Omnitest® 5

en Blood glucose test strips

2017/04/07

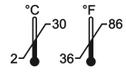

Consult operating instructions


Use by

In vitro diagnostic medical device

Batch code

Catalogue number

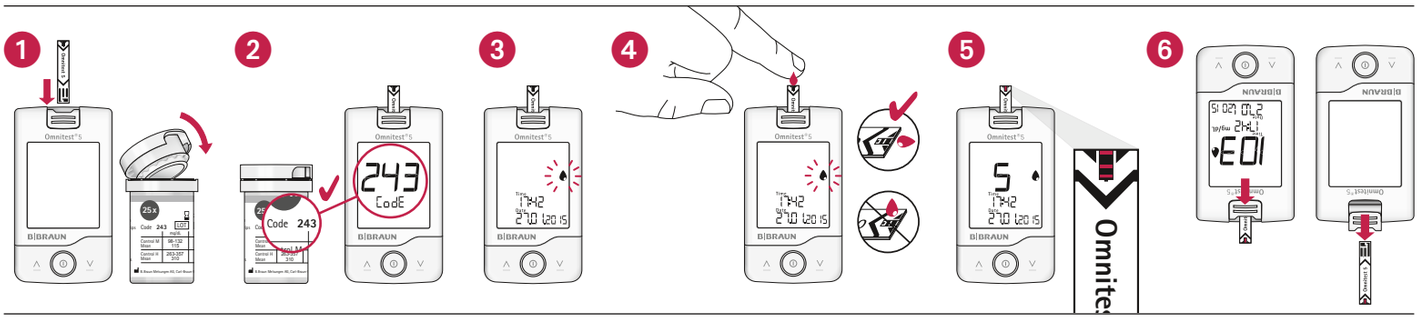


Store between

Use within 6 months after first opening


Do not re-use


Manufacturer



en Instructions for use

IMPORTANT
Please read this information and your **Omnitest® 5** meter manual before using **Omnitest® 5** blood glucose test strips.

Intended use:
Omnitest® 5 test strips are only to be used with blood glucose meters from the **Omnitest® 5** meter range for the measurement of glucose in fresh capillary or venous whole blood. The **Omnitest® 5** system is plasma-calibrated to allow easy comparison of results with laboratory methods. **Omnitest® 5** test strips are for testing outside the body (in vitro diagnostic use only). Patients with diabetes use this system for self-monitoring their blood glucose levels.

Storage and handling:
- Prior to first use, check that the vial is undamaged and closed.
- Store the **Omnitest® 5** test strip vials in a cool, dry place between 2 - 30 °C (36 - 86 °F). Keep out of direct sunlight. Do not freeze. Do not use test strips which had been stored under inappropriate conditions.
- Store test strips in its original vial only. Do not put the test strips in new vials or in any other container.
- Close the vial immediately after removing an **Omnitest® 5** test strip. This keeps the strips fully functional right up to the expiry date.
- Use test strip immediately after removing it from the vial.
- Do not use test strips 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** test strips 6 months after first opening the vial.
- Never touch the test strip with wet or dirty hands. Your fingers must be absolutely clean of food residues when handling the strips.
- Do not bend, cut or alter an **Omnitest® 5** test strip. Use only undamaged test strips.
- Do not alter the areas for automatic coding on the rear side of the test strip.
- **Omnitest® 5** test strips are intended for single use only.
- Do not perform blood glucose tests at temperature below +10 °C (50 °F) or above +40 °C (104 °F) and above 90 % relative humidity.

WARNING
Keep the test strip bottle away from children. A child could choke on the cap or the test strips. The test strips and the vial cap contain agents that may be harmful if swallowed.

Precautions in obtaining accurate results:
Please use the check strip and the **Omnitest® 5 Control** solution to check that the system is working properly. For more information refer to the **Omnitest® 5** meter manual.

Testing your blood glucose:
Cleanliness: Wash your hands with warm soapy water. Rinse and dry hands thoroughly. You may alternatively use an alcohol wipe to clean the puncture area. Make sure it is completely dry before you obtain the blood sample. Contact with food (especially fruits), alcohol, sweat and dirt before testing can distort the results.
Lancing: Prepare the lancing device and lancet. Insert an unused needle (lancet) in the lancing device. Refer to the **Omnitest® 5** meter manual for more information.

1 Insertion of test strip:
Remove test strip from the vial. Recap the vial immediately to prevent moisture from affecting the other strips. Insert the test strip.
2 Automatic coding of the meter:
The meter will automatically turn on and displays the code number.
The **Omnitest® 5** automatically recognizes the test strip code and adjusts the meter accordingly.
3 Applying blood sample:
Blood icon will be displayed on the screen. Date and time information are shown at the bottom. Prick the area where you have decided to obtain the blood.
4 Touch your finger to the tip of **Omnitest® 5** test strip.
5 The measurement chamber of the test strip will draw automatically the blood of your finger. Your finger should remain still, until the confirmation window is completely filled and you hear the „beep" sound. The minimal sample volume is 0.5 µL.

NOTE
Do not force your finger against the test strip. Do not try to apply a smeared sample. Do not add blood to the test strip after the „beep" sound. Do not squeeze the fingertip. It is less painful to prick side of the finger tip.

Accurate results in seconds:
Your blood glucose result will be displayed in 5 seconds. Check that the right test result unit is displayed. Your blood glucose results are automatically stored in the meter memory.
6 Remove tested strip by ejector:
Slide the ejector button forward to remove the test strip from the meter. The meter is turned off with the removal of the test strip.

