# Easy•Touch® HealthPro Glucose Monitoring System

User Manual

# Dear **Easy • Touch**® HealthPro™ Glucose Monitoring System Owner

Thank you for choosing the EasyTouch® HealthPro™ Glucose Monitoring System. This manual contains everything you need to know about your new glucose meter and how it works. Please read the complete manual before using the EasyTouch® HealthPro™ Glucose Monitoring System.

The EasyTouch® HealthPro™ Glucose Monitoring System offers a fast, accurate, and convenient way to read your glucose levels. The meter has been designed to automatically turn on when the test strip is inserted into the meter, automatically code the meter to the strip, and automatically turn off after the reading. Please take a moment to read this manual to learn of more convenient features to help you manage your diabetes. After doing so, we hope you will agree, the EasyTouch® HealthPro™ Glucose Monitoring System is designed to offer a better user experience.

Always consult with your healthcare professional before making any changes to your diabetes management. The EasyTouch® HealthPro™ Glucose Monitoring System is for in-vitro diagnostic use only. MHC Customer Service is available toll free at (877) 358-4342, Monday thru Friday, 9am to 5pm EST.

#### Intended Use

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

The EasyTouch® HealthPro™ Glucose Monitoring System is intended for self-testing by people with diabetes at home and on the go, and also for healthcare professionals in a clinical setting. The EasyTouch® HealthPro™ 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 blood samples drawn from the fingertips, ventral palm, dorsal hand, upper arm, forearm, calf and/or thigh.

The EasyTouch® HealthPro™ Glucose Control Solutions are for use with the EasyTouch® HealthPro™ Meter and Test Strips to check that the meter and test strips are working together properly. The test also serves as a quality control to ensure the accuracy of the glucose test results.

## **Important Information**

The EasyTouch® HealthPro™ Glucose Monitoring System provides a quick and easy way for patients with diabetes to measure their blood sugar levels.

It should only be used with fresh capillary blood samples. It is designed for in-vitro diagnostics use only and should not be used for any purpose other than monitoring blood sugar levels. It should not be used for the diagnosis of diabetes or for the testing of newborns (neonates).

#### WARNING:

Do not change your medication based on the EasyTouch® HealthPro $^{\!\top\!}$  meter test results without contacting your physician or healthcare professional.

#### Important Safety Instructions

The Centers for Disease Control and Prevention (CDC) and the US Food and Drug Administration (FDA) have become increasingly concerned about the risks for transmitting Hepatitis B virus (HBV) and other blood born pathogens to persons undergoing finger stick procedures for blood sampling (Ex. Persons with diabetes who require assistance monitoring their blood glucose levels). Reports of HBV infection outbreaks linked to diabetes care have been increasing. This notice serves as a reminder that finger stick devices should never be used for more than one person.

#### WARNING:

- The EasyTouch® HealthPro™ Meter and Lancing Device are for single patient use only. Do not share them with anyone, including other family members. Do not use on multiple patients.
- All parts of the kit are considered bio-hazardous and can potentially transmit infectious diseases, even after you have cleaned and disinfected.
- 3. Always use a new sterile lancet. Lancets are for single use only.
- 4. Avoiding getting hand lotions, oil, dirt or debris in and/or on the lancets and lancing device.
- 5. Please refer to page 33 for cleaning and disinfecting the EasyTouch® HealthPro™ Glucose Monitoring System.

<sup>&</sup>quot;FDA Public Health Notification: Use of Finger stick Devices on More than One Person Poses Risk for Transmitting Blood born Pathogens: Initial Communication Update 11/29/2010"

http://www.fda.gov/medicaldevices/safety/alertsandnotices/ucm224025.htm

<sup>&</sup>quot;CDC Clinical Reminder: Use of Finger stick Devices on More than One Person Poses Risk for Transmitting Blood born Pathogens" (2010) http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html

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# About your New **Easy •Touch**® HealthPro™ Glucose Monitoring System

#### EasyTouch® HealthPro™ Kit Contents

#### The following items are included:

- 1. EasyTouch® HealthPro™ Meter
- 6. 10 Twist Lancets

2. Carrying Case

7. 1 Lancing Device

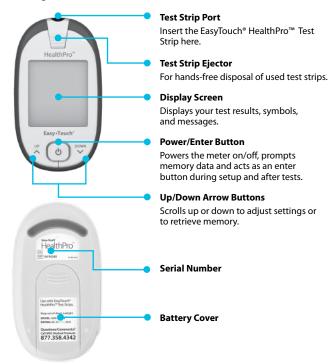
- 3. Instruction Manual
- 4. Logbook
- 5. Two 3V Coin Batteries, CR2032

Your EasyTouch® HealthPro™ Glucose Monitoring System has been sealed to protect the contents. If you find your seal has been broken, please return it to the place of purchase.

## **Easy • Touch**® HealthPro™ Meter

## **Easy • Touch**® HealthPro™ Meter Display

#### **Meter Diagram**



#### CAUTION:

Do not use the EasyTouch® HealthPro™ Glucose Meter in an environment with humidity below 10%, especially if synthetic materials are present. Synthetic clothes, carpets, etc., may cause damaging static discharges in an arid environment.

