Omnitest® 5 Control

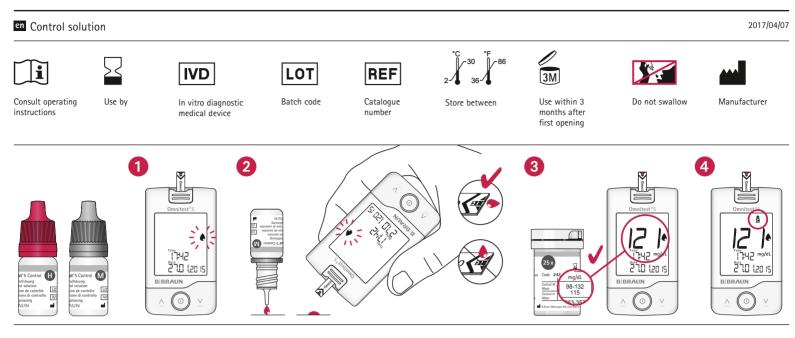|								
Consult operating instructions	Use by	In vitro diagnostic medical device	Batch code	Catalogue number	Store between	Use within 3 months after first opening	Do not swallow	Manufacturer

Instructions for use

IMPORTANT
Please read this information and your **Omnitest® 5** meter and test strip manual before using **Omnitest® 5 Control** solution.

Intended use:
Omnitest® 5 Control control solution is only for use with blood glucose meters from the **Omnitest® 5** meter range and **Omnitest® 5** test strips as a quality control measure to verify the accuracy of the blood glucose test results. The **Omnitest® 5 Control** solution is for in vitro diagnostic use.

WARNING
Keep the control solution away from children. A child could choke on the cap or the bottle. The control solution contains agents that may be harmful if swallowed or applied to the skin or eyes. Do not drink the **Omnitest® 5 Control** solution, it is meant to be used on the test strips only.

Summary and explanation:
The **Omnitest® 5 Control** solution is used to check that the blood glucose monitoring system consisting of the meter and the test strips is working correctly. The **Omnitest® 5 Control** solution is a liquid containing a measured amount of glucose which reacts with the **Omnitest® 5** test strip. If used according to the same procedure as for blood, the control solution should give results within the expected range printed on the test strip vial. Obtaining a single result within the expected range is sufficient to verify the system performance. Use only **Omnitest® 5 Control** solution for the **Omnitest® 5** monitoring system.

The control solution should be used in the following cases:

- For any suspected malfunction of the device or test strips
- If your blood glucose readings do not match your symptoms or if you suspect that the readings are not accurate

- If the meter was dropped
- For quality control in professional applications
- For training purposes and when learning to operate the system

Storage and handling:
- Store the **Omnitest® 5 Control** solution in a dry place between 2 – 30 °C (36 – 86 °F). Keep out of direct sunlight.
- Do not freeze. Do not use control solution which had been stored under inappropriate conditions.
- Store control solution in its original vial only. Do not fill the control solution in new vials or in any other container.
- Wipe off the dispenser tip of excess solution with a clean tissue before replacing the cap.
- Do not use control solution after the expiration date printed on the package or vial since it may cause inaccurate results.
- Make a notation of the date on the vial label when you first open it. Discard remaining **Omnitest® 5 Control** solution 3 months after first opening a bottle.

Using control solution:
To perform a control solution test, follow the same test procedure as for a blood glucose test, substituting control solution for the drop of the blood. Refer to the **Omnitest® 5** meter manual for further test instructions (see "Testing Your Blood Glucose"). If the control solution is cold, do not use until the solution has warmed up to room temperature.

❶ Insertion of test strip
Control solution tests have to be done in a temperature range 20–25 °C (68–77 °F). Insert a test strip as far as possible into the meter without bending it. The meter switches on automatically.

❷ Apply control solution
Gently shake the control solution. Remove the cap and squeeze the container. Discard the first drop and wipe the tip of the bottle with a clean tissue to ensure an accurate result. If large bubbles are present at the tip of the vial, wipe the bubbles off before applying the drop of control solution to the test strip. Squeeze the container again to release a

drop. Apply a drop of control solution on a clean and none absorbing base. Guide the tip of the test strip towards the drop until it is drawn up by the test strip. You will hear the signal tone when the test strip is completely filled with the control solution. The meter counts down from 5 to 1 and then displays the result.

❸ Comparing control solution results
The actual lot-specific ranges are printed on the **Omnitest® 5** test strips vial (Control M ...; Control H ...). The **Omnitest® 5 Control** solution test should fall within the range stated in mg/dL or mmol/L. The average value of the range is printed underneath (mean). Repeat the test if the level displayed falls outside the range. Results that fall outside of the range can be caused by one or more of the following reasons:

- Error when performing the test
- Control solution was not shaken
- Expired or contaminated control solution
- Control solution too warm or too cold
- First drop of control solution was not discarded or the tip of the container was not wiped clean
- Contamination of the control solution e.g. if the drop of the control solution is taken back into the control vial
- Meter malfunction
- Damaged test strip

IMPORTANT
Do not use the **Omnitest® 5** system to test your blood glucose until you get a control solution test result that falls within the specified range.

❹ Marking function
Press ∧ or ∨ button after the measurement to choose the control solution symbol ⓒ among the available symbols.

NOTE
Mark all control solution tests with symbol ⓒ to distinguish from blood glucose tests in the meter memory. Control solution labelled results are not included in the calculation of average levels.

Chemical composition:
The **Omnitest® 5 Control** solution is an aqueous solution with D-glucose as the reactive ingredient.

Ingredients and approximate concentrations of the **Omnitest® 5 Control** solutions:

Control M	Control H
0.11 wt % glucose	0.26 wt % glucose
99.89 wt % nonreactive ingredients	99.74 wt % nonreactive ingredients

If you have any questions about use of the **Omnitest® 5** product, please contact your nearest B. Braun representative or go to **www.bbraun.com/omnitest**