Dear Harmony™ Owner

Thank you for choosing the Harmony Blood Glucose Monitoring System to help monitor your patient’s blood glucose levels. The Harmony Blood Glucose Monitoring System is an auto-coding system that does not require you to code the meter manually, so testing errors can be greatly reduced. All of the information you need to use and maintain the blood glucose meter is included in this manual. Please read it carefully.

The Harmony Blood Glucose Monitoring System contains many convenient features to help you easily manage your patient’s diabetes, such as hypoglycemia/hyperglycemia warnings, before/after meal marking, and asterisk marking. The test result from the Harmony blood glucose meter is plasma-calibrated for easy comparison to lab results. If you need assistance, please call Technical Service number at 1-866-274-2131 Monday through Friday from 8am to 5pm CST.

This system is for Rx only.
The Harmony Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in venous whole blood, or capillary whole blood drawn from fingertips, palm, or forearm. Alternative site testing should be performed only during steady-state (when glucose is not changing rapidly). Testing is done outside the body (In Vitro Diagnostic Use). It is intended for multiple-patient use in professional healthcare settings as an aid to monitoring the effectiveness of diabetes control program. This system should only be used with single-use, auto-disabling lancing devices. It is not indicated for the diagnosis of or screening for diabetes or for neonatal use.

The Harmony Blood Glucose Monitoring System is comprised of the Harmony Blood Glucose Meter, Harmony Blood Glucose Test Strips and Harmony Glucose Control Solution.

Important:
- Dehydration – Severe dehydration may lead to inaccurate blood glucose test results. If you suspect the patient is severely dehydrated, do not use the system.
- Hematocrit range – A hematocrit range that is higher than 70% or lower than 10% can cause inaccurate blood glucose test results.
- Testing is done outside the body (In Vitro Diagnostic Use).
- Not intended for use on neonates.
- This system should only be used with single-use, auto-disabling lancets.
**Important Safety Instructions**

- Users need to adhere to standard precautions while handling or using this device.
- The meter should be disinfected after use on each patient. This blood glucose monitoring system may only be used for testing multiple patients when standard precautions and the manufacturer’s disinfection procedures are followed.
- Only auto-disabling, single-use lancets may be used with this device.
- The link of public health notification and standard practice guideline are:
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Understanding the Harmony Blood Glucose Monitoring System

Each Harmony system may include the following items:

- The Harmony Meter
- The Harmony Blood Glucose Test Strip
- Harmony Level 1 Glucose Control Solution
- Harmony Level 3 Glucose Control Solution
- Harmony User Guide

NOTE:
- Harmony Blood Glucose Test Strips and Harmony Glucose Control Solution are necessary but sold separately. Please call Medline’s customer service number at 1-800-MEDLINE Monday through Friday from 8:00 AM to 5:00 PM CST for purchasing information.
The Harmony Meter

Test Strip Port
This is where you insert the test strip and the meter will turn on automatically.

Meter Display
Shows the blood glucose test results, memory values, and other messages.

Enter (✓) and ▲▼buttons
Press and hold Enter (✓) for 2 seconds to turn the meter on or off, or press enter (✓) to toggle through set up mode when not testing. Press ▲ or ▼ to enter control mode with test strip inserted, during meter setup, or to navigate the stored test values.
Test Strip Ejector
Slide to eject a used test strip.

Battery Compartment
Holds two CR 2032 3V Lithium coin cell batteries.

Data Port
Transmits data to computer. (Feature not currently available)
The Harmony Meter Display Screen

- **MEMORY**
- **ALARM CLOCK**
- **BEEPER**
- **HYPO/HYPER**
- **ASTERISK MARKER**
- **UNIT**
- **HOUR/MINUTES**
- **BATTERY**
- **TEMPERATURE**
- **CONTROL SOLUTION MODE (CTL)**
- **MEAL MARKER**
- **BLOOD DROP**
- **TEST STRIP**
- **mg/dL**
MEMORY .................................. Indicates the number in the display area is a stored test value (see page 52).
MAIN DISPLAY AREA ........ Displays test results, stored test values, and messages.
BATTERY .............................. Appears when the batteries are low and need to be replaced.
TEMPERATURE ................... Appears when it is either too hot or too cold to test (outside the ranges of 41˚F~113˚F).
TEST STRIP .......................... This icon will flash to prompt you to insert a test strip for testing.
UNIT ....................................... Unit of measurement for your blood glucose.
CTL ......................................... This icon indicates a control solution test (see page 30).
TONE ..................................... Indicates the beeper is on (see page 22).
ALARM CLOCK .................... Indicates the alarm function is turned on.
BLOOD DROP ........................ This icon will flash to indicate the meter is ready for testing.

HYPO ..................................... Setting up the hypoglycemic threshold value (see page 26).
Indicates the test result is at or below the hypoglycemic threshold value.
HYPER .................................. Setting up the hyperglycemic threshold value (see page 27). Indicates your test result is at or below the hypoglycemic threshold value.

MEAL MARKER ................. Display when marking a result as before or after meal, or viewing a marked result.

