User's Manual and Quick Start Guide

Blood Glucose Monitoring System



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/!\ IMPORTANT INFORMATION FOR PERFORMING A BLOOD GLUCOSE TEST

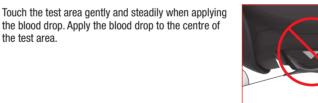
An incorrectly performed blood glucose test may lead to incorrect test results which can cause the wrong therapy recommendation to be made and thus produce serious adverse health effects. Therefore, follow these instructions carefully to perform a blood glucose test correctly.

Wash your hands with warm water and soap and

rinse well. Drv vour hands thoroughly with a clean towel before obtaining blood.



Always use a small, fresh and well-formed blood



or spread blood drop. Do **not** smear the blood drop on the test area.

Do not

Do **not** perform a blood

are unwashed, soiled or

food or drink residue).

Do **not** perform a blood

glucose test with a smeared

alucose test if your fingers

sticky (for example, due to

Do **not** press the test area and the finger together. Avoid trembling or shaky movements.



Do **not** wait before applying

An incorrectly performed blood glucose test may lead to falsely elevated blood glucose results and thereby delivery of an inappropriately high insulin amount. Falsely elevated test results are caused by the

- Fingers are unwashed, soiled or sticky.
- If the blood drop spreads on the finger or if the blood drop becomes smeared on the test area, the risk of contamination of the test area increases (for example, due to food or drink residue on the finger).
- The test area is pressed against the finger.

test result.

- Trembling or shaky movements during the blood alucose test.
- The blood glucose test is not performed immediately or the finger stays on the test area for too long. Pay attention to the beep tone. The beep tone helps you to obtain a reliable

6 Rotatable cap for setting 12 Tip cover

7 Tip cover, closed (below right: open)

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Quick Start Guide

Start Here



1 Release button (priming 8 Test area (at the tip of the and pricking)

Power and enter button

3 Down/Up buttons Window showing number

5 Lever for loading a new

the penetration depth 13 Test cassette

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cassette ready for a test)

9 Lancet drum

Slide button to release the finger pricker

 Slide button to open the cassette compartment

monitoring by an individual person only. They must not be used to

■ The Accu-Chek Mobile

meter and Accu-Chek

FastClix finger pricker are

intended for patient self-

test blood glucose from more than one person as they do not incorporate any features to quard against cross-infection. The meter and the finger pricker are not to be shared between family members or used by healthcare professionals to obtain blood or test blood glucose from more than one

not replace the detailed User's Manual for your Accu-Chek Mobile blood alucose monitorina system. Be sure to comply with the safety information in the User's Manual and in the package insert of the test

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the test area.

Apply the blood drop to the test area immediately after you have obtained the blood drop. Remove your finger from the test area when the beep tone sounds and *Test in progress* is displayed. **Note:** You can only hear the beep tones when they are turned on. See Setting tones in the User's Manual.

the blood drop to the test area. Do **not** continue to hold your finger on the test area after the beep tone sounds and *Test in progress* is

1. Starting to use the blood glucose monitoring system

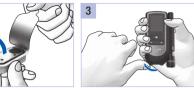


Open the test cassette box at the perforation. Take out the from the plastic container. plastic container.



Remove the new test cassette Open the tip cover.







2. Preparing the finger pricker

Remove the cap from the finger Insert the new lancet drum. pricker.



white end first.



Do **not** remove the lancet drum until all 6 lancets have been

damage the cap and finger

pricker. Instead, correct the

position of the lancet drum.

3. Performing a blood glucose test

Before you perform a blood alucose test: Observe the important instructions on performing a blood glucose test.



Wash your hands with warm

Dry your hands thoroughly with



water and soap and rinse well. a clean towel before you obtain

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Australia

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Customer Support and Service Centre

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Accu-Chek ExtraCare line: 6272 9200

Pump Support: 1800 633 457

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cassette compartment cover meter. Press the cassette upwards in the direction of the compartment cover closed.



Insert the test cassette in the Close the tip cover.



Pull the protective strip of the batteries backwards out of the meter. Remove the protective film from the display.



The lancet drum is properly inserted when it is completely inside the finger pricker and only the front edge protrudes.



Place the cap back on again. The cap is on correctly when it is pushed back as far as it will go, and you hear and feel it click into place.



Open the tip cover.



against the selected puncture way down.



Press the finger pricker firmly Press the release button all the

Press of for about 2 seconds until the meter turns on.



(highlighted in yellow).

Press .



Rotate the cap until the desired Loading a new lancet: Prepare penetration depth lines up with the finger pricker for obtaining the indicator.

Tip: When obtaining blood, start Push the lever 1 in direction A with a medium penetration



depth, such as 3.



blood again.

and then back again in direction B.



Touch the centre of the test area gently and steadily with the blood drop.



Take your finger away from the Testing is complete after



test area as soon as *Test in* approximately 5 seconds. Read progress appears on the screen. the test result and close the tip

Last update: 2015-02



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User's Manual

Blood Glucose Monitoring System



These instructions for use feature the following 3 symbols:



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 finger pricker.



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 years. There is a risk of suffocation if small parts (e.g. covers, caps or similar objects) are swallowed.

Last update: 2015-02

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 Accu-Chek Mobile meter and Accu-Chek FastClix finger pricker are intended for patient self-monitoring by an individual person only.

They must not be used to test blood glucose from more than one person as they do not incorporate any features to guard against cross-infection. The meter and the finger pricker are not to be shared between family members or used by healthcare professionals to obtain blood or test blood glucose from more than one person. This meter and finger pricker are therefore not suitable for professional use in healthcare facilities and institutions.

 Visually impaired people must be assisted by a sighted person when performing a blood glucose test.

Accu-Chek FastClix finger pricker

Finger pricker with adjustable penetration depth for obtaining capillary blood from the fingertip with Accu-Chek FastClix lancet drums and, when a special AST cap is used, also from alternative sites (AST = alternative site testing), such as the palm.



The Accu-Chek FastClix finger pricker is intended for personal use only!

It may only be used by **one and the same** person for obtaining blood.

There is a risk of infections being transmitted if the finger pricker is used by other people, even by family members, or if healthcare professionals use this finger pricker to obtain blood from different people. This finger pricker is therefore not suitable for professional use in healthcare facilities and institutions.

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The major features

- Test cassette instead of test strips
 50 test areas on a continuous tape
- Test
 Test starts by opening the tip cover
- Measuring time
 About 5 seconds for a test, depending on the blood glucose concentration
- Docked finger pricker
 Use the finger pricker in its docked or undocked state
- Finger pricker with lancet supply 6 sterile lancets in a lancet drum

Automatic coding

- Meter is automatically coded

 Control over amount of blood
 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 7 reminders and 4 test reminders
- Target range for test results
 Personal target range for blood glucose values
- Flagging of results
 Flagging results with symbols
- Memory 2,000 memory locations available
- Data analysis on a PC
 Display and analysis of data on a PC
- Data transfer
 USB port for data transfer
- Error messages
 Displays an error code and a message

About this User's Manual

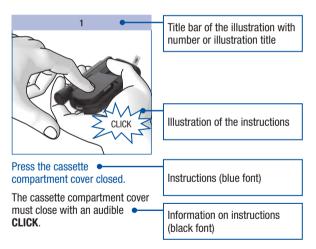
Read this User's Manual carefully and completely before testing blood glucose for the first time. If you have any questions, contact the customer support and service centre (see page 134).

These instructions for use provide you with the information you need to operate and care for your meter and finger pricker, and for troubleshooting. Be sure to operate the meter and the finger pricker correctly as well as to observe the operating instructions.

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

You can only hear the beep tones of the meter when they are turned on and the volume level is not set to 1 (Mute). This User's Manual presumes that the beep tones are turned on (see Setting tones page 49).

All instructions appear as shown in the example below.



Getting to know your meter and finger pricker

Overview of meter





Getting to know your meter and finger pricker

- Battery door (above right: open)
- 2 Batteries (see page 114 and page 130 for information on possible battery types)
- 3 Display
- 4 Finger pricker (docked)
- 6 Power and enter button
- 6 Down/Up buttons
- 7 Tip cover, closed (below right: open)
- Test area (at the tip of the cassette, ready for a test)

- USB port interface to be used for data analysis on a computer (below left: open USB port)
- Type plate
- Slide button to release the finger pricker
- Slide button to open the cassette compartment cover
- Cassette compartment cover (below right: open)
- Test cassette (in place in the meter)

Overview of finger pricker



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

Using the buttons and menus

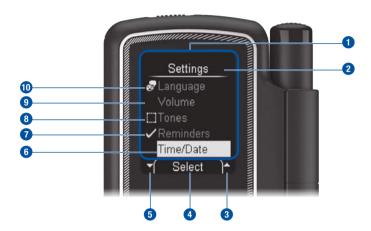
This chapter tells you how to use the buttons to operate the meter and navigate through the menus, how the menus are structured and what the different symbols in them mean.

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 on the screen above the button (press and release the button only) Example: The Select command selects the option highlighted in the menu. |
| | Down button | - | This button 1 allows you to: Navigate down in a menu or list Decrease numerical values |
| 2 | Up button | • | This button ② allows you to: • Navigate up in a menu or list • Increase numerical values |



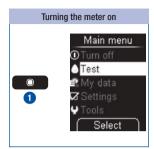
Menu structure of the meter



- Menu
- 2 Title of a screen or menu (for example, Settings)
- The symbol means that there are more options listed above the first visible option.
- The command displayed here (for example, Select) will be executed when you press the
 ■ button. The command that is shown depends on the current screen.
- The symbol means that there are more options listed below the last visible option.
- A selected option is highlighted with a yellow bar. If you press the ● button, this option will be selected.

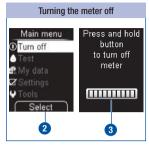
- 7 The **v** symbol indicates that the function (for example, *Reminders*) is on.
- 3 The symbol indicates that the function (for example, *Tones*) is off.
- Unselected option in the menu.
- The options in the main menu and the Language option in the Settings menu have a symbol on their left-hand side to identify the menu item should the language accidentally change to one that you do not understand for Language for example).

Operation



Pressing and holding 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.

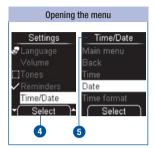


Select 2 (press and release the button) selects the highlighted Turn off command $((\bar{1}))$.

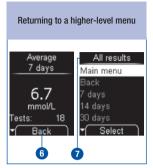
0r

Press and hold the button until all bars on the screen are filled (approx. 2 seconds) 3.

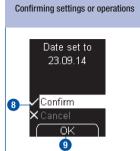
The meter turns off after displaying the number of tests still available.



Select (1) (press and release the button) selects the highlighted Time/Date option from the Settings menu. The Time/Date menu opens (5).



Back (5) (press and release the (5) button) opens the higher-level menu (7) of the currently displayed menu.

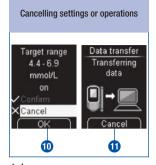


Confirm (√) 3 is highlighted.

