Accutrend Plus

cobas®

User's Manual

Roche

Date of issue: January 2009

The system fulfills the Canadian and U.S. safety requirements (UL LISTED, in accordance with UL 3101-1 and CAN/CSA C22.2 no. 1010-1).

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 is 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:


Consult instructions for use.


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


Store at


Use by date


Manufacturer

REF Catalog number

LOT Batch number

IVD *In vitro* diagnostic medical device.

CE This product fulfills the requirements of the European 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 two blood parameters: **glucose** and **cholesterol**. The reflectance photometric measurement is performed using test strips specific for each of these blood parameters. For detailed information about the two tests, see the package inserts of the respective test strips.

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. Familiarize 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.

Last update: January 2009

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Introduction

The Accutrend Plus instrument

The Accutrend Plus instrument is used for quantitative measurement of 2 blood parameters: glucose and cholesterol. 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, call the ACCU-CHEK Customer Care Service Center 24 hours a day, 365 days a year at 1-800-440-3638

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. To run a test, an unused test strip is taken from the container and inserted into the instrument. When inserted, the application area of the test strip is illuminated by an LED (light-emitting diode) from below. Before sample application, the reflection behavior of the test strip is determined by means of the light which is reflected from the application area (blank value).

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 (dependent on the test parameter), the color 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, using the previously measured blank value and the lot-specific information from the code strip. Finally, the result is displayed and simultaneously stored in the memory.

Checking the contents

- Accutrend Plus meter
- User's Manual
- Four 1.5 V AAA alkaline batteries
- Quick Reference Guide
- Carrying Case
- Warranty Card

Safety information

Protection against infection

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
- Discard used test strips in a sharps container or sturdy container with lid
- Follow all other locally applicable health and safety regulations
- Use a professional lancing device such as the Accu-Chek Safe-T-Pro to prevent cross contamination.

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: 18-30ºC (64-86ºF)
  - For glucose: 18-32ºC (64-90ºF)
- Use the instrument only at a relative humidity of 85% or less
- 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.

Integrated control functions

The Accutrend Plus instrument has numerous integrated or available control functions, including the following:

- An automatic check of the electronic components and functions when the instrument is powered 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 is in memory.
- A check of the optical system and the overall function by means of control solutions. For more information, refer to the Quality control recommendation section of this user's manual.

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 colored 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.

Example of an instruction:

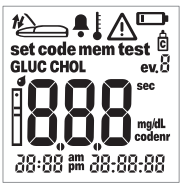
The left column contains an illustration of the instrument.

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

1 Press the On/Off button ⏻, to power 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 the display screen, for example:

Every time the instrument is powered 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 results.

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.

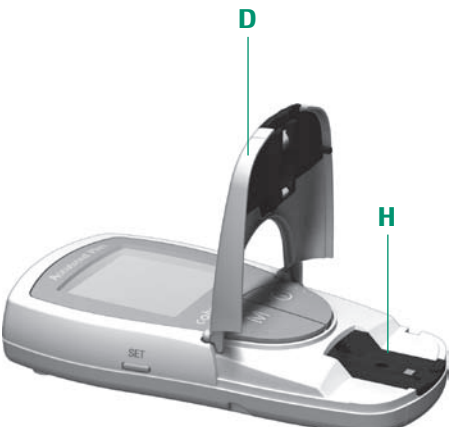
C On/Off button
By pressing this button, you power the instrument on and off.

D Measurement chamber flap
To apply the sample, open this flap. To start the measurement, close the flap.

E Test strip guide
Insert the test strip here.

F Set button
By pressing this button, you access the various instrument settings which are changed using the M button. You also use this button to switch between the different test parameters to show the currently stored code numbers (before measurement), or to review results (when in memory mode).

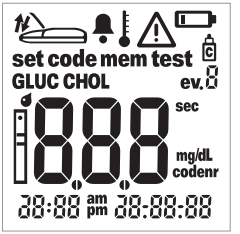

G


D
H
SET

G **Battery compartment lid**
Provides access to the battery compartment (4 AAA 1.5 alkaline batteries).

H **Measurement chamber cover (with test strip guide)**
You can remove this cover to clean the test strip guide and optics cover.

Display and symbols



Every time the instrument is powered on, you should 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:

	Close measurement chamber flap		Open measurement chamber flap
	Beeper turned on		Temperature warning
	Error		Battery warning (batteries almost dead)
	Flagged as a function check with control solution		Flag for specific events (event 0-9)

set	Set mode	**code**	Code display
mem	Memory mode	**test**	Test mode (measurement)
GLUC	Test parameter: glucose	**CHOL**	Test parameter: cholesterol
	Test strip flashes: insert		Test strip and blood drop: apply blood
sec	Measurement time in seconds	**codenr**	Display of the code number
am	In the morning (with 12h time format set)	**pm**	In the afternoon (with 12h time format set)
mg/dL	Unit for glucose and cholesterol		

Power

To save power, the instrument powers 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 approximately 1,000 measurements. When the battery warning is displayed for the first time, approximately 50 measurements can still be performed, but replace the batteries as soon as possible.

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

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

Please respect the environment and discard 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 beeper.