#### **Display Layout**



#### **Symbol Bank**



Low Battery Warning Symbol



**Alarm Symbol** 



**Troubleshooting Symbol** 

ALL DEL AVG

**Delete Results** 



**Average Test Result System** 



**Before Having a Meal** After Having a Meal





**After Taking Medication** 



**After Sport Activity** 



**Control Solution Symbol** 



**Blood Drop Symbol for Test** 



Strip Code Symbol



**Test Result Unit Symbol** 



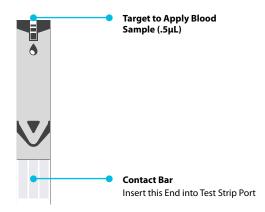
Temperature / Date

88:88

Time / Test Result Amount

## **Easy • Touch**® HealthPro™ Glucose Test Strips

#### **Test Strip Diagram**



- Store the EasyTouch® HealthPro™ Test Strip vials in a cool, dry place. Keep out of direct sunlight. Do not freeze.
- 2. Store test strips in their original vial only. Do not mix the test strips in new vials or in any other container.
- 3. Immediately replace the vial cap and close tightly after removing any test strips from the vial.
- Make a note of the discard date, which is three months from the date you first open a new vial of strips. Throw the EasyTouch® HealthPro™ Test Strips and vial away after the discard date.
- 5. Do not use the test strips after the expiration date printed on the package or vial since it may cause inaccurate results.
- 6. EasyTouch® HealthPro™ test strips are for single use only. DO NOT RE-USE.
- 7. Do not test at temperatures below 50°F, or above 104°F.
- 8. Do not test with humidity below 10% or above 90%.
- 9. Do not bend, cut, or alter the test strip.
- 10. Avoid getting dirt, food, and/or water on the test strip.
- 11. Avoid getting dirt, food, and/or water on the vial label.
- Refer to additional information in the EasyTouch® HealthPro™ Test Strip package.

## **Before Your Test**

Make sure to read this section and the test strip package insert found in the test strip box carefully. You will need to have all of the necessary items to begin testing:

#### **Necessary Items:**

- 1. EasyTouch® HealthPro™ Meter
- 2. EasyTouch® HealthPro™ Test Strip
- 3. Lancing Device
- 4. Sterile Lancet

If the meter is moved from one temperature to another, allow 30 minutes for the meter to adjust to the new temperature before testing. Make sure that the EasyTouch® HealthPro™ Meter and Test Strips have adjusted to the temperature of the location from where you are testing. Do not operate the EasyTouch® HealthPro™ system in direct sunlight.

#### CAUTION:

To reduce the chance of infection:

- 1. The lancing device and sterile lancets should NOT be shared with others.
- 2. Always use a new sterile lancet and a new glucose test strip.
- 3. Practice using the lancing device and become accustomed with its use.
- 4. Lancets and glucose test strips are for single use only.
- 5. Wash your hands with soap and warm water before testing.
- 6. Avoid getting hand lotion, oils, dirt or debris on the lancets or on the lancing device.
- 7. Dry your hands completely before testing.

## **Comparing Your Meter & Lab Results**

Test results with the EasyTouch® HealthPro™ Glucose Monitoring System are plasma-equivalent. This method will help you and your healthcare professional compare your meter results with laboratory test results. The EasyTouch® HealthPro™ test results and laboratory test results both are expressed in plasma-equivalent units. However, your glucose monitor results may differ from your laboratory results due to normal variation. Your glucose monitor results can be affected by factors and conditions that do not affect laboratory results in the same way.

Your EasyTouch® HealthPro™ monitor value is considered accurate when it is within ± 20% of the laboratory measurement. There are some specific situations that could cause a difference of more than ± 20%.

- 1. You are severely dehydrated.
- You have eaten recently. The blood glucose level from blood obtained from a fingertip can be up to 70mg/dL higher than blood drawn from a vein (venous sample) used for a lab test.
- Your hematocrit is above 60% or below 20%. Sacks, D.B.: Carbohydrates: Carbohydrates: Burits, C.A. and Ashwood, E.R. (ed.), Tietz Textbook of Clinical Chemistry. Philadelphia: W.B. Saunders Company (1994), 959

If you perform a blood sugar test with the system at a temperature near the low end of the operating range, it could result in a false high blood sugar. Repeat the test in a warmer environment with a new test strip as soon as possible. For additional information on possible limitations for accuracy on precision, please refer to your test strip insert. In order to make the most accurate comparison to your laboratory results, please follow a few basic quidelines:

#### Before going to the Lab

Do not eat for at least two hours before you test your blood. Perform a control solution test to make sure the meter is working properly. Take your meter with you to the lab.

#### While at the Lab

Follow all instructions in this owner's booklet for performing a blood sugar test with your meter. Conduct your meter test within 15 minutes of lab test. Use only fresh capillary blood obtained from the fingertip.

You may still experience a difference from the laboratory test results because blood sugars can change very rapidly over a short period of time. This is due to a variety of reasons such as exercise, medication, stress or loss of body fluids.

