ACCU-CHEK® Instant

Roche

User's Manual

Blood Glucose Meter

ACCU-CHEK®

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Introduction

The Accu-Chek Instant System

The Accu-Chek Instant test strips with the Accu-Chek Instant meter are intended to quantitatively measure glucose in fresh capillary whole blood from the finger, palm, forearm, and upper arm as an aid in monitoring the effectiveness of glucose control.

The Accu-Chek Instant test strips with the Accu-Chek Instant meter are intended for in vitro diagnostic self-testing by people with diabetes.

The Accu-Chek Instant test strips with the Accu-Chek Instant meter are intended for in vitro diagnostic use by healthcare professionals in clinical settings. Venous, arterial, and neonatal blood testing is limited to healthcare professional use.

This system is not for use in the diagnosis of diabetes mellitus, nor for testing neonate cord blood samples.

Suitable for self-testing

The system includes:

Accu-Chek Instant meter with batteries, Accu-Chek Instant test strips*, and Accu-Chek Instant control solutions*.

*Some items may not be included in the kit. They are a separate purchase.

⚠ WARNING

- **Choking hazard. Small parts. Keep away from children under the age of 3 years.**
- **Keep new and used batteries away from children. Ingestion or insertion into the body may cause chemical burns, perforation of soft tissues, and death. Severe burns may occur within 2 hours of swallowing. If you think a battery might have been swallowed or placed inside any part of the body, seek medical attention immediately.**
- **If the battery compartment does not close securely, stop using the product and keep it away from children. Contact Roche.**

- **Any object coming into contact with human blood is a potential source of infection (see: Clinical and Laboratory Standards Institute: Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline – Fourth Edition; CLSI document M29-A4, May 2014).**

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NOTE

It is strongly recommended to have a back-up testing method available. Failure to test could cause a delay in therapy decisions and lead to a serious medical condition. Examples of back-up testing methods include a back-up meter and test strips. Ask your healthcare professional or pharmacist about other possible back-up methods.

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1 Your New System

The Accu-Chek Instant Meter

Right Side View | Front View | Left Side View

1. **Meter Button**
   Press to turn the meter on and off, move to the next screen, or make a selection.
2. **Display**
   Shows results, messages, and test results stored in memory.
3. **Target Range Indicator**
   Indicates whether your blood glucose result falls above, within, or below a pre-set range of values.
4. **Micro USB Port**
   Transfers data from the meter to a computer (PC).

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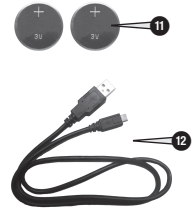
1 Your New System

Back View

Underside View

5. Battery Door
Open to replace batteries.

6. Test Strip Slot
Insert test strip here.



7. Test Strip Container*
(for example)

8. Test Strip - Metallic End
Insert this end into the meter.

9. Test Strip - Yellow Edge
Touch blood drop or control solution here.

10. Control Solution Bottle*

11. Batteries

12. USB Cable*
Connects the meter to a PC.

*Some items may not be included in the kit. They are a separate purchase.

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Using the Meter Button

Your new meter has only one button, but it performs many actions. Press the meter button once to turn the meter on and see your most recent blood glucose result. Continue pressing to view your 7, 30, and 90-day blood glucose averages.

When instructed to press the meter button, press it briefly and release it.

When instructed to press and **hold** the meter button, press and hold it for 3 or more seconds.

Time and Date

To display or change the time and date on the meter, pair the meter to a mobile device, or connect it to a PC with diabetes management software installed. Follow the diabetes management software instructions to set the time and date. The meter display will then show the time and date along with your test results.

Target Range

Consult your healthcare professional for the blood glucose range appropriate for you. It is very important to stay within your target range.

The target range is set by default at 70–160 mg/dL (3.9–8.9 mmol/L). The target range can be set from a lower limit of 60–140 mg/dL (3.3–7.8 mmol/L) to an upper limit of 90–300 mg/dL (5.0–16.6 mmol/L).

