BETACHEK® C50

Cassette Blood Glucose Monitoring System

User's Manual

Model C50 -1

EN

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NDP

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This user's guide can be viewed at www.betachek.com

Explanation of symbols

Manufactured by

Expiry date

This product fulfils the requirements of IVDR on in vitro diagnostic medical devices.

In vitro diagnostic medical device

Read instructions before use

Storage temperature range

Important information accompanies this product

Authorised representative in the European Community

Lot number

Unique Device Identifier

For self testing

Single patient, multiple use

EC REP

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Intended use

The BETACHEK C50 system is for the quantitative determination of glucose in fresh capillary blood, for the management of diabetes. Suitable for self-testing only. The meter may only be used for blood glucose testing by one person. There is a risk of infection being transmitted if the meter is shared with other people, or if health care professionals use the same meter for testing blood glucose in more than one person.

Lancing device The integrated lancing device is intended for personal use only. Sharing the lancing device could transmit infection. It may not be shared with other people. The lancing device is therefore not suitable for professional use in health care centres, doctors offices or hospitals.

Main features

- No test strip handling or disposal - Cassette System
- Fully integrated lancing device with 10 penetration settings
- Wireless automatic data transfer to Apple or Android device
- Results in approx. 5 seconds
- Only 0.6µl sample needed
- Optimal accuracy with RFID auto coding
- Auto on and auto off
- 1 and 2 hour test reminders
- Flagging results
- 500 in meter memory locations with time and date
- 7, 14, 30 and 90 days averaging

1 Getting to know your C50 Meter

Parts summary

1	Sensor cover	8	Lancet ejector
2	Display	9	Test cassette
3	Sample/settings button	10	Thumbwheel
4	Memory recall button	11	Battery cover
5	Penetration depth selector	12	Lancing device cover
6	Lancet holder	13	Penetration depth indicator
7	Lancet	14	Sensor window

System components

- BETACHEK C50 Meter and battery
- BETACHEK C50 Test Cassette
- BETACHEK Control Solutions
- BETACHEK Lancets

Button functions

M
Memory - recall test results and averages (sensor cover closed)
S
Sample - fire the lancing device (sensor cover open)
Settings menu (sensor cover closed)
S & **M**
Turn meter off
System tools menu (sensor cover closed)

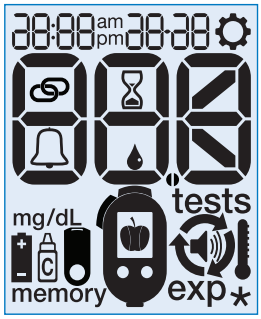
2 Meter set up

Checking the unit of measure

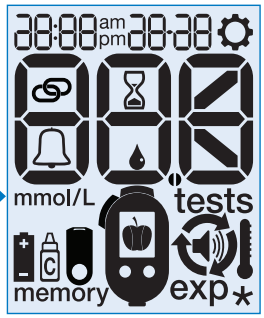
Blood glucose results can be displayed in two different units of measurement (mmol/l or mg/dl). Your meter is factory set to display only one. This unit of measure can be checked during the:

- Display check (See section Checking the display)

mg/dL meter

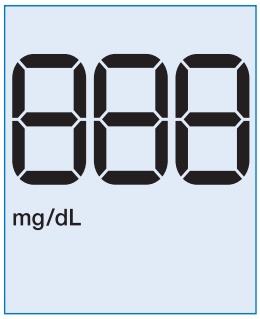


mmol/L meter

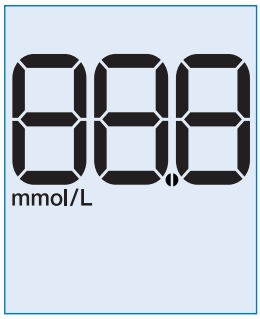


- Numeric display check (See section Test procedure)

mg/dL meter



mmol/L meter



Using the wrong unit of measurement will cause you to misinterpret the results. If you do not know which is the right unit of measurement for you, please ask your doctor.
If the wrong unit is displayed by your meter or if any of the display elements are missing, please contact support@betachek.com to arrange for your meter to be replaced.

Inserting a test cassette

A test cassette must be inserted before testing can begin. Test cassettes are sold separately.

Important: Test cassettes must be used within 90 days of opening. Only remove a test cassette from its container when you are ready to insert it into the meter. The container protects the test cassette against damage and moisture. Once you have loaded a cassette into the meter there is no need to remove it from the meter, unless the meter is being cleaned.

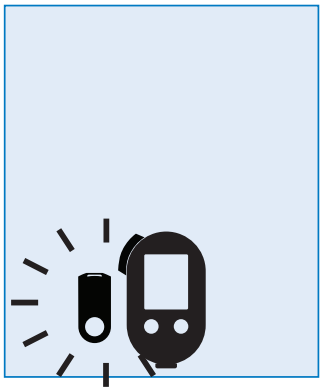
Step 1 Open the sensor cover

Slide the sensor cover in the direction of the arrow as far as it will go. This will turn the meter on.

Step 2

Insert test cassette

When the insert cassette symbol is displayed, remove a cassette from the container and press it into position rounded end first. The test cassette should lock into place securely and lie flat in the meter.



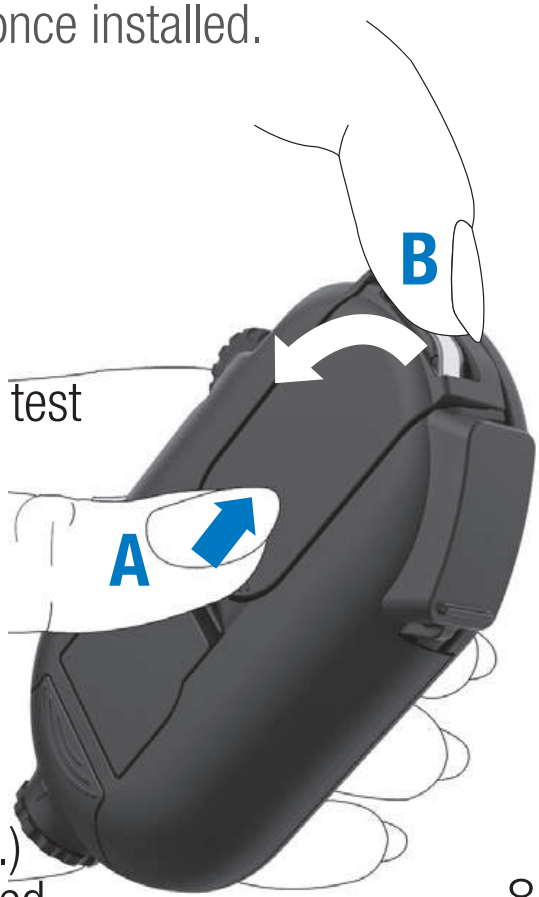
Important:
Check the cassette is locked in place.
It should not lift out once installed.

Removing a test cassette

After all 50 tests have been used, remove the used test cassette and dispose of it your household waste.

Step 1 **Slide open the sensor cover**

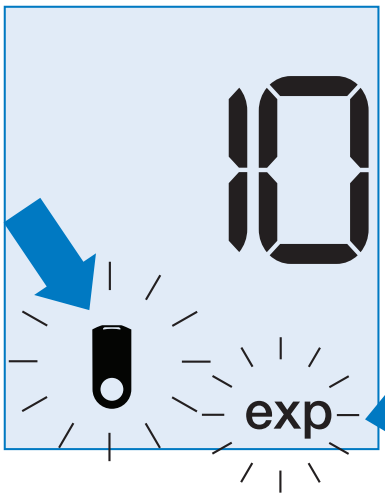
Step 2 **Remove test cassette**



A. Push the cassette forward slightly as shown. (There are curved grips on the cassette to press on.)
AND **B**. lift the cassette out from the top as illustrated.

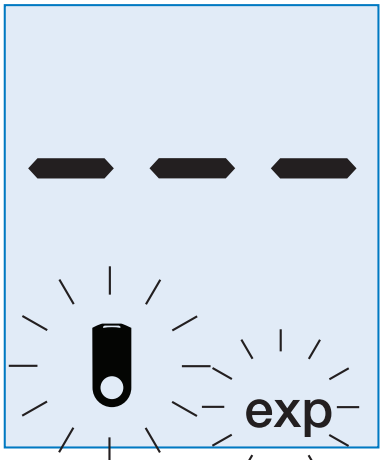
Test cassette expiry - 90 days from opening

An unopened test cassette can be used until the expiry date printed on the container label or once loaded, the meter reads the test cassette ID number and starts a 90 day countdown for that cassette. The meter displays the countdown of days remaining before expiry, see section Checking the expiry date of an opened test cassette.



10 days until expiry

You will receive notifications 10, 3, 2 and 1 day(s) before the use by period expires when commencing a test.



Cassette expired

If either of the two dates are exceeded, the validity of the test cassette has expired and no further tests should be performed.

Remove the expired test cassette and insert a new test cassette to continue testing, see section Inserting a test cassette and Removing a test cassette.

Note: if you have set the time incorrectly with a year in the future the meter will display the exp symbol.

3 Changing settings incl. time & date

In order to properly understand test results you need to set the correct time and date. If the meter is paired to a mobile device, this is done automatically, so you may prefer to go straight to the pairing section. You can still perform a test without adjusting the meter settings.

Enter Settings menu

To enter the Settings menu, hold down the S button for approx. 3 seconds with the sensor cover closed. 12h will appear flashing.

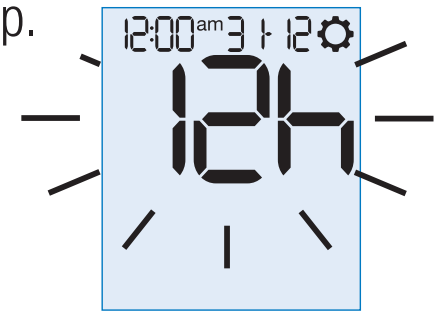
To set up meter preferences scroll through the options using the buttons shown below. The flashing item may be changed or accepted.

Accept

Change

Step 1 **Select time format (24h/12h)**

Press the M button to switch between options, or, press the S button to accept and proceed to the next step.



