Overview

You have 2 options to display and analyze blood glucose results on a PC.

1. **Data Transfer** – this option transfers the data to special software for diabetes management in a PC.
2. **PC Reports** – the meter generates data reports that open in an Internet browser and can be printed.

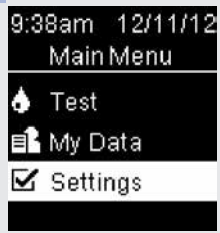
The option you select remains as the default until you change it.

NOTE

- You cannot perform a blood glucose test while the meter is connected to a computer with a USB cable. If you connect the meter to a PC when a test is in progress, the test is cancelled.
- The meter has a port on the side for the small end of the USB cable. The large end of the USB cable is inserted into the USB port of a PC.

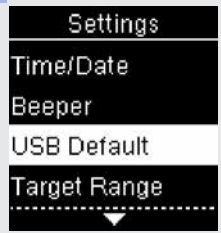
Set Data Transfer as the Default (Main Menu > Settings > USB Default > Data Transfer)

1



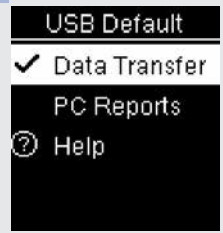
Turn the meter on by briefly pressing OK. From **Main Menu**, press ▼ to highlight **Settings**. Press OK.

2



Press ▲ or ▼ to highlight **USB Default**. Press OK.

3



Press ▲ or ▼ to highlight **Data Transfer**. Press OK to move ✓ to the option. Press OK to set the option and return to **Settings**.

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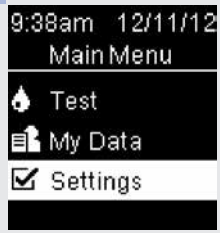
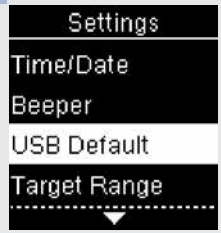
Set PC Reports as the Default (Main Menu > Settings > USB Default > PC Reports)

1



Turn the meter on by briefly pressing OK. From **Main Menu**, press ▼ to highlight **Settings**. Press OK.

2



Press ▲ or ▼ to highlight **USB Default**. Press OK.

3

Press ▲ or ▼ to highlight **PC Reports**. Press OK to move ✓ to the option. Press OK to set the option and return to **Settings**.

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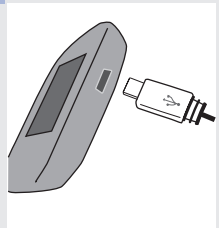
View the Data in Compatible Diabetes Management Software

These steps assume that the USB default option is set to **Data Transfer**.

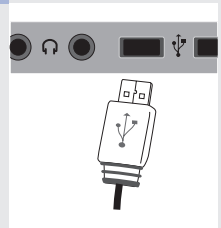
The meter can be off or on.

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 a PC.

If the meter is off, it turns on.

3

Start the software for data analysis and initiate a data transfer.

4

The meter transfers the data to the software.

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NOTE

If you would like to view the data in **PC Reports** instead, follow these steps:

1. Unplug the USB cable. **Connection Lost** appears.
2. Press ⬅ to return to **Main Menu**.
3. Select **My Data**>**PC Reports**.
4. Reconnect the USB cable.
5. **PC Reports** appears.

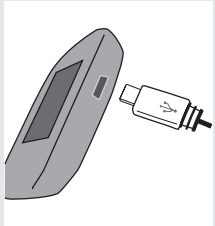
View the Data on a PC (in an Internet Browser)

These steps assume that **USB Default** is set to **PC Reports**.

The meter can be off or on.

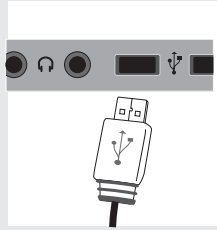
Once the meter is disconnected from the PC, the data disappears from the PC (but not the meter) unless you save it on the PC.

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 a PC.

If the meter is off, it turns on and displays **PC Reports**.

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3

Open the file manager (for example, Microsoft Windows Explorer) on the PC.

The meter appears as a drive (USB storage device) in the file manager.

4

Double click on the ACCU-CHEK drive icon.

5

Click on **Start.html**.

The Internet browser opens and the default reports appear.

NOTE

If you would like to view the data in special diabetes management software instead, follow these steps:

1. Unplug the USB cable. **Connection Lost** appears.
2. Press ⬅ to return to **Main Menu**.
3. Select **My Data**>**Data Transfer**>**USB Cable**.
4. Reconnect the USB cable.
5. **Data Transfer** appears.

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Shortcut

Here is a shortcut to get to **Data Transfer** or **PC Reports**. This is a quick way to transfer the data to software or to view the meter's data on a PC.

1. Turn the meter off.
2. Press and hold both ◣ and OK until **Activity** appears.
3. Select either **Data Transfer** or **PC Reports**.