To change the target range, pair the meter to a mobile device, or connect it to a PC with diabetes management software installed. Then follow the diabetes management software instructions.

⚠ WARNING

This function is no substitute for hypoglycemia training by your healthcare professional.

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1 Your New System

Symbols

Symbol	Description
	Last test result symbol. This indicates that you are viewing your last blood glucose result.
7 day 7 ave	7-day average symbol. This indicates that you are viewing the 7-day average of your blood glucose results.
30 day 30 ave	30-day average symbol. This indicates that you are viewing the 30-day average of your blood glucose results.
90 day 90 ave	90-day average symbol. This indicates that you are viewing the 90-day average of your blood glucose results.
	Drop symbol
	Bluetooth symbol
	Control bottle symbol
	Hourglass symbol
	Low battery symbol
---	No data to display
	Pairing symbol.
	Target range indicator arrow. When flashing, your blood glucose result is outside the target range.
	Temperature warning symbol
	Wireless symbol.

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⚠ WARNING

Blood glucose results can be displayed in either mg/dL or mmol/L. The back label of the meter shows the unit of measurement. If the meter shows the wrong unit, contact Roche. If you do not know which unit of measurement is correct for you, contact your healthcare professional. Using the wrong unit of measurement may cause misinterpretation of your actual blood glucose level and may lead to improper therapy.

mg/dL or mmol/L is printed here

Using the Accu-Chek Instant System

- Use only Accu-Chek Instant test strips.
- Use the test strip immediately after removing it from the test strip container.
- Do not apply blood or control solution to the test strip before inserting it into the meter.
- Close the test strip container tightly immediately after removing a test strip to protect the test strips from humidity.
- Store the unused test strips in their original test strip container with the cap closed.
- Check the use by date on the test strip container. Do not use the test strips after that date.
- Store the test strip container and meter in a cool, dry place such as a bedroom.
- Refer to the test strip package insert for test strip storage and system operating conditions.

⚠ WARNING

Do not store test strips in high heat and moisture areas (bathroom or kitchen)! Heat and moisture can damage test strips.

Performing a Blood Glucose Test with Blood from Your Fingertip

NOTE

- You need the meter, a test strip, and a lancing device with a lancet inserted to perform a blood glucose test.
- A blood glucose test cannot be performed while the meter is connected to a PC with a USB cable.

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2 Blood Glucose Tests

1

Wash your hands with warm soapy water and dry thoroughly.

Prepare the lancing device.

2

Check the use by date on the test strip container.

Do not use test strips past the use by date.

3

Remove a test strip from the test strip container.

Close the cap tightly.

4

Insert the metallic end of the test strip into the meter. The meter turns on.

5

When a flashing drop symbol appears, perform a fingerstick with the lancing device.

6

Gently squeeze your finger to assist the blood flow. This helps you get a blood drop.

7

Touch the **yellow edge** of the test strip to the blood drop. Remove your finger from the test strip when the flashing hourglass symbol appears. Do not put blood on top of the test strip.

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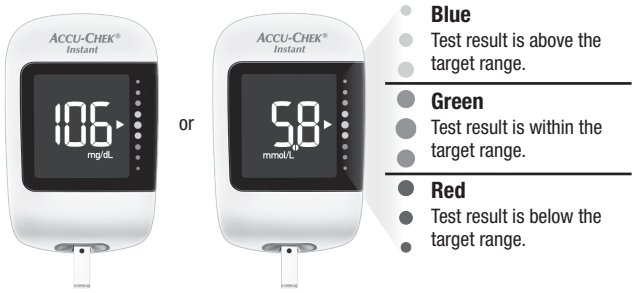
8



Your test result appears with an arrow. This arrow shows if your test result falls above, within, or below the target range.* The target range is represented by the green region of the target range indicator. The arrow will flash if your test result falls above or below this range.

Remove and discard the used test strip.

*The target range is set by default at 70–160 mg/dL (3.9–8.9 mmol/L). To change the target range, pair the meter to a mobile device, or connect it to a PC with diabetes management software installed. Consult your healthcare professional before changing the target range.