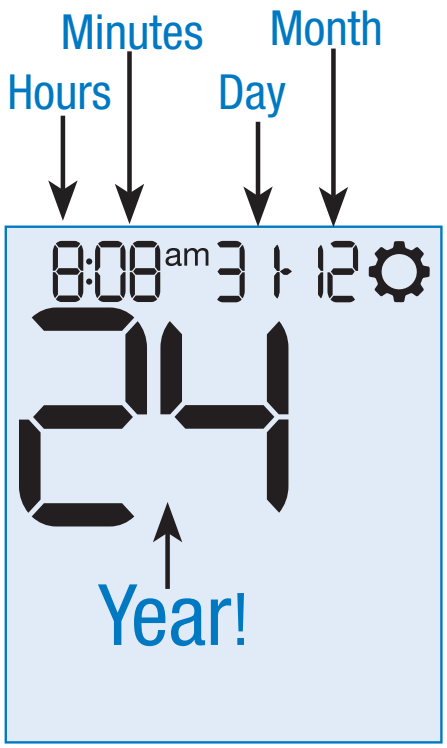
Order of Settings menu
Press and hold S button
Time format (24 or 12)
S
Time (Hour)
S
Time (Minute)
S
Date (Year)
S
Date (Month)
S
Date (Day)
S
Date format (dd-mm or mm-dd)
S
Sound (On or Off)
S
Wireless (On or Off)
S
Meter off

Step 2 **Set the hour**
In the top left corner the hour will be flashing. Press M to change the number. When you have the correct hour press S to save.

Step 3 **Set the Minutes**
The minutes will now flash. Press M to change and S to save.

Step 4 **Set the Year**
The year will now flash as two large numbers. Press M to change and S to save the year.

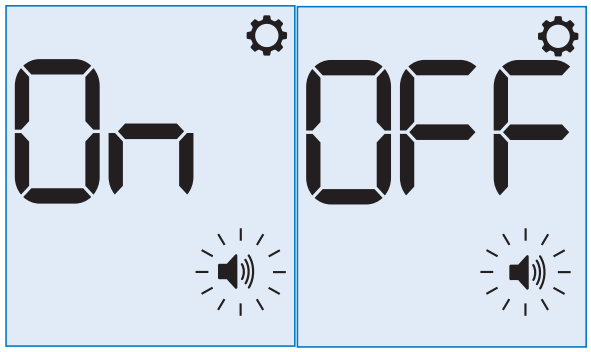
Step 5 **Set the Month**
The month will now flash. Press M to change and S to save the month.



Step 6 **Set the Day**
The day will now flash. Press M to change and S to save the day.

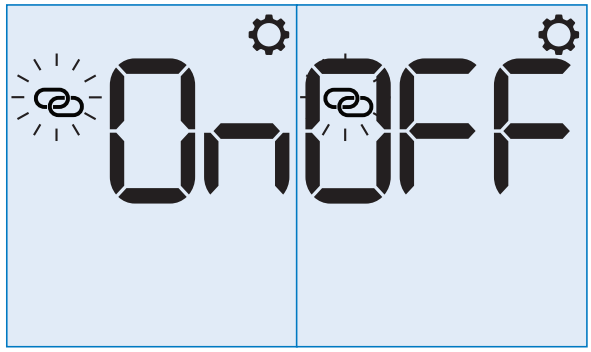
Step 7 **Set order: Day/Month or Month/Day**
The day and month will flash. Press M to change and S to save.8

Step 8 **Turning the sound on and off**
Select On for sound OR Select OFF for no sound.
Press M to switch between options, or press S to accept.



Sound ON Sound OFF

Step 9 **Turning wireless off (Flight mode)**
Select *On to turn the wireless on OR Select OFF.
Press M to change, or press S to accept.The meter will save the settings and turn off. *or equivalent symbol

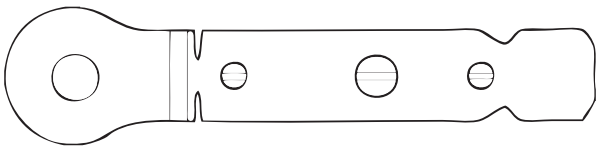


Wireless ON Wireless OFF

4 Preparing the lancing device

Inserting a lancet

The BETACHEK C50 meter has an integrated lancing device compatible with BETACHEK C50 Lancets.



Important: The lancing device is intended for personal use only. It may only be used by one person for obtaining blood. If used by other people, there is a risk of infection being transmitted.

Step 1

Open the lancet cover

Push the curved grips as shown and slide the cover away from the meter. It will then spring open.

Step 2

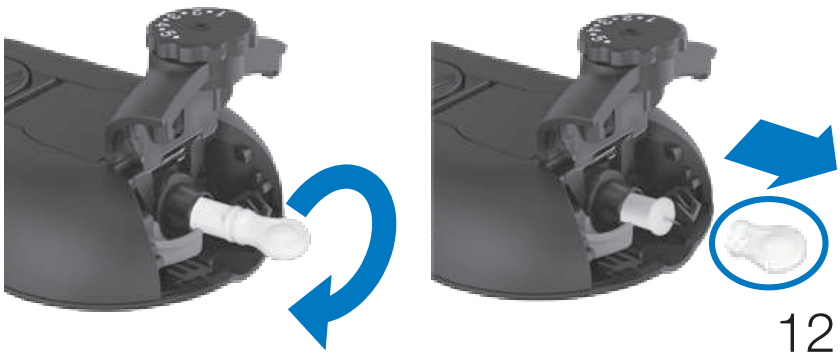
Insert a lancet

Insert the lancet into the lancet holder. Push the lancet in as far as it will go.

Step 3

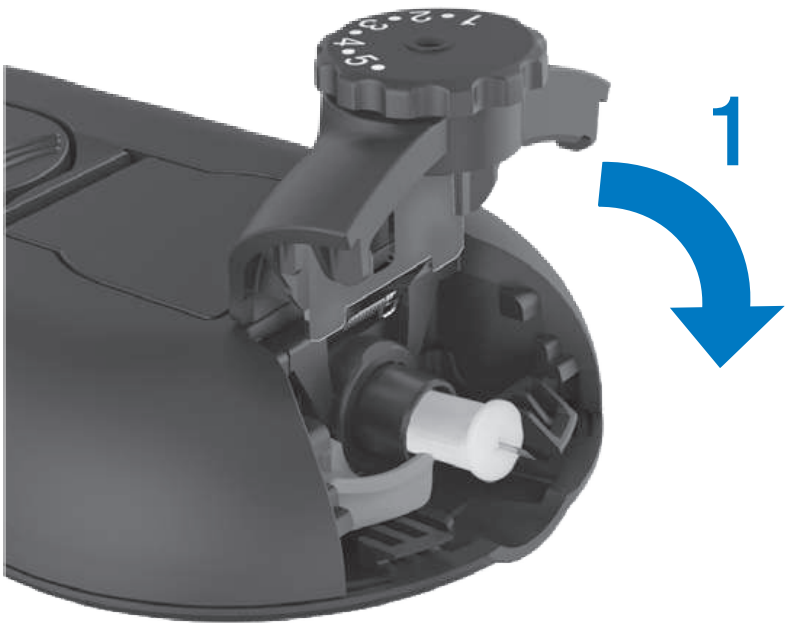
Remove protective lancet cap

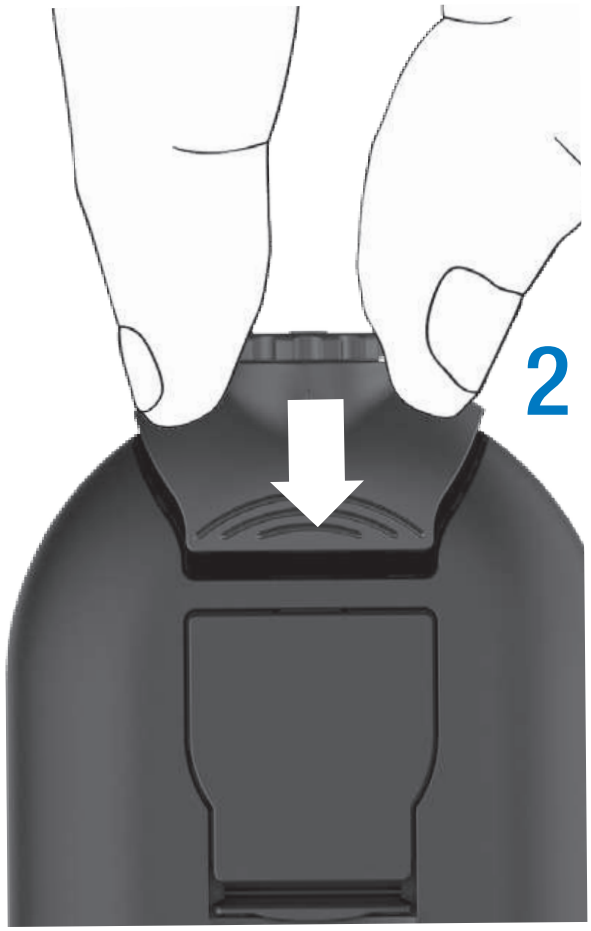
Twist off the protective lancet cap and close the lancing device cover.



Step 4 Close the lancet cover

Press the lancet cover down and then slide it back until the cover is closed.





Setting the penetration depth

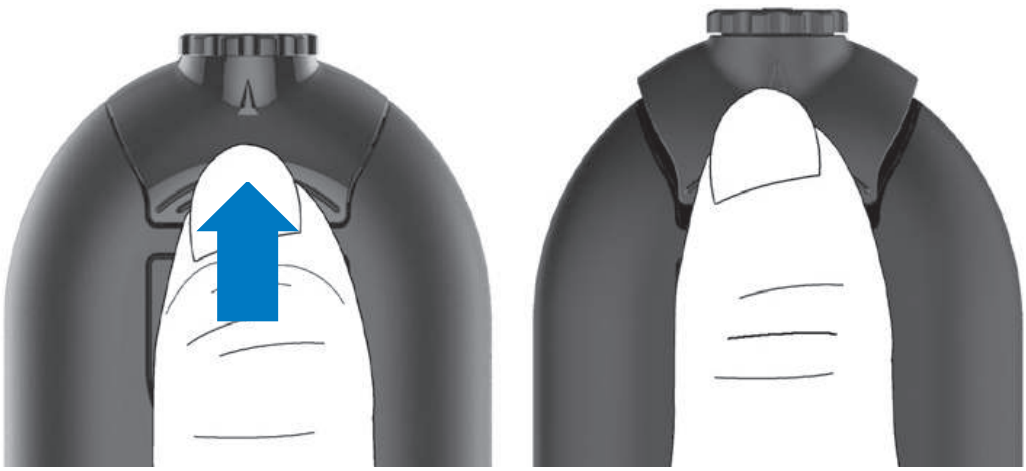
To produce virtually pain free sampling, you can set the penetration depth to one of 10 settings; "•" being the lowest penetration and 5 being the highest. If you are unsure, begin with 3, and adjust as required.

