

iHealth[®]

Control Solution (LEVEL I/ II/ III)

Model: Level II

Instructions for Use

INTENDED USE

The iHealth Control Solution is intended to be used with the iHealth Blood Glucose Monitoring Systems. The iHealth Control Solution contains a specific quantity of glucose concentrate which reacts with the test strips, it's used to verify the accuracy of blood glucose test results.

WHEN TO USE

The iHealth Control Solution is used to ensure the blood glucose meter and test strips are working correctly together and are not defective.

It should also be used in the following situations:

- Each time you open a new vial of test strips.
- If you suspect a dysfunction of the blood glucose meter or test strips.
- To familiarise yourself with the practice of testing.
- If you suspect that the results are not accurate.
- After the blood glucose meter has been dropped or damaged.

WARNING AND PRECAUTIONS

- The iHealth control solution is intended to be used for in vitro diagnostic only.
- Do not swallow or ingest the control solution.
- The control solution is recommended to confirm the performance of the system and can't under any circumstances be substituted to a capillary blood test to test your blood glucose level.
- The control solution should be used before the expiry date printed on the bottle label.
- The control solution must be used within 90 days of opening the vial. (Shelf-life after opening)
- Do not use the control solution after the expiry date or after the shelf-life after opening, whichever comes first, at the risk of getting erroneous results.
- For self-testing.

TEST PROCEDURES

Follow these instructions and refer to the iHealth Blood Glucose Monitoring Systems Owner's Manual for further information.

Step 1

Launch the iHealth Gluco-Smart app.

Go to MENU > Settings > Press "Test with control solution" and choose which blood glucose meters you are using.

Step 2

Insert the test strip into the blood glucose meter slot.

Step 3

Shake the control solution vial vigorously before each use.

Press a drop of control solution onto a clean plastic surface (for example, the bottle cap). For best results, we recommend to throw the first drop and use the second to perform your measures.

Then hold your blood glucose meter and put the test strip reading window into contact with the control solution.

Once the test strip reading window is completely filled, the meter will start counting down, then you can remove the test strip from the control solution sample.

Note: To avoid contamination of the control solution, do not apply it directly to the test strip from the bottle.

Step 4

The test result with the control solution is displayed on your smartphone screen. Compare the result with the range of values printed on the test strips vial label. The result must be within the specified range. If the test result is out of range, repeat the test.

EXPECTED VALUES

Refer to the specified range on the test strips vial label. Several factors can cause out-of-range test results, including:

- The previously mentioned test instructions have not been followed.
- The control solution is contaminated, out-of-date or its shelf-life after opening is exceeded.
- The test strip is damaged or out-of-date.
- The plastic surface that received the drop of control solution during measurement was not wiped.
- The storage temperature of the control solution (between 2°C and 30°C (36°F - 86°F)) has not been observed.
- The iHealth blood glucose meter is failing.

IMPORTANT

If test results with the control solution continue to sit outside the range of values printed on the iHealth Test Strips vial, do not use the meter, test strips, or control solution and contact iHealth Customer Care.

COMPOSITION

The iHealth Control Solution contains a specific quantity of glucose concentrate and 99% non-reactive ingredients.

STORAGE AND HANDLING

- Keep the control solution at a temperature between 2°C and 30°C (36°F - 86°F) and at a humidity rate of 10% to 85%.
- Do not expose to direct sunlight or place near heat sources.
- Use before the expiry date mentioned on the vial.
- Use the control solution within 90 days of initial opening of the vial.
- Close the vial immediately after each use.
- To avoid contamination of the control solution, do not apply directly it to the test strip from the bottle.
- Dispose of used equipment according to regulations applicable in your country.

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If you have questions or need assistance outside the operational hours and days, please contact your healthcare provider.



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EXPLANATION OF SYMBOLS



Manufacturer



Should be recycled



Authorized representative in Europe Community



Catalogue number



Batch number



Consult instructions for use



Storage temperature Limit



Do not use if the package damaged



Use by date



Keep away from direct sunlight or near heat sources.

CE0197

Complies with the requirements of the European IVD Directive (98/79/EC)