ACCU-CHEK® Mobile

Accu-Chek® Mobile

BLOOD GLUCOSE MONITORING SYSTEM

User's Manual

ACCU-CHEK®

This User's Manual features three types of warning:

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

This symbol draws attention to actions that could result in **damage to the meter, the test cassette or the lancing device.**

This symbol draws your attention to important information.

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.

Last update: 2011-11

Intended use

Accu-Chek Mobile blood glucose meter

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

Suitable for self-testing only.

- **The meter may only be used for blood glucose testing by one person.**
  There is a risk of infections being transmitted if the meter is used by other people, or if healthcare professionals use the same meter for testing blood glucose in more than one person. This meter is therefore not suitable for professional use in healthcare facilities or institutions.
- Visually impaired people should not test their blood glucose without assistance from a sighted person.

Accu-Chek FastClix lancing device and AST cap

Lancing device with adjustable penetration depth setting for obtaining capillary blood from a fingertip with Accu-Chek FastClix lancet drums and, when a special AST cap is used, also from alternate sites such as the ball of the thumb.

The lancing device and the AST cap are is intended for personal use only!
They may only be used by one person for obtaining blood. There is a risk of infections being transmitted if the lancing device or the AST cap is used by other people, or if healthcare professionals use this lancing device or the AST cap to obtain blood from more than one person. This lancing device and this AST cap are therefore not suitable for professional use in healthcare facilities or institutions.

Contents

The major features

- **Test cassette instead of test strips**
  50 test areas on a continuous tape
- **Easy testing**
  Test starts by opening the tip cover
- **Short measuring time**
  About 5 seconds for a test, depending on the blood glucose concentration
- **Docked lancing device**
  Use the lancing device in its docked or undocked state
- **Lancing device with lancet supply**
  6 sterile lancets in a lancet drum
- **No coding**
  Meter is automatically coded
- **Blood volume checking**
  Meter detects the amount of blood that is necessary
- **Luminous display**
  Yellow display on black background
- **Text-supported operation**
  Meter takes you through all operation steps
- **Menu-driven operation**
  Menu-driven settings and functions
- **Reminder**
  A total of 11 reminders
- **Target range for test results**
  Personal target range for blood glucose test results
- **Flagging of results**
  Flagging results with symbols
- **Memory**
  2000 memory locations available
- **Data analysis on the PC**
  Display and analysis of data on the PC
- **Data transfer**
  USB port for data transfer

About this User's Manual

Please read this User's Manual 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 page 128).

These instructions for use provide you with the information you need to operate and care for your meter and lancing device, and to deal with errors that might occur. Please be sure to operate the meter and the lancing device correctly as well as to observe the operating instructions.

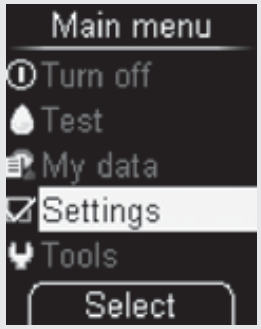
Please note:
All dates, times or results displayed in this User's Manual are intended only as examples.
Results are displayed in the unit *mmol/L*, data in the format *Day.Month.Year* and times in the *24-hour format*.

You can only hear the beep tones of the meter when they are turned on and the volume is not set to level 1 (*Mute*). This User's Manual presumes that the beep tones are turned on.

All instructions appear in a grey frame as shown below. Sometimes they are combined with pictures.

1 Place your finger on the corrugated area on the tip cover and push it in the direction of the arrow as far as it will go.

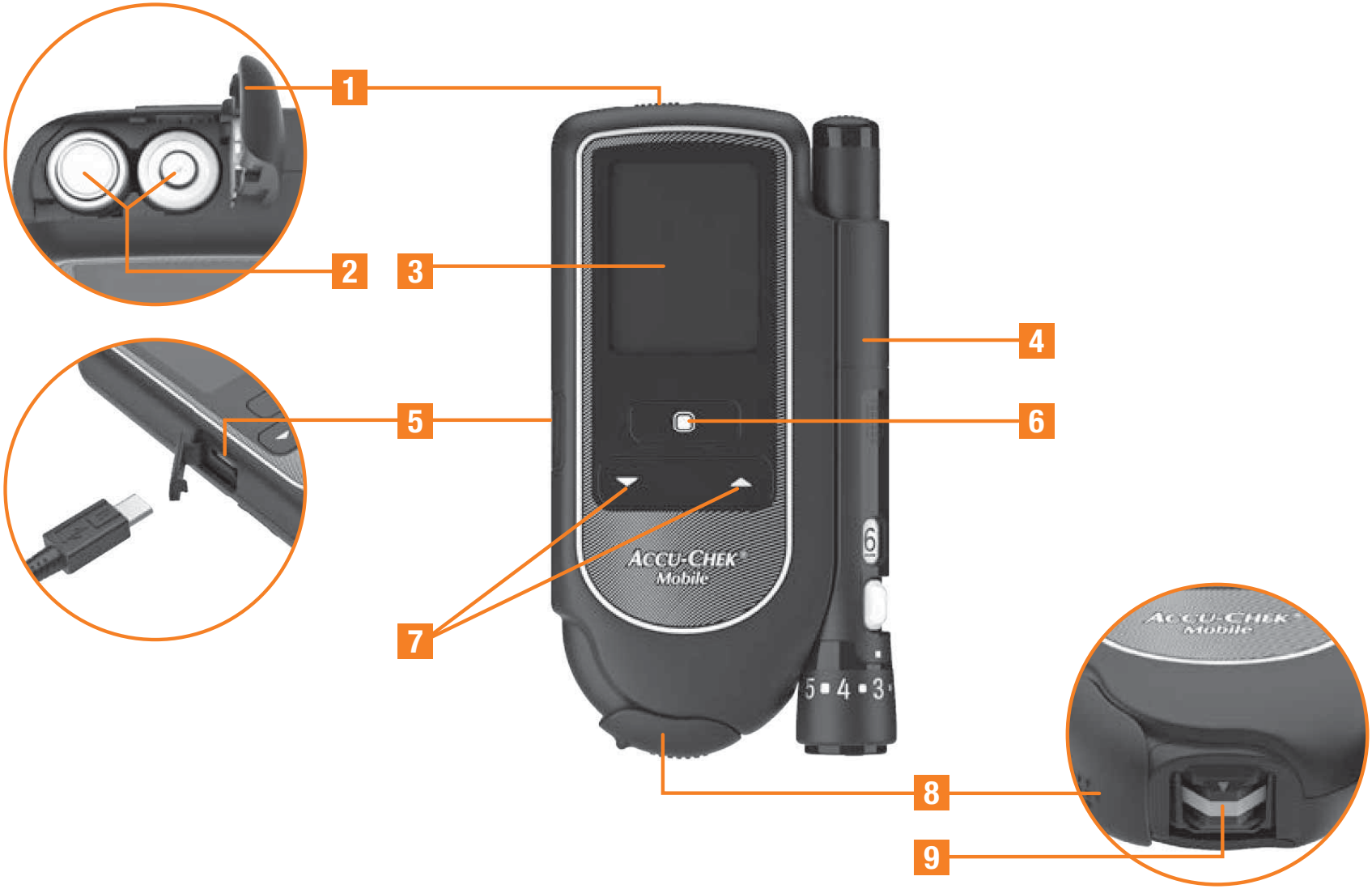
Instructions to open the menus (➪*menu name)* presume that the meter is turned on and the main menu is open. Example:



1 Open ➪*Settings*.

1 Getting to know your meter and lancing device

1.1 Your meter at a glance



1 Battery compartment cover (left: from above, open)

2 Batteries [1.5 V, type AAA, alkaline-manganese or high energy batteries (2 batteries required)] or NiMH batteries (type AAA)

3 Display

4 Lancing device (docked)

5 USB port – interface to be used for data evaluation on a computer (left: open USB port compartment)

6 Power and Enter button

7 Down/Up buttons

8 Tip cover (bottom right: open)

9 Test area (at the tip of the cassette ready for a test) – this is where you apply the blood

10 Slide button to release the lancing device

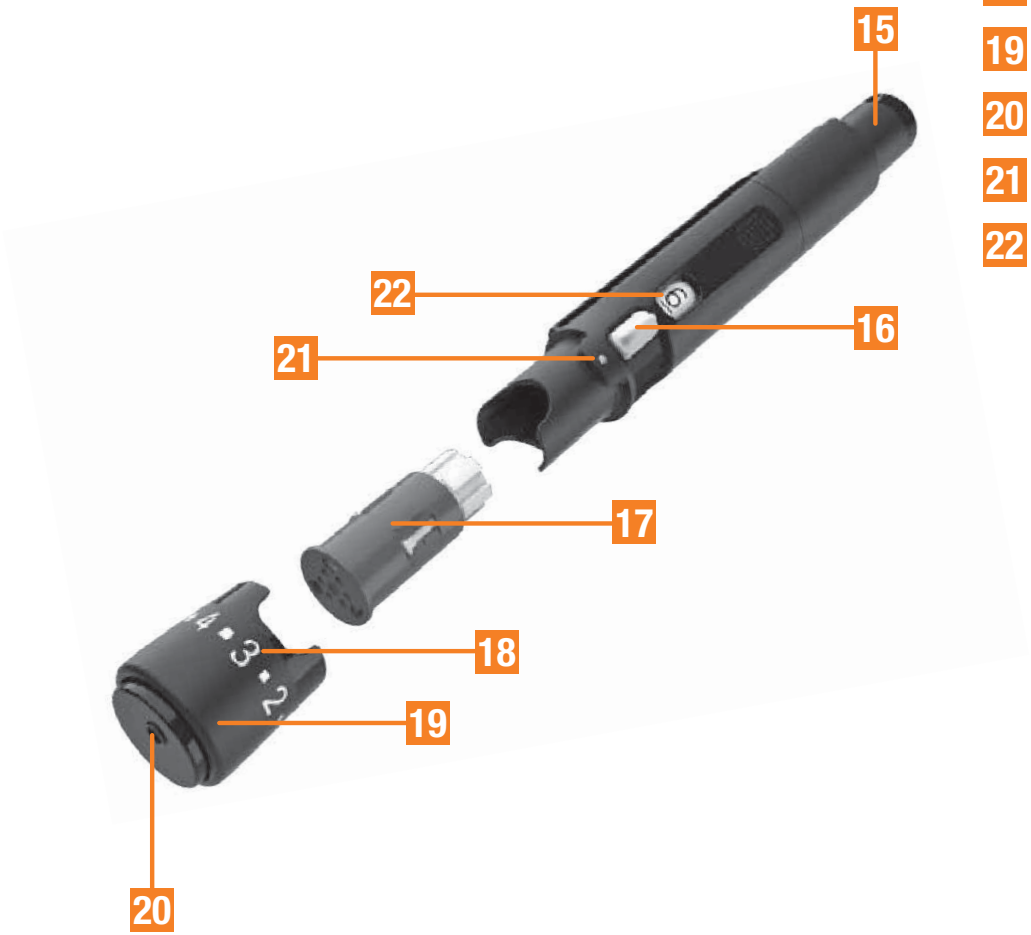
11 Type plate

12 Slide button to open the cassette compartment cover

13 Cassette compartment cover (right: open)

14 Test cassette (in place in the meter)

1.2 Overview of the lancing device



15 Release button (priming and pricking)
16 Lever for loading a new lancet
17 Lancet drum containing 6 lancets
18 Number values for penetration depth (11 settings)
19 Rotatable cap for setting the penetration depth
20 Pin-hole opening for lancet
21 Penetration depth indicator
22 Window showing number of available lancets

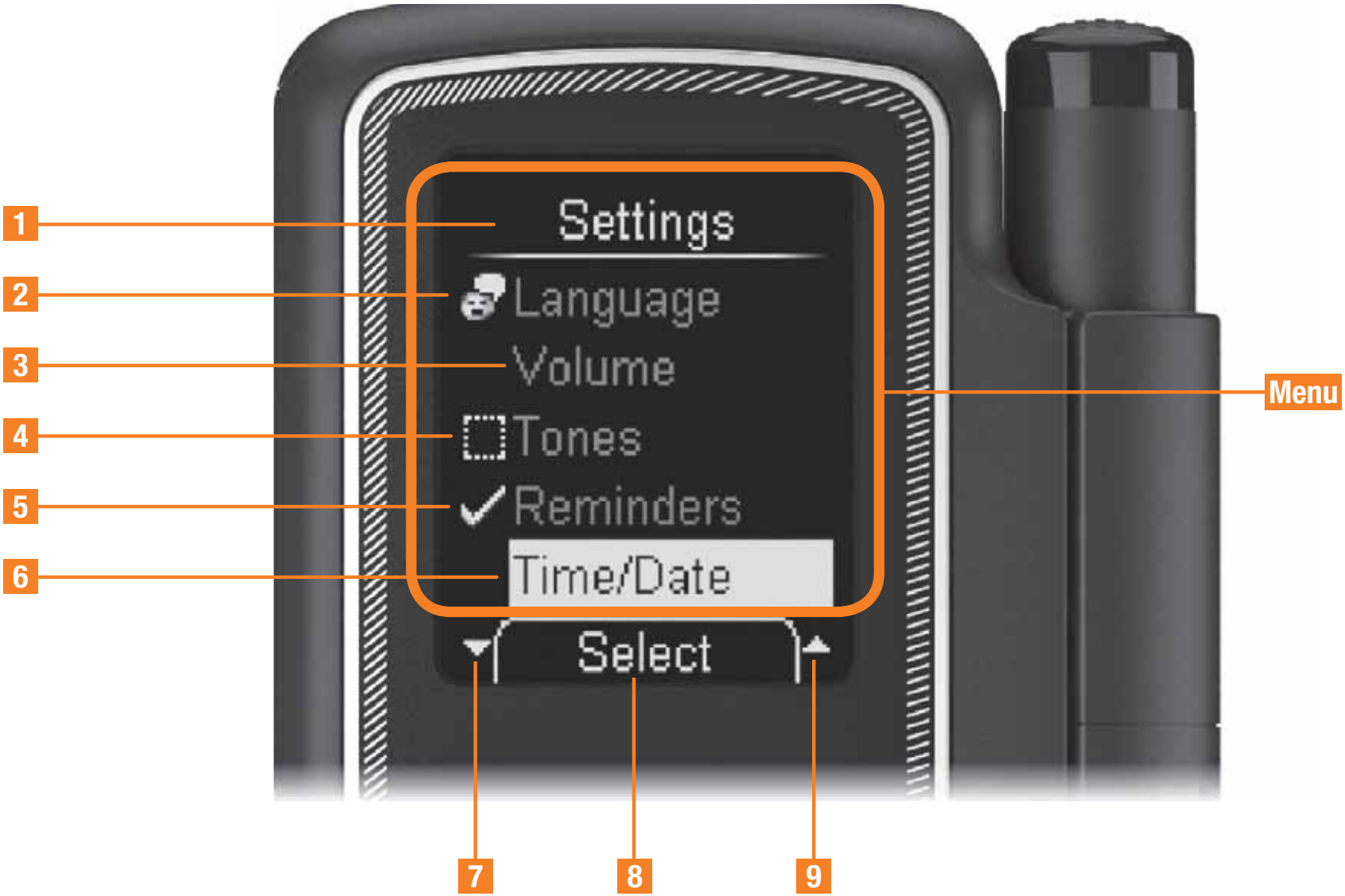
1.3 Using the buttons and navigating through the menus

This chapter tells you how to use the buttons to operate the meter and navigate through the menus, how the menus are arranged and what the different symbols in them mean.

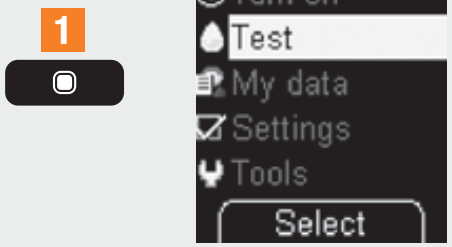
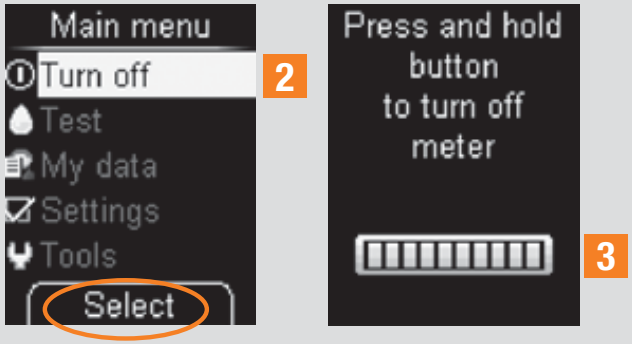
Meter buttons

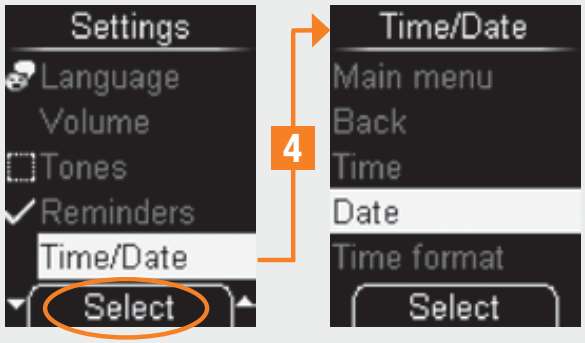
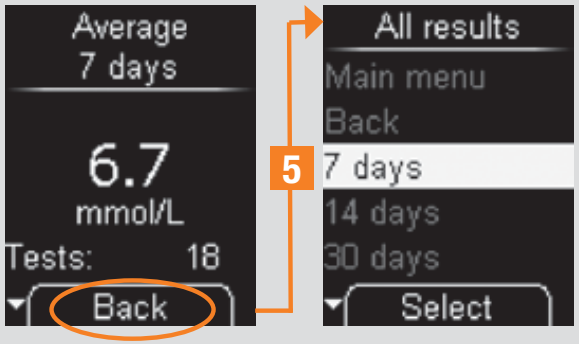
Button	Name	Symbol	Function
	Power button, Enter button	▣	This button allows you to: ■ Turn the meter on or off; to do so, press and **hold** the button (for approx. 2 seconds) ■ Execute the command displayed above the button (press the button **briefly**) Example: The Select command selects the item highlighted in the menu.
	Down button	▼	1 This button allows you to: ■ Navigate down in a menu or list ■ Decrease number values
	Up button	▲	2 This button allows you to: ■ Navigate up in a menu or list ■ Increase number values

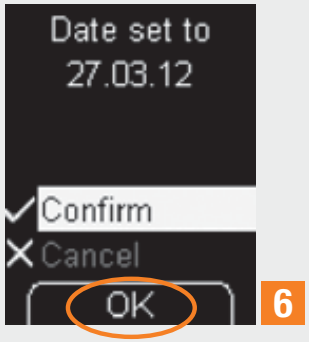
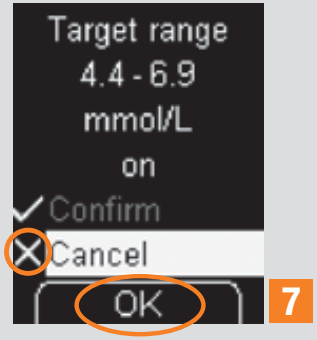
Menu structure of the meter

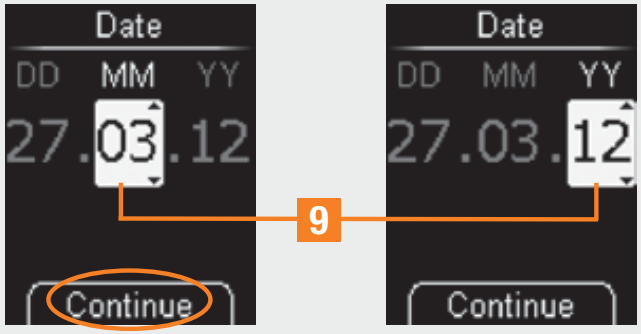


Key	Display	Explanation
1	Title	Title of the display or menu (e.g. *Settings*)
2		The items of the main menu and the *Language* item of the *Settings* menu have a symbol on their left-hand side.
3	Item	Unselected item of the menu.
4		The symbol indicates that the function (e.g. *Tones*) is deactivated.
5		The symbol indicates that the function (e.g. *Reminder*) is on.
6	Selected item	A selected item is highlighted with a yellow bar. If you press the ◉ button, this item will be selected (*Select* command).
7		The symbol means that there are further items below the last item visible on the display.
8		The command displayed here (e.g. Select) will be executed if you press the ◉ button. The command that is shown depends on the current display.
9		The symbol means that there are further items above the first item visible on the display.

