Omnitest[®] 5

Blood Glucose Monitoring System





Important notes

The Omnitest® 5 system provides a quick and easy way to measure the blood glucose level. It can be used for self-monitoring of blood glucose levels by patients with diabetes. Omnitest® 5 is not intended for any purpose other than measuring the blood glucose level and is intended for use exclusively with fresh capillary or venous whole blood samples. It should not be used to diagnose diabetes or for newborn testing (neonates). Omnitest® 5 is intended for use outside the body (in vitro diagnostic use only).

NOTE

Prior to use, read all of the instructions in this manual for the Omnitest® 5 meter and the additional information in the test strip instructions for use. Practice the correct and safe procedure for measuring blood glucose. You should follow the recommendations of your diabetes care professional for correct use of this meter and daily management of your diabetes. Do not change your treatment based on the Omnitest® 5 blood glucose readings without consulting your physician beforehand.

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Overview

Contents

Omnitest® 5 Set
Blood glucose meter Omnitest® 5
Display symbols
Test strips Omnitest® 5
Lancing device Omnican® Lance

Omnitest® 5 Set

Components of the Omnitest® 5 Set:

- Protective meter case
- Omnitest® 5 blood glucose meter incl. 2 batteries
- Omnitest® 5 test strips
- Omnican® Lance lancing device with Omnican® Lance soft lancets
- Check strip
- User manual and quick reference guide







Blood glucose meter

Test strips

Lancing device with lancet

The blood glucose meter case offers many benefits for daily use:

- 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.

Blood glucose meter Omnitest® 5

Front

- 1 Illuminated test strip port
- 2 Eject button
- 3 Illuminated display
- 4 Up and Down button
- 5 ON/OFF and selection button



Back

- 6 Product label
- Battery cover
- 8 Strap holder
- Data transfer port (Micro-USB port)



Display symbols

Symbol	Meaning
	Drop flashing – Omnitest® 5 is ready for measuring. Drop lit up – Test was performed.
•	Test was performed with control solution.
	Test was preprandial (before meal).
Ĭ	Test was postprandial (after meal).
	Timer (Reminder for follow-up test) is activated.
*	Test is associated with a special event (e.g. perceived low blood sugar).
Ø	One or more alarms are active. Up to 5 alarms can be set in the Omnitest® 5.
	Indicator lit: Battery voltage is low. Change the batteries without delay.
	Indicator flashing: Battery voltage not sufficient to perform test. Change the batteries without delay.

Symbol	Meaning
mg/dL	Unit of measure display. NOTE: The unit of measure is preset at the factory and cannot be changed.
Memory	Displaying stored readings. Up to 500 readings can be stored.
Average	Display of average levels. The average levels for 7 days, 30 days and 90 days are displayed.
Settings	Basic settings for the Omnitest® 5 and personal setting options for the user.
Time	Time
Date	Date
	Preset target level (= optimal level)
Y	Deviation from the target level: Plus levels show a deviation upwards, minus levels show a deviation downwards.

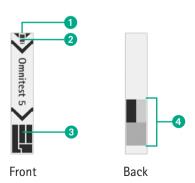
Test strips Omnitest® 5

Use of Omnitest® 5 test strips

For accurate analysis of your blood glucose level, the Omnitest® 5 blood glucose meter must be used with the Omnitest® 5 blood glucose test strips.

- 1 Opening of the measuring chamber
- 2 Confirmation window
- 3 Meter contacting leads
- 4 Auto-coding label





- Prior to first use, check that the vial is undamaged and closed.
- Store the test strips in the original vial in a cool, dry place between +2 °C to +30 °C (+36 °F to +86 °F).
- Close the vial cap immediately after removing a test strip and use the test strip immediately.
- Do not use test strips after the expiration date.
- Avoid getting dirt, food or water on the test strip. All parts
 of the test strip could be touched with dry and clean fingers.
- Do not bend, cut or alter an Omnitest® 5 test strip and coding on the backside.
- Blood glucose tests may only be performed between +10 °C and +40 °C (+50 °F and +104 °F) and at a relative humidity of less than 90%.

