ACCU-CHEK® Active

BLOOD GLUCOSE SYSTEM

Reference Manual

Roche

Please read this manual carefully and completely before performing the first measurement. Should you have any questions, please contact our customer support and service centre. You will find our address in Chapter 10.4.

The Accu-Chek Softclix finger pricker is intended for patient self-monitoring by a single person.

It must not be used to collect blood in a multi-patient setting as it does not incorporate any features to guard against cross-infection.

On packaging, on the type plate and in the parts of this manual dealing with your Accu-Chek Active meter you may encounter the following symbols, shown here with their meaning:

IVD	For in vitro diagnostic use
CE 0088	This product fulfils the requirements of Directive 98/79/EC on in vitro diagnostic medical devices.
REF	Catalogue number
	Please consult instructions for use
	Caution (refer to accompanying documents). Please refer to safety-related notes in the manual accompanying this instrument.
	Manufacturer

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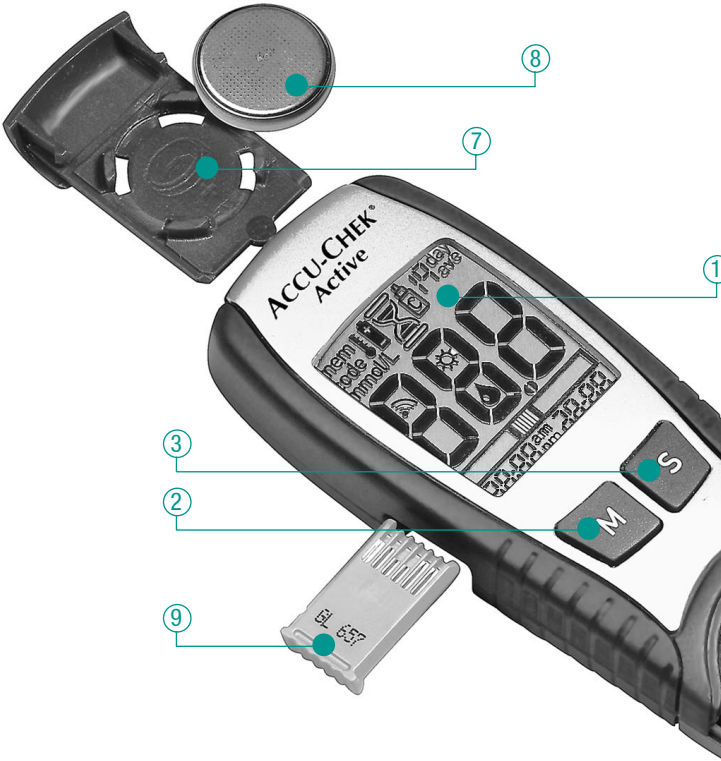

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1 Introduction

Your Accu-Chek Active blood glucose meter is a state-of-the art precision instrument that will enable you to test your blood glucose simply and with confidence.

Before using your Accu-Chek Active meter or Accu-Chek Softclix finger pricker for the first time, please refer to the Getting Started Guide included in this pack. Should you require further information, please study this reference manual.

This manual may tell you a lot of what you know already, but it will also introduce many features that will be new to you. At the end of this introduction you will find a brief summary of your meter's main properties and functions. Each of the functions will be described in more detail later in this manual.

If there are any other points you are unclear about – Chapter 10.4 provides the address and telephone numbers of our customer support and service centre.

Last update: 2006-11

1.1 The meter's main features at a glance

- Testing in record time: With a testing time of about 5 seconds, your Accu-Chek Active is one of the fastest blood glucose meters available.
- New design: Your new Accu-Chek Active was designed for good looks, and ergonomic functionality.
- Tiny blood sample: Your Accu-Chek Active requires only a tiny drop of blood – 1 to 2 µL – if you apply the blood drop to the middle of the test pad. If at any time the drop you apply is too small, the meter will detect this and issue a warning.
- Easy to operate: No need to press buttons when you carry out the test.
- Easy-to-use data analysis function: Accu-Chek Active has a 200-value memory for saving results (together with date and timestamp) as well as an infrared interface for communicating with a PC running a suitable analysis program.

1.1 The meter's main features at a glance

- Integrated data evaluation: From the results stored in memory your meter can calculate the average of your blood glucose results over the last 7 or 14 days.

- Out-of-meter dosing: After activating the test cycle you may remove the test strip to apply blood (e.g. from an earlobe), and then insert it again in the meter.

- Accurate results: Application of blood to the test strip starts a colour reaction. The final colour is accurately read (measured photometrically) by the meter's optical system and the result is converted to a blood glucose value.

- Dependable coding: Each pack of test strips contains a coding chip that holds all of the important information that is needed to evaluate the strips from that particular pack. Whenever you open a new pack of strips, simply insert the new coding chip in the coding chip slot.

- Easy-to-read display: Numbers and messages are clearly presented on a spacious display screen. Clear symbols give you additional easy-to-follow instructions.

- Intelligent power supply: Accu-Chek Active shuts off automatically after 1–2 minutes of non-use. Naturally, all of your results and other data remain safe in memory. Also, you receive a warning when the battery has only enough power for about another 50 tests.

1.2 About this reference manual

This manual will help you get to know your new Accu-Chek Active meter step by step. It will provide you with all the information you need to operate, troubleshoot, clean and care for your meter. It is important to remember that, in order to keep your meter in tip-top condition, you need to comply with the care instructions in addition to following the correct operating procedures. Accu-Chek Active is a precision instrument. Dirt or the wrong cleaning agent can impair its function.

Please read carefully all text in this manual that is preceded by the following symbols:

This warns of a situation that may pose a risk to your health (e.g. as a result of you calculating the wrong insulin dose).

This symbol indicates that your meter is at risk of being damaged.

This symbol highlights important information that will help you get the most out of your meter.

We recommend that you start by familiarizing yourself with all of the elements of your Accu-Chek Active shown on pages 4–7 of this manual. Practise all of the operations described in this manual, and also practise testing. That way you can feel confident in testing whenever you need.

2 Modes

As you will have gathered, your Accu-Chek Active meter can do much more than just measure blood glucose. It offers a number of additional functions, which fall into three groups. “Mode” refers to a group of functions that you can call upon. You select a mode simply by turning on the meter or by the way in which you turn it on. Detailed information on the various ways of turning on your meter and the options available in each mode is provided later in this manual.

2.1 Test Mode

This is the main mode in which you will use your Accu-Chek Active meter and is used exclusively for testing your blood glucose.
By inserting a test strip in the test strip guide, you automatically enter this mode.

2.2 Memory Mode

Memory Mode provides you with various functions to help you evaluate your results. To enter this mode, turn on your Accu-Chek Active meter by pressing the **M**(emory) button.

- You can retrieve up to 200 results.
- Your Accu-Chek Active meter can calculate the average of your glucose results over the last 7 or 14 days.
- You can download your results to a PC from the meter's memory (Accu-Chek Compass software available separately).
- You can erase the most recent result.

2.3 Set Mode

To enter Set Mode, turn on your Accu-Chek Active meter by pressing the **S**(et) button.

- You can choose the format in which you wish the date and time to be displayed.
- You can enter the date and time (required once only).
- You can enable and disable the beep tone.

3 Initial steps before testing

3.1 After opening the pack

Accu-Chek Active is sold complete with one lithium battery already inserted. A plastic film protects the battery against becoming drained prematurely. Before using the meter, remove the film covering the battery.

- The film is visible at the top of your Accu-Chek Active meter, projecting from the battery compartment. Simply pull the film directly away from the top of the meter.

- This will open the battery compartment. Then you can remove the protective film.

- Slide the battery compartment back into the meter and press gently inwards until it clicks into place.

