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ACCU-CHEK[®] *Active*

Blood Glucose Meter

Instructions for use



Explanation of symbols

On the packaging and on the type plate of the meter you may encounter the following symbols shown here with their meanings:



Consult instructions for use



Caution (refer to accompanying documents). Please refer to safety-related notes in the manual accompanying this instrument.



Temperature limitation (Store at)



Manufacturer

REF

Catalogue number

LOT

Batch code

IVD

In vitro diagnostic medical device



This product fulfils the requirements of the European Directive 98/79/EC on in vitro diagnostic medical devices.



This product fulfils the legal requirements of the People's Republic of China on the use of certain substances in electronic products.

The explanation of any other symbols can be found in the instructions/inserts, accompanying components within the packaging.

Last update: 2010-08

Intended use

The Accu-Chek Active blood glucose meter

Meter for quantitative determination of blood glucose values in fresh capillary blood using Accu-Chek Active test strips.

Suitable for self-testing.

The meter may be used by patients who test their own blood glucose as well as by healthcare professionals for monitoring patients' blood glucose values.

Visually impaired persons must not use the meter.



Healthcare professionals must also read the instructions in Chapter 10 “Testing blood glucose in more than one patient – Information for healthcare professionals”.



Any object coming into contact with human blood is a potential source of infection (see: Clinical and Laboratory Standards Institute: Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline – Third Edition; CLSI document M29-A3, 2005).

About these Instructions for use

Please read these Instructions for use carefully and completely before testing blood glucose for the first time. If you have any questions, please contact your customer support and service centre (see Chapter 17).

These Instructions for use will help you get to know your new meter step by step. They will provide you with all the information you need to operate, troubleshoot and care for your meter. It is important to

remember that, in order to keep your meter in tip-top condition, you need to comply with all instructions given in addition to following the correct operating procedures. The meter is a precision instrument. Improper handling can impair its operation.

We recommend you start by studying the location of the key features of your meter (see Chapter 1.1). Practise all of the operations described in these Instructions for use, and also practise testing.

In these Instructions for use you will come across three kinds of notes. Please read these very carefully.



This symbol indicates **a possible risk of injury or of damage to your own health or the health of others.**



This symbol draws attention to actions that could result in damage to **your meter.**

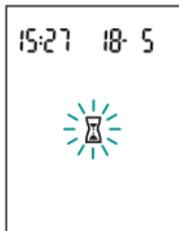


This symbol draws attention to important information.

All instructions appear in a coloured frame as shown below:

1 Insert the test strip into the meter.

In these Instructions for use you will see examples of display screens. Elements that are surrounded by a halo in these examples actually flash on the meter's display.



Please note:

All dates, times or results shown on the display screens in these Instructions for use are intended only as examples. They show results in units of mmol/L (e.g. 7.1 mmol/L), dates in the day-month format (e.g. 18- 5) and times in the 24-hour clock (e.g. 15:27). Others can (and will) be shown on your meter's display screen. Your meter can, for example, display results in mg/dL (e.g. 128 mg/dL), dates in the month-day format (e.g. 5-18) and times in the 12-hour clock (e.g. 3:27pm).

Contents

1	Getting to know your meter	12
1.1	Your meter at a glance	12
1.2	The main features at a glance.....	14
2	Steps before testing	16
2.1	Checking the contents	16
2.2	Checking the unit of measurement for blood glucose	17
2.3	Removing the protective film from the battery.....	18
2.4	Performing a display check.....	19
3	Setting the time and date	21
3.1	Overview.....	22
3.2	Making settings	24
4	Coding	28

5	Testing blood glucose	30
5.1	Preparing to test blood glucose	30
5.2	Testing blood glucose.....	31
	Turning the meter on	31
	Applying blood with the test strip in the meter	34
	Applying blood with the test strip outside the meter.....	36
	Turning the meter off	39
	Flagging test results	40
5.3	Checking the test result using the test strip control window	43
5.4	Symbols seen before, during or after testing and what they mean.....	45
5.5	Notes on blood glucose testing.....	46
5.6	Evaluating results.....	49
	Measuring range	50
	Implausible results – possible sources of error	51

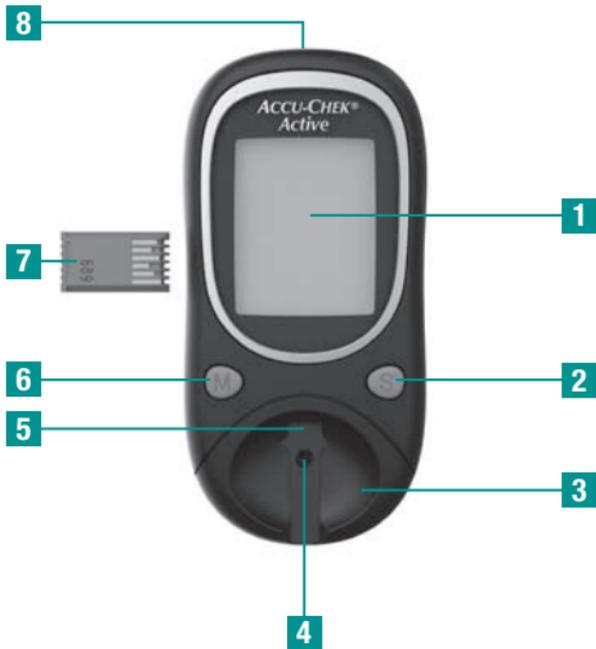
6	Using the meter as a diary	53
6.1	Memory	53
6.2	Retrieving results from the memory	54
6.3	Retrieving averages	58
6.4	Downloading test results.....	64
	If downloading is unsuccessful	69
7	Checking your meter	70
7.1	Preparing for a performance check	71
7.2	Carrying out a performance check	72
7.3	Possible sources of error during performance checks.....	79
8	Cleaning the meter	82
8.1	External parts.....	83
8.2	Test strip guide and measuring window	83

9	Changing the battery	87
10	Testing blood glucose in more than one patient – Information for healthcare professionals	91
10.1	Testing blood glucose.....	93
10.2	Disinfecting the meter.....	95
11	Measurement and storage conditions	96
11.1	Temperature	96
11.2	Atmospheric humidity	98
11.3	Light conditions	98
11.4	Sources of interference.....	99
12	Symbols, problems and error messages	100
12.1	Symbols shown in the display	101
12.2	Problems	107
12.3	Error messages.....	109

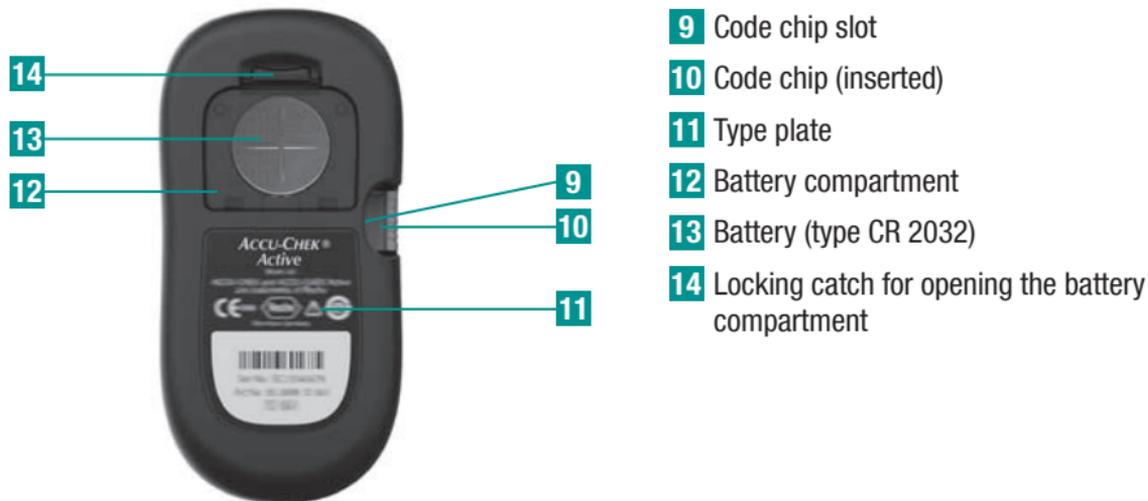
13	Technical data	116
14	Disposing of your meter	121
15	System components	122
16	Customer support and service	123
16.1	Information service and troubleshooting.....	123
16.2	Addresses.....	123
17	Alphabetical index	124

1 Getting to know your meter

1.1 Your meter at a glance



- 1 Display
- 2 S button (retrieving settings for time and date)
- 3 Measuring window cover
- 4 Measuring window (underneath the cover)
- 5 Test strip guide
- 6 M button (retrieving readings from the memory, changing time / date)
- 7 Code chip
- 8 Infrared window



Keep the blood glucose monitoring system and all its components away from children under the age of 3. There is a risk of suffocation if small parts (e.g. covers, caps, or similar objects) are swallowed.

1.2 The main features at a glance

■ **Fast testing**

The meter needs only approximately 5 seconds for each test.

■ **Easy testing**

For testing, you do not need to press a single button. You insert a test strip into the meter, which switches it on, apply blood to the test strip, read the value and then pull the test strip out of the meter.

■ **Blood volume checking**

To perform a test, the meter requires 1–2 μL blood (1 μL (microlitre) = 1 thousandth of a millilitre). The meter detects if the applied amount is not sufficient.

■ **Flagging results**

You can flag results with different symbols, which indicate particular situations during the test.

■ **Memory**

The meter automatically saves up to 350 results with the time and date of the test and all other information that is important for the test.

■ **Integrated data analysis**

From the stored test results your meter can calculate your average values for the last 7, 14 or 30 days.

- **Data transfer**

The meter has an infrared port enabling you to download stored test results to a computer.