ASTERISK MARKER ............ Marks any result as being unique or different in some way and for which you may want to make notes in the logbook. Seeing a result with this symbol next to it in the memory will help remind you that there is more information recorded about this test result.
The Harmony Blood Glucose Test Strip

Contact Points
Insert this end to the test strip port on the meter

Harmony™

Sampling End
Apply blood or control solution here

The Harmony Blood Glucose Test Strip is a glucose specific, biosensor-based test strip that can test glucose in capillary or venous whole blood in as quickly as 8 seconds and requires very little blood sample. The test result is plasma referenced for easy comparison to lab results and has under-fill detection to alert you when there is not enough blood to perform a test, so you can be assured that each reading you get is an accurate and meaningful result.

Important:
- Be sure to use only the Harmony Blood Glucose Test Strip with the Harmony Meter. Other brands of test strips will not work with the meter.
- It is important to close the vial cap of the test strip bottle tightly after each use. DO NOT leave any test strips outside the bottle while not in use. For foil-wrapped test strip, DO NOT open the foil wrapping until performing tests.
- Carefully discard used test strips and lancets in proper waste containers according to your local regulations.
- DO NOT reuse test strips. Test strips are single use only.
Setting Up the New System

Inserting (or Changing) the Batteries

The batteries need to be inserted before using the Harmony Meter for the first time or when the “Battery” icon appears on the meter display.

Material you will need:
- Two CR 2032 3V Lithium coin cell batteries
- The Harmony Meter

Step 1.
Turn the meter off. Remove the battery cover on the back of the meter by pushing the tabs and pulling the door up. Remove the old batteries.
Step 2.
Insert the new batteries with the + side up. They do not snap into place but rest on the metal contact. The door holds the batteries down.
Put the battery door back in the place and snap it closed.

NOTE:
- After changing the batteries, the meter automatically prompts you to check the time and date when it is turned on either by inserting a test strip or pressing “ ”. If it is correct, press “ ” to confirm setup and exit, or if the time and date are not correct, turn to page 16 for Setting Time and Date.
- Meter memory will not be erased when the batteries are being changed.
- Discard used batteries according to the local regulation.
- The meter uses two 3-volt lithium batteries, coin cell CR2032. This type of battery can be found in many stores.
- Be sure the batteries go in + side up.
- Remove the batteries if unused for a long time.
Setting Time and Date

Material you will need:
• The Harmony Meter

Begin Set Up

Step 1.
Press and hold “)” to turn on the meter.

Step 2.
The flashing test strip icon will appear on the meter display screen.

Step 3.
Press “▲” twice until meter display screen shows “ ” and set.
Set Year

Step 4.
Press “ ” and the current year will flash. Use “▲” or “▼” to select the correct year.
Press “ ” to confirm and advance to set the month.

Set Month

Step 5.
The current month will flash. Use “▲” or “▼” to select the correct month.
Press “ ” to confirm and advance to set the day.

Set Day

Step 6.
The current day will flash. Use “▲” or “▼” to select the correct day.
Press “ ” to confirm and advance to set the 12-hour or 24-hour time format.
Set 12-hour or 24-hour Time Format

Step 7.
The time format will flash. Use “▲” or “▼” to select the time format of your choice. Press “ ” to confirm and advance to set the hour.

Set Hour

Step 8.
The current hour will flash. Use “▲” or “▼” to select the correct hour. Press “ ” to confirm and advance to set the minutes.

Set Minutes

Step 9.
The current minutes will flash. Use “▲” or “▼” to select the correct minutes. Press “ ” to confirm and exit time setup.
NOTE:
• Anytime during setup, you may either press “.power” to exit, or insert a Harmony Blood Glucose Test Strip to begin testing. The changes you have done so far will be memorized by the meter.

After setting up the time and date, you can turn off the meter by pressing and holding “.power”, continue to set the meter, or insert a test strip to begin testing (see Blood Glucose Testing on page 37 or Control Solution Testing on page 30).
Setting the Alarm

You can set up to three alarms on the Harmony Meter. You must set the time and date before setting the alarms. When an alarm rings, the meter will beep several times in a row. Pressing “ ” or inserting a test strip will silence the alarm.

Materials you need:
• The Harmony Meter

Step 1.
Press and hold “ ” to turn on the meter.

Step 2.
The flashing test strip icon will appear on the meter display screen.

Step 3.
Press “ ” or “ ” until “ ” starts to flash. Press “ ” to enter alarm setting.
Step 4.
The display screen will indicate alarm 1 status (the default is OFF). You can turn it on by pressing “▲” or “▼”. Press “０” to confirm and advance to set hours.

Step 5.
The hours will flash. Press “▲” or “▼” to select the hour. Press “０” to confirm and advance to set minutes.

Step 6.
The minutes will flash. Press “▲” or “▼” to select the correct minutes. Press “０” to confirm and advance to set alarm 2.

