Easy•Touch®

BLU Link®

Glucose Test Strips

IMPORTANT: Please read this information and your EasyTouch® BluLink® Instructions for use before using the EasyTouch® BluLink® test strips. If you have any questions regarding the EasyTouch® BluLink® Blood Glucose Monitoring System, please call us at 877-358-4342(toll free). MHC Customer Support is available Monday thru Friday, 9 to 5pm Eastern Time.

Intended Use:
The EasyTouch® BluLink® Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood. The EasyTouch® BluLink® Blood Glucose Monitoring System is intended to be used by a single patient and should not be shared.

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

The EasyTouch® BluLink® test strips are for use with the EasyTouch® BluLink® meter to quantitatively measure glucose in fresh capillary whole blood. Fresh capillary whole blood samples may be drawn from the fingertips, ventral palm, dorsal hand, upper arm, forearm, calf and/or thigh.

General:
EasyTouch® BluLink® test strips have the new bio-sensor technology, requiring only a tiny drop of blood. EasyTouch® BluLink® meter can store 365 readings in memory with date & time. All your results are easily downloadable to your computer.

Storage and Handling:
- Store the test strip vial in a cool, dry place between 36-86°F (2-30°C). Keep out of direct sunlight. Do not freeze.
- Store test strips in its original vial only. Do not mix the test strips in new vials or in any other container.
- Immediately replace the cap and close tightly after removing a test strip.
- Use test strip immediately after removing it from the vial.
- Do not use test strips after the expiration date. It may cause inaccurate results.
- Make a notation of the discard date when you first open it.
- Discard any remaining test strips after 6 months of first opening.
- Avoid getting dirt, food, and water on the test strip. Do not handle test strips with wet hands.
- Do not bend, cut, or alter test strips in anyway.

Cautions and Safety Information section:
- For in vitro diagnostic use only
- The single-patient use system is for single-patient use only and should not be shared.
- Not for neonatal use
- Do not use for diagnosis of or screening for diabetes mellitus.
- Not for use on critically ill patients, patients in shock, dehydrated patients or hyper-osmolar patients
- Alternative site testing (AST) should only be performed during periods of steady-state blood glucose conditions (when glucose is not changing rapidly).
- AST should not be used to calibrate continuous glucose monitors (CGMs).
- AST should not be used for insulin dose calculations.
- All parts of the kit are considered biohazardous and can potentially transmit infectious diseases, even after you have performed cleaning and disinfecting.
- Always use a new, sterile lancet. Lancets are for single use only.
- Avoid getting hand lotions, oils, dirt or debris in or on the lancets and the reusable landing device.
- Please refer to the Instructions for use for cleaning and disinfecting EasyTouch® BluLink® glucose monitoring system.
- Make sure to fill the strip with sufficient amount of blood to avoid inaccurate result.
- Verify the meter code matches the code number printed on the test strip vial.
- Do not reuse test strip. Test strip is for single use only.
- If you experience any symptoms that are not consistent with your test results, call your Healthcare Professional.
- Do not make significant changes to your diabetes control program without consulting your Healthcare Professional.
- Do not ignore problems without consulting your Healthcare Professional.
- Do not perform tests at temperatures below 50°F(10°C) or above 104 °F (40°C).
- Do not perform tests with humidity below 10% or above 90%.
- Avoid getting dirt, food, and water on the color-coded label (back of test strip).

Test Principle:
Sugar in the blood sample will react to the electrodes in the test strip, generating an electrical current that will stimulate a chemical reaction. This reaction is measured by the meter and displayed as your result.

Note: Different levels of reactions will occur depending on the amount of sugar in the blood sample.

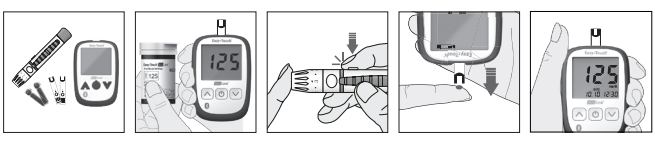
Reagent Composition:
Each EasyTouch® BluLink® Test Strip contains:
- Glucose Dehydrogenase (Aspergillus sp.): 7.2%
- Mediator (Hexaammineruthenium Chloride): 42.8%
- Binder: 2.2%
- Stabilizer: 47.8%

The procedure for Blood Glucose Measurement:
- Materials provided: EasyTouch® BluLink® Test strips
- Materials required but not provided: EasyTouch® BluLink® meter, Instructions for use, lancets, and reusable lancing device.
- Optional Materials: Control solution (Low (Level 1) and High (Level 3))

Obtaining Blood Sample:
The test strips are designed to be used with fresh capillary whole blood. The meter gives you the ability to obtain a blood sample for testing your sugars from different areas of your body. You may obtain a blood drop from either a fingertip or an alternative site (dorsal hand, ventral palm, upper arm, forearm, calf, and thigh).