- **Applying blood outside the meter**

When the meter prompts you to apply blood, you can remove the test strip from the meter, apply the blood and insert it back into the meter.

2 Steps before testing

2.1 Checking the contents

Check that the contents of the package are complete. You will find a list with the contents on the box.

If anything is missing, please contact your customer support and service centre (see Chapter 17).

2.2 Checking the unit of measurement for blood glucose

Blood glucose results can be displayed in two different units (mmol/L or mg/dL). Two different versions of the same meter are therefore available. Please check if your meter displays the unit you are accustomed to.



Type plate

You can find the unit of measurement that your meter displays on the type plate on the back of your meter. If you do not know which is the right unit for you, ask your doctor.



The unit of measurement that your meter displays cannot be changed. If the wrong unit is printed on the type plate, please consult your dealer or pharmacy. A wrong unit of measurement could lead to test results being misinterpreted.

2.3 Removing the protective film from the battery



The meter is supplied with a battery inserted. The battery contacts are covered with a protective film to prevent the battery from becoming drained prematurely. Before using the meter, remove the protective film. You will see the film projecting from the battery compartment on the back of the meter.

- 1 Simply pull the film vertically out of the meter. You do not need to open the battery compartment to do this.

 For how to change the battery, see chapter 9.

2.4 Performing a display check



You can check if all of the display elements are properly displayed, by carrying out a full display check.

- 1 With the meter turned off, press the M and S buttons at the same time until the meter is switched on automatically (more than 3 seconds).



mmol/L meter



mg/dL meter

- 2 Compare the display of your meter with the one shown here.

If any of the display elements are missing or the unit shown for the blood glucose results is not the correct one, please ask your dealer/pharmacy to exchange the meter.

- 3 Press any button to terminate the display check and turn off the meter.

3 Setting the time and date

The time and date is not preset in new meters. You can still, perform blood glucose tests. In this case, however, the meter displays the time 0:00 (0:00am) and the date 0- 0. This means that test results are saved without a time and date. Averages cannot be calculated, and when downloaded to a computer, the statistical evaluation of test results is very restricted or cannot be performed at all.

So that test results are saved with a time and date, you must set the time and date and, if required, change the format in which they are displayed.

When you set the time and date for the first time, the factory defaults are displayed.

The settings are made in the following order (default in brackets):

1. Time and date format (24-hour display with day-month date format)
2. Time – hour, minute (0:00)
3. Year (year of manufacture)
4. Date – month, day (month of manufacture, day 15)

If you do not wish to set the time and date, proceed to Chapter 4 “Coding”.

3.1 Overview



Turning the meter on

Press the S button and hold it down (for more than 3 seconds) until the depicted display appears.

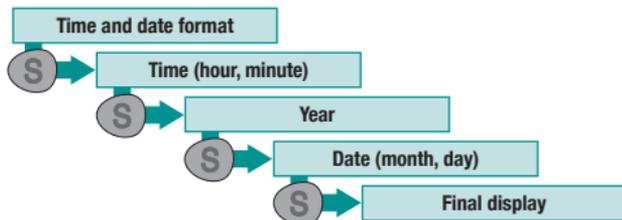
When **set-up** appears in the display, you can make changes to the time and date.

Changing settings

Press the M button.

Holding down the M button increases the number quickly.

For a detailed description of how to set the time and date, see Chapter 3.2.



Confirming the change and continuing with the next setting

Press the S button briefly.

Turning the meter off at any time

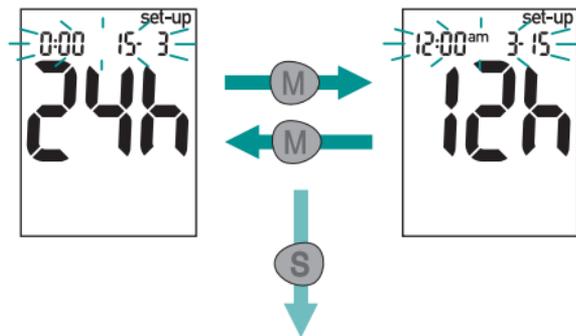
Press the M and S buttons briefly at the same time.

First confirm your last change with the S button, since the change will otherwise be lost.

If you do not press any buttons, the meter turns off automatically after approx. 30 seconds. In this case, all changes are lost and the original settings remain unchanged.

3.2 Making settings

Setting the time and date format



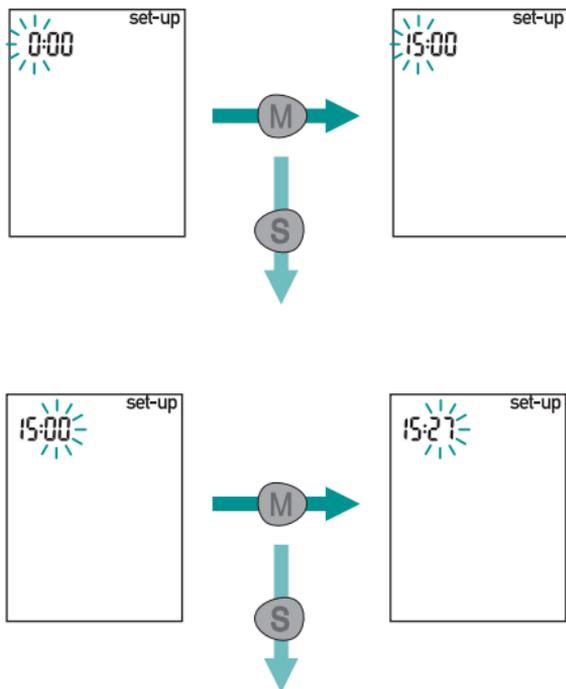
You can choose between two formats:

- 24-hour format → time from 0:00 to 23:59, date in the day-month format (DD-MM)
- 12-hour format → time from 12:00 to 11:59 followed by am or pm, date in the month-day format (MM-DD)

When you change the time and date format, the time and date are changed accordingly.

- 1 Press the M button briefly to switch from one format to the other.
- 2 Press the S button to go to the time.

Setting the time



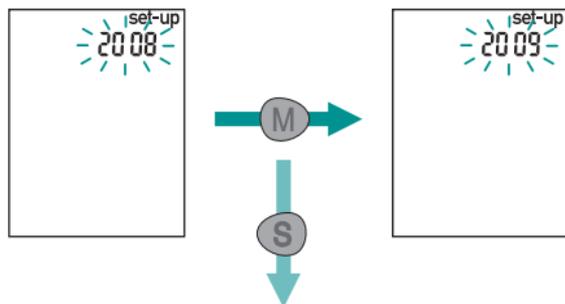
The hours flash in the upper left corner of the display.

- 1 Press the M button to set the hours.
- 2 Press the S button to go to the minutes.

The minutes flash in the display.

- 3 Press the M button to set the minutes.
- 4 Press the S button to go to the year.

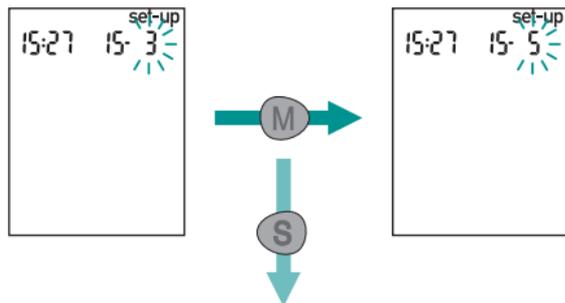
Setting the year



The year flashes in the upper right corner of the display.

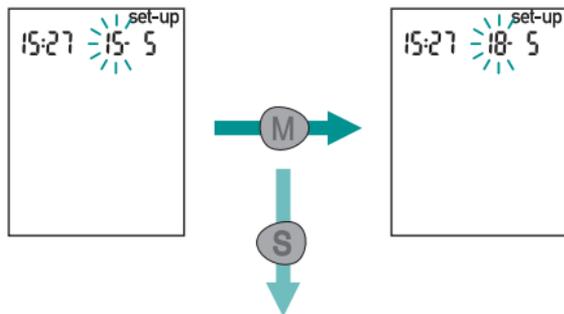
- 1 Press the M button to set the year.
- 2 Press the S button to go to the month.

Setting the date

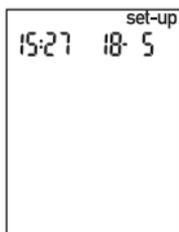


The month flashes in the upper right corner of the display.

- 1 Press the M button to set the month.
- 2 Press the S button to go to the day.



Final display



The day flashes in the display.

- 3 Press the M button to set the day.
- 4 Press the S button, and you will see the final display.

- 1 Check that time and date are correct.
- 2 Press any button to turn off the meter.

4 Coding

A code chip is used to give the meter information about the properties of the test strips. This is why each pack of test strips contains a code chip.



Each time you open a new pack of test strips, you must replace the old code chip from the meter with the new one from the pack. Code chips from other packs may contain information that is incorrect for your new test strips, and can therefore lead to incorrect test results. Incorrect results can cause the wrong therapy recommendation to be made and so lead to serious adverse health effects.



- 1 Compare the code number on the chip with the corresponding code number on the label of the test strip container.

The three-digit number on the code chip (e.g. 689) must match the three-digit number on the label.



Leave the meter turned off.

- 2 Gently slide the code chip into the slot on the side of the meter.

You must feel the code chip lock into place.

5 Testing blood glucose

Please also consult the section “Notes on blood glucose testing” (Chapter 5.5).

5.1 Preparing to test blood glucose

You need the following items to carry out the test:

- your meter with the code chip inserted
- the pack of Accu-Chek Active test strips that belong to the code chip
- a lancing device to collect blood
- a lancet for the lancing device

- 1 Read the package insert which came with the test strips.
- 2 Wash your hands with warm water and soap, and dry them well before you start to perform the test.

This helps remove any residues from the skin (e.g. from food, drinks or skin cream) which can disturb the test. This also stimulates blood flow and reduces contamination of the puncture site.

