Button after your test result is displayed. The icon for post-meal (🍴) will be displayed on your screen. Press the 'C' Button to toggle between pre-meal (🍴), post-meal (🍴) and control solution (🧪). After you have identified the activity you would like to flag simply remove the test strip. (see explanation of display on page 13)

Notice:

Control Solution Test results are not included in the 14-day average.

Alternate Site Testing:

Contact a healthcare professional before using any alternative sites to test patients blood glucose.

- Alternative site results may be different from fingertip results when glucose levels are changing rapidly (e.g., after a meal, after taking insulin, or during or after exercise).
- Use alternative site testing only two hours or more after taking insulin, two hours or more after a meal, two hours or more after exercise.
- Do not use alternative site testing if patient glucose level is not as stable as usual, or if you think the patient may have hypoglycemia (low blood glucose) hyperglycemia (high blood glucose), or you think the patients blood glucose may be rising or falling rapidly.
- Do not use alternative site testing if the patients alternative site testing results do not match the way they feel.
- AST measurements should never be used to calibrate continuous glucose monitors (CGM).
- AST measurements should never be used in insulin dosing calculations.

Do not rely on test results at an alternative sampling site, but use samples taken from the fingertip, if any of the following applies:

- You think the patients blood sugar is low.
- You are not aware of symptoms when the patient became hypoglycemic.
- The test results do not agree with the way they feel.
- After a meal.
- After exercise.
- During illness.
- During times of stress.

CAUTION:

Never change any treatment without first consulting the physician or a healthcare professional.

Never ignore symptoms of high or low blood glucose.

If the patients blood glucose does not match how they feel, perform a fingertip test to confirm the result.

If the fingertip test result still does not match how they feel, call their healthcare professional.

Lancing and Sampling from an Alternate Site:

Sampling from the palm or forearm allows you to use their fingertips less often. You may find that obtaining a blood sample from an alternative site is less painful than using a fingertip. Getting a blood sample from the forearm or palm is different than getting a sample from their fingertips.

Forearm sampling: Choose a fleshy area of the forearm away from the bone, visible veins and hair. Sometimes there is less blood flow to the forearm than to the fingertips. To help patients get a large enough drop of blood, you may gently massage or apply warmth to their site to increase blood flow.

Palm sampling: Choose a fleshy area on the palm below the thumb or little finger. Select an area away from veins or deep creases which may cause the blood sample to smear.



Fore arm

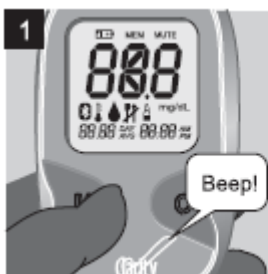


Pa lm

NOTICE:

- You may need to wait a little longer to get a large enough drop of blood from the forearm or palm. Do not squeeze the site excessively.
- If the sample drop of blood runs or spreads due to contact with hair or a crease in the palm, do not use that sample. Try puncturing again in a smoother area.

Setting Up Your Meter:



1. Press and hold the 'M' button for roughly three seconds, you will hear a beep sound and the LCD Screen will display the screen icons of the meter.

2. Continue to hold the 'M' button and "SET" will appear on the screen.



3. Setting the Month: When the month blinks, press and release the 'C' Button until the correct month appears, then press the 'M' Button to set the correct month and move to the date setting.

4. Setting the Date: When the date blinks, press and release the 'C' Button until the correct date appears, then press the 'M' Button to set the correct date and move to the time setting.

5. Setting the Time Format: The meter can be set to show the time in AM/PM 12 hour format or 24 hour "Military Time". With the "12h" blinking press the 'C' Button to move between 12h and 24h, then press the 'M' Button to set and move to the hour setting.



6. Setting the Hour: When the hour blinks, press and release the 'C' Button until the correct hour appears, then press the 'M' Button to set the correct hour and move to the minute setting.

7. Setting the Minute: When the minute blinks, press and release the 'C' Button until the correct minute appears, then press the 'M' Button to set the correct minute and move to the year setting.

8. Setting the Year: The year will appear on the screen, press and release the 'C' Button until the correct year appears, then press the 'M' Button to set the correct year and move to confirming the Measurement Unit Type mode.



9. Measurement Unit: The glucose measurement unit is defaulted to "mg/dl ". Press the 'M' Button to move on to turning the "Beeping" sound on or off.

NOTICE: This cannot be changed, if you have any questions concerning the Measurement Unit Type contact Clarity Diagnostics Customer Service at 1-877-722-6339.

