

**IMPORTANT:** Please read this information and your EasyTouch® HealthPro™ user manual before using the EasyTouch® HealthPro™ Test Strips. MHC Customer Support is available Monday thru Friday, 9 to 5pm Eastern Time. Please call toll free: (877) 358-4342.

## Indications For Use:

The EasyTouch® HealthPro™ Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, ventral palm, dorsal hand, upper arm, forearm, calf and/or thigh. The EasyTouch® HealthPro™ Blood Glucose Monitoring System is intended to be used by a single patient and should not be shared.

The EasyTouch® HealthPro™ Blood Glucose Monitoring System is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes at home and on the go, or by Healthcare professionals in a clinical setting, as an aid to monitor the effectiveness of diabetes control. The EasyTouch® HealthPro™ Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use. Alternative site testing should be done only during steady-state times (when glucose is not changing rapidly).

The EasyTouch® HealthPro™ Glucose Test Strips are for use with the EasyTouch® HealthPro™ Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, ventral palm, dorsal hand, upper arm, forearm, calf and/or thigh.

## General:

EasyTouch® HealthPro™ Glucose Test Strips have new bio-sensor technology, requiring only a tiny drop of blood. The EasyTouch® HealthPro™ Meter can store 365 readings in memory with date & time. All your results are easily downloadable to your computer.

## Storage and Handling:

- Store strips vial in a cool, dry place between 36-86°F (2-30°C). Keep out of direct sunlight. Do not Refrigerate. 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 3 months after 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.
- Test strips are for single use only. Do not re-use.
- Do not perform tests at temperatures below 50°F or above 104 °F.
- Do not perform tests with humidity below 10% or above 90%.
- Avoid getting dirt, food, and water on the color-coding label (backside of test strip).

## Care Procedures:

- Double check that the meter code matches the code number printed on the test strip vial.
- Do not reuse test strips. Strips are for single use only.
- If you experience any symptoms that are not consistent with your test results, call your doctor.
- Do not make significant changes to your diabetes control program without consulting your doctor.
- Do not ignore problems without consulting your doctor.

## 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® HealthPro™ Glucose Test Strip contains:**

Glucose Oxidase (*Aspergillus niger*): 12 µg  
Mediator (Hexaammineruthenium chloride): 100 µg  
Binder: 3.16 µg  
Stabilizer: 47.7 µg

## The procedure for Blood Glucose Measurement:

Materials provided: EasyTouch® HealthPro™ Glucose Test Strips.  
Materials required but not provided: meter, user manual, reusable lancing device, lancets and alcohol prep pads.

## 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.

## CAUTION:

- The EasyTouch® HealthPro™ 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 in the user's manual for cleaning and disinfecting the EasyTouch® HealthPro™ system.

## To obtain 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 test site. 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 user manual for more information).

**CAUTION:** Reusable lancing device is intended for self-monitoring by an individual person only.

**Step 3:** Remove test strip from the vial. Recap the vial immediately to prevent moisture from affecting the other strips. Insert the test strip, into the port of the meter, with the arrow mark facing up. 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, you must change the number accordingly. Refer to owner's manual.

**CAUTION:** You may get an inaccurate result if the blood sample is not completely filled.

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

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

**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 strip.

## Important Information About Using Alternative Sites Testing:

- Alternate 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 alternate sites may differ significantly from fingertip samples.
- The conditions in which these differences are more likely to occur are 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 alternate 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 alternate sites sample.
- Use alternate sites samples only for testing prior to or more than two hours after 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 symptoms to indicate as insulin reaction), as forearm testing may fail to detect hypoglycemia.
- Alternative site testing results should never be used to calibrate continuous glucose monitoring systems.
- Alternative sampling results should never be used in insulin dosing calculations.

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

## 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.

Consult with your doctor immediately in how to treat extremely low blood sugar (hypoglycemia). If the test result is above 600mg/dL, "Hi" will appear on the meter display. This indicates extremely high blood sugar (hyperglycemia). Seek medical assistance immediately.

**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 physician to determine the best range of expected blood glucose values for you.

## Expected blood glucose values for nondiabetic 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(2013) Diabetes Care, Vol 36, 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 doctor.