Performing a Blood Glucose Test with Blood from Your Palm, Forearm, or Upper Arm (Alternative Site Testing)

⚠ WARNING

Do not use alternative site testing to calibrate a continuous glucose monitoring system or to make insulin dosing calculations.

You have the option of obtaining a blood sample from other sites on your body besides the fingertip. Alternative sites include the palm, forearm, and upper arm.

Blood obtained from the fingertip and palm can be used at any time to perform a blood glucose test.

If blood from the forearm or upper arm is used, there are certain times when testing is not appropriate. This is because your blood glucose level changes faster in your fingertip and palm than in the forearm and upper arm. These differences may cause you to misinterpret your actual blood glucose level, leading to improper therapy and potential adverse health effects.

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Read the next section before you try testing from the forearm or upper arm.

You may perform a forearm or upper arm test	• immediately before a meal. • while fasting.
You may NOT perform a forearm or upper arm test	• up to 2 hours following a meal, when blood glucose values can rise quickly. • after injecting bolus insulin, when blood glucose values can decrease rapidly. • after exercise. • if you are sick. • if you think your blood glucose is low (hypoglycemia). • if you sometimes do not notice when your blood glucose is low.

If you are interested in AST, talk to your healthcare professional first.

To obtain an AST cap and detailed AST instructions, contact Roche.

Unusual Blood Glucose Results

If your blood glucose result does not match how you feel, check this list to help solve the problem.

Troubleshooting Checks	Action
Did you wash your hands?	Wash your hands with warm soapy water and dry thoroughly. Repeat the blood glucose test with a new test strip.
Were the test strips expired?	Discard the test strips if they are past the use by date. Repeat the blood glucose test with an unexpired test strip.
Was the cap on the test strip container always closed tightly?	Replace the test strips if you think the test strip container was uncapped for some time. Repeat the blood glucose test.
Was the test strip used immediately after it was removed from the test strip container?	Repeat the blood glucose test with a new test strip.

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Troubleshooting Checks	Action
Were the test strips stored in a cool, dry place?	Repeat the blood glucose test with a properly stored test strip.
Did you follow the directions?	Read the chapter Blood Glucose Tests and repeat the blood glucose test. Contact Roche if you still have problems.
Are the meter and test strips working properly?	Perform a control test. See the chapter Control Tests for instructions.
Are you still unsure of the problem?	Contact Roche.

Symptoms of Low or High Blood Glucose

Being aware of the symptoms of low or high blood glucose can help you understand your test results and decide what to do if they seem unusual.

Low blood glucose (hypoglycemia): Symptoms of hypoglycemia may include, but are not limited to, anxiety, shakiness, sweating, headache, increased hunger, dizziness, pale skin color, sudden change in mood or irritability, fatigue, difficulty concentrating, clumsiness, palpitations, and/or confusion.

High blood glucose (hyperglycemia): Symptoms of hyperglycemia may include, but are not limited to, increased thirst, frequent urination, blurred vision, drowsiness, and/or unexplained weight loss.

⚠ WARNING

If you are experiencing any of these symptoms, or other unusual symptoms, test your blood glucose from the fingertip or palm. If your blood glucose result is displayed as LO or HI, contact your healthcare professional immediately.

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3 Control Tests

When to Perform a Control Test

Performing a control test lets you know the meter and test strips are working properly. You should perform a control test when:

- you open a new test strip box.
- you left the test strip container open.
- you think the test strips are damaged.
- you want to check the meter and test strips.
- the test strips were stored in extreme temperatures, humidity, or both.
- you dropped the meter.
- your test result does not match how you feel.
- you want to check if you are performing the test correctly.

About the Control Solutions

- Use only Accu-Chek Instant control solutions.
- Close the control solution bottle tightly after use.
- Write the date you open the control solution bottle on the bottle label. The control solution must be discarded 3 months from the date the control solution bottle was opened (discard date) or on the use by date on the bottle label, whichever comes first.
- Do not use control solution that is past the use by or discard date.
- Refer to the control solution package insert for control solution storage conditions.
- The meter automatically recognizes the difference between the control solution and blood.
- The control solution can stain fabric. Remove stains by washing with soap and water.