OK (3) (press and release the

■ button) confirms the setting

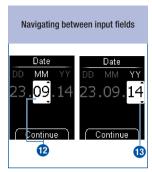
vou made.



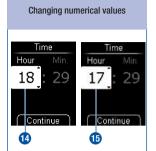
(X) *Cancel* is highlighted.

OK (1) (press and release the button) cancels the setting you made.

Cancel (1) (press and release the button) cancels the operation (data transfer).



Continue (press and release the button) switches from month 12 to year 13.



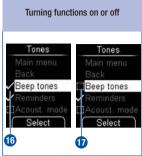
Pressing the **b**utton **1**increases the numerical value.

Pressing the

→ button

to decreases the numerical value.

Pressing the button once increases or decreases the number by 1. If you press and hold the button, the number continues to count until you release the button.



A tick **f** in front of an option means that the function is on.

A checkbox in front of an option means that the function is off.

Select (press and release the button) sets (= on) or removes (= off) the tick.



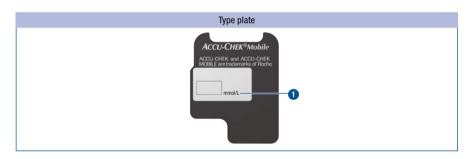
Steps before testing

Checking the unit of measurement

Blood glucose results can be displayed in two different units of measurement (mg/dL or mmol/L). Consequently, there are two different versions of the same meter. Check that your meter displays the unit of measurement you are accustomed to. You can find the unit of measurement 1 that your meter displays on the type plate on the back of your meter. If you do not know which unit of measurement is correct for you, ask your healthcare professional.



The unit of measurement that your meter displays cannot be changed. If the wrong unit of measurement is printed on the type plate, contact the customer support and service centre (see page 134). Using the wrong unit of measurement may cause misinterpretation of your test results and can cause the wrong therapy recommendation to be made, and thus produce serious adverse health effects.



Inserting the first test cassette

Before using your new 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.



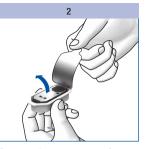
- Read the test cassette package insert. It contains further important information, for example, on storage and possible causes of incorrect test results.
- If the plastic container or the foil cover of the test cassette is damaged, you must not use the test
 cassette. Otherwise, there is a risk that you might obtain incorrect test results. Incorrect test results
 can cause the wrong therapy recommendation to be made and thus produce serious adverse health
 effects.
- Only open the plastic container when you want to insert the test cassette in the meter. The unopened
 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 (see page 98). If you want 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. Note that the table only applies to test cassettes in this box. For test cassettes from other boxes, other tables apply.



Open the test cassette box at the perforation. Take out the plastic container.



Remove the test cassette from the plastic container.



Open the tip cover.

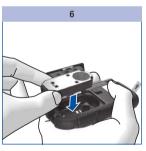


Turn the meter over so that the back is facing upwards.



Push the slide button for the cassette compartment cover upwards in the direction of the arrow.

The cassette compartment cover opens.



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



Close the cassette compartment cover.



Press the cassette compartment cover closed.



Close the tip cover.

The cassette compartment cover must close with an audible **CLICK**.



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: The period in which the test cassette must be used up after the foil cover of the plastic container was opened. The use by period in days is printed on the box and in the package insert of the test cassette next to the ≤ symbol.

Use by date: Date until which a test cassette sealed in the plastic container is valid. The use by date is shown on the box of the test cassette or foil cover next to the symbol \supseteq .

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 test cassette will soon expire or has already expired, a message appears to inform you.

The first message appears 10 days before the validity expires, the others follow 5, 2 and 1 day(s) before expiry (see *Error messages* page 124).

If the validity of the test cassette has expired, a message appears (see Error messages page 124).

Removing protective film and strip

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



Remove the protective film from the display.



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

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 language.



Use **▼** ▲ to select a language.

Press
to select the desired language.

The meter displays the language you have selected.



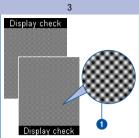
Press • to confirm the selected language.

The meter then runs a display check.



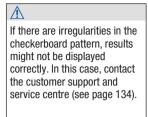
change this setting later (see *Making settings* page 47).
The *Language* menu is marked with the symbol

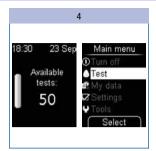




Check if there are any irregularities in the checkerboard pattern (see *Performing a display check* page 101).

The meter automatically exits the display check after about 2 seconds





The meter displays the number of tests in the test cassette that are still available.

Afterwards the main menu is shown.

Now you can decide what you want to do (for example, turn the meter off, perform a blood glucose test or make settings).

Preparing the finger pricker

You can use the finger pricker to obtain blood from a fingertip. You can set the penetration depth to 11 different levels to suit the individual texture of your skin.

You insert a new lancet drum with 6 sterile lancets into the finger pricker. You can obtain blood with a sterile lancet 6 times before the lancet drum needs changing.

You can use the finger pricker either docked on to the meter or separately from the meter.

You can also use the finger pricker to obtain blood from other (alternative) sites. For this purpose, you need a special AST cap, which enables you to obtain capillary blood from alternative sites.

If you would like to order an AST cap, contact the customer support and service centre (see page 134).



- The Accu-Chek Mobile meter and Accu-Chek FastClix finger pricker are intended for patient self-monitoring by an individual person only.
 - They must not be used to test blood glucose from more than one person as they do not incorporate any features to guard against cross-infection. The meter and the finger pricker are not to be shared between family members or used by healthcare professionals to obtain blood or test blood glucose from more than one person. This meter and finger pricker are therefore not suitable for professional use in healthcare facilities and institutions.
- Wear and tear of the materials can lead to malfunction of the device. In extreme cases a lancet can
 protrude from the cap so that injury cannot be completely ruled out. You should therefore handle the
 finger pricker with particular care once a lancet drum has been inserted.



- Only use the Accu-Chek FastClix finger pricker with Accu-Chek FastClix lancet drums. Using any
 other lancets or lancet drums may severely damage the finger pricker or impair its function.
- A used Accu-Chek FastClix lancet drum has a built-in locking mechanism. You cannot reinsert a lancet drum that has already been removed. Used lancet drums must not be reused.



Take a new lancet drum 1.

You can recognise used lancet drums by the red stripe 2.



Remove the cap from the finger pricker.



You must not insert the lancet drum into the finger pricker and simultaneously press the release button or hold the finger pricker with the release button resting on a surface such as a table top. This could release a lancet and inadvertently cause injury.



Insert the new lancet drum, white end first.

The lancet drum is properly inserted when it is completely inside the finger pricker and only the front edge protrudes.



Place the cap back on again.

The cap is on correctly when it is pushed back as far as it will go, and you hear and feel it click into place.



The cap can only be easily placed on up to the stop position when the lancet drum is completely inside the finger pricker. Do not use force to push the cap on. This could damage the cap and finger pricker. Instead, correct the position of the lancet drum.

Setting the penetration depth

You can set the penetration depth of the lancet to 11 different levels. The levels are divided into 6 half-settings and 5 whole settings (0.5–5.5, 0.5 is the lowest, 5.5 is the highest). Set the penetration depth suitable for you. This allows virtually pain-free collection of blood and control over the amount of blood needed. The penetration depth indicator on the finger pricker (silver square) indicates the current penetration depth setting. The higher the number, the greater the penetration depth. The half-settings are located between the numbers.

If you have no experience with using this finger pricker, we recommend a medium penetration depth setting such as 3.



- 1 = penetration depth indicator
- 2 = half-setting



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

Loading a new lancet

When you have inserted a new lancet drum, a new lancet is automatically ready for use.

If you have already used the finger pricker to obtain blood, you will need a new lancet the next time you obtain blood. The following steps show you how to load a new lancet:



Push the lever
in direction A and then back again in direction B.



The window ② on the side of the finger pricker now shows one less available lancet (for example, 5 instead of previously 6).



If the number 1 appears in the window showing the number of available lancets 2, the lever 1 will be blocked by a locking mechanism. Do not force the lever beyond this locking mechanism as this will damage the finger pricker. Instead, replace the lancet drum with a new one.

Replacing the lancet drum

When you have used the sixth and last lancet, the number 1 appears in the window on the finger pricker. Replace the lancet drum with a new one.



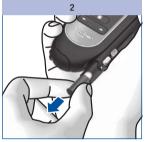
A used lancet drum has a built-in locking mechanism and cannot be reused.



Used lancet drums can be disposed of in household waste if no other regulations apply locally.



Remove the cap from the finger pricker.



Pull the lancet drum out of the finger pricker.



Insert a new lancet drum, white end first.

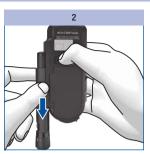
Place the cap back on again.

Keep in mind the information on page 22.

Undocking the finger pricker



Push the slide button for the finger pricker in the direction of the arrow as far as it will go. Hold the slide button in that position.



Slide the finger pricker out in the direction of the arrow.

Docking the finger pricker



When docking the finger pricker, the tracks of the finger pricker

and those of the meter 2

must interlock



Slide the finger pricker along the side of the meter in the direction of the arrow until it slots into place.

Performing a blood glucose test

Once you have inserted a lancet drum into the finger pricker and set the penetration depth, you can start to perform a blood glucose test.



Important information for performing a blood glucose test

Performing a blood glucose test incorrectly may lead to incorrect test results which can cause the wrong therapy recommendation to be made and thus produce serious adverse health effects. Therefore, follow these instructions carefully to perform a blood glucose test correctly.

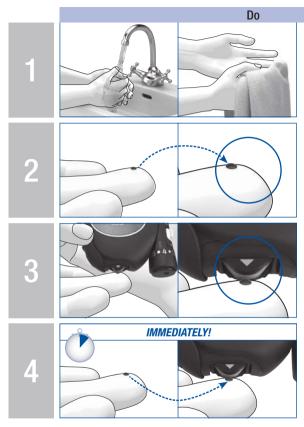


Visually impaired people must be assisted by a sighted person when applying a blood drop.

If you are using the acoustic mode: Pay attention to the beep tones. Read the *Acoustic mode* chapter carefully (see page 89).



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



Wash your hands with warm water and soap and rinse well.
Dry your hands thoroughly with a clean towel before obtaining blood

Always use a small, fresh and well-formed blood drop.

Touch the test area gently and steadily when applying the blood drop. Apply the blood drop to the centre of the test area

Apply the blood drop to the test area immediately after you have obtained the blood drop. Remove your finger from the test area when the beep tone sounds and *Test in progress* is displayed.

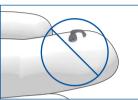
Note: You can only hear the beep tones when they are turned on.

See *Setting tones* page 49.



Do not

Do **not** perform a blood glucose test if your fingers are unwashed, soiled or sticky (for example, due to food or drink residue).



Do **not** perform a blood glucose test with a smeared or spread blood drop. Do **not** smear the blood drop on the test area.