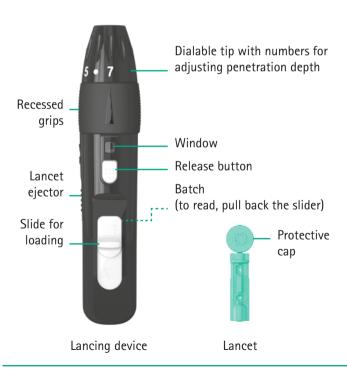
NOTE

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.

Lancing device Omnican® Lance

Use of Omnican® Lance lancing device

In combination with Omnican® Lance soft lancets, the Omnican® Lance lancing device is your reliable partner for a soft blood collection.



- Use a new sterile Omnican® Lance soft lancet for blood collection after every use to ensure as little pain as possible.
- 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.
- Clean the Omnican® Lance lancing device on a regular basis and whenever blood or other contamination is present after taking a sample to prevent from the transmission of infectious diseases.

Further handling instructions can be found starting of page 20. Additional cleaning instructions can be found on page 27.

NOTE

To avoid transmission of infectious diseases, the lancing device must only be used for one patient.

Measuring blood glucose

Contents

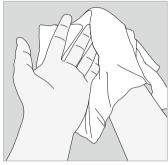
Preparing for the measurement
Collecting blood with the lancing device
Measuring blood glucose
Marker function and display
Target level deviation indicator
Lighting the display

Preparing for the measurement

Cleanliness

The easiest way of collecting a blood drop is by firstly washing the hands with warm and soapy water, let them dry completely afterwards. This supports blood circulation in the finger tips.





The puncture site can alternatively be wiped with an alcohol-soaked swab. Please ensure that the site is completely dry before collecting the blood sample.

Taking the blood sample from clean finger tips prevents incorrect blood glucose measurements due to residues on skin surface of the fingertip. E.g. contact with food (especially fruits), alcohol, sweat and dirt before testing can distort the results.

Blood collection

Prepare the lancing device and lancet. Use a new sterile lancet for every blood sample. The lancing device is determined for one's personal use only or for use with only one patient since its tip may be contaminated after use.

Further information on blood collection can be found starting on page 22.

NOTE

Please read the additional information in the test strip instructions for use.

Your diabetes care professional will tell you your optimal blood glucose ranges. Consult your physician before making any changes to your diabetes therapy.

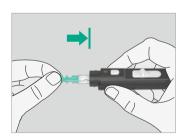
Collecting blood with the lancing device

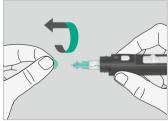
Preparing the lancing device

Unscrew the cap of the Omnican® Lance device.



Firmly insert a new Omnican® Lance soft lancet into the lancet holder. Remove the protective cap from the Omnican® Lance soft lancet carefully in straight direction. Take care not to harm the delicate tip.





Screw the cap of Omnican® Lance on the device again.



The dialable tip of Omnican® Lance provides 7 finely graduated settings of penetration depths. Setting 1 is for most shallow, setting 7 for deepest penetration depth. Choose the penetration depth that is most suitable for your personal condition of skin:

- 1-3 for soft or thin skin,
- 4 for normal skin,
- 5-7 for thick or calloused skin.

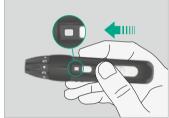
In order to adjust penetration depth, hold the device with one hand at recessed grips and turn the dialable tip with number values with the other hand. Turn it until the marking arrow points at the desired number.

Collecting blood with the lancing device

Loading the lancing device

To load the lancing device, push the slide for loading backwards. You can hear that the tensioning spring snaps into place whilst the window turns red. The Omnican® Lance lancing device is now ready to use.





NOTE

The batch code for the device is printed under the slide for loading. It becomes visible when the slide is moved backwards.

Releasing the lancing device

Take the Omnican® Lance lancing device and place it on the side of your finger tip. The device should lay flatly and without too much pressure against the surface of your skin. Press the release button and lift off the lancing device.

It is less painful if you use the side of your fingertip for puncturing.



Place the Omnican® Lance device aside and wait seconds for a blood drop to form. You can improve the flow of blood by keeping your hands warm, lowering them to hip height and massaging the finger softly.