Performing a Control Test

You need the meter, a test strip, and control solution Level 1 or Level 2.

1

Check the use by date on the test strip container. Do not use test strips past the use by date.

2

Remove a test strip from the test strip container.

Close the cap tightly.

3

Insert the metallic end of the test strip into the meter. The meter turns on.

A flashing drop symbol appears.

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4

Select the control solution to test. You will enter the level later in the test.

5

Remove the bottle cap. Wipe the tip of the bottle with a tissue. Squeeze the bottle until a tiny drop forms at the tip.

6

Touch the drop to the **yellow edge** of the test strip. Do not put control solution on top of the test strip.

A flashing hourglass symbol appears when there is enough control solution in the test strip.

7

or

The control result appears. Press the meter button.

8

or

If you tested with Level 1 control solution, the L-1 screen appears. Press and hold the meter button to confirm that you tested with Level 1 control solution.

If you tested with Level 2 control solution, the L-2 screen appears. Press and hold the meter button to confirm that you tested with Level 2 control solution.

Press the meter button to alternate between L-1 and L-2.

9

or

OK appears if the control result is within range.

Err appears if the control result is out of range.

10

Wipe the tip of the bottle with a tissue. Cap the bottle tightly.

Remove and discard the used test strip.

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3 Control Tests

NOTE

The meter turns off 90 seconds after a successful test or 15 seconds after the test strip is removed, provided no other action is taken.

Understanding Out-of-Range Control Results

⚠ WARNING

The control ranges are printed on the test strip container label. If the control result is out of range, check this list to help solve the problem.

Troubleshooting Checks	Action
Were the test strips or control solutions expired?	Discard the test strips or control solution if either is past the use by date. If the control solution was opened more than 3 months ago, discard it. Repeat the control test with an unexpired test strip and an unexpired control solution.
Did you wipe the tip of the control solution bottle before use?	Wipe the tip of the bottle with a tissue. Repeat the control test with a new test strip and a fresh drop of control solution.
Were the caps on the test strip container and the control solution bottle always closed tightly?	Replace the test strips or control solution if you think either was uncapped for some time. Repeat the control test.
Was the test strip used immediately after it was removed from the test strip container?	Repeat the control test with a new test strip and a fresh drop of control solution.
Were the test strips and control solutions stored in a cool, dry place?	Repeat the control test with a properly stored test strip or control solution.
Did you follow the directions?	Read the chapter Control Tests and repeat the control test.

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3 Control Tests

Troubleshooting Checks	Action
Did you choose the correct control solution level, either 1 or 2, when you performed the control test?	If you chose the wrong control solution level, you can still compare the control result to the range printed on the test strip container.
Are you still unsure of the problem?	Contact Roche.

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4 Review Your Data

Overview

- The meter automatically stores at least 720 blood glucose results in memory, but only the last blood glucose result and your 7, 30, and 90-day averages can be viewed on the meter. To view stored blood glucose results, transfer them to a compatible software application.
- The meter automatically stores at least 30 control results in memory, but only the current control result can be viewed on the meter. To view stored control results, transfer them to a compatible software application.
- If more than 720 blood glucose tests are performed within a 90-day period, only the 720 most recent test results are included in the 90-day average.
- Control results are not included in the 7, 30, or 90-day averages.

⚠ WARNING

Do not change your therapy based on an individual test result in memory. Talk to your healthcare professional before changing therapy based on test results in memory.

Reviewing Your Last Blood Glucose Result

1

With the meter off, press the meter button to turn the meter on. The last test result symbol ⮌ indicates that you are viewing your last blood glucose result.