Step 7.
Set alarm 2 and 3 by following steps 4 through 6. After you have finished setting up alarm 3, press “０” to exit alarm setup.
NOTE:
• Alarm will follow the time format (12-hour or 24-hour) you chose when setting up time and date.
• Alarm settings will not be erased when changing batteries.

Begin testing by inserting a Harmony Blood Glucose Test Strip (see Blood Glucose Testing on page 37 or Control Solution Testing on page 30), or press and hold “ู่” to turn off the meter.

Turning ON/OFF Tone Sound

The Harmony Meter comes with a beeper sound ON as preset. The beeper will sound once to notify you when turning on/off the meter, applying samples, or ending countdown. You will get two beep sounds warning if the results show “hypo”, “hypr”, “HI” or “LO”.

Step 1.
Press and hold “ู่” to turn on the meter.

Step 2.
The flashing test strip icon will appear on the meter display screen.
Step 3.
Press “▲” or “▼” until meter display screen shows “ ” and set.

Step 4.
Press “ ” to enter tone setting. Use “▲” or “▼” to turn on/off the tone.

Step 5.
Press “ ” to exit once you have made the selection.

NOTE:
• Anytime during setup, you may either press “ ” to exit, or insert a Harmony Blood Glucose Test Strip to begin testing. The changes you have done so far will be memorized by the meter.

Begin testing by inserting a Harmony Blood Glucose Test Strip (see Blood Glucose Testing on page 37 or Control Solution Testing on page 30), or press and hold “ ” to turn off the meter.
Setting Hypo/Hyper Values

The Harmony Meter has a feature to set the high and low blood glucose threshold (hyperglycemia and hypoglycemia values). Based on the values you have set up, the LCD screen will show “hypo” if blood glucose test result is below the low glucose threshold value (hypoglycemia level), or the LCD screen will show “hypr” if blood glucose test result is above the high glucose threshold level value (hyperglycemia level).

Important:
- Do not alter or stop the medication based on this feature always consult the patient’s healthcare provider before altering or stopping medication.
The factory preset threshold value is 250 mg/dL for hyper and 70 mg/dL for hypo. The allowable range of the threshold setting is 100 to 600 mg/dL for hyper and 20 to 130 mg/dL for hypo, but the meter will never allow the hyper value to be lower than the hypo value. Follow the steps below to adjust the hyper and hypo threshold values.

Material you will need:
• The Harmony Meter

Step 1.
Press and hold “ ” to turn on the meter.

Step 2.
The flashing test strip icon will appear on the meter display screen.
Setting up hypo (hypoglycemia) warning value

Step 3.
Press “▲” or “▼” until the meter display screen shows “hypo”.

Step 4.
Press “○” to enter hypo setup.

Step 5.
Press “▲” or “▼” to select the desired value. Press and hold either “▲” or “▼” to accelerate numbering. Press “○” to confirm and exit hypo setup. You will return to the meter display screen.
Setting up hyper (hyperglycemia) warning value

Step 6.
Press “▲” or “▼” until the main display screen shows “hypr”.

Step 7.
Press “ู่” to enter hyper setup.

Step 8.
Press “▲” or “▼” to select the desired value. Press and hold either “▲” or “▼” to accelerate numbering. Press “ู่” to confirm and exit hyper setup. You will return to meter display screen.

After setting up the hypo and hyper values, you can either press and hold “ู่” to turn off the meter, or insert a test strip to begin testing (see Blood Glucose Testing on page 37 or Control Solution Testing on page 30).
Enable/Disable QC Lock Mode

The Harmony Meter offers you a choice to lock in the QC lock mode. When the QC lock mode is on and no control test has been performed in the past 24 hours, the message “qC” will flash on the screen and you will need to perform a control test before running a glucose test.

Materials you will need:
- The Harmony Meter

Step 1.
Press and hold “ ” to turn on the meter.

Step 2.
The flashing test strip icon will appear on the meter display screen.

Step 3.
Press “▲” or “▼” until the meter display screen shows “ctl”.

Step 4.
Press “ ” to enter QC lock setting. Use “▲” or “▼” to turn on/off QC lock.
Step 5.
Press “☐” to confirm and exit QC lock setup. You will return to meter display screen.

Begin testing by inserting a Harmony Blood Glucose Test Strip (see Blood Glucose Testing on page 37 or Control Solution Testing on page 30), or press and hold “☐” to turn off the meter.

If the QC lock is on and no control test has been executed in the past 24 hours, the screen will show the flashing message “QC” when you insert a test strip. You will not be able to run glucose tests without running a control test first.

Press “▼” to select control level (L1 or L3), see Control Solution Testing on page 30 for details.
Control Solution Testing

Performing a Control Solution Test

The purpose of the control solution testing is to validate the performance of the Harmony Blood Glucose Monitoring System using the testing solution with a known range of glucose. Control solutions are necessary but sold separately, please call 1-800-Medline, Monday through Friday from 8:00 AM to 5:00 PM CST for purchasing information.

