

BETACHEK G5

Blood glucose Monitoring System

User Manual

The Betachek G5 meter has been designed to give years of reliable and trouble free use. Its speed and unique memory card system will save you time and inconvenience.

Please read this manual thoroughly so that you are aware of all the features that have been incorporated into this state of the art device.

Overview of main features:

- 5 second test time
- Small sample required
- Unlimited result storage with unique memory card system – all results saved permanently
- 250 in meter memories with time and date
- 7 and 14 day averaging
- Auto on and Auto shut off
- Auto calibration with memory card plug in
- Large, easy to read screen
- 12 or 24 hour time format
- Sound or silent operation
- Small and lightweight
- Easy to operate

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System components

- Betachek® G5 Meter and batteries
- Betachek® Lancing device and lancets
- Carry case



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Manufactured by



Expiry date



This product fulfils the requirements of Directive 98/79/EC on in vitro diagnostic medical devices and Directive 89/336 EEC on electromagnetic compatibility



For in vitro diagnostic use



Please read instructions before use



Storage temperature range



Important information accompanies this product



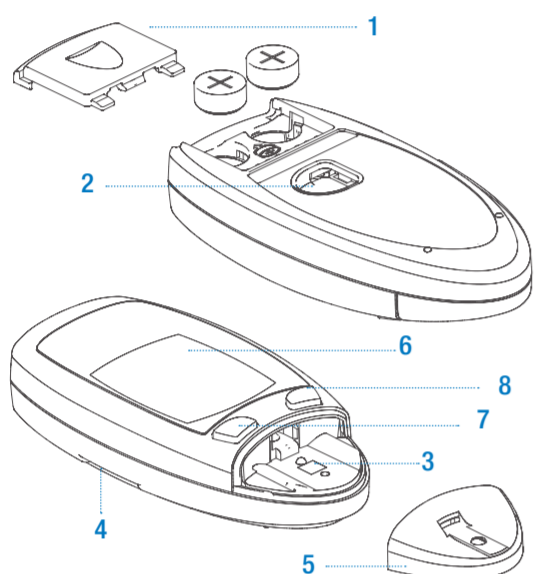
Authorised Representative in the European Community

Technical data

Test Time	Approx. 5 seconds
Measuring method	Reflex photometry
Assay method	Glucose Oxidase
Blood sample	Fresh capillary blood
Sample size	1 - 2µl
Memory	250 readings with time and date
Permanent memory	Unlimited memory card storage (50 readings with time and date per card)
Batteries	2 button batteries type LR44 (Panasonic) or A76 (Ucar) V13GA (Varta) or G13 (Toshiba); alternatively, 2 lithium batteries type CR1/3N (Varta) or DL1/3N (Duracell)
Battery life	2000 tests
Measuring range	10-500mg/dL (0.6 – 27.7 mmol/L)
Auto power off	120 seconds
Storage of meter	Humidity <85% Temperature -40°C & + 70°C (-40°F & + 158°F)
Optimum Operating Temperature	10 - 40°C (50 - 104°F)
Dimensions	95 x 45 x 20mm
Weight	Approx. 55g
Item/Serial Number	Located on meter label
Safety Class	III

1. Meter set up

Parts summary

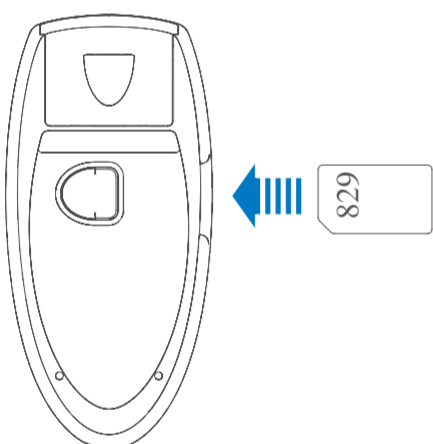


1. Battery cover
2. Finger slot for removing memory card
3. Measurement optics
4. Memory card slot
5. Test strip guide
6. Display
7. Power button
8. Memory recall button

Procedure for coding

Step 1: Insert memory card

Take the memory card from the pack of test strips and insert it into the meter.



The meter will sound a chime when the card is correctly inserted and the coding is completed*.

* If you have the sound turned off, there will be no chime.

