ACCU-CHEK®
Active

BLOOD GLUCOSE MONITOR

User's Manual

$C\,\epsilon$ **0088**

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Roche

Please read this manual carefully and completely before performing the first measurement. Should you have any questions, please contact one of our customer support and service centres. You will find a list of addresses in Chapter 9.4.

On packaging, on the type plate and in the User's Manual 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

[i] Please consult instructions for use

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

Manufacturer

Last update: June 2004

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1   Introduction

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

No matter whether Accu-Chek Active is your first blood glucose monitor or whether you have already used another type; in your own interest, please take time to read this manual through carefully before you attempt to use your monitor.
To use it correctly and dependably, you need to have a thorough understanding of the way it operates, what the screen displays mean and what the individual functions are for.

This User's 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 monitor'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 9.4 provides a list of addresses and telephone numbers of our customer support and service centres.

1.1   The monitor'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 monitors available.

▶ New design: Your new Accu-Chek Active was designed for ergonomic functionality with good looks.

▶ 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 monitor 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 (e.g. Accu-Chek Compass or Camit software).

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

▶ Out-of-monitor 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 monitor.

▶ Accurate results: Application of blood to the test strip starts a colour reaction. The final colour is accurately read (measured photometrically) by the monitor'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. Easily understood symbols give you additional information and 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 user's manual

This User's Manual will help you get to know your new Accu-Chek Active monitor step by step. It will provide you with all the information you need to operate, troubleshoot, clean and care for your monitor. It is important to remember that, in order to keep your monitor 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 (use only cold water or 70% alcohol) 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 monitor is at risk of being damaged.

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

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 will always have a dependable partner to accompany you through the day.

2   Modes

As you will have gathered, your Accu-Chek Active monitor 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 monitor or by the way in which you turn it on. Detailed information on the various ways of turning on your monitor 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 monitor 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 monitor by pressing the **M**(emory) button.

► You can retrieve up to 200 results.

► Your Accu-Chek Active monitor 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 monitor's memory (with Accu-Chek Compass or Camit software – available separately).

► You can erase the most recent result.

2.3 Set Mode

To enter Set Mode, turn on your Accu-Chek Active monitor 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 monitor, remove the film covering the battery.

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

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

▶ Slide the battery compartment back into the monitor and press gently inwards until it clicks into place.

3.2   Basic settings

When you turn on your Accu-Chek Active monitor 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 your usual unit (**mg/dL** or **mmol/L**) is displayed above the large numerals in the display (*888*). Ask your doctor if you do not know which is the right unit for you. This setting cannot be changed. If you have a monitor showing the wrong unit, please ask your dealer for a replacement.

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

Turning the monitor 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 monitor for the first time

► flashing: the current date, or 0.0 (0-0) when you turn on the monitor for the first time
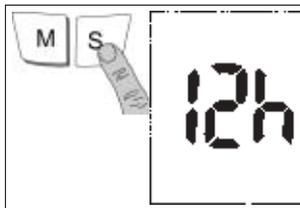
The way in which the date and time are displayed from here on depend on the chosen display format.

► 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.
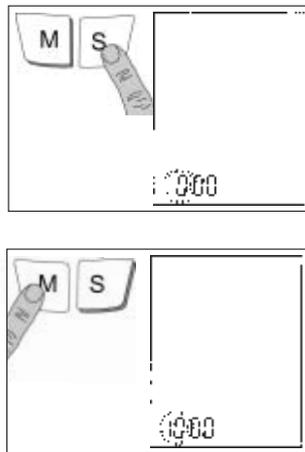
Setting the date and time

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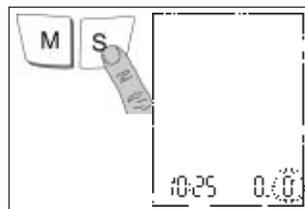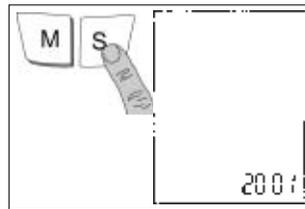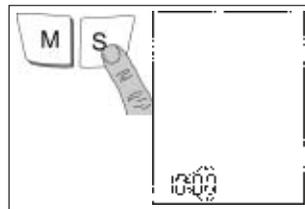
► Confirm the setting by pressing the **S** button again. The display moves on automatically to the next unit of time, which again flashes.