You should perform control solution testing when:

- Using the meter for the first time
- You open a new package of Harmony Blood Glucose Test Strips
- You leave the cap of the test strip vial open
- You drop the meter
- You suspect the Harmony Meter and Harmony Blood Glucose Test Strips are not working properly
- The blood glucose test results do not reflect how the patient feels
- You want to practice the testing procedure
Important:
• Use only the Harmony Glucose Control Solution (Level 1 and Level 3) with the Harmony Blood Glucose Test Strip. Other brands of control solution will produce inaccurate results.
• Always check the expiration date. DO NOT use control solutions if expired.
• Mark the newly opened bottle of control solution with the date opened. Discard any unused control solution three months after opening.
• DO NOT FREEZE or REFRIGERATE. Store the control solutions at 39°F~86°F.

Materials you will need:
• Harmony Glucose Control Solution (Level 1 and Level 3)
• The Harmony Meter
• A new Harmony Blood Glucose Test Strip

Step 1.
Insert a Harmony Blood Glucose Test Strip into the meter with the blood sample reaction zone facing up. Make sure the test strip contact points are inserted all the way into the meter.
Important:

- Do not use a test strip that has expired. Check the expiration date which is printed on the test strip bottle (for vial test strips) or box (for foil-wrapped test strips).
- Use each test strip immediately after removing it from the bottle or opening a foil wrapping.
- For vial test strip, replace the bottle cap immediately and close it tightly after removing a test strip from the bottle.
- Do not use wet, bended or damaged test strips.
- Keep away from direct sunlight and heat. Store the test strip in a dry, cool place.
- For vial test strips, record the “date opened” on the test strip bottle label when you first open it. Six months after first opened, discard the bottle and any remaining test strips.
- For foil-wrapped test strip, do not use scissors to open the foil wrapping. Scissors can damage test strips.
- Make sure you are testing in an environment between 41°F~113°F and 20~90% RH, and allow 10 to 15 minutes for it to reach the new temperature before use. The meter will not begin testing if it detects an out-of-range temperature.
- This is an auto-coding meter. You do not need to insert a code card.
- You must see a flashing blood drop icon if the test strip has been inserted to the test strips port.
Step 2.
Wait until the flashing blood drop and test strip icons appear on the lower left of the meter display screen.

Step 3.
Press “▼” to enter the control mode. You will see “ctl ” on the lower left of the screen. Use “▲” or “▼” to select control level (L1 or L3).

Step 4.
Squeeze a drop of glucose control solution (Level 1 or Level 3) onto a clean, dry, non-absorbent surface. Do not apply control solution to the test strip directly from the bottle. Replace the bottle cap on the control solution bottle immediately after use.

Step 5.
Hold the meter and touch the control solution to the edge of the sampling end of the test strip. The control solution will be automatically pulled into the reaction area of the test strip.
Step 6.
The screen will begin to count down. After 8 seconds, the control solution testing result will appear on the meter display screen. A “ctl” flag will also be attached when results are shown on the screen.

Step 7.
Compare the reading on the screen to the control range printed on the test strip bottle or box. If the reading does not fall within the control range printed on the test strip bottle or box, see Control Solution Troubleshooting on page 36.

NOTE:
• Control solution testing results will be stored into the meter’s memory and indicated by “ctl” icon.
• Different vials or foil packages may have different control ranges.
Step 8.
Remove the used test strip by sliding the test strip ejector. Eject the test strip into a proper waste container.
Insert a new test strip to perform the next test, or press and hold “กด” to turn off the meter.

**IMPORTANT:**
- Do not reuse test strips.

Perform the other level of control solution testing by repeating the above steps.
## Control Solution Troubleshooting

If your control solution testing is out of range (too high or too low), it may be caused by the following:

<table>
<thead>
<tr>
<th>Possible Causes</th>
<th>What you can do ...</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Wrong brand of control solution being used</td>
<td>• Make sure you are using Harmony Glucose Control Solution (Level 1 and Level 3).</td>
</tr>
<tr>
<td>• Expired or contaminated control solution or damaged test strips</td>
<td>• Make sure the testing environment is between 41°F<del>113°F and 20</del>90% RH.</td>
</tr>
<tr>
<td>• Meter malfunction</td>
<td>• Check the expiration and opened date on bottles of both control solution and test strips. Repeat the test using a new test strip. If the result is still out of range, use a new bottle of control solution and retest.</td>
</tr>
<tr>
<td>• Control solution not at room temperature</td>
<td>• Please call Technical Service number at 1-866-274-2131 Monday through Friday from 8:00 AM to 5:00 PM CST</td>
</tr>
</tbody>
</table>
Blood Glucose Testing

Materials you will need:

- The Harmony Meter
- A new Harmony Blood Glucose Test Strip
- An auto-disabling, single use lancet

Before you begin, make sure:

- Set up the meter properly and run a control test. See Setting Up the New System on page 14 and Control Solution Testing on page 30 for more details.

- Wash your hands and testing site thoroughly with soap and warm water, and dry well.

- You are testing in an area between the temperature ranges of 41°F~113°F and relative humidity ranges of 20~90%. The meter will not test outside of this range and will display “     ”. Move the meter into an area that is between 41°F~113°F and 20~90% RH, and let it sit for 10 to 15 minutes before testing again.