## **Battery Installation**

To begin, place the meter on a flat surface and take the back of the battery cover off the meter. Both batteries are to be inserted into the meter with he Positive (+) side of the battery facing upward, away from the prongs. Replace the battery cover. The batteries will lock into place once the battery cover is slid back onto the meter.







**NOTE:** Make sure the Positive (+) side of the batteries face upward, away from the prongs



#### Low Battery/Battery Replacement:

The low battery icon will appear in the upper left corner of the LCD display to alert you when the battery power is running low, indicating a new battery is needed immediately.

Your EasyTouch® HealthPro™ Meter uses only two 3V lithium batteries (CR2032), which are included. When replacing the batteries, only CR2032 or equivalent lithium battery should be used.

#### Follow-up Action:

- 1. Check your meter with the glucose control solution.
- 2. Perform your test again.
- 3. If you are experiencing symptoms that are not consistent with your blood glucose test results, call you healthcare professional.

#### NOTE:

Make sure your date and time are correct after changing your battery.

## **Setting Up Your Meter**

The EasyTouch® HealthPro™ Meter has a wide variety of functions from which to choose. From the setup mode you have the ability to turn activity/meal flags, set the date/time, designate three averages and set up to five daily alarms.



#### Power On

Press & for at least 3 seconds.



#### **User Activity Option**

After pressing and releasing either ▲ or ▼ buttons to turn the User Activity Option on/off, confirm with ♂. For more detail, turn to page 16.



#### Year

After pressing and releasing either ▲ or ▼ buttons to set the year, confirm with ⇔.



#### Date / Time

After pressing and releasing either ▲ or ▼ buttons to set the date and time, confirm each with ♂.



#### Test Unit

Your meter is pre-set to mg/dL as test units. Just confirm it with  $\phi$ . The correct units of the measurement in U.S. are mg/dL.



#### **Temperature Unit**

Press and release either ▲ or ▼ buttons to set °C or °F, confirm with ♂.

## **Setting Up Your Meter, Cont.**



#### Days for Avg.

After pressing and releasing either ▲ or ▼ buttons to set the number of days, confirm with ⇔.



#### Alarm On/Off

After pressing and releasing either ▲ or ▼ buttons to turn the alarm on/off, confirm with ♂.



#### **Alarm Time**

After pressing and releasing either ▲ or ▼ buttons to set the alarm hour and minute, confirm with ♂.



#### Alarm

After programming the number of desired alarms (5 alarms possible), confirm with (b).

#### IMPORTANT:

- 1. Your EasyTouch® HealthPro™ Meter is pre-set to mg/dL as test unit. If you find out that the meter is not set to mg/dL, please contact MHC Customer Support at (877) 358-4342 immediately.
- 2. The correct units of the measurement in U.S. are mg/dL.
- 3. Without setting the date properly, the average glucose level and the results in memory will not show proper values. It is recommended to set the meter before use immediately after new batteries are installed.
- 4. You can't test your blood glucose in the setting mode.
- 5. To turn the meter off during the setup, press  $\ensuremath{\mathfrak{G}}$  for at least 5 seconds.

## **User Activity Options**

These options give you the choice for the meter to save your chosen activity with your glucose reading in the memory of the meter. These activity options may be turned off, SEE OPTION 2. See option 1 if you would like to continue using Activity Options.

#### Option 1

Before each glucose test, you must choose an Activity Option using the Up or Down Arrow on te meter to scroll through the Activity Options and then use the Power Button to select the Activity Option chosen for the glucose reading to move forward to the glucose test. The next screen on the meter will show a test strip symbol prompting you to begin your glucose test.

#### **User Activity Options:**

Before Having a Meal

After Having a Meal

After Taking Medication

After Sport Activity

Control Solution Symbol

#### Option 2

Turn off Activity Options. To turn off Activity Options and move forward with a glucose reading, you must hold down the Power Button for 5-6 seconds until you see the word ON. Use the Up Arrow to change the setting to OFF, thus turning off Activity Options. After this step, the user must continue following the setup instructions on page 14.

## **Auto-coding Function**



 The EasyTouch® HealthPro™ has an automatic code recognition function.

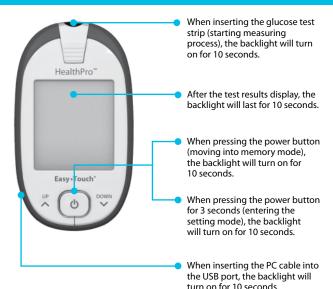


The code number on the glucose meter is set automatically and should match the code on your test strip vial.

#### CAUTION:

- 1. Do not bend the glucose test strip. Bending could cause automatic code recognition failure.
- If the code recognition label is damaged, the code recognition may fail. Please check the code number on the LCD window with the code number on the test strip.

## **Backlight Function**



#### **Performing a Control Solution Test**

The control solutions contain a known amount of glucose that reacts with the EasyTouch® HealthPro™ Glucose Test Strips. By comparing your control solution test results with the expected range printed on the test strip vial, it is able to check if the meter and test strips are working properly and that you are performing the test correctly. It is very important that you perform the control solutions test routinely to make sure you get accurate results.

