BLOOD GLUCOSE TEST STRIP 333 INSERT

Intended Use

The GE Blood Glucose Monitoring System **333** is used by individuals with diabetes. It's for checking on glucose levels of whole blood from capillary. Capillary blood can be sampled from the fingertip, palm and forearm. It's as an aid in management of diabetes at home and clinical sites.

The GE Blood Glucose Monitoring System **333** is intended for self-testing outside the body (*in vitro* diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The GE Blood Glucose Monitoring System **333** should not be used for the diagnosis of, or screening for diabetes or for neonatal use. Alternative site testing should be done only during steady - state times (when glucose is not changing rapidly).

The GE Blood Glucose Monitoring System **333** aid to diabetes control, could be used by healthcare professionals in clinical setting, also by people to use at home.

The GE Blood Glucose Monitoring System **333** tests the capillary blood and provides results equivalent to a laboratory instrument (Plasma equivalent).

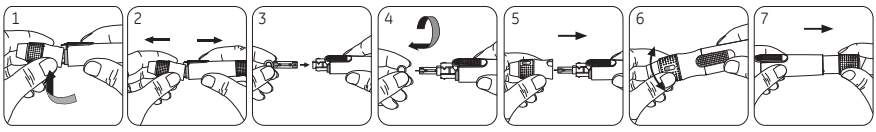
The GE Blood Glucose Test Strip **333** is designed for use with the GE Blood Glucose Meter **333** to obtain accurate results.

Test Procedure

Preparing the Lancing Device

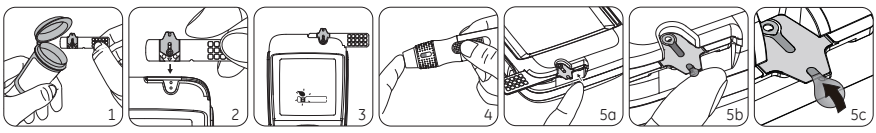
Wash your hands with warm soapy water and dry thoroughly before you start the test.

1) Hold the depth adjustable cap in one hand and hold the base in the other hand. Bend the cap towards the down side, until a gap appears between the cap and base.
2) Pull the cap and base off in opposite directions, remove the cap.
3) Insert a new disposable lancet firmly into lancet carrier .
4) Twist off and set aside the protective cover of the disposable lancet.
5) Replace the depth adjustable cap.
6) The adjustable cap with 7 depth levels allows you to select the depth of penetration by rotating the cap until the preferable depth display in the window. Settings are based on skin type " " for soft or thin skin; " " for average skin; " " for thick or calloused skin.
7) Hold the base in one hand and pull on the plunger in the other hand. The device will be cocked. Release the plunger, it will automatically move back to its original position near the base.



Performing a Test

1) Take one test strip from the vial. Close the vial cap immediately.
2) Insert the strip into the strip port of the meter with the sample window facing up. Push the strip in until it clicks and stops. The meter will automatically detect the code number.
3) When the blood drop icon flashes on the display window, blood sample is ready to be applied to the test strip port (apply within 2 minutes).
4) Place the lancing device to your fingertip and press the release button.
5) Touch and hold the drop to the edge of sample entry until you hear a " beep " (if volume is turned on) and the View Window is totally filled with blood. If the View Window is not totally filled with blood or the test does not start, please discard the test strip and repeat the test with a new test strip.

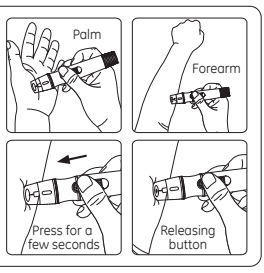


Sample Size Example

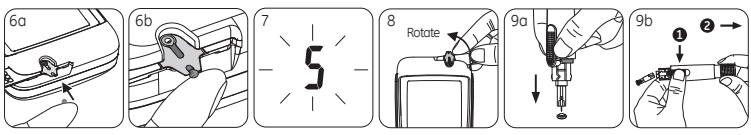
Please use a minimum blood drop size of 0.75 µL to perform the test on glucose monitoring system. Blood drop sizes greater than 3.0 µL are too large and may contaminate the test strip port of the meter.