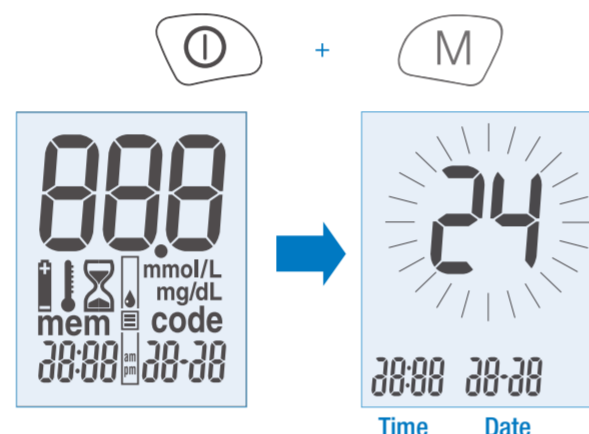
Getting started

Before using your meter for the first time, insert batteries in the battery compartment. See **Changing the batteries** section of this manual.

Setting the time, date and sound

Enter Set Up

To enter set up, hold down both buttons simultaneously, until the following display appears (approx. 3 seconds), then release the buttons:



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

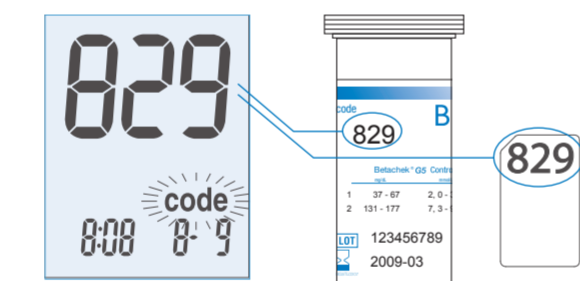


Procedure for coding

Step 2: Check code number

The meter will then display a three-digit code number.

The following is an example only:



Check that the number displayed matches the number printed on the container of the test strips and memory card.

Example: In the above case, the screen, the memory card and the label should all have the code number 829.

Caution: It is critical that a pack of test strips be used only with the memory card supplied. The memory cards are not interchangeable as each has different calibration information.

The memory card carries calibration data only for the pack with which it is supplied. When the meter is programmed with this data it is able to give accurate results for that pack only.

If the code number on the screen does not match the code number on the pack of tests, the meter will give incorrect readings!

Setting the time, date and sound

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

Step 2: Set Time and Date

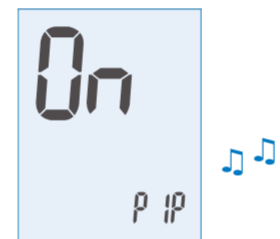


Step 3: Select date format

(dd-mm) OR (mm-dd)

Step 4: Turning the sound on and off

When the sound is on, the meter will display:



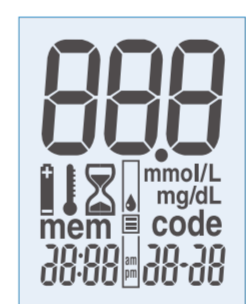
Change to PIP OFF for the meter to be silent.

Press (M) to select your preference and the meter will save the settings and turn off.

2. Checking the Display

The G5 meter has an LCD that should be checked periodically to ensure it is showing all segments correctly.

Turn on the meter using the (M) button and the meter will perform a screen test by lighting all segments for 3 seconds.



Check that all the segments are functioning correctly as shown above.

3. Performance Characteristics

Accuracy

Comparison against capillary whole blood by hexokinase method produced the following regression:

$$y(\text{mg/dL}) = 1.0307x - 6.4114 \quad R^2 = 0.9815$$

Precision

The repeatability obtained with the blood samples is shown in the following Table. The table gives the pooled standard deviation and pooled CV% with 95% confidence intervals for the five levels of glucose tested (n=100). No outliers were detected and excluded from data analysis.

At glucose concentrations of 44.7, 96.1, 132, 170 and 276 mg/dL coefficients of variation (CVs) of 3.7, 3.5, 2.3, 2.8 and 2.1% were obtained respectively, indicating a high degree of precision. At all glucose levels tested the coefficient of variation was below 4%.