► 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 monitor automatically recognises, and allows for, leap years.
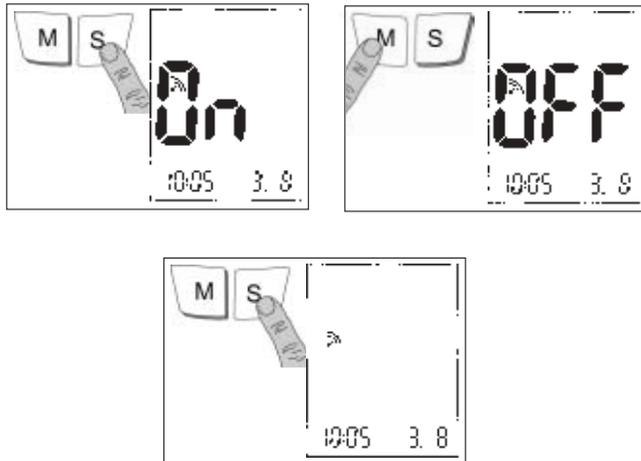
Setting the beep tone

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 monitor. If any of the settings are incorrect, you may repeat the settings procedure (after turning the monitor on again).

3.3   Coding

The properties of the Accu-Chek Active test strips you use with the monitor may differ very slightly from one pack to another (because of lot-to-lot differences). Your Accu-Chek Active monitor 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.

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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 monitor. 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 monitor 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 monitor will display the code number.

Inserting the coding chip

When coding, leave your Accu-Chek Active monitor 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 monitor ⑩ (see parts summary).

▶ Ensure that you push the coding chip until it clicks into place.

▶ 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 Measuring blood glucose with your Accu-Chek Active monitor

4.1 Materials for testing blood glucose

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

▶ your Accu-Chek Active monitor with the coding chip inserted,

▶ the pack of Accu-Chek Active test strips you took the coding chip from,

▶ a suitable lancing system (such as Accu-Chek Softclix and Accu-Chek Softclix Lancet).

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With your Accu-Chek Active monitor 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 monitor, 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 lancing device.

▶ 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.

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 mg/dL / 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 guide ④ of your monitor, until you hear it click into place.

Inserting the test strip automatically puts the monitor in Test Mode. Please remember that your monitor 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.

▶ The monitor 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 your customer support and service centre.
If "code" is flashing and you see three horizontal bars (– – –) instead of a number, you have not inserted the coding chip.
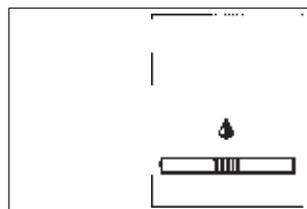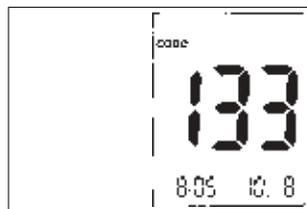
▶ Check that the correct date and time are displayed.

⚠️

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 monitor 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 monitor, please read on. For out-of-monitor dosing please see page 55.

In-monitor dosing

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

▶ Massage a fingertip to stimulate the circulation and make blood collection easier.

▶ Use the lancing device 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 monitor 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.
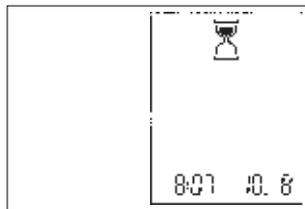
▶ The hourglass symbol indicates that testing is in progress.

▶ The monitor 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 monitor, which will now automatically turn off.