Caution :
- EasyTouch® BluLink® meter and reusable lancing device are for single patient use only. Do not share them with anyone including other family members! Do not use on multiple users!
- All parts of the kit are considered biohazardous and can potentially transmit infectious diseases, even after you have performed cleaning and disinfection.
- Never share a lancet or a reusable lancing device with anyone.
- Always use a new, sterile lancet. Lancets are for single use only.
- Avoid getting hand lotions, oils, dirt or debris in or on the lancets and the reusable landing device.
- Please refer to pages 32-35 in the Instructions for use for cleaning and disinfecting EasyTouch® BluLink® Blood Glucose Monitoring System.

To test a drop of blood, follow these steps:



Step 1: Wash your hands and test site with warm soapy water. Dry thoroughly. You may also use an alcohol wipe to clean. Make sure it is completely dry before testing. (Dirt, oil, lotion, or sweat may affect the test result).

Step 2: Prepare the lancing device. Insert a lancet into the lancing device. The device holds, positions, and controls how deeply the lancet goes into the skin. (Refer to the Instructions for use for more information).

Step 3: Remove a test strip from the vial. Recap the vial immediately to prevent moisture from affecting the other test strips. Insert the test strip into the port of the meter with the "arrow" mark pointing down.The meter will automatically turn on and display the code number. Make sure the code number matches the code number on the test strip vial. If the code numbers do not match, do not use it and contact customer support immediately. Refer to Instructions for use.

Step 4: Poke the test site. Only a small drop of blood is necessary for accurate test results. Touch the top edge of your test strip to the drop of blood and do not remove it until you hear the "beep" sound. The meter will countdown from 5 to 1 and a test result will be displayed.

Note : Poking the side of your fingertip is less painful. Do not squeeze or milk the puncture site

Step 5: The meter will automatically store your results in the memory to be retrieved at anytime. Push the ejector button forward to discard the test strip.

Important Information about Using Alternate Sites Testing:
- Alternative sites where you can test are dorsal hand, ventral palm, upper arm, forearm, calf, and thigh.
- Under certain conditions, blood glucose test results obtained using samples taken from your alternative sites may differ significantly from fingertip samples.
- The conditions in which these differences are more likely to occur is when your blood glucose is changing rapidly such as following a meal, insulin dose, or physical exercise.
- When blood glucose is changing rapidly, fingertip samples show these changes more quickly than alternative sites samples.
- When your blood glucose is falling, testing with a fingertip sample may identify a hypoglycemic (low blood sugar) level sooner than a test with an alternative site sample.
- Use alternative sites samples only for testing prior to or more than two hours after a meal, insulin doses, or physical exercise.
- Testing performed within two hours after meals, insulin doses, or physical exercise or whenever you feel that your glucose levels may be changing rapidly should be done from the fingertip.
- You should also use fingertip testing whenever you have a concern about hypoglycemia (insulin reactions) particularly if you suffer from hypoglycemic unawareness (lack of symptom to indicate as insulin reaction), as forearm testing may fail to detect hypoglycemia.

Test Results:
The results are displayed on the meter as milligrams of glucose per deciliter of blood (mg/dL). The meter displays results between 20~600mg/dL. If the test result is below 20mg/dL, "Lo" will appear on the meter display. If your blood glucose result does not match how you feel and you have followed the instructions in this User's Manual, follow your healthcare professional's instructions, or contact your healthcare professional.

IMPORTANT NOTE: Blood sugars may be altered by your food, physical activity, and/or stress.

Range of Expected Values:
Self-testing of blood glucose levels provides a way to control your diabetes. Consult with your healthcare professional to determine the best range of expected blood glucose values for you.

Expected blood glucose values for non-diabetic adults are as follows:
Before eating < 100 mg/dL (5.6 mmol/L)
One to two hours after meals < 140 mg/dL(7.8 mmol/L)
Reference:
American Diabetes Association, Clinical Practice Recommendations (2019) Diabetes Care, Vol. 42, Supplement 1, p S1 - S100

IMPORTANT:
If your blood glucose result is unusually low or high, repeat the test again with a new test strip. If the results are still inconsistent, please consult your Healthcare Professional.

