Accutrend® Plus cobas®

Roche

User's Manual

Date of issue: March 2007 © 2007, Roche Diagnostics All rights reserved.

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This instrument complies with DIN EN 61010-1 ("Safety requirements for electrical equipment for measurement, control and laboratory use; General requirements") and was in a perfect safety condition when it left the factory.

Installation, use and maintenance of the Accutrend Plus instrument lies in the full responsibility of the user.

The packaging material, the identification plate of the instrument and the manual may contain the following symbols or abbreviations which are listed below with their meaning:



Please consult instructions for use.



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



Store at



Use by / Expiry date



Manufacturer

REF

Catalogue number

LOT Lot number

IVD For in vitro diagnostic use.

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

The Accutrend Plus instrument

Thank you for your purchase of the Accutrend Plus instrument!

The Accutrend Plus instrument is used for quantitative measurement of four blood parameters: **glucose**, **cholesterol**, **triglycerides** and **lactate**. The reflectance photometric measurement is performed using test strips specific for each of these blood parameters. For detailed information about the single tests, please see the package inserts of the respective test strips.

Please note: This manual contains all the information needed to use the instrument and keep it ready to operate. Please read this manual **carefully** before using the instrument. Familiarise yourself with the required preparations and the measurement procedure before performing the first measurement. Also read the package inserts of the test strips to be used for the planned test.

Last update: March 2007



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Introduction

The Accutrend Plus instrument

The Accutrend Plus instrument is used for quantitative measurement of four blood parameters: **glucose**, **cholesterol**, **triglycerides** and **lactate**. The instrument is suitable for professional use as well as for self-testing.

If you have any questions which are not answered by this manual, please call your local customer support and service centre. You will find the telephone number on page 133.

Introduction

Test principle

By means of a code strip, the instrument reads the lot-specific characteristics of the test strips currently in use. This information is stored (and must therefore only be read once per test strip container). Then an unused test strip is taken from the container and inserted into the instrument. While inserted, the application area of the test strip is illuminated by an LED (light-emitting diode) from below. Before the actual measurement is performed, the reflection behaviour of the test strip is determined by means of the light which is reflected (from the application area).

The blood sample is then applied to the application area and the measurement chamber flap is closed. The constituent to be determined in the applied sample undergoes an enzymatic reaction with formation of a dye. The amount of dye formed increases with the concentration of the substance to be determined.

After a certain period of time (depends on the test parameter), the colour intensity is measured by illuminating the application area again from below using the LED. The intensity of the reflected light is measured with a detector (reflectance photometry). The measured value is determined from the signal strength of the reflected light, with the previously measured blank value and the read lot-specific information (code strip) also being considered. Finally, the result is displayed and simultaneously stored in the memory.

Checking the contents

- Accutrend Plus instrument
- User's manual
- Four batteries (1.5 V, AAA)

Safety information



Protection against infections

There is a potential risk of infection. Medical staff and other persons using the Accutrend Plus instrument to perform measurements for more than one patient must be aware that any object coming into contact with human blood is a potential source of infection.

- Use gloves.
- When performing several measurements, apply blood outside the instrument (see page 75).
- Dispose of used capillary pipettes and test strips in a sturdy container with lid.
- Follow all other locally applicable health and safety regulations.
- Use a professional lancing device such as the Accu-Chek Softclix Pro or Accu-Chek Safe-T-Pro to prevent cross contamination of blood.

Operating conditions

To ensure proper function of your Accutrend Plus instrument, observe the following guidelines:

- Operate the instrument only within the acceptable temperature range. This range is test-dependent:
 - For cholesterol and triglycerides 18-30 °C
 - For glucose 18-32 °C
 - For lactate 15-35 °C
- Use the instrument only at a relative humidity of up to 85 %.
- In order to perform a measurement, place the instrument on a level surface or hold it in your hand.



Electromagnetic interference

Strong electromagnetic fields may impair the function of the instrument. Do not use the instrument close to sources of strong electromagnetic radiation.

Introduction

Quality control

The Accutrend Plus instrument comprises numerous integrated or available control functions such as the following:

- An automatic check of the electronic components and functions when the instrument is switched on.
- An automatic check of the ambient temperature before and during the measurement.
- An automatic check of the test strip to make sure that the code information necessary for measurement exists.
- A check of the optical system and the overall function by means of control solutions.

About this manual

Page layout

The page layout of this manual enables you to easily locate the most important information.

Where illustrations are used, they always appear on the left side with the accompanying explanation on the right.

All instructions which require you to perform an action, in addition to very important information, appear on a coloured background.



This symbol draws attention to the possible risk of sustaining injury or of damaging your health (and to possible application errors during measurement which may result in a health hazard).

About this manual

Example of an instruction:

The left column contains an illustration of the instrument.



The right column states what you should do at this point, for example:

1 Press the **On/Off** button ①, to switch the instrument on for measurement.

Example of a display screen:

This column contains the illustration of a display screen.



This column contains information relating to this display screen, for example:

Every time the instrument is switched on, you can check the display. The instrument temporarily shows all symbols that may appear in the display.

Regularly check that all display elements are functioning correctly to prevent misinterpretations due to a defective display.



The Accutrend Plus instrument

Overview of instrument elements



A Display

Shows measurement results, information, symbols and all stored measured values.

B M button (memory)

By pressing this button, you can retrieve all stored values and (together with the **Set** button) you can change the instrument settings.

C On/Off button (1)

By pressing this button, you switch the instrument on and off.

D Measurement chamber flap

To apply the sample, open this flap.

E Test strip guide

Insert the test strip here.

F Set button

By pressing this button, you amend the various instrument settings. You also use this button to switch between the different test parameters to show the currently stored code numbers (before measurement).

G Infrared window

The infrared interface allows you to transfer stored data.



The Accutrend Plus instrument

D Measurement chamber flap Opened to apply sample.

H Battery compartment lid

Provides access to the battery compartment (4 AAA 1.5 V alkaline manganese batteries).

Measurement chamber cover (with test strip guide)

You can remove this cover to clean the test strip guide.