Lo

1:02   9. 8

Hi

6:10   9. 8
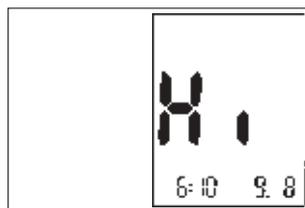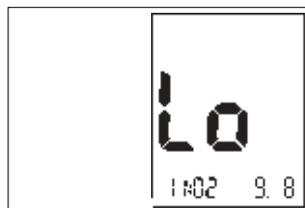
Plausible results

Your Accu-Chek Active monitor measures blood glucose within a defined range (10-600 mg/dL or 0.6-33.3 mmol/L). Values outside this range are displayed as "Lo"- meaning the result is less than 10 mg/dL or 0.6 mmol/L - or "Hi"- meaning the result is greater than 600 mg/dL or 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.
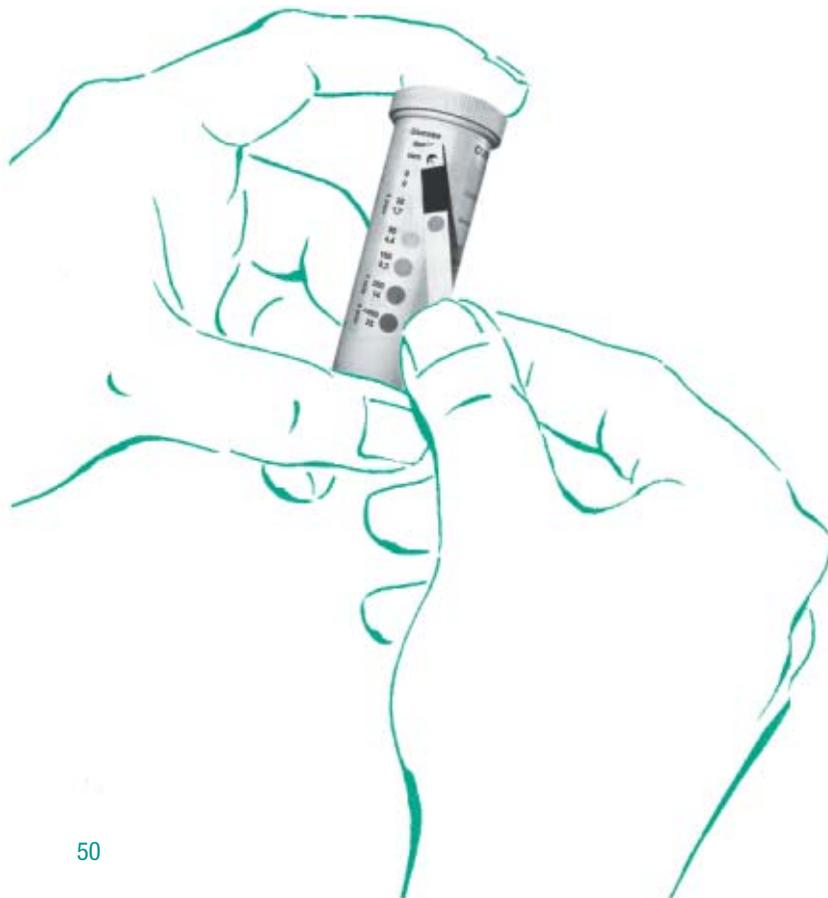
▶ Turn over the test strip to reveal the round control window on the back.

▶ 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 match, the result is corroborated and the test successfully concluded. You can discard 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 monitor, 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 monitor?

► 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 monitor 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.

Out-of-monitor dosing

The test procedure is mostly identical with "Testing blood glucose" 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 lancing device to prick the selected site.

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

► Pull the strip out of the monitor. 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 monitor 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.

4.3 Testing blood glucose

► Gently push the test strip back into the test strip slot of your Accu-Chek Active monitor, until you feel it click into place.

► Your Accu-Chek Active monitor 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 hour glass symbol indicates that testing is in progress.