3 Insert code strip (can also be done directly before performing the measurement).

Inserting batteries

1 Ensure the instrument is switched off and turn it over.

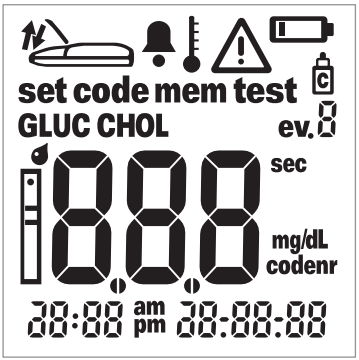
2 Open the battery compartment by slightly pressing the tab towards the center of the instrument.

3 Lift the lid upwards to remove it from the instrument.

4 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 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.


Alkaline (AAA)
Alkaline (AAA)
Alkaline (AAA)
Alkaline (AAA)



5 Replace and close the battery compartment lid.

6 Power the instrument on to test the function of the new batteries.

7 Check that the display functions correctly by comparing it to the diagram on the left to prevent misinterpretations due to defective display elements.

Tip:
To make the display screen appear for a longer time, hold down the On/Off button ⏻ when powering on. 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) Month-Day-Year (12-31-00)	Month-Day-Year
Date		12-31-00
Time format	24-hour time format (24h) 12-hour time format (12h), with am/pm	12h
Time		12:01 a.m.
Beeper	On Off	On

* "Default setting" describes the instrument setting at the time of shipping.

General procedure for setting up the instrument (set mode)

You make all settings using the **Set** and **M** buttons as described below. The instrument must be powered off before you can activate the set mode.

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

2 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

To leave the set mode (this is only possible if a date and time setting is made), press the On/Off button ⏻.

Note: If the meter display reads **dEL** LASt you have entered the set mode incorrectly and reached a mode we do not recommend. To exit this mode and enter the set mode correctly, immediately turn off the meter by pressing and holding down the On/Off button ⏻. After the meter is powered off, press the **Set** button twice to enter the set mode and then continue to the next step.

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 or time format, and beeper) are turned on/off or switched with the **M** button.

5 Press the **Set** button again to save 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 ⏻. The settings made up to that point are saved.

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:

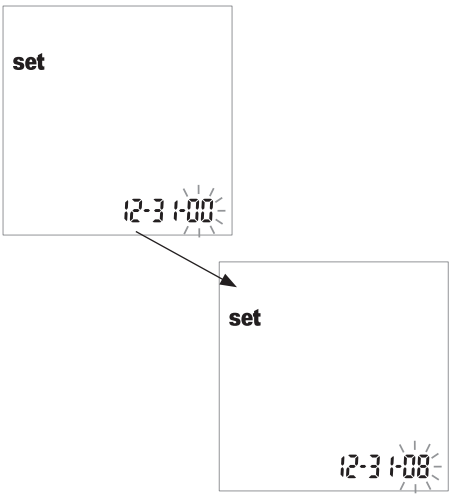
- 31.12.00 Day.Month.Year
- 12-31-00 (= default setting) Month-Day-Year

1 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 save this setting. The display then automatically switches to the mode for setting the current date.

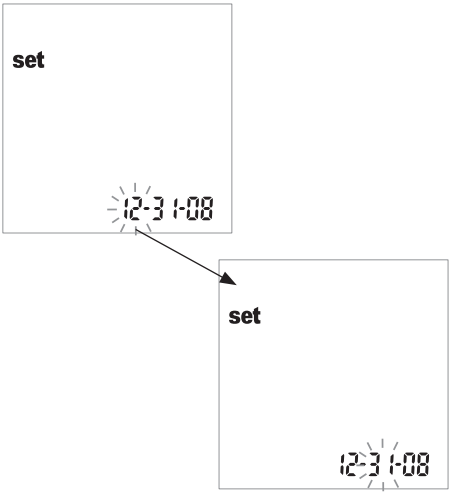
Setting the date

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



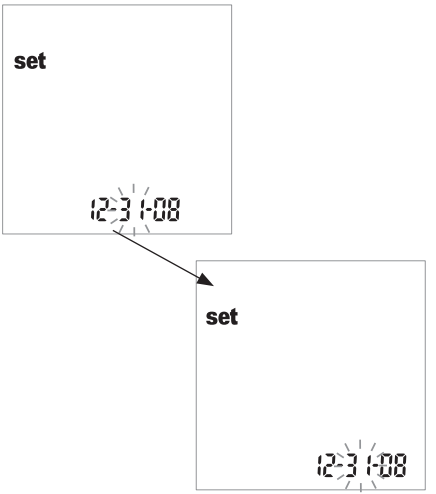
1. Press the **M** button to change the currently flashing figure and to set the current year.
2. Press the **Set** button to save the displayed year. The display then automatically switches to the mode for setting the current month.

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



3 The default month flashes. Press the **M** button until the desired month is displayed.

4 Press the **Set** button to save the setting. The display then automatically switches to the mode for setting the current day.