Grand mean (mg/dL)	44.7	96.1	132	170	276
Pooled SD (mg/dL)	1.7	3.4	3.0	4.8	5.8
95% CI (mg/dL)	1.5-3.0	3.0-6.2	2.6-5.4	4.2-8.7	5.1-10.7
Pooled CV%	3.7	3.5	2.3	2.8	2.1
95% CI	3.2-6.7	3.1-6.4	2.0-4.1	2.5-5.2	1.9-3.9

Sources of interference

Do not carry out a test in direct sunlight. Strong electromagnetic fields (e.g. mobile phones, microwave ovens) may affect performance. Betachek G5 will detect this and an error message will be displayed.

4. Memory

The G5 meter has two memory systems that work automatically and in conjunction to provide you with a record of your results.

1. Card Memory
2. Meter Memory

Why two systems?

The meter has a storage capacity of 250 results. When full, the oldest results are deleted to make room for new ones. This is a "first in, first out" system which means results are not stored permanently.

Conversely, the memory card supplied with each pack of test strips provides a permanent record of results from a single pack of strips.

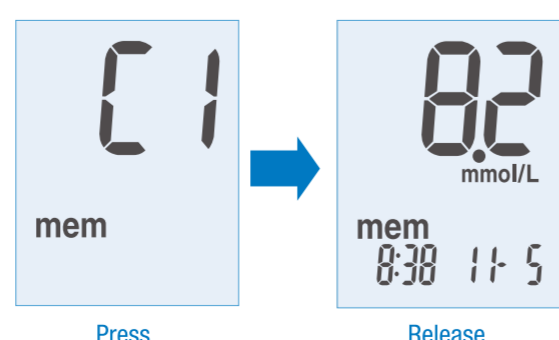
1. Card memory

Each new pack of test strips comes with a memory card that will permanently store the 50 results with time and date.

When a test is performed, the result is automatically stored on the memory card. Once the pack is finished, you should have 50 test results stored on the memory card. The memory card stores these results permanently and it should be kept for future reference. An extended chime indicates that the memory card is full.

Recalling results from the memory card using the memory button

With the card inserted, press and hold the (M) button until 'C1' appears, this indicates that the card is being read. When the button is released, the most recent test result will be displayed. Use the (M) button again to read 'C2, 3, 4...' to a maximum of 50.



Note: The prefix 'C' means card memory.

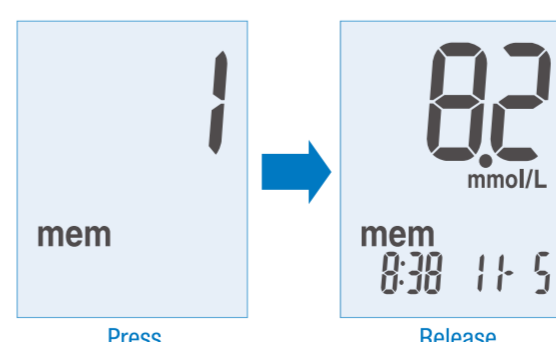
2. Meter memory

Your meter stores 250 test results with time and date. Each time a test is performed and a result displayed, the meter automatically stores the value in memory. If 250 results are already stored, then the oldest result is deleted to make space for the newest result.

Recalling results from the meter using the memory button

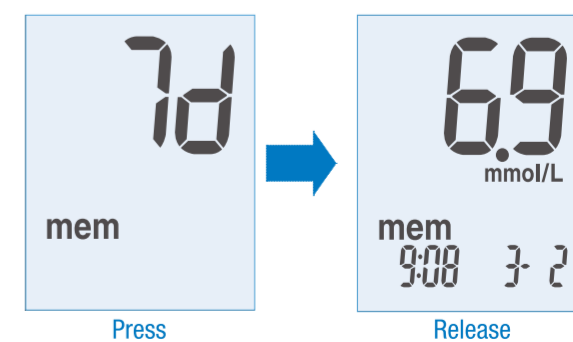
Remove the memory card and press the (M) button. This will recall a maximum of 250 results in the meter.

When pressing and holding (M) button, the memory number will be displayed and when the button is released, the result will be displayed.