Example	Operation
	**Turning the meter on** **1** Pressing the button ◙ (for approx. 2 seconds) turns the meter on. After the display check, the meter first displays the number of tests still available on the test cassette and then opens the main menu.
	**Turning the meter off** **2** *Select* selects the highlighted *Turn off* command (symbol ⏻) (press the ◙ button **briefly**). The meter turns off after displaying the number of the tests still available. or **3** Pressing the ◙ button until all bars in the display are filled (approx. 2 seconds) turns the meter off.

Example	Operation
	**Opening the menu** **4** *Select* (press the ◉ button), selects the highlighted *Time/Date* item from the *Settings* menu. The lower-level *Time/Date* menu opens.
	**Returning to a higher-level menu** **5** *Back* (press the ◉ button) opens the higher-level menu of the currently displayed menu.

Example	Operation
	**Confirming settings or operations** **6** *OK* (press the ◉ button) confirms the setting you made. (✓) *Confirm* is highlighted.
 	**Cancelling settings or operations** **7** *OK* (press the ◉ button) cancels the setting you made. (✕) *Cancel* is highlighted. **8** *Cancel* (press the ◉ button) cancels the operation (data transfer).

Example	Operation
	**Navigating between input fields** **9** *Continue* (press the ◉ button) switches from month to year.
	**Changing numbers** **10** Pressing the ▲ button increases the number value. Pressing the ▼ button decreases the number value. If you press the button once, the number increases by 1. If you hold the button down, the number continues to increase until you release the button.

Example	Operation
 11  12	**Activating or de-activating functions** 11 A tick ✓ in front of an item means that the function is activated. 12 A checkbox ☐ in front of an item means that the function is deactivated. *Select* (press the ◉ button) sets (= on) or removes (= off) the tick.

2 Initial steps before testing

2.1 Checking the unit of measurement

Blood glucose results can be 1 displayed in two different units (mg/dL or mmol/L). Consequently, two different versions of the same meter are sold. Check that your meter displays the unit of measurement you are accustomed to. 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 of measurement for you, ask your healthcare professional.

The unit of measurement that your meter displays cannot be changed. If the wrong unit is printed on the type plate, ask your dealer to change the meter or contact your customer support and service centre. An incorrect unit of measurement can cause the test results to be misinterpreted and the wrong therapy recommendation to be made and thus result in serious adverse health effects.

2.2 Inserting the first test cassette

Before using your meter for the first time, you must insert a test cassette.

Insert the very first test cassette in the meter before you remove the protective strip from the batteries and start using the meter.

- Please read the test cassette package insert. It contains important information, e.g. on storage and possible causes of incorrect test results.
- If the foil-sealed plastic container or the foil is damaged, you must not use the test cassette. Otherwise, there is a risk that you might obtain incorrect test results. Incorrect test results can cause the wrong therapy recommendation to be made and so result in serious adverse health effects.
- Only open the foil-sealed plastic container when you want to insert the test cassette into the meter. The unopened foil-sealed plastic container protects the test cassette against damage and moisture.

A table is printed on the test cassette box which shows the permitted results for control tests (checking the meter with glucose control solution). The meter automatically checks whether the result of a control test is correct. If you wish to check the control result yourself as well, you can do this with this table. Keep the test cassette box in case you need it for this purpose. Please note that the table is only valid for the test cassette that comes in this box. For test cassettes from other boxes, other tables apply.

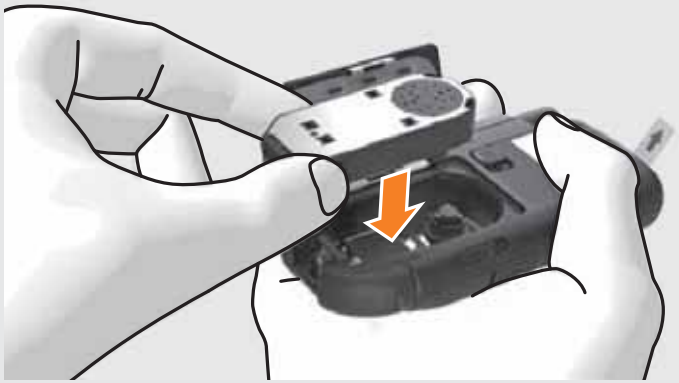
1 Push the tip cover in the direction of the arrow.

2 Turn the meter over.

3 Push the slide button in the direction of the arrow so that the cassette compartment cover springs open.

The cassette compartment cover is fully opened when it is at an angle of slightly more than ninety degrees – as shown in the illustration.

4 Remove the test cassette from the foil-sealed plastic container.



5 Insert the test cassette in the meter with the silver side facing upwards.

6 Close the cassette compartment cover.

7 Press the cassette compartment cover closed. You must hear an audible CLICK.

8 Push the tip cover in the direction of the arrow as far as it will go.

Validity of the test cassette

The validity of the test cassette depends on the use by period and the use by date.

Use by period: A period of 3 months in which the test cassette must be used up after having been inserted for the first time.

Use by date: Date up to which a test cassette stored in a closed plastic container is valid. The use by date is shown on the box of the test cassette/foil-sealed plastic container next to the symbol ⌛.

If either of the two dates – use by period or use by date – is exceeded, you will not be able to perform any more tests with this test cassette.

If you start a test and the validity of the cassette is about to expire shortly or has already expired, the meter will inform you of this.

The first notification appears 10 days before the validity of the cassette expires, the following appear 5, 2 and 1 day(s) before expiry (see page 119).

If the validity of the test cassette has expired, a message appears (see page 119).

2.3 Removing protective film and strip

The meter's battery contacts are covered with a protective strip and the display with a protective film.

Remove the protective film from the display.

Pull the protective strip of the batteries backwards out of the meter.

2.4 Setting the language

The meter automatically prompts you to set the language the first time you turn it on.

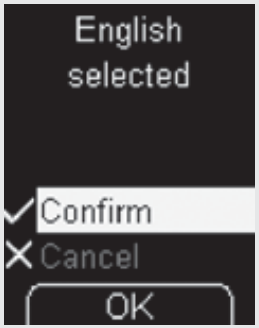
When you turn the meter on for the first time, the language selection menu is automatically displayed.

You can either select the default language or replace it with a different one.

1 Press ▼ or ▲ repeatedly until the desired language is highlighted.

2 Then press ◉ below the display to select the highlighted language.

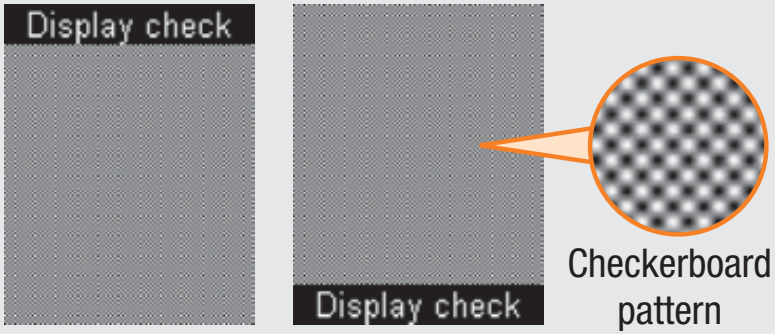
The meter will then display the language you just selected.



3 Confirm the selection with ◉ *(OK)*.

If you selected the wrong language by mistake you can change this setting later (see page 47). The Language menu is marked with the symbol . It will, however, be displayed in the language you selected until you change it.

The meter then runs a display check.

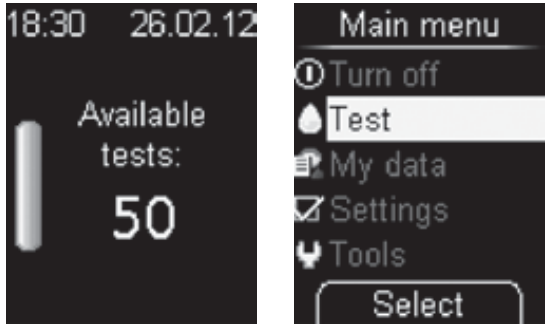


Check if there are any irregularities in the checkerboard pattern (see also *Performing a display check,* page 95).

If there are irregularities in the checkerboard pattern, results might not be displayed correctly. In this case, ask your dealer to change the meter or contact your customer support and service centre.

The meter automatically exits the display check after about 2 seconds and then displays the number of tests still available on the test cassette.

Afterwards the main menu is shown. Now you can choose what you want to do (e.g. turn the meter off, perform a blood glucose test or make settings).



3 Preparing the lancing device

You can use the lancing device to obtain blood from a fingertip. You can choose one of 11 different penetration depth settings to suit your own skin type.

You insert a lancet drum with 6 lancets into the lancing device. You can lance 6 times, using a new sterile lancet each time, before the lancet drum needs changing.

You can use the lancing device either docked on to the meter or separately from the meter.

You can also use the lancing device to obtain blood from other (alternate) sites. For this purpose, you need a special AST cap, which enables you to collect capillary blood from alternate sites.

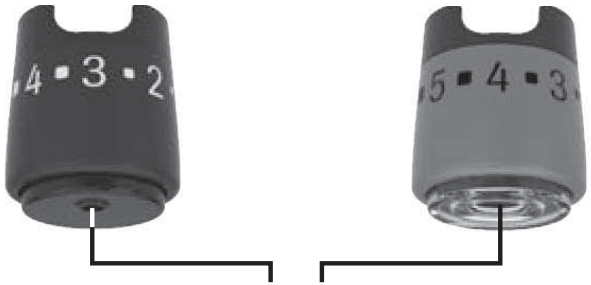
If you want to order an AST cap, please contact your customer support and service centre.

- **The lancing device and the AST cap are intended for personal use only!**
  They may only be used by one person for obtaining blood. There is a risk of infections being transmitted if the lancing device or the AST cap is used by other people, or if healthcare professionals use this lancing device or this AST cap to obtain blood from more than one person. This lancing device and this AST cap are therefore not suitable for professional use in healthcare facilities or institutions.
- Wear and tear can lead to material failure. In extreme cases a lancet can protrude from the cap so that injury cannot be completely ruled out. You should therefore handle the lancing device with particular care once a lancet drum has been inserted.

- Only use the Accu-Chek FastClix lancing device with Accu-Chek FastClix lancet drums. Using any other lancets or lancet drums may damage the lancing device or impair its function.
- A used lancet drum has a built-in locking mechanism. This mechanism prevents a lancet drum which has already been inserted in a lancing device from being reused. Used lancet drums must not be reused.

Black cap for obtaining blood from the fingertip

Grey AST cap for obtaining blood from alternate sites



3.1 Inserting a lancet drum

1 Take a new lancet drum.

2 Remove the cap from the lancing device.

3 Insert the new lancet drum – white end first – into the lancing device.

The lancet drum is properly inserted when it slots into position with an audible CLICK.

4 Place the cap back on again.

3.2 Setting the penetration depth

You can set the penetration depth of the lancet to 1 of 11 possible settings (0.5–5.5). Choosing your individual penetration depth allows pain-free collection of blood and control of the amount of blood needed.

The penetration depth indicator on the lancing device indicates the current penetration depth setting. The higher the number, the deeper the penetration depth. The half-settings are located between the numbers.

If you have no experience with using this lancing device, we recommend that you start with a medium penetration depth setting such as 3.

Rotate the cap of the lancing device until the desired penetration depth is level with the indicator.

3.3 Loading a new lancet

You do **not** need to load a new lancet if you just inserted a new lancet drum.

If you have already used the lancing device to obtain blood, you will need a new lancet the next time you obtain blood.

Push the lever at the side of the lancing device as far as it will go in direction ① and then back in direction ②.

The window on the side of the lancing device now shows one less available lancet (e.g. 5 instead of previously 6).

If 1 appears in the window, the lever will be blocked by a locking mechanism. Do not force the lever beyond this locking mechanism as this will damage the lancing device.

3.4 Replacing the lancet drum

When you have used the sixth and last lancet, you need to replace the used lancet drum with a new one.

A used lancet drum has a built-in locking mechanism. Used lancet drums must not be used again.

Used lancet drums can be disposed of in household waste.

1 Remove the rotatable cap from the lancing device.

2 Pull the lancet drum out of the lancing device.

3 Insert a new lancet drum. Place the cap back on again.

3.5 Undocking the lancing device

1 Push the slide button for the lancing device in the direction of the arrow as far as it will go.

2 Remove the lancing device by sliding it out in the direction of the arrow.

3.6 Docking the lancing device

1 Slide the lancing device along the side of the meter in the direction of the arrow until it slots into place.

When docking the lancing device, the tracks of the lancing device and the meter must fit into each other.

4 Performing a blood glucose test

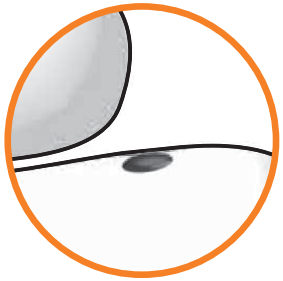
When you have inserted a lancet drum into the lancing device and set the penetration depth, you can now start to perform a blood glucose test.

> ⚠
>
> Incorrect test results can cause the wrong therapy recommendation to be made and so result in serious adverse health effects.

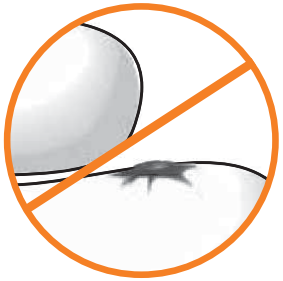
Therefore, please follow the following instructions to meticulously perform a blood glucose test:

- Wash your hands with warm water and soap. Dry your hands well before obtaining blood. This helps ensure that the puncture site is clean and stimulates blood flow.

- Create a blood drop that is large enough and well-formed. Do not apply the blood drop if it has spread.



Blood drop that is well-formed



Blood drop that has spread

- Immediately apply the blood to the test area after you have created the blood drop.
- Touch the blood drop to the test area **gently**. Do not press the test area onto the finger and do not spread the blood drop.
- Do not hold the meter with the test area pointing upwards. If you hold the meter with the test area pointing upwards, blood could enter the meter and soil it.

- Apply the blood drop **at the centre** of the cassette tip and not at the edge.

- Do not use one and the same blood drop for several tests.

Visually impaired people should not apply a blood drop without assistance from a sighted person.

When the meter prompts you to apply a blood drop, you have about 2 minutes time to apply blood to the test area. If you do not apply blood during this time, the meter will turn off and the test area will be lost.

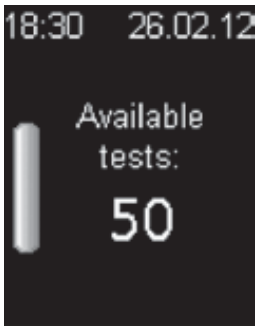
4.1 Performing a blood glucose test

Place your finger on the corrugated area on the tip cover and push it in the direction of the arrow as far as it will go.

If the meter was turned off, it now turns on.

A beep sounds and the meter runs a display check.

Check that there are no irregularities in the checkerboard pattern (see also *Performing a display check,* page 95).



The number of available tests and the instruction to wash your hands are shown in succession.

In doing so, the meter advances a test area to the tip of the cassette.

Do not touch the tape while a test area is advanced and do not approach the band with any objects.

Shortly after the test area has been advanced, the prompt *Apply drop* will appear and a beep will sound.

You can also open the tip cover if the meter is already turned on. In this case, the meter then switches to *Test*. There are the following exceptions:

- If you are in the *Settings* menu entering a number (e.g. to change the time) or in the selection list (e.g. to change the volume): In this case, when you open the tip cover you will be asked whether you really want to perform a test (see page 114).
- If you had turned the meter on using the ▼ or ▲ button (see page 60 or page 97): In this case, the meter does **not** switch to *Test*. You must first turn the meter off. Then you can start the blood glucose test.

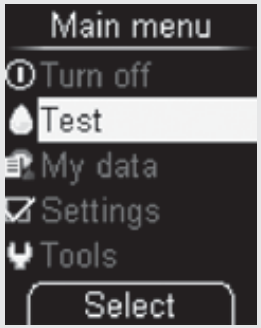
You can also start testing blood glucose using the *Main menu*.

With the meter off:

1a Turn the meter on with ◉.

1b Wait for the *Main menu*.

With the meter on:



1 Switch from the currently displayed menu to the Main menu.

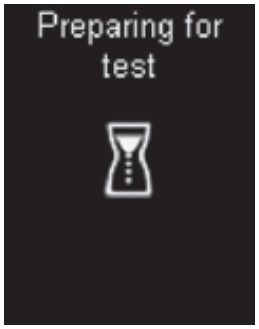
2 Use ▾▴ to select *Test* (💧 symbol).

3 Use ◉ to open the *Test* menu.

If the tip cover is closed, the prompt *Open tip cover* appears on the display.

If you do not want to perform a test after all, press the ◉ button (*Cancel)*.

4 Open the tip cover all the way.



After the instruction to wash your hands, a new test area is advanced and the prompt "*Apply drop*" appears on the display. You can now begin testing.

4.2 Obtaining a blood drop

In general, you can obtain blood from each finger. Certain fingers can be unsuitable if, for example, a skin or fingernail infection is present. We recommend obtaining capillary blood from the side of a fingertip, as this registers the least pain.

- Use a new lancet each time you obtain blood. This decreases the risk of infection and blood collection remains virtually pain free.
- **Only** use the lancing device when the cap is attached. If the cap is not attached, the lancet penetrates too deep and may cause discomfort.

Using the release button, you can prime the lancing device and trigger the lancet in one step. When being triggered, the lancet penetrates the skin.

1 Press the lancing device firmly against the selected puncture site.

2 Press the release button all the way down.

This triggers the lancet, which penetrates the skin.

3 Massage the finger in the direction of the fingertip to encourage a blood drop to form.

The amount of blood that emerges at the puncture site depends on the penetration depth and the pressure used to hold the lancing device against the skin.

If the amount of blood you obtain is too small, apply more pressure the next time you obtain blood. If you still obtain insufficient blood, repeat the procedure with progressively deeper penetration depths.

If too much blood emerges, reduce the penetration depth.

The blood drop must be large enough and well formed.

4.3 Applying the blood drop

You can hold the meter in your hand or lay it down while you apply blood to the test area.

1 As soon as the blood drop has formed, bring it towards the **centre** of the test area at the tip of the cassette.

Touch the blood drop to the tape **gently**.

Do **not** hold the meter with the test area pointing upwards.

The blood drop is drawn up by the test area.

2 Take your finger away from the test area as soon as *Test in progress* and the hourglass symbol appear on the display.

The test area has then drawn up enough blood and a beep sounds. The hourglass symbol indicates that the test is in progress.

Testing is complete after approx. 5 seconds, depending on the blood glucose concentration. The test result appears on the display and the meter beeps. At the same time, the meter automatically saves the test result. The used test area is transported away from the tip of the cassette.