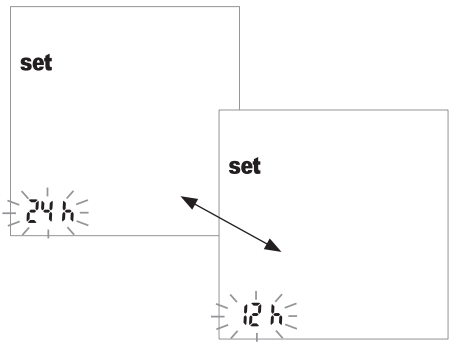


5 The default day flashes. Press the **M** button until the desired day is displayed.

6 Press the **Set** button to save the selected setting and to continue setting the time format. The display then automatically switches to the mode for setting the time format.

Setting the time format

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

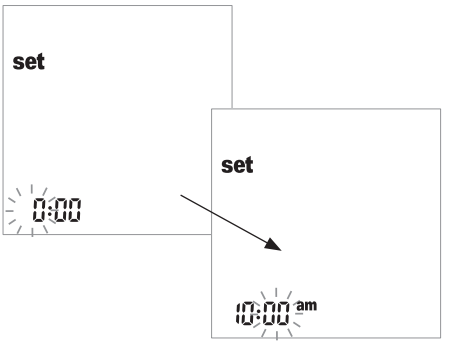


7 Press the **M** button to switch between the *24h* and *12h* displays.

8 Press the **Set** button to save 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* or vice versa.

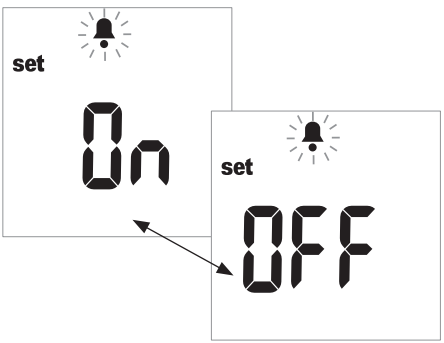
If you use the instrument without any time set, all measured values will be stored without time information.

10 Press the **Set** button to save the desired setting and to continue setting the beeper.

Setting the beeper

After setting the time, you can set the beeper by choosing *On* or *OFF*. We recommend that you always leave the beeper enabled. If the beeper is enabled, 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 save the selected setting. The display briefly displays “End” and automatically goes to test mode.

Performing a measurement

What you need:

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

Brief overview of the steps to be carried out

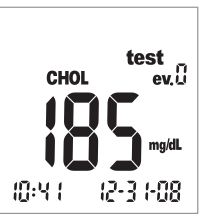
Code the instrument (once per test strip lot)

Insert the test strip

Apply blood

4

Start measurement by closing the measurement chamber flap



5

Display of measurement results

Important notes

Always …

- operate the instrument at the acceptable test-specific temperatures (see also the test strip inserts):
  - For cholesterol: 18–30°C (64-86°F)
  - For glucose: 18–32°C (64-90°F)
- 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 the Cleaning chapter of this manual).

Note: If you would like to do a total cholesterol test after you finish your glucose test (or vice versa), get a blood drop from a different finger.

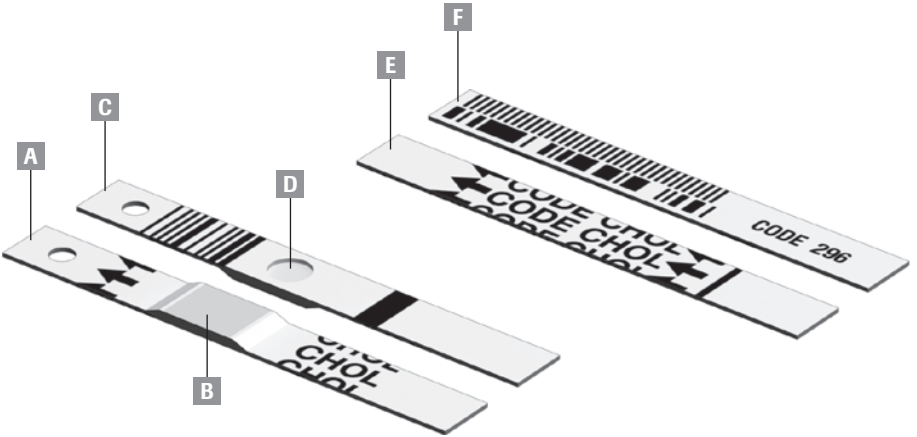
Never …

- touch or remove the test strip during actual measurement (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 the Product specifications chapter of this manual and test strip inserts)
- store the instrument and test strips under humid or damp conditions without suitable protection (see the Product specifications chapter of this manual and test strip inserts).

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

Test strips

Code strips



A **Test strip** (top side, CHOL 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 visually check whether blood was applied correctly.

E **Code strip** (top side, CHOL in the example)
Supplied with each test strip container.

F **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 specific properties of the respective test strip. The code strip is required at least when a new test strip container is opened and before the strips are used. The properties of these test strips are then stored in the instrument. The instrument stores the data of only **one** code strip per test parameter (i.e., a total of two 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, but we recommend that you keep it until the container of strips has been used completely.

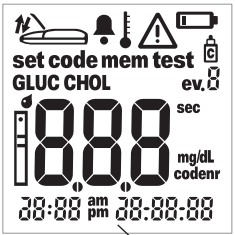
Store the code strip in the external packaging and **not** in the test strip container. The imprint on the code strip may impair the test strip quality, leading to incorrect measurement results.