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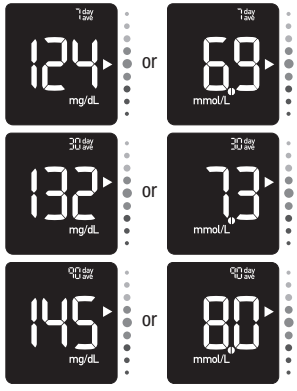
4 Review Your Data

Reviewing Your Test Result Averages

The meter uses all of your blood glucose results from the past 7, 30, or 90 days to calculate a single number. This number is called the average, and helps you to understand your blood glucose results over a given period of time.

1



With the meter off, press the meter button to turn the meter on. Press the meter button to view your 7, 30, and 90-day averages.

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5 Wireless Communication and Meter Pairing

Overview

The process of creating a connection between the meter and the mobile device is called pairing. You will need an application on your mobile device that can accept the meter data. You can use this application to wirelessly and automatically synchronize your diabetes information between the meter and the mobile device.

Pairing

The meter can only pair with 1 device at a time. Pairing with a second device overwrites the first pairing.

The meter and the device to be paired should be within 1 meter of each other.

1

On Your Mobile Device

Open the app and select **Pair Meter**. If prompted, turn on Bluetooth.

2

On Your Meter

With the meter off, press and hold the meter button until the Bluetooth symbol appears. The pairing symbol and wireless symbol both appear and flash.

3

On Your Mobile Device

Within the app, select your meter from the list of found meters. When prompted, enter the 6-digit pin number located on the back of your meter.

4

On Your Meter

or

OK appears if pairing is successful. **Err** appears if pairing is unsuccessful.

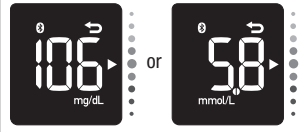
Transferring Data Wirelessly

If the meter is paired with a mobile device and Bluetooth is on, your test results will be sent to the paired device automatically.

Turning Bluetooth Off

Turn Bluetooth off to disable wireless communication (flight mode). Turning Bluetooth off will not unpair your meter.

1



With the meter off, press the meter button to turn the meter on. The last test result screen appears.

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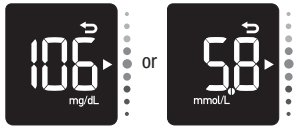
2

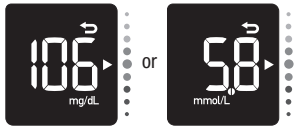


Press and hold the meter button until the Bluetooth symbol disappears.

Turning Bluetooth On

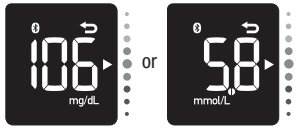
If you have turned Bluetooth off, follow the steps below to turn it back on. This will enable wireless communication with your mobile device.

1



With the meter off, press the meter button to turn the meter on. The last test result screen appears.

2



Press and hold the meter button until the Bluetooth symbol appears.

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6 Connecting to a PC

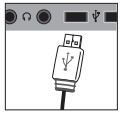
Connecting the Meter to a PC Using a USB Cable

Follow the steps below to access diabetes management software on a PC. You can use this software to view stored results, set the meter time and date, and change the target range.

1

Plug the small end of the USB cable into the meter.

2



Plug the large end of the USB cable into a USB port on the PC.

If the meter is off, it turns on.

3

Start the diabetes management software and initiate a data transfer.

4

The meter transfers the data to the software.

NOTE

The USB cable does not charge the meter batteries. Remove the USB cable after you have finished.

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7 Meter Maintenance and Troubleshooting

Meter Maintenance

The meter automatically tests its own systems every time you turn it on and lets you know if something is wrong. See the Error Messages section of this chapter.

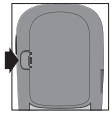
If you drop the meter or think the results are not accurate, contact Roche.

⚠ WARNING

Keep new and used batteries away from children. See the warning in the Introduction of this User's Manual for additional information.

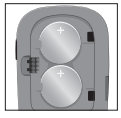
Changing the Batteries

1



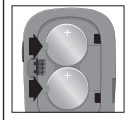
Open the battery door on the back of the meter by pushing the tab in the direction of the arrow and pulling the door up.