Collecting blood with the lancing device

Removing the used lancet

To remove the Omnican® Lance soft lancet, unscrew the cap of the Omnican® Lance lancing device. Push the lancet ejector with your thumb forward until the lancet is completely ejected.



NOTE

For safety reasons and to prevent from cross-contamination, dispose of the used lancet in a suitable container for sharps or for hazardous biological waste according to local quidelines.

Cleaning the lancing device

The Omnican® Lance device may only be wiped on the outside with a mild soap and water solution. You may additionally unscrew the cap to clean the cap inside. Leave the device to dry properly afterwards.

NOTE

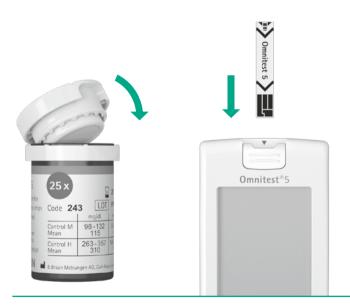
Replace your Omnican® Lance device with a new one after 10,000 times of usage or not later than 5 years after first use.

Measuring blood glucose

Inserting the test strip

Remove a test strip from the test strip vial and check it for any damage. Close the vial again immediately to protect the remaining test strips from moisture.

Insert the test strip into the meter unit as far as it will go, without bending the test strip. The meter now switches on automatically.

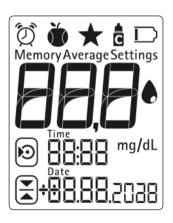


Display test

Every time the test strip is inserted and the device switches on, a self-test of the electronics occurs. The entire display is shown for 3 seconds to check the display elements. If there is a problem, an error message appears.

NOTE

The battery segment is displayed as part of the display test. It does not reflect the current battery status. Notes on the low battery indicator can be found on page 84.



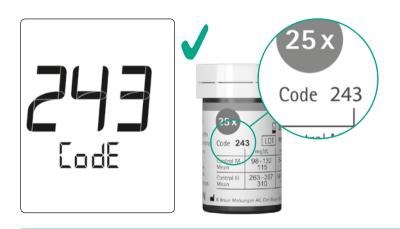
Measuring blood glucose

Code detection

The test strip code detection occurs automatically and is displayed for checking. Check to ensure the codes match between the test strip vial and the display.

NOTE

If the code numbers do not match, the blood glucose will not be measured accurately. Make sure to compare the code number with the correct test strip vial. Check that the coloured fields on the back of the test strip are undamaged.



Ready to measure

If the blood symbol • is flashing on the display, the Omnitest® 5 is ready to measure. Date and time are displayed on the lower edge.

NOTE

The meter switches off after 3 minutes automatically if no test was performed with the test strip. When this happens, the test strip must be reinserted.



Measuring blood glucose

Applying blood

Touch your finger to the tip of the Omnitest® 5 test strip. Ensure that blood is not applied from above.





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. The minimal sample volume is 0.5 μ L.

NOTE

Do not squeeze the fingertip. Do not attempt to apply a smeared blood sample. The measuring chamber must be filled in one draw. Reapplying can lead to incorrect readings. Do not force your finger against the test strip, the test strip must not be bent.

Measuring process

After a sufficient volume of blood has been absorbed into the test strip, a signal beeps and the test starts automatically.





Remove your finger from the test strip as soon as you hear the "beep".

NOTE

Do not add blood to the test strip after the "beep" sound. Ensure that no blood flows from the test strip into the device. The device may no longer be used if blood, control solution or other fluids penetrate the test strip port.

Measuring blood glucose

Measuring process

During the measuring process, the remaining seconds are displayed on the display until it has ended. The result appears after 5 seconds.







Reading display

The reading is displayed in mg/dL (milligrams of glucose per decilitre of blood). You cannot alter the unit of measure.

The Omnitest® 5 meter can display results between 10 and 600 mg/dL.



NOTE

Your meter was preset and is locked to display results in mg/dL. If your display shows mmol/L instead of mg/dL, contact our customer service. The use of the wrong unit of measure can lead to a misinterpretation of the blood glucose levels and result in incorrect treatment.