View PC Reports

Overview

- An Internet connection is not necessary to view **PC Reports**.
- When the meter and PC successfully connect, the following reports are displayed in the Internet browser:
  - Trend Report – This report shows the trend for several test results over the selected time period (past 3, 7, 14, 30, or 90 days).
  - Standard Day Report – This report shows all data in a 24-hour grid.
  - Standard Week Report – This report shows all blood glucose results according to the time when the test was performed and the day of the week.
  - List Report – The list report (record list) shows the test results sorted by date and time of the test.

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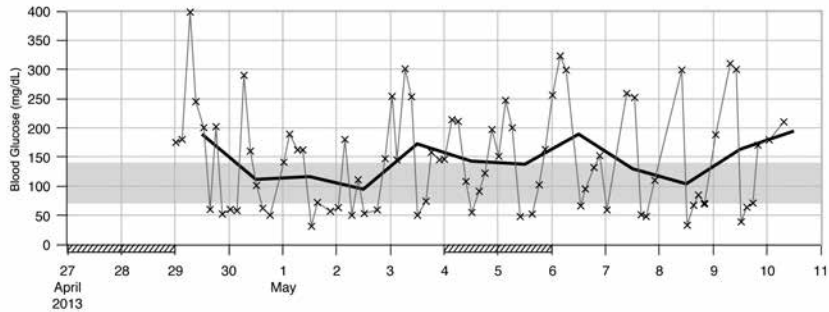

Statistics

Number of tests:	80	Average tests per day:	5.7	Above target range	>140 mg/dL: 51.2%	(41)
Average (mg/dL):	143.9	HI:	0	Within target range	70—140 mg/dL: 18.8%	(15)
Standard deviation (mg/dL):	87.4	LO:	0	Below target range	0—70 mg/dL: 30.0%	(24)
Highest value (mg/dL):	398	Low blood glucose index:	6.8			
Lowest value (mg/dL):	31	High blood glucose index:	8.0			

Key

× Measurement	Result(s) above graph	Blood glucose target range
✖ Multiple measurements	HI	Non-work day
— Average	LO	

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Statistics

Below the chart of a report, you will find a statistical analysis of all test results plotted with the following information:

- Number of tests
- Average
- Standard deviation – The standard deviation is the variance of the analyzed results.
- Highest value
- Lowest value
- Average tests per day – Average number of blood glucose tests per day
- HI or LO – Blood glucose results outside the measuring range
- Low blood glucose index or High blood glucose index – Further information can be found in **References**
- Above target range – Blood glucose results above the target range
- Within target range – Blood glucose results within the target range
- Below target range – Blood glucose results below the target range

Key

x	Blood glucose result
X	Several blood glucose results
——	Average blood glucose results in the selected time period
^	Blood glucose result above the chart range
^ (red caret)	Blood glucose may be higher than the measurement range of the system
v	Blood glucose may be lower than the measurement range of the system
(green)	Your personal blood glucose target range (shown as a green bar on the PC monitor)
(black)	Non-work days

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Print Report

Do not use the print function of the Internet browser. Use the **Print reports** button instead.

Excluded Data

The following blood glucose results are not included in a report:

- Test results outside the selected time period
- Control results
- LO or HI test results

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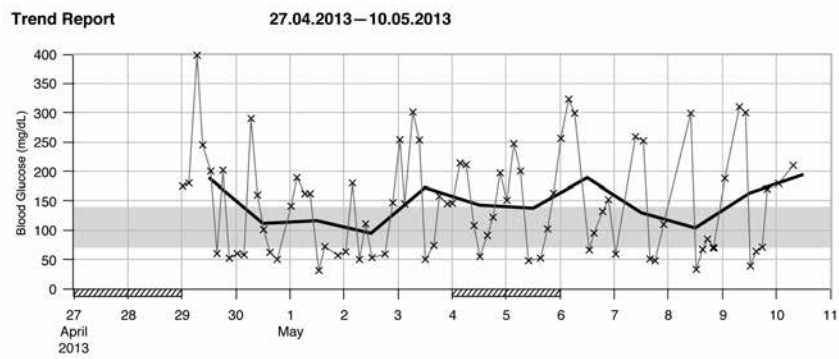

The Trend Report shows the trend of blood glucose results over the selected time period.

The date appears on the horizontal x-axis. The blood glucose results appear on the vertical y-axis. The test results are connected by a thin black line in chronological order.

If you set a target range in the meter, it appears as a green bar on the chart. Non-work days are marked with diagonal slashes on the horizontal x-axis.

The trend of the day-to-day average blood glucose result is represented by a thick black line.

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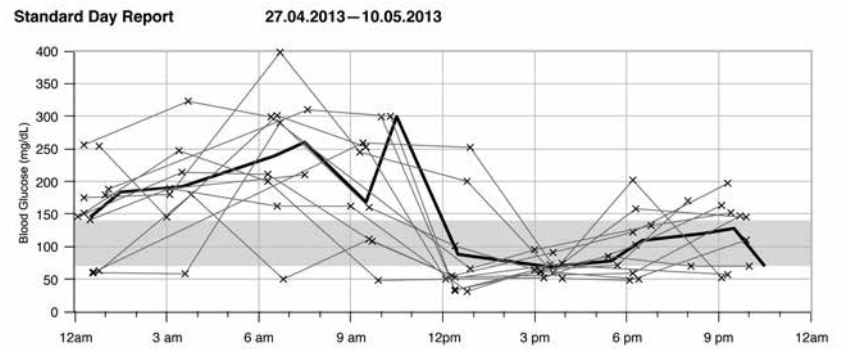

The Standard Day Report makes it easier to recognize daily patterns. All blood glucose results are placed on a 24-hour grid. Therefore, all tests performed at (approximately) the same time are shown at the same position on the horizontal time axis.