Display and symbols





Close measurement chamber flap



Sound turned on



Error (see description starting on page 119)



Flagged as a function control with control solution

Every time the instrument is switched on, you can check the display. The instrument temporarily shows all symbols that may appear in the display.

Regularly check that all display elements are functioning correctly to prevent misinterpretations due to a defective display. The symbols in the display have the following meaning:

<i>†</i>	Open measurement chamber flap
	Temperature warning
	Battery warning (batteries almost empty)
ev. 🗓	Flag for specific events (event 0-9)

set	Set mode	
mem	Memory mode	
GLUC	Test parameter: glucose	
LAC	Test parameter: lactate	
	Test strip flashes: insert static: is inserted	
BL	Lactate displayed as a whole blood value	
mmol/L	Standard unit for lactate and (in some countries) for glucose, cholesterol and triglycerides	
sec	Measurement time in seconds	
am	In the morning (with 12h time format set)	

Code display
Test mode (measurement)
Test parameter: cholesterol
Test parameter: triglycerides
Test strip and blood drop: apply blood
Lactate displayed as a plasma value
Unit for glucose, cholesterol and triglycerides (in some countries)
Display of the code number
In the afternoon (with 12h time format set)

Power supply

To save power, the instrument turns itself off after 2 minutes unless a button is pressed or a new test strip is inserted. When the instrument turns itself off, all test results obtained so far remain in the memory. With a set of fresh batteries, you will normally be able to perform at least 1,000 measurements. When the battery warning is displayed for the first time, approximately 50 measurements can still be performed. In this case, replace the batteries as soon as possible.

When replacing batteries, you must insert new batteries within two (2) minutes to keep the set date and time. If this time period is exceeded, you must re-enter the date and time. Use only AAA alkaline manganese batteries.

Measurement results, including the related measurement date and time, as well as all other instrument settings, remain stored even when no batteries are inserted.

Please respect the environment and dispose of used batteries according to your local regulations and laws.



Do not throw batteries onto an open fire. There is a risk of explosion!



Operating the instrument

Before using the instrument for the first time, perform the following steps:

- 1 Insert batteries.
- 2 Set date, time and sound.
- 3 Select how lactate measurements are to be displayed (blood or plasma value).
- 4 Insert code strip (can also be done directly before performing the measurement).

Operating the instrument

Inserting batteries







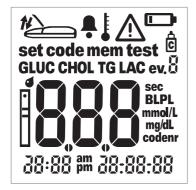
- 1 Ensure the instrument is switched off and turn it over.
- Open the battery compartment by slightly pressing the tab towards the centre of the instrument.
- 3 Lift the lid upwards to remove it from the instrument.
- Insert four batteries into the compartment according to the illustrations. Please note the orientation of the "+" (battery head) and "-" terminals (flat end). Use only alkaline manganese batteries (1.5 V, AAA).

Always replace all four batteries at the same time because batteries with different capacities may impair the function of the instrument. Do not use rechargeable batteries.

Operating the instrument







- 5 Close the battery compartment lid.
- **6** Turn the instrument on to test the function of the new batteries.
- 7 Check that the display is functioning correctly by comparing it to the diagram on the left to prevent misinterpretations due to defective display elements.

Tip:

If you think the display screen does not appear for long enough, you can hold down the **On/Off** button ① (the next time you switch on the instrument). The display screen is then shown for the time the button is pressed.



Instrument settings

Brief overview of the instrument settings

The following table provides an overview of the available settings.

Setting	Options	Default setting *
Date format	Day.Month.Year (31.12.00)	Day.Month.Year
	Month-Day-Year (12-31-00)	
Date		31.12.00
Time format	24-hour time format (24h)	24h
	12-hour time format (12h), with am/pm	
Time		0:00
Sound	On	On
	Off	
LAC result display	Blood (BL)	BL
	Plasma (PL)	

^{* &}quot;Default setting" describes the instrument setting at the time of shipping.

Instrument settings

General procedure for setting up the instrument (set mode)

You make all settings using the **Set** and **M** buttons as described below. Please note that the instrument must be switched off before you can activate the set mode as described in the following.



 Press the **Set** button (on the left side of the instrument) to switch the instrument on in set mode. set

10:20

2.40.08

The date and time as well as the set symbol now appear on the display. To actually make or change settings, press the Set button again, located on the left side of the instrument

If you want to leave the set mode instead (this is only possible if a date and time setting is made), press the **On/Off** button ①.

Instrument settings



- 3 If the displayed setting is correct (e.g. the date is correct and you want to change the time only), you can continue directly to the next setting by pressing the Set button or:
- 4 Press the M button to change the currently flashing setting. You can press the M button as many times as needed (or keep it pressed) until the desired setting (value) is reached. Settings with only two options (date/time format, sound, LAC display and unit) are turned on/off or switched with the M button.



5 Press the **Set** button again to confirm (store) the current setting and go to the next setting.

You can only move forward through the settings. Moving backwards is not possible. Corrections can only be made by repeating the settings.

The setting procedure can be terminated at any time by pressing the **On/Off** button **①**. The settings made up to that point will be stored.

Instrument settings

Setting the date format

In the first step, you set the date format (the entire date flashes).

In the following illustrations, flashing display elements are represented by a "beam circle".

The following date formats are available:

- 31.12.00 (= default setting) Day.Month.Year
- 12-31-00 Month-Day-Year



- Press the **M** button to select the date format. Each time you press the button, the (flashing) formats 31.12.00 and 12-31-00 appear in alternation. When the desired format is displayed, do the following:
- 2 Press the Set button to store this setting. The display then automatically switches to the mode for setting the current date.

40

Setting the date

With the next three settings, you first enter the **year**, then the **month** and finally the **day**.

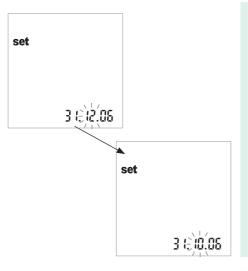


- 1 Press the **M** button to change the currently flashing figure and to set the current year.
- 2 Press the Set button to adopt the displayed year. The display then automatically switches to the mode for setting the current month.