Turn the penetration depth selector dial until the desired number aligns with the penetration depth indicator see section Parts summary.

Removing a lancet

Step 1 **Open cover**

Push the curved grips as shown and slide the cover away from the meter. It will then spring open.



Step 2 **Eject lancet**

Pull the green lancet ejector in the direction of the arrow (1 cm) until the lancet comes out of the lancet holder. Return the lancet ejector to its original position.

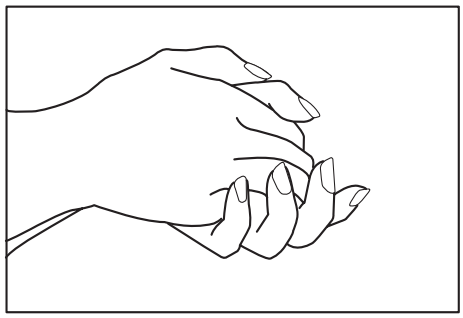
Note: Used lancets may be disposed of in household waste. Lancets should first be placed in a suitable sharps container to prevent accidental injury. Any screw cap plastic container such as an empty milk or juice container can be used.

5 Performing a blood glucose test

Preparation

You need a BETACHEK C50 Meter with cassette and lancet loaded. (See previous sections for details on how to load a cassette and lancet).

Wash your hands with **warm** soapy water. This removes traces of glucose from your hands that may contaminate the test sample and increases blood flow to your fingers to make it easier to obtain a blood drop without excessive squeezing.



Important: Dry your hands thoroughly!

- **Use a blood drop that is large enough to cover the red illuminated area.**
- **You may press down on the drop to spread it over the area illuminated by the red light, but do not touch the test zone.**
- **Do not smear the blood drop on the test zone when applying blood.**
- **Only apply blood to the test zone when the blood drop symbol is flashing on the display.**
- **If you spill blood onto the meter or under the tape, remove the cassette and clean the meter.**

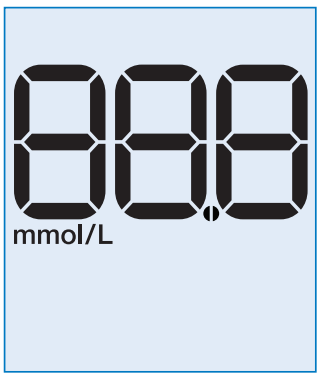
Test procedure

Step 1 Open sensor cover

Slide sensor cover in the direction of the arrow.

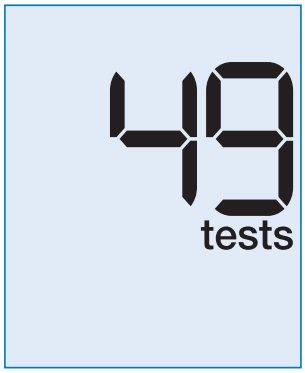
The meter will turn on and run a numeric display check.
Check that all the segments are functioning correctly as shown below.

mg/dL meter



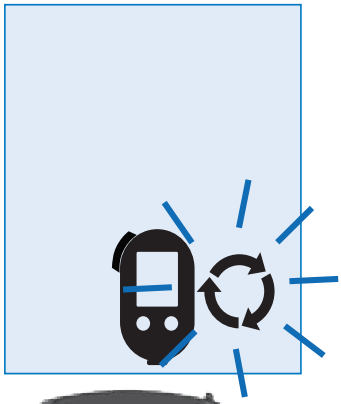
mmol/L meter

The meter will then display the number of tests remaining.



Step 2 Wind on test

Next the meter will flash arrows in a circle, this indicates the thumbwheel should be turned.



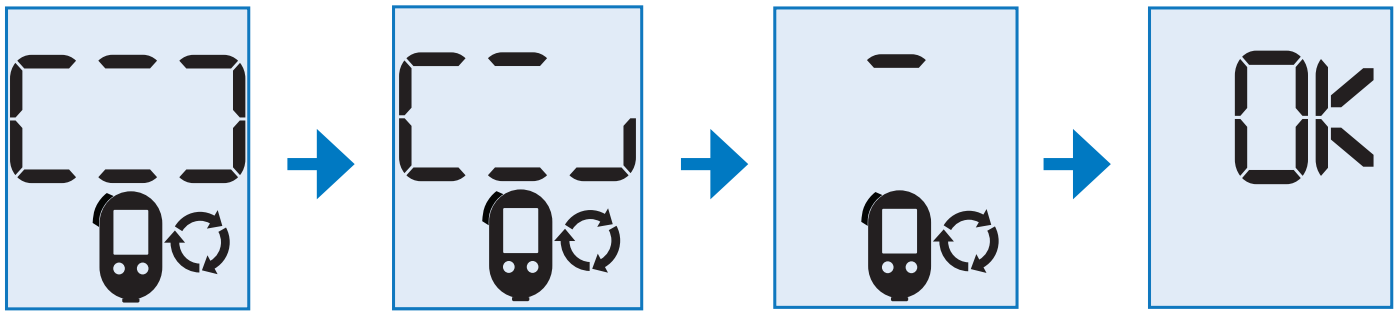
Before blood can be applied, a test zone needs to be moved into position. This is done by turning the thumbwheel.

Note: The thumbwheel is locked when the sensor cover is closed.

Turn the thumbwheel in the direction of the flashing arrow to bring a test into position.

If the thumbwheel is turned in the wrong direction a loud clicking noise will be heard. There is no harm caused to the meter if this occurs.

The meter will display the progress with a segment countdown until the test is in place. Slow the winding when only one segment remains.



- Start looking for the yellow test zone when there is only one segment left.
- Stop winding when the test zone is in the middle over the sensor.
- The meter will beep (if sound is on) and display OK.

Note: If a test zone is wound too far (past the sensor) an error message will be displayed (E-6). Keep winding until OK is displayed, then close the sensor cover and repeat the test

The meter will then display a flashing blood drop symbol.

- **Do not apply blood before the blood drop symbol is displayed. Doing so will waste a test.**

Step 3 Obtain a blood sample

Press your finger firmly against the tip of the lancing device. Press the S button to fire the lancing device.

Gently squeeze the selected finger at the base moving toward the tip. This should be repeated several times to encourage a drop of blood to form.

If the amount of blood is insufficient, close the sensor cover and open it to repeat the lancing step. You may need to select a higher number on the penetration depth adjuster and warm your fingers if they are cold.

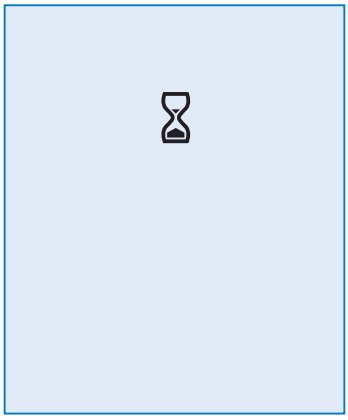
Warning: If you have profuse bleeding you need to select a lower penetration depth for the lancet. Excess blood can spill off the test zone and under the tape and necessitate cleaning of the sensor window. See section Meter maintenance.

Note: You have approx. 2 minutes after the blood drop symbol appears to apply blood to the test zone. If you do not apply blood in this time, the meter will turn itself off. Close and open the sensor cover to restart.

Step 4 Apply blood

- A flashing red light in the test zone will indicate where to put the blood.
- Aim to cover the red light.
- Keep the palm of your hand facing downwards. A hanging drop is ideal.
- You may press down on the drop to spread it over the area illuminated by the red light, but do not touch the test zone.

Warning: If you do not cover the area illuminated by the red light, you could get an inaccurate result or E-7 error message.

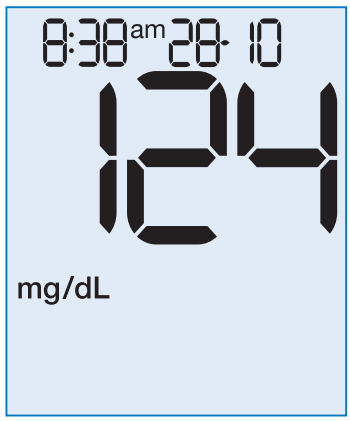


When a blood drop has been applied, the meter will sound a beep (if sound on) and commence measuring. The flashing hourglass symbol indicates the test is underway, until a result is displayed.

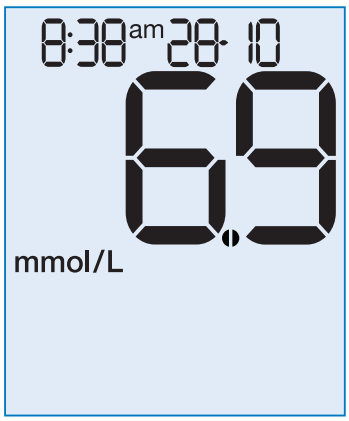
Test results are displayed in approx. 5 seconds.

Step 5 Result

The meter will display the result with the time and date. The result will automatically be saved to memory.
Do not close the sensor cover if you want to attach a flag to your result.



mg/dL meter



mmol/L meter

Note:

The meter will display:

LO If your test result is lower than 20 mg/dL (1.1 mmol/L)

HI If your test result is higher than 600 mg/dl (33.3 mmol/L)

Step 6 Flag result

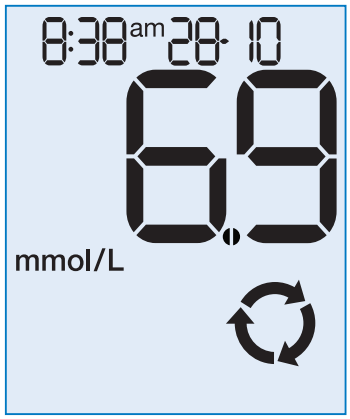
- If you want to flag a test result, press the M button repeatedly whilst the result is still displayed.
- When you find the desired flag, press the S button to save the flag with your result. See section Flagging results.