3.2 Basic settings

When you turn on your Accu-Chek Active meter for the first time, it has the following settings (which you can change):

- Display format for the date: day.month/DD.MM (or alternatively month.day/MM-DD)
- Display format for the time: 24h (or alternatively 12h)
- Year: year of manufacture
- Date: 0.0 (or alternatively 0-0)
- Time: 0:00 (or alternatively 0:00 a.m.)
- Beep tone: on

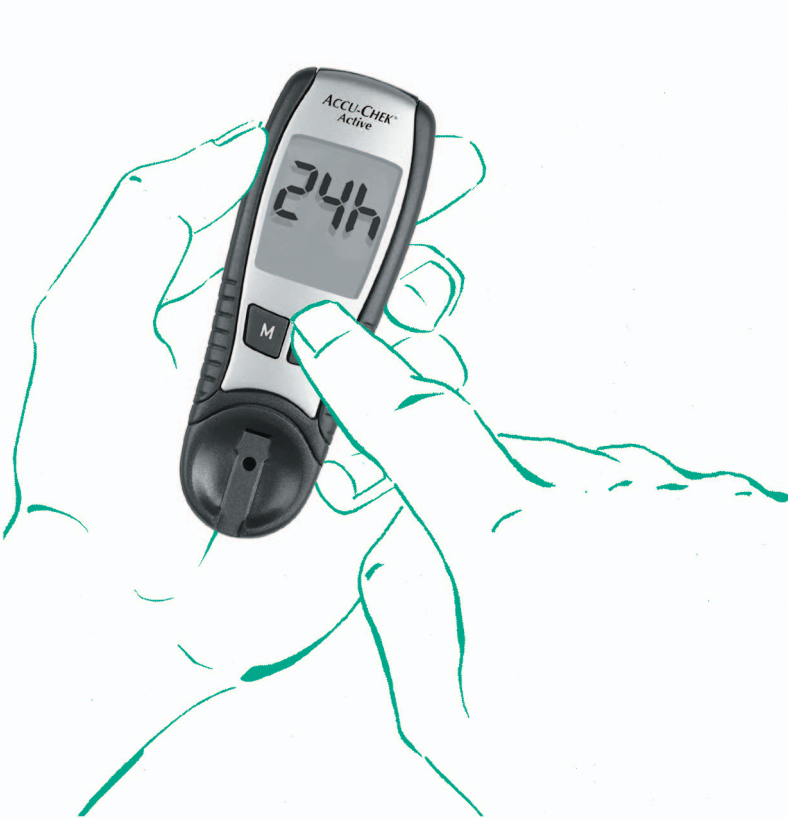
3.2 Basic settings

Accu-Chek Active comes in 2 versions.

When you first turn on your Accu-Chek Active, please be sure to check that the meter is set to display **mmol/L** (for millimoles per litre) above the large numerals in the display (888). Ask your doctor if you do not know which is the right unit for you. If this is not displayed, please contact the Accu-Chek Customer Careline free on 0800 701000 (UK) or 1 800 709600 (Ireland) for a replacement meter.

If you see the correct unit, please enter the date and time as described. Only then can your results be properly saved in “memory” with the correct date and timestamp.

3.2 Basic settings



Turning the meter on in Set Mode

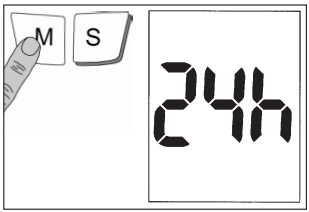
You use only the **M** and **S** buttons on the front of your Accu-Chek Active to enter the desired settings.

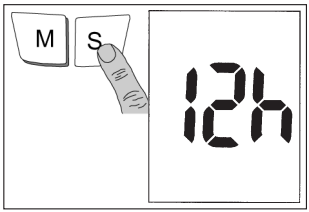
- Briefly press the **S** button (for less than 3 seconds). Accu-Chek Active is now turned on and in Set Mode.

In the display you see the following:

- the current time display format (24h/12h)
- flashing: the current time, or 0:00 (a.m.) when you turn on the meter for the first time
- flashing: the current date, or 0.0 (0-0) when you turn on the meter for the first time

3.2 Basic settings



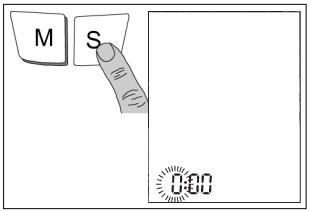


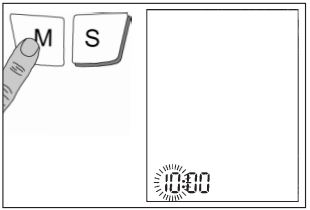
The way in which the date and time are displayed from here on depend on the chosen display format.

- If you wish to change the time display format, press the **M** button now. This allows you to choose between 24h and 12h display format.

- When you see the desired format, press the **S** button once to proceed to the date and time settings.

3.2 Basic settings





Setting the date and time

The procedure for setting the date and time is essentially the same for all units of time (day, hour, etc.):

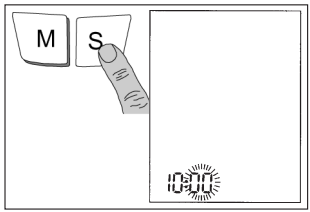
- Use the **S** button to select the unit of time you wish to change. The unit will flash, indicating that it is ready to be changed.

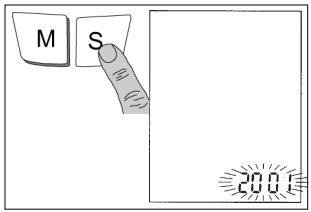
- Use the **M** button to modify the unit of time selected.

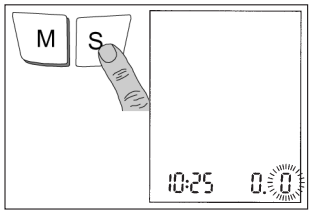
- Pressing the **M** button once will increment the value of the unit by one (one hour, one minute, etc.). Settings where there are only two options (time format, beep tone) are simply toggled backwards and forwards when you press the **M** button.

- Keeping the **M** button depressed enables you to fast-scroll the value forward.

3.2 Basic settings







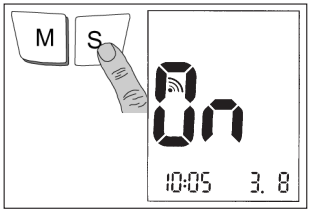
- Confirm the setting by pressing the **S** button again. The display moves on automatically to the next unit of time, which again flashes.

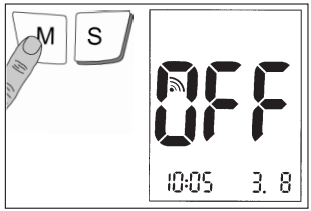
- Use the same procedure to set all the remaining units of time.

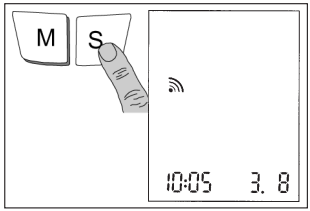
The date and time are set in the following sequence:
hours –> minutes –> year –> month –> day

The year is already set.
Press the **S** button to confirm.
The meter automatically recognises, and allows for, leap years.

3.2 Basic settings







Setting the beep tone

After you have set the day and pressed the **S** button, you can either enable or disable the beep tone.

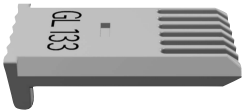
- Press the **M** button to turn the beep tone on and off.

- Press the **S** button to complete the settings procedure.

Check that all the settings now shown on the display are correct. Press the **S** button again to turn off your Accu-Chek Active meter. If any of the settings are incorrect, you may repeat the settings procedure (after turning the meter on again).

3.3 Coding

The properties of the Accu-Chek Active test strips you use with the meter may differ very slightly from one pack to another (because of batch-to-batch differences). Your Accu-Chek Active meter must be programmed to allow for these differences in properties in a process known as “coding”. All the information relating to the strips in a particular pack of Accu-Chek Active test strips is held in the coding chip that comes with that pack.



Each time you open a new pack of test strips, you will need to insert the coding chip that came with that pack into your meter. Coding chips from other packs contain the wrong information for your new strips, so test results will be incorrect. Leave the coding chip in the meter until you have used up all of the test strips from a particular pack.

Check that the three-digit code (e.g. 133) printed on the chip matches the code printed on the label of the container the test strips came in. When coding is complete, your Accu-Chek Active meter will display the code number.

3.3 Coding

Inserting the coding chip

When coding, leave your Accu-Chek Active meter turned off.

- Take the new coding chip from the pack of test strips.
- Gently slide the coding chip into the slot on the side of the meter ⑩ (see parts summary).
- Ensure that you push the coding chip fully home.
- That's all there is to it!

When you subsequently perform your first blood glucose test with the new coding chip (and new test strips), check that the code number you see in the display is the same as the number printed on the container the test strips came in. For further information please refer to the next chapter.

4 Testing blood glucose with your Accu-Chek Active meter

4.1 Materials for testing blood glucose

Please have the following items ready to carry out the test:

- your Accu-Chek Active meter with the coding chip inserted,
- the pack of Accu-Chek Active test strips you took the coding chip from,
- a suitable finger pricker (such as the Accu-Chek Softclix finger pricker and Accu-Chek Softclix Lancet).

With your Accu-Chek Active meter use only Accu-Chek Active test strips. Any other test strips will give incorrect results. Sometimes the error can be significant, causing the wrong therapeutic decision to be taken and so producing adverse health effects!