Blood glucose results are connected by a thin black line in chronological order. A thick black line represents the trend of the average level (in intervals of 1 hour if a test result falls in each interval).

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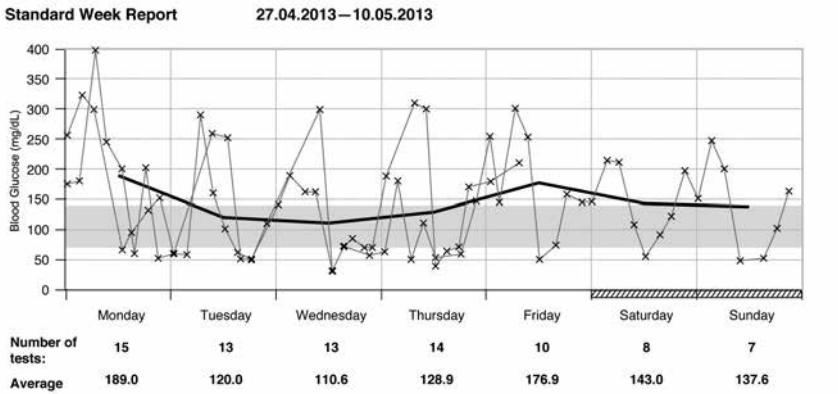

The Standard Week Report makes it easier to recognize weekly patterns. For example, you might find trends brought about by your occupation.

All blood glucose results are plotted on the chart according to the time and day the test was performed. Blood glucose results are connected by a thin black line in chronological order. A thick black line represents the trend of the average level for each day.

The number of tests and the daily blood glucose average are listed below the chart.

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List Report **05/08/2013—05/10/2013**

Date and Time		Blood Glucose (mg/dL)	Events
05/10/2013	07:30am	**210**	Before meal
	01:01am	**179**	
05/09/2013	08:00pm	**170**	After meal
	05:45pm	71	Before meal
	03:00pm	**64**	After meal
	12:27pm	**39**	Before meal
	10:18am	**300**	After meal
	07:37am	**310**	Before meal
	01:10am	**188**	
05/08/2013	10:00pm	70	After meal
	08:10pm	70	After meal
	05:27pm	85	Before meal
	03:17pm	**67**	After meal
	12:25pm	**33**	Before meal
	10:01am	**299**	After meal

The List Report shows the test results sorted by date and time of the test. All blood glucose results are listed chronologically with any additional information about the test result.

The list contains the following columns:

- Date and Time
- Blood Glucose
- Events – Event connected to this test result

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Working with Reports

Analyzing Data in External Applications

If you want to analyze the test results using external software, you can save the data as a CSV file (Comma Separated Values). CSV files can be opened with a text editor or spreadsheet program.

The CSV file contains all test results saved in the meter. Test results transferred at an earlier date are transferred again.

1. Press the **Save file** button on the user interface.

   Depending on the configuration of the PC, the CSV file may be directly opened in a spreadsheet program. In this case, you can save the data using the **Save** function of the spreadsheet program.

2. In the dialog box that opens, select the option to save the file.

   Where you find the CSV file on the PC depends on the settings in the operating system for data download.

The CSV file contains the following information:

- Serial number: Serial number of the meter.
- Download date, download time: date and time when the meter transferred the test results to the computer.
- Date, time, result and unit of the results saved in the meter.
- Flags added to the results, indicated by an **X**.

In the CSV file, the date is always displayed as DD.MM.YYYY and the time as 24-hour format (hh:mm). The time format set in the meter has no influence on the format of the date and time in the CSV file.

Security Settings within the Internet Browser

The settings of the Internet browser can influence working with reports. The reports use pages with active content (JavaScript). This active content can be suppressed by security settings in the browser, causing warnings or restricted functionality. If this happens, check the Internet browser settings.

In many cases, you can create different security settings for using the Internet and working with reports (for example, at user login to the PC or by defining user profiles in the browser).

If you select the Internet browser security settings appropriately (for example, **Allow active content to run in files on My Computer**), you can work with reports without any restrictions.

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NOTE

Some newer Internet browsers do not allow the **Save** function (e.g., Mozilla Firefox version 15 and higher). The files can be saved from Windows Explorer and subsequently opened using programs that are compatible with *.CSV files.

Troubleshooting

Troubleshooting Check	Action
The ACCU-CHEK drive symbol with the **start.html** file does not appear on the PC.	Check whether **PC Reports** is selected as the default.
	Check whether the PC or operating system supports data transfer via USB.
	Check whether the USB connector is firmly plugged into the correct port on the PC.
The meter is still not detected as a drive.	Plug the meter into a different USB port on the PC.

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What is the difference between cleaning and disinfecting?