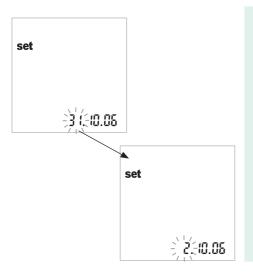


If you use the instrument without any date set, all measured values will be stored without date information.

Instrument settings



- **3** The default month flashes. Press the **M** button until the desired month is displayed.
- 4 Press the **Set** button to store the setting. The display then automatically switches to the mode for setting the current day.

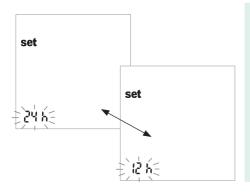


- **5** The default day flashes. Press the **M** button until the desired day is displayed.
- 6 Press the Set button to store the selected setting and to continue setting the time format. The display then automatically switches to the mode for setting the time format.

Instrument settings

Setting the time format

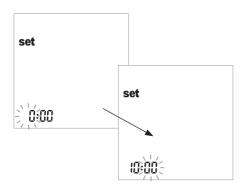
Now select the time format to be used: either the international format (24h display = default setting) or the Anglo-American format (12h display with am or pm).



- **7** Press the **M** button to switch between the *24h* and *12h* displays.
- 8 Press the Set button to store the desired setting and to continue setting the time. The display then automatically switches to the mode for setting the current time.

Setting the time

First enter the current hour and then the minutes.



9 Press the M button to change the currently flashing figure. The next time the Set button is pressed, the minutes can be set (again with the M button).
If you have selected the 12h time format and the time "12:xx" is reached, the display

switches between am and pm.



If you use the instrument without any time set, all measured values will be stored without time information.

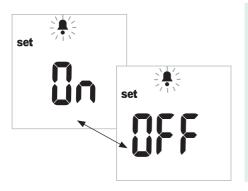
10 Press the **Set** button to store the desired setting and to continue setting the sound.

Instrument settings

Setting the sound

After setting the time, you can set the sound by choosing *On* or *OFF*. We recommend that you always leave the sound turned on. If the sound is turned on, you will hear a beep in the following situations:

- When the instrument detects that the test strip is inserted.
- When the result appears.
- When an error occurs.



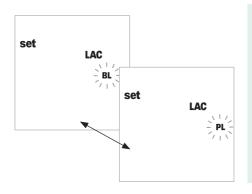
- **11** Press the **M** button to switch between *OFF* and *On* (default setting).
- **12** Press the **Set** button to store the selected setting. The display automatically switches to the next setting option.

Setting the lactate display

In the default setting, lactate values are represented based on a whole-blood measurement (BL is displayed). If you want to display the values as plasma values (PL), you can switch the representation. This setting affects **only** the (internally converted) representation of the value.



Only fresh or heparinised capillary blood is permitted as sample material. Do **not** use **plasma** for measurement.



- **13** Press the **M** button to switch between *BL* (blood) and *PL* (plasma).
- 14 Press the Set button to store the selected setting. The display automatically switches to the next setting option.

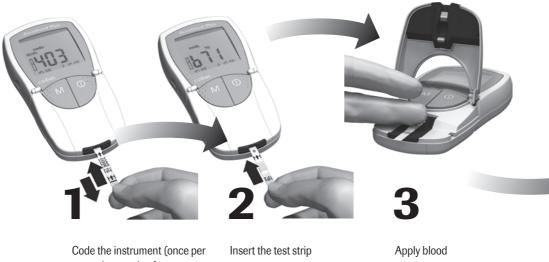


What you need:

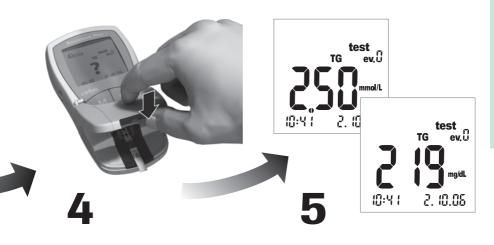
- Your Accutrend Plus instrument
- Test strips for the desired measurements with the related code strip:
 - Accutrend Glucose
 - Accutrend Triglycerides
 - Accutrend Cholesterol
 - BM-Lactate
- Lancing device (For healthcare professionals a finger pricker suitable for multipatient use in a professional setting must be used i. e. Accu-Chek Softclix Pro, Accu-Chek Safe-T-Pro)
- Alcohol or cellulose pad, if required

Note: Not all items are available in all countries.

Brief overview of the steps to be carried out



test strip container)



Start measurement by closing the measurement chamber flap

Display of measurement results

Important notes

Always ...

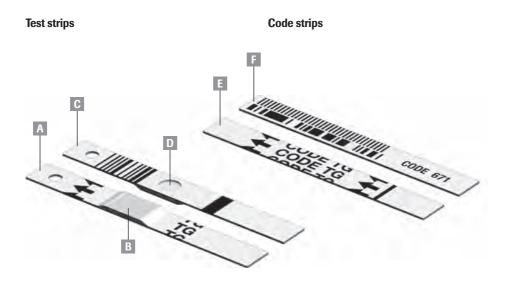
- operate the instrument at the acceptable test-specific temperatures (see also the test strip inserts):
 - For cholesterol and triglycerides 18–30 °C
 - For glucose 18–32 °C
 - For lactate 15–35 °C
- ... place the instrument on a level surface or hold it steady in your hand.
- ... make sure that all display elements are displayed during the self-test.
- ... read the test strip inserts.
- ... keep the test strip guide and housing clean (see description starting on page 113).

Never ...

- ... touch or remove the test strip during actual measurement (although this is possible before starting
 the measurement when blood is applied outside the instrument).
- ... delay starting the measurement after blood application.
- ... subject the instrument to sudden movements during a measurement.
- ... store the instrument and strips at extreme temperatures (see "Product specifications" on page 131 and test strip inserts).
- ... store the instrument and test strips under humid or damp conditions without suitable protection (see "Product specifications" on page 131 and test strip inserts).



Failure to comply with the above may lead to false results.



- **A Test strip** (top side, TG in the example) Contains the application area.
- B Application area
 Apply the sample here.
- C Test strip (bottom side)
 The imprinted barcode is used to identify the type and lot of the test strip.
- D Reaction area Used to optically check whether blood has been applied correctly.

