

BETACHEK® C50/G5

BETACHEK® C50/G5 Control Solutions
Instructions for use
Device for self-testing

Intended use: For use with BETACHEK® C50 or G5 Blood Glucose monitoring systems as a quality control check to verify accuracy. Suitable for self-testing.

Description: BETACHEK® C50/G5 Control Solutions are water based solutions containing a known amount of glucose which when used in place of blood will react with BETACHEK® G5 Test Strips or C50 test cassettes. The Control Solution should give results within the expected range printed on the container label. Obtaining a result within the expected range is sufficient to verify system performance.

When to carry out a control test: Control Solution should be used

- If you obtain unexpected results.
- After opening a new pack of test strips or test cassette
- After you have replaced the batteries.
- After you have cleaned your meter.
- Whenever you suspect the meter or test strips may not be functioning properly.

Use of Control Solution is also recommended for teaching or learning how to use the system.

Contents of the pack: 1 package insert, glucose Control Solution (see outer packaging for quantities).

Also required: BETACHEK® C50 or G5 Meter and instruction manual, BETACHEK® C50 Cassette or G5 Test Strips
Chemical composition¹

	Control 1
Glucose	0.03
Buffer	0.70
Preservative	0.40
Non reactive constituents	18.00
Water	80.87

¹Values are expressed as a percentage by weight and vary depending on the control level. Figures given are for control 1.

Precautions and limitations

- For *in vitro* diagnostic use only.
- Do not allow Control Solution to enter the meter, use only on cassettes/test strips.
- Discard any unused Control Solution 3 months after opening. Note the discard date on the Control Solution label.
- Use a fresh test zone/strip if the drop of Control Solution has not completely wet the test pad.
- Use one drop of Control Solution only. If several drops were applied repeat the test.
- If the drop applied contained air bubbles, repeat the test.

Storage and handling

- Store the Control Solution between 2 and 30°C (35 and 85°F).
- Use before the expiration date shown on the label.
- Wipe the bottle tip and reseal tightly after each use.

Procedure

Test procedure: To perform a Control Solution test, follow the same test procedure that is used for a blood glucose test, substituting Control Solution for a drop of blood. Refer to 'Performing a test' in your Meter instruction manual for further test instructions.

- Discard the first drop of Control Solution.
- If large bubbles are present at the tip of the bottle, wipe the bubbles off with a clean tissue before applying the drop of Control Solution to the test zone/strip.
- Apply one drop to the test zone/strip.
- To avoid contaminating the Control Solution with enzyme, DO NOT touch the test strip with the tip of the Control Solution bottle.

Expected results: See the G5 test strip container or C50 test cassette container for acceptable control values. If the result is within the stated range, the meter and test strips are performing correctly. If the control result is outside the stated range, check that you have followed the correct procedures (see below 'sources of error'). After eliminating all potential sources of error, repeat the control test. If the control result is still outside the stated range after the second test, please call your Betachek representative.

Sources of error: If test results fall outside the acceptable range, the test should be repeated. Results which fall outside the acceptable range may indicate user error, control solution or test strip expiration, control solution contamination, test strip deterioration, meter malfunction, or extremes in testing temperature. Refer to the meter instruction manual 'Troubleshooting' for assistance. Ensure;

- That the optics area is clean (see Instruction manual),
- That the test cassette/strips and Control Solution you used were correctly stored (expiry date, storage conditions),
- That the meter, test cassette/strips and Control Solution were at the correct temperature during the control test.

 **IMPORTANT:** If your Control Solution results fall outside of the acceptable range, the system is not functioning properly. DO NOT use the system to test your blood glucose until you obtain a Control Solution result that lies within the acceptable range.

Key to symbols: On the box, label and instructions for use you may encounter the following symbols:

 Do not reuse

 $+2^{\circ}\text{C}$ $+38^{\circ}\text{F}$ $+30^{\circ}\text{C}$ $+85^{\circ}\text{F}$ Temperature limitation

 **LOT** Batch code

 **REF** Catalogue number

 Caution

 Manufacturer

 Consult instructions for use

 Use by (unopened container)

 Use by (opened container)

 **EC REP** Authorised Representative in the European Community

 **IVD** In vitro diagnostic medical device

 **CE** ₀₁₂₃ This product fulfils the requirements of European Directive 98/79/EC on in vitro diagnostic medical devices

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