4.2 Preparing for the blood glucose test

If you are not yet familiar with the concept of blood glucose self-monitoring using a meter, practise first by carrying out a quality control test as described in Chapter 6. A quality control test is carried out in the same way as a normal test, but with control solution (a standardized glucose solution) instead of blood.

- Carefully read the pack inserts that came with the test strips and the finger pricker.

- Thoroughly wash and dry the site you intend to collect blood from. Any moisture remaining can dilute the blood and so produce an incorrect result.

- Remove a test strip from its container. Close the container immediately. The cap contains a drying agent which ceases to function if the container is left open, rendering the test strips unusable.

4.3 Performing a blood glucose test

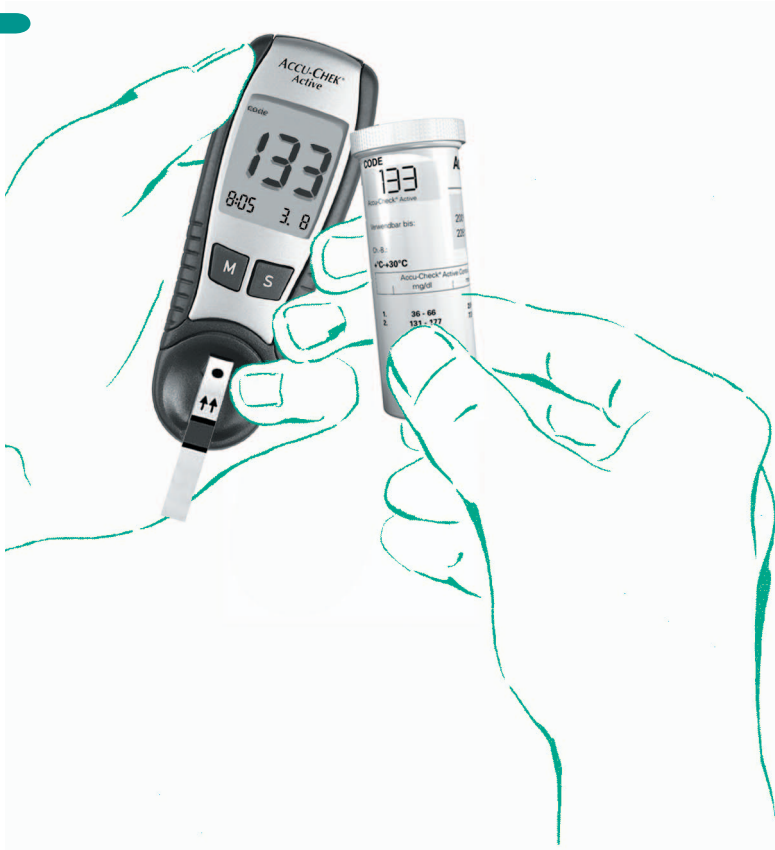
Check the round control window on the back of the test strip with the colour scale printed on the test strip container. The colour of the control window must match that of the colour interval at the top (0 mmol/L). If the test strip shows a different colour, do not use it.

Hold the test strip so that the application area and arrows are facing upwards. Gently push the test strip in the direction of the arrows into the test strip slot ④ of your meter, until you hear it click into place.

Inserting the test strip automatically puts the meter in Test Mode. Please remember that your meter automatically turns off after about 1–2 minutes of non-use (i.e. when no button is pressed).
If this happens, remove the test strip and repeat the procedure described above with a **new** test strip.

Now watch the display.

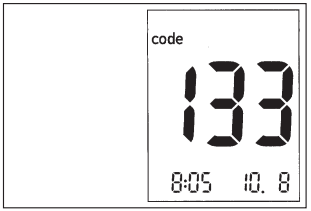
4.3 Performing a blood glucose test

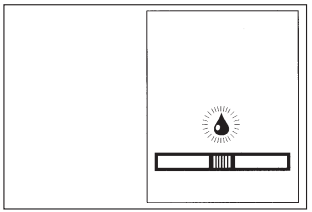


- The meter carries out a display test (for details see page 87), then shows the code number. Is this the number printed on the test strip container? If not, check that you really did insert the coding chip from the new pack. If you are using the right coding chip but the number in your display is wrong, please call the Accu-Chek Customer Careline free on 0 800 701000 (UK) or 1 800 709600 (Ireland).

  If “code” is flashing and you see three horizontal bars (- - -) instead of a number, you have not inserted the coding chip.

4.3 Performing a blood glucose test





- Check that the correct date and time are displayed.

Do not carry out any tests if the code number in the display is not the same as the number on the test strip pack. Incorrect coding produces incorrect results. Sometimes the error can be significant, causing the wrong therapeutic decision to be taken and so producing adverse health effects.

When the display test has been successfully completed and the code number matches, your Accu-Chek Active meter is ready for testing.

- The flashing drop symbol is your cue to apply a drop of blood (within two minutes). If you wish to apply blood while the test strip is in the meter, please read on. For out-of-meter dosing please see page 55.

4.3 Performing a blood glucose test

In-meter dosing

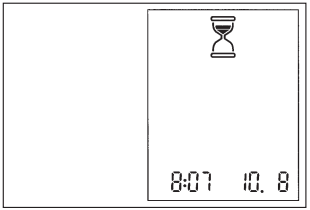
If you have opted for in-meter dosing, proceed as follows:

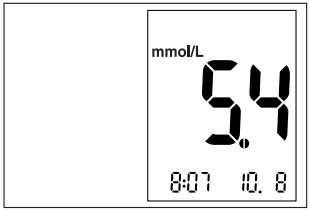
- Massage a fingertip to stimulate the circulation and make blood collection easier.
- Use the finger pricker to prick the side of the massaged fingertip.
- Without pressing too hard, encourage a small drop of blood to form.

- Apply the drop of blood on to the middle of the orange-coloured, square application area (pad). It is OK to touch this area when applying blood, but do not attempt to spread the blood. If you suspect the amount of blood may not suffice, you may apply a second drop within 5 seconds.

- Your Accu-Chek Active meter beeps briefly (provided the beep tone is enabled) to acknowledge application of blood and to announce the start of testing. Make sure you do not move the test strip during testing, or an incorrect result may be obtained.

4.3 Performing a blood glucose test



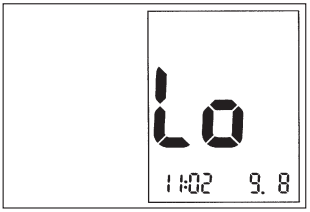


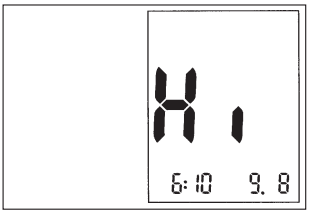
- The hourglass symbol indicates that testing is in progress.

- The meter beeps again after about 5 seconds to signal that the test is complete. The result appears in the display and is automatically saved together with the date and time.

- Remove the test strip from the meter, which will now automatically turn off.

4.3 Performing a blood glucose test





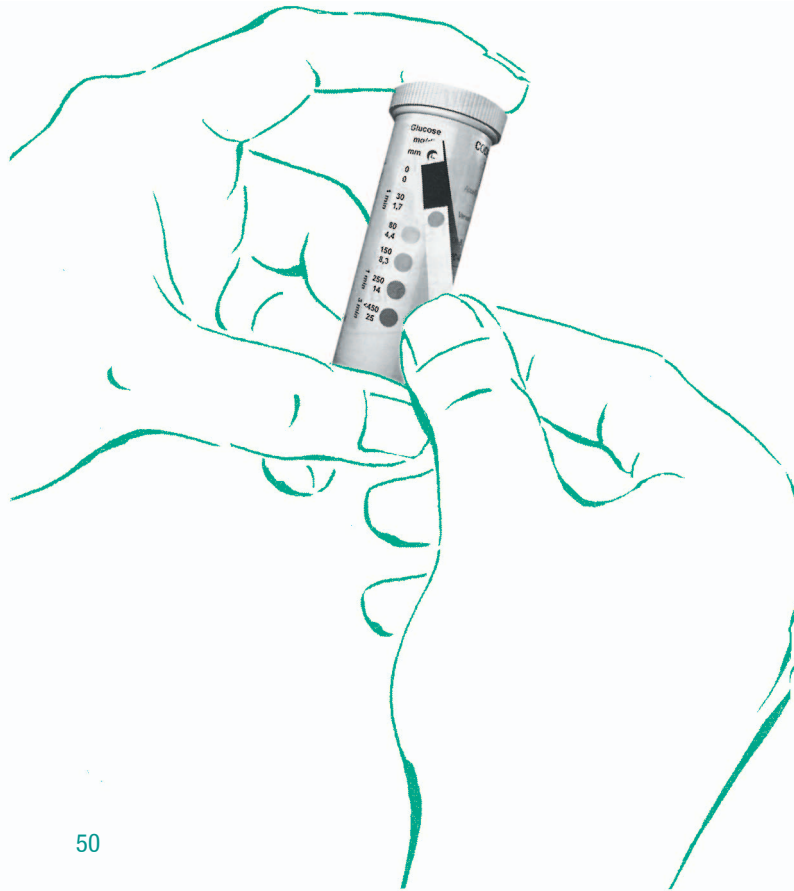
Plausible results

Your Accu-Chek Active meter measures blood glucose within a defined range (0.6-33.3 mmol/L). Values outside this range are displayed as “Lo”- meaning the result is less than 0.6 mmol/L - or “Hi”- meaning the result is greater than 33.3 mmol/L.