Cleaning is the removal of dirt from the meter or lancing device.[3]

Disinfecting is the removal of most, but not all, disease-causing and other types of microorganisms (bloodborne pathogens) from the meter or lancing device.[3]

Approved Cleaning and Disinfecting Product

The following product has been approved for cleaning and disinfecting the meter and lancing device:

Super Sani-Cloth (EPA* reg. no. 9480-4)

Super Sani-Cloth can be purchased from Amazon.com, Officedepot.com, and Walmart.com.

- Do not use any other cleaning or disinfecting solutions. Using solutions other than the Super Sani-Cloth could result in damage to the meter and lancing device.
- The effect of using more than one product interchangeably to clean and disinfect the meter and lancing device has not been tested. Always use Super Sani-Cloth to clean and disinfect the meter and lancing device.
- Roche has tested the approved product for a total of 260 disinfection cycles, which is equal to disinfecting once per week over a 5 year period.

*Environmental Protection Agency

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NOTE

For technical assistance or questions on cleaning and disinfecting, contact the ACCU-CHEK Customer Care Service Center at 1-800-858-8072.

Cleaning and Disinfecting the Meter

WARNING

If the meter is being operated by a second person who is providing testing assistance to the user, the meter and lancing device should be cleaned and disinfected prior to use by the second person.

To clean and disinfect without damaging the meter, follow these procedures carefully.

When to Clean and Disinfect the Meter

- Clean the meter to remove visible dirt or other material prior to disinfecting.
- Clean and disinfect the meter at least once per week and when blood is present on the surface of the meter.
- Clean and disinfect the meter before allowing anyone else to handle the meter. Do not allow anyone else to use the meter on themselves for testing purposes.

NOTE

Using cleaning and disinfecting products could result in damage to the meter. If you notice any of the following signs of deterioration after cleaning and disinfecting your meter, stop using your meter and contact the ACCU-CHEK Customer Care Service Center at 1-800-858-8072: residue around buttons, clouding of display, button malfunction, out-of-range control results.

What to Clean and Disinfect

The following parts of the meter should be cleaned and disinfected:

- The area around slots and openings (do not get any moisture in slots or openings)
- The meter display
- The entire meter surface

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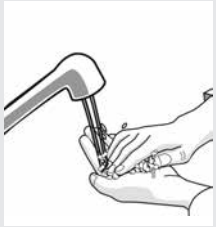
How to Clean and Disinfect the Meter

WARNING

Failure to follow these instructions will damage the meter and stop it from working properly.

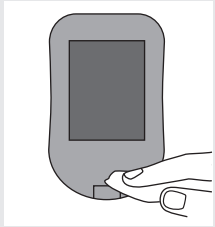
- DO NOT clean or disinfect the meter while performing a blood glucose or control test.
- DO NOT get any moisture in slots or openings.
- DO NOT spray anything onto the meter.
- DO NOT immerse the meter in liquid.
- Always use the same product for both cleaning and disinfecting.

1



Wash hands thoroughly with soap and water.

2



Turn the meter off and wipe the entire meter surface with a Super Sani-Cloth. Carefully wipe around the test strip slot and other openings.

Make sure that no liquid enters any slot or opening.

3

A separate Super Sani-Cloth should be used for cleaning and disinfection. For disinfecting the meter, get a new cloth and repeat step 2, making sure the surface stays wet for 2 minutes.

Make sure that no solution is seen in any slot or opening.

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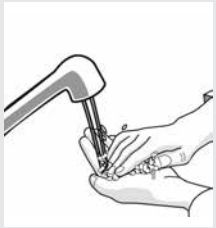
4



Wash hands thoroughly with soap and water.

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Cleaning and Disinfecting the Lancing Device

To clean and disinfect without damaging the lancing device, follow these procedures carefully.

When to Clean and Disinfect the Lancing Device

- Clean the lancing device to remove visible dirt or other material prior to disinfecting.
- Clean and disinfect the lancing device at least once per week to remove visible dirt or other material for safe handling.
- Clean and disinfect the lancing device before allowing anyone else to handle the lancing device, for instance, if you have someone assisting you. Do not allow anyone else to use the lancing device.

NOTE

- Do not throw away the cap after each use. Use the approved cleaning and disinfecting product on the cap.
- Always remove the lancet drum before cleaning or disinfecting the lancing device.
- Using cleaning and disinfecting products could result in damage to the lancing device. If you notice any of the following signs of deterioration after cleaning and disinfecting your lancing device, stop using your lancing device and contact the ACCU-CHEK Customer Care Service Center at 1-800-858-8072: residue around buttons, difficulty in priming the device, difficulty in inserting the lancet drum.
- You might observe a slight discoloration of the lancing device after multiple cleaning and disinfecting cycles. This does not affect the functionality of the lancing device.

What to Clean and Disinfect

The following parts of the lancing device should be cleaned and disinfected:

- The entire lancing device surface
- The cap

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How to Clean and Disinfect the Lancing Device

WARNING

Failure to follow these instructions may damage the lancing device and stop it from working properly.

- DO NOT get any moisture into any openings.
- Always use the same product for both cleaning and disinfecting.

1

Wash hands thoroughly with soap and water.