If you want to flag the test result, do not turn the meter off (see section *Flagging results,* page 45).

3 Close the tip cover to turn the meter off.

4.4 Alternate site testing

Capillary blood for blood glucose testing can be obtained, not only from the fingertips, but also from other sites - the palm (below the thumb and below the little finger), the forearm, the upper arm, the calf and the thigh - which is referred to as Alternate Site Testing (AST). The Accu-Chek FastClix M1 AST cap is a special cap for the Accu-Chek FastClix M1 lancing device enabling you to obtain capillary blood from alternate sites.

⚠

- Please read these User's manual before you perform an alternate site test.
- **Before you decide to** perform an alternate site test, **please consult your healthcare professional.**
- If the test result for blood taken from alternate sites does not reflect how you feel, you should perform a test with blood taken from the fingertip. If this test result also does not reflect how you feel, please contact your healthcare professional.

- Blood obtained from a fingertip can be used at any time to test blood glucose. If blood from alternate sites is used, there are certain times when testing is not appropriate (see the section "*The right moment*"). The results may differ from the results taken from the fingertips at these times. These differences can cause the wrong therapeutic decision to be taken, thus leading to adverse health effects.
- **The Accu-Chek FastClix M1 lancing device and the AST cap are intended for personal use only!**
- They must not be used for obtaining blood on more than one person.
  There is a risk of infections being transmitted if the lancing device and the AST cap are used by other people, or if healthcare professionals use this lancing device and the AST cap to obtain blood from more than one person. The Accu-Chek FastClix M1 lancing device and the AST cap are therefore not suitable for professional use in healthcare facilities and institutions.

- Use the AST cap only to obtain blood from alternate sites. If you use the AST cap to obtain blood from the fingertip, the lancet penetrates too deep and could possibly cause very painful injuries.
- Keep the lancing device with all its components out of reach of children under 3 years. There is a risk of suffocation if small parts (e.g. caps or similar objects) are swallowed.

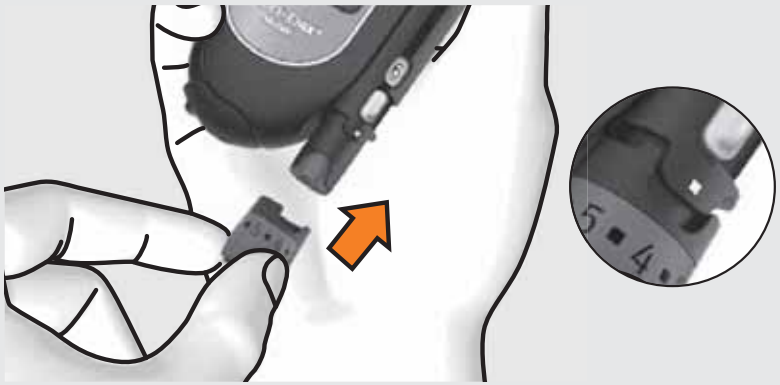
Use the Accu-Chek FastClix M1 AST cap only together with the Accu-Chek FastClix M1 lancing device.

The right moment

Do **not** perform an alternate site test,

- up to two hours following a meal, when blood glucose values can rise quickly,
- after having administered bolus insulin, when blood glucose values can fall quickly,
- after exercise,
- if you are ill,
- if you suspect that your blood glucose is extremely low (hypoglycemia),
- if you know that you sometimes do not notice when you are hypoglycemic.

1 Remove the black cap from the lancing device.



2 Place the grey AST cap on the lancing device. The cut-out section at the edge of the cap must fit over the correspondingly shaped curvature with the penetration depth indicator (square mark). You must hear and feel the cap click into place.

3 Rotate the AST cap of the lancing device until the desired penetration depth is level with the indicator.

To obtain a sufficiently large blood drop from alternate sites, lancing must be deeper than on the fingertips. However, these sites are usually less painful.

4 Choose a fleshy area of the alternate site and wash it with warm, soapy water. Allow the skin dry thoroughly afterwards.

Only use the lancing device when the AST cap is attached. If the cap is not attached, the lancet penetrates too deep and could possibly cause very painful injuries.

5 Press the lancing device firmly against the selected puncture site.

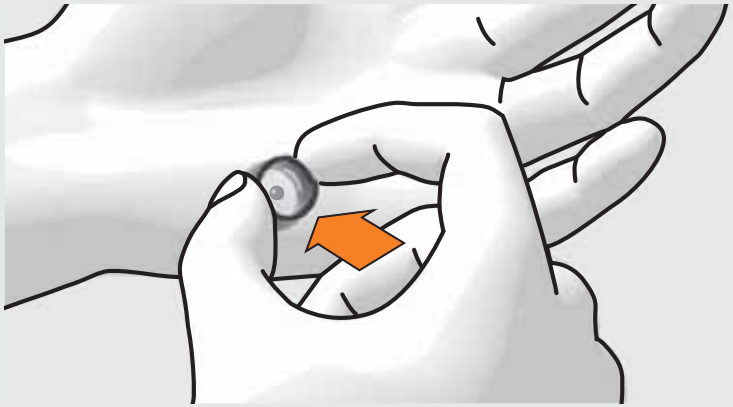
6 Press the release button all the way down. This triggers the lancet, which penetrates the skin.

7 Remove the lancing device from the puncture site.

8 Remove the AST cap from the lancing device.

9 Open the tip cover of the meter. If the meter was turned off, it now turns on.

10 Put the meter aside.



11 Take the AST cap and press it against the puncture site.
The lancet exit point on the AST cap must be in the same position on the skin as during puncture. This ensures that a proper blood drop can form and prevents the AST cap from coming into contact with the blood.

The blood drop should be approximately this size: •

If the drop is smaller, release the pressure for a few seconds, without removing the AST cap from the puncture site. Then re-apply pressure on the AST cap until you get a sufficiently large blood drop.

12 Pick up your meter again.

13 As soon as the blood drop has formed, bring it towards the centre of the test area at the tip of the cassette.
Touch the puncture site lightly with the tape.
The blood drop is drawn up by the test area.

14 Do not press the test area onto the puncture site and do not spread the blood drop.

15 Take the puncture site away from the test area as soon as *Test in progress* and the hourglass symbol appear on the display.

The test area has then drawn up enough blood and a beep sounds (if *Beep tones* is turned on). The hourglass symbol indicates that the test is in progress.

Testing is complete after approx. 5 seconds, depending on the blood glucose concentration. The result appears on the display and the meter beeps (if *Beep tones* is turned on).

16 Replace one of the two caps on the lancing device.

4.5 Symbols in connection with test results

The following symbols can be displayed together with the test result:

Symbol	Meaning
	The batteries are almost empty.
	The temperature during the test was outside the permitted range of +10 to +40 °C.
	The test result is higher than the upper limit of the target range set.
	The test result is lower than the lower limit of the target range set.

4.6 Symbols instead of test results

The meter measures blood glucose test results in the range from 0.6–33.3 mmol/L. If the test result is outside this range, one of the following symbols will be displayed:

Symbol	Meaning
LO	The test result is lower than 0.6 mmol/L.
HI	The test result is higher than 33.3 mmol/L.

The display LO may indicate that your blood glucose is very low (possibly a severe hypoglycemia). The display HI may indicate that your blood glucose is very high (possibly a severe hyperglycemia).

Follow the relevant instructions given by your healthcare professional immediately and repeat the test.

4.7 Flagging results

You can flag results to describe certain events connected to the result, or particular characteristics of the result. You can only flag a result if you open the *Set flag* menu while the result is still displayed after a test.

Selecting *Set flag* ◉ with the test result displayed, opens the *Set flag* menu that allows you to set the desired flags.

1 The test result in the above example is marked with the symbol ✱ *Other*.

The *Set flag* menu offers you a choice of 4 flags:

Symbol	Meaning
	Before meal (apple symbol): For test results that you have tested before your meals.
	After meal (apple core symbol): For test results that you have tested after your meals.
✱	*Other* (asterisk symbol): You can define the meaning of this flag yourself.
	Control test (applicator symbol): For control tests in which you apply control solution to the test area instead of blood.

You can add the following flags to a test result together:

- *Other* and *Before meal*
- *Other* and *After meal*

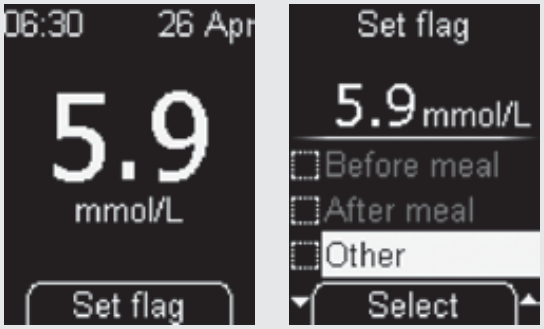
You cannot flag a test result with *Before meal* and *After meal* together.

You can change (add or remove) flags again as long as you are still in the *Set flag* menu. As soon as you leave the menu, the flags chosen will be saved and can no longer be subsequently changed.

Selecting *Control test* also takes you out of the *Set flag* menu and opens the *Control solution* menu.

The symbol for the flag that has been activated is displayed to the right above the test result.

Other, Before meal and *After meal*



1 Press ◉ *(Set flag)*.

2 Use ▾▴ to select *Before meal*, *After meal* or *Other*.

3 Press the ◉ button *(Select)*.

If you want to add a further flag to the test result, repeat steps 2 and 3.

Removing a flag again:

1 Use ▼▲ to select the flag, *Other*, for example.

2 Press ◉ to delete the flag.

Leaving the *Set flag* menu:

1 Turn the meter off with ◉.

or

2 Use ▼▲ to select *Main menu* and press ◉.

3 Close the tip cover.

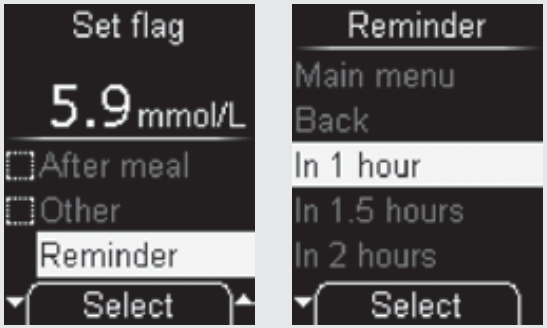
4.8 Setting reminders

The *Reminder* item allows you to directly set a reminder from the *Set flag* menu after a test if you would like to check your blood glucose again later.

The meter can give you a one-time reminder to perform a test in 1 hour, in 1.5 hours, in 2 hours or in 3 hours. You do not need to set a time for this. These reminders can be useful if you wish to check a test result you just obtained, for example. When the reminder has been given, it is automatically deleted.

When the test result is displayed:

1 Press ◉ *Set flag*.



2 Open ⇨*Reminder*.

3 Use ▼▲ to select a reminder time (e.g. *In 1 hour*).

4 Press ◉.

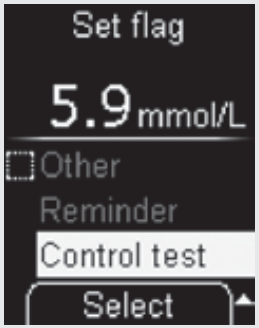
The meter returns to the *Set flag* menu.

For information on the options you have when the set reminder appears, see page 115.

Control test

When the control result is displayed:

1 Press ◉ *Set flag*.



2 Use ▼▲ to select *Control test*.

3 Press ◉.

The further procedure for performing a control test (test with control solution) is described in the *Checking the meter* chapter (page 88)

4.9 Evaluating test results

The test results depend on factors such as food intake, medication, health situation, stress and physical activity.

- If the displayed test result does agree with how you feel, continue as instructed by your healthcare professional. If the displayed test result does not agree with how you feel, perform a control test. Then repeat the blood glucose test. If the new test result still does not agree with how you feel, contact your healthcare professional.
- Do not change your treatment based only on a single test result.
- The display LO may indicate that your blood glucose is very low (possibly a severe hypoglycemia). The display HI may indicate that your blood glucose is very high (possibly a severe hyperglycemia).

Follow the instructions given by your healthcare professional immediately and repeat the test.

Sources of error for implausible test results

If your meter repeatedly displays implausible test results or error messages, please check the points listed below. If any of your responses to the questions in the table differ 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 test results or error messages, contact your customer support and service centre.

Did you perform the blood glucose test according to the User's Manual?	yes
Did you wash your hands with warm water and soap and dry them well?	yes
Did you wait for the application prompt to be displayed before applying blood?	yes
Did you apply the blood drop to the test area immediately?	yes
Did you apply a well-formed blood drop?	yes

Did you press the test area onto the finger or spread the blood drop while applying it?	no
Did you use the same blood drop for several tests?	no
Did you test within the correct temperature range (+10 to +40 °C)?	yes
Did you observe the proper storage conditions for the meter and test cassette?	yes
Have you paid attention to the sources of error stated in the test cassette package insert?	yes

If your meter has been dropped while *Apply drop* appears, perform a control test.

If your meter has been dropped, that can also lead to implausible test results or error messages. In this case, you should also call your customer support and service centre.

5 Making settings

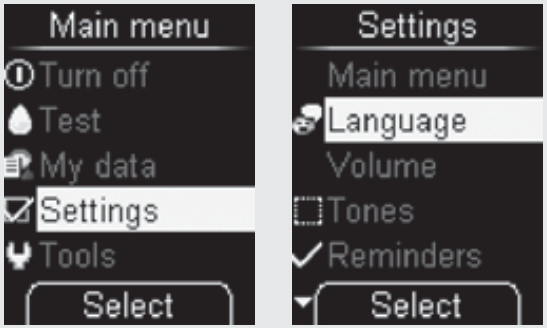
5.1 Settings overview

Menu	Available options
Language	Different languages
Volume	5 levels (*Mute* and 4 volume levels)
Tones	*Beep tones:* Turns the beep tones on or off *Reminders:* Turns the beep tone for reminders on or off *Acoustic mode:* Turns the acoustic mode on or off
Reminders	7 times – freely selectable daily reminders
Time/Date	Time: Sets the time Date: Sets the date Time format: Sets the time format (8 time formats) (format for time and date)
Target range	Sets the upper and lower limits Turns the target range on/off
Brightness	3 levels

The meter has several features which you can only use after making the appropriate settings. Most of these features are intended primarily to enable you to adapt the meter to your personal needs (e.g. beep tones and acoustic reminders).

You can perform blood glucose tests without adjusting any of the settings on the meter.

To open the *Settings* menu:



1 Use ▼▲ in the *Main menu* to select *Settings* (symbol ☑).

2 Press ◉.

5.2 Setting the language

You can choose a language from the list for the text appearing on the display.

1 Open ➪*Settings*, ➪*Language* (symbol 🗣).

The currently set language is highlighted.

2 Use ▼▲ to select the desired language.

3 Press ◉.

The selected language is displayed.

4 Press ◉ *(OK)*.

Correcting a wrongly-set language

You can change the language if you selected the wrong language by mistake:

1 Turn the meter on with ◉.

2 Wait until the display does not change anymore.

3 Press ▼ 2 times.

The "*Settings*" ☑ menu is now highlighted.

4 Press ◉.

The "*Language*" menu is now highlighted.

5 Press ◉.

The "*Language*" menu is now open.

6 Use ▼▲ to select the desired language.

7 Press ◉.

The selected language is displayed.

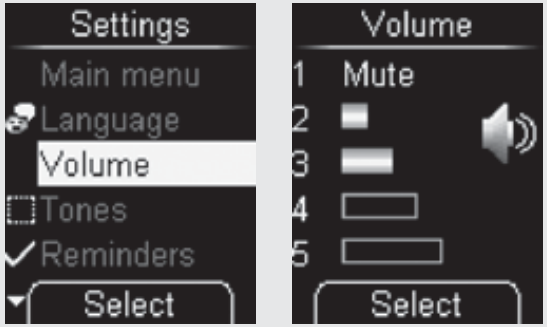
8 Press ◉ *(OK)*.

The meter returns to the "*Settings*" menu.

5.3 Setting the volume

You can set the volume for the beep tones to one of 5 different levels.

The longer the bar on the display is, the louder the volume is. At volume level 1 *Mute* no beep tone is audible.



1 Open ⇨*Settings*, ⇨*Volume*.

2 Use ▼▲ to set the volume.

Each time you press the button, a beep sounds in the new volume selected.

3 Press ◉.

5.4 Setting tones

In the *Tones* menu you can turn the beep tones, the acoustic reminders and the acoustic mode on or off.

Beep tones: If *Beep tones* is turned on and the volume is not set to 1 (*Mute*), a beep will sound during a test,

- when the meter advances a test area to the tip of the cassette,
- when the prompt *Apply drop* is displayed and you can apply blood or control solution to the test area,
- when *Test in progress* is displayed and the test begins,
- when the result is displayed,
- when an error message is displayed (a double beep 4 times in succession).

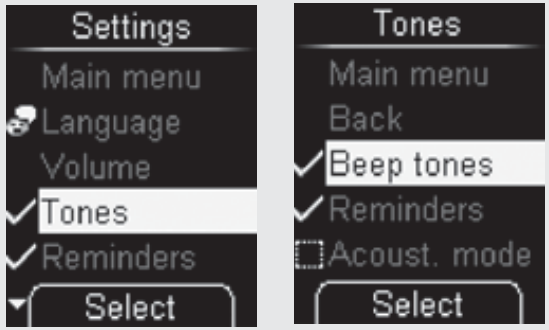
Reminders: If *Reminders* is turned on, the beeps will sound.

Acoustic mode: If the acoustic mode is turned on, the meter guides you through performing a test with the previously mentioned beeps (see Chapter *Acoustic mode*, page 81).

Turning tones on or off

Beep tones, reminders and acoustic mode can only be turned on and off.

Procedure using the example of Beep tones:



1 Open ⇨*Settings*, ⇨*Tones*.

2 Use the ▼▲ to select *Beep tones*.

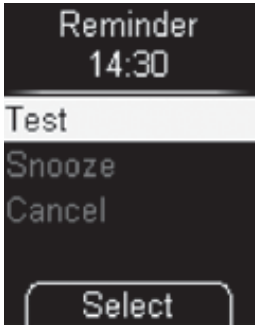
3 Press ◉ to turn the beep tones on (✓) or off (☐).

If you wish to use the acoustic mode, you must turn both *Acoustic mode* and *Beep tones* on.

5.5 Setting reminders

You can set up to 7 reminder times.

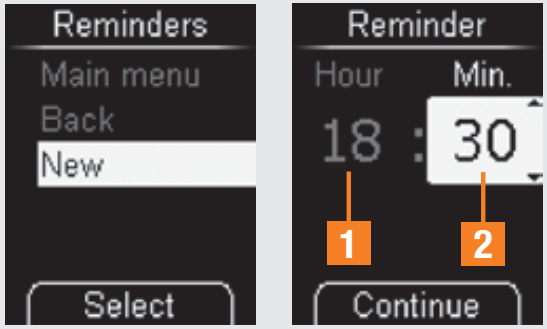
If the meter is turned off, *Reminder* and the time of the reminder will be displayed daily at the time you have set. If you have turned *Reminders* in the *Tones* menu on, beeps will also sound (see page 115).



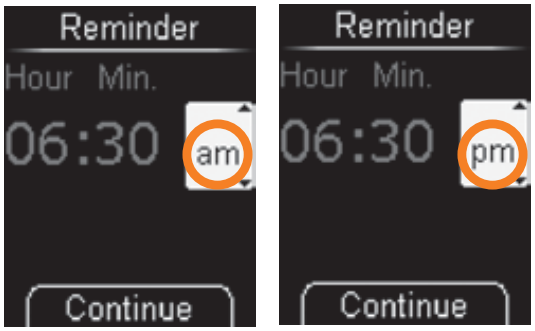
When the message with the reminder appears, you can turn off the beeps by pressing any button. If you do not press a button, the meter turns off automatically after 20 seconds. The reminder will not be repeated.