If you applied too little blood, please repeat the test with a new test strip.

Now perform a plausibility check. It is important that this check be performed within 30–60 seconds after blood was applied. Any later than this and comparison is no longer possible owing to excessive discolouration of the test strip. This colour comparison is solely for the purpose of checking the result. Therapeutic decisions must be based on the result given in the display.

4.3 Performing a blood glucose test



- Turn over the test strip to reveal the round control window on the back.

- On the label of the test strip container is a colour scale with blood glucose values printed alongside. Select the blood glucose value that best approximates the reading you obtained.

- Compare the colour of the control window with the colour you selected on the label.

The colours must be a fairly close match. If there is a great disparity, repeat the test. If you cannot obtain a close match even after several attempts at testing, please call the Accu-Chek Customer Careline.

If the colours match, the result is confirmed and the test successfully concluded. You can dispose of the used test strip with your regular domestic waste.

Implausible results

If the displayed result does not reflect the way you feel or seems unusually high or low, or if colours do not match, please check the following:

- With your Accu-Chek Active meter, are you using only Accu-Chek Active test strips?
- Have you really used a test strip from a pack with the same code number as that displayed by your Accu-Chek Active meter?
- Did you apply the drop of blood within 3 minutes after removing the test strip from its container?
- Are both the test strip guide and measurement optics clean?

- Was the test strip container you are presently using kept properly closed?

- Have the test strips expired?

- Have the test strips been kept under suitable temperature conditions (i.e. not in a car in very hot or cold weather)?

If the answer to all these questions is “yes”, carry out a quality control check with a new test strip as described in Chapter 6. If this check confirms the meter is working properly, please read the instructions in Chapter 4.3 again and perform another blood glucose test with a new test strip. If you feel the new result is also implausible, please speak to your doctor about it.

4.3 Performing a blood glucose test

Out-of-meter dosing

The test procedure is mostly identical with “Performing a blood glucose test” on page 38. Follow the instructions given there up to the point where you are instructed to apply blood.

- Clean and massage the site you intend to collect blood from (for example, an ear lobe). This will stimulate the circulation and make blood collection easier.

- Use the finger pricker to prick the selected site.

- Without pressing too hard, encourage a drop of blood to form.

4.3 Performing a blood glucose test

- Pull the strip out of the meter. The two symbols (blood drop and test strip) are flashing. You now have 20 seconds to apply blood to the test strip and re-insert it before the meter switches off. After 15 seconds a beep tone once per second indicates that the time for measurement has expired.

- Apply the drop of blood to the middle of the orange-coloured pad. It is OK to touch this application area when applying blood, but do not attempt to spread the blood.
- Gently push the test strip back into the test strip slot of your Accu-Chek Active meter, until you feel it click into place.
- Your Accu-Chek Active meter beeps briefly to acknowledge application of blood and to announce the start of testing. Make sure you do not move the test strip during testing, or an incorrect result will be obtained.
- The hourglass symbol indicates that testing is in progress.

4.3 Performing a blood glucose test

- The meter beeps again after about 10 seconds to signal that the test is complete. The result appears in the display and is automatically saved together with the date and time.

Testing by healthcare professionals

The out-of-meter dosing feature of the Accu-Chek Active meter makes it ideal for testing in a professional environment. For each patient use a separate lancet and finger pricker, or alternatively use the specially developed Accu-Chek Softclix Pro, or Safe-T-Pro lancet devices.
Collect used lancets and test strips in a sturdy sharps container with lid. Be sure to observe all relevant Health and Safety regulations.

A potential infection risk exists. Medical staff and other persons using Accu-Chek Active to test blood glucose from more than one patient must be aware that any item coming into contact with human blood is a potential source of infection. (Please see "Protection of Laboratory Workers from Infectious Diseases Transmitted by Blood, Body Fluids, and Tissues"; Second Edition, Tentative Guideline, 1991, Document M29-T2, National Committee for Clinical Laboratory Standards).

5 Using Accu-Chek Active as an electronic diary

5.1 Results memory

Your Accu-Chek Active meter has a 200-value memory for saving results together with date and time. You do not need to save a result specially; the meter does it all for you. Once all the memory locations are full, the meter automatically erases the oldest entry. All results in memory are consecutively numbered from 1 (most recent) to a maximum of 200 (oldest).

In addition to results, your meter also stores all relevant additional information and display messages. For example, results flagged as control results are displayed together with a bottle symbol incorporating the letter “C”. Results obtained at a temperature outside the permitted range are displayed together with a thermometer symbol. Please refer to Chapter 8 for a complete list of display messages and symbols.

5.2 Retrieving results

To use the memory functions of your Accu-Chek Active meter, you must turn it on in Memory Mode.

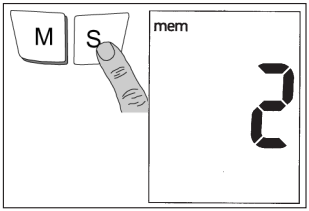
- Briefly press the **M** button (for less than 3 seconds).

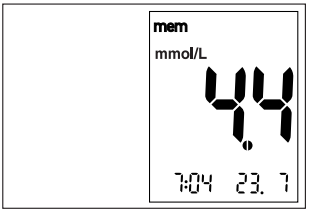
In the display you see the following:

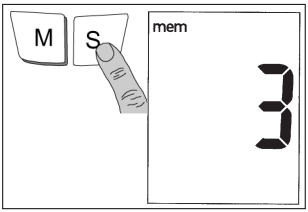
- at top left, “mem” (short for “memory”)

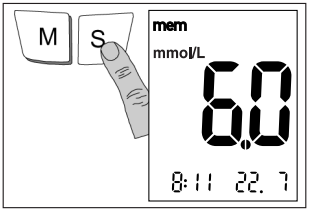
- followed by the most recent result (in memory location “1”), together with the time and date.

5.2 Retrieving results









To recall earlier results (in memory locations 2-200):

- Press the **S** button once to move back one result in time. As long as you keep the button pressed, the number of the memory location is displayed. As soon as you release the button, the result appears.

- By holding down the **S** button, you can scroll quickly through the results. As soon as you release the button, the result saved in that location appears.

- When you reach the last memory location containing a result, the display reverts to memory location “1”.

5.2 Retrieving results

Finding the 7 or 14 day average of glucose results

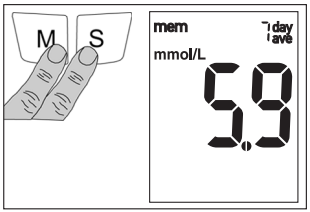
As well as just showing the results in memory, your Accu-Chek Active meter can calculate and display average values for the last 7 or 14 days.

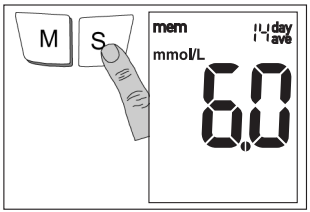
- Start by pressing the **M** button to turn on your Accu-Chek Active meter in Memory Mode.

- Then press the **M** and **S** buttons at the same time.

The display shows “7 day ave” at top right. The figure shown is the average of glucose results for the last 7 days.

5.2 Retrieving results





- Then press the **M** and **S** buttons again at the same time.
- The display changes; the figure shown is now the average value for the last 14 days.

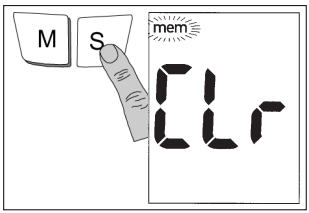
To exit from the “average” screen, press the **S** button. The display reverts to the last result shown before the average value.

Averages can only be calculated as long as you have set the date and time (see Chapter 3.2). Without these settings the meter cannot identify the results from the last 7 or 14 days. For safety reasons no average value can be displayed when the date has been manipulated into the future.