- 3 Prepare your lancing device to collect blood.

5.2 Testing blood glucose

Turning the meter on



- 1 Take a test strip from the container and close the container again immediately.
- 2 Hold the test strip so the arrows printed on it and the orange square face upwards.
- 3 Without bending it, gently push the test strip into the test strip guide in the direction of the arrows. You should feel the test strip lock into place.



mmol/L meter



mg/dL meter

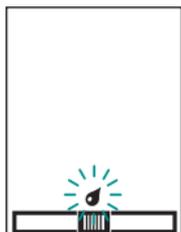


The meter turns on and first performs a default display check (approx. 2 seconds).

- 4 Check that all the segments of the numeric display **000** (mmol/L meter) or **000** (mg/dL meter) are displayed.

If segments are missing, please contact your customer support and service centre (see Chapter 17).

Following the display check, the code number is displayed (689 is just an example).

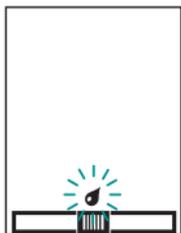


- 5 Check that this code number is the same as the code number on the label of the test strip container.

If the numbers do not match, even though the code chip in the meter is the one that belongs to the test strip container, please contact your customer support and service centre.

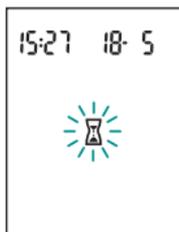
Following the code number, the test strip symbol and the flashing blood drop appear on the display. The meter is now ready to perform a blood glucose test.

Applying blood with the test strip in the meter



When the test strip and the flashing blood drop symbols are displayed, you have approx. 90 seconds to apply blood to the test strip. After this the meter turns itself off.

- 1 Prick the side of a fingertip with your lancing device.
- 2 Encourage a drop of blood to form by gently massaging your finger towards the fingertip.
- 3 Apply the drop of blood to the centre of the orange field and then remove your finger from the test strip.



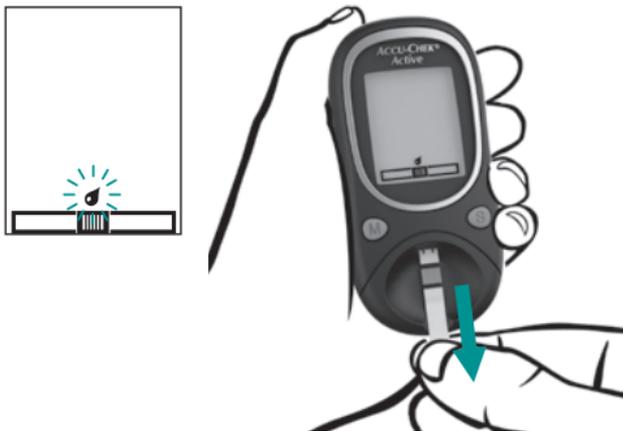
The flashing hourglass symbol  indicates that the test is in progress.

The test is complete after approx. 5 seconds and the result appears on the display. The meter automatically saves the result.

Now you can

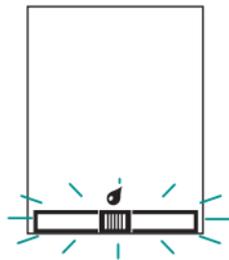
- turn the meter off (see “Turning the meter off”),
- or flag the result (see “Flagging test results”),
- or go to the saved test results (see Chapter 6.1).

Applying blood with the test strip outside the meter

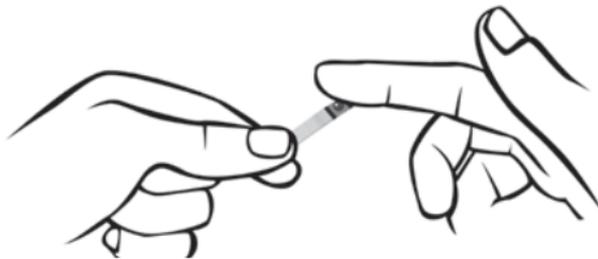


When the test strip and the flashing blood drop symbols are displayed:

- 1 Remove the test strip from the meter.



The test strip and blood drop symbols flash in the display. Now you have approx. 20 seconds to apply blood to the test strip and to re-insert it into the meter. If you do not re-insert the test strip within this time, the meter displays the error message $\text{E} - 1$.



- 2 Prick the side of a fingertip with your lancing device.
- 3 Encourage a drop of blood to form by gently massaging your finger towards the fingertip.
- 4 Apply the drop of blood to the centre of the orange field.



- 5 Push the test strip back into the test strip guide in the direction of the arrows. You should feel the test strip lock into place.



The test starts and the flashing hourglass symbol  indicates that the test is in progress.

The test is complete after approx. 10 seconds and the result appears on the display. The meter automatically saves the result.

Now you can

- turn the meter off (see “Turning the meter off”),
- or flag the result (see “Flagging test results”),
- or go to the saved test results (see Chapter 6.1).

Turning the meter off



1 Remove the test strip from the meter.

The meter turns itself off.

You can dispose of used test strips in your household waste.

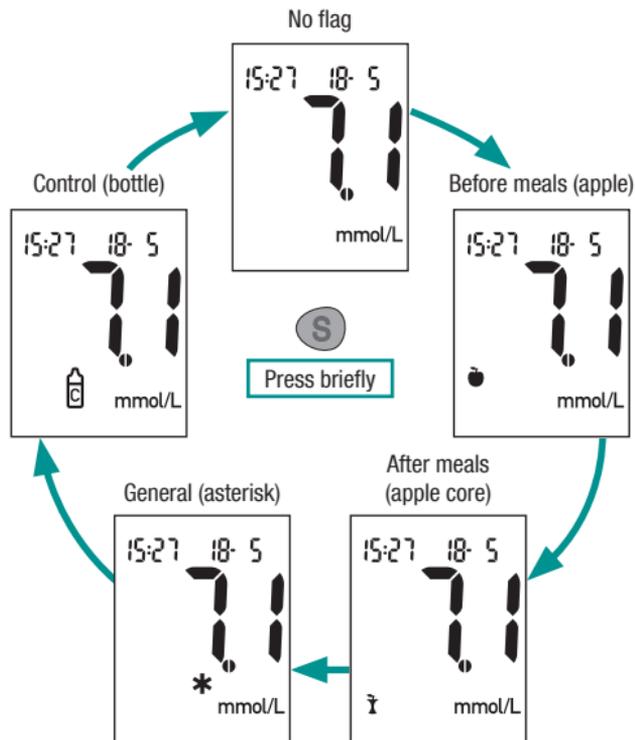
If you do not remove the test strip and do not press any buttons, the meter turns off automatically after approx. 30 seconds.

Flagging test results

You can flag test results to describe certain events connected to the result or particular characteristics of the result. You can only flag a test result while the test strip is still in the meter and the result is being displayed.

You can choose from 4 flags:

- The Before Meals flag (apple symbol 🍏) is intended for test results that you have measured before your meals.
- The After Meals flag (apple core symbol 🍏) is intended for test results that you have measured after your meals.
- The General flag (asterisk symbol ✱): You can define the meaning of this flag yourself. For example, you can use it for test results that you have obtained from alternative sites or after physical activities.
- The Control flag (bottle symbol 🍷) is intended for performance checks in which you apply control solution to the test field instead of blood (see Chapter 7).



While the test result is displayed:

- 1 Press the S button repeatedly until the desired flag is displayed.

The flags appear in the following order:

1. Before meals 🍏
2. After meals 🍏
3. General *
4. Control 🍷

If you decide to not flag the test result, press the S button repeatedly until no further symbol is displayed.

After choosing the desired flag, you can

- turn the meter off (see “Turning the meter off”),
- or go to the saved test results (see Chapter 6.1).

In both cases, the test result is saved with the flag.

5.3 Checking the test result using the test strip control window

The test strip itself allows you to estimate the test result and thus also to check the displayed result.

Before the test

There is a round coloured control window on the back of the test strip.



- 1 Compare the colour of this window with the coloured dots on the label of the test strip container.

The colour of the control window must match the colour of the top coloured dot (0 mmol/L, 0 mg/dL). If the control window is a different colour, you must no longer use the test strip.

After the test

The label on the test strip container shows blood glucose values in mmol/L and mg/dL next to each colour sample.

- 1 Look for the value which is closest to your test result.

Within 30–60 seconds after applying blood:

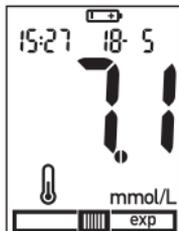
- 2 Compare the colour of the control window on the back of the test strip with the coloured dots on the label of the test strip container.

If you find there is a noticeable disparity, repeat the test. If you cannot obtain a match, even after several tests, contact your customer support and service centre.

Only the test results displayed by the meter should be used for therapeutic recommendations. The colour comparison serves only as a plausibility check of the test results.

5.4 Symbols seen before, during or after testing and what they mean

The following symbols can appear on the display before, during or after a test. For further information, please refer to Chapter 12.1.



 The battery is almost empty.

 The temperature during the test was outside the permitted range of +10 to +40 °C.

Lo instead of a result: The result is lower than 0.6 mmol/L (10 mg/dL).



Lo may indicate that your blood glucose is very low (possibly a severe hypoglycemia). Follow the relevant instructions given by your doctor immediately and repeat the test.

Hi instead of a result: The result is higher than 33.3 mmol/L (600 mg/dL).



The test strips are past their expiry date.

5.5 Notes on blood glucose testing



Incorrect results can cause the wrong therapy recommendation to be made and so lead to serious adverse health effects.