Measuring blood glucose

Removing the used test strip

To remove the test strip from the meter, push the ejector button forwards while the meter is directed downwards. Discard the used test strip and the lancet in accordance with local regulations.



Marker function and display

Enter marker

After testing, press the buttons \wedge or \vee to select one of the following markers:



Test with control solution



Test before meal (preprandial)



Test after meal (postprandial)



Timer activated (Reminder for a follow-up test)



General markings (Special circumstances)

To select, press the button \odot . The result is automatically saved with the marker displayed.

Marker function and display

Mark reading as "Test with control solution"

After testing, choose the symbol $\hat{\mathbf{c}}$ with \wedge or \mathbf{V} . The symbol for the control solution $\hat{\mathbf{c}}$ flashes. Confirm your choice with the button $\hat{\mathbf{O}}$. The device switches off.



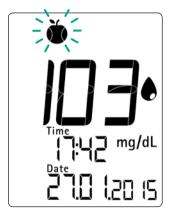
Mark the reading as "Test before/after a meal"

After testing, choose the symbol $\textcircled{\bullet}$ with \land or \lor . The symbol for a test before a meal $\textcircled{\bullet}$ (preprandial) flashes. Confirm by pressing 0. The device switches off.

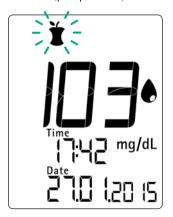
You additionally have the option to activate the timer (see page 40).

For a test after a meal (postprandial), choose the symbol $\tilde{\mathbf{x}}$ with Λ or ∇ and confirm your choice with the button \mathbf{O} .

Test before a meal (preprandial)



Test after a meal (postprandial)



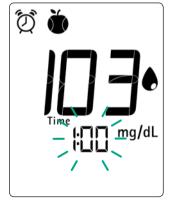
Marker function and display

Activate timer

The timer O $\textcircled{\bullet}$ can help to remember a follow-up test after mealtimes. After testing, choose the symbol O $\textcircled{\bullet}$ with \land or \lor . Press the button O to activate the timer. The timer alarm is preset to one hour after the current test. To lengthen or shorten the preset time, press the button \land or \lor to change it in 15-minute intervals.

Press the button ① again briefly to start the timer. The device switches off.

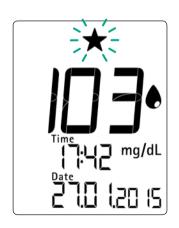




Mark reading as "General Marking"

The result is marked to indicate special circumstances or an exceptional reading. More detailed information about this can be noted in your diabetes diary.

After testing, choose the symbol \bigstar with \land or \lor . The symbol for general marking \bigstar flashes. Confirm your choice with the button \odot . The device switches off.



Target level deviation indicator

Target level deviation indicator

By pressing the buttons \wedge or \vee the target level \bigcirc and deviation from the target level \bigcirc are shown according to your settings.

NOTE

To display the target level and the deviation from the target level, the target level must be defined and activated in the Omnitest® 5 (see page 56).

Enter the target level only in consultation with your physician or your diabetes educator.





Defined target level



Deviation of the current measured level from the target level

Lighting the display

Lighting the display

The display illuminates and the test strip port switches on shortly after inserting the test strip. If nothing else happens, the backlight turns off to reduce power consumption after a short time. By pressing a button, the backlight can be switched back on.

After 3 minutes of inactivity, the device shuts off entirely. To switch it on again, remove the unused test strip and reinsert it.

Stored readings

Contents

Displaying stored readings

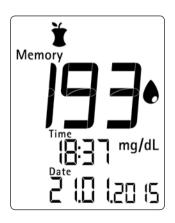
Transferring readings

Displaying stored readings

Displaying stored readings

When the device is off press the button \odot to bring up your stored readings on the meter.

Omnitest® 5 stores 500 readings. The newest reading is displayed first. The button \mathbf{V} allows you to search for an older reading. After 500 data entries, the oldest readings are replaced by the newest.