Do **not** press the test area and the finger together. Avoid trembling or shaky movements.



Do **not** wait before applying the blood drop to the test area. Do **not** continue to hold your finger on the test area after the beep tone sounds and *Test in progress* is displayed.

Why

An incorrectly performed blood glucose test can lead to falsely elevated blood glucose results and thereby delivery of an inappropriately high insulin amount. Falsely elevated test results are caused by the following:

- Fingers are unwashed, soiled or sticky.
- If the blood drop spreads on the finger or if the blood drop becomes smeared on the test area, the risk of contamination of the test area increases (for example, due to food or drink residue on the finger).
- The test area is pressed against the finger.
- Trembling or shaky movements during the blood glucose test.
- The blood glucose test is not performed immediately or the finger stays on the test area for too long. Pay attention to the beep tone. The beep tone helps you to obtain a reliable test result.



Starting a blood glucose test

There are 2 ways to start a blood glucose test: By opening the tip cover (A) or from the Main menu (B).

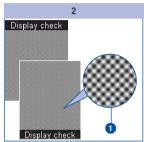
A - Starting a blood glucose test by opening the tip cover:



Open the tip cover.

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

A beep tone 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 101).



The number of available tests 2 and the prompt to wash your hands 3 are shown in succession

At the same time the meter advances a test area to the tip of the cassette.



Do not touch the tip of the cassette while a test area is being advanced and do not approach the tip of the cassette with any objects.



Shortly after the test area has been advanced, the prompt *Apply drop* appears and a beep tone sounds again.

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 (for example, to change the time) or in a selection
 list (for example, 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 Messages and problems page 121).
- You are in the PC analysis menu and have started an analysis from Data transfer or Reports.

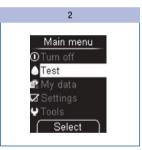
B – Starting a blood glucose test from the Main menu:

If the meter is off.

Turn the meter on with .

1

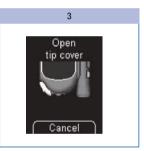
Main menu appears on the screen.





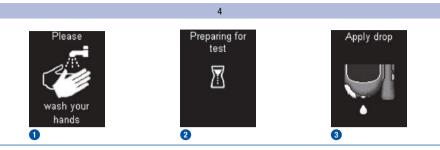
Press .

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



Open the tip cover.

Press • if you want to cancel the test.



After the prompt wash your hands 1, a new test area is advanced 2 and the prompt Apply drop 3 appears.

Obtaining a blood drop

In general, you can obtain blood from any finger. Certain fingers can be unsuitable if, for example, a skin or fingernail infection is present. We recommend obtaining capillary blood from the sides of the fingertips as these areas are the least sensitive to pain.



- Use a new lancet each time you obtain blood. This reduces the risk of infection and blood collection remains virtually pain free.
- Only use the finger pricker when the cap is attached. If the cap is not attached, the lancet penetrates
 too deeply and the puncture may cause discomfort.



Press the finger pricker firmly against the selected puncture site.

Press the release button all the way down.

The lancet is primed and released in one step. The lancet penetrates the skin.

2

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

Apply the blood drop to the test area immediately after you have obtained the blood drop.



Do **not** wait before applying the blood drop to the test area.

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

If not enough blood emerges, apply more pressure with the finger pricker the next time you obtain blood. If that is not sufficient, increase the penetration depth progressively too.

If too much blood emerges, reduce the penetration depth.

The blood drop must be large enough and well formed.



Applying the blood drop

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



Apply the blood drop to the centre of the test area.

Touch the blood drop to the test area gently.



- Do not hold the meter with the test area pointing upwards.
- Do not press the test area and the finger together.
- Avoid trembling or shaky movements.

The blood drop is drawn up by the test area.



Remove your finger from the test area when the beep tone sounds and *Test in progress* is displayed.

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



You can only hear the beep tones when they are turned on (see *Setting tones* page 49).



Testing is complete after approx. 5 seconds, depending on the blood glucose concentration. The test result appears on the screen and the beep tone sounds. The meter saves the test result at the same time. 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 *Flagging results* page 37).

Close the tip cover to turn the meter off.

Symbols associated with test results

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

| Symbol | Meaning |
|--------|---|
| -+ | The batteries are almost out of power. |
| | The temperature during the test was outside the permitted range of $+10$ to $+40$ °C. |
| Î | The test result is higher than the upper limit of the target range set. |
| Ţ | The test result is lower than the lower limit of the target range set. |

Performing a blood glucose test

Symbols instead of test results

The meter measures blood glucose values in the interval from 0.6 to 33.3 mmol/L. If the test result is outside this interval, one of the following symbols is 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 screen LO may indicate that your blood glucose value is very low (possibly a severe hypoglycaemia). The screen HI may indicate that your blood glucose value is very high (possibly a severe hyperglycaemia).
- Follow the relevant instructions given by your healthcare professional immediately and repeat the test.
- If you are using the acoustic mode: See page 91 for the beep tones for the symbols LO and HI.

Flagging results

You can flag results to describe certain events connected to this result or particular characteristics of the result. You can only flag a result while the result is still displayed after a test.



Press .

The *Set flag* menu is displayed. You can flag the test result here. There are 4 different flags to choose from. The symbol for the flag that has been activated is displayed to the right above the result. The test result in the above example is flagged with the symbol **#** *Other* 1.



Performing a blood glucose test

You have the choice of the following 4 flags:

| Symbol | Meaning |
|--------|--|
| ě | Before meal (apple symbol): For test results that you obtained from tests before meals. |
| Ť | After meal (apple core symbol): For test results that you obtained from tests after meals. |
| * | Other (asterisk symbol): You can define the meaning of this flag yourself. |
| ā | Control test (applicator symbol): For control tests in which you applied control solution to the test area instead of blood. |

You can add the following flags to a test result at the same time:

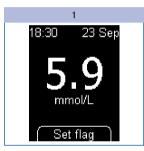
- Other and Before meal
- Other and After meal

You cannot flag a test result with *Before meal* and *After meal* at the same time.

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 are saved and can no longer be changed.

Selecting the *Control test* flag takes you out of the *Set flag* menu. The *Control solution* menu then opens (see Chapter 9, *Checking the meter*).

Selecting the *Before meal*, *After meal* or *Other* flag:



Press .



Press .

If you want to add a further flag to the test result, repeat step 2.

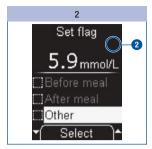


Removing a flag again:



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

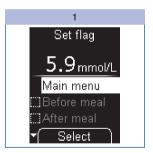
The symbol displayed to the right above the test result shows which flag has been selected 1.



Press
to delete the flag.

The flag is deleted. The symbol on the screen disappears 2.

Leaving the Set flag menu:



Turn the meter off with .

0r

Use ightharpoonup to select *Main menu* and press ightharpoonup.



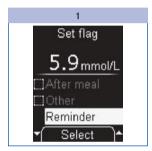
Close the tip cover.

Setting a reminder

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

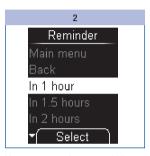
The meter can give you a one-time reminder to perform a test in 1 hour, in 1.5 hours, in 2 hours or in 3 hours. You do not need to set a time for this. Once the reminder has occurred, it is automatically deleted. For more information on reminders, see *Setting reminders* page 51.

When the test result is displayed:



Use **▼** ▲ to select *Reminder*.

Press .



Press .

The meter returns to the *Set flag* menu.

4

Performing a blood glucose test

Evaluating blood glucose results

Blood glucose results are influenced by, amongst other things, the type of food consumed, medication taken, state of health, stress and physical activity.

Ŵ

- . Do not change your therapy without consulting your healthcare professional first.
- Consult your healthcare professional if the test result is below or above the blood glucose range you
 have set together with your healthcare professional.
- If the test result matches how you feel, follow the instructions given by your healthcare professional.
- If the test result does not match how you feel, for example, it is unexpectedly high or low, perform a
 control test with Accu-Chek Mobile control solutions. Then repeat the blood glucose test. If the new
 blood glucose result still does not match how you feel, contact your healthcare professional.
- Consult your healthcare professional immediately if your blood glucose values are too low or too high.
- The screen LO may indicate that your blood glucose is very low (possibly a severe hypoglycaemia).
 The screen HI may indicate that your blood glucose is very high (possibly a severe hyperglycaemia).

 Follow the instructions given by your healthcare professional immediately and repeat the blood glucose test.
- If test results repeatedly do not match how you feel, check the points listed in the following section Implausible results - possible sources of error.

Implausible results - possible sources of error

If your meter repeatedly displays implausible test results or error messages, check the points listed below. Answer the guestions in the following overview with yes or no.

- If your answer to the question is no, make the respective corrections and repeat the blood glucose test.
- If you have answered yes to all these questions and still obtain implausible test results or error messages, contact your customer support and service centre (see page 134).

Source of error

Did you perform the blood glucose test according to the User's Manual?

Did you wash your hands with warm water and soap and dry them well?

Did you wait for the prompt on the screen before applying blood?

Did you apply the blood drop to the test area immediately?

Did you apply a well-formed blood drop?

Did you apply the blood drop to the centre of the test area?

In doing so, did you touch the blood drop to the test area gently?

Did you hold the finger and meter steady while applying the blood drop?

Did you remove the finger from the test area immediately after applying the blood drop?

Did you use a new blood drop for every test?

Did you perform the test within the correct temperature range (+10 to +40 °C)?

4

Performing a blood glucose test

Did you observe the storage conditions for the meter and test cassette?

Did you pay attention to the sources of error stated in the test cassette package insert?

Did you perform a control test after your meter was dropped while Apply drop was being displayed?



If your meter has been dropped, this can also lead to implausible test results or error messages. In this case, you should also contact the customer support and service centre (see page 134).

Selecting settings

Settings overview

| Menu | Available options |
|--------------|---|
| Language | Different languages |
| Volume | 5 levels (<i>Mute</i> and 4 volume levels) |
| Tones | Beep tones: Turn the beep tones on or off Reminders: Turn the beep tone for reminders on or off Acoustic mode: Turn Acoustic mode on or off (see Acoustic mode page 89) |
| Reminders | 7 times of day – freely selectable daily reminders |
| Time/Date | Time: Set the time Date: Set the date Time format: Set the time format (8 time formats) (format for time and date) |
| Target range | Set the upper and lower limit Turn the target range on/off |
| Brightness | 3 levels |

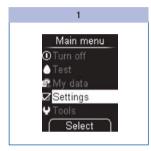
5

Selecting settings

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 (for example, beep tones and acoustic reminders).

However, blood glucose tests can be performed independently of the settings. You can still perform a blood glucose test even if you have not made settings in the *Settings* menu.

To open the Settings menu:



In the Main menu, use \checkmark to select *Settings* (\checkmark).

Press

.

The Settings menu is displayed.