2

Wipe the entire surface of the lancing device and the inside of the cap with an approved cleaning and disinfecting product.

3

A separate Super Sani-Cloth should be used for cleaning and disinfection. For disinfecting the lancing device, use a new cloth and repeat step 2 making sure the surface stays wet for 2 minutes.

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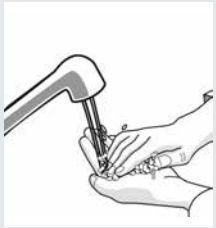
4



Wash hands thoroughly with soap and water.

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Meter Maintenance

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

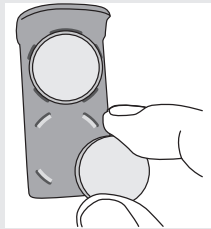
If you have problems with the meter or think the results are not accurate, perform a control test with an unexpired test strip and control solution. If the control result is not within the acceptable range, contact the ACCU-CHEK Customer Care Service Center at 1-800-858-8072.

Changing the Batteries

1

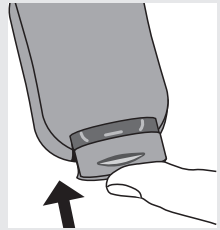
Use your thumb to slide the battery drawer out of the meter.

2



Remove the old batteries and place the new ones in the battery drawer with the **(+) side facing down**.

3



Slide the battery drawer back into position until it locks into place.

NOTE

- The meter uses two 3-volt lithium batteries, coin cell type CR2032. This type of battery can be found in many stores. It is a good idea to have spare batteries available.
- Always replace both batteries at the same time and with the same brand.
- The logbook data is saved when you replace the batteries.

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Error Messages

WARNING

Never make therapy decisions based on an error message.

The meter will not turn on or the display is blank.	⚠Test Not Allowed Remove strip or USB cable.	⚠Connection Lost Reconnect USB cable and retry.
Batteries are dead.	The meter is connected to a PC and a test cannot be performed.	The connection between the meter and PC was lost.
Insert new batteries.	EITHER remove the USB cable and perform a test OR remove the test strip and start a data transfer.	Disconnect and reconnect the USB cable and retry the connection. Contact the ACCU-CHEK Customer Care Service Center if the connection is lost again.
Display is damaged. / Meter is defective.		
Contact the ACCU-CHECK Customer Care Service Center at 1-800-858-8072.		
Extreme temperatures.		
Move the meter to a more temperate area.		

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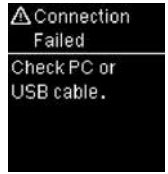
There is no connection between the meter and PC.

Connect the USB cable and retry the connection.

Blood glucose results were not transferred to a paired device.

Make sure the paired device is within range of the meter and turned on.

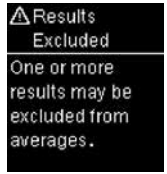


Data could not be transferred from the meter to the PC.

Check the PC or USB cable.

Data cannot be sent to a paired device because the meter is in **Flight Mode**.

Retry the data transfer when the meter is not in **Flight Mode**.



One or more blood glucose results are excluded from the selected averages because the results are invalid or out of the system measurement range.

The date entered is not valid.

Enter the correct date.

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⚠Flight Mode Active Wireless is off. Selected setting was saved.	⚠Flight Mode Active Wireless is off. Pairing is not allowed.	⚠Auto-Send Not Complete Transfer still pending. Ensure paired device is within range and turned on.
A meter setting was changed while in **Flight Mode**.	Pairing to a device cannot be performed while in **Flight Mode**.	The blood glucose result has not been sent to the default paired device. The transfer is still pending.
The setting change will not take effect until **Flight Mode** is turned off.	Retry pairing when the meter is not in **Flight Mode**.	Place meter and paired device closer together.

⚠Pairing Failed Retry pairing.	⊗Bad Strip Error Reinsert or replace with new strip. (E-1)
The meter was unable to pair with a device.	The test strip may be damaged or not properly inserted.
Retry the pairing.	Remove and reinsert the test strip or replace it if damaged.

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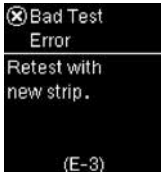

A meter or test strip error has occurred.

Your blood glucose may be extremely high or a meter or a test strip error has occurred.

- If your test result matches how you feel, contact your healthcare professional immediately.
- If your test result does not match how you feel, repeat the blood glucose test. See the **Unusual Blood Glucose Results** section in the chapter **Blood Glucose Tests**.
  - If the E-3 code still appears for your blood glucose test, your blood glucose result may be extremely high and above the system's reading range. Contact your healthcare professional immediately.
- If the second test result does not match how you feel, perform a control test with the control solution and a new test strip.
  - If the control result is within the acceptable range, review the proper testing procedure and repeat the blood glucose test with a new test strip.
  - If the control result is not within the acceptable range, see the **Understanding Out-of-Range Control Results** section in the chapter **Control Tests**.

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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 blood or control drop was applied to the test strip too late.

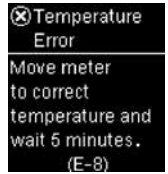
Discard the test strip and repeat the blood glucose or control test.