Therefore, please follow the following instructions:

- Only use the Accu-Chek Active meter with Accu-Chek Active test strips that are approved by Roche Diagnostics GmbH. Other test strips deliver incorrect results.
- If the code number on the display does not match the code number on the test strip container, do not perform blood glucose tests. Incorrect coding produces incorrect results.
- Use only test strips with an expiry date which has not been exceeded. Test strips with an expiry date that has already passed can produce incorrect results. If the expiry date has passed, the **exp** symbol will be displayed in the test strip symbol. Check the expiry date on the label of the test strip container. You will find it next to the   symbol. Also check that the current date is set in the meter and that the inserted code chip belongs to the test strip you are using.

- The test strips are sensitive to humidity and moisture. Only remove test strips from the container when your hands are completely dry. Close the test strip container again tightly with its original cap immediately after removing a test strip. The cap of the test strip container contains a drying agent which protects the strips from moisture. If moisture gets into the test strip container through handling test strips with moist hands or if the container is left open, the drying agent loses its effect. Unusable test strips may lead to incorrect results.
- If you have not applied blood to the test strip in the available time and the meter has turned off: Remove the test strip and dispose of it. Start the blood glucose test again with a new test strip.
- If you have removed the test strip from the meter and the error message $E - 1$ is displayed: You must not use this test strip any more even if you have not yet applied any blood. Start the blood glucose test again with a new test strip.

- You can touch the test field when you apply blood, but do not rub the drop of blood into the test field.
- Do not store used test strips in a container which still contains unused test strips. This could make the unused test strips unusable. Unusable test strips can lead to incorrect results.

Please also note the following points, as incorrect results or error messages can otherwise occur:

- Do not bend the test strip while inserting it into the meter.
- Do not to bend or move the test strip before or while applying blood, or while the test is performed.
- Do not apply blood to the test strip before the drop symbol flashes in the display.
- If **888** or **888** are not shown completely during the default display check (e.g. **8?8**), results cannot be displayed correctly. In this case, contact your customer support and service centre.

 Further information

- If you missed the code number in the display after you inserted the test strip, remove it from the meter and re-insert it.
- If you want to apply blood to a test strip which is not inserted into the meter: Do not remove the test strip until the drop symbol flashes in the display. If you remove the test strip before this time, the meter turns itself off.

5.6 Evaluating results

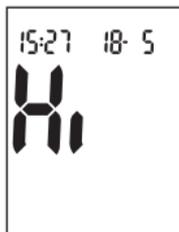
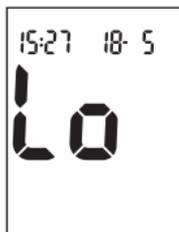


If the displayed test result reflects the way you feel, continue as instructed by your doctor. If the displayed test result does not reflect the way you feel, please perform a performance check with an Accu-Chek Active control solution (see Chapter 7). Repeat the blood glucose test afterwards. If the latest test result still does not reflect the way you feel, please contact your doctor.



Do not change your treatment based on just one result.

Measuring range



The meter measures blood glucose results in the range from 0.6 to 33.3 mmol/L (10–600 mg/dL).

If the result is lower than 0.6 mmol/L (10 mg/dL), **Lo** is displayed instead of a result.



Lo may indicate that your blood glucose is very low (possibly a severe hypoglycemia). Follow your doctor's instructions immediately and repeat the test.

If the result is higher than 33.3 mmol/L (600 mg/dL), **Hi** is displayed instead of a result. Repeat the test.

Implausible results – possible sources of error

If your meter repeatedly displays implausible results or error messages, please check the following points.

If your responses to the questions listed below are different from those given, make the respective corrections when you perform the next test. If you have taken all of these points into account and still obtain implausible results or error messages, contact your customer support and service centre.

Did you take the test strip from the container to which the code chip in the meter belongs?	yes
Did you perform the test according to the instructions for use?	yes
Did you wash your hands with warm water and soap? Did you dry your hands thoroughly?	yes
Did you massage your finger only gently in the direction of the fingertip?	yes
Did you use a used test strip?	no

Did you bend the test strip while inserting it into the meter? no

Did you wait for the drop symbol to flash in the display before applying blood? yes

Did you apply the drop of blood immediately after it formed? yes

Did you bend or move the test strip before or during the test? no

Are the test strips past their expiry date (check next to the  symbol on the test strip container label and also the **exp** symbol on your meter's display)? no

Is the test strip guide and measuring window clean? yes

Did you measure within the correct temperature range (10–40 °C)? yes

Did you observe the storage conditions for the meter and test strips (see Chapter 11 and the package insert that came with the test strips)? yes

Did you take the sources of error into account that are referred to in the package insert that came with the test strips? yes

If your meter has been dropped, it can also lead to implausible results or error messages. In this case also contact your customer support and service centre.

6 Using the meter as a diary

6.1 Memory

Your meter can save up to 350 test results with their time and date. You do not need to do anything to save the results. The meter automatically saves all test results.

If all the memory locations are occupied, the oldest test result is deleted to create space for the new one when you perform a new test.

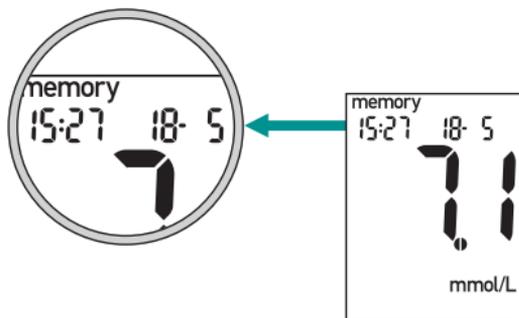
In addition to the results, the time and the date, your meter also saves other information that is important for the test. This includes all symbols which are displayed with the result (except the battery symbol) and the flags with which you marked the results.

6.2 Retrieving results from the memory

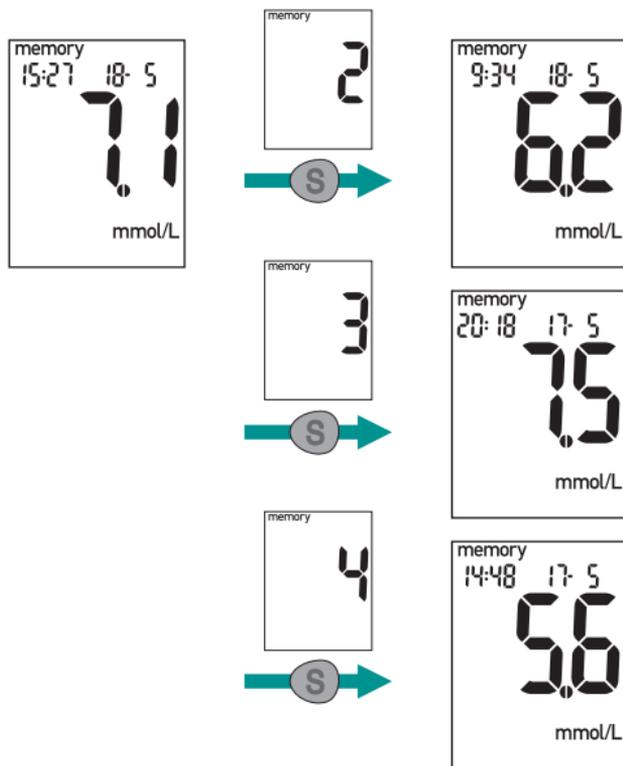


1 With the meter turned off, press the M button.

You can also go directly to the saved results after a test. To do so, press the M button while the result is displayed.



The last saved (latest) result is displayed with the time, date and **memory**.



Retrieving older results:

2 Press the S button.

While you press the S button, the memory location number is displayed. When you release the button, the corresponding result is displayed.

If you keep the S button pressed, the occupied memory locations are displayed in quick succession. Once you release the button, the corresponding result is displayed.

After the oldest result in the memory, the latest result is displayed again.



Turning the meter off again:

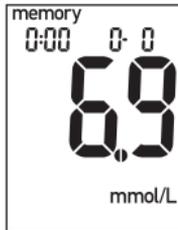
3 Press the M button briefly.

You can directly switch from the saved results to the test by inserting a test strip into the meter.



No result in the memory

If there are no results saved in the meter, the display shown next to this text appears.



Time and date not set

If the time and date were not set at the time of testing, 0:00 and 0- 0 are displayed instead.

6.3 Retrieving averages

The meter can calculate averages from the saved results.

The averages are calculated for three groups of results and for three time periods per group. The calculation is performed in the following order:

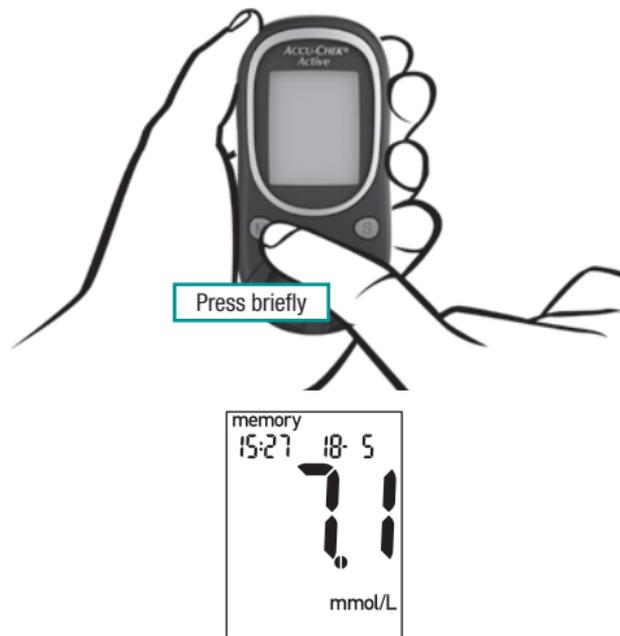
1. All results
 1. for the last 7 days
 2. for the last 14 days
 3. for the last 30 days
2. Only results which have been flagged with 🍎 (Before Meals)
 1. for the last 7 days
 2. for the last 14 days
 3. for the last 30 days

3. Only results which have been flagged with 🍌 (After Meals)
 1. for the last 7 days
 2. for the last 14 days
 3. for the last 30 days

Then the 7-day average for all results is displayed again.