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

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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 monitor has a 200-value memory for saving results together with date and time. You do not need to save a result specially; the monitor does it all for you. Once all the memory locations are full, the monitor 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 monitor also stores all relevant additional information and display messages. For example, results flagged as control results are displayed together with a bottle symbol incorp- orating 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 monitor, 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.
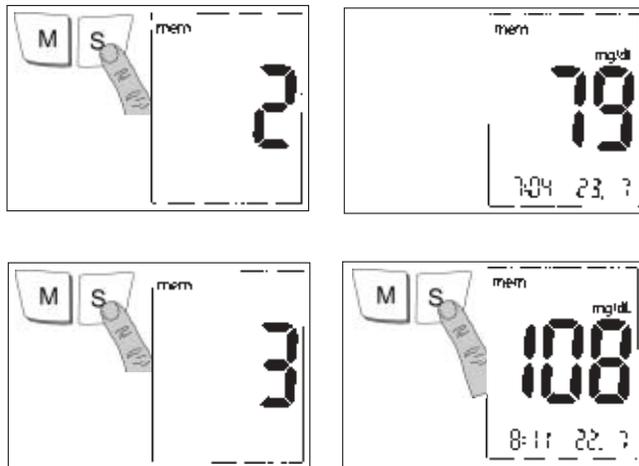
To recall earlier results (in memory locations 2-200):

▶ 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".

Finding the 7 or 14 day average of glucose results

As well as just showing the results in memory, your Accu-Chek Active monitor 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 monitor 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.

66

67
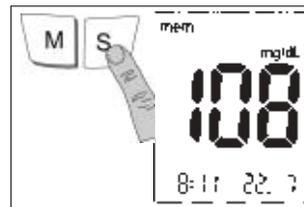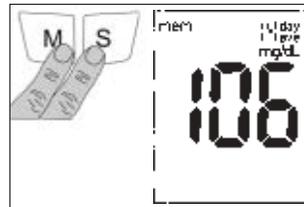
► Then press the **M** and **S** buttons again at the same time.

► 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.

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Averages can only be calculated as long as you have set the date and time (see Chapter 3.2). Without these settings the monitor 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.

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When averages are being calculated, all control readings are ignored.
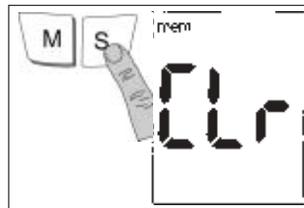
Erasing results from memory

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 monitor by keeping the **S button** pressed **for longer than 3 seconds**.

▶ The display shows "Clr" and "mem" (flashing).

longer than 3 seconds

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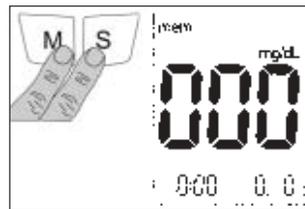
▶ Keep the **M** and **S** buttons pressed together for longer than **3** seconds.

▶ The current result is displayed.

longer than 5 seconds

▶ 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 monitor turns off automatically after you have cleared the result.

**General information
about data downloading**

Roche Diagnostics offers a variety of special software programs (e.g. Accu-Chek Compass, Accu-Chek Pocket Compass, Accu-Chek Camit Pro and the Accu-Chek Smart Printer System) to expand the memory functions integrated in your Accu-Chek Active monitor. 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 your local
Roche Diagnostics representative or your dealer.**

For data downloading you need a suitable PC program as well as the Accu-Chek Infrared Cable. For further information please contact your local Roche Diagnostics representative or your dealer. For further information please contact your local Roche Diagnostics representative or your dealer.

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

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 monitor about 10 cm from the infrared cable. Point the two infrared windows towards one another.

► Turn on your Accu-Chek Active monitor by keeping the **M** button pressed (for longer than 3 seconds) until "PC" appears flashing in the display. This indicates the monitor is ready to communicate.
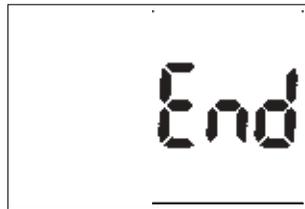
▶ Start downloading at the PC. The PC sends an instruction to the Accu-Chek Active monitor.