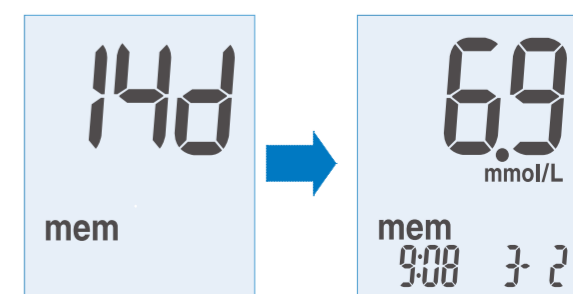


Recalling 7 and 14 day averages

1. Turn the meter off.
2. Press and hold the (M) button until 7d appears (approximately three seconds).



The result that appears immediately after releasing the (M) button is the 7 day average. Press again (M) and 14d appears, release for the 14 day average.



Note: Time and date must be set.

5. Performing a test

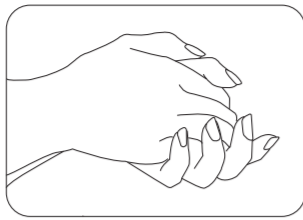
Materials needed

- Betachek G5 Meter
- Test strips and the memory card supplied with the test strips
- Lancing device with lancet

Preparation

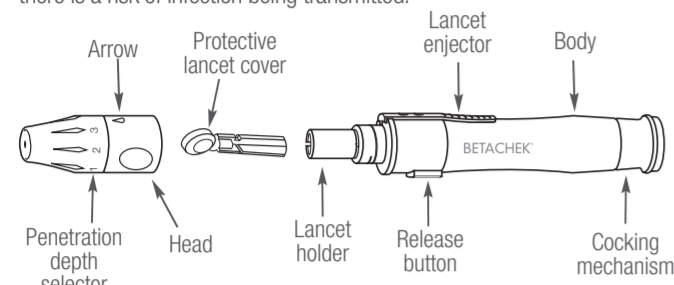
Check test strips have not past the expiry date printed on the label.

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



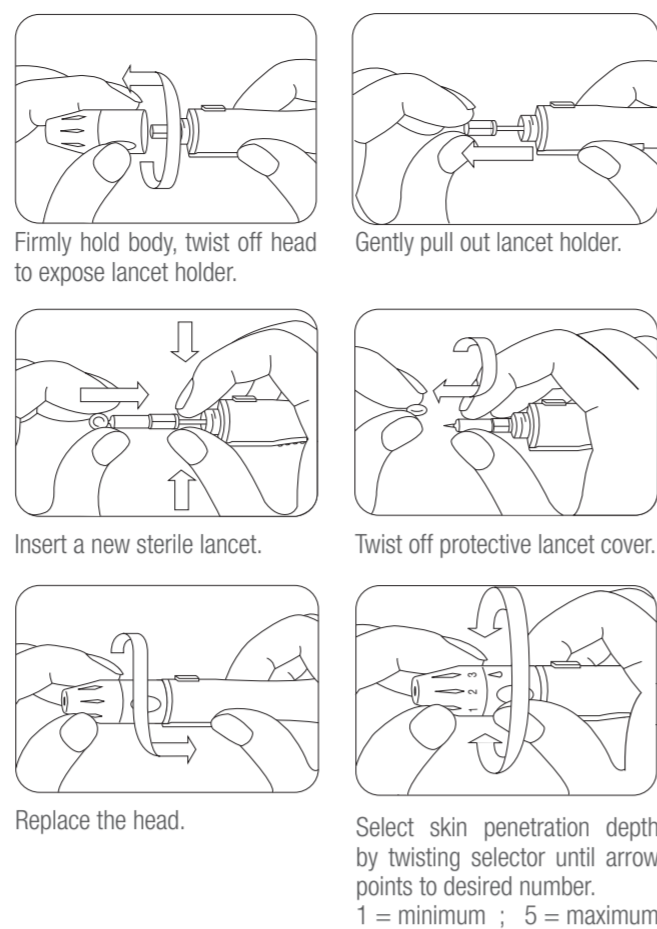
Lancing Pen

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.



Note: After use, remove used lancet and replace the protective lancet cover onto the lancet tip. Dispose of lancet in a suitable sharps container.