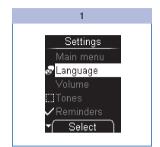


From the *Settings* menu, you can open the following menus:

- Language
- Volume
 - Tones
- Reminders
- Time/Date
- Target range
- Brightness

Setting the language

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



In the *Settings* menu, use to select *Language* ().

Press .

The language currently set is highlighted.

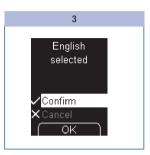


Use **→ ★** to select the desired language.

Press

.

The selected language is displayed.



Press

.

You have confirmed the language selection.

Correcting a wrongly set language

You can change the language if you selected the wrong one by mistake, as follows:

1
Turn the meter on with .

Wait until the screen does not change anymore.

The *Settings* () menu is now highlighted.

Press

The *Language* () menu is now highlighted.

2

Press

.

The Language menu is open.

Use **▼** ▲ to select the desired language.

3

Press .

The selected language is displayed.

Press .

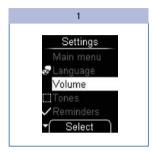
The meter returns to the *Settings* menu.



Setting the volume

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

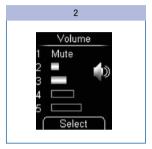
The longer the bar on the screen, the louder the volume. At volume level 1 (Mute) no beep tone is audible.



In the *Settings* menu, use **▼** ▲ to select *Volume*.

Press .

The *Volume* menu is displayed.



Use **▼** ▲ to set the volume.

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

Press

.

You have confirmed the volume selection.

Setting tones

In the *Tones* menu you can turn the beep tones, the beep tone for reminders and the acoustic mode on or off. The different beep tone settings are as follows:

Beep tones: If Beep tones is turned on, a beep tone sounds 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 the test begins and Test in progress is displayed,
- · when the result is displayed,
- when an error message is displayed.

In order to be able to hear the beep tones, the volume must be set between volume levels 2 and 5. If you have set volume level 1 (Mute), no beep tones are audible. See Setting the volume page 48.

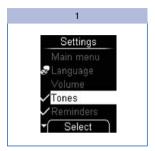
Reminders: If *Reminders* is turned on, a beep tone sounds for a set reminder (see *Setting reminders* page 51).

Acoustic mode: If acoustic mode is turned on, the meter guides you through the blood glucose test using the previously mentioned beep tones (see *Acoustic mode* page 89).

Turning tones on and off

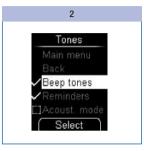
You can turn the Beep tones, Reminders and Acoustic mode tones on and off.

Procedure using the example of *Beep tones*:



In the *Settings* menu, use **▼** ▲ to select *Tones*.

Press .



Use **▼** ▲ to select *Beep tones*.

Press \bigcirc to turn the beep tones on (\checkmark) or off (\checkmark) .

Press

.

You have set the beep tones.



Note:

- If you want to use reminders, you must turn on both Reminders and Beep tones.
- If you want to use acoustic mode, you must turn on both Acoust. mode and Beep tones.

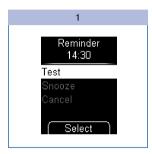
Setting reminders

You can set up to 7 reminder times.

If the meter is turned off, the *Reminder* message will be displayed daily at the time you have set. If you have turned on *Reminders* in the *Tones* menu, beep tones will also sound (see *Turning tones on and off* page 50).

2

Turning off the Reminder message beep tone



If you do not press a button, the meter turns off automatically after 20 seconds. The reminder is then only repeated on the following day.

If you perform a blood glucose test 10 minutes or less before a reminder, the reminder does not occur.

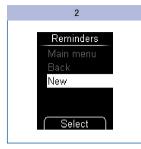
When the reminder is displayed, you can turn off the beep tones.

Setting a new reminder



In the *Settings* menu, use **▼** ▲ to select *Reminders*.

Press .



Use **▼** ▲ to select *New*.

Press .



Use \checkmark to set the hour \bigcirc .

Press .

Use **▼** ▲ to set the minutes **2**.

Press .



Only for times in 12-hour time format:

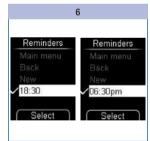
Use **→ △** to select *am* or *pm*.

Press .



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

Press .



The meter returns to the *Reminders* menu.

The set reminder time is displayed.

Turning a reminder on or off

A list of the reminders that have already been set appears on the screen.



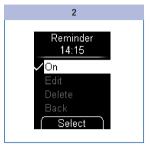
In the *Settings* menu, use **▼** ▲ to select *Reminders*.

Press .

You recognise an activated reminder by the **v** symbol and a deactivated reminder by the symbol.

Press

.

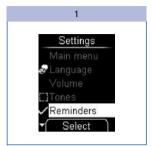


The menu option *On* is highlighted.

Press • to turn the reminder on () or off ().

A reminder that reminds you once to check your blood glucose value is not displayed in the list (see *Setting a reminder* page 41).

Changing a reminder



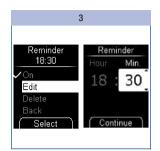
In the *Settings* menu, use **▼** ▲ to select *Reminders*.

Press .



Use **→** ★ to select the reminder time you wish to change.

Press .



Press .

Set the new reminder time.

The reminder time has now been changed.

Deleting a reminder

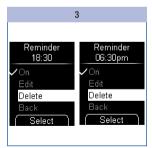


In the *Settings* menu, use **▼** ▲ to select *Reminders*.

Press .



Press .



Use **▼** ▲ to select *Delete*.

Press .

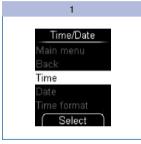
The reminder time has now been deleted.

Setting the time, date and time format

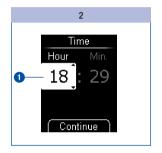
The time and date are preset in the meter. If you want to use reminders or analyse your test results with a computer, for example, you should check the time and date and correct them if they deviate from the current time or date.

All test results are saved together with the time and date. It is only possible to analyse the test results meaningfully in terms of time if the time and date are set correctly.

Setting the time







Use ✓▲ to set the hour ①.

Press ②.





Press .

Use **▼** ▲ to select *Time*.

Press

.



Only for times in 12-hour time format:

Use **→ ▲** to select *am* or *pm*.

Press .



The set time is displayed.

Press .

You have confirmed the time set.

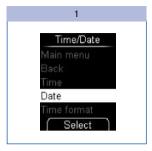
Setting the date

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:



Selecting settings



In the *Settings* menu, use **▼** ▲ to select *Time/Date*.

Press

Use **▼** ▲ to select *Date*.

Press .



Use \checkmark to set the day \bigcirc .

Press .



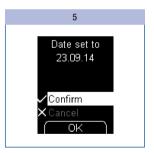
Use **→ △** to set the month **②**.

Press .



Use **→ ▲** to set the year **3**.

Press .



The set date is displayed.

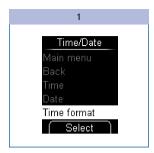
Press .

You have confirmed the date set.



When you confirm the last entry with *Continue* (step 4), if the date you have set does not exist (for example, 31 April), the meter returns to the first item for entry (step 2).

Setting the time format



In the *Settings* menu, use ▼▲
to select *Time/Date*

Press .

Use **▼** ▲ to select *Time format*.

Press .

The currently set time format is highlighted.



Use **▼** ▲ to select the desired time format

Press .



The selected time format is displayed.

Press .

You have confirmed the selected time format.

If you do not want to set the selected time format, use ▼ ▲ to select *Cancel*. Press to return to the *Time/Date* menu.



Setting the target range

You can enter your personal target range for blood glucose values (default setting: Off). Test results above this target range are flagged with the symbol $\dot{\bot}$. Test results below this target range are flagged with the symbol $\dot{\bot}$.

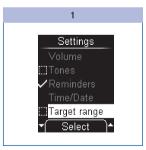
The target range comprises the blood glucose values which should be achieved if the therapy is optimal. Consult your healthcare professional for the target range appropriate for you.

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 want to use the lower limit of the target range as an indicator of a possible hypoglycaemia (low blood glucose), it is important to remember the following: The indicator is only reliable if the limit has been properly selected. We therefore strongly recommend that you only set the limit in consultation with your healthcare professional. This function is not a substitute for hypoglycaemia training by your healthcare professional or diabetes team.

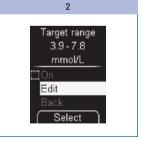
Setting a target range



In the *Settings* menu, use **— •** to select *Target range*.

Press

.



Use **▼** ▲ to select *Edit*.

Press .

Press

menu

5 Use ▼ ▲ to select *Back*

The meter returns to the Settinas



Use

to set the lower limit O.

Press .

Use

to set the upper limit 2

Press

4 Target range 4.4-6.9 mmol/L On

Press .

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

If you do not want to set a target range, use - to select Cancel and then press
to return to the Settings menu.

Use \checkmark to select On.

Press
to turn the target range on () or off ().

You recognise an activated target range by the symbol and a deactivated target range by the symbol.

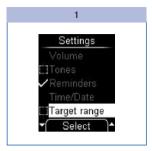
Turning the existing target range on/off



In the Settinas menu, use -to select Target range.

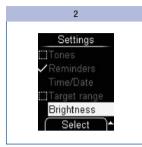
Press .

Changing a target range



In the *Settings* menu, use **— •** to select *Target range*.

Press .



Use **▼** ▲ to select *Edit*.

Press

.



Set the new target range.

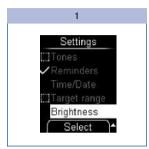
The changed target range is displayed.

Press to confirm the set target range.

The target range is also turned on.

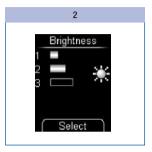
Setting the brightness

You can set the brightness of the texts and symbols appearing on the screen to one of 3 different levels. The more bars filled on the screen, the brighter the screen.



In the *Settings* menu, use **— •** to select *Brightness*.

Press .



Use \checkmark to set the desired brightness.

Press .

You have confirmed the selected brightness.



Using the meter as a diary

The meter can store up to 2,000 results with the time and date. The meter stores the following information:

- · all results,
- · all symbols displayed with the result,
- · all flags that were set.

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

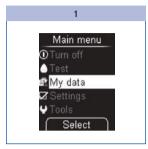
The following options are available in the *My data* menu:

- . All results: Display all the stored results
- Averages: Display the averages for the last 7, 14, 30 or 90 days
- PC analysis: Display and analyse the stored test results on the computer (PC) (see Analysing test results on the PC page 70)

Retrieving stored results

There are 2 ways to retrieve stored results: By opening the *My data* menu (A) or by pressing the button (B).

A - Retrieving stored results via the My data menu:

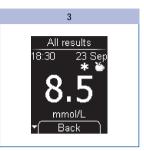


In the *Main menu*, use **→ △** to select *My data* (**△**).

Press .

The My data menu is displayed.





The last saved result is displayed.

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

B – Retrieving stored results using the lacksquare button:

1

The last saved result is displayed.