Quality Control (System Maintenance):
Control Solution is designed to ensure that the meter and the test strips are working together properly.

NOTE:
Control Solution is not included in the system package. Levels 1 and 3 control solutions are sold separately. Please contact your local representative or customer service for purchasing.

EasyTouch® BluLink® Blood glucose control solution can be used with the EasyTouch® BluLink® meter and EasyTouch® BluLink® test strips only.

Always perform a control solution test when:
- A new vial of test strips is opened.
- Any suspicion that the meter or test strips are not working properly.
- When your blood glucose test results are not consistent with your symptoms.
- If you drop the meter.

When the control solution is applied to the top edge of the test strip, you should get results within the expected range printed on the label of the test strip vial. If the control solution test results fall outside the range, repeat the test. Results that fall outside the range may be caused by:
- Error in performing the test.
- Failure to shake the control solution bottle well (must shake vigorously).
- Failure to discard the first drop of control solution.
- Expired or contaminated control solution.
- Test strip deterioration.
- Meter malfunction.
- Control solution that is too warm or cold.

IMPORTANT NOTE:
If the control solution test results continually fall outside the range printed on the vial, the EasyTouch® BluLink® Blood glucose monitoring system may not be functioning properly. DO NOT use the system to test your blood until you receive a control solution test result that falls within the correct range. If you continue to have problems, contact your local representative immediately.

Limitations of System:
The EasyTouch® BluLink® test strips provide accurate results when the following constraints are observed: Inaccurate results may occur in severely hypotensive individuals or patients in shock. Inaccurate low results may occur for individuals experiencing a hyperglycemic-hyperosmolar state, with or without ketosis. Critically ill patients should not be tested with this meter.
- Use only the EasyTouch® BluLink® test strips with the EasyTouch® BluLink® meter.
- Use fresh capillary whole blood only.
- The test strips are for single use only. Do not reuse.
- Dehydration may cause higher test results.
- Inaccurate results may occur when in shock, hypotensive, hyperglycemic, or hyperosmolar state and with or without ketosis.
- EasyTouch® BluLink® test strips used above altitudes of 10,000 feet will have an effect on test results.

Please note the following interferences that may affect test results:
The EasyTouch® BluLink® test strips provide accurate results when the following constraints are observed: Inaccurate results may occur in severely hypotensive individuals or patients in shock. Inaccurate low results may occur for individuals experiencing a hyperglycemic-hyperosmolar state, with or without ketosis. Critically ill patients should not be tested with this meter.
- EasyTouch® BluLink® test strip results can be used with hematocrit levels in the range of 20% to 65%. If the hematocrit range is out of the range(20%~65%), then the test results may be lower or higher than the actual value.
- Interferences: Acetaminophen, uric acid, ascorbic acid (vitamin C), and other reducing substances (when occurring in normal blood or normal therapeutic concentrations) do not significantly affect results. However, abnormally high concentrations in blood may cause inaccurately high results.
  Samples containing Bilirubin up to 30.0 mg/dL, Ascorbic acid up to 3.0 mg/dL & Ibuprofen up to 37.5 mg/dL do not significantly affect results.
- Lipemic samples; Cholesterol up to 500 mg/dL or triglyceride up to 3000 mg/dL do not significantly affect the results. Values beyond these levels should be interpreted with caution.
- Do not use during or soon after xylose absorption testing. Xylose in the blood will cause interference.
- Icodextrin does not interfere with EasyTouch® BluLink® test strips.

Performance Characteristics:
The performance of the test strips has been evaluated in clinical trials. Measurement Range: The measurement range of the EasyTouch® BluLink® Blood glucose monitoring system is 20 to 600 mg/dL.

Accuracy:
The accuracy results obtained with the EasyTouch® BluLink® Blood glucose monitoring system were compared to glucose results obtained with the YSI 2300 Auto analyzer, a laboratory instrument.

Glucose levels were measured on 100 fresh capillary specimens at three different clinical centers.