▶ 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 monitor with the **M** button, if the PC has not already shut down the monitor. 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 monitor.
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 monitor,

▶   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 monitor 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 mg/dL / 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 guide ④ of your Accu-Chek Active monitor, until you hear it click into place.

Inserting the test strip automatically puts the monitor in Test Mode. Please remember that your Accu-Chek Active monitor 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.

▶ The monitor 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.
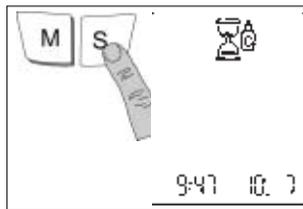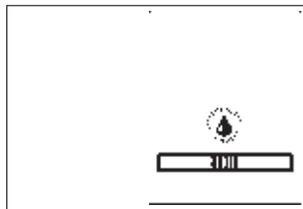
6.3 Quality control test procedure

When the display test has been successfully completed and the code number matches, your Accu-Chek Active monitor 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
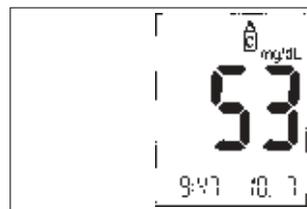
► Apply one drop of the selected control solution to the test pad of the strip.

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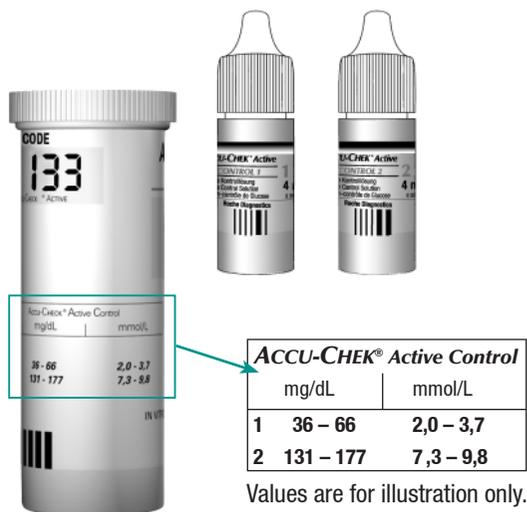
Now check that the displayed value is within the permitted range. Examine the test strip container and locate the "Accu-Chek Active Control" table.
The table has two rows listed as "1" and "2", as well as two columns giving ranges in mg/dL and mmol/L.

► 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 monitor. The result is saved as a control reading (which is ignored when the averages are calculated), and the monitor 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 monitor has been successfully concluded.
The monitor 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 monitor as instructed in Chapter 7.1.

6.4 Performing a full display check

longer than 3 seconds
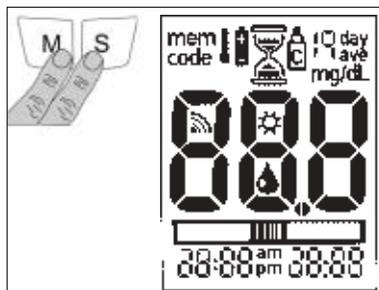
The standard power-on display test checks the most important display elements. To verify that all of the elements are functioning correctly, you can carry out a full test.

► 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 "mg/dL" or "mmol/L" will be visible depending on the country-specific setting.

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

7   Keeping your monitor in tip-top condition

Your Accu-Chek Active monitor 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 monitor

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

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 monitor or impair its measuring function.

► Slide off the test strip guide towards you (see illustration).

► After removal of the test strip guide from the monitor, 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.

► 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 monitor 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 monitor. 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 monitor

Cleaning and disinfection in the professional area

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 monitor 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 monitor as follows:

► Turn your Accu-Chek Active monitor over.

► At the top you see the recess for opening the battery compartment cover. Use your thumb to slide the cover out of the monitor.

► 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 monitor 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. Dispose of used batteries sensibly.

Remove the battery if your Accu-Chek Active monitor 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 monitor 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. A 🌡 is displayed.