CAUTION:

- Use of the wrong unit of measure may cause you to misinterpret the blood glucose level, and incorrect treatment.
- Contact a healthcare professional if you have any questions about measuring units.

10



10. Turning the Beep Sound On or Off: The meter has the Beep sound defaulted to "On". To turn the Beep sound off on the meter press the 'C' Button until "OFF" is displayed on the screen, then press the 'M' Button to confirm and move to Deleting Your Test Results.

NOTICE: Turning the Beep sound On or Off does not affect your glucose measurement.

11



12



13



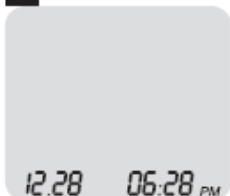
11. Deleting Your Test Result: Select the 'C' Button to toggle between "YES" and "NO". If you want to keep your readings in the memory toggle to "NO" then select the 'M' Button to confirm.

12. If you want to delete all of the readings in the memory toggle to "YES" then select the 'M' Button to confirm.

13. After deleting, the screen will show as pictured above. Press the 'M' Button again and the meter will turn off.

Reviewing Test Results:

1



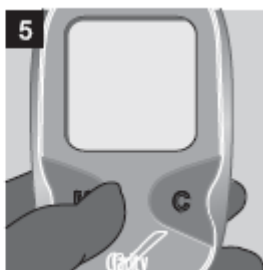
2



3



1. Begin with the meter off. Press the 'M' Button, you will hear a beeping sound and the meter will turn on.
2. The screen will display the date and time. After 2 seconds, the last 14 days average result will be displayed with a sign "14 DAY AVG" and the number of test results for 14 days on the display. For example, "8n" above the picture means that there are eight (8) test results saved on the memory during the last 14 days.
3. Press the 'C' Button once and the screen will show the most recent test result.



4. Each time you continue to press the 'C' Button the screen will show the previous test result.
5. After you are done reviewing your test results, press the 'M' Button to turn off the meter.

NOTICE: The meter has an automatic shut off and will turn off in roughly two (2) minutes if no changes are detected.

Downloading Test Results to PC:

You can transfer test results from the Clarity BG1000 Blood Glucose Meter to a computer where they can be summarized in a report with graphs and tables. To use this feature you will need to download the Clarity BG1000 Diabetes Management Software and use the Clarity BG1000 USB Cable.

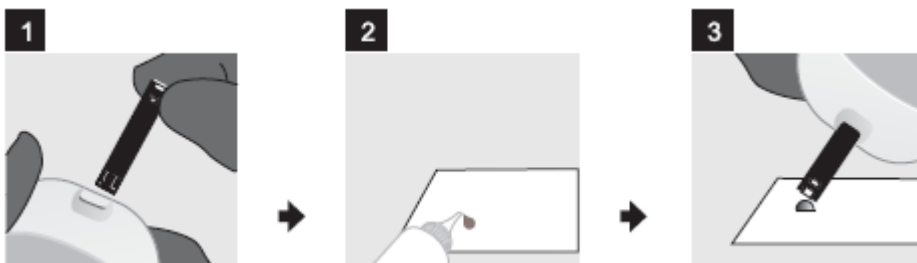
For more information , please contact Clarity Customer Service at 1-877-722-6339 or visit our website at www.claritydiagnostics.com.

Control Solution Test

Performing a Control Test:

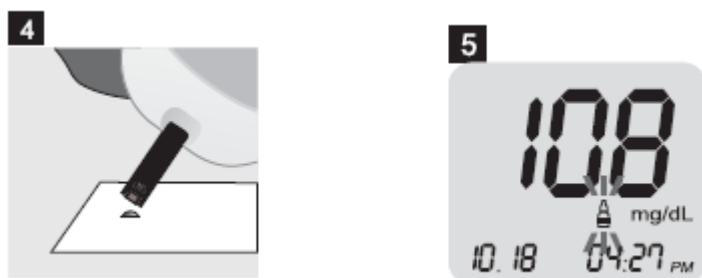
- You open a new box of test strips.
- You left the test strip container open.
- You want to check whether the meter and test strips are working correctly or not.
- Test strips were stored in extreme temperature or humidity.
- You dropped the meter.
- Test result does not agree with how patients feel.
- You want to check if you are testing correctly.