Test results:
Blood glucose test results are displayed on the **Omnitest® 5** meter as either milligrams of glucose per decilitre of blood (mg/dL) or millimoles of glucose per litre of blood (mmol/L), depending on the fixed test result unit. The **Omnitest® 5** meter displays results between 10 - 600 mg/dL (0.6 - 33.3 mmol/L).
If the test result is below 10 mg/dL (0.6 mmol/L), „Lo" will appear on the meter display. „Lo" results indicate severe hypoglycaemia (low blood glucose). You have to treat this hypoglycaemia as recommended by your physician and you should seek medical assistance.
If the test result is above 600 mg/dL (33.3 mmol/L), „Hi" will appear on the meter display. „Hi" results indicate severe hyperglycaemia (high blood glucose). Consult your physician immediately.
In the case of error messages, please follow the instructions of the **Omnitest® 5** meter manual.

IMPORTANT NOTE
- Follow your physicians advice when to measure your blood glucose.
- Self-testing of blood glucose levels provides a way to control your diabetes. Your health care professional will advice you on your ideal blood glucose range.
- If you have a test result below 60 mg/dL (3.3 mmol/L) or over 240 mg/dL (13.3 mmol/L) contact your physician immediately.
- If your blood glucose result is unusually low or high, or you do not feel the way the result indicates, repeat the test again with a new test strip.
- If the results are still inconsistent, please consult your physician before making any changes to your diabetes therapy.
- If you experience any symptoms that are not consistent with your blood glucose test results and you have followed the instructions described in your **Omnitest® 5** operation manual, call your physician.
- Do not ignore physical symptoms without consulting your physician.
- Blood glucose measurement at alternative test sites could result in blood glucose values different from measurements at the finger tip. These differences are most prominent if the blood glucose level is changing rapidly e.g. after a meal, after insulin injection or during physical activity. Talk to your doctor before starting measurements at alternative test sites.
- Objects which had been in contact with blood bear the potential risk for infectious disease. Please discharge these materials according to the local regulations.

Reagent composition:
Each **Omnitest® 5** test strip contains:
- FAD Glucose dehydrogenase (FAD-GDH) 2 international units
- Other ingredients (e.g. buffer, mediator) ≥ 0.15 mg
- The vial contains about 2.5 g of molecular sieve as drying material.

Test principle:
The enzyme glucose dehydrogenase on the test strip reacts specifically with the blood glucose. The current generated is converted and displayed as blood glucose value.

Limitations of the system:
Omnitest® 5 test strips provide accurate results when the following constraints are observed:
- Use only the **Omnitest® 5** test strips with the **Omnitest® 5** meter.
- Use fresh capillary or venous whole blood only. Do not use plasma or serum.
- Dehydration may lower test results. If you are severely dehydrated, contact you physician immediately.
- Do not use for neonates.
- Inaccurate results may occur when in shock, hypotensive individuals, hyperosmolar state, with or without ketosis.
- **Omnitest® 5** test strips may be used at an altitude up to 3,000 m (10,000 feet) without an effect on test results.

Interferences that may affect test results:
- Haematocrit: Extremes in haematocrit may affect test results. Low haematocrit levels can cause falsely high results and high haematocrit levels can cause falsely low results. Blood glucose measurement may be disturbed under the following conditions: Haematocrit levels < 20 % or > 60 %.
  If you do not know your haematocrit level, consult your healthcare professional.
- Interferences: Acetaminophen (paracetamol), uric acid, ascorbic acid (vitamin C), salicylates, gentisic acid, dopamine and other reducing substances (when occurring in normal blood or normal therapeutic concentrations) do not significantly affect results. However, abnormally high concentrations in blood may cause inaccurately high results.
- Lipemic samples: Cholesterol up to 500 mg/dL (12.9 mmol/L) or triglycerides up to 3000 mg/dL (33.9 mmol/L) do not significantly affect the results. Glucose values in specimens beyond these levels should be interpreted with caution.
- Icodextrin does not interfere with **Omnitest® 5** test strip. Do not use during or soon after xylose absorption testing. Xylose within the blood could lead to falsely high results.
- Antiglycolysis and anticoagulants in blood samples may affect the test results. EDTA and heparin do not affect the measurement.

Performance characteristics:
The performance of **Omnitest® 5** test strips has been evaluated in laboratory and in clinical tests.
The results obtained with the **Omnitest® 5** system were compared to glucose results obtained with the YSI 2300 STAT plus, a laboratory instrument. Glucose levels were measured on 600 fresh capillary specimens at a clinical center.

System accuracy results for glucose concentration < 100 mg/dL (5.55 mmol/L)

Within ± 5 mg/dL (within ± 0.28 mmol/L)	Within ± 10 mg/dL (within ± 0.56 mmol/L)	Within ± 15 mg/dL (within ± 0.83 mmol/L)
104/162 (64 %)	150/162 (93 %)	162/162 (100 %)

System accuracy results for glucose concentration ≥ 100 mg/dL (5.55 mmol/L)

Within ± 5 %	Within ± 10 %	Within ± 15 %
214/438 (49 %)	385/438 (88 %)	428/438 (98 %)

The study shows that the **Omnitest® 5** system compares well with the laboratory method and complies with the requirements of EN ISO 15197.
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**

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