You can not flag a result after you wind off the used test, however you can add a flag at a later time to results uploaded to the Betachek Diabetes Management App, available for free download on the Apple App store or Google Play store.

Step 7 Wind off used test

5 seconds after your result is displayed or a flag is selected, the wind symbol is displayed.

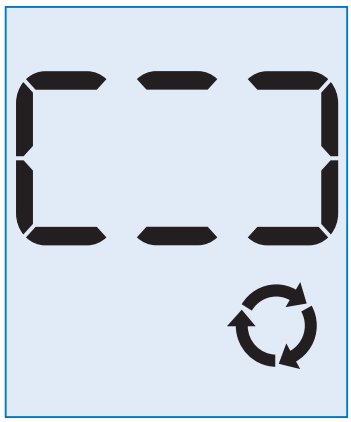
mg/dL meter

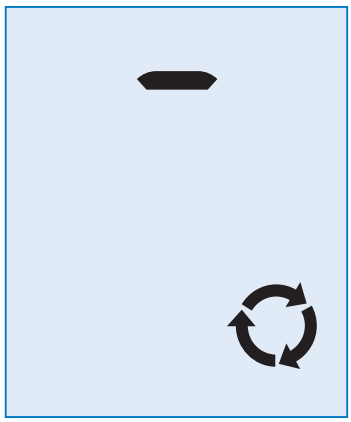


mmol/L meter

Turn the thumbwheel to move the used test into the used test storage compartment of the cassette.

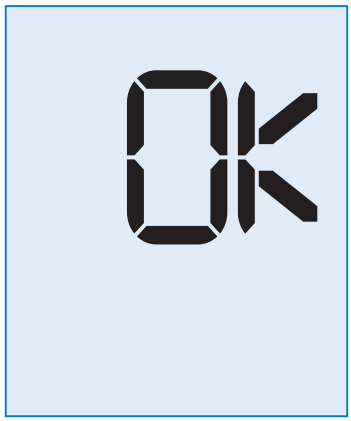
The meter will display the progress with a segment countdown until the used test is in the correct position.





Step 8 Close sensor cover

Stop winding when the meter beeps and displays OK. The close sensor cover symbol will then flash.
Close the sensor cover and the meter will turn off.



Note: If you forget to wind away the used test and close the sensor cover the meter will display **E-3**. Simply open the cover and wind away the used test to resolve this.

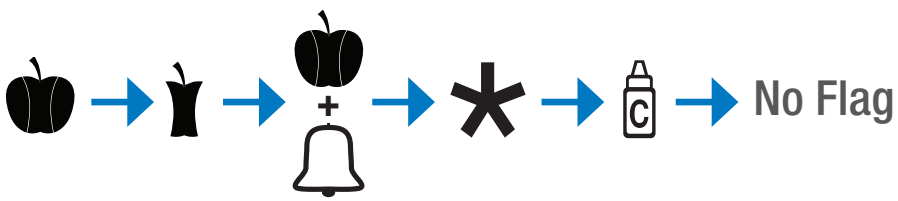
Flagging results

You can flag test results to help you spot blood glucose trends for certain activities and to help describe an event connected with the result.

You can only flag a result whilst it is still being displayed after the test.

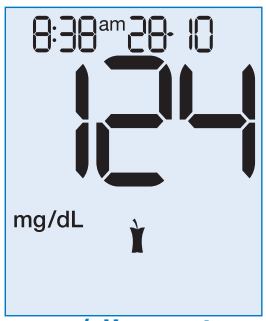
Symbol	Description
	Before meal: Indicates a test performed before a meal.
	After meal: Indicates a test performed after a meal.
	After meal reminder: Indicates a test performed before a meal with an after meal test reminder set.
	Other: Indicates a test performed after an activity or event of your own choosing e.g. physical activity. (Details can be added on the app.)
	Control Test: Indicates a test obtained using control solution in place of blood.

Press the M button repeatedly until the desired flag is displayed along side your result. The flag symbols will appear in the following order:

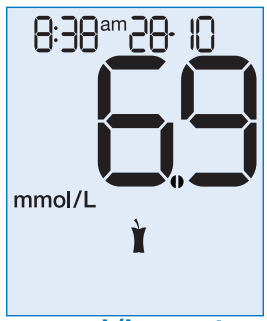


Once you locate the desired flag symbol, press the S button to accept and save the flag.

The following is an example of a test result flagged with the After Meal symbol.



mg/dL meter

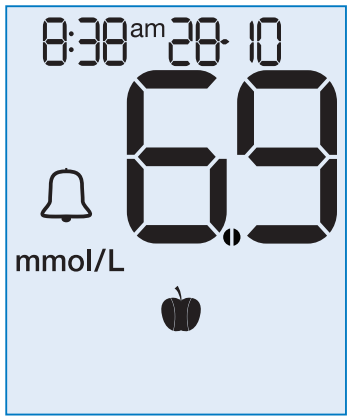


mmol/L meter

Setting the after meal test reminder

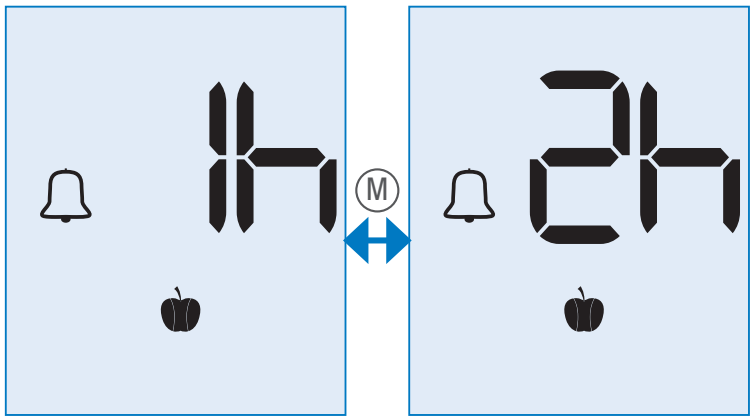
If you select the after meal test reminder in the flag menu, you will be prompted to set a time for your test reminder.

mg/dL meter



mmol/L meter

Press the M button to change between 1 and 2 hour test reminder time options.



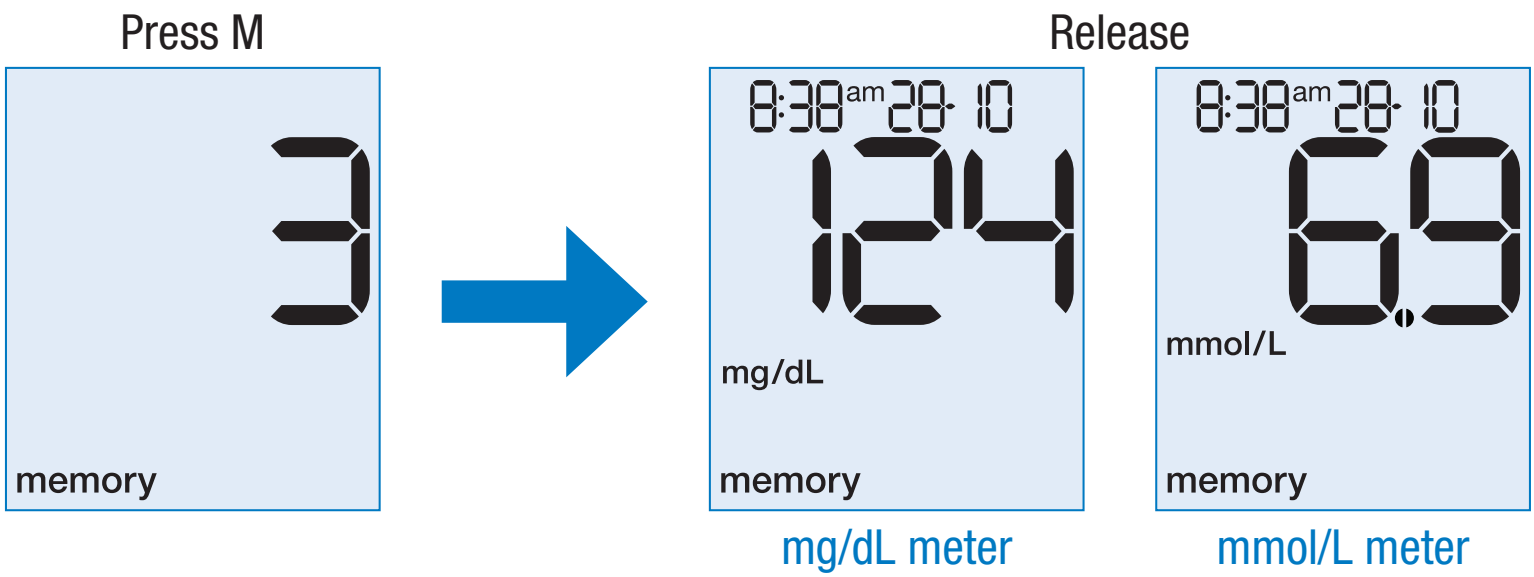
Press the S button to select the time and set the after meal test reminder. The meter will save the test reminder and your result will be saved with the before meal flag. At the selected time (1 or 2 hours after the after meal test reminder was set) your meter will beep to remind you to perform an after meal test. The test reminder will sound for 20 seconds. To perform a test or turn off the test reminder, press any button or open the sensor cover. The test result will be saved together with the After Meal flag.

Note: If a test is done up to 1 hour before the alarm, the test reminder will be cancelled. If a test is performed within half an hour of the test reminder, the result will be saved with an after meal flag.

6 Memory

Recalling saved test results

The BETACHEK C50 meter stores 500 test results along with the time and date. The meter automatically stores the result in memory each time a test is performed. If 500 results are already stored, then the oldest result is deleted to make space for the newest result.
Press and hold the M button with the sensor cover closed until the last saved (most recent) test result is displayed.
If you flagged the test result, or a system flag was indicated at the time of the test, this will be displayed with your result.
To scroll through earlier results, repeatedly press the M button.
When pressing the M button, the memory number will be displayed. When the button is released, the result will be displayed.