Blood or control solution was applied to the test strip before **Apply drop** appeared.

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

An electronic error occurred, or in rare cases, a used test strip was removed and reinserted.

Remove the batteries, press any button, and reinsert the batteries. Perform a blood glucose or control test.



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, wait 5 minutes, and repeat the blood glucose or control test. Do not artificially heat or cool the meter.

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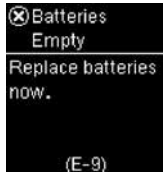
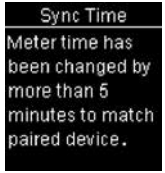


The batteries are out of power.

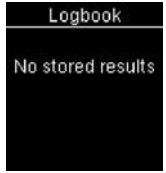
Change the batteries now. If the message reappears after the batteries have been replaced, slide the battery drawer out of the meter, press any meter button, then reinsert the battery drawer into position.

The time and date setting may be incorrect.

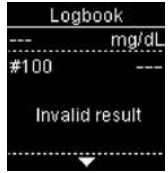
Make sure the time and date are correct and adjust, if necessary.



The meter time and date have been changed to match the paired device.



There are no results in the Logbook.



There is an invalid result in the Logbook.

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 There are no results in range for the selected average.	 Blood glucose may be higher than the measurement range of the system. See the **Unusual Blood Glucose Results** section in the chapter **Blood Glucose Tests**.	 Blood glucose may be lower than the measurement range of the system. See the **Unusual Blood Glucose Results** section in the chapter **Blood Glucose Tests**.

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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 Measurement range Test strip storage conditions System operating conditions	Refer to the test strip package insert.
Meter storage conditions	Temperature: -13–158 °F
Memory capacity	750 blood glucose results and 30 control results with time and date
Automatic off	90 seconds
Power supply	Two 3-volt lithium batteries (coin cell type CR2032)
Display	LCD
Dimensions	80 × 47 × 19 mm (LWH)
Weight	Approx. 40 g (with batteries)
Construction	Hand-held
Protection class	III
Meter type	The ACCU-CHEK Aviva Connect meter is suitable for continuous operation.
Control solution storage conditions	Refer to the control solution package insert.

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Bluetooth® Wireless Technology

The meter uses *Bluetooth* smart class II wireless technology to communicate and transfer information. *Bluetooth* wireless technology is a form or radio frequency (RF) technology that operates in the unlicensed industrial, scientific and medical band at 2.4 to 2.485 GHz. The RF channel utilized for communication between the meter and other devices, such as a smartphone, is not an open channel. The meter can only communicate with the device that

1. is *Bluetooth* smart,
2. it is paired with, and
3. has an application that can accept the meter's data.

This device complies with United States Federal Communication Commission (FCC) standards. The device complies with FCC Part 15 Rules. Operation of the device is subject to the following conditions:

1. This device may not cause harmful interference and
2. must accept any interference received, including interference that may cause undesired operation.

Compliance with these guidelines means that under normal, daily circumstances, the device should not affect the operation of other devices. In addition, the device should operate normally in the presence of other devices.

In the event there is interference from another device, it is recommended that you increase the distance between the meter and that device. You can also turn off the interfering device. In addition, you can turn off *Bluetooth* wireless technology on the meter. Changes or modifications to the device not expressly approved by Roche could void the user's authority to operate the device. The device has been tested and found to comply with the limits for a Class B digital device. The device generates, uses, and can radiate radio frequency energy.

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Electromagnetic Compatibility – This meter meets the electromagnetic immunity requirements as per EN ISO 15197. The chosen basis for electrostatic discharge immunity testing was basic standard IEC 61000-4-2. In addition, the meter meets the electromagnetic emissions requirements as per EN 61326. The meter's electromagnetic emission is thus low. Interference from the meter to other electrically-driven equipment is not anticipated.

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

This equipment complies with FCC and IC radiation exposure limits set forth for an uncontrolled environment. This equipment is in direct contact with the body of the user under normal operating conditions. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

NOTE

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

Changes or modifications not expressly approved by the party responsible for compliance (i.e. the manufacturer) could void the user's authority to operate the equipment.

Performance Analysis – Refer to the test strip package insert.

Test Principle – Refer to the test strip package insert.

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Product Safety Information

WARNING

- This meter meets IEC 61010-1, IEC61010-101 and IEC 609501-1 safety standards.
- 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.

Travel Documentation

If you are traveling on a commercial airline, you may be required to provide documentation certifying that this meter meets environmental conditions and test procedures for Airborne Equipment (RTCA DO-160) section 21 Emission of Radio Frequency Energy. Visit accu-chek.com or contact the ACCU-CHEK Customer Care Service Center at 1-800-858-8072 to obtain a copy of the document.

Discarding the Meter, Test Strips, Lancing Devices, Lancets, and Batteries

WARNING

- 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.

Roche is committed to recycling and sustainability. 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 the following points when discarding used testing materials:

Consider recycling 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 discarded accordingly.

Disinfect the meter before recycling or discarding.