C – Retrieving older results:

1

Retrieve the stored results (see page 65).

2

Press
to go to the next newest result.

If you press and hold the vor button, the results are displayed in quick succession, starting with a slow speed and becoming faster. The screen stops at the oldest and the newest (latest) result.

No results stored

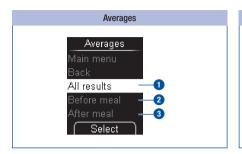


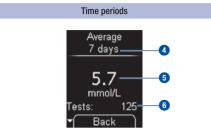
If the last (most recent) result in the memory is displayed as *XX.X mmol/L* with dashes instead of the time and date, the last test did not deliver a result. This means that during the last test either an error message was displayed or you did not apply blood (or control solution) after the prompt *Apply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

XX.X mmol/L is also displayed if no results are stored in the meter.

Retrieving averages

The meter can calculate averages from the stored test results.





You can choose which test results are used for calculating 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 is calculated from all test results that match your selection. However, the following results are not included in the calculation:

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

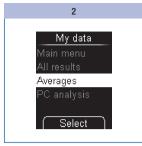
Selecting the time period 4 only determines which average is displayed first. You can use the \checkmark buttons to switch directly from one time period to the others. The calculated average 5 is displayed, together with the number of test results (called Tests) from which the average was calculated 5.





In the Main menu, use \checkmark to select *My data* (\blacksquare 2).

The My data menu is displayed.



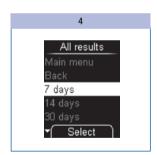
Use **▼** ▲ to select *Averages*.

Press

.

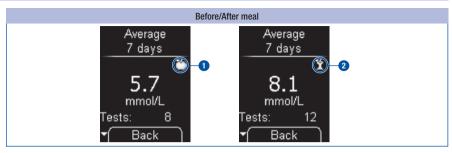


Press .



Use \frown to select the time period in which the test results were obtained: 7, 14, 30 or 90 days.

Press .



Averages *Before meal* are marked with the symbol • 1. Averages *After meal* are marked with the symbol • 2.



- The meter calculates the average for a time period even when the stored test results cover a shorter period (for example, only 5 days).
- If no averages 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 time period. The following test
 results are not taken into account for the calculation of averages:
 - Test results outside the time period selected
 - Test results without date and time
 - Tests with control solution
 - Tests outside the measuring range (marked with HI or LO)



Analysing test results on the PC

The meter has a built-in USB port (Universal Serial Bus) 1 for transferring stored test results to an appropriately equipped computer (PC).



You need 1 USB cable to connect the meter to a PC. The USB cable must have the following connectors:

- Micro B connector 2 to establish a connection with the meter.
- USB A connector 3 to establish a connection with the PC.

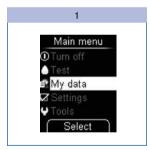
There are **two wavs** of displaying the test results on a PC via the *PC analysis* menu:

- Reports allows you to display and analyse the test results on a PC by means of the meter's built-in diary function software and an Internet browser, no additional software is required (see Reports page 77).
- Data transfer transfers the test results to the PC. You can use special software products for diabetes management (for example, Accu-Chek 360° Diabetes Management System or Accu-Chek Smart Pix software) to display the data on a PC and analyse it (see *Data transfer* page 74). With this setting, the meter also supports data exchange between medical devices with the Continua Certified® logo from the Continua Health Alliance.

These analysis options help you and your healthcare professional to manage your data and the graph and table views help you to better understand your test results.

Defining the default

You can define how the meter reacts after being turned on when you connect it to a PC.



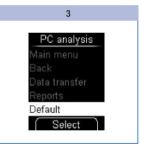
In the Main menu, use - to select My data.

Press .



Use **▼** ▲ to select *PC analysis*.

Press .



Use

to select Default.

Press .



Use **▼** ▲ to select *Data transfer*

or

Reports.

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 PC (for example, Accu-Chek 360° Diabetes Management System or Accu-Chek Smart Pix software). For more information, contact the customer support and service centre (see page 134).

If you already have a software product for transferring and analysing test results, the software may not recognise more recent meters and therefore the test results may not be able to be transferred. You may need a more recent version of your software. In this case, contact the customer support and service centre (see page 134).

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



You only need special diabetes management software to analyse stored test results if you would like to use the data transfer function. For transferring data between Continua Certified® products, you may also need to install a PHDC driver (PHDC = Personal Health Device Class) on your PC. Whether you need a PHDC driver depends on the diabetes management software used.

Viewing a report (Accu-Chek Mobile report) with your Internet browser does not require any additional software.

Connecting the meter to the PC



Plug the Micro B connector of the USB cable into the USB port on your meter.

Connect the other end of the USB cable to your PC.

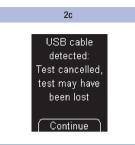
2a and 2h

2a - With the meter off:

The meter turns on. Depending on the selected default (see *Defining the default* page 71), the analysis of the test results is started with *Data transfer* or *Reports*.

2b - With the meter on:

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



If you connect the meter to a PC while a test is in progress, the test is cancelled and a message appears on the screen.

Press .

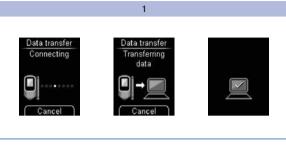
The meter starts data analysis via *Data transfer* or *Reports*, depending on the default.

<u>(i)</u>

- 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 battery power is not consumed unnecessarily.
- You cannot perform a test while the meter is connected to the PC.



Starting data transfer



If necessary, start the software program for test result analysis on the PC.

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

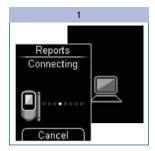
Make sure the meter is connected to the PC (see Connecting the meter to the PC page 73).

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



- To analyse the data by means of *Data transfer*, you need additional software (for example, Accu-Chek 360° Diabetes Management System or Accu-Chek Smart Pix software).

Displaying reports



Make sure the meter is connected to the PC (see Connecting the meter to the PC page 73).

While the connection is being established, you are informed of the progress on the screen. The PC symbol on the meter screen flashes when the meter has successfully connected to the PC.

2

Open the file manager of your operating system.

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

3

Double click on the (ACCU-CHEK) drive icon to open it.

Double click on the *Start.html* file to open it.

The Internet browser opens and the default reports appear.



Analysis with a meter already connected

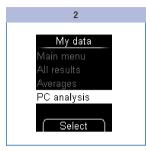
If you have already connected the meter to a PC with the USB cable but the meter is off, proceed as follows:





In the Main menu, use ▼▲ to select *My data*.

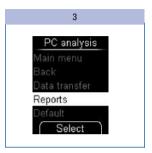
Press .



Use ▼ ▲ to select PC analysis.

Press

.



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

Test results start transferring when you select *Data transfer*.

The meter connects to the PC when you select *Reports*.

Press
to confirm your selection.

Reports

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

Overview

The reports can be displayed on a PC using an Internet browser and can be printed by a printer. You do not need an Internet connection to display the reports. The reports are stored in the meter and retrieved from there.



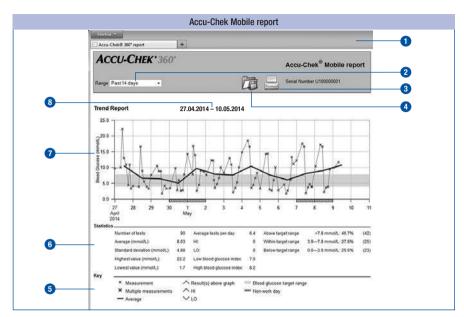
You can find the license agreement for using the meter's built-in *Reports* software at the end of the User's Manual (see page 142).

When you have successfully connected the meter to the PC, the following reports are displayed on a page of the Internet browser:

- Trend Report
 This report shows the trend of several blood glucose results over the selected time period.
- Standard Day Report
 This report displays all data in a 24-hour grid.
- Standard Week Report
 This report displays 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 shows the test results sorted by date and time of the test.



User interface



Control elements:

- Window of the Internet browser
- 2 Drop-down menu for selecting the time period
- 3 Print reports button
- Save file button

Display panes:

- Legend for explanation of symbols
- Statistics on test results analysis
- Chart (graphic representation of the report)
- 8 Time period



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, test results are plotted in the analysis by means of different symbols.

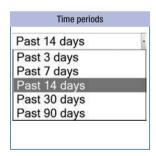
The symbols and graphic elements in the charts have the following meaning:

| Symbol | Meaning |
|--------|--|
| × | Test: Blood glucose value from a test |
| × | Several tests: Blood glucose values from several tests |
| _ | Average: Average of the blood glucose values in the selected time period |
| | Target range for blood glucose values: Personal target range for blood glucose values (represented on the screen as a green bar) |
| ^ | Test result(s) above chart. The blood glucose value cannot be represented because it is above the chart |
| yuu. | Non-work day: Usually non-working days (weekends) |

Report time periods

Reports can be created for the following time periods:

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



Select the desired time period in the drop-down menu (for example, *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 reports* (—) button on the user interface.

1

Click 🖶 on the user interface.

The print dialogue box of your Internet browser opens.

2

Select the desired printer from the print dialogue box of the Internet browser.

In the print dialogue 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.

Start the printing process.

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

Analysed data

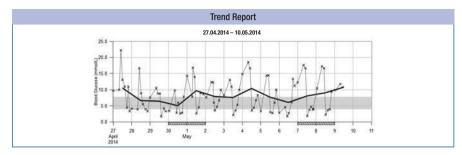
The following data is not included in the statistical analysis:

- Test results outside the selected time period
- · 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 adopted for data analysis:

- Language (see page 47)
- Date (see page 57)
- Time format (see page 59)

Trend Report



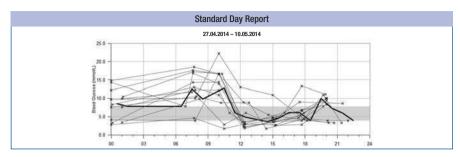
The *Trend Report* shows you the trend of blood glucose results over the selected time period.

You will find the days and months on the horizontal x-axis and the blood glucose values on 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 diagonal slashes on the horizontal x-axis.

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

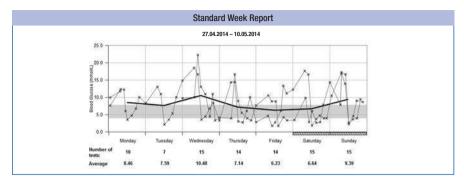
Standard Day Report



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

All blood glucose results 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 trend of the average level (in intervals of one hour if a test result falls in each interval).

Standard Week Report



The Standard Week Report makes it easier to recognise repeated patterns depending on the day of the week. For example, it may be possible to recognise changes in metabolic situation brought about by your lifestyle patterns.

All blood glucose results 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 trend of the average level on the different days of the week.

The number of tests and the average for the respective day of the week are listed below the chart.