Performing a Control Solution Test:



1. Insert the test strip with the black side and three(3) black line facing up and pointing towards the test strip port. The code number will appear on the screen, verify that the code number displayed matches with the code number on the vial of test strips. If the two code numbers do not match, call Clarity Diagnostics Customer Service at 1-877-722-6339.

2. Shake the control vials well before using. Discard the first drop and wipe the dispenser tip. Squeeze a drop of control solution onto a clean, dry, non-absorbent surface. Do not apply control solution to the test strip directly from the vial. Replace the lid on the control solution vial immediately after use.



3. Gently touch the drop of the control solution to the tip of the test strip.

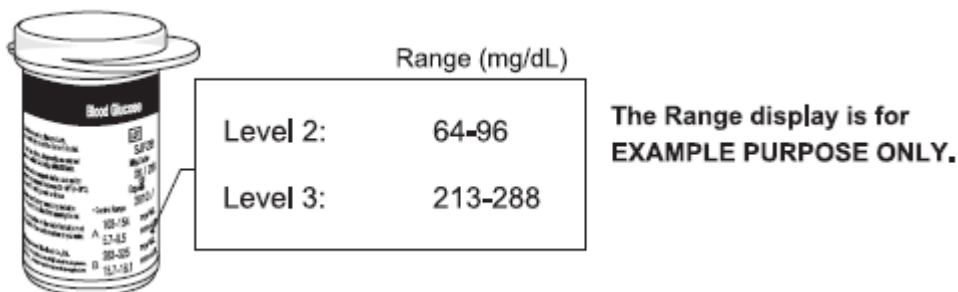
4. When the test strip confirmation window is full, the meter will beep. The meter will count down from five seconds and then show the reading. Make sure the reading on the screen is between the ranges displayed on your test strip vial (refer to page 39 for the control solution ranges.)

5. Mark all control solution test with 'Control Solution Mark' to distinguish them from blood glucose test results in the meter memory. Marked control solution result will not be included in 14 day average. For more detailed information of Flagging Your Test Results refer to page 21 for help.

CAUTION:

- If you continue to get control solution results that fall outside of the range printed on the vial, the system may not be working properly. Do not use the meter. Please contact Clarity Diagnostics Customer Service at 1-877-722-6339.
- User should periodically compare the test system to another test system known to be well maintained and monitored by a healthcare provider.
- Use Clarity BG1000 Glucose Control Solution with the Clarity BG1000 Glucose Meter.

Understanding Control Solution Test Results:



- The example label shown above on the test strip vial shows the acceptable ranges for Level 2 and Level 3 Control Solution for the Clarity BG1000 Glucose Meter.
- The result you get should be within this range. Make sure you compare the result to the correct level of control.
- Each batch of test strips has different acceptable ranges.

Cleaning and Disinfecting:

The meter should be cleaned and disinfected to prevent the transmission of blood borne pathogens as follows. Cleaning is to remove germs, dirt, and impurities from surfaces or objects. Disinfection is to kill germs on surfaces or objects;

- User should wear disposable gloves when cleaning and disinfecting the meter.
- CaviWipes® has been validated for use with this meter to clean and disinfect the outside of the meter. The towelette is available for purchase through your distributor. Also you can get this product from large online retail distribution sites such as www.amazon.com , www.officedepot.com , etc.
- CaviWipes® disinfectant products have been shown to be safe for use with the Clarity BG1000 Blood Glucose Monitoring System. Please note, any disinfectant product with the EPA registration number of 46781-8 may be used on the Clarity BG1000 Blood Glucose Meter.
- The Clarity BG1000 Blood Glucose Monitoring System has demonstrated that there was no change in performance or in the external materials of the meter after 11,000 cleanings with disinfection cycles designed to simulate three years of device use.

CAUTION:

Do not use other cleaners or disinfectants because they may damage the meter.

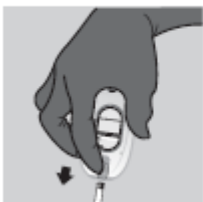
Cleaning Instructions:

Use CaviWipes® towelette to wipe the meter exterior of the front, the back and the sides thoroughly.

Disinfection Instructions:

The meter must be cleaned and disinfected between patient uses by wiping it with a CaviWipes® Towelette in between tests. After cleaning the meter with a CaviWipes® Towelette use a second Caviwipes® Towelette to thoroughly wet the pre-cleaned meter surface. Allow it to remain wet for two minutes at 68°F as specified by the manufacturer of the disinfectant wipes and allow to air dry.

STEP1



STEP2



STEP3



STEP1: Dispose of the used test strip.