The following results are not included in the calculation:

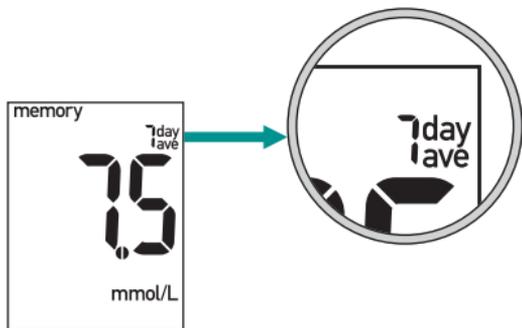
- performance checks (flagged with 🏠),
- results which were displayed as **L** or **H**.



- 1 With the meter turned off, press the M button briefly.

You can also briefly press the M button directly after a test while the result is being displayed.

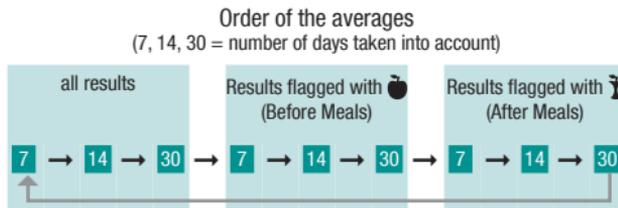
The last saved (latest) result is displayed together with the time, date and **memory**.



2 Press the M and S buttons briefly at the same time.

You can not only call up the averages from within the last saved result, but also from within each saved result.

The first average, the 7-day average of all results, is displayed. The number of days taken into account for the calculation of the average is displayed in the upper right corner of the display.



To go the next average:

3 Press the M and S buttons briefly at the same time.

The averages are displayed in the order shown next to this text.

Averages “before meals” are flagged with 🍎.

Averages “after meals” are flagged with 🍷.

Go back to saved results



From within each average you can either go back to the saved results or turn the meter off.

4 Press the S button briefly to go back to the saved results.

The result which was shown before the average was calculated is displayed again.

or

turn the meter off.



Or:

4 Press the M button briefly to turn the meter off.

If there are no results saved for the selected average, three dashes - - - are displayed.

The meter calculates the average for a period even when the saved results cover a shorter period. For example: Tests were only performed in the last 5 days. In this case, the results of the last 5 days are used to calculate the averages for all three periods (7, 14 and 30 days).

In the event that you changed the date or time, performed a test and then re-set the date/time, only those test results that the meter saved in uninterrupted chronological order will be taken into account. If the chronological order has been interrupted, the earlier results will not be taken into account.

You can switch directly from displaying any average value to testing by inserting a test strip into the meter.

6.4 Downloading test results



Your meter has a built-in infrared port which enables wireless data downloading to a suitably equipped computer or handheld device (PDA), or to a special analysis system.

The infrared port is located at the front of the meter.

Roche Diagnostics offers a variety of special hardware and software products for analysing your data and which enhances the integrated notebook functions of your meter. With these products you and your doctor can manage your data more effectively and, using the graph and table views you can better understand your test results.

Depending on which type of analysis you opt for, you will require either a special software programme and/or special hardware products. For more information please contact your customer support and service centre.

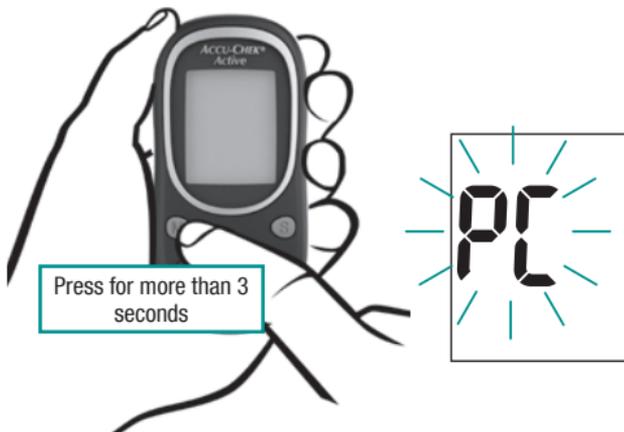
If you already have a hardware or software product from Roche Diagnostics for transferring and evaluating test results, it may not recognise more recent meters and the results will therefore not be downloaded. You may need a more recent software version for your hardware or software product. In this case

please contact your customer support and service centre.

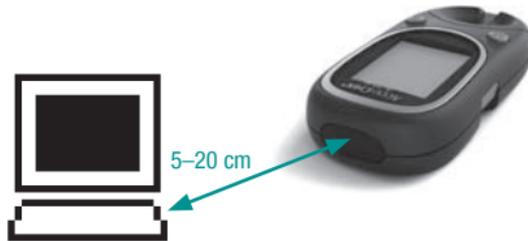
Your test results can only be fully analysed if all of the results have been saved with the date and time, i.e. if you have set the date and time.

The results remain in the meter's memory after downloading.

You cannot perform a test while results are being downloaded.



- 1 Read the operating instructions supplied with the software and hardware you are using. There you will find all the information needed for downloading data.
- 2 Prepare the receiving end (software product or hardware) for downloading the test results.
- 3 With the meter turned off, press and hold the M button (for more than 3 seconds) until **PC** flashes in the display.



- 4 Place the meter approx. 5-20 cm away from the infrared port of the receiving end. Position the two infrared ports so that they are facing towards one another.
- 5 If necessary, start the test result download at the receiving end (software product or hardware).



The meter automatically downloads all of the results from its memory. While the data is downloaded, PC does not flash.



End

If the meter was not turned off automatically by the receiving end when the download was completed, **End** is displayed.

6 Press the M button briefly to turn the meter off.



If downloading is unsuccessful

If the results are not downloaded (PC is still flashing in the display), the meter turns off automatically after approx. 90 seconds. There can be different reasons for a failed download. Eliminate the cause and start the download again.

- The infrared ports are too far apart or not properly facing one another.
Reduce the distance between the two infrared ports to 5-20 cm and position them so they are facing one another.
- Another device with an infrared source turned on or a strong light source is too close to one of the infrared ports.
Remove the device or light source.
- Communication between the two infrared ports is blocked, e.g. by an object.
Remove the object.
- The infrared port is dirty.
Clean the port (see Chapter 8).
- The infrared port is defective.
Please contact your customer support and service centre.
- A download error or an error at the receiving end has occurred.
Try again.

7 Checking your meter

You can check whether the meter provides correct results. To perform this performance check, a glucose control solution is applied to the test strip instead of blood.

Also read the instructions in Chapter 5.5.

Perform a performance check using Accu-Chek Active control solutions,

- whenever you open a new pack of test strips,
- after you change the battery,
- after you clean the test strip guide and the measuring window,
- if you are in doubt about a test result.

Please ask your customer support and service centre where you can obtain the control solutions.

7.1 Preparing for a performance check



For a performance check, you need:

- the meter with the code chip inserted
- the Accu-Chek Active test strips that belong to the code chip
- Accu-Chek Active control solution Control 1 (low glucose concentration) or Control 2 (high glucose concentration)
- the concentration table for the control solutions (see label on the test strip container)

A performance check is in its main steps the same as a normal test, except that you apply control solution to the test strip instead of blood.

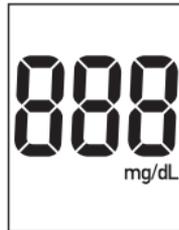
7.2 Carrying out a performance check



- 1 Read the package insert which came with the control solutions.
- 2 Take a test strip from the test strip container and close it again immediately.
- 3 Hold the test strip so that the arrows printed on it and the orange square face upwards.
- 4 Without bending it, gently push the test strip into the test strip guide in the direction of the arrows until you feel it lock into place.



mmol/L meter



mg/dL meter



The meter turns on and first performs a default display check (approx. 2 seconds).

- 5 Check that all the segments of the numeric display **888** (mmol/L meter) or **888** (mg/dL meter) are displayed.

If segments are missing, please contact your customer support and service centre (see Chapter 17).

Following the display check, the code number is displayed (689 is just an example).



- 6 Check that this code number is the same as the code number on the label of the test strip container.

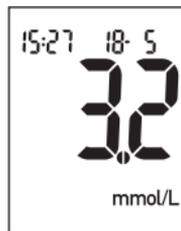
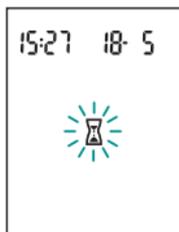
If the numbers do not match, even though the code chip in the meter belongs to the test strip container, please contact your customer support and service centre.



Following the code number, the test strip symbol and the flashing blood drop symbol appear in the display. Now you have approx. 90 seconds to apply control solution to the test strip. After this time, the meter turns itself off.

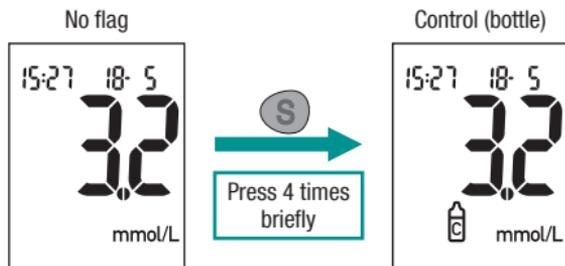


- 7 Open a bottle of control solution.
- 8 Wipe the tip of the dropper with a clean, dry paper towel to remove any dried-on residues.
- 9 Invert the bottle and hold it downwards at an angle. Squeeze it gently until a small drop which is free of any air bubbles is suspended from the tip.
- 10 Apply **one** drop to the centre of the orange field without touching it with the tip of the dropper. The field must be completely covered with solution.