- If the meter is being operated by a second person who is providing testing assistance to the user, the meter should be cleaned and disinfected appropriately when testing is conducted by the second person.
Preparing the Lancets

CAUTION:

• Users need to adhere to standard precautions when handling or using this device.
• All parts of the glucose monitoring system should be considered potentially infectious and are capable of transmitting blood-borne pathogens between patients and healthcare professionals. Please follow the practice guidelines below:
• “Biosafety in Microbiological and Biomedical Laboratories (BMBL)” found at http://www.cdc.gov/biosafety/publications/bmbl5/

Only auto-disabling single-use lancets should be used to take a blood sample. Follow manufacturer’s instruction for how to use the lancets.

Please call Medline’s Customer Service number at 1-800-MEDLINE Monday through Friday from 8:00 AM to 5:00 PM CST for the purchasing information of auto-disabling single-use lancets.
Important Information on Alternative Site Testing (AST)

The Harmony Blood Glucose Monitoring System can test for blood glucose from two sites other than your fingertip. These alternative sites are your palm and forearm (alternative site testing, or AST). Alternative site testing can be less painful than fingertip testing, but because of the physiological difference between fingertip, palm and forearm, AST result may be significantly different than results from fingertip testing under certain conditions. Alternative site testing can be used only during steady-state blood glucose condition.

DO AST ONLY in the following intervals:

- In a pre-meal or fasting state (more than 2 hours since last meal)
- 2 hours or more after taking insulin
- 2 hours or more after exercise

Alternative site testing should be performed only during steady-state (when glucose is not changing rapidly).

Alternative site measurements should never be used to calibrate continuous glucose monitors (CGMs).

Alternative site measurements should never be used for insulin dosing calculations.
AST SHOULD NOT be used when:

- The patient has hypoglycemic unawareness (not able to tell if you have low blood sugar).
- Within 2 hours of a meal, exercise, or medication.
- The patient be operating machinery or driving a car.
- The patient is sick.
- The patient's blood glucose is low.
- Testing for hyperglycemia.
- The patient's routine glucose results are often fluctuating. Consult with the patient's healthcare provider to decide if AST is right for them.

NOTE:

- If results from AST do not agree with how the patients feel, use fingertip testing instead.

Performing a Blood Glucose Test

Step 1.
Insert a test strip to turn on the meter.

Important:

- Check the expiration date printed on the test strip bottle (for vial test strips) or box (for foil-wrapped test strips). Do not use expired test strips.
- Use each test strip immediately after removing it from the bottle.
- Do not use wet, bent or damaged test strips.
- Keep away from direct sunlight and heat. Store the test strips in a dry, cool place.
- Record the “date opened” on the bottle label. Discard the bottle and any remaining test strips after six months from date of opening.
- Insufficient blood specimen may cause incorrect results.
- You must see a flashing blood drop icon if the test strip has been inserted into the test strip port.
- For healthcare professionals, a new pair of clean gloves should be worn by the user before testing each patient.
Step 2. Wait until the flashing blood drop and test strip icons appear on the lower left of the meter display screen.

Step 3. Obtain a blood sample.

For Fingertip Testing:
Hold the single-use lancet against the side of the fingertip and press the release button to create a puncture. Follow manufacturer’s instruction for how the lancets should be used.

TIP:
• Gently massage the hand and finger toward the puncture site to form a drop of blood. Do not “milk” or squeeze around the puncture site.
• Lance the side of the fingertip to avoid soreness. To avoid calluses, choose a different lancing site each time.
• If alcohol wipes are used to cleanse the fingertip, make sure the fingertip is dry before the blood sample is obtained.
For Palm and Forearm Testing:

Complete only when it is more than two hours after a meal, diabetes medication, or exercise. Select a puncture site on forearm or palm. Avoid a test site that has veins, hair, moles, bone, and tendon.

Important:
- If results from AST do not agree with how the patient feels, use fingertip testing instead.

Step 4.
You must see the flashing blood drop icon before applying blood. Gently bring the test strip to the drop of blood at a slight angle. The test strip acts like a straw to pull the blood in.
Step 5.
The screen will start to count down from 8 to 1. After the count down, the patient’s glucose test result will appear on the meter display screen.

Step 6.
With the test result on the display, and the test strip still in the meter, press either “▲” or “▼” to select ⌁ for before meal, ⬇ for after meal, or blank if the test result does not apply. Press “_confirmation” to confirm your choice and advance to select asterisk marker.
Step 7 - Select the asterisk marker
After selecting meal state, a flashing “⭐” icon appears in the middle of the screen. You can mark the result for an event such as an AST result or exercise. Use “▲” or “▼” to turn the option on/off, and press “☐” to confirm. The result will be stored in memory.

The test result will be stored without markers if the strip is removed without selection.
CAUTION:

- If you see “HI” or “LO” is displayed, the blood glucose level may be beyond the meter measurement range (above 600 mg/dL or below 20 mg/dL). Test again using fingertip testing, DO NOT test on palm or forearm. If the patient still receives the same result, call the patient’s healthcare provider immediately.