When averages are being calculated, all control readings are ignored.

5.2 Retrieving results

longer than 3 seconds



Clearing (erasing) results from memory

You can clear the current value (and only this) from memory. This feature is useful, for instance, if you have obtained an implausible result. Both the result and the time and date information are erased, though the memory location remains occupied.

An average value cannot be displayed when the most recent result has been erased from memory. Results arising after a value has been erased are included in calculation of the average.

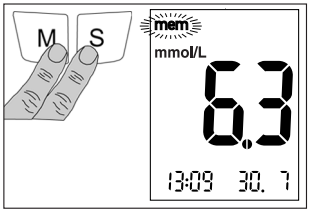
Clearing the current value:

- Turn on your Accu-Chek Active meter by keeping the **S button** pressed **for longer than 3 seconds**.

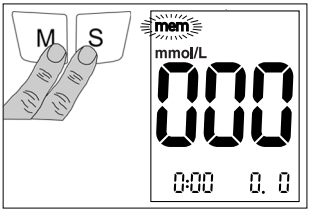
- The display shows “Clr” and “mem” (flashing).

5.2 Retrieving results

longer than 3 seconds



longer than 5 seconds



- Keep the **M** and **S** buttons pressed together for longer than **3** seconds.

- The current result is displayed.

- Keep the **M** and **S** buttons pressed together for longer than **5** seconds. You will hear 5 beeps.

- All information relating to the current result is cleared and set to zero. The memory location remains occupied.

Your Accu-Chek Active meter turns off automatically after you have cleared the result.

5.3 Downloading data to a PC

General information about data downloading

Roche Diagnostics offers a variety of special software programs (e.g. Accu-Chek Compass, and the Accu-Chek Smart Printer System) to expand the memory functions integrated in your Accu-Chek Active meter. Such programs enable you and your doctor to manage your data more effectively and, through graph and table views, make it easier for you to understand your self-testing data.
For further information please contact the Accu-Chek Customer Careline 0800 701000 (UK) or 1 800 709600 (Ireland)

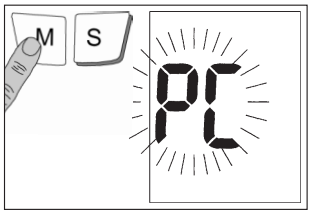
For data downloading you need a suitable PC program as well as the Accu-Chek Infrared Cable. For further information please contact the Accu-Chek Customer Careline 0800 701000 (UK) or 1 800 709600 (Ireland) (see Chapter 10.4).

Data can only be evaluated on a PC as long as you have set the full date and time (see Chapter 3.2).

Your Accu-Chek Active meter has an inbuilt infrared interface ⑪ (see illustration on pages 6–7), permitting cordless data downloading to a suitably equipped PC. All results in memory are downloaded each time. After download the data are still in the meter's memory.

5.3 Downloading data to a PC

longer than 3 seconds



Downloading procedure

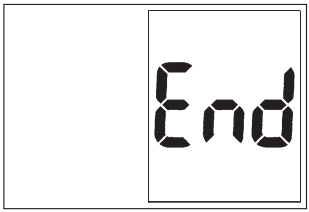
To download data, proceed as follows:

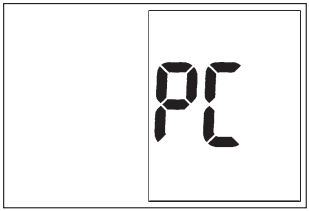
- Set up the program and infrared cable according to manufacturer's instructions so you can start data transfer with a mouse click.

- Position your Accu-Chek Active meter about 10 cm from the infrared cable. Point the two infrared windows towards one another.

- Turn on your Accu-Chek Active meter by keeping the **M** button pressed (for longer than 3 seconds) until "PC" appears flashing in the display. This indicates the meter is ready to communicate.

5.3 Downloading data to a PC





- Start downloading at the PC. The PC sends an instruction to the Accu-Chek Active meter.
- During active downloading, “PC” remains constant in the display
- On completion of downloading, “End” appears in the display.

Following the download you can turn off your Accu-Chek Active meter with the **M** button, if the PC has not already shut down the meter. In the latter case the “End” message may not be displayed.

6 Checking Accu-Chek Active

6.1 Quality control testing with control solution

To ensure your results are always dependable, you must periodically check the performance of your Accu-Chek Active meter.

Perform a quality control test:

- after you have opened a new pack of Accu-Chek Active test strips and consequently replaced the coding chip,
- after you have inserted a new battery,
- after you have cleaned your Accu-Chek Active meter,
- if you have reason to doubt the validity of a result.

6.2 Preparing for the quality control test

For the quality control test, please have the following items ready:

- your Accu-Chek Active meter with the coding chip inserted,
- the pack of Accu-Chek Active test strips you took the coding chip from,
- the Accu-Chek Active Control solutions.

Carefully read the pack inserts that came with the test strips and the control solutions, and select a control solution.

6.3 Quality control test procedure

- Remove a test strip from its container. Close the container immediately. The cap contains a drying agent which ceases to function if the container is left open, rendering the test strips unusable.

- Check the round control window on the back of the test strip against the colour scale printed on the test strip container. The colour of the control window must match that of the colour interval at the top (0 mmol/L).
  If the test strip shows a different colour, do not use it.

- Hold the test strip so that the application area and arrows are facing upwards. Gently push the test strip in the direction of the arrows into the test strip slot ④ of your Accu-Chek Active meter, until you hear it click into place.

Inserting the test strip automatically puts the meter in Test Mode. Please remember that your Accu-Chek Active meter automatically turns off after about 1–2 minutes of non-use (i.e. when no button is pressed). If this happens, remove the test strip and repeat the procedure described above with a new test strip.

Now watch the display.

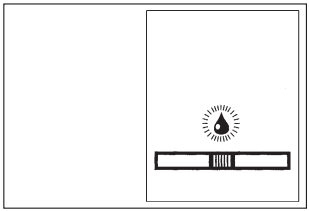
6.3 Quality control test procedure

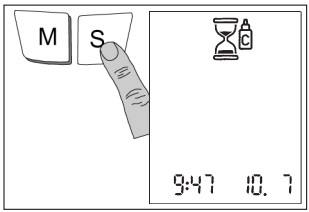
- The meter performs a display test lasting 2 seconds. Check that all the segments making up the numerals ("888" or "88.8") are properly displayed. If a segment is missing, test results may be displayed inaccurately (e.g. through 9 being confused with 3). If this happens, call your customer support and service centre.

- The current code number then appears in the display. Is this the number printed on the test strip container? If not, check that you really did insert the coding chip from the new pack. If "code" is flashing and you see three horizontal bars (- - -) instead of a number, you have not inserted the coding chip. You can still do this now (while the display is flashing).

- Check that the correct date and time are displayed.

6.3 Quality control test procedure





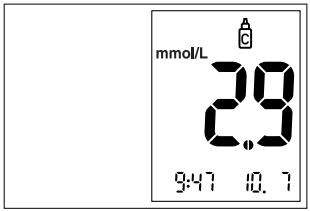
When the display test has been successfully completed and the code number matches, your Accu-Chek Active meter is ready for testing. The display screen that follows signals:

- That the test strip has been inserted.
- The flashing drop symbol is your cue to apply the control solution (blood in the case of a real test).

To make quality control results stand out later from blood glucose test results, you can place what is known as a “flag” against them.

- Press the **S** button once. In the display you see an hourglass symbol along with the control test flag (a bottle with the letter “C”). You can insert the flag at this point. If you pressed the **S** button inadvertently, you can press it again (before testing is complete) in order to remove the flag.

6.3 Quality control test procedure



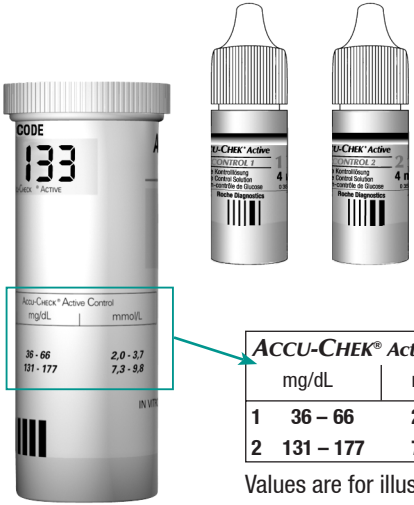
- Apply one drop of the selected control solution to the test pad of the strip.

- Your Accu-Chek Active meter beeps briefly to acknowledge application of solution and to announce the start of testing.