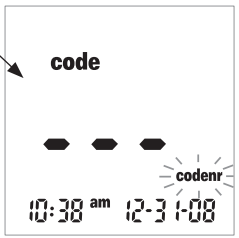
- Each code strip belongs to one particular test strip container or lot. If possible, store the test strip container together with the code strip in the external packaging in order to have the latter at hand for recoding the instrument if needed (e.g., after battery replacement due to completely dead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

Switching on the instrument

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

Note: To power the instrument off again, press and hold the On/Off button ⏻ until the meter shuts off



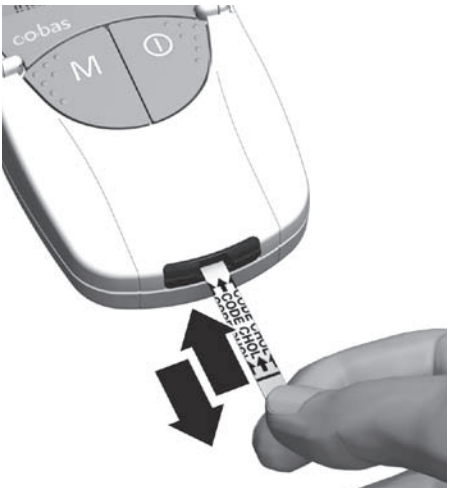


2 Check that the whole display is functioning correctly to prevent misinterpretations due to defective display elements.

3 Also always check the battery condition after the display test. When the battery symbol is shown with a measurement screen (except during the display test), you will only be able to perform a few more measurements.

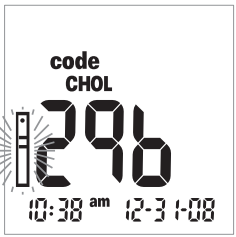
When the display test completes, the last stored code displays. If no code has been stored in the instrument so far, you will see the display shown on the left.
The flashing *codenr* symbol instructs you to insert a code strip.

Inserting the code strip



1. 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 on either side.
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, a short beep confirms successful coding (if beeper is enabled).



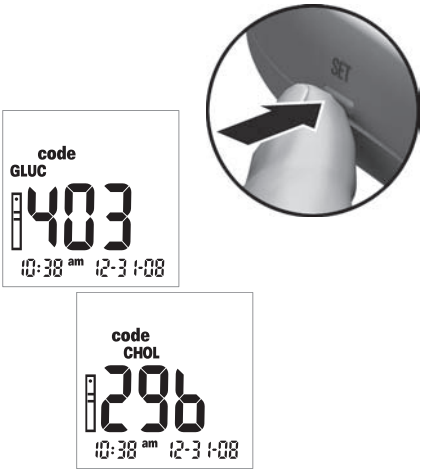
The three-digit code number (which is also printed on the reverse side of the code strip and on the test strip container) is shown in the display.

If any problems occur during coding, the meter displays an error message (see Error Messages chapter of this manual). If an error occurs, repeat insertion of 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 The code number last stored or used is displayed after powering on the instrument. Press the **Set** button to switch to the code number for the other parameter. Each time you press the button, the display shows the code number of the test strips in succession.

Note: This display is for information purposes only. You do not need to display the test parameter to be measured.

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, refer to the test strip package insert.

Note that all handling of 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 people 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 the Performing a Measurement chapter of this manual).
- Dispose of used test strips in a clinical waste bin.
- Follow all other locally applicable guidelines and regulations on health and safety.

Preparing to perform a measurement

1 Get the test strip container for the required measurement.

2 Check the expiration date of the test strip. Always use test strips **before** their expiration date has passed.

3 Make sure the code strip belonging to these test strips is at hand (unless the instrument has already been coded with this code strip).

Note: Environmental influences (e.g., air humidity and light) on the test strips may damage test strips and lead to false measurements or error messages.
Do not remove the test strips from the strip container until immediately before performing a measurement.

4 Prepare the lancing device by inserting a new lancet.

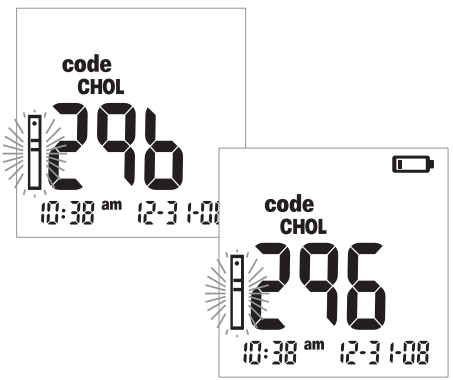
Self-testers: Do not lance yourself before being instructed to do so in the course of this description.

In the professional, multi-patient sector you should use a suitable single-use lancing device to prevent cross contamination. We recommend the Accu-Chek Safe-T-Pro or Accu-Chek Safe-T-Pro Plus single-use lancing device.

We recommend the Accu-Chek Multiclix lancing device for self-testers.