2



Remove the old batteries. Press and hold the meter button for at least 2 seconds.

3



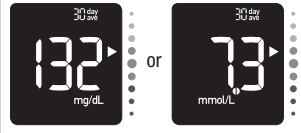
Slide the new batteries under the tabs with the **(+) side facing up**. Put the battery door back in place and snap it closed.

NOTE

- Always have a spare set of batteries.
- Battery life may vary due to factors such as temperature and battery manufacturer.
- The meter uses two 3-volt lithium batteries, coin cell type CR2032. This type of battery can be found in many stores.
- Always replace both batteries at the same time and with the same brand.
- Meter data is not lost when you replace the batteries.

Checking the Meter Display

1



With the meter off, press the meter button to turn the meter on. Press the meter button twice to display the 30-day average screen.

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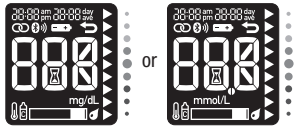
2



Press and hold the meter button until all display segments appear. Check the meter display for missing segments. All segments should look like the picture above. If any segments are missing from the display, contact Roche, as there may be a problem with the meter.

Cleaning and Disinfecting the Meter

Keep the meter free of dust. If you need to clean or disinfect it, follow these guidelines carefully to help you get the best performance possible.

⚠ WARNING

- **If the meter is being operated by a second person who is providing testing assistance to the user, the meter should be disinfected prior to use by the second person.**
- **Do not clean or disinfect the meter while performaing a blood glucose or control test.**
- **Do not allow liquid to enter any openings in the meter.**
- **Do not spray anything directly onto the meter.**
- **Do not immerse the meter in liquid.**

When to clean or disinfect the meter:

- Clean the meter to remove visible dirt or other material.
- Disinfect the meter between each patient use.

What to clean or disinfect:

- The area around slots and openings.
- The meter display.
- The entire meter surface.

1

Make sure the meter is turned off.

Gently wipe the meter surface with a soft cloth slightly dampened (wring out any excess liquid) with one of these solutions:

To clean the meter

Mild dishwashing liquid mixed with water

To disinfect the meter

70 % isopropyl alcohol

Note: During disinfection, make sure that the meter surface stays wet with isopropyl alcohol for a minimum of 2 minutes. Additional wiping of the surface with cloths dampened with isopropyl alcohol may be necessary.

2

Dry the meter thoroughly with a soft cloth.

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Error Messages

⚠ WARNING

- **Never make therapy decisions based on an error message.**
- **If you have any concerns or see any other error message, contact Roche.**

NOTE

The error code and **Err** will alternate on the display for all coded error messages (E-1 through E 14).

The meter will not turn on or the display is blank.

- Batteries are dead.

Insert new batteries.

- Display is damaged. / Meter is defective.

Contact Roche.

- Extreme temperatures.

Move the meter to a location within the stated temperature limits.

The meter is connected to a PC and a blood glucose or control test cannot be performed.

EITHER remove the USB cable and perform a blood glucose or control test OR remove the test strip and start a data transfer.

The meter was unable to pair with a mobile device.

Retry the pairing.

The batteries are almost out of power.

Change the batteries now. If the symbol reappears after the batteries have been replaced, remove the batteries again, press and hold the meter button for at least 2 seconds, then reinsert the batteries.

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(The error code and **Err** will alternate on the display.)

The test strip may be damaged, not properly inserted, or was previously used.

Remove and reinsert the test strip, or replace it if damaged or previously used.

(The error code and **Err** will alternate on the display.)

A meter or test strip error has occurred.

This error message could appear if the cap on the test strip container was not closed tightly. The test strips may have been damaged due to improper storage or handling.

Never make therapy decisions based on an error message.

Repeat the blood glucose test. If a second E-3 error message appears, perform a control test with the control solution and a new test strip. See the section Performing a Control Test in the chapter Control Tests. If you continue to receive an E-3 error message, use an alternate method for testing your blood glucose, such as a back-up meter and test strip. If the alternate method gives an extremely high blood glucose result, or if an alternate method is not available, **contact your healthcare professional immediately**.