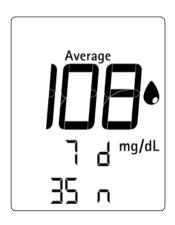


Display of average levels

Use the buttons \land or \lor to change between individual stored readings. After the last reading or before the first reading, the calculated average levels are displayed for different time periods consecutively:

- Average level for 7 days
- Average level for 30 days
- Average level for 90 days

In the example shown, within the past 7 days (7 d) 35 tests (35 n) performed and gives the average blood glucose level of 108 mg/dL.

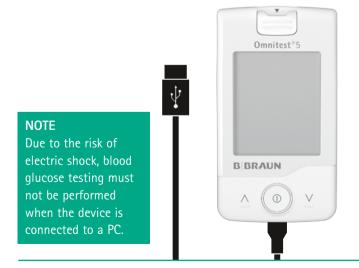


Transferring readings

Data transfer of stored readings

Readings can be transferred from the Omnitest® 5 to a computer for further analysis. A PC connection cable (standard USB to micro-USB connector) is needed to be able to use this function. The cable can also be purchased as an accessory. The device cannot be charged via the cable. Directions for changing the battery can be found on page 84.

When connected to your PC, the Omnitest® 5 display shows PC . Your data remains stored on the Omnitest® 5.



The data transfer proceeds as follows:

- Connect the PC connection cable to your computer
- Then connect your Omnitest® 5 to the PC connection cable
- Start the data transfer according to the instructions in the software

Compatible diabetes diary software is required to display your readings.

An overview of compatible electronic diaries can be found at www.bbraun.com/diabetes-datamanagement



Settings

Contents

Time and date	
Acoustic signal	
Timer	
Target level	
Alarms	
Exit settings	

Settings

Changing the device settings

To change the device settings, press the button \odot and hold for more than 3 seconds until the symbol **SEt** flashes.

When adjusting the settings, **Settings** is continuously shown at the top of the main display.

The following pages show the setting options that can be selected for the blood glucose meter.

Use the button \odot to switch between the setting options.

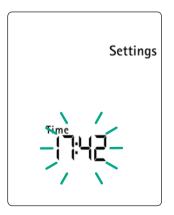
After changing the batteries, the device settings are also called up automatically.



Time and date

Time and date

Press the button \odot to set the hours, minutes, year, month and day one after another. With the buttons \wedge or \vee you can change the flashing value.

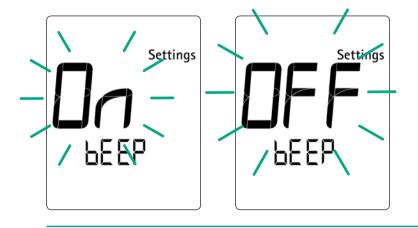




Acoustic signal

Acoustic signal

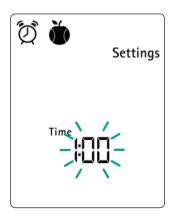
Acoustic signals **(bEEP)** are activated by default on the Omnitest® 5. Press the button \land or \lor to change the status from **On** to **OFF**. Confirm your choice with the button \boxdot .



Timer

Timer

Use the timer as a reminder for a follow-up test after a meal. The preset alarm time for the timer 0 is one hour. To lengthen or shorten the preset alarm time, push the button \land or \lor to change it in 15-minute intervals. Press the button 0 to save the alarm time for the timer.



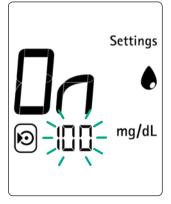
Target level

Display and setting target level

If the display is activated, you can change the preset target level of 100 mg/dL using the buttons \land and \lor to increase or reduce it.

Afterwards press the button ① to confirm the target level.



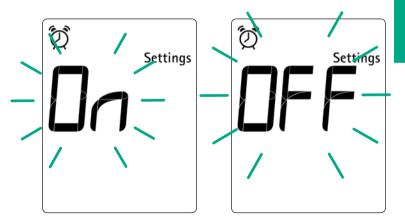


Alarms

Switch off all alarms

Alternate with the buttons Λ or V between \mathbf{On} and \mathbf{OFF} and confirm your choice with the button \mathbf{O} .

If an alarm time is set, but the alarm sound is switched off, before a test the symbol \bigcirc **OFF** appears.