System accuracy results for Glucose concentration <75 mg/dL

Within ±5 mg/dL	Within ±10 mg/dL	Within ±10 mg/dL
35/51 (68.6%)	48/51 (94.1%)	51/51 (100.0%)

System accuracy results for glucose concentration ≥75 mg/dL

Within ±5%	Within ±10%	Within ±15%	Within ±20%
148/249 (59.4%)	222/249 (89.2%)	248/249 (99.6%)	249/249 (100.0%)

Regressions between EasyTouch® BluLink® Blood Glucose Monitoring System results and the YSI 2300 for the capillary whole blood samples:

Linear regression	95% CI Slope	R2	N
y= 0.9886x - 0.3843	(0.978, 0.999)	0.9916	300

The study shows that the EasyTouch® BluLink® Blood glucose monitoring system compares well with the laboratory method.

Precision.
Precision Results for venous whole blood samples.

Blood Conc. Level	N	44 mg/dL	83 mg/dL	125 mg/dL	208 mg/dL	332 mg/dL
grand mean	300	43	81	127	209	332
pooled variance	300	2.4	4.4	11.7	27.9	76.3
pooled SD	300	1.6	2.1	3.4	5.3	8.7
95% CI		(1.57, 1.63)	(2.04, 2.16)	(3.33, 3.47)	(5.18, 5.42)	(8.53, 8.87)
pooled CV (%)	300	3.7	2.6	2.7	2.5	2.6

Precision Results for control solutions.

Control solution Conc. Level	N	45mg/dL	111 mg/dL	307 mg/dL
grand mean	600	51	111	311
pooled variance	600	4.8	7.5	60.2
pooled SD	600	2.2	2.7	7.8
95% CI		(2.18, 2.22)	(2.67, 2.73)	(7.67, 7.93)
pooled CV (%)	600	4.3	2.4	2.5

Alternative Site Testing Accuracy:
The EasyTouch® BluLink® Blood glucose monitoring system was evaluated for alternative site testing accuracy by comparing blood glucose results of alternate sitesmeasured by patients and health professionals using EasyTouch® BluLink® Blood glucose monitoring system, and the results measured by the YSI 2300 Autoanalyzer, a laboratory instrument. Glucose levels were measured on 150 fresh capillary specimens at three different clinical centers.

Table 1. Data analysis at DORSAL HAND
Patient DORSAL HAND vs YSI 2300 Finger

System accuracy results for glucose concentration <75 mg/dL (4.2 mmol/L)

Within ± 5mg/dL (within ± 0.28 mmol/L)	Within ± 10 mg/dL (within ± 0.56 mmol/L)	Within ± 15mg/dL (within ± 0.83 mmol/L)
2/4 (50%)	4/4 (100%)	4/4 (100%)

System accuracy results for glucose concentration ≥75 mg/dL (4.2 mmol/L)

Within ±5%	Within ±10%	Within ±15%	Within ±20%
92/146 (63%)	123/146 (84%)	143/146 (98%)	146/146 (100%)

Table 2. Regressions analysis at DORSAL HAND
Patient DORSAL HAND vs YSI 2300 Finger

Linear regression	95% CI Slope	95% CI Intercept	R^2	N
y = 0.9922x + 8.3679	(0.975, 1.009)	(3.616, 13.120)	0.9891	150

Table 3. Data analysis at VENTRAL PALM
Patient VENTRAL PALM vs YSI 2300 Finger
System accuracy results for glucose concentration ≥75 mg/dL (4.2 mmol/L)

Within ± 5mg/dL (within ± 0.28 mmol/L)	Within ± 10 mg/dL (within ± 0.56 mmol/L)	Within ± 15mg/dL (within ± 0.83 mmol/L)
2/3 (67%)	3/3 (100%)	3/3 (100%)

System accuracy results for glucose concentration ≥75 mg/dL (4.2 mmol/L)

Within ±5%	Within ±10%	Within ±15%	Within ±20%
100/147 (68%)	130/147 (88%)	144/147 (98%)	147/147 (100%)

Table 4. Regressions analysis at VENTRAL PALM
Patient VENTRAL PALM vs YSI 2300 Finger

Linear regression	95% CI Slope	95% CI Intercept	R^2	N
y = 0.9834x + 4.4829	(0.966, 1.001)	(-0.332, 9.298)	0.9885	150

Table 5. Data analysis at UPPER ARM
Patient UPPER ARM vs YSI 2300 Finger

System accuracy results for glucose concentration <75 mg/dL (4.2 mmol/L)

Within ± 5mg/dL (within ± 0.28 mmol/L)	Within ± 10 mg/dL (within ± 0.56 mmol/L)	Within ± 15mg/dL (within ± 0.83 mmol/L)
3/4 (75%)	4/4 (100%)	4/4 (100%)