- After 5 seconds a second beep tone indicates that testing is complete, and the result appears in the display. If you have not already flagged this quality control result, you may do so now.

The value displayed here is an example. The result shown on your Accu-Chek Active meter will not necessarily agree.

6.3 Quality control test procedure



ACCU-CHEK® Active Control		
	mg/dL	mmol/L
1	36 – 66	2,0 – 3,7
2	131 – 177	7,3 – 9,8

Values are for illustration only.

Now check that the displayed value is within the permitted range. Examine the test strip container and locate the “Accu-Chek Active Control” table.
The table has two rows listed as “1” and “2”, as well as two columns giving ranges in mmol/L and mg/dL.

- If you performed the test with Accu-Chek Active Control 1, refer to row 1 for the permitted range.

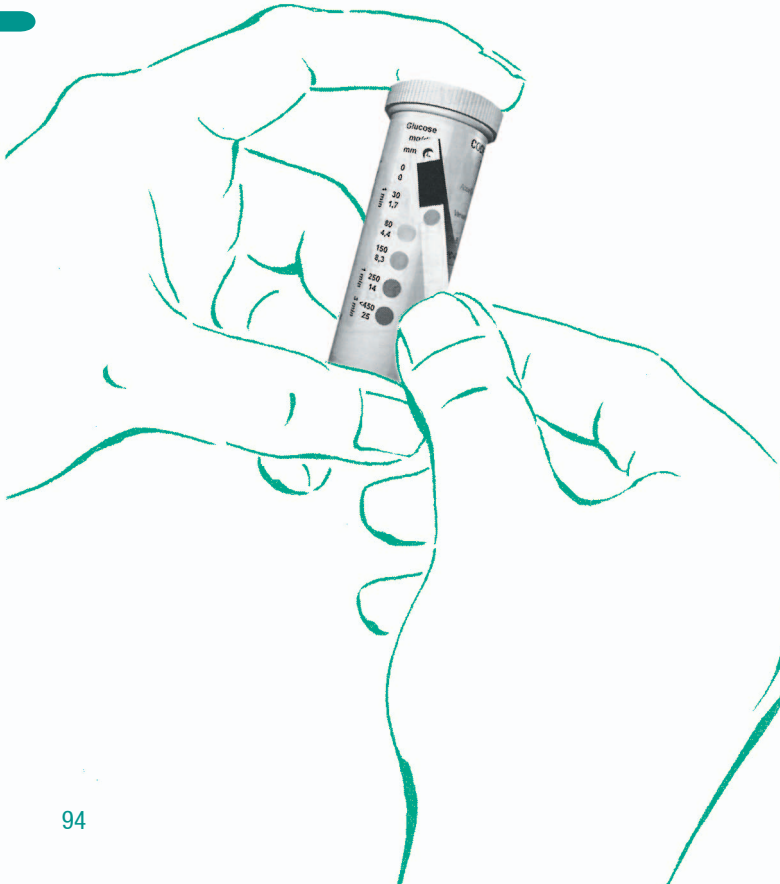
- If you performed the test with Accu-Chek Active Control 2, refer to row 2 for the permitted range.

If the result is within the stated range, you need to still carry out a visual plausibility test. It is important that this check be performed within 30–60 seconds after control solution was applied. Any later than this and comparison is no longer possible owing to excessive discolouration of the test strip.

If the result is outside the stated range, perform a second quality control test. If the second result is still outside the range, please call your customer support and service centre.

- Pull the strip out of the meter. The result is saved as a control reading (which is ignored when the averages are calculated), and the meter switches off.

6.3 Quality control test procedure



- Turn over the test strip to reveal the round control window on the back.

- On the label of the test strip container is a colour scale with blood glucose values printed alongside. Select the blood glucose value that best approximates the reading you obtained.

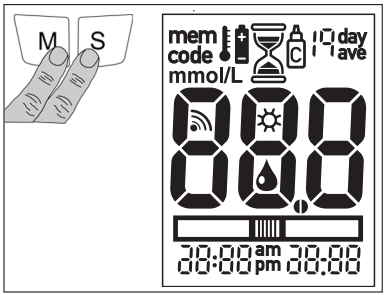
- Compare the colour of the control window with the colour you selected on the label.

The colours must be a fairly close match. If there is a great disparity, repeat the test. If you cannot obtain a close match even after several attempts at testing, please call your customer support and service centre.
If the colours are a close match, quality control testing of your Accu-Chek Active meter has been successfully concluded.
The meter is now ready to perform further blood glucose tests.

If the measurement optics or any other part of your Accu-Chek Active become soiled during testing, please clean the meter as instructed in Chapter 7.1.

6.4 Performing a full display check

longer than 3 seconds



The standard power-on display test checks the most important display elements. To verify that all of the elements are functioning correctly, you can carry out a full test.

- Press and hold down the **M** and **S** buttons together for longer than 3 seconds.

- All the elements of the liquid crystal display (LCD) are shown at once. Either “mmol/L” or “mg/dL” will be visible depending on the country-specific setting.

- Press any key to terminate the display test and turn off your Accu-Chek Active meter. If you do not press a key, the meter will shut off automatically after about 2 minutes.

7 Keeping your meter in tip-top condition

Your Accu-Chek Active meter has no moving parts and so will not suffer any mechanical wear and tear. As with any precision instrument, however, you will need to look after it carefully to keep it at its best.

7.1 Cleaning your Accu-Chek Active meter

Accu-Chek Active utilises an optical measuring method that relies heavily on all of its components being clean. Be sure to clean the meter, therefore

- whenever it is showing signs of soiling, however slight (especially on the test strip guide or the measurement optics located below it),
- whenever you open a new pack of test strips,
- every 2 months at the latest.

7.1 Cleaning your Accu-Chek Active meter

Clean the measurement optics carefully with nothing other than cold water, soft lint-free cloths and cotton swabs. For disinfection you may use 70 % alcohol. Any other cleaning agents may damage the meter or impair its measuring function.

- Slide off the test strip guide towards you (see illustration).
- After removal of the test strip guide from the meter, clean it with cold water.
- Afterwards you may wipe the test strip guide with 70% alcohol.
- Wipe off the alcohol immediately from the test strip guide and allow it to dry thoroughly.

7.1 Cleaning your Accu-Chek Active meter

- Wipe the measurement optics components with a soft lint-free cloth and/or a cotton swab. The cloth/cotton swab may be slightly moistened with water or 70% alcohol. Make sure that no liquid enters the meter itself. Avoid scratching the measurement optics, as this will impair the measuring function.

- When all of the components are thoroughly dry, you may slide the test strip guide back onto the meter. Ensure it clicks back into place.

Then perform a quality control test (see Chapter 6, “Checking Accu-Chek Active”).

7.1 Cleaning your Accu-Chek Active meter

Cleaning and disinfection in the professional environment

Be sure to observe all relevant Health and Safety regulations.

A potential infection risk exists. Medical staff and other persons using Accu-Chek Active to test blood glucose from more than one patient must be aware that any item coming into contact with human blood is a potential source of infection. (Please see "Protection of Laboratory Workers from Infectious Diseases Transmitted by Blood, Body Fluids, and Tissues"; Second Edition, Tentative Guideline, 1991, Document M29-T2, National Committee for Clinical Laboratory Standards).

For cleaning use only cold water and cotton swabs. 6 % formaldehyde solution may be used for disinfection. Please take into account the time it takes for the agents used to act. Any other cleaning agents may damage the meter or impair its measuring function.

7.2 Battery life and battery replacement

A new battery provides enough power for about 1,000 tests. When you first see the battery symbol displayed, there is still enough power for about 50 tests, though we recommend that in this event you replace the battery as soon as possible. By then the battery will have been considerably drained, and changeable conditions (cold surroundings) can affect its performance even further.

Insert a new battery into the meter as follows:

- Turn your Accu-Chek Active meter over.
- At the top you see the recess for opening the battery compartment cover. Use your thumb to slide the cover out of the meter.
- Within the cover is the circular chamber for the battery. Four supports stop the battery falling out.
- Place the battery in the chamber with the "+" symbol facing downwards. Apply gentle pressure on the battery until it is properly located within the supports.

7.2 Battery life and battery replacement

- Slide the battery compartment back into the meter and press gently inwards until it clicks home.

- After replacing the battery, check the performance of the monitor as described in Chapter 6.

If you complete the replacement within about 1 minute, the date and time settings will be retained. All of the other results will be retained however long it takes to replace the battery.

Think of the environment. Please take your used batteries to a collection point if you have one locally.

Remove the battery if your Accu-Chek Active meter is to remain unused for some time.

Never throw batteries into a fire.
This is dangerous because they will explode.