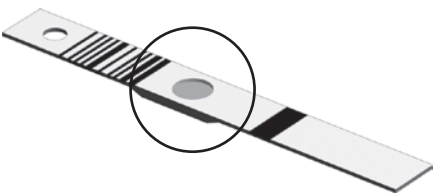
Performing a measurement

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



Check the following displays before performing the measurement:

1. Are date and time correct? If the measured values are to be stored with time information, enter the correct settings (refer to the Instrument Settings chapter of this manual).
2. Does the battery symbol appear? If it appears, only few more measurements can be performed. Replace the batteries as soon as possible (refer to the Operating the Instrument chapter of this manual).



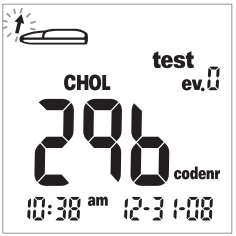
3 Now take the test strip from the test strip container.

Close the container immediately after removing strip to protect the desiccant and strips, otherwise, the test strips may become unusable before their expiration date. Liquids must not enter the test strip container.

4 With glucose test strips, check the reaction area on the back of strip for discoloration before starting measurement. If you detect discoloration, this test strip is unusable. For detailed information, see the test strip package insert.

5 Hold the test strip with thumb and index finger so that the sample application area is facing upwards.

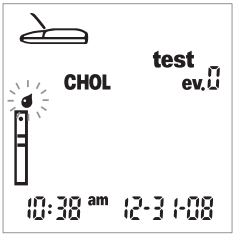
6 Insert the test strip into the test strip guide up to the stop. When the test strip reaches the correct position, you will hear two beeps (short – long; if beeper is enabled).


test
ev.0
CHOL
296
codenr
10:38 am
12-31-08


Accutrend Plus
test
ev.0
CHOL
296
cobas

A flashing arrow now instructs you to open the measurement chamber flap to apply the blood. Explanations on flagging this measurement (events, *ev. 0* display or control flag) 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 or outside the instrument.

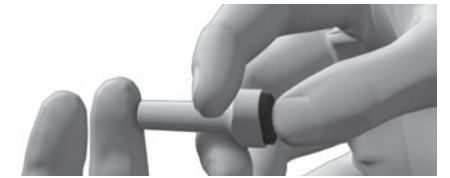
Recommendations for the collection and measurement of capillary blood

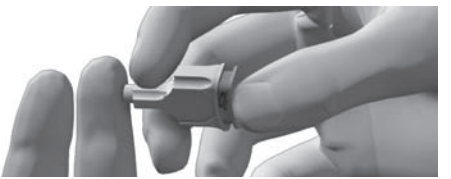
To obtain a suitable blood drop:

- 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.

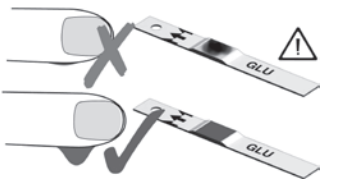
For determination of **cholesterol** only, wipe off the first drop of blood with a cotton ball and use the second drop of blood for the test.

Blood collection





8 Lance the outer side of the fingertip using the lancing device to obtain a large **hanging drop of blood**.



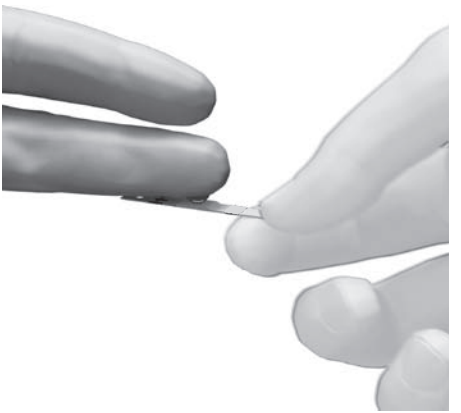
Blood application in the instrument:

9 Apply a large **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 may lead to an incorrect result.

For cholesterol testing, wipe away the first drop and immediately apply the second drop.

Alternative blood application outside the device:



10 Withdraw the test strip after opening the flap (leave it open).

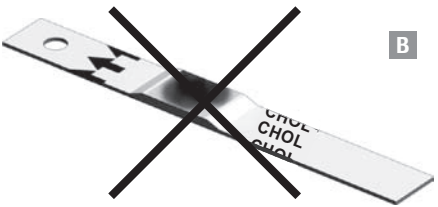
11 Apply the free hanging drop of blood directly from the finger to the yellow sample application area of the test strip. Refer to the insert of the respective test strip.

Do not touch the application area with your skin.

12 With the measurement chamber flap open, insert the test strip back into the instrument.

Checking the applied blood:

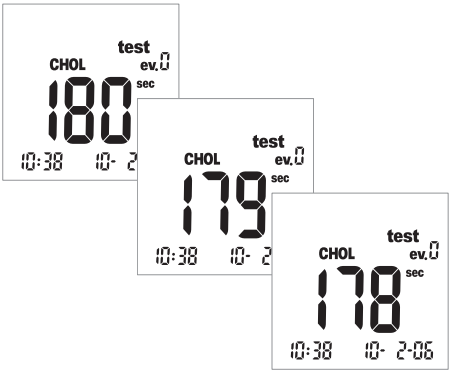
The application area must be completely covered with blood (example **A**), otherwise incorrect values may be obtained.