System accuracy results for glucose concentration ≥75 mg/dL (4.2 mmol/L)

Within ±5%	Within ±10%	Within ±15%	Within ±20%
105/146 (72%)	130/146 (89%)	142/146 (97%)	146/146 (100%)

Table 6. Regressions analysis at UPPER ARM
Patient UPPER ARM vs YSI 2300 Finger

Linear regression	95% CI Slope	95% CI Intercept	R^2	N
y = 0.9819x + 4.7354	(0.967, 0.997)	(0.449, 9.022)	0.9909	150

Table 7. Data analysis at FORE ARM
Patient FORE ARM vs YSI 2300 Finger

System accuracy results for glucose concentration <75 mg/dL (4.2 mmol/L)

Within ± 5mg/dL (within ± 0.28 mmol/L)	Within ± 10 mg/dL (within ± 0.56 mmol/L)	Within ± 15mg/dL (within ± 0.83 mmol/L)
2/3 (67%)	3/3 (100%)	3/3 (100%)

System accuracy results for glucose concentration ≥75 mg/dL (4.2 mmol/L)

Within ±5%	Within ±10%	Within ±15%	Within ±20%
102/147 (69%)	125/147 (85%)	141/147 (96%)	147/147 (100%)

Table 8. Regressions analysis at FORE ARM
Patient FORE ARM vs YSI 2300 Finger

Linear regression	95% CI Slope	95% CI Intercept	R^2	N
y = 0.9989x - 0.0575	(0.981, 1.017)	(-5.167, 5.052)	0.9874	150

Table 9. Data analysis at THIGH
Patient THIGH vsYSI 2300 Finger

System accuracy results for glucose concentration <75 mg/dL (4.2 mmol/L)

Within ± 5mg/dL (within ± 0.28 mmol/L)	Within ± 10 mg/dL (within ± 0.56 mmol/L)	Within ± 15mg/dL (within ± 0.83 mmol/L)
1/4 (25%)	3/4 (75%)	4/4 (100%)

System accuracy results for glucose concentration ≥75 mg/dL (4.2 mmol/L)

Within ±5%	Within ±10%	Within ±15%	Within ±20%
98/146 (67%)	124/146 (85%)	140/146 (96%)	146/146 (100%)

Table 10. Regressions analysis at THIGH
Patient THIGH vs YSI 2300 Finger

Linear regression	95% CI Slope	95% CI Intercept	R^2	N
y = 0.9827x + 1.3423	(0.965, 1.001)	(-3.693, 6.377)	0.9875	150

Table 11. Data analysis at CALF
Patient CALF vs. YSI 2300 Finger

System accuracy results for glucose concentration <75 mg/dL (4.2 mmol/L)

Within ± 5mg/dL (within ± 0.28 mmol/L)	Within ± 10 mg/dL (within ± 0.56 mmol/L)	Within ± 15mg/dL (within ± 0.83 mmol/L)
3/4 (75%)	4/4 (100%)	4/4 (100%)

System accuracy results for glucose concentration ≥75 mg/dL (4.2 mmol/L)

Within ±5%	Within ±10%	Within ±15%	Within ±20%
101/146 (69%)	128/146 (88%)	140/146 (96%)	146/146 (100%)

Table 12. Regressions analysis at CALF
Patient CALF vs YSI 2300 Finger

Linear regression	95% CI Slope	95% CI Intercept	R^2	N
y = 0.9907x + 5.6915	(0.974, 1.008)	(0.878, 10.505)	0.9888	150

IMPORTANT:
- Before using the EasyTouch® BluLink® meter and test strips, read all of the operating instructions in the Instructions for use.
- Consult with your Healthcare Professionals on managing your diabetes daily with the EasyTouch® BluLink® brand Blood glucose monitoring system.

OUR COMMITMENT TO YOU:
We understand that self-testing your blood sugar levels provides a way to control your diabetes. As a result, the EasyTouch® BluLink® Blood glucose monitoring system was developed to help you manage your diabetes by the most comfortable and convenient way possible. Our goal is to provide you the best quality products and superior customer service. If you have any questions or comments, please contact customer support toll free: 877-358-4342. MHC Customer Support is available Monday thru Friday, 9 to 5pm Eastern Time.

MHC | MEDICAL PRODUCTS.

Questions or Comments?
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