NOTE:

- “hypo” or “hypr” icons may appear on screen depending on the threshold limit you have set up. Refer to Setting Hypo/Hyper Values on page 24.
- Clean and disinfect the meter after the test. Refer to Cleaning and Disinfection the Meter on page 56.
Step 8.
Remove the used test strip by pushing the test strip ejector and discarding into a proper waste container. Insert a new test strip to perform the next test, or press and hold “_PAYMENT” to turn off the meter.

Step 9.
Discard the used single-use lancet into a proper waste container.

**Important:**
- Used lancets and test strips are biohazardous materials and can transmit blood-born disease. Please follow local government regulation regarding proper disposal of used lancets and test strips.
- Wash hands thoroughly with soap and water after handling the meter, lancets, or test strips.
Understanding Blood Glucose Test Results

Blood glucose values will vary depending on food intake, medication, health, stress, and exercise. The ideal ranges for adults without diabetes are\(^{(2)}\):

- less than 100 mg/dL before meals.
- less than 140 mg/dL two hours after meals.

If the meter displays a result which is “HI” or “LO”, or the patient gets a result which is more than the high or low blood glucose threshold value AND the patient feels ill:

- Treat the patient’s diabetes according to the instruction from the patient’s doctor and/or consult with the patient’s healthcare provider.

If the meter displays a result which is “HI” or “LO”, or the patient gets a result which is more than the high or low blood glucose threshold value AND the patient DOES NOT feel ill:

- Test the meter with a control solution, refer to Control Solution Testing on page 30.
- Test again on fingertip using a new test strip.
- Call Medline Technical Service at 1-866-274-2131 Monday through Friday from 8am to 5pm CST.

It is important to consult with the patient's healthcare provider to determine an appropriate target range for the patient.

Limitation

- 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.
- This meter has not be evaluated in the critically ill.
- Not for use on neonates.
- Altitude higher than 10,335 feet may cause inaccurate results.
- Hematocrit range higher than 70% or lower than 10% can cause inaccurate results.
- Severe dehydration may lead to inaccurate blood glucose test results.
- For In vitro diagnostic only.
- For multiple-patient use.
- Alternative site testing should be performed only during steady-state (when glucose is not changing rapidly).
- Alternative site measurements should never be used to calibrate continuous glucose monitors (CGMs).
- Alternative site measurements should never be used for insulin dosing calculations.
- If individual has certain conditions that may cause their blood level of uric acid to rise (>10.25 mg/dL in your blood), such as gout or kidney disease, then your blood glucose results may be inaccurate with this meter. If you are unsure, ask your healthcare professional.
FOR HEALTHCARE PROFESSIONAL USE:

- DO NOT use plasma or serum samples.
- DO NOT test on arterial blood samples.
- Do not test blood glucose during or soon after a Xylose Absorption test (>7.5 mg/dL in your blood) since the patient’s blood glucose results may be inaccurate with this meter.
- If the patient is taking high doses of the pain medication acetaminophen (such as Tylenol, certain cold or flu remedies, and certain prescription drugs) (>7.5 mg/dL in your blood), then you should know that this drug might affect the reliability of your blood glucose results. If you are unsure, please ask the patient’s healthcare professional.
- If the patient is taking high doses of the Tolazamide (>23 mg/dL in your blood), then you should know that this drug might affect the reliability of your blood glucose results. If you are unsure, please ask the patient’s healthcare professional.
- If the patient is taking high doses of the Paralidoxime Iodide (PAM) (>125 mg/dL in your blood), then you should know that this drug might affect the reliability of the blood glucose results. If you are unsure, then ask the patient’s doctor.
- Uric acid levels above 10.25mg/dL may give falsely low test results (reference range: 2.5-8 mg/dL).
Meter Memory

The Harmony Meter can store up to 1000 test and control results with date and time. You will need to set the meter date and time before using the memory, see Setting Up the New System on page 14. The meter will not memorize any test or control results if the date and time are not set.

Material you will need:
• The Harmony Meter

Step 1.
Press and hold “○” to turn on the meter.

Step 2.
The flashing test strip icon will appear on the meter display screen.
Step 3.
Use “▲” or “▼” until meter display screen shows “mem”.

Step 4.
Press “确认” to confirm.

Step 5.
The most recent test result will appear on screen. Press “▲” to view the results from the most recent to the oldest. Press and hold either “▲” or “▼” will accelerate scrolling.
NOTE:
- Control test results will be flagged by a “ctl” icon on lower left of the unit measurement.
- Hypoglycemic readings and hyperglycemic readings will be accompanied by the corresponding icons.
- If the patient gets a result of “HI” or “LO”, it will be stored automatically in memory as 600 mg/dL or 20 mg/dL without markers.
- If error messages appear, see Troubleshooting on page 62.

After you finish viewing memory, either begin testing by inserting a Harmony Blood Glucose Test Strip (see Blood Glucose Testing on page 37 or Control Solution Testing on page 30), or press and hold “_pressed key” to turn off the meter.