- **Code strip** (top side, TG in the example) Supplied with each test strip container.
 - Code strip (bottom side)

 The imprinted barcode contains lot-specific information which is read and stored in the instrument.

Code strips

The code strip provides the instrument with important information on the production-specific properties of the respective test strip container. The code strip is required at least when a new test strip container is opened; the properties of these test strips are then stored in the instrument. The instrument always stores the data of only **one** code strip per test parameter (i.e. a total of four codes at a time).

Do not forget to have the code strip, which is supplied with each new test strip container, at hand before performing the first measurement. Once the code strip data is stored in the instrument (before a new test strip is used), you normally do not need it any more.



Store the code strip in the external packaging and **not** in the test strip container. The imprint on the code strip may impair the test strip quality, leading to incorrect measurement results.

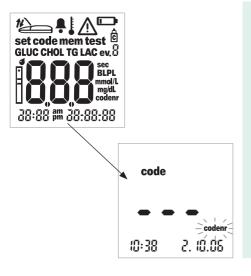
Each code strip belongs to one particular test strip container. If possible, store the test strip container together with the code strip in the external packaging in order to have the latter at hand for recoding the instrument, if needed (e.g. after battery replacement due to completely empty batteries).

Switching on the instrument



Place the instrument on a level surface or hold it in your hand. Switch on the instrument by pressing the **On/Off** button ①.

After measurement (or at any other time), you can switch the instrument off again by pressing the **On/Off** button ① for a longer period of time.



- 2 Check that the whole display is functioning correctly to prevent misinterpretations due to defective display elements.
- 3 Also always check the battery condition after the display test. When the battery symbol is shown for the first time (outside the display test), you will only be able to perform a few more measurements.

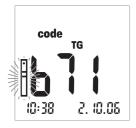
When the display test is complete, the last stored code is displayed. If no code has been stored in the instrument so far, you will see the display shown on the left.

The flashing *codenr* symbol instructs you to insert a code strip.

Inserting the code strip



- Hold the code strip with thumb and index finger in the white area located at the end of the strip. Do not touch the printed area (behind the black bar).
- 2 Insert the code strip smoothly into the test strip guide up to the stop in the direction of the printed arrows. Withdraw it immediately afterwards. Leave the measurement chamber flap closed during this procedure.
 - If the instrument reads the barcode information correctly, successful coding is confirmed with a short beep (if sound is turned on).



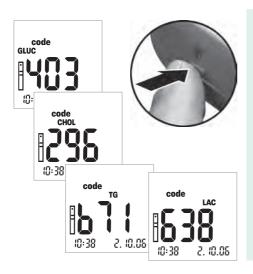
The three-digit code number (which is also printed on the reverse side of the code strip and on the test strip container) is shown in the display.

If any problems occur during reading, an error message will be displayed (see description starting on page 119). In this case repeat reading the code strip after a few seconds.

The flashing strip symbol prompts you to insert the test strip.

Switching the code display

You can switch between the display of the stored code numbers for information purposes.



1 If the last stored or used code number is displayed after turning on the instrument, press the **Set** button to switch to the next stored code number. Each time you press the button, the display shows the code numbers of the test strips in succession GLUC > CHOL > TG > LAC (if already stored).

This display is for information purposes only, you do not need to display the test parameter used for the following measurement.

Sample material

Fresh capillary blood is used as sample material. You need a free hanging blood drop for measurement. For more information on sample material and use of heparinised blood, please refer to the documentation of the related test strip.



Please note that all handling of foreign blood samples represents a risk of infection. Therefore take the corresponding safety measures, such as wearing disposable gloves while working.

Performing measurements in the professional sector



Protection against infections: There is a potential risk of infection. Medical staff and other persons using the Accutrend Plus instrument to perform measurements for more than one patient must be aware that any object coming into contact with human blood is a potential source of infection.

- Use gloves.
- Apply blood outside the instrument (see page 75). When measuring glucose in several persons, clean and disinfect the instrument before each measurement as blood cannot be applied using capillary pipettes.
- When measuring cholesterol, triglycerides and lactate in several persons, always use capillary pipettes to apply blood outside the instrument.
- Dispose of used capillary pipettes and test strips in a clinical waste bin.
- Follow all other locally applicable guidelines and regulations on health and safety.

Preparing to perform a measurement





- Prepare the test strip container for the required measurement (e.g. measurement of triglycerides).
- 2 Check the expiry date of the test strip. Always use test strips **before** their expiry date has passed.
- Make sure the code strip belonging to these test strips is at hand (unless the instrument has already been coded with this code strip).

Please note: Environmental influences (e.g. air humidity and light) on the test strips may cause damage to the test strips and lead to false measurements or error messages! Do not remove the test strips from the packaging until immediately before performing the measurement.



4 Prepare the lancing device by inserting a new lancet.

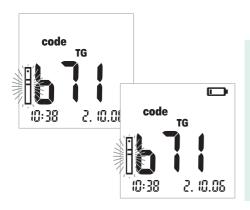
Do not lance yourself before being instructed to do so in the course of this description.

In the professional sector you should use a multi patient lancing device to prevent cross contamination, such as Accu-Chek Softclix Pro or you may consider using Accu-Chek Safe-T-Pro single-use lancing devices.

Note: Not all items are available in all countries.

Performing a measurement

After it is switched on and coded, the instrument expects you to insert the test strip. Using the barcode on the reverse side, the instrument detects which test parameter is to be measured and to which code strip the test strip belongs. If the barcode has not been read yet, a respective error message will be displayed after inserting the test strip.



Check the following displays before performing the measurement:

- Are date and time correct? If the measured values are to be stored with time information, correct these settings (see description starting on page 41).
- 2 Does the battery symbol appear? If it appears, only few more measurements can be performed. Replace the batteries as soon as possible (see description starting on page 30).

3 Now take the test strip from the test strip container.



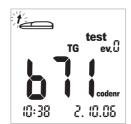
Close the container immediately after opening to protect the desiccant, otherwise the test strips will become unusable before their expiry date. No liquids must enter the test strip container. Do not mix up the caps of different test strip containers!