STEP2: Remove a new, fresh wipe from the container (please refer to the CaviWipes[®] labeling for safety instructions). You may need to wring wipe slightly to remove excess liquid.

STEP3: Completely wipe the Glucose Meter including the front, back and sides, and take care not to get any liquid in the test strip, test strip port and serial port. Do not wrap the meter in a wipe. Take extreme care not to get liquid in the test strip, test strip port and serial port of the meter. Allow to remain wet for two (2) minutes. Allow to air dry.

STEP4: Dispose of the wipe when finished. After disinfection, user's gloves should be removed and hands washed thoroughly with soap and water before proceeding to the next patient.

References:

1. "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/ArtsandNotices/ucm224025htm>
2. "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>

For more information on cleaning and disinfecting, contact Clarity Diagnostics Customer Service at 1-877-722-6339.

CAUTION:

- Squeeze the excess liquid from the cloth before you wipe the meter's surface.
- The meter must be off when you clean or disinfect the meter.
- Do not get moisture on the test strip or in the test strip port or serial port.
- Do not spray any cleaning solution directly onto the meter.
- Do not put the meter under water or liquid.
- Immersing the meter in water will cause damage.
- Please dispose of wipes and gloves after cleaning/disinfecting.

The life of the device is three (3) years. The Clarity BG1000 meter has demonstrated that there was no change in performance or in the external materials of the meter after 11,000 cleanings with disinfection cycles designed to simulate three (3) years for ten (10) times per day. However, if any of the following physical and functional signs of deterioration appear after cleaning and disinfection of the devices, stop using the device and contact Clarity Diagnostics Customer Service at 1-877-722-6339 immediately.

- Clouding display window of meter.
- Corrosion or erosion of the plastic housing and rubber button.
- Any damage including corrosion or erosion of the test strip port and data transport port.
- Meter buttons do not function.
- Data transfer function from meters to PC does not work.

For more information on cleaning and disinfecting, contact Clarity Diagnostics Customer Service at 1-877-722-6339.

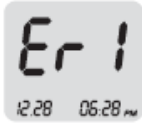

Replacing the Batteries:




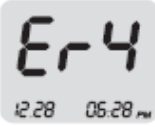

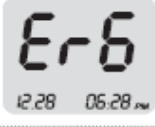
1. When the batteries are low the screen will display and blink the low battery icon in the top left hand corner. This indicates that there is only enough power left in the meter for about fifty more tests and the batteries should be replaced. When replacing the batteries your test results will be stored in the meter, however you may need to reset the date and time. Refer to pages "Setting up Your Meter" for more information.



2. Open the battery compartment lid on the back of the meter and remove the batteries and replace them with two new CR2032 batteries. Make sure to align the + side facing up towards you. Once the new batteries are in place, snap the battery lid back onto the meter.

Screen Messages:

Messages	Descriptions	Solutions
	The meter has detected a problem with the test strip. The test strip is either used or damaged.	Repeat the test with a new test strip.
	The blood sample was applied to the test strip before the blood symbol (♠) appeared on the screen.	Remove and discard the test strip and insert a new one. Apply blood to the test strip after the blood symbol appears on the screen.


Messages	Descriptions	Solutions
	The temperature is above or below the proper range for testing.	The temperature should be 50-104°F. Move the meter and test strips to an area that is within the temperature range to perform the test. Wait about twenty minutes or until the meter has reached the proper range and retest. Do not raise or lower the meter temperature artificially.

Messages	Descriptions	Solutions
	There is not enough blood in the strip to perform a test.	Repeat the test with a new test strip and make sure enough blood has been applied to the strip.
	The wrong strip is being used with the meter.	Make sure you are using the Clarity BG1000 test strip and repeat the test.
	There is an internal error with the meter .	Please contact Clarity Diagnostics Customer Service at 1-877-722-6339

Messages	Descriptions	Solutions
	When the test result is higher than 600mg/dL, the screen will show the "Hi" mark. This indicates that the value of your blood glucose is too high.	Retest with new test strip. If "Hi" mark appears again, please call the doctor or healthcare professional immediately.
	When the test result is lower than 20mg/dL, the screen will show the "Lo" mark. This indicates that the value of your blood glucose is too low.	Retest with new test strip. If "Lo" mark appears again, please call the doctor or healthcare professional immediately.