Inserting a lancet

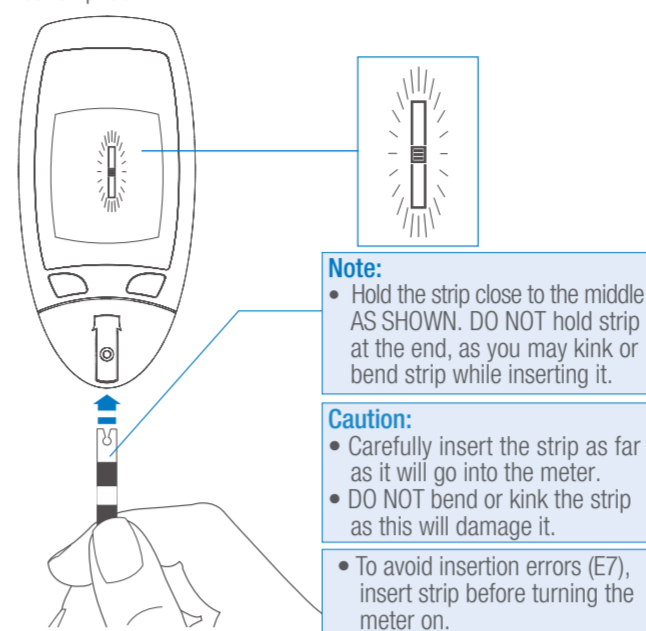


Test procedure

IMPORTANT: Remove a test strip from the container and quickly reseal it. The cap contains a drying agent that will be exhausted if the cap is not quickly replaced.

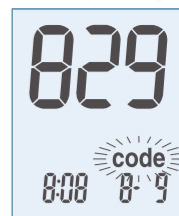
Step 1: Insert a test strip

Note: A test strip may be inserted either before or after turning the meter on. If you turn the meter on using the button and have not inserted a test strip, the meter will prompt you by flashing the test strip icon:

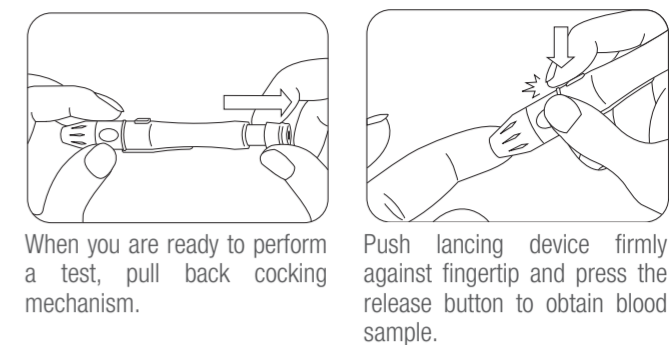


The meter will display the code number and flash the word code. Check the code number matches the code number printed on the test strip label.

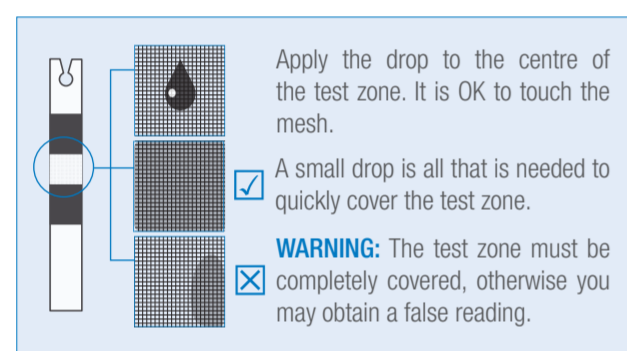
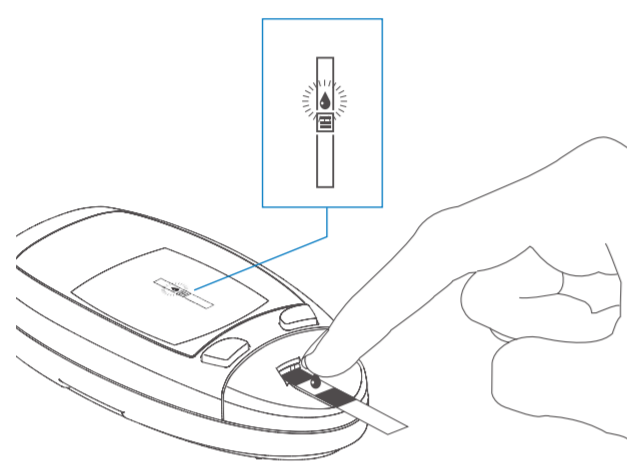
Example Only:



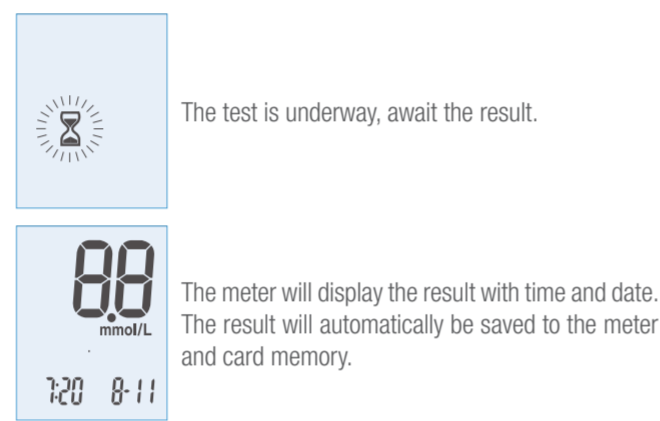
Step 2: Obtain Blood Sample



Step 3: Apply blood with the strip in the meter

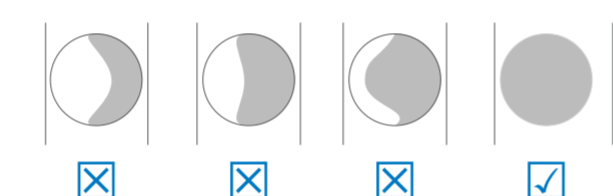


When a blood drop has been applied, the meter will give a beep and commence measuring. Do not move the test strip as this will lead to an incorrect result. The hourglass icon will flash until a result is displayed.



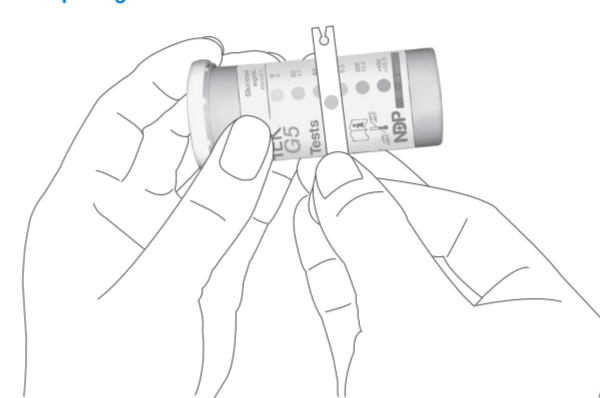
Was enough blood applied?

Remove the test strip from the meter and check that the circular window on the back of the strip is even in colour. If it is not even, then you have not applied enough blood. You will need to repeat the test.



Double Checking the Result

Comparing colour



Does the meter result match the colour chart?

On the test strip container label, you will find a range of colours, each corresponding to a glucose concentration.

- Match the colour in the circular window to the nearest colour on the chart.
- Compare the value from the chart to the value you obtained from the meter.

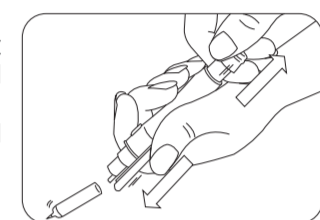
This should be done between 30 and 60 seconds after applying blood to the test strip.

If the two values approximately agree then the result is confirmed. If they do not agree then repeat the test. If the problem persists you should perform a control test and see the **Meter maintenance** section of this manual.

Disposal

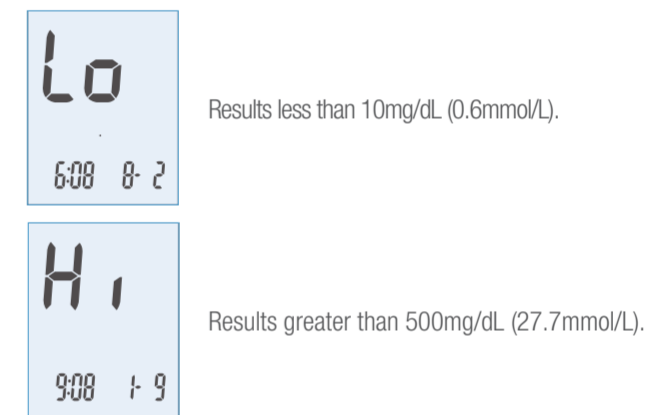
As blood is potentially infectious, please dispose of the used test strip and lancet in a contaminated waste container or in another suitable way.