*29 CFR 1910.1030 – Bloodborne pathogens

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Explanation of Symbols

⚠	Caution, refer to safety-related notes in the instructions for use accompanying this product.
	3-volt coin cell type CR2032

Additional Supplies

Test Strips: ACCU-CHEK Aviva Plus test strips

Control Solutions: ACCU-CHEK Aviva control solutions

Lancets: ACCU-CHEK FastClix 102-ct. lancet drums (17-6 ct. drums)

Low Blood Glucose Index or High Blood Glucose Index[4,5,6]

These figures represent the frequency and the resulting risk of blood glucose values being too low or too high. Figures should be as low as possible.

The following table provides an overview to assess the risk of blood glucose values being too low or too high:

Risk	Low blood glucose index	High blood glucose index
minimal	≤1.1	≤5.0
low	1.1–2.5	5.0–10.0
medium	2.5–5.0	10.0–15.0
high	>5.0	>15.0

WARNING

The index values for low blood glucose or high blood glucose in the table are not blood glucose values. Ask your healthcare professional if you want to change your therapy based on the index values.

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References

[1] FDA Public Health Notification: "Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication, (2010). Update 11/29/2010." http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm. Accessed March 20, 2012.

[2] CDC Clinical Reminder: "Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens, (2010)." http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html. Accessed March 20, 2012.

[3] Healthcare Infection Control Practices Advisory Committee (HICPAC), William A. Rutala, Ph.D., M.P.H., and David J. Weber, M.D., M.P.H. Centers for Disease Control and Prevention, 2008. "Guideline for Disinfection and Sterilization in Healthcare Facilities." Atlanta.

[4] Boris P. Kovatchev, Martin Straume, Daniel J. Cox, Leon S. Farhy (2001) "Risk analysis of blood glucose data: a quantitative approach to optimizing the control of insulin dependent diabetes." *Journal of Theoretical Medicine,* 3: pp 1-10.

[5] Boris P. Kovatchev, Daniel J. Cox, Anand Kumar, Linda Gonder-Frederick, William L. Clarke (2003) "Algorithmic Evaluation of Metabolic Control and Risk of Severe Hypoglycemia in Type 1 and Type 2 Diabetes Using Self-Monitoring Blood Glucose Data." *Diabetes Technology & Therapeutics*, 5(5): pp 817-828.

[6] Boris P. Kovatchev (2006) "Is Glycemic Variability Important to Assessing Antidiabetes Therapies." *Current Diabetes Reports*, 6: pp 350-356.

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Warranty

ACCU-CHEK Aviva Connect Meter 30-day Money-back Guarantee for Qualifying Consumers

Roche Diagnostics offers qualifying consumers that purchase an ACCU-CHEK Aviva Connect meter, a 30-day money back guarantee. If you are not fully satisfied with your ACCU-CHEK Aviva Connect meter, contact the ACCU-CHEK Customer Care Service Center toll-free at 1-800-858-8072 to determine whether you qualify to receive a full refund within 30 days of purchase. If you are covered under Medicare, Medicaid, other federal/state programs, or private insurance you are NOT eligible for this money-back offer. Consumers affected by this exclusion may instead request a different ACCU-CHEK meter/system. The refund will be limited to the amount paid by you net of any rebates. You must have a copy of the dated itemized purchase receipt and the original packaging to obtain this refund.

ACCU-CHEK Aviva Connect Meter Limited 3-Year Warranty

Roche Diagnostics warrants to the original purchaser of the meter that your ACCU-CHEK Aviva Connect meter will be free from defects in materials and workmanship for three years from the date of purchase. If, during this 3-year period, the meter does not work properly because of a defect in materials or workmanship, Roche Diagnostics will replace it with a new ACCU-CHEK Aviva Connect meter or equivalent product free of charge. The warranty on the replacement meter will expire on the date of the original warranty expiration or 90 days after the shipment of a replacement system, whichever period is longer. The purchaser's exclusive remedy with respect to the ACCU-CHEK Aviva Connect meter shall be replacement.

This warranty does not apply to the performance of an ACCU-CHEK Aviva Connect meter that has been damaged by accident or has been altered, misused, tampered with, or abused in any way. Roche Diagnostics will handle meters that show damage or abuse according to its Non-Warranty Service Policy described on the following page.

THE ABOVE WARRANTY IS EXCLUSIVE OF ALL OTHER WARRANTIES, AND ROCHE DIAGNOSTICS MAKES NO OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION, THE IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. IN NO EVENT SHALL ROCHE DIAGNOSTICS BE LIABLE TO THE PURCHASER OR ANY OTHER PERSON FOR ANY INCIDENTAL, CONSEQUENTIAL, INDIRECT, SPECIAL, OR PUNITIVE DAMAGES ARISING FROM OR IN ANY WAY CONNECTED WITH THE PURCHASE OR OPERATION OF THE METER OR ITS PARTS. NO WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, IF ANY IS IMPLIED FROM THE SALE OF THE METER, SHALL EXTEND FOR A LONGER DURATION THAN THREE YEARS FROM THE DATE OF PURCHASE.

Some states do not allow limitations on how long an implied warranty will last or the exclusion of incidental or consequential damages, so the above limitation and exclusion may not apply to you. This warranty gives you specific legal rights, which vary from state to state.