7.3 Measurement and storage conditions

When testing blood glucose, pay close attention to the following points. They affect the dependability of your Accu-Chek Active meter and the accuracy of your results.

Temperature range

- For performing blood glucose tests the permitted range is from +10 °C to +40 °C.
- A test can be performed at the limits of the permitted range (between +5 °C and +10 °C or +40 °C and +45 °C), but the result should be interpreted with caution. If the temperature range is at limits a is displayed.
- Tests cannot be performed if the temperature is below (under +5 °C) or above (over +45 °C) these limits; a message is then displayed.
- Ensure your Accu-Chek Active meter is stored between –40 °C and +70 °C.
- The meter will issue a message if it is too warm or too cold to carry out a blood glucose test (see Chapter 8.2).

7.3 Measurement and storage conditions

Do not use results obtained at the limits of the permitted temperature range as a basis for therapeutic decisions.

Never try to speed up warming or cooling of your Accu-Chek Active meter artificially (e.g. by placing it on a radiator or in a refrigerator). Doing so can damage your meter and cause it to give incorrect results.

Light conditions

- Do not carry out a test where the meter and test strips are exposed to direct sunlight.
- If the light is too bright, a ☼ symbol will appear in the display of your Accu-Chek Active meter.
- If you see this symbol, find a shady location to carry out the test, or use your own body as a screen.
- Avoid measuring in places where the light level is very changeable. Flash photography, for instance, can affect the result.

Atmospheric humidity

- Relative humidity must be below 85%.

- Sudden changes in temperature cause condensation within the meter. You may find you are unable to turn on your Accu-Chek Active. Allow the meter to return slowly to room temperature, and never keep it in a room that is likely to harbour condensation (e.g. a bathroom).

Sources of interference

- Strong electromagnetic fields may interfere with the proper operation of the meter. Do not use the meter close to sources of strong electromagnetic radiation.

8 Summary: All the display messages on your Accu-Chek Active meter

8.1 About the display messages

When you use your Accu-Chek Active meter, various letters and symbols will appear on the display, at times also error messages. Some of these display messages, those occurring in routine use, have already been explained. We now present a complete list of display messages, what they mean, and what action you should take in case you see an error message.

Please watch out for any messages displayed when you use the meter. Every message provides you with important information. Therefore, if you do not recognise a symbol or do not understand a message, please refer immediately to this chapter for an explanation. Otherwise you run the risk of misinterpreting your blood glucose results.

8.2 Messages and symbols

This message appears ...	and means:
mem • in Memory Mode	• This is a value saved in memory.
• (flashing) when a result is being cleared	• You are in the process of clearing a value from memory.
code • after the display test in association with the code number	• Check the code number.
• (flashing) after the display test in association with "- - -"	• The coding chip is missing.
mmol/L mg/dL test • while the result is displayed (Test and Memory)	• This is a pre-programmed unit used to state the blood glucose result.

8.2 Messages and symbols

This message appears ...	**and means:**
	
• in Test Mode • when the result is displayed (Test and Memory)	• The ambient temperature is/was close to the limit at the time of testing. Do not use the result as a basis for therapeutic decisions.
	
• in all modes	• When this symbol first appears, the battery still has power for about 50 tests. Replace the battery at the earliest opportunity.

This message appears ...	and means:
 • during testing	• The test is in progress.
 • during testing, when enabled • attached to results in memory	• This is/was a quality control test.
 • in Memory Mode	• The figure is the 7/14 day average.
 • in Set Mode	• The beep tone is enabled.

8.2 Messages and symbols

This message appears ...	and means:
 • in Test Mode	• The light is too bright, testing is not possible. Please move to another location.
 • (flashing) in Test Mode	• Apply a drop of blood now.
 • in Test Mode • (flashing) in Test Mode	• The test strip is inserted. • Re-insert the test strip (out-of-meter testing).

8.3 Troubleshooting

This error message means ...

The test strip has been inserted incorrectly. Insert the strip, test pad upwards, in the direction indicated by the arrows, until it snaps into place.

The wrong coding chip is inserted. This coding chip does not belong to Glucose test strips from the Glucotrend or Accu-Chek Active blood glucose systems. Remove this coding chip, insert the correct coding chip.

The coding chip cannot be read. Remove the chip and re-insert it. If you again see the error message, you cannot use the chip and pack of test strips.

8.3 Troubleshooting

Measurement optics error. Clean the measurement optics (Chapter 7.1). Check that the test strip is lying flat and straight in the test strip guide. If the message persists, the meter has a fault. Please call your customer support and service centre. Although rarely occuring - you applied too little blood to the strip. Repeat the test with a new Accu-Chek Active test strip.

The measurement optics are dirty or you have inserted a test strip that has already been used or is expired. Clean the measurement optics (Chapter 7.1) and repeat the test with a new Accu-Chek Active test strip.

The meter was exposed to a strong electro-magnetic field. Move somewhere else.

The coding chip was removed during testing, has a fault, or is not properly inserted in the meter. Remove the coding chip and re-insert it.

The test strip was not fully inserted, was moved during testing, or was dosed with blood too soon. Repeat the test with a new test strip and ensure that it snaps into place.

The coding chip is missing or has a fault.

The Accu-Chek Active meter has a fault and cannot be used. Please call your customer support and service centre.

You applied too little blood to the test strip, or the test strip was not lying flat and straight in the test strip guide. Repeat the test with a new test strip.

The ambient temperature or the temperature of the meter is outside the permitted range. Move the meter to a room-temperature environment and wait until the meter has acclimatised and the error message has disappeared.

8.4 Possible sources of error

If you receive frequent error messages or if you often obtain implausible results, please check the following:

- With your Accu-Chek Active meter, are you using only Accu-Chek Active test strips?
- Does the battery still have enough power, and is it properly inserted?
- Have you carefully read the reference manual and carried out tests as instructed?
- Have you read the pack inserts that came with the test strips? Have you stored and used the strips correctly?
- Have you observed all the proper measurement and storage conditions?

- Are the test strips and/or control solution still within the stated expiry date?

- Have you cleaned your Accu-Chek Active meter (especially the test strip guide and measurement optics) as instructed in Chapter 7.1?

- Have you used only test strips with a code number matching that displayed by the meter?

If you have observed all these points and still are having problems, please contact the Accu-Chek Customer Careline.

On the finger pricker itself and on the packaging of Accu-Chek Softclix Lancet you may encounter the following symbols, shown here with their meaning:

Please read this note with special care

For single use only

The lancets may only be used up to the expiry date specified on the box.

Lot number

The lancets have been sterilised with at least 25 kGy

This product fulfils the requirements of Directive 93/42/EEC of 14th June 1993 on medical devices.

9 Accu-Chek Softclix

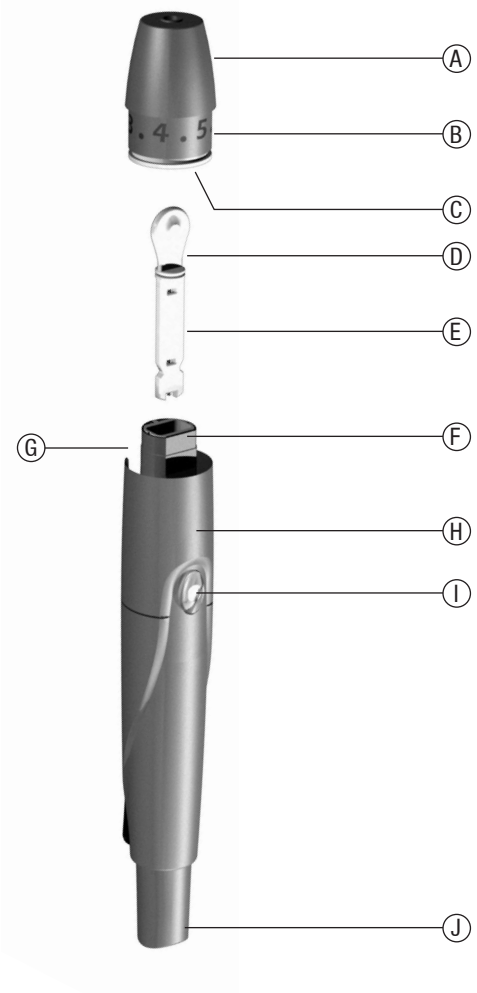
Introduction

Accu-Chek Softclix is an easy to use finger pricking device for obtaining blood from the tip of the finger or the earlobe virtually without pain.
Penetration depth can be adjusted precisely to suit individual skin requirements.

The Accu-Chek Softclix finger pricker is intended for patient self-monitoring by a single person.
It must not be used to collect blood in a multi-patient setting as it does not incorporate any features to guard against cross-infection.