For safe removal of used lancet from lancing pen, twist of head to expose lancet holder. Push the lancet ejector with thumb and simultaneously pull back cocking mechanism.



Measurement range

The G5 meter measures blood glucose between 10-500mg/dL (0.6 – 27.7mmol/L). Values outside this range are reported as 'Lo' or 'Hi'.



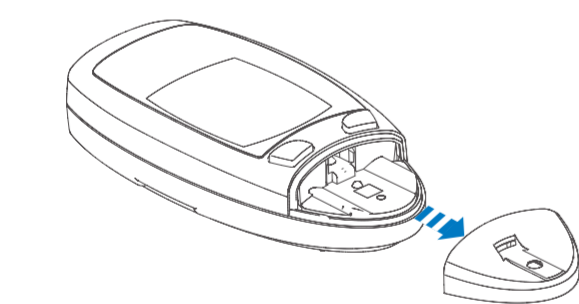
6. Meter maintenance

Caring for the G5 meter

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, clean it immediately.

Cleaning the strip guide

The black area where the strip is inserted may be removed for cleaning. Slide it off and rinse it with cold soapy water. Check it is clean on both sides and then dry it.

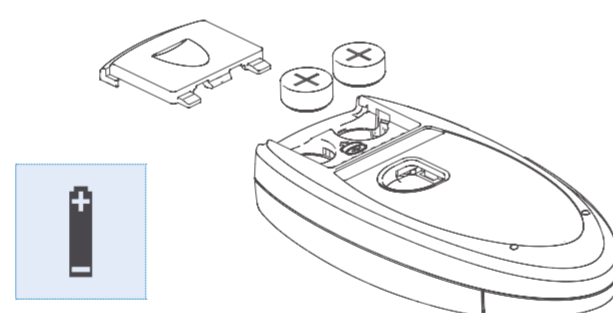


The optics area under the strip guide can be cleaned using a cotton tip or soft damp cloth. Be careful not to get water into the meter!

Do not scratch the optics area as this will lead to incorrect readings.

Changing the batteries

When the battery warning symbol appears, it is time to replace your batteries. Approximately 50 tests may still be conducted before the batteries completely fail.



Battery types

- 2 button batteries LR44 (Panasonic) or
- A76 (Ucar) or
- V13GA (Varta) or
- G13 (Toshiba)

alternatively;

- 2 batteries type CR1/3N (Varta) or
- DL1/3N (Duracell)

Note

Results stored in the meter's memory will not be lost if the batteries are removed, however time and date will need to be reset.

Betachek G5 Control Solutions

Checking the meter's accuracy

Special solutions of glucose are available as a quality check to verify the accuracy of your Betachek G5 blood glucose system.

BETACHEK® G5 Control Solutions are water based solutions containing a known amount of glucose which when used in place of blood will react with BETACHEK® G5 Test Strips. The Control Solution should give results within the expected range printed on the memory/coding card. Obtaining a result within the expected range is sufficient to verify system performance.

When to carry out a control test:

- If you obtain unexpected results.
- After opening a new pack of test strips
- After you have replaced the batteries.
- After you have cleaned your meter.
- Whenever you suspect the meter or test strips may not be functioning properly.

Use of Control Solution is also recommended for teaching or learning how to use the system.

Also required: BETACHEK® G5 Meter and BETACHEK® G5 Test Strips.

Chemical composition ¹	
Glucose	0.03
Buffer	0.70
Preservative	0.40
Non reactive constituents	18.00
Water	80.87

¹Values are expressed as a percentage by weight and vary depending on the control level. Figures given are for control 1.

Precautions and limitations

- Do not allow Control Solution to enter the meter, use only on test strips.
- Discard any unused Control Solution 3 months after opening. Note the discard date on the Control Solution label.

- Use fresh test strip if drop of Control Solution has not completely wet test pad.
- If the drop applied contained air bubbles, repeat the test.

Storage and handling of control solution

- Store the Control Solution between 4 and 30°C (39 and 85°F).
- Do not refrigerate.
- Use before the expiration date shown on the label.
- Wipe the bottle tip and reseal tightly after each use.

Procedure: To perform a Control Solution test, follow the same test procedure that is used for a blood glucose test, substituting Control Solution for a drop of blood. Refer to **Performing a test**.

