



Blood Glucose
Measurement

Omnitest® 5 & Omnican® Lance FAQ – FREQUENTLY ASKED QUESTIONS

FAQ Omnitest® 5 & Omnican® Lance

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TOP TEN Omnitest® 5

- 1. Does Omnitest® 5 meet the requirements of ISO 15197:2013?**
Yes.
- 2. Which sort of blood has to be used?**
Omnitest® 5 measures the blood glucose level with fresh capillary or venous whole blood.
- 3. Why could the result be different from a competitor device?**
 - General measurement deviation of $\pm 15\%$ according to ISO standard possible
 - Different blood sample (e.g. time, puncture site, venous or capillary)
- 4. Which medications may affect the measurement?**
No effect in case of normal therapeutic concentrations.
See also instructions for use (IFU) for test strips.
- 5. Can Omnitest® 5 be used to measure blood glucose levels in gestational diabetes?**
Yes.
- 6. Is Omnitest® 5 also intended for use in hospitals?**
Yes, basically it can be used in hospitals, with the exception of newborns.
- 7. What happens if the code on the screen does not correspond to the one on the test strip vial?**
If the codes do not correspond, the error is in the automatic coding and the blood sugar can't be determined correctly.
- 8. How do I perform a functional test on Omnitest® 5 to make sure it is working correctly?**
There are two possibilities: the use of the check strip for the device or the measurement with the control solutions Omnitest® 5 Control with a defined glucose content.
- 9. Can I switch the measurement unit of the device (mmol/L or mg/dL)?**
No. For safety reasons, the used measurement unit is fixed.
- 10. How is the proper working order of Omnitest® 5 ensured?**
Every time the test strip is inserted, the device carries out a self-test. For function control, the entire display is shown for 3 seconds. If there is a problem, an error message appears.

TOP THREE Omnican® Lance

- 1. Why should I use Omnican® Lance soft lancets only once?**
If used multiple times, the tip of the lancet becomes increasingly blunt and supports the formation of calluses as well as the risk of infection.
- 2. May the lancing device be used by more than one person?**
No. The lancing device is determined for one's personal use only. It should only be used by one person since its tip may be contaminated after use.
- 3. Does Omnican® Lance feature a lancet ejector?**
Yes, the lancing device has an ejector, which may be operated with one hand.

Overview

Does Omnitest® 5 meet the requirements of ISO 15197:2013?	Yes	
Which sort of blood has to be used?	Omnitest® 5 measures the blood glucose level with fresh capillary or venous whole blood.	
What is the hematocrit range?	20 – 60 % within 10 – 600 mg/dL or 20 – 60 % within 0.6 – 33.3 mmol/L.	
Why could the result be different from a competitor device?	<ul style="list-style-type: none"> ▪ General measurement deviation of ± 15 % according to ISO standard possible ▪ Different blood sample (e.g. time, puncture site, venous or capillary) 	
Which medications may affect the measurement?	No effect in case of normal therapeutic concentrations. See also instructions for use (IFU) for test strips.	
What is the test principle of Omnitest® 5?	The FAD-glucose dehydrogenase enzyme on the test strips reacts specifically with glucose in blood. The current generated is converted and displayed as a blood glucose value.	
What is Omnitest® 5 calibrated against?	The Omnitest® 5 system is plasma-calibrated to allow easy comparison of results with laboratory methods. Blood glucose meters which are calibrated against a whole blood method may have different results in comparison to the Omnitest® 5 results.	
Which laboratory system was used for the calibration of Omnitest® 5?	The laboratory system used to calibrate the Omnitest® 5 system is YSI 2300 STAT plus, which is equipped with a glucose oxidase system.	
What are the components of the Omnitest® 5 Set?		<ul style="list-style-type: none"> ▪ 1 protective meter case ▪ 1 Omnitest® 5 blood glucose meter incl. 2 batteries ▪ 10 Omnitest® 5 test strips ▪ 1 Omnican® Lance lancing device with ▪ 10 Omnican® Lance soft lancets ▪ 1 check strip ▪ 1 user manual ▪ 1 quick reference guide ▪ 1 proper test instructions
What are the components of Omnitest® 5 (Solo version)?		<ul style="list-style-type: none"> ▪ 1 protective meter case ▪ 1 Omnitest® 5 blood glucose meter incl. 2 batteries ▪ 1 check strip ▪ 1 user manual ▪ 1 quick reference guide ▪ 1 proper test instructions