#### The glucose control solution should be used:

- Whenever you suspect the glucose test meter or glucose test strip is not functioning properly.
- If your glucose test results are not consistent with your symptoms or if you think they are not accurate.
- If you have dropped the blood glucose test meter.
- · For quality control in the point of care usage.
- · For teaching or learning the system.

## Testing with the **Control Solution**



Firmly insert the test strip into the meter test port. Insert down firmly in direction of arrow on test strip. Do not insert the glucose test strip upside down. When you insert the glucose test strip into the glucose meter, the meter will automatically turn on and identify the strip code.



If activity/meal is ON, scroll through the icons with the ▲ or ▼ button until the control solution bottle is blinking: press ♂.



If activity/meal is OFF, press and release either the ▲ or ▼ button until the icon appears; press &.



Check the expiration date before performing a control solution test. Do not use if expired. Please note the expiration date on the control solution bottle.



Gently shake the control solution before use.



Discard the first drop of control solution, this will eliminate any residue. Place a drop of control solution on a clean dry surface (e.g. the lid of the test strip vial).



Dip the test strip into the control solution. Results will appear in 5 seconds. Compare the result to the range printed on the test strip vial, the result should fall within that range.

## Testing with the **Control Solution, Cont.**

#### **CAUTION:**

The Control Solution Range is printed in the lower right of the test strip vial label. This will allow you to differentiate between a control solution test and an actual blood test.

#### For example:

If you are using the High (Level 3) Control Solution, according to this particular vial of strips, your meter should show a number between 255 and 345. Likewise, if you are using the Low (Level 1) Control Solution, your meter should show a number between 35 and 65.



**Note:** The control values on the test strip vial shown in the picture are not control ranges. The control ranges of the control solutions are much greater.

#### ATTENTION:

- It is recommended that glucose control solution is stored at room temperature (46-86°F/8-30°C) before testing.
- Check the expiration date before performing a glucose control solution test.
- 3. Do not use if expired. Once opened, the control solution expires after 3 months.

## If your control solution test falls out of range, please follow the next steps before contacting MHC Customer Support:

- Check the expiration dates on all the products you are using. Be sure you
  are using EasyTouch® HealthPro™ Glucose Control Solution.
- Try another control solution test.
- If this test falls out of range, try another control solution test with a new unopened bottle of strips.
- If the control test still falls out of range after following the appropriate steps do not perform a glucose test. Please call our toll free MHC Customer Support at (877) 358-4342.

## **Follow-up Actions**

- 1. Check your meter and strip with the glucose control solution.
- 2. Perform your test again.

#### CAUTION:

- If your glucose control solution falls out of range, do not perform a glucose test and please contact MHC Customer Support at (877) 358-4342.
- 2. The glucose control solution range is not the recommended range for your blood glucose level.
- 3. Please discard control solutions according to your local regulations.

## **Performing Your Test**

#### Performing a Blood Test with Your Fingertip

#### Step 1



Firmly insert the test strip into the meter test port. Insert down firmly in direction of arrow on test strip. Please do not insert the glucose test strip upside down. When you insert the glucose test strip into the glucose test meter, the meter will automatically turn on with the code and temperature.



Make sure the code number matches the code on the strip bottle (e.g. C21). The meter automatically recognizes the test strip code number and adjusts the meter accordingly.



If during the setup process you chose to use the activity/ meal flags ( $\bullet$ ,  $\uparrow$ ,  $\bullet$ ,  $\not$ ), press and release  $\blacktriangle$  or  $\blacktriangledown$  button to select the activity that will correlate with your results, then press and release  $\circlearrowleft$ .



A blinking test strip will appear at the top of the screen indicating the meter is ready for testing.

#### CAUTION:

- 1. If the code is not displayed automatically, pull the glucose test strip out of the port, and re-start the procedure from the beginning.
- 2. If the code on the LCD display window and on the glucose test strip vial does not match, try another new glucose test strip. If the mismatch persists, please contact MHC Customer Support for help.
- 3. For a more accurate test result, avoid testing under direct sunlight.
- 4. If you apply your blood sample before the blood symbol blinks, Er5 message will appear on LCD (Please refer to Page 38).

## **Performing Your Test, Cont.**

#### Step 2

Before obtaining a blood sample, wash your hands with soap and warm water. Dry hands completely before testing.

#### WARNING:

- The EasyTouch® HealthPro™ Meter and Lancing Device are for single patient use only. Do not share them with anyone, including other family members. Do not use on multiple patients.
- 2. All parts of the kit are considered bio-hazardous and can potentially transmit infectious disease, even after you have performed cleaning and disinfection.
- 3. Avoiding getting hand lotion, oil, dirt or debris in or on the lancets (single use only) and the lancing device.
- Please refer to page 33 for cleaning and disinfection your EasyTouch® HealthPro™ Glucose Monitoring System.
- 5. Wash your hands thoroughly with soap and warm water after handling the meter, lancing device and/or test strip.



Unscrew the lancing device cap.



Insert a sterile lancet into the lancing device.



Twist the protective cover off.
Do not discard.