Alarms

Setting alarms

In the Omnitest® 5, up to 5 alarms ② can be set, which can be individually activated/deactivated. An activated alarm signals every day at the preset time. Deactivated alarms are not deleted.



Select with the buttons \land and \lor an alarm and confirm your choice with the button \odot to activate it.

Afterwards you can use the buttons Λ and V to set the alarm time and save this time with the button 1 before setting the next alarm.

NOTE

Press any button to end an alarm.

When performing a blood glucose test, the alarm does not work. The volume of the alarm is designed to remind you of the next blood glucose measurement, but not to wake you from a deep sleep.



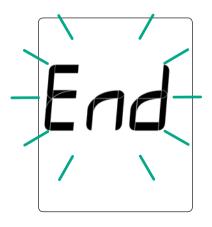
Exit settings

Exit settings

After exiting the settings, the display flashes **End** and the Omnitest® 5 switches off. If you wish to alter more settings, start the settings again.

NOTE

You can exit device settings at any time by holding the button ${\bf O}$ for longer than 3 seconds.



Functional check

Contents

Check strip

Control solution

Check strip

Monitoring with the check strip

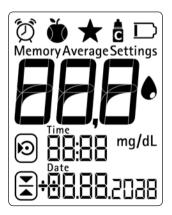
The check strip verifies whether the Omnitest® 5 meter is working properly. Insert the check strip into the meter. The meter switches on automatically.



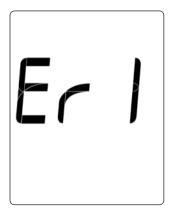
If an error message appears on the display, repeat the procedure 2 to 3 times. If an error message continues to be displayed, the meter may not be used for measuring blood glucose levels. Contact your local representative for warranty services.

It is recommended to perform this test before the first use and after any a malfunction is suspected.

Meter is in proper order and switches off again.



Meter is defective. Er 1 is displayed.



Control solution

Verification with control solution

The control solution Omnitest® 5 Control verifies that the blood glucose monitoring system is functioning properly.

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



NOTE

Use only Omnitest® 5 Control for the Omnitest® 5 monitoring system. The control solution is sold separately.

Preparation of the verification

Control solution tests must be performed within a temperature range of +20 °C to +25 °C (+68 °F to +77 °F).

If the control solution is cold, do not use it until it has warmed to room temperature.

Insert a test strip as far as possible into the meter without bending it. The meter switches on automatically.

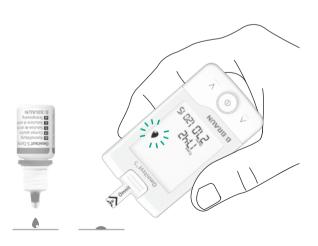


Control solution

Applying the 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. Squeeze the container again to release a drop.

Apply a drop of control solution to 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.

Compare the displayed result with the range printed on the test strip vial. The result should fall within the range. Repeat the test if the level displayed falls outside the range.



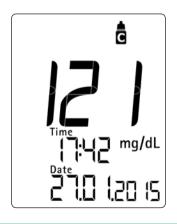
Control solution

Mark reading

When you have performed a test with control solution, you can now use the button \wedge or \vee to mark the measured level with the symbol $\overset{\bullet}{\mathbf{G}}$ and $\overset{\bullet}{\mathbf{O}}$ confirm it.

NOTE

Control solution labelled results are not included in the calculation of average levels.



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
- Meter malfunction
- Damaged test strip

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

Appendix

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Error messages and troubleshooting	
Maintaining your Omnitest® 5	
Changing batteries	
Technical data and tips	
Conversion table mg/dL – mmol/L	

Error message	Cause
Erl	There is a problem with the meter. An incorrect signal from the check strip occurred.
Er2	The error message may have been caused by a used or wet test strip.
Er3	There was not enough blood or control solution applied.
Er4	There is a problem with the test strip.
Er5	The blood sample or control solution was applied before the symbol • was shown on the display.

What to do
Remove both batteries and insert them again. Repeat the test with the check strip. If the error message continues to be displayed, the meter must be replaced.
Repeat the test with a new test strip.
Repeat the test with a new test strip and sufficient volume of blood or control solution.
The test strip is damaged. Repeat the test with a new test strip.
Repeat the test with a new test strip. Apply blood or control solution only after the symbol • has been shown on the display.