Hold M button down to scroll through results in quick succession.
Press and hold the S and M buttons at the same time for approx. 3 seconds to turn the meter off.

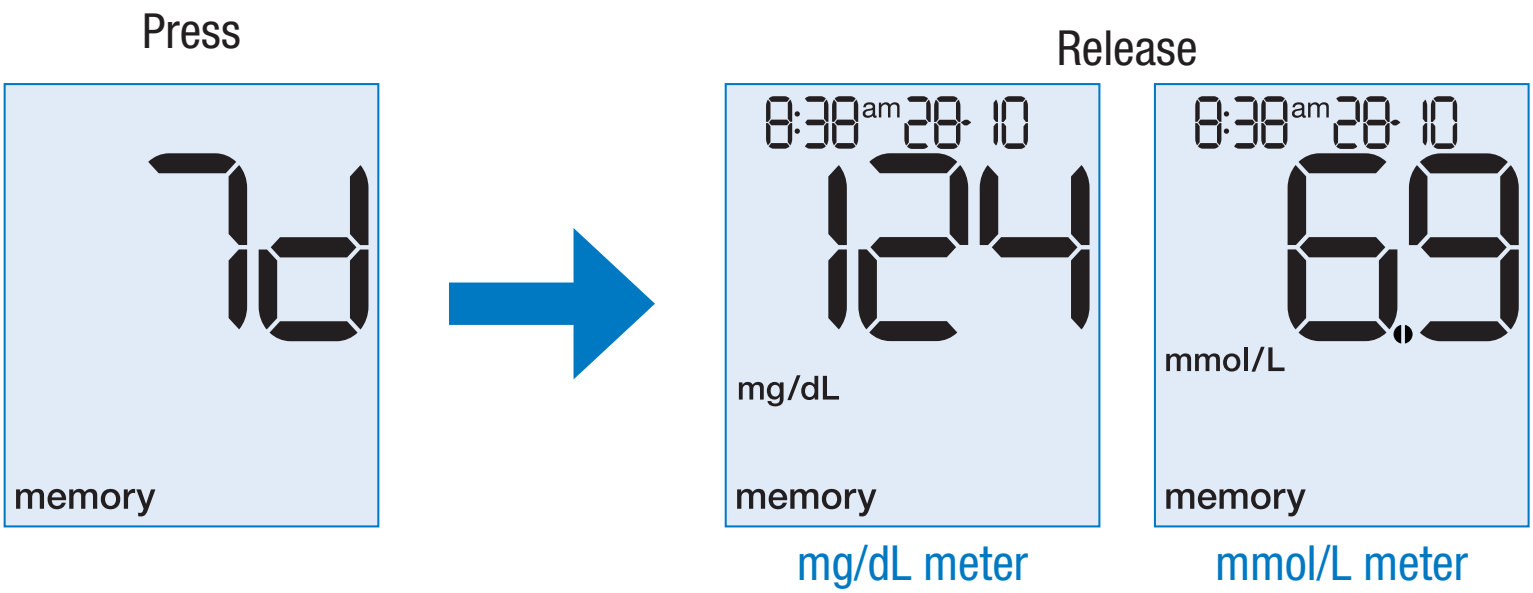
Recalling averages

Note: Time and date must be set to use this function.

The C50 meter can calculate averages from the saved test results for 7, 14, 30 or 90 days.

To enter the memory function (saved test results), press and hold the M button with the sensor cover closed. Then press the S button until 7d is displayed.

The result that appears immediately after releasing the S button is the 7 day average.



Press the S button repeatedly to scroll through the day averages

7 day → 14 days → 30 days → 90 days

Press the M button to return to saved test results.

Press and hold the S and M buttons at the same time for approx. 3 seconds to turn the meter off.

7 System tools

The System Tools menu allows you to:

- Perform a display check,
- Check your meter's firmware version number,
- Check the number of tests remaining on the cassette, and
- Check the number of days remaining until casette expiry.

Note: The number of tests remaining and the number of days remaining can only be checked if you have a cassette inserted in the meter.

See section Checking the number of available tests remaining and Checking the expiry date of an opened test cassette.

Order of System Tools menu
Press and hold S & M buttons
Display check (release buttons)
M
Check firmware version
M
Number of tests remaining
M
Number of days remaining
M
Meter off

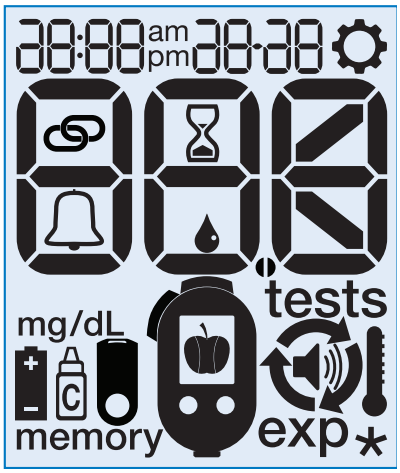
Checking the display

(S) & (M) → Display check - release buttons immediately

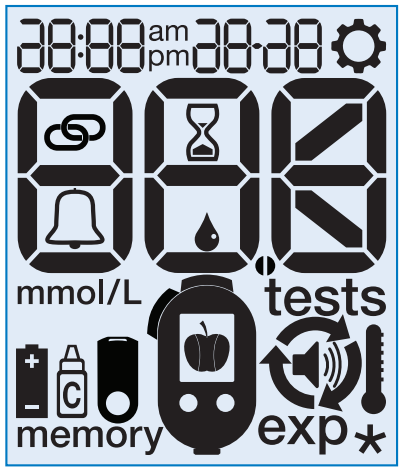
Check the LCD screen periodically to ensure all segments are being correctly displayed.

Press and hold the S and M buttons for approx. 3 seconds with the sensor cover closed. The meter will perform a display test by lighting up all the segments of the LCD screen. Check that all the segments are functioning correctly as shown below.

Press the M button to proceed through the System Tools menu.Press the S button to exit the System Tools menu.



mg/dL meter



mmol/L meter

Note: If any segments are missing, contact your local distributor or customer service line to change the meter.

Checking the version number of your meter's firmware

(S) & (M) → LCD test - release buttons → (M) → Firmware version

To check the firmware version number of your meter, press and hold the S and M buttons for approx. 3 seconds with the sensor cover closed. This will run a display check. Release the buttons when the LCD segments are displayed.

Press the M button to view your meter's firmware version number.

Press the S button to exit the System Tools menu.

Checking the number of tests remaining

(S) & (M) → (M) → (M) → Number of tests remaining

The BETACHEK C50 Meter can automatically track the number of tests left on the test cassette. With the cassette inserted in the meter, press and hold the S and M buttons for approx. 3 seconds with the sensor cover closed. This will run a display check (release the buttons when the LCD segments are displayed).

Press the M button 2 times to view the number of tests remaining.

Press the S button to exit the System Tools menu.

Checking the expiry date of an opened test cassette

(S) & (M) → (M) → (M) → (M) → Number of days remaining

The BETACHEK C50 Meter can automatically track the validity of the test cassette in the meter. When the cassette is first inserted, the meter will begin to count down the use by period (90 days).

You will receive notifications at 10, 3, 2 and 1 day(s) before the use by period expires when opening the sensor cover.

You can also check the expiry date of an opened test cassette in the System Tools menu.

With the cassette inserted in the meter, press and hold the S and M buttons for approx. 3 seconds with the sensor cover closed. This will run a display check (release the buttons when the segments are displayed).

Press the M button 3 times to view the number of days remaining until test cassette expiry.

Press the S button to exit the System Tools menu.

8 Downloading results for Analysis

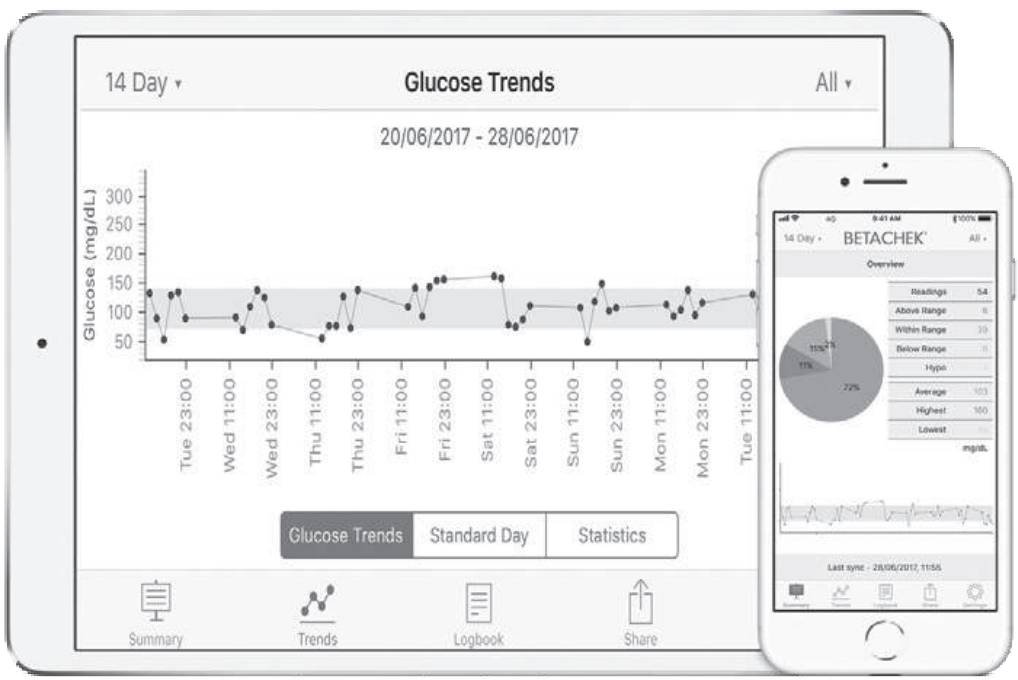
Downloading results for analysis

The **BETACHEK® Diabetes Management App** is a free app for Apple® and Android mobile devices. Download it to your mobile device from the Apple App Store or the Google Play Store. BETACHEK test results are automatically uploaded to your mobile device where the BETACHEK Diabetes Management App creates charts, tables and reports. Share your results via SMS, email or printout.