Replace the lancing device cap by twisting it on tightly.



Depth setting: Use 1-2 for soft skin, 3 for avg. skin, 4-5 for thick or calloused skin



Pull the end of the lancet device back.



To prick your finger, push the center button

#### CAUTION:

- 1. If the blood smears or runs, do not use that sample. Dry the area and gently squeeze another drop or puncture a new site.
- 2 Do not share reusable lancing device with anyone, including other family members.

## **Performing Your Test, Cont.**

#### Step 3

#### Correct





#### Incorrect





The EasyTouch® HealthPro™ Meter only requires 0.5 μL sample volume.

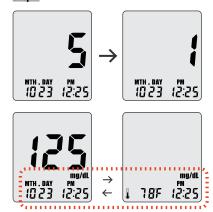
- Place the edge of the test strip to the drop of blood.
- The blood will automatically be drawn into the test strip channel.
- When the test strip has collected a large enough blood sample the meter will automatically count down.

#### CAUTION:

- 1. If the countdown does not start, do not add more blood to the glucose test strip. Discard the glucose test strip and start over with a new strip.
- If you do not conduct the test within 5 minutes, the glucose test meter will automatically power off to save battery life. In this case the test procedure should start again from the beginning.
- 3. You may get an inaccurate result if the blood sample does not completely fill the test strip channel.

## **Performing Your Test, Cont.**

#### Step 4



- After the beeping sound, the test will begin automatically and your results will appear in 5 seconds. It should begin counting down from 5 to 1 second on the LCD display window. The LCD window will display the result of your blood glucose level, temperature and time.
- Record the result value in your logbook. When the glucose test strip is removed, the glucose test meter turns off automatically.

#### CAUTION:

- If the test result is out of the test range, the Hi/Lo message will be shown on the LCD. Please contact your healthcare provider immediately if there is a Hi/Lo result.
- 2. Please contact your healthcare provider for instructions on disposing glucose test strips and lancets.

## **Performing Your Test, Cont.**

#### **Removing and Disposing of Used Test Strip**



Once the test is complete, push the strip forward to remove the test strip from the meter.

Used test strips may be considered bio-hazardous waste in your area. Be sure to contact your healthcare provider for instructions on disposing the test strips.

#### **Disposing of Your Lancet**



Push the needle into the protective cover.



Slide the button forward to eject the lancet. Be sure to contact your healthcare provider for instructions on disposing the lancets.

## **Reviewing Your Results**

The EasyTouch® HealthPro™ Meter stores up to 365 test results in its built-in memory, along with the average sugar level for the number of days, which you had preset the glucose test meter to calculate.

#### **Reviewing Your Blood Sugar**



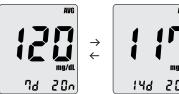
Third Latest

Second Latest

Latest

Press and release & button. The most recent result appears first. Note the time and day of your blood sugar result. Press and release the ▼ button and your previous result will appear on the display.

#### **Reviewing Your Average**



7-Day Average from the Test Date 20n

14-Day Average from the Test Date

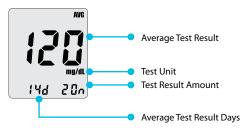


21-Day Average from the Test Date

Press and release the **\( \Delta\)** button and your average result will appear on the display.

## **Reviewing Your Results, Cont.**

#### **Results Diagram**





#### **Deleting Individual Test Result**

To delete any individual test result in the memory, press ▲ or ▼ button for 3 seconds. While the test result is being deleted, the **DEL** message will blink. After the second beep sound, the deletion will be completed.



#### **Deleting All Test Results**

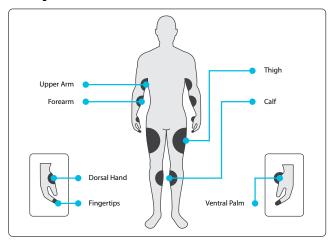
To delete all test results in the memory press ▲ and ▼ button for 3 seconds. While the test result is being deleted, **ALL DEL** message will blink. After the third beep sound, the deletion will be completed.

#### **CAUTION:**

The deleted test results cannot be recovered. Please be careful in deleting the test results.

## **Alternate Site Testing**

#### **AST Diagram**



The EasyTouch® HealthPro™ Glucose Monitoring System gives you the ability to obtain a blood sample for testing your sugar from different areas of your body. The figure shown above displays the areas where you can test using your EasyTouch® HealthPro™ Meter. You may test you blood sugar from your forearm, upper arm, palm (ventral palm or dorsal hand), fingertips, thigh, or calf. It is recommended that alternate site testing be used when sugars are stable: before meals and before bedtime. However, when sugars are changing, blood from the fingertip may show these changes sooner than blood from other sites

#### LIMITATION:

- 1. Alternative site testing results should never be used to calibrate continuous glucose monitoring systems.
- 2. Alternative sampling results should never be used in insulin dosing calculations.

# Lancing and Sampling from an **Alternate Site Area**

Sampling from your upper arm, forearm, dorsal hand, ventral palm, thigh, or calf allows you to use your fingertips less often. You may find that obtaining a blood sample from an alternate site is less painful than using a fingertip. Getting a blood sample from your forearm or palm is different than getting a sample from your fingertip.