Alternate site testing: palm or forearm blood sampling

- To perform a test using samples obtained from alternative sites, install the clear cap on the lancing device (For more information on how to install, see the Instructions for the lancing device).
- To increase the blood flow, massage the puncture area of palm or forearm for a few seconds.
- Immediately after massaging the puncture area, press and hold the lancing device with the clear cap against palm or forearm.
- Then press the release button.
- Continue holding the lancing device against palm or forearm and gradually increase pressure for a few seconds until the blood sample size is sufficient (Refer to Instructions for the lancing device).



6) Touch and hold the drop to the edge of sample port until you hear a " beep " (if volume is turned on) and the sample window is completely filled with blood. If the view window is not completely filled with blood the test will not start. If this is the case, discard the test strip and repeat the test with a new test strip.
7) The countdown mode will begin on the display window. After 5 seconds your test result will appear.
8) Remove the test strip from the meter. Please follow your local regulations to properly discard the used strip.
9) To remove the lancet, pull off the depth adjustable cap of the lancing device. Without touching the used disposable lancet, insert the lancet tip into the protective cover. Hold the release button of the lancing device in one hand and pull on the plunger with the other hand to safely eject the used disposable lancet into an appropriate puncture-proof or biohazard container.



For more information on how to use your meter and understand your test results, see the GE Blood Glucose Monitoring System 333 User's Manual.

Test Result

- Blood glucose test results are shown on the meter as mg/dL.
- If your blood glucose result is unusually high or low, or if you question your results, repeat the test with a new test strip. You can also run a Quality Control Test with the GE Control Solution **333** to check your meter and test strip. If the test result still remains unusually high or low, contact your Physician or the nearest Emergency Healthcare Services immediately.
- If you are experiencing symptoms that are not consistent with your blood glucose test results and you have followed all the instructions in this insert, contact your Physician or the nearest Emergency Healthcare Services immediately.
- The GE Blood Glucose Meter 333 display results between 20 and 600 mg/dL. If your test result is below 20 mg/dL, " Lo " will appear on the screen. Please repeat your test with a new strip. If you still get a " Lo " result, you should immediately contact your Physician or the nearest Emergency Healthcare Services.
- If your test result is above 600 mg/dL, " Hi " will appear on the screen. Please repeat your test with a new strip. If you still get a " Hi " result, you should immediately contact your Physician or the nearest Emergency Healthcare Services.

Expected glucose values without diabetes [1]	
Status	Range (mg/dL)
Fasting	< 100 mg/dL
Two hours after meals	< 140 mg/dL

Precautions

- Check the expiration date printed on the test strip vial. Do not use expired test strips.
- Close the test strip vial immediately after taking test strip out from the vial.
- Do not perform a control solution test with expired control solution.
- Do not bend or twist the test strip. A damaged test strip may cause incorrect test results.
- Do not reuse test strips.
- Do not reuse lancets. Discard used lancets properly.
- If the GE Blood Glucose Meter 333 is exposed to a significant change in temperature, please wait at least 45 minutes before performing a test.
- If you want to purchase new control solutions, please contact Customer Service.
- Test results may vary if blood samples are taken from different sites or under certain conditions where glucose levels can change rapidly such as: following a drink, a meal, an insulin dose or exercise. In these cases, only the fingertip should be used.
- Users should wash their hands thoroughly with soap and water after handling the meter, lancing device, control solution and test strips.
- The GE Blood Glucose Monitoring System 333 should be cleaned and disinfected periodically (please refer to the GE Blood Glucose Monitoring System 333 User's Manual for cleaning and disinfecting procedures).

Warning

- Keep the test strips and vial cap away from children; they may cause a choking hazard. If a test strip or vial cap is swallowed, contact your Physician immediately.
- Please refer to the cleaning and disinfecting instructions in the User's Manual.