If you perform a blood glucose test 10 minutes or less before a reminder, the reminder will not be given.

Setting a new reminder



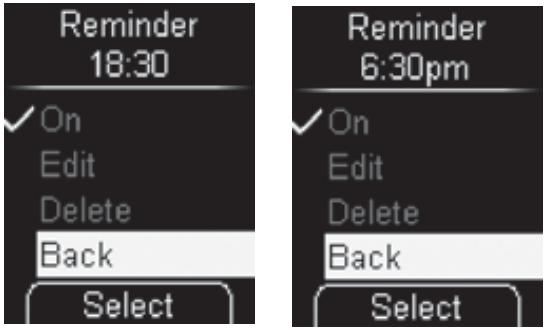
1 Open ➪*Settings*, ➪*Reminders*.
2 Use ▼▲ to select *New*.
3 Use ◉ to open *New*.
4 Use ▼▲ to set the hour **1**.
5 Press ◉ *(Continue)*.
6 Use ▼▲ to set the minutes **2**.
7 Press ◉ *(Continue)*.



Only for times in 12-hour time format:
The suffix *am* (morning) or *pm* (afternoon) is highlighted.

7a Use ▼▲ to select *am* or *pm*.

7b Press ◉ *(Continue)*.

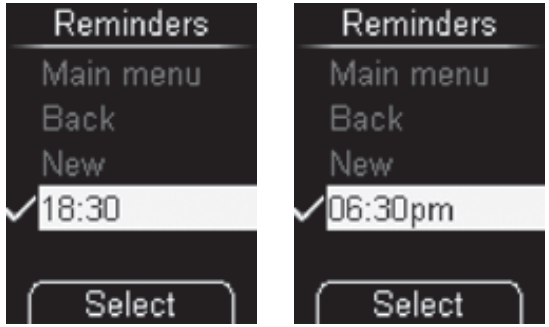


24-hour time format | 12-hour time format

The meter shows you the set reminder time. The reminder is also turned on.

Press ◉.

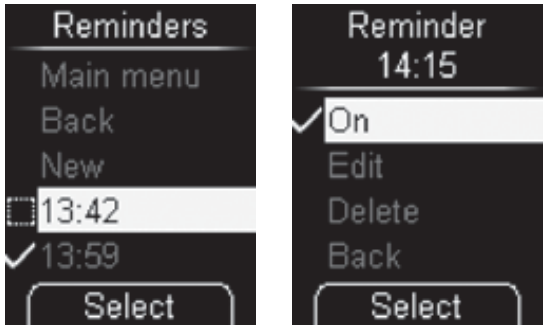
The meter returns to the *Reminders* menu.



24-hour time format | 12-hour time format

The set reminder time is displayed.

Turning a reminder on or off



A list with the reminders that have already been set appears on the display.

1 Open ➪*Settings*, ➪*Reminders*.
2 Use ▼▲ to select the reminder time you wish to turn on or off.
3 Press ◉.
4 Use ▼▲ to select *On*.
5 Press ◉ to turn the reminder on or off.

A test reminder that reminds you once to check your blood glucose value is not displayed in the list (see also page 42).

Changing a reminder

1 Open ➪*Settings*, ➪*Reminders*.
2 Use ▼▲ to select the reminder time you wish to change.
3 Press ◉.
4 Use ▼▲ to select *Change*.
5 Press ◉.
6 Set the new reminder time.

The reminder time has now been changed.

Deleting a reminder

1 Open ➪*Settings*, ➪*Reminders*.
2 Use ▼▲ to select the reminder time you wish to delete.
3 Press ◉.
4 Use ▼▲ to select *Delete*.
5 Press ◉.

The reminder time has now been deleted.

5.6 Setting the time, date and time format

The time and date are already set in the meter. If you want to use reminders or analyse your test results with a computer, for example, you should check the time and date and correct them if they deviate from the current time or date.

All test results are saved together with the time and date. Only when the time and date are correctly set, can the test results be analysed properly as a function of time.

Setting the time

1 Open ➪*Settings*, ➪*Time/Date*, ➪*Time*.

2 Use ▼▲ to set the hour 1.

3 Press ◉ *(Continue)*.

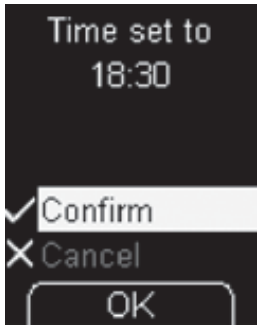
4 Use ▼▲ to set the minutes 2.

5 Press ◉ (*Continue*).

Only for times in 12-hour time format:
The suffix *am* or *pm* **3** is highlighted.

5a Use ▼▲ to select *am* or *pm*.

5b Press ◉ *(Continue)*.



6 Press ◉ *(OK)*.

The set time is displayed.

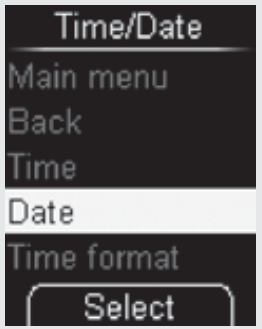
Setting the date

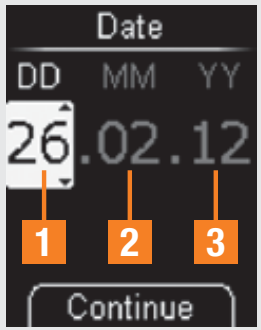
The sequence in which you set the day, month and year while setting the date depends on the time format you have set. Apart from the sequence, the procedure is the same in all cases. The following sequences are possible:

Day.Month.Year

Month/Day/Year

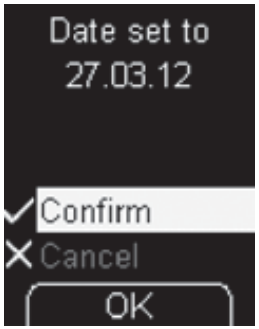
Year/Month/Day





1 Open ➪*Settings*, ➪*Time/Date*, ➪*Date*.

2 Use ▼▲ to set the day 1.
3 Press ◉ *(Continue)*.
4 Use ▼▲ to set the month 2.
5 Press ◉ *(Continue)*.
6 Use ▼▲ to set the year 3.
7 Press ◉ *(Continue)*.

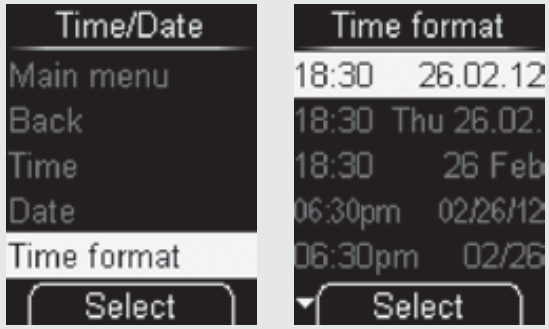


The set date is displayed.

8 Press ◉ *(OK)*.

ⓘ
If the date you have set does not exist (e.g. 31 April), the meter returns to the first setting position when you confirm the last entry with *Continue* (step 7).

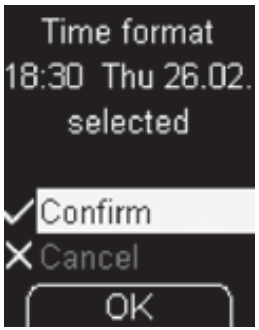
Setting the time format



1 Open ⇨*Settings*, ⇨*Time/Date*, ⇨*Time format*.

The currently set time format is highlighted.

2 Use ▼▲ to select the desired time format.
3 Press ◉.



The selected time format is displayed.

4 Press ◉ *(OK)* to confirm the selected time format.

If you do not want to set the selected time format, choose *Cancel*. Press the ◉ button *(OK)* to return to the *Time/Date* menu.

5.7 Setting the target range

You can enter your personal target range for blood glucose values (default setting: Off). Test results above this target range will be flagged with the symbol ⊺. Test results below this target range will be flagged with the symbol ⊺.

The target range gives the blood glucose values which should be achieved if the treatment is optimal. Discuss with your healthcare professional what target range you should set.

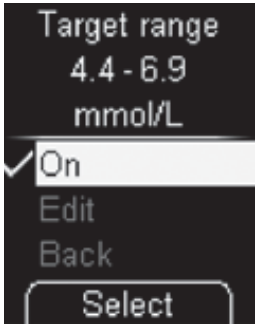
You set the target range by entering the lower and upper limits. The lower limit can be set to between 2.8 and 5.5 mmol/L. The upper limit can be set to between 5.5 and 11.1 mmol/L. Both limits can be set in steps of 0.1 mmol/L.

If you wish to use the lower limit of the target range as an indicator of a possible hypoglycemia (low blood glucose), it is important to remember the following: The indicator will only be reliable if the limit has been properly selected. We therefore strongly recommend that you talk to your healthcare professional before you set the limit. This function is no substitute for hypoglycemia training by your healthcare professional or healthcare team.

Setting a target range

1 Open ➪*Settings*, ➪*Target range*.
2 Use ▼▲ to select *Edit*.
3 Press ◉.
4 Use ▼▲ to set the lower limit 1.
5 Press ◉ *(Continue)*.
6 Use ▼▲ to set the upper limit 2.
7 Press ◉ *(Continue)*.
8 Press ◉ *(OK)* to confirm the set target range.

If you do not want to set a target range, use ▼▲ to select *Cancel* and then press the ◉ button *(OK)* to return to the *Settings* menu.



The set target range is displayed. It is also turned on.

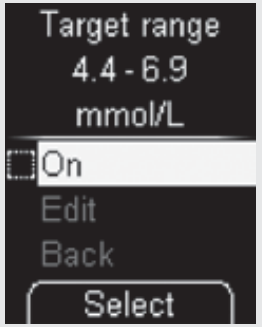
9 Use ▼▲ to select *Back*.

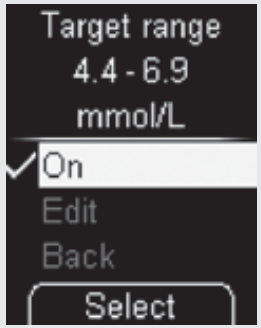
10 Press ◉.

The meter returns to the *Settings* menu.

Turning the existing target range on/off

1 Open ➪*Settings*, ➪*Target range*.





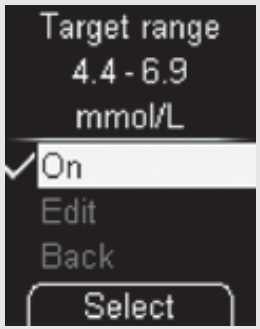
2 Use ▼▲ to select *On*.

3 Press ◉ to turn the target range on or off.

A checkbox ☐ indicates that the target range is turned off, a tick ✓ that it is turned on.

Changing a target range

1 Open ➪*Settings*, ➪*Target range*.



2 Use ▼▲ to select *Change*.

3 Press ◉.

4 Set the new target range.

5 Press ◉ *(OK)* to confirm the set target range.

The changed target range is displayed. It is also turned on.

5.8 Setting the brightness

You can set the brightness of the texts and symbols appearing on the display to one of 3 different levels.

The longer the bar on the display is, the brighter the display is.

1 Open ➪*Settings*, ➪*Brightness*.

2 Use ▼▲ to set the desired brightness.

3 Press ◉.

6 Using the meter as a diary

The meter has a 2000-value memory for saving results together with the time and date. You do not need to save the results manually. All results, all symbols that are displayed together with the result and all flags are automatically saved by the meter. 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.

The following options are available in the *My data* menu:

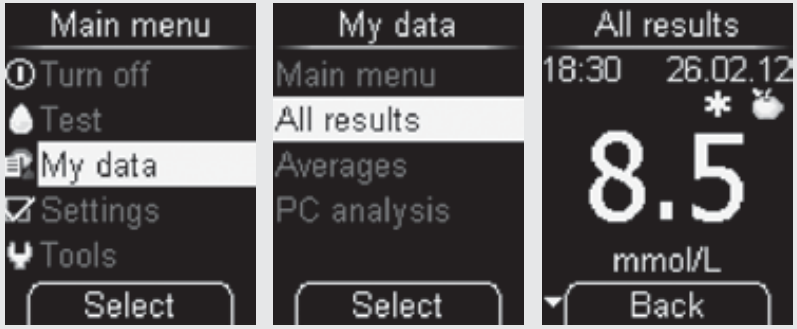
- *All results:* Display all the saved test results
- *Averages:* View the averages for the last 7, 14, 30 or 90 days
- *PC analysis:* Display and analyse the saved test results on the computer (see page 64)

6.1 Retrieving saved results

You have the option of retrieving all saved test results via the *My data* menu or by using the ▼ button.

Symbols saved together with the test result appear to the right above the test result.

To retrieve saved test results via the *My data* menu, proceed as follows:



Open ➪*My data* (symbol), ➪*All results*.

The last saved test result is displayed.

To retrieve saved test results using the ▼ button, proceed as follows:

With the meter off:

Press and hold ▼ until the meter turns on (longer than 2 seconds).

The last saved test result is displayed.

Retrieving older test results:

Press ▼ to go to the next older test result.

Press ▲ to go to the next newer test result.

If you keep the buttons pressed, the test results are displayed in quick succession, starting with a slow speed and becoming faster. When the oldest or newest (latest) test result is achieved, the display stops.

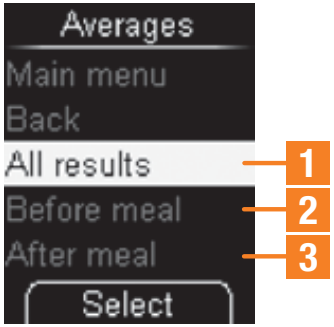
If the last (most recent) test result in the memory is displayed as XX.X with dashes instead of the time and date, the last test did not deliver any test result. In this case, an error message was displayed during the last test, or you did not apply blood (or control solution) after the prompt *Apply drop* was displayed. After the next test that delivers a test result, the test result displayed as XX.X will be deleted from the memory.

XX.X is also displayed when no test results are saved in the meter.

6.2 Retrieving averages

The meter can calculate averages from the saved test results.

You can choose which test results are used for calculation of the averages:



- All results 1
- Only test results that were flagged with *Before meal* 2
- Only test results that were flagged with *After meal* 3

When you have made this selection, you can choose the period of time in which the test results were obtained. The last 7, 14, 30 or 90 days.

The average will be calculated from all test results corresponding to your choice. However, the following test results will not be included in the calculation:

- Control tests (flagged with),
- Test results displayed as LO or HI.

1 Open ➪*My data*, ➪*Averages*.

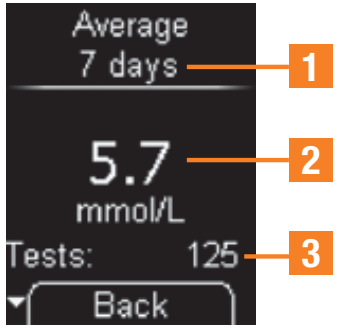
2 Use ▼▲ to select *All results, Before meal* or *After meal*.

3 Press ◉.

4 Use ▼▲ to select the period in which the test results were obtained: 7, 14, 30 or 90 days.

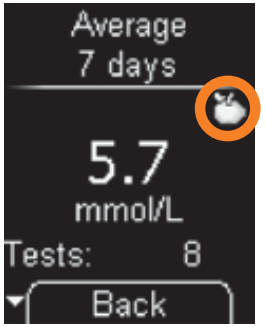
5 Press ◉.

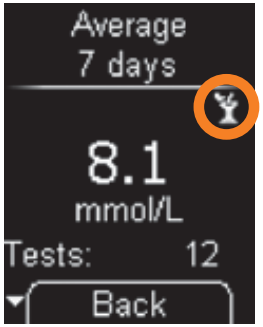
Selecting the time period 1 only determines which average will be displayed first. You can use the ▼▲ buttons to switch directly from one time period to the others.



The selected average 2 is displayed, together with the number of test results (called *Tests*) from which the average was calculated. 3

Averages *Before meal* are marked with the symbol .
Averages *After meal* are marked with the symbol .





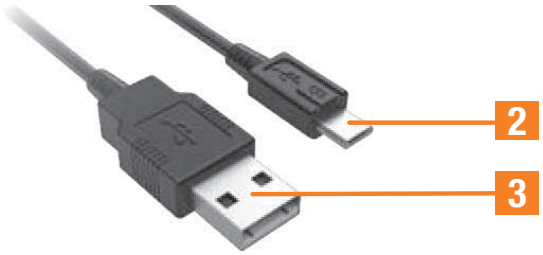
- The meter calculates the average for a period even when the saved test results cover a shorter period (e.g. only 5 days).
- If no average can be calculated, XX.X (mmol/L) is displayed instead of a value and the number of test results (tests) is given as zero. This is the case if either no test results or only test results which are not used for calculation of averages were saved in the specified period.

7 Analysing test results on the PC

The meter has a built-in USB (Universal Serial Bus) port for transferring saved results to a computer (PC) being equipped accordingly.

The USB port 1 is located on the left side of the meter.

The supplied USB cable has two different connectors: The Micro B connector 2 is intended to establish a connection to the meter, the USB A connector 3 is intended to establish a connection to the computer.



There are two ways of displaying the results on the computer via the *PC analysis* menu:

- *Data transfer* transfers the results to the computer. Using special software products for diabetes management (e.g. Accu-Chek 360° software by Roche Diagnostics), you can display and analyse the data.
- *Reports* allows you to display and analyse the results on the computer by means of the meter's built-in diary function software and an Internet browser.

With these analysis options, you and your healthcare professional can manage your data more effectively and, using the graph and table views, you can better understand your test results.

7.1 Defining the default

You can define how the meter will react after being turned on when it is connected to the computer.

1 Open ➪*My data*, ➪*PC analysis*, ➪*Default*.

2 Use ▼▲ to select *Data transfer* or *Reports*.

3 Press ◉.

Depending on the default you select, the analysis of the test results is started with *Data transfer* or *Reports*. To analyse the data by means of *Data transfer*, you need a special software product for your computer (e.g. Accu-Chek 360° software by Roche Diagnostics). For further information, please contact your customer support and service centre.

If you already have a software product from Roche Diagnostics for transferring and analysing results, the software may not recognise more recent meters and the results will therefore not be downloaded. You may need a more recent version of your software. In this case, contact your customer support and service centre.

You cannot perform a test while test results are being transferred.

7.2 Connecting the meter to the PC

1 Plug the USB connector (Micro B connector) into the USB port on your meter.

2 Connect the other end of the USB cable to your computer.

With the meter off:

The meter turns on. Depending on the selected default (see section *Defining the default*), the analysis of the test results is started with *Data transfer* or *Reports*.

With the meter on:

The meter opens the *PC analysis* menu. Other running operations are aborted.

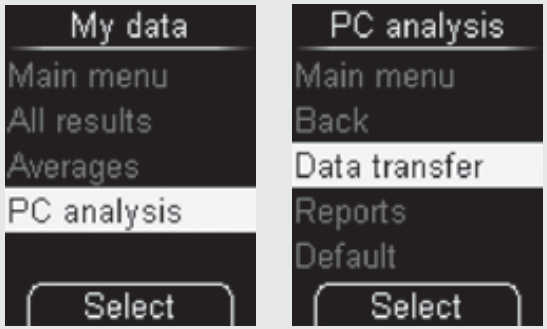
If you connect the meter to the computer while a test is in progress, the test is aborted and the following message appears:

Press ◙ *(Continue)*.

The meter starts data analysis via *Data transfer* or *Reports*, depending on the default.