#### Ventral Palm/Dorsal Hand

Choose a fleshy area on the palm, below your thumb or pinky finger. Select a spot without any visible veins and away from any deep lines. This may cause your blood sample to smear.

#### Forearm/Upper Arm/Calf/Thigh

Choose a fleshy area of the forearm, upper arm, thigh, or calf away from bone, visible veins and/or hair. Sometimes there is less blood flow to these areas than to the fingertip. To help you get a large enough drop of blood, you may gently message or apply a heating pad to the site to increase blood flow.

#### IMPORTANT:

We recommend that you test on your fingertips if you are testing for hypoglycemia (low blood glucose) or if you are suffering from hypoglycemia unawareness.

# Lancing and Sampling from an Alternate Site Area, Cont.

#### Accuracy

To ensure accurate results when lancing your arm (forearm or upper arm), leg (calf or thigh), or palm (ventral palm or dorsal hand), clean the test site with soap and warm water. Make sure there is no cream or lotion on the test site. Thoroughly dry your hands and test site.

#### WARNING:

To reduce the chances of getting infection never share a lancet or a lancing device with anyone.

## Lancing Using the Clear Cap for an **Alternate Site Area**



1. Remove the lancing cap by twisting off.



Insert lancet and replace with the clear cap.



 Rub the test site for a few seconds until you feel it getting warm. Applying heat may be heloful.



 Continue to hold the lancing device and gradually increase pressure for several seconds.



5. While holding the lancing device on your test site, look through the clear cap until a round drop of blood appears.



 Lift the lancing device straight up; be careful not to smear the blood on your testing site.



7. Place the edge of the test strip to the drop of blood. The blood will automatically be drawn up.

# Lancing Using the Clear Cap for an Alternate Site Area, Cont.

#### REMEMBER:

- Consult with your healthcare professional before using alternate site testing.
- 2. Choose a different puncture site each time you test. Repeated punctures in the same spot may cause soreness and calluses.
- 3. If bruising occurs at an alternate site or you have difficulty getting a sample, consider sampling from a fingertip instead. You may want to review the choice of sites with your healthcare professional.
- 4. Do not share lancing device with anyone, including other family members.

#### **CAUTION:**

Do not test on your upper arm, forearm, dorsal hand, ventral palm, thigh, or calf when:

- 1. You think you blood glucose is rapidly falling. For example within two hours of exercise, rapid-action insulin injection, or an insulin pump bolus.
- 2. Testing with a fingertip sample may identify hypoglycemia or an insulin reaction sooner than testing with a forearm or palm sample.

## Caring for Your **EasyTouch®** HealthPro™ System

#### **Cleaning Your Meter and Maintenance**

Why should cleaning and disinfecting the meter and the lancing device be performed?

Blood glucose meters and lancing devices are at the high risk of becoming contaminated with blood born pathogens such as Hepatitis B Virus(HBV). Transmission of this virus has been documented due to contaminated blood glucose devices. According to the Centers for Disease Control and Prevention, cleaning and disinfection of meters and lancing devices can prevent the transmission of this virus through indirect contact.

The cleaning is to remove soil and dirt on all surfaces of the devices while the disinfecting is to kill the blood born pathogens stated above.

In addition, whenever the meter gets dirty and has blood or liquid on it, the cleaning and disinfecting procedure should be performed. It also should be cleaned and disinfected periodically. We recommend that you perform the cleaning and disinfecting procedures on it once per week.

#### Materials Needed:

Cleaning and disinfecting can be completed by using any commercially available EPA-registered disinfectant with the EPA registration number 46781-8, such as CaviWipesXL<sup>™</sup> towelettes. Please refer to the disinfectant labeling for additional instructions on the safe use of the disinfectant.

#### NOTE:

- 1. Please note any disinfectant product with the EPA registration number of 46781-8 may be used on this device. Other cleaning agents have not been validated with the meter and lancing device.
- Please call MHC Customer Support at (877) 358-4342 if you have any questions regarding proper cleaning and disinfection procedure and purchasing the materials needed.

## Caring for Your **EasyTouch**® HealthPro™ System, Cont.

#### **Cleaning and Disinfecting Procedures**

- Wash your hands before performing cleaning and disinfecting procedures.
- Remove a wipe from the container and follow the product label instruction to clean and disinfect.
- 3. Check if the meter is turned off.
- 4. Wipe the outside of the meter carefully. (3 horizontal and vertical passes.)
- 5. Dispose of used wipes.
- 6. Wash your hands thoroughly with soap and warm water after handling the meter, lancing device or test strips.
- 7. Whenever the reusable lancing device gets dirty and has blood or liquid on it, cleaning and disinfection procedure should be performed. It also should be cleaned and disinfected periodically. We recommend that you performed the cleaning and disinfection procedures on it once per week.









- To clean the meter, wipe it with an approved disinfecting towelette.
- To disinfect the meter, wipe it with another towelette and leave it wet for two minutes.