Overview

<p>What benefits does the meter case offer in daily use?</p>	<p>You can leave the meter in the case when measuring. All functions are easily accessible when in the case. The lancing device has a fixed place in the pouch and can be used inside and outside of the pouch. The test strip vial is safely secured against falling out.</p>
<p>My device switched off before I carried out the measurement. What should I do?</p>	<p>After 3 minutes of inactivity, the device shuts off entirely. To switch it on again, remove the unused test strip and reinsert it.</p>
<p>Can I switch the measurement unit of the device (mmol/L or mg/dL)?</p>	<p>No. For safety reasons, the used measurement unit is fixed.</p>
<p>Can I clear readings on the Omnitest® 5?</p>	<p>No.</p>
<p>Is Omnitest® 5 able to display average levels?</p>	<p>Yes. After the last reading or before the first reading, the calculated average levels are displayed consecutively for 7, 30 and 90 days.</p>
<p>What are the benefits of the test strip ejector?</p>	<p>The test strip ejector enables a safe and hygienic removal of the strip, without having to touch the end of the test strip which is contaminated with blood. This is particularly important if a third party does the measuring.</p>
<p>The battery symbol flashes. How do I recharge Omnitest® 5?</p>	<p>Recharging empty batteries with the PC connection cable is not possible. If the battery symbol lights up, you should put in two new 3V lithium batteries type CR2032.</p>
<p>When should I replace my Omnitest® 5?</p>	<p>Replace the blood glucose meter with a new device after a maximum of 5000 tests (roughly corresponds 2,5 years with 5 measurements a day) or 5 years after first use at the latest.</p>
<p>How should defective meters be disposed?</p>	<p>Remove the batteries and send these for recycling according to local provisions. Used meters can be soiled with blood and must therefore be discarded according to the different local regulations for disposal of contaminated medical devices.</p>
<p>What is the target level function?</p>	<p>Thanks to the target level function you can see instantly how much the measurement result differs from what it is supposed to be.</p>

Application Range and Target Groups

Is it possible to use Omnitest® 5 in veterinary medicine – in particular for cats and dogs?	Using Omnitest® 5 for animals is not intended and has therefore not been tested.
Could the system be used for neonates?	No, the hematocrit of neonates fluctuates from 35 % to 68 % and is therefore sometimes out of range.
Can Omnitest® 5 be used to measure blood glucose levels in gestational diabetes?	Yes.
Is Omnitest® 5 also intended for use in hospitals?	Yes, basically it can be used in hospitals, with the exception of newborns.
Is Omnitest® 5 suitable for dialysis patients?	Yes. Dialysis treatment does not interfere with Omnitest® 5.

Test Strips

Which test strips can be used in the Omnitest® 5?	Omnitest® 5 blood glucose meters may only be used with the Omnitest® 5 blood glucose test strips. It is not possible to take correct measurements with other test strips.
Can I use Omnitest® 5 test strips several times?	No. Test strips are single use products.
Why do the test strips have to be stored in the original vial?	In order to grant the imprinted expiry date, the test strips have to be protected against humidity – the desiccant contained in the lid of the vial absorbs moisture.
How long can I use my test strips before and after opening?	Discard remaining Omnitest® 5 test strips 6 months after first opening the vial or after the expiration date printed on the package or vial.
Why are there specifications on the test strip vial?	The label on the vial contains information on the maximum shelf life of the test strips, correct coding and the acceptable value ranges for test measurements with the control solution. Caution: These specifications only apply to the test strip lot indicated on the box, if in doubt check each new vial of test strips.
Why is the code displayed, although Omnitest® 5 features automatic encoding?	The code is displayed for safety reasons and enables the user to check the correspondence of the code of test strip vial and screen.
What happens if the code on the screen does not correspond to the one on the test strip vial?	If the codes do not correspond, the error is in the automatic coding and the blood sugar can't be determined correctly.