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

13 Close the measurement chamber flap. This starts the actual measurement.



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:

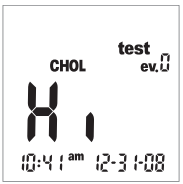
- For glucose: 12 seconds
- For cholesterol: 180 seconds

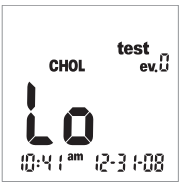
The last 4 seconds of the measurement time are each accompanied by one short beep (if beeper is enabled). Completion of the measurement and the subsequent display of results are indicated by a longer beep.

Display of results

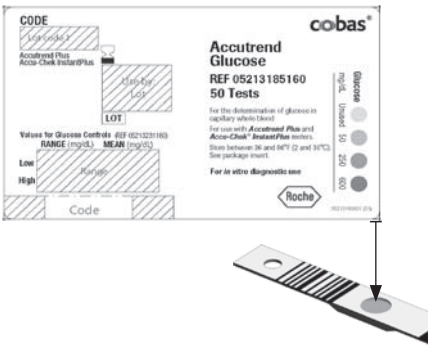
When measurement is finished, the result is displayed. If you are measuring glucose, perform the plausibility check described on the next page.

Measurement results which fall outside the meter 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 color field scale on the label of the test strip container.

The color of the reaction area must approximately match the color assigned to your measurement result. If there is a great deviation, perform a meter function check. Note the information provided in the test strip insert.

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 meter function using a new test strip (see the Control Check with Control Solution chapter of this manual). If this check confirms proper functioning of the instrument, 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, consult your doctor.

If you do not want to flag the measurement result with an event or as a control, the measurement is now complete. Open the measurement chamber flap and remove the test strip. Press the On/Off button ⏻ until the instrument powers off. Properly dispose of the used lancet and test strip according to local laws and guidelines. Clean the instrument if necessary (see the Cleaning chapter of this manual).

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

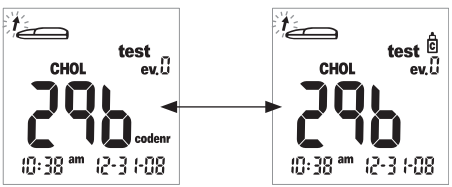
Flagging measurements

You can add additional information to measurements, for example, to characterize a particular value with regard to special circumstances (e.g., meals or exercise). In addition, you can flag measurements carried out with control liquids as 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.

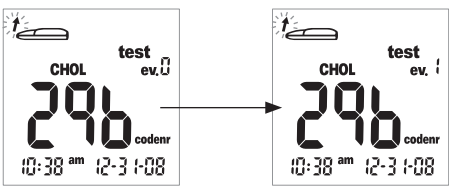
Flagging the measurement as a control:



You flag measurements as 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 control (bottle symbol). Pressing the **M** button again turns the flag off.

Assigning additional information to a measurement:



Optionally, you can assign one of nine different events to a measurement. The event "0" represents "no flagging." If used, you must 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."

Quality control recommendation

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

- If you leave the cap off the container of test strips.
- When you open a new container of test strips.
- Before using your meter for the first time.
- If you drop the meter.
- When your glucose test does not agree with the way you feel.
- When you want to check the way you are performing your blood glucose or total cholesterol test.
- When you want to check the performance of the meter and test strip.
- If you have repeated a test and the result is still higher or lower than expected.

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

What you need:

- Your Accutrend Plus instrument
- Test strips for the desired measurements with the related code strip:
  - Accutrend Glucose
  - Accutrend Cholesterol
- Control solutions for the respective test parameter:
  - Accutrend Glucose Control Low Level
  - Accutrend Glucose Control High Level
  - Accutrend Cholesterol Control Low Level
  - Accutrend Cholesterol Control High Level

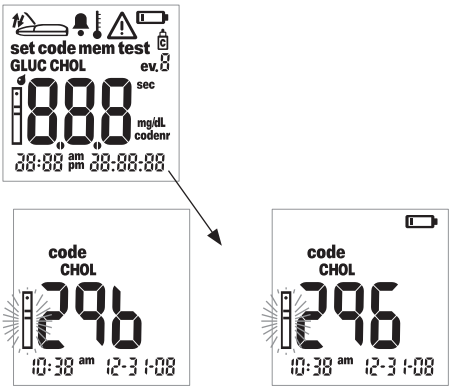
Preparing to perform a control test

1. Get the test strip container for the required measurement (e.g., cholesterol).
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 lot).
3. Get the proper control solutions for 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 *Inserting the code strip* section of this manual.

Performing a control test

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 ⏻.



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.

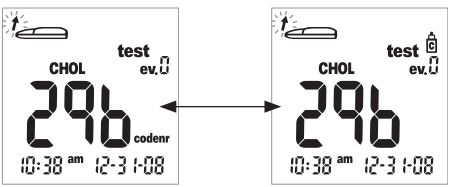
3 Are date and time correct? If the measured values are to be stored with time information, enter the correct settings (see the *Setting the date* section of this manual).

4 Does the battery symbol appear? If it appears (except during the display check at start up), only a few more measurements can be performed. Replace the batteries as soon as possible (see the *Inserting batteries* section of this manual).

5 Now take the test strip from the test strip container. Close the container immediately after removing strip to protect the desiccant and strips, otherwise the test strips may become unusable before their expiration date.