- If you disconnect the cable between meter and PC, the meter turns off.
- Remove the USB cable after analysing the test results on the PC so that the meter batteries are not consumed unnecessarily.

7.3 Starting data transfer

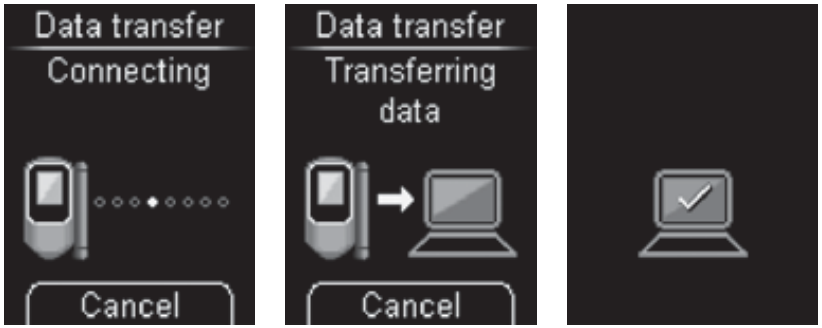


1 Open ➪*My data*, ➪*PC analysis*.

2 Use ▼▲ to select *Data transfer*.

3 Press ◙ to start transferring the results.

4 If necessary, start the software product for test result analysis on the computer.

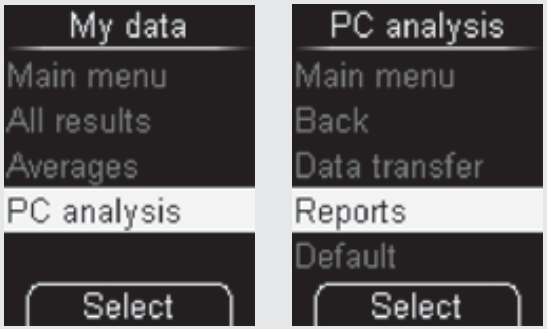


While the connection is being established and data is being transferred, you will be informed of the progress these operations on the display.

If you do not want to transfer the results after all, you can abort the transfer using the ◙ button. The meter returns to the *My data* menu (if you came from the *My data* menu) or turns off (if you turned the meter on using the ▼ and ▲ buttons).

When transfer of the results is finished, the meter turns off automatically.

7.4 Displaying reports



1 Open ⇨*My data*, ⇨*PC analysis*.

2 Use ▼▲ to select *Reports*.

3 Select ◉ to establish the connection to the computer.

While the connection is being established, you are informed of the progress on the display. The PC symbol on the meter's display flashes when the connection to the computer is successful.

4 Open the file manager (e.g. Microsoft Windows Explorer) on your computer.

The meter is displayed as a drive (USB storage device) in the file manager.

5 Open the drive symbol (ACCU-CHEK) with a double-click.

6 Open "start.html" with a double-click.

The Internet browser (e.g. Mozilla Firefox) is opened and shows you the default reports.

7.5 Reports

Reports are used to easily and automatically analyse saved blood glucose results from your Accu-Chek Mobile meter.

Overview

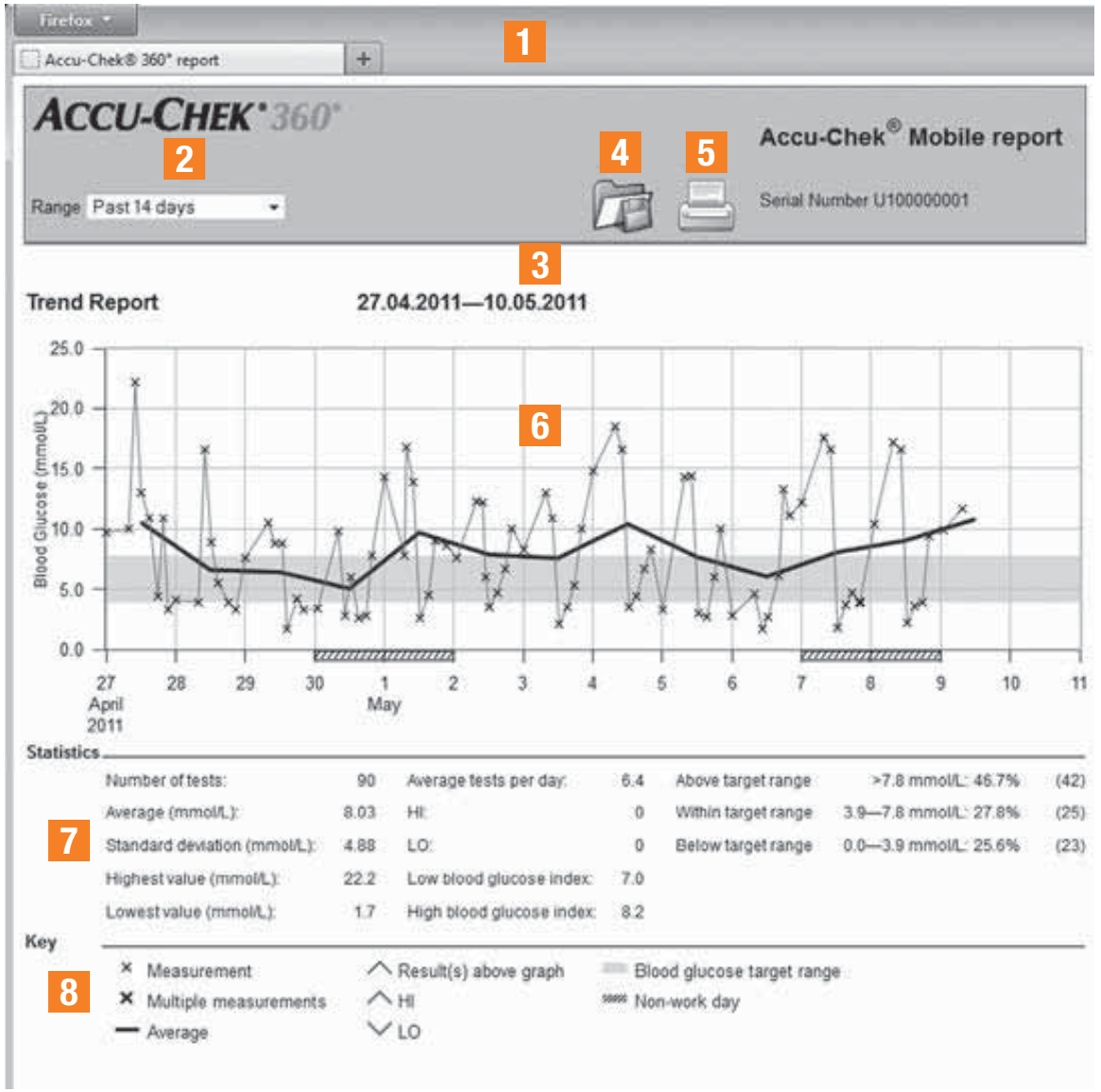
The reports can be displayed on a computer using an Internet browser and can be output to a printer. You do **not** need an Internet connection to display the reports. The report data is saved in the meter and is retrieved from there.

The license agreement for using the meter's built-in diary function software can be found at the end of User's Manual.

When connection between the meter and the computer is successfully established, the following reports are displayed on a page of the Internet browser:

- Trend Report
  This report shows the trend for several test results over the selected period.
- Standard Day Report
  This report shows all data in a 24-hour grid.
- Standard Week Report
  This report shows all blood glucose values according to the time when the test was performed and the respective day of the week.
- List report
  The list report (record list) shows the test results sorted by date and time of the test.

User interface



1 Window of the Internet browser

2 Drop-down menu for selecting the period

3 Period

4 *Save file* button

5 *Print reports* button

Display panes:

6 Chart (graphic representation of the report)

7 Statistics on test results analysis

8 Legend for symbol explanation

The test results are represented in the unit mg/dL or mmol/L, depending on the version of the meter.

Symbols

Within the report charts, the test results are plotted into the analysis by means of different symbols.

The symbols and graphic elements in the charts have the following meaning:

Test
Blood glucose result of a test

Several tests
Blood glucose results of several tests

Average
Average of the blood glucose results in the selected period

Blood glucose target range
Personal blood glucose target range (represented on the monitor as a green bar)

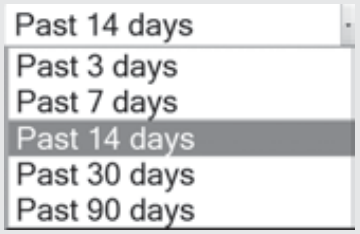
Test result(s) above chart
The blood glucose value cannot be represented because it is outside the chart

Non-work day
Usually, non-working days (weekends)

Report periods

Reports can be created for the following periods:

- Past 3 days
- Past 7 days
- Past 14 days
- Past 30 days
- Past 90 days



Select the desired period in the drop-down menu (e.g. *Past 14 days*).

Printing reports

All the reports displayed on the screen can also be printed out together.

Do not use the integrated print function of the browser to print the reports, instead use the Print report button on the user interface.

1 Click the button on the user interface.

The print dialog box of your Internet browser opens.

2 Select the desired printer from the print dialog box of the Internet browser.

In the print settings dialog box, you have the option of making further settings for the print process.

3 Select whether the report is to be printed in portrait or landscape format.

4 Start the printing process.

Depending on operating system and system configuration, the procedure for selecting the print settings on your computer may vary.

Analysed data

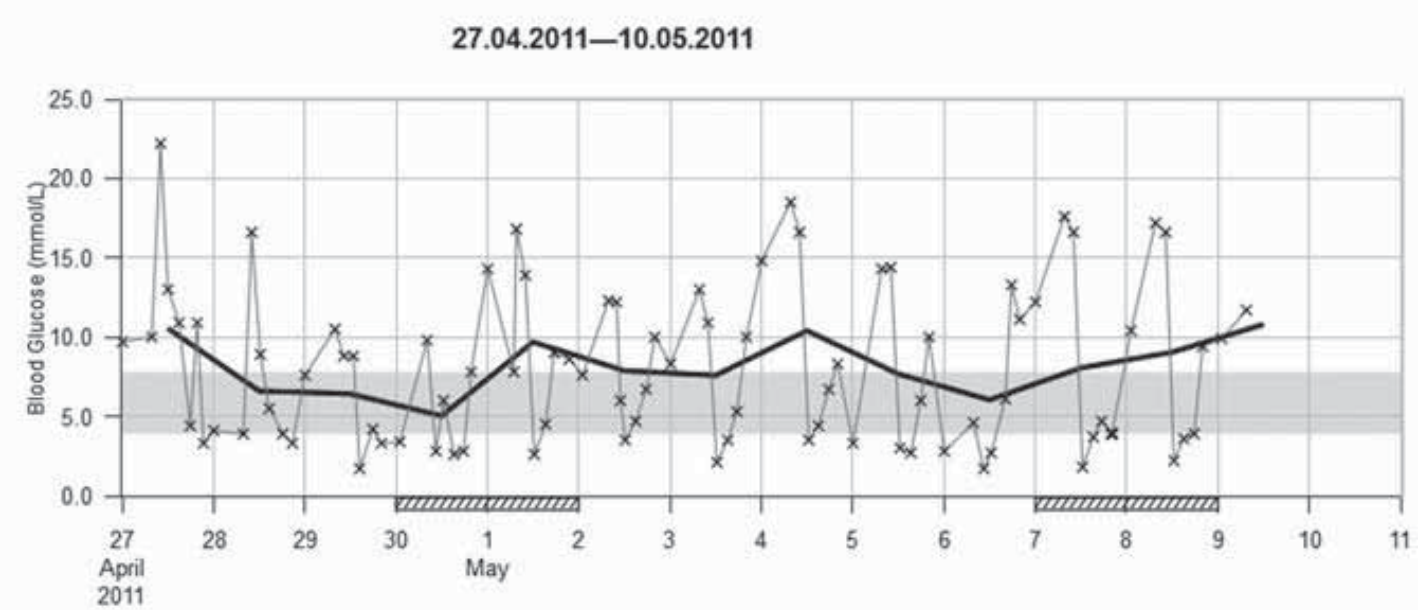
The following data is not included in the statistical analysis:

- Test results outside the period selected
- Test results without date and time
- Tests with control solution
- Tests outside the measuring range (marked with HI or LO)

The following settings made in the blood glucose meter are accepted for data analysis:

- Language (see page 46)
- Date format (see page 53)
- Time format (see page 54)

Trend Report



The *Trend Report* shows you the trend of several blood glucose values over the selected period.

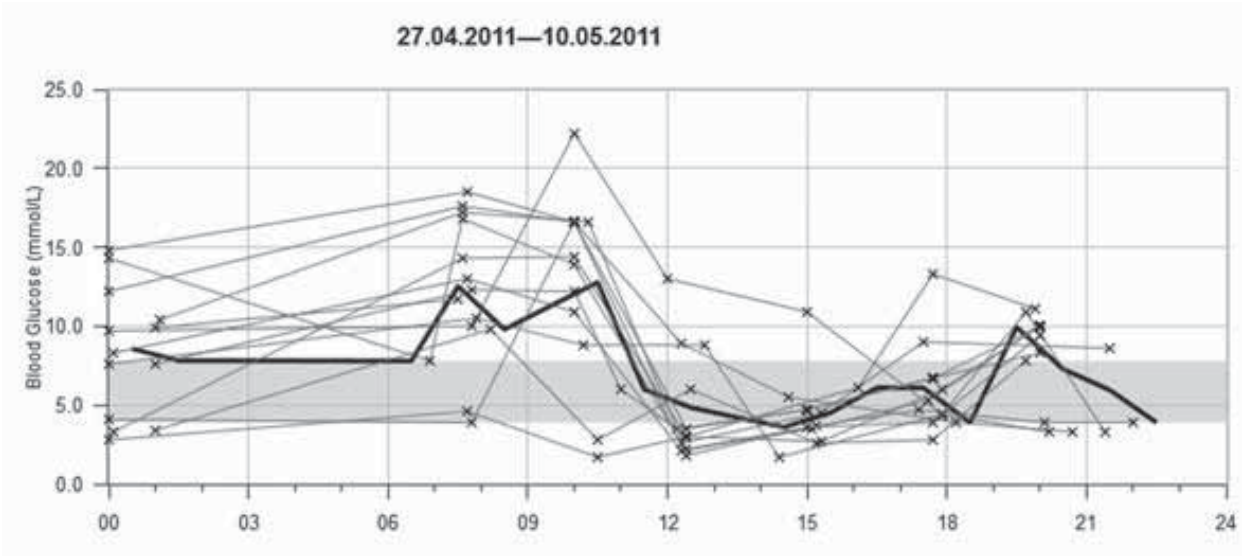
You will find the days and months along the horizontal x-axis and the blood glucose test results along the vertical y-axis. The values are connected by a thin black line in chronological order.

For further guidance, you can see the set blood glucose target range as a green bar in the background of the chart. Days that are usually non-working days (weekends) are marked with an additional shading on the horizontal x-axis.

The individual blood glucose values are connected through thin lines.

The trend of the day-to-day average blood glucose value is represented by a thick black line.

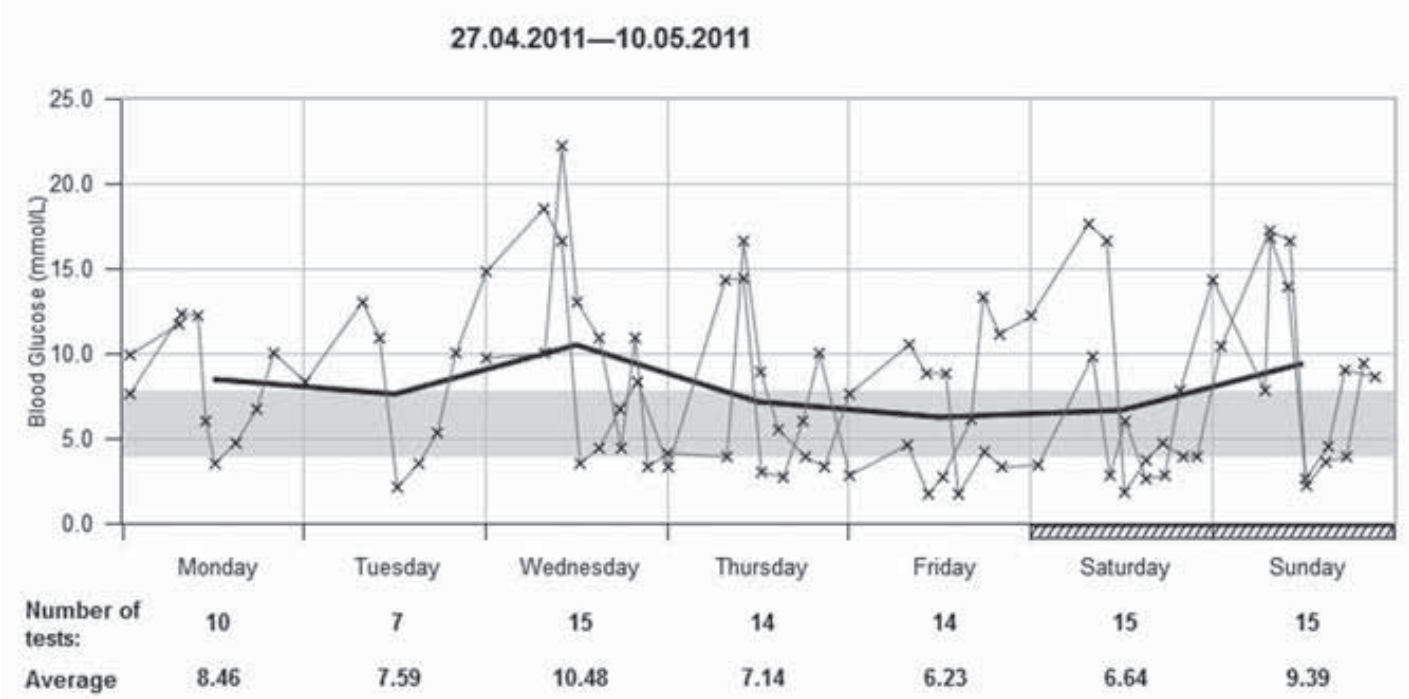
Standard Day Report



The *Standard Day Report* is used to make it easier to recognise patterns repeated daily. For this purpose, all the data is placed on a 24-hour grid. As a result all the tests performed at (approximately) the same time of day are shown at the same position on the time axis.

All the blood glucose values are plotted at the relevant time of day according to the time when the test was performed. The values are connected by a thin black line in chronological order. A thick black line represents the development of the mean level (in intervals of one hour if a test result falls in each interval).