BETA CHEK

Download on the App Store

GET IT ON Google Play



Pairing the BETACHEK® C50 meter with your mobile device

The BETACHEKC50 Meter allows you to wirelessly synchronise your saved test results with a mobile device. This is done via wireless connection between your meter and mobile device.

Step 1 **Install the BETACHEK® mobile app (mobile device)**

You must install the BETACHEK Diabetes Management application on your mobile device before you can connect to the BETACHEK C50 meter. Go to the Apple App store or Google play store and search for BETACHEK Diabetes Management App.

Step 2 **Enable wireless on your mobile device**

Step 3 **Enter pairing mode (BETACHEK C50)**

To put the BETACHEKC50 meter into pairing mode, hold down the ‘S’ and ‘M’ buttons simultaneously and keep holding until the flashing wireless pairing symbol appears.

Step 4 **Open the Betachek App (mobile device)**

Open the BETACHEK C50 app. and go to settings. Under settings go to 'selected device'. The app will search for the BETACHEK C50 meter and show any meter in range. Press connect when prompted.
Once successfully paired the meter will beep and the wireless pairing symbol will stop flashing. The App will show the word 'Paired' under settings » selected device.

Pairing Unsuccessful

If the pairing was unsuccessful, E-0 will appear on the display. Repeat the process ensuring the devices are within 1 meter of each other.
If pairing is still unsuccessful;

a. Shut down the BETACHEK app.

b. Open the BETACHEK App. and go to settings/selected device then press Forget

c. Hold down the S and M buttons on the meter until the pairing symbol appears.

d. Ensure the mobile device and the BETACHEK C50 meter are less than 1 metre apart.

e. Open the app and follow pairing instructions

Not pairing: If pairing is still unsuccessful, delete the app and go into bluetooth settings on the mobile device and delete BETACHEK®C50. Download the app and try again.

App Refresh: Once paired all results will download to your mobile device each time the app is opened. To force downloading if the app is open, swipe down on the summary or logbook screens.

Time and Date: When the BETACHEK® C50 is paired with a mobile device the time and date will sync with the mobile device.

Wake the meter to sync: If the meter has been off for longer than two minutes press the M button to turn it on.

9 Checking your meter's accuracy

You can check your meter's accuracy by performing a control test. To perform a control test, BETACHEK Control Solution is applied to the test instead of blood.

Ideally, you could perform a control test:

- Whenever you open a new test cassette,
- After replacing the batteries,
- After cleaning, or,
- If you are in doubt about a blood glucose result.

At the end of the test, you must flag the result with the "Control Test" flag and select which control solution was used (control 1 or 2).

The meter automatically calculates whether the control test obtained with control solution is correct and informs you of the control result.

Note: Using a control solution other than BETACHEK® Control Solution will give inaccurate or misleading results.

Preparation

Read the package insert which comes with the control solutions.

For a control test, you need:

- BETACHEK® C50 Meter
- BETACHEK® C50 test cassette
- BETACHEK® Control Solution 1 (low glucose concentration) or BETACHEK® Control Solution 2 (high glucose concentration)
- Clean white tissue.

Performing a control test

Note: Control Solution contains a specific amount of glucose. If the cap is left off the control solution bottle, water can evaporate and the glucose concentration can increase. Similarly, when control solution wets the inside of the cap after use, it dries and leaves glucose that contaminates the tip of the bottle. Follow the steps below to deal with this glucose.

Step 1 Prepare the control solution

Gently roll the control solution to mix without creating bubbles.

a. Remove the cap from the control solution bottle

b. Discard the first drop.

c. Wipe the tip of the control solution bottle clean with tissue

Step 2 Turn on the meter

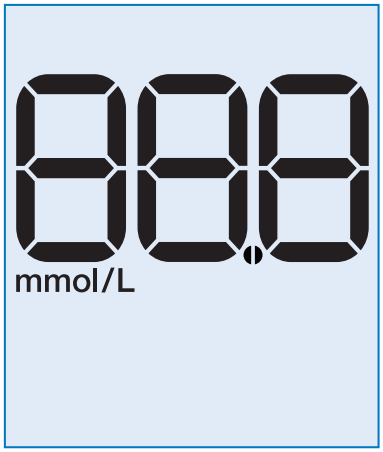
Slide the sensor cover in the direction of the arrow.

This will turn the meter on and run a numeric display check by lighting up the numeric segments and meter unit of measure. Check that all the segments are functioning correctly as shown.

Note: If any numeric segments are missing, contact:

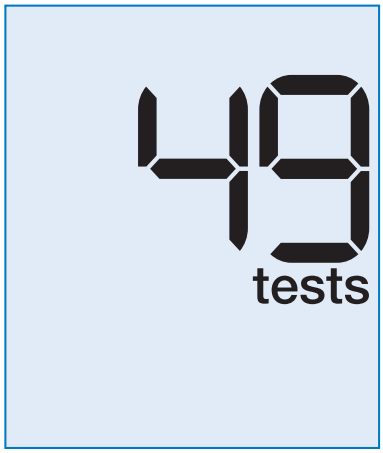
support@betachek.com

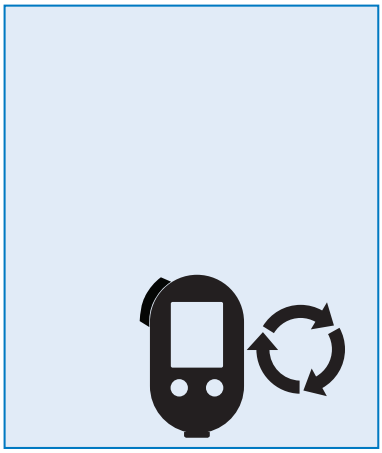
mg/dL meter



mmol/L meter

The meter will display the number of tests remaining, then flash the wind symbol:





Step 3 Wind on a test zone

Turn the thumbwheel in the direction of the flashing arrow to bring a test into position.

The meter will sound a beep (if sound on) and display "OK" when a test zone is in position.

Check the blood drop symbol is flashing. (you have 2 minutes to apply the control solution)

Step 4 Apply Betachek control solution

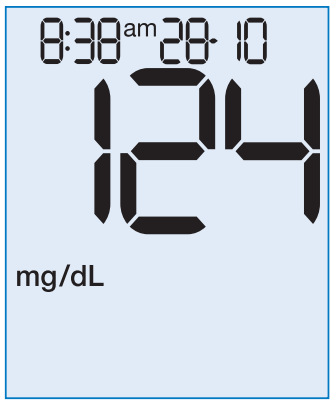
Apply a small drop of control solution to the test zone, being careful not to touch the test zone with the tip of the control solution.

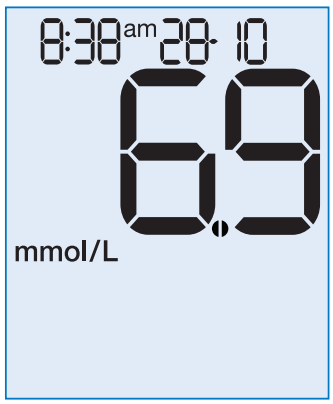
Warning: The test zone requires a small amount of control solution. To avoid spilling control solution over the sensor area, practice squeezing out one small drop away from the meter.

When the control solution has been applied, the meter will sound a beep (if sound on) and commence measuring. The flashing hourglass symbol indicates when the test is underway, until a result is displayed.
Test results will be displayed in approx. 5 seconds.

Step 5 Result

The meter will display the result with the time and date.
The result will automatically be saved to memory.
Do not turn the meter off.





Step 6 Flagging the control test

To distinguish this control test result from blood glucose results, you need to flag it as a control test.

a. Press the M button repeatedly whilst the result is still displayed until the "Control Test" flag is displayed.

b. Press the S button to confirm the "Control Test" flag.

c. Press the M button to select between Control 1 or Control 2.

d. Press the S button to save.

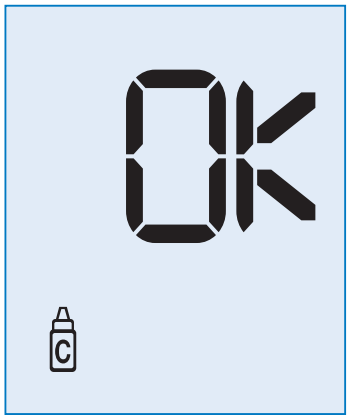
Note: You can not flag a result after you wind off the used test. See section Flagging results.

Your meter will automatically check if the control test result is within the acceptable ranges.

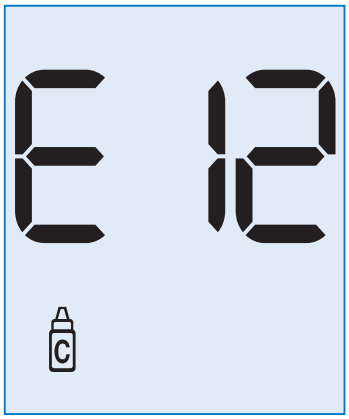
Additionally, you can check the result against the acceptable ranges printed on the Test Cassette bottle label.

If the control test result is within the acceptable ranges, the meter will display "OK" along with the "Control Test" flag.

If the control test result is outside the acceptable ranges, the meter will display "E12" along with the "Control Test" flag.



Control test within acceptable range



Control test outside acceptable range

Step 7 Wind off used test

Approx. 5 seconds after your control test result is displayed, the wind symbol will appear. Turn the thumbwheel to move the used test into the used test storage compartment of the cassette. Stop winding when "OK" is displayed.

Step 8 Close sensor cover

When the test zone is in the storage compartment, the meter will beep (if sound is on) and display "OK". Stop winding. The meter will prompt you to close the sensor cover. Closing the sensor cover will turn the meter off.

Note: If you applied too much control solution you may dab it with a tissue after the result has been displayed and before winding it into the waste compartment.

Possible sources of error

If the result of the control test is outside the specified concentration range, repeat the control test. If the result of the second test is also outside the specified concentration range, check the following points.

- Did you select the correct control solution (1 or 2) in the flag menu?
- Did the control solution cover the red illuminated area of the test zone?
- Was the drop of control solution free of air bubbles?
- Are the control solutions within their use by date?
- Did you wipe the tip of the control solution bottle before you applied control solution to the test zone?
- Did you perform the test within +10°C to +40°C?
- Did you check the result with the range on the cassette container label?
- Is the sensor window of the meter clean?
- Has the control solution been open for less than 3 months?