The flashing hourglass symbol  indicates that the test is in progress. The test is complete after approx. 5 seconds and the result appears on the display. The meter automatically saves the result.

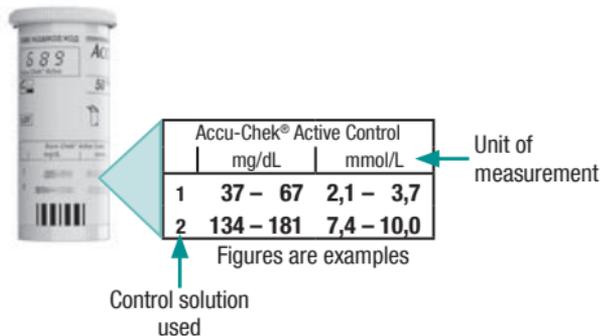
To distinguish this performance check from blood glucose test results at a later date, you need to flag it as a performance check.



While the test result is displayed:

11 Press the S button briefly 4 times.

The  symbol for control is displayed (see also Chapter 5, “Flagging test results” section).



After flagging the result as a performance check:

12 Compare the test result with the concentration table on the label attached to the test strip container.

The result must be within the specified concentration range.

Make sure that you compare the test result with the concentration data that corresponds to the relevant control solution used (1 or 2) and to the unit of measurement displayed by the meter (mmol/L or mg/dL).



13 Then remove the test strip from the meter.

The meter turns itself off.

You can dispose of used test strips in your household waste.

7.3 Possible sources of error during performance checks

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

If your responses to the questions below are different from those given, make the respective corrections when you perform the next test. If you have taken all of these points into account and the results are still outside the specified concentration range, contact your customer support and service centre.



If a performance check produces results that are outside the specified concentration range, it is no longer certain that the meter and test strips are functioning properly. Blood glucose tests may then produce incorrect results. Incorrect results can cause the wrong therapy recommendation to be made and so lead to serious adverse health effects.

Did you take the test strip from the container which the code chip in the meter belongs to?	yes
Did you perform the performance check according to the instructions for use?	yes
Did you bend the test strip while inserting it into the meter?	no
Did you use a used test strip?	no
Did you wipe the tip of the dropper before you applied control solution to the test strip?	yes

Did you apply a suspended drop of control solution?	yes
Did you apply only one drop of control solution?	yes
Were there air bubbles in the drop?	no
Did you wait for the drop symbol to flash in the display before applying control solution?	yes
Was the orange field completely covered with control solution?	yes
Did you bend or move the test strip before or during the test?	no
Did you measure within the correct temperature range (10–40 °C)?	yes

Did you compare the test result with the concentration range that corresponds to the control solution you used?	yes	Did you observe the proper storage conditions for the meter, the test strips and the control solution (see Chapter 11 and the package inserts)?	yes
Is the concentration table on the test strip container from which you removed the test strip?	yes	Has the expiry date of the test strips or the control solution elapsed see the label on the test strip container (next to the   symbol and the label on the bottle next to the  symbol and eventually the exp symbol on the display of the meter)?	no
Is the test strip guide and measuring window clean?	yes		
Has the control solution been open for less than 3 months? Once opened, control solutions are stable for only 3 months and must not be used after this period.	yes	If your meter has been dropped, it can also lead to implausible results or error messages. In this case also contact your customer support and service centre.	
Have you read the section “Treating the control solutions properly” in the package insert for the control solution?	yes		

8 Cleaning the meter

You may need to clean the meter if it becomes dirty through improper use.



Healthcare professionals using the meter to test several patients' blood glucose must also read the instructions on disinfection in Chapter 10.2.



Use **only** cold water or 70 % ethanol to clean the meter. Any other cleaning agents may damage the meter or impair its measuring function.

Use a lightly moistened cloth or a lightly moistened cotton swab. Do not spray anything onto the meter and do not immerse it in the cleaning liquid. Internal components could become damaged and thus impair the proper functioning of the meter.

8.1 External parts

If the case of the meter or the display is dirty:

- 1 Wipe away any dirt using a cloth lightly moistened with cold water or 70 % ethanol.

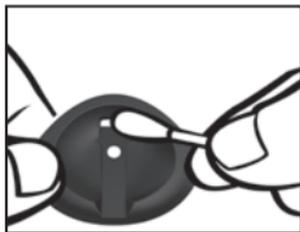
8.2 Test strip guide and measuring window

You only need to clean the test strip guide and measuring window

- if you notice that the test strip guide or the measuring window located beneath the cover are visibly dirty,
- if the error message E-4 or E-5 is displayed. A dirty measuring window may be the cause.



- 1** Pull the cover of the measuring window straight towards you.



- 2** Wipe the cover and the test strip guide from the outside and the inside using a lightly moistened cloth or cotton swab.



3 Carefully wipe the measuring window and its surrounding area using a lightly moistened cloth or a cotton swab.



Make sure that no liquid enters the meter. Avoid scratching the measuring window, as doing so could impair its measuring function.

4 Remove any fluff or lint that may remain.

5 Allow areas you have wiped time to dry thoroughly.



6 Place the cover straight and centred onto the meter.

7 Slide it closed until it audibly clicks into place.

In doing so, the guides on the inside of the cover and on the meter must be perfectly aligned.

8 Carry out a performance check (see Chapter 7).

9 Changing the battery

When the battery symbol  appears in the display for the first time, the battery is almost empty. You can perform approximately 50 more tests with the battery. We recommend that you replace the battery as soon as possible. By then it will have lost a lot of power and changeable conditions (e.g. a cold environment) can affect its performance even further.

You need 1 battery of the type CR 2032.

With a new battery you can perform approx. 1000 tests or test for approx. one year.

When you change the battery, your results always remain saved. Time and date only remain saved as long as

- you change the battery within one minute,
- you do not press any button while the battery is removed,
- you do not insert a test strip in the test strip guide without the battery inserted,
- you insert the battery the right way up, i.e. with the  symbol facing upwards.

If any of the four conditions stated above is not met, you will need to re-enter the time and date. For information on how to re-enter the time and date see Chapter 3.



The battery compartment is located on the back of the meter.

1 Push the locking catch downwards and remove the battery compartment cover.

2 Remove the used battery.



3 Place the new battery in the compartment, with the + symbol facing upwards.



4 Re-attach the battery compartment cover so the two prongs on its lower edge engage with the slots in the battery compartment.



5 Press the cover closed. It will **CLICK** into place audibly.



Never throw batteries into a fire. They may explode.



Dispose of used batteries in an environmentally friendly way at a collection depot or through your dealer.



Remove the battery if you will not be using the meter for a longer period of time.

10 Testing blood glucose in more than one patient – Information for healthcare professionals

Only staff working in doctors' practices, hospitals and diabetes training centres, and nurses are allowed to perform blood glucose tests on more than one patient using the same Accu-Chek Active meter.

When using the meter always follow the recognised procedures for handling objects that are potentially contaminated with human material. Practise the health and safety policy of your laboratory or institution.

Please also follow the instructions on the following pages to prevent the meter becoming contaminated.



Any patient with an infection or suffering from an infectious disease and any patient who is a carrier of a multi-resistant micro-organism must be assigned his/her own meter. This also applies if it is suspected that a patient has one of the above. During this time the meter must not be used to test any other patient.



Patients and medical staff are potentially at risk of becoming infected if the same Accu-Chek Active meter is used to test blood glucose in several patients. All objects that come into contact with human blood are potential sources of infection (see: Clinical and Laboratory Standards Institute: Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline – Third Edition; CLSI document M29-A3, 2005).



Residues of water or disinfectant on the skin can dilute the drop of blood and so produce incorrect results.



Dispose of used lancets or disposable lancing devices and used test strips according to the health and safety policy of your laboratory or institution.

10.1 Testing blood glucose

- 1 Wear protective gloves.
- 2 The patient's hands should be washed with warm water and soap and then dried well. If you are using alcohol wipes, the finger must also be completely dry. On dry skin the drop of blood cannot spread so easily.
- 3 Use only lancing devices approved for use by healthcare professionals.
- 4 Use a lancing device with adjustable penetration depth settings.
- 5 Select a penetration depth to suit the nature of the patient's skin. Start with a shallow depth setting.
- 6 Select a puncture site along the side of a fingertip.
- 7 Turn the finger so that the chosen puncture site is facing upwards, and keep it facing upwards. Then the drop of blood cannot spread so easily later.
- 8 Prick the side of the fingertip.

- 9** Encourage a drop of blood to form by gently massaging the finger towards the fingertip. A proper drop of blood must form.
- 10** Apply the drop of blood to the test strip.
We recommend that you apply the blood to the test strip while it is outside the meter (see Chapter 5.2, section “Applying blood with the test strip outside the meter”).

10.2 Disinfecting the meter

The following parts of the meter may become contaminated:

- the case
- the measuring window cover
- the measuring window

The meter, the cover of the measuring window and the measuring window itself must be thoroughly cleaned and disinfected at least once a day after use. Remember to also clean recesses, grooves and gaps.

Cotton swabs, wipes and cloths lightly moistened with disinfectant are all suitable for disinfecting the meter.

Use a mixture of 1-propanol, 2-propanol and glutaraldehyde, known in some countries under the brand Bacillol plus.

Allow areas you have wiped time to dry thoroughly.



Make sure that no liquid enters the meter.



Do not spray anything onto the meter and do not immerse it in liquid. Internal components could become damaged and thus impair the proper functioning of the meter.

11 Measurement and storage conditions

So that the meter works reliably and you obtain accurate results, make sure that the conditions listed on the following pages are met.

11.1 Temperature

- For blood glucose tests and performance checks the temperature must be between +10 and +40 °C.
- If the temperature is at the limits of the permitted range (between +5 and +10 °C or between +40 and +45 °C), you can still perform a test. The

thermometer symbol will, however, be displayed (see also Chapter 12.1).