Error message	Cause
Er6	There is a problem with automatic code detection.
Er7	The ambient temperature is too high or too low.
500	There is a problem with automatic code detection.
	The Omnitest® 5 contains no readings.

What to do
Repeat the test with a new test strip. If the problem persists, contact the B. Braun representative in your area.
Put the meter in a location within the operating temperature range $(+10 ^{\circ}\text{C to} +40 ^{\circ}\text{C} / +50 ^{\circ}\text{F to} +104 ^{\circ}\text{F})$ for at least 10 minutes and repeat the test.
If the display alternates displaying Sun and Er6 , avoid direct sunlight entering the test strip port and repeat the test.
The memory for the measurement results is empty until you have performed the first blood glucose test.

Error message	Cause
H, •	The reading is above 600 mg/dL.
La.	The reading is below 10 mg/dL.
2.00 f50 i2	Low battery voltage indicator. The battery symbol is displayed during use.
深	The battery voltage is no longer sufficient to turn on the Omnitest® 5. The battery symbol flashes if a button is pushed or if a test strip is inserted.

In case of doubt with regard to the blood glucose level, check the meter with the control solution. If the result is normal, re-tes with a blood sample 2 to 3 times. If the Hi (high) message persist please consult a physician promptly for assistance. In case of doubt with regard to the blood glucose level, check the meter with the control solution. If the result is normal, re-tes with a blood sample 2 to 3 times. If the Lo (low) message persist consult a physician promptly for assistance. Change the batteries immediately.
the meter with the control solution. If the result is normal, re-terwith a blood sample 2 to 3 times. If the Hi (high) message persist please consult a physician promptly for assistance. In case of doubt with regard to the blood glucose level, check the meter with the control solution. If the result is normal, re-terwith a blood sample 2 to 3 times. If the Lo (low) message persist consult a physician promptly for assistance. Change the batteries immediately.
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consult a physician promptly for assistance. Change the batteries immediately.
,
Change the batteries immediately.

Problem	Cause
Different readings in comparison to another device.	The other device has been calibrated to whole blood while the Omnitest® 5 is calibrated to plasma.
	The blood samples were not collected at the same time.
	The puncture site was not cleaned.
	The blood sample was smeared or could not be taken in one draw from the test strip.
The meter does not turn on.	The battery voltage is not adequate or there is a problem with the meter.
After applying the sample the test does not start.	The sample volume is not adequate or there is a problem with the test strips or the meter.
The result is doubtful.	There is a potential problem with the test strips.
	The meter code and the code printed on the test strip vial differ.

What to do
To check the accuracy of your system, please use the control solution Omnitest® 5 Control or compare readings to a laboratory device that works with plasma.
Repeat the test and take the blood samples at the same time for comparison.
Repeat the test with a blood sample from a clean puncture site.
Repeat the test with a sufficiently large fresh blood sample.
Change the batteries. If the problem persists, contact your retailer or B. Braun representative in your area.
Apply a sufficient sample volume to the new test strip and repeat the test. Perform a test with the control solution or the check strip.
Repeat the test with a new test strip. Test with control solution.
Repeat the test with a new test strip. If the problem persists, contact your retailer or B. Braun representative in your area.

Maintaining your Omnitest® 5

Cleaning

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.

Meters that come into contact with blood present a potential risk of transmitting infectious diseases. If necessary, an alcohol-soaked swab can also be used to clean the external surfaces of the meter.

NOTE

DO NOT use chemical solvents such as benzene or acetone because these may corrode the surface of the Omnitest® 5 and damage it.

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.

Storage

Do not store the meter and test strips near open flames or microwave ovens. Strong electromagnetic fields (e.g. from mobile phones, microwave ovens) can interfere with the measurement function.

After testing, store the Omnitest® 5 components in its case in a cool dry place out of the reach of children. Do not refrigerate. Keep out of direct sunlight.

Detailed storage instructions for the Omnites® 5 test strips can be found in the Omnitest® 5 test strips instructions for use.

Discard used objects/materials in accordance with local guidelines for contaminated materials.