Standard Week Report



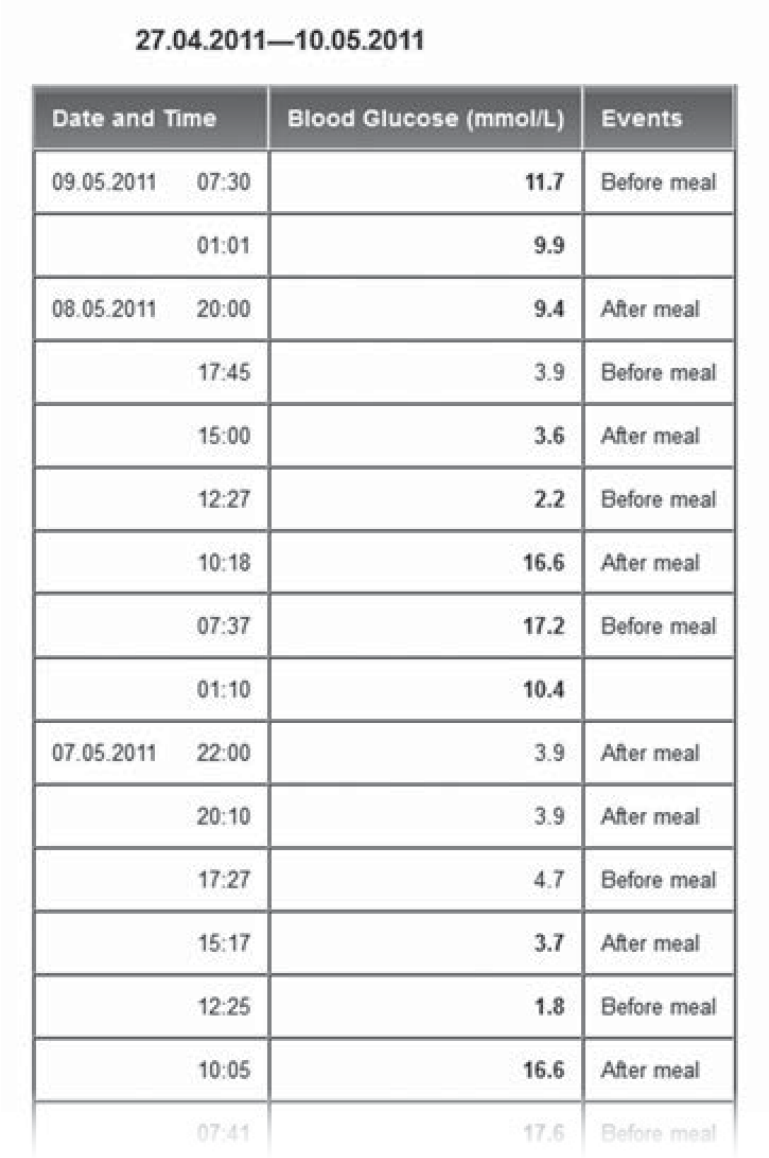
The *Standard Week Report* is used to make it easier to recognise repeated patterns depending on the day of the week. For example, it is possible to recognise changes in the metabolic situation brought about by your occupation.

All the blood glucose values are plotted on the chart according to the time when the test was performed and the respective day of the week. The values are connected by a thin black line in chronological order.

A thick black line represents the development of the mean level on the different days of the week.

Below the chart, the number of tests and the average for the respective day of the week are listed.

List report



27.04.2011—10.05.2011

Date and Time	Blood Glucose (mmol/L)	Events
09.05.2011 07:30	11.7	Before meal
01:01	9.9	
08.05.2011 20:00	9.4	After meal
17:45	3.9	Before meal
15:00	3.6	After meal
12:27	2.2	Before meal
10:18	16.6	After meal
07:37	17.2	Before meal
01:10	10.4	
07.05.2011 22:00	3.9	After meal
20:10	3.9	After meal
17:27	4.7	Before meal
15:17	3.7	After meal
12:25	1.8	Before meal
10:05	16.6	After meal
07:41	17.6	Before meal

The list report shows the test results sorted by date and time of the test. All blood glucose values are represented in a chronological way and together with additional information on the events (see Chapter *Flagging results*, page 39).

The list contains the following columns:

- **Date and Time**
- **Blood Glucose (mmol/L)**
- **Events**
  Event that is connected to this test result

Statistics

Below the chart of a report, you will find a statistical analysis of all test results plotted with the following information:

- **Number of tests**
- **Average (mmol/L)**
- **Standard deviation (mmol/L)**
  The standard deviation is the variance of the analysed results.
- **Highest value (mmol/L)**
- **Lowest value (mmol/L)**
- **Average tests per day**
  Average number of blood glucose tests per day
- **HI or LO**
  Blood glucose values outside the measuring range
- **Low blood glucose index or High blood glucose index**
  Further information can be found in the appendix (see page 135).
- **Above target range**
  Blood glucose values above the target range
- **Within target range**
  Blood glucose values within the target range
- **Below target range**
  Blood glucose values below the target range

Analysing data in external applications

If you want to analyse the test results using external software, you can save the data as a CSV file. The file extension CSV stands for Comma Separated Values. CSV files can be opened with a text editor or spreadsheet program, for example.

The CSV file always contains all the test results saved in your meter. Test results already transferred at an earlier date are transferred again.

1 Press the  *Save file* button on the user interface.

Depending on the configuration of your computer, the CSV file may be directly opened in a spreadsheet program. In this case, you can save the table using the save function of the spreadsheet program.

2 In the dialog box that opens, select the option to save the file.

Where you find the CSV file on your computer depends on the settings in your operating system for data download.

The CSV file contains the following information:

- Serial number: Serial number of the meter
- Download date, download time, data and time when the meter transferred the test results to the computer.
- Date, time, result and unit of the results saved in the meter.
- Flags added to the results, indicated by an “X”.

In the CSV file, the date is always displayed in the format DD.MM.YYYY and the time always in the 24-hour time format (hh:mm). The time format set in the meter has no influence on the format of the date and time in the CSV file.

Security settings within the Internet browser

The settings of your Internet browser can have an influence on working with reports.

The reports use pages with so-called “active content” (JavaScript). This active content can be suppressed by making appropriate security settings in the browser, causing warnings to be issued or functionality to be restricted. If this happens, check the relevant Internet browser settings in order to ensure smooth operation.

In many cases, you can create different security settings for using the Internet and working with reports (e.g. at user login to the PC or by defining user profiles in the browser).

If you choose the Internet browser security settings appropriately (e.g. “Allow active content to run in files on My Computer” or similar), you can work with reports without any restrictions.

Error signals and troubleshooting

The ACCU-CHEK drive symbol with the “start.html” file does not appear on the PC:

- Check whether *Reports* is selected in the defaults for PC analysis (see page 71).
- Check whether your PC or operating system supports data transfer via USB.
- Check to make sure the USB connector is firmly plugged into the correct socket on the PC.

If the meter is still not detected as a drive:

- Plug the meter into a different USB socket on your computer (you may be able to use a USB hub or choose between USB sockets on the front and rear of your PC).

Please refer to the customer support and service centre, if the problem persists.

8 Acoustic mode

The procedure for turning the acoustic mode on is described in Chapter *Setting tones* (see page 48). When the acoustic mode is turned on, the meter guides you through the blood glucose test using beeps and announces the test result as a series of beeps. The meter beeps additionally when the batteries are almost empty, the test cassette is empty or an error message is displayed.

An intimate knowledge of how test results are announced as beeps and how to distinguish test results from other beeps is crucial to reliably recognising the test result.

The sections below explain the beeps in detail. In addition, training software (the BeepLearn program) to help you interpret test results announced in the form of beeps is available on CD from your customer support and service centre.

Visually impaired people should only use the acoustic mode if they have familiarised themselves fully with the acoustic mode with the assistance of a sighted person and have demonstrated that they are able to understand test results correctly without exception, using the acoustic mode.

The acoustic mode should always be used with great care. Otherwise, there is a risk that the test results will be misinterpreted by the person performing the test. An incorrect insulin dose resulting from a misinterpreted test result can cause considerable health damage and can even be fatal. Especially if unexpected and abnormal blood glucose values are obtained using the acoustic mode, the test result must be checked by repeating the test together with a sighted person.

Visually impaired people should not test their blood glucose without assistance from a sighted person.

The meter must be regularly checked by a sighted person for outwardly visible contamination.

There are two types of beep tones, differing in pitch. Warnings have a higher pitch (Tone 2, represented herein as ▬) than the other beep tones (Tone 1, represented herein as ▬). The following table shows which tone sounds for which event.

Tone 1: ▬
Turning on
Test area is advanced to the tip of the cassette
Prompt to apply blood or control solution
Start of test
Announcement of the test result

Tone 2: ▬ (warning)
Signal that test results are about to be announced
Announcement of an error message
Notification that the batteries are almost empty
Notification that the cassette is empty

8.1 Beep tone when turning on

When the acoustic mode is turned on, you hear a beep (▬) when you turn the meter on.

This is irrespective of how you turn the meter on:

- By opening the tip cover (see page 33)
- Using the Power button ◙ (see page 35)
- Via the ▼ button (see page 59)

8.2 Beep tones during a test

After the power-on beep, you will hear the following beep while you test when:

- The meter advances a test area to the tip of the cassette,
- You can apply blood or control solution,
- The test begins.

You will hear the test result, which is composed of different beep tones.

You will hear several beep tones when the meter displays an error message.

8.3 Test result announcement after a test

In the acoustic mode, whenever the meter displays a test result following a blood glucose test, it also announces the test result as a series of beeps. The test result is not treated as an entity, but is broken down into individual digits.

Examples:

The test result 7.6 mmol/L is announced as
0 – 7 – decimal point – 6.

Each digit is represented by the corresponding number of beeps, e.g. 4 beeps for the number 4 (▬ ▬ ▬ ▬). Zero is represented by a long beep (▬▬▬).

Test results which are lower than 0.6 mmol/L and are displayed as LO are announced acoustically as 0 – 0 – 0 or 0 – 0 – decimal point – 0.

Test results which are higher than 33.3 mmol/L and are displayed as HI are announced acoustically as 9 – 9 – 9 or 9 – 9 – decimal point – 9.

The meaning of the symbols LO and HI is explained in Chapter 4.5 on page 39.

The test result is announced three times in succession. Each announcement is preceded by 2 short beeps (▬ ▬). Altogether, therefore, you hear:
▬ ▬ test result ▬ ▬ test result ▬ ▬ test result.

Symbols, such as  or  , which are displayed together with the test result are not announced acoustically.

If you turn the meter off using the Power button ◙ while the test result is being announced acoustically, the announcement will be interrupted and 2 short beeps will sound four times in succession (▬ ▬ ▬ ▬ ▬ ▬ ▬ ▬).

mmol/L meters: First the tens are announced, then the units followed by the decimal point and finally the tenth. There is a short pause between each group of beeps. The tens are always announced, even when the test result is below 10. The tens in this case are represented by 1 long beep, signifying zero. The decimal point is announced by a very short beep (▬).

13.8 mmol/L:
1 beep – pause – 3 beeps – pause – 1 very short beep – pause – 8 beeps
= ▬ ▬▬▬ ▪ ▬▬▬▬▬▬▬▬

4.0 mmol/L:
1 long beep (for 0 tens) – pause – 4 beeps – pause – 1 very short beep – pause – 1 long beep
= ▬▬▬ ▬▬▬▬ ▪ ▬▬▬

8.4 Announcement of saved test results

Only the last (most recent) of the saved test results is announced acoustically.

The test result is announced three times in succession. The announcement follows the same pattern as the announcement of a test result immediately after the test. You will hear:
– – test result – – test result – – test result.

If you directly retrieve saved test result using the button ▼, you will at first hear the power-on beep and immediately afterwards the test result:
▬ – – test result – – test result – – test result.

Flags are not acoustically announced (e.g. *Before meal*).

If XX.X is displayed as the last (most recent) test result, the last test did not deliver any test result (see page 60). In this case, the sounded beeps are identical to those for an error message.

There is no acoustic announcement when the last saved result is a control test flagged with , when no result is saved or when you retrieve an average.

8.5 Announcements of warnings and error messages

When the batteries will soon be empty or the test cassette has been used up, the meter issues an acoustic warning. This consists of two short beeps sounded three times in succession (- - - - - -).

The warning is given at different times.

- Batteries almost empty:
  The acoustic warning sounds after you have turned the meter on, together with the corresponding message on the display (see page 107).
- Test cassette empty:
  The acoustic warning sounds when the number of available tests is displayed as zero when turning the meter off.

If error messages appear on the display (see page 119), these are announced by two short beeps sounded four times in succession (- - - - - - - -). This sequence is sounded only once and is not repeated. The same sequence of beeps is sounded for all error messages, i.e. they are not differentiated acoustically.

9 Checking the meter

You can check whether the meter delivers correct test results. To perform this control test, a glucose control solution is applied to the test area instead of blood. At the end of the test, the meter automatically checks whether the control result obtained with glucose control solution is correct and informs you of the control result.

Always perform a control test using Accu-Chek Mobile control solutions:

- After you have inserted a new test cassette,
- After you have changed the batteries,
- After you have cleaned the cassette and the inside of the meter,
- If you are in doubt about a test result.

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

Different control solutions are sold in different countries. The control solutions have labels with different text colours (blue, red or grey).

Text colours:
Control1 = blue
Control2 = red
Control3 = grey

At the end of the control test, the meter asks you to enter the colour of the text on the control solution you have used (see page 97). The meter offers you a choice of all three colours, even if you only have one or two control solution(s) to choose from.

⚠

Visually impaired people should not perform a control test without assistance from a sighted person.

9.1 Preparing for a control test

For a control test, you need the meter with inserted test cassette and an unopened applicator with Accu-Chek Mobile control solution.

The solution in the applicators is for one-time use only.

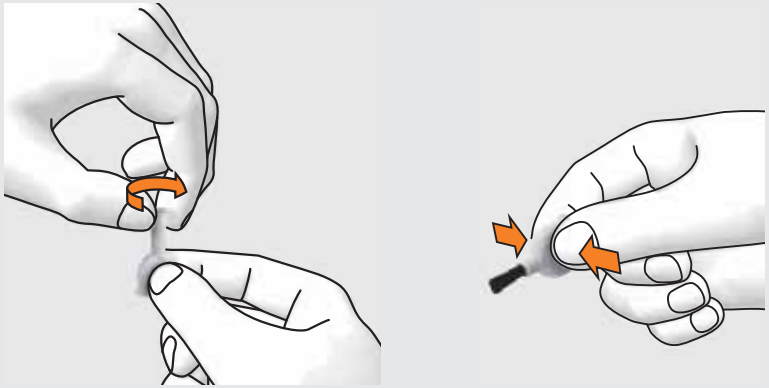
A control test in its main steps is the same as a normal test except that you apply control solution to the test area instead of blood.

Please read the package insert provided with the control solutions.

9.2 Performing a control test

Either open the tip cover or select *Test* in the *Main menu*.

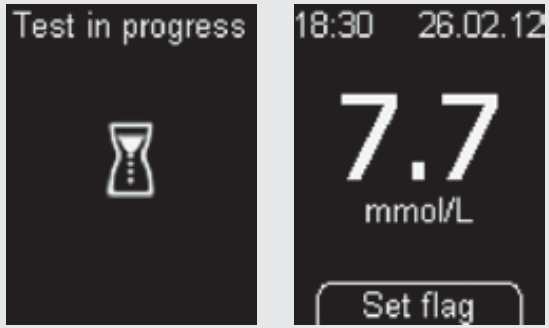
Shortly after the test area has been advanced to the tip of the cassette, the prompt *Apply drop* will appear and a beep will sound.



1. Twist the cap off the applicator.
2. Hold the applicator at a slight angle with the brush pointing downwards.
3. Squeeze the applicator gently until you see a small drop appear at the end of the brush.
4. Then stop squeezing.

Do not hold the meter with the test area pointing upwards while you apply control solution because the solution could enter the meter and soil it.

5 Apply the control solution to the centre of the test area at the tip of the cassette using the tip of the brush.



6 Take the brush away from the test area as soon as *Test in progress* appears on the display.

7 Press ◙ (*Set flag*).

The test area drew up sufficient control solution, the beep sounds and the control result is displayed.

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

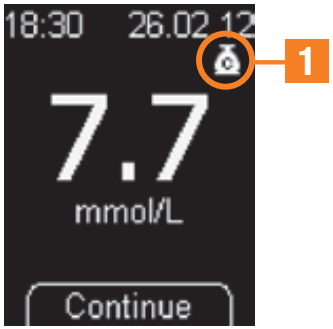
If you have set a target range and the control result obtained with control solution is outside this range, the symbols ↥ or ↧ will be displayed together with the control result. The symbols will be deleted automatically when you flag the control result as a control test.

8 Use ▼▲ to select *Control test*.

9 Press ◉.

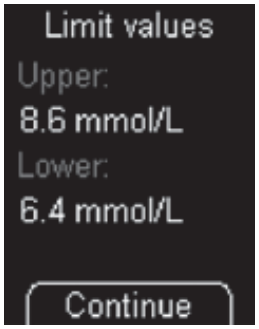
10 Use ▼▲ to select the colour of the text on the applicator label (see page 94).

11 Press ◉.



The control result flagged as 1 for *Control test* is displayed.

12 Press ◉ (*Continue*).

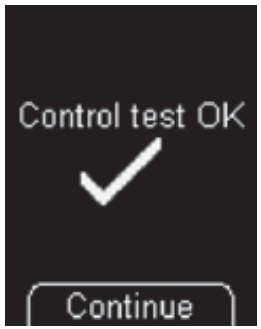


Values are only examples

The meter displays the upper and lower limits of the concentration range. The concentration range displayed depends on the colour of control solution selected.

13 Press ◉ (*Continue*).

The meter automatically checks whether the control result is within the concentration range displayed.



or

If the control result is within the concentration range displayed, *Control test OK* is displayed.

If the control result is not within the concentration range displayed, *Control test not OK Repeat control test* is displayed (see Chapter *Possible sources of error*, page 99).

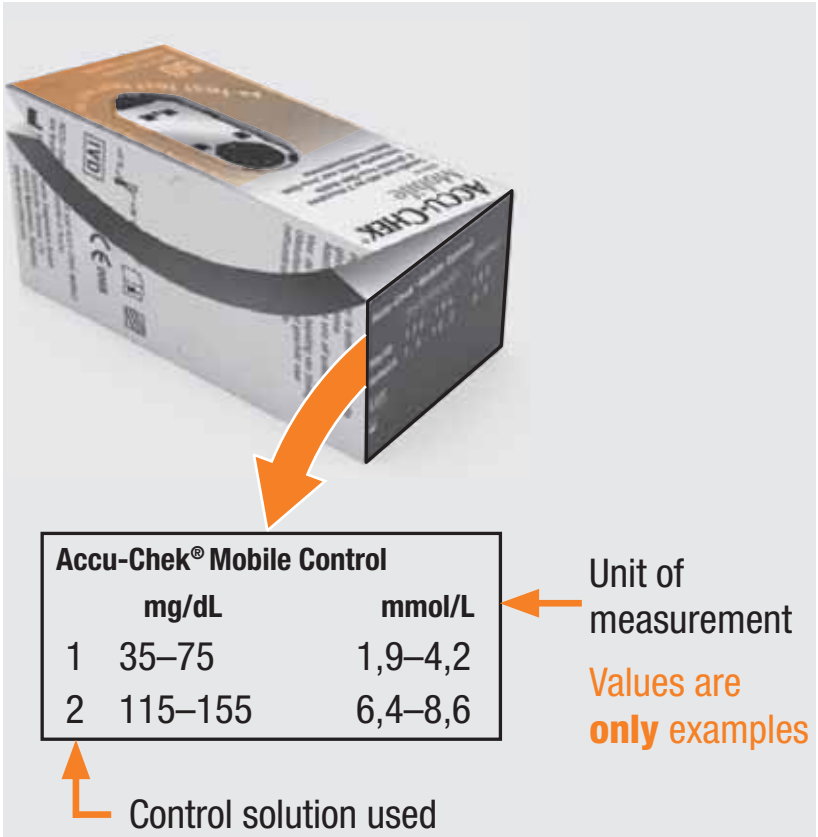
14 Press ◉ (*Continue*).

The meter returns to the Main menu.

15 Turn the meter off and close the tip cover.

16 Dispose of the applicator in your household waste.

You can also check yourself whether the control result is within the right concentration range.



To do this, compare the control result with the concentration table on the test cassette box.

The control result must be within the printed concentration range.

9.3 Possible sources of error

If *Control test not OK Repeat control test* is displayed, the control result obtained is not within the concentration range displayed. Check the points listed on the following overview. If your answer is different from the answer given, make the respective corrections and repeat the test. If you have taken all of these points into account *and Control test not OK* is still displayed, contact your customer support and service centre.