#### NOTE:

- 1. The meter should be cleaned prior to each disinfection. (Two disinfecting towelettes in total.)
- To achieve disinfection of the stated efficacy kill claim, the meter and lancing device should remain visibly wet for two minutes after disinfecting.
- 3. Take extreme care not to get liquid in the test strip, test strip port, control buttons and data port. Do not use spray of any sort.

#### CAUTION:

If the meter is being operated by a second person who is providing testing assistance to the user, the meter and lancing device should be decontaminated prior to use by the second person.

## Caring for Your **EasyTouch**® HealthPro™ System, Cont.

### **Lancing Device**

- 1. Wash your hands before performing cleaning and disinfecting procedures.
- 2. Remove a wipe from the container and follow the product label instruction to clean and disinfect.
- 3. Check to make sure used lancet has been removed.
- 4. Wipe the outside of the reusable lancing device carefully.
  - \* To clean the lancing device, wipe it with an approved disinfecting towelette.
  - \* To disinfect the lancing device, wipe it with another towelette and leave it wet for two minutes.

#### CAUTION:

- · To achieve disinfection of the stated efficacy kill claim, the lancing device should remain visibly wet for two minutes after the completion of disinfecting.
- 5. Dispose of used wipes.
- 6. Wash your hands thoroughly with soap and warm water after handling the lancing device.
- 7. Whenever the reusable lancing device gets dirty and has blood or liquid on it, cleaning and disinfection procedure should be performed. It also should be cleaned and disinfected periodically. We recommend that you performed the cleaning and disinfection procedures on it once per week.

Your EasyTouch® HealthPro™ Meter has an expected life of at least 3 years and should withstand the cleaning and the disinfecting recommended in this User Manual. We tested the meter and the lancing device with CaviWipes™ representing daily cleaning and disinfecting (two separate steps) for three (3) years (Once per day (365 days) x 3 years x 2 cleaning/disinfecting steps for a total of 1,095 times) and did not observe any change in performance, accuracy, or appearance.

#### NOTE:

If any of the following physical and/or functional signs of deterioration appear after cleaning and disinfecting the devices, stop using and contact MHC Customer Support at (877) 358-4342.

- Cloudy meter display
- Meter displays broken character or icons
- Meter will not power on
- Meter buttons or strip ejector does not function
- · Control solution test falls out of range
- Lancing device does not function

## Caring for Your **EasyTouch**® HealthPro™ System, Cont.

#### WARNING:

Do not share lancing device with anyone, including other family members.

#### Storage of your EasyTouch® HealthPro™ System

To avoid the meter and test strips from accumulating dirt, dust or other contaminants, please wash and dry your hands thoroughly before use.

#### Meter Storage:

- Storage conditions: 36-86°F or 2-30°C (Temperature)
- Always store or transport the meter in its original carrying case.
- Avoid dropping and strong impact.
- Avoid direct sunlight.

#### Strip Storage:

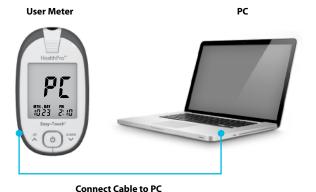
- Storage conditions: 36-86°F or 2-30°C (Temperature)
- Store your test strips in their original vial only. Do not transfer to other container.
- Store test strip packages in a cool and dry place. Keep away from direct sunlight and heat.
- After removing a test strip from the vial, immediately replace the vial cap and close it tightly.
- · Record the expiration date (3 months after opening the test strips) on the strip label.
- Do not use if expiration date has passed.
- Use the test strip with clean and dry hands.

#### Control Solution Storage:

- Storage conditions: Store in a cool, dry place between 46-86 °F or 8-30 °C (Temperature).
- After use, close cap tightly.
- Record the expiration date (date opened plus 3 months) on the control solution on the bottle.
- Do not use if expiration date has passed.

## **Transferring Your Results**

You can transfer test results from the EasyTouch® HealthPro™ Meter to a computer. You will need to download the software from the following web site (http://www.mhcmed.com > Products > HealthPro) and purchase the computer cable from your local pharmacy or call MHC Customer Support for a retailer near you. \*The cable is sold separately.



## **Troubleshooting**

The following chart may help you identify certain problems, but may not solve all problems that can occur. Contact your authorized representative or MHC Medical Products customer support if the problem persists.

Message	What it means	Action required
MTH. DAY PM 10:2 1	Hardware is defective.	Reboot the meter by removing and then replacing the batteries while no test strip is inserted. Contact MHC Customer Support at (877) 358-4342 if the problem persists.
M.H. 195 S 1 15:5 1	Test strip may be contaminated or used.	Please insert a new glucose test strip and perform your test again.
MTH - DAY PM 10 23 12:2 1	Insufficient amount of sample blood is placed on the test strip.	Please insert a new glucose test strip and apply the blood sample until confirming the window is completely filled.
MTH - DAY PM 10 23 12:2 1	Inadequate sample of blood or control solution on test strip.	Please insert a new glucose test strip and perform your test again.
MTH - DAY PM 10 23 12:2 1	Blood sample is placed on the test strip before the symbol for blood blinks.	Wait for the meter to display the blinking icon before applying your blood sample.