▶ Tests cannot be performed if the temperature is below (under +5 °C) or above (over +45 °C) these limits; a *ᴸᴸᴸ* message is then displayed.

▶ Ensure your Accu-Chek Active monitor is stored between −40 °C and +70 °C.

▶ The monitor 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 monitor artificially (e.g. by placing it on a radiator or in a refrigerator). Doing so can damage your monitor and cause it to give incorrect results.

Light conditions

▶ Do not carry out a test where the monitor 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 monitor.

▶ 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 monitor. You may find you are unable to turn on your Accu-Chek Active. Allow the monitor 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 monitor. Do not use this monitor in close vicinity to sources of strong electromagnetic radiation.

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

8.1 About the display messages

When you use your Accu-Chek Active monitor, 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 monitor. 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

- (flashing) when a result is being cleared

- This is a value saved in memory.
- 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 |

- during the display 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 ...

- in Test Mode
- when the result is displayed (Test and Memory)

- in all modes

and means:

- 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.

- When this symbol first appears, the battery still has power for about 50 tests. Replace the battery at the earliest opportunity.

This message appears ...

- during testing

- during testing, when enabled
- attached to results in memory

- in Memory Mode

- in Set Mode

and means:

- The test is in progress.

- This is/was a quality control test.

- The figure is the 7/14 day average.

- 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-monitor
testing).

8.3 Troubleshooting

This error message means ...

E-1

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.

E-2

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.

E-3

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

E-4 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 monitor 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.

E-5 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.

E-7 The monitor was exposed to a strong electro-magnetic field. Move somewhere else.

E-8 The coding chip was removed during testing, has a fault, or is not properly inserted in the monitor. Remove the coding chip and re-insert it.

E-9 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.

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

Err 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.

ttt The ambient temperature or the temperature of the monitor is outside the permitted range. Move the monitor to a room-temperature environment and wait until the monitor 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 monitor, 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 User's 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 monitor (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 monitor?

If you have observed all these points and still are having problems, please contact your dealer or your customer support and service centre.

9   Appendix

9.1   Technical data

Monitor type	Accu-Chek Active
Catalogue number/ serial number	See type plate on the back of the monitor
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	10–600 mg/dL (0.6–33.3 mmol/L)
Measuring time	approx. 5 seconds (in-monitor 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 CR 2032 or type DL 2032
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 electro-magnetic emissions requirements as per EN61326. Its electromagnetic emission is thus low. Interference from other electrically driven equipment is not to be anticipated.

9.2   System components

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

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

For virtually pain-free blood sampling we recommend the Accu-Chek Softclix lancing device and Accu-Chek Softclix Lancet lancets. These are available in various pack sizes:

▶   25 Accu-Chek Softclix Lancet

▶   200 Accu-Chek Softclix Lancet

For healthcare professionals we recommend the Accu-Chek Softclix Pro lancing device and special lancets Accu-Chek Softclix Pro Lancet.

⚠

All of the system components are carefully matched. With your Accu-Chek Active monitor 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.

9.3   Guarantee

The statutory guarantee provisions governing the sale of consumer goods in the country of purchase shall prevail.

9.4   Local customer support and service

Customer support and service

Customer support:
If you have any questions on how to use your monitor, if any of the results you obtain seem implausible, or if you suspect the monitor has a fault, please contact your customer support centre. See the next Chapter for addresses.

Service:
Please note that any repair, adjustment, or other change of the monitor must only be performed properly by persons who have been authorised by Roche Diagnostics. If you suspect that the monitor has a fault, please start by contacting your Roche Diagnostics customer support centre. 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 monitor together with the test strips you used and (if applicable) the completed warranty card to your local Roche Diagnostics representative.