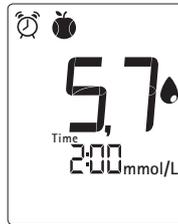
Settings and Stored Readings

What markers can I select for my measurement results?

Following markers are available:

-  Test with control solution
-  Test before meal (preprandial)
-  Test after meal (postprandial)
-  General markings (special circumstances)

What is the   "timer"?



The timer can help to remember a follow-up test after mealtimes.

NOTE:

With the activation of the timer, the current measurement result is automatically saved as "preprandial".

What is the difference between timer and alarm?

The timer can only be activated immediately after measurement and reminds you of the follow-up measurement after a defined period of time. An activated alarm, however, works like an alarm clock and goes off every day at the set time.

Are alarm times permanently deleted, if I deactivate the corresponding alarms?

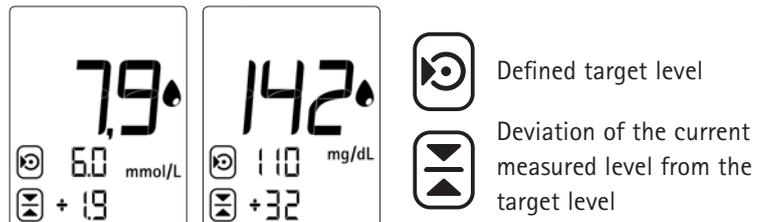
No. The alarm times are retained and can be reactivated at any time.

When do I use  "general marking"?

With this marker, you may indicate unusual circumstances or an extraordinary result. Further information should then be recorded in your diabetes diary.

What benefits offers the storage of my target level in Omnitest® 5?

On the basis of the stored target value, the device automatically calculates any deviation right after the measurement is taken. This is then shown as a positive or negative value on the screen. It lets you assess your blood glucose level more easily and, when appropriate, initiate corrective action. By pressing the buttons  or  after the display of the measurement result, the target level and deviation from the target level are shown according to your settings.



How many measurement results can be stored in Omnitest® 5?

Omnitest® 5 stores 500 readings. The newest reading is always displayed first when you switch on the device via . The button  allows you to search for an older reading. Once the memory capacity has been reached, the oldest readings are replaced by the newest.

Functional Check

How is the proper working order of Omnitest® 5 ensured?	Every time the test strip is inserted, the device carries out a self-test. For function control, the entire display is shown for 3 seconds. If there is a problem, an error message appears.
When should I do a functional check?	It is recommended to perform this test before the first use and after any a malfunction is suspected.
How do I perform a functional check on Omnitest® 5 to make sure it is working correctly?	There are two possibilities: the use of the check strip for the device or the measurement with the control solutions Omnitest® 5 Control with a defined glucose content.
What is the check strip and what do I need it for?	The check strip verifies whether the Omnitest® 5 meter is working properly. If all display elements are shown, the meter is in proper order. If Er1 is displayed, the meter is defective.
When should I use the control solution?	<ul style="list-style-type: none"> ▪ For any suspected malfunction of the device or test strips ▪ If your blood glucose readings do not match your symptoms ▪ 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
Which control solution should I use for the functional check of Omnitest® 5?	Use only Omnitest® 5 Control for the Omnitest® 5 monitoring system. The control solution is sold separately.
How do I carry out a function check with control solution?	Shake the vial with the control solution gently several times so the solution is mixed thoroughly. After unscrewing the cap and taking a first drop, wipe the tip. Then, use a drop of control solution instead of a drop of blood for the measurement. If the result is within the value range printed on the test strip container for the specific type of control solution, the test has been passed.
Why is it important to label measurements with control solutions with the control solution symbol?	The results labelled as being made with control solution are not included in the calculation of average levels. This ensures that the average blood glucose level is not distorted.
What are possible reasons for control solution results outside the range printed on the test strip vial?	<ul style="list-style-type: none"> ▪ Error when performing the test (sample volume too small, blood sample not applied in one step, failure to wipe the dispenser tip clean or to discard the first drop) ▪ Control solution was not shaken ▪ Expired or contaminated control solution ▪ Control solution too warm or too cold ▪ Meter malfunction ▪ Damaged test strip
What are the target results for control solution?	Target results are written on the test strip vial label.
Can the meter be calibrated with control solution?	No, the control solution is only for testing the device.