With cholesterol and glucose test strips, check the reaction area for discolouration before starting measurement. If you detect discolouration, this test strip is unusable. For detailed information, see the insert of the respective test strip.





- 5 Hold the test strip with thumb and index finger so that the printed measurement parameter is facing upwards.
- 6 Insert the test strip into the test strip guide up to the stop. When the test strip reaches the correct position, you will hear two beeps (short - long; if this function is turned on).

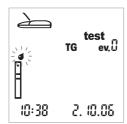






A flashing arrow now instructs you to open the measurement chamber flap in order to apply the blood. Explanations on flagging this measurement (events, ev. 0 display or function controls) are provided later in this chapter.

7 Open the measurement chamber flap. The flap firmly locks into place when it reaches a vertical position.



The flashing drop symbol (above the strip symbol) now instructs you to apply the blood.

Blood can be applied either in the instrument (when used by a single user) or outside the instrument (when measurements are performed in the professional sector with heparinised capillary pipettes, for example).

Recommendations for the collection and measurement of capillary blood

To obtain a suitable blood drop:

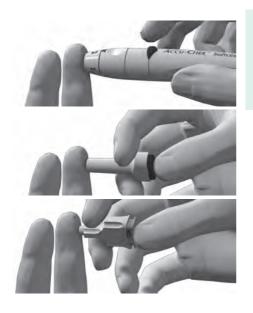
- Wash your hands with warm water.
- Ensure hands are warm and dry before lancing
- If needed, massage your fingertip. After lancing yourself, try to obtain a sufficiently large free hanging drop without excessive pressing or squeezing.
- We recommend obtaining the capillary blood from the side of the fingertip as this part is the least sensitive to pain.



Factors to be considered for **triglyceride** measurement: Nearly all creams and many soap products (e.g. shower gel and shampoo) contain fat. Even if only small quantities of these substances come into contact with the test strips, the measurement will be incorrect. It is therefore particularly important to wash your hands very thoroughly and rinse them with plenty of clear water when performing this measurement.

For determination of **cholesterol** or **triglycerides**, wipe off the first drop of blood with a cellulose pad and use the second drop of blood for the test.

Blood collection



Then lance the outer side of the fingertip using the lancing device.

Performing a measurement

Blood application in the instrument:



9 Apply the free hanging drop of blood directly from the finger to the yellow sample application area of the test strip. Do not touch the application area with the finger!

The drop of blood must be applied to the test strip **immediately** after lancing the fingertip. Blood which is applied later will lead to an incorrect result as the coagulation process has already begun.

Alternative blood application outside the device:



- **10** Withdraw the test strip after opening the flap (and leave it open).
- 11 Also apply the free hanging drop of blood directly from the finger (or, particularly in the professional sector, from the pipette) to the yellow sample application area of the test strip. Do not touch the application area with your skin!

 Heparinised capillary pipettes can be used to apply blood. Please refer to the insert of the respective test strip.
- **12** With the measurement chamber flap open, insert the test strip back into the instrument.

Performing a measurement

Checking the applied blood:



The application area must be completely covered with blood (example A), otherwise wrong values may be determined.

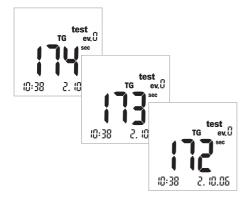
If too little blood is applied (example **B**), do not try to spread it or apply a second drop as this may lead to a false measurement. Repeat the measurement with a new test strip.

Starting the measurement



A flashing arrow now instructs you to close the measurement chamber flap. This starts the actual measurement.

13 Close the measurement chamber flap.



Measurement starts. The time needed to evaluate the sample varies depending on the test parameter. This time is shown in the display and counted down to "0". The measurement times of the individual test parameters are:

- For glucose 12 seconds
- For cholesterol 180 seconds
- For triglycerides approx. 174 seconds

 (a possible shorter measurement time is indicated by three short beeps)
- For lactate 60 seconds

The last four seconds of the measurement time are each accompanied by one short beep (if turned on). Completion of the measurement and the subsequent display of results is indicated by a longer beep.

Display of results



(0:41

test

2.40.08



2.40.08

(0:4)



When measurement is finished, the result is displayed. If you are measuring glucose, please carry out the plausibility check described on the next page.

Measurement results which fall outside the measurement range are displayed as *Hi* (above the measurement range) or *Lo* (below the measurement range).

When the result is displayed, the *ev. 0* event (no event) is displayed. For an explanation on how to use the event display to apply additional information to the result, see the next section.



Plausibility check after glucose measurement:

- Remove the test strip and turn it with the bottom side upwards.
- Compare the reaction area on the bottom side of the strip with the colour field scale on the label of the test strip container.

The colour of the reaction area must approximately match the colour assigned to your measurement result. If there is a great deviation, perform a function check. Please note the information provided in the insert of the test strips.

If the displayed result (particularly when blood glucose is measured) does not match your state of health or seems to be unusually high or low, check the function using a new test strip (see description starting on page 85). If this check confirms proper functioning of the instrument, please read again the preceding instructions on performing a measurement. Perform another measurement using a new test strip. If the new result also seems to be not plausible, please consult your doctor.

If you do not want to flag the measurement result with an event or as a function control, the measurement is now complete. Open the measurement chamber flap and remove the test strip. Keep the **On/Off** button ① pressed until the instrument switches off. Properly dispose of the used lancet and test strip according to local laws and guidelines. Clean the instrument if necessary (see description starting on page 113).

Doctors and nursing staff must observe the disposal guidelines of the respective hospital or doctor's surgery.

Performing a measurement

Flagging measurements

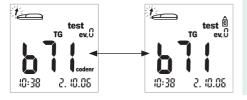
You can add additional information to measurements, for example to characterise a particular value with regard to the conditions of its generation (meals, sport etc.). In addition, you can flag measurements carried out with control liquids as function controls. You can flag a measured value at different points in time:

- At the start of the measurement after inserting the test strip.
- When the test result is displayed.

You cannot flag a value while measurement is in process.

Flagging the measurement as a function control:





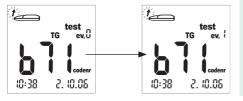
You flag measurements as function controls when they have been performed using a control solution (as described in the following chapter).