Troubleshooting:

Causes	Solutions
The meter does not work after the blood is applied.	<ul style="list-style-type: none"> Make sure that the test strip is inserted into the test strip port completely. See if the test strip is covered in debris or lint. Make sure the blood is applied to the test strip correctly. Make sure the test strip is inserted correctly and repeat the test.
The test result is abnormal.	<ul style="list-style-type: none"> See if the test strip is covered in debris or lint. Also make sure the test strip has not been out of its container for any extended period of time. Make sure the test strip has not been used before. Verify the expiration date on the test strip vial.

Causes	Solutions
	<ul style="list-style-type: none"> Make sure the test strip vial has not been opened for longer than three (3) months. Make sure the meter code and test strip code match.
The thermometer icon () appears on the screen.	<ul style="list-style-type: none"> Place the meter and test strip in a temperature environment with the temperature in the range of 50-104°F. You should use it after about 20 minutes in the appropriate conditions. If the thermometer icon is constantly showing, contact Clarity Diagnostics Customer Service at 1-877-722-6339.
The meter does not work after the test strip is inserted.	<ul style="list-style-type: none"> Make sure the test strip is completely inserted into the test strip port. Make sure the batteries are inserted correctly, with the + sign up and facing in the correct direction.

Technical Information and Warranty

Specifications:

Product Name	Clarity BG1000 Blood Glucose Monitoring System
Test Sample	Fresh capillary whole blood
Calibration	Plasma-equivalent
Sample size	0.5µl
Test Strip Type	Clarity BG1000 Blood Glucose Test Strip
Measuring Range	20 - 600 mg/dL
Measuring Time	5 Seconds
Power	(2) 3.0 Volt CR2032 lithium batteries
Battery Life	Approximately 1000 tests
Memory Capacity	300 test results
Data Transport	USB Data Transfer Cable
Display	LCD
Operating Temp	50 - 104°F
Operating Humidity	10 - 90 % RH
Storage Temp	39.2 - 86°F
Dimensions	18 x 51 x 88 mm
Weight	48g (with batteries)

Warranty:

Clarity Diagnostics guarantees that the Clarity BG1000 Blood Glucose Meter shall be free of defects in material and workmanship for a period of three years. This guarantee is valid from the date of purchase. This guarantee extends only to the original purchaser and is not transferable.

The warranty ceases to apply under the following conditions:

- The meter is damaged as a result of incorrect use.
- The meter is damaged as a result of natural disasters (e.g. hurricane, earthquake, etc.)
- The meter is damaged due to using incompatible products.
- The meter is damaged as a result of attempting to repair the meter.

Disposing of your Meter:

During blood glucose measurement the meter itself may come into contact with blood. Used meters therefore carry a risk of infection. Please dispose of your used meter - after removing the batteries - according to the regulations applicable in your area. For information about correct disposal, please contact your local council and authority.

Blood Glucose Target Range:

Normal blood glucose reference value for non-diabetics is as follows:

- Before eating : < 100 mg/dl
- 2 hours after meals : <140 mg/dl

In case results are out of reference range, please contact a healthcare professional and follow their advice.

Reference: American Diabetes Association, Clinical Practice Recommendations (2015) Diabetes Care, Vol.38, Supplement 1, p S1 -S93

EMC Test Results:

- It is the manufacturer's responsibility to provide equipment electromagnetic compatibility information to the customer or user.
- It is the user's responsibility to ensure that a compatible electromagnetic environment for the equipment can be maintained in order that the device will perform as intended.
- The equipment complies with the emission and immunity requirements described in EN 61326-2-6.
- The electromagnetic environment should be evaluated prior to operation of the device.
- Do not use this meter near cellular or cordless telephones, walkie talkies, garage door openers, radio transmitters, or other electrical or electronical equipment that are sources of electromagnetic radiation, as these may interfere with proper operation of the meter.

Additional Supplies Available:

The following supplies and accessories are available from your distributor, for more information contact Clarity Diagnostics Customer Service at 1-877-722-6339.

Clarity Data Transfer/USB Cable

Clarity BG1000 Diabetes Management Software Clarity

BG1000 Blood Glucose Test Strips

Clarity BG1000 Glucose Control Solution

PROCEDURE MANUAL



Manufactured for:

Clarity Diagnostics, LLC.

1060 Holland Drive, Suite A&D

Boca Raton, FL 33487 USA

Call Customer Service Toll Free

Mon-Fri 8:30AM-5:30PM EST

1-877-722-6339

or visit our website www.claritydiagnostics.com

If you have questions or need assistance outside the operational days and times, please contact your healthcare provider.