If *Control test not OK Repeat control test* is displayed, it is no longer certain that the meter and test cassette are functioning properly. Blood glucose tests may then deliver incorrect test results. Incorrect test results can cause the wrong therapy recommendation to be made and so result in serious adverse health effects.

Did you perform the control test according to the User's Manual?	yes
Did you wait for the application prompt to be displayed before applying control solution?	yes
Did you apply the control solution immediately after opening the applicator?	yes
Did you enter the correct colour?	yes
Did you test within the correct temperature range (+10 to +40 °C)?	yes
Has the use by date for the control solution been reached (see label on the bottom of the bottle next to the symbol ⌛)?	no
Did you read the section *Treating the control solutions properly* in the package insert for the control solution?	yes

Did you observe the proper storage conditions for the meter, test cassette and control solutions (see Chapter *13 Measurement and storage conditions,* page 110 and the test cassette and control solution package inserts)?	yes

If your meter has been dropped, that can also lead to control results which are not within the concentration range displayed and for which *Control test not OK* is displayed. In this case, you should also contact your customer support and service centre.

10 Menu Tools

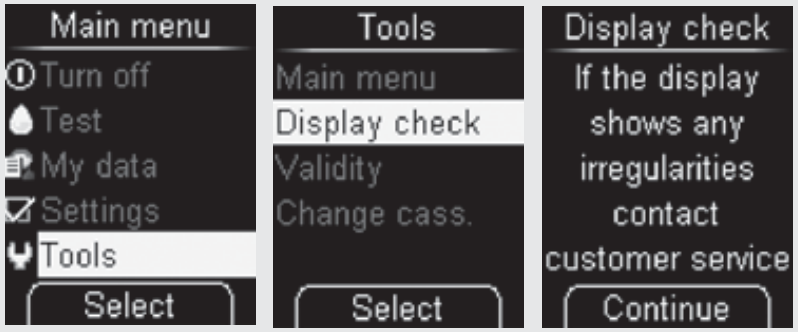
The *Tools* menu on the one hand offers you some extra means of checking the meter. On the other hand, you must also use this menu to prepare for cleaning the meter and changing a test cassette that has not been used up.

The following options are available in the *Tools* menu:

- *Display check:* Performs a separate display check
- *Validity:* Displays the validity of the test cassette
- *Change cass.:* Prepares the meter for removing a test cassette which still has unused test areas

10.1 Performing a display check

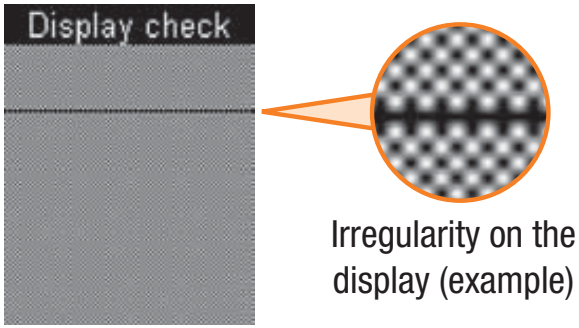
If you wish to check whether the display is working properly, you can also do this, in addition to after turning the meter on, via the display check in the *Tools* menu. In this case, the display check is displayed not only for about 2 seconds, but until you cancel it (but not longer than 1 minute).



1 Open ⇨*Tools* (symbol), ⇨*Display check*.

2 Press ◉ *(Continue)*.

The meter runs the display check in which a black and yellow checkerboard pattern of small illuminated dots is displayed.



Irregularity on the display (example)

3 Check whether there are any irregularities in the checkerboard pattern.

After pressing ◙ *(Continue)*, the meter returns to the *Tools* menu.

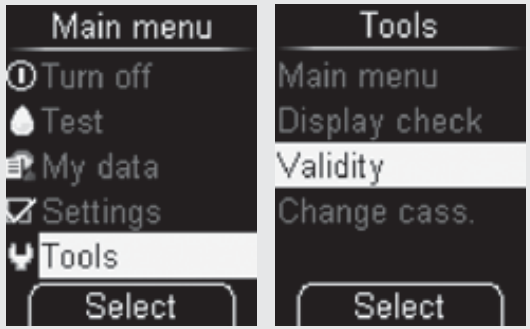
If you do not press the ◙ button, the meter displays the display check for about 1 minute. Then it displays the number of available tests and turns off automatically.

⚠

If there are irregularities in the checkerboard pattern, results might not be displayed correctly. In this case, ask your dealer to change the meter or contact your customer support and service centre.

10.2 Viewing the validity of the test cassette

You can check how long the test cassette in the meter is valid as follows:



1 Open ➪*Tools* , ➪*Validity*.

The validity is displayed.

2 Press ◙ (*Back*).

The meter returns to the *Tools* menu.

10.3 Viewing the number of available tests

With the meter off:

Press and hold ▲ until the meter turns on (longer than 2 seconds).

The number of available tests is displayed. The meter turns off again a short time later.

10.4 Replacing the test cassette

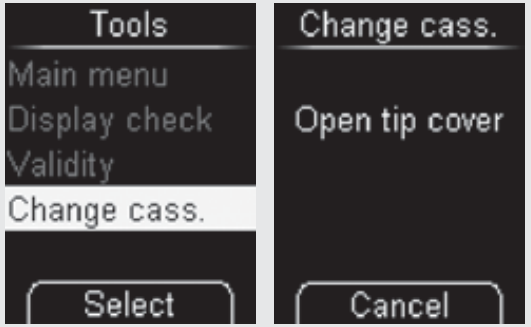
If you want to replace an empty test cassette or an expired test cassette, please continue reading in section *Replacing the cassette*.

If you want to remove a partly used test cassette which still has unused test areas, you must first perform the preliminary steps described in the section *Preparing cassette replacement*.

If you re-insert the partly used cassette into the meter and there was another cassette in the meter before this, the partly used cassette loses a test area.

Preparing cassette replacement

The preliminary steps for cassette replacement are only necessary if you want to remove a partly used test cassette which still has unused test areas:



1 Open ➪*Tools*.

2 Use ▼▲ to select *Change cass.*.

The meter now prompts you to open the tip cover. If you do not want to replace the cassette after all, you can cancel the operation with ■.

You can re-insert a partly used cassette into the meter at a later date. In the meantime, store this cassette in a dry place protected from light.

Replacing the cassette

If the cassette in the meter is empty 1 or defective 2 or has expired 3, the appropriate message or error message appears after the display check and the number of available tests (see also page 113 and page 119). Shortly after this, the meter turns off automatically.

If you have prepared for the cassette replacement via *Change cass.* the meter prompts you to replace the test cassette 4. Shortly after this, it turns off automatically.

1 Place your finger on the corrugated area on the tip cover and push it in the direction of the arrow as far as it will go.

2 Turn the meter over.

3 Push the slide button in the direction of the arrow so that the cassette compartment cover springs opens.

4 Remove the cassette from the cassette compartment.

5 Remove the new test cassette from the foil-sealed plastic container.

6 Insert the test cassette in the meter with the silver side facing upwards.

7 Close the cassette compartment cover and press it closed.

When you have closed the cassette compartment cover, the meter turns on again and first runs the display check. Afterwards the validity of the cassette and the number of available tests are displayed.

The meter then returns to the Main menu.

Used test cassettes can be disposed of in household waste.

11 Cleaning the meter and lancing device

11.1 Cleaning the meter

The mode of operation of the meter with the test cassette means that the meter will not normally come into contact with blood or control solution. Regular cleaning is therefore not necessary. In the event of the meter becoming soiled through improper use, cleaning it may become necessary.

Visually impaired people should not clean the meter without assistance from a sighted person.

Use **only** cold water or 70 % ethanol for cleaning.
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 fluid.

The outside

If the casing of the meter or the display is visibly soiled:

Wipe these with a cloth lightly moistened with cold water or 70 % ethanol.

The inside

You only need to clean the inside of the meter or test cassette when the message with the text *Cassette dirty: Clean per user's manual (E-4)* is displayed. The error message might be caused by fluff, crumbs or the like inside the tip of the cassette.

Cleaning as a result of an error message

If you are prompted to clean the meter by the message *Cassette dirty: Clean per user's manual (E-4)*, proceed as follows:

1 Press ◉ (Continue).

2 Open the tip cover all the way.

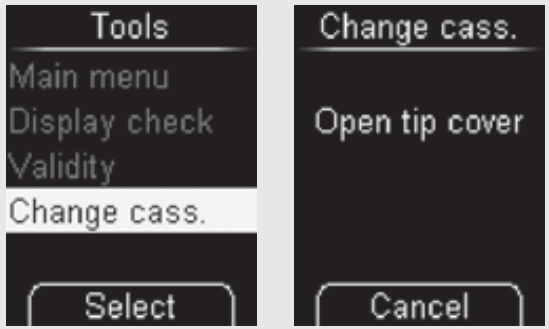
3 Follow the instructions (steps 3 to 17) for cleaning the meter in section *Cleaning procedure* (page 108-111).

ⓘ

If the error message *E-4* was displayed, a test area is lost when you later re-insert the test cassette.

Cleaning procedure

If you notice that the area around the tip of the cassette is visibly soiled and you want to clean the meter, proceed as follows:



1 Open ➪*Tools,* ➪*Change cass.*

The meter now prompts you to open the tip cover.

2 Open the tip cover all the way.

If you do not want to clean the meter now, press the ◉ button *(Cancel)*.

The meter then prompts you to remove the test cassette. About 2 seconds later, it turns off automatically.

The steps 3 to 6 that follow below are identical to the steps 2 to 5 in Chapter 10, section *Replacing the cassette*, which are accompanied by pictures (see page 98/99).

3 Turn the meter over.

4 Push the slide button for the cassette compartment cover upwards so that it springs open.

5 Open the cassette compartment cover all the way.

6 Remove the cassette from the cassette compartment.

7 Check whether you can see any fluff, crumbs or the like inside the tip of the cassette.

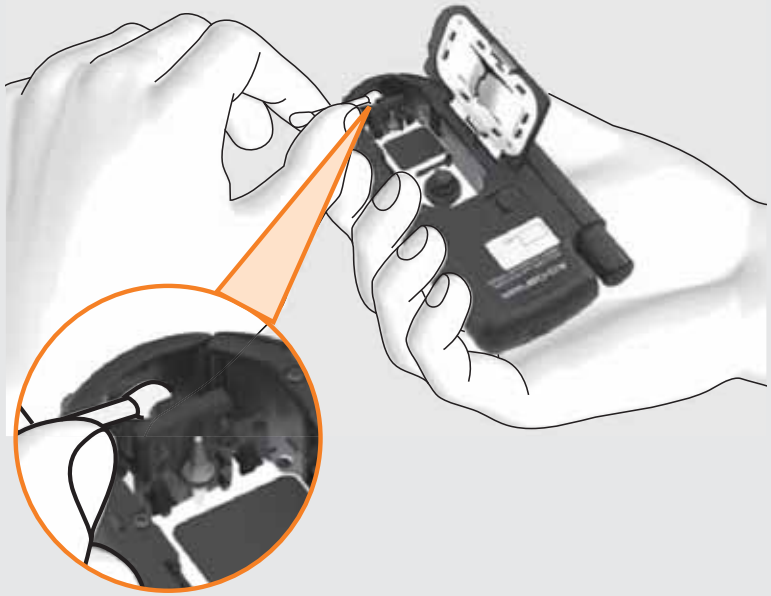
8 If so, remove these carefully.

If the measuring optics are visibly soiled, clean the inside of the meter:

Make sure that no liquid enters the meter. Avoid scratching the measuring optics.

9 Carefully wipe the measuring optics and the front opening of the meter with a lightly moistened cotton swab.

10 Leave the cassette compartment cover open and close the tip cover.



11 Carefully wipe the interior of the tip cover with a lightly moistened cotton swab.

12 Remove any fluff or lint that may remain.

13 Allow the meter time to dry thoroughly.

14 Open the tip cover again.

15 Re-insert the test cassette into the meter.

16 Close the cassette compartment cover and press it closed.

17 Close the tip cover.

11.2 Cleaning the lancing device

Clean the lancing device regularly, and when there is blood on it, to keep it working properly and prevent a potential infection risk. If you want to clean the lancing device, detach it from the meter.

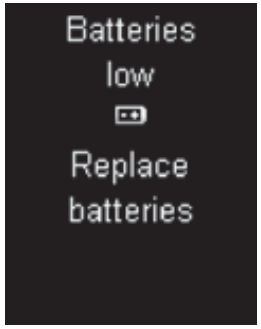
Clean the outside of the lancing device only. Wipe it once a week with a cloth moistened with 70 % ethanol or 70 % isopropanol (available from your pharmacy).

Also clean the inside of the rotatable cap and the AST cap with a moistened cotton swab.

Allow the lancing device, the rotatable cap and the AST cap time to dry thoroughly.

- Visually impaired people should not clean the lancing device without assistance from a sighted person.
- Never dip the lancing device or the AST cap in cleaning fluid.
- Use only 70 % ethanol or 70 % isopropanol as cleaning agents.

12 Changing the batteries



This message appears when the batteries are almost empty. It appears every time you turn the meter off if you have not yet changed the batteries. The first time the message appears, you can still perform about 50 tests.

Change the batteries as soon as possible.

You need 2 alkaline-manganese or high-energy batteries type AAA, LR 03, AM4 or micro (1.5 V) or 2 rechargeable NiMH batteries (type AAA). Always replace both batteries at the same time.

With a new set of batteries, you can perform approximately 500 tests or test for about 1 year.

When you use rechargeable batteries, please observe the following:

- The number of tests that can be performed per battery charge is much smaller than with regular batteries.
- When the prompt to change the batteries is displayed for the first time, considerably fewer than 50 tests can be performed; with old and used up batteries, no more test might be possible.

Results and settings remain saved in the meter while you change the batteries or if you store the meter without batteries.

The meter has an inbuilt backup battery. This provides the power when there are no batteries inserted. The backup battery has a life expectancy of about 2 years. It cannot be replaced if it is empty.

If the backup battery is empty, the meter loses the set time and date and dashes appear on the display instead of the time and date. In this case, set the time and date again.

- Visually impaired people should not change the batteries without assistance from a sighted person.
- Never throw batteries into a fire. This is dangerous, because they may explode.

- Only remove the batteries when the meter is turned off.
- Remove the batteries if you will not be using the meter for a longer period of time.

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

1 Push the battery compartment cover in the direction of the arrow as far as it will go.

2 Raise the battery compartment cover as illustrated.

3 Turn the meter so that the batteries fall downwards out of the battery compartment.

4 Insert two new batteries in the battery compartment. Ensure that the polarity (+ and –) of the batteries is correct.

5 Close the battery compartment cover again.

6 Push the battery compartment cover in the direction of the arrow as far as it will go.

13 Measurement and storage conditions

13.1 Temperature

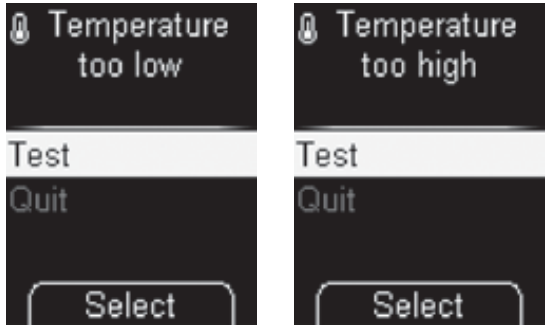
So that the meter and lancing device work reliably and you obtain accurate results, make sure that the following conditions are met.

Storage	Temperature
without batteries, without cassette	-25 to +70 °C
with batteries, without cassette	-10 to +50 °C
with batteries, with cassette	+2 to +30 °C

- At temperatures above +50 °C, the batteries could leak and damage the meter.

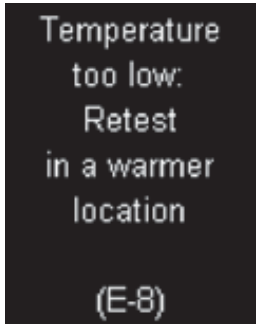
For blood glucose tests and control tests, the permitted temperature range is between +10 and +40 °C.

If the temperature is between +8 and +10 °C or between +40 and +42 °C, the meter will still allow you to perform a test. However, the following warning will appear (see also page 121).



Do not use blood glucose results obtained despite this warning as a basis for making therapeutic decisions. These test results may be incorrect. Incorrect test results can cause the wrong therapy recommendation to be made and so result in serious adverse health effects.

- Tests cannot be performed at temperatures below +8 and above +42 °C. In this event, the following error message appears:



Never try to speed up the cooling or warming of your meter, e.g. by placing it in the refrigerator or on a radiator. Doing so can damage the meter and cause it to deliver incorrect test results. Incorrect test results can cause the wrong therapy recommendation to be made and so result in serious adverse health effects.

- Never keep the lancing device at very low or high temperatures, e.g. in a hot car.

13.2 Atmospheric humidity

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

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

Sudden changes in temperature cause condensation to form in or on the meter. If this happens, do not turn the meter on. Make sure that it returns to ambient temperature slowly. Never store the meter in a room that is likely to harbour condensation (e.g. bathroom).

13.3 Light conditions

Displayed text, numbers and symbols appear yellow. Bright light shining on the display may make them difficult to read. Shield the meter if necessary, with your body, for example.

Keep the meter away from very strong light sources (e.g. direct sunlight). These may interfere with the proper functioning of the meter and lead to error messages.

13.4 Sources of interference

- Strong electromagnetic fields may interfere with the proper operation of the meter. Do not use the meter close to sources of strong electromagnetic radiation.
- To avoid electrostatic discharge, do not use the meter in a very dry environment, especially one in which synthetic materials are present.

NOTICE:
This device complies with Part 15 of the FCC Rules and with RSS-210 of Industry Canada.

Operation is subject to the following two conditions:
(1) this device may not cause harmful interference, and
(2) this device must accept any interference received, including interference that may cause undesired operation.

NOTICE:
Changes or modifications made to this equipment not expressly approved by Roche Diagnostics GmbH, Germany may void the FCC authorization to operate this equipment.

Classification with respect to U.S. telecommunication requirements (47CFR §15.105)

NOTE:
This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

Classification with respect to the Canadian telecommunication requirements

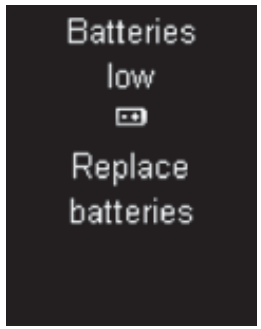
NOTICE:
This Class B digital apparatus complies with Canadian ICES-003.

14 Messages and problems

14.1 Messages

This message appears at the start of a test if the test cassette is only valid for 10 more days. The message is repeated when the test cassette is only valid for 5, 2 and 1 more day(s).

Press the ◙ button *(Continue)* to start a test.

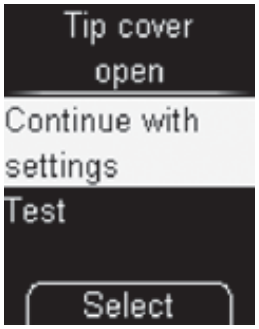


This message appears when the batteries are almost empty. It appears every time you turn the meter off and if you have not yet changed the batteries. The first time the message appears, you can still perform about 50 tests.

Change the batteries as soon as possible.

This prompt appears if you turn the meter off and the tip cover is still open.

Close the tip cover.



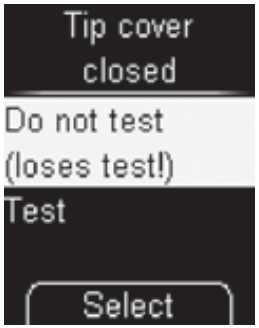
This message appears if you are in the process of changing a setting (e.g. the date) or entering a new setting (e.g. a reminder) and open the tip cover.