Do not use results obtained at the limits of the permitted temperature range as a basis for making therapeutic decisions, as they could be incorrect. Incorrect results can cause the wrong therapy recommendation to be made and so lead to serious adverse health effects.

- Tests cannot be performed at temperatures below +5 °C and above +45 °C. In this case the following appears in the display:



Never try to speed up warming or cooling of the meter, e.g. in a refrigerator or on a radiator. The meter can be damaged and provide incorrect results. Incorrect results can cause the wrong therapy recommenda-

tion to be made and so lead to serious adverse health effects.

- Keep the meter **without** battery at a temperature between -25 and +70 °C.
- Keep the meter **with** battery at a temperature between -10 and +50 °C.



At temperatures above +50 °C the battery could leak and damage the meter.



At temperatures below -10 °C the battery does not have enough power to keep the internal clock functioning.

11.2 Atmospheric humidity

Only test blood glucose when atmospheric humidity is below 85 %.

Keep the meter below 93 % atmospheric humidity.

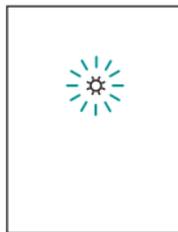


Sudden changes in temperature cause condensation to form in or on the meter. If this has occurred, do not turn the meter on. Allow the meter to slowly cool down or warm up. Never keep it in a moisture-prone area (e.g. a bathroom).

11.3 Light conditions

Do not perform a test when the meter and the test strips are 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, tests cannot be performed. In this case the following appears in the display:



11.4 Sources of interference



Avoid sudden changes in light conditions while testing. The flashlight of a camera, for example, can lead to incorrect results.



Keep the meter away from very strong light sources (e.g. direct sunlight, studio lighting, etc.). These may stop the meter from functioning correctly and lead to error messages.



Strong electromagnetic fields may interfere with the proper operation of the meter. Do not use the meter in close proximity to a strong electromagnetic field.



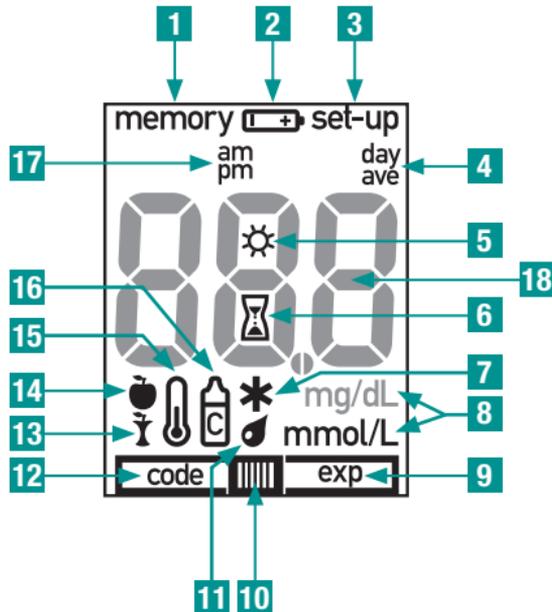
To avoid electrostatic discharge, do not use the meter in a very dry environment, especially one in which synthetic materials are present.

12 Symbols, problems and error messages

In addition to test results, time and date other symbols and error messages also appear in your meter's display. Some of the screens that you see in normal use have already been explained in previous chapters.

On the following pages you will find a complete overview of symbols and error messages, what they mean and what actions you should take. Please pay attention to all symbols and messages when you use the meter. They provide you with important information. If you do not recognise a symbol or do not understand an error message, please refer to this chapter for an explanation. Otherwise, you run the risk of misinterpreting your blood glucose results.

12.1 Symbols shown in the display



1 memory

You are in the test-result memory. Either a saved test result or an average is being displayed.

2

The battery is almost empty.

When the symbol first appears in the display, you can perform approx. 50 more tests.

When the battery is so low that no more tests can be performed, the meter turns itself off immediately.

3 set-up

You are in the settings for time and date.

4 day ave

When an average is displayed (test-result memory): the symbol is preceded by the number of days taken into account.

5 (flashing)

The meter is exposed to too much light.

6 (flashing)

A test is in progress or an average is being calculated.

7 *

General flag

8 mmol/L or mg/dL

The unit your meter uses to display the blood glucose result, either mmol/L or mg/dL.

9 exp

+
10 The test strips are past their expiry date. Change the test strips and code chip. Check the time and date settings, as the meter compares these against the expiry date encoded in the code chip.

10  (flashing)

11  (flashing)
The test strip was removed from the meter before blood or control solution was applied, for example to apply blood outside the meter.

11  (flashing)

Now you can apply blood or control solution to the test strip.

12 code
The number being displayed is the code number.

code (flashing) together with 

- The code chip has not been correctly inserted into the meter. Remove the code chip and re-insert it.

- There is no code chip in the meter. Insert the code chip belonging to the Accu-Chek Active test strips you are currently using.
-

13 

After Meals flag

14 

Before Meals flag

15 

While the test is performed the temperature is or was outside the permitted range of +10 to +40 °C.

Do not use the result as a basis for therapeutic decisions.

Ensure that the ambient temperature is between +10 and +40 °C and wait for the meter to adapt to that temperature. Repeat the test with a new test strip.



Flag for performance check



Additional time information if 12-hour time format is set.

18 Symbols appearing in the numeric field

In the numeric field **888** (mmol/L meter) or **888** (mg/dL meter) the following symbols can appear:



together with a flashing code:

- The code chip has not been correctly inserted into the meter. Remove the code chip and re-insert it.
- There is no code chip in the meter. Insert the code chip belonging to the Accu-Chek Active test strips you are currently using.

together with **memory**:

Averages cannot be calculated because

- you have not set the time and date,
- only test results without a time and date are saved,
- only test results that are not included in the calculation are saved, e.g. results from performance checks,
- no test results were saved in the period in question, e.g. all results in memory are more than 7 days old,
- the date set is in the past,

- you changed the time and date and then performed a test. Then you re-set the time and date and have not performed any more tests since.

Lo

The result is lower than 0.6 mmol/L (10 mg/dL).



Lo may indicate that your blood glucose is very low (possibly a severe hypoglycemia). Follow your doctor's instructions immediately and repeat the test.

H_i

The result is higher than 33.3 mmol/L (600 mg/dL).
Repeat the test.

◐

Decimal point: displayed by mmol/L meters and is part of the result (e.g. 8.2 mmol/L is displayed as 8.2).

000

together with **memory**:

No results have been saved.

00

together with **memory**:

The result has been lost from memory.

PC (flashing)

You have turned the meter on to download test results.

PC

The meter is downloading test results.

End

The meter has finished downloading test results.

12.2 Problems

The meter will not turn on.

- You have not removed the protective film from the battery.

Remove the film from the battery (see Chapter 2.3).

- The battery is empty or there is no battery in the meter.

Insert a new battery.

- You have inserted the battery the wrong way round.

Remove the battery and place it in the battery compartment as specified.

- The ambient temperature is low and the battery is almost empty.

Ensure that the ambient temperature is between +10 and +40 °C and wait for the meter to warm up. Insert a new battery.

- The electronics have become damp through condensation.

Allow the meter to dry slowly.

- The meter is defective.

Please contact your customer support and service centre.

The meter is turned on, but the display is blank.

The display is defective.

Please contact your customer support and service centre.

The clock has stopped or the clock is slow.

The meter was exposed to a temperature below $-10\text{ }^{\circ}\text{C}$ and the battery is beginning to freeze.

Turn the meter off. Ensure that the ambient temperature is between $+10$ and $+40\text{ }^{\circ}\text{C}$ and wait for the meter to adapt to that temperature.

The time is shown as 0:00 or 0:00am and the date as 0- 0.

- The meter was exposed to a temperature below $-10\text{ }^{\circ}\text{C}$ and the battery is beginning to freeze.

Turn the meter off. Ensure that the ambient temperature is between $+10$ and $+40\text{ }^{\circ}\text{C}$ and wait for the meter to adapt to that temperature.

- You have not set the time and date.

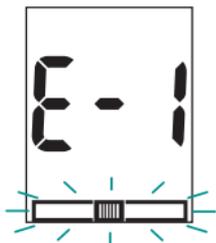
Set the time and date (see Chapter 3).

12.3 Error messages

If an error message is displayed, turn the meter off. Depending on the situation, either by briefly pressing the M or S button or by removing the test strip from the meter.

If these error messages occur frequently, contact your customer support and service centre.

If your meter has been dropped, it can also lead to error messages. In this case also contact your customer support and service centre.



- You did not insert the test strip correctly or completely. Hold the test strip so the arrows printed on it and the orange square face upwards. Without bending it, gently push the test strip into the test strip guide in the direction of the arrows until you feel it lock into place.
- You removed the test strip from the meter in order to apply blood and did not re-insert it within 20 seconds. Dispose of the test strip, even if blood has not been applied yet. Start the blood glucose test from the beginning with a new test strip.



- A code chip from another blood glucose system has been inserted into the meter. The code chip does not belong to the Accu-Chek Active test strips. Remove the code chip and insert the code chip that belongs to the Accu-Chek Active test strips you are currently using.



- The code chip cannot be read.
Remove the code chip and re-insert it into the meter. If the error message appears again, you cannot use the code chip and test strips belonging to it.
- A code chip from another blood glucose system has been inserted into the meter. The code chip does not belong to the Accu-Chek Active test strips.
Remove the code chip and insert the code chip that belongs to the Accu-Chek Active test strips you are currently using.



- Your blood glucose may be very low (possibly a severe hypoglycaemia).
If you have typical symptoms of a very low blood glucose you should follow your doctor's instructions for such cases. Repeat the test afterwards.
- The measuring window is dirty.
Clean the measuring window (see Chapter 8).
- The test strip is bent or is not positioned straight and flat in the test strip guide.
Repeat the test with a new test strip.