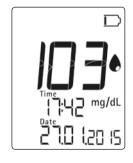
Changing batteries

Information on changing the batteries

Discharged batteries are shown by the illuminated battery symbol \square on the top right of the display. Change the batteries immediately when this occurs.

The meter requires two 3V lithium batteries (CR2032) that are supplied with the meter. Open the battery cover on the back of the unit and insert two new batteries. Ensure that the batteries are inserted in the right direction (imprinted plus sign to the top).





After inserting new batteries, all elements are initially shown on the display. After a few seconds, an internal test of the electronics is performed. The numbers shown only represent the internal electronic tests. You will be automatically moved to the settings (SEt). Correct the time setting and date from there.

Further information on device settings can be found starting on page 52.

NOTE

Without correctly setting the date, the correct values for the average blood glucose level and the results in the memory will not be displayed correctly. It is strongly recommended to set the meter before use and to check the time after inserting a new battery. A blood glucose test is not possible when the settings mode is activated.

Technical data and tips

Risk of infection and cross-contamination

To prevent infections and/or cross-contamination, strictly observe hand hygiene and clean your Omnitest® 5 as well as the corresponding accessories regularly.

System limitations

For more information on system limitations or factors which could impact test results, please read the Omnitest® 5 test strips instructions for use. The Omnitest® 5 blood glucose monitoring system complies with EN ISO 15197 requirements. Replace the blood glucose meter with a new device after a maximum of 5000 tests or at the latest 5 years after the first use.

Test principle

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.

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. The laboratory system used to calibrate the Omnitest® 5 system is YSI 2300 STAT plus, which is equipped with a glucose oxidase system.

Instructions for disposal of defective meters

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.

Technical data and tips

Specifications	
Measurement range	10 – 600 mg/dL
Measurement time	5 seconds
Memory capacity	500 readings with date, time and additional data
Operating temperature	between +10 °C and +40 °C (+50 °F and +104 °F)
Operating humidity	10 - 90%
Sample type	Fresh capillary or venous whole blood
Sample volume	0.5 μL
Screen type	Backlit LCD
Dimensions (L x W x H)	78 mm x 43 mm x 16 mm
Weight incl. batteries	45 g
Power supply	Two 3V lithium batteries (CR2032)
Battery life	min. 1,000 tests

Symbols and labels						
[]i	Consult instructions for use					
\subseteq	Use by					
C € 0123	This product fulfils the requirements of Directive 98/79/EC on in vitro diagnostic medical devices					
IVD	In vitro diagnostic medical device					
LOT	Batch code					
REF	Catalogue number					
SN	Serial number					
1	Temperature limitation					
2	Do not reuse					
3M 6M	Use within 3 or 6 months after first opening					
	Direct current					
	Biohazard. Device could be contaminated with infectious material after use					
	Responsible manufacturer					
	Omnican® Lance soft: Do not use if the protective cap is missing or damaged.					

Conversion table mg/dL - mmol/L

Blood glucose levels conversion table (mg/dL in mmol/L)

mg/dL	10	15	20	25	30	35	40	45	
mmol/L	0.6	0.8	1.1	1.4	1.7	1.9	2.2	2.5	
mg/dL	95	100	110	120	130	140	150	160	
mmol/L	5.3	5.6	6.1	6.7	7.2	7.8	8.3	8.9	
mg/dL	260	270	280	290	300	325	350	375	
mmol/L	14.4	15.0	15.5	16.1	16.7	18.0	19.4	20.8	

Conversion factor: 1 mg/dL = 0.0555 mmol/L resp. 1 mmol/L = 18.018 mg/dL

50	55	60	65	70	75	80	85	90
2.8	3.1	3.3	3.6	3.9	4.2	4.4	4.7	5.0
170	180	190	200	210	220	230	240	250
9.4	10.0	10.5	11.1	11.7	12.2	12.8	13.3	13.9
400	425	450	475	500	525	550	575	600
22.2	23.6	25.0	26.4	27.8	29.1	30.5	31.9	33.3

For further questions on using the Omnitest® 5 system, contact the B. Braun representative in your area or visit us at www.bbraun.com.



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