Limitations

- The meter readings of the blood glucose may be significantly lower than "true glucose levels" in a hyperglycemic-hyperosmolar state, with or without ketosis.
- Caution is advised when glucose values in the interpretation of glucose values are below 50 mg/dL or above 250 mg/dL. Consult a Physician as soon as possible, if values in this range are obtained.
- Healthcare professionals should evaluate their technique and their patients' technique regarding the use of the GE Blood Glucose Monitoring System 333 regularly. To accomplish this, it is recommended that blood glucose monitoring results be compared with a concurrently obtained laboratory measurement on the same blood sample. A proven clinical laboratory method employing hexokinase or glucose oxidase should be used as the comparative method.
- Hands and fingers contaminated with sugar from foods or beverages may cause falsely elevated results.
- The results of blood glucose measurements are different for measurements with whole blood and plasma.
- Storage of strips near bleach as well as bleach containing products will affect the results of the GE Blood Glucose Test Strips 333.
- Inaccurate test results may be obtained at altitudes greater than 10,000 feet (3,048 meters) above sea level.
- Hematocrit should be between 20 - 60%. If you do not know your hematocrit, ask your healthcare professional.
- Severe dehydration and excessive water loss may cause inaccurately low results.
- Do not perform the blood glucose test at temperatures below 50°F (10°C) or above 104°F (40°C), nor below 10% or above 90% relative humidity.The suggested temperature range for the control solution test is 59 ~ 104°F (15 ~ 40°C).
- GE Blood Glucose Test Strips 333 are designed for use with capillary whole blood samples. Do not use serum or plasma samples.
- Not for screening or diagnosis of diabetes mellitus.
- Not for use on critically ill patients, patients in shock, dehydrated patients or hyper-osmolar patients.
- Not for neonatal use
- Alternate site testing should not be used to calibrate continuous glucose monitoring systems (CGMs).
- Alternate site testing should only be done during steady-state times (when glucose is not changing rapidly).
- Results from alternate site testing should not be used in insulin dose calculation.

NOTE
- Keep meter free of dust and liquids including water.

Storage and Handling
- Store the strips in the original capped vial at temperatures between 39°F to 86°F (4°C to 30°C) and 10 - 90% relative humidity.
- Replace vial cap immediately and close lid tightly after removing a test strip. If the strip is exposed to the air too long, it will absorb the moisture and cause inaccurate test results.
- When you open a new vial of test strips please write the opening date on the label. Use test strips within 3 months after first opening or until the expiration date printed on the label (whichever comes first).

Quality Control
Please refer to the Quality Control section of the GE Blood Glucose Monitoring System **333** User's Manual.

Troubleshooting and Customer Service
For more information on error messages and troubleshooting, please refer to the Error Messages and Troubleshooting section of the GE Blood Glucose Monitoring System **333** User's Manual.
You may also contact customer service by calling toll free at +886 800-241-688 (Monday through Friday 8:30 AM to 5:30 PM GMT+08:00). (At all other times, you could contact your healthcare professional for help)

Additional Information for Healthcare Professionals

Detection Principle [2]
The glucose oxidase and potassium ferricyanide in the strip react with the glucose in the sample to produce an electrical current which is proportional to the amount of glucose in the sample. The meter measures the current and converts it to the corresponding glucose concentration.

Performance Characteristics

Measurement Range
The measurement range of the GE Blood Glucose Monitoring System **333** is 20 to 600 mg/dL.

Precision
The precision was evaluated with (i) venous whole blood sample (ii) 3 different glucose concentrations in 10 days by 10 meters.

(i) venous whole blood sample

Sample	P-01	P-02	P-03	P-04	P-05
(1) Total test numbers (n)	300	300	300	300	300
(2) Mean mg/dL (mmol/L)	42.8 (2.4)	90.5 (5.0)	130.6 (7.3)	213.8 (11.9)	359.8 (20.0)
(3) SD mg/dL (mmol/L)	1.7 (0.09)	1.4 (0.08)	1.7 (0.09)	3.0 (0.17)	4.7 (0.26)
(4) CV (%)	3.9%	1.5%	1.3%	1.4%	1.3%

(ii) Control solution

Glucose levels	Level 1	Level 2	Level 4
(1) Total test numbers (n)	300	300	300
(2) Mean mg/dL (mmol/L)	41.0 (2.3)	95.7 (5.3)	282.5 (15.7)
(3) SD mg/dL (mmol/L)	1.3 (0.07)	1.5 (0.09)	4.0 (0.22)
(4) CV (%)	3.1%	1.6%	1.4%