In rare cases, an E-3 error message may indicate that your blood glucose is extremely high and above the system's measuring range. **See the Unusual Blood Glucose Results section in the chapter Blood Glucose Tests for other possible causes of the error message**.

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(The error code and **Err** will alternate on the display.)

Not enough blood or control solution was drawn into the test strip for measurement or was applied after the test had started.

Discard the test strip and repeat the blood glucose or control test.

(The error code and **Err** will alternate on the display.)

Blood or control solution was applied to the test strip before the flashing drop symbol appeared on the display.

Discard the test strip and repeat the blood glucose or control test.

(The error code and **Err** will alternate on the display.)

An electronic error occurred.

Remove the batteries, press and hold the meter button for at least 2 seconds, and reinsert the batteries. Perform a blood glucose or control test.

(The error code and **Err** will alternate on the display.)

The temperature is above or below the proper range for the system.

Refer to the test strip package insert for system operating conditions. Move to an area with the appropriate conditions and repeat the blood glucose or control test. Do not artificially heat or cool the meter.

(The error code and **Err** will alternate on the display.)

The batteries may be out of power.

Turn the meter back on. **If you are in a cold environment, move to a location with a more moderate temperature and retest**. If the message continues to appear after several attempts, replace the batteries. If the message reappears after the batteries have been replaced, remove the batteries, press and hold the meter button for at least 2 seconds, then reinsert the batteries.

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(The error code and **Err** will alternate on the display.)

The meter's internal clock may need to be reset.

Press the meter button. If the time and date were set, you will need to reset them. See the Time and Date section in the chapter Your New System.

(The error code and **Err** will alternate on the display.)

The test strip may be damaged.

Repeat the blood glucose or control test with a new test strip.

(The error code and **Err** will alternate on the display.)

Your blood sample may contain a high level of ascorbate.

Contact your healthcare professional.

(The error code and **Err** will alternate on the display.)

Fluid or foreign material may be present in the test strip slot.

Remove and reinsert the test strip or repeat the blood glucose or control test with a new test strip. If the error persists, contact Roche.

(The error code and **Err** will alternate on the display.)

An electronic error has occurred.

Contact Roche.

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Blood glucose may be higher than the measuring range of the system.

See the Unusual Blood Glucose Results section in the chapter Blood Glucose Tests.

Blood glucose may be lower than the measuring range of the system.

See the Unusual Blood Glucose Results section in the chapter Blood Glucose Tests.

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8 Technical Information

Product Limitations

See the literature packaged with the test strips and control solutions for the latest information on product specifications and limitations.

Specifications	
Blood volume Sample type Measuring time Measuring range Test strip storage conditions System operating conditions	Refer to the test strip package insert.
Meter storage conditions	Temperature: -25–70 °C
Memory capacity	1 blood glucose result and 7, 30, and 90-day test result averages (at least 720 blood glucose results and at least 30 control results are also stored and can be viewed with external software).
Automatic off	90 seconds after performing a test, 15 seconds after a test strip is removed, or 5 seconds from the last test result screen.
Power supply	Two 3-volt lithium batteries (coin cell type CR2032)
Display	LCD
Dimensions	77.1 × 48.6 × 15.3 mm (LWH)
Weight	Approx. 40 g (with batteries)
Construction	Hand-held
Protection class	III
Meter type	The Accu-Chek Instant meter is suitable for continuous operation.
Control solution storage conditions	Refer to the control solution package insert.
Continua CERTIFIED Interfaces	USB: micro-B connector; Bluetooth low energy technology; Continua Certified® to a Continua Certified manager.
Radio frequency connectivity	Bluetooth low energy technology operating in the frequency band of 2402 MHz to 2480 MHz with a maximum transmitted power of 0 dBm (1 mW).

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Electromagnetic Compatibility – The meter meets the electromagnetic emission requirements as per EN 61326-2-6. Its electromagnetic emission is thus low. Interference on other electrically-driven equipment is not anticipated.