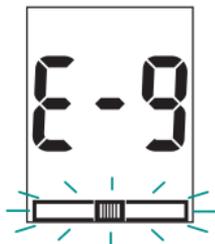
- You have inserted a used test strip into the meter.
Start again from the beginning with an unused test strip.
- The measuring window is dirty.
Clean the measuring window (see Chapter 8).
- You did not insert the test strip correctly or completely.
Hold the test strip so that the arrows printed on it and the orange square face upwards. Without bending it, gently push the test strip into the test strip guide in the direction of the arrows until you feel it lock into place.



- You applied blood or control solution to the test strip too soon, i.e. before the drop symbol flashed in the display.
Repeat the test with a new test strip.
- The test strip was bent or moved while testing was in progress.
Repeat the test with a new test strip.
- The meter was exposed to a strong electromagnetic field.
Change your position or turn off the source of radiation.



- You removed the code chip while testing was in progress.
Re-insert the code chip into the meter and repeat the test with a new test strip.

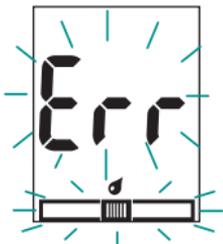


- The test strip was bent or moved while testing was in progress.
Repeat the test with a new test strip.
- You did not insert the test strip correctly or completely.
Hold the test strip so that the arrows printed on it and the orange square face upwards. Without bending it, gently push the test strip into the test strip guide in the direction of the arrows until you feel it lock into place.



A meter error has occurred.

Start again from the beginning. If the error message appears again, the meter is defective. Please contact your customer support and service centre.



You applied too little blood or control solution to the test strip.

Repeat the test with a new test strip and a larger amount of blood or control solution.



The ambient temperature or the temperature of the meter is too low or too high for a test.

Ensure that the ambient temperature is between +10 and +40 °C and wait for the meter to adapt to that temperature.

13 Technical data

Meter type	Accu-Chek Active (Model GC)
Catalogue no./Serial no.	See type plate on the back of the meter
Test principle	<p>Determination of glucose in fresh capillary blood by reflectance photometry. If using other sample material, please refer to the package insert that came with the Accu-Chek Active test strips.</p> <p>Blood glucose concentrations may be tested in whole blood or plasma. Although you always apply whole blood to the test strip, the blood glucose results displayed by your meter correspond to those in plasma. You will find information on how the system works, on the test principle and on reference methods in the Accu-Chek Active test strip package insert.</p>

Measuring range	0.6–33.3 mmol/L (10–600 mg/dL)
Sample size	1–2 μL (1 μL (microlitre) = 1 thousandth of a millilitre)
Measuring time	approx. 5 seconds if the test strip is in the meter when blood is applied (depends on concentration) approx. 10 seconds if the test strip is outside the meter when blood is applied (depends on concentration)
Power supply	1 battery (type CR 2032)
Battery life	approx. 1000 tests or approx. 1 year
Automatic power-off	after 30 or 90 seconds depending on operating status
Memory	350 test results with time and date, as well as 7, 14 and 30 day averages

Temperature

during testing	+10 to +40 °C
during storage	
without battery	-25 to +70 °C
with battery	-10 to +50 °C

Atmospheric humidity

during testing	up to 85 % relative humidity
during storage	up to 93 % relative humidity

Altitude	sea level to 4000 m
-----------------	---------------------

Dimensions	104.5 × 51.5 × 22 mm
-------------------	----------------------

Weight

without battery	approx. 55 g
with battery	approx. 60 g

Display	96-segment liquid crystal display (LCD)
Interface	infrared port
Safety class	III
LED/IRED	Class 1
Electromagnetic compatibility	<p>This meter meets the electromagnetic immunity requirements as per ISO 15197 Annex A. The chosen basis for electrostatic discharge immunity testing was basic standard IEC 61000-4-2.</p> <p>In addition, it meets the electromagnetic emissions requirements as per EN 61326. Its electromagnetic emission is thus low. Interference on other electrically driven equipment is not anticipated.</p>

Performance analysis

The performance data for the Accu-Chek Active system (Accu-Chek Active meter with Accu-Chek Active test strips) was obtained using capillary blood from diabetic patients (method comparison, accuracy), venous blood (repeatability) and control solution (reproducibility). The system is calibrated with venous blood containing various glucose concentrations. The reference values for this were obtained using the hexokinase method. This reference method is traceable to a NIST standard by means of the ID-GCMS method, the method with the highest metrological quality. For method comparison, the results were compared with results obtained using the hexokinase method with deproteinization (automatic analyser).

The Accu-Chek Active system meets the ISO 15197 requirements.

14 Disposing of your meter

During blood glucose testing the meter itself may come into contact with blood. Used meters therefore carry a risk of infection. After having removed the battery, please dispose of your used meter according to the regulations applicable in your country. For information about correct disposal, please contact your local council or authority.

The meter falls outside the scope of the European Directive 2002/96/EC (Directive on waste electrical and electronic equipment).



Dispose of used batteries in an environmentally friendly way at a collection depot or through your dealer.

15 System components

The Accu-Chek Active blood glucose monitoring system comprises the following components in addition to the meter:

- **Accu-Chek Active test strips**
Use only these test strips when you test blood glucose using the Accu-Chek Active meter.
- **Accu-Chek Active control solutions**
Use only these control solutions when you carry out performance checks using the Accu-Chek Active meter and the respective test strips.

16 Customer support and service

16.1 Information service and troubleshooting

For questions on how to operate your Accu-Chek Active meter, or regarding implausible results, or if you suspect the meter to be defective, please contact your customer support and service centre. Do not attempt to repair or modify the meter yourself. Our staff will help you solve any problems you might be experiencing with the meter or test strips from Roche Diagnostics. For the customer support and service addresses, see the next section.

16.2 Addresses

Roche Diagnostics Australia Pty Ltd.
31 Victoria Avenue, Castle Hill,
NSW 2154, **Australia**
ABN 29 003 001 205
Accu-Chek Enquiry Line: 1 800 251 816
www.accu-chek.com.au

17 Alphabetical index

A

- Alternative sites 40
- Apple (symbol) 40, 103
- Apple core (symbol) 40, 103
- Asterisk (symbol) 40, 102
- Atmospheric humidity 98, 118
- ave (symbol) 60, 102
- Averages 58

B

- Battery
 - changing 87
 - life 87, 117
 - removing protective film 18
 - symbol 45, 87, 101
 - type 13, 87, 117
- Battery compartment 13, 88

Blood

- applying to test strip
 - with test strip inside the meter 34
 - with test strip outside the meter 36
 - too little applied 114
 - volume 14, 117
- Bottle (symbol) 40, 76, 104

C

- Causes of error
 - downloading of results 69
 - performance check 79
 - test 51
- Checking, meter 70
- Cleaning 82
- code (symbol) 103, 104
- Code chip 12, 28

Code number 29, 32
Coding 28
Concentration table 71, 77
Control solution 70
 stability 81
Control window, test strips 43
Customer support and service 123

D

Data downloads 15, 64
Date setting 26
day (symbol) 60, 102
Disinfection 95
Display 12
 example 6
 symbols in the ~ 101
Display check 20, 32

Disposal
 battery 90, 121
 meter 121
 test strips 39, 78
Downloading, results 64
 causes of error 69
Drop (symbol) 33, 103

E

E and number (display) 110
EEE (display) 114
Electromagnetic compatibility 119
End (display) 68
Error messages 100, 109
exp (symbol) 46, 52, 102
Expiry date
 control solution 81
 test strips 52, 81

F

Flagging, result 40

H

Healthcare professionals 3, 91

Hi (display) 45, 50, 106

Hourglass (symbol) 35, 102

I

Infection risk 91, 92

Infrared port 12, 64

Intended use 3

L

Light conditions 98

Lo (display) 45, 50, 105

M

M button 12

Measurement conditions 96

Measuring range 50, 117

Measuring time 35, 38, 117

Measuring window 12

cleaning 83, 85

Memory 53

memory (symbol) 54, 101, 105

Memory, results 53

Meter

checking 70

cleaning 83

disinfecting 95

disposal of 121

overview 12

storage 96

turning off 23, 39, 56

turning on 22, 31, 54, 66

mg/dL (symbol) 102
mmol/L (symbol) 102

O

Overview
 meter 12
 symbols 101

P

PC (display) 66, 106
Performance analysis 120
Performance check
 causes of error 79
 flagging 76
 procedure 70
Problems 107

R

Result
 averages 58
 downloading 64
 flagging 40
 retrieving from memory 54

S

S button 12
Settings (date and time) 21
 changing, overview 22
 date 26
 factory defaults 21
 order 21
 time 25
 time and date format 24
 year 26

set-up (symbol) 22, 102
Sources of electromagnetic interference 99
Sources of interference
 electromagnetic ~ 99
 light 98
Storage conditions 96
Sun (symbol) 98, 102
Symbols 101
 during testing 45
System components 122

T

Technical data 116
Temperature 96, 118
Testing
 causes of error 51
 healthcare professionals 93
 procedure 30

Test principle 116
Test strip guide 12
 cleaning 83, 84
Test strips
 disposal of 39, 78
 expiry date 52, 81
 symbol 33, 36, 102, 103
Thermometer (symbol) 45, 103
Time and date format setting 24
Time setting 25
ttt (display) 97, 115
Turning off
 after testing 39, 78
 automatic ~ 34, 39, 69
 closing settings 23, 27
 exiting memory 56

Turning on

changing settings 22

downloading results 66

retrieving results 54

testing 31

Type plate 13, 17

UUnit of measurement for results (mmol/L, mg/dL)
17, 102**Y**

Year setting 26