If you answered no to any of the questions above, make the respective corrections when you perform the next test. If you have taken all of these points into account and the test results are still outside the specified concentration range, contact support@betachek.com

Warning: If a control test produces results that are outside the specified concentration range, it is no longer certain that the meter and test cassette are functioning properly. Blood glucose tests may then produce incorrect results.

10 Meter maintenance

The meter must be kept clean and stored safely away from water, moisture (<85% humidity), extremes of heat or cold and dust. Avoid getting blood on the meter. If you do, cleaning the meter is necessary.

Cleaning your meter (E-4, E-5, E-9, E-12)

Notes on cleaning your meter:

- Use only cold water as a cleaning agent.
- Clean the meter using a lightly moistened tissue or a lightly moistened cotton swab.
- Do not spray anything onto the meter and do not immerse it in any liquid.
- Make sure that no water enters the meter.
- Avoid scratching the sensor window.

Cleaning the exterior of the meter

If the meter or the display is dirty - wipe it using tissue lightly moistened with cold water.

Cleaning the sensor area

You only need to clean the sensor area of the meter if it is visibly dirty or if you are prompted to clean the meter by the message E-4: Measurement sensor dirty (See section Error messages), E-5, E-9 or E-12.

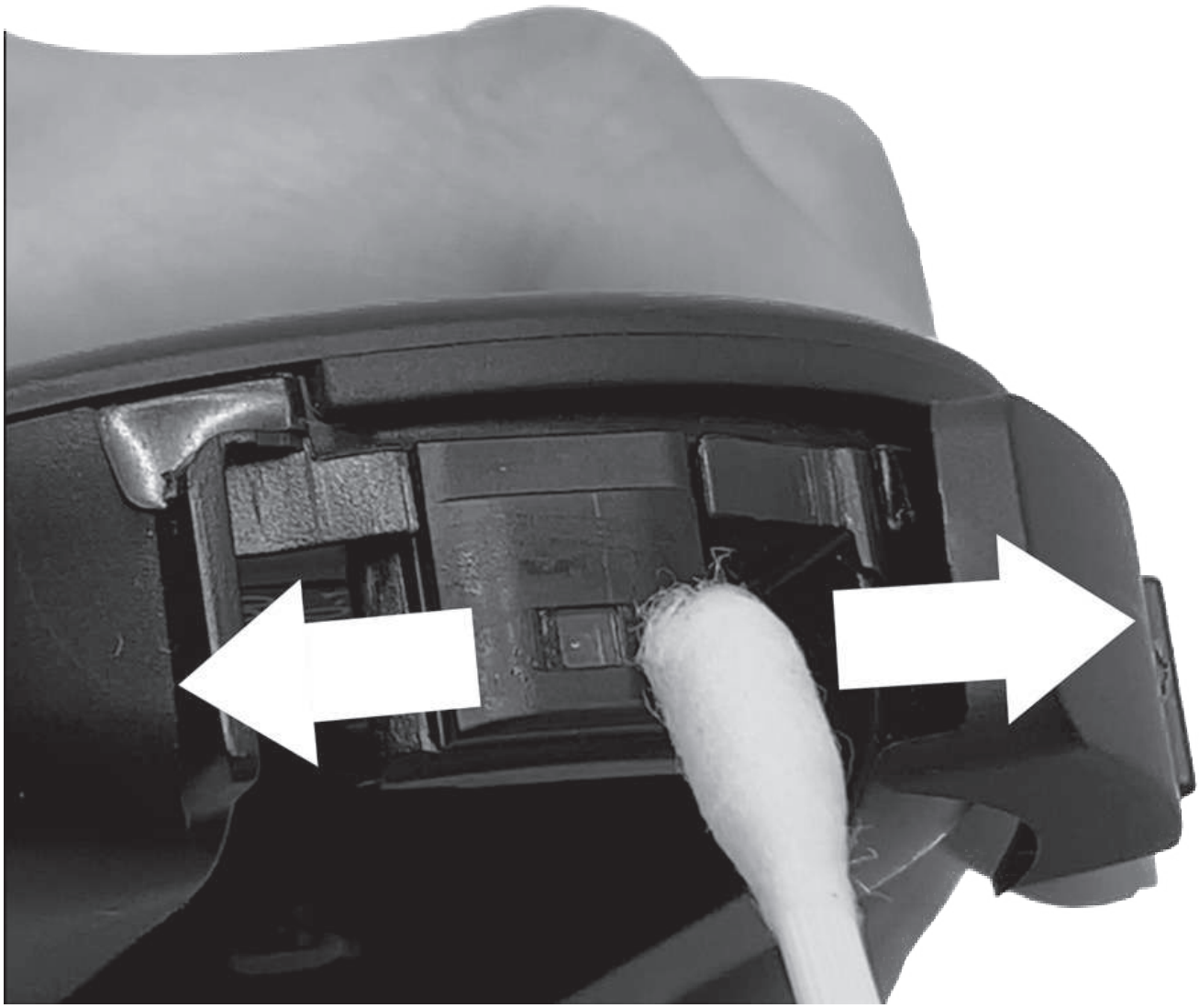
Step 1 **Remove test cassette**

Remove the test cassette prior to cleaning your meter. See section Removing a test cassette.

Step 2 Cleaning the cassette bay

If the cassette bay is visibly dirty, clean the area with a lightly moistened tissue or cotton swab/tip.

Step 3 Cleaning the sensor window



Clean sensor window with a damp cotton tip or tissue in the direction shown. Do this when dirty and each time a cassette is replaced.

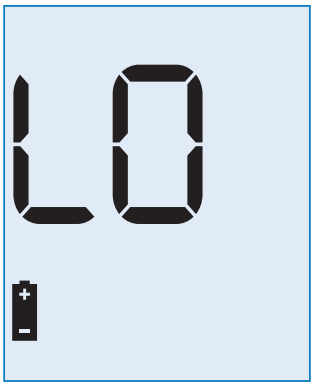
Cleaning the lancing device

Dampen a tissue with water. Wipe the exterior and interior of the lancing device. Do not immerse in any liquids. Dry the lancing device with a dry tissue.

Disinfecting

Wipe the lancing device thoroughly with a tissue dampened with 70% isopropanol. After disinfecting, allow to air dry.

Replacing the battery



When the battery is almost empty, and the meter is turned on, the low battery warning is displayed. At this point you can still perform approximately 25 more tests.
Change the battery as soon as possible.
You need 1x CR2032 battery.

With a new battery you can perform approximately 1000 tests or test for approx. 1 year. The number of tests can vary depending on the battery manufacturer and your usage of apps.

- Your saved test results will always remain saved, even when you change the battery
- time and date will be lost when the battery is removed or flat. (Connecting to the Betachek Diabetes App will reset the date or it can be reset by entering settings mode).

If you ignore the low battery warning and allow the battery to run flat, an E-10 error message will appear on the display. See section Symbols, problems and error messages.

Note:
- Only remove the battery when the meter is turned off.
- Remove the battery if you will not be using the meter for a long time.

Warning:
- **Keep out of reach of children. Swallowing a coin battery can cause death in children in under 2 hours. Seek emergency medical treatment if swallowed!**
- **Never throw the battery into a fire. It may explode.**

Step 1 Remove the battery

The battery compartment is located on the back of the meter. **A** Push the locking catch away from the cassette and **B** lift out the battery cover. Remove used battery.

Step 2 Insert new battery

After removing the old battery, place the new battery in the compartment with the + symbol facing upwards.

Step 3 Replace battery cover

Replace the battery cover by inserting the prong on the lower edge first then press the spring end into position. It will click into place audibly. The meter will give a beep if the battery has connected correctly. If there is no beep check the battery terminals are contacting the edge of the battery.

11 Test and storage conditions

Temperature

Make sure that the following conditions are met so that the meter and lancing device operate reliably and you obtain accurate results.

Testing

- For blood glucose tests and control solution tests the temperature must be +10°C to +40°C (+50°F to +104°F).
- If the temperature is at the limit of the permitted range: +5°C to +10°C (41°F to 50°F) or +40°C to 45°C (104°F to 113°F), the meter will still allow you to perform a test. However, the thermometer symbol will be displayed and saved with test results obtained within the temperature limits. You will also receive a temperature warning (E11) when the sensor cover is opened.
- Tests cannot be performed at temperatures below +5°C and above +45°C. If temperatures exceed these limits, the temperature error appears on the display after opening the sensor cover. You will not be able to use the meter for testing. See section Symbols, problems and error messages.

Temperature error

Warning:
- Do not use blood glucose results obtained despite the temperature warning as a basis for making therapeutic decisions. These test results could be incorrect. Incorrect results can cause the wrong therapy recommendation to be made and so produce serious adverse health effects.
- Never try to speed up warming or cooling of the meter, e.g. in a refrigerator or on a radiator.

Storage

- Meter without battery and cassette:-25°C to 70°C (-13°F to 158°F).
- Meter with battery, without cassette: -20°C to +50°C (-13°F to +158°F).
- Meter with battery and cassette: +2°C to +30°C (+35.6°F to +86°F).

Note:

- At temperatures above 50°C the battery could leak and damage the meter.
- At temperatures below 5°C the battery may not have enough power to keep the internal clock functioning.

Humidity

Testing

Only perform blood glucose tests at a relative humidity of between 15% and 85%.

Storage

Store the meter in a place with a relative humidity of between 15% and 93%.