List Report

List Report

27.04.2014 - 10.05.2014

| Date and Time | | Blood Glucose (mmol/L) | Events |
|---------------|-------|------------------------|-------------|
| 09.05.2014 | 07:30 | 11.7 | Before meal |
| | 01:01 | 9.9 | |
| 08.05.2014 | 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 | |
| 07.05.2014 | 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 listed chronologically and with any additional information about events (see Flagging results page 37).

The list contains the following columns:

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

Statistics

Below the chart of a report, you will find a statistical analysis of all plotted test results 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 blood glucose value (mmol/L)
- Lowest blood glucose value (mmol/L)
- Average tests per day Average number of blood glucose results per day
- HI or LO Blood glucose results outside the measuring range
- Low blood glucose index or High blood glucose index Further information can be found in the appendix (see page 140).
- Above target range Blood glucose results above the target range
- Within target range Blood glucose results within the target range
- Below target range
 Blood glucose results 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 (CSV = Comma Separated Values). CSV files can be opened with a text editor or spreadsheet program, for example.

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

1

Click on the user interface.

Depending on the configuration of your PC, 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 dialogue 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 downloading files.

The CSV file contains the following information:

- Serial number of the meter.
- Download date, download time date 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 as DD.MM.YYYY and the time as 24-hour 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 in the Internet browser

The settings of the Internet browser can influence working with reports.

The reports use pages with so-called *active content* (JavaScript). This *active content* can be suppressed by security settings in the browser. If you suppress JavaScript, it may cause warnings or restricted functionality. For this reason, check the relevant JavaScript settings in the Internet browser to ensure smooth operation.

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

If you select the Internet browser security settings appropriately (for example, *Allow active content to run in files on My Computer* or similar), you can work with reports without any restrictions.



Error messages and troubleshooting

| Error message | Troubleshooting |
|--|--|
| The ACCU-CHEK drive | Check whether <i>Reports</i> is selected in the defaults for PC analysis (see <i>Defining the default</i> page 71). |
| symbol with the Start.html file does | Check whether your PC or operating system supports data transfer via USB. |
| not appear on the PC: | Check whether 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 PC (you may be able to use a USB hub or choose between USB sockets on the front and rear of your PC). |

Contact the customer support and service centre (see page 134) if the problem persists.

Acoustic mode

The procedure for turning the acoustic mode on is described in *Setting tones* (see page 49).

When the acoustic mode is turned on, the meter guides you through the blood glucose test using beep tones and announces the test result as a series of beep tones. The meter also beeps 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 with beep tones and how to distinguish beep tones for test results from other beep tones, is crucial to interpreting the test result correctly.

The sections that follow explain the beep tones in detail. In addition, training software (the BeepLearn program) to help you interpret test results announced in the form of beep tones is available on CD from the customer support and service centre (see page 134).



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 damage to health and can even be fatal. 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 must be assisted by a sighted person when performing a blood glucose test.

The meter must be checked regularly 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.

| Beep tones | | | |
|--|--|--|--|
| Tone 1: — | Tone 2: — (warning) | | |
| Turning on | Announcement of an error message | | |
| Test area is advanced to the tip of the cassette | Notification that the batteries are almost empty | | |
| Prompt to apply blood or control solution | Notification that the test cassette is empty | | |
| Start of test | | | |
| Signal that test results are about to be announced | | | |
| Announcement of the test result | | | |

Beep tone when turning on

When the acoustic mode is turned on, you hear 1 beep tone (—) when you turn the meter on, regardless of how you turn the meter on.

Beep tones during a test

After the power-on beep, you hear 1 beep tone (—) during the test when:

- · the meter advances a test area to the tip of the cassette,
- · you are prompted to apply blood or control solution,
- · the test begins.

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

You hear several beep tones when the meter displays an error message (—).

Test result announcement after a test

In the acoustic mode, when a test result is displayed following a blood glucose test, the meter also announces it as a series of beeps. The test result is not announced 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 beep tones, for example, 4 beep tones for the number 4 (————). Zero is represented by 1 long beep tone (———).

The decimal point of a test result is announced by 1 very short beep tone (=).

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

Test results which are higher than 33.3 mmol/L and are displayed as \mathbf{H} are announced acoustically as 9-9- decimal point -9.

The meaning of the symbols LO and HI is explained in the chapter *Symbols instead of test results* on page 36.

The test result is announced three times in succession. Each announcement is preceded by 2 short beep tones (- -) as an introduction. Therefore, altogether you hear: - - test result - - test result - - test result.

Symbols, such as $\dot{\bot}$ or $\dot{\blacksquare}$, 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 is interrupted and 1 long beep tone will sound ().



mmol/L meters

First the tens are announced, then the units followed by the decimal point and finally the tenths. 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 tone, signifying zero. The decimal point is announced by 1 very short beep tone (–).

13.8 mmol/L:

4.0 mmol/L:

```
2 short preceding beep tones – 1 long beep tone (for 0 tens) – pause – 4 beep tones – pause – 1 very short beep tone – pause – 1 long beep tone = - – - – - – - – - – -
```

Announcing stored test results

Only the last (most recent) of the stored 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 stored test results using the button \checkmark , you will first hear the power-on beep and immediately afterwards the test result:

- - test result - - test result - - test result.

If XX.X is displayed as the last (most recent) test result, the last test did not deliver a test result (see page 66). In this case, the beep tones issued are identical to those for an error message.

Flags are not announced acoustically (for example, *\bigcep* Before meal).

There is no acoustic announcement if the last saved result is a control test flagged with $\underline{\Delta}$, if there are no stored results or if you retrieve an average.

Announcing warnings and error messages

When battery power is low or the test cassette has been used up, the meter issues an acoustic warning. This consists of 2 short beep tones (--) 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 screen (see *Changing the batteries* page 114).
- · 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 screen (see *Error messages* page 124), these are announced by 2 short beep tones (——) sounded four times in succession (——————). This sequence is sounded only once and is not repeated. The same sequence of beep tones is sounded for all error messages, i.e. they are not differentiated acoustically.



Checking the meter

You can check whether the meter is delivering 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 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 cleaned the inside of the tip of the cassette and tip cover, as well as the measuring
 optics and the front opening of the meter.
- . If you are in doubt about a test result.

Contact the customer support and service centre (see page 134) to find out where you can obtain the control solutions.





Visually impaired people must be assisted by a sighted person when performing a control test.

Different control solutions are sold in different countries. The control solutions have labels with different text colours ($Control1 = blue \ \)$ or $Control2 = red \ \)$.

At the end of the control test, you must tell the meter which text colour of the control solution you have used (see page 97). The meter offers you a choice of two colours.

Preparing for a control test

For a control test, you need:

- · The meter with inserted test cassette
- An unopened applicator with Accu-Chek Mobile control solution
- · A clean, dry paper towel.

The solution in the applicators is intended for single use only.

Read the control solution package insert.

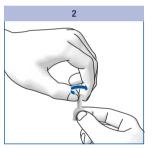
Performing a control test

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.

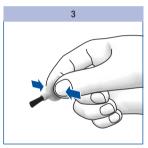
1

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* appears and a beep tone sounds.



Twist the cap off the applicator.



Hold the applicator at a slight angle with the brush pointing downwards.

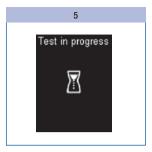
Squeeze the applicator gently until you see a small drop appear on the brush.



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



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.



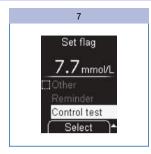
Take the brush away from the test area as soon as *Test in progress* appears on the screen.

The test area has absorbed sufficient control solution, the beep tone sounds and the control result is displayed.



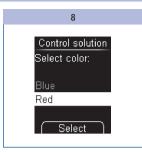
Press .

The test ends after 5 seconds and the meter displays the result.



Use **▼** ▲ to select *Control test*.

Press .



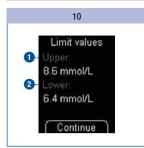
Use \checkmark to select the colour of the text on the applicator label (see page 94).

Press .



The control result flagged as 6 for Control test is displayed.

Press .

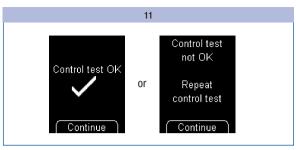


The meter displays the upper 1 and lower 2 limits of the concentration range. The concentration range displayed depends on the colour of control solution selected.

Note: The values in the illustrations are **only** examples.

Press

.



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

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

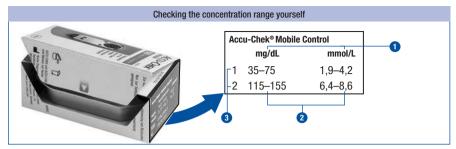
If the control result is not within the concentration range displayed, *Control test not OK Repeat control test* is displayed (see *Possible sources of error* page 99).

Press .

The meter returns to the Main menu.

Turn the meter off and close the tip cover.

Discard the used applicator according to local regulations.



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 2.

Note: The values in the illustrations are **only** examples.

1 = unit of measurement, 2 = concentration range, 3 = control solution used

Possible sources of error

If *Control test not OK Repeat control test* is displayed, the control result is not within the concentration range displayed. Answer the questions in the following overview with yes or no.

- If your answer to the question is **no**, make the respective corrections and repeat the test.
- If you answered yes to all the questions and Control test not OK is still displayed, contact the customer support and service centre (see page 134).



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

Checking the meter

Source of error

Did you perform the control test according to the User's Manual?

Did you wait for the application prompt to be displayed before applying control solution?

Did you apply the control solution immediately after opening the applicator?

Did you enter the correct colour in the Control test menu?

Did you test within the correct temperature range (+10 to +40 °C)?

Did you check the use by date for the control solution? Is the control solution still valid (use by date: see label on the bottom of the applicator; next to the \square symbol)?

Did you observe the section *Storing and using control solutions properly* in the package insert for the control solution?

Did you observe the storage conditions for the meter, test cassette and control solutions (see *Measurement and storage conditions* page 117, and the test cassette and control solution package inserts)?

Did you use the meter properly? The meter has **not** been dropped? If your meter has been dropped, this 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, contact the customer support and service centre (see page 134).

Tools menu

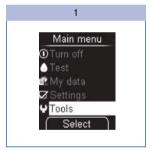
On the one hand, the *Tools* menu offers you some extra means of checking the meter. On the other hand, you must also use this menu to prepare for cleaning the meter and changing a test cassette that has not been used up.

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 (for example, when you clean the meter).

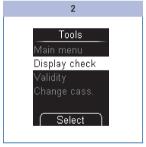
Performing a display check

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





Press .

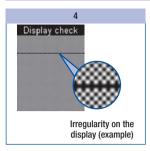


The Display check is displayed.



Press .

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



If there are irregularities in the checkerboard pattern, test results might not be displayed correctly. In this case, contact the customer support and service centre (see page 134).

Press .

The meter returns to the *Tools* menu.

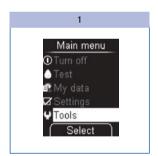
5

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

Check whether there are any irregularities in the checkerboard pattern.

Displaying the validity of the test cassette

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



Press

.