14 Press the **M** button (after inserting the test strip or when the result is displayed) to flag the measurement as a function control (bottle symbol). Pressing the **M** button again turns the flag off.

Performing a measurement

Assigning additional information to a measurement:





You can assign one of nine different events to a measurement. The event "0" represents "no flagging". You may define the events and their respective event numbers yourself. Make sure that your assignments are unique and reproducible.

15 Press the **Set** button (after inserting the test strip or when the result is displayed) to flag the measurement with an event. Pressing the **Set** button increases the displayed event number in increments of one. After event "9", the event display is reset to "0".

Control check with control solution

To ensure that the instrument is functioning properly, you should regularly use control solution for a control check. For each test parameter, a separate control solution is available. Make a habit of carrying out a control check in the following situations:

- When you open a new test strip container.
- After replacing the batteries.
- After cleaning the instrument.
- When you doubt that the measured values are correct.

A control check is performed in the same way as a regular measurement with the difference that control solutions are used instead of blood.

Control check with control solution

What you need:

- Your Accutrend Plus instrument
- Test strips for the desired measurements with the related code strip:
 - Accutrend Glucose
 - Accutrend Triglycerides
 - Accutrend Cholesterol
 - BM-Lactate
- Control solutions for the respective test parameter
 - Accutrend Control G (Glucose)
 - Accutrend Control TG1 (Triglyceride)
 - Accutrend Control CH1 (Cholesterol)
 - BM-Control Lactate

Preparing to perform a control check



- Prepare the test strip container for the required measurement (e.g. measurement of triglycerides).
- 2 Make sure the code strip belonging to these test strips is at hand (unless the instrument has already been coded for this test strip container).
- **3** Prepare the control solution matching the test strips.

The following description assumes that the instrument has already been coded for the test strips used here. If this is not the case, see the description starting on page 59.

Control check with control solution

Performing a control check



1 Place the instrument on a level surface or hold it in your hand. If required, switch on the instrument by pressing the **On/Off** button ①.







After switching on the instrument, check the following displays:

- 2 Check that the whole display is functioning correctly to prevent misinterpretations due to defective display elements.
- 3 Are date and time correct? If the measured values are to be stored with time information, correct these settings (see description starting on page 41).
- 4 Does the battery symbol appear? If it appears, only few more measurements can be performed. Replace the batteries as soon as possible (see description starting on page 30).

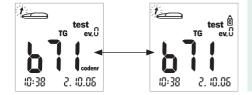
Control check with control solution



- 5 Now take the test strip from the test strip container. Close the container immediately after opening to protect the desiccant, otherwise the test strips will become unusable before their expiry date.
- 6 Hold the test strip with thumb and index finger so that the printed measurement parameter is facing upwards.
- Insert the test strip into the test strip guide up to the stop. When the test strip reaches the correct position, you will hear two beeps (short - long; if this function is turned on).



8 Press the **M** button to flag the measurement as a function control (bottle symbol).



Control check with control solution



Open the measurement chamber flap. The flap firmly locks into place when it reaches a vertical position.

Applying the control solution



Apply a large free hanging drop of control solution directly from the bottle to the test strip. Ensure that neither the bottle nor the finger touches the application area. The application area must be completely covered.

The sample can (as with performing a measurement using blood) also be applied outside the instrument as described on page 75.

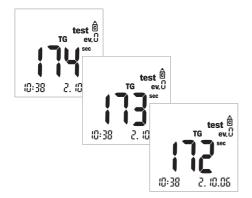
Control check with control solution

Starting the measurement



A flashing arrow now instructs you to close the measurement chamber flap. This starts the actual measurement.

11 Close the measurement chamber flap.



Measurement starts. The time needed to evaluate the sample varies depending on the test parameter. This time is shown in the display and counted down to "0". The measurement times of the individual test parameters are:

- For glucose 12 seconds
- For cholesterol 180 seconds
- For triglycerides approx. 174 seconds

 (a possible shorter measurement time is indicated by three short beeps)
- For lactate 60 seconds

The last four seconds of the measurement time are each accompanied by one short beep (if turned on). Completion of the measurement and the subsequent display of results is indicated by a longer beep.

Control check with control solution

Display of results





When measurement is finished, the result is displayed in the set unit.

Now check whether the displayed result falls within the acceptable range.

Information on the target values which should be obtained when measurements are performed using control solutions can either be found on the labels or on the package inserts for the test strips or control solutions. If the value is outside the range, repeat the control check. If the second result is again outside this range, please contact your local customer support and service centre.

Memory

The Accutrend Plus instrument has four memory areas, each of which can be used to store up to 100 measured values together with date, time and flags.



If you have not set any date and time (see description starting on page 41), all measured values will be stored without time information.

Displaying stored measured values



1 Switch on the instrument directly in memory mode by pressing the **M** button, or by pressing this button when the instrument is in coding mode.

You can exit memory mode by pressing the **On/Off** button **①**.

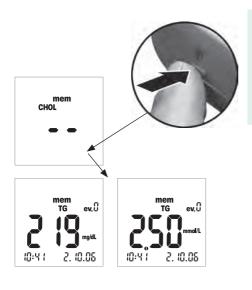
Memory



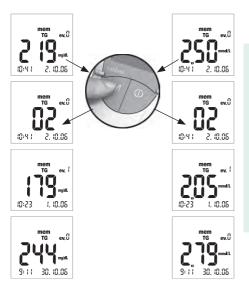


After the usual display test has been performed when switching on the instrument, the last stored measured value is displayed.

The *mem* symbol indicates that the instrument is in memory mode. The date and time on the display match the time at which the measurement was performed, and not the current time. The colon in this time display does not flash – in contrast to the current time display.



Press the Set button to switch between the memory areas of the four test parameters. Each time you press the Set button, the last stored value of each memory area is displayed (GLUC > CHOL > TG > LAC > GLUC > ...) unless measured values are stored in the respective area.



To navigate within one memory area, use the **M** button.

3 Press the M button to show the next oldest measured value within one memory area. When you press the button, the place of the measured value within the memory is displayed (here: 02); the actual value is not shown until you release the button.