## **Troubleshooting, Cont.**

Message	What it means	Action required
CHK PA 12:2 1	Color bar of the strip is dirty, not good or there is too much light. Action required.	Please insert a new glucose test strip and perform your test again. Contact MHC Customer Support at (877) 358-4342 if the problem persists.
CHK CHK	The ambient temperature is less than 50°F (10°C).	Place the meter at a temperature between 50-104°F (10-40°C) for 10 minutes or more and test again.
H 42E	The ambient temperature is over 104°F (40°C).	Place the meter at a temperature between 50-104°F (10-40°C) for 10 minutes or more and test again.
10 23 12:2 1	The test result is lower than 20mg/dl.	If "Lo" appears on the LCD screen for the Glucose result, the measured concentration is below 20mg/dl. The test should be repeated to ensure that the test procedure was done correctly. If you are certain the meter is functioning correctly and that no errors were made during the test procedure and the blood glucose is still consistently measured as "Lo", the result may indicate severe hypoglycemia (low blood glucose). You should inform your health care professional immediately.

## **Troubleshooting, Cont.**

Message	What it means	Action required
MTH. DAY PM 1023 12:21	The test result is higher than 600mg/dl.	If "HI" is displayed for the glucose result, the measured concentration is above 600mg/dl. The test should be repeated to ensure accuracy. If you are certain the meter is functioning correctly and that no errors were made during the test procedure and the blood glucose is still consistently measured as "HI", the result may indicate severe hyperglycemia (high blood glucose). You should inform your health care professional immediately.
•••	There are no readings stored in the meter.	-
ave	Not enough readings in the memory to display designated averages.	-
The glucose test meter does not power its ON.	Battery is dead or there is a problem with the meter.	Change the battery and if the problem persists, contact your local representative.
The glucose test meter does not start after applied blood sample.	Insufficient amount of blood.	Please insert a new test strip and perform your test again.
The results are inconsistent.	There may be a problem with the glucose test strip.	Please insert a new test strip and perform your test again.

## **Inconsistent or Unexpected Test Results**

If you continue to get unexpected results, check your system with the control solution. If you experience symptoms that are not consistent with your glucose results, review and follow all instruction in this manual. Never ignore symptoms or make significant changes to your diabetes control program. Inform health care professional of symptoms and/or concerns.

#### CAUTION:

- Low Glucose Results: If your result is lower than 70mg/dL, it may mean hypoglycemia (low blood sugar). This may require immediate treatment according to your healthcare professional's recommendations. Although this result could be due to a test error, it is safer to treat first.
- 2. High Glucose Results: If your test result is higher than 180 mg/dL, it may mean hyperglycemia (high blood sugar). If you are uncertain about your test results, consider re-testing. Your health care professional will help you to decide how to take action. If the meter displays HI all the time, please re-test your blood sugar. If it's still higher, please contact your healthcare professional immediately.

#### Range of Expected Values:

Self-testing of blood glucose levels provide a way to control your diabetes. Consults with your physician to determine the best range of your expected blood glucose values.

#### 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. 51-5100.

## **True Lifetime Warranty**

#### Manufacturer's Warranty

MHC Medical Products offers a True Lifetime Warranty to the original purchaser. MHC Medical Products will repair or replace the meter if it is found to be defective or fails to perform as designed. Proof of purchase may be required. Please contact MHC Customer Support at (877) 358-4342.

#### **Limitations of Warranty**

This warranty is subject to the following exceptions and limitations:

- MHC Medical Products shall not be required to replace any units which are damaged or malfunction due to product expiration, abuse, accidents, alteration, neglect, misuse or maintenance by someone other than MHC Medical Products.
- MHC Medical Products reserves the right to make changes in design without obligation to incorporate such changes into previously manufactured instruments.
- 3. MHC Medical Products reserves the right to replace defective meters with a new meter of a different model.

#### **For Warranty Service**

Purchaser must contact MHC Customer Support by calling toll free (877) 358-4342 for assistance.

#### Service Information

MHC Medical Products has trained specialists to help you.

#### IMPORTANT:

Contact an MHC Customer Support at (877) 358-4342 before returning your meter for any reason. You will be given the information needed to get your questions and concerns handled correctly and efficiently. Keep your meter, test strip and control solution nearby when you call.

## **Specifications**

Sample Type	Capillary Whole Blood
Sample Volume	0.5 μL
Test Range	20-600 mg/dL
Reading Time	5 seconds
Calibration	Plasma-Equivalent
Altitude	Up to 10,000 feet (3050 meter)
Operating Temperature	50-104°F (10-40°C)
Operating Humidity	10-90%
Strip Storage Temperature	Store 36-86°F or 2-30°C and no direct sunlight. Do not Refrigerate. Do not Freeze.
Display Type	LCD (Including backlight model)
Dimension	88.4 X 50.3 X 18.5 (mm)
Weight	46±1g (Including batteries)
Power Source	3V (Coin Battery, CR2032 X 2EA)
Battery Life	Running 1,000 Tests

## **Symbol Reference**

Β	Use by date
LOT	Batch code
SN	Serial number
REF	Catalogue number

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