9.1 The Accu-Chek Softclix at a glance

A	Cap
B	Comfort Dial (for selecting penetration depth)
C	Notch
D	Protective cap
E	Accu-Chek Softclix lancet
F	Lancet holder
G	Semi-circular cutout
H	Ejector
I	Transparent release button
J	Priming button


A
B
C
D
E
F
G
H
I
J

9.2 Selecting the penetration depth of your Accu-Chek Softclix finger pricker

Depth of penetration should be selected so that only the amount of blood necessary for testing is obtained.

For this purpose Accu-Chek Softclix can be set to different penetration depths ranging from 0.5 to 5.5. They are indicated on the cap by the numbers 1 to 5.
The additional intermediate settings marked with dots enable a particularly precise adjustment of Accu-Chek Softclix to suit individual skin type.

The markings on the device shows the depth of penetration selected. Penetration depth can be altered by turning the front part of the cap. You will hear the cap click into position, indicating adjustment to a new depth and simultaneously preventing any accidental alteration of penetration depth.

Number 0.5 corresponds to the smallest depth of penetration and number 5.5 the greatest. When selecting the individual penetration depth it is recommended to start with level 1 or 2 to see if the amount of blood obtained is enough to carry out the test. Thicker skin will require a higher level.

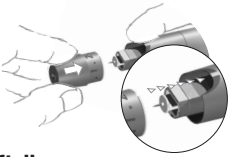
Recommended Penetration Settings

- 0.5-1.5 for soft skin
- 2-3.5 for normal skin
- 4-5.5 for thicker skin

9.3 Using the Accu-Chek Softclix finger pricker

1. **Pull off the Accu-Chek Softclix cap. Insert a new Accu-Chek Softclix lancet in the lancet holder and push it in until it clicks.**
   Remove the protective cap from the lancet with a twisting motion. To avoid injuries, keep cap and replace on lancet before discarding. Use a new lancet each time you take blood to prevent infection and to ensure virtually painless blood sampling.

2. **Press the Accu-Chek Softclix cap on again until it clicks.**
   Be sure to align the notch on the cap with the centre of the semicircular cutout on the ejector.



3. **Rotate the Comfort Dial on the Accu-Chek Softclix cap to set the penetration depth.**
   If you are using the Accu-Chek Softclix finger pricker for the first time, set the Comfort Dial to 1. For thicker or calloused skin, select a higher setting.

4. **Press in the priming button until it clicks.**
   Be careful not to press the release button at the same time. The finger pricker is primed when a yellow dot appears in the transparent release button. Do not prime the Accu-Chek Softclix finger pricker until you are ready to take blood.

5. **Gently press the Accu-Chek Softclix finger pricker against the side of the fingertip or earlobe and press the release button.**
   Take care not to push against the priming button or to impede its free movement.

   Wait a few seconds to allow a droplet of blood to form or gently squeeze the fingertip to develop a drop of blood. Gently touch the front edge of the test strip against the blood.
   If you do not obtain sufficient blood, try the test again with progressively higher settings. After obtaining the blood sample, wipe the puncture site with a dry, clean paper towel. If necessary, gently press the towel onto the site and, if bleeding persists, cover with a bandage.

6. **To remove the lancet, remove the Accu-Chek Softclix cap. Place the protective cap back on the lancet and slide the ejector forwards to release the lancet.**
   Dispose of lancet in a safe container (an empty drinks can, for instance).

9.3 Using the Accu-Chek Softclix finger pricker

Selecting the Puncture Site
The best place to take capillary blood is from the side of a fingertip as it has the best blood supply and registers the least pain.

Preparing Fingertip or Earlobe
Wash your hands in warm water and dry them well. This helps ensure proper hygiene and stimulates blood flow, since the drop may be too small if the finger to be pricked is too cold or circulation is poor. In addition finger or earlobe should be massaged before pricking.

Subsequent Treatment of the Puncture Site
Wipe the puncture site with a dry, clean tissue. If it continues to bleed apply gentle pressure to the puncture site with a plaster to protect it from dirt or infection.

Cleaning and Disinfecting Accu-Chek Softclix
To clean Accu-Chek Softclix use any mild liquid detergent and a soft cloth. Avoid immersing the device completely in liquid. In addition, disinfect the cap thoroughly about once a week by placing it for 10 minutes in a 70% alcohol solution (available at your chemist), or use another commercially available disinfectant (follow the manufacturer's instructions).

Safety Remarks
Only use a Softclix lancet with the Accu-Chek Softclix device since the use of other lancets may prevent or impair proper function of Accu-Chek Softclix.

Important note for Healthcare Professionals:
If handling devices returned after use by patients, please ensure that the patient has removed the used lancet from Accu-Chek Softclix prior to handling the device.

10 Appendix

10.1 Technical data

Meter type	Accu-Chek Active
Catalogue number/ serial number	See type plate on the back of the meter
Test principle	Determination of glucose in fresh capillary blood by reflectance photometry. When using different specimen material please refer to the package insert that came with the Accu-Chek Active test strips.
Measuring range	0.6–33.3 mmol/L
Measuring time	approx. 5 seconds (in-meter dosing)
Sample size	1–2 µL
Memory capacity	200 blood glucose results with date and time, 7 and 14 day average
Dimensions	118 x 43 x 22 mm
Weight	56 g without battery
Display	96-segment liquid crystal display

Automatic power-off	1–2 minutes after last button press
Power supply	1 lithium battery type CR2032 or type DL2032
Battery life	approx. 1,000 tests in one year
Safety class	III
Interface	infrared interface, LED/IRED Class 1
System operating temp.	10 – 40 °C
Atmospheric humidity	up to 85% relative humidity
Storage temperature	–40 °C to +70 °C

Electromagnetic compatibility

This device meets the electromagnetic immunity requirements as per ISO 15197 Annex A. The chosen basis for the immunity tests was basic standard IEC 61000-4-2. In addition it meets the electromagnetic emissions requirements as per EN61326. Its electromagnetic emission is thus low. Interference from other electrically driven equipment is not to be anticipated.

10.2 System components

With your Accu-Chek Active meter use only Accu-Chek Active test strips. These are available from your pharmacist.

For quality control testing of your Accu-Chek Active meter use only Accu-Chek Active Control solutions (see Chapter 6).

For virtually pain-free blood sampling we recommend the Accu-Chek Softclix finger pricker and Accu-Chek Softclix Lancet lancets. These are available in the following pack size:

- 200 Accu-Chek Softclix Lancet

For healthcare professionals we recommend the Accu-Chek Softclix Pro finger pricker and special lancets Accu-Chek Softclix Pro Lancet, or Safe-T-Pro disposable lancet devices.

All of the system components are carefully matched. With your Accu-Chek Active meter use only Accu-Chek Active test strips. Any other test strips will give incorrect results. Sometimes the error can be significant, causing the wrong therapeutic decision to be taken and so producing adverse health effects.

10.3 Manufacturer's warranty and guarantee

Manufacturer's warranty:
As part of the Accu-Chek Commitment, Roche Diagnostics warrants that the meter and finger pricker shall be free from detects in material and workmanship under the terms as specified on the warranty card. Your statutory rights are not affected.

The meter and finger pricker must have been subjected to normal use. No claim will be entertained if the meter or finger pricker has been improperly handled, used or serviced, or has been tampered with.

We undertake to repair faulty components free of charge or, at our discretion, to provide a fault-free replacement meter.

Guarantee:
The manufacturer's warranty is in addition to, and in no way affects, your statutory rights or any warranty claims you may have against the seller of the meter under the terms of your sales contract.

Be sure to fill out your warranty card that came with your Accu-Chek Active system and return to Roche Diagnostics.

10.4 Customer support and service

Customer support and service

Customer support:
If you have any questions on how to use your meter or finger pricker, if any of the results you obtain seem implausible, or if you suspect the meter has a fault, please contact the **Accu-Chek Customer Careline**.

Service:
Please note that any repair, adjustment, or other change of the meter must only be performed properly by persons who have been authorised by Roche Diagnostics. If you suspect that the meter has a fault, please start by contacting the **Accu-Chek Customer Careline**. Our staff will attempt to identify and solve your problem over the phone. Some problems, however, cannot be solved over the phone, in which case you will be asked to send your Accu-Chek Active meter together with the test strips you used and (if applicable) the completed warranty card to your Customer Support Centre.

Roche Diagnostics Ltd,
Charles Avenue, Burgess Hill, West Sussex, RH15 9RY
UNITED KINGDOM
UK Freephone number: 0800 701 000
ROI Freephone number: 1800 709 600

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CE 0088

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