When you hold down the \mathbf{M} button, older memory places (02 ... 03 ... 04 ... and so on) continually appear in the display until you release the button. Then the measured value in the last displayed memory place is shown.

Special cases:







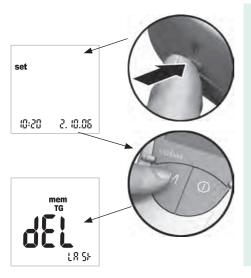
■ If the entire memory is empty, three dashes (- - -) will appear in the display.

■ If the entire memory area of a test parameter is empty, two dashes (- -) will appear in the display.

If a single measured value is stored incorrectly (or deleted), one dash (-) will appear in the display.

Memory

Deleting stored measured values



- 1 Switch on the instrument by pressing the **Set** button (on the left side of the instrument).
 - The date and time as well as the *set* symbol now appear on the display.
- 2 Now press the **M** button to display the options for deleting measured values.

You can exit delete mode at any time by pressing the **On/Off** button ①.

All the following descriptions start with this display (*dEL LASt*).

You can choose between three different deletion variants:

- You can delete the last individual measured value.
- You can delete all measured values of a single test parameter at once.
- You can delete all measured values of all test parameters at once.

It is not possible to delete specific individual values (which are not the last measured value).

Memory

Deleting the last measured value



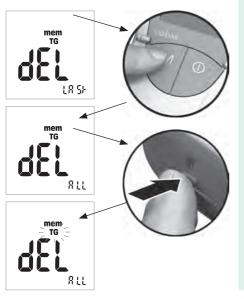
- 3 To delete the last measured value (dEL LASt display), press the Set button. The related test parameter is displayed.
- 4 To delete the displayed value from the memory, press and hold down the Set button for more than 3 seconds. While you hold down the button, the measured value flashes. At the same time you will hear a short beep once a second.

mem TG

After 3 seconds the value is deleted; this is confirmed by the display (–) as shown on the left. Once you release the **Set** button, you automatically exit the delete mode.

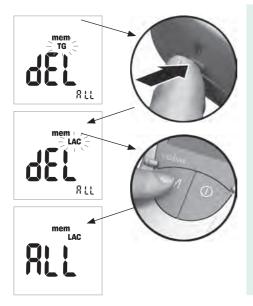
Memory

Deleting all measured values of a test parameter



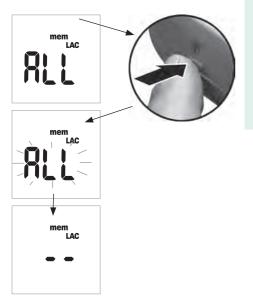
- 5 If you want to delete all measured values of a test parameter, press the M button. The display shows dEL - ALL, and the currently selected test parameter (here: TG) is displayed.
- 6 If the displayed test parameter is not the parameter for which you want to delete measured values, press the Set button.

The currently selected test parameter flashes.



- 7 Press the **Set** button again to select a different test parameter.
 Each time you press the button, the next test parameter appears in the display (GLUC > CHOL > TG > LAC ...).
- **8** To select the displayed test parameter for deletion, press the **M** button.

The display switches to ALL.

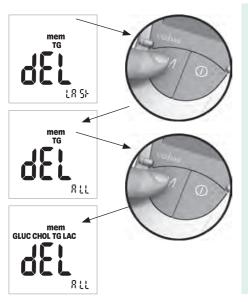


9 To delete the measured values of the currently displayed test parameter from the memory, press and hold down the Set button for more than 3 seconds.

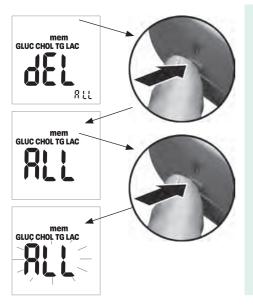
While you hold down the button, the ALL display flashes. At the same time you will hear a short beep once a second.

After 3 seconds all values of the selected test parameter are deleted; this is confirmed by the display as shown on the left (– –). Once you release the **Set** button, you automatically exit the delete mode.

Deleting all measured values



10 If you want to delete all measured values of all test parameters, press the M button twice. The display shows dEL - ALL, and all test parameters are shown.



11 Press the **Set** button to select this delete mode.

The display switches to ALL.

12 To delete all measured values from the memory, press and hold down the Set button for more than 3 seconds.

While you hold down the button, the *ALL* display flashes. At the same time you will hear a short beep once a second.

mem GLUC CHOL TG LAC After 3 seconds all values are deleted; this is confirmed by the display as shown on the left (– –). Once you release the **Set** button, you automatically exit the delete mode.

Memory

Data transfer

Results can be downloaded from memory via an inbuilt infrared interface.

For more information on downloading results to a suitable system (such as a PC), please call your local customer support and service centre (see page 133).

Cleaning

A clean optical measuring system is a basic prerequisite for determining precise measured values. Therefore clean the instrument regularly and immediately after it becomes dirty. Always switch off the instrument before cleaning it!

Use only the following items for cleaning:

- Ordinary lint-free cotton buds
- Ordinary lint-free tissues
- Ordinary disinfecting tissues

Mild soap suds as well as 70 % ethanol or isopropyl alcohol are suitable for cleaning. When used in the professional sector (e.g. doctor's surgeries), a mixture consisting of 1-propanol, 2-propanol and glutaraldehyde (brand name "Bacillol plus") is recommended.



Do **not** use any disinfectant sprays or tissues or cotton buds which are dripping wet as the liquid may enter the instrument and damage it.

Cleaning

Cleaning the outer instrument components

- Ensure the instrument is switched off.
- Wipe the outside of the instrument with a lightly moistened, lint-free cotton cloth. In the professional sector, the outside of the instrument can be cleaned with "Bacillol plus".

Cleaning the inner instrument components



- 1 Open the measurement chamber flap.
- 2 Remove the measurement chamber cover (including the test strip guide) by slightly pushing it to the centre of the instrument and then pulling it upwards.



3 In case of significant dirt, you can rinse the measurement chamber cover (separately from the instrument) under warm running water. Dry the measurement chamber cover with a fresh cloth.