6 Hold the test strip with thumb and index finger so that the printed measurement parameter is facing upwards.

7 Insert the test strip into the test strip guide until it stops. When the test strip reaches the correct position, you will hear two beeps (short – long; if beeper is enabled).



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

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

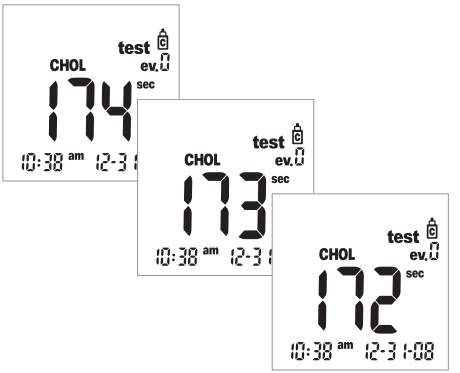
Applying the control solution

10 Apply a large free hanging drop of either the glucose or cholesterol low level control solution directly from the bottle to the test strip. Ensure that neither the bottle nor your fingers touch 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 68.

Starting the measurement

11 Close the measurement chamber flap. This starts the actual measurement.



The measurement time 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

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

Display of results

When measurement is finished, the result is displayed.

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

Target values which should be obtained 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, contact your local customer support and service center.

Repeat steps 1-11 using either the glucose or cholesterol high level control.

Memory

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

If you have not set any date and time (see the *Setting the date* section of this manual), all measured values will be stored without date and time information.

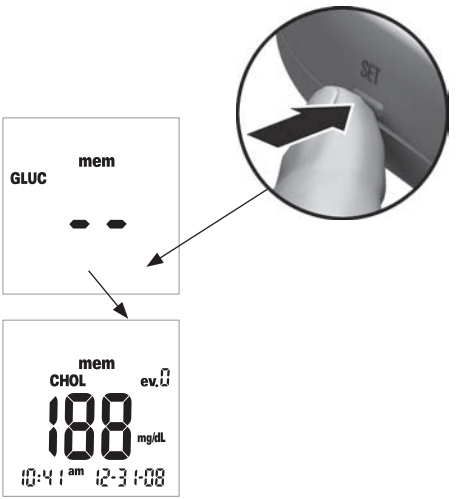
Displaying stored measured values

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

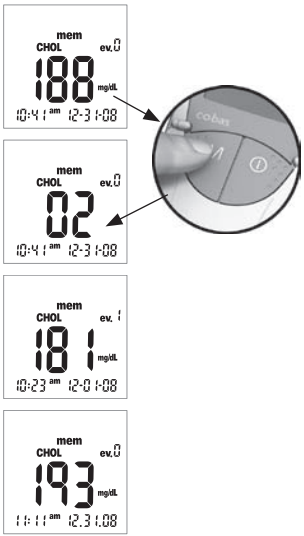
You can exit memory mode at any time by pressing the On/Off button ⏻.

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 when not in memory mode.



2 Press the **Set** button to switch between the memory areas of the two test parameters. Each time you press the **Set** button, the last stored value of each memory area, if any, is displayed. If the area contains no stored values, two dashes are displayed.

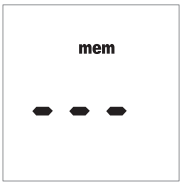


To navigate within one memory area, use the **M** button.

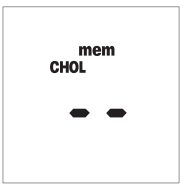
3 Press the **M** button to show the next oldest measured value within one memory area. When you press the button, the place of the measured value within the memory is displayed (here: 02); the actual value is not shown until you release the button.

When you hold down the **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.

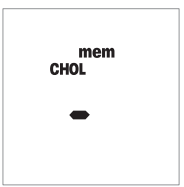
Special cases:



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, one dash (–) will appear in the display.

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 power off the instrument before cleaning it!

Use only the following items for cleaning:

- Ordinary lint-free cotton balls
- 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 offices), 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 balls which are dripping wet as the liquid may enter the instrument and damage it.

Cleaning the outer instrument components

- Ensure the instrument is powered 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 the test strip guide by slightly pushing it forward and then pulling it upwards.

3 If needed, you can rinse the strip guide (separately from the instrument) under warm running water. Dry the strip guide with a clean cloth.

Cleaning the optical measuring system

4 Clean the easily accessible areas of the optical measuring system under the strip guide with a lint-free pad or a moistened cotton ball. Make sure that ***no*** liquid enters the instrument. Do not insert any objects into the instrument.

5 Allow the instrument to dry thoroughly.

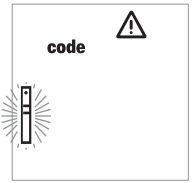
6 Do not put the strip guide back in the instrument until it is completely dry. Press the front end of the strip guide slightly downwards until you feel it click into place.

7 Close the measurement chamber flap.

The instrument is now ready for operation again. Perform a function check (see description starting on page 78).

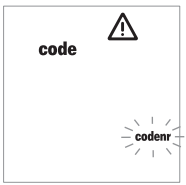
Error messages

In certain circumstances error messages may appear on your display. Generally, you should first try the following solutions. If the problem persists, please contact your local customer support and service center.