Use ▼▲ to select *Validity*.

The validity is displayed.



Press

.

The meter returns to the *Tools* menu.

Viewing the number of available tests

With the meter off:

1

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.

Replacing the test cassette

If you want to replace an empty test cassette or a test cassette that has expired, continue reading in the section *Replacing the test cassette* (see page 105).

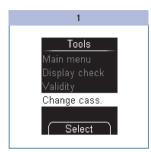
If you want to remove a partly used test cassette which still has unused test areas, you must first perform the preparatory steps described in the section *Preparing test cassette replacement* (see page 104).



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

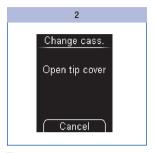
Preparing test cassette replacement

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



In the *Tools* menu, use **▼** ▲ to select *Change cass*..

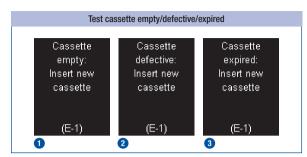
Press .



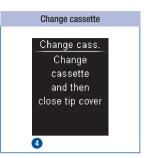
The meter now prompts you to open the tip cover. If you do not want to replace the test cassette after all, you can cancel the operation with .

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

Replacing the test cassette



If the test cassette in the meter is empty 1 or defective 2 or has expired 3, the appropriate message appears after the display check and the number of available tests (see also page 120). Shortly after this, the meter turns off automatically.



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



Open the tip cover.

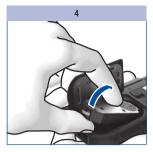


Turn the meter over so that the back is facing upwards.



Push the slide button for the cassette compartment cover upwards.

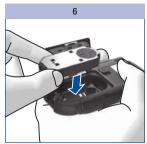
The cassette compartment cover opens.



Remove the old test cassette from the cassette compartment.



Take the new test cassette out of the plastic container.



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



Close the cassette compartment cover.



Press the cassette compartment cover closed.

The cassette compartment cover must close with an audible **CLICK**.

The meter turns on and runs a display check. Afterwards the validity of the test cassette and the number of available tests are displayed.

Then the main menu is displayed.



Used test cassettes can be disposed of in household waste if no other regulations apply locally.

Cleaning the blood glucose monitoring system

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 may become necessary.



Visually impaired people must be assisted by a sighted person when cleaning the meter.



- Use only cold water or 70 % isopropanol for cleaning. Any other cleaning agents may damage the
 meter or impair its measuring function.
- Use a slightly dampened cloth or a slightly dampened cotton swab. Do not spray anything directly
 onto the meter and do not immerse it in cleaning fluid.

The outside

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

1

Wipe the casing or display with a cloth slightly dampened with cold water.

2

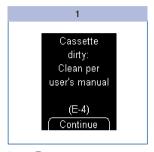
Repeat step 1 with a cloth slightly dampened with 70 % isopropanol.

Cleaning the blood glucose monitoring system

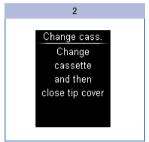
The inside

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

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



Press .
Open the tip cover.



Follow the instructions (steps 3 to 11) for cleaning the meter in the section *Cleaning* (see page 109).



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

Cleaning

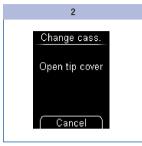
If you notice that the area around the tip of the cassette is visibly soiled and you want to clean the meter, proceed as follows:



In the *Tools* menu, use **▼** ▲ to select *Change cass.*.

Press .

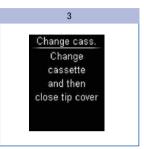
The meter prompts you to open the tip cover.



If you do not want to clean the meter now, press .

If you do want to clean the meter, open the tip cover.

The meter prompts you to change the test cassette. About 2 seconds later, the meter turns itself off automatically.



The steps that follow are identical to steps 2 to 4 in Chapter 10, section *Replacing the test cassette*, which are accompanied by illustrations (see page 105).

Turn the meter over so that the back is facing upwards.

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

Remove the test cassette from the cassette compartment.



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



Check whether you can see any dirt inside the tip of the cassette.

If so, remove this carefully.

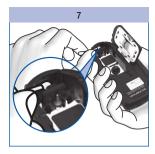
If the measuring optics are visibly soiled, clean the inside of the meter.



Carefully dab the measuring optics and the front opening of the meter with a slightly dampened cotton swab.



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



Carefully dab the interior of the tip cover with a slightly dampened cotton swab.

Remove the dirt that was left behind.

Allow the meter to dry thoroughly.



Open the tip cover again.



Re-insert the test cassette in the meter.



Press the cassette compartment cover closed.

The cassette compartment cover must close with an audible **CLICK**.



Close the tip cover.

Cleaning the blood glucose monitoring system

Cleaning and disinfecting the finger pricker

To prevent the transmission of infections, you must regularly clean and disinfect the finger pricker and cap:

- · at least once a week,
- · when there is blood on them,
- · always before someone else handles the finger pricker, for example, to assist you.

You need lint-free cloths in which you can wrap the whole finger pricker, water and 70 % isopropanol. Before you disinfect the finger pricker and the cap, you first have to clean them to remove blood and other dirt.



- · Visually impaired people must be assisted by a sighted person when cleaning the finger pricker.
- . Do not immerse the finger pricker and the cap in the fluids.
- Use only water for cleaning and only 70 % isopropanol for disinfecting.

Preparation

1

Remove the finger pricker from the meter.

Remove the cap from the finger pricker.

2

Remove the lancet drum from the finger pricker.

3

Cleaning

1

2

3

Slightly dampen a cloth with water.

Wipe the finger pricker and the cap thoroughly; the finger pricker from the outside only and the cap from the outside and the inside.

Dry the finger pricker and cap with a dry cloth.

Disinfecting

1

2

__

Dampen a cloth well with 70 % isopropanol.

Wipe the finger pricker and the cap thoroughly for 2 minutes each; the finger pricker from the outside only and the cap from the outside and the inside.

Place the cap back on again.

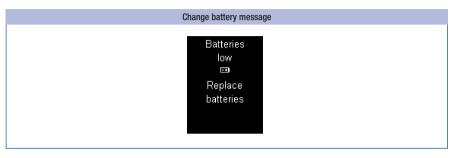
Wrap the whole finger pricker in the cloth.

Leave the finger pricker wrapped up for 8 minutes.

Unwrap the finger pricker and let it dry in the air.

Changing the batteries

The message *Batteries low Replace batteries* appears on the screen when the batteries are almost empty. It appears every time you turn the meter off if you have not yet changed the batteries. After the message appears for the first time, you can still perform about 50 tests.



Change the batteries as soon as possible.

You need 2 alkaline-manganese batteries type AAA, LR 03, AM 4 or micro (1.5 V) or 2 lithium batteries type AAA, FR 03, L 92 or 2 rechargeable NiMH batteries (type AAA). Always replace both batteries at the same time.

With the batteries supplied, you can perform approximately 500 tests or perform tests for about 1 year. When you use new batteries, the number of tests can vary depending on the battery manufacturer. In order to be able to continue performing a high number of tests, use batteries with as high performance characteristics as possible (high energy content and low self-discharge).

Specific settings increase the power consumption and thereby reduce the life expectancy of the batteries. The following settings increase the power consumption:

- Brightness of screen set to level 3
- Volume set to level 4 or 5
- · Acoustic mode on

When you use rechargeable batteries, note 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, it is possible that no more tests can be performed.

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

The meter has an built-in backup battery. This provides the power to maintain the clock function when there are no batteries inserted. The backup battery has a life expectancy of about 2 years. It cannot be replaced with a new battery.

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



- Visually impaired people must be assisted by a sighted person when changing the batteries.
- · Never throw batteries into a fire. 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.



Dispose of used batteries in an environmentally-friendly way at an appropriate collection depot.

For information about correct disposal, contact your local council or authority.



Push the battery door in the direction of the arrow as far as it will go to open it.



Lift up the battery door.



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



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



Close the battery door again.



Push the battery door in the direction of the arrow as far as it will go to close it.

Testing and storage conditions

Temperature

Make sure that the following conditions are met so that the meter and finger pricker operate reliably and you obtain accurate test results:

| Storage | Temperature |
|--|---------------|
| Blood glucose monitoring system without batteries, without test cassette | -25 to +70 °C |
| Blood glucose monitoring system with batteries, without test cassette | -10 to +50 °C |
| Blood glucose monitoring system with batteries, with test 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 message *Temperature too low* or *Temperature too high* appears (see *Messages and problems* page 122):



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 thus produce serious adverse health effects.

13

Testing and storage conditions

Tests cannot be performed at temperatures below +8 or above +42 °C. In this case, the E-8 message Temperature too low: Retest in a warmer location or Temperature too high: Retest in a cooler location appears (see Messages and problems page 128).



Never try to artificially speed up a temperature change in your meter, for example, by placing it in the refrigerator or on a radiator. Doing so can damage the meter and cause it to produce incorrect test results. Incorrect test results can cause the wrong therapy recommendation to be made and thus produce serious adverse health effects.

Do not store the finger pricker at very low or high temperatures, for example, in a hot car.

Humidity

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

Store the meter in a place with a relative humidity of 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. Allow the meter to return to ambient temperature slowly. Do not store the meter in high moisture areas (for example, in a bathroom).

Light conditions

Displayed text, numbers and symbols appear in 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 (for example, direct sunlight). These may interfere with the proper functioning of the meter and lead to error messages.

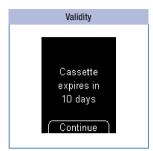
Sources of interference in the surrounding area



- 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.

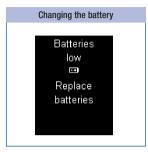
Messages and problems

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
to start a test.



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. After the message appears for the first time, 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 (for example, the date) or entering a setting again (for example, a reminder) and open the tip cover.

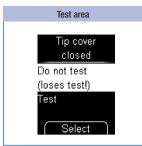
Close the tip cover again if you want to continue with the setting.

۸r

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

Press .

- Continue with settings: The meter returns to the Settings menu.
- Test: The setting procedure is interrupted (any changes you have already made are lost) and a test area is advanced.



This message appears if you close the tip cover once the meter has advanced a new test area.

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

Ô٢

Use **→** ★ to select *Do not test* or *Test*.

Press .

- 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.

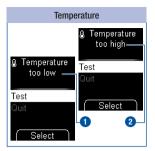
If you want to perform a test, use

۸r

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

0r

Press .



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.

Press .

- 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 result is flagged with the symbol $\widehat{\mathbf{M}}$ and stored.



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 thus produce 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.