Performance Analysis – Refer to the test strip package insert.

Test Principle – Refer to the test strip package insert.

Declaration of Conformity – Hereby, Roche declares that the radio equipment type Accu-Chek Instant blood glucose meter is in compliance with Directive 2014/53/EU. The full text of the EU declaration of conformity is available at the following internet address: http://declarations.accu-chek.com

Communication Protocol – The Accu-Chek Instant blood glucose meter is Continua Certified. Continua Certified signifies that this product complies with applicable IEEE 11073-10417 standards and that it has been tested and certified against the 2015 Continua Design Guidelines which include the Blood Glucose specification for Bluetooth, *Bluetooth SIG, Glucose Profile, Version 1.0* and *Bluetooth SIG, Glucose Service, Version 1.0*.

Product Safety Information

⚠ WARNING

- **Strong electromagnetic fields may interfere with the proper operation of the meter. Do not use the meter close to sources of strong electromagnetic radiation.**
- **To avoid electrostatic discharge, do not use the meter in a very dry environment, especially one in which synthetic materials are present.**

Discarding the Meter

⚠ WARNING

- **During blood glucose testing, the meter itself may come into contact with blood. Used meters therefore carry a risk of infection. Before discarding the meter, remove the battery or batteries. Discard used meters according to the regulations applicable in your country. Contact the local council and authority for information about correct disposal.**
- **The meter falls outside the scope of the European Directive 2012/19/EU (Directive on waste electrical and electronic equipment (WEEE)).**
- **Discard used batteries according to local environmental regulations.**

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8 Technical Information

Explanation of Symbols

These symbols may appear on the packaging, on the type plate, and in the instructions for the Accu-Chek Instant meter.

	Consult instructions for use
	Biological Risks – used meters carry a risk of infection.
	Caution, refer to safety-related notes in the instructions for use accompanying this product.
	Temperature limit (store at)
	Use by
	Manufacturer
REF	Catalogue number
LOT	Batch code
IVD	In vitro diagnostic medical device
GTIN	Global Trade Item Number
SN	Serial number
CE 0123	This product fulfils the requirements of the European Directive 98/79/EC on in vitro diagnostic medical devices.
	3-volt coin cell type CR2032
	Keep new and used batteries away from children.

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Additional Supplies

Test Strips: Accu-Chek Instant test strips

Control Solutions: Accu-Chek Instant control solutions

Information for Healthcare Professionals

⚠ WARNING

Healthcare Professionals: Follow the infection control procedures appropriate for your facility. Refer to the test strip package insert for additional healthcare professional information.

Sample Handling

Always wear gloves when handling blood-contaminated items. Always adhere to the recognized procedures for handling objects that are potentially contaminated with human material. Follow the hygiene and safety policy of your laboratory or institution. Prepare the selected blood collection site per facility policy.

Refer to the test strip package insert for additional information regarding acceptable sample types, anticoagulants, and handling instructions.

Recommending Alternative Site Testing to Patients

Decisions about whether to recommend Alternative Site Testing (AST) should take into account the motivation and knowledge level of the patient and his or her ability to understand the considerations relative to diabetes and AST. If you are considering recommending AST for your patients, you need to understand that there is a potential for a significant difference between fingertip or palm test results and test results obtained from the forearm or upper arm. The difference in capillary bed concentration and blood perfusion throughout the body can lead to sample site-to-site differences in blood glucose results. These physiological effects vary between individuals and can vary within a single individual based upon his or her behavior and relative physical condition.

Our studies involving alternative site testing of adults with diabetes show that most persons will find their glucose level changes more quickly in blood from the fingertip or palm than in blood from the forearm or upper arm. This is especially important when blood glucose levels are falling or rising rapidly. If your patient is used to making therapy decisions based upon fingertip or palm test results, he or she should consider the delay, or lag time, affecting the test results obtained with blood from the forearm or upper arm.

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9 Guarantee

Guarantee

The statutory provisions on rights in consumer goods sales in the country of purchase shall apply.

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