- Discard the first drop of Control Solution.
- If large bubbles are present at the tip of bottle, wipe off the bubbles with a clean tissue before applying a drop of Control Solution to the test strip.
- Apply one drop to the test strip.
- To avoid contaminating the Control Solution with enzyme, DO NOT touch the test strip with the tip of the Control Solution bottle.

Expected results: See Memory/Code card for the acceptable range of values. If result is within the stated range, the meter and test strips are performing correctly. If control result is outside the stated range, check that you have followed the correct procedures (see **Sources of error**). After eliminating all potential sources of error, repeat the control test. If control result is still outside stated range after the second test, please call your NDP representative.

Sources of error: If test results fall outside the acceptable range, the test should be repeated. Results which fall outside the acceptable range may indicate user error, Control Solution or test strip expiration, Control Solution contamination, test strip deterioration, meter malfunction, or extremes in testing temperature. Refer to **Troubleshooting** for assistance. Ensure:

- That the test strip guide is clean (see **Caring for the G5 meter**).
- That the test strips and Control Solution you used were correctly stored (expiry date, storage conditions).
- That the meter, test strips and Control Solution were at the correct temperature during the control test.

7. Troubleshooting

Key to symbols

- Low battery warning**
When this symbol appears the meter will still perform another 50 tests. You should replace the batteries.
- Ambient temperature**
The ambient temperature is/was outside the recommended range 10-40°C (50-104°F). The result will be stored in memory with this symbol. Do not make treatment decisions based on this result.
- Apply blood**
Apply blood to the test strip.
- Testing underway**
Test is underway, await result.
- Insert strip**
When this symbol flashes, insert a test strip into the meter.
- Mem Memory recall**
Memory result recalled.

Key to error messages

- E-0 EMC error**
EMC error (electromagnetic field) move away from possible source e.g. mobile phone, microwave.
- E-1 Flat battery**
Flat battery, no test may be performed.
- E-2 Calibration error**
Out of calibration, return to supplier.
- E-3 Check test strip**
Damaged or used test strip or strip not fully inserted or the measurement optics are dirty. See section **Caring for the meter - Cleaning**.
- E-4 Memory card full**
Replace with a new memory card from a fresh pack of test strips.
Note: Some models will sound a warning chime instead of E-4.
- E-5 Too much light**
Too much ambient light or strip removed during test. Move out of direct sunlight.

Key to error messages

- E-7 Strip inserted incorrectly**
Review test procedures or try inserting the strip BEFORE turning the meter on.
OR Blood applied too early
Blood applied too early, repeat the test and wait for the blood drop icon.
- E-8 Test strip removed**
Test strip removed during testing, repeat the test and leave test strip in the meter until the test is completed.
- E-9 Faulty test strip**
Faulty test strip. Check that you have stored and handled the test strips as instructed in the package insert.
- Check memory card**
Memory card not properly inserted or has a fault.
- E-C Memory card failure**
Memory card cannot be read. Remove your card and reinsert. If the problem persists, you cannot use the card or test strips.
- !!! Incorrect temperature**
Temperature outside permissible range. Tests cannot be performed outside permitted limits 5-45°C (41 - 113°F).

Problem solving

Error message

If the meter displays an error message or warning symbol, consult the section, **Key to symbols and error messages** for an explanation.

Implausible results

If a result which has been obtained is not plausible, then repeat the test. If the problem persists then check through the following list:

- Does the code number on the screen match the one on the test strips?
- Was enough blood put on the strip?
- Is the circular window on the back of the test strip even in colour?
- Are the test strips within their expiry date?
- Is the optical area under the strip guide clean?
- Are your hands clean and dry?
- Was the strip inserted fully and was it straight and flat in the guide?
- Was the blood sample capillary blood (obtained from a finger prick)?
- Have the strips been stored and handled in accordance with the test strip instructions? e.g. in the container and away from heat or cold?

If you answered no to any of the above then repeat the test after addressing the problem. See the section **Checking the meter's accuracy** if you continue to obtain implausible results.

Meter not turning on

Check the following:

- Are batteries in the meter?
- Are they facing the correct way?
- Is contact being made with the terminals (they may have been bent when the batteries were inserted)?
- Has the meter been dropped? If so it will need to be returned for repair.