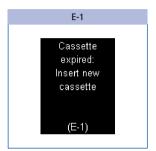
Problems

| Problem and possible causes | Solution to the problem | |
|--|--|--|
| The meter will not turn on. | | |
| The batteries are almost empty, empty or none are inserted. | Insert new batteries. | |
| The batteries were inserted the wrong way. | 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 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 made the electronics damp. | Allow the meter time to dry slowly. | |
| The meter is defective. | Contact the customer support and service centre (see page 134). | |
| The meter displays dashes instead of the time and date. | | |
| The meter has no longer saved the time and date. The meter was stored without batteries and the built-in backup battery is empty. | Reset the time and date. | |
| The meter is turned on, but the display remains blank. | | |
| The display is defective. | Contact the customer support and service centre (see page 134). | |

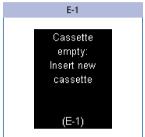
Error messages

On the following pages you can find a description of all error messages and how to solve them.

- If an error message appears, follow the instructions on the screen.
- If error messages occur frequently, contact the customer support and service centre (see page 134).
- If your meter has been dropped, this can also lead to implausible test results or error messages. In this
 case, contact the customer support and service centre (see page 134).

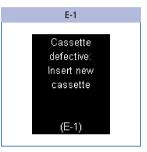


The use by period or use by date of the test cassette is exceeded. Insert a new test cassette in the meter.



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

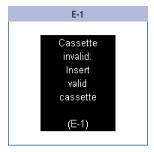
Insert a new test cassette in the meter.



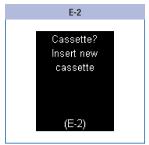
Remove the test cassette from the meter and re-insert it.

0r

Insert a new test cassette in the meter.

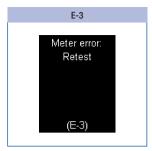


Insert a test cassette suitable for this meter type.



There is no test cassette in the meter.

Insert a new test cassette in the meter.

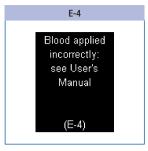


Your blood glucose value may be very low.

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

A meter error has occurred or the meter is defective.

If the error message is still displayed after turning the meter on again, contact the customer support and service centre (see page 134). The meter may be defective.

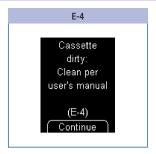


You have applied too little blood to the test area.

0R

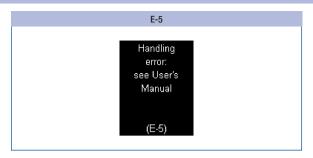
You did not apply the blood to the centre of the test area or applied it too much to one side.

Repeat the test with a larger amount of blood. Apply the blood drop to the centre of the test area.



Remove the dirt inside the tip of the cassette and, if necessary, carefully clean the measuring optics.

Press if you want to go directly to the *Clean* menu.



E-6 Too bright: Retest in shade (E-6)

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

Repeat the test.

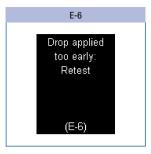
You...

- · have not washed your fingers or they are soiled or sticky.
- applied a contaminated blood drop (for example, due to food or drink residue on your finger).
- · pressed your finger on the test area.
- moved the tape of the test cassette.
- smeared the blood on the test area.
- · were trembling or shaking.
- did not remove your finger from the test area as soon as you heard the beep tone.

Wash your hands with warm water and soap and rinse well. Dry your hands thoroughly with a clean towel before obtaining blood.

Touch the test area gently and steadily with the blood drop or control solution. Apply the blood drop or control solution to the centre of the test area. Avoid trembling or shaky movements.

Remove your finger from the test area as soon as the beep tone sounds and *Test in progress* is displayed. The beep tone helps you to obtain a reliable test result.



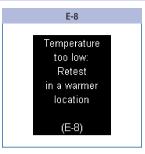
Do not apply blood or control solution to the test area until the prompt Apply drop is displayed.

Repeat the test.

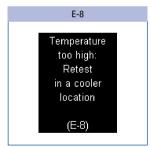


If the error message reappears after turning the meter on again:

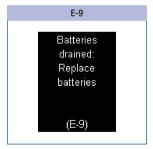
Contact the customer support and service centre (see page 134).



Move to a place where the 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 temperature is at most +40 °C and wait for the temperature of the meter to adjust to this temperature.



Insert two new batteries.

Discarding the blood glucose monitoring system

During blood glucose testing, the meter may come into contact with blood. Used meters therefore carry a risk of infection. Discard your used meter, after removing the batteries, according to local regulations.

The meter falls outside the scope of the European Directive 2012/19/EC (Directive on waste electrical and electronic equipment).

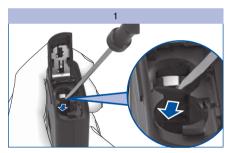
Dispose of used batteries in an environmentally-friendly way at an appropriate collection depot. For information about correct disposal, contact your local council or authority.

Used lancet drums and test cassettes can be disposed of in household waste if no other regulations apply locally.

Removing the backup battery

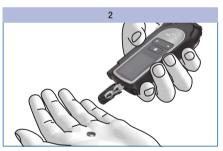
In addition to the two batteries in the battery compartment, there is a third battery in the side of the battery compartment; the backup battery. You must also remove this battery before discarding the meter.

Remove the backup battery as follows:



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

The battery then drops into the battery compartment.



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

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 samples, refer to the package insert of the Accu-Chek Mobile test cassette. Your meter displays blood glucose values that refer to plasma although you always apply whole blood to the test area. You can find information on how the test works and on the referenced test principle in the package insert of the Accu-Chek Mobile test cassette. |
| Measuring interval | See the package insert of the Accu-Chek Mobile test cassette |
| Blood volume | See the package insert of the Accu-Chek Mobile test cassette |
| Measuring time | Approx. 5 seconds (depending on the concentration) |
| Power supply | 2 alkaline-manganese batteries (1.5 V; type AAA, LR 03, AM 4 or micro) or 2 lithium batteries (1.5 V; type AAA, FR 03, L 92), backup battery: 3-volt lithium coin cell type CR1025 |
| Battery life | Approximately 500 tests or approximately 1 year (less if the brightness of the screen 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 |

| +10 to +40 °C | |
|--|--|
| 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 |
| | |
| 15 to 85 % relative humidity | |
| 15 to 93 % relative humidity | |
| Sea level to 4,000 m above sea level | |
| 2,000 results with time and date, averages for 7, 14, 30 and 90 days | |
| $121\times63\times20$ mm with finger pricker | |
| Approx. 129 g with finger pricker, batteries, test cassette and lancet drum | |
| OLED (Organic Light Emitting Diode) display | |
| USB (Micro B) | |
| This device meets the electromagnetic immunity requirements as per EN ISO 15197 Annex A. The chosen basis for immunity testing (on electrostatic discharge) was basic standard IEC 61000-4-2. In addition, the device meets the electromagnetic emissions requirements as per EN 61326. Its electromagnetic emission is thus low. Interference from the device to other electrically driven equipment is not anticipated. | |
| | Meter without batteries and without test cassette: Meter with batteries and without test cassette: Meter with batteries and with test cassette: 15 to 85 % relative humidity 15 to 93 % relative humidity Sea level to 4,000 m above sea level 2,000 results with time and date, averages for 7, 14, 30 121 × 63 × 20 mm with finger pricker Approx. 129 g with finger pricker, batteries, test cassette OLED (Organic Light Emitting Diode) display USB (Micro B) This device meets the electromagnetic immunity require EN ISO 15197 Annex A. The chosen basis for immunity telectrostatic discharge) was basic standard IEC 61000-4 In addition, the device meets the electromagnetic emiss |

| Performance assessment | The performance characteristics of the Accu-Chek Mobile system (Accu-Chek Mobile meter and Accu-Chek Mobile test cassette) were determined using capillary blood from patients with diabetes (system accuracy), venous blood (repeatability) and control solution (intermediate precision). |
|------------------------------|--|
| Calibration and traceability | The system is calibrated with whole blood containing various glucose concentrations as a calibrator. The reference values are obtained using the hexokinase method which is calibrated using the ID-GCMS method. The reference method is traceable to a NIST standard using the ID-GCMS method, which is the method of highest metrological quality (order). |

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

Declaration of conformity

The Accu-Chek Mobile blood glucose meter conforms with the basic requirements and other relevant regulations of the European Directive 1999/5/EC on radio and telecommunications terminal equipment (R&TTE). The conformity declaration may be found at the following Internet address: http://declarations.accu-chek.com

System components

Accu-Chek Mobile meter (Model U1)

Accu-Chek Mobile test cassettes

Use only these test cassettes when you perform blood glucose tests 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.



Contact your customer support and service centre (see page 134) for information on where you can obtain the test cassettes and control solutions.

Accu-Chek FastClix finger pricker

Accu-Chek FastClix lancet drums

Use only these lancet drums when you obtain blood with the Accu-Chek FastClix M1 finger pricker. You can find the type designation 1 on the side of the finger pricker.



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Customer Support and Service Centre

If you need advice on how to operate the Accu-Chek Mobile meter or the Accu-Chek FastClix finger pricker, if you seem to be obtaining implausible test results, or if you suspect that the meter, test cassette, finger pricker or lancet drum might be defective, contact the Customer Support and Service Centre. Do not attempt to repair or modify the meter or finger pricker yourself. Our staff will help solve any problems you might be experiencing with the meter, test cassette, finger pricker or lancet drum from Roche.

Australia

Accu-Chek Enquiry Line: 1800 251 816

Pump Support: 1800 633 457 www.accu-chek.com.au

Singapore

Accu-Chek ExtraCare line: 6272 9200

www.accu-chek.com.sg

United Kingdom

Roche Diabetes Care Limited Charles Avenue, Burgess Hill

West Sussex, RH15 9RY, United Kingdom

Accu-Chek Customer Careline 1)

UK Freephone number: 0800 701 000 ROI Freephone number: 1 800 709 600 1) calls may be recorded for training purposes

www.accu-chek.co.uk www.accu-chek.ie

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Explanation of symbols

Explanation of symbols

The following symbols may appear on the packaging, on the type plate of the meter and on the finger pricker. They have the following meanings:

| (i | Consult instructions for use |
|-------------|---|
| \triangle | Caution, refer to safety-related notes in the instructions for use accompanying this product. |
| 1 | Temperature limitation (store at) |
| \square | Use by |
| (2) | Use only once |
| STERILE R | Sterilized using irradiation |
| <u>~~</u> | Manufacturer |
| REF | Catalogue number |
| LOT | Batch code |
| IVD | In vitro diagnostic medical device |
| GTIN | Global Trade Item Number |



Blood glucose meter: This product fulfils the requirements of the European Directive 1999/5/EC on radio and telecommunications terminal equipment (R&TTE).

€ 0088

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

€ 0088

Finger pricker and lancet drum:

These products fulfil the requirements of the European Directive 93/42/EEC on medical devices.



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



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 other symbols can be found in the instructions for use and inserts accompanying components within the packaging.



According to Continua Health Alliance guidelines



Certified by USB implementers forum

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 blood glucose* or *high blood glucose* in the table are **not** blood glucose values. Ask your healthcare professional if you want to change your therapy based on the index values.

References

Low Blood Glucose Index / High Blood Glucose 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

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

21 Appendix

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.