Accuracy
For the alternate site testing:
The accuracy of the alternate site test study of GE Blood Glucose Monitoring System 333 was tested by comparing whole blood (plasma equivalent) glucose values on the GE Blood Glucose Meter 333 with plasma glucose values on a YSI 2300 lab instrument. A total of 160 patients joined. Each collected and tested their own blood samples (from the fingertip, palm and forearm) with GE Blood Glucose Monitoring System 333. Another blood sample was collected within 5 minutes and was tested with a laboratory reference method (YSI 2300 analyzer). Minimum of 98.0% of GE Blood Glucose System 333 values were within ± 15% of YSI values at glucose concentrations ≧ 75 mg/dL and within ± 10 mg/dL at glucose concentrations < 75 mg/dL.

Table 1: represents samples for glucose results lower than 75 mg/dL.

Capillary samples collected from different testing sites	The percent (and number) of samples for which the difference between the GE Blood Glucose Meter **333** value (Alternate site) and the YSI 2300 value were within the following intervals.		
	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
Fingertip	(4/4) 100.0%	(4/4) 100.0%	(4/4) 100.0%
Palm	(4/4) 100.0%	(4/4) 100.0%	(4/4) 100.0%
Forearm	(3/4) 75.0%	(4/4) 100.0%	(4/4) 100.0%

Table 2: represents samples for glucose results greater than 75 mg/dL.

Capillary samples collected from different testing sites	The percent (and number) of samples for which the difference between the GE Blood Glucose Meter **333** value (Alternate site) and the YSI 2300 value were within the following intervals.			
	Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
Fingertip	(70/153) 45.8%	(136/153) 88.9%	(151/153) 98.7%	(153/153) 100.0%
Palm	(76/153) 49.7%	(131/153) 85.6%	(153/153) 100.0%	(153/153) 100.0%
Forearm	(78/150) 52.0%	(123/150) 82.0%	(147/150) 98.0%	(147/150) 98.0%

Note: When glucose meter results are compared to the laboratory results, variation values below 75 mg/dL are expressed in mg/dL, while those above 75 mg/dL are expressed in percent.

Table 3: Linear regression of GE Blood Glucose Monitoring System **333** (YSI 2300 as reference)

	GE BGMS 333 fingertip vs. YSI 2300-Plasma	GE BGMS 333 palm vs. YSI 2300-Plasma	GE BGMS 333 forearm vs. YSI 2300-Plasma
Test range	67.4 - 480.0	67.4 - 480.0	67.4 - 480.0
Test number	157	157	154
Slope	1.01	1.00	1.00
Intercept	-0.19	2.02	-0.89
R	0.99	0.99	0.99

Interferences
The following compounds may interfere with the glucose measurement at the concentrations listed: High concentrations of Uric acid ≧ 10 mg/dL, Cholesterol ≧ 600 mg/dL, Ascorbic acid (Vitamin C) ≧ 5 mg/dL may interfere with the glucose test causing inaccurate test results.

NOTE
Acetaminophen, Dopamine HCl, Ibuprofen, L-Dopa, Methyldopa, Salicylic Acid, Tetracycline, Tolbutamide, Bilirubin conjugated, Creatinine, Triglyceride, Maltose, Xylose, Galactose, Lactose and Icodextrin (when occurring in normal blood or normal therapeutic concentrations) do not significantly affect results. However, abnormally high concentrations in blood may cause inaccurate results.

Reagents
Each Blood Glucose Test Strip contains the following reagents:

Glucose Oxidase (Aspergillus niger) (GOD)	14.8%
Potassium ferricyanide	39.5%
Non-reactive ingredients	45.7%

References
1) American Diabetes Association: Diabetes Care, January 2015, volume 38 (Suppl. 1) S8-S16.
2) *In vitro* Diagnostics in Diabetes : Meeting the Challenge. Clinical Chemistry 45:9, 1596-1601 (1999).

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www.gediabetes.com
(Monday through Friday 8:00 AM to 5:00 PM PST.
If you have questions or need assistance outside the operational days and times, please contact your health care provider.)

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