9.5 Addresses

Argentina
Productos Roche S.A.Q. e I. -
DIAGNOSTICS DIVISION
Rawson 3150, B1610BAL Ricardo Rojas -
Partido de Tigre (Buenos Aires)
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31 Victoria Avenue, Castle Hill,
NSW 2154, Australia
Extracare Enquiry line: 1800 251816
www.rochediagnostics.com.au/extracare

Austria
Roche Diagnostics GmbH
Engelhorngasse 3, A-1211 WIEN
Tel.Nr.: (01) 277 87-0
Hotline für DIABETIKER:
(01) 277 87-355
www.accu-chek.at

Brazil
Roche Diagnostica Brasil Ltda
Diabetes Care
Av. Engenheiro Billings
1729 – Jaguaré
05321-010 São Paulo, SP
Accu-Chek Responde:
0800 77 20 126

Chile
Productos Roche Ltda.
Avda. Quilín 3750
Macul, Santiago
Tel: 56 (2) 441 3200
Fax: 56 2 4626687
Línea gratuita: 800 471 800

PR China
Roche Diagnostics (Shanghai) Limited
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Colombia
Productos Roche S.A.
Carrerra. 44 No. 17-21
Santa Fé de Bogota, D.C.
Línea gratuita (en Bogota):
57 1 4254199
Línea gratuita nacional:
018000 11 79 11

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Roche s.r.o.
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Karlovo náměstí 17
120 00 Praha 2
Informace na bezplatné lince o
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Ecuador
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e Isla Isabella
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www.accu-chekcentroamerica.com
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12190 Jakarta
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Numero Verde: 800-822189
www.accu-chek.it

9.5 Addresses

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46200 Petaling Jaya
Selangor Darul Ehsan
Toll-Free Line: 1-800-88-1313

Mexico
Productos Roche S.A. de C.V.
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Коммерческая Башня «Меридиан»,
ул. Смольная 24Д, 13 этаж
Информационный центр:
8-800-200-88-99 (звонок бесплатный для
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www.roche.com/diabetes
www.roche.ru

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16-01-06 Tiong Bahru Plaza
Singapore 168730
Tel.: + 652727500

Slovakia
Roche Diagnostics Division
Intes Poprad s.r.o.
Cesta mládeže 1
830 07 Bratislava 37
Tel.: 02/5478 8509

South Africa
Roche Products (Pty) Ltd. South Africa
Diagnostics Division
9, Will Scarlet Road / Ferndale
P.O. Box 1927
Randburg 2125
Accu-Chek Care Line
080-DIABETES
(dial 080-34-22-38-37)
www.diabetes.co.za

South Korea
Roche Diagnostics Korea Co. Ltd.
15th floor, Sam-Wha-Building
144/17, Samsung-dong
Kangnam-ku
135-092 Seoul
Toll-Free Line : 080-909-2222

Taiwan
Roche Diagnostics Ltd.
11F, No. 35 Sec.
3 Min Quan East Road, 104 Taipei
Toll-Free Line: 0800-060-333

Thailand
Roche Diagnostics (Thailand) Ltd.
18th Floor, Rasa Tower,
555 Phaholyothin Road
10900 Ladyao, Chatuchak, Bangkok
Phone: +66 2 937 08 40
Fax: +66 2 937 08 50
Costumer Service Line:
+66 2 937 02 83

Turkey
Roche Diagnostics Sistemleri
Ticaret A.Ş.
Gazeteciler Sitesi – Matbuat Sokak No. 3
34394 Esentepe – Istanbul
Ücretsiz Destek Hattı:
0-800-211 36 36
www. diyabetevi.com

USA
Roche Diagnostics
9115 Hague Road, Indianapolis
IN 46256
Contact Accu-Chek Customer
Care at 1-800-440-3638
www.accu-chek.com

10. Alphabetical index

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Warranty Card

_____
Name

_____
Street

_____
City/post code

_____
Telephone No.

_____   _____
Date   Signature
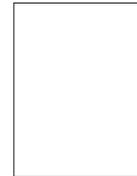
Accu-Chek Active Warranty Card

Please let this card be completed by the dealer and preserve it carefully. If this card was not filled out at the time of purchase please submit the original receipt with your claim.

The statutory guarantee provisions governing the sale of consumer goods in the country of purchase shall prevail.

Serial-No.

_____ _____ _____
Date of purchase

Stamp and signature of dealer