FOR HEALTHCARE PROFESSIONAL USE:
- When using the meter on multiple patients, be aware that the results from different patients will be kept together in the meter memory chronologically.
Upload Data

* This function is not available yet
Caring for the Meter

Caring for the Harmony Meter is easy. Follow these simple guidelines to keep the Harmony Meter working properly.

NOTE:

- Do not get water inside the Harmony Meter. Never immerse the meter or hold it under running water.
- Do not use glass or household cleaners on the meter.
- Do not try to clean the test strip holder.
- Do not contaminate the strip holder with blood or control solution.
- Handle the meter with care; severe shock, such as dropping the meter, could damage the electronics.

Cleaning and Disinfecting the Meter

Cleaning and disinfecting are different and both should be performed. Cleaning can remove visible soil, blood and oily substances prior to disinfecting, but does not kill germs effectively. Disinfecting can destroy most recognized pathogenic microorganisms to reduce your exposure to disease. For cleaning and disinfecting information, see pages 56-61 in this manual.

The Harmony Meter should be cleaned and disinfected between each patient. The meter is validated to withstand a cleaning and disinfecting cycle of ten times per day for an average period of 3 years. The following products have been validated for cleaning and disinfecting the meter:

- Dispatch® Hospital Cleaner Disinfectant Towels with Bleach (EPA Registration Number: 56392-8)
- Medline Micro-Kill+™ Disinfecting, Deodorizing, Cleaning Wipes with Alcohol (EPA Registration Number: 59894-10)
- Clorox Healthcare® Bleach Germicidal and Disinfectant Wipes (EPA Registration Number: 67619-12)
- Medline Micro-Kill™ Bleach Germicidal Bleach Wipes (EPA Registration Number: 37549-1)

Only the above wipes have been validated for use in cleaning and disinfecting the meter. Any disinfectant product with these EPA registration numbers may be used on this device.

Cleaning and disinfecting frequency: The device must be cleaned before every disinfection step and should be cleaned and disinfected after each test.
WARNING:
• These disinfectants were validated separately. Only one disinfectant should be used on the device for the life of the device, as the effect of using more than one disinfectant interchangeably has not been evaluated.

Materials needed:
• Harmony Meter
• Gloves
• A validated disinfecting wipe

1. Wash hands with soap and water and dry thoroughly. Put on single-use medical protective gloves.

2. Inspect for blood, debris, dust, or lint anywhere on the meter. Blood and bodily fluids must be thoroughly cleaned from the surface of the meter.
3. To clean the meter, blood/body fluids must be thoroughly cleaned from surface and objects before disinfecting. Wipe surface with one of the four validated disinfecting wipes until completely wet. Wipe all external areas of the meter using the same validated wipes for cleaning and for disinfection. Avoid wetting the test strip holder and data port. Discard used towel.

4. To disinfect the meter, dispense a wipe from the canister. Oily substances must be removed prior to disinfection. Wipe all external areas of the meter including both front and back surfaces until visibly wet. Use the same validated wipes for cleaning and for disinfection. Avoid wetting the test strip holder and data port.

Allow the surface of the meter to remain wet at room temperature for:
- At least 30 seconds for Medline Micro-Kill™ Bleach
- At least 1 minute for Dispatch® and Clorox Healthcare®
- At least 2 minutes for Medline Micro-Kill+™
5. Allow to air dry.

6. Remove gloves, wash hands with soap and water, and dry thoroughly.

Disposal of infectious material
Blood, body fluids and cleaning materials should be disposed of according to federal, state and local regulations for infectious waste disposal.

FOR HEALTHCARE PROFESSIONAL USE:
• Single-use medical protective gloves should always be worn during disinfection procedures and also by anyone performing blood glucose testing on another person.
• Used gloves should be removed and hands should be washed before proceeding to the next patient.
• Healthcare professionals should change gloves between patients, even if patient dedicated testing devices and single-use, self-disabling lancets are used.
• Glucose meters used in a clinical setting for testing multiple persons must be cleaned and disinfected between patients.
• Keep disinfecting wipes out of reach of children and stored according to its instruction.
• Do not flush towels down toilet.
If you notice any of the below signs after cleaning and disinfecting the meter, stop using the meter and call Medline Technical Service at 1-866-274-2131 Monday through Friday from 8am to 5pm CST.

- Control solution out of range
- Clouding of the LCD display
- Corroding of the plastic housing or buttons
- Cracking of plastic housing
- Malfunction of any meter buttons

Purchase Information for Validated Disinfecting Wipes

To find a local distributor in your area, call Medline Customer Service at 1-800-MEDLINE Monday through Friday from 8:00 AM to 5:00 PM CST. You can also purchase the disinfecting wipes at the website:

- http://www.amazon.com
- http://www.staples.com
Storage and Precautions

• Handle the meter with care. Severe shock, such as dropping the meter, could damage the electronics.

• The meter and the test strips are designed to be used within the temperature ranges between 41°F~113°F and the relative humidity ranges between 20~90%.