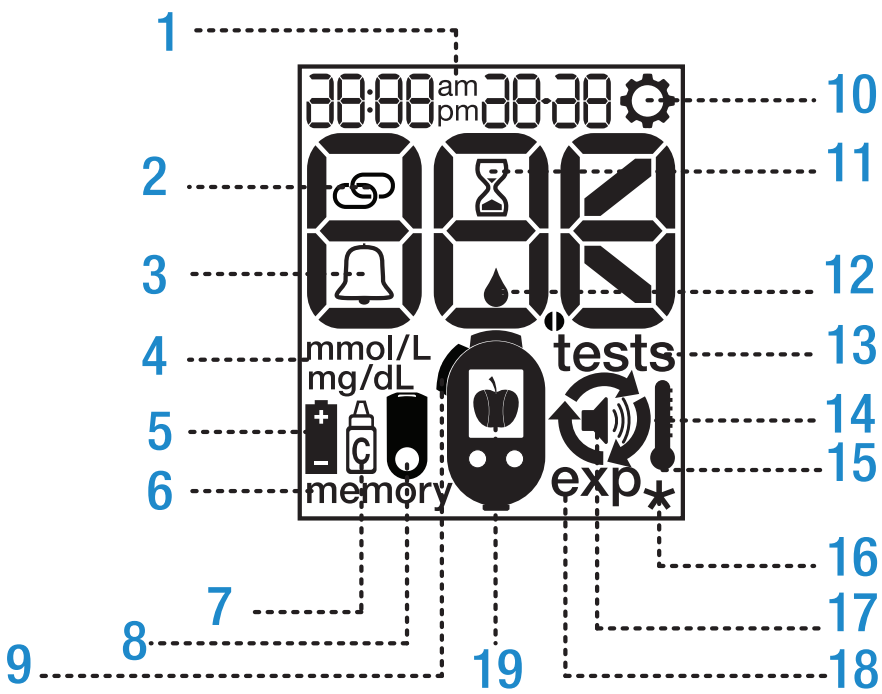
Note: Do not store the meter in high moisture areas (e.g. in a bathroom).

Light conditions

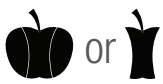
Do not perform a test when the meter is exposed to direct sunlight. Go to a shaded place or shade the meter, for example, with your body.
If the meter is exposed to too much light, it does not allow any tests to be performed. In this case the error message E-5 will appear on the display. (E-5 can also appear if the meter's sensor window is dirty). See: Symbols, problems and error messages.

12 Symbols, problems and error messages

Symbols



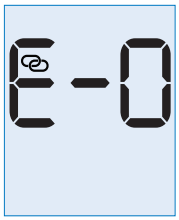
Symbol	Meaning
1 am pm	Additional time information if 12-hour time format is set.
2	Wireless pairing symbol. Flashes when trying to connect.
3	The alarm bell symbol.
4 mmol/L mg/dL	The unit of measure. Factory set to mg/dL OR mmol/L.
5	Low battery warning. You can perform approx. 50 more tests.
6 memory	You are in the Memory Menu for test results and averages.
7	“Control Test” flag.
8	Test cassette symbol. Replace or insert a test cassette.

Symbol	Meaning
9	Close sensor cover.
10	You are in the Settings Menu for time format, time, date and sound.
11	Hourglass symbol. A test is underway.
12	Blood drop symbol. You can now apply blood or control solution to the test zone.
13 tests	The number of tests remaining is being displayed. The symbol is preceded by the number of tests remaining.
14	Wind symbol. Wind on a new test or wind off a used test using the thumbwheel.
15	If the ambient temperature at the time of testing is or was between 5°C to 10°C or 40°C to 45°C.
16	“Other” flag.
17	You are in the Settings Menu for sound.
18 exp	If your test cassette has passed the exp date on container or 90 days of use or the meter’s date is set in the future.
19 	“Before Meal” or “After Meal” flag.

Problem and possible causes	Solution to the problem
E-4, E-5, E-9, E-12	
Sensor window dirty	Remove cassette and clean sensor.
E-7	
Blood did not cover red light	Use a larger drop or press down on drop to spread it. Do not touch the test zone.
The meter will not turn on	
The battery flat or no battery.	Insert new battery.
The battery inserted the wrong way.	Insert with PLUS sign facing up.
Extreme temperatures.	Ensure room temperature is between 5°C and 45°C.
The meter is defective.	Contact support@betachek.com
Exp with new cassette	
Date (Year) was set in the future	Set the time and date correctly.
The meter is turned on, but the display remains blank.	
The display is defective.	Contact support@betachek.com

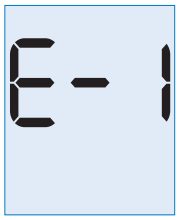
Error messages

When an error occurs, **look up the meaning of the error message** and correct the issue so the error is not repeated. Do not apply bood until you get a blood drop symbol or a test will be wasted.



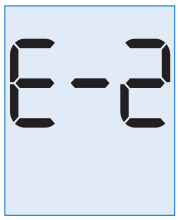
E-0: Pairing error

The meter was unable to pair with a device.
Retry the pairing. Make sure the devices are within 1 meter of each other.



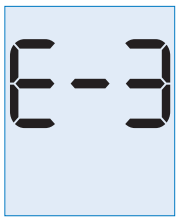
E-1: Calibration error

Your meter is out of calibration.
Please contact support@betachek.com



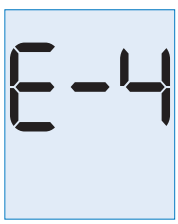
E-2: RFID tag on the cassette cannot be read error

Check that the cassette has an RFID label. If not check the container it came in. Make sure there is a cassette inserted in the meter. If the problem persists. Please contact support@betachek.com



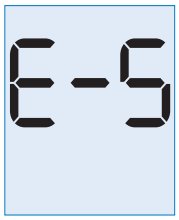
E-3: Used test not wound into waste chamber

Open the sensor cover and wind the used test into the waste chamber.



E-4: Blood applied too early/Sensor window dirty

Blood applied before blood drop symbol appears on the display.
Repeat the test with a new test zone.
Sensor window dirty.
Clean the sensor window with a damp cotton tip or tissue.

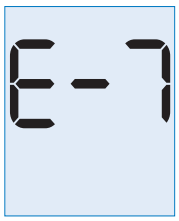


E-5: Sensor window dirty or too much ambient light

Remove the cassette and clean the sensor window.
The meter is exposed to too much light.
Go to a shaded place or shade the meter.

E-6: Test zone wound too far.

New test zone wound past sensor window.
Test is wasted. Continue winding until “OK” appears on the display. Close the sensor cover to turn meter off.
Used test wound too far.
Continue winding until ‘OK’ appears on the display. Next test must be used as it has been withdrawn from the cassette.

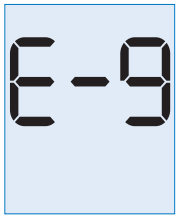


E-7: Insufficient blood applied to cover the red illuminated area

Repeat the test by pressing on the drop to spread it out. Do not touch the test zone. Make sure that the area illuminated by the red light is covered with blood. Do not use a drop that is too small. Do not smear the blood over the test zone.

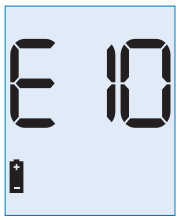
E-8: Test cassette error

Test cassette removed while a test is underway.
Test cassette wound while a test is underway.
Start the blood glucose test from the beginning with a new test.



E-9: Meter sensor window dirty or Test zone damaged

Remove the cassette and clean the sensor window.
Start the blood glucose test from the beginning with a new test.



E10: Insufficient battery power

There is insufficient battery power to perform a test.

Replace the battery. See section Replacing the battery.

E11: Temperature warning

The temperature is at the limit of the permitted testing range

Testing is still possible,however, it is recommended that you allow the meter to cool down or heat up to be within the permitted temperature range for testing.

E12: Control test error

The control solution test result is not within the acceptable ranges - repeat the control test. If the result of the second test is also outside the specified concentration range, see section Possible sources of error.

E13: Meter reset

The meter has reset. The time, date and pairing must be reset.

LO: Low battery warning

The battery is almost empty.

Change the battery as soon as possible. See section Replacing the battery.

ttt: Temperature warning

If the temperature exceeds the limit of the permitted testing range (<5°C or >45°C).

No tests can be performed. Allow the meter to cool down or heat up until it is within the permitted temperature range for testing.

13 Technical data

Meter name	BETACHEK C50
Intended use	For self testing of blood glucose. Not suitable for multi patient testing.
Integrated lancing device	Single patient use only, 10 penetration depths Lancet: Betachek® C50 lancets
Test time	Approx. 5 seconds
Measuring method	Reflex photometry
Test Principle	Refer to test cassette package insert
Blood sample	Fresh capillary blood only
Sample size	Minimum: 0.6µl / Maximum: 5µl
Units of measure	Factory set to: mmol/L or mg/dL
Memory	500 results with time and date, averages for 7, 14, 30 and 90 days
Measurement range	20 - 600 mg/dL (1.1 - 33.3 mmol/L)
Power supply	One 3 volt lithium battery (coin cell type CR2032)
Battery life	Approx. 1000 tests or 1 year
Auto power off	After 60 or 120 seconds depending on
Temperature	During testing: +10°C to +40°C (+50°F to +104°F) During storage without battery and test cassette: -25°C to +70°C (-13°F to +158°F) During storage with battery, without test cassette: -20°C to +50°C (-4°F to +122°F) During storage with battery and test cassette: +2°C to +30°C (+35.6°F to +86°F)
Atmospheric humidity	During testing: 15% to 85% relative humidity During storage: 15% to 93% relative humidity
Altitude	Sea level to 4000m
Meter dimensions	105mm x 58mm x 19.5mm
Cassette dimensions	22.2mm x 13mm x 48.2mm

Meter interface	Wireless 2.4 Ghz to connect to smart phone RFID to connect to test cassette
Cassette interface	RFID to connect to meter
Weight	Meter only: 60g Meter with battery and cassette: 70g
Model/Serial Number	Located on meter label inside the cassette bay.
Safety class	III
LED	Class 1
Electromagnetic compatibility	This blood glucose meter meets the electromagnetic immunity requirements as per EN 61326-2-6 and EN ISO 15197: 2015 Annex A. The chosen basis for electrostatic discharge immunity testing was basic standard IEC 61000-4-2. Its electromagnetic emission is thus low. Interference on other electrically-driven equipment is not anticipated.
Performance analysis	Refer to test cassette package insert.
Calibration and traceability	The glucose values used as reference values are obtained using the YSI method. The YSI method is traceable to a primary NIST standard. BETACHEK C50 blood glucose monitoring system meets the requirements of EN ISO 15197: 2015. Freshly obtained capillary blood is the only allowable sample. Results displayed are the plasma equivalent. See the instructions for use supplied with the test cassette for further information.

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