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Non-Warranty Service Policy

Roche Diagnostics Non-Warranty Service Policy applies to meters where the above warranty has not become effective, has become inapplicable, or has expired. Roche Diagnostics will replace, at its option, meters returned to it for a service charge (not to exceed $35).

Replacement will be with the same or similar product. Replacement meters will be warranted for a period of 90 days from shipment under a limited warranty providing for replacement of parts and labor at no charge.

Warranty and Service Instructions

All requests for return of ACCU-CHEK Aviva Connect meters under the above warranty or service policy must be made to the ACCU-CHEK Customer Care Service Center. You will be mailed a return authorization label, which must be affixed to your carton for shipping the system to Roche Diagnostics. Cartons received without this label will be returned to you at your expense.

Customers experiencing difficulties should review the troubleshooting information in **Meter Maintenance and Troubleshooting** of this manual. Further inquiries should be directed to the ACCU-CHEK Customer Care Service Center.

Be sure to fill out and mail the Warranty Card that comes with the ACCU-CHEK Aviva Connect system.

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Limited License

WARNING

CAUTION – A RESTRICTED LICENSE LIMITS USE OF THE ACCU-CHEK AVIVA CONNECT SYSTEM IN THE UNITED STATES – READ CAREFULLY THE LIMITATIONS RECITED BELOW.

The ACCU-CHEK Aviva Connect system (meter and test strips) and its use are protected by U.S. Patent Nos. 6,645,368 (expires 22-December-2017); 7,276,146 (expires 4-October-2022); 7,276,147 (expires 4-October-2022); 7,407,811 (expires 9-May-2020); 8,298,401 (expires 4-October-2022); 8,303,801 (expires 4-October-2022); 8,329,026 (expires 4-October-2022); 7,452,457 (expires 2-May-2026); 7,488,601 (expires 1-February-2026); 7,494,816 (expires 29-December-2019); 7,569,126 (expires 28-December-2026); and 7,604,721 (expires 12-August-2026). A license to use the ACCU-CHEK Aviva Connect system is required until the expiration of the last-to-expire patent listed above and is only granted when the ACCU-CHEK Aviva Connect meter is used with the ACCU-CHEK Aviva Plus test strips.

ACCU-CHEK Aviva Plus test strips are specifically manufactured for operation with the ACCU-CHEK Aviva Connect meter. Use of other test strips supplied by another manufacturer may prevent or impair the proper function of the ACCU-CHEK Aviva Connect system.

Using the ACCU-CHEK Aviva Connect system indicates your acceptance of the restricted license to use the ACCU-CHEK Aviva Connect system only with ACCU-CHEK Aviva Plus test strips. If you do not agree to the terms and conditions of the restricted license, you may return, at the place of purchase, the unused ACCU-CHEK Aviva Connect system for a full refund. If you have any questions, please call the ACCU-CHEK Customer Care Service Center at 1-800-858-8072.

Except where prohibited by statute, all warranties covering the ACCU-CHEK Aviva Connect system are voided by use of the ACCU-CHEK Aviva Connect system with any test strips other than ACCU-CHEK Aviva Plus test strips.

WARNING

A RESTRICTED LICENSE LIMITS USE OF THE ACCU-CHEK FASTCLIX SYSTEM (lancing device and lancet drums). READ CAREFULLY THE LIMITATIONS RECITED BELOW.

The ACCU-CHEK FastClix system (device and lancet drums) and its use are protected by U.S. Patent Nos 7,322,998 (expires 3-March-2020); and 7,785,338 (expires 5-January-2026). A license to use the ACCU-CHEK FastClix system is required until the expiration of the last-to-expire patent listed above and is only granted when ACCU-CHEK FastClix lancet drums are used with the ACCU-CHEK FastClix device.

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12 License and Warranty

ACCU-CHEK FastClix lancet drums are high precision components that are produced to the close tolerances required for satisfactory operation with the ACCU-CHEK FastClix device. Use of other lancet drums with the ACCU-CHEK FastClix device may prevent or impair proper function of the ACCU-CHEK FastClix device.

Using the ACCU-CHEK FastClix device indicates your acceptance of the restricted license to use the ACCU-CHEK FastClix device only with ACCU-CHEK FastClix lancet drums. Further, if you have purchased an ACCU-CHEK FastClix device that includes this restricted license, then this restricted license applies regardless of any additional offers found in ACCU-CHEK FastClix device packages. If you do not agree to the terms and conditions of the restricted license, you may return, at the place of purchase, the unused ACCU-CHEK FastClix device for a full refund. If you have any questions, contact the ACCU-CHEK Customer Care Services Center at 1-800-858-8072.

Except where prohibited by statute, all warranties covering the ACCU-CHEK FastClix device are voided by use of the ACCU-CHEK FastClix device with any lancet drums other than ACCU-CHEK FastClix lancet drums.

Patent Information

U.S. Pat.: http://www.roche-diagnostics.us/patents

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Continua Certified signifies that this product complies with applicable IEEE 11073-10417 standards and that it has been tested and certified against the 2014 Continua Design Guidelines.

Roche Diagnostics
9115 Hague Road
Indianapolis, IN 46256
www.accu-chek.com

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