Display	Error meaning and description
	**Error: Unknown barcode** The barcode of test strips or code strips could not be read.

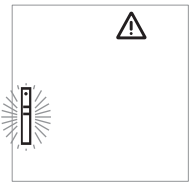
Solution

- 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 interference caused by electromagnetic fields in the vicinity of the instrument. Move meter away from such sources (e.g., X-ray equipment).

Display	Error meaning and description
	**Error: Strip code does not match stored code** The test strip belongs to a different test strip lot than the container which was last coded for this parameter.

Solution

- Remove the strip and repeat using a test strip matching the last code for the test being attempted.
- Code the instrument with the code strip corresponding to the test strips being used.

Display	Error meaning and description
	**Error: Test strip is unusable** The test strip has already been used or is dirty.

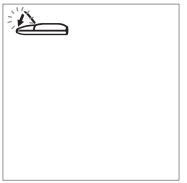
Solution

- Remove and discard the strip. Repeat the measurement using a new test strip.

Display	Error meaning and description
	**Error: Temperature** The instrument or ambient temperature does not fall within the acceptable range for the selected test.

Solution

- Move the instrument to an environment which has an appropriate temperature and repeat the measurement after several minutes. Do not artifically heat or cool the meter by any means.

Display	Error meaning and description
	**Error: Flap open (displayed after instrument has been powered on)** The measurement chamber flap is not closed properly.

Solution

- Close the measurement chamber flap.

Display	Error meaning and description
	**Error: Flap open (displayed during measurement)** The measurement chamber flap is not closed properly.

Solution

- Close the measurement chamber flap.

Display	Error meaning and description
	**Error: Flap not closed after blood application** The measurement chamber flap was not closed properly after blood application; the measurement was not started in time.

Solution

- Remove and discard the strip. Repeat the measurement using a new test strip.

Display	Error meaning and description
	**Error: Internal error (example shown: 142)** The instrument has detected an internal error.

Solution

- Power the instrument off and on again.
- Clean the strip guide and optics area. If the error still persists, the instrument is defective. Call your local customer support and service center.

Further information

Ordering information

Please contact your specialist supplier.

Item	Description	Cat. No.
Accutrend Glucose Test Strips	50 test strips for determining blood glucose	05213185160
Accutrend Glucose Control	Control solution to be used with Accutrend Glucose test strips	05213231160
Accutrend Cholesterol Test Strips	25 test strips for determining cholesterol in the blood	05213312160
Accutrend Cholesterol Control	Control solution to be used with Accutrend Cholesterol test strips	05219957001
Accutrend Plus instrument kit	Meter kit	05346754160

Product limitations

Please read the insert packaged with the test strips or control solutions for detailed information on product data and limitations.

Product specifications

Operating conditions and technical data

Temperature range for measurement	Cholesterol: 18–30 °C Glucose: 18–32 °C
Relative humidity	10-85 %
Measurement range	Blood glucose: 20–600 mg/dL Cholesterol: 150–300 mg/dL
Memory	100 measured values, optional with date, time and additional event information, per test parameter
Battery operation	4 x AAA 1.5 V alkaline batteries
Number of measurements	Approximately 1,000 measurements (with new batteries)
Protection class	III
Dimensions	154 x 81 x 30 mm (6.1 x 3.2 x 1.2 inches)
Weights	Approximately 140 g (4.9 oz) without batteries Approximately 187 g (6.6 oz) with batteries

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 (for meter only)
Relative humidity	10 to 85 % (no condensation)

Disposal of instrument, strips, lancets and batteries

Any product coming in contact with blood is considered contaminated (potentially infectious).* During normal testing any blood glucose meter may come in contact with blood. Lancing devices may also be considered sharps. Disposal of sharps is regulated by law in many jurisdictions

The European Union has a requirement for improving waste management practices for certain electronic equipment, but meters fall outside the scope of the European Directive 2002/96/EC.** This is not a requirement for the U.S.A.; however, Roche is committed to recycling and sustainability. Please consider the following points when disposing of your used testing materials:

- Comply with any laws or ordinances relating to the disposal of sharps and/or contaminated products. Contact your local health department or other appropriate authorities for proper handling and disposal of used meters, used test strips, used lancets, and used batteries.

- Consider recycling of the meters and batteries at an appropriate facility. Be aware the meter is potentially hazardous electronics scrap (e-scrap) and should be disposed of accordingly. The batteries are potentially hazardous also and should be disposed of accordingly.

- Decontaminate the meter before recycling or disposing. Wipe the outside of the meter with dilution of bleach solution, one part bleach to nine parts water.

- Users in professional environments (i.e., healthcare professionals) should follow their existing policies and procedures that govern the proper handling and disposal of potentially infectious waste, electronics scrap (e-scrap), and batteries.

**29 CFR 1910.1030-Bloodborne pathogens*
***Directive 2002/96/EC-Directive on waste electrical and electronic equipment (WEEE)*

Service information

For technical assistance or information, contact the Accu-Chek® Customer Care Service Center at 1-800-440-3638, 24 hours a day, 365 days a year.

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Alphabetical index

Patents:
US 5,463,467; US 5,424,035; US 5,334,508; US 5,206,147; US 5,240,860;
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