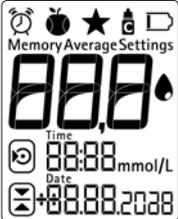
Data Management

<p>Can I transfer the data from my Omnitest® device?</p>	<p>Yes. The measurement results can be transferred via computer to an electronic diary.</p>
<p>Which electronic diaries are compatible with Omnitest® 5?</p>	<p>For data analysis, you can transfer your data to the free-of-charge online portal Omnitest® Center (www.omnitestcenter.com).</p> <p>You can also use other data management solutions from external providers such as DIABASS® (mediaspects GmbH). An overview can be found at: www.bbraun.com/diabetes-datamanagement</p>
<p>What cable do I need for the data transfer from Omnitest® 5 to an electronic diary?</p>	<p>For the data transfer, you only need a PC connection cable (standard USB). The cable can also be purchased from B. Braun as an accessory.</p>
	
<p>Will the data be deleted from my Omnitest® 5 after transferring?</p>	<p>No, the last 500 results are stored on the Omnitest® 5.</p>
<p>What do I need to transfer the data to an electronic diary?</p>	<p>The data transfer is carried out using a PC connection cable (standard USB) and an internet browser. For it to work correctly, you need to install a driver and allow Java applets in your browser. Further information and relevant driver, see: www.bbraun.com/diabetes-datamanagement</p>
<p>How are the stored measurement results transferred to an electronic diary?</p>	<p>The data transfer is carried out in three easy steps:</p> <ol style="list-style-type: none">1. Connect the PC connection cable (standard USB) to your computer.2. Then connect your Omnitest® 5 to your computer with the PC connection cable (standard USB).3. Now start the data transfer according to the instructions of the software/online diary.

Cleaning and Storage

<p>How do I clean Omnitest® 5?</p>		<p>Wash and dry your hands before use to prevent damage to the meter and test strips. The meter should be cleaned with a soft cloth or paper towel if necessary. DO NOT apply pure alcohol directly to the meter for cleaning. Instead, use a tissue that has been moistened with a small amount of alcohol. Allow the meter to dry completely after cleaning in a cool location away from direct sunlight. The meter and test strips must not be immersed in water or other fluids. See also "Cleaning Information" available as PDF.</p>
<p>What should I not use to clean Omnitest® 5?</p>	<p>DO NOT use chemical solvents such as benzene or acetone because these may damage the surface of the Omnitest® 5 and damage it.</p>	
<p>How should I store Omnitest® 5?</p>	<p>After testing, store the Omnitest® 5 components in its case in a cool dry place out of the reach of children.</p>	
<p>What should I avoid when storing Omnitest® 5?</p>	<p>Do not store the meter and test strips near sources of heat, direct sunlight or in the refrigerator. Strong electromagnetic fields (e.g. from mobile phones or microwave ovens) can interfere with the measurement function.</p>	

Troubleshooting

<p>Why does the Omnitest® 5 device need five seconds to take a measurement and require a larger blood sample than Omnitest® 3?</p>	<p>The new measurement system with the new test strip enzyme and the third electrode for underfill detection require a sample volume of 0.5 µL and a measurement time of 5 seconds.</p>	
<p>Why does my Omnitest® 5 calculate e.g. averages of only 490 measurements, while 500 readings are stored?</p>	<p>The apparently missing ten measurements in this example were made with the control solution and therefore do not appear in the averages.</p>	
<p>Why does an empty battery symbol appears when I turn it on even though my device is new?</p>		<p>The battery segment is displayed as part of the display test when switching on the meter – as well as all other display segments. This display is made for safety reasons and does not reflect the current battery status.</p>