Cleaning

Cleaning the optical measuring system



- Clean the easily accessible areas of the optical measuring system with a lint-free pad or a moistened cotton bud.
 Make sure that no liquid enters the instrument. Do not insert any objects into the instrument.
- **5** Allow the instrument to dry thoroughly.



- 6 Do not fit the measurement chamber cover into the instrument until it is completely dry. Press the front end of the measurement chamber cover slightly downwards until you feel it click into place.
- 7 Close the measurement chamber flap.

The instrument is now ready for operation again. Perform a control check (see description starting on page 85).



Error messages

In certain circumstances error messages may appear on your display. Generally, you should first try the solutions suggested for the respective error. If the problem persists, please contact your local customer support and service centre (see page 133).

Error messages

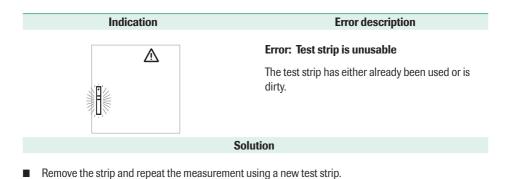
Indication Error description Error: Unknown barcode The barcode of test strips or code strips could not be read. Solution

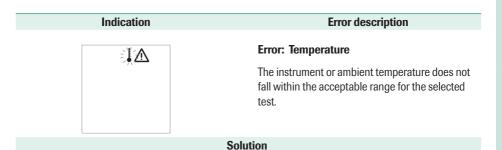
- All strips: Remove the strip and check the barcode for dirt.
- Test strips: Repeat the procedure with a new strip.
- Check whether there may be interferences caused by electromagnetic fields in the direct environment of the instrument.

Indication Error description Error: Strip code does not match stored code The test strip belongs to a different test strip container than the container which was last coded. Solution

- Remove the strip and repeat the measurement using a test strip from the matching test strip container.
- Code the instrument with the corresponding code strip.

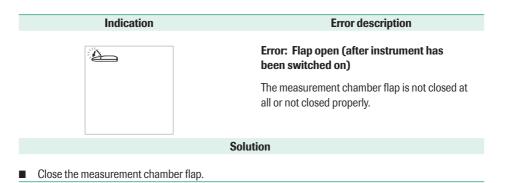
Error messages

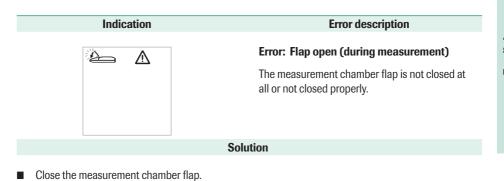




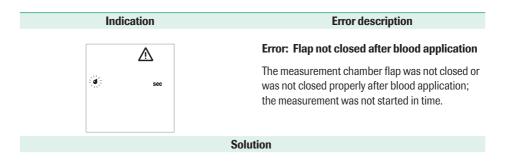
Move the instrument to an environment which has an appropriate temperature and repeat the measurement after several minutes.

Error messages





Error messages



Remove the strip and repeat the measurement using a new test strip.

Indication Error description Error: Internal error (example 142) The instrument has detected an internal error. Solution

Switch the instrument off and on again. If the error still persists, the instrument is defective.
 Please call your local customer support and service centre.



Further information

Ordering information

Please contact your specialist supplier.

Item	Description
Accutrend Glucose 50	50 test strips for determining blood glucose
Accutrend Glucose 25	25 test strips for determining blood glucose
Accutrend Control G	Control set to be used with Accutrend Glucose test strips
Accutrend Cholesterol 25	25 test strips for determining cholesterol in the blood
Accutrend Cholesterol 5	5 test strips for determining cholesterol in the blood
Accutrend Control CH1	Control solution to be used with Accutrend Cholesterol test strips
Accutrend Triglycerides 25	25 test strips for determining triglycerides in the blood
Accutrend Control TG1	Control solution to be used with Accutrend Triglycerides test strips

Further information

Item	Description	
BM-Lactate 25	25 test strips for determining lactate in the blood	
BM-Control Lactate	Control solution to be used with BM-Lactate test strips	
Accutrend Plus instrument		

Note: Not all items are available in all countries.

Product limitations

Please read the insert of the test strips for detailed information on product data and limitations.

Product specifications

Operating conditions and technical data

Dependent on test parameter:
Cholesterol and triglycerides 18–30 °C
Glucose 18-32 °C
Lactate 15–35 °C
10-85%
Blood glucose: 20-600 mg/dL (1.1-33.3 mmol/L)
Cholesterol: 150-300 mg/dL (3.88-7.76 mmol/L)
Triglycerides: 70-600 mg/dL (0.80-6.86 mmol/L)
Lactate: 0.8-21.7 mmol/L (blood value), 0.7-26 mmol/L (plasma value)
100 measured values, optional with date, time and additional information per test parameter
Infrared interface, LED/IRED Class 1
4 x AAA 1.5 V alkaline manganese batteries
More than 1,000 measurements (with new batteries)
III
154 x 81 x 30 mm
Approx. 140 g

Product specifications

Sample material

Sample type	Fresh capillary blood (for detailed information see package insert)
Sample volume	A free hanging drop of blood
Interactions	See test strip insert

Storage and transport conditions

Temperature range	−25 °C to +70 °C
Relative humidity	10 to 85 % (no condensation)

Disposal of instrument

The instrument may come into contact with blood while measurements are performed. Therefore used instruments may represent a risk of infection. Dispose of your used instrument according to your local regulations after removing the batteries. For information on proper disposal, contact your local authority.

The instrument does not fall under the scope of the EC Directive 2002/96/EC (Directive on waste electrical and electronic equipment).

Information service

If you have any further questions, please contact your local support and service centre.

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Australia

Roche Diagnostics Australia Pty Ltd. 31 Victoria Avenue, Castle Hill, NSW 2154 Telephone 02-9899 7999

New Zealand

Roche Diagnostics N.Z. Ltd, 15 Rakino Way, Box 62-089, Mt. Wellington, Auckland Telephone 09-276-4157

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Patents:

US 5,463,467; US 5,424,035; US 5,334,508; US 5,206,147; US 5,240,860; US 5,382,523; US 5,521,060; US 5,268,269; US 6,506,575; US 5,281,395



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