Close the tip cover again if you wish to continue with the setting.

or

Use ▼▲ to select whether you wish to *Continue with settings* or *Test*.

- *Continue with settings:* In this case, the meter prompts you to close the tip cover.
- *Test:* The setting procedure will be interrupted (any changes you have already made will be lost) and a test area will be advanced.



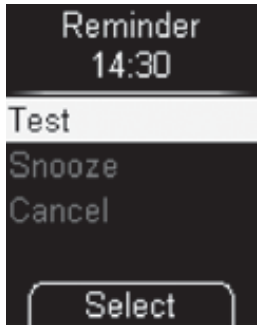
This message appears if you close the tip cover while the meter is advancing a test area.

Open the tip cover again if you wish to continue with the test.

or

Use ▼▲ to select *Do not test* or *Test*.

- *Do not test:* The meter opens the Main menu. A test area is lost.
- *Test:* The meter prompts you to open the tip cover.



If you have set reminders, this message appears at the set time.

If you want to perform a test, use ▼▲ to select *Test*.

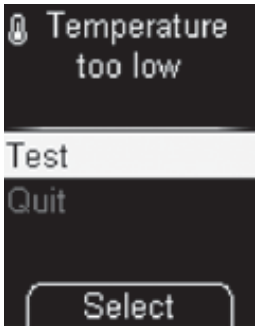
or

If you want to be reminded again in 15 minutes, use ▼▲ to select *Snooze*.

or

To delete the reminder and turn the meter off, use ▼▲ to select *Cancel*.

Then press ◉.



1

2

This message appears at the start of a test if the ambient temperature or the temperature of the meter is between +8 and +10 °C 1 or between +40 and +42 °C. 2

Use ▼▲ to select whether you wish to *Test* or *Quit*.

- *Test:* The meter advances a test area.
- *Quit:* The meter opens the Main menu. Close the tip cover.

If you decide to perform the test in spite of the warning, the test results will be flagged and saved with the symbol .

⚠

Do not use blood glucose results obtained despite this warning as a basis for making therapeutic decisions. These test results may be incorrect. Incorrect test results can cause the wrong therapy recommendation to be made and so result in serious adverse health effects. Move to a place where the temperature is between +10 and +40 °C and wait for the temperature of the meter to adjust to this temperature.

14.2 Problems

Problem/Cause of problem	Solution to the problem
The meter will not turn on.	
The batteries are empty or none are inserted.	Insert new batteries.
You have inserted the batteries the wrong way round.	Remove the batteries and re-insert them as shown in the battery compartment.
The ambient temperature is low and the batteries are almost empty.	Move to a place where the ambient temperature is between +10 and +40 °C and wait for the temperature of the meter to adjust to this temperature. Insert new batteries.
Condensation has affected the electronics.	Allow the meter time to dry slowly.
The meter is defective.	Contact your customer support and service centre.
The meter only displays dashes instead of the time and date.	
The meter has lost the time and date. You have changed the batteries or stored the meter without batteries and the built-in backup battery is empty.	Reset the time and date.

Problem/Cause of problem	Solution to the problem
The meter is turned on, but the display remains blank.	
The display is defective.	Contact your customer support and service centre.

14.3 Error messages

The following pages describe all error messages and how they can be remedied.

If an error message appears, follow the instructions on the display.

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

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

The use by period or use by date of the test cassette is exeeded.

Insert a new test cassette in the meter.

This message appears if you start a test and all test areas in the test cassette have been used.

Insert a new test cassette in the meter.

Remove the test cassette from the meter and re-insert it.

or

Insert a new test cassette in the meter.

Insert a test cassette suitable for this meter type.

There is no test cassette in the meter.

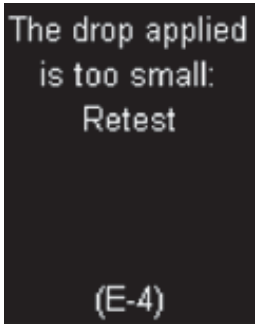
Insert a new test cassette in the meter.

- Your blood glucose value may be very low.

If the way you feel agrees with a very low blood glucose value, immediately follow the relevant instructions given by your healthcare professional. Repeat the test afterwards.

- A meter error has occurred.

If the error message is still displayed after turning the meter on again, please contact your customer support and service centre.



The test area has drawn up too little blood or control solution.

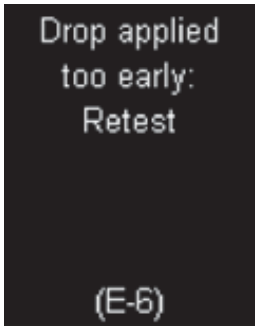
Repeat the test with a larger amount of blood or control solution.

Remove the dirt from the inside of the cassette tip.

Press ◉ (*Continue*) if you want to go directly to the *Clean* menu.

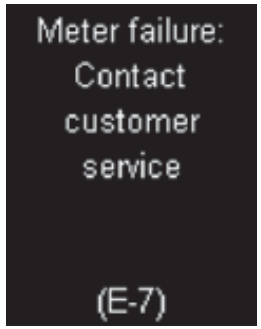
Move into the shade or shield the meter with your body, for example.

Repeat the test.



Do not apply blood or control solution to the test area until the prompt *Apply drop* is displayed.

Repeat the test.



If the error message is displayed after turning the meter on again:

Contact your customer support and service centre.

Move to a place where the ambient temperature is at least +10 °C and wait for the temperature of the meter to adjust to this temperature.

Move to a place where the ambient temperature is not higher than +40 °C and wait for the temperature of the meter to adjust to this temperature.

Batteries drained: Replace batteries (E-9)	Insert two new batteries.

15 Disposing of the meter

During blood glucose testing, the meter may come into contact with blood. Therefore used meters carry a risk of infection. Please dispose of your used meter, after removing the batteries, according to the regulations applicable in 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).

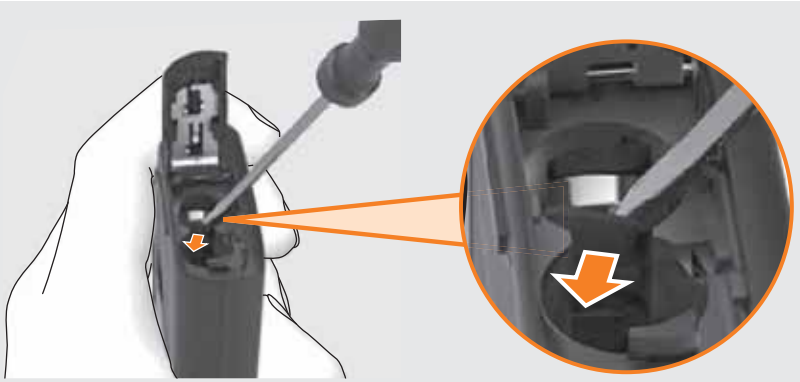
Please dispose of the batteries in an environmentally friendly way at a collection depot or through your dealer.

Used test cassettes can be disposed of in household waste.

Removing the backup battery

Apart from the two batteries in the battery compartment, there is also a third battery in the side of the battery compartment, the backup battery. You must also remove this battery before disposing of the meter.

Remove the backup battery as follows:



1 Use a small screwdriver to break out the partition wall in front of the battery.

The battery then drops into the battery compartment.

2 Turn the meter over so that the backup battery falls out.

16 Technical data

Meter type	Accu-Chek Mobile, Model U1
Catalogue no./ serial no.	See type plate on the back of the meter
Test principle	Determination of glucose in fresh capillary blood by reflectance photometry. When using different specimen material, please refer to the package insert that came with the Accu-Chek Mobile test cassette. Although you always apply whole blood to the test area, 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 Mobile test cassette package insert.
Measuring range	See the Accu-Chek Mobile test cassette package insert
Sample size	See the Accu-Chek Mobile test cassette package insert
Measuring time	See the Accu-Chek Mobile test cassette package insert
Power supply	2 alkaline-manganese or high energy batteries (1.5 V, type AAA, LR 03, AM 4 or micro), backup battery: 3V lithium button cell type CR1025
Battery life	Approximately 500 tests or approximately 1 year (less if the brightness of the display is set to level 3 or the volume is set to level 4 or 5 or in acoustic mode due to the higher power consumption)

Automatic power-off	After 1 or 2 minute(s), depending on the operating status
Temperature	
During testing	See the Accu-Chek Mobile test cassette package insert
During storage	Meter without batteries and without test cassette: -25 to +70 °C Meter with batteries and without test cassette: -10 to +50 °C Meter with batteries and with test cassette: +2 to +30 °C
Humidity	
During testing	See the Accu-Chek Mobile test cassette package insert
During storage	See the Accu-Chek Mobile test cassette package insert
Altitude	Sea level to 4000 m
Memory	2000 results with time and date, averages for 7, 14, 30 and 90 days
Dimensions	121 × 63 × 20 mm with lancing device
Weight	Approx. 129 g with lancing device, batteries, test cassette and lancet drum
Display	OLED (Organic Light Emitting Diode) display
Interface	USB (Micro B)

Electromagnetic compatibility	This instrument meets the electromagnetic immunity requirements according to EN ISO 15197 Annex A. The chosen basis for the immunity tests (on electrostatic discharge) was basic standard IEC 61000-4-2. In addition, the instrument meets the electromagnetic emissions requirements according to EN 61326. Its electromagnetic emission is thus low. Interference on other electrically-driven equipment is not anticipated.
Performance evaluation	The performance data for the Accu-Chek Mobile system (Accu-Chek Mobile meter with Accu-Chek Mobile test cassette) were determined using capillary blood from patients with diabetes (method comparison, accuracy), venous blood (repeatability) and control solutions (reproducibility). The system is calibrated with venous blood containing various levels of glucose. The reference values are obtained using the hexokinase method. The reference method is traceable to a NIST standard using the ID-GCMS method, which is the method of the highest metrological quality. The method comparison was conducted by comparing the results from the system with those of the hexokinase method with deproteinization using an automatic analyzer.

The Accu-Chek Mobile blood glucose monitoring system complies with the requirements of EN ISO 15197.

Roche Diagnostics hereby declares that the Accu-Chek Mobile blood glucose meter conforms with the basic requirements and other relevant regulations of the European Directive 1999/5/EC. The conformity declaration may be found at the following Internet address:
http://mobile.accu-chek.com.

17 System components

Accu-Chek Mobile meter (Model U1):

Accu-Chek Mobile test cassettes

Use only these test cassettes when you test blood glucose using the Accu-Chek Mobile meter.

Accu-Chek Mobile control solutions

Use only these control solutions when you perform control tests using the Accu-Chek Mobile meter and the respective test cassette.

Accu-Chek FastClix M1 lancing device:

Accu-Chek FastClix lancet drums

Use only these lancet drums when you obtain blood with the Accu-Chek FastClix M1 lancing device.

Accu-Chek FastClix M1 AST cap

Use only this AST cap when you obtain blood from alternate sites with the Accu-Chek FastClix M1 lancing device.

If you want to order the Accu-Chek FastClix M1 AST cap, please contact your customer support and service centre (see section “Customer support and service centre”).

18 Customer support and service centre

18.1 Advice and troubleshooting

If you need advice on how to operate the Accu-Chek Mobile meter or the Accu-Chek FastClix lancing device, if you seem to be obtaining implausible test results, or if you suspect that the meter, test cassette, lancing device or lancet drum might be defective, please contact your local Roche Diagnostics customer service. Do not attempt to repair or modify the meter or lancing device yourself. Our staff will help solve any problems you might be experiencing with the meter, test cassette, lancing device or lancet drum from Roche Diagnostics. The addresses of the customer support and service centres are listed in the next section.

18.2 Addresses

Roche Diagnostics
201 Armand-Frappier Blvd.
Laval, Quebec H7V 4A2, **Canada**
Accu-Chek Customer Care: 1-800-363-7949
www.accu-chek.ca

19 Index

20 Explanation of symbols

On the packaging, on the type plate of the meter and on the lancing device, you may encounter the symbols shown below. They have the following meanings:

	Consult instructions for use
	Caution (refer to accompanying documents)! Refer to safety-related notes in the instructions for use accompanying this instrument.
	Temperature limitation (Store at)
	Use by
	Use only once
	Sterilised using irradiation
	Manufacturer
	Catalogue number
	Batch code
	In vitro diagnostic medical device

	Blood glucose meter: This product fulfils the requirements of the European Directive 98/79/EC on in vitro diagnostic medical devices.
	Blood glucose meter: This product fulfils the requirements of the European Directive 1999/5/EC on radio and telecommunications terminal equipment (R&TTE).
	Lancing device and lancet drum: These products fulfil the requirements of the European Directive 93/42/EEC on medical devices.
	AST cap: This product fulfils the requirements of the European Directive 93/42/EEC on medical devices.

FC	This device complies with Part 15 of the FCC Rules and with RSS-210 of Industry Canada.
N20091	The compliance mark indicates that the product complies with the applicable standard and establishes a traceable link between the equipment and the manufacturer, importer or their agent responsible for compliance and for placing it on the Australian and New Zealand market.

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

21 Appendix

Low blood glucose index or High blood glucose index

These figures represent the frequency and the resulting risk of blood glucose values being too low or too high. Figures should be as low as possible.

The following table provides an overview to assess the risk of blood glucose values being too low or too high:

Risk	Low blood glucose index	High blood glucose index
minimal	≤1.1	≤5.0
low	1.1–2.5	5.0–10.0
medium	2.5–5.0	10.0–15.0
high	>5.0	>15.0

The index values for Low BG or High BG in the table are not blood glucose values. Ask your healthcare professional, if you want to change your therapy based on the index values.

Literary references

Low BG index / high BG index

Boris P. Kovatchev, Martin Straume, Daniel J. Cox, Leon S. Farhy (2001)
'Risk analysis of blood glucose data: a quantitative approach to optimizing the control of insulin dependent diabetes.'
Journal of Theoretical Medicine, **3**: pp 1-10.

Boris P. Kovatchev, Daniel J. Cox, Anand Kumar, Linda Gonder-Frederick, William L. Clarke. (2003)
'Algorithmic Evaluation of Metabolic Control and Risk of Severe Hypoglycemia in Type 1 and Type 2 Diabetes Using Self-Monitoring Blood Glucose Data'
Diabetes Technology & Therapeutics, **5**(5): pp 817-828

Boris P. Kovatchev (2006)
'Is Glycemic Variability Important to Assessing Antidiabetes Therapies?'
Current Diabetes Reports, **6**: pp 350-356

ACCU-CHEK® 360° reports License

By using this software, you, or the entity on whose behalf you are using the software (here in after "Licensee") agree to be legally bound to the following provisions.

1 License

1.1 Roche Diagnostics GmbH, Sandhofer Strasse 116, 68305 Mannheim, Germany ("Roche Diagnostics") grants to Licensee, a non-exclusive, perpetual and worldwide license to use the ACCU-CHEK 360° reports software, here in after referred to as SOFTWARE, upon the terms and conditions contained in this Software License Agreement.

1.2 Licensee may use the SOFTWARE on all computer systems owned, leased or otherwise controlled by Licensee. Licensee may use the SOFTWARE only to manage the ACCU-CHEK 360° reports.

1.3 Due to Roche Diagnostics being obliged to commit market observations, Licensee shall notify Roche Diagnostics of name and address of the receiving party in case of any transfer of the SOFTWARE product and shall oblige the receiving party to enter into an equivalent agreement with Roche Diagnostics.

1.4 Except as expressly permitted by Swiss law, Licensee may not: Copy the SOFTWARE in whole or in part except as expressly provided in this Software License Agreement or for purposes of backup; rent, license or sublicense the SOFTWARE; create derivative works based on SOFTWARE; modify, adapt, translate, reverse engineer, decompile or disassemble the SOFTWARE, separate the SOFTWARE into its component parts, or in any way reverse engineer or attempt to reconstruct or discover any source code or algorithms of the SOFTWARE by any means whatsoever unless and until Licensee has first requested the required information from Roche Diagnostics in writing, and Roche Diagnostics, at its sole discretion, has not complied with Licensee's request within a commercially reasonable period of time; remove any product identification, trademark, copyright, confidentiality, proprietary or other notices contained on or within the SOFTWARE.

1.5 If Licensee is an entity, then License shall cause Licensee's employees, if any, to comply with the terms and conditions of the Software License Agreement.

1.6 Licensee shall cooperate with Roche Diagnostics, and shall render all reasonable assistance requested by Roche Diagnostics, to assist Roche

Diagnostics in preventing and identifying any use of, or access to, the SOFTWARE in violation of the Software License Agreement.

1.7 Licensee acknowledges and agrees to the terms and conditions of any open source software license contained in or referred to in the software including relevant copyright notices.

2 Proprietary Rights

All right, title and interest including, but not limited to, copyright, trademarks and other intellectual property rights in and to the SOFTWARE are owned by Roche Diagnostics and its licensors, if any. Such rights are protected by the Urheberrechtsgesetz (URG), Markenschutzgesetz (MSchG) and other laws. Roche Diagnostics retains all rights not expressly granted herein.

3 Warranty

3.1 Roche Diagnostics warrants that the SOFTWARE licensed under this Software License Agreement will substantially provide the key functions described in its product specification in effect on the date of conclusion of this Software License Agreement and that the SOFTWARE will be free of defects for a period of one year from shipment.

3.2 During the warranty period Roche Diagnostics shall, at Roche Diagnostics' sole discretion correct errors detected in licensed software or provide a reasonable workaround SOFTWARE, after receiving notification from Licensee of such errors. Error corrections will if technically possible be provided by way of a patch or update to the SOFTWARE. The warranties set out herein are exclusive of and in lieu of all other conditions and warranties, either express or implied, statutory or otherwise. Notwithstanding this, Roche Diagnostics may from time to time provide proactively updates (including service releases).

3.3 This warranty is void if failure is the result of accident, abuse, misuse, alteration, use with unauthorized software or hardware or not having installed latest updates of the SOFTWARE provided by Roche Diagnostics according to Sec. 3.2.

4 Limitation of Liability

4.1 Irrespective of the cause of action, Roche Diagnostics liability shall be limited to damages caused by Roche Diagnostics, its employees or subcontractors due to wilful misconduct, gross negligence or, in case of a violation of an essential contractual duty, simple negligence.

4.2 If Roche Diagnostics is held liable for simple negligence under Section 4.1, Roche Diagnostics' liability shall be limited to those typical damages

that were reasonably foreseeable at the time the Agreement was concluded or, at the latest at the time of the violation of the relevant contractual duty.

4.3 Roche Diagnostics' liability for any damages caused by the breach of a specific warranty (Garantie) or for damages to be compensated under the Product Liability Act and for damages due to loss of life, injury or prejudice to health remains unaffected.

4.4 The Licensee is obliged to carry out regular backups. In case of any loss of data Roche Diagnostics is only liable for the costs to restore such backups.

5 Miscellaneous

5.1 Changes to this Software License Agreement require written form to be effective. This also applies for any amendment or rescinding of this written form clause.

5.2 This Software License Agreement is subject to Swiss law, to the exclusion of the UN Convention on the International Sale of Goods as well as to the exclusion of the regulations of international civil law that are alterable subject to mutual agreement.

5.3 For disputes arising from or in connection with this contract, the courts of Basel, Switzerland have jurisdiction internationally and locally.

5.4 Should individual clauses of the Software License Agreement be ineffective, the effectiveness of the contract remains unaffected otherwise. Ineffective clauses shall be replaced by the legal regulation.

CE 0088

ACCU-CHEK, ACCU-CHEK MOBILE and FASTCLIX
are trademarks of Roche.

Roche Diagnostics GmbH
Sandhofer Strasse 116
68305 Mannheim, Germany
www.accu-chek.com

06597025001(01) – 2011-11 M_Version01_Rev04