## Quality Control (System Maintenance):

Control Solution was designed to ensure that the meter and the test strips are working together properly.

**NOTE:** The High (Level 3) and Low (Level 1) Control Solutions are sold separately. Please visit your local pharmacy, or contact MHC Customer Support at (877) 358-4342 for a retailer near you.

The EasyTouch® HealthPro™ Glucose Control Solution is for use with the EasyTouch® HealthPro™ Meter and Glucose Test Strips.

## 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, or if you think they are not accurate.
- 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 enough (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:** If the control solution test results continuously falls outside the range printed on the bottle, the EasyTouch® HealthPro™ system may not be functioning properly. DO NOT use the system to test your blood until you get a control solution test result that falls within the correct range. If you continue to have problems, contact MHC Customer Support immediately at (877) 358-4342.

## Limitations of System:

The EasyTouch® HealthPro™ Glucose 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® HealthPro™ Glucose Test Strips with the EasyTouch® HealthPro™ Meter.
- Use fresh capillary whole blood only.
- The test strips are for single use only. Do not reuse.
- Dehydration may lower test results.
- Inaccurate results may occur when in shock, hypotensive, hyperglycemic, or hyperosmolar state and with or without ketosis.
- Using the test strips above altitudes of 10,000 feet will have an effect on test results.

## Doctors - Please note the following interferences that may affect test results:

- The EasyTouch® HealthPro™ test strip results can be used with hematocrit levels in the range of 20% to 60%. If the hematocrit range is out of the range(20%-60%), then the test results may be lower or higher than 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.
- 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.
- Blood samples that contain a high concentration of dissolved oxygen may lower the test result.
- EDTA containing tube is recommended as an anticoagulant tube.

## Performance Characteristics:

The performance of the test strips has been evaluated in clinical trials. Measurement Range: The measurement range of the EasyTouch® HealthPro™ System is 20 to 600 mg/dL.

## Accuracy:

The accuracy results obtained with the EasyTouch® HealthPro™ System were compared to glucose results obtained with the YSI 2300, a laboratory instrument. Glucose levels were measured on 160 fresh capillary specimens at three different clinical centers.

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

Strip Lot	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)
Lot 1	18/27 (70 %)	26/27 (96 %)	27/27 (100 %)
Lot 2	17/27 (63 %)	27/27 (100 %)	27/27 (100 %)
Lot 3	19/27 (70 %)	25/27 (93 %)	27/27 (100 %)
Combined	54/81 (67 %)	78/81 (96 %)	81/81 (100 %)

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

Strip Lot	Within ±5%	Within ±10%	Within ±15%	Within ±20%
Lot 1	90/133 (68%)	120/133 (91%)	132/133 (99%)	133/133 (100%)
Lot 2	73/133 (55%)	114/133 (86%)	128/133 (96%)	133/133 (100%)
Lot 3	79/133 (59%)	111/133 (83%)	130/133 (98%)	132/133 (99%)
Combined	242/399 (61%)	345/399 (86%)	390/399 (98%)	398/399 (99%)

The study shows that the EasyTouch® HealthPro™ System compares well with the laboratory method.

## Precision:

Precision Results for venous blood samples and control solutions. Precision Results for venous blood samples.

	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5
Mean (mg/dL)	44.7	80.8	132.2	202.4	313.0
SD (mg/dL)	1.7	2.2	3.2	5.9	7.5
CV (%)	3.8	2.8	2.5	2.9	2.4

## Precision Results for control solutions.

	Sample 1	Sample 2	Sample 3
Mean (mg/dL)	51.0	111.3	303.8
SD (mg/dL)	1.8	2.2	5.9
CV (%)	3.5	1.9	1.9

## Alternative Site Testing Accuracy:

The EasyTouch® HealthPro™ system was approved for alternative site testing accuracy by comparing blood glucose results of alternate sites measured by patients and health professionals using the EasyTouch® HealthPro™ system.

## IMPORTANT:

- Before using the EasyTouch® HealthPro™ Meter and Test Strips, read all of the operating instructions in the user manual.
- Consult with your doctor on daily management of your diabetes with the EasyTouch® HealthPro™ brand system.
- If you have any questions about use of the products, please call MHC Customer Support at (877) 358-4342.

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