• Avoid leaving the meter in extremely hot or cold place, such as near a heat source or in an extremely hot or cold car.

• Do not store or use the meter or test strips where they may be exposed to high humidity levels, such as in a bathroom or kitchen.

• Always close bottle cap immediately after removing a test strip and make sure it is closed tightly.

• Do not take the meter apart. Doing so will void the warranty.

• If there are technical problems or questions, please call Technical Service at 1-866-274-2131 Monday through Friday from 8:00 AM to 5:00 PM CST.
**Troubleshooting**
This section details the significant display screen messages and error codes you may encounter when using the Harmony Meter and Harmony Blood Glucose Test Strips.

<table>
<thead>
<tr>
<th>Message</th>
<th>What it Means</th>
<th>What You Should Do</th>
</tr>
</thead>
</table>
| Er1     | Damaged meter electronic or test strip | • Remove the batteries and turn the meter on again.  
• Remove the test strip and insert a new test strip again.  
• If problem persists, call 1-866-274-2131 Monday through Friday from 8am to 5pm CST. |
<p>| Er2     | Used or contaminated test strip | • Repeat the test with a new test strip. Wait until you see the flashing blood drop icon before you add blood or control solution sample. |</p>
<table>
<thead>
<tr>
<th>Message</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Er 3</td>
<td>Not enough sample on the test strip to start the test</td>
<td>• Remove the test strip and repeat the test with a new test strip. See Blood Glucose Testing on page 37.</td>
</tr>
<tr>
<td>Er 4</td>
<td>Premature sample application</td>
<td>• Remove the test strip and repeat the test with a new test strip, apply blood AFTER flashing blood drop icon appeared. See Blood Glucose Testing on page 37.</td>
</tr>
<tr>
<td>HI</td>
<td>Test result higher than 600 mg/dL</td>
<td>• Wash and dry the patient hands and repeat the test on patient’s fingertip with a new test strip. If the result is still “HI”, refer to page 48 or call 1-866-274-2131 Monday through Friday from 8:00 AM to 5:00 PM CST.</td>
</tr>
<tr>
<td>Message</td>
<td>What it Means</td>
<td>What You Should Do</td>
</tr>
<tr>
<td>---------</td>
<td>---------------</td>
<td>-------------------</td>
</tr>
<tr>
<td><img src="image" alt="LO" /> mg/dL</td>
<td>Test result lower than 20 mg/dL</td>
<td>• Wash and dry the patient's hands and repeat the test on patient’s fingertip with a new test strip. If the result is still “LO”, refer to page 48 or call 1-866-274-2131 Monday through Friday 8:00 AM to 5:00 PM CST.</td>
</tr>
<tr>
<td><img src="image" alt="Low Battery" /></td>
<td>Low battery</td>
<td>• Change the batteries according to instructions for Inserting (or Changing) the Batteries on page 14.</td>
</tr>
</tbody>
</table>
| ![No Memorized](image) | No memorized results in the meter | • Check if the date and time on the meter is set up. See Setting Up the New System on page 14.  
• Start testing blood glucose, see Blood Glucose Testing on page 37. |
<table>
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</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Temperature out of range</td>
<td>• Move the meter into an area that is between 41°F~113°F, and allow 10 to 15 minutes for it to reach the new temperature.</td>
</tr>
</tbody>
</table>
Product Warranty

Medline Industries LP warrants the Harmony Meter to be free of defects in workmanship and materials under normal use for a period of three (3) years from the date of purchase to the consumer.

The liability of Medline Industries LP is limited to repair or replacement and in no event shall Medline Industries LP be liable for any collateral or consequential damages or loss.

Instruments subjected to misuse, abuse, neglect, unauthorized repair or modification will be excluded from this warranty.

This guarantee specifically excludes expendables and consumables.

All warranty claims must be directed to the Medline Industries LP authorized dealer responsible for the sale of the system.

The warranty applies only to the original purchaser of the system.

If the equipment is used in a manner not specified by the manufacturer, the protection provided by the equipment may be impaired.
Specifications

Test Strips: Harmony™ Blood Glucose Test Strip
Test Range: 20~600 mg/dL
Calibration: Plasma
Blood Sample Size: Minimum 0.8 μL
Hematocrit Range: 10~70%
Event management: Before/After meal marker and asterisk marker
Warnings: User configurable hypoglycemia and hyperglycemia warnings, underfill warning
Display Type: LCD screen with back lighting
Memory: 1000 test results with date and time
Dimensions: 105L x 60W x 14.5H (mm)
Weight: 51g (without batteries)
Battery: 2 x CR 2032 3V Lithium coin cell batteries
Battery Life: 1000 tests of continuous use or one year
Automatic Power-Off: After 2 minutes inactivity
Operating Temperature: 41˚F~113˚F
Operating RH%: 20~90%
Alarms: 3
Storage/Transport: Meter at -4˚F~122˚F, <93% RH
Test Strip Condition: Test strip at 39˚F~86˚F, 10~85% RH