INTENDED USE
Harmony Glucose Control Solution is used with the Harmony Blood Glucose Monitoring System to verify that the meter and test strip are working together properly and that the test is performing correctly.

SUMMARY
Harmony Glucose Control Solution contains a measured amount of glucose. These solutions are used with the Harmony Blood Glucose Test Strips to confirm the meter and test strips are working correctly.

CONTROL SOLUTIONS SHOULD BE USED WHEN:
- Using the meter for the first time.
- Using a new bottle or box of Harmony Blood Glucose Test Strips.
- At least once per week to verify that the meter and test strips are working properly together.
- The test strip bottle is left open (for vial test strips).
- The meter is dropped.
- You suspect the meter and test strips are not working properly together.
- A patient’s test results do not agree with how they feel.
- A patient’s readings appear to be abnormally high or low.
- Test strips have been exposed to a condition outside the specified storage conditions.
- Practicing your testing technique.

CHEMICAL COMPOSITION
The Harmony Glucose Control Solution is an aqueous solution. It contains D-glucose in concentrations of:
- Level 1 Control 60 mg/dL.
- Level 3 Control 160 mg/dL.

The non-reactive ingredients included in the solution are buffers, stabilizer and preservative.

WARNINGS AND PRECAUTIONS
Control solutions are for in vitro diagnostic use only and are not intended for human consumption or injection.
- Shake the Harmony Glucose Control Solutions well before using.
- DO NOT apply a second drop of control solution to the reaction zone end of the test strip.
- DO NOT smear the solution with the tip of the bottle.
- Replace the cap of the control solution immediately after use.
- Use only Harmony Glucose Control Solutions.
- Always check the expiration date.
- DO NOT use expired control solutions.

STORAGE AND HANDLING
- Control solutions should be stored between 39°F – 86°F (4°C – 30°C).
- DO NOT FREEZE OR REFRIGERATE.
- DO NOT use past the expiration date.
- Discard any unused control solution 90 days after first opening or after expiration date, whichever comes first.

CONTROL SOLUTION TEST PROCEDURE
Materials needed to perform control solution tests include:
- Harmony Glucose Control Solutions (Level 1 and Level 3).
- Harmony Meter and User’s Guide.
- Harmony Blood Glucose Test Strips.

Conduct test as follows:
1. Newly opened bottles of control solutions must be marked with the date opened on the space provided on the control solution labels. Check the expiration date of the control solutions to make sure they have not expired. Discard any unused control solutions 90 days after opening or after expiration date, whichever comes first.
2. Refer to the User’s Guide for instructions on how to run a control solution test.

EXPECTED VALUES
The Harmony Control Solutions testing should provide results within the expected range. The expected range is shown on the test strip bottle (for vial test strips) or the box (for foil wrapped test strips). If results are out of range, review each step of your technique before doing another test. Any error in technique could cause results to be out of range. If control values continue to be out of range and your technique is correct, repeat test with a test strip from an unopened test strip bottle (for vial test strips) or the box (for foil wrapped test strips). If readings are still out of range, please call Technical Support at 1-866-274-2131, Monday through Friday from 8am to 5pm CT.

CAUTION
If control solution results continue to be out of range after all instructions have been followed, the system is not working properly. DO NOT use the system to test blood glucose until you get a control solution reading that is within the acceptable range.

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(8:00 am – 5:00 pm CT / Monday – Friday)
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Harmony™
GLUCOSE CONTROL SOLUTIONS

REF MPH6560