Example Views

	<p>DISPLAY OF STORED MEASUREMENT RESULTS</p>
<p>mmol/L Result: 10.7 mmol/L with a postprandial measurement on 21st of January</p>	<p>mg/dL Result: 193 mg/dL with a postprandial measurement on 21st of January</p>
	<p>EXAMPLE: DISPLAY OF AVERAGE LEVELS</p>
<p>mmol/L Within the past 7 days (7 d) 35 tests (35 n) were performed – this results in an average blood glucose level of 6.1 mmol/L.</p>	<p>mg/dL Within the past 7 days (7 d) 35 tests (35 n) were performed – this results in an average blood glucose level of 108 mg/dL.</p>
	<p>DATA TRANSFER OF STORED MEASUREMENT RESULTS</p>
<p>When connected to your computer, PC becomes visible in the Omnitest® 5 display. Your data remains stored on the meter.</p>	
<p>Meter is in proper order and switches off again. Meter is defective. Er 1 is displayed.</p>	<p>FUNCTIONAL CHECK WITH THE CHECK STRIP.</p>
	<p>MEASUREMENT RESULT MARKED AS MEASUREMENT WITH CONTROL SOLUTION.</p>

Overview

How many different penetration depths are available with Omnican® Lance?	Omnican® Lance provides 7 finely graduated settings of penetration depths.
What are the advantages of different penetration depths?	<p>Thanks to the finely graded penetration depth settings, you can choose the most suitable setting for your skin texture:</p> <p>1-3 for soft or thin skin, 4 for normal skin, 5-7 for thick or calloused skin.</p> <p>To obtain blood as painlessly as possible, choose a penetration depth that is as shallow as possible and only goes as deep as necessary to get sufficient blood for the device.</p>
What is a signal window and how does it work?	The window offers a visual signal when the lancing device is correctly primed – it turns red. This indicates that the lancing device is set and ready for use.
Does Omnican® Lance feature a lancet ejector?	Yes, the lancing device has an ejector, which may be operated with one hand.
How does the lancet ejector work?	Unscrew the cap of the Omnican® Lance lancing device. Push the lancet ejector with your thumb forward until the lancet is completely ejected.
What are the advantages of the lancet ejector?	The eject function of the lancing device Omnican® Lance allows safe disposal of the used lancet into an appropriate container. The contaminated lancet tip is not touched during this procedure.
Where do I find the batch code on the lancing device?	The batch code for the device is printed under the slide for loading. It becomes visible when the slide is moved backwards.
When do I have to replace my lancing device with a new one?	Replace your Omnican® Lance device with a new one after 10,000 pricks and no later than 5 years after the first use.
How often should the Omnican® Lance device be cleaned?	Clean the Omnican® Lance lancing device on a regular basis and whenever blood or other contamination is present.
How should I clean the lancing device Omnican® Lance?	The Omnican® Lance device may only be wiped on the outside with a mild soap and water solution.
Can I rinse the Omnican® Lance device under the tap in case of higher levels of contamination?	You may additionally unscrew the cap to clean the cap inside. Leave the device to dry properly afterwards.
May I use Omnican® Lance soft lancets more than once?	Use a new sterile Omnican® Lance soft lancet for blood collection after every use to ensure as little pain as possible. Omnican® Lance soft are sterile single-use medical devices and should only be used once.
Why should I use Omnican® Lance soft lancets only once?	If used multiple times, the tip of the lancet becomes increasingly blunt and supports the formation of calluses as well as the risk of infection.
May the lancing device be used by more than one person?	No. The lancing device is determined for one's personal use only. It should only